William C.S. Meng · Hester Y.S. Cheung
David T.Y. Lam · Simon S.M. Ng *Editors*

Minimally Invasive Coloproctology

Advances in Techniques and Technology

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Editors
William C.S. Meng
Department of Surgery
Matilda International Hospital
HongKong
China

David T.Y. Lam
City Medical Center Room 833, 8/F,
Office Tower 1, Grand Plaza
Hong Kong
China

Hester Y.S. Cheung
Department of Surgery
Pamela Youde Nethersole Eastern Hospital
Hong Kong
China

Simon S.M. Ng
Department of Surgery
Prince of Wales Hospital The Chinese University of Hong Kong
Hong Kong
China

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Preface

Starting from the conception throughout the making and final delivery of this volume, we have all along borne in mind the purpose of it all, not to replicate just another operative manual in colorectal surgery, but something handy, succinct, and evidence based. As far as it is practicable, we adopt a one-surgery, one-chapter layout with state-of-the-art technology and knowledge. We absent the book with academically loaded discourses not because they are irrelevant, rather in the contrary, we believe the speed of academic development will inevitably make any textbook dwelled in academic discussion obsolete by the time it is published. Seasoned surgeons will certainly turn to conferences and web-based medical literature to locate such discussions.

We gathered together writers who are practicing surgeons in colorectal surgery, drawing from whose experience tips, tricks, and cautionary notes scattered throughout the text will hopefully turnout helpful to the surgeon in training, and interesting in the eyes of the experienced surgeons.

This volume is the fruit of friendship between surgeons and the common aspiration of the Hong Kong Society for Coloproctology. It is our aspiration to contribute to the maturing field of colorectal surgery in Hong Kong, in China, in Asia Pacific Region, and also internationally.

We hope our readers will see our concept embodied in the text. Finally we wish to acknowledge our families without whose support and tolerance, we could not have completed this volume.

Hong Kong, China

William Meng
Hester Cheung
David Lam
Simon Ng

Contents

1 Robotic Endolaparoscopic Operating Theatre

Michael Li

The set-up of the operating theatre (OT) has evolved and diversified from its humble beginnings to as simple as a kitchen table [1] centuries ago to a theatre today with high-definition technology and all the equipment and tools at the surgeons' fingertips.

Previously the OT was designed to accommodate the patient. The surgeon and the operating room staff adapted to the environment. With the coincident development and refinement in anaesthesia, undergoing surgery became safer, and more operations were being performed. Designs for renovation of the OT to accommodate the growing needs for equipment and tools of both the surgeon and the anaesthesiologist started to unfold.

Through the twentieth and twenty-first century, we have seen the transition of operation from open surgery to minimally invasive surgery (MIS). With the merging of endoluminal therapy and MIS [2], the needs of both fields in the same OT became a concern. We have witnessed the development initially of an MIS theatre, which transitioned to an endolaparoscopic theatre [3, 4]. With the introduction of the robot in the late 1990s [5–10], we integrated the robot in our theatre. We present our robotic endolaparoscopic theatre, hopefully making it a framework for future OT design.

M. Li
Department of Surgery,
Pamela Youde Nethersole Eastern Hospital,
Hong Kong, SAR China
e-mail: michaelli@hksh.com

1.1 Robotic Endolaparoscopic Operating Theatre

The vision is to incorporate all the tools of MIS and endoluminal therapy into the OT. The new OT has the space and capabilities as the previous endolaparoscopic OT but integrates the special needs of the new tool in MIS, the robot.

The OT is equipped with the following:

1. Two 3-dimensional screens, a 45-in. screen, beside the robotic console and a 19-in. screen, for the surgical assistant and operating room team (Fig. 1.1).
2. The robot and the robotic console.
3. Ceiling mounted architecture holding both laparoscopic and endoscopic equipments (Fig. 1.2).
4. Two 63-in. LCD monitor screens and multiple 19-in. LCD screens covering the area 360° around the OT table (Figs. 1.3 and 1.4).
5. Cameras located on the ceiling and on the overhead lights.
6. Blue light installed to make the figures in the LCD screen sharper.
7. Centralized display and control with an easy touch screen for operating room personnel

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Fig. 1.1 Professor Li at the robotic console. The 45-in. 3D plasma screen on the upper right and special 3D glasses below the screen are provided for observers who want to appreciate the same 3D image as the console surgeon the (*white arrow*) pointing to the monitor that mentioned on the citations

Fig. 1.2 The 3D monitor for the assistants mounted on the ceiling on the far right (*white arrow*)

for table control, audio and video control of various MIS and endoscopic equipment (Fig. 1.5).

8. Centralized endoalpha, audio and video system to enhance communication between the endolaparoscopic OT and the training centre for training and teleconference.
9. Centralized patient data system inside the OT.

1.2 Rationale for a Robotic Endolaparoscopic Operating Theatre

The rapid advancement in technology allows surgeons to conduct more advanced operations through minimally invasive incisions with improved clinical outcomes. With the

Fig. 1.3 One of the 63 in. 2D plasma screens at the back of the operating team the (*white arrow*) pointing to the monitor that mentioned on the citations

Fig. 1.4 LCD monitors surrounding 360° axis around the operating table

Fig. 1.5 Centralized video and audio display with touch screen

introduction of the robot in the late 1990s [5, 6], it has paved its way to becoming an integral part of the armamentarium of MIS. The robot was integrated into the current robotic endolaparoscopic OT because it serves as one of the tools of MIS. Further, MIS tools are concurrently used in applying the best technique to the patient when it is needed. The robot is viewed as no different from the other tools in MIS.

1.2.1 Benefit for the Surgeon

The robot was designed specifically to compensate for the technical limitations of laparoscopic instruments [11]. Its capability to reproduce complete hand and wrist-like movements at the instrument tip overcomes the limited degrees of freedom and fixed trocar axis points found in standard laparoscopic instruments [5–8].

The current display system in laparoscopic surgery has two types of visual problems: impaired depth perception and difficulty in varying the perspective of point of view of the operative field [9]. The 3D depth cues that naturally provide humans with the sense of depth perception (parallax, stereopsis and disparity) are missing in endoscopic surgery [9].

With the addition of a 3-dimensional view in robotic surgery, depth perception is almost as good as in open surgery. The robot is used in instances where precision is paramount, enabling

Fig. 1.6 The blue light on the right provides a clearer and definite image on the monitors in the operating theatre

more accurate and precise surgery [12] and predictably should result in fewer complications and improved patient outcomes. However, this view in robotic operating theatres around the world is limited to the surgeon operating at the robotic console, while the assistants and the observers see the image only in its 2-dimensional view.

A unique, clear, high-definition 3-dimensional software technology was specifically designed by our medical physicist for Pamela Youde Nethersole Eastern Hospital. This design is called the 'stereotactic visualization system for robotic and laparoscopic surgery'.

The innovation of this robotic endolaparoscopic Operating Theatre is the presence of two 3D monitors, a 19-in. screen for the assistant surgeons and scrub nurses, and a 45-in. plasma screen for teaching purposes. With these, the 3D view appreciated by the surgeon working at the robotic console is translated and shared not only to the assistants, but also to the operating room staff and observers. This results in the assistants working in synchrony and harmoniously with the surgeon. The big plasma 3D screen aids in teaching and sharing of skills wherein trainees and observers are provided with special glasses to appreciate the 3D view during robotic surgery, a view which was previously limited only to the surgeon.

The theatre is also equipped with two 63-in. 2-dimensional plasma screens and six 19-in. 2-dimensional flat screens. The lighting in the new operating theatre makes use of blue light; this important feature results in improved clarity and resolution of the images in the screens around the operating theatre. With the current OT set-up, it makes the OT easier for the surgeon as a variety of minimally invasive and endoscopic equipment are available anytime the surgeon needs it (Fig. 1.6).

Communication capabilities are available within this new theatre. Routing of images from the endoscope, laparoscopic or robotic camera, cameras mounted on operating room lights and overhead cameras to strategically placed flat panel monitors around the operating theatre can be performed using a central control unit. The integrated audio and video system of the new robotic endolaparoscopic theatre allows communication and telesurgery [13] from the operating theatre to the conference room down the hall, across the street, to teaching and training centres and hospitals not only in Hong Kong but also to other countries around the world.

1.2.2 Benefit for the Operating Room Staff

The ceiling mounted beams hold both laparoscopic and endoscopic equipment. This design saves space and rids the operating theatre of bulky equipment [13–17]. It also facilitates theatre set-up by the operating room staff, in that the equipment and cords are off the floor, and there is no need to do equipment connection or reconnection all the time [13–17]. The clean-up after operation is also made easier, with improved theatre turnover overall. Occupational safety is better as electric cables are not on the floor, and thus hazard is minimized [14].

There is no question that suspending the major equipment and the screens greatly increases the amount of floor space available, thereby improving the OR staff's traffic patterns, and making it easier for the surgeon to keep track of the procedure. In our endolaparoscopic theatre there was a 38% reduction in OR set-up time (6.7 vs. 10.8 min), 46% reduction in turnover time (6.3 vs. 11.6 min) and a 60 % reduction in time required to set up an additional scope (4.6 vs. 11.6 min) [3].

1.2.3 Benefit for the Patient

The benefit of MIS for patients includes both short- and long-term benefits. Short-term outcomes include faster perioperative recovery, less pain, shorter hospital stay and cosmesis. Long-term outcomes include equivalent oncologic outcomes, equivalent recurrence rates and equivalent quality of life outcomes as compared to the traditional open surgery [18–22].

However, the benefit of the robot to patients has not been established as of yet. However, using the robot in specific parts of the operation, using it when it is needed most, allows the surgeon to see better, perform better and hopefully results in optimal clinical outcomes.

1.3 Operating Theatre of the Future

The goal is to provide the best environment for the surgeon and the operating team [13, 14]. An optimal work environment that prevents errors and discomfort is also dependent on factors such as the environment, equipment, and medical staff. Working conditions are improved without sacrificing safety, efficiency, and comfort [14].

By providing the best environment, hospitals need to invest in hospital equipment; however, a major deterrent in setting up is the cost. However, investing in hospital equipment may result in better delivery of patient services and shorter hospital stay [15].

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2 Evidence-Based Minimally Invasive Surgery for Colorectal Cancer

Dennis Chung Kei Ng and Ka Lau Leung

2.1 Introduction

Colorectal cancer is a major health problem worldwide. It accounts for 9 % of cancer incidence. It is also the third most common cancer and the fourth most common cause of death in the world [1, 2]. The incidence of colorectal cancer in Hong Kong raised from 3,210 per 100,000 persons in 2,000 to 4,450 per 100,000 persons in 2011, and it also become the commonest cancer in Hong Kong [3]. Traditionally, cancer surgery consisted of laparotomy and resection of the involved colon or rectum, together with its blood supply and lymphatic drainage. With the advancement of technology, there are many varieties of minimally invasive approach in managing this condition. Enormous data, ranging from case reports to well-organized randomized control trials (RCT) and meta-analyses are available in the literature. We review the local data as well as the international data of different minimally invasive approach in this chapter.

Generally speaking, minimally invasive surgery for colorectal cancer can be classified into local excisions, i.e., endoscopic submucosal dissection (ESD) and transanal endoscopic microsurgery (TEM), colorectal resection with laparoscopic approach, derivatives of laparoscopic surgery such as hand-assisted laparoscopic surgery (HALS), single incision laparoscopic surgery (SILS), and natural orifice transluminal endoscopic surgery (NOTES), to the newest robotic surgery. Each approach has its own advantage and limitation.

2.2 Endoscopic Submucosal Dissection (ESD)

Endoscopic submucosal dissection is a novel endoscopic technique which consisted of submucosal injection and elevation, mucosal incision, submucosal dissection, and on-bloc removal of the lesion. It is most commonly performed in Japan. The current recommendation by the Colorectal ESD Standardization Implementation Working Group included those lesions difficult to be removed en bloc with a snare endoscopic mucosal resection (EMR); those lesions with fibrosis due to biopsy or peristalsis; sporadic localized lesions in chronic inflammation such as

D.C.K. Ng, MBChB, FRCSEd, FCSHK, FHKAM (✉)
Department of Surgery,
North District Hospital, Hong Kong SAR, China
e-mail: dennis_ckng@yahoo.com.hk

K.L. Leung
Department of Surgery,
Prince of Wales Hospital, Hong Kong SAR, China

Department of Surgery,
CUHK, Hong Kong SAR, China

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ulcerative colitis; and local residual early carcinoma after endoscopic resection [4–6].

The role of ESD in colorectal cancer is less well defined. In view of the technical limitation, it can only remove those lesions without submucosal invasion. Therefore, besides being a diagnostic tool, it can only be used as a curative treatment for those early cancers without submucosal invasion or lymph node metastasis. Hon et al. compared the technique of ESD versus local excision in the treatment of early rectal neoplasm. They showed that ESD offered better short-term clinical outcomes in terms of faster recovery and possibly lower morbidity than local excision [7].

In conclusion, ESD is an option in managing early colorectal cancers, providing that expertise is available (Table 2.1).

2.3 Transanal Endoscopic Microsurgery (TEM)

Transanal endoscopic microsurgery was first described by Professor Gerhard Buess from Tubingen, Germany, in the early 1980s [9]. This minimally invasive technique revolutionizes the local resection of rectal lesions. By making use of an operating microscope, it permits resection of rectal lesions with adequate margin, which may require a major proctectomy or even an abdominoperineal resection in some patients. It has the advantage of scarless operation, faster recovery, shorter hospital stay, reduced morbidity and mortality, and decreased long-term dysfunction [10–13].

How about its role in colorectal cancer? TEM was proposed as standard treatment for lower rectal T1 tumor in the past two decades. Wu et al. performed a meta-analysis on TEM versus conventional rectal surgery (CRS) in the treatment of T1 rectal cancer [14]. Five studies and 397 patients were enrolled in the meta-analysis. Only one of them was RCT [15]. The complications were observed in 16/196 in the TEM group and 77/163 in the CRS group ($p=0.01$). Mortality was 3.68 % in CRS group and 0 in TEM group ($p=0.01$). There was more recurrence in the TEM group (12.0 % vs. 0.5 %), but this difference did not transfer to the 5-year survival rates [14].

On the contrary, the evidence of TEM alone in the management of T2 tumor is less favorable. The main reason is the higher chance of lymph node metastasis in more advanced tumor. Borschitz et al. performed a review on the effect of local excision in more advanced rectal tumors [16]. They identified 8 studies and 124 patients in the literature in whom their T2 carcinoma was locally excised as the sole procedure. The local recurrence rate was 19 % after R0 resection by local excision alone, and rose to 52 % if high risk factors also present. By immediate radical reoperation, the recurrence rate decreased to 7 %. The recurrence rate for local excision after adjuvant therapy and neoadjuvant chemoradiotherapy was 16 % and 9 %, respectively. Eleven percent of patients developed metastasis after adjuvant therapy [16].

In a recent RCT in 2012, Lezoche et al. compared the endoluminal locoregional resection versus laparoscopic total mesorectal excision for T2 rectal cancer after neoadjuvant therapy [17]. They demonstrated significantly shorter operative time, lesser blood loss, lesser analgesic requirement, shorter hospital stay, and less stoma (temporary and definitive) in the TEM group. At long-term follow-up, local recurrence had developed in four patients (8 %) after TEM and three (6 %) after TME. Distant metastases were observed in two patients (4 %) in each group. There was no statistically significant difference in disease-free survival ($P=0.686$) [17].

In summary, TEM is a recognized option in the treatment of T1 rectal cancer. For more advanced tumor, TEM alone is not recommended. Combination with adjuvant or neoadjuvant therapy may be considered in selected patients and on research basis (Table 2.1).

2.4 Laparoscopic Colorectal Resection

After the first successfully laparoscopic colectomy in 1991 [18], the treatment of colorectal cancer was completely revolutionized in the past

Table 2.1 Evidence of different minimally invasive approach in colorectal cancer surgery

	Applications	Short-term benefits	Long-term outcomes
Endoscopic submucosal dissection (ESD)	Early colonic or rectal cancer without submucosal invasion	Faster recovery and possibly lower morbidity when compared with local excision (Level 3[a])	Data insufficient
Transanal endoscopic microsurgery (TEM)	T1 rectal cancer, or selected T2 rectal cancer when combined with adjuvant or neoadjuvant therapy	Scarless operation, faster recovery, shorter hospital stay, and reduced morbidity and mortality when compared with open surgery (Level 3[a])	T1: More recurrence but no survival difference when compared with open rectal surgery (Level 3[a]) T2: More recurrence when used alone (Level 3[a]) Insufficient data when combined with adjuvant or neoadjuvant therapy
Laparoscopic colectomy	Colonic cancer	Less blood loss, less pain, shorter hospital stay, less ileus, better pulmonary function, better quality of life, and less morbidity when compared with open surgery (Level 1[a])	Long-term survival and disease-free survival are comparable to open surgery (Level 1[a])
Laparoscopic proctectomy	Rectal cancer	Less blood loss, less pain, faster first defecation, shorter hospital stay, fewer wound complications, and less morbidity when compared with open surgery (Level 1[a])	Long-term survival, disease-free survival, and sexual and bladder function are comparable to open surgery (Level 1–2[a])
Hand-assisted laparoscopic surgery (HALS)	Colonic or rectal cancer	Less blood loss, less wound infection, less ileus, shorter wound length, faster recovery of gastrointestinal function, and shorter hospitalization stay when compared with open surgery (Level 1[a]) No significant advantage over conventional laparoscopic surgery (Level 2[a])	Data insufficient
Single incision laparoscopic surgery (SILS)	Selected small colonic cancer	Shorter wound length and shorter hospital stay when compared to laparoscopic surgery (Level 3[a])	Data insufficient
Nature orifice transluminal endoscopic surgery (NOTES)	Selected colonic or rectal cancer under research condition	Better pain score and lesser wound infection when compared to laparoscopic surgery (Level 2[a])	Data insufficient
Robotic surgery	Rectal cancer	Lower conversion rate, longer operative time and higher costs when compared with laparoscopic surgery (Level 3[a])	No difference in lymph node harvested and circumferential margin when compared with laparoscopic approach (Level 3[a]) Data insufficient in survival

[a]The Oxford 2011 Levels of Evidence [8]

two decades. Many RCTs and meta-analyses were performed and published in the literature. More and more colorectal surgeons changed their practice from the conventional open to the laparoscopic approach. Many technical obstacles were gradually resolved with the advancement of technology. Nowadays, laparoscopic resection is the "gold" standard in many of the world leading colorectal centers.

The short-term benefit of laparoscopic colorectal cancer resection was well addressed in the literature. The first RCT was published by Lacy et al. in 2002, 219 patients were randomized into laparoscopic and open groups. They showed that laparoscopic approach was more effective in terms of morbidity, hospital stay, tumor recurrence, and cancer-related survival [19]. However, this study was being challenged for the high recurrence rate in the open group (14 %) and inadequate lymph node harvest from both groups. In 2004, Leung et al. [20] from Hong Kong published another RCT on the laparoscopic resection of rectosigmoid cancer. Four hundred and three patients were randomized into open and laparoscopic group. They showed that laparoscopic approach was no different from open group in terms of distal margin, number of lymph node harvested, morbidity, and mortality. The only difference was longer operative time but the hospital stay was shorter. There was no difference in both the 5-year survival (laparoscopic 76.1 % vs. open 72.9 %) and disease-free survival (laparoscopic 75.3 % vs. open 78.3 %) between two groups [20].

When compared to single center RCTs, multicenter RCTs can recruit more patients in a shorter period of time. There were multiple landmark large-scale multicenter RCTs carried out in the subsequent years – COST [21], CLASICC [22], and COLOR [23] trials. In the COST trial, 48 institutions and 872 patients were involved. Twenty-one percent conversion rate was seen in the laparoscopic group. Short-term benefits including shorter hospital stay (5 days vs. 6 days, $p<0.001$), briefer use of parenteral narcotics (3 days vs. 4 days, $p<0.001$), and oral analgesics (1 day vs. 2 days, $p=0.02$) were observed. The rates of intraoperative complications, 30-day postoperative mortality, complications at discharge and 60 days, hospital readmission, and reoperation were very similar between groups. The overall survival rate at 3 years was also very similar between the two groups (86 % in the laparoscopic-surgery group and 85 % in the open-colectomy group; $p=0.51$; hazard ratio for death in the laparoscopic-surgery group, 0.91; 95% CI: 0.68–1.21) [21].

While in the CLASICC trial, 794 patients with colorectal cancer were recruited from 27 UK centers. The conversion rate was 29 %. No differences were recorded between open surgery and laparoscopic-assisted surgery for colorectal cancer with respect to tumor and nodal status, short-term endpoints, and quality of life. Eighty-one (10 %) patients had intraoperative complications, with no difference between treatments (difference 0.2 %, 95 % CI –4.2 % to 4.6 %, χ^2 test, $p=0.93$). Complication rates were higher for rectal procedures, (51 (13 %) of 381 vs 30 (7 %) of 413, respectively). The complication rate was also higher in converted patients than in nonconverted patients and in those who underwent open surgery, even after adjustment for stratification factors ($p=0.002$) [22].

In the COLOR trial, 1,248 patients with right, left, or sigmoid colon cancer were recruited from 29 hospitals. Laparoscopic group had less blood loss compared with those assigned to open resection (median 100 mL [range 0–2,700] vs. 175 mL [0–2,000], $p<0.0001$), although laparoscopic surgery lasted 30 min longer than did open surgery ($p<0.0001$). Conversion to open surgery was needed in 91 (17 %) patients. Number of removed lymph nodes and length of resected bowel did not differ between groups. Laparoscopic colectomy was associated with earlier recovery of bowel function ($p<0.0001$), fewer analgesics requirement, and a shorter hospital stay ($p<0.0001$) when compared with open colectomy. There was no difference in morbidity and mortality [23].

We can see that the short-term benefits were very obvious in these RCTs, and it was further summarized in a meta-analysis in 2005 [24]. Twenty-five RCTs with 3,526 patients were included in this meta-analysis. It demonstrated that laparoscopic technique was associated with the following advantages: blood loss was reduced (−72 cc), pain was less intense (−8 to −12 mm on a 100 mm VAS for pain), pulmonary function was improved (0.38–0.56 l on postoperative day 1 and 3), duration of postoperative ileus was shorter (−1.0 day), postoperative duration of hospital stay was less (−1.4 days), and quality of life might be improved in the early postoperative course (10 points on a 0–100 scale on day 7, 14 points on day 30, not any more at day 60). Furthermore, the risk of postoperative morbidity was decreased by the laparoscopic approach (RR 0.72 [95 % CI 0.55–0.95]), namely because of reduced surgical morbidity (wound infection [RR 0.56; 95% CI 0.39–0.82] and postoperative mechanical ileus [RR 0.42; 95 % CI 0.24–0.75]). However, the incidence of general postoperative complications was not decreased by the laparoscopic approach (RR 0.85 [95 % CI 0.61–1.18]) [24].

How about the long-term outcomes? Survival is the most important outcome indicator in any cancer surgery. In 2008, the same group of researcher performed a meta-analysis on the long-term results of laparoscopic colorectal cancer resection for the Cochrane Database of Systematic Reviews [25]. Thirty-three RCTs were identified while 12 of these trials, involving 3,346 patients, reported long-term outcome and were included. No significant differences in the occurrence of incisional hernia, reoperations for incisional hernia, or reoperations for adhesions were found between laparoscopically assisted and open surgery. Rates of recurrence at the site of the primary tumor were similar. No differences in the occurrence of port-site or wound recurrences were observed. Similar cancer-related mortality was found after laparoscopic surgery compared to open surgery (colon cancer: 5 RCTs, 1,575 patients, 14.6 % vs 16.4 %; OR (fixed) 0.80 (95 % CI 0.61–1.06) ($p=0.15$); rectal cancer: 3 RCTs, 578 patients, 9.2 % vs 10.0 %; OR (fixed) 0.66 (95 % CI 0.37–1.19) ($p=0.16$)). Four studies were included on hazard ratios for tumor recurrence in laparoscopic colorectal cancer surgery. No significant difference in recurrence rate was observed between laparoscopic and open surgery (hazard ratio for tumor recurrence in the laparoscopic group 0.92; 95 % CI 0.76–1.13). No significant difference in tumor recurrence between laparoscopic and open surgery for colon cancer was observed (hazard ratio for tumor recurrence in the laparoscopic group 0.86; 95 % CI 0.70–1.08). However, the long-term results on rectal cancer were not sufficient in the literature [25].

In view of insufficient data on the long-term outcomes to justify the recommendation of laparoscopic rectal cancer excision, many researchers try to retrieve the long-term survival data from their existing RCTs. One of which was from the group of the Chinese University of Hong Kong [26]. Two hundred and seventy eight patients with rectal cancer were recruited from three RCTs previously performed. The median follow-up time of living patients was 124.5 months in the laparoscopic group and 136.6 months in the open group. At 10 years, there were no significant differences in locoregional recurrence (5.5 % vs. 9.3 %; $p=0.296$), cancer-specific survival (82.5 % vs. 77.6 %; $p=0.443$), and overall survival (63.0 % vs 61.1 %; $p=0.505$) between the laparoscopic and open groups. There was a trend toward lower recurrence rate at 10 years in the laparoscopic group than in the open group among patients with stage III cancer ($p=0.078$). The Cox regression analysis showed that stage III cancer, lymphovascular permeation, and blood transfusion, but not the operative approach, were independent predictors of poorer cancer-specific survival.

Until recently, the first meta-analysis compared on the RCTs of laparoscopic versus open resection for rectal cancer was published in 2012 [27]. It demonstrated that laparoscopic surgery for rectal cancer had a statistically significant advantage over open surgery in terms of intraoperative blood loss, number of blood transfusions, hospital stay, postoperative ileus, postoperative abdominal bleeding, long-term complications, and long-term morbidity including obstruction by adhesions [27]. However, another meta-analysis by Huang et al. [28] focused on the oncologic adequacy of resection and long-term oncologic outcomes. Their meta-analysis suggested that there were no differences between laparoscopic-assisted and open surgery in terms of number of lymph nodes harvested, involvement of circumferential margin (CRM), local recurrence, 3-year overall survival, and disease-free survival for rectal cancer from six RCTs [28].

Finally, comparison between open and laparoscopic total mesorectal excision (TME) of rectal cancer is always a hot discussion among colorectal surgeons. A latest meta-analysis in 2014 addressed this issue. Fourteen RCTs met the inclusion criteria. The mean conversion rate was 14.5 % (range 0–35 %). There was moderate quality evidence that laparoscopic and open TME had similar effects on 5-year disease-free survival (OR 1.02; 95 % CI 0.76–1.38, 4 studies, $N=943$). The estimated effects of laparoscopic and open TME on local recurrence and overall survival were similar, although confidence intervals were wide, both with moderate quality evidence (local recurrence: OR 0.89; 95 % CI 0.57–1.39 and overall survival rate: OR 1.15; 95 % CI 0.87–1.52). There was moderate to high quality evidence that the number of resected lymph nodes and surgical margins were similar between the two groups. For the short-term results, length of hospital stay was reduced by 2 days ((95 % CI −3.22 to −1.10), moderate quality evidence), and the time to first defecation was shorter in the laparoscopic group (−0.86 days; 95 % CI −1.17 to −0.54). There was moderate quality evidence that 30 days morbidity were similar in both groups (OR 0.94; 95 % CI 0.8–1.1). There were fewer wound infections (OR 0.68; 95 % CI 0.50–0.93) and fewer bleeding complications (OR 0.30; 95 % CI 0.10–0.93) in the laparoscopic group. There was no clear evidence of any differences in quality of life between laparoscopic and open groups regarding functional recovery, bladder, and sexual function [29].

In conclusion, laparoscopic approach for colonic cancer has a better short-term outcome while comparable long-term oncological survivals to its open counterpart on multiple large-scale RCTs and meta-analyses. The short-term benefit for laparoscopic approach over open approach for rectal cancer has also been proven by multiple RCTs and meta-analyses, and the long-term oncological outcomes are comparable in the latest meta-analysis, although the quality of evidence is moderate (Table 2.1).

2.5 Hand-Assisted Laparoscopic Surgery (HALS)

Laparoscopic surgery for colorectal cancer is technically difficult with steep and long learning curve. In the early 1990s, hand-assisted laparoscopic colectomy was introduced to facilitate the transition from open to laparoscopic approach [30]. HALS allows the surgeon to insert his or her hand into the abdominal cavity through a relatively small incision while preserving the ability to work under pneumoperitoneum. However, this technique is getting out of favor as the advancement and mature of the laparoscopic technique.

As HALS acts as a bridge between open surgery and laparoscopic surgery, comparison can be made with both approaches. A recent meta-analysis in 2014 compared the hand-assisted laparoscopic surgery versus open surgery in colorectal disease [31]. There were twelve studies that included 1,362 patients were studied. Five of them were RCTs, while 7 are retrospective studies. The conversion rate was 2.66 %. Compared with the open surgery group, blood loss, wound infection, and ileus were significantly less in the HALS group; and length of incision, recovery of gastrointestinal function, and hospitalization stay were shorter. There were no significant differences in operating time, hospitalization costs, mortality, and complications between the groups [31]. However, long-term oncological outcomes were lacking.

Another meta-analysis compared the HALS with the conventional laparoscopic colorectal surgery [32]. Only three RCTs with 189 patients met the criteria. One study focused on the malignant lesions, one on benign lesions, while the remaining one had 1/3 malignant lesions. Conversion rates (odds ratio 0.32 [95% CI: 0.11, 0.90]) were significantly decreased in patients undergoing hand-assisted surgery but there was no statistically significant difference in operative time or complication rates. There were no significant differences in both the minor and major complications, pain score, bowel function, quality of life, and length of stay. No mortality was reported and long-term oncological outcomes were lacking. All studies were associated with methodological limitations [32].

In summary, hand-assisted laparoscopic colectomy has better short-term outcomes than open approach, and comparable short-term outcomes to laparoscopic approach, however, the evidence was not strong (Table 2.1). Long-term oncological data was lacking.

2.6 Single Incision Laparoscopic Surgery (SILC)

Single incision laparoscopic colectomy was first reported by Remzi and colleagues [33] and Bucher and coworkers [34]. Its potential benefits include less patient trauma, better cosmetic result, and patient satisfaction, less postoperative pain, and faster recovery; however, the manipulation of the instrument and the limitation of the movement on the single port may have resulted in more complications and inferior oncological outcomes.

In 2012, Maggiori et al. published the first meta-analysis on this topic [35]. Fifteen comparative studies with total 1,075 procedures (494 single incision and 581 multiport laparoscopies) were included. There were no differences in conversion rate, morbidity, and operation time, but a significantly shorter total skin incision (Weight Mean Difference (WMD) 0.52 (0.79, 0.25); $p<0.001$) and a significantly shorter postoperative length of stay (WMD 0.75 (1.30, 0.20); $p=0.008$) after single incision laparoscopic surgery compared with multiport laparoscopic approach. However, the data on the lymph node harvested and long-term oncological outcomes were lacking [35].

Several RCTs published after this meta-analysis, one of the larger studies was from the Hong Kong University [36]. Twenty-five patients with small colonic cancer (<4 cm) were randomized in each arm. There were no significant differences in patient's demographics, tumor characteristics, operating time, blood loss, complication rate, number of lymph nodes harvested, and resection margin between the two groups. The SILS group had consistently lower median pain score in the whole postoperative course and shorter length of hospital stay, and the difference was statistically significant [36].

In conclusion, based on the nonrandomized comparative trials and small RCTs, single incision laparoscopic colectomy has better pain control and length of hospital stay when compared to conventional laparoscopic colectomy. The long-term oncological outcomes were lacking (Table 2.1). It should only be applied in selected patients with colorectal cancer.

2.7 Natural Orifice Transluminal Endoscopic Surgery (NOTES)

Natural orifice transluminal endoscopic surgery was first described in 2004 [37]. The technique was initially tested in animal model and later it was mainly used in specimen retraction in colorectal surgery [38]. When it is combined with the traditional laparoscopic colectomy, it becomes a hybrid NOTES approach which was described by Cheung and her team in 1999 from Hong Kong [39].

Further, an RCT was performed by the same group to compare this innovative approach with the conventional laparoscopic surgery. Thirty-five patients with left-sided colonic cancer were randomized into each group in a 3-year interval. There were no significant differences observed between the two groups with respect to operating time, blood loss, or length of hospital stay. The pain score (1 vs. 2, $p=0.017$) and wound infection (0 vs. 4, $p=0.005$) were significantly lower in the hybrid NOTES group [40].

The latest development in this approach is the transition from the hybrid NOTES to pure NOTES. Leroy and colleagues reported the first case in 2003 [41]. A middle-aged woman with mid-rectal cancer underwent a pure transanal total mesorectal excision with a coloanal anastomosis without a diverting stoma successfully.

In summary, NOTES and hybrid NOTES are still at the experimental stage. It may have potential short-term benefit in terms of pain and wound complications when compared to the conventional laparoscopic surgery in selected patients (Table 2.1). It should not be used routinely in daily practice.

2.8 Robotic Colorectal Surgery

The advantages of laparoscopic surgery in colorectal cancer are well demonstrated previously. However, the long and steep learning curve, limited two-dimensional vision, and reduced dexterity of movement are major challenges. Bulky low rectal tumor in obese male patient is always a nightmare for laparoscopic colorectal surgeons. Robotic surgery, on the other hand, carried a three-dimensional vision with better dexterity especially in a narrow space, although with a much higher cost. Theoretically, it may have a better rectal dissection which may have resulted in a better circumferential margin and better nerve preservation of sexual and bladder function. Many studies were published in this topic in the recent past; however, most were case series and nonrandomized comparative studies.

One of the first systematic reviews in robotic surgery published in 2009 included 17 studies and 288 procedures. Study heterogeneity precluded a meta-analysis of the data. They found that robotic procedures tended to take longer and cost more, but might reduce the length of stay, blood loss, and conversion rates. Complication profiles and short-term oncological outcomes were similar to laparoscopic surgery [42]. This review failed to demonstrate the potential benefits of robotic surgery. One of the reasons was that most procedures are actually colectomy – the expected potential benefit was small when compared to rectal surgeries.

Therefore, subsequent comparative studies and meta-analyses were performed on comparison between robotic surgery and laparoscopic surgery in rectal cancer patients. Memon and coworkers had retrieved seven comparative studies in their meta-analysis. A total of 353 robot-assisted laparoscopic surgery proctectomies and 401 conventional laparoscopic surgery proctectomies were analyzed. Robotic surgery was associated with a significantly lower conversion rate ($p=0.03$; 95 % CI: 1–12). There were no differences in complications, circumferential margin involvement, distal resection margin, lymph node yield, or hospital stay [43]. Another meta-analysis by Trastulli et al. also achieved similar results. The conversion rate to open surgery in the robotic group was significantly lower than that with laparoscopic surgery (OR = 0.26, 95 % CI: 0.12–0.57, $p=0.0007$). There were no significant differences in operation time, length of hospital stay, time to resume regular diet, postoperative morbidity and mortality, and the oncological accuracy of resection [44]. A latest systematic review in 2013 [45] further concluded that robotic rectal surgery was associated with increased cost and operating time, but lower conversion rates, even in obese individuals, distal rectal tumors, and patients who had preoperative chemoradiotherapy, regardless of the experience of the surgeon. There was also marginally better outcome in anastomotic leak rates, circumferential resection margin positivity, and perseveration of autonomic function, but this did not reach statistical significance [45].

In conclusion, the benefits of robotic colectomy were not obvious on the literature. Robotic rectal surgery has a lower conversion rate with similar hospital stay, bowel function, morbidity and mortality when compared to the conventional laparoscopic approach. The oncological outcomes and preservation of autonomic function were far from conclusion (Table 2.1). However, most data were retrieved from nonrandomized comparative studies; large-scale, well-designed RCT should be the future direction.

Conclusion

Different minimally invasive approach has different benefits and limitations. Provided that expertise is available, all approaches are safe and feasible and beneficial to our patients. Careful selection of the technique with proper training and credentialing is the key to success.

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3 Laparoscopic Colectomy

Samuel Kwok and Kam Hung Kwok

3.1 Introduction

Laparoscopic colectomy is a broad term that includes resection of the colon at any part of the colon along its length from the terminal ileum to the rectosigmoid junction. Commonly resection of the colon can be divided into right hemicolectomy, transverse colectomy, left hemicolectomy, sigmoid colectomy, and subtotal colectomy. The above division of colectomies is based on the location of the colonic disease and surgical removal of colon is usually segmental and depends on which major blood supply to the colonic segment has to be taken. In this way, right hemicolectomy normally includes removal of a short segment of terminal ileum and sigmoid colectomy may include the rectosigmoid junction.

3.2 Historical Background

The development of laparoscopic colectomy in Hong Kong started very early and the first case was a case of laparoscopic sigmoid colectomy in April 1992 at the Prince of Wales Hospital. The sigmoid colectomy was initially chosen because it was thought that sigmoid, being the most redundant part of the colon, should provide the simplest model of laparoscopic colectomy. Subsequently, a series of sigmoid colectomy, anterior resection involving upper part of rectum and other colectomies were carried out. In fact, laparoscopic colectomies involving different segment of colon requires very different approaches and techniques. In the early days, transverse colectomy was considered the most difficult because of the need to handle omentum and more complicated mesenteric structures. The cutting devises were not as convenient as the current instruments that we use such as harmonic devices or bipolar cutting devices that can both coagulate and cut efficiently. Mobilization of the splenic flexure of the colon was not an easy undertaking either due to the same reason of the need to deal with more vascular structures.

In the course of the operation, the positioning of the operating table in terms of head up or down and tilting sideways should be adjusted according to the need of the surgeon at the time. The principle is that the loops of small bowel should be allowed to gravitate away from the site of interest. In sigmoid and left colon mobilization, the patient should be in the head down and right tilt position except when splenic flexure mobilization is carried out, wherein the patient should be at the head up and right tilt position. For right

S. Kwok (✉)
Colorectal Surgery, Hong Kong Pedderclinic,
Hong Kong, China
e-mail: pa1@pedderclinic.hk

K.H. Kwok
Department of Surgery,
Queen Elizabeth Hospital,
Kowloon, Hong Kong, China

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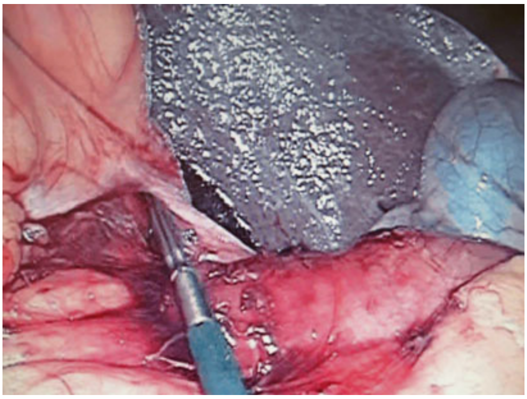

Fig. 3.1 Hepatic flexure mobilization

hemicolectomy, a gentle left tilt is usually enough. The addition of head up for hepatic flexure mobilization (Fig. 3.1) and head down when cecal or terminal ileal mesenteric attachment is dealt with is also useful. For most of the transverse colon case, head up position should be in order.

3.3 Contraindications

The analysis of our first 100 cases of laparoscopic colectomy in 1996 found that the reasons that lead to failure to proceed meaning conversion to open surgery were large tumor, intestinal obstruction and significant adhesions. In modern day laparoscopy, these factors were still true as contraindications for laparoscopic colectomy. Excessively large tumor should be excluded for laparoscopy mainly because a large abdominal incision would be eventually required for tumor extrication and therefore negates the benefit of laparoscopic surgery of small wounds. In frank intestinal obstruction, intra-abdominal space is not enough for safe laparoscopic manipulation and therefore should be contraindicated. Some degrees of intra-abdominal adhesions usually do not interfere with laparoscopic colectomy so much and most adhesions can be lysed laparoscopically before proceeding to colectomy. Only those with extensive dense intra-abdominal adhesions will lead to conversions nowadays and those usually are evident when on initial entering of the laparoscope into the abdominal cavity. Therefore, if extraordinary adhesions were found, decision for conversion should be made early.

3.3.1 Patient Positioning and Surgeons Position

In all laparoscopic colectomies except for sigmoid colectomy, the patient can be put in the supine position with both upper limbs alongside the body. The patient should be put on an antislip mattress to avoid body movement of the patient when the operating table is adjusted to steep angles.

The alternative is all laparoscopic colectomy including the sigmoid colectomy be in the Lloyd-Davis position in which both legs of the patient be put in stirrups and spread apart to allow access of the surgeon to the perineal region. This is necessary in sigmoid colectomy where colorectal anastomosis is fashioned with the help of transanal circular stapler. In the case of other colectomies, the surgeon can gain access to the abdomen by standing between the legs of the patient. It is particularly useful in transverse colon mobilization and splenic flexure mobilization.

3.3.2 Port Site Plans for Laparoscopic Colectomy

In the usual multiport laparoscopic colectomy as opposed to the single port version, four ports are normally required. Umbilical port should be used as the laparoscopic port. Two ports on the side of abdomen opposite to the side of target lesion should be used by the chief surgeon and one on the side of the lesion should be used by the assistant surgeon. If the case turns out to be quite difficult in the handling of the structures, an extra port can be put in on the assistant side for his two hand assistance. One of these port sites can be converted into a small incision for colon extrication at certain stage and it usually would be the site that is nearest to the lesion. The distance between port sites should be at least 10 cm to avoid instrument clashing and most commonly each port should be in one quadrant of the abdomen and this plan of port position is the most versatile and ergonomically friendly. All peripheral ports should be 5 mm ports except one which the surgeon choose for inserting bigger instruments such as endoscopic staplers or large vascular clips. Usually, the one on the surgeons' right hand is best suited for this purpose.

3.4 Special Instruments

3.4.1 Cutting Devices

As in most of the mobilization of the colon in laparoscopic colectomy, the dissection is best to go along avascular tissue planes, such as cutting along the line of Toldt where the colon meets the peritoneum and the plane between the colonic mesentery and the retroperitoneal fat. The use of ordinary laparoscopic cutting scissors with monopolar diathermy is good enough. However, in cases the mesentery has to be traversed at points where the mesenteric vessels have to be dealt with or when going across lesser omentum in transverse colon mobilization or in taking down the splenic or the hepatic flexure, a cutting devise with better haemostatic function such as the Harmonic scalpel, bipolar cutters such as the Ligasure or the Thunderbeat which has both harmonic and bipolar functions are good choices as cutting devises. If those more hemostatic cutting devices are used, they can actually replace the use of ordinary laparoscopic scissors.

3.4.2 Grasping Forceps

It is better for the chief surgeon to use a more pointed and shorter jaws atraumatic laparoscopic forceps such as the Maryland type forceps or a short blade bowel forceps for traction and counter traction of the bowel or mesenteric tissues in the course of dissection because they are more precise and stronger in the handling of the tissue. The assistant can use one or two long blade atraumatic bowel forceps to hold bowel or tissues up for the chief surgeon's dissection. Longer blade bowel forceps can hold larger piece of mesenteric tissue or bowel without easy slippage and therefore it can provide a steady platform for dissection.

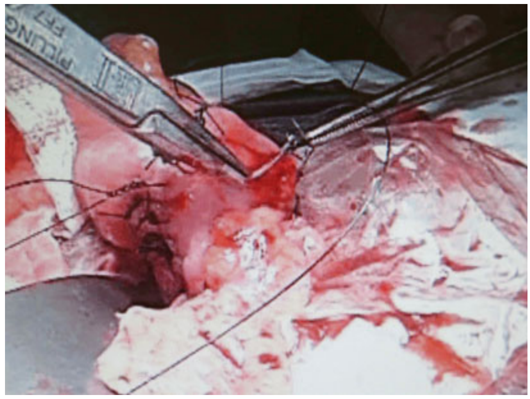

Fig. 3.2 Extracorporeal hand-sewn anastomosis

3.4.3 Stapling Devices

It is common to use endoscopic stapler for bowel transection in the course of laparoscopic colectomy. It also depends on whether one prefer a totally laparoscopic version where one would transect and perform bowel anastomosis intracorporeally under laparoscopic guidance or one adopts the laparoscopic full bowel mobilization followed by exteriorization of bowel loops for external bowel transection and anastomosis. In sigmoid colectomy where the distal bowel transection is at the recto-sigmoid junction or at the upper rectum, the rectal stump is too short to bring up to the abdominal wound for operation; therefore, in this situation, distal bowel transection has to be performed with the use of endoscopic stapler and the subsequent colorectal anastomosis is fashioned with the use of transanal circular stapler for intra-corporeal anastomosis creation. In all other colectomies where both ends of bowel can be brought out of the abdominal wound for operation, it is common to bring the bowel loops out for extracorporeal transection and anastomosis (Fig. 3.2), saving the more tedious intra-corporeal bowel transection and anastomosis.

3.5 Sigmoid Colectomy

3.5.1 Patient Position

The patient should be put in the Lloyd-Davis position with both legs spread out on stirrups. Plane of thighs should be low down and is almost parallel to the anterior abdominal wall. Both upper limbs should be put alongside body. Operating table should be tilted head down and towards the right. Chief surgeon should be on the right side and assistant surgeon on the left side of the patient.

3.5.2 Ports Position

Central umbilical port is reserved for laparoscopy. Two right-sided ports, one 5 mm on the upper quadrant, and one 12 mm port at the lower quadrant are inserted for the chief surgeon. One left lower quadrant 5 mm port is inserted for the assistant.

3.5.3 Procedure of Sigmoid Colectomy

All small bowel loops are moved away from the pelvic cavity and the sigmoid colon and rectum are fully exposed. There are two alternative approaches to mobilization of the sigmoid colon, i.e., from lateral to medial approach or the medial to lateral approach. Here the lateral-to-medial approach is described and it is the method developed from the early days of laparoscopic colectomy in Hong Kong and is more similar to the open approach and very good in the easy localization of the left ureter.

By dividing the attachment of the sigmoid colon to the left pelvic brim and the lateral parietal peritoneum gradually from rectosigmoid junction up to the descending colon and dissecting the meso-sigmoid colon from its retroperitoneal attachment, the sigmoid colon and its mesentery can be freed up to the medial leave of meso-sigmoid colon and completely exposing the left ureter and left gonadal vessel. The sigmoid colon is then lifted up by the assistant using the bowel forceps to hold up the meso-sigmoid and tighten up the medial leave of meso-sigmoid. The medial leave is then incised at its root and the bifurcation of the aorta is exposed leaving a layer of retroperitoneal tissue embedding the superior hypogastric trunks which can usually be seen clearly and be preserved. A cotton tape can be passed to encircle the sigmoid loop with its mesentery and the assistant can make use of this tape to retract and control the sigmoid colon when the surgeon is dissecting the root of mesentery at the inferior mesenteric vessels. The inferior mesenteric artery and vein near their origin can be defined by trimming the surrounding fat and lymphatic tissue and the artery and vein can then be clipped and cut separately.

Attention can then be turned to the distal sigmoid and upper rectum. The cotton tape can be moved to the distal sigmoid below the tumor. This can provide strong traction onto the sigmoid for further rectosigmoid dissection. The mesorectum of the upper rectum is then dissected along its avascular plane from the parietal fascia of the pelvis. The level of distal bowel transection is then determined according to the level of tumor. For a sigmoid tumor, a level near to the rectosigmoid junction above the peritoneal reflection is usually chosen. The mesorectum is then cut and clear from the rectal muscle tube with the harmonic device along the chosen plane of bowel transection. A rectal wash with pethidine solution trans-anally can be performed at this stage with the cotton tape tightened around the sigmoid colon below the distal tumor margin. After the rectal wash, the rectosigmoid junction is ready for transection with an endoscopic linear stapler. The rectal transection can usually be completed with one or two applications of the stapler (Fig. 3.3). The free end of the sigmoid colon is then grasped with a endoscopic grasper with lock.

The sigmoid colon is ready to be extricated from the abdominal cavity. The laparoscope is then removed and the abdomen desufflated. The left lower quadrant port site is then extended to about 4 cm or a size of wound through which the sigmoid colon with the tumor can get through

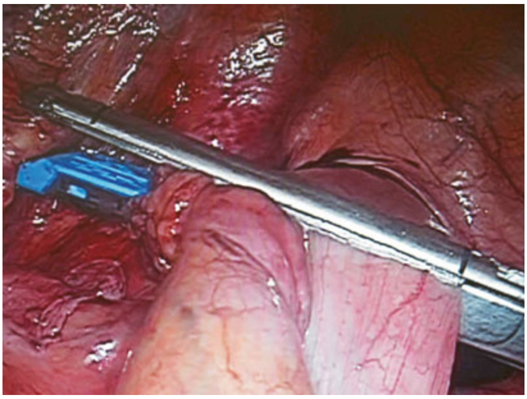

Fig. 3.3 Sigmoid colon transection

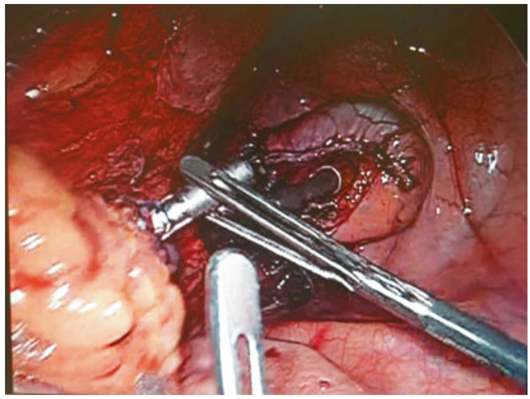

Fig. 3.4 Colorectal anastomosis with stapler

without excessive traction force. A wound protector usually in the form of a plastic sleeve is then applied to the extended port site and the sigmoid colon is then retrieved from the abdomen with the cut free end coming out first. The sigmoid colon is completely exteriorized and the proximal bowel transection is done extracorporeally. Care is taken to make sure the remaining length of colon should reach the rectum comfortably for a colorectal anastomosis. After excision of sigmoid colon, the proximal colonic end is prepared for intra-corporeal anastomosis with the use of trans-anal circular stapler. The anvil of the stapler should first be inserted into the proximal colonic end and secured with a 2/0 prolene purse-string suture. The closed end of the bowel with the anvil, is then returned to the abdominal cavity and the extended wound for specimen retrieval can be temporally sealed with a large-size glove.

The abdomen is then reinsufflated and laparoscope reinserted. Under guidance of the laparoscope, the free end of colon is then anastomosed to the rectal stump with the introduction of the chosen trans-anal circular stapler into the rectum and the spike of the stapler made to come out the cut end of the rectum (Fig. 3.4). The anvil is made to lock on with the spike of the stapler and colorectal anastomosis is then created. The anastomosis can be checked for air tightness by infusing air into the rectum via the anus using a bladder syringe and the pelvic cavity filled with physiologic saline.

3.6 Colectomy

The other colectomies are similar in the techniques of the operation and therefore are described together. Only the site of segment of colon removed is different and the main difference lies in whether the splenic flexure or the hepatic flexure has to be taken. After mobilization of the relevant segment of colon, the whole loop of colon or in the case of right hemicolectomy the terminal ileum as well can be exteriorized via an extended port site for an extracorporeal excision and anastomosis. As the required incision for taking out the specimen is normally enough to do the extracorporeal part of the operation, this is the preferred method as opposed to the intra-corporeal excision and anastomosis of bowel.

3.6.1 Patient Position

Patient can lie supine in all colectomies as it is not necessary to do transanal stapling as in sigmoid colectomy or anterior resection of the rectum. One might choose to put patient in the Lloyd-Davies position for an extra position for access between the legs of the patient. If splenic flexure mobilization is involved, patient should be put head up and left side up while if the hepatic flexure is the interest spot, the patient should be position head up and right side up.

3.6.2 Ports Position

Umbilical port for laparoscopy should be universal. For left hemicolectomy, chief surgeon should stand on the right side and two ports on the right should be used while for right hemicolectomy, the surgeon should stand on the left side and two ports should be on the left side. Normally, one port for the assistant should be enough and should be put on the opposite side of the surgeon and near to the site of lesion.

3.6.3 Procedure of Colectomy

The vascular first approach is preferred in colectomies. The respective supplying vascular pedicle should be taken by dissecting out the origin of them and taken with the use of Hemolok clips and cut in-between. In the case of left hemicolectomy, it should be the left colic vessels coming off the inferior mesenteric vessels and may be one or two sigmoid branches as well depending on the location of the tumor in question. The inferior mesenteric vessels should not be taken if not necessary in order to preserve blood supply to the sigmoid colon which is needed for subsequent bowel anastomosis extracorporeally. However, lymphadenectomy around the inferior mesenteric artery can be performed laparoscopically if needed without taking the inferior mesenteric artery. In the case of right hemicolectomy, the ileocolic vessels can be found by lifting the medial leave of meso-ascending colon and incising on the peritoneum covering at the lower edge of the third part of duodenum. The ileocolic vessels can then be taken between Hemolok clips. After taking the vascular pedicle, the root of the mesentery can be easily lifted off the retroperitoneal layer by sweeping across the plane because it is quite an avascular plane.

3.7 Splenic Flexure Dissection

With the assistant holding up the greater curve of the stomach, the gastro-colic ligament is then incised in the middle to gain access into the lesser sac. By lifting the colon, the whole lesser omentum to the left up to the splenic flexure can be incised using the hemostatic cutting devise. The left colon can be totally freed by incising the lateral attachment from the sigmoid colon up to the splenic flexure. The whole left colon including the splenic flexure should now be totally mobilized and ready for taking out for extracorporeal procedure.

3.8 Hepatic Flexure Mobilization

For right hemicolectomy, attention is turned to the hepatic flexure after the taking of the ileocolic vessels and exposing the second and third parts of the duodenum. By lifting the antrum of the stomach, the lesser omentum is incised to gain access to the lesser sac. The cutting of the lesser omentum is continued to the right by taking the superficial leave and the duodenum will be totally exposed. The peritoneal leave lateral to the duodenum is incised with the hemostatic cutter to expose the Gerota's fascia. Hemostatic cutter should be used because the vessels lining the peritoneal layer can bleed a lot if not properly coagulated. Then the right colon and the terminal ileum can be mobilized by lifting the cecum by the assistant and the root of the terminal ileum mesentery can be incised and the lateral attachment of the right colon can be totally divided. At this juncture, the whole right colon and the terminal ileum should be nearly completely mobilized save for a few adhesion of the colon to the retroperitoneum and those can be divided easily when the right colon is lifted up by the assistant. What remains is the small bowel mesentery which can be incised along the ileocolic vessel up to the terminal ileum with a hemostatic cutter. By this time, the right colon and terminal ileum is ready to take out for external excision and anastomosis.

3.9 Excision of Colon and Anastomosis

By passing a cotton tape around the piece of mobilized colon laparoscopically, it can serve as the point where the mobilized colon can be retrieved from the abdomen to the outside via a mini-incision of about 4 cm or a size that allow the colon and tumor to be taken out without much force. The mini-incision has to be protected by a plastic sleeve when the colon is exteriorized. After the right or left colon is taken out, the relevant mesenteric attachment should be trimmed to the supposed level of bowel transection and a right or left hemicolectomy can be effected with conventional open instruments. The bowel anastomosis can be performed either by hand-sewn or in a functional end-to-end fashion using linear stapler as in open surgery. The mesenteric window can be closed by suture down to where the wound can allow in access of the mesenteric edge. At this point the colectomy is completed and the anastomosed colon can be reduced into the abdomen and the wounds closed.

4 Hand-Assisted Laparoscopic Colorectal Surgery

Jian Jiang Lin and Fan Long Liu

Laparoscopic technique finds wide application in abdominal surgery for its benefits such as smaller wounds and quicker recovery. Laparoscopic colorectal cancer surgery of a curative intent has become popularised since Fowler and Jacobs demonstrated the first laparoscopic sigmoid colectomy in 1990. A few limitations remain, though, as follows: (1) The loss of tactile feedback together with a two-dimensional image makes it difficult for the operator to determine the extent of tumour infiltration and lymph node metastasis. (2) Costly, specialised equipment and longer operating time mean higher cost to patient. (3) It is technically demanding to the surgeon. The learning curve is steep and it takes about 50 cases for an operator to become familiar with the technique. (4) Late stage tumours cannot be excised laparoscopically. It is not feasible to resect T4 lesions, and conversion is required for most of these cases. (5) Bleeding has been a dreaded case, where conversion has often been necessary. With technical improvement and technological advancement, in particular with the appearance of the ultrasonic dissector, laparoscopic colorectal resection has steadily become another commonly performed complex surgery following laparoscopic cholecystectomy.

J.J. Lin (✉) • F.L. Liu
Department of Colorectal Surgery, The First Affiliated Hospital of Zhejiang University, Hangzhou, China
e-mail: ljjzju@163.com; fanlong_liu@163.com

Successful extirpation of a tumour depends on the degree of tumour differentiation, staging, extent of surgical excision, no-touch technique and integrated post-operative care. Laparoscopic surgery provides an adequacy of lighting into deep recesses, magnification and a degree of precision that surpass open surgery, thus ensuring complete excision of the primary lesion and its lymphatic drainage area. Evidence suggests that laparoscopic resection gives a length of the resected specimen, area of excision and number of lymph nodes removed that is no different from open surgery. Hartley et al. demonstrated by randomised trail no significant difference in the rate of recurrence, wound recurrence or trocar recurrence between laparoscopic and open surgery. Ongoing multicentre prospective randomised trials in the USA and Europe will hopefully offer conclusive remarks on the role of the laparoscopic technique in colorectal resection. Similar studies are ongoing in China [5].

4.1 Hand-Assisted Laparoscopic Surgery

Hand-assisted laparoscopic surgery (HALS) is gaining popularity in recent years. It refers to a new model of surgery, whereby the operator inserts his dominant hand into the peritoneal cavity through a specialised port to assist in the laparoscopic surgery. Owing to its safety, minimally

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invasive nature, shorter operating time and relative ease of learning, HALS has undergone rapid development among abdominal surgeons. While retaining the benefits of minimally invasive surgery, HALS has made laparoscopic surgery easier, and made it technically feasible for surgeons to accomplish feat that would otherwise have been impossible with the laparoscopic techniques. It has in fact been instrumental in promoting the adoption of saparoscopic abdominal surgery. Preliminary data from studies conducted by the FDA (US) comparing HALS and standard laparoscopic surgery indicated that HALS colorectal resection is as safe as standard laparoscopic colorectal resection, has similar postoperative recovery, similar conversion rate but much less instrument and a shorter operating time. HALS retains the advantages of minimally invasive surgery and allows the surgeon to accomplish more complex surgical feats.

HALS follows the surgical principles of total mesorectal excision (TME): (1) Dissection follows the pre-sacral (retrorectal) plane under direct laparoscopic vision, such that (2) the entire pelvic fascia remains intact. (3) The distal margin has to be at least 5 cm or in the case where the total mesorectum is excised, the distal margin has to be at least 2 cm. HALS has certain advantages in comparison with open TME surgery: more refined definition of the pre-sacral (retrorectal) plane allows more precise dissection; more exact identification of the pelvic autonomic plexuses facilitates its preservation during surgery; and sharp dissection using the ultrasonic dissector allows for complete removal of the mesorectum.

4.2 Indications for HALS

- Resection of any solid or hollow organ that requires a wound in the abdominal wall for its retrieval.
- Laparoscopic surgical operations that are difficult, expensive and come with high conversion rate.
- With respect to difficult laparoscopic surgical operations, HALS provides a safe alternative to conversion, providing the same tactile feedback as open surgery.
- Surgical operation that is too complex and technically demanding if performed by the traditional, laparoscopic method.

4.3 Contraindications

1. Relative contraindications include tumours greater than 6 cm, and/or tumours infiltrating surrounding structures, extensive intraperitoneal adhesions, emergency surgical operation for colorectal cancers (acutely obstructed, perforated, etc.) and patients with impaired cardiorespiratory function.
2. Absolute contraindications include patients with poor general health that cannot be optimised before surgery, and patients with cardiac, respiratory, hepatic or renal failure who are unable to sustain the proposed surgery.

4.4 Facilities and Equipment

1. Routine facilities

   High definition video capturing and monitoring system, automatic high flow insufflator, irrigation and suction devices, video and photo capturing and storage facility, routine laparosopic surgical equipment includes Varess Needle, 5–12 mm tracer and cannula, dissector, atruamtic bowel graspers, scissors, needle holder, vascular clips, clip applicators, laparoscopic retractors, laparoscopic hook, specimen bag, etc.
2. Special equipment

   Includes hand-assisted laparoscopic device, ultrasonic dissector, bipolar diathermy coaptation cutter, bipolar diathermy, various types of linear and circular staplers.

4.5 Preparation

1. Staging workup for potential metastases to the liver and lymphatic spread to the retroperitoneal lymph nodes and mesocolic lymph nodes.
2. Control medical conditions that might affect surgical risk, such as hypertension, coronary

artery disease, diabetes mellitus, respiratory dysfunction and renal diseases.
3. Correct anaemia, hypoalbuminaemia, electrolye and acid-base disturbances, optimise nutritional status.
4. Bowel prep and vaginal prep as necessary for surgery.

4.5.1 Pre-operative Preparation

The pre-operative preparation for HALS colorectal surgery is identical with the corresponding open surgery, and includes bowel prep and fasting. Other preparation such as general assessment, prophylactic antibiotics, pre-operative staging by ultrasound or CT scan to elucidate disease extent in affected organs are by and large identical with that of open surgery.

4.5.2 Positioning

Patient positioning is essential for better exposure with the laparoscopic technique.

4.5.3 Port Sites

Three to four port sites, starting with the subumbilical incision (Fig. 4.1). Port-site position and number for HALS colorectal cancer surgery: usually 2 is adequate in addition to the hand port site, although sometimes a third port is helpful.

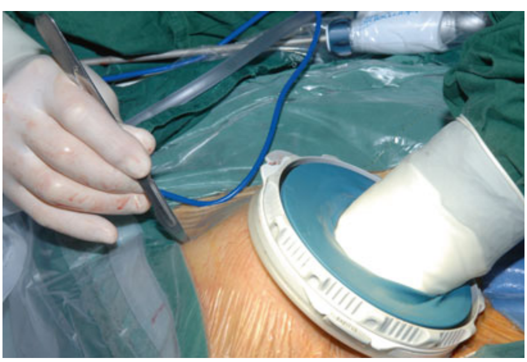

Fig. 4.1 Port insertion

4.6 Sigmoid Colon and Rectal Surgery

Operative steps include the following:

1. Diagnostic laparoscopy
2. Installation of the hand port
3. Dissection of the bowel
4. Excision of the bowel and mescolon or mesorectum
5. Bowel anastomosis

Advantages

1. HALS is minimally traumatic, facilitates postoperative recovery of function.
2. Making use of the ultrasonic dissector, it allows for good resection of curative intent.
3. Hand in the abdomen provides tactile sensation, and allows for retraction, triangulation and blunt dissection.
4. Allows for relative ease to handle unforeseen intraoperative events such as major bleeding.
5. Reduces the risk of tumour implantation in the wound, and allows for rapid conversion to open surgery.
6. The hand port can be transformed into a stoma site or for the removal of specimen without the need for a separate wound.

4.6.1 Tips and Tricks

- Tactful positioning of the relative positions of the hand port and other trocars facilitates not only the retraction and exposure of operative site, but also the use of other laparoscopic instruments, and prevents adjacently placed trocars from damaging the intraabdominal portion of the hand port.
- The size of the wound for the hand port should be half the width of the operator’s glove.
- The wound for the hand port can be flexibly used for dissection and ligation of mesocolic vessels under direct vision.

Attention should be paid to the following:

- The insufflation channel on the hand port is akin to a big trocar. It should be positioned in triangulation with the laparoscope and other instruments.

- The hand port incision should not be too close to the operative site in order to avoid the forearm from obstructing the view. When deciding on where to make the hand port site, consideration should be made to the possibility of conversion.
- The hand port should be so placed that the organ structure to be resected remains close to the front of the operative field. The arm should remain in a neutral position in order to reduce fatigue. The non-dominant hand is inserted just beyond the wrist into the abdomen, leaving the dominant hand to handle laparoscopic instruments.
- The specimen should be recovered inside a specimen bag or through a protected wound in order to avoid contacting the wound edges.

4.6.2 Inadequacies of HALS

The hand manoeuvring inside the abdomen may come into contact with the lens of the laparoscope and impairs the view. The operator and the cameraman should work well with one another to avoid compromising the view. Bleeding and oozing are possible from manipulation of intraabdominal structures using the hand. A piece of gauze helps to wipe clean the operative field and maintain a clear vision. HALS reduces the difficulty of laparoscopic colorectal surgery and provides wound protection. It may be used for the training of laparoscopic surgeons, or it can be a strategy for a seasoned surgeon to handle difficult cases. Prospective randomised trial is needed in order to establish the relative role of HALS and standard laparoscopic surgery.

4.6.3 Post-operative Management

1. Close observations of the patient's vital signs, the nature and volume of drainage
2. Maintain electrolyte and acid-base balance, antibiotics to avoid infection
3. Avoid pressuring the gastrointestinal tract, allows liquid diet upon passage of flatus, to be stepped up steadily to a full diet
4. Integrated anticancer therapy provide adjuvant chemotherapy, radiotherapy or immunotherapy where indicated

4.6.4 Detailed Operative Method

Install the 'Lapdisc' hand-assisted device at the hand port incision site (centring on the umbilicus, make a periumbilical incision of about 5 cm). The laparoscope and the ultrasonic dissector are inserted through different sites, depending on the type of surgery to be performed Table 4.1. The operator's left (non-dominant) hand is inserted into the peritoneal cavity via the hand port (Fig. 4.2).

Pneumoperitoneum is established. The peritoneal cavity is inspected in accordance with the

Table 4.1 Patient positioning, surgical wounds and surgeon's positioning

	Patient position	Hand port location	Laparoscope port site	Ultrasonic dissector	Operating surgeon
Right hemicolectomy	Supine	Periumbilical 5 cm	Level with umbilicus and 15 cm laterally	4–5 cm subxiphoid	Patient's left
Left heicolectomy	Lloyd-Davies	Periumbilical 5 cm	4–5 cm subxiphoid	Left lateral, 15 cm from and level with umbilicus	Between legs
Sigmoid colectomy	Lloyd-Davies	Periumbilical 5 cm	2 cm above pubic symphysis	Right lateral, 15 cm from and level with umbilicus	Patient's right
Anterior resection	Lloyd-Davies	Periumbilical 5 cm	2 cm above pubic symphysis	Right lateral, 15 cm from and level with umbilicus	Patient's right

Note: positioning of the laparscopic port site and the ultrasonic dissector port site can be adjusted to suit individual circumstances.

Fig. 4.2 Operative set-up

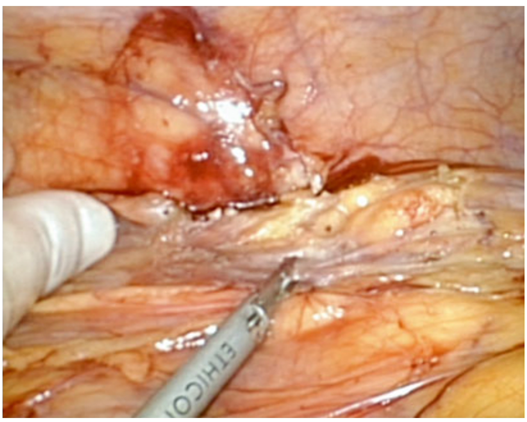

Fig. 4.3 Bowel dissection with intracorporeal hand assistance

standard requirement for curative resection of colorectal malignancy. Inspection should allow the doctor to check for metastases and to confirm tumour location. The ultrasonic dissector is used to dissect, separate and divide the respective mesocolon, lateral peritoneal reflection and blood vessels as close to the root as possible (Fig. 4.3).

Once the bowel is dissected, it can be exteriorised via the Lapdisc (appropriate for right hemicolectomy, left hemicolectomy and sigmoid colectomy of curative intent). The tumour bearing segment of the colon is excised after the bowel is exteriorized, and an anastomosis made using linear staplers or biodegradable colon rings. In the course of rectal tumour surgery, distal bowel transection makes use of a laparoscopic linear cutter. The resection end is exteriorised via the Lapdisc, and proximal bowel transection takes place. Pneumoperitoneum is re-established and anastomosis fashioned using the trans-anal circular stapler.

4.6.5 Low Anterior Resection

1. Under general anaesthesia, patient is positioned in a 30° head down and 30° right rotated (left side up) Lloyd-Davies position.
2. The operating surgeon stands on the patient's right side, while the first assistant stands on the patient's left side and the camera man stands either opposite the operating surgeon or in between the patient's legs.
3. A 5 cm periumbilical incision is made for the Lapdisc. Insert a 10 mm port through the hand port device and pass in a 30° laparoscope for diagnostic laparoscopy. The port is removed after diagnostic laparoscopy, and the surgeon's left hand is inserted together with a piece of gauze. A 10 mm incision is made 2 cm rostral to the pubic symphysis for the 30° laparoscope. A 10 mm working port with a 5 mm reducing cap is inserted along the right linear semilunaris slightly 15 cm away from, and just caudal to the level of the umbilicus.
4. The sigmoid mesocolon is dissected from its right edge. The surgeon should mind the left

and right ureters during dissection. The inferior mesenteric artery (IMA) and vein are exposed, and the lymph nodes at the IMA root is taken into the specimen side. The IMA or the superior rectal artery is divided together with their accompanying veins. Care should be taken to preserve left colic artery in order to avoid inadequate blood supply to the anastomotic and the consequential leak.

5. Sharp dissection in the 'holy plane' between the mesorectal fascia and the pelvic fascia. In the case of low rectal tumour, dissection should be carried down to the tip of the coccyx.
6. Division of the anterior peritoneal reflection, and dissect along the Denovillier's fascia to separate the anterior rectal envelop from the seminal vesicles (along the rectovaginal plane in female patients).
7. Distal bowel transection using laparoscopic stapler 3 cm distal to the gross tumour margin, the proximal bowel is exteriorised throughout the hand port device and transected. The anvil of a circular stapler is inserted into the proximal loop, and pneumoperitoneum is re-established. Anastomosis between the sigmoid colon and the remaining rectum is effected under direct laparoscopic vision by means of a circular stapler. The anastomosis must be tension free.
8. Lavage of the pelvis follows, and a drain is placed in the vicinity of the anastomosis.

4.7 Advantage of HALS

As a new type of surgical operation, HALS comes with the advantages of laparoscopic surgery and retains the direct vision of traditional, open surgery. It is gaining wider and wider acceptance in the surgical community. Literature is supportive of better outcome of HALS in comparison with traditional and total laparoscopic rectal surgery [1, 4, 6, 7]. Combining literature with our experience, the author is of the opinion that HALS rectal cancer curative surgery is advantageous in (1) combination of touching and seeing: the biggest advantage of HALS to a surgeon is the ability to feel and the possibility of eye-hand coordination. Through manipulation by the hand, a better exposure can be obtained at the operative field. It also comes with an ease for haemostats, and more precise localisation of the pathology. (2) Safe operation for complete tumour extirpation: The hand in HALS is in itself an instrument for blunt dissection, it guides the ultrasonic dissector to operate for a high precision sharp dissection. Palpable pulses at the mesocolic root allow for precise identification of the blood vessels, and facilitate easier haemostasis. Magnification under the laparoscope allows a clear definition of adjacent structures, organs, blood vessels and blood vessels, so as to avoid collateral damage to these structures. Through palpation, enlarged lymph nodes at mesocolic roots are more readily detected and excised. In the case of low anterior resection of the rectum, in particular in male patient with narrow pelvis, laparoscopic surgery allows dissection into the depth of the pelvis, with relative ease and completeness in comparison with open surgery. (3) Good recovery after laparoscopic surgery: HALS comes with a 5 cm main wound and a smaller number of port sites than traditional laparoscopic surgery. With less surgical trauma, recovery time is shortened. Reduced exposure of the internal organs to the external environment, less evaporative fluid loss and an overall reduced impact on the patient means quicker return of bowel function, less post-operative complications and shortened hospital stay. (4) Ease of mastering, short learning curve: compared to traditional laparoscopic surgery, the combined visual and tactile feedback with HALS reduces difficulty and makes it an easier technique for surgeons to master – in other words, a shorter learning curve. (5) Specialised hand port device – 'Lapdisc': In contradistinction to earlier versions of hand port devices, the Lapdisc comes in a single piece with an iris valve. With the base abutting closely the peritoneum, the Lapdisc provides a good occlusive effect and capacious intra-peritoneal working space. The base effectively protects the wound from tumour tissues and prevents port-site tumour implantation. (6) The diseased bowel can be exeteriorized through the base during resection and anastomosis, making the procedure safe and convenient, and reduces the risk of peritoneal infection and tumour implantation.

4.8 Lesson Learned from HALS Colorectal Cancer Surgery of Curative Intact

4.8.1 Choice of Port-Site

Many centres choose a location for the hand-port site according to the tumour location [2, 3, 9]. While it has certain advantages such as ease of exposure and convenience with manipulation, it comes with disadvantages of incomplete diagnostic laparoscopy, difficult wound extension in case of conversion and poor cosmetic outcome. Therefore in our centre, we universally use a 5 cm peri-umbilical incision. It is noteworthy that the wound cannot be too big, lest occlusive effect is impaired. A trapezoid incision that is smaller superficially than deeply gives a better cosmetic outcome, allows for ease of hand port device insertion and ensures air occlusion during surgery. The author contends that periumbilical incision is advantageous in terms of (1) a 'universal incision' such that tumour at different locations can be tackled using the same wound, and avoids the embarrassment of a wrongly sited wound for wrong pre-operative tumour localization; (2) a centrally located wound provides a capacious intraperitoneal working space for complete diagnostic laparoscopy; (3) making use of the natural dimpling appearance of the umbilicus, a periumbilical wound heals nicely and (4) the wound can readily be extended in case conversion is called for.

4.8.2 Conversion and Post-operative Complications

Conversion rates differ between centres, and ranges from 0 to 10.9 % in national literature [2, 3, 9]. The corresponding figure ranges from 0 to 15 % in international literature. Reasons for conversion include colorectal cancer distant metastasis, peritumoural infiltration, infiltration of adjacent organs, giant tumour size, etc. Our conversion rate is 2.7 % (3/111), which is lower than the average reported in the literature. The author believes that optimal pre-operative assessment and mastery of laparoscopic surgical technique contribute towards the low conversion rate. Complication rate of HALS is lower than open surgery, especially in respect of wound-related complications [7]. Studies from abroad showed comparable complication rate for HALS and purely laparoscopic surgery [1, 6]. Our post-operative complication rate is 4.5% (5/111), amongst which cases urine leak and bile leak are in the author's opinion related to burns injury sustained during surgical dissection due to heat generated from the ultrasonic dissector. It is evident that proper use of the ultrasonic dissector and adequate protection of surrounding organ structures are of prime importance in reducing post-operative complication.

4.8.3 Completeness of Tumour Extirpation

Cure from a malignant tumour depends on tumour differentiation, pathological staging, extent of surgical excision, no-touch technique during surgery, post-operative integrated treatment etc. Good visualisation of deeply located structures and magnification with laparoscopic surgery ensures complete removal of the primary tumour and its lymphatic drainage [10]. Literature shows that the number of lymph nodes harvested from HALS colorectal surgery compares with purely laparoscopic surgery [11]. In our experience, HALS gives us an upper hand to locate the tumour accurately, define the tumour resection margins precisely and therefore a more thorough curative resection, particularly with low anterior resection with TME. Our average number of harvested lymph nodes is 12.6 ± 5.8, in line with the literature.

4.8.4 Inadequacy of HALS

From an economic point of view, the higher cost of HALS comparing with open surgery is one reason why HALS is not widely accepted by majority of the patients. HALS is technically more demanding than open surgery. HALS has a finite complication rate, especially burns injury from the heat of ultrasonic dissector. Movement of the operating hand in the peritoneal cavity may inadvertently come into contact with the laparoscopic lens, thereby blurring it. To avoid such inconvenience, good cooperation between the surgeon and the camera man is needed. The hand can cause structures to bleed, and increases the risk of future adhesions. Trocar site tumour implantation remains an issue of concern in the development of laparoscopic surgery.

Conclusion

HALS Colorectal Cancer Curative Surgery retains the advantages of minimally invasive surgery while reducing its technical difficulty. It provides safe and effective wound protection, is quick to complete and is minimally invasive. It is good for a training strategy, and at the same time it remains a viable alternative for experienced surgeon to adopt in dealing with complex situations. HALS has already demonstrated benefits in colorectal surgery and other intraperitoneal surgery. Its' application, principles of utilisation and indication are still areas awaiting further definition. We believe that with further improvement in laparoscopic instruments, technical advancement and the ever expanding accumulated experience, HALS will find wider use in the future.

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5 Hybrid Natural Orifice Transluminal Endoscopic Surgery (NOTES)

Hester Yui Shan Cheung

5.1 Introduction

Laparoscopic colectomy for colonic cancer has improved postoperative patient recovery and outcomes in terms of less postoperative pain, less pain and wound-related complications, faster return of bowel function, as well as comparable oncological outcomes as open colectomy [1–3]. However, specimen retrieval requires a mini-laparotomy wound that might cause postoperative pain, wound infection as well as incisional hernia. Thus, the benefits of minimally invasive surgery might be compromised.

5.2 NOTES: Natural Orifice Transluminal Endoscopic Surgery

Since Kalloo et al. described flexible transgastric peritoneoscopy in a swine model in 2000 [4], Natural Orifice Transluminal Endoscopic Surgery (NOTES) is rapidly developing and is applied in different diagnostic and therapeutic procedures via various transvisceral accesses. NOTES can completely abolish the pain and wound complications, and may be the next revolution of development in minimally invasive surgery. A recent review of NOTES reported that transcolonic route is the second commonest route after transgastric route in NOTES techniques [5].

5.3 Application of Hybrid NOTES in Colorectal Resection

Soon after Whiteford et al. had reported successful NOTES radical sigmoid colectomy in three cadavers in 2007 [6], there have been a number of reports in the literature on this NOTES colectomy [7–9]. However, this technique still has many unresolved technical issues; currently NOTES is not widely applied in colorectal pathologies.

Natural orifice specimen extraction (NOSE) is an important step in evolution towards "scarless" surgery for colorectal diseases. A *hybrid procedure* combining laparoscopic surgery and NOSE, in which lymph node dissection, proximal and distal transection and anastomosis are performed laparoscopically followed by transanal retrieval of specimen, can overcome the technical difficulty in NOTES colectomy. This technique does not involve an abdominal incision for specimen retrieval, thus reducing pain and wound-related complications (Fig. 5.1).

For application of NOSE in colorectal surgery, the specimen can be retrieved transvaginally or through the anorectum. Transvaginal route may

H.Y.S. Cheung
Department of Surgery,
Pamela Youde Nethersole Eastern Hospital,
3 Lok Man Road, Hong Kong, China
e-mail: cheuys@ha.org.hk

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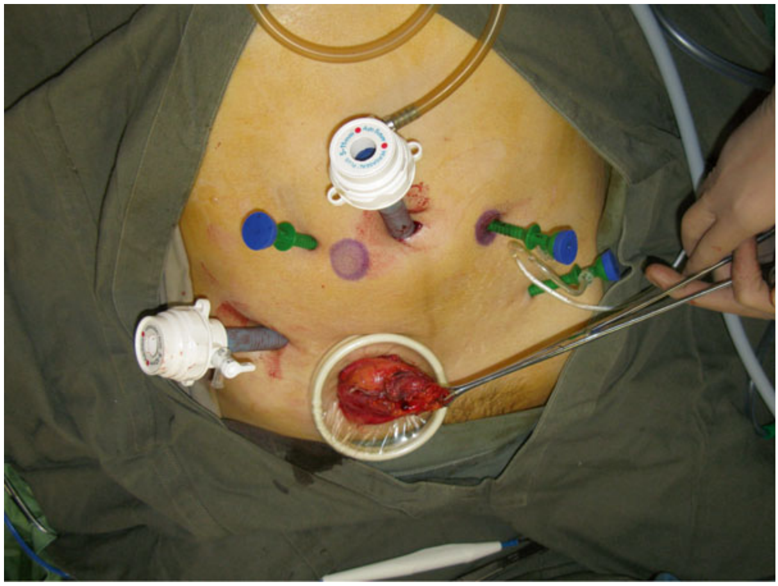

Fig. 5.1 Laparoscopic colorectal resection with mini-laparotomy for specimen retrieval

be complicated and is limited to female patients only [10]. However, it may give additional benefits, especially when performed together with a gynecological procedure [11]. Specimen extraction via the anorectum can be applied in both gender and is widely reported in a number of studies [11–21]. In our unit, we have described a novel technique of hybrid NOTES colectomy for patients suffering from left-sided colonic tumors with the use of the transanal endoscopic operation (TEO) device (Karl Storz Endoscopy, Tuttlingen, Germany) [12].

5.4 Patient Selection and Preparation

This technique can be suitably applied to patients with left-sided colonic tumor from splenic flexure to upper rectum with the tumor size up to maximum size of 4 cm in transverse diameter (as measured in computed tomography). Some patients are contraindicated for the usage of this technique:

- Tumors larger than 4 cm in size are contraindicated as such tumors are too large to be safely extracted transanally via the TEO device (which itself measures 4 cm in diameter).
- Mid- or low-rectal tumors necessitate total mesorectal excision and division of the rectal tube at the anorectal junction, which precludes placement of the TEO device in the lower rectum.
- The presence of anal stricture which precludes insertion of the TEO device.
- Finally, the patients presenting with acute surgical emergencies and the presence of synchronous tumors are also contraindications of this technique.

Apart from computed tomography to assess the size of the lesion, patients should have mechanical bowel preparation the day before the operation. Prophylactic antibiotic was given on induction.

5.5 Technique of the Hybrid NOTES Colectomy

The position of the surgical team, the equipment, and the port sites are shown in Figs. 5.2 and 5.3, respectively. The patient is put in Lloyd-Davies

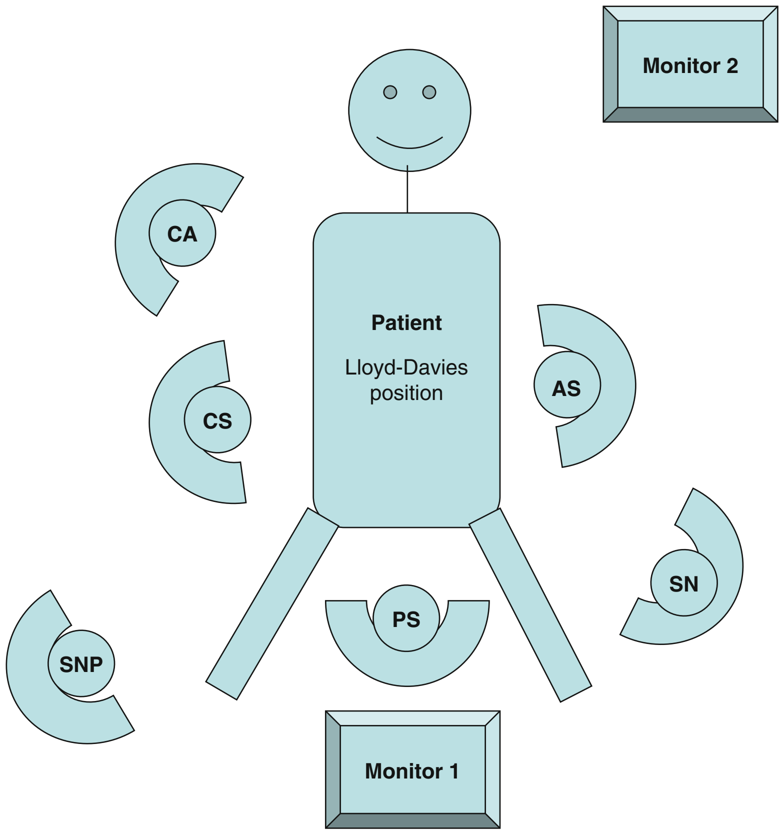

Fig. 5.2 Position of the surgical team for hybrid NOTES colectomy

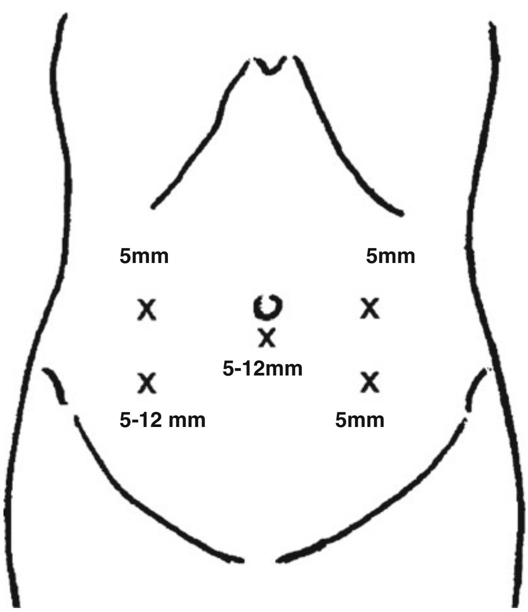

Fig. 5.3 Port sites for hybrid NOTES colectomy

Fig. 5.4 TEO device inserted into anus

position, with both legs abducted and slightly flexed so the perineal surgeon could insert the TEO device with ease (Fig. 5.4). Sacral support is used to raise the pelvis and therefore the tip of the coccyx could be readily palpable from below. Trendelenburg position with a right-side down tilt is used to get rid of the small bowel from the operative field. The chief surgeon uses a 5 mm port and a 12 mm port in the right iliac fossa which allow passage of endostaplers or endoclips. The assistant surgeon uses two 5 mm ports in the left iliac fossa.

After pneumperitonum is established, a thorough diagnostic laparoscopy was performed and on-table colonoscopy may be needed for localization of small lesion that could not be visualized over the serosal surface. Either medial or lateral approach could be used for the mobilization of left-sided colon and the control of the inferior mesenteric vessels. Then presacral dissection is carried out distal to the tumor. After adequate dissection to the level below the tumor, the abdominal surgeon will then use a pair of atraumatic laparoscopic bowel forceps to occlude the bowel just distal to the tumor, the perineal surgeon then carries out cytocidal rectal washout with povidone-iodine solution so as to reduce the risk of tumor seedling and peritoneal contamination. Non-cutting endostaplers is then applied at the chosen level distal to the tumors to exclude the tumor distally. An alternative way to exclude the tumor is by tying the colon with a cotton tape.

Following this, the perineal surgeon inserts the TEO device (Fig. 5.4) through the anus and it is fixed externally. The abdominal surgeon then divides the rectum just distal to the staple line or the cotton tape by energy device until the rectal stump is opened (Fig. 5.5). The TEO device helps to main pneumoperitoneum by simultaneously insufflating the rectum with carbon dioxide. The edge of the rectal stump is grasped either side by atraumatic forceps in order to keep the rectal stump open. The detachable anvil (with the spike anchored on it) from a circular stapler is then passed via the TEO device and manipulated into the peritoneal cavity by the perineal surgeon under direct vision (Fig. 5.6).

Next, the colonic mesentery at the intended level of proximal bowel division is divided. Again, the abdominal surgeon uses non-cutting linear endostapler or cotton tape for the proximal exclusion of the bowel from the tumor. A colotomy is then made over the anti-mesenteric side of the proximal colon just above the tumor and the anvil is gently inserted through this colotomy into the proximal colon. The abdominal surgeon then carefully manipulates the anvil such that the spike is piercing out from the antimesenteric side of the colon proximal to the intended line of proximal transection (Fig. 5.7). The spike can then be easily removed via the 12 mm port in the right iliac fossa or via the TEO device through the anus. The colon is finally transected proximal to the colotomy site by a cutting endostapler (Fig. 5.8). The specimen is now free and then being extracted through the TEO device under both laparoscopic and endoscopic guidance (Fig. 5.9). The TEO

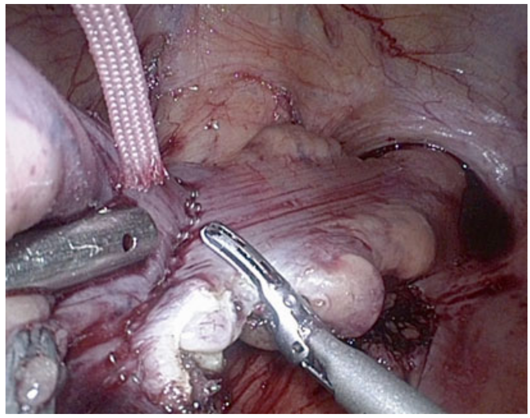

Fig. 5.5 The rectal stump is opened by using the energy source distal to the staple line

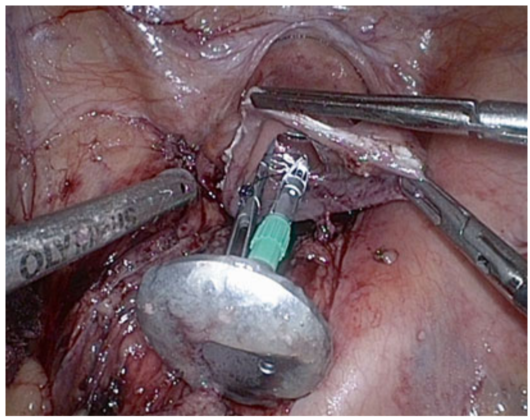

Fig. 5.6 The anvil of the circular stapler is passed via the TEO device into peritoneal cavity

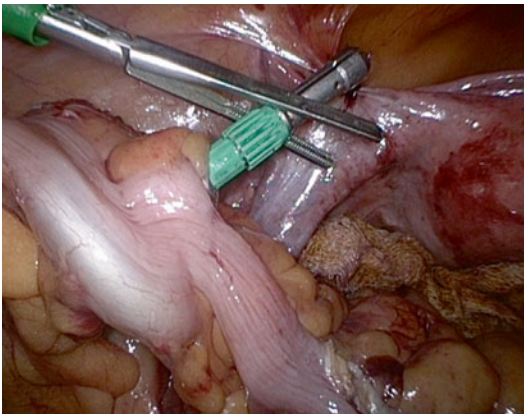

Fig. 5.7 The anvil is being inserted into the proximal colon via the colotomy

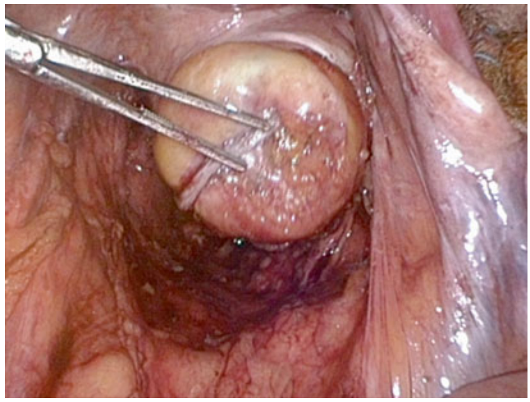

Fig. 5.10 Intra-corporeal side to end colorectal anastomosis is performed under direct laparoscopic visualization

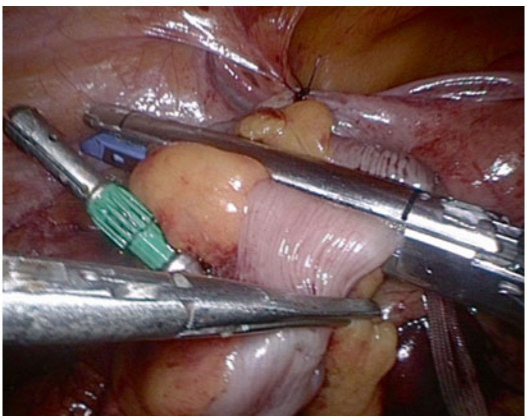

Fig. 5.8 The colon is finally transected proximal to the colotomy by an endostapler

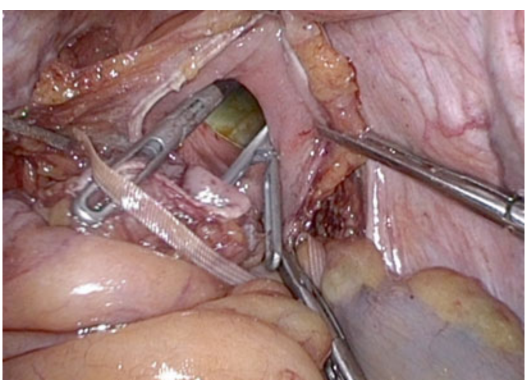

Fig. 5.9 The specimen is now being extracted through the TEO device

device serves as a stable conduit against tumor seedling and this technique avoids the need to create a mini-laparotomy wound for specimen retrieval (Fig. 5.1).

The abdominal surgeon continuously applies traction to the edge of the open rectal stump and fires another endostapler to close the rectal stump before transanally inserting a circular stapler for tension free intra-corporeal side-to-end colorectal anastomosis in usual manner under direct visualization of the laparoscope (Fig. 5.10). At the end of the procedure, it is our routine to perform an on-table flexible sigmoidoscopy to check for any staple line bleeding. At the same time, the gas leak test is performed to ensure an airtight anastomosis. Finally, the fascial layers of the subumbilical port and the 12 mm port are closed and the skin is approximated with steri-strips.

5.6 Postoperative Care

Fluid diet is allowed on the first postoperative day and this is stepped up to solid diet if tolerated by the patient. The urinary catheter is usually removed on the first postoperative day too. Patient usually would be discharged on the fourth or fifth postoperative day once they can tolerate oral diet well, ambulatory and without the need of parental analgesics.

5.7 Discussion

To avoid tumor seedling and injury to the anorectum in the hybrid NOTES colectomy with transanal specimen extraction, there are various kinds of techniques and devices in transanal specimen retrieval including TEM rectoscope [22], transanal endoscopic operation (TEO) device [12, 16], Alexis wound retractor (Applied Medical, Rancho Santa Margarita, CA, USA) [14], the plastic McCartney tube (Tyco Healthcare, Norwalk, CT, USA) [15], specimen retrieval pouch (e.g., Endo Catch II, Covidien, USA) [18, 19], or turning the bowel inside out [20]. Some surgeons do not use any device for protection of the rectum [13, 17, 21]. The TEO device is advantageous because it allows the passage of the anvil into peritoneal cavity under direct vision with simultaneous CO_2 insufflation to maintain pneumoperitoneum, thus maintaining a good laparoscopic view. Moreover, this stable conduit prevents injury of the rectum and anus as well as tumor seedling during specimen retrieval [12]. Most investigators used circular stapler to perform colorectal anastomosis with a triple-stapling technique, while Nishimura and Hara et al. used double-stapled technique [14, 20]. The average operation time ranges from 90 to 293 min. Most investigators inserted the anvil transanally, while Akamatsu inserted the anvil via an enlarged port site [13]. Major complication rates (including anastomotic leakage) are comparable to conventional laparoscopic procedure. Average postoperative stays ranges from 5 to 11 days. Mean pain scores range from 0.85 to 2.81 [12, 18, 21]. Anal dysfunction was only reported in one study in which the author commented the cause of fecal incontinence is multifactorial [10].

Opening the rectum in the peritoneal cavity raises the concerns of tumor seedling and peritoneal contamination. Tumor exclusion proximally and distally by non-cutting endostaplers and then followed by cytocidal rectal washout before opening the rectum are the key steps to prevent tumor seedling. To prevent peritoneal contamination, prophylactic antibiotics and good mechanical bowel preparation are essential.

Leroy et al. reported all peritoneal cultures were positive for polybacterial growth in a series of 16 patients who underwent NOSE sigmoidectomy for diverticulitis; however, no infective complications were observed [17]. Federico et al. reported a higher peritoneal contamination in transanal specimen extraction in laparoscopic left-sided colorectal resections for sigmoid diverticulitis compared to transabdominal extraction. However, the difference is not statistically significant and there were no significant differences in clinical outcomes [21].

Another concern of this technique is the cost of multiple endostapler uses but the use of cotton tape tie can be used as another alternative to exclude the tumor. On the other hand, wound infection means prolonged hospital stay and delay in return to work. Reduction in wound infection has the potential benefit of reduced cost to the health care system as well as to the community. Although this hybrid NOTES technique has promising short-term results, it should be performed in selective patients by experienced laparoscopic surgeons. Though all studies showed that the technique of NOSE is feasible with low morbidity and short postoperative hospital stay, this has inherent limitations, such as not feasible in patients with anal stenosis, narrow rectum and/or bulky tumor.

Conclusion

NOTES and NOSE are safe and feasible techniques and can be integrated during surgery for various colorectal pathologies to minimize pain and wound-related complications. Further randomized control trials with long-term results are necessary to prove the benefits of laparoscopic procedures with NOSE over conventional laparoscopic colorectal resection.

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6 Single Incision Laparoscopic Colectomy

Jensen T.C. Poon and Dominic C.C. Foo

6.1 Introduction

Over the past two decades, minimal invasive surgery has brought a major breakthrough in the standard of care in patients undergoing colonic resection. Reduction in surgical trauma results in less wound pain, prompt return of gastrointestinal function, and shorter hospital stay [1–3]. With widespread adoption of laparoscopic techniques, there is a continual effort to further minimize surgical trauma. The natural orifice transluminal endoscopic surgery (NOTES) received much attention but its clinical use remains limited. Similar technique and experience, however, has been put forward to a new standard in colonic resection, the single incision laparoscopic surgery (SILS). In SILS, laparoscopic surgery is performed via a single incision on the abdominal wall via a specialized single port device.

Compared to conventional laparoscopic surgery (CLS), the potential benefits of SILS are (1) better cosmetic outcomes and (2) reduction of abdominal wall trauma. When a transumbilical incision is used, the scar would be well hidden within the umbilicus and therefore giving excellent cosmetic result (Fig. 6.1a, b). With decrease in the number of abdominal incision, it would be logical to expect less postoperative pain and hence earlier recovery.

SILS has been shown to be a feasible procedure [4–10]. Yet, it does require surgeons to overcome certain technical hurdles. These include lack of triangulation and counter traction, instruments clashing and coaxial alignment of the camera and instruments. SILS is, therefore, skill demanding and raises concern for higher cost, longer operating time, and safety. Despite that, SILS is gaining popularity in various centers. This chapter focuses on the technique and evidence of SILS colectomy.

6.2 Patient Selection and Preoperative Preparation

Patient selection criteria are similar to that of CLS. Studies have shown body mass index (BMI) of over 25 kg/m^2 could increase SILS difficulty [11–13], although studies have shown SILS is still feasible for patients with BMI up to 40 kg/m^2 [5]. For SILS, the size of the lesion should not exceed 4 cm, as beyond that, a larger incision has to be used to retrieve the specimen and hence the benefit of SILS diminished.

Preoperative preparation includes optimizing patient's medical co-morbidities. For small

J.T.C. Poon, MS, FRCSEd (Gen) (✉)
D.C.C. Foo, MBBS, FRCSEd (Gen)
Department of Surgery, Queen Mary Hospital, The University of Hong Kong, 12 Pokfulam Roam, Hong Kong, China
e-mail: jp@hkma.org; ccfoo@hku.hk

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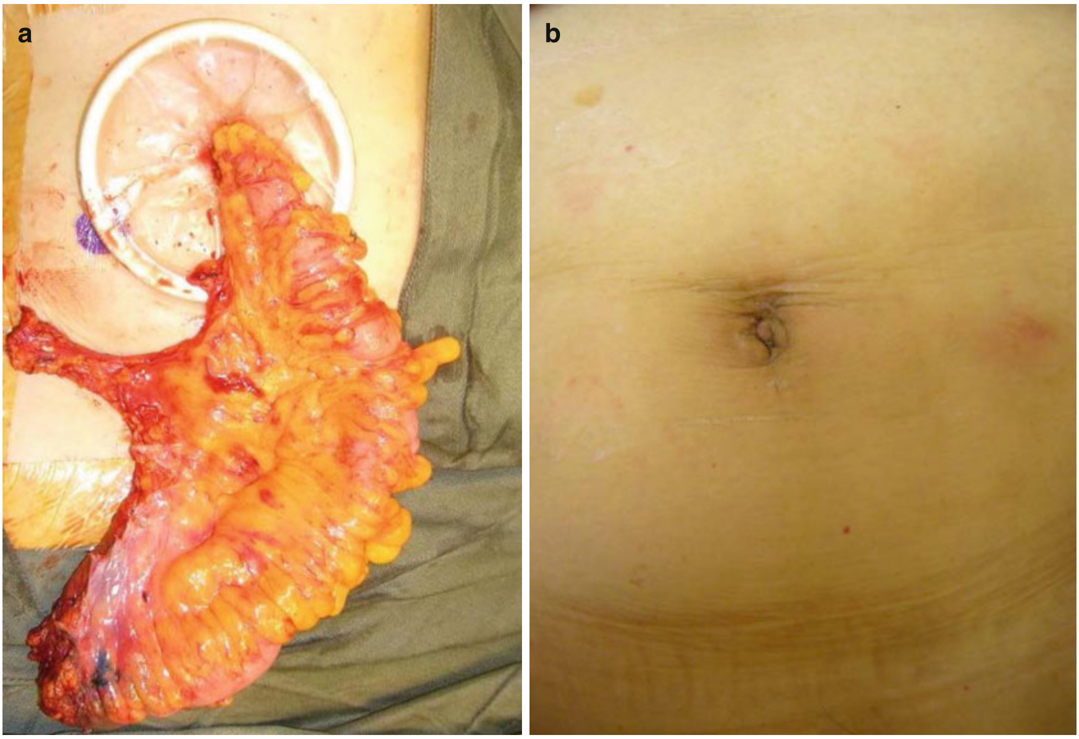

Fig. 6.1 (**a**) Single incision laparoscopic anterior resection. (**b**) Wound after single incision laparoscopic anterior resection

lesions, which are not readily identified on the serosal side, endoscopic tattooing of the lesion should be done beforehand. Computed tomography is performed to assess stage of the disease, tumor size and exclude local invasion to nearby structures. Mechanical bowel preparation is shown to be not necessary for colectomy [14–16], with the exception that when intraoperative colonoscopy is anticipated. Prophylactic antibiotics and deep vein thrombosis prophylaxis are applied similar to CLS.

6.3 Equipment

Examples of specialized SILS access port include the TriPort™ Access System (Olympus, Japan), the SILS™Port (Covidien, USA), and the OCTO™Port (Dalim, Korea) (Fig. 6.2). They provide three to four smaller ports ranging from 5 to 12 mm. The glove-port technique and GelPoint (Applied Medical, USA) technique has also been described [17–20].

For SILS, one could use straight laparoscope or endoscope with deflectable tip, e.g., Deflectable Tip EndoEYE™ Video Laparoscope (Olympus, Japan) and the IdealEye™ (Stryker, USA). An endoscope with deflectable tip can maintain a good view of the operative field with the endoscope held at an axis which is different to the operating instruments. It reduces clashing between the hands of operating surgeon and camera assistant remarkably. However, the controlling of the deflectable tip endoscope is more difficult and requires more experienced camera assistant. For straight endoscope, 30°, extra-long bariatric endoscope with co-axial light cable connection at the posterior end of the endoscope is preferred. The hands of camera assistant holding the extra-long endoscope will be placed further away from the patient's abdominal wall than the operating surgeons and this helps to avoid

Fig. 6.2 A transumbilical incision made for SILS colectomy

clashing. The use of 5 mm scope, which takes up less space, has also been suggested but it gives poorer operative field which is very important in SILS.

Articulating laparoscopic instruments are designed and promoted for use in SILS. The articulation serves to place two hands of operating surgeon apart and reduces clashing. However, the use of articulating instrument requires adaptation and takes time for surgeon to be familiarized with it. At present, most of the articulating instruments cannot hold the heavy bowel mesentery firm enough, and hence, the authors do not find them helpful. Conventional straight laparoscopic instrument can be used in SILS and are preferred by the author. The advantages are the cost-effectiveness, familiarity, and better control of tissue. The main disadvantage is the "chopsticks" effect and more frequent clashing of both hands. These difficulties can be overcome by the "cross hand technique" which will be elaborated in the next section.

6.4 Operative Technique

A transumbilical incision is usually chosen because the scar can be hidden within the umbilicus and it gives best cosmetic result (Fig. 6.2). A transumbilical incision also provides easy and fast access to peritoneal cavity via open cut down technique because the peritoneum is adherent to umbilicus and requires no extra dissection. The skin and fascia are enlarged to about 2 cm long in order to house the single port access system. Pneumoperitoneum is created with carbon dioxide insufflation. At the end of operation, this incision will be extended for specimen retraction. The size of incision after operation generally ranges from 3 to 4 cm in the literature and is ultimately determined by the size of the specimen [21–23]. Apart from transumbilical access, Giovanni et al. describe an alternative technique of suprapubic SILS right hemicolectomy [24].

6.4.1 Colonic Mobilization

The principle of colonic mobilization is the same as CLS. Traction and countertraction in SILS, however, is not as straightforward as CLS. It is crucial to put patient in steep Trendelenburg position and one side up, i.e., right side up for right hemicolectomy and left side up for left hemicolectomy or anterior resection. With gravity providing natural traction to the small bowel towards the medial and cranial side, the pedicle is tented up and identified by upward traction to the mesentery. During the mobilization, it is sometimes useful to use the "cross hand technique" (Fig. 6.3) to avoid the "chopsticks effect" (Fig. 6.4). Usually,

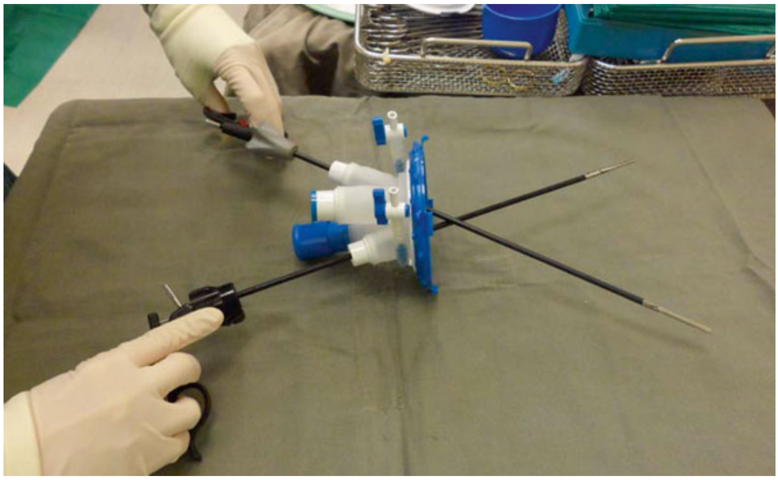

Fig. 6.3 "Cross hand" technique for SILS colectomy

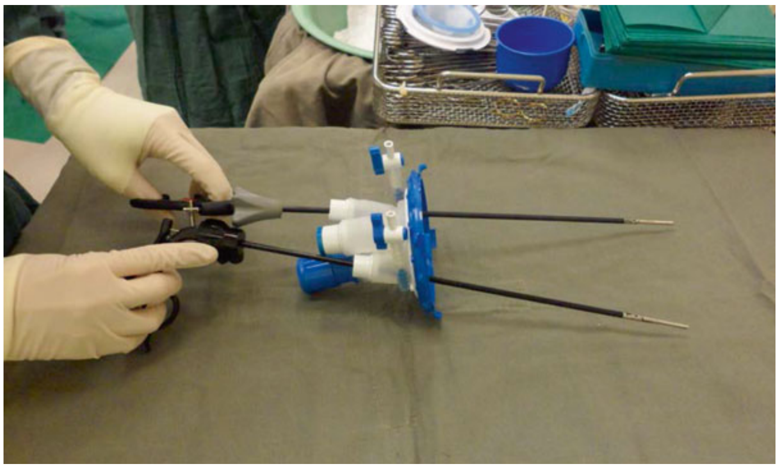

Fig. 6.4 "Chopstick effect" during SILS colectomy

the left hand of surgeon retracts on structure in the right side of the operative field and right hand of surgeon performs dissection on the right side of operative field. The mesentery should be grasped at a place far away from the dissecting plane. This would minimize clashing of instruments. After incising on the peritoneum, the avascular plane between the mesentery and retroperitoneum is developed. The mesentery can be tented up underneath by a laparoscopic Debakey forceps with opened jaws. The alternative is to use a laparoscopic fan retractor which can provide very effective retraction. Important structures including ureter and gonadal vessels for anterior resection, duodenum for right hemicolectomy is identified and safeguarded. The pedicle is ligated close to origin and divided. The author routinely applies 10 mm Lapro-clip (Covidien, USA) to the pedicle. When medial dissection is completed, the colon is further mobilized by incising the lateral peritoneal attachment.

6.4.2 Medial to Lateral Approach Versus Lateral to Medial Approach

Although both approaches are feasible for CLS, medial to lateral approach is preferred over lateral to medial approach in SILS. The reason is the lateral peritoneal attachment of colon provides countertraction for the surgeon. On the other hand, a floppy colon after lateral mobilization gives additional challenge to the SILS surgeon, in the situation when retraction by assistant surgeon is usually very difficult.

6.4.3 Use of Additional Traction Unique to SILS

For anterior resection, Brunner described the use of transabdominal sutures to retract the sigmoid colon [19]. For similar purpose, Leroy uses flexible sigmoidoscopy to retract the sigmoid colon. Also, with an anvil introduced transanally into the left colon, an extracorporeal magnet provides traction to the left colon [25]. Some single port access system provides four trocars, adding one addition laparoscopic instrument for the assistant to retract is generally not recommended as this would lead to overcrowding and clashing of instruments. In the author's experience, additional traction is not required. If small bowel cannot be kept out of operative field adequately by gravity, a piece of large gauze can be inserted to wrap around the small bowel and give additional control.

6.4.4 Taking Down the Flexures of Colon

The hepatic flexure for right hemicolectomy and the splenic flexure for left hemicolecotmy and anterior resection are taken down. Now, it is preferable to put the patient in a head-up position. With the greater omentum tracted upwards and the transverse colon hanging down by the effect of gravity, the gastrocolic ligament and colo-omental adhesion is divided. The lesser sac is entered and the dissection plane is further developed both medially and then laterally until the previous lateral plane of dissection is met. This would allow complete mobilization of the flexures.

6.4.5 Bowel Transection and Extracorporeal Anastomosis: Right Hemicolectomy and Left Hemicolectomy

For right and left hemicolectomy, extracorporeal anastomosis is performed. The single port access system is removed and the transumbilical incision is extended to 3–4 cm long. The right colon or the left colon is brought out via the transumbilical wound over a wound protector. The bowel is transected, allowing adequate margin, and anastomosis is performed. The author performs a functional side-to-side anastomosis with linear stapler in most cases. The technique of intracorporeal anastomosis for right hemicolectomy, which is facilitated by adopting supra-pubic single incision, has also been reported [24].

6.4.6 Intracorporeal Anastomosis: Anterior Resection

For anterior resection, the upper rectum is transected with articulating laparoscopic linear stapler. One key technique for transecting the rectum is to insert the endoscopic stapler from posterior side of the rectum in an antero-posterior manner, instead of inserting transversely, as in CLS. This would markedly reduce slanting of the staple line and prevent "dog-ear" formation. Thereafter, the specimen is retrieved as described above. Anvil is tied with purse-string suture to the colon after proximal transection. Intracorporeal colorectal anastomosis is performed with a circular stapler in the usual manner. The wound is closed after infiltrating the subfascial plane with local anesthetic.

6.5 Conversions

Bleeding, poor progression, dense adhesions, locally advanced tumor, and ureteric injury may necessitate the need for conversion. Multiport laparoscopy can easily be achieved by inserting additional trocars. In a systematic review of over 1000 SILS colectomies, the conversion rate to multiport laparoscopy and laparotomy was 7 % and 1 %, respectively [26].

6.6 Postoperative Management

Patient would be managed according to a standard enhanced recovery protocol. Antibiotics would be given for an additional of 24 h. Mobilization starts early. Urinary catheter would be taken off on the first day. Fluid diet is allowed

6 h after operation. Patient should be ready for discharge on the second to third day after an uneventful operation. Deviation from an expected swift recovery should raise the suspicion of intra-abdominal complications and be investigated.

6.7 Complications

Complications are similar to that of CLS. They include, bleeding, wound infection, postoperative ileus, ureteric injury, anastomotic leak, etc. Incisional hernia has been reported [6, 27]. In one systematic review by Fung et al., the overall complication rate in 565 patients undergoing SILS colectomy was 10.8 % [28].

6.8 Current Evidence for SILS Colectomy

Since Remzi and Bucher published the first SILS right hemicolectomy, there has been multiple case series in literature supporting the feasibility of SILS colectomy [4–10, 29, 30]. SILS is also feasible in performing complicated procedures like total colectomy and restorative proctocolectomy [31]. From a meta-analysis by Yang et al., the results of SILS and CLS were comparable [23]. A recent multicenter case-controlled study by Champagne et al., which included 330 patients, showed similar operating time, hospital stay, and complication rate [32]. The rate of conversion from SILS to CLS was 11 %. However, both CLS and SILS have similar conversion rate to laparotomy. SILS was reported to result in shorter operating time than CLS in similar studies by Velthuis et al. and Yun et al., which focus right hemicolectomy [33, 34]. The complications rate and number of harvested lymph node were also similar. Another study by Kim et al., which included rectal resection, showed significant longer operating time but less blood loss for SILS [35]. Both Kim et al. and Champagne et al. noted reduced pain score or narcotic use in the postoperative period [32, 35]. This finding was substantiated by a randomized control trial (RCT) by Poon et al. [11]. In this study, 50 patients were randomized to either SILS or CLS. The postoperative pain score for SILS was significantly lower than CLS from 60 min till second day post-operation. The hospital stay was significantly shorter in patients who underwent SILS colectomy (4 versus 5 days, $p<0.001$). Huscher et al. [36] published the only other RCT comparing SILS and CLS colectomy; it included 16 patients on each arm and reported comparable operating time, number of lymph node harvested, complication rate and hospital stay between the two procedures. However, postoperative pain was not evaluated in this study. The initial results on SILS colectomy were very promising but the patients involved in those reported are highly selective and are mostly non-obese patient with small tumors and no pervious major abdominal operation.

6.9 Summary

Single incision laparoscopic colectomy is a feasible and safe alternate to conventional laparoscopic colectomy but it increases difficulty in operation and requires adaptation of operative skill. The outcomes of SILS are shown to be similar to CLS by comparative studies from dedicated centers. Apart from better cosmetic results, SILS colectomy benefits patient with reduced postoperative pain and potential of earlier discharge. Although technically demanding, the operating time of SILS is not significantly longer than CLS colectomy. However, the evidence is based on highly selected patients operated by very experienced surgeons. While SILS colectomy serves as an attractive option to benefit patients further, its practice must be carefully planned on only suitable cases by experienced surgeons.

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7 Self-Expandable Metallic Stent (SEMS)

Hester Yui Shan Cheung

7.1 Introduction

While obstructing right-sided colonic cancer can usually be treated with one-stage resection with primary anastomosis, controversy continues to revolve around the optimal surgical treatment for left-sided colonic cancer presenting with obstruction. Before the turn of the century, available options included:

1. 3-staged operation (stoma creation – resection – stoma closure)
2. 2-staged operation (resection and stoma creation – stoma closure)
3. 1-staged operation (primary resection and anastomosis after on-table colonic lavage)

At the Consensus Conference of the World Society of Emergency Surgery (WSES) and Peritoneum and Surgery (PnS) Society held in Bologna in 2010, these options of treatment were thoroughly discussed to generate an evidence-based recommendation for the treatment of obstructed left colonic cancer [1]. And the consensus was that Hartmann's procedure (2-staged operation) was definitely superior to 3-staged operation and is the treatment of choice in patients with high surgical risk and high risk for anastomotic dehiscence. Subtotal or total colectomy with primary anastomosis should be contemplated in the presence of cecal perforation or synchronous tumors.

Since the introduction of colonic self-expandable metallic stent (SEMS) in 1991 [2], SEMS is increasingly used as a bridge to subsequent elective surgery. SEMS allows elective definitive surgery, preferably conducted in laparoscopic approach, to be performed at a later date following patient stabilization, full preoperative staging, and work-up. Data from systematic review and our previous randomized study have confirmed the short-term benefits of this endo-laparoscopic approach, including shorter hospital stay, reduced mortality and morbidity rates, and most importantly a lower rate of colostomy formation [3–5] (Fig. 7.1).

7.2 Patient's Selection and Indication

Self-expandable metallic stent (SEMS) can be suitably applied to all patients presented with emergency left-sided colonic obstruction. In the absence of peritonitis or close loop obstruction, an urgent water-soluble single-contrast enema or contrast computed tomography of the abdomen and pelvis was performed to determine the level

H.Y.S. Cheung
Department of Surgery, Pamela Youde Nethersole Eastern Hospital, Hong Kong, China
e-mail: cheuys@ha.org.hk

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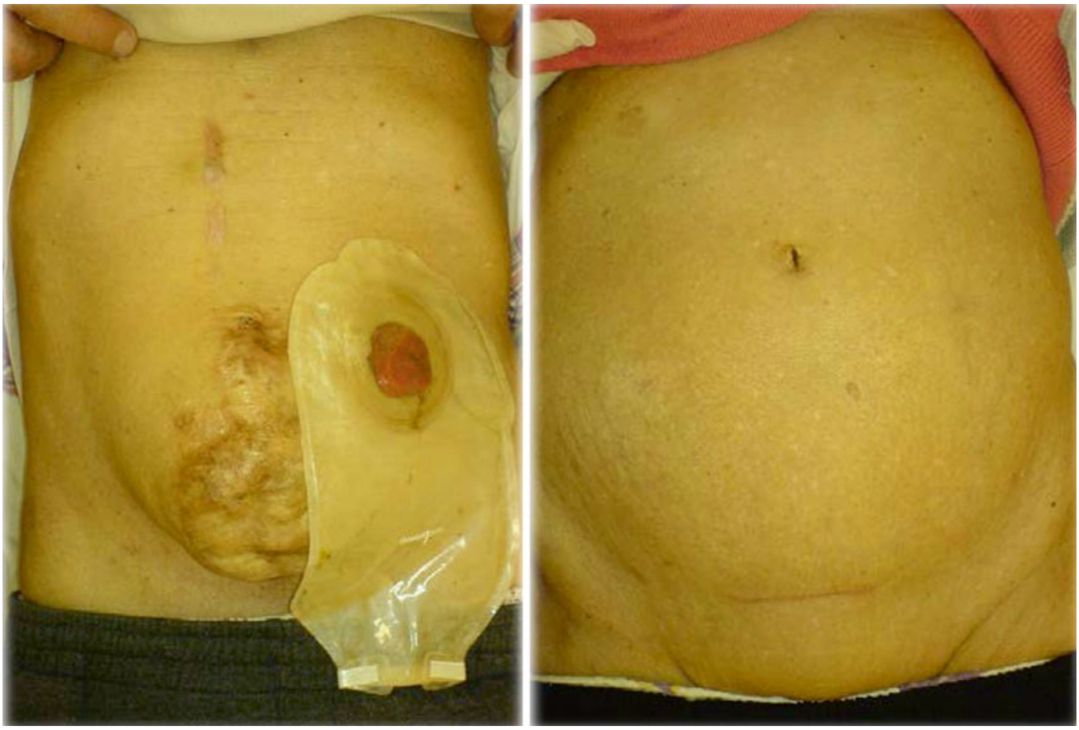

Fig. 7.1 Comparing conventional open approach versus endo-laparoscopic approach for obstructing left-sided colonic tumors

of obstruction within 24 h after emergency admission. Patients were suitable for stenting if the lower border of an obstructing tumor was found between the splenic flexure and rectosigmoid junction. Patients with tumor lower down than the rectosigmoid junction are not suitable for stenting due to the tenesmus caused by the stent over the rectum. Patients should also be well informed about the complications related to stenting which include immediate or delayed perforation, stent migration, and delayed blockage.

7.3 Technique of SEMS Placement and Postoperative Management

Self-expandable metallic stent (SEMS) was preferably being placed under both endoscopic and fluoroscopic guidance by dedicated team of colorectal specialists. The length of the stents was chosen so that the funnel-shaped ends were at least 2 cm beyond the limits of the tumor, more than one stent was placed if required (Fig. 7.2). Abdominal radiography was performed on the next day following technical successful endoscopic decompression by SEMS (Fig. 7.3). Successful decompression was defined as clinical and radiological evidence of resolution of the obstruction within 24 h of placement of SEMS. As bowel edema after obstruction takes time to resolve, too early the operation within the same admission after endoscopic decompression by SEMS will result in more difficult operation as well as increasing the risk of anastomotic leakage. So after clinical success of endoscopic decompression, an oral diet was introduced, and the patients were discharged from the hospital once they had a bowel movement. Preoperative work-up for cancer staging was carried out, and patients were admitted for elective laparoscopic colectomy around 2 weeks after placement of the SEMS (Fig. 7.4). Patients who had failed decompression by SEMS underwent emergency open surgery on the same day.

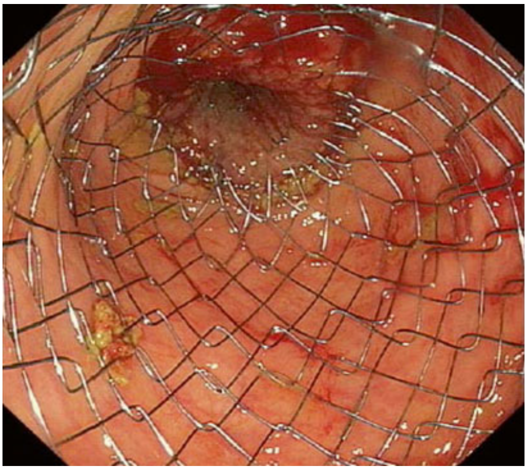

Fig. 7.2 The length of the stent was chosen so that the funnel-shaped end was at least 2 cm beyond the limit of the tumor

Fig. 7.3 Abdominal radiography was performed on the next day following technical successful decompression by SEMS

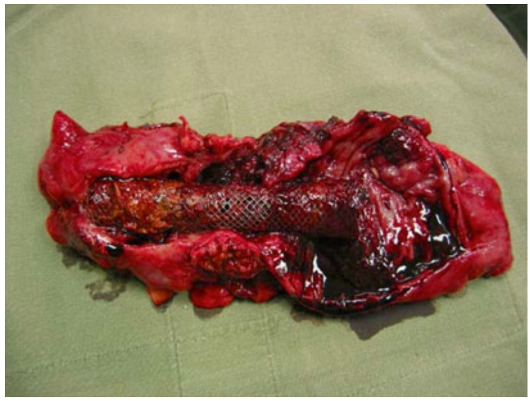

Fig. 7.4 Photo of the cut-opened specimen with SEMS inside after elective laparoscopic colectomy around 2 weeks after placement of the SEMS

7.4 Discussion

However, little is known about the oncologic outcomes of using SEMS as a bridge to elective surgery. From the oncologic perspective, stent insertion for malignant tumor can potentially compromise the oncologic outcomes: There is a risk of tumor perforation or dislodgement during stent insertion, which results in tumor seeding [6]. Moreover, shear forces that act on the tumor during endoscopic advancement, insufflation, and application of trans-abdominal pressure and manipulation of patient position could disseminate cancer cells into the peripheral circulation [7]. Maruthachalam et al. reported a significant increase in cytokeratin 20 mRNA expression following stent insertion [7]. All these raise the concern that SEMS insertion could possibly compromise patients' oncologic outcomes.

In 2009, Kim et al. conducted a retrospective study comparing SEMS as bridge to surgery in the management of obstructing left-sided colon cancer with nonobstructing elective surgery [8]. Their results showed SEMS had an adverse effect on the 5-year overall survival rate (38.4 % versus 65.6 %; $p=0.025$) and 5-year disease-free survival rate (48.3 % versus 75.5 %; $p=0.024$). However, the study was limited by selection bias as colonic obstruction per sec was a well-known poor prognostic factor; hence little meaningful conclusion could be drawn in a study which compared outcomes of surgery in nonobstructing tumors with those in obstructing tumors.

To our knowledge, first RCT in the literature – "endo-laparoscopic approach (using SEMS as a bridge to surgery followed by laparoscopic colectomy) versus conventional open surgery in the treatment of obstructing left-sided colon cancer" was first conducted in Hong Kong in 2002. Our initial data suggest endoscopic placement of self-expanding metal stents (SEMS) serves as a safe and effective bridge to laparoscopic surgery in patients with malignant colonic obstruction, providing time for stabilization and necessary work-up. This endo-laparoscopic approach makes a one-stage operation more feasible and is shown to be associated with reduced incidence of permanent stoma creation, such that patients can enjoy the full benefits of minimally invasive surgery [3]. The follow-up long-term results of this RCT has recently been published in 2013 [9]; it represents the first report comparing, in the context of a randomized trial setting, the oncologic outcomes of SEMS as a bridge to surgery with those of open surgery for obstructing left-sided colonic cancer. While our data indicated endo-laparoscopic group had slight better overall and disease-free survival than open surgery group, the difference did not reach statistical significance; this might be due to inadequate sample size of the randomized trial. However, the oncologic clearance in terms of lymph nodes harvest was significantly better in the endo-laparoscopic group. This reflects the suboptimal oncologic surgery during emergency setting for obstructing colonic cancer, where surgeons spend most of the efforts on the relief of obstruction rather than lymphatic clearance. Our results are in keeping with a large non-randomized study from Japan [10]. By virtue of a randomized trial, we were able to show a more sound comparison of the oncological outcomes between the two groups.

Conclusion

Self-expanding metallic stent (SEMS), besides being a safe and effective bridge to subsequent elective laparoscopic surgery, has not been shown to have deleterious effect on the oncological outcomes and patient survival [9]. Based on the current evidence, this endo-laparoscopic approach is the treatment of choice and should be considered for selected patients suffering from malignant left-sided colonic obstruction in the centers with expertise available.

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Colorectal ESD

8

Sophie S.F. Hon

8.1 Introduction and Development

Endoscopic submucosal dissection (ESD) describes the removal of mucosal or early invasive lesions through the submucosal plane by endoscopic technique. It was first applied in stomach, which has a thicker wall and is more spacious for scope manipulation. With further technology advancement and maturation of ESD technique, its application has expanded to large bowel since early 2000s [1–3].

Endoscopic piecemeal mucosal resection (EPMR) and colectomy used to be the accepted treatment options for lesions not amenable to conventional polypectomy [4–7]. ESD has revolutionized the management of such lesions over the past decade. The benefits of ESD were well demonstrated in large series and systematic review, namely lower recurrence rate as a result of higher en bloc resection rate when compared with EMR [8–10]. Although the risk of bleeding and perforation is higher than EMR, these complications seldom necessitate surgical salvage. Recent retrospective study comparing ESD and laparoscopic colectomy showed lower morbidities associated with ESD [11].

8.2 Indications

The role of ESD is to deal with lesions that are not amendable to en bloc resection by conventional EMR technique. Diameter less than or equal to 2 cm is the accepted upper limit for EMR in general. Therefore, the main indication for ESD is lateral spreading tumour (LST) larger than 2 cm which shows no obvious endoscopic features of massive submucosal invasion. Other less common indications for ESD are the presence of submucosal fibrosis due to previous endoscopic procedures or chronic inflammation. Table 8.1 shows the recommended indications of ESD for colorectal tumour developed by the Colorectal ESD Standardization Implementation Working Group [3]. Different centres may have slight variation in terms of lesion size, but the underlying principles are the same [12]. Theoretically, there is no upper limit for the lesion size.

8.3 Case Selection

The Japanese guideline is developed upon the excellent result and safety profile of colorectal ESD carried out in their expert centres. These favourable results may not be reproducible

S.S.F. Hon, MD
Division of Colorectal Surgery,
Department of Surgery, Prince of Wales Hospital,
Hong Kong, China
e-mail: hsfei@hotmail.com

W.C.S. Meng et al. (eds.), *Minimally Invasive Coloproctology: Advances in Techniques and Technology*, DOI 10.1007/978-3-319-19698-5_8

outside Japan [13, 14], probably due to lack of experience.

The endoscopist should be familiar with image-enhanced endoscopy in order to increase the detection rate of flat lesions while the lesions with massive submucosal invasion would not be subjected for ESD. Besides, individual endoscopist's experience and the availability of safe alternatives are very important considerations during case selection. Lesions with severe fibrosis and large lesions should be reserved for experienced endoscopists. Alternatively, laparoscopic colectomy is always a viable option if high perforation rate or prolonged procedure is anticipated.

8.4 Equipment in PWH

8.4.1 Endoscope

Thin calibre endoscope with water jet function is recommended. Thin calibre scope enables more flexible scope manipulation and finely tuned movement of the dissection knife. It also allows retroflexion of scope without overstretching of the colonic wall. The water jet function helps keep the dissection view clear even if bleeding occurs, while the working channel is ready for use of haemostatic device. In the author's centre, gastroscope is used for rectal and left-sided lesions while paediatric colonoscope is used for right-sided lesions (PCF-Q260JL and GIF-Q260J; Olympus Medical Systems Corp, Tokyo, Japan). Throughout the procedure, a transparent soft cap is attached to the tip of the endoscope for tissue retraction.

CO_2 insufflation is routinely used to reduce abdominal discomfort from gaseous distension, which is expected in prolonged procedure.

Table 8.1 Indications of colorectal ESD

1	Large-sized (>20 mm in diameter) lesions in which en bloc resection using snare EMR is difficult, although it is indicative for endoscopic treatment
	LST-NG, particularly those of the pseudodepressed type
	Lesions showing Vi-type pit pattern
	Carcinoma with submucosal infiltration
	Large depressed type lesion
	Large elevated lesion suspected to be carcinoma
2	Mucosal lesions with fibrosis caused by prolapse due to biopsy or peristalsis of the lesions
3	Sporadic localized tumours in chronic inflammation such as ulcerative colitis
4	Local residual early carcinoma after endoscopic resection

8.4.2 Energy Platform

Colon and rectum provide a very limited working space for ESD, overcoagulation or overshooting of cutting act can easily result in delayed or immediate perforation. On the other hand, undercoagulation would result in bleeding. Therefore, a good electrosurgical unit, which allows safe and effective dissection, is essential. VIO300D (ERBE Elektromedizin GmbH, Germany) is currently used in our centre. It differs from other conventional electrosurgical units since it is voltage-controlled rather than current controlled. Therefore, the incision and depth of coagulation is constant disregarding changes in tissue resistance.

The endoscopists may adjust the setting according to their preference of energy strength and dissection tool. Table 8.2 shows the author's preferred energy setting.

Table 8.2 Example of energy setting

Device	Mucosal incision	Submucosal dissection	Coagulation
Dual knife	ENDO CUT Q E2 D4 I3	SWIFT COAG E4 30W	SOFT COAG E4 30W
IT nano	DRY CUT E3 60W	SWIFT COAG E2 40W	SOFT COAG E2 40W
Coagrapser	–	–	SOFT COAG E2 50W

8.4.3 Dissection Tool/ESD Knives

Dual knife (KD-650U, Olympus Medial Systems Corp, Tokyo, Japan) is commonly used for mucosal incision and submucosal dissection. Alternatively, Insulated-tip knife nano (KD-612U, Olympus Medical Systems Corp, Tokyo, Japan) can be used for submucosal dissection.

8.4.4 Submucosal Injection

A cocktail solution consisting of normal saline, adrenaline, hyaluronic acid and indigo carmine is mixed to create a long-lasting submucosal cushion. However, injection of this long-lasting fluid into wrong tissue plane may mislead the dissection and result in troublesome bleeding from an inadvertent perforation. Before creating this long-lasting submucosal cushion, the more easily absorbed indigo carmine stained normal saline can be injected to develop the submucosal layer.

8.4.5 Haemostasis

Coagrasper (FD-411UR, Olympus Medical System Corp, Tokyo, Japan) is used for cauterization of submucosal vessels. Its fine tip facilitates precise haemostasis. Endoclips are usually reserved till dissection is completed because they may hinder further dissection.

8.4.6 Specimen Retrieval

Roth Net (US Endoscopy, Ohio, USA) facilitates retrieval of specimen intact.

8.5 Colorectal ESD Procedures

All ESD procedures are done under conscious sedation with intravenous administration of midazolam and pethidine. Intravenous Buscopan is used if significant colonic spasm is encountered during ESD. The procedures are performed using water jet gastroscope or paediatric colonoscope with a transparent cap attached to the tip. Carbon dioxide insufflation is routinely used to reduce patients' discomfort. The margin of the neoplasm was determined by either chromoendoscopy with dye spray of 0.4 % indigo carmine or narrow band imaging. Marking of margin is not required. A mixture of normal saline, adrenaline, indigo-carmine and sodium hyaluronate is used for creation of submucosal cushion. Alternating mucosal incision, submucosal dissection are done using Dual knife or Insulated Tip Knife (Olympus Medical System, Tokyo, Japan), depending on the lesion's location and individual endoscopist's preference. Submucosal injection is repeated whenever the submucosal plane cannot be seen clearly or confidently. Patient's position is often changed during the procedure to get the best benefit of traction by gravity. Haemostasis after ESD is achieved by coagrasper (Olympus Co. Ltd., Tokyo, Japan). The specimen is carefully retrieved in a Roth net and then pinned on a foam broad for pathological examination. Steps of the procedure are shown in Fig. 8.1.

8.6 Pitfalls for Beginners

Careful case selection is the key for safe and successful ESD for beginners. Lesions with non-lifting sign and sessile wide base polyp (Isp or Is) are challenging lesions as dense adhesions and brisk bleeding are frequently encountered. ESD for rectal lesions in patients with poor anal tone is not always feasible because the working space cannot be adequately maintained as a result of air leak. This problem may not declare itself at the beginning of the procedure, it will become more severe later on due to patient's fatigue and increasing colonic distension. ESD performed via colostomy is also foreseeable to be difficult, partly because of the air leak problem and partly because of postural limitation. These patients cannot be kept in prone or left lateral position to achieve the best counter-traction by gravity. Technical challenge is sometimes created by unfriendly colonic configuration. During the index diagnostic endoscopy, if the scope cannot be kept steadily around the lesion, then the patient should not be subjected to ESD. Steady scope

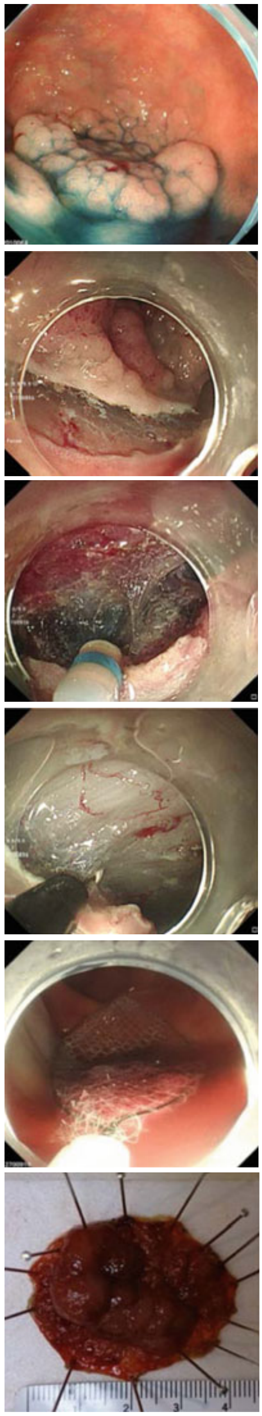

Fig. 8.1 Steps of colorectal ESD. (**a**) LST-G at the ascending colon, stained by indigocarmine. (**b**) Mucosal incisional was done after submucosal injection. (**c**) Submucosal dissection using Dual knife. (**d**) Submucosal dissection using IT knife. (**e**) Specimen retrieval with Roth net. (**f**) Specimen pinned on a foam broad

a. LST-G at the ascending colon, stained by indigocarmine.

b. Mucosal incisional was done after submucosal injection.

c. Submucosal dissection using Dual knife.

d. Submucosal dissection using IT knife.

e. Specimen retrieval with Roth net.

f. Specimen pinned on a foam broad.

position is of utmost importance for such a precise and lengthy procedure.

Though ESD performed by world experts is considered to be much less invasive than colectomy, for treatment of benign lesions, it should not be proposed as an alternative for patients deemed unfit for general anaesthesia. The inherent risks of ESD should be seriously addressed. This is particularly true for beginners because the perforation rate is known to be much higher among the less-experienced endoscopists. The possibility of salvage surgery has to be taken into account whenever ESD is considered.

8.7 Complications of ESD and Risk Factors

Bleeding (Fig. 8.2) and perforation (Fig. 8.3) are the major complications of colorectal ESD. The incidence of bleeding is actually quite low, which is far less than 2 % in most Japanese series [8, 9, 15–17]. No surgery was required for haemostasis in a recent systematic review including 2774 patients [8].

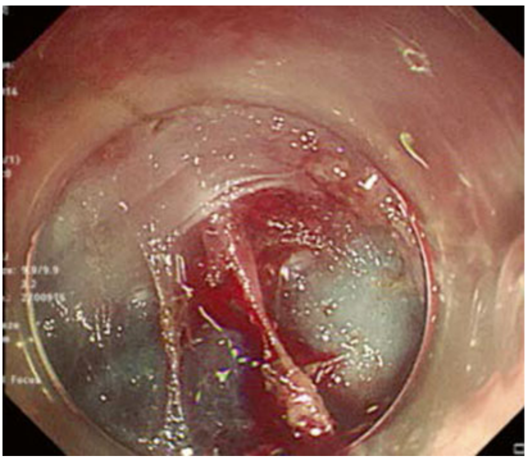

Fig. 8.2 Bleeding from a vessel in submucosal plane

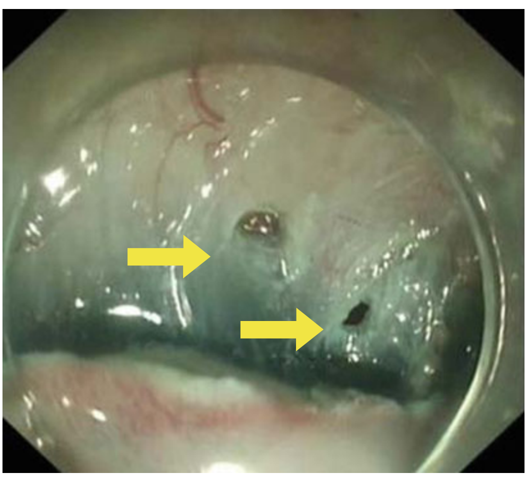

Fig. 8.3 Two minute perforations in caecum, later managed by endoscopic clipping

On the other hand, high perforation rate forms a major obstacle for the adoption of ESD technique outside Japan. Colonic perforation and the resulting faecal peritonitis can lead to significant morbidities or even mortality. Up till now, there was no reported mortality directly or indirectly related to ESD [8]. The reported perforation rate ranged from 1.4 to 10 % [18, 19] in large Japanese series though it could be as high as 20.4 % elsewhere [14]. Repici et al. reported a 4 % perforation rate in their systematic review [8]. Most of these perforations could be managed by endoscopic clipping without surgery.

Several risk factors were identified to be associated with perforations, namely large-sized lesions, submucosal fibrosis, colonic location and inexperienced endoscopists [14, 20, 21].

8.8 Interpretation of Pathology Report

One of the advantages of ESD over EPMR is the availability of an intact specimen for accurate pathological assessment. However, only a dedicated pathologist could make the hard work of the endoscopist meaningful. Statuses of the resection margin and muscularis mucosae are the key parameters to evaluate in the pathology report.

The mucosa consists of epithelium with basement membrane, lamina propria and muscularis mucosae (Fig. 8.4). Integrity of muscularis mucosae reflects good-quality submucosal dissection, which prevents recurrent disease due to incomplete dissection. Any lesion, which penetrates beyond the muscularis mucosa, is defined as invasive carcinoma (AJCC, 7th edition). The depth of invasion into the submucosal layer is measured from muscularis mucosa, sm1 means less than 1000 μm. The estimated risks of nodal metastasis for sm1, sm2 and sm3 lesions were <1 %, 6 % and 14 % respectively [22]. In addition to the degree of differentiation, the presence of lymphovascular permeation is another

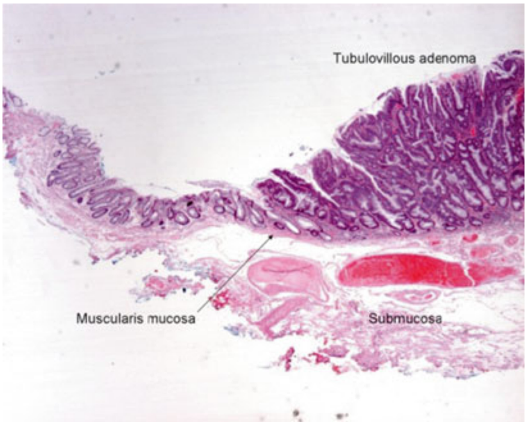

Fig. 8.4 H&E section of a tubuvillous adenoma

important histological marker studied in risk stratification of malignant lesions.

8.9 Salvage Surgery

Salvage surgery is indicated for complications, mainly bleeding or perforation not manageable endoscopically or unfavourable pathology.

In considering salvage surgery for malignant lesions, comprehensive review of pathological features is essential. Preferably, direct communication with the involved pathologist would be necessary for some difficult lesions. Surgery is generally recommended for the following scenario: sm2/deeper invasion, presence of lymphovascular permeation, poorly differentiated cancer or Grade 2/3 budding at the site of deepest invasion [23, 24]. Pre-operative staging work up is similar to advanced colorectal adenocarcinoma. Other indications for salvage surgery include failed ESD and recurrence not amenable to endoscopic treatment.

In practice, balancing the risks and benefits from salvage surgery is essential for each individual patient. This is especially true when we are dealing with elderly patients with multiple co-morbidities.

8.10 Training Programme

Colorectal ESD was originated from Japan. The classical training begins with acquisition of gastric ESD skill before proceeding to colorectal ESD, which starts with rectal lesions under direct supervision [25–27]. Some Japanese expert centres recommended that 30–40 cases under supervision were required to complete the learning curve or to perform colorectal ESD safely with no more than 5 % perforation rate.

Based on the difference in incidence of gastric neoplasms between Japan and Hong Kong, it is almost impossible to adopt the same training system in our locality. We have far fewer upper gastrointestinal pathologies suitable for endoscopic treatment; however, we have far fewer experts available for proctorship training. In Prince of Wales Hospital, our endoscopists visited renowned Japanese endoscopy centres for live case observation and underwent supervised hands-on training in training models. Since the year 2009, we have developed our own porcine colon model for colorectal ESD training [28]. When the endoscopist is familiarized with the endoscope manipulation and dissection skill in this porcine model, then he or she will embark on human ESD, starting with rectal lesions. We have compared the early outcome of colorectal ESD after in vitro porcine model training versus gastric ESD training. There were no differences in terms of en bloc resection, perforation and bleeding rates [29].

Video recording of each procedure is highly recommended, such that the whole procedure could be retrospectively reviewed for any technical errors, especially if complications had occurred.

8.11 Local Data and Personal Data

In Hong Kong, there are at least eight centres performing colorectal ESD. Table 8.3 shows the data of those with publications in peer-reviewed journals or conference proceedings.

In Prince of Wales Hospital, we started our first colorectal ESD in 2008 by Professor Philip Chiu, then the author performed her first ESD in rectum in 2009 [30]. Both gastroenterologists and surgeons are actively involved in the ESD programme. The number of colorectal ESD procedure has been on rapidly rising trend since it was first introduced.

Table 8.3 Published local data

	NDH[a]	QEH[b,c]	PYNEH[c]	UCH[d]
First author	Poon CM	Lee HM	Cheung HYS	Joeng KMH
Study period	Jan 2009–Dec 2010	Apr 2009–Mar 2011	Jan 2008–Jul 2011	Jan 2010–May 2013
Number of patients	23	16	8	18
Size of lesion	375 mm^2	36 mm × 31 mm	2 cm	46 mm
Operative time	130 min	198 min	120 min	180 min
En bloc resection rate	78.3 %	81.3 %	/	100 %
Perforation rate	17.4 %	6.3 %	/	11.1 %

[a]North District Hospital
Surgical Practice 2011; 15 (Suppl): S14–S15. Joint ASM of HKSC & HKSMAS, 26 February 2011
[b]Queen Elizabeth Hospital
Surgical Practice 2010; 14(Suppl): S18. RCSEd/CSHK Conjoint Scientific Congress, 25–26 September 2010
[c]Pamela Youde Nethersole Eastern Hospital
Conference Proceedings, 4th Master Workshop on Novel Endoscopic Technology & ESD, CUHK, 21–23 July 2011
[d]United Christian Hospital
Conference Proceedings, 6th Master Workshop on Novel Endoscopic Technology & ESD, CUHK, 7–8 June 2013

Table 8.4 Comparison for short-term outcomes and overall complications rate

	ESD (n = 33)	LC (n = 28)	P value
Overall complication	4 (12.1 %)	10 (35.7 %)	0.02
Time to resume diet (mean days ± SD)	0.81 ± 1.19	5.00 ± 2.49	<0.001
Time to ambulation (mean days ± SD)	0.42 ± 0.85	3.71 ± 2.54	<0.001
Hospital stay (mean days ± SD)	2.87 ± 1.95	9.04 ± 5.37	<0.001

Table 8.5 Procedure outcomes of ESD versus local excision (LE)

	ESD (n = 14)	LE (n = 30)	P value
Operative time (min, median and range)	78 (25–180)	50 (10–270)	0.081
Morbidity (%)	1 (7.1 %)	10 (33.3 %)	0.076
Time to full ambulation (days, median and range)	0 (0–1)	1.0 (0–4)	0.005
Hospital stay (days, median and range)	2.5 (1–5)	4.0 (2–15)	0.129

We have compared our earliest 30 colorectal ESD procedures with laparoscopic colectomy. ESD showed significantly lower overall complication rate and earlier recovery (Table 8.4) [31]. Clinical benefits can also be demonstrated in rectal procedures (Table 8.5) [32]. ESD offered better short-term clinical outcomes including faster recovery and possibly lower morbidity when compared to local excisional procedures (transanal excision and transanal endoscopic microscopic surgery).

We are currently conducting a randomized controlled trial comparing ESD versus laparoscopic colectomy. We are expecting positive results from the study, which would provide a higher level of clinical evidence for colorectal ESD in the treatment of early colorectal neoplasms.

8.12 Summary

Colorectal ESD is a safe and efficient procedure for the treatment of advanced colorectal neoplasm especially LST. The results of our ongoing randomized trial will better define the benefits of colorectal ESD.

Though we have difficulty in establishing an ideal training programme in Hong Kong due to a low incidence of early gastric neoplasms, colorectal ESD is gradually developing over the past few years. Live case observation, animal model training and careful case selection are keys for successful training and development of safe colorectal ESD in our locality.

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9 Laparoscopic Rectal Surgery

Tony W.C. Mak and Simon S.M. Ng

9.1 Introduction

Colorectal cancer (CRC) is the third most commonly diagnosed cancer around the world. In the United States, there is an annual incidence of 143,000 cases with approximately 52,000 cancer deaths each year. Colorectal cancer death also represents around 9% of all cancer mortality [1]. The most recent cancer data from Hong Kong has even shown that the annual incidence of colorectal cancer has surpassed the incidence of lung cancer [2] (Fig. 9.1). While population screening for colorectal cancer is currently being developed in Hong Kong, strategies for effective surgical treatments are also required.

One of the most challenging areas for the surgical treatments of colorectal cancer is the treatment of rectal cancer. It has been recognized that local recurrence rate and morbidities associated with rectal cancer surgery are significantly higher than colon cancer surgery. The reasons can be broadly divided into patient factor, surgeon factor, and limitation of surgical instruments. Examples of these challenges are: (1) obese male patient with a bulky low rectal tumor with a narrow pelvis; (2) limited visual field with poor lighting in an open rectal resection or limitations of the straight laparoscopic instruments preventing access around corners in a deep pelvis; (3) the side effects and the subsequent response of neoadjuvant chemoradiation treatment by the patient; and (4) the steep learning curve required by the surgeon in both open and laparoscopic surgery to achieve good-quality total mesorectal excision (TME).

The aim of this chapter is to give a comprehensive overview of the current evidence and status in laparoscopic rectal surgery.

9.2 Rectal Cancer: Treatment Options

Rectal cancer can be defined as malignancies found within 15 cm from the anal verge. Typical presenting symptoms include: (1) fresh per rectal

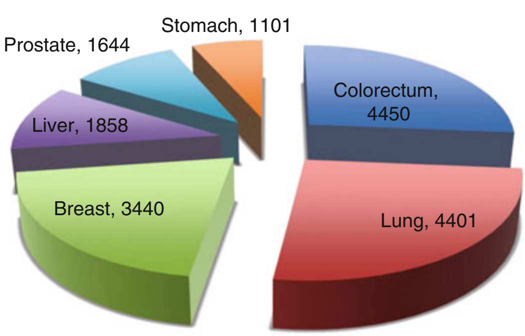

Fig. 9.1 Top ten cancers in Hong Kong 2011 [2]

T.W.C. Mak (✉) • S.S.M. Ng
Division of Colorectal Surgery,
Department of Surgery,
The Chinese University of Hong Kong,
Hong Kong, China
e-mail: tonymak2000@hotmail.com;
simonng@surgery.cuhk.edu.hk

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bleeding; (2) passage of mucus; (3) change in bowel habits; (4) tenesmus; (5) lower abdominal pain; and (6) constitutional symptoms such as weight loss and loss of appetite. On clinical examination, often mid-to-low rectal tumor can be felt during digital rectal examination and visualized with a rigid sigmoidoscope.

Following full colonoscopic assessment with tissue biopsy for tumor confirmation and staging imaging to assess for synchronous lesions, local and distant metastasis, respectively, treatment options of rectal cancer is dependent on several key factors: (1) position of the cancer; (2) its depth of invasion; (3) the mesorectal nodal involvement; and (4) the status of the circumferential resection margin. These factors will help to determine the overall treatment strategy (i.e., whether neoadjuvant/adjuvant treatments are required and the type of operation) for the patient. Standard surgical treatment aims to resect the tumor with sufficient distal, proximal, and circumferential margins, as well as removal of regional lymph nodes. This is paramount as incomplete resection will lead to local recurrence. Whether the surgery is performed laparoscopically or via open technique, the type of operations can be divided into anterior resection, low anterior resection, Hartmann's operation, or abdominoperineal resection.

Alternative treatments for early low rectal cancers (e.g., transanal endoscopic microsurgery (TEMS), transanal endoscopic operation (TEO) or transanal minimally invasive surgery (TAMIS)), and the controversies on complete response tumor (yP0) following neoadjuvant treatment will not be covered in this chapter.

9.3 Benefits with Laparoscopic Surgery

Laparoscopic colorectal resection was first described in 1991 [3]. Locally, the first paper published in Hong Kong was in 1993 on a comparison study of laparoscopic verses conventional anterior resection on sigmoid and upper rectal cancers [4]. Although prior to this, laparoscopic surgery had already been widely adopted in other general surgical operations (e.g., appendicectomy, adrenalectomy, bariatric surgery, and cholecystectomy), various concerns on laparoscopic rectal cancer resection were immediately raised. These concerns were on its oncological safety such as port site and abdominal wall metastasis and local oncological clearance [5–9]. These have largely been resolved by large clinical trials, which showed no difference in local tumor clearance, lymph node harvest, tumor recurrence rates, and long-term survivals. The short-term advantages of laparoscopic surgery when compared with conventional open surgery were quickly realized, which include shorter hospital stay, less pain, better postoperative respiratory function, less blood loss, less postoperative ileus, and better quality of life [10].

These benefits can be translated and be complemented with the enhanced recovery after surgery (ERAS) program in order to improve patient recovery from major colorectal operations. Indeed, laparoscopic colonic surgery is now a recognized component of the ERAS protocol [11, 12].

Despite the endorsement of laparoscopic colonic surgery, a question mark still remains on the efficacy of laparoscopic rectal surgery. The main concern is whether the surgical principles championed by Professor Bill Healed can be translated from open to laparoscopic surgery. Total mesorectal excision (TME) has been regarded as the gold standard treatment for middle and low rectal cancers. Preservation of the mesorectal envelope with accurate dissection along the correct plane is paramount for reducing the risk of local recurrence and potential complications such as pelvic nerve injury and pelvic bleeding. The Medical Research Council Conventional versus Laparoscopic Assisted Surgery in Colorectal Cancer (MRC CLASSIC) trial has highlighted the technical expertise required for laparoscopic rectal surgery. In this trial, problems of positive circumferential margins (CRM) and the high conversion rate to open surgery were apparent. Interestingly, these did not translate to a higher local recurrence rate at 3 years follow-up [13].

9.4 Current Evidence

In the field of colorectal cancer surgery, the benchmark for quality is on oncological and perioperative outcomes. Four meta-analyses published comparing oncological outcomes between laparoscopic and open resection for rectal cancer have shown no difference between the groups in terms of overall survival, disease-free survival, local recurrence rates, number of lymph nodes harvested, or circumferential resection margin positivity rate [14–17].

In terms of perioperative outcomes, morbidities from laparoscopic rectal surgery have been analyzed and compared with open surgery. For laparoscopic rectal surgery, complications can generally be divided into intraoperative and postoperative complications. Early data on morbidity and oncological outcomes have largely been the similar to more recent results [18–27] (Table 9.1). Meta-analysis published by Arezzo et al. from 23 studies has found laparoscopic group with a lower complication rate (31.8%) when compared to the open group (35.4%) (RR = 0.83, 95% CI: 0.76–0.91, $P < 0.001$) [28]. Importantly, anastomotic leak rates have also been shown to be low and comparable between the two groups, which the author suggested that it might have been due to improved stapling and energy devices.

Mortality rates have been shown to be comparable between laparoscopic (1%) and open rectal surgery (2.4%) in meta-analysis (RR = 0.46) [28].

Conversion rate for laparoscopic rectal surgery varies between studies (<1–34%) with prospective trials, randomized controlled trials, and meta-analysis quoting 13.3%, 12.5%, and 13%, respectively [28]. RCTs also compared the two groups with operative times and found laparoscopic group to be significantly longer [13, 29–31]. However, other trials have also shown that there is significant reduction in operative time as the surgeon becomes more experienced with laparoscopic technique [32]. Length of stay has been shown in three trials to be shorter in the laparoscopic group (mean difference between 1 and 3.6 days) [29, 31–33]. The laparoscopic group when compared to the open group was found to have a significantly lower estimated blood loss [29–31].

Bowel function recovery is quicker in the laparoscopic group at variable parameters such as first time to flatus or stool, time when oral feeding commenced [17, 28]. This benefit may be because laparoscopic surgery allows early mobilization, which is known to be beneficial to postoperative bowel function recovery.

Postoperative pain and the level of analgesia required is less in the laparoscopic group where most of these studies used the visual analogue score as the measurement tool.

Common sites of potential pelvic nerve damage leading to sexual dysfunction are: (1) superior hypogastric plexus, leading to ejaculation dysfunction in male patients and impaired lubrication in females; and (2) pelvic splanchnic nerves or the pelvic plexus – leading to erectile dysfunction in men. The CLASICC trial reported a 41% sexual dysfunction in men after laparoscopic rectal surgery when compared with 23% in the open rectal surgery group. Studies also looked into bladder function between the two groups but did not find any significant difference [34].

9.5 Challenges and Technical Considerations of Laparoscopic Rectal Surgery

The technical challenges of laparoscopic rectal surgery are often realized when operating on patients with a bulky tumor within a narrow pelvis. Difficult surgery may compromise the quality of the TME specimen (i.e., leading to increased rate of local recurrence), causing excessive intraoperative blood loss, injury to pelvic nerves, and increased conversion rate. Laparoscopic instruments have been designed to substitute parts that are normally performed by hand in a laparotomy such as dissection of tissue, hemostasis, and anastomosis. Hence these technical advances and surgeon experience have allowed complex surgery to be performed with good result.

Kayano et al. looked into the learning curve for 250 consecutive laparoscopic low anterior resections and found the operative time using the

Table 9.1 Early experience of perioperative and oncological outcomes of laparoscopic rectal resection

Author (year)	Patient no.	Procedure (%)	Mean no. of lymph node harvested	Positive margin (%)	Median operative time (min)	Anastomotic leak (%)	Overall morbidity (%)	Conversion (%)	Mortality (%)	Local recurrence (%)	Survival (%)
Larach (1993) [19]	4	APR (100)	1–8	NA	323	NA	25	25	25	NA	NA
Fleshman (1999) [18]	42	AR (50) : APR (50)	9.7	12	234	NA	55	21.4	0	19	74
Yamamoto (2002) [20]	70	AR (93) : APR (6)	14.3	0	NA	9.2	18.6	2.9	0	2.9	100 at 5 years
Zhou (2003) [21]	82	LAR (100)	120	1.2	120	1.2	3.6	1.2	0	2.4	NA
Morino (2003) [22]	100	AR (100)	12.8	0	250	17	36	12	2	4.2	74 at 5 years
Leroy (2004) [23]	102	AR (84.7) : APR (13.3)	8	0	202	17	27	3	2	6	65 at 5 years
Leung (2004) [24]	203	AR (100)	11.1	0	190	0.5	25.1	23.2	2.5	6.6	76 at 5 years
Baik (2009) [25]	57	LAR (57)	18.4	7.1	191	7	19.3	10.5		NA	NA
Park (2013) [26]	40	ISR (40)	NA	5	184	5	12.5	0	0	NA	NA
D'Annibale (2013) [27]	50	NA	13.8	0	280	22	22	12	0	NA	NA

AR anterior resection, *APR* abdominoperineal resection, *LAR* low anterior resection, *ISR* intersphincteric resection, *NA* non-applicable moving average stabilizes at 50 cases. The conversion rate also decreases significantly between 151 and 200 cases. Risk factors affecting the learning curve include male sex and the T staging of the disease: which may be interpreted as narrow pelvis and large tumor, respectively [35].

Minimal invasive surgery can exist in many forms. For laparoscopic colorectal surgery, single-port surgery and hand-assisted surgery have proven to be feasible [36–38]. However, for low rectal surgery, the practice of the above-mentioned techniques has not been widely adopted. The likely explanation of this is that single-port surgery may cause excessive instrumental collision, in particular with difficulty to accommodate the endostapler during distal rectal transection. Hand-assisted laparoscopic surgery may allow tactile feedback and facilities dissection, but within a confined space such as a narrow pelvis, its role may also be limited due to the lack of working space. Robotic rectal surgery may offer advantages over conventional laparoscopic technique such as 3-D high definition vision, tremor free, endowrist technology, surgeon-control camera, and better ergonomics for the surgeon. However, currently, randomized controlled trial such as the ROLARR (RObotic versus LAparoscopic Resection for Rectal cancer) is still ongoing and the result may not be available for some time [39]. Other randomized controlled trials are also in progress in Korea, Mainland China, and Hong Kong.

The main difference between laparoscopic rectal surgery to other laparoscopic operations (e.g., laparoscopic Nissen fundoplication, laparoscopic cholecystectomy, and laparoscopic adrenalectomy) is that it contains multiple steps with multi-quadrant dissection. Hence it makes the operation more complex and technically more challenging. Special instruments have been designed to tailor surgical needs. Bowel graspers are designed to permit surgeon to hold and manipulate small and large bowel without damaging the serosa or cause an inadvertent enterotomy. Division of vessels can usually be divided with hemostatic clips, staples, or energy device. In our unit, hemostatic clips such as the Hem-o-lok® (Weck Closure Systems, Research Triangle Park, NC, USA) are being used on larger vessels >7 mm diameter such as the inferior mesenteric artery and vein. Judicious dissection of the vessel prior to clipping is advised as the clip may not close if too much perivascular tissue is involved or the vessel within the tissue bundle may slip and cause significant bleeding. The innovation of stapling technology has allowed simultaneous stapling and transection of tissue and vessels to be carried out laparoscopically. Hemostatic staples, with 2.5-mm staples, can close and divide vessels with good hemostasis. There are several energy devices in the market with the capability of tissue and vessel division and dissection. They are broadly classified into ultrasonic-based (Harmonic ACE®, Ethicon Endo-Surgery, Inc, Cincinnati, OH, US), electrocautery-based (LigaSure®, Covidien plc., Mansfield, MA, USA or Enseal®, Ethicon Endo-Surgery, Inc, Cincinnati, OH, USA), or both (Thunderbeat®, Olympus America, Center Valley, PA, USA). Despite the above technological advances, we feel that diathermy dissection may still have a role in laparoscopic rectal surgery as it allows a precise dissection of tissue plane for better visualization of important anatomy. However, the disadvantage of diathermy includes high thermal dissipation and modest hemostatic ability. High-definition video imaging has allowed identification of anatomy and allowed precision dissection to compensate for the lack of tactile feedback. Currently on the market, 3-D articulating high-definition scope is available (Endoeye flex 3D, Olympus America, Center Valley, PA, USA) with the aim to provide depth of perception, flexible head for better visualization of obscured area, autofocus function, and Narrow Band Imaging® to assess capillary patterns. Whether these technological advances can improve the core aim of rectal cancer surgery above remains to be seen [40].

9.6 Techniques, Tips and Tricks: Laparoscopic Low Anterior Resection

After induction of general anesthesia, an orogastric tube and foley catheter is inserted to deflate the stomach and keep the bladder empty,

Fig. 9.2 Dan Allen stirrups used with pneumatic compression stockings

Fig. 9.3 Gel pad placed to the lower back to aid intra-abdominal small bowel placement

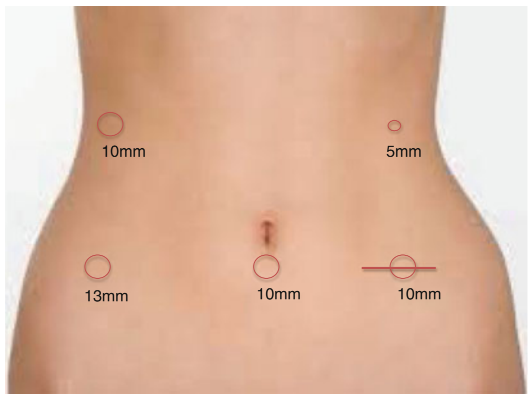

Fig. 9.4 Port position with size for low anterior resection with specimen extraction site via an extended left lower quadrant port site wound

respectively. The patient is positioned supine in a Trendelenburg position. As the majority of our patients' BMI are relatively low, we do not feel that there is a particular need for chest strapping or for the use of a vacuum positioning system. Legs are placed in Dan Allen stirrups with pneumatic compression device as part of thromboembolic prophylaxis (Fig. 9.2).

We routinely place a gel pad in the patient's lower back in order to lessen the sacral angle, which in turn prevents small bowel from falling into the pelvis during the operation (Fig. 9.3).

The first umbilical port is inserted using the Hassan technique. Care is taken not to make the fascial defect too big as it may risk gas leak and surgical emphysema. Silk stay stitches can be used to secure the umbilical port to minimize the gas leak. Carbon dioxide pneumoperitoneum is then established at a pressure of 12 mmHg.

Following camera insertion, a routine four-quadrant inspection is performed. Port positioning is as illustrated in Fig. 9.4. The assistant now moves to the patient's right side, standing cranial to the surgeon. The patient is then tilted approximately 30° head down and rotated left side up. This will help the small bowel to move out of the pelvis to the right side of the abdomen as well as the use of gel pad mentioned above.

In our unit, we adopt the lateral-to-medial mobilization with the identification of the left

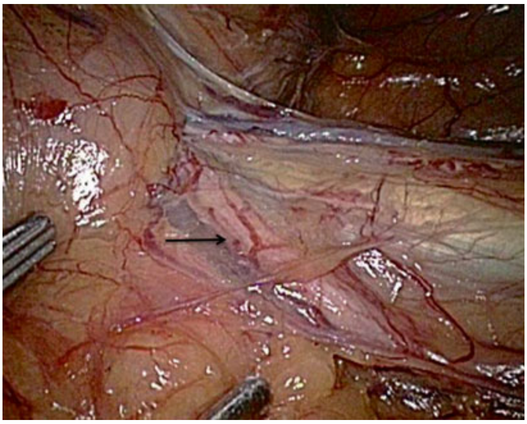

Fig. 9.5 Identification of the left ureter (*arrow*) during lateral-to-medial dissection

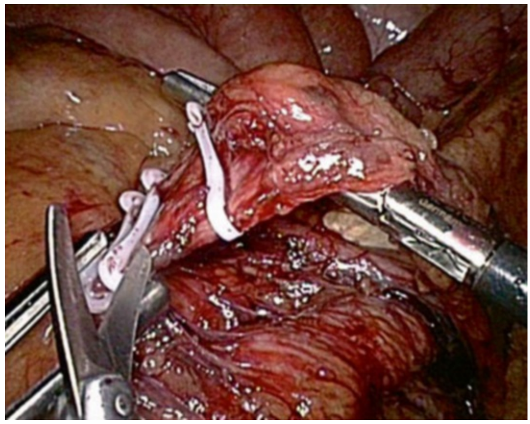

Fig. 9.6 Inferior mesenteric artery clipped with hem-o-loks before transection

gonadal vessels and left ureter (Fig. 9.5). The ureter is located medial to the gonadal vessels just deep to the parietal peritoneum but on some occasions, the left ureter may not be as easily recognized. Dissection cranially may help to find the proximal ureter. If this fails, changing to the medial-to-lateral approach may help. Surgeon should be wary not to dissect too deeply around the sacral promontory as this may risk damaging the iliac arteries and veins. In laparoscopic surgery, use of transilluminating ureteric stents instead of standard ureteric stent may allow rapid identification of the ureter [41]. Following the identification of the ureter, the dissection is continued up to the origin of the inferior mesenteric artery (IMA). Hemostatic clips are used before the artery is divided (Fig. 9.6). The inferior mesenteric vein (IMV) can also be divided at the level of the duodenal-jejunal flexure using hemostatic clips.

The left colon is then mobilized along the line of Toldt. The plane between the descending colon mesentery and the anterior surface of the Gerota's fascia should be identified and developed. As the dissection moves cranially, care should be taken to identify the pancreas in order to avoid inadvertent injury.

Usually, dissection to the level of the splenic flexure is enough for length, as Asian patients are known to have a longer sigmoid colon, which allows pelvic floor anastomosis without splenic flexure mobilization. If splenic flexure mobilization is required, patient is first tilted to a reverse Trendelenburg position with left-sided tilt. Additional 5 mm port may be placed in the left upper quadrant to aid retraction. Dissection is performed via a bidirectional approach: (1) by entering into the lesser sac and into the avascular plane between the greater omentum and transverse colon and (2) to continue with the lateral mobilization of the proximal descending colon toward the splenic flexure. In order to avoid excessive caudal traction causing splenic capsular tear, gentle cranial countertraction toward the spleen by the assistant is advised. In our unit, we do not routinely free the splenic flexure when performing laparoscopic low rectal anterior resection (unpublished data of ~30%) as the majority of our population have a relatively low BMI and long sigmoid colon. This view is also shared by other centers that perform the operation [42, 43].

The patient is then returned to the Trendelenburg position with a left-sided tilt. Bowel clamp is then used through the left-sided port to stretch the sigmoid cranially so that the rectosigmoid junction is straightened and elevated. We believe diathermy dissection via the TME plane (a.k.a. Holy plane) allows sharper tissue dissection with the hypogastric nerves identified and preserved. Anteriorly at the level of the peritoneal reflection, seminal vesicles or rectovaginal septum will be encountered

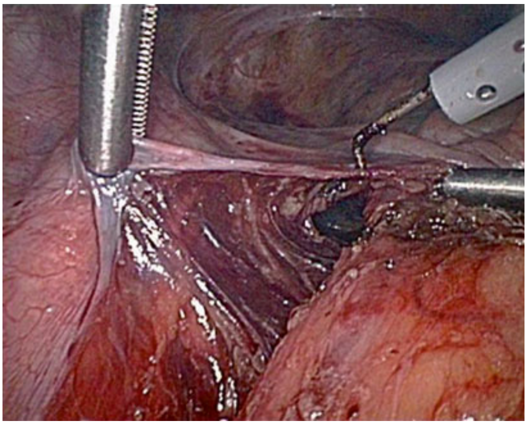

Fig. 9.7 Pelvic dissection on the left side of pelvis

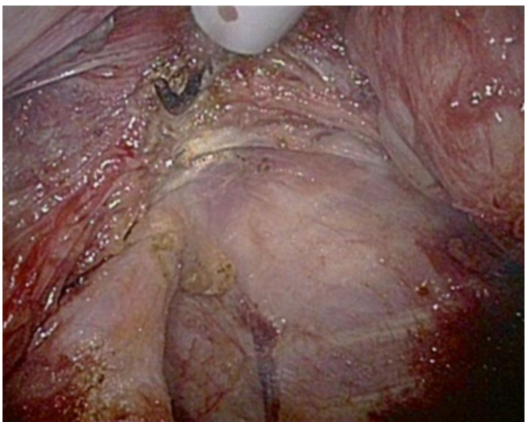

Fig. 9.8 Pelvic dissection down to pelvic floor

once the peritoneum is divided. Dissection between fascia propria of rectum and the posterior to the Denonvillier's fascia, separating the prostate or vagina from the rectum, is performed in order to preserve the cavernous nerves as injury to them may cause sexual and voiding dysfunction [44]. At the lateral portion of the mid-rectum, dissection close to the mesorectal envelope is advised in order to avoid inadvertent injury to the pelvic nerve plexus. The dissection is continued down to the muscle tube of the rectum, passing the most inferior portion of the mesorectum (Figs. 9.7 and 9.8). The laparoscopic steps shown at this point are essentially the same for low anterior resection, intersphincteric resection, or abdominoperineal resection.

Continuing for a low anterior resection, transection of the low rectum can be performed by using an articulating staple-powered device. If possible, surgeon should aim for minimal firings of the stapler. Some surgeons make a small pfannenstiel incision to allow better placement of the stapling device down in the pelvis for distal rectal transection Some studies believe multiple firings may be associated with anastomotic leak [35–45].

The specimen is delivered via an extended left iliac port site wound or a small midline wound or a small pfannenstiel wound. A wound protector is used to prevent contamination and tumor seedling as well as to facilitate specimen extraction. Proximal transection is performed followed by a low circular stapled anastomosis. Inspection of the donuts excised and digital rectal examination after the anastomosis is performed to confirm to ensure intact staple line and minimal bleeding. We routinely perform a defunctioning ileostomy until the healing of the anastomosis is confirmed.

Conclusion

Laparoscopic rectal surgery can benefit patient recovery, overall outcome, and quality of life. Appropriate training is essential in order to produce at least equivalent oncological results to open surgery.

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10 Total Mesorectal Excision: From Open to Laparoscopic Approach

Hok Kwok Choi and Wai Lun Law

10.1 Introduction

Rectal cancer surgery has undergone a rapid evolution in the last few decades. Adoption of total mesorectal excision (TME) dramatically reduced the local recurrence rate and improved the survival rate [1]. TME became the standard procedure for cancer of the middle and lower rectum soon after its introduction. The use of laparoscopic approach in resection of colorectal cancer started in the early 1990s. Laparoscopic resection for colon cancer was widely advocated subsequently as most randomized trials had proven that the oncological outcome comparable to that of open colectomy could be achieved, in addition to the intrinsic benefits of minimally invasive surgery [2–7]. Rectal cancer was rarely included in early randomized trials comparing laparoscopic and open surgery because of the relative complexity of rectal cancer resection, in particular, TME. The first laparoscopic TME was only reported in 2001 [8]. Concerns about oncological safety of laparoscopic TME existed as there were limited studies to compare the long-term outcomes of laparoscopic and open TME on a randomized setting.

10.2 Total Mesorectal Excision: Open Approach

Total mesorectal excision, the most significant advance in rectal cancer treatment, was reported by Heald in 1982 [9]. He described the "holy plane" between the visceral mesorectal fascia and the parietal pelvic fascia along which meticulous and sharp dissection under direct vision should be carried out down to the level of levator muscles in order to remove the rectum and mesorectum as an intact unit. The principle of TME was soon adopted worldwide for the treatment of cancers in the middle and lower rectum.

The practice of TME for rectal cancer has led to several favorable outcomes. Before the introduction of TME, the commonly performed blunt dissection in pelvis often resulted in inadequate resection of mesorectum within which cancer cells might have spread. Quirke demonstrated presence of lateral margin involvement by cancer in 14 out of 52 curatively operated patients and 85 % of those with positive lateral margin developed local recurrence [10]. Local recurrence rates of more than 30 % were frequently observed following resection of locally advanced T3 or node-positive rectal cancers [11]. In contrast, Heald in

H.K. Choi, MBBS, FRCS (Ed)
W.L. Law, MBBS, MS, FRCS (Ed), FACS (✉)
Department of Surgery,
Queen Mary Hospital, The University of Hong Kong,
102 Pokfulam Road, Hong Kong, China
e-mail: lawwl@hkucc.hku.hk

W.C.S. Meng et al. (eds.), *Minimally Invasive Coloproctology: Advances in Techniques and Technology*, DOI 10.1007/978-3-319-19698-5_10

1998 reported a local recurrence rate of only 3 % at 5 years and 4 % at 10 years in 405 patients with curative resection using the principle of TME. Disease-free survival in this group of patients was 80 % at 5 years and 78 % at 10 years [1]. Since 1993, TME has become the standard procedure for middle and distal rectal cancers in our institution. In our previous analysis involving 270 patients with TME performed, all anastomoses were located within 5 cm from the anal verge and local recurrence rate was 7.3 % [12]. Other studies also reported impressively low local recurrence rate after adopting Heald's surgical technique [13–15]. The success of TME in the treatment of rectal cancer was further supported by a Norway study. A Norwegian national audit of rectal cancer resections performed between 1986 and 1988 identified a local recurrence rate of 28 % and a 5-year survival rate of 55 %. A TME training program was initiated in 1994 and subsequent review showed that local recurrence rate had dropped to 8 % and survival improved to 71 %, with only a minority of patients having undergone neoadjuvant therapy [16]. A recent study by Maurer, in which all patients had been followed up for at least 7 years or until death, showed that the technique of TME had markedly reduced local recurrence of rectal cancer from a rate of 20.8 to 5.9 % [17].

Abdominoperineal resection (APR), the previously used standard operation for rectal cancers, has been performed less frequently since the introduction of TME. Using the technique of TME, even rectal cancers lying close to the pelvic floor can undergo a sphincter-saving resection. In Heald's report, among the 519 patients with rectal cancer, only 37 patients (7.1 %) underwent APR [1]. In his series of 136 operations for cancer below 5 cm from the anal verge, only 31 operations (23 %) were APR [18]. In our reports on 205 patients with rectal cancer within 6 cm from the anal verge, the percentage of APR decreased from 36 to 20 % following the introduction of TME [19]. Data from a national audit in the Netherlands showed that, with the practice of TME, the ratio of APR versus low anterior resection dropped by 32 % comparing sequential time periods in the mid-to-late 1990s [20]. A similar decline in the utilization of APR was also reported in a Swedish study. The proportion of APR decreased from more than 50 to 27 % [21].

In the past, blunt dissection in the pelvis during rectal cancer resection frequently resulted in damage of the pelvic autonomic nerves, which innervated the urogenital organs. Bladder dysfunction was seen in more than 50 % of patients, loss of erection in up to 80 %, and lack of ejaculation in up to 81 % [22–24]. The incidence of bladder and sexual dysfunction was reduced in the era of TME. With proper dissection in the "holy plane," pelvic autonomic nerves can be more easily identified and preserved. Functional results in a group of 136 patients with TME and deliberate autonomic nerves preservation showed urinary problem in 27 % of males and 36 % of females [25]. In the Dutch TME trial, erection and ejaculation disorders occurred in 47 % and 32 %, respectively [26]. Similar figures were reported in other studies [27, 28].

An important drawback of TME is the increase in risk of anastomotic leakage. Carlsen compared two groups of consecutive patients, one group with non-TME and the other with TME performed, which showed an increase in anastomotic leakage rate from 8 to 16 %. All patients with anastomotic leakage in the TME group required reoperation [29]. The reported incidence of anastomotic leakage after TME was about 8–19 % [30–34] In view of this relatively high incidence of anastomotic leakage, which is potentially life threatening and requires reoperation, routine construction of diverting ileostomy or transverse colostomy to protect the anastomosis is a common practice. A diverting stoma may not influence the occurrence of anastomotic failure, but it minimizes the clinical consequences due to leakage of anastomosis [34, 35]. Besides resulting in sepsis, anastomotic leakage after TME was associated with poorer prognosis. Local recurrence rate was reported to be higher in patients with anastomotic leakage [32, 36, 37].

10.3 Total Mesorectal Excision: Laparoscopic Approach

Laparoscopic surgery for colorectal resection has rapidly developed since it was first reported in 1991 [38]. The advantages of laparoscopic approach have been well documented, including reduction in postoperative pain, earlier return of bowel function, decreased length of hospital stay and better cosmesis, together with less immune function disruption [39, 40]. For colon cancer, there has been a general recognition that laparoscopic resection can achieve oncological outcomes at least equivalent to that of open surgery [2–7]. Laparoscopic resection has become more or less a standard approach for colon cancer. The role of laparoscopic resection in rectal cancer, however, is less well defined.

Laparoscopy provides a much better view of the pelvic structures, particularly in male patients with narrow pelvis, compared to open surgery. During operation for rectal cancer, laparoscopy may thus enable surgeons to identify more easily important structures like the pelvic autonomic nerves, seminal vesicles, and posterior vaginal wall, and to perform more meticulous dissection under direct and magnified vision. The positive pressure of pneumoperitoneum during laparoscopic surgery can help open up the plane that separates the pelvic parietal fascia and visceral fascia of the mesorectum and aid dissection along this bloodless plane. On the other hand, due to the complexity of rectal cancer resection like TME, inadequate excision has been a concern for laparoscopic rectal cancer surgery.

Early reports confirmed feasibility of laparoscopic surgery for rectal cancer including sphincter-saving TME. Nevertheless, the procedure of laparoscopic TME was technically demanding with a conversion rate of 9–12 %. Operative mortality was about 2–3 % [41, 42]. In Rullier's series, laparoscopic TME with preservation of sphincter was performed in 32 patients with rectal cancer located 5 cm from the anal verge. Macroscopically, intact mesorectal excision was achieved in 29 patients. Resection margins were clear microscopically in 30 patients. The superior hypogastric plexus could be identified and preserved in all patients. Bilateral hypogastric nerves and pelvic plexuses were identified and preserved in 24 patients.

10.3.1 Surgical Technique

To perform a laparoscopic TME, the patient is placed in a lithotomy position with the thighs minimally elevated above the abdomen to avoid collision with the surgeon's hands when mobilizing the splenic flexure. Camera port is inserted through a subumbilical wound by open method. Pneumoperitoneum is created with intra-abdominal pressure maintained at a maximum of 12 mmHg. Under direct vision, a 12-mm port is placed at the right lower quadrant lateral to the rectus abdominus to allow the subsequent use of clipping and stapling devices. Three 5-mm ports are inserted at the right upper quadrant, left lower quadrant, and left upper quadrant, respectively. Using a 30° laparoscope, a diagnostic laparoscopy is performed to assess the primary tumor and to exclude peritoneal metastasis. The patient is then put in a head-down position to facilitate placement of small bowel loops cranially and to the right side, in order to expose the root of the sigmoid mesocolon. The sigmoid is then mobilized from the medial to lateral aspect. While the assistant is holding the sigmoid ventrally and to the left under traction, the peritoneum is incised at the root of its mesocolon at the medial side starting at the level of sacral promontory. A window is made at the avascular plane between the mesocolon containing the arch of inferior mesenteric artery and the retroperitoneum. Dissection continues along this plane laterally till the white line of Toldt using ultrasonic dissector. The left ureter and gonadal vessels should be identified and safeguarded. The inferior mesenteric artery is dissected up to its origin, care being taken not to injure the superior hypogastric plexus. The artery is skeletonized, clipped, and divided near the origin. Skeletonization of the inferior mesenteric artery ensures that the artery can be clipped securely and confirms that the left ureter will not be injured in this step. We do not recommend the use of vascular stapler for division of this artery. The inferior mesenteric vein, lying just lateral to the inferior mesenteric artery, is identified and dissected upward till the lower border of the pancreas near the duodenojejunal flexure. Again the inferior mesenteric vein is skeletonized, clipped, and divided at this level. The avascular plane between the mesocolon and retroperitoneum is further opened upward anterior to the pancreas and laterally toward the descending colon and splenic flexure. The lateral peritoneal attachment of the sigmoid and descending colon is then divided to complete their mobilization. The greater omentum is divided close to the transverse colon so that the lesser sac is opened. Further division of the omentum is carried out in order to separate it from the transverse colon from the midline to the splenic flexure. Now the splenic flexure can be taken down quite easily. Dissection should stay close to the bowel wall to avoid injury of the spleen. Mobilization of the splenic flexure should be performed routinely to facilitate a tension-free anastomosis to be subsequently constructed in the pelvis.

The principle of pelvic dissection in laparoscopic TME is the same as that of open TME. Before starting the pelvic dissection, it is important to identify, at the level of sacral promontory, the avascular plane between the visceral fascia of mesorectum and the pelvic parietal fascia. The shiny and smooth surface of mesorectum should be clearly recognized under laparoscopy. After incising the peritoneum attached to the rectum bilaterally, the rectosigmoid junction is retracted anteriorly and the plane is further opened inferiorly toward the pelvic floor. The rectosacral ligament can be easily divided by ultrasonic dissector. The hypogastric nerves should be identified and protected from injury by the ultrasonic dissector. Along the same plane, the mesorectum is separated from the pelvic side wall. The lateral ligament and the middle rectal artery are divided during this lateral dissection. After division of the lateral ligament, the lateral mesorectum can be followed down to the pelvic floor. Injury to the inferior hypogastric plexus at the pelvic side wall should be avoided. Anterior dissection during laparoscopic TME can be difficult, particularly in female patients due to the presence of uterus. If necessary, a straight needle attached with strong suture can be inserted percutaneously into the pelvis, pierced through the broad ligament anteroposteriorly on one side and then in a reverse direction, the broad ligament on the other side so as to form a loop below the uterus. The needle is passed through the abdominal wall and tied tightly at the skin so that the uterus is slung anteriorly to expose the operating field. Peritoneal incisions on both sides are joined anteriorly just above the pelvic peritoneal reflection. The anterior mesorectum is mobilized along the plane in front of the Denonvilliers' fascia for oncological reason [43]. The Denonvilliers' fascia forms the glistening white surface of the anterior mesorectum. Liang reported that the fascia and its boundaries could be clearly recognized by laparoscopy in more than 90 % of male patients, but in female patients the fascia was less obvious [44]. At the lateral edges of this fascia, it is important to avoid damaging the inferior hypogastric plexus and the medially tapering nerve bundle which innervates the urogenital organs. The mesorectum has a very definite end which is about 1–2 cm above the pelvic floor. There is no mesentery distal to this point with just a muscular tube of bowel connected to the pelvic floor. A 30-mm or 45-mm roticulating stapler is inserted through the right lower quadrant port for transection of the rectum. During this step, the assistant may push on the perineum from below to elevate the pelvic floor to avoid an oblique transection of the rectum. Ideally, the rectal transection should be accomplished with a single stapler firing. In a retrospective study, Ito showed that the risk of anastomotic leakage is higher in patients who required three or more stapler firings for rectal transection compared to those with less number of firings [45]. A small transverse incision is made at the left lower abdominal wall for retrieval of the rectal tumor. A plastic sleeve-like wound protector should be placed before the tumor is being delivered to prevent wound recurrence. The colon is divided at a level where blood supply is good, proximal margin adequate, and anastomosis can be performed without tension. The anvil of a 28-mm or 29-mm circular stapler is anchored at the cut end followed by re-establishment of pneumoperitoneum. The colorectal anastomosis is performed under direct vision. It is important to make sure that the vagina is not trapped by the circular stapler before firing in order to avoid formation of a rectovaginal fistula. A colonoscopy is performed afterward to assess the completeness of staple line and ensure no bleeding from the anastomosis. An air leak test can also be carried out to test the integrity of the anastomosis. A suction drain is placed near the anastomosis and exited at the left lower quadrant port site. We routinely construct a diverting ileostomy on completion of the operation.

A sphincter-saving TME can still be performed even for tumor lying as low as the anorectal junction provided the levator ani and external anal sphincter are not invaded. Laparoscopic mobilization is continued downward below the levator ani along the intersphincteric plane. A stapled transection below the tumor laparoscopically will be difficult. Therefore, the next phase of operation is often carried out transanally. If the tumor is located proximal to the anorectal junction, a circumferential incision is made and internal anal sphincter divided at the dentate line. Intersphincteric dissection is completed from below. If the tumor has involved the upper internal anal sphincter, the whole internal sphincter is removed by intersphincteric dissection. A distal margin of at least 1 cm should be aimed. After resection of the tumor, the colon is brought down to the anal canal where a transanal handsewn coloanal anastomosis is performed. An APR is required for rectal cancers that are located further down or have invaded levator ani or external sphincter. After laparoscopic mobilization of the whole mesorectum is achieved, a perineal procedure is carried out to complete the APR.

TME is a technically demanding operation. The oncological benefits of open TME for treatment of rectal cancer have been well recognized. Whether this operation can be performed laparoscopically to achieve a comparable standard is not certain. In the literature, there are more than 200 publications related to laparoscopic TME. However, the majority are case series or nonrandomized comparative studies. There are only several randomized controlled trials, and long-term results comparing laparoscopic and open TME are limited. To determine if laparoscopic approach can be used as an alternative to open approach for TME, a number of issues need to be addressed.

10.3.2 Operating Time

In the literature, the mean operating time of laparoscopic TME was commonly reported to be 180–280 min [46–64]. In Akiyoshi's study, the mean pelvic operative time, which was defined as the time required for dissection of rectum from the pelvis, intracorporeal transection and anastomosis, was 153 min [65]. In nearly all the comparative studies and randomized trials, operating time for laparoscopic resection was significantly longer than that of open surgery. The difference in operating time was approximately 50 min according to randomized trials [50, 51, 63, 64]. Besides a reflection of the complexity and difficulty of operation, operating time is also closely associated with surgeon's experience. In Laurent's study comparing laparoscopic and open TME with intersphincteric resection, all the patients were operated on by two surgeons. The operating time of laparoscopic surgery was significantly decreased, with experience, from 435 min during the earlier study period to 330 min in the later period [66]. Although current evidence has showed that laparoscopic TME requires a longer operating time at present, it is not unreasonable to expect a smaller difference in future when laparoscopic TME becomes more widely practiced.

10.3.3 Operative Blood Loss

Laparoscopy provides a magnified view of the operating field and allows a precise dissection. During laparoscopic surgery, blood vessels can be more easily identified and thus lower blood loss can be achieved. From the articles on laparoscopic TME, operative blood loss was commonly in the range of 90–300 ml [46, 49–51, 53, 57–59, 61–63, 67–70]. In three particular series on sphincter-preserving laparoscopic TME with number of patients from 10 to 177, the operative blood loss was as low as 17–50 mL [56, 65, 71]. Focusing on the comparative studies and randomized trials, Denoya reported no significant difference in operative blood loss: 313 mL in the laparoscopic TME group and 279 mL in the open TME group [60]. In essentially all other reports, operative blood loss was significantly lower in the laparoscopic group [46, 50, 51, 59, 61–64, 69, 72]. The difference in operative blood loss between laparoscopic and open approach was at least 200 mL in some studies [50, 51, 62, 69].

10.3.4 Intraoperative Complications

To assess if laparoscopic approach for TME is safe, an important issue that needs attention is the risk of iatrogenic injury during operation. Damage to important structures can be caused by laparoscopic instruments, including energy devices such as ultrasonic dissector. In the majority of studies, no major intragenic injury during laparoscopic TME was reported. Nonetheless, a very low incidence of iatrogenic injury was seen in some studies. Ureteric injury was documented in three reports. The incidence was not mentioned in one report while injury of ureter occurred at an incidence of about 1.5 % in the other two reports [64, 73, 74]. In one case series, Lim reported internal iliac artery injury in 1 out of 111 patients [58]. In Runkel's case series of 274 patients, thermal bowel perforation occurred in two patients [75]. One colonic perforation and one inferior mesenteric vein injury were reported in Sartori's study involving 174 patients [54].

In Gong's randomized trial, only one ureteric injury occurred in the laparoscopic group [64]. In the randomized trial by Zhou, no major intraoperative complication was noted in both laparoscopic and open TME groups [76]. In the COLOR II trial, intraoperative complications including bowel perforation (<1 %), ureteric injury (1 %), and perforation of tumor (<1 %) were observed in the laparoscopic group. However, no significant difference was found compared to the same complications in the open group [51].

10.3.5 Conversion to Open Surgery

Conversion rate is an indicator to feasibility of laparoscopic surgery. In laparoscopic colon resection, most reports provided a definition of conversion, which was commonly described as either premature abdominal incision to allow for vascular control or mobilization, or abdominal incision of more than 6 or 7 cm [72]. Regarding laparoscopic rectal cancer resection, a clear definition of conversion definition is provided in probably less than half of the relevant studies and the definitions varied a lot (Table 10.1).

Whatever the definition is, conversion indicates an encounter of difficulties and failure to continue the operation solely by laparoscopic means. Among the 470 laparoscopic rectal resections performed in our institution over the last 11 years, the conversion rate was 6.8 % [46]. According to the reports on laparoscopic TME, conversion to open occurred at a rate of 0 % to about 22 % [41, 50, 51, 53–55, 57, 58, 61–66, 69, 71, 73,

Table 10.1 Definitions of conversion

Study	Definition
Guillou [77]	Vertical abdominal incision greater in size than that needed for specimen retrieval
Fukunaga [53], Kim [78], Gouvas [79]	Requirement of any additional unplanned incision to complete the procedure
Staudacher [49]	Interruption of laparoscopic procedure
Braga [80]	Abdominal incision longer than 7 cm
Biondo [73], Laurent [81]	Need for laparotomy
Gonzalez [61], Gong [64], Cheung [71], Ng [82]	Any part of the procedure with an open technique, other than specimen retrieval
Kang [63], Glancy [83]	Incision longer than that required for specimen extraction
Runkel [75]	Extension of the retrieval site incision for additional open access surgery
Van der Pas [51]	Incomplete laparoscopic dissection of mesorectum

75, 79, 83–92]. At least two case series and two comparative studies with number of laparoscopic resection 18 to 79 reported no conversion [61, 65, 87, 91]. In six randomized trials, rate of conversion in the laparoscopic resection group ranged from 3 to 17 % [50, 51, 62–64, 92]. A number of conditions had been reported as the reasons for conversion. However, the majority of them were not related to technical failure but unfavorable situations for which laparoscopic surgery was deemed not appropriate. These included fixation due to advanced rectal cancer, tumor invasion of pelvic side wall or ureter, large tumor size, extensive adhesions, obesity with narrow pelvis, and intraoperative cardiopulmonary intolerance to pneumoperitoneum. Conversion to open surgery in these circumstances to ensure operation quality and patient safety could be regarded as appropriate judgment rather than failure. Nevertheless, a minority of conversions was due to technical failure such as severe bleeding, ureteric injury, iliac artery injury, and dehiscence of rectal stump staple line. On the other hand, a reduction in conversion rate can be expected with increase in surgeons' experience. In the study carried out in Spain involving seven hospitals over a 2-year period, conversion rate decreased from 25.5 % in the first year to 18.9 % in the second year. When the conversion rate was analyzed according to number of laparoscopic procedures, it was 19.6 % in three hospitals with higher number of laparoscopic resections compared to 45 % in the other four hospitals with fewer procedures performed [73]. In our experience, conversion rate was 13 % in our first 100 laparoscopic rectal resections and 5.1 % among the subsequent 370 cases [46].

Conversion during laparoscopic rectal resection has been suggested to result in worse oncologic outcomes. In Ströhlein's comparative series of 389 patients, an increase in metachronous metastasis and local recurrence in the converted group was reported when compared with successful laparoscopic resection group and open surgery group (metachronous metastasis: 26.3 % vs. 17.8 % vs. 14.9 %, respectively; local recurrence: 16 % vs. 6.9 % vs. 9.5 %, respectively) [93]. On the contrary, Penninckx reported in another study with more than 2000 patients that the oncological quality of surgery was not worse after converted laparoscopic TME than after open or fully laparoscopic TME. The relative survival rate at 3 years after converted laparoscopic TME was 92.2 %, not significantly different from 89.2 % after purely laparoscopic TME and 88.1 % after open TME [88]. From the long-term results of the CLASICC trial, conversion was associated with worse survival compared to open surgery and successful laparoscopic surgery in colon cancer. But neither overall nor disease-free survival appeared to be influenced adversely by intraoperative conversion in patients with rectal cancer [94].

10.3.6 Recovery After Operation

The general benefits of minimally invasive surgery in terms of early return of bowel function, quicker resumption of diet, decrease in wound pain, and shorter hospital stay have been consistently associated with laparoscopic TME. Following resection of rectal cancer laparoscopically, most patients had bowel movement 2–5 days after operation and could tolerate normal diet starting from postoperative day 3 to day 6 [47, 48, 50, 51, 78, 79, 95, 96]. The duration of hospital stay was commonly reported to be 6–10 days [51, 60, 62, 63, 66, 69, 76, 84, 86, 89, 91]. With adoption of an enhanced recovery pathway after laparoscopic TME, hospital stay as short as 3 days has been reported [56]. Comparing laparoscopic with open TME, most reports showed advantages of laparoscopic approach in return of bowel function, resumption of diet, and/or length of hospital stay [50, 51, 60, 61, 63, 64, 76, 77, 79, 91]. Four randomized trials documented requirement of less analgesia following laparoscopic resection [50, 51, 63, 64]. Ng's randomized trial also demonstrated a shorter time to walk independently after laparoscopic TME [50].

10.3.7 Morbidity and Mortality

Rectal cancer surgery is associated with high morbidity rates. TME reduces the local recurrence rate but complete removal of the mesorectum devascularizes the rectal stump and increases the risk of anastomotic leakage. In our recent study, anastomotic leakage occurred at a rate of 5.73 % after laparoscopic resection of rectal cancers within 7 cm from the anal verge and 1.59 % for more proximal rectal cancers. The morbidity rate and 30-day mortality rate after laparoscopic rectal resection were 22 % and 0.4 %, respectively [46]. Other studies generally reported that laparoscopic TME was associated with a risk of anastomotic leakage at 5–15 %, postoperative morbidity rate at 16–40 %, and mortality rate at 0–2 % [51, 53, 54, 69, 73, 83, 85, 88, 89]. No comparative or randomized study has ever demonstrated a significant difference in anastomotic leakage rate between laparoscopic and open TME. In Sartori's series of 174 laparoscopic sphincter-saving TME, anastomotic leakage occurred at a rate of 14 %. Male sex, location of cancer in the lower rectum, and absence of diverting stoma were found to have significant association with anastomotic leakage [54]. Male sex was also identified as a risk factor in Gouvas' study, in which it was also found that patients with anastomotic leakage had a significantly greater body mass index as compared to those without leakage [79]. A trend of increase in anastomotic leakage when a diverting of stoma was not performed, although not statistically significant, was observed in Morino's study [41]. Concerning postoperative morbidity, the CLASICC trial reported a higher incidence of chest infection in the laparoscopic rectal resection group than in the open group [77]. No other randomized trial or comparative study has reported similar finding to our knowledge. The COLOR II trail reported same incidence of respiratory complication in both laparoscopic and open groups [51]. Indeed, most reports showed similar morbidity rates between laparoscopic and open TME. Some studies actually reported less morbidity after TME by laparoscopic approach [50, 61, 79, 88, 91]. The mortality rate between laparoscopic and open TME was similar. Only one study reported a significantly higher mortality rate after open TME at 3.5 % versus 0.5 % [73].

10.3.8 Bladder and Sexual Function

One of the advantages of TME is preservation of the pelvic autonomic nerves that innervates the genitourinary organs. However, the incidence of bladder and sexual dysfunction after open TME was still significant [25–28]. Laparoscopic TME may allow better preservation of the pelvis nerves because identification of the nerves may be easier under the magnified view provided by laparoscope. Using a nerve-oriented concept by which pelvic autonomic nerves served as landmarks for a standardized navigation along fascial planes, laparoscopic rectal resection was performed in Runkel's series of 274 patients. Prolonged urinary catheterization was needed in only 1.8 % of patients after surgery [75]. Similar figure of bladder dysfunction was also reported in Cheung's case series [71]. Other reports generally described bladder dysfunction affected 6–15 % of patients after laparoscopic TME [55, 87, 97–99]. Sexual dysfunction occurred after laparoscopic TME in 5–28 % of male patients who were sexually active before surgery [50, 75, 98, 99]. Asoglu also reported a decrease in overall level of sexual function in 7 % of female patients [99]. In Liang's report, the sexual function became poor after laparoscopic TME in 27 % of female patients who were sexually active before surgery [44].

Studying the genitourinary function of the CLASICC trial's patients, Jayne reported that laparoscopic rectal resection did not adversely affect bladder function compared to open resection but there was a trend toward worse male sexual function. This might be explained by the higher rate of TME in the laparoscopic rectal resection group [100]. In Ng's randomized trial, the incidence of bladder dysfunction and erectile dysfunction was not significantly different between the laparoscopic and open TME groups [50]. Nevertheless, the potential benefit of laparoscopic surgery in preservation of genitourinary function was seen in other studies. In Asoglu's comparative study, laparoscopic TME was associated with significantly less sexual dysfunction in both male and female patients while the incidence of bladder dysfunction was similar after laparoscopic and open TME [99]. In the COREAN trial, there was no difference regarding postoperative male sexual problems between the laparoscopic and open TME groups. However, the laparoscopic group showed significantly fewer micturition problems than the open group at 3 months after surgery [63].

10.3.9 Oncological Outcome

Cancer recurrence and survival are no doubt the most important parameters to measure the success of a cancer surgery. In rectal cancer, the main advantage of TME is that an intact mesorectum is removed and thus avoid leaving cancer cells, which might have spread to the mesorectum. Besides, TME allows preservation of the anal sphincters even for very distal rectal cancer. The most important factors that determine the oncological outcome or success of a TME operation are therefore the integrity of the excised mesorectum as well as the clearance of circumferential resection margin and distal resection margin.

The integrity of mesorectum in resected specimen was commonly assessed by the method described by Quirke and classified as complete, nearly complete or incomplete [10, 101]. In about 75–90 % of cases, a complete mesorectum was removed by means of laparoscopic TME [50, 51, 73, 75, 87]. Integrity of mesorectum was analyzed in three randomized trials. All of them showed no difference in completeness of the excised mesorectum between laparoscopic and open resection groups. In these randomized trials, the number of lymph nodes retrieved was also analyzed. No significant difference was found between the two groups in terms of lymph node retrieval [50, 51, 63]. In a randomized study carried out specifically for comparison of lymph node retrieval after TME, Pechlivanides reported that the mean number of lymph nodes retrieved was 19.2 in both laparoscopic and open TME groups. The number of regional, intermediate, and apical lymph nodes was also very similar between the two groups [92]. In one comparative study, Gouvas reported that 97 % of resected mesorectum in the laparoscopic TME group were complete, which was significantly higher than that of the open TME group (79 %). The Denonvilliers' fascia at the anterior aspect of mesorectum was also more intact in the laparoscopic group. The author commented that more complete TME after laparoscopic approach was attributed to the perfect deep pelvic view offered by laparoscopy [90].

The incidence of circumferential resection margin involvement after laparoscopic TME varied from 0 to 15 % [41, 50, 52–54, 58, 63, 65, 66, 69, 71, 73, 83–85, 96]. In the study that reported a margin positive rate of 15 %, all patients underwent sphincter-saving TME for cancer at the lower rectum within 6 cm from the anal verge. The relatively high margin positive rate was probably related to the close proximity of tumor to the anorectal junction where the mesorectum was thin or absent. In the same study, the rate of positive radial margin was lower in the open surgery group but the difference was not statistically significant [66]. Actually, no report including randomized trials has shown a significant difference in circumferential resection margin involvement between laparoscopic and open TME. In the CLASICC trial, it was stated that circumferential margin positivity was greater in patients undergoing laparoscopic anterior resection than in open anterior resection, but the difference was not significant (12 % vs. 6 % $p = 0.19$) [77]. Moreover, it did not translate into an increased incidence of local recurrence [6]. As expected, distal resection margin was rarely involved in laparoscopic TME. Most studies reported a positivity rate of either zero or less than 1 % [53, 54, 58, 65, 80, 83, 84]. The length of distal resection margin achieved by laparoscopic and open TME was similar [50, 63, 64, 66, 89, 90].

Comparison of oncological outcome between laparoscopic and open TME in nonrandomized comparative studies and randomized trials were shown in Tables 10.2 and 10.3, respectively. According to the results of comparative studies, laparoscopic TME could achieve an oncological outcome as least equivalent to that of open

Table 10.2 Oncological outcomes from nonrandomized comparative studies

Study	No. of patients	Follow-up (months)	Local recurrence	Overall survival	Port site recurrence
Morino [48]	(L) 98 (O) 93	46	(L) 3.2 % (O) 12.6 %[a]	(L) 80 % (5 years) (O) 69 %	2.1 %
Laurent [66]	(L) 110 (O) 65	53	(L) 5 % (O) 2 %	(L) 85 % (5 years) (O) 82 %	0 %
Mohamed [46]	(L) 470 (O) 593	60	Overall 7.1 % No difference	(L) 73 % (5 years) (O) 63 %[a]	NA
Li [89]	(L) 113 (O) 123	75	(L) 9.1 % (O) 6.4 %	(L) 78 % (5 years) (O) 79 %	0 %
Penninckx [88]	(L) 764 (O) 1896	NA	NA	(L) 81 % (3 years) (O) 79 %	NA

(*L*) laparoscopic group, (*O*) open group, *NA* not available
[a]Significant difference

Table 10.3 Oncological outcomes from randomized trials

Study	No. of patients	Follow-up (months)	Local recurrence	Overall survival	Port site recurrence
Braga [80]	(L) 83 (O) 85	54	(L) 4 % (O) 5.2 %	No difference	NA
Jayne [7] (CLASICC)	(L) 253 (O) 128	56	(L) 9.4 % (ASP) (O) 7.6 %	(L)60 % (5 years) (O)53 %	2.4 %
Green [94] (CLASICC)	(L) 253 (O) 128	63	No difference	(L)83 months (median overall survival) (O) 66 months	NA
Ng [96] (APR)	(L) 51 (O) 48	90	(L) 5 % (O) 11 %	(L) 75 % (5 years) (O) 77 %	0 %
Ng [50] (ASP)	(L) 40 (O) 40	76	(L) 2.8 % (O) 8.9 %	(L) 86 % (5 years) (O) 91 %	0 %

(*L*) laparoscopic group, (*O*) open group, *NA* not available, *ASP* anal sphincter preservation, *APR* abdominoperineal resection

TME. No difference in terms of local recurrence and survival was demonstrated in Laurent, Li, and Penninckx's studies [66, 88, 89]. In Morino's report, however, laparoscopic surgery was associated with significantly less local recurrence. There was no significant difference in 5-year survival rate after laparoscopic or open TME. But upon stage-by-stage comparison, a significantly better survival for stage III and stage IV patients was noted in the group-treated laparoscopically [48]. In our institution, a similar survival benefit of laparoscopic rectal surgery was reported recently by Mohamed. Analysis of our data from 1063 patients showed that laparoscopic resection was associated with better 5-year overall and cancer-specific survival. On subgroup analysis of each cancer stage, there was no difference in survival in patients with stage I disease. However, for stage II and stage III disease, patients who underwent laparoscopic resection were associated with significantly higher survival rate [46].

There were about 10 randomized studies related to laparoscopic TME in the literature but most of them reported only short-term outcomes. Comparison of long-term results after laparoscopic and open TME in a randomized setting were provided by only a few trials. All these trials reported that laparoscopic and open TME achieved similar oncological outcome [7, 50, 80, 94, 96]. Two of these trials were performed by Ng, one on abdominoperineal resection and the other sphincter preservation TME. Although the two studies consisted of relatively small number of patients, the median follow-up period was more than 6–7 years. The results of these two studies did provide valuable evidence to support comparable oncological results by laparoscopic and open TME [50, 96]. The COLOR II was the largest randomized trial on laparoscopic versus open surgery for rectal cancer in which more than 1000 patients were recruited. The short outcomes were published last year. The results on locoregional recurrence were expected to be available soon [51]. After a median follow-up of 63 months, the long-term results of the CLASICC trail were reported last year. There was no difference in terms of median overall and disease-free survival between the laparoscopic and open rectal resection group. Interesting, a trend toward better survival rate in the early postoperative period was observed in the laparoscopic group. The authors suggested that this might be due to improved functional recovery resulting from the minimally invasive nature of the surgery. The authors also concluded that laparoscopic surgery should be the treatment of choice, enabling patients to benefit from earlier functional recovery with no detriment to long-term survival outcomes [94].

10.4 Robotic Total Mesorectal Excision

Robotic surgery has been increasingly adopted for more than a decade. Comparing with laparoscopic surgery, robotic surgery is advantageous in that a three-dimensional view of the operating field is provided using a stable camera platform; it eliminates the adverse effect of surgeon's hand tremor and it offers better dexterity of movement, especially when working in a narrow space such as the pelvis. The robotic system also enables the surgeon to control the camera and thus spare the need of a camera assistant. Robotic TME has become popularized in recent years. There are two methods for robotic TME. One is a hybrid technique in which colon is mobilized laparoscopically and pelvic procedure performed by using the robotic system. The other method is a totally robotic procedure. In the literature, there are a number of nonrandomized comparative studies to evaluate the benefit of robotic TME against laparoscopic TME. Prospective randomized trial, however, is very limited. Bianchi performed a comparative study in which 25 patients received robotic TME and 25 patients laparoscopic TME. Patient assignment to one or another group was based solely on availability of robotic platform. No difference was observed between the two groups in any of the perioperative or postoperative parameters including operating time, conversion to open surgery, time of first bowel movement, hospital stay, intraoperative and postoperative complications, number of lymph nodes retrieved, circumferential resection margin involvement, and length of distal resection margin [102]. Very similar findings were obtained in Baek's case-matched study [103]. In Kwak's and Park's studies, however, operating time of robotic TME was found to be significantly longer [104, 105]. Nonetheless, potential benefit of robotic surgery was observed in D'Annibale's study in which the conversion and circumferential resection margin positivity rate were lower in the robotic than laparoscopic arm [106]. In a randomized trial comparing robotic versus laparoscopic low anterior resection, Baik also showed that robotic rectal surgery was associated with a lower conversion rate. In addition, a more complete mesorectum specimen and less complication were found in the robotic group [107]. The three-dimensional magnified view of the pelvis and enhanced dexterity provided by robotic surgery may further facilitate pelvic autonomic nerve identification and preservation. Kim reported that robotic TME was associated with earlier recovery of voiding and sexual function compared to laparoscopic TME [108]. Better recovery of erectile function after robotic TME was also reported by D'Annibale [106]. The consensus from these studies showed that compared to laparoscopic TME, robotic TME may take longer but potentially can achieve a lower conversion rate, more complete mesorectal excision, and better preservation of urogenital function. At present, no details on long-term oncological outcome of robotic TME is available.

Conclusions

The advantages of minimally invasive surgery are well demonstrated in laparoscopic TME. Using laparoscopic approach, even a complicated procedure like TME can be benefited by reduced blood loss, better recovery, and shorter hospital stay. Besides, genitourinary functions can potentially be more preserved. There is no difference between laparoscopic and open TME in terms of morbidity and mortality. Although laparoscopic TME is associated with longer operating time and conversion to open surgery cannot be completely avoided, improvement is expected when the procedure becomes widely adopted. Most importantly, the concern and controversies about oncological outcome of laparoscopic TME should have diminished after recent publications on long-term survival associated with this operation. The long-term results of the COLOR II and COREAN trial are still eagerly awaited. Yet, it appears quite likely that similar oncological outcome between laparoscopic and open TME will be reported from both studies. Robotic TME may be a step forward, but more randomized trials are required to define its role in rectal cancer.

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11 Transanal Endoscopic Microsurgery (TEM)

William Chia Shing Meng

11.1 Introduction

Surgery of the rectum is difficult, as it is located within the confines of the narrow bony pelvis. This precludes good lighting and good exposure. With the proximity of nerve plexuses and venous plexuses to the pelvic organs, it is very demanding to attain good oncological surgery with optimal functional outcomes. Transanal endoscopic microsurgery (TEM) is a form of minimally invasive surgery developed by Buess et al. in 1984 as a means of local resection of early rectal tumor (T0, Tis, and low risk T1). It is a technically demanding local resection, operating through the anus, and avoiding any skin incision. It may not be an overstatement to say that TEM is actually the “Minimally Invasive Surgery of Minimally Invasive Surgery” in rectal operation.

Total mesorectal excision (TME) [1] is the current gold standard of rectal resection. Even with the development of minimally invasive surgery (MIS) approach, laparoscopic TME [2] is still an ultra-major surgery with the requirement of temporary covering ileostomy. With the understanding of the adenoma–carcinoma sequence [3], we can appreciate that rectal tumor is actually a spectrum of disease. Hence, it is quite logical that total mesorectal excision (TME) may not be the best answer to all rectal tumors. We should have different MIS for different stages.

TEM is also a platform for exciting developments for various advanced MIS surgery. Local excision with TEM with neoadjuvant therapy of chemoradiation may be the way forward for rectal conservative therapy (RCT). TEM itself is single-port access (SPA) surgery and the rectoscope of TEM can serve as a port to retrieve the specimen, i.e. natural orifice specimen retrieval (NOSE) as well. Transanal total mesorectal excision (TaTME) is another hot topic whereby synchronous laparoscopic and transanal TME serves to complement each other to fulfill the stringent requirement proper TME. With further development in robotic surgery, this may be another pathway for natural orifice transluminal endoscopic surgery (NOTES) in the future.

With advancement in technology and concepts, it will be ideal if we can apply the same techniques and technology on rectal tumor, which is actually a spectrum of disease ranging from early to late stage. Hence, following our oncological principles stringently, we should modify our treatment accordingly so that patients can enjoy the benefits of minimally invasive surgery (MIS).

W.C.S. Meng, MBChB(CUHK), FRCSEd, FHKAM, FACS, MD
Department of Surgery, Matilda International Hospital, Hong Kong, China
e-mail: wmeng@netvigator.com

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11.1.1 Adenoma-Carcinoma Sequence

Colorectal cancer is believed to occur through two main pathways [4], and the first and the most common is the adenoma-carcinoma sequence. The transformation from polyp to cancer is originated due to the accumulation of numerous genetic abnormalities (Fig. 11.1), e.g., p53, K-ras, and deleted in colorectal carcinoma (DCC) and chromosomal instability, e.g., loss of heterozygosity (LOH) [5]. Two-thirds of colorectal cancers are believed to evolve as a consequence of this pathway.

The second pathway involves mutation in mismatch repair (MMR) genes seen in hereditary non-polyposis colorectal cancer (HNPCC) [6]. It involves the silencing of mismatch repair genes through a process of methylation without mutation. Loss of mismatch repair as a consequence of mutation accounts for up to 5% of hereditary cancers and methylation of mismatch repair genes account for 10–15% of sporadic cancers [7]. This pathway has been termed the microsatellite instability (MSI) pathway.

From the study of age distribution curves, it is shown that polyps are recognized about 4 years before cancer [8]. This may be an underestimate because the diagnosis of benign tumor at early stage is more inaccurate than for cancer. Furthermore, the malignant potential of adenomas of the colon and rectum varies with size, histological type, and grade of epithelial atypia. It was known that most colorectal cancer progressed through the adenoma-carcinoma sequence, although the majority of adenomas do not become cancerous during a normal adult life span. Unfortunately, there are no reliable criteria to predict the progression or recurrence. Nevertheless, it is known that after removal of the precursor polyps, one-third of the patients will have further adenoma [9]. Hence, we have the policy of endoscopic surveillance after all polypectomies [10].

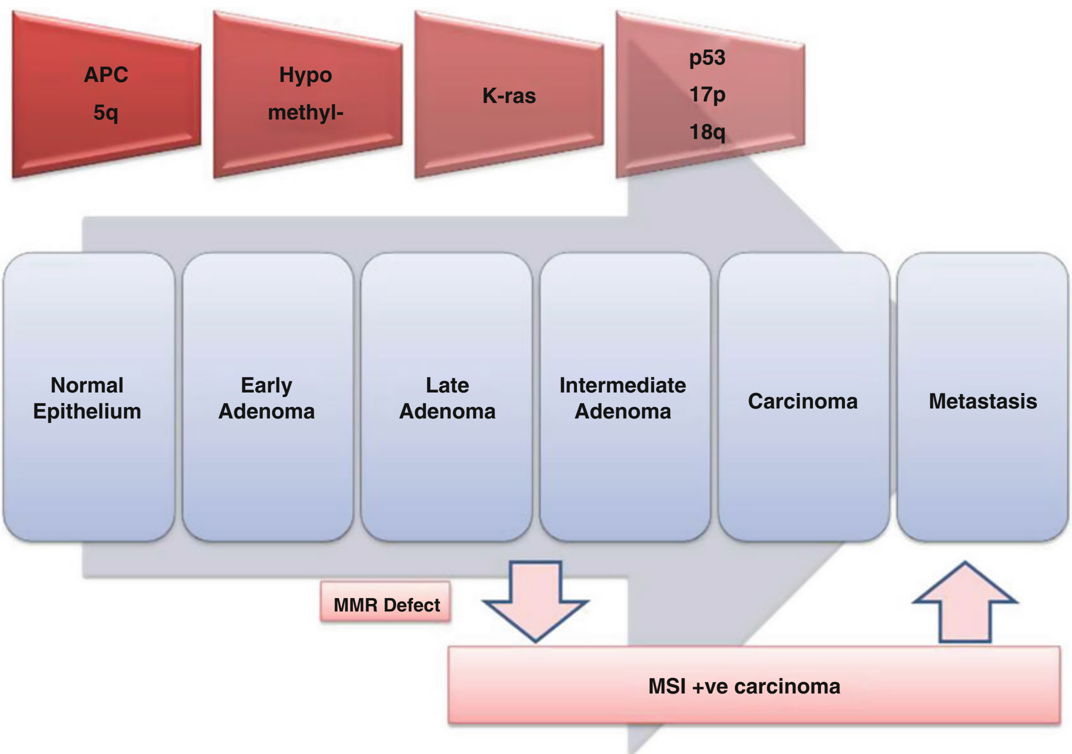

Fig. 11.1 Adenoma-carcinoma sequence and microsatellite instability (*MSI* microsatellite instability, *MMR* mutation mismatch repair)

11.1.2 TNM Staging

The TNM staging system [11] was developed and is maintained by the American Joint Committee on Cancer (AJCC) and the Union for International Cancer Control (UICC). The TNM staging system is based on the extent of the tumor (T), the extent of spread to the lymph nodes (N), and the presence of metastasis (M). For T staging of rectal tumors, it ranges from rectal tubular or villous adenoma (T0), carcinoma in situ (Tis), early rectal tumor that is limited to submucosa (T1), to late-stage carcinoma (T2–T4).

cTNM is the clinical classification and pTNM is the pathologic classification. The y prefix is used for those cancers that are classified after neoadjuvant pretreatment (e.g., ypTNM). The r prefix is to be used for those cancers that have recurred after a disease-free interval (rTNM). Furthermore, according to the investigations, we have the u prefix for transrectal ultrasonography, ct prefix for CT scan, and mr prefix for MRI staging.

11.1.3 Staging of Malignant Colorectal Polyp

For early tumor and malignant polyps, we will use the Kikuchi classification [12], which aimed at describing the depth of invasion into the submucosa. It divides the submucosa (Sm) into thirds and then the horizontal spread of tumor has also been described separately within the upper most third layer (Sm1: invasion to a depth of 200–300 μm). Sm1a is less than a quarter of the width of the tumor invading the submucosa; Sm1b is a quarter to half the width of the tumor invading the submucosa; Sm1c is more than half the width of the tumor invading the submucosa; Sm2 is intermediate between Sm1 and Sm3; and Sm3 is carcinoma invasion near to the muscularis propria.

11.2 Method and Indications

Transanal endoscopic microsurgery (TEM) was first developed by Professor Gerhard Buess for the local resection of rectal tumor [13]. It was popularized and the technique was promulgated around the world and TEM was first introduced into Hong Kong in 1995 [14].

We were very stringent in our case selection. Indications for curative resection are rectal villous adenoma (T0) or early rectal tumor including Tis and low-risk T1 (i.e., well-differentiated carcinoma with no lymphovascular permeation). Palliative resection is only offered to elderly patient with multiple comorbidities with mobile tumor on digital examination.

For rectal villous adenoma with transrectal ultrasonography showing no sign of invasion (uT0), we will proceed with submucosal dissection. We aim at 1 cm circumferential margin at the least. For early tumor with biopsy showing malignancy, we will aim for full-thickness excision with at least 1 cm resection margin. The specimen is then pinned on corkboard for detailed pathological examination.

11.2.1 Preoperative Management

Complete history with emphasis on fecal and urinary continence should be recorded and thorough physical examination should be done. Fecal continence to solid, liquid, and flatus should be assessed and in case of incontinence, whether it is occasional or frequent episodes, should be asked (Williams' Score). For urinary continence, we should screen for stress incontinence, urge incontinence or a mixed type.

Digital rectal examination and rigid sigmoidoscopy are mandatory as the position, site, and size of the tumor would determine the patient position on the operation table. With the tumor situated at 6 o'clock, 12 o'clock, 3 o'clock, and 9 o'clock, the patient operative position should be lithotomy, prone, left lateral, and right lateral accordingly.

We advocate the detailed documentation of the tumor: (1) distance from the dentate line (e.g., 6–8 cm); (2) position (e.g., from 6 to 10 o'clock position); and (3) percentage of the circumference involved (e.g., 30% of circumference). The relative position to the middle Valve of Houston should be noted as this may signify the approximate position of peritoneal reflection. All these are of significance in planning and position of the operation.

Apart from transrectal ultrasonography, chromoendoscopy, magnifying colonoscopy, and narrow band imaging (NBI) in colonoscopy will be helpful in determining the local staging. Many a times, eye-balling the morphology of the polyp may be a more practical approach if sophisticated investigations are not available. However, in case of malignancy, magnetic resonance imaging (MRI) of the rectum as a base line is indicated. Preoperative colonoscopy is also essential to screen and to deal with synchronous polyps or tumors.

Full bowel preparation with polyethylene glycol was preferred and prophylactic antibiotics (Cefuroxime 1.5 gm IV and Metronidazole 500 mg IV) should be given. TEM would be performed under general anesthesia.

11.2.2 Operation Setup and Instruments

Due to the sole access through the anus and the limited space for surgical manipulations, specific instruments are being designed (Fig. 11.2). TEM machine was manufactured by Richard Wolf (Knittlingen, Germany). It consists of a rectoscope of 4 cm in diameter (12 cm or 20 cm in length) with the edge being either oblique or flat. Rectoscope of different length can be applied for tumors at different distance away from the anal verge. The optimal location of the tumor is from 5 cm to about 20 cm from the anal verge.

There are three working channels sealed with special rubber sleeves with caps. The working channels can accommodate custom-made angulated instruments including a diathermy needle, dissecting forceps, needle holder, and suction cannula.

In addition, there is another optical channel for stereoscope, which enables three-dimensional stereoscopic imaging for direct visualization with 13.8 mm OD, 50° angle of view, 75° field of view. This is installed with adjustable stereo eyepiece and anti-droplet rinsing feature. The image is also shared to an integrated documentation optics for monitor viewing or recording. In the second generation of TEM, this documentation optics has changed to pointing upward. This allows for less obstruction for the manipulation of instruments. Furthermore, high-density (HD) monitors and signals are used.

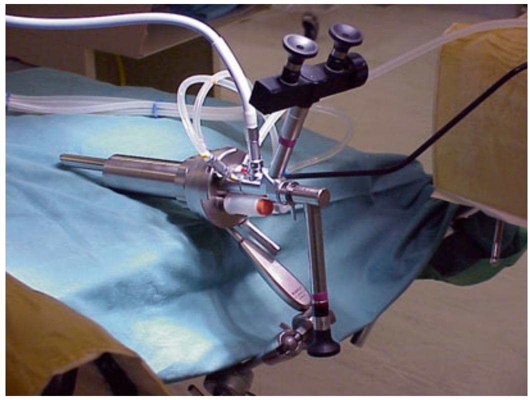

Fig. 11.2 TEM

The selected rectoscope is mounted to the operating table via the U-shaped support arm consisting of three joints and a single screw, which is called the Martin arm. The position of the rectoscope is secured by turning a single screw knob and it relies on mechanical fixation. Recently, a new locking mechanism is introduced and the whole system can be locked securely by the press of a button rather than the slow turning of the screw.

The combined endosurgical unit of TEM provides the automated carbon dioxide insufflation with real-time barometric feedback. This is particularly important in difficult cases when optimal view and exposure depends crucially on insufflation of the rectal lumen. The surgical instruments (Fig. 11.3) include the specially designed diathermy needle, and needle for injection. Custom-made angulated forceps, needle holders, and suction probes are designed such that they can reach out to the different region as shown in the field of view of the rectoscope. There are clip applicators for the silver clips, which anchors onto the suture and also the scissors for cutting sutures.

Simplified version of the equipment namely Transanal Endoscopic Operation (TEO) device (Karl Storz, Tuttlingen, Germany) are also available, and recently, several disposable transanal ports have been introduced in the market.

Fig 11.3 Specially designed surgical instruments for TEM

11.2.3 Operative Procedure

11.2.3.1 Patient Positioning

The position of the patient on the operating table is such that the rectal lesion is at the lower half of the operating field of view (Fig. 11.4). An anterior lesion requires prone position; left rectal wall lesion requires the left lateral position and vice versa; and a posterior lesion requires lithotomy position.

11.2.3.2 Technique of TEM

First, we will mark the resection margin with the diathermy needle before the dissection. We can operate in usual laparoscopic positions but when we want precise and fine dissection, we will use the stereoscope, which provides excellent 3D images (Fig. 11.6). Manipulation of the instruments is different from the usual skill sets of laparoscopic surgery with particular emphasis on elbow movement. Hence, surgeons should have specific training.

Fig 11.4 TEM operative setup

11.2.3.3 Submucosal Excision

For rectal villous adenoma, we will perform submucosal dissection using the diathermy needle. The mucosa is elevated by injecting modified gelatin (colloid) mixed with methylene blue into the submucosal plane. We tried adding adrenaline in but apart from vasoconstriction, the hemostatic effect was not significantly impressive. We have also tried saline but the absorption was too quick and repeated injections were needed. Mixing with methylene blue will highlight the submucosal plane and the inner muscular layer to facilitate sharp dissection with diathermy needle.

In situations whereby the mucosa cannot be elevated despite correct injection to the submucosal plane, we have to be aware such a "non-lifting" sign may indicate malignant infiltration and we should convert to full-thickness excision.

11.2.3.4 Full-Thickness Excision

For lesions with possibility of carcinoma or biopsy revealing malignancy, we should go for full-thickness excision with ultrasonic dissector. Reusable ones are more cost-effective. We have tried using electrocautery but the smoke generated within the confined rectal lumen would obscure the view and would not settle quickly. Technically, we found that there is less smoke in using the 5-mm curved-tip Harmonic Ace (Ethicon Endo-surgery, Johnson & Johnson) [15] as compared to the high-frequency needle knife. Furthermore, the hemostasis of ultrasonic dissector is perfect, in contrast to the use of electrocautery where time and again, we have occasional spurting of blood onto the optics.

11.2.3.5 Intracorporeal Suturing

After both types of dissection, the specimen will be retrieved via the rectoscope and we will always irrigate with cytocidal solutions to prevent tumor cell implantation. The defect can then be closed with a single-layer continuous monofilament suture with silver clips anchoring at either ends. This avoids the difficult intracorporeal and intraluminal knot tying; we do it in a transverse manner to avoid stricture. Some will skip this step of suturing the defect, in particular for submucosal dissection. However, in case of full-thickness excision, we recommend to suture to prevent rectal stenosis.

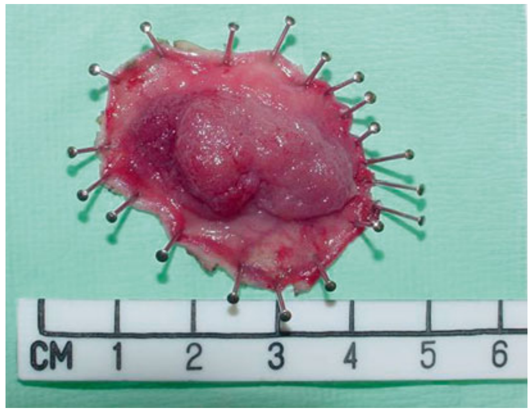

Fig 11.5 Mounted specimen of TEM

11.2.3.6 Mounting of Specimen

The specimen is orientated during the retrieval. It should then be mounted on a Foam board (Fig. 11.5) and sent to the pathologist. By and large, this is a technically demanding local excision inside the rectum. It avoids skin incision and does not have a stoma. Furthermore, it provides a nice specimen en bloc, enabling precise staging by pathologist.

11.2.3.7 Postoperative Management and Complications

After full-thickness excision, the patients may have a typical two-day fever, which will subside spontaneously. We suspected that this was a reflection of the inflammatory response in healing. Nevertheless, we will always cover with perioperative antibiotics. Severe necrotizing fasciitis has been reported in the literature [16].

For complications, there were also reports of postoperative bleeding. Since the application of ultrasonic energy, hemostasis is usually not a problem. Two patients in our local series complained of temporary flatus incontinence. Subsequent endoanal ultrasonography revealed no structural sphincter damage. Both of the patients were fully continent within a week. Anorectal physiology studies showed reduced volume but no significant changes in pressure [17].

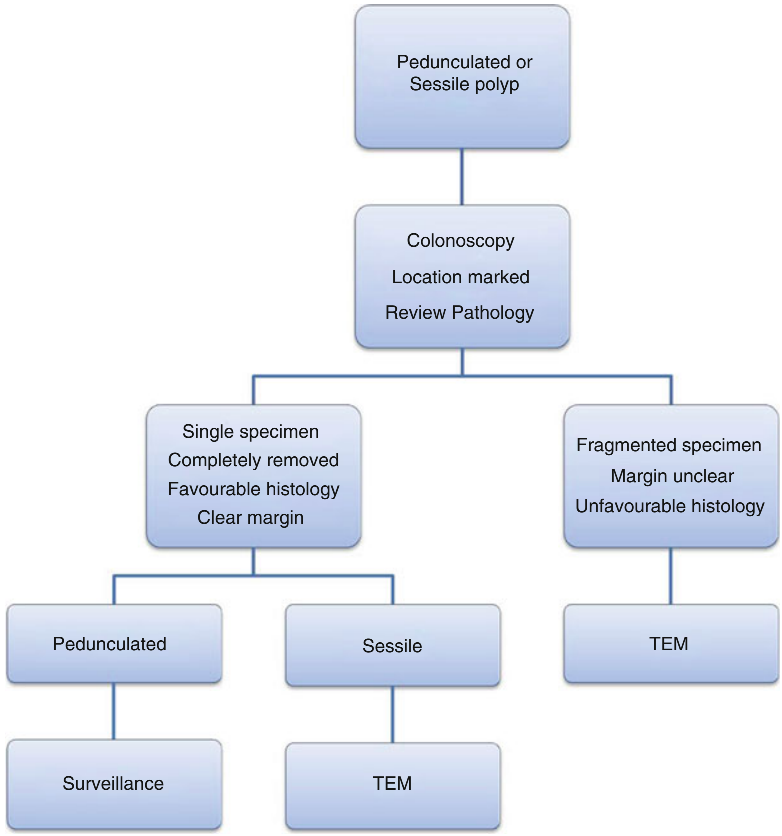

Fig 11.6 Management flowchart of early rectal polyp

11.2.4 Practical Algorithms

11.2.4.1 Case Selection

TEM provided a means of complete excision of early rectal tumor. This is a method of low morbidity and mortality and avoids the creation of stoma [18]. The National Comprehensive Cancer Network (NCCN) [19] provides guidelines for management of the rectal polyps and cancer.

According to the surgical principles of the NCCN guidelines, transanal excision is recommended in the condition as indicated (Fig. 11.6). When the lesion is adequately identified in the rectum, TEM may be used.

11.2.4.2 Giant Rectal Villous Adenoma Extending to Dentate Line

For villous adenoma located within 4–5 cm from the anal verge, we would agree that Park's peranal excision is a recognized approach (Fig. 11.7). However, when we are faced with carpet-like rectal villous adenoma with extensive involvement or tumor high up in the mid or upper rectum, we may have difficulty. Lack of good exposure may lead to lack of precision of resection, piecemeal removal, and hence high recurrence rate.

In these cases, we propose a hybrid approach where we will start off with the distal resection via Park's peranal approach and submucosal dissection with mucosal elevation by submucosal injection. Headlight seems to be helpful in this part of the operation (Fig. 11.8). We shall proceed cranially as far as possible, usually 2–3 cm above the dentate line.

Then we will start off with the proximal submucosal dissection by TEM. Methylene blue was mixed with modified gelatin (colloid) for elevation of the mucosa. We can then link up the dissection and attain a complete specimen en bloc.

11.2.4.3 Pathological Surprise of uT1 pT2

Lymph node involvement was quoted as 5% in pT1, over 10% in pT2, and up to 20% in pT3 tumor [20]. In our series, we had two pT2 and one pT3 patient and all three patients were understaged by preoperative transrectal ultrasonography. They were all cases early in our series and we attribute to the learning curve of ultrasonography. We offered laparoscopic TME with covering ileostomy for all three patients within one week of TEM as salvage surgery. All three final reports came back as negative for over 12 harvested lymph nodes (pN0) (Fig. 11.9).

11.2.4.4 Down-Staging After Neoadjuvant Therapy: ypT1

As a routine, for preoperative mrT3 tumor, we will offer neoadjuvant therapy after assessment by oncologist. Time and again, repeat MRI revealed down-staged lesions and we are possible to proceed with sphincter-sparing surgery. According to our present protocol of treatment of rectal cancer, we still offer laparoscopic TME. Time and again, final pathology came back as ypT1. On reflection, should we have performed TEM or other minimally invasive radical surgery in these cases [21]? Are we "overkilling"? These are questions to be answered by on-going trials in Netherlands and France.

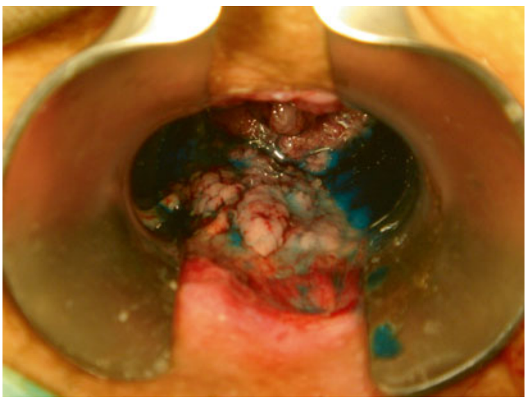

Fig 11.7 Giant villous adenoma extending to dentate line

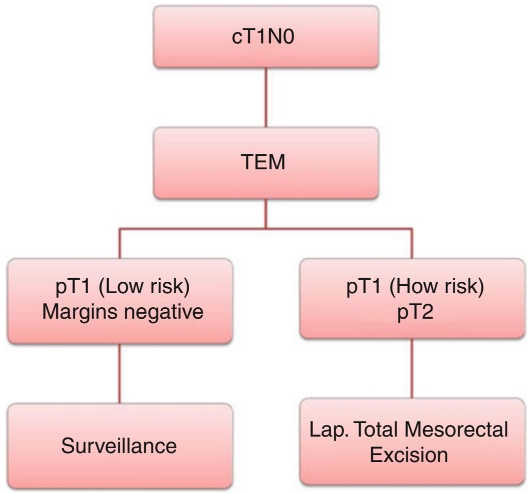

Fig 11.9 Algorithm for uT1pT2

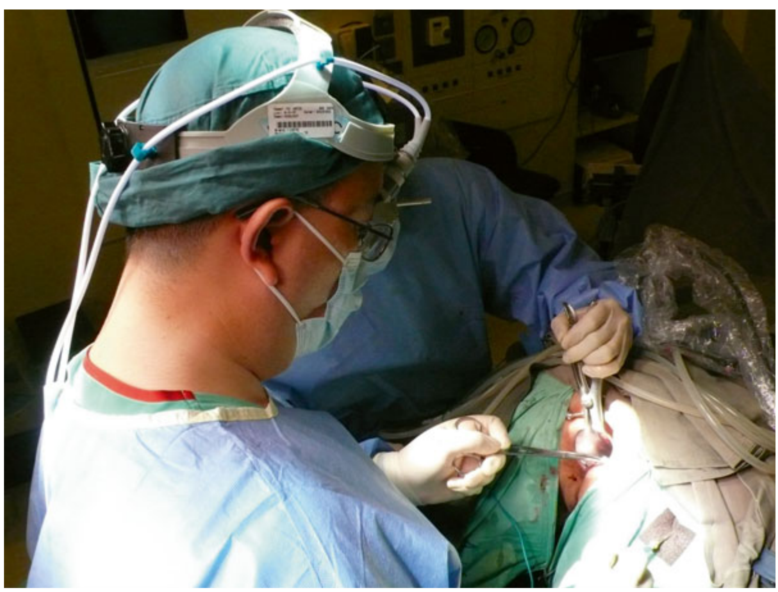

Fig 11.8 Park's peranal approach

11.2.4.5 Perforation into Peritoneum

For starters of TEM, it is always a nightmare to enter into the peritoneum. We have two such cases early in our series. They are all villous adenoma by final pathology.

To tackle with such situation, firstly, we will insert the TEM suction device into the peritoneum to reduce the pneumoperitoneum. Then we will close off the peritoneum by continuous suture. Despite these tense situations, we must stay calm and perform the suture step by step. In fact, by going slowly, the carbon dioxide pumped into the peritoneum will be absorbed. The pneumo-rectum will be reestablished slowly and the defect can be closed by routine TEM suturing.

Nevertheless, prevention is better than cure and it would be nice to plan ahead. If the tumor is located at more proximal position, and pathology reviewed sessile polyp only, we may proceed with submucosal excision. In case of tissue biopsy confirming malignancy, we may elect transabdominal approach of laparoscopic anterior resection.

11.3 Future Direction of Development

11.3.1 Single-Port Access (SPA) Surgery with TEM

As a start, disposable ports were used for single-port access (SPA) surgery and traditional laparoscopic instruments were utilized with great difficulty. Nevertheless, appendectomy, cholecystectomy, and colectomy were attempted. Operation time was long and the technique was demanding. TEM with articulated instruments with its specific dissection technique was actually ideal for single-port access. The articulated tip of the instrument provided triangulation, which facilitated the vision of the dissection field.

A feasibility study on cholecystectomy was firstly assessed in porcine model. It was followed by successful application in human. Problem to overcome was the extra length from the umbilicus to the gallbladder fossa. This resulted in the imbalance of the pivot point and hence the overshooting of dissecting movements.

It was concluded that, single-port access (SPA) cholecystectomy is feasible with transanal endoscopic microsurgery (TEM) instruments [22]. The special TEM technique of manipulation within a confined space is beneficial for single-port surgery. The TEM port is more cost-effective as it is reusable. Furthermore, the extended indication in cholecystectomy would improve the value for money of the TEM instruments, which was limited to early rectal tumors beforehand.

11.3.2 Rectal Conservative Therapy (RCT)

TEM allows surgeons to excise more proximally located rectal lesions that cannot be excised by traditional peranal methods of excision. Lezoche reported on preoperative chemoradiotherapy and TEM for selected patients who have T2N0 rectal cancer [23]. It is possible to achieve the same long-term oncologic results observed after laparoscopic resection with total mesorectal excision, which is our current gold standard, in terms of local recurrence and survival. Furthermore, for mobile T2 or T3 carcinoma, TEM would be a good palliation.

Bökkerink reported on a multicenter trial [24] investigating the role of a rectum saving treatment modality using chemoradiation therapy and local excision by TEM for rectal cancer. We regard this as analogous to breast conservative therapy (BCT) of carcinoma of breast and hence coined rectal conservative therapy (RCT).

According to the study, patients over 18 years of age and with cT1-T3 tumor on imaging are recruited. All patients will receive neoadjuvant chemoradiation (CRT), consisting of radiotherapy with a total dose of 50 Gy, which is given in 25 fractions during 5 weeks. Patients will receive 825 mg/m^2 capecitabine b.i.d. 7 days per week during the whole treatment period. At 8–10 weeks after the end of the neoadjuvant treatment, patients with a ycT0-2 tumor after CRT will undergo TEM. The other patients will undergo total mesorectal excision (TME) surgery. After histological examination of the resected specimen, all patients with an ypT2-3 tumor, positive resection margins, or lymphangio-invasive growth, will undergo radical surgery within 4–6 weeks after the TEM procedure. This is the so-called The CARTS study: Chemoradiation therapy for rectal cancer in the distal rectum followed by organ-sparing transanal endoscopic microsurgery. We are looking forward to the long-term results.

11.3.3 Transanal Total Mesorectal Excision (taTME) with TEM

Low anterior resection (Lap LAR) and total mesorectal excision (TME) [25] is the gold standard of minimally invasive surgery (MIS) for mid and low rectal tumors. However, the pelvic resection in particular for bulky tumor in the narrow male pelvis has always been a challenge for surgeons.

Due to the curvature of the pelvis, in particular at the prostate level or at the Pouch of Douglas, we are working at a difficult angle-up position. Transanal TME [26], as a bottom-up approach, provided a straight end-on view for the distal part of TME, which made the pelvic dissection much easier.

Synchronous laparoscopic LAR and transanal total mesorectal excision (taTME) by and TEM [27] is a newly developed method. The abdominal as well as the perineal surgeon could often guide each other in the dissection at the "Holy plane" in a "rendezvous" manner, i.e. to meet each other in the middle. It saved quite significant operation time and ensured dissection along correct planes.

This coloanal anastomosis (CAA) was made feasible by KOL (Touchstone, Suzhou, Jiangsu, China) stapling gun. The mechanism was like that in stapled hemorrhoidopexy whereby the purse-string and additional anchorage suture can be pulled from within the ring of staples.

In conclusion, transanal total mesorectal excision (taTME) by synchronous laparoscopic LAR and TEM is feasible. We are combining operative techniques that are well-established, currently available and cost-effective. Most important of all, it complied with the oncological principles and made the most difficult part of TME much easier.

11.3.4 Natural Orifice Specimen Extraction (NOSE) Using TEM

Amongst all the natural orifices, e.g. oral, vaginal, urethral, the anal opening is the least controversial option. Retrieval of specimen through the vagina [28] was also reported but there is the problem of postoperative pain and dysparuenia.

With the protection of the TEM rectoscope of the rectal stump, direct contact of the tumor to the rest of the bowel is avoided. Natural orifice specimen extraction (NOSE) preferably done via the rectal stump [29] is more acceptable by colorectal surgeons. This will help in decreasing the number and size of the ports of laparoscopic proctectomy.

11.3.5 Natural Orifice Transluminal Endoscopic Surgery (NOTES)

Last but not the least, the dimensions of the TEM can potentially be extended from bottom up to encompass all facets of surgical treatment of rectal cancer. In the future, with the development of single-port robotic surgery, TEM may possibly be the platform to enable natural orifice transluminal endoscopic surgery (NOTES).

Conclusions

Transanal endoscopic microsurgery is the "Minimally Invasive Surgery of Minimally Invasive Surgery in rectal operation". Developed by Professor Gerhard Buess, it is a means of local resection of early rectal tumor. As a technically demanding operation through the natural orifice, it has its own skill sets different from that of laparoscopic surgery. It is also the platform of development for single-port access surgery, natural orifice specimen retrieval and natural orifice translumenal endoscopic surgery and has recently applied as an adjunct for total mesorectal excision. Future developments of organ-sparing surgery and robotic surgery on this basis are well under way. In this chapter, we have concluded our experience on the indications of various applications and tips and tricks to share with fellow surgeons.

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12 Robotic Rectal Surgery

Simon Siu-Man Ng

12.1 Introduction

Laparoscopic colectomy for colon cancer has been shown by several large-scale multicenter randomized controlled trials and meta-analyses to have faster postoperative recovery and similar long-term oncologic outcomes compared with open surgery [1–4]. The role of laparoscopic surgery for rectal cancer, on the other hand, is still under intensive investigation [5]. Laparoscopic surgery for mid or low rectal cancer is technically more challenging than that for colon cancer; these technical challenges include difficulties in pelvic exposure, precise rectal dissection with total mesorectal excision (TME) in the narrow pelvis, and preservation of anal sphincter and pelvic autonomic nerves [6, 7]. Consequently, recent studies comparing laparoscopic and open surgery for rectal cancer have reported high rates of conversion, circumferential resection margin positivity, and operative morbidity in patients undergoing laparoscopic surgery [3].

S.S.-M. Ng, MBChB, MD, FRCSEd, FACS, FASCRS
Division of Colorectal Surgery, Department of Surgery, The Chinese University of Hong Kong, Prince of Wales Hospital, Room 64045, 4/F, Lui Che Woo Clinical Sciences Building, Shatin, New Territories, Hong Kong SAR, China
e-mail: simonng@surgery.cuhk.edu.hk

One of the most significant technical advances in the field of minimally invasive colorectal surgery in recent years is the introduction of the *da Vinci* Surgical System (Intuitive Surgical, Inc., Sunnyvale, CA, USA). This robotic system comprises three main components: the console, the robotic cart with four robotic arms, and the endoscopic stack. The operating surgeon sits comfortably at the console, with his or her hands placed on master handles. His or her movements are then translated via computer software to the robotic arms at the site of the operation. The system provides a stable camera platform with magnified 3D view, and intuitively transfers movements from the handle to the tip of the instrument with tremor filtering. Dexterity is enhanced via EndoWrist technology, returning 7° of freedom to the surgeon [8]. The robotic surgical system can essentially overcome the technical disadvantages of conventional laparoscopic surgery for rectal cancer in terms of visualization and maneuverability, which may enable surgeons to perform precise rectal dissection easily even within the narrow pelvis, with better preservation of the pelvic autonomic nerves [9]. In a recent systematic review, robotic surgery for rectal cancer is found to have lower conversion rate, less blood loss, and higher rate of complete mesorectum compared with the laparoscopic counterpart [10].

Typically, a low anterior resection for rectal cancer entails dissection in multiple abdominal quadrants; the operative steps include mobilization

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of the left-sided colon and the splenic flexure, ligation of the inferior mesenteric vessels, TME down to the pelvic floor, and construction of the anastomosis. Despite improvements made since its introduction, the current version of the *da Vinci* Surgical System is still not appropriate for multi-quadrant surgery because of the limited range of motion of the robotic arms and the difficulty in moving the bulky robotic cart during surgery [11]. Furthermore, once the robotic cart is docked with the arms engaged to the instruments, repositioning of the operating table to facilitate exposure and colonic mobilization is not feasible. In order to overcome these limitations, special operative approaches have been developed for robotic rectal surgery, which include the hybrid approach and the totally robotic approach.

The purpose of this article is to briefly discuss the technical steps and the pros and cons of various operative approaches for robotic TME. Our technique of totally robotic single docking TME will also be described.

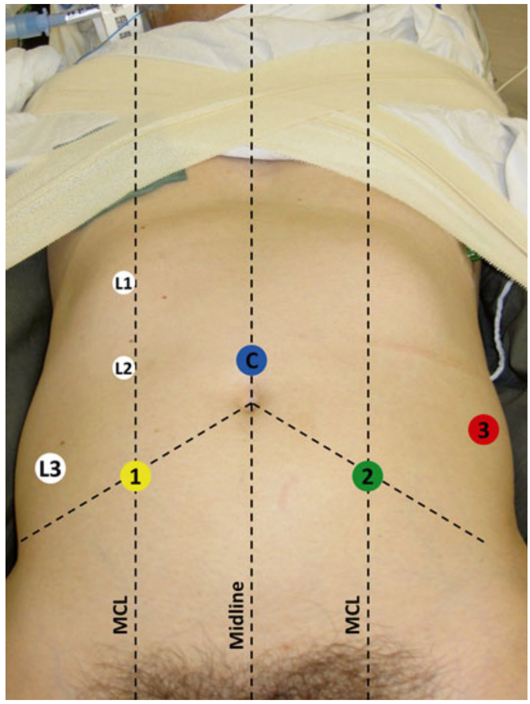

Fig. 12.1 Port placement for the hybrid approach (Professor Alessio Pigazzi [13]). *MCL* midclavicular line, *C* camera port, *1* robotic port for arm 1, *2* robotic port for arm 2, *3* robotic port for arm 3, *L1* 12-mm laparoscopic port, *L2-3* 5-mm laparoscopic ports

12.2 Hybrid Approach

12.2.1 Conventional Hybrid Approach

The hybrid approach combines laparoscopic left-sided colonic mobilization and vascular control with robotic technique for rectal dissection. This technique was first described by Pigazzi et al. in 2006 [12]. Although the location of robotic trocars and working ports for the hybrid approach varies with surgeon's/center's preference (Figs. 12.1 and 12.2) [13, 14], the operative steps are essentially similar. The approach is divided into three phases: (1) the abdominal phase, (2) the pelvic phase, and (3) the creation of anastomosis. In the abdominal phase, medial-to-lateral dissection with high ligation of the inferior mesenteric vessels is carried out laparoscopically, followed by laparoscopic mobilization of the left-sided colon and splenic flexure. Thereafter, the robotic system is docked between the legs, and TME is performed using robotic assistance. Adequate retraction is facilitated by the third robotic arm. When the robotic or pelvic phase is completed, the robot is undocked, the specimen is extracted through a 4-cm minilaparotomy wound (created by extension of one of the port wounds) or a Pfannenstiel incision, and a standard end-to-end anastomosis is created using a circular stapler under laparoscopic visualization. In cases of very low tumors, an intersphincteric resection (ISR) with transanal specimen extraction and hand-sewn coloanal anastomosis can be performed (Fig. 12.3). Choi et al. described a novel technique of complete intracorporeal rectal resection and anastomosis using the robotic system, with transanal and transvaginal retrieval of specimens [15]. This technique is indicated for selected cases with small tumors, and side docking of the robotic cart is preferred. Briefly, on completion of robotic TME, the distal rectum is ligated with a suture and divided. The specimen is retrieved either through the anus or vagina (through a colpotomy, which is later closed by robotic intracorporeal suturing) with the

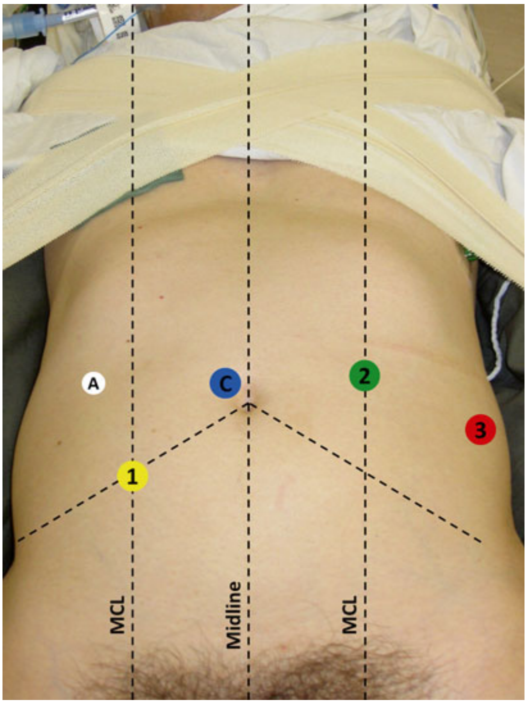

Fig. 12.2 Port placement for the hybrid approach (Professor Gyu-Seog Choi [14]). *MCL* midclavicular line, *C* camera port, *1* robotic port for arm 1, *2* robotic port for arm 2, *3* robotic port for arm 3, *A* 5-mm assistant port

protection of a plastic bag. Thereafter, purse-string sutures are applied to the colonic side and the rectal stump using the robotic system. An anvil is then transferred through the rectal (or vaginal) opening to be placed at the end of the proximal colon, and the anastomosis is completed using a circular stapler introduced transanally. This natural orifice specimen extraction technique with intracorporeal suturing is greatly facilitated by the dexterity and precision of the EndoWrist instruments of the robotic system.

Advocates for the hybrid approach believe that the surgery can be accomplished faster because there is no need for any repositioning of the robotic cart to cover different abdominal quadrants, and the splenic flexure can be mobilized easily using the laparoscopic approach without the fixed-docking limitations of the robotic system. Furthermore, the patient can enjoy the benefits of the robotic system during the most crucial operative step of the surgery – rectal dissection with TME. The hybrid approach also serves as a good operative platform for surgeons who wish to transition from laparoscopic to robotic surgery. It is still debatable whether prior laparoscopic experience is essential before starting robotic surgery, and there are robotic surgeons who were actually novice in laparoscopy when they first started robotic surgery – the hybrid approach is obviously not a good option for these surgeons who lack laparoscopic experience [16].

12.2.2 Reverse Hybrid Approach

In the conventional hybrid approach, ligation of the inferior mesenteric vessels and colonic mobilization are first performed laparoscopically, followed by robotic rectal dissection. However, this approach does not take full advantage of the robotic system, especially during lymphovascular dissection. Meticulous dissection around the origin of the inferior mesenteric vessels is necessary to ensure adequate nodal clearance and preservation of the preaortic autonomic nerves. Park et al. described a reverse hybrid technique to maximize the combined benefits of the robotic and laparoscopic approaches for low anterior resection [17]. In this reverse hybrid approach, robotic lymphovascular dissection, sigmoid colon mobilization, and rectal TME are performed before laparoscopic descending colon and splenic flexure mobilization. The patients can therefore enjoy the full advantages conferred by the robotic system during lymhovascular and rectal dissection where the working volume is small and the precision requirements are high. Furthermore, similar to the conventional hybrid approach, the reverse hybrid approach allows splenic flexure mobilization to be performed laparoscopically without the fixed-docking limitations of the totally robotic technique. Full splenic flexure mobilization is routinely necessary in Caucasian patients for the creation of a tension-free anastomosis because they have relatively short sigmoid colon and the incidence of sigmoid diverticulitis is high. The reverse hybrid approach is indeed a good alternative to the totally robotic approach in tall Caucasian patients who often require a second docking of the robotic system to adequately

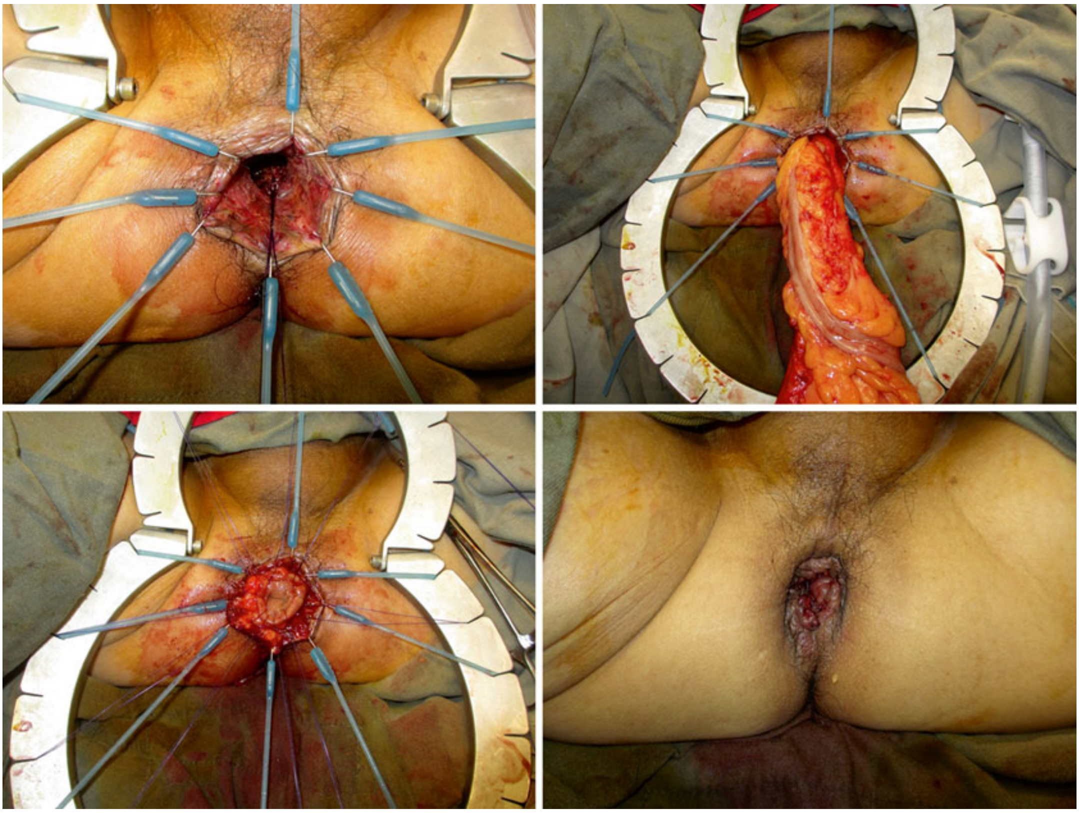

Fig. 12.3 Intersphincteric resection with transanal specimen extraction and hand-sewn coloanal anastomosis

mobilize their high splenic flexures and complete the distal rectal dissections.

12.3 Totally Robotic Approach

In the totally robotic approach, the entire procedure is performed using the robotic system. Proponents for the totally robotic approach argue that the patients can enjoy the maximal benefits of robotic surgery during different phases of dissection. Furthermore, the surgeons can spend more time at the robotic console per case, and hence their learning curve may be overcome faster. However, the totally robotic approach can be technically demanding. Splenic flexure mobilization still remains one of the major difficulties of this approach, but different techniques including redocking of the robotic system or repositioning of the robotic arms have been developed to overcome this limitation. In fact, the totally robotic approach can be classified into different types according to the number of movements or dockings/redockings of the robotic cart. Spinoglio et al. reported the “triple docking” technique in 2008 that involved docking/redocking of the robotic cart at three different positions during different phases (splenic flexure takedown, vascular control, and rectal dissection) of the low anterior resection [18]. This technique is not commonly practiced now because of its cumbersome nature. Most centers that practice totally robotic rectal surgery today use either the single docking or dual docking approach.

12.3.1 Totally Robotic Single Docking Approach

The first series of totally robotic single docking TME was reported by Hellan *et al*. in 2008 [19]. This technique literally involves single docking

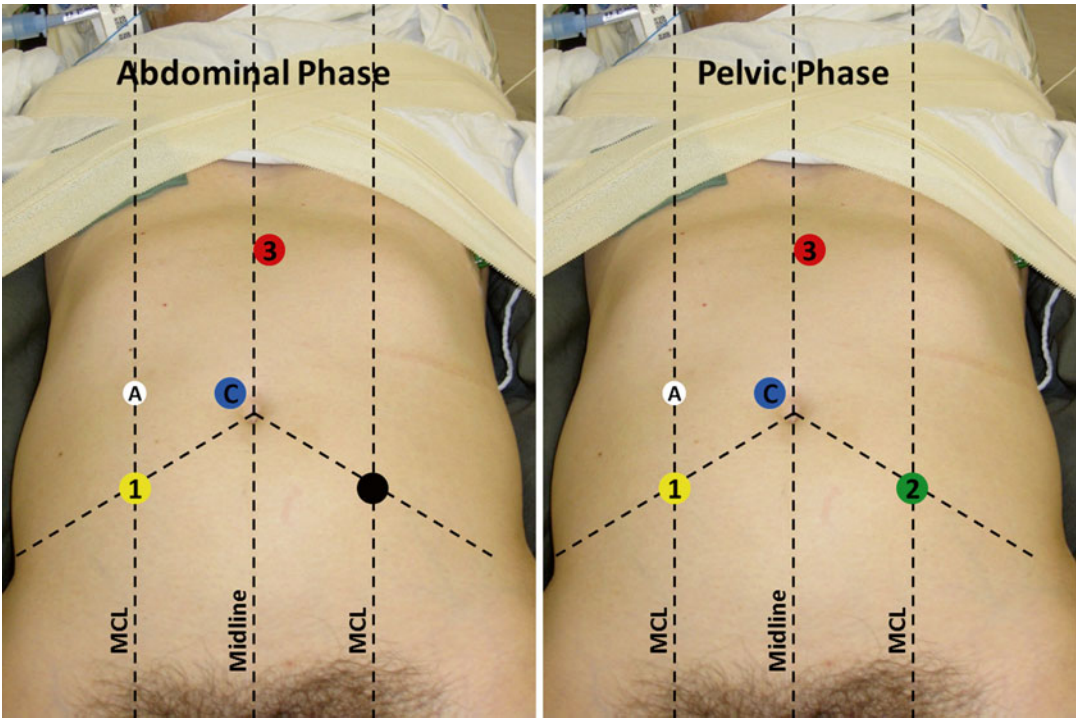

Fig. 12.4 Port placement for the totally robotic single docking approach reported by Hellan et al. [19]. *MCL* midclavicular line, *C* camera port, *1* robotic port for arm 1, *2* robotic port for arm 2, *3* robotic port for arm 3, *A* 5-mm assistant port

of the robotic cart over the left hip of the patient for the entire procedure from splenic flexure mobilization to pelvic TME without repositioning of the robotic arms to different trocar positions (Fig. 12.4). Vascular control and splenic flexure mobilization are performed using only two robotic arms, whereas pelvic TME is performed with the addition of a third robotic arm. The major advantage of this approach is convenience because there is no need for repositioning of the robotic cart or the patient during surgery. However, this technique cannot be recommended for obese patients for whom multiple repositioning of the operating table is needed to deal with the abundant intra-abdominal fat [19]. Furthermore, this technique does not maximally utilize the robotic system during splenic flexure mobilization as the third arm is unused. A modified version of this technique, known as the "flip" arm technique, was introduced by Obias et al. in 2011 [20]. This modified technique uses all three robotic arms for both the splenic flexure and the pelvis, but with only one docking position. The third arm (placed in the left lower quadrant trocar), which aims cephalad during splenic flexure mobilization and helps with retraction, is flipped to the other side of the robotic cart and aims caudally during pelvic phase dissection. This technique allows the surgeon to fully utilize all the robotic arms for retraction and dissection and therefore can maximize the benefits of the robotic system.

The Korean surgeons developed a totally robotic approach that involves only one single docking of the robotic cart but requires repositioning of the robotic arms to different trocar positions during different phases of the procedure. This is probably the most popular and widely practiced totally robotic single docking approach today. There are a few subtypes, among which the most well known are the one pioneered by the Yonsei University group [21] and the other one developed by Professor Seon-Hahn Kim of the Korea University [9, 22]. Apart from the trocar positions and the robotic arm arrangements, the two Korean techniques are very similar in terms of the position of the robotic cart and the operative steps. This approach is basically divided into the abdominal phase and the pelvic phase dissection. Briefly, the robotic cart is docked over the left hip of the patient at a 45° angle. In the abdominal phase, inferior mesenteric vessels ligation, left-sided colonic mobilization, and splenic flexure takedown are performed using the robotic system. On completion of the abdominal phase, the position of the robotic cart remains unchanged, but two of the robotic arms are detached and repositioned to different trocar positions to allow for pelvic phase dissection and TME. The anastomosis is created as described above (see "Conventional Hybrid Approach").

Park et al. reported the technical details and the outcomes of the Yonsei University technique in 2010 [21]. Their technique utilizes seven ports including one 12-mm camera port, five 8-mm robotic working ports, and one 5-mm port for the assistant (Fig. 12.5). Despite the fact that the robotic ports are widely scattered over different areas of the abdomen, external collision between the robotic arms during splenic flexure mobilization is still perceived as one of the technical difficulties of this approach. Interestingly, in their original series, only 1 out of 45 patients required a full splenic flexure mobilization. In fact, routine splenic mobilization is not necessary in Asian patients because they usually have redundant and healthy sigmoid colon. This renders the totally robotic approach a more attractive option in Asian countries because splenic flexure mobilization can be avoided in most cases (except for ISR or for those patients with diseased sigmoid) and the patients can enjoy the full benefits of robotic surgery during lymphovascular and rectal dissection. In Western countries where splenic flexure mobilization is mandatory, the reverse hybrid approach may be a better option.

The technical details of the Korea University technique will be described below.

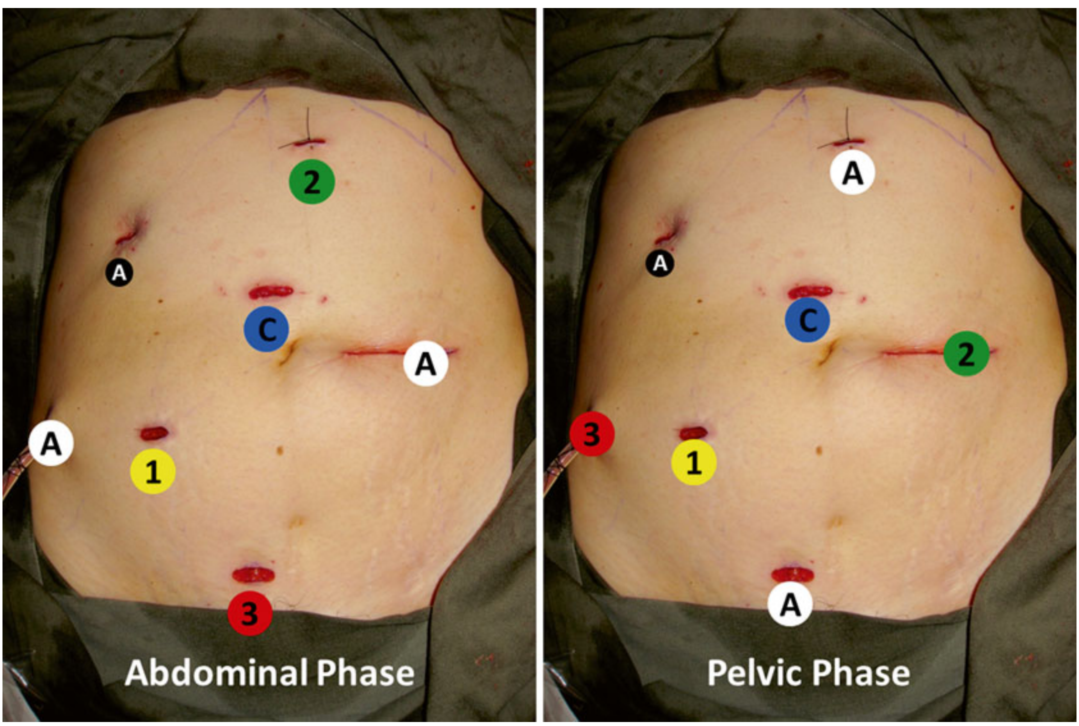

Fig. 12.5 Port placement for the totally robotic single docking approach pioneered by the Yonsei University group [21]. *C* camera port, *1* active robotic port for arm 1, *2* active robotic port for arm 2, *3* active robotic port for arm 3, A (white circle), 8-mm robotic ports; A (black circle), 5-mm assistant port

12.3.2 Totally Robotic Dual Docking Approach

The totally robotic dual docking approach was first introduced by Professor Byung-Soh Min of the Yonsei University [23, 24]. This technique entails reorientation of the operating table and docking/redocking of the robotic cart twice during the procedure. The main advantage of this technique is that it permits an easier splenic flexure mobilization even for the more difficult patients, while achieving precise lymphovascular and rectal dissection. This technique is also recommended especially for initial experience or as a transition from hybrid to totally robotic single docking approach [23].

In this approach, the operating table is rotated from stage 1 (vascular control and splenic flexure mobilization) to stage 2 (rectal dissection) (Fig. 12.6). The trocar positions are similar to the single docking approach reported by the Yonsei University group. During stage 1, the robotic cart is positioned over the left upper quadrant, approaching the patients at about 15°. With this position, vascular ligation, left-sided colonic mobilization, and complete splenic takedown are performed. If needed, the whole transverse colon can also be mobilized. After the completion of stage 1, the robotic cart is undocked and pulled back, the operating table is rotated about 60° counterclockwise until a 45° angle is created between the robotic cart and the operating table, and thereafter the robotic cart is pushed forward and redocked with the robotic arms repositioned to the stage 2 trocar positions.

12.4 Totally Robotic Single Docking TME: How We Do It

We have adopted the totally robotic single docking approach developed by Professor Seon-Hahn Kim of the Korea University since 2011 [9, 22]. The surgery is performed without changing the

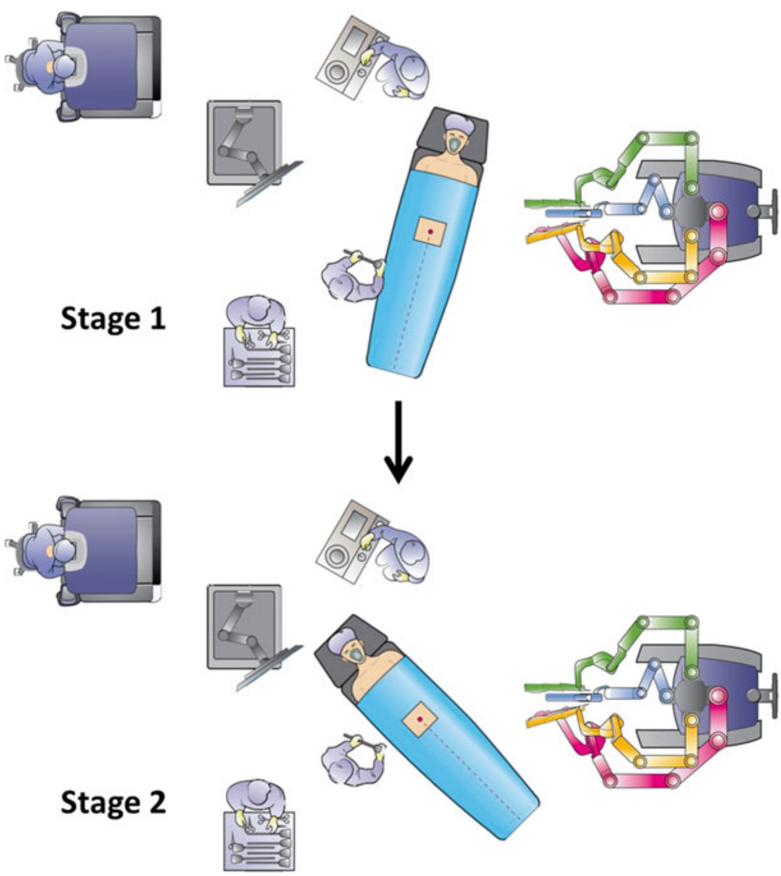

Fig. 12.6 Operating room setup for the totally robotic dual docking approach (Professor Byung-Soh Min [23, 24]). The operating table is rotated from stage 1 (vascular control and splenic flexure mobilization) to stage 2 (rectal dissection)

Fig. 12.7 Operating room setup for our totally robotic single docking approach

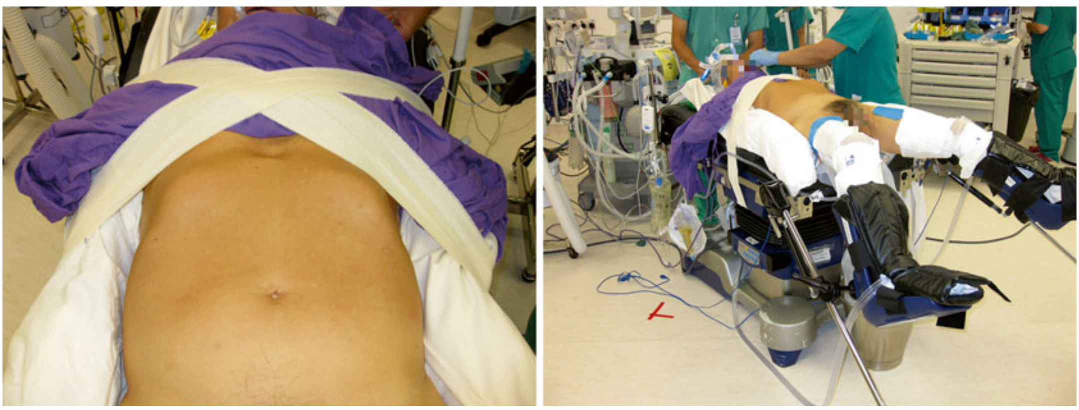

Fig. 12.8 Patient positioning and the "cross-torso" strapping method

position of the robotic cart. Instead, only the robotic arms are repositioned between the two phases: (1) abdominal phase for vascular control and colonic mobilization; and (2) pelvic phase for TME.

12.4.1 Operating Room Setup, Patient Positioning, and Port Placement

The operating room setup is shown in Fig. 12.7. After the induction of general anesthesia, the patient is placed in the modified Lloyd-Davies position. Both of the patient's arms are tucked at the sides of the body to allow enough room for an assistant and the robotic cart. The patient's thighs are slightly extended below the abdominal wall level to prevent being compressed by the robotic arms. The left leg of the patient should also be less abducted to provide more room for the robotic cart during docking. To prevent cephald sliding of the patient during steep head-down position, we have adopted a heavily padded, cross-torso method of securing two elastic adhesive straps from each shoulder to the contralateral hip (Fig. 12.8). We do not use shoulder braces to minimize the risk of brachial plexus injury.

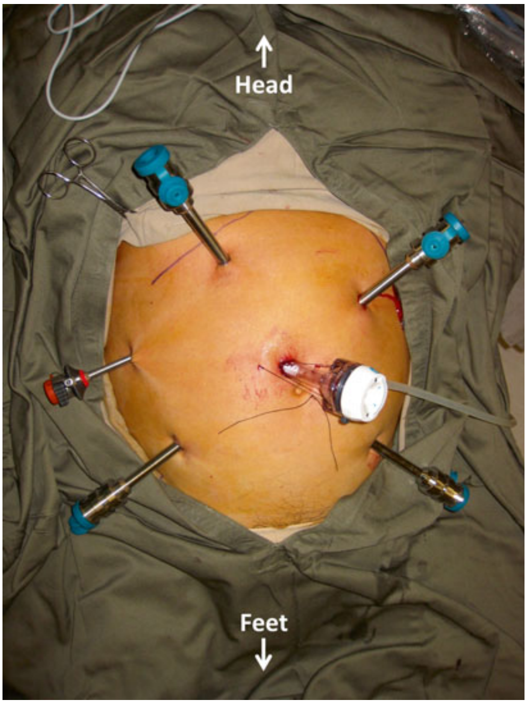

Fig. 12.9 Port placement for our totally robotic single docking approach. Six ports are created, including one 12-mm camera port, four 8-mm robotic ports, and one 5-mm port for the assistant

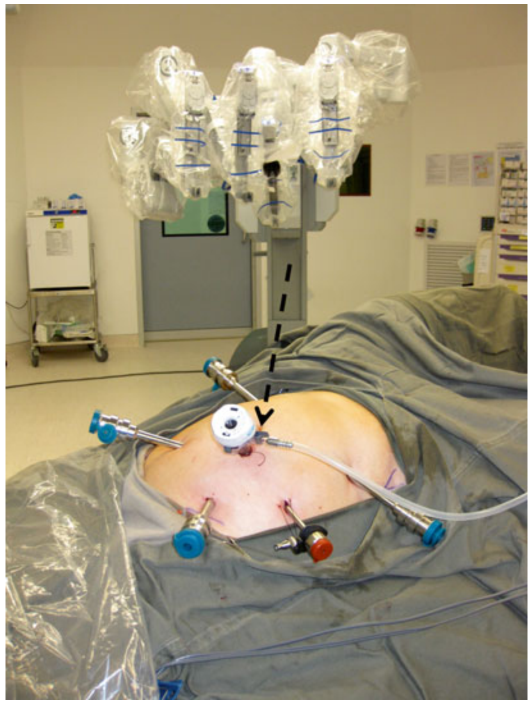

Fig. 12.10 Side docking of the robotic cart over the left lower quadrant along the imaginary line from the camera port to the left anterior superior iliac spine

Six ports are created, including one 12-mm camera port, four 8-mm robotic ports, and one 5-mm port for the assistant (Fig. 12.9). Pneumoperitoneum is established with the open Hasson's technique, and the 12-mm camera port is placed at 2–3 cm to the right of and 2–3 cm above the umbilicus. A zero-degree robotic camera is used for the whole procedure. The first robotic port is placed at the right lower quadrant (RLQ) near the McBurney's point. The second robotic port is placed at the right upper quadrant (RUQ) just inferior to the costal margin and 2 cm medial to the right midclavicular line (MCL). The third robotic port is placed at the left upper quadrant (LUQ) 8 cm below the costal margin and 2 cm medial to the left MCL. The fourth robotic port is placed at the left lower quadrant (LLQ) about 2 cm lateral to the left MCL. The distance between the robotic ports should be at least 8 cm to avoid external collisions between the robotic arms. A 5-mm assistant port is placed in the right flank area, near the anterior axillary line, at the umbilicus level. This is used for retraction of tissues, suction/irrigation, and introduction of energy sources for hemostasis.

Following port placement, the patient is tilted to the right side and placed in the 30° Trendelenburg position. The small bowel loops are retracted out from the pelvic cavity and away from the surgical field to expose the base of the inferior mesenteric artery. The robotic cart of the *da Vinci S* Surgical System (Intuitive Surgical, Inc., Sunnyvale, CA, USA) is then positioned obliquely at the LLQ along the imaginary line from the camera port to the left anterior superior iliac spine, and the robotic arms are docked to the robotic ports (Fig. 12.10).

12.4.2 Abdominal Phase: Operative Steps

For the abdominal phase, the RLQ (robotic arm 1, surgeon's right hand), RUQ (robotic arm 3,

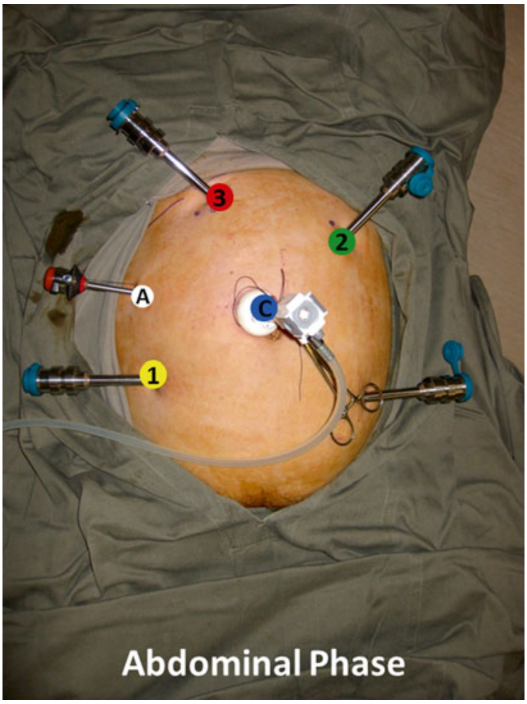

Fig. 12.11 Port placement for the abdominal phase dissection of the totally robotic single docking approach. *C* camera port, *1* robotic port for arm 1, *2* robotic port for arm 2, *3* robotic port for arm 3, *A* 5-mm assistant port

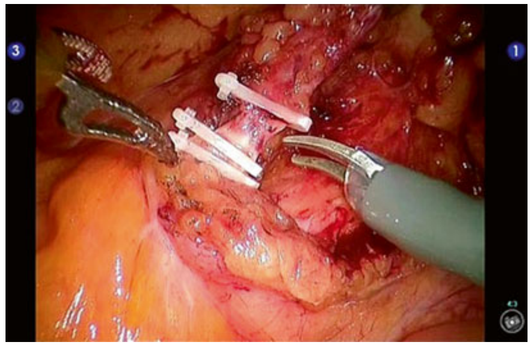

Fig. 12.12 Division of the inferior mesenteric artery between robotic Hem-o-lok clips

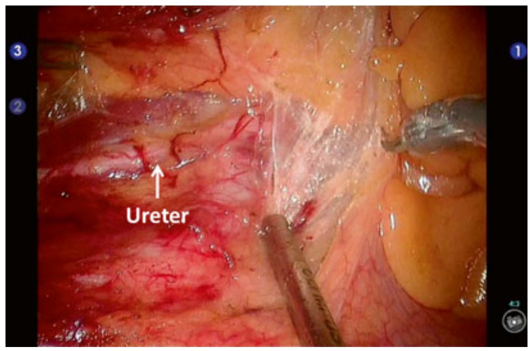

Fig. 12.13 Medial-to-lateral dissection along the retroperitoneal plane

surgeon's left hand), and LUQ (robotic arm 2, surgeon's second left hand) robotic ports are used; the LLQ port is not used (Fig. 12.11). We prefer the following robotic instruments: monopolar curved scissors for arm 1, Maryland bipolar forceps for arm 3, and Cadiere forceps for arm 2. The abdominal phase begins with incision and dissection of the peritoneum around the base of the inferior mesenteric artery with robotic monopolar scissors. The periaortic, superior hypogastric nerves are carefully preserved. The inferior mesenteric artery is divided near the origin between robotic Hem-o-lok clips (Teleflex Medical, Research Triangle Park, NC, USA) (Fig. 12.12). Dissection is then continued superiorly toward the ligament of Treitz, and the inferior mesenteric vein is identified and divided near the inferior border of the pancreas. The left-sided colon is mobilized from medial to lateral, with dissection of the mesocolon away from the retroperitoneum and the Gerota's fascia (Fig. 12.13). The left ureter and gonadal vessels are identified and safeguarded. The retroperitoneal dissection is continued superiorly over the pancreas until the lesser sac is entered. Further division of the transverse mesocolon along the pancreas is performed if splenic flexure takedown is needed. The lateral dissection is then completed by incision of the white line of Toldt from the pelvic brim up to the splenic flexure. The splenic flexure is completely taken down if extra bowel length is needed to facilitate the construction of a tension-free anastomosis. During splenic flexure mobilization, robotic arm 2 in the LUQ is temporarily undocked to avoid external collisions between robotic arms 1 and 3. Full mobilization of the splenic flexure is achieved by complete division of the renocolic and splenocolic ligaments, and detachment of the greater omentum from the transverse colon.

12.4.3 Pelvic Phase: Operative Steps

After completion of the abdominal phase dissection, robotic arms 2 and 3 are repositioned to prepare for the pelvic phase dissection. The position of the robotic cart and robotic arm 1 (surgeon's right hand; monopolar curved scissors) remains unchanged. Robotic arm 2 (surgeon's second left hand; Cadiere forceps) is repositioned from the LUQ to the LLQ port, whereas robotic arm 3 (surgeon's left hand; Maryland bipolar forceps) is repositioned from the RUQ to the LUQ port (Fig. 12.14). This repositioning allows the assistant to utilize two upper right-sided ports to provide maximal assistance, with the RUQ robotic port used for cephald retraction of the rectosigmoid, and the 5-mm assistant port used for retraction and suction/irrigation (Fig. 12.15). With a cotton tape placed around the sigmoid colon, the assistant applies traction to the rectum in the cephalad direction (Fig. 12.16). Further traction and countertraction are provided by the two robotic arms 2 and 3. Pelvic TME begins with incision of the peritoneum on both sides of the mesorectum at the level of the sacral promontory. The avascular "Holy plane" between the presacral fascia posteriorly and the fascia propria of the mesorectum is identified and divided sharply using robotic monopolar scissors. During posterior TME dissection, the mesorectum is retracted superiorly and anteriorly with the Cadiere forceps, while posterior countertraction is

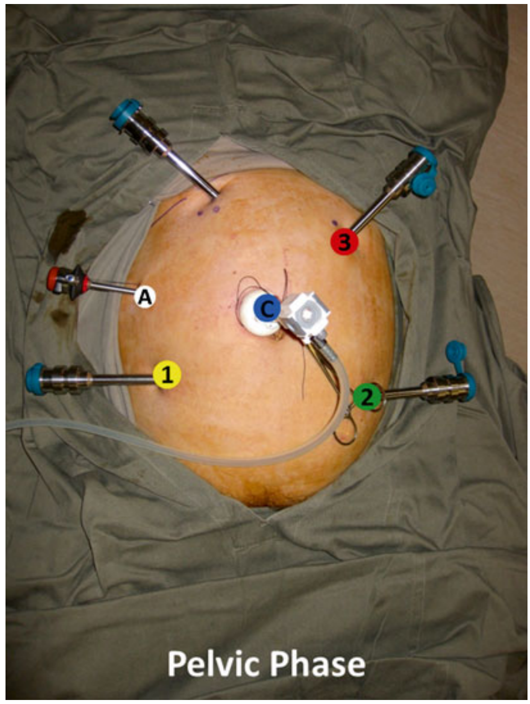

Fig. 12.14 Port placement for the pelvic phase dissection of the totally robotic single docking approach. *C* camera port, *1* robotic port for arm 1, *2* robotic port for arm 2, *3* robotic port for arm 3, *A* 5-mm assistant port

Fig. 12.15 The assistant utilizes two upper right-sided ports to provide maximal assistance

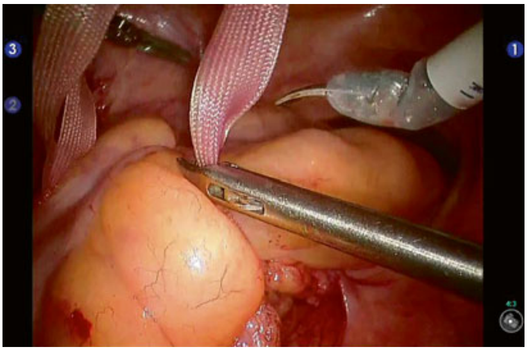

Fig. 12.16 With a cotton tape placed around the sigmoid colon, the assistant applies traction to the rectum in the cephalad direction

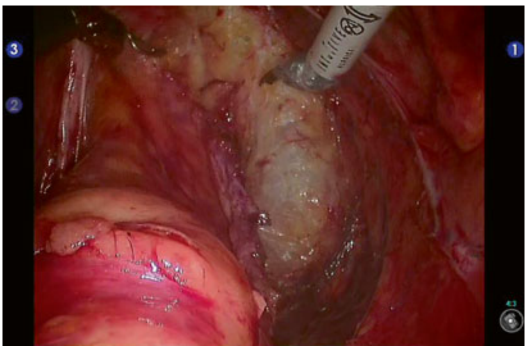

Fig. 12.17 Total mesorectal excision is performed around the rectum in a sequential fashion, from posterior to lateral, and then anterior

provided by the Maryland bipolar forceps. The dissection then continues circumferentially around the rectum in a sequential fashion, from posterior to lateral, and then anterior (Fig. 12.17). The inferior hypogastric nerves (lying posterior to the presacral fascia), and distally, the pelvic parasympathetic nerve plexus (at the lateral pelvic sidewalls) are identified and carefully preserved. Anteriorly, the peritoneal reflection is incised, and the dissection is continued along the Denonvillier's fascia in men or the rectovaginal septum in women (Fig. 12.18). Finally, TME is completed by division of the lower lateral ligaments bilaterally and the Waldeyer's fascia posteriorly, and the dissection is carried out down to the level of the pelvic floor. Once the rectal dissection is completed, the RLQ 8-mm robotic port is changed to a 12-mm laparoscopic port, and the lower rectum

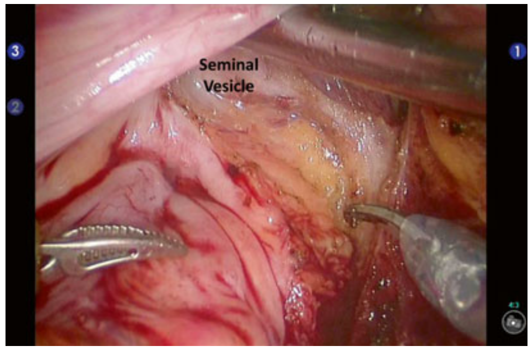

Fig. 12.18 Anterior dissection along the Denonvillier's fascia

is transected with laparoscopic linear staplers. The remaining steps are performed as described above (see "Conventional Hybrid Approach").

Conclusions

The introduction of robotic surgery has revolutionized the management of rectal cancer in the past decade. The robotic surgical system offers a number of technical advantages over laparoscopy for TME in the narrow pelvis where precise dissection is needed. However, rectal surgery also requires dissection in multiple abdominal quadrants, and there are several disadvantages of the current robotic surgical system that limit its utility in multiquadrant surgery, such as limited range of motion of the robotic arms, and inability to move the robotic cart or reposition the operating table after docking. In order to compensate for these limitations, various operative approaches have been developed, including the hybrid approach (conventional or hybrid) and the totally robotic approach (single docking or dual docking). Until now, the optimal surgical approach for robotic TME has yet to be defined. The surgeons should understand the pros and cons of each approach, and factors such as the body habitus of the patients, the perceived difficulty in splenic flexure mobilization, and the availability of laparoscopic expertise should be considered when choosing the most appropriate technique. Regardless of the operative approaches, the safety and feasibility of robotic TME for rectal cancer have been established [10, 23].

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Anorectal Physiology Testing

13

Lau Churk Ning Kevin
and William Chia Shing Meng

13.1 Introduction

Defecation is a complex process, which has close association with colonic and rectal motility. Normal anorectal function is responsible for evacuation of stool and also maintenance of continence. This is dependent on intact anatomy and a complex interaction between sensory and motor innervations that are coordinated by the central nervous system. The complicated nature implied a specialty in the realm of colorectal surgeons.

Patients tend not to express or discuss with their doctors in details regarding their problems with incontinence or constipation. They are also very tolerant of their conditions and reluctant for surgery for these benign conditions. Anorectal physiology testing can thus provide a more objective picture of their condition, and help defining the underlying pathophysiology.

This chapter reviews the different available modalities to assess anorectal function, and their clinical applications in different conditions such as constipation, obstructed defecation, rectocoele, and fecal incontinence. We would also like to share our experience and practical tips that hopefully would be helpful to others.

13.2 Anorectal Manometry

Anorectal manometry provides useful information about the tone and function of anal sphincter muscles and rectum. It has a simple setup and can be performed easily in an office setting. It is also well tolerated by patients.

13.2.1 Equipments

There are four essential components. We need a probe/catheter; a pressure recording system (pressure transducers, amplifiers, and perfusion system); a displaying device (monitor, printer, or chart recorder); and data process/storage facility (computer system/software) (Fig. 13.1).

13.2.2 Pressure Transducers

13.2.2.1 Air/Water Filled Balloons

The use is limited since the measured pressure is a sum of all forces acting upon the balloon. The large balloons also produce more distortion of the anal canal as well as a poorer frequency response. These factors can affect the reproducibility of results.

L.C.N. Kevin, MBBS, MPhil, FRACS (✉)
W.C.S. Meng, MBChB, FRCSEd, FCSHK, FHKAM
Department of Surgery,
Matilda International Hospital,
118 Shatin Pass Road, Wong Tai Sin, Kowloon,
Hong Kong, China
e-mail: kcnsurgery@gmail.com;
wmeng@netvigator.com

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Fig. 13.1 Setup of anorectal manometry

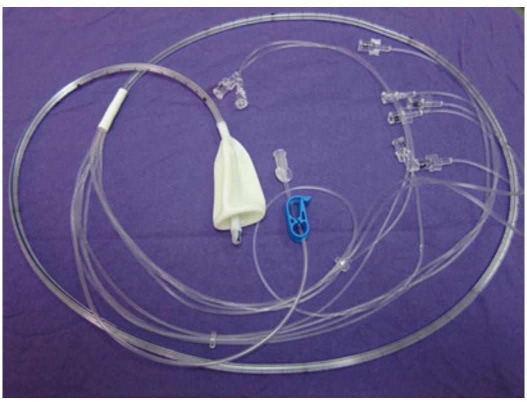

Fig. 13.2 Anorectal manometry catheter

13.2.2.2 Water-Perfusion Systems

The continuous perfusion fills up the space between the catheter and the anus. When the "yield pressure" is reached, the fluid will leak into the rectal ampulla or out of the anus. As the catheter is drawn through the anus, the mucosa will be in contact with the catheter port, thereby impeding the flow of water. The yield pressure then becomes the pressure required to overcome this obstruction. This is transmitted via capillary tubing to transducers and the pressure is recorded (Fig. 13.2).

Catheters vary in terms of rigidity, diameter, and number and location of ports. They are available as reusable and single-use types. Withdrawal motors are used as the rate of retraction is more easily standardized. Hydraulic capillary infusion systems are used, or alternatively, a drip set device to allow for perfusion of each transducer catheter channel separately. High-resolution manometry is now more of the current standard with increased number of ports in the catheter design (available as 8/20/24/36 channels). Line graphs can be displayed instead as color maps (e.g., Clouse contour plot) for better viewing (Fig. 13.3).

This is the most frequently used system. The several disadvantages to this system are that it requires the patient to be in a stationary left lateral position and hence ambulatory studies are not possible; it has a limited frequency response; it is difficult to set up and use; and it is prone to artifacts due to movement of the connecting tubing or air bubbles in the system.

13.2.2.3 Solid-State Transducer

They consist of microtransducers located at the tip of the catheter. It eliminates the use of continuous water perfusion and thus the side effects of skin/anal sphincter irritation and its associated artifacts. This is most expensive and the transducers are easily breakable. But the advantage is that it has good high-frequency response, is easy to use, and can be used for ambulatory recordings.

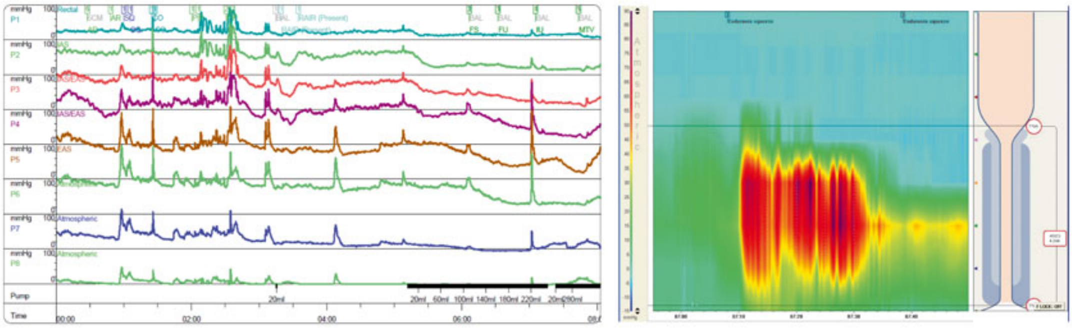

Fig. 13.3 Anorectal manometry pressure curves and Clouse contour plot

13.2.3 Technique

We prefer all patients to receive sodium phosphate enema to clear the lower rectum prior to the examination. Patients lie in a left lateral position, with knees bent and hip flexed to 90°. The catheter and pressure recording system are connected. The first step is to calibrate the catheter at the level of anus. The catheter is initially inserted into anus for a length of 10 cm, then slowly withdrawn (usually to 5 cm) in order to obtain an optimal position for measurement across all the levels of anal and anorectum.

Slow waves are commonly seen. They have amplitude of about 15 mmHg and frequencies of 10–20 cycles/min. Intermediate waves are seldom seen with a frequency of 4–8 cycles/min. They occur in patients with neurogenic fecal incontinence or following ileal pouch-anal anastomosis. *Ultraslow waves* have frequencies of 0.5–1.5 cycles/min and can be 100 mmHg in amplitude. They are found in patients with high resting anal pressure, e.g., anal fissure, hemorrhoids. *High-pressure zone (HPZ)* is defined as the zone bounded caudad by a rise in pressure of 20 mmHg and cephalad by a fall in pressure of 20 mmHg in at least 50% of the channels.

Resting pressure is the mean of the peak and trough pressure at rest in the high-pressure zone. Normal value is between 59 and 74 mmHg. *Maximum squeeze pressure* records the best effort of the patient with a period of rest in between. It analyses external sphincter contraction. *Endurance squeeze pressure* measures the function of the external anal sphincter. Patient is asked to perform a long (~30 s) squeeze. The graph consists of an initial sharp rise classed up to the peak pressure, followed by a lower amplitude plateau pressure. Peak pressure measures the maximum contractile potential, while the plateau pressure measures the sustain ability of the contraction. The fatigue slope is then calculated. *Cough pressure* records the reflex EAS contraction in response to sudden increase of abdominal pressure (in case of incontinence). *Push pressure* measures EAS relaxation (rectal-sphincter responses), e.g., when evaluating patients with dyssynergia or obstructed defecation (Fig. 13.4).

Rectoanal inhibitory reflex (RAIR) can be observed with the distension of balloon (usually ~50 ml of air) at the lower rectum eliciting an external anal sphincter contraction that is followed by reflex internal sphincter relaxation. This can be detected as an initial sharp increase in pressure followed by a drop in anal canal pressure. This reflex is mediated via the myenteric plexus. It allows detection of rectal contents to reach consciousness via the ascending spinal pathways associated with the mucosal receptors in the upper region of the anal canal and thus facilitates rectal emptying. It is absent in Hirschsprung's disease and diminished in neurogenic fecal incontinence and megarectum. However, the clinical significance is limited. False negatives can be due to the nonphysiological way of measurement, e.g., lying on left lateral position, altered sensation between catheter balloon and feces (Fig. 13.5).

Rectal sensation can then be assessed by determining the volumes, in mL of air, that initiate specific sensations. The levels of sensation are explained to the patient prior to the inflations

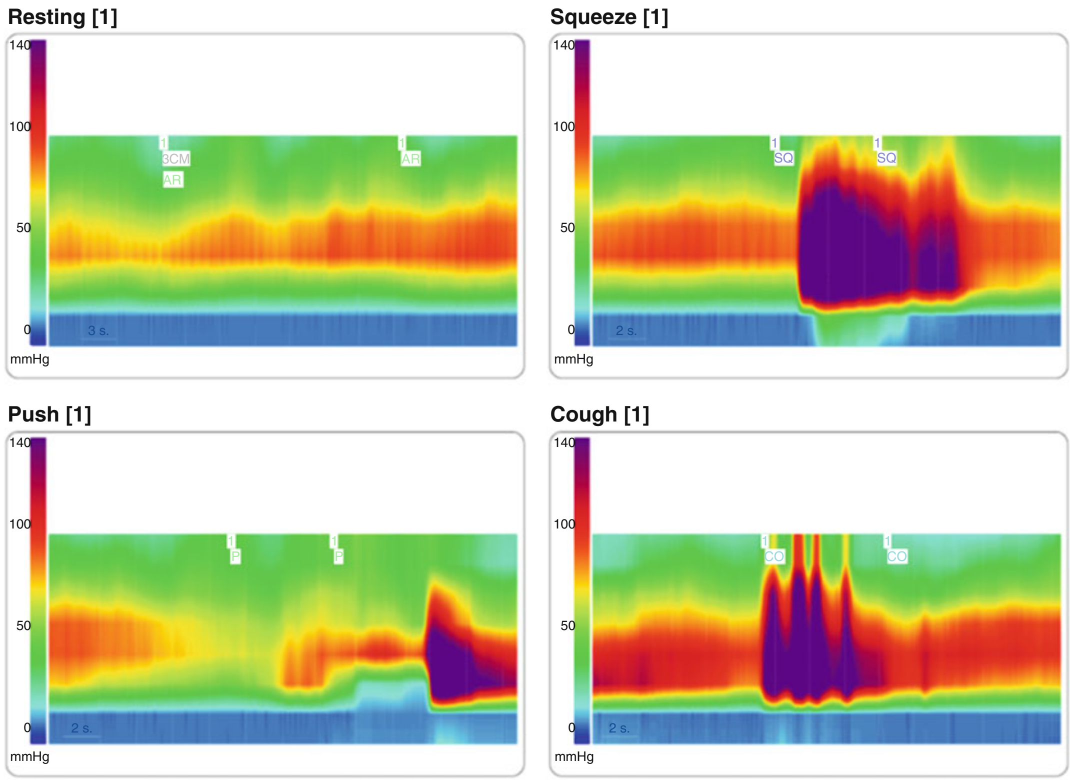

Fig. 13.4 Normal anorectal manometry pressure graphs

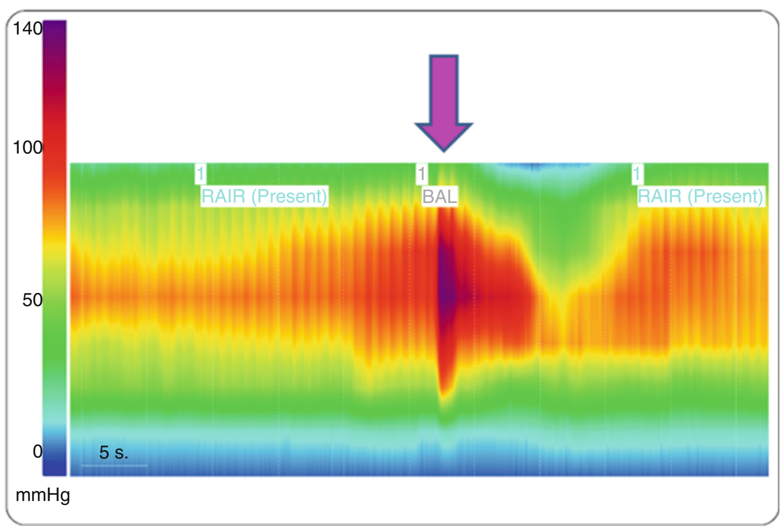

Fig. 13.5 Rectoanal inhibitory reflex (**Arrow* indicated time of balloon inflation)

and again just before each new sensation that is to be described. The volumes for the *first sensation*, *urge sensation*, and *maximal tolerable volume (MTV)* are recorded. The *first sensation* is when patient has a transient sensation of fullness or bloating or gas. *Urge sensation* is when the patient has a desire to pass bowel motion. *Maximal tolerable volume* is the maximal distension tolerable by patient with or without pain. Patients are instructed to voice out when these sensations were felt. However, if the patient still does not report any discomfort or desire to defecate after infusing 250 mL of air, further distensions should be then aborted.

Practical Tips
Patients may find it difficult to relax during this examination, thus leading to variation in the measured pressures. In particular, any manipulation of the rectum, including digital examination or movement of catheter should be followed by a period of rest (5 min) to allow patient to relax and anal tone to return to basal level. This is important in order to obtain accurate/consistent measurements. Also be aware that the catheter can be pushed further out of the anus voluntarily/involuntarily during *push phase*; so it is better to secure position of the catheter initially by tape, and to record the *push phase* at the end of the pressure recording cycle. Specific instructions prior to sensation volume measurements should be explained to patient as they may have different interpretations.

13.2.4 Report (Fig. 13.6)

Our Lady of Maryknoll Hospital
Anorectal Physiology unit

Patient Label

Anorectal Physiology

Exam date:

Physician:

History:

Indication:

Findings:

		Reference Male	Reference Female	
Manometry:				
Functional anal canal length: EAS	mm			
IAS	mm			
Mean resting pressure:	mmHg	59-115	47-101	mmHg
Maximum squeeze pressure (MSP):	mmHg	91-170	61-140	mmHg
EAS Push pressure %relaxation	%			
Rectal sensation:				
Volume of first sensation:	ml	45-136	42-130	ml
Volume of urgency:	ml	44-174	65-170	ml
Maximum tolerable volume:	ml	115-247	109-221	ml

Electrophysiology:

Recto-anal inhibitory reflex:	Absent/Present	
Pudendal nerve terminal motor latency (PNTML)	Right:	ms
+	Left:	ms

Pelvic Floor Coordination:

	At rest	Contraction	Push
Rectal Pressure:	cmH2O	cmH2O	cmH2O
Anal Pressure:	cmH2O	cmH2O	cmH2O
EMG:			

Comment:

Diagnosis:

Plan:

Fig. 13.6 Anorectal manometry sample report

13.2.5 Interpretation

There is a lot of variation in the normal range values due to the variation of techniques. In the western literature, there is considerable difference in normal values from different centers [1]. As a result, many laboratories will establish their own "normal" range. There are also differences between sexes, as well as different age groups. Females and elderly have been found to have reduced pressures [2, 3]. Patients with symptomatic hemorrhoids tend to have higher resting and squeeze pressures [4]. In the clinical setting, low resting and squeeze pressures may be observed in patients with fecal incontinence. However, the clinical value of pressures alone may not correspond to the clinical level of continence in patients.

Patients who experience urgency and frequency may be demonstrated objectively by low sensation volumes. Treatment can be facilitated via biofeedback therapy. Treatment progress and improvements can also be monitored via anorectal manometery. Patients with fecal incontinence often have decreased rectal sensitivity as shown in anorectal manometry [5]. While anorectal manometry values may not be good prognostic factors for success after surgery [6], they can be used to correlate with the clinical improvement after biofeedback therapy [7]. Patients with constipation/obstructed defecation/rectocoele often have increased rectal sensation volumes [8]. Patients with obstructed defecation may show paradoxical response of anorectum during push phase (failure to relax rectal/sphincter pressure) [9].

13.3 Electrophysiology Testing

13.3.1 Motor Nerve Conduction Studies

Pudendal nerves innervate the external sphincters bilaterally. St. Mark's pudendal nerve stimulating device is used to measure the function of pudendal nerve. The unit delivers a 50-volt square-wave stimulus of 0.1 ms in duration at the fingertip. The pudendal nerve is stimulated confirmed by the contraction of the external anal sphincter. The time taken for the impulse to be transmitted is known as pudendal nerve terminal motor latency (PNTML) (Fig. 13.7).

During the study, sensitivity is set at 50 μV, the low-frequency filter is set at 2 Hz and the high-frequency filter is set at 5 kHz. Typical tracings can be seen (Fig. 13.8). The normal value is about 2 ms.

Practical Tips

It can be operator dependent. Fingertip at the coccyx, then rotation to either side toward ischial spine is the usual landmark for pudendal nerve; however, the response may not be optimal until the site of maximal contraction of the sphincter muscles can be felt by the examiner's finger. Diligent search for the response may be required and amplitude of stimulation may need to be slightly adjusted. Warn the patient prior to examination that there may be some discomfort during the process of stimulation.

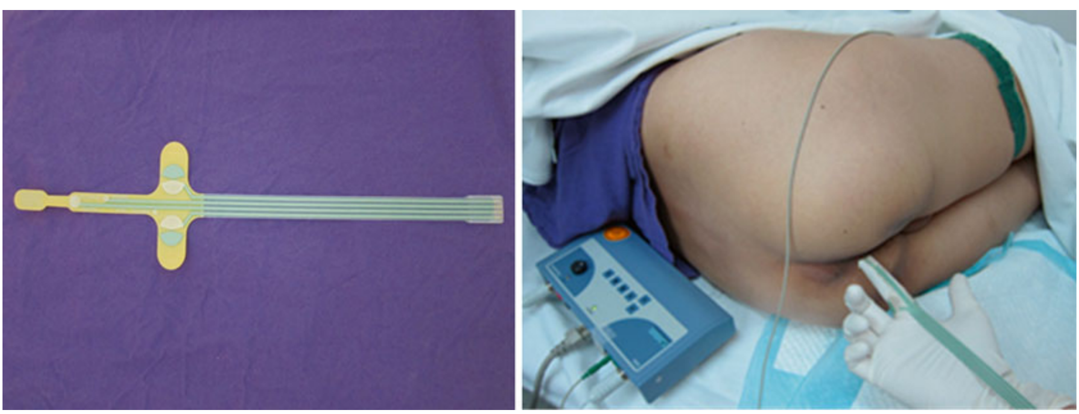

Fig. 13.7 PNTML equipment

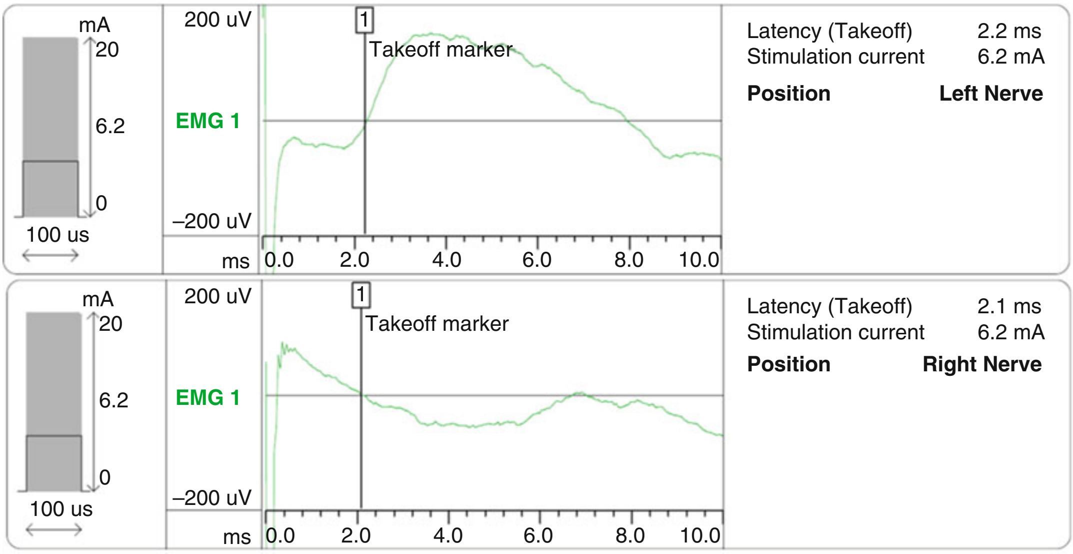

Fig. 13.8 PNTML tracing

Interpretation

Latency may be increased or absent in pelvic nerve injury. It may also be seen in the setting of incontinence or chronic rectal prolapse, which indicates impaired nerve function. PNTML test has, however, relatively low sensitivity and specificity for clinical value.

13.3.2 Electromyography (EMG)

This involves the measurement of depolarization activity from muscle fibers of external sphincter muscle and puborectalis. More commonly, it involves activity from a motor unit action potential. There are four kinds: (1) concentric needle EMG; (2) single-fiber EMG; (3) surface anal plug EMG; and (4) simultaneous ambulatory EMG. Most of them involve insertion of needle to the anal sphincter or they can only provide crude information of the sphincter as a whole. We prefer surface electrodes as it is less invasive. It also causes less patient discomfort and risk of infection (Fig. 13.9).

Interpretation

EMG activities are recorded during resting/cough/push phases. While the exact values/amplitude may not be reliable or reproducible, the comparison between different phases is more useful. Normally, the relaxation of puborectalis muscles is seen during the push phase of defecation, but in patients with constipation, paradoxical puborectalis contraction is shown as persistent EMG activity.

13.4 Measurement of Colonic Function

13.4.1 Colonic Transit

Colonic transit studies are good for indirect measurements of motility in colon and rectum. The common modalities used are radiopaque markers and scintigraphy.

13.4.1.1 Radiopaque Markers

We used the Metcalf [10] technique of ingesting three boluses of 20 Sitz markers each at 24-h interval. X-rays are taken at 24 h, and on 4th and 7th day. Markers located at the right or the spinous processes of the vertebrae and above a line drawn from the fifth lumbar vertebra to the pelvic outlet are in the *right colon*. Markers to the left of the vertebral spinous processes and above a line from the fifth lumbar vertebra to the iliac crest are in the *left colon*. Markers below the line of the pelvic brim on the right and iliac crest on the left

Fig. 13.9 EMG testing

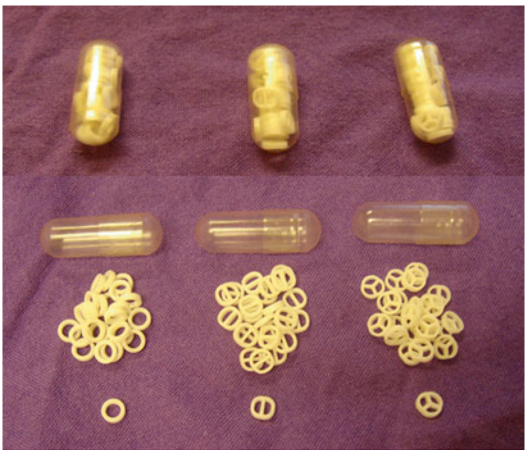

Fig. 13.10 Sitz markers used in colonic transit study

Fig. 13.11 Colonic transit study showing pelvic outlet obstruction

are said to be in the *rectosigmoid and rectum*. The number and distribution of markers provide an estimate of overall and regional colonic transit time (Figs. 13.10 and 13.11).

Practical Tips

Patients were instructed to abstain from laxatives, enema, or medication, which may alter bowel function; however, the results were not obviously affected by different sorts of diet. It can also be difficult to distinguish markers in the exact anatomical location, e.g., a low transverse colon from those in the sigmoid. Be aware that females and pregnant tend to have slower transit rates.

Interpretation

There are three subtypes of chronic constipation: slow transit constipation; pelvic outlet obstruction; and chronic idiopathic (normal transit) constipation. Slow transit constipation is defined by global slow colonic transit time (presence of markers scattered throughout the colon); pelvic outlet obstruction or paradoxical puborectalis contraction is defined by slow rectosigmoid transit (grouped markers remained in the rectosigmoid/pelvis); chronic idiopathic (normal transit) constipation is defined by normal transit time. However, at times, it can be difficult to distinguish markers in the exact anatomical location, e.g., a low transverse colon from those in the sigmoid. Pelvic outlet obstruction may also cause non-propagation or back propagation of markers in the proximal colon, leading to misdiagnosis of colonic inertia. The results are fairly reproducible, especially for chronic idiopathic constipation (normal transit study) [11].

13.4.1.2 Colonic Scintigraphy

Scintigraphy is a form of radioisotope study that is safe and noninvasive. It provides an accurate assessment of overall and segmental colonic transit, as well as the whole gut. The isotope used is 111Indium – DTPA (diethylene triamine penta-acetic acid), followed by scanning the abdomen using a wide field-of-view gamma camera and medium energy collimator. Many isotopes have been described before, e.g., Technitium 99, but were not useful in patients with constipation due to its short half-life. 111Indium – DTPA is a nonabsorbable isotope that has a long half-life.

Technique

Radioisotope is normally bound to resin and ingested as a liquid meal. Anterior and posterior images are taken. Images are captured at 2, 6, and 24 h, and then every 24h until all radioactive tracers are excreted. Frequent imaging in the first few hours can even monitor gastric and small bowel transit time. Images are then analyzed to determine the center of tracer activities in different segments of colon (i.e., ascending, transverse, descending, and rectosigmoid colon) and the rectum. The weighted average of the radioactivity counted over specific regions of the bowel is termed the "geometric center (GC)." A low value implies that the radioactive material is close to the cecum, while a high value indicates it is in the rectosigmoid or in the stools.

Interpretation

Colonic inertia or slow colonic transit is defined by overall prolonged colonic transit time whereas obstructed defecation is defined by prolonged sigmoid/rectal transit. It can also assess segmental colonic transit (right versus left colon) and small bowel transit.

13.4.1.3 Comparison Between Radiopaque Markers and Scintigraphy

A number of studies have compared the accuracy of radiopaque marker colonic transit study with scintigraphy. Radiopaque marker colonic transit studies are simple, cheap, and widely available. There is a reasonable correlation between radiopaque markers and scintigraphic measurements of colonic transit, but radioisotopes studies provide more accurate information about regional colonic transit, because multiple images can be obtained with a low radiation dose. Infrequent radiographs used in radiopaque marker studies may lead to unreliable results in constipated patients with irregular colonic movements, because the radiograph could be taken just before or after such an event. It is possible that most of slow descending colon transit is interpreted as rectosigmoid delay on radiopaque marker study. Scintigraphy gives a clearer delineation of the different colonic regions, even in subjects with a significant overlap of bowel segments. It identifies differential transit in the right or left colon, and allows differentiation between slow transit constipation and pelvic outlet obstruction. The use of a radiolabelled meal also yields information about gastric emptying and small bowel transit.

Scintigraphy is well tolerated by patients and does not add total dosage of radiation even with repeated imaging, which is of an advantage compared with radiopaque markers in patients with prolonged colonic transit. Disadvantages are related to the handling of the radioisotope, higher costs, need for specialized equipment (i.e., a gamma camera), and specialized radiologist expertise. Analysis of data of scintigraphy for geometric center can be unreliable and interpreter dependent.

13.4.2 Defecation Proctography

Defecation proctography is a dynamic radiological study that provides information for both the anatomy and function of the anorectum. This is the best simulation of defecation and is particularly useful in pelvic floor dysfunction and evacuation disorders, e.g., constipation, outlet obstruction, suspected prolapse, and rectocoele (Fig. 13.12).

Technique

We need a standard *fluoroscopic control* with a *commode* that has to be radiolucent. For *contrast media*, we use liquid barium sulfate thickened with porridge oats placed in caulking gun for injection. For women, water-soluble contrast is injected into vagina for outlining this structure.

For our routine, we ask the patient to relax and hold the contrast, squeeze, and push. Lateral X-rays and fluoroscopy videos were taken while the patient is in sitting position. Then we record the post-evacuation volume. Traditionally, there are several measurements to be noted. *Anorectal angle* is the angle between the axis of the posterior rectal wall and the axis formed by the anal canal. *Puborectalis length* is the minimal distance between the anterosuperior aspect of the symphysis pubis and the puborectalis notch. *Perineal descent* is the length of a perpendicular dropped from the pubococcygeal line to the anorectal junction.

Practical Tips

We also have to bear in mind that the patient is in an awkward position and is asked to defecate in public. Failure to evacuate is too easily counted as a false-positive diagnosis of outlet obstruction. Measurements may vary. Eyeballing serves as the best method to get meaningful interpretation.

Fig. 13.12 Defecating proctogram showing rectocoele

Interpretation

Obstructed defecation can be seen as failure of relaxation of the puborectalis muscle, and an increase in anorectal angle during defecation. Rectocoele can be seen as barium trapping in the posterior wall of vagina. Suspected rectal prolapse can be demonstrated objectively on the fluoroscopic video. Descending perineal syndrome can be seen as an anal canal descent of >3 cm during resting period.

13.4.2.1 Scintigraphic/MRI Defecography

The use of radioactive isotopes – scintigraphy and MRI defecogram – to perform a quantitative assessment of evacuation is a more recent technique. This can provide good quantitative information about the percentage of rectal contents evacuated per unit time. However, this is not readily available.

13.5 Endoanal Ultrasound

This will be discussed in detail in other chapters.

13.6 Clinical Applications of Anorectal Physiology Testing

Anorectal physiology tests can be applied in a variety of clinical settings. It can be used to obtain objective diagnosis; to predict success for surgery and therefore tailor specific type of treatment; to assess outcome of surgery; and as a form of treatment, i.e., biofeedback.

13.6.1 To Obtain Objective Information for Diagnosis

Summary of key features in different conditions:

	ARM	PNTML	EMG	Colonic transit study	Defecating proctogram
Slow transit constipation				↑ Total transit	
Obstructed defecation			↑ EMG activity during push phase	↑ Sigmoid/rectal transit	Pelvic floor incoordination Paradoxical ↓ in anorectal angle during defecation
Chronic idiopathic (normal transit) constipation	Normal	Normal	Normal	Normal transit	
Rectocoele				↑ Sigmoid/rectal transit	Presence of rectocoele during defecation
Hirschsprung's disease		Absent			
Incontinence	↓ Resting and squeeze pressure due to sphincter damage	↓ in pelvic nerve injury			

13.6.2 Preoperative Assessment as a Predictor for Success of Surgery

Anorectal physiology can help providing information for better patient selection for surgery. One of the examples is surgery for constipation. Colonic transit studies can differentiate slow transit constipation, pelvic outlet obstruction, and chronic idiopathic (normal transit) constipation depending on colonic transit time. Only patients with slow transit constipation are likely to benefit from surgery [12–14], while surgery has only limited role in chronic idiopathic (normal transit) constipation and obstructed defecation. The underlying pathophysiology of obstructed defecation generally stems from incoordination of pelvic floor muscles; therefore, patients with this condition are best to start with biofeedback therapy. In a comprehensive review by Knowles et al. [15], the incidence of recurrent constipation after colectomy for constipation is much lower after proper patient selection with preoperative investigations. Most studies believe that subtotal colectomy with ileorectal anastomosis offer the best result for patients with slow transit constipation [15, 16]. However, there are risks of intractable diarrhea and incontinence after subtotal colectomy. Ileosigmoid and cecorectal anastomosis were attempted to prevent diarrhea, but the incidence of recurrent constipation was very high [16, 17]. Segmental colectomies were performed, but with disappointing functional results initially. Segmental colectomy can be performed with success in specific cases where colonic transit study can delineate right- or left-sided colonic slow [18, 19].

Another example is surgery for fecal incontinence. Studies show patients with underlying pudendal neuropathy is likely to have a poor outcome after sphincter repair for incontinence [20].

Anorectal physiology testing also helps with the selection of type of surgery for rectal prolapse. While abdominal procedure such as rectopexy provides good result for treatment of rectal prolapse, at the same time, it results in a high chance of constipation postoperatively. Sezai found that for patients with preoperative slow colonic transit studies, rectopexy in conjunction with sigmoid resection would result in a lower rate of postoperative constipation [21].

13.6.3 Postoperative Monitoring as an Evaluation After Surgery

Colonic transit study and manometry could be used as an objective measurement of improvement or outcome of surgery. This also helps to clarify reasons when treatment fails. It provides meaningful information during assessment of postoperative complications, e.g., after stapled hemorrhoidopexy/open hemorrhoidectomy/anal fistulotomy/coloanal anastomosis. Postoperative events such as urgency, frequency, and/or incontinence can occur after these operations, which anorectal physiology testing can help defining the underlying condition of rectum and anus.

Anal sphincter repair is intuitively thought to be successful in correcting sphincter defects and fixing the problems of incontinence. However, many reports showed poor long-term results (40–50% success rate) after 6–10 years of anal sphincter repairs [22]. Anorectal manometry provides objective measurements for comparison.

Sacral nerve stimulation has been a new technique for modulation of colonic, rectal, and anal activity. Its mechanism of action is complex. It has been used to treat patients with fecal incontinence. Michelsen et al. [23] demonstrated significant decrease in antegrade colonic transit from ascending colon, while there was increase in retrograde transport from descending colon in patients who underwent sacral nerve stimulation for fecal incontinence. This correlated with reduction of frequency of bowel motion.

13.6.4 As a Therapeutic Treatment: Biofeedback

While manometry can help with diagnosis of certain conditions, it can also be used for performing and predicting responses to biofeedback training; treatment whereby patients are trained to be more aware of and responsive to biological information provided to them. Provision of visual or auditory feedback of the muscular tone within the external sphincter/puborectalis complex is of importance. Response to therapy can be related by patients via means of balloon pressure, EMG activities, and verbal feedback. It changes the patients' psychological aspect as well as physiological function of the rectum [24].

In fecal incontinence, it improves patients' awareness of their sphincter mechanism and the muscular function of this apparatus. A majority of patients report improvements in their symptoms after biofeedback [7]. For obstructed defecation, it heightens the awareness of the sphincters so that they can be trained to consciously relax these muscles during evacuation [25]. Results of biofeedback treatment are reflected as a significant modification of the anal relaxation during attempted defecation, duration of maximal voluntary contraction, and rectal sensation [26]. Several studies reported significant clinical improvements of symptoms in a large proportion of patients [27]. Biofeedback has been shown to improve patients with constipation [9, 24]. Follow-up anorectal physiology measurement can be instituted to compare with the pretreatment parameters.

Conclusion

Anorectal physiology is no longer viewed as a research tool. It provides objective data in conditions such as obstructed defecation and fecal incontinence, which shall give us the direction of successful and reasonable management of colorectal disease. It is also a prerequisite for colorectal surgeons to assess the functional results.

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14 Three-Dimensional Endoanal Ultrasonography in Anal Fistulas

Giulio A. Santoro

14.1 Introduction

The pathogenesis of anorectal abscesses and fistulae is generally attributed to an infection of the anal glands, usually located in the subepithelial position, the intersphincteric space, or the external sphincter, with ducts that enter at the base of the anal crypts of Morgagni at the dentate line level [1]. Infection of the glands can result in an abscess which can spread in a number of directions, usually along the path of least resistance, and can lead to the subsequent development of anal fistula. Five presentations of anorectal abscesses have been described [1]: (a) perianal abscess; (b) submucosal abscess; (c) intersphincteric abscess; (d) ischioanal abscess; and (e) supralevator and pelvirectal abscesses. Sepsis can spread through the different perianal spaces and become a horseshoe infection.

Anorectal fistula represents a communication between two epithelial surfaces: the perianal skin and the anal canal or rectal mucosa [1]. Any fistula is characterized by an internal opening, a primary tract, and an external or perineal opening. Moreover, the primary tract can present a secondary extension, or a fistula is without a perineal opening. In relation to the sphincters, fistulas have been classified into four types [1]: (a) intersphincteric tract; (b) trans-sphincteric tract; (c) suprasphincteric tract; and (d) extrasphincteric tract. Secondary tracts may develop in any part of the anal canal or may extend circumferentially in the intersphincteric, ischioanal, or supralevator spaces (horseshoe extensions). According to the American Society of Colon and Rectal Surgeons (ASCRS) [2], an anal fistula maybe termed "complex" when the tract crosses more than 30–50 % of the external anal sphincter (EAS) (high trans-sphincteric, suprasphincteric, and extrasphincteric), is anterior in a female, has multiple tracts, is recurrent, or the patient has pre-existing incontinence, local irradiation, or Crohn's disease.

The configuration of perianal sepsis and the relationship of abscesses or fistulae with anal sphincters are the most important factors influencing the results of surgical management [2]. Preoperative identification of all loculate purulent areas and definition of the anatomy of the primary fistulous tract, secondary extensions, and internal opening plays an important role in adequately planning the operative approach in order to ensure complete drainage of abscesses, to prevent early recurrence after surgical treatment, and to minimize iatrogenic damage of sphincters and the risk of minor or major degrees of incontinence. Useful information can be obtained by clinical assessment [2]. However, physical examination reaches a very good accuracy in

G.A. Santoro, MD, PhD
Department of Colorectal Surgery,
Digestive Disease Institute,
Cleveland Clinic Abu Dhabi, Abu Dhabi,
UAE
e-mail: giulioasantoro@yahoo.com

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identifying superficial and trans-sphincteric tracts, but it appears inadequate for both supralevator and intersphincteric tracts and to detect most of the internal openings and secondary extensions [3–5].

Endoanal ultrasonography (EAUS) has been demonstrated to be a very helpful diagnostic tool in accurately assessing perianal sepsis and provides sufficient information for clinical decision making in many cases [6]. However, with the currently available ultrasonographic equipment and techniques, a good deal of relevant information may remain hidden. The advent of high-resolution three-dimensional (3D) EAUS promises to improve the accuracy, providing the visualization of the anatomic structures in the pelvis, the axial and longitudinal extension of anal sphincter, the anatomy of the fistulous tract in complex perianal sepsis in greater detail [7, 8].

This chapter is devoted to discussing the methods for generating and using the 3D-EAUS particularly with regard to the advantages of this technique in the diagnostic imaging of anal fistulas.

14.2 Ultrasonographic Technique

EAUS may be performed with a high multi-frequency (9–16 MHz), 360° rotational mechanical probe (type 2052, B-K Medical, Herlev, Denmark) or a radial electronic probe (type AR 54 AW, frequency: 5–10 MHz, Hitachi Medical Systems, Japan) [8]. The difference between these two transducers is that the 3D acquisition is free-hand with the electronic transducer, whereas the mechanical transducer has an internal automated motorized system that allows an acquisition of 300 aligned transaxial 2D images over a distance of 60 mm in 60 s, without any movement of the probe within the tissue. The set of 2D images is instantaneously reconstructed into a high resolution 3D image for real-time manipulation and volume rendering. The 3D volume can also be archived for offline analysis on the ultrasonographic system or on PC with the help of dedicated software [8].

Before the probe is inserted into the anus, a digital rectal examination should be performed. During ultrasound, the patient may be placed in the dorsal lithotomy, in the left lateral or in the prone position. However, irrespective of the position, the transducer should be rotated so that the anterior aspect of the anal canal is superior (12 o'clock) on the screen, right lateral is left (9 o'clock), left lateral is right (3 o'clock), and posterior is inferior (6 o'clock). The length of recorded data should extend from the upper aspect of the "U"-shaped sling of the puborectalis (PR) to the anal verge.

14.3 Endosonographic Anatomy of the Normal Anal Canal

On ultrasound, five hypoechoic and hyperechoic layers can be seen in the normal anal canal [9]. The ultrasonographer must have a clear understanding of what each of these five lines represent anatomically (Fig. 14.1):

1. The first hyperechoic layer, from inner to outer, corresponds to the interface of the transducer with the anal mucosal surface.

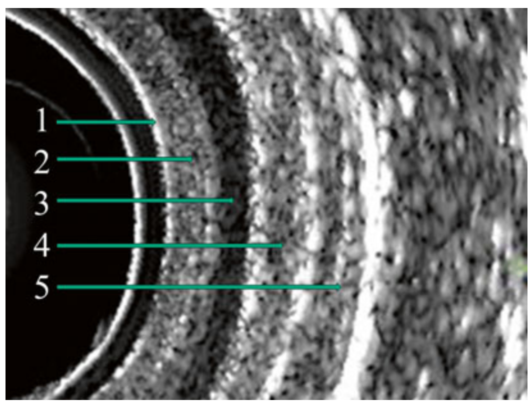

Fig. 14.1 The ultrasonographic five layers of the normal anal canal: (1) the first hyperechoic layer corresponds to the interface of the transducer with the anal mucosal surface; (2) the second layer represents the subepithelial tissues and appears moderately reflective; (3) the third hypoechoic layer corresponds to the internal anal sphincter; (4) the fourth hyperechoic layer represents the longitudinal muscle; and (5) the fifth mixed echogenicity layer corresponds to the external anal sphincter

2. The second layer represents the subepithelial tissues and appears moderately reflective. The mucosa as well the level of dentate line is not visualized. The muscularis submucosae ani can be sonographically identified in the upper part of the anal canal as a low reflective band.
3. The third hypoechoic layer corresponds to the internal anal sphincter (IAS). The sphincter is not completely symmetric, either in thickness or termination. It can be traced superiorly into the circular muscle of the rectum, extending from the anorectal junction to approximately 1 cm below the dentate line. In older age groups, the IAS loses its uniform low echogenicity, which is characteristic of smooth muscle throughout the gut, to become more echogenic and inhomogeneous in texture.
4. The fourth hyperechoic layer represents the longitudinal muscle (LM). It presents a wide variability in thickness and not always is distinctly visible along the entire anal canal. The LM appears moderately echogenic, which is surprising as it is mainly smooth muscle, however, an increased fibrous stroma may account for this. In the intersphincteric space, the LM conjoins with striated muscolar fibers from the levator ani, particularly the puboanalis, and a large fibroelastic element derived from the endopelvic fascia to form the "conjoined longitudinal layer" (CLL). Its fibroelastic component, permeating through the subcutaneous part of the EAS, terminates in the perianal skin.
5. The fifth mixed echogenic layer corresponds to the EAS. The EAS is made up of voluntary muscle that encompasses the anal canal. It is described as having three parts: (1) the deep part is integral with the PR. Posteriorly, there is some ligamentous attachment. Anteriorly some fibers are circular and some decussate into the deep transverse perineii; (2) the superficial part has a very broad attachment to the underside of the coccyx via the anococcygeal ligament. Anteriorly there is a division into circular fibers and a decussation to the superficial transverse perineii; and (3) the subcutaneous part lies below the internal anal sphincter.

Ultrasound imaging of the anal canal is divided into three levels in the axial plane (upper, middle, and lower) referring to the following anatomical structures (Fig. 14.2) [9]:

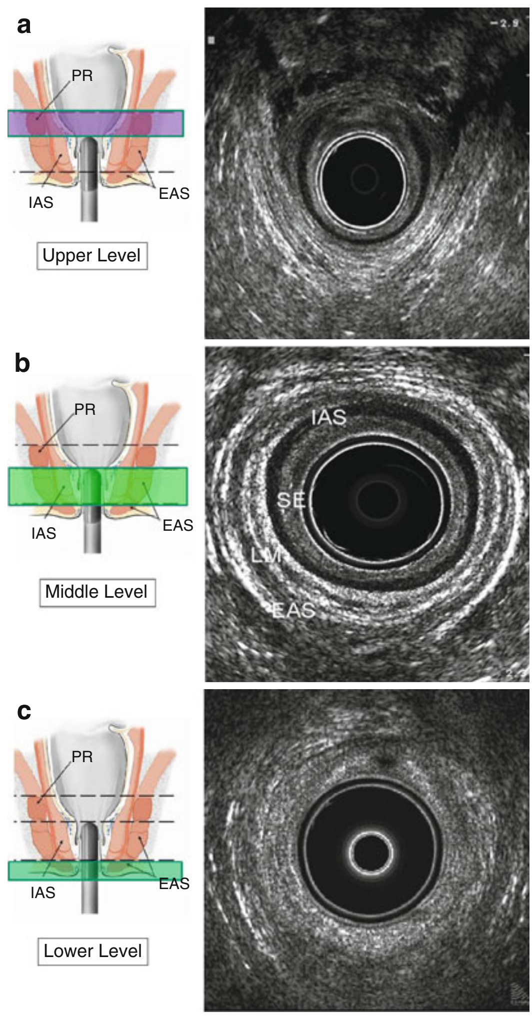

Fig. 14.2 The ultrasonographic three levels of the normal anal canal: (**a**) Upper level: the sling of the mixed echogenicity puborectalis muscle (*PR*). (**b**) Middle level: the subepithelial tissue, the hypoechoic ring of the internal anal sphincter (*IAS*), the longitudinal muscle (*LM*), the hyperechoic ring of the external anal sphincter (*EAS*). (**c**) Lower level: the subcutaneous part of the EAS

1. Upper level: the sling of the puborectalis (PR), the deep part of the EAS, and the complete ring of IAS.
2. Middle level: the superficial part of the EAS (complete ring), the CLL, the IAS (complete ring), and the transverse perineii muscles.
3. Lower level: the subcutaneous part of the EAS.

The anal canal length is the distance between the proximal canal, where the PR is identified, and the lower border of the subcutaneous EAS. It is significantly longer in male than in female, as a result of a longer EAS, whereas there is no difference in PR length. The anterior part of the EAS differs between genders. In males, the EAS is symmetrical at all levels; in females, it is shorter anteriorly, and there is no evidence of anterior ring high in the canal. In examining a female subject, the ultrasonographic differences between the natural gap (hypoechoic areas with smooth, regular edges) and sphincter ruptures (mixed echogenicity, due to scarring, with irregular edges) occurring at the upper anterior part of the anal canal must be kept in mind. Multiplanar 3D reconstructions provide detailed imaging of the components of the anal canal. Williams et al. [10] reported that the anterior EAS occupied 58 % of the male anal canal compared with 38 % of the female canal ($P<0.01$). There was no difference in the length of the PR, indicating that the gender difference in anal canal length is solely due to the longer male EAS. The IAS did not differ in length between males and females. Regadas et al. [11] confirmed the asymmetrical shape of the anal canal and the shorter length of the anterior part of the EAS in female. West et al. [12] reported similar results, with IAS and EAS volumes found larger in males than in females.

14.4 Endosonographic Assessment of Anal Fistulas

Endoanal ultrasound has been extensively used for the evaluation of fistula-in-ano. It is simple, rapid, and usually well tolerated in most patients. It can be easily repeated to choose the optimal timing and modality of surgical treatment, to evaluate the integrity of or damage to sphincters after operation, and to identify recurrence of fistula. It also gives information about the state of the anal sphincters, which is valuable in performing successful fistula surgery. A fistula affecting a minimal component of the muscles can be safely excised, but where the bulk of the EAS is affected, it is best treated by seton drainage or mucosal advancement flap.

The ultrasound examination is generally started using 10–13 MHz, changing to 7 or 5 MHz to optimize visualization of the deeper structures external to the anal sphincters. The PR, EAS, LM, and IAS should always be identified and used as landmarks for the spatial orientation of the fistula or abscess [6]. An anal abscess appears as a hypoechoic dyshomogeneous area, sometimes with hyperechoic spots within it, possibly in connection with a fistulous tract directed through the anal canal lumen. Abscesses are classified as superficial, intersphincteric, ischioanal, supralevator, pelvirectal, and horseshoe (Figs. 14.3, 14.4, 14.5, and 14.6).

Anal fistula appears as a hypoechoic tract, which is followed along its crossing of the subepithelium, IAS or EAS, and through the perianal spaces. With regard to the anal sphincters, the fistulous primary tract can be classified into four types: (a) intersphincteric tract, which is presented as a band of poor reflectivity within the longitudinal layer, causing widening and distortion of an otherwise narrowed intersphincteric space (Fig. 14.7). The tract goes through the intersphincteric space without traversing the EAS fibers; (b) trans-sphincteric tract, appearing as a poorly reflective tract running out through the EAS and disrupting its normal architecture (Fig. 14.8). The trans-sphincteric fistulas are divided into high, medium or low, corresponding to the ultrasound level of the anal canal. The low transsphincteric tract traverses only the subcutaneous EAS; the medium trans-sphincteric fistula traverses both sphincters, at the middle level of the anal canal; the high trans-sphincteric tract traverses both sphincters just below the PR; (c) suprasphincteric tract, which goes above or through the PR level (Fig. 14.9). It can be very dif-

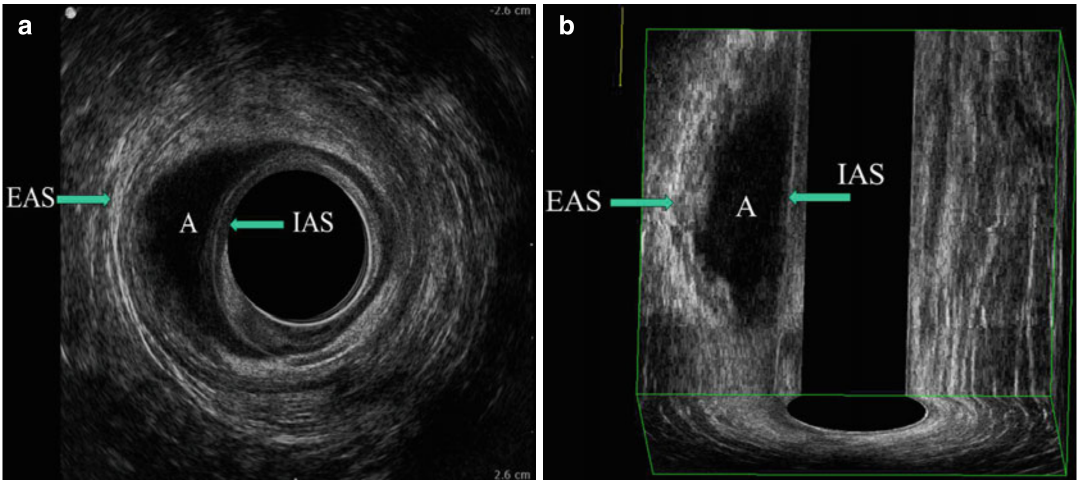

Fig. 14.3 Intersphincteric abscess (*A*) appears as a hypoechoic dyshomogeneous area between the internal (*IAS*) and external (*EAS*) anal sphincter (**a** axial plane; **b** coronal plane)

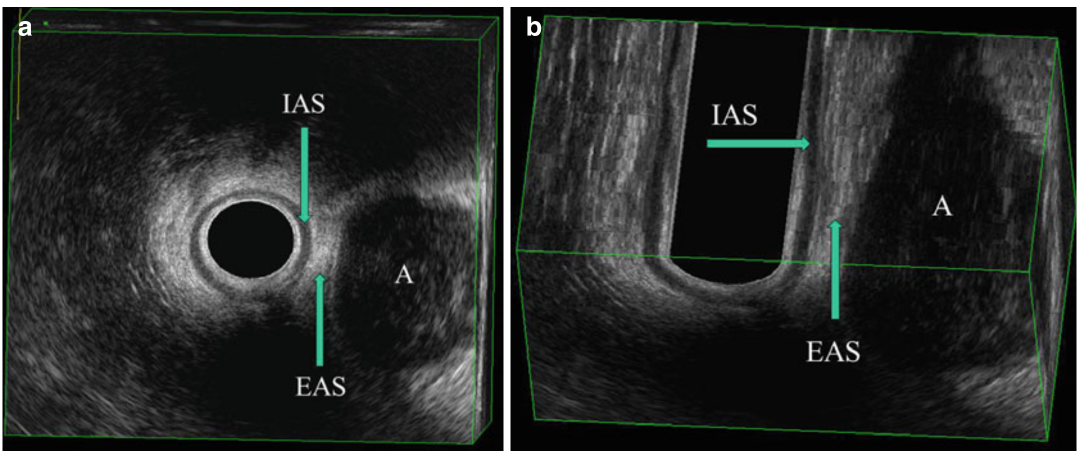

Fig. 14.4 Ischioanal abscess (*A*) appears as a hypoechoic dyshomogeneous area outside the external anal sphincter (*EAS*) (**a** axial plane; **b** coronal plane) (*IAS* internal anal sphincter)

ficult to determine a suprasphincteric extension because EAUS is not able to visualize the precise position of the levator plate that lies in the same plane as the ultrasound beam; (d) extrasphincteric tract, which may be seen close to but more laterally placed around the EAS. Secondary tracts, when present, are related to the main one and are classified as intersphincteric, transsphincteric, suprasphincteric, or extrasphincteric (Fig. 14.10). Similarly, horseshoe extension, are defined as intersphincteric, suprasphincteric, or extrasphincteric.

The exact location (radial site and anal canal level) of the internal opening can be difficult to define, as the dentate line cannot be identified as a discrete anatomical entity on EAUS. It is assumed to lie at approximately mid-anal canal level, which is midway between the superior border of the PR and the most caudal extent of the subcutaneous EAS. According to this, the site of the internal opening is categorized as being above, at, or below the dentate line, or in the rectal ampulla. In addition, the site can also be characterized by the clock position, being classified

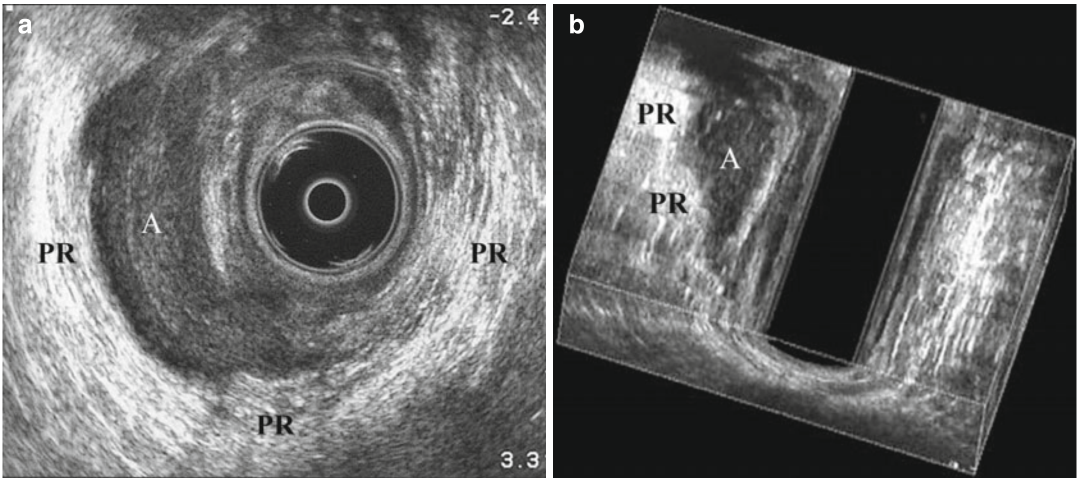

Fig. 14.5 Supralevator abscess (*A*) appears as a hypoechoic dyshomogeneous area above the puborectalis muscle (*PR*) (**a** axial plane; **b** coronal plane)

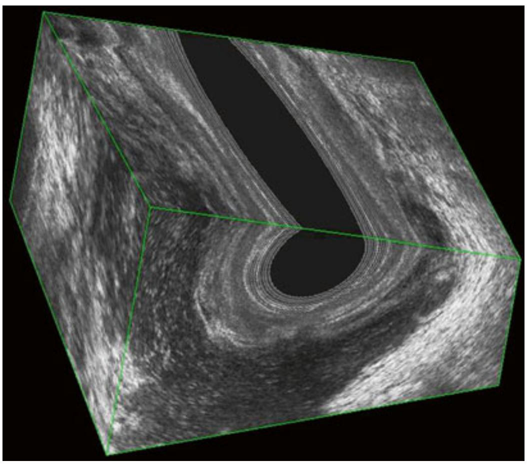

Fig. 14.6 Horseshoe, posterior, intersphincteric abscess

from 1 o'clock to 12 o'clock. The internal opening can be visualized as hypoechoic (when acute inflammation is present) or hyperechoic area (when chronically inflamed).

Due to its ability to provide multiplanar images with very high spatial resolution of the anal sphincter complex, 3D-EAUS offer many advantages compared to conventional 2D-EAUS. In addition, postprocessing technique (volume render mode), maybe used to limit the artifacts due to injection of hydrogen peroxide (HP) into the external opening of the fistula (Fig. 14.11) [8]. In 21 patients with a cryptoglandular fistula, West et al. [13] compared 3D HP-enhanced EAUS with endoanal MRI and surgery. Agreement for the classification of the primary fistula tract was 81 % for HP-enhanced 3D EAUS and surgery, 90 % for endoanal MRI and surgery, and 90 % for HP-enhanced 3D EAUS, and endoanal MRI. For secondary tracts, agreement was 67 % for HP-enhanced 3D EAUS and surgery, 57 % for endoanal MRI and surgery, and 71 % for HP-enhanced 3D EAUS and endoanal MRI in case of circular tracts and 76 %, 81 %, and 71 %, respectively, in case of linear tracts. Agreement for the location of an internal opening was 86 % for HP-enhanced 3D EAUS and surgery, 86 % for endoanal MRI and surgery, and 90 % for HP-enhanced 3D EAUS and endoanal MRI [13].

To distinguish Crohn's anal fistulas from cryptoglandular fistulae in patients with Crohn's disease, Blom et al. [14] suggested to consider the presence of 2 or 3 of the following ultrasonographic criteria: (1) bifurcation or secondary extension; (2) cross-sectional width ≥3 mm; and (3) content of hyperechoic secretions.

14.5 Discussion

Endoanal ultrasound is a simple, rapid, and minimally invasive procedure that can accurately detect and classify perianal fistulas. It is also use-

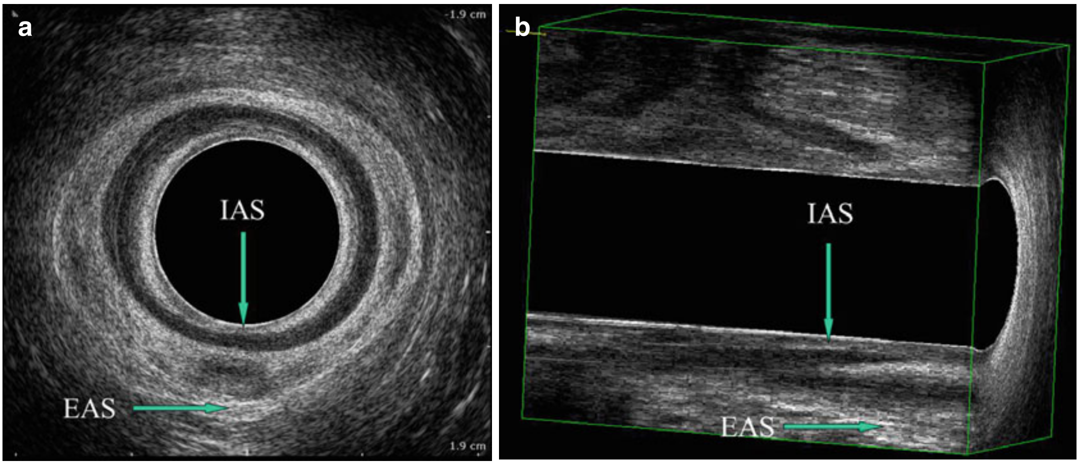

Fig. 14.7 Intersphincteric fistula appears as a band of poor reflectivity going through the intersphincteric space without traversing the external anal sphincter (*EAS*) (**a** axial plane; **b** longitudinal plane) (*IAS* internal anal sphincter)

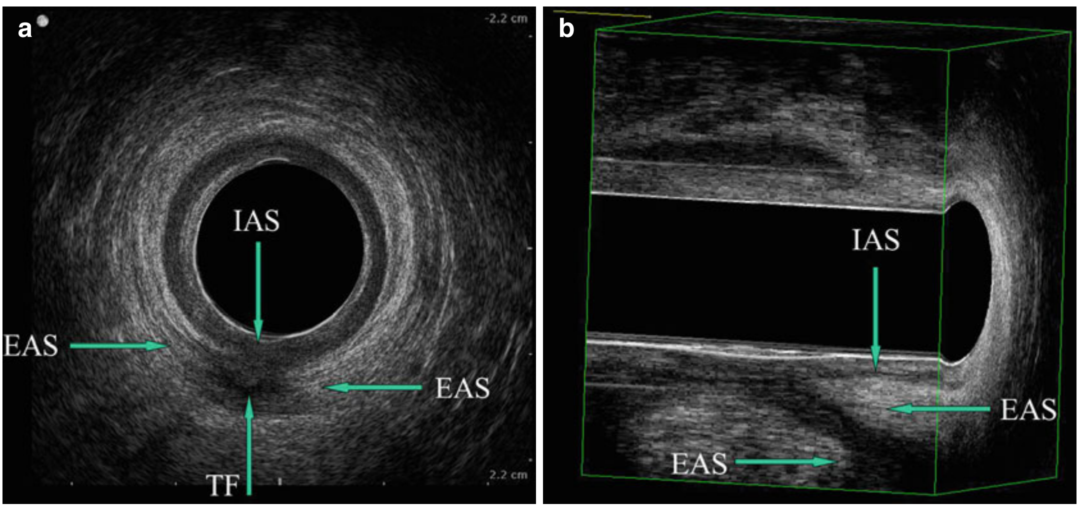

Fig. 14.8 Transsphincteric fistula (*TF*) appears as a band of poor reflectivity running out through the external anal sphincter (*EAS*) (**a** axial plane; **b** longitudinal plane) (*IAS* internal anal sphincter)

ful to guide the management of patients and to monitor the patients after treatment [15]. The accuracy of this technique may vary, according to the complexity of perianal disease and the expertise of investigators. Initial experiences with EAUS [6] reported a good accuracy for the selective identification of fistula (91.7 %) and abscess (75 %) configurations. However, a significant number of the internal openings (33.3 %) were not detected. Worse results in the identification of the internal opening were reported by Poen et al. [4] (5.3 % accuracy), and Deen et al. [3] (11 % accuracy). The most probable reason for the poor results in the identification of internal openings by EAUS is the ultrasonographic criteria used. Seow-Choen et al. [16] described revised ultrasonographic criteria for identifying an internal opening, which included one or more of the following features: a hypoechoic breach of the subepithelial layer of the anorectum, a defect in the circular muscles of the IAS, and a hypoechoic lesion of the normally hyperechoic LM abutting

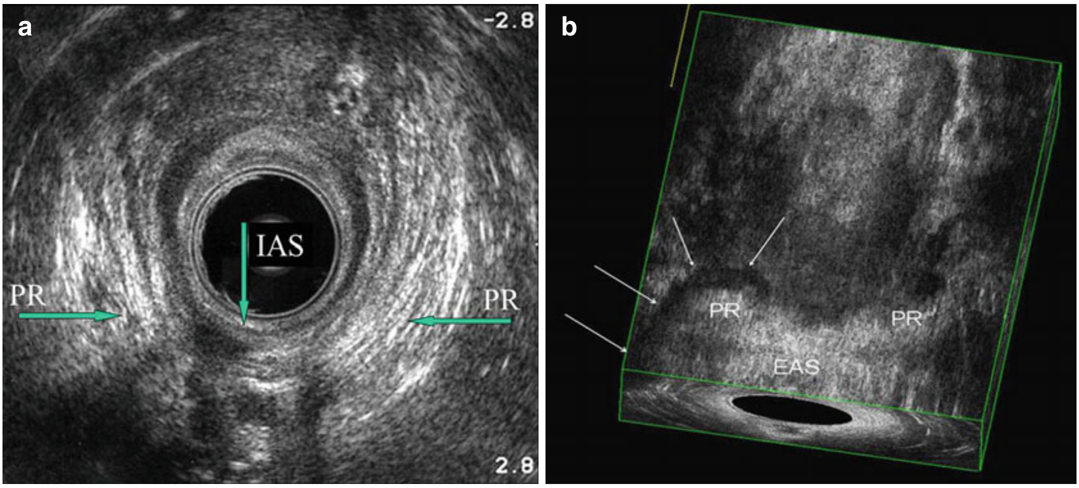

Fig. 14.9 Suprasphincteric fistula appears as a band of poor reflectivity going above the puborectalis muscle (*PR*) (**a** axial plane; **b** coronal plane) (*EAS* external anal sphincter)

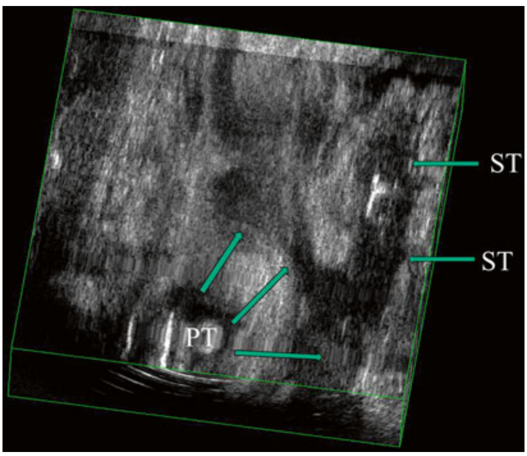

Fig. 14.10 Primary transphincteric tract (*PT*) with supra-levator secondary tract (*ST*)

on the normally hypoechoic circular smooth muscle. In spite of the improvement in accuracy (73 %) in identifying the internal openings, they found no significant difference between EAUS and digital examination. Cho [17] proposed the following endosonographic criteria to define the site of the internal opening: Criteria 1. an appearance of a root-like budding formed by the intersphincteric tract, which contacts the IAS; Criteria 2. an appearance of a root-like budding with an IAS defect; and Criteria 3. a subepithelial breach connected to the intersphincteric tract through an IAS defect. Using a combination of these three criteria, the author reported 94 % sensitivity, 87 % specificity, and 81 % and 96 % positive and negative predictive values.

The majority of problems while investigating primary tracts with EAUS occur because of the structural alterations of the anal canal and perianal muscles and tissues, which can overstage the fistula, or poor definition of the tract when filled with inflammatory tissue, which can downstage the fistula. The disappointing results of EAUS in diagnosing the extrasphincteric fistulae could be due to the echogenicity of the fistulae, especially those with a narrow lumen, which is practically identical to the fat tissue in the ischioanal fossa, and to the short focal length of the transducer, which prevents imaging of fistula that are located at large distance from the anal canal. For this reason, performing ultrasonography after injecting 1.0–2.0 ml of 3 % HP through the external opening of the fistula appears to be particularly useful. This technique allows identification of tracts whose presence has not been definitively established, or distinction of an active fistulous tract from postsurgical or posttrauma scar tissue [6]. Gas is a strong ultrasound reflector, and after injection, fistula tracts become hyperechoic and the internal opening is identified as an echogenic breach at the submucosa. Because the injected HP often results in bubbling into the anal canal,

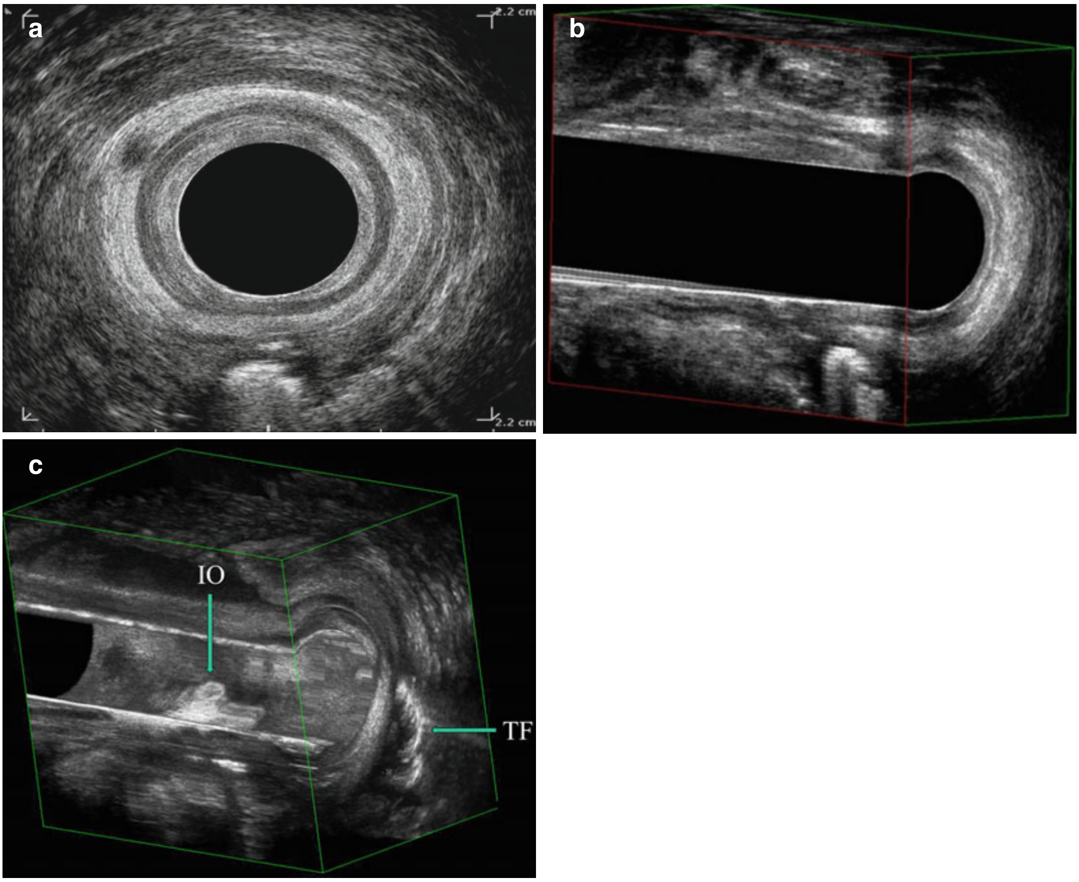

Fig. 14.11 After injection of hydrogen peroxide into the external opening, the transphincteric fistula (*TF*) tract becomes hyperechoic (**a** axial plane; **b** longitudinal plane) and the internal opening is identified as an echogenic breach at the submucosa (**c**)

which then acts as a barrier to the ultrasound wave, injection should be performed in two phases: an initial injection of a small amount of HP, and a further injection at a greater pressure [6]. A disadvantage inherent to HP injection is the very strong reflection that occurs at a gas/tissue interface, which blanks out any detail deep to this interface. The bubbles produced by HP induce acoustic shadowing deep to the tract, so all information deep to the inner surface of the tract is lost. The reported diagnostic accuracy of HP-EAUS ranges from 71 to 95 % for primary tracts and from 63 to 96.1 % for secondary tracts, while that of standard EAUS ranges from 50 to 91.7 % for the primary tract and from 60 to 68 % for secondary tracts [4, 5, 13, 18]. The highest concordance is usually reported for primary trans-sphincteric fistulas, while the major diagnostic difficulty is still the adequate identification of primary supra- and extrasphincteric fistulas. Injection can also contribute to a more accurate identification of the internal opening (HP-EAUS accuracy ranging from 48 to 96.6 % vs. EAUS accuracy ranging from 5.3 to 93.5 %) [7, 13, 18].

The availability of a 3D imaging system has further improved the accuracy of EAUS. With this technique, the operator can follow the pathway of the fistulous tract along all the desired planes (axial, coronal, sagittal, oblique). In addition, volume render mode can facilitate depiction of a tortuous fistula tract after HP injection, due to the transparency and depth information [8]. Buchanan et al. [19] reported a good accuracy of 3D-EAUS in detecting primary tracts (81 %), secondary tracts (68 %), and internal openings (90 %) in 19 patients with recurrent or complex fistulae. The addition of HP did not improve these features (accuracies of 71 %, 63 %, and 86 %, respectively). Using 3D imaging, Ratto et al. [18] reported an accuracy of 98.5 % for primary tracts, 98.5 % for secondary tracts, and 96.4 % for internal openings, compared with 89.4 %, 83.3 %, and 87.9 %, respectively, when the 2D system was used. Our experience [7] on 57 patients with perianal fistulas confirmed that 3D reconstructions improve the accuracy of EAUS in the identification of internal opening compared to 2D-EAUS (89.5 % vs. 66.7 %; $P=0.0033$). Primary tracts, secondary tracts, and abscesses were similarly evaluated by both procedures.

In recent years, MRI has emerged as a highly accurate technique in diagnosing perianal fistulas [13, 19]. Active tracts are filled with pus and granulation tissue and thus appear as hyperintense longitudinal structures on T2-weighted or STIR sequences.

The most valuable use of MRI is the assessment of recurrent sepsis not visualized on EAUS [20–23]. A variety of investigators have directly compared EAUS with MRI, both with and without an endoanal coil, and these comparisons have found EAUS variously superior [24], equivalent [25], or inferior [19]. In most studies comparing EAUS and MRI, surgical findings have been used as the gold standard. This, however, may be discussed and questioned, especially for those patients who did not heal after surgery. The difficulty of defining a true reference standard for fistula-in-ano is related to the following potential source of bias: the operators who perform the assessments can have differing levels of experience with EAUS or with MRI and, similarly, the surgeons who perform the operations have different levels of experience. Buchanan et al. [19] classified 108 primary tracts using clinical examination, EAUS, and MRI, and compared the findings to a reference standard that was based on ultimate clinical outcome. Digital evaluation correctly classified 61 % of primary tracts in comparison to 81 % for EAUS and 90 % for MRI. While MRI was superior in every comparison made by the authors, EAUS was particularly adept at correctly predicting the site of the internal opening, achieving this in 91 % compared to 97 % for MRI. Barker et al. [26] showed that 9 % of all fistulas do not heal, because fistulous tracts that were identified by endoanal MRI were not recognized during surgery. Therefore, using clinical outcome as the final arbiter can minimize potential biases. Because it is well established that the most common cause of fistula recurrence is infection that has been missed at surgical examination, patients should be followed up to determine clinical outcome and to identify any patients who require further unplanned surgery because of a failure to heal or further recurrence. Fistula healing is, otherwise, the only definitive assurance that all infection has been identified and treated. Thus, if there is disagreement between findings at EAUS, MRI, and surgical examination, the findings associated to fistula healing should be assumed to be correct. This is defined as the outcome-derived reference standard [19]. Chapple et al. [27] found that MRI classification of fistulas into simple and complex enhanced the chance of recurrence being predicted much more accurately than by EAUS alone (positive predictive value 73 % vs. 57 %). Successful surgery for perianal fistula is contingent upon accurate preoperative classification of the primary tract and its extensions. Sahni et al. [28], using an "evidence-based medicine" method, assessed the optimal technique for fistula classification. MRI was found to be more sensitive (0.97) than clinical examination (0.75) but comparable to EAUS (0.92) for discriminating complex from simple fistula. The authors concluded that MRI is the optimal technique for discriminating complex from simple perianal fistula, although EAUS is superior to clinical examination, and may be used if MRI availability is restricted. Anal endosonography has some clear advantages related to the fact that it is relatively cheap and simple to perform, it is rapid and well tolerated by patients and, unlike MRI, can be performed easily in the outpatient clinic or even on the ward since the machines are easily portable. It is vastly superior to digital examination and is therefore well worth performing. The major advantage of MRI over EAUS is the facility with which it can image extensions that would otherwise be missed since they can travel several centimeters from the primary tract. It is especially important to search for supralevator extensions, since these are not only difficult to detect but pose specific difficulties with treatment. Complex extensions are especially common in patients with recurrent fistulae or those who have Crohn's disease. It should also be borne in mind that MRI and EAUS provide complementary and additive information, and there are no disadvantages to performing both procedures in the same patient where local circumstances, availability, and economics allow this.

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15 Procedure for Prolapse and Hemorrhoid (PPH)

Dennis Chung Kei Ng
and William Chia Shing Meng

15.1 Introduction

Hemorrhoid is one of the commonest perianal condition managed by colorectal surgeons in the daily practice. Its management ranged from lifestyle modification, dietary advice, oral and local rectal medications, office bedside procedure, to the conventional hemorroidectomy. However, traditional hemorrhoidectomy is associated with pain, bleeding, complications, and significant loss of function [1]. A new minimally invasive approach, therefore, was introduced by Longo in 1998 [2]. This approach involves a circumferential excision of the rectal mucosa above the hemorrhoids by circular stapler, so that the prolapsed hemorrhoidal tissue was reduced back to its anatomic position without disturbing the anal sphincters. This is named procedure for prolapse and hemorrhoid (PPH) or stapled hemorrhoidopexy.

D.C.K. Ng, MBChB, FRCSEd, FCSHK, FHKAM (✉)
Department of Surgery,
North District Hospital, Hong Kong, China
e-mail: dennis_ckng@yahoo.com.hk

W.C.S. Meng, MBChB, FRCSEd, FCSHK, FHKAM
Department of Surgery,
Drs. Anderson & Partners,
Hong Kong, China
e-mail: wmeng@netvigator.com

15.2 Indications and Contraindications

A consensus statement was made by a group of international experts in 2003 [3]. They recommended the following indications:

1. Prolapsing hemorrhoids requiring manual reduction (Grade III)
2. Uncomplicated hemorrhoids, irreducible by the patient but reducible at surgery (Grade IV)
3. Irreducible hemorrhoids at surgery but by a modified surgical technique
4. Selected prolapsing hemorrhoids with spontaneous reduction (Grade II)
5. Failure to alleviate hemorrhoidal symptoms by other methods (e.g., rubber band ligation)

On the other hand, those patients with abscess, gangrene piles, anal stenosis, and full-thickness rectal prolapse should be avoided from the procedure.

15.3 Procedure

The detail of the procedure was described by the same group of experts [3]. The instruments required included a circular hemorrhoidal stapler, a circular anal dilator, a purse-string suture

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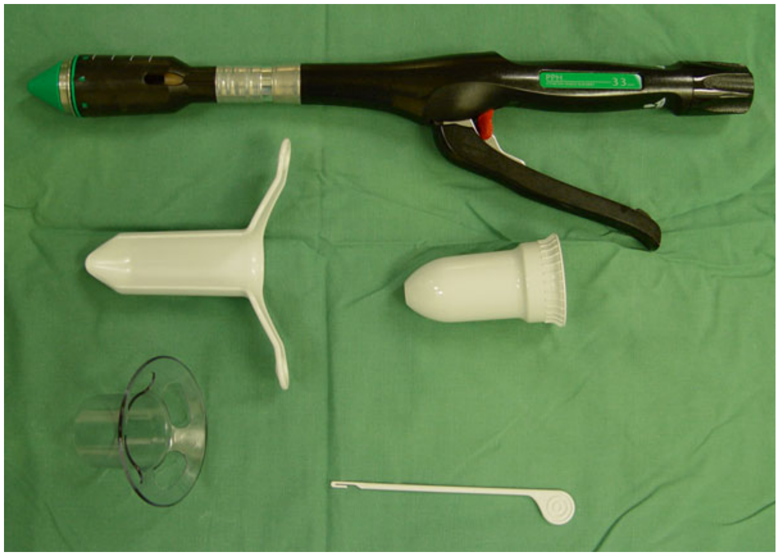

Fig. 15.1 The instruments needed for stapled hemorrhoidopexy

anoscopy, and a suture threader (Fig. 15.1). The procedure can be performed under sedation with local-, regional-, or general anesthesia:

Step 1: Positioning

Patient placed in Lloyd-Davis position and surgeon sat in between patient's legs. The other option is prone Jackknife position.

Step 2: Assessment of hemorrhoids

Insert protoscopy and assess the hemorrhoids. Abort procedure if stenosis precludes passage.

Step 3: Insert circular anal dilator (Fig. 15.2)

Insert well-lubricated circular anal dilator without sphincter stretch. Counter-traction can be applied on skin to facilitate insertion. The external component should be reduced as much as possible. The obturator is removed after insertion. The circular anal dilator should be fixed to skin with suture to maintain position. It allows easy introduction of instruments, maintain good view of dentate line, and protection of internal sphincter [3].

Step 4: Placement of purse-string suture

Place submucosal purse-string suture 2 cm above the apex of hemorrhoids with the aid of anoscope (Fig. 15.3). Its rotation allows the placement of a circumferential purse-string at the correct height and depth (Fig. 15.4). The adequacy of the purse-string should be checked afterwards (Fig. 15.5) [3].

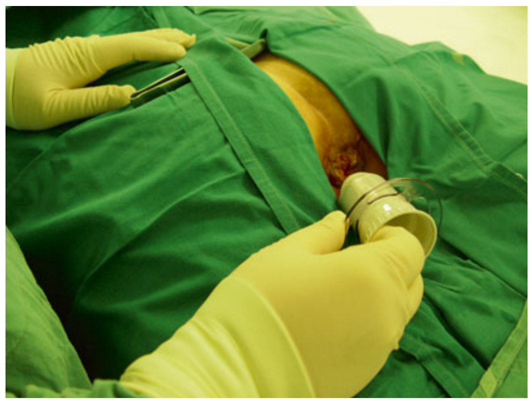

Fig. 15.2 Insert well-lubricated circular anal dilator and obturator without sphincter stretch

Fig. 15.3 Insert the purse-string suture anoscopy through the circular anal dilator

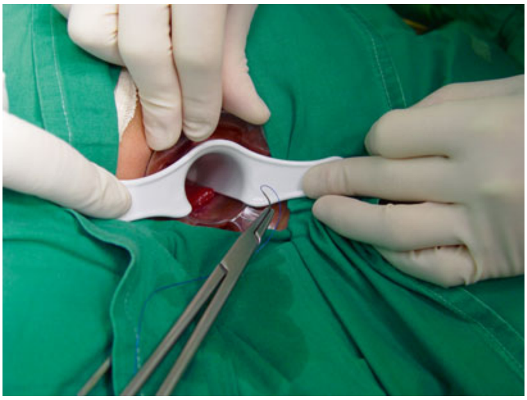

Fig. 15.4 Making use of a purse-string suture anoscopy to facilitate purse-string suture placement

Fig. 15.5 The adequacy of the purse-string should be checked afterwards

Step 5: Insertion of circular stapler

Insert fully opened stapler head through purse-string. The anvil is positioned beyond the purse-string which is tied onto the rod with just a throw-knot. Secure purse-string under direct visualization. The tails of the purse-string are drawn down through the lateral channels in the head of the stapler making use of the suture threader. The tails are knotted externally or fixed using forceps [3].

Step 6: Stapler's positioning

The head of the stapler is positioned into the anal canal until it is at least 2 cm beyond the dentate line. Align stapler along axis of the anal canal, and close stapler while maintaining moderate tension on the purse-string [3].

Fig. 15.6 Inspection of staple line after firing

Step 7: Closing and firing

Moderate traction on the purse-string when inserting the stapler draws the mucosal prolapse into the head of the stapler. In most cases the stapler is closed all the way down (1 mm closed staple height) by using the adjustable staple height to ensure the staples are tight enough to optimize hemostasis. At the end of the closure, the 4 cm mark should be at the level of the anal verge. If the patient is a woman, check the vaginal wall to be certain that it has not been incorporated. Fire the stapler. Open the stapler head and remove stapler [3].

Step 8: Inspection

Inspect the staple line for bleeding and reinforce if necessary (Fig. 15.6). Electrocoagulation should be used with caution because of the presence of the staples. A strip of mucosa above hemorrhoids is removed (Fig. 15.7). A circular staple line, ideally at least 2 cm proximal to the dentate line is evident. The anal mucosa with both internal and external hemorrhoids is pulled cephalad (Fig. 15.8). The specimen is sent for pathology and smooth muscle inclusion is a very common finding [3].

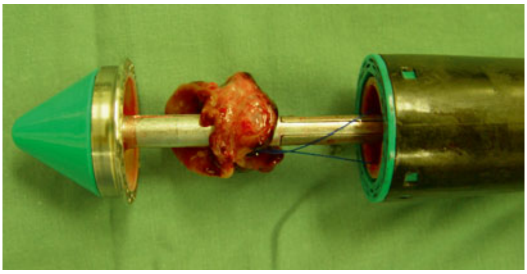

Fig. 15.7 A strip of mucosa above hemorrhoids is removed and inspected

Fig. 15.8 The appearance after the operation

15.4 Stapled Hemorrhoidopexy Versus Conventional Excisional Hemorrhoidectomy

Since the invention and popularization of this new technique in 1998, many studies including randomized controlled trials (RCTs) were reported in the literature. Most of the studies reported a favorable short-term outcome of this technique. However, until the recent publication of long-term outcomes and meta-analyses, a more comprehensive view of this technique appeared. All meta-analyses [4–10] reported that stapled hemorrhoidopexy had better short-term outcomes. One meta-analysis in 2007 [4] reported that stapled hemorrhoidopexy was associated with less operating time (weighted mean difference, −11.35 min; $P=0.006$), earlier return of bowel function (weighted mean difference −9.91 h; $P<0.00001$), and shorter hospital stay (weighted mean difference, −1.07 days; $P=0.0004$). There was less pain after stapled hemorrhoidopexy, as evidenced by lower pain scores at rest and on defecation and 37.6 % reduction in analgesic requirement. The stapled hemorrhoidopexy allowed a faster functional recovery with shorter time off work (weighted mean difference, −8.45 days; $P<0.00001$), earlier return to normal activities (weighted mean difference, −15.85 days; $P=0.03$), and better wound healing (odds ratio, 0.1; $P=0.0006$). The patient satisfaction was significantly higher with stapled hemorrhoidopexy. The overall complication rate did not differ significantly from that of conventional procedure (stapled vs. conventional: 20.2 vs. 25.2 %; $P=0.06$). Compared with conventional surgery, stapled hemorrhoidopexy has less postoperative bleeding (odds ratio, 0.52; $P=0.001$), wound complication (odds ratio, 0.05; $P=0.005$), constipation (odds ratio, 0.45; $P=0.02$), and pruritus (odds ratio, 0.19; $P=0.02$).

However, stapled hemorrhoidopexy is associated with a higher long-term risk of hemorrhoid recurrence and the symptom of prolapse. It is also associated with a higher likelihood of long-term symptom recurrence and the need for additional operations compared to conventional excisional hemorrhoid surgeries [5–10]. A recent update of the meta-analysis from the Cochrane group [5] in 2010 reported that patients with stapled hemorrhoidopexy were significantly more likely to have recurrent hemorrhoids in long-term follow-up at all-time points than those with conventional hemorrhoidectomy (12 trials, 955 patients, OR 3.22, CI 1.59–6.51, $p=0.001$). There were 37 recurrences out of 479 patients in the stapled group versus only 9 out of 476 patients in the conventional group. Similarly, in trials where there was follow-up of 1 year or more, stapled hemorrhoidopexy was associated with a greater proportion of patients with hemorrhoid recurrence (5 trials, 417 patients, OR 3.60, CI 1.24–10.49, $p=0.02$). Furthermore, a significantly higher proportion of patients with stapled hemorrhoidopexy complained of the symptom of prolapse at all-time points (13 studies, 1191 patients, OR 2.65, CI 1.45–4.85, $p=0.002$).

In studies with follow-up of greater than one year, the same significant outcome was found (7 studies, 668 patients, OR 3.14, CI 1.20–8.22, $p = 0.02$). Patients undergoing stapled hemorrhoidopexy were more likely to require an additional operative procedure compared to those who underwent conventional hemorrhoidectomy (8 papers, 553 patients, OR 2.75, CI 1.31–5.77, $p = 0.008$). When all symptoms were considered, patients undergoing conventional hemorrhoidectomy were more likely to be asymptomatic (12 trials, 1097 patients, OR 0.59, CI 0.40–0.88).

15.5 Stapled Hemorrhoidopexy Versus LigaSure™ Hemorrhoidectomy

LigaSure™ hemorrhoidectomy is a fast procedure characterized by limited postoperative pain, short hospitalization, fast wound healing and convalescence when compared with the conventional excisional hemorrhoidectomy [11]. So, how was it compared with stapled hemorrhoidopexy? Two meta-analyses were carried out in 2013 [12, 13].

Yang's group performed a literature search which resulted in five randomized control trials in this topic [12]. Among the five studies, all described a comparison of the patient baseline characteristics and showed that there was no statistically significant difference between the two groups. Although most of the analyzed outcomes were similar between the two operative techniques, the operating time for stapled hemorrhoidopexy was significantly longer than for LigaSure™ hemorrhoidectomy ($P < 0.00001$; OR = −6.39, 95%CI: −7.68 to −5.10). The incidence of residual skin tags and prolapse was significantly lower in the Ligasure™ Hemorrhoidectomy group than in the stapled hemorrhoidopexy group (2/111 (1.8 %) vs 16/105 (15.2 %); $P = 0.0004$; OR = 0.17, 95%CI: 0.06–0.45). The incidence of recurrence after the procedures was significantly lower in the LigaSure™ group than in the stapled group (2/173 (1.2 %) vs 13/174 (7.5 %); $P = 0.003$; OR = 0.21, 95%CI: 0.07–0.59].

The other meta-analysis [13] included four randomized trials showed similar results. None of the studies in the analysis indicated a significant difference between stapled hemorrhoidopexy and LigaSure™ Hemorrhoidectomy for the outcomes VAS pain score, recurrence rate, or postoperative bleeding. Pooled analysis revealed a significant OR in favor of the stapled hemorrhoidopexy method for recurrent prolapse (OR = 5.529, $P = 0.016$) for up to 2 years after surgery. No significant differences between the two methods were identified for VAS pain scores (OR = −1.060, $P = 0.149$) or postoperative bleeding (OR = 1.188, $P = 0.871$). Pooled analysis of RCT results comparing stapled hemorrhoidopexy to LigaSure™ Hemorrhoidectomy for symptomatic hemorrhoids revealed a significantly greater incidence of recurrent prolapse for stapled hemorrhoidopexy. The two techniques were associated with similar levels of postoperative pain and postoperative bleeding.

15.6 Stapled Hemorrhoidopexy Versus Transanal Hemorrhoidal De-arterializations (THD)

Transanal hemorrhoidal de-arterializations (THD) was first introduced in 1995 [14, 15]. In making use of a specially designed proctoscope coupled with a Doppler probe, terminal hemorrhoidal branches of the superior hemorrhoidal artery was localized and ligated. Vessel ligation results in the decongestion of hemorrhoidal tissue. This decreased tension allows regeneration of connective tissue within the anal cushions, which in turn facilitates the shrinkage of the piles, reduction in the prolapse, and alleviation of symptoms. Case series and randomized controlled trials were published to evaluate its efficacy.

How is it compared with stapled hemorrhoidopexy? A recent systematic review published in 2012 [16] addressed this issue. Three randomized controlled trials encompassing 150 patients were analyzed systematically. There were 80 THD patients and 70 stapled hemorrhoidopexy patients. THD and stapled hemorrhoidopexy were statistically equivalent in terms of treatment success rate ($P = 0.19$), operation time ($P = 0.55$), postoperative complications ($P = 0.11$), and recurrence ($P = 0.46$). THD was associated with significantly less postoperative pain (MD, −2.00; 95 % CI, −2.06, −1.94; $z = 63.59$; $P < 0.00001$) compared to stapled hemorrhoidopexy; therefore, THD may be considered a preferred procedure. However, a large multicenter randomized trial was suggested to validate the findings and investigate other variables.

15.7 Complications

All systematic reviews and meta-analyses [4–10, 12, 13] reported that stapled hemorrhoidopexy is a safe procedure with comparable complication profile to its open counterpart. However, rare but fatal septic complications were reported in the literature after stapled hemorrhoidopexy from time to time. Faucheron's group reviewed the literature and summarized these rare complications following stapled hemorrhoidopexy [17]. From 2000 to the 2010, 29 articles reporting complications in 40 patients were identified. Thirty-five patients underwent laparotomy with fecal diversion and a further patient was treated by low anterior resection. A specific complication was rectal perforation with peritonitis. Factors that led to life-threatening sepsis were identified in 30 patients. The causes of severe sepsis can be classified into four groups: full-thickness rectal wall resection, delayed staple-line dehiscence due to tension, electrocautery use and anal sex, bleeding leading to hematoma formation, and obstruction causing the split of staple line. Despite surgical treatment and resuscitation, there were four deaths (10 %). The author concluded that severe sepsis can complicate stapled hemorrhoidopexy. Rectal perforation and peritonitis are a particular risk of this technique and the associated mortality rate is high.

Conclusion

Stapled hemorrhoidopexy is a safe and feasible treatment option. It is associated with less pain, shorter hospital stay, faster recovery, and less time back to work. However, the recurrent prolapse and the need for additional operations in the long term are higher when compared to conventional excisional hemorrhoidal surgeries. Rare but fatal septic complication and rectal perforation were observed. A careful selection of patients, clear explanation before operation, and surgery by experienced colorectal surgeons are the keys to success.

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Tissue-Selecting Technique for Haemorrhoid Prolapse

16

Donglin Ren, Hongcheng Lin, and Juan Li

16.1 Introduction

Haemorrhoid is a common disease with an incidence of 46.3 % [1]. The current theory of its aetiology is the prolapse of pathological anal cushion along with engorged perianal subcutaneous vascular plexus, hyperplasia and stagnant vascular flow. Various clinical manifestations include bleeding, prolapse, sense of fullness or incomplete emptying [2] and oedema caused by acute incarceration. According to the survey from the USA, about 10–20 % requires surgical treatment [3].

Surgery is the mainstay of treatment. The ultimate aim of development of various surgical approaches is to achieve symptomatic relief and at the same time to decrease complications as well as hospital stay. Along with new findings in pathophysiology, new theories in surgical management and also advances in techniques, we are now focusing in preservation of anal function, preservation of normal tissue and also individualized treatment customized to patients [4].

Traditional surgeries including Whitehead haemorrhoidectomy (circumferential excision) operation, Milligan-Morgan ligation excision, etc., were standard treatment. However, they are not without complications, e.g. serious postoperative pain, mucosal eversion and anal stenosis. The anorectal functions are greatly compromised [5]. In 1975, Thomson introduced the "anal cushions" theory [6] which was indeed a breakthrough in the aetiology of haemorrhoid. Based on this concept of anal cushions, Longo developed the Procedure for Prolapse and Haemorrhoids (PPH) in 1998 [7]. Since then, a number of randomized controlled trials and multiple clinical studies were carried out to look at the efficacy of PPH. Compared with traditional surgery; PPH enjoyed the advantages of less pain, less detrimental effect on anorectal function and shorter hospital stay [8]. Hence, PPH has been generally accepted by colorectal surgeons worldwide and has become one of main surgical treatments of haemorrhoids.

Since the introduction of PPH of more than 10 years ago, it has been considered as the ideal minimally invasive surgical treatment of haemorrhoids. It is significantly effective in the treatment of prolapse as the main symptom. However, in clinical practice, haemorrhoids are prolapsing with different severity and are often asymmetrical, uneven and with normal mucosa bridge in between (Fig. 16.1). Hence, the use of a single technique of PPH in the treatment of a spectrum of disease may not be ideal. Bearing in mind our focus on protection of normal tissue as well as anorectal function, we should have preserved the

D. Ren (✉) • H. Lin • J. Li
The Sixth Affiliated Hospital, Sun Yat-sen University, Yuanchun Erheng Road, 510655 Guangzhou, People's Republic of China
e-mail: rendl111@163.com; linhongcheng@hotmail.com; hanyilj123@gmail.com

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Fig. 16.1 Normal mucosa bridge in between prolapsing haemorrhoid

normal mucosa in between the prolapsing haemorrhoids [9]. With the widespread use of PPH, this intrinsic defect of the surgical technique gradually emerges.

On long-term follow up studies, PPH has a higher recurrence rate than traditional surgery [10]. This higher recurrence rate was attributed to inadequate resection of the prolapsing tissue [11]. In recent European guidelines, PPH was not recommended for the treatment of severe haemorrhoid prolapse. Hence, despite the theoretical advantages of PPH, this "one treatment for all" technique cannot satisfy the requirement of current clinical standard. The treatment of haemorrhoids should be tailor-made for the specific clinical condition. For mild circumferential prolapse, PPH is the treatment of choice. For isolated prolapse, PPH resected the pathological tissue along with the normal mucosa, which should have been preserved. For severe prolapse, the amount of tissue resected by PPH is inadequate which lead to high recurrence rate. Therefore, the surgical management of haemorrhoid prolapse calls for individualized treatment, and it is imperative to improve on the PPH technology as well as to customize for each patient.

16.2 Tissue-Selecting Technique (TST) Set

We proposed tissue-selecting technique (TST), a new technique of selective haemorrhoid mucosal resection for the treatment of isolated prolapsed haemorrhoids. The TST set (Touchstone International Medical Science Co. Ltd., Suzhou, China) includes a stapler and a dilator-anoscope-obturator (DAO) unit which consists of options of a single or two or three fenestrations to accommodate haemorrhoidal tissue (Fig. 16.2). PPH is designed for compulsory circumferential resection of all the mucosa, be it normal or pathological. TST, on the other hand, has the liberty of selecting to resect only the pathological tissue leaving the normal mucosa behind.

The outer diameter of the TST stapler is 33 mm consisting of 32 staples with leg length of 3.8 mm, configured as double concentric rows in a staggered manner. After firing, the titanium staple will conform into a B-shaped structure of about 1.5 mm in height. The TST anoscope is a hollow cylinder with a small opening at the proximal end. Laterally, there are options of single, double or triple fenestrations. Clinical studies have shown that it has the same efficacy as PPH but has the advantages of decrease in anal stenosis and rectovaginal fistula and better anorectal function [12–14].

Furthermore, in order to reduce recurrence rate in severe haemorrhoid prolapse, TST Starr+ was developed with a larger diameter of 36 mm with enlarged housing such that to accommodate more tissue. Early studies revealed that TST Starr+ can excise more prolapsing tissue and has better "lifting-up" effect of the mucosa than PPH. With the acknowledgement of new treatment philosophy and in-depth clinical research, we believe that the management of haemorrhoid should be individualized. With improvement of the PPH stapler, we should be able to customize our treatment accordingly.

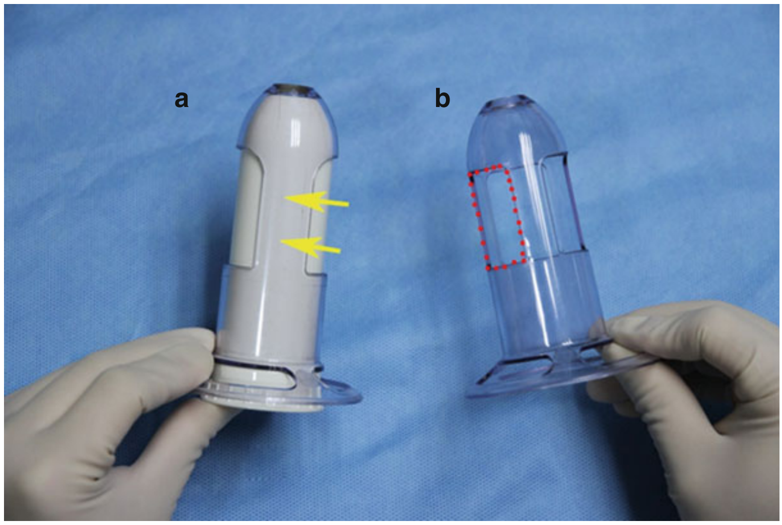

Fig. 16.2 Anoscope *A* with obturator has double fenestrations (protective plate for normal mucosa indicated by *yellow arrows*); anoscope *B* has triple fenestrations (outlined in *red*)

16.3 TST Operative Procedure

16.3.1 Pre-operative Preparation and Anaesthesia

All patients will undergo bowel preparation and prophylactic antibiotics given. We prefer combined spinal and epidural anaesthesia, which can fully relax the anal sphincter for the insertion of the anoscope.

16.3.2 Positioning

We favour the prone jackknife position which enables excellent exposure of the surgical field and also facilitates the assistant to stand at a comfortable position to help out the surgeon. In addition, the decreased venous pressure at the perianal region in this position may reduce the bleeding. Furthermore, the blood will be drained away from the operative field due to gravity, and this contributes to better visualization and hence better haemostasis. However, in patients with severe cardiopulmonary dysfunction, we will recommend the lithotomy or the left lateral position.

16.3.3 Insertion of Anoscope

Firstly, the dilator lubricated with paraffin oil is gently inserted into the anus. After dilatation of the anus, the anoscope is then inserted with the obturator in situ. After which, we shall adjust by rotation of the anoscope such that the fenestrations are facing directly onto the redundant prolapsing tissue. In general, with respect to haemorrhoids located at the classical positions of 3, 7 and 11 o'clock, we will recommend the use of the anoscope with triple fenestrations. For haemorrhoids which are circumferential or located atypical positions, we will suggest the use of anoscope with double fenestrations. It should be noted that for anoscope with double fenestrations, the circumferential width of the opening of each fenestration is larger. Hence, the amount of tissue removed will be increased.

For female patients, we will try to align the interim plate of the anoscope to cover the position of the rectovaginal septum so as to avoid rectovaginal fistula (Fig. 16.3). After insertion of the anoscope with the obturator, the prolapsed mucosa will all be pushed and lifting up back into the normal position. With the retrieval of the obturator, the redundant haemorrhoidal tissue

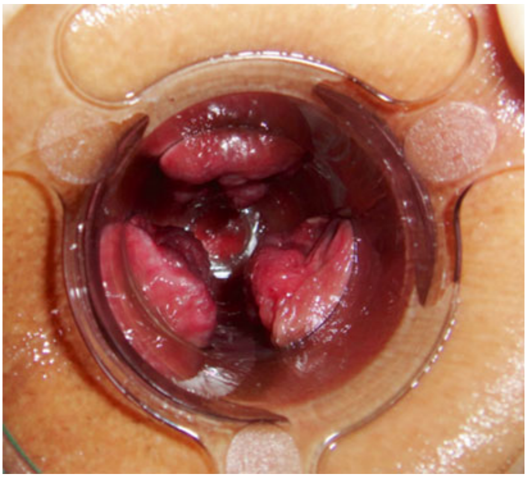

Fig. 16.3 The protective plate of the anoscope is placed at the rectovaginal septum in female. After removal of obturator, the prolapsed mucosa is lifted up and reduced to the normal position. Only the redundant haemorrhoidal tissues to be excised are prolapsing into the lumen through the fenestrations

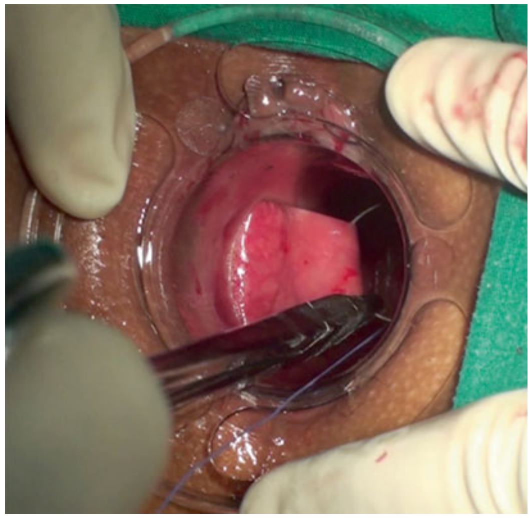

Fig. 16.4 Purse-string suture of tissue through the one of the windows of the anoscope with triple fenestrations

will protrude into the lumen of the anoscope through the fenestrations or windows.

16.3.4 Placement of Purse-String Suture and Insertion of Stapler

In TST operation, we can clearly identify the location of the dentate line, through the transparent anoscope. The surgeon can then determine the level of placement of the purse-string suture. A continuous submucosal stitch can be placed at approximately 3–4 cm above the dentate line, and an absorbable monofilament 00 suture can be used (Fig. 16.4). Due to the fenestrations of the anoscope, the interim separation in between the windows will only allow segmental suturing rather than the circumferential suturing as in PPH. During the suturing, we can rotate the anoscope slightly in order to maximizing our grasp of redundant prolapsing tissue.

After completion of the purse-string suture, we will unscrew the stapler completely in a counterclockwise direction in order to fully extend the anvil away from the housing compartment. The anvil is then inserted through the purse-string, of which is subsequently tightened. The shaft of the TST is designed in a longer fashion such as to facilitate easy tightening of the purse-string suture. With continuous traction of the suture, the stapler is closed by clockwise rotation. Two to three separate chunks of rectal tissues are pulled inside the housing compartment until the stapler reaches its firing range. This will be shown by the indicator at the handle of the stapler. The position of the indicator can still have some minor adjustment according to the different thickness of the tissue; this will in turn determine location of anastomosis as well as the leg length of the staples. After tightening the stapler and waiting for 30 s, we can fire the TST stapler, and prolapsing tissues are cut and stapled selectively. The stapler is then released and unscrewed by rotating in a counterclockwise manner. The whole TST stapler along with the resected prolapsing tissue can then be retrieved out of the anus (Fig. 16.5).

16.3.5 Management of Mucosal Bridge and Dog-Ears

After retrieval of the stapler, mucosal bridges (Fig. 16.6) can be seen in between the anastomosis. This is similar to the traditional stapled transanal rectal resection (STARR) operation. These mucosal bridges can be divided simply by

Fig. 16.5 Two prolapsing rectal tissue being pulled into the housing lumen of the stapler

Fig. 16.7 "Dog-ear" formation; terminal end of staple line (*yellow arrow*); normal tissue (*green arrow*)

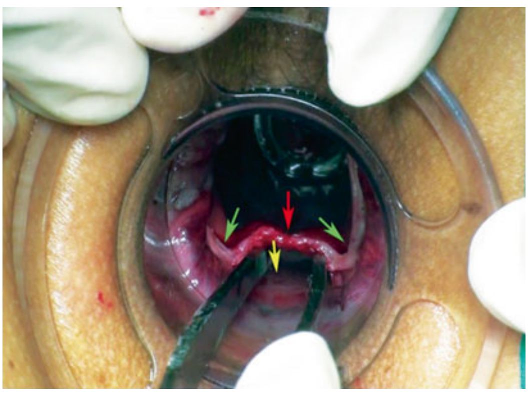

Fig. 16.6 Mucosal bridge in between two staple lines (*red arrow*). Staple lines (*green arrows*); preserved normal mucosa (*yellow arrow*)

scissors. In general, we do not suggest the use of diathermy for fear of collateral damage due to conductivity of titanium staples to electrical current and heat.

The division of mucosal bridge may result in "dog-ear" formation (Fig. 16.7) at the terminal ends of each anastomosis. These again can be ligated. Finally, the anastomosis should be inspected and carefully checked for haemostasis. In case of active bleeding, haemostatic suture can be applied. Residual perianal skin tags can be removed with small incisions. The resected tissue can then be sent for pathological examination.

16.3.6 Advantages of TST

In comparison to PPH, TST made use of the special anoscope to selectively excise the pathological tissue and at the same time preserve normal mucosa. Clinical studies have shown that TST shared the same advantages as PPH, namely, simple operation, less painful, less bleeding and early recovery for patients. TST is also superior to PPH in terms of prevention of anal stenosis, rectovaginal fistula and other complications of circumferential resection including difficulty in defaecation.

TST maximizes the preservation of normal rectal mucosal bridges avoiding circumferential scarring and hence prevent anal stricture. The anoscope wall in between the fenestrations can be placed right next to the rectovaginal septum and prevent the occurrence of rectovaginal fistula. In addition, the preservation of normal mucosa in between the excised tissue will improve sensation, compliance and segmental contraction in the rectal, hence resulting in better anorectal function (Fig. 16.8).

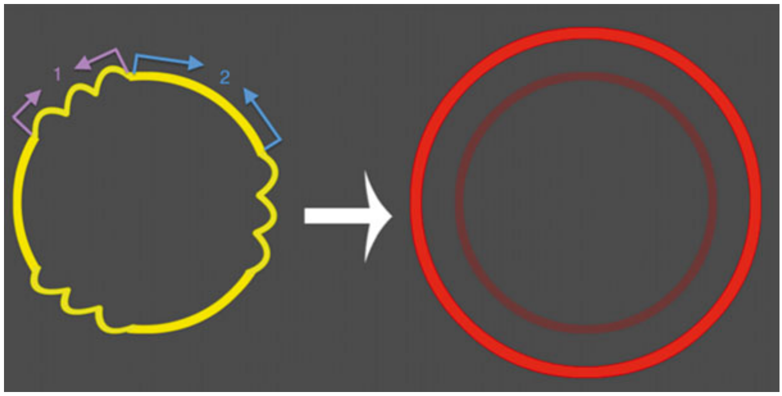

Fig. 16.8 TST maximally preserves the rectal compliance and hence the anorectal function; normal rectal wall (*purple arrow 1*); staple line (*blue arrow 2*)

16.4 TST Stapled Transanal Rectal Resection (STARR+) Operation

The preoperative preparation, anaesthesia and surgical position of tissue-selecting therapy stapled transanal rectal resection-plus (TST STARR+) is the same as TST. The main difference is the increased diameter of the stapler of up to 36 mm. The operative procedure is as follows.

Firstly, the anoscope is inserted after gentle anal dilation. Then the obturator is removed revealing the redundate tissue for removal. A purse-string is placed at about 3–4 cm above dentate line with the use of absorbable polyglactin 00 suture. We should aim for the submucosa for the depth of pursestring placement (Fig. 16.9).

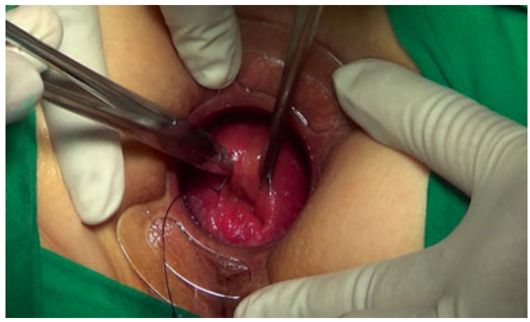

Fig. 16.9 Aiming for the submucosa for the depth of pursestring placement

Additionally, another traction method, we call it parachute technique, can be chosen based upon some surgeons' preference. In this way, traction sutures are placed at six points circumferentially by using absorbable polyglactin 00 suture (Fig. 16.10). The stapler is then unscrewed, and the anvil is fully extended along the shaft and subsequent inserted through the purse-string. The traction sutures are passed through the housing via suture threader. The redundant tissues are encased in the housing when we closed the stapler in a clockwise fashion.

Fig. 16.10 Six points traction stitch (parachute technique)

Finally, the firing range is attained and the staples deployed and tissue cut circumferentially. After waiting for thirty seconds, the stapler is released by anticlockwise rotation of three to four turns. The stapler is then retrieved from the and haemostasis secured. We can see the perirectal fat in the majority of specimen signifying full-thickness excision (Fig. 16.11).

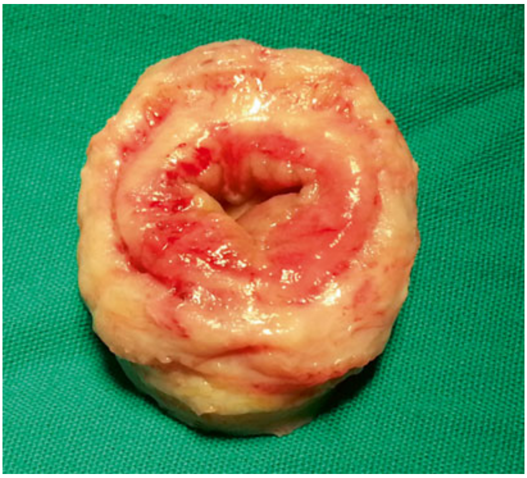

Fig. 16.11 TST Starr+specimen demonstrating perirectal fat signifying full-thickness rectal resection

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17 The Role of High Volume Devices in the Prevention of Residual/Recurrent Haemorrhoidal Prolapse After Stapled Haemorrhoidopexy: Experimental and Clinical Data

Giuliano Reboa and Marco Gipponi

17.1 Background

Haemorrhoids represent one of the most frequent proctologic diseases, ranging in the adult population from 4 to 34 % [1]. Bleeding during or soon after evacuation, anal pain and/or discomfort and haemorrhoidal prolapse are the most common findings. According to the "Unitary Theory of Rectal Prolapse", haemorrhoids are determined by an internal rectal prolapse that can be limited to the rectal mucosa (*mucosal prolapse*) or involve the muscle wall (*full-thickness rectal prolapse*) as well [2]. During defecation, this internal prolapse can descend down to the anal canal, up to or even beyond the anal verge, thus pushing out anorectal mucosa and haemorrhoids. This dynamic prolapse weakens over time the supporting structures, such as *Treitz's* and *Parks'* ligaments, with a progressive sliding down of the haemorrhoids, which is primarily due to the internal recto-anal prolapse.

Stapled haemorrhoidopexy (SH), by correcting the inherent internal rectal prolapse, achieves not only less post-operative pain, superior functional recovery with earlier return to normal activities and improved patient satisfaction with respect to conventional haemorrhoidectomy (CH) but it can also ameliorate the symptoms of obstructed defecation, frequently reported in these patients, thus representing a standard of treatment [3–11]. As a matter of fact, data reported in systematic reviews have clearly demonstrated that SH proved to be superior as compared to CH as for shorter inpatient stay (weighed mean difference, WMD, = 0.95 days; 95 % confidence interval, CI: 1.32–0.59; $P<0.001$), operating time (WMD = 11.42 min; 5 % CI: 18.26–4.59; $P=0.001$), consistent reduction of post-operative pain (42.3 %) both at rest and on defecation, coupled with a 37.6 % reduction in the post-operative requirement for analgesia, faster return to normal activities (WMD = 11.75 days; 95 % CI: 21.42–2.08; $P=0.017$) and less difficulty due to outlet obstruction or anal stenosis (Relative Risk, RR = 0.51: 0.15–1.47), with an overall similar incidence of recurrent haemorrhoidal symptoms [8–12].

However, SH is associated with a higher rate of objective recurrent haemorrhoidal prolapse (RR = 2.29–3.85). This observation cannot simply be explained by a less than optimal surgical technique but, mostly, to the extent of the internal rectal prolapse that is associated to the haemorrhoids. Actually, 30–40 % of patients with haemorrhoids have a large internal rectal prolapse,

G. Reboa, MD
Colo-Proctology Unit,
Casa di Cura San Camillo – Forte dei Marmi,
Lucca, Italy

M. Gipponi, MD (✉)
General Surgery and Breast Unit,
IRCCS "San Martino-IST",
L.go R. Benzi, 10 – 16132, Genoa, Italy
e-mail: marco.gipponi@hsanmartino.it

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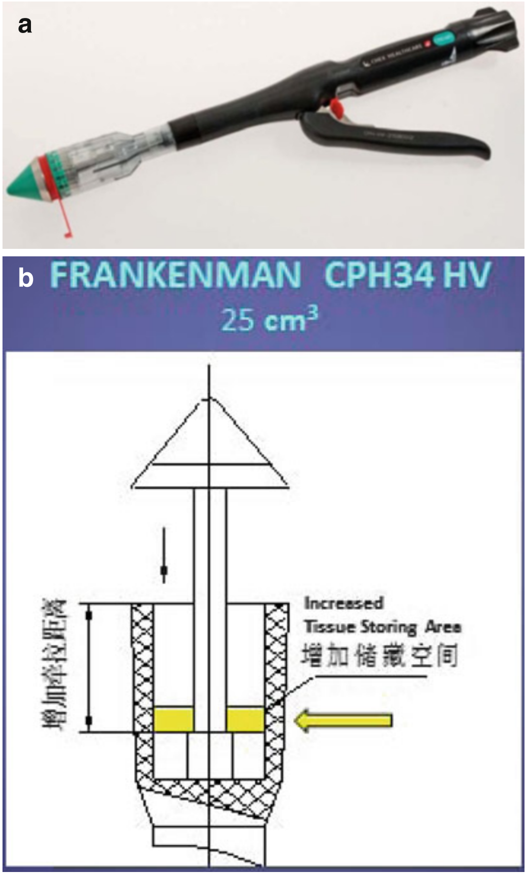

Fig. 17.1 (**a**) CPH34 HV. (**b**) Section of CPH34 HV

which is a prolapse exceeding more than half of the length of the Circular Anal Dilator (CAD) at the intraoperative assessment, and haemorrhoidal recurrence after SH can be expected in up to 29.4 % of these cases [13, 14].

So, the real problem is to perform an adequate prolapse resection in order to avoid a residual/recurrent disease. However, currently available stapler devices pose some questions as to the extent of rectal prolapse that can be actually resected, especially in such patients with a large internal rectal prolapse. In order to accomplish a more satisfactory prolapse resection, stapled transanal rectal resection (STARR) was proposed as a surgical option instead of SH to overcome such technological limitations, with a significant reduction of residual and/or recurrent haemorrhoids up to 1.9–9.6 % [13–15].

Recently, a new device for trans-anal stapler-assisted surgery, CVPH34 HV (Fig. 17.1a, b), has been developed with a high volume (HV) stapler casing (25 cm^3) in order to guarantee a wider prolapse resection as compared to most of currently available staplers such as PPH03-33, whose estimated volume of the casing is equal to 17.4 cm^3 [14].

For these reasons, firstly, an experimental study was performed to test the efficacy and the safety of this new instrument as compared to the other available devices dedicated to stapler-assisted trans-anal surgery for haemorrhoids; hence, its performance as regards the reduction of residual/recurrent haemorrhoidal prolapse after SH was verified into the clinical setting.

17.2 Experimental Study [16]

17.2.1 Materials and Methods

A total of 16 pigs (mean weight, 40 kg; standard deviation (SD), 1.5 kg) were selected to undergo a stapled transanal rectal resection at the Experimental Center of Vila do Conde (Centro de Cirurgia Experimental Avancada, Portugal) in October 2010. They were randomly assigned to rectal prolapsectomy with PPH03-33 (Ethicon Endo-Surgery, Inc., Rome, Italy) in four cases, CPH34 (Chex Surgical Staplers; Frankenman International Limited, Hong Kong) in four cases, CPH34 HV (Chex Surgical Staplers) in four cases, HEEA (Covidien; Tyco Healthcare Group LP, Norwalk, CT, USA) in two cases and PPH-01 (Ethicon Endo-Surgery, Inc.) in two cases, performing an anterior and posterior rectal resection using two stapler devices in one procedure. The stapler casing or tissue storing volume was calculated and gave the following measures: 25 cm^3 for CPH34 HV, 20.6 cm^3 for CHP34, 22.5 cm^3 for HEEA and 17.4 cm^3 for PPH03-33 and PPH-01.

The pigs were monitored for 3 days before autopsy in order to detect early and delayed post-operative complications such as suture bleeding, intraparietal or extra-wall haematoma, suture dehiscence, pelvic infection and damage to surrounding organs. In each case, the length, height, weight and volume of the resected specimen were determined by the same examiner; the volume was calculated using a graduated ampulla filled with saline solution, by measuring the volume increase when the surgical specimen was put into the ampulla. A histological examination was blindly performed regarding the type of stapler used, and the pathologist also calculated the percentage of mucosa, submucosa and muscularis propria within the surgical specimen. Moreover, transrectal echotomography (ETG) was performed on the third post-operative day to check for the development of extrarectal haematoma or surrounding organ damage. The study protocol was submitted and approved by the Ethic Committee of the Institution.

17.2.1.1 Stapled Transanal Rectal Resection

Surgery was performed under general anaesthesia, with the pig placed in a lithotomy position. Controlled digital stretching was performed initially with two fingers (index fingers) introduced carefully inside the anus, to perform a moderate traction laterally (gradually separating the two index fingers) and in an antero-posterior direction, in order to ease the introduction of the CAD that was manually held in place during the operation. Once the obturator was removed, the operative anoscope was inserted into the lumen of the CAD and a 2-0 Prolene purse-string suture was performed approximately 3–4 cm above the dentate line, in order to make the anastomotic line at the end of the procedure approximately 2–3 cm proximal to the dentate line. The circular stapler was inserted fully open and the purse-string suture was secured to the central axis. The suture threads were then retrieved through the suture conduits positioned on either side of the head and secured in a manner to allow gentle digital pressure on the suture to draw the tissue into the stapler casing. When the HEEA stapler was used, the lowest anchor point (more proximal with respect to the surgeon) was selected on the central rod of the anvil and the purse string was secured and knotted. The stapler was then fired in order to perform the prolapsectomy and rectopexy. Once the stapler was removed, the integrity of the mucosal cylinder removed (doughnut) was checked. After prolonged observation for 5 min to check that haemostasis was complete, an absorbable plug was placed in the anal canal. This concluded the intervention.

17.2.1.2 Statistical Analysis

The comparison between the different types of staplers was performed using analysis of variance (ANOVA) with Scheffe internal comparisons and the non-parametric Kruskal-Wallis test. The differences between CPH34 HV and PPH1 were analysed using the unpaired student's *t*-test. The level of significance was set at $p = 0.05$. Statistical analysis was carried out with StatView (SAS Institute, Cary, NC, USA)

17.2.2 Results

The mean operative time was 20 min (standard deviation, SD = 2.5 min). The measurements of the surgical specimen are reported in Table 17.1. Significant differences of the volumes and weights of the resected specimens were observed by type of stapler ($P = 0.0298$ and $P = 0.0278$ with ANOVA test, respectively, confirmed with non-parametric test). Notably, for both volume and weight, this observation was mainly due to the staplers CPH34 HV and PPH03-33 (by means of internal comparison: $P = 0.0402$ and $P = 0.0375$, respectively).

The average percentages of volumes were 17.1 % lower for CPH34, 30.2 % lower for HEEA and 34.7 % lower for PPH03-33 with respect to CPH34 HV, with a relative differential increase for CPH34 HV ranging from 20 to 53 %. No significant increase of the resection volume (7.5 %) was observed between STARR with two PPH-01 (considering the two operative specimens) vs a single CPH34 HV. Moreover, CPH34 allowed resection volume increases of 15.7 % compared to HEEA and 21.1 % compared to PPH03-33. Finally, HEEA gave a resection volume increase of 6 % compared to PPH03-33.

With regard to the histological examination, the surgical specimens were always represented by normal anorectal wall, including mucosa, submucosa and *muscularis propria*, whose

Table 17.1 Measures of the surgical specimens

Stapler	Length (mm)	Height (mm)	Weight (g)	Volume (ml)
CPH34 HV (*n*=4)	90-90-80-94	60-56-35-58	13.8-14-10-10.5	14-14-10-11
Mean	88.5	52.25	12.07	12.25
SD	5.9	11.6	2.1	2.0
CPH34 (*n*=4)	100-85-92-111	60-45-56-53	12-8-8-10.5	12.5-8.5-8.6-11
Mean	97	53.5	9.6	10.15
SD	11.1	6.3	1.9	1.9
HEEA (*n*=2)	85–95	36–45	7.0–9.5	7.2–9.9
Mean	90	40.5	8.25	8.55
SD	7.0	6.3	1.7	1.9
PPH03-33 (*n*=4)	84-90-95-85	47-40-35-32	8.5-8-6.7-7.8	9-8-7-8
Mean	88.5	38.5	7.75	8.0
SD	5.0	6.5	0.7	0.8
PPH-01[a] (*n*=2)	120–110	70–60	13–12	13.5–13
Mean	115	65	12.5	13.25
SD	7.0	7.0	0.7	0.3

SD standard deviation
[a]Sum of the corresponding measures of the two tissue samples

Table 17.2 Percentage of mucosa, submucosa and *muscularis propria* within the surgical specimen by type of stapler

Stapler	Mucosa (%)	Submucosa (%)	*Muscularis propria* (%)
CPH34 HV (n=4)	15	35	50
	25	25	50
	5	45	50
	30	20	50
Mean	*18.75*	*31.25*	*50*
CPH34 (n=4)	25	25	50
	10	40	50
	20	40	40
	15	35	50
Mean	*17.50*	*35*	*47.5*
HEEA (n=2)	20	30	50
	20	30	50
Mean	*20*	*30*	*50*
PPH03-33 (n=4)	20	40	40
	15	35	50
	10	40	50
	20	40	40
Mean	*16.25*	*38.75*	*45*
PPH-01[a] (*n*=2)	15	40	45
	20	35	45
Mean	*17.50*	*37.50*	*45*

[a]Sum of the corresponding measures of the two tissue samples

percentages are reported in Table 17.2. The highest percentage of *muscularis propria* was observed into the surgical specimens collected with CPH34 HV and HEEA (50 %), followed by CPH34 (47.5 %), and PPH03-33 and PPH-01 (45 %).

No intraoperative or early post-operative complications occurred. Transrectal ETG detected three intraparietal haematomas ranging from 3 to 15 mm (one with each of CPH34 HV, PPH03-33 and PPH-01) and two extrarectal haematomas (one with each of CPH34 and HEEA) which were always confirmed at autopsy.

17.2.3 Conclusions

The results of this experimental study confirmed the safety and the higher volume of resection achievable with CPH34 HV, with an increase of the volume of rectal wall resection ranging from 20 to 53 % compared to other currently available staplers. The higher volume of resection obtained with CPH34 HV correlated well with the corresponding weight of the specimens and their percentage of *muscularis propria*. Hence, notwithstanding the similar square surface, CPH34 HV guaranteed a thicker specimen of resection compared to the other types of stapler. As the weight and volume provide better information regarding the extent of prolapse resection compared to the resection dimensions (length and height), these parameters should always be collected when assessing the quality of resection and the efficacy of SH or STARR procedures.

On these grounds, a retrospective observational multicenter clinical study was undertaken in patients with haemorrhoidal prolapse undergoing SH by means of CPH34 HV with the aim of assessing its safety and efficacy, with special care to the haemostatic properties of this HV stapler as well as the adequacy of prolapse resection and control of residual/recurrent disease.

17.3 Clinical Study

17.3.1 Patients and Methods

The clinical charts of 430 patients with symptomatic third- or fourth-degree haemorrhoids, 18–80 years of age, who underwent SH in the period 2012–2013 were consecutively reviewed. The study group consisted of 209 (48.6 %) males and 221 (51.4 %) females with a mean age of 51 years (SD, 13.4 years; range, 19–80 years). All patients underwent complete preoperative proctologic examination, with flexible colonoscopy performed according to age, risk factors for colorectal cancer and associated bowel symptoms. The clinical characteristics of patients are reported in Table 17.3. Patients with symptoms of obstructed defecation syndrome (ODS) who had an internal rectal prolapse associated to second degree rectocele (2–4 cm), and a Wexner's constipation score more than 15 did not undergo SH but were eligible to the STARR procedure [17].

Table 17.3 Clinical characteristics of patients ($N=430$)

		N	%
Age, years			
Mean (SD)	51 (13.4)		
Range	19–80		
Sex			
Male		209	48.6
Female, *n*. (%)		221	51.4
Specific symptoms:			
Pain score (VAS: 0–10)			
Mean (SD)	4.2 (2.1)		
Range	0–10		
Bleeding, *n*. (%)		363	84.4
Haemorrhoidal prolapse, *n*. (%)		363	84.4
Constipation, *n*. (%)		190	44.2
Soiling, *n*. (%)		57	13.3
Diarrhoea, *n*. (%)		53	12.3
Goligher's classification:			
III		169	39.3
IV		261	60.5
Constipation Scoring System			
Mean (SD)	9.3 (3.6)		
Range	1–15		
Previous anorectal surgery		55	12.8

SD standard deviation

Patients usually underwent a one-day surgical procedure, with a preoperative self-administered rectal enema on the evening before and the morning of the operation; no antibiotic prophylaxis was given. Each patient gave his/her written informed consent and the study protocol was submitted to the Ethic Committee approval.

Preoperative clinical data included (i) specific symptoms of haemorrhoids such as pain (Visual Analogue Scale, VAS = 0–10), (ii) bleeding, (iii) haemorrhoidal prolapse/swelling, (iv) Wexner's Constipation Scoring System (CSS = 0–30) and (v) Goligher's classification of haemorrhoids (III or IV degree). Perioperative data included (i) operative time, (ii) surgical team, (iii) intraoperative assessment of the extent of internal rectal prolapse, (iv) associated procedures, such as excision of skin tags, excision of anal fissure, fistulotomy/fistulectomy, etc., (v) technical failures of the stapler, (vi) specimen sizes (length, height and volume), (vii) early complications (within 7 days), such as spontaneous or post-defecation anal pain, bleeding, urinary retention, faecal impaction, faecal urgency and haemorrhoidal thrombosis; (viii) inpatient stay (days) and (ix) early reoperations (within 30 days) due to bleeding, haemorrhoidal thrombosis, dehiscence of the staple line, severe anal pain or abscess.

Clinical follow-up consisted of outpatient visits that were scheduled at 6 and 12 months after the operation, as soon as the complete healing was achieved. Residual prolapse was defined as the reduction, without disappearance, of prolapsed tissue (haemorrhoids and/or rectal prolapse) within 6 months after the operation; recurrent disease was defined as the reappearance of prolapsed tissue after a symptom-free period of at least 6 months. Moreover, clinical follow-up data included (i) post-operative complaints such as urgency, itching, mucous discharge haemorrhoidal thrombosis and faecal incontinence (grade I: gas, grade II: liquid stool, grade III: solid stool), (ii) late postoperative complications such as local or systemic infections, anal fissures, anal fistula, recto-vaginal fistula, residual skin tags, anorectal stenosis, (iii) associated symptoms of recurrent haemorrhoidal disease, such as anal pain (spontaneous and/or post-defecation: VAS = 0–10) or bleeding and (iv) grade of satisfaction (VAS = 0–10) and (v) the CSS score (range: 0–30).

17.3.2 Surgical Details

The operation was always performed by surgeons who were well trained in stapler-assisted transanal surgery, having performed at least 50 SH and 30 STARR procedures. Patients usually underwent spinal anaesthesia, and were placed in a lithotomic position with a *Trendelenburg*'s tilt. Controlled digital stretching was performed initially with two fingers (index fingers) introduced carefully inside the anus and performing moderate traction laterally (gradually separating the two index fingers) and in an antero-posterior direction with fingers stretched (taking care not to hook the muscles of the pelvic floor). Then, the fingers were moved in a circular motion around the anus to gently break the inner sphincter fibres. Afterwards, two fingers on each hand were inserted repeating the circular motion to increase anal dilatation. Then, the lubricated CAD was inserted with an obturator, an integral part of the CPH34 HV™ kit (Frankenman International Limited, Hong Kong). This was sutured to the perianal skin with four stitches. Once the obturator was removed, an intraoperative assessment of the rectal prolapse was accomplished in order to define whether it involved more than half of the length of the CAD. A surgical anoscope was then inserted into the lumen of the CAD and a 2-0 Prolene purse-string suture was undertaken about 4–5 cm above the dentate line, to make the suture line at the end of the procedure approximately 2–3 cm proximal to the dentate line. The head of the circular stapler was introduced fully open proximal to the purse-string, which was tied with a closing knot; the ends of the suture were then pulled through the lateral holes of the instrument.

When the "Parachute" technique was used instead of a traditional Longo's procedure (i.e., with the single purse-string suture), six separated stitches at 3, 9, 1, 11, 5 and 7 h or 12, 6, 2, 5, 7 and 10 h were placed proximally at the same distance from the dentate line, as previously described. The single suture threads were secured to each other in two groups in order to allow them to be retrieved through the lateral suture conduits positioned on the right and left side of the circular stapler [18].

With both procedures, the ends of the sutures were fixed externally using a clamp and a gentle digital pressure on the sutures was maintained while tightening the stapler to draw the prolapsed rectal wall into the stapler casing. Hence, the stapler was fired in order to perform the prolapsectomy and rectopexy, having completed all necessary check to avoid recto-vaginal fistula. Once the stapler was removed, the integrity of the mucosal cylinder removed (doughnut) was checked measuring into the operative room the specimen measures (length, mm, height, mm and volume, ml with a graduated ampulla half filled with water), and then sent for histological examination. Haemostatic stitches were placed along the suture line in reabsorbable material (Vicryl 3-0) when required, and their number was recorded into the operative description. After prolonged observation to check for haemostasis, an absorbable plug was placed into the anal canal, thus concluding the intervention.

17.4 Results

Intraoperatively, 341 (79.3 %) patients out of 430 had an internal rectal prolapse exceeding more than half of the length of the CAD while 89 (20.7 %) had a rectal prolapse within half of the length of the CAD. A standard *Longo*'s procedure was performed in the great majority of patients ($n = 394$; 91.6 %) while the "Parachute" technique was used in 36 patients (8.4 %). The mean operative time was 26.1 (SD, 6.9; range, 15–60) min. One technical failure of the device did occur (0.2 %) without any untoward effect as for the operation; only in a minority of patients haemostatic stitches were required to achieve complete haemostasis of the suture line, with a mean number of 1.3 stitch/patient (SD, 1.7; range, 0–7). Associated procedures were performed in 168 (39 %) of patients, such as skin tags excision ($n = 73$; 43.4 %), anal

Table 17.4 Intra- and early post-operative findings ($N=430$ patients)

		N	%
Operative time, min			
Mean (SD)	26.1 (6.9)		
Range	15–60		
Prolapse involving more than half of the length CAD			
No		89	20.7
Yes		341	79.3
Type of prolapsectomy			
Traditional "stapled anopexy"		394	91.6
"Parachute" technique		36	8.4
Haemostatic stitches, *n*.			
Mean (SD)	1.3 (1.7)		
Range	0–7		
Technical failures of the device		1	0.2
Associate procedures, *n*. (%)		168	39.0
Skin tags excision		73	43.4
Anal fissure		53	31.4
Condiloma		17	10.2
Fistulotomy/fistulectomy		5	3.0
Miscellaneous		20	12.0
Hospital stay, days			
Mean (SD)	1.6 (1.0)		
Range	1–4		
Early post-operative complications		62	14.4
Anal pain (spontaneous/post-defecation)		28	6.5
Bleeding		12	2.8
Acute urinary retention		5	1.2
Urgency		14	3.3
Thrombosed haemorrhoids		1	0.2
Others		2	0.4
Re-operation (within 30 days)		2	0.4

SD standard deviation

fissure diathermy ($n=53$; 31.4 %), condiloma excision ($n=17$; 10.1 %) and fistulotomy/fistulectomy ($n=5$; 3.0 %). The mean in-hospital stay was 1.6 days (SD, 1; range, 1–4); it was prolonged beyond 1 day in 20 patients (4.6 %) due to mild bleeding or post-operative pain, representing the more frequent early post-operative complications (Table 17.4). After stratification by the extent of the internal rectal prolapse, the mean volume of the doughnuts was significantly higher (13.8 ml; SD, 1.5) in the group of 341 patients with an internal rectal prolapse exceeding more than half of the length of the CAD than in the group of 89 patients with smaller prolapse (8.9 ml; SD, 0.7) (P-value <0.05) (Table 17.5).

As regards follow-up data at 6 months, residual haemorrhoidal disease occurred in 8 out of 430 patients (1.8 %), 6 of them (75 %) having originally a large internal rectal prolapse. Moreover, a high index of patient satisfaction (VAS = 8.3; SD, 1.2) and a clinically relevant reduction of the constipations scores (CSS = 6.0; SD, 2.6) were reported (Table 17.6). Recurrent haemorrhoidal disease was detected at 12-month follow-up in 5 out of 254 patients (1.9 %), all of them having originally a large internal rectal prolapse; again, a high index of patient satisfaction (VAS = 8.9; SD, 0.9) coupled with a persistent reduction of constipation scores (CSS = 5.0, SD, 2.2) was observed (Table 17.7).

Table 17.5 Specimen measures stratified by type of prolapsectomy (traditional Longo's procedure or "Parachute" technique) and extent of rectal prolapsed

	Mean (SD)	Range	
Total patients ($n=430$)			
Length, mm	82.8 (11.3)	65–96	
Height, mm	37.5 (4.3)	28–45	
Volume, ml	12.7(2.1)	7–18	
Stapled anopexy ($n=394$)			
Length, mm	82.5 (11.3)	65–92	
Height, mm	37.4 (4.3)	28–45	
Volume, ml	12.4 (2.1)	7–15	$P = 0.09$
"Parachute" technique ($n=36$)			
Length, mm	85.6 (5.2)	83–96	
Height, mm	38.7 (2.3)	33–43	
Volume, ml	15.1 (1.8)	12–18	
Prolapse more than half of CAD ($n=341$)			
Length, mm	85.0 (5.6)	80–96	
Height, mm	38.4 (3.9)	35–45	
Volume, ml	13.8 (1.5)	10–18	$P < 0.05$
Prolapse less than half of CAD ($n=89$)			
Length, mm	75.0 (16.3)	65–85	
Height, mm	34.7 (4.3)	28–43	
Volume, ml	8.9 (0.7)	7–10	

SD standard deviation

Table 17.6 Follow-up at 6 months in 430 patients

		N.	%
Residual disease (within 6 months)			
Spontaneous pain score (VAS: 0–10)			
Mean (SD)	1.6 (1.2)		
Range	1–7		
Pain at defecation (VAS: 0–10)			
Mean (SD)	1.8 (1.2)		
Range	1–7		
Bleeding, *n.* (%)		6	1.4
Residual haemorrhoidal prolapse		8	1.8
Other symptoms/signs			
Urgency		20	4.7
Pruritus		2	0.4
Soiling		1	0.2
Incontinence		0	–
Anal stenosis		1	0.2
Anal fissure/abscess/fistula		0	–
Haemorrhoidal thrombosis		1	0.2
Residual skin tags		10	2.3
Patient satisfaction (VAS: 0–10)			
Mean (SD)	8.3 (1.2)		
Range	2–10		
Constipation Scoring System			
Mean (SD)	6.0 (2.6)		
Range	0–14		

SD standard deviation

Table 17.7 Follow-up at 12 months in 254 patients

		N.	%
Recurrent disease (after 6 months)			
Spontaneous pain score (VAS: 0–10)			
Mean (SD)	1.3 (0.8)		
Range	1–3		
Pain at defecation (VAS: 0–10)			
Mean (SD)	1.2 (0.4)		
Range	1–2		
Bleeding, *n.* (%)		1	0.4
Residual haemorrhoidal prolapse		5	1.9
Other symptoms/signs			
Urgency		3	1.2
Pruritus		1	0.4
Soiling		1	0.4
Incontinence		0	–
Anal stenosis		0	–
Anal fissure/abscess/fistula		0	–
Haemorrhoidal thrombosis		1	0.4
Residual skin tags		12	4.7
Patient satisfaction (VAS: 0–10)			
Mean (SD)	8.9 (0.9)		
Range	6–10		
Constipation Scoring System			
Mean (SD)	5.0 (2.2)		
Range	0–13		

SD standard deviation

Conclusions

The interim analysis of this retrospective multicentric clinical study in patients undergoing SH by means of CPH34 HV for haemorrhoids, with a high prevalence (79.3 %) of associated large internal rectal prolapse, suggests that the higher volume of the doughnuts well correlated with a clear-cut reduction of both residual (1.8 %) and recurrent (1.9 %) haemorrhoidal prolapse, which translated into a high index of patient satisfaction and clinically relevant reduction of constipations scores, thus emphasizing the need to perform a more than complete prolapse resection.

Worth of note, such findings are even better than most of the previous clinical experiences with the STARR procedure [13–15]. Moreover, both intra- and early post-operative bleeding complications were seldom reported, thanks to the haemostatic properties of this new stapler device; complete follow-up data will define further the safety and efficacy of this new stapler device.

Disclosure The authors have no conflict of interest in any of the products, devices, or drugs mentioned in this chapter.

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18 Transanal Hemorrhoidal Dearterialization (THD)

Cyrus Tak Yin Tse

18.1 Introduction

Hemorrhoids remain a highly prevalent anal disorder, affecting both genders over a wide age spectrum. Around half of these patients will experience symptoms to various degrees, most commonly presenting with per rectal bleeding, prolapse, or anal pain. Hemorrhoids originating above the dentate line are known as internal and those below the dentate line are termed external. The Goligher classification is commonly used to classify the severity of hemorrhoids into four grades [1]. Management usually begins conservatively with dietary advice and lifestyle modification and extends to procedures that can be performed under most clinic settings including rubber band ligation, sclerotherapy, or infrared coagulation. Nonetheless, many patients eventually require more definitive surgical treatment which can be broadly classified into conventional hemorrhoidectomy (Milligan-Morgan or Ferguson), stapled hemorrhoidopexy, or transanal hemorrhoidal dearterialization (THD).

C.T.Y. Tse
Department of Surgery, Tuen Mun Hospital,
23 Tsing Chung Koon Road, Tuen Mun,
NT, Hong Kong
e-mail: cyrus.tse@utoronto.ca

18.2 Background of THD

THD was first introduced by Morinaga in 1995 and is now most commonly defined as a Doppler-guided localization and transfixion of the terminal branches of the superior rectal artery with or without mucopexy [2]. It is also referenced in some literature as hemorrhoidal artery ligation (HAL) or Doppler-guided HAL (DGHAL).

Aigner and his team in Austria did anatomical study and demonstrated that terminal branches of superior rectal artery solely contribute to the arterial blood supply of the hemorrhoidal plexus and that these branches are dilated with increased blood flow in patients with hemorrhoidal disease [3, 4]. Therefore, it has been hypothesized that controlling the inflow of blood from these arterial branches will improve hemorrhoidal control.

18.3 Technique on Dearterialization and Mucopexy

THD is performed with a specially designed protoscope coupled with a Doppler transducer, where after inserting into the anal canal will assists in mapping out the terminal arterial branches in the hemorrhoidal cushions (Fig. 18.1). Then plication sutures are applied over these sites around 2–3 cm above the dentate line, aiming at a reduction in blood inflow and subsequently shrinkage of the

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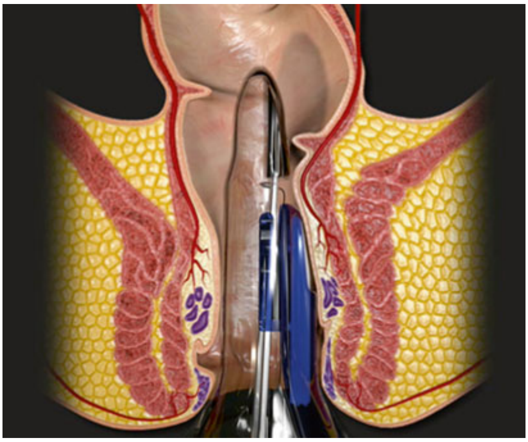

Fig. 18.1 Specially designed protoscope couple with Doppler transducer for arterial mapping and ligation

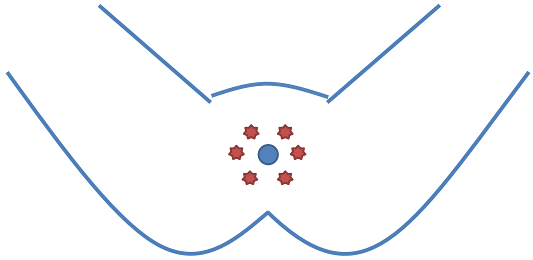

Fig. 18.2 Common locations of the terminal branches of superior rectal artery at 1, 3, 5, 7, 9, and 11 o'clock positions

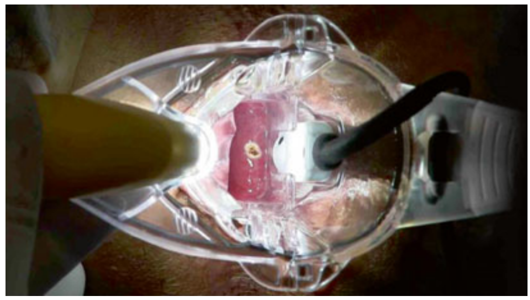

Fig. 18.3 Using a diathermy to mark the site with maximal Doppler signal

hemorrhoidal cushions and symptomatic relief. Most surgeons advocate the application of six sutures roughly at the 1, 3, 5, 7, 9, and 11 o'clock positions, but this can be expanded up to eight sutures if necessary (Fig. 18.2). This part of the procedure is also known as distal Doppler-guided dearterialization (DDD).

As it has been proposed that mucosal prolapse is a predictor for disease recurrence and also need for second procedure, commonly a concurrent mucopexy is added to dearterialization. Ratto advised performing the mucopexy by first using a diathermy to mark the site with maximal Doppler signal and then pushing the protoscope fully back into distal rectum [5] (Fig. 18.3). Starting with a "Z-stitch" at the apex, a running suture is placed at 5 mm intervals cranial-caudally until the distal mark is seen again. There the surgeon carefully continues by running the suture just proximal and distal to the marker in order to entrap the hemorrhoidal artery, in essence performing a DDD (Fig. 18.4). Finally, the suture is tightened with the proximal apex stitch end, lifting the loosened connective tissues of the hemorrhoidal cushion and resulting in a mucopexy (Fig. 18.5). In one study performing a mucopexy instead of a simple figure-of-8 plication has decreased the recurrent prolapse rate from 6 to 3.7 % and 50 to 11.1 % in third- and fourth-degree hemorrhoids, respectively, although both failing to reach statistical significance due to a small sample size [6].

18.4 Complications and Results

THD can be performed under locoregional or general anesthesia, and since there is no excision involved, it is believed that it can be safely performed in patients with relatively high operative risk. Postoperative complications remain rare although there have been reported cases of significant postoperative hemorrhage up to 1.3 L [7]. There has also been one single case report of a patient complicated with brain abscess after THD [7].

A systematic review of 17 studies and 1,996 patients shows that at 1 year or more postoperatively, the recurrence rate was 10.8 % for prolapse, 9.7 % for bleeding, and 8.7 % for pain [8]. The recurrence rate was, expectedly, most severe in fourth-degree hemorrhoids. The conclusion of the authors is that THD is a potential non-excisional technique for the treatment of second-degree and third-degree hemorrhoids, with minimal postoperative pain and quick recovery.

Long-term results of THD are lacking, together with the evolving technique and custom

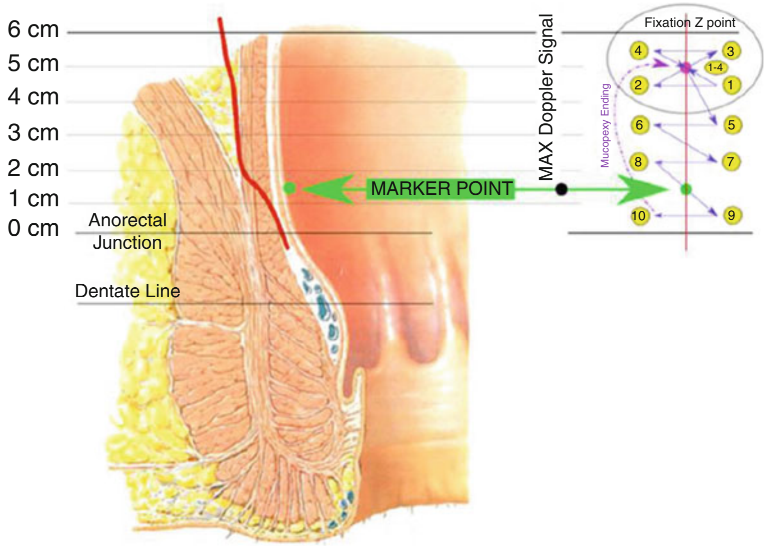

Fig. 18.4 Suturing schema with reference to the diathermy marker point

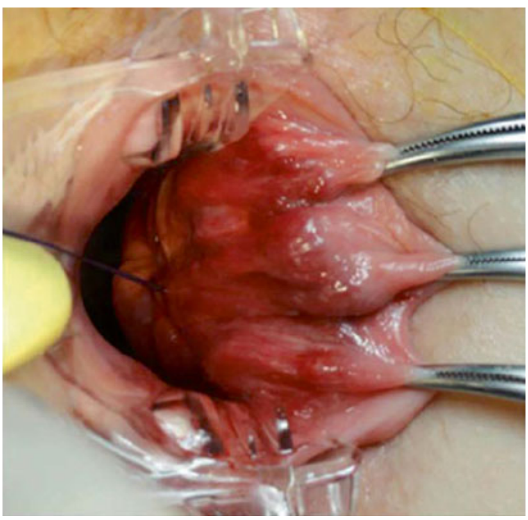

Fig. 18.5 Tying the proximal and distal stitch ends to complete the mucopexy

device, making the sustainability of effect questionable. One of the studies with the longest follow-up was by Dal Monte where 219 patients were followed up for a mean of 46 months (22–79 months) [6]. In this group recurrent bleeding rate is 10/142 (7.0 %), and recurrent prolapse rate is 9/119 (7.6 %).

A NICE (National Institute for Health and Clinical Excellence) guideline under NHS (National Health Service) published in May 2010 states that current evidence on hemorrhoidal efficacious alternative to conventional hemorrhoidectomy and stapled hemorrhoidopexy in the short and medium term and that there are no major safety concern [9].

18.5 Postoperative Pain

Postoperative pain appears to be minimal across most studies, although the true difference compared to other treatment modalities is uncertain. In a non-blinded randomized trial comparing THD to open hemorrhoidectomy, the early postoperatively peak pain score is lower in the THD group, but there is no difference in average pain score or analgesic requirement [10]. Comparing with stapled hemorrhoidopexy, it appears that both postoperative pain and analgesic intake are lower with THD [11, 12].

18.6 Anorectal Physiology

Effect of THD on anorectal physiology has been studied in 20 patients, with clinical assessment, anorectal manometry, rectal volumetry, and endorectal ultrasound all performed preoperatively and at 6 months postoperatively [13]. After THD, there is no reported urgency or fecal incontinence, and there is no difference between the pre- and postoperative manometry. The functional anal canal length, high pressure zone, and rectal sensation values remain unchanged. The recto-anal inhibitory reflex (RAIR) remains normal, and both internal and external sphincters are intact on endorectal ultrasound. The author concluded that THD does not alter anorectal function or physiological parameters.

18.7 Impact of Doppler Transducer

Financial impact of THD has been debated because a standard Doppler kit costs upward of 300 Euros. A Dutch study has been carried out to compare hemorrhoidal artery ligation with or without the Doppler transducer and concluded that at 6 weeks and 6 months after the operation, there is significant improvement with regard to blood loss, pain, prolapse, and problems with defecation in both arms [14]. However, adding the Doppler transducer does not seem to contribute to this beneficial effect. In the same study no additional procedure is required in the non-Doppler group, but two additional hemorrhoidectomies and three additional rubber banding procedures are performed in the Doppler group. The authors hypothesized that it seems unnecessary to ligate the main artery itself, but compromising the blood flow in the microcirculation of the pathological tissue may suffice.

18.8 Emergency THD

THD has also been shown to be effective in emergency setting. In an Italian study by Cavazzoni, 11 patients with severe anal bleeding underwent emergency THD with successful hemostasis [15]. There were no major complications, and no patient required a blood transfusion. Also worth noting is 7 of the 11 patients were on antiplatelet agent and/or warfarin, where the medications were not discontinued in all but one patient.

18.9 Our Experience

In our center most of the patients selected for THD have severe per rectal bleeding and anemia prior to the procedure, with a mean hemoglobin of 6.5 g/dL (4.4–9.6 g/L). The mean operative time is 55.4 min (37–82 min), and there is no transfusion needed intra- or postoperatively. There is no major complication postoperatively, and all patients reported immediate significant improvement in terms of bleeding control. All patients are discharged the day after the operation as a protocol of our unit, although it certainly appears feasible to perform THD as an ambulatory day surgery. With subsequent follow-up up to 19 months, 1/11 patients reported recurrent bleeding after 16 months and subsequently underwent a stapled hemorrhoidopexy. There is no reported chronic pain, recurrent prolapse, or anal stricture.

We also found THD to be a potentially beneficial alternative to patients with otherwise challenging situations. One of the patients had end-stage renal failure together with multiple comorbidities, was immunocompromised, and was put on aspirin. He presented second-degree hemorrhoids with massive per rectal bleeding and a hemoglobin level of 4.9 g/dL. He was determined unfit for general anesthesia, and we wanted to avoid excisional procedure if possible. A THD was performed for him with immediate and complete termination of his per rectal bleeding.

Another patient was referred to us after undergoing an unsuccessful stapled hemorrhoidopexy, complicated with persistent per rectal bleeding and moderate anal stricture. Both conventional hemorrhoidectomy and a second stapled hemorrhoidopexy were determined unsuitable due to the anal stricture, so a THD was performed and the patient remains asymptomatic up to follow-up at 19 months.

Conclusion

The literature supports THD as a non-excisional alternative for the treatment of hemorrhoids, with promising short- to medium-term result, offering good control of bleeding, minimal postoperative pain, and quick recovery.

Adding a mucopexy to arterial ligation may assist in preventing recurrent prolapse. Postoperative complications are rare, and it can be considered even in high-risk patients or in emergency setting. Long-term results are lacking at this moment, and recurrence appears considerably higher in fourth-degree hemorrhoids. Larger-scale comparative studies with longer follow-up will be needed to determine its true efficacy.

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19 Ligation of the Intersphincteric Fistula Tract (LIFT)

Oswens Siu Hung Lo

19.1 Introduction

Anal fistula is one of the most common anorectal diseases pertaining and its treatment strategies have been described in the most ancient medical literatures [1]. A fistula is defined as an abnormal communication between two epithelial surfaces. Anal fistula is a communication between the anorectal mucosa and the perianal skin. Most of the anal fistulas are originated from the infection of anal glands which are connected to the anal crypts at the dentate line (cryptoglandular origin) [2].

Parks' classification of anal fistulas [3] is the most commonly used to describe the anatomy of anal fistulas (Fig. 19.1a): (a) intersphincteric: if the tract lies between the internal and external sphincteric muscles; (b) transphincteric: if the tract crosses the external sphincteric muscles from the anus to the perineum; (c) suprasphincteric: if the tract starts in the intersphincteric plane and extends upward into the supralevator compartment, where it can break through the levator diaphragm into the ischiorectal fossa, discharging into the perineum; and (d) extrasphincteric: if the tract enters the rectum outside the anorectal ring.

O.S.H. Lo
Department of Surgery,
The University of Hong Kong, Hong Kong, China
e-mail: oswenslo@yahoo.com

Simple fistulas such as intersphincteric or low transsphincteric fistulas can be treated successfully with fistulotomy without high risk of incontinence. For complex fistulas, the decision of surgical interventions may be in a dilemma as higher risk of incontinence and postoperative recurrence. Different management strategies, including fistulotomy, fistulectomy, seton placement, anorectal advancement flap, fibrin glue, and anal fistula plug, have been described for both cryptoglandular and noncryptoglandular fistulas. However, despite these different approaches, recurrent rate varies from 0 to 32 % and incontinence rate from 0 to 63 % [4, 5].

Ligation of the intersphincteric fistula tract (LIFT) procedure is a novel sphincter saving technique first described in 2007 by Rojanasakul [6]. Its rationale of LIFT procedure is that fecal particles can enter the primary internal opening and leads to infection in unhealed fistulas. As the fistula tract is compressed between sphincter muscles, this causes intermittent closed septic foci and persistent sepsis [7]. Removal of the intersphincteric tract and ligation of the tract close to internal opening prevents further contamination and allows time for the remained fistula tract to heal (Fig. 19.1b). As sphincter muscles are minimally disturbed, there is less likelihood of incontinence. Initial study indicated that success rate can be as high as 94.4 % with negligible risk of incontinence [6].

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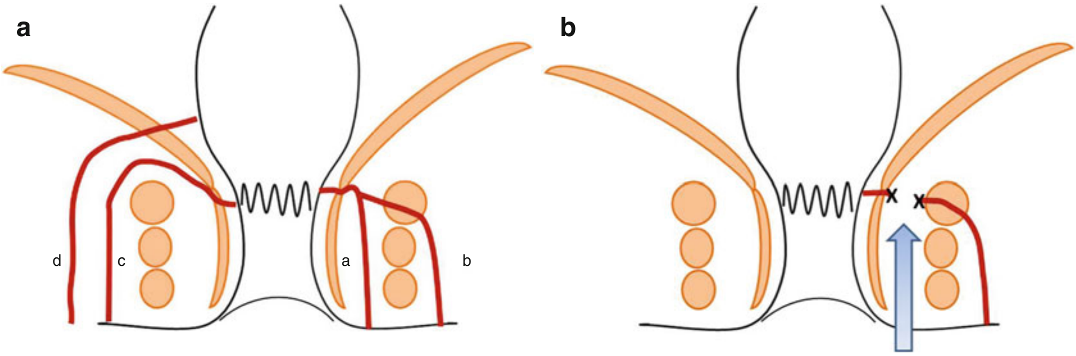

Fig. 19.1 (**a**) Parks' classification of anal fistulas; (**b**) ligation of the intersphincteric fistula tracts (*arrow* indicate the route of the intersphincteric dissection)

19.2 Indications/ Contraindications

Our current indications for the LIFT procedures are mainly for the following [6]:

- Low transphincteric fistulas
- High transphincteric fistulas
- Suprasphincteric/extrasphincteric fistula where the tract transverses the intersphincteric plane
- Recurrent fistulas

The following conditions may not be suitable for the procedure:

- Intersphincteric fistulas (as these fistulas could be managed with simple fistulotomy)
- Active anorectal sepsis
- Active inflammatory bowel disease
- Malignancy
- Other noncryptoglandular fistulas (e.g., tuberculosis, postradiation)

19.3 Surgical Procedure

19.3.1 Preoperative Planning

Informed consent is obtained for the procedure. A bottle of sodium phosphate enema (Fleet Enema®, C.B. Fleet, USA) is given at the morning of the procedure for bowel preparation. Prophylactic antibiotic (amoxicillin sodium 1 g+clavulanic acid 200 mg) is given on induction of anesthesia. The procedure is performed under general or regional anesthesia.

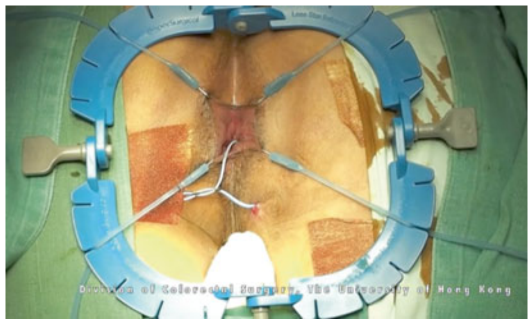

Fig. 19.2 Patient in jackknife-prone position

19.3.2 Positioning

The procedure is performed in the jackknife-prone position (Fig. 19.2) with the buttocks retracted with tape. The perianal area is then prepped and draped. Local anesthetic with noradrenaline is infiltrated into lateral to the sphincteric muscles for postoperative analgesics in case of general anesthesia.

19.3.3 Identification of the Intersphincteric Fistula Tract

If no seton is inserted previously, the internal opening is identified by Lockhart-Mummery probes. In case of difficulty in finding the internal

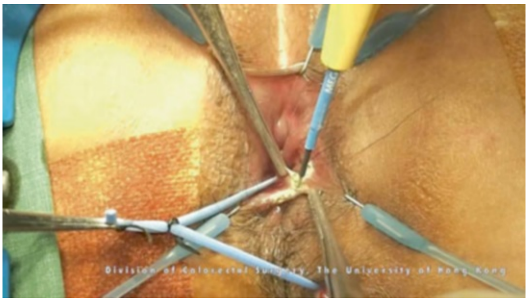

Fig. 19.3 An incision is made at intersphincteric groove

opening, hydrogen peroxide could be irrigated via the external opening to assist identification. Once the fistula tract is identified, the tract should be threaded with a fistula probe or a silicone vessel loop.

19.3.4 Skin Incision

A curvilinear skin incision is made at the intersphincteric groove, which is the landmark between external and internal sphincteric muscles (Fig. 19.3). A 3–4 cm incision is usually sufficient for exposure. In order to facilitate visualization through the incision, the Lone Star self-retaining retracting system (Cooper Surgical, Inc., Trumbull, CT, USA) can be used.

19.3.5 Dissection of the Fistula Tracts

A combination of sharp and blunt dissection with S-shaped retractors is used to identify the fistula tract (Fig. 19.4). A fine-tipped right angle dissector can be used to delineate the fistula tract which is slung with a silicone vessel loop (Fig. 19.5).

19.3.6 Ligation and Division of the Fistula Tract

Ligation of the fistula tract is performed at both sides (i.e., at its entrance into the external and internal sphincter in the intersphincteric plane). Suture ligation of the tract is performed using

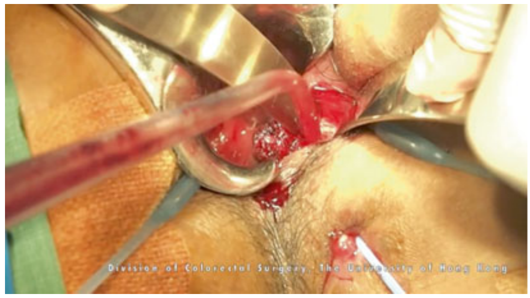

Fig. 19.4 The intersphincteric plane is bluntly dissected using S-shaped retractors

Fig. 19.5 The fistula tract is dissected with a right-angled dissector

4–0 Vicryl sutures (Figs. 19.6 and 19.7). The tract is simply divided or a segment of fistula tract is removed (Fig. 19.8). The granulation tissue is scraped out from the external tract and the defect medial to the external anal sphincter is sutured. Saline is irrigated via the external opening to secure no communication into the intersphincteric plane (Fig. 19.9). Finally the perianal incision is closed with interrupted 4–0 Vicryl sutures.

19.3.7 Postoperative

Oral analgesia (such as paracetamol or opioid-based analgesics) and stool softeners are prescribed postoperatively. The patients would then be followed up in outpatient clinics in postoperative 2–4 weeks, 2 months and then every 6 months. Time for fistula closure and perianal wound healing will be recorded. Any complication, such as bleeding or incontinence, will be asked during the follow up. Failure was defined

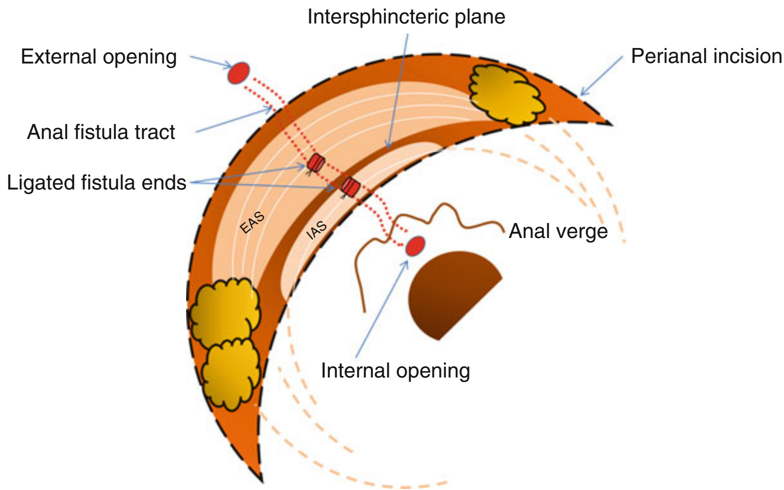

Fig. 19.6 Schematic diagram to show the suture ligation of the fistula tract (*EAS* external anal sphincter, *IAS* internal anal sphincter)

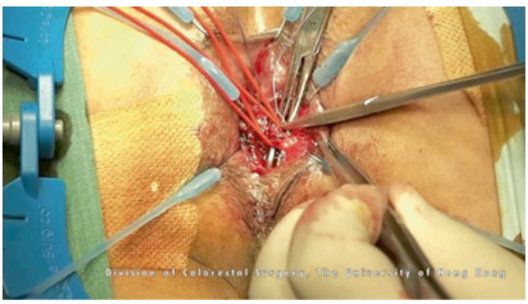

Fig. 19.7 The fistula tract is transfixed and ligated in the intersphincteric plane

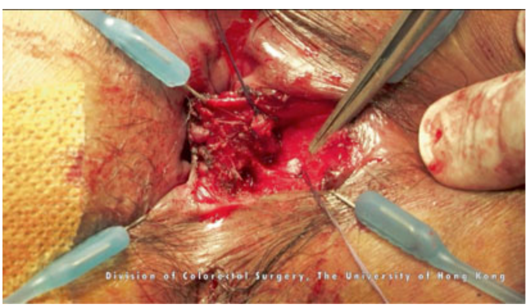

Fig. 19.8 The fistula tract is resected after suture ligation

as the presence of persistent discharge through the external opening or the intersphincteric wound. Recurrence was defined as the reappearance of a fistula after the initial wound had healed [8].

Fig. 19.9 No communication is secured after saline irrigation via the external opening

19.4 Results

Thirty-eight patients were included (30 male and 8 female) with mean age of 50.0 years (range, 22–73). There were 35 patients with transsphincteric fistulas and three with supra/extrasphincteric fistulas. The mean distance between the external opening and the anal verge was 3.8 ± 2.3 cm. Twenty-two patients had first presentation of anal fistulas while the others had recurrent fistulas with previous interventions, including 15 fistulotomy, 9 seton insertion, and 2 anal fistula plug. Five patients had more than one procedure before the LIFT procedure.

The LIFT procedure was attempted in two patients but the fistula tracts could not be identified due to extensive scarring. Therefore, 36

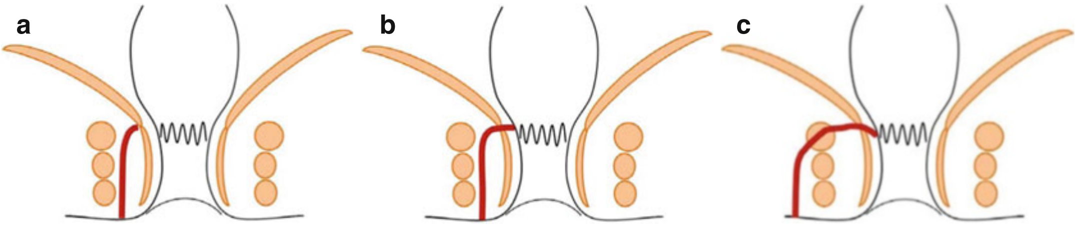

Fig. 19.10 Classification of failure and recurrence after the LIFT procedure (**a** localized failure; **b** partial failure; **c** complete failure) [8]

patients underwent LIFT procedure with mean operating time of 38.9 ± 11.9 min. 44.7 % of the patients could be discharged within 24 h after operation. Median length of hospital stay was only one day (0.5–4). Perianal incision wound was found to be healed completely in 31.6 % (12/38) in the first follow up and up to 86.8 % (33/38) in the second follow up, at the mean time of 34 ± 22 days. Closure of external opening of anal fistulas was noted in 66.7 % (24/36) in the first follow up and 83.3 % (31/36) in the second follow up, at the mean time of 29.3 ± 16 days. There were no complications such as incontinence or bleeding.

During the median follow-up of 61.1 (3.3–169) weeks, four patients had failures (three partial and one complete failure) and two patients had recurrences (Fig. 19.10). Those three patients with partial failures (i.e., fistula tract from the internal opening to the intersphincteric wound) underwent primary fistulotomy. The other patient with complete failure underwent seton insertion and then staged fistulotomy later.

For patients with fistula recurrence, one patient presented with perianal abscess at 11 months after the LIFT procedure. The fistula was managed after abscess drainage and seton insertion. The other patient had suprasphincteric fistula with the external opening near the right ischial tuberosity. After 2 months, the perianal wound healed well but the external opening had persistent discharge. Subsequent fistulography showed long fistula tract and it was successfully controlled with fibrin glue injection at 6 months after the LIFT procedure.

19.5 Discussion

The management of complex and recurrent anal fistulas was always a challenge to many colorectal surgeons. In the past decade, many sphincter-saving procedures were described to decrease the fecal incontinence rate but the recurrence rate was still high [4, 5, 9]. Though anal fistula plug (AFP) and fibrin glue injection were popularly used, the result was still not satisfactory when compared with other traditional procedures [10–12]. Loose seton insertion and then staged fistulotomy could achieve minimal incontinence rate and avoid to jeopardize the sphincter injury. However, the patient may need lengthy follow up and healing time on repeated procedures, therefore causing unnecessary huge cost on medical expenses [1].

The LIFT procedure is a novel procedure for management of cryptoglandular fistulas. Though described by Rojanasakul in 2007 [6], a similar approach was reported by Robin Phillips from St Mark's Hospital in 1993 [13]. The difference is that the latter procedure involved excision of the external tract with oversewing of the internal anal sphincter defect. However, the LIFT technique did not take on because of its complexity in reaching the intersphincteric plane especially for high transphincteric and suprasphincteric fistulas. Although the internal sphincter was sutured, it was not able to remedy the injury to the sphincter muscle. The initial result of this method is less satisfactory, with continence rate only 54 % [13]. It must be noted that the author only utilized this method on patients with very complex fistulas such as rectovaginal fistulas, suprasphincteric fistulas and fistulas in patients suffering from

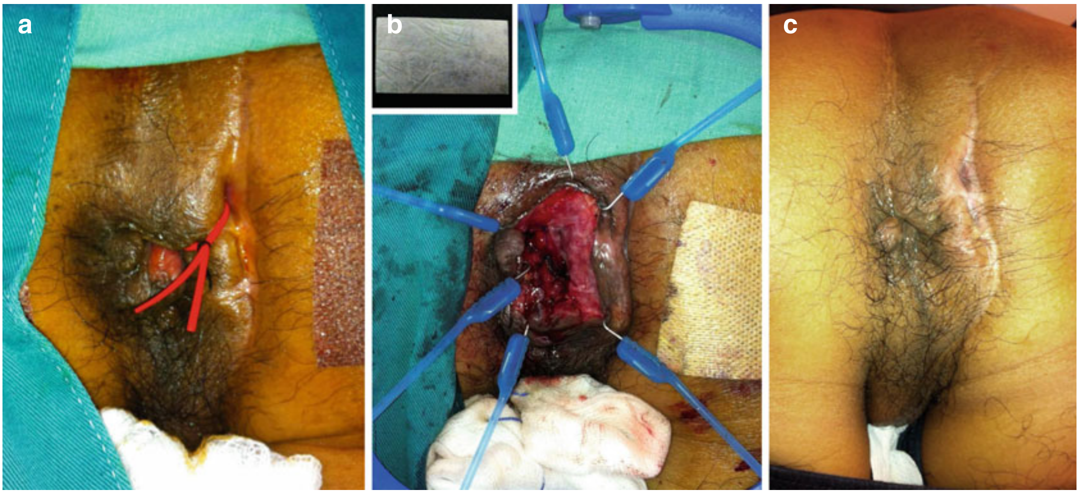

Fig. 19.11 Bioprosthetic graft used in the LIFT procedure (BioLIFT) (**a**) before operation; (**b**) the bioprosthetic graft (*inset*) placed into the intersphincteric plane; (**c**) 1 month after operation

Crohn's disease [14]. As being securely ligated in proximity to the internal opening in the LIFT procedure, the internal sphincter muscles are minimally disturbed. This technique modification probably explains the much improved outcome.

Until now, a few studies on the efficacy of this technique were reported with success rates of 57–94 % [15, 16]. Our fistula closure rate of 83 % is very similar to results of these other LIFT studies. No patient had complained of significant incontinence after operation. There were no other significant comorbidities such as postoperative pain or bleeding. With the advent of endoanal ultrasonography and MR imaging, the anatomy of anal sphincter complex can be precisely mapped. These preoperative imaging provided a good roadmap in aiding the operation, particularly in the management of the complex and recurrent anal fistulas [17]. This may be another reason for good surgical outcomes by the LIFT procedure.

Nevertheless, the other advantage of the LIFT procedure was that this technique is a very economical procedure, as no additional equipment needed, like AFP and fibrin glue. Also the patients could be spared from the repeated procedures and anesthesia when compared with the one off-LIFT procedure. Another advantage was that the LIFT procedure will not prohibit the use of other modalities of treatment in cases of failure. In case of postoperative recurrence, the fistula would transform into an intersphincteric or low transsphincteric fistula in which the patient will be amenable to a simple fistulotomy [8].

In some situations, the LIFT procedure may not be ideal. In order to perform the procedure smoothly, a well-formed fibrous fistula tract was needed and this may be fleshy and friable granulation tissue after the immediate drainage of anorectal abscess. Also, in more complex fistulas such as with multiple tracts or horseshoe extensions, it would be difficult to perform multiple intersphincteric tract ligations. Also in case of multiple secondary tracts draining to the same internal opening, the risk of sphincteric injury theoretically will be increased [6]. More studies on the structure and function of the anal sphincter from the LIFT procedure may help clarify this issue in future.

As the presence of persistent anorectal sepsis and recannulation of the fistula tract have been suggested to be possible causes of procedure failure, the placement of bioprosthetic material in intersphincteric plane (BioLIFT) could be a possible way to deal with this problem. Bioprosthetic grafts (Surgisis Biodesign® 4-layer Tissue Graft, Cook Medical Inc, Bloomington IN, USA) were able to tolerate contamination and remodeled without foreign body reaction (Fig. 19.11). This would reinforce the closure of the fistula tract by acting as a physical barrier to separate the transected ends of the fistula tract. Ellis et al. firstly published the first study of BioLIFT in 31 patients in the management of anal fistulas with a closure rate of 94 % (29/31) and no incontinence [18]. This study, although had very good fistula closure rate, was unable to demonstrate any additional improvement in outcomes. Tan et al. also performed the BioLIFT procedure in 13 patients with 16 fistulas with the primary healing rate of 68.8 % (11/16) over a median follow up of 26 weeks. Two patients with failures underwent lay-open fistulotomy, giving a secondary success rate of 81.3 % (13/16) [19]. The authors preferred to reserve the BioLIFT procedure for patients who had failed the LIFT procedure. For those patients with potentially failed LIFT procedure, such as large internal fistula opening and scarring at intersphincteric plane, the insertion of the bioprosthetic graft could be considered. However, the biosynthetic material was very expensive and the BioLIFT procedure required more extensive intersphincteric dissection for harboring the graft inside [19]. This might cause stretch injury to the sphincter and then potentially higher risk of incontinence.

Recently, apart from the insertion of bioprosthetic graft, Han et al. modified the LIFT procedure by combining LIFT with the technique of AFP. The bioprosthetic plug was placed into the anal fistula tract through the opening in the external sphincter to the external opening in the skin (LIFT-Plug technique). After the LIFT procedure was performed, a 3 cm × 5 cm human cellular dermal matrix was rolled into a conical configuration, placed into the intersphincteric plane and then pulled through the curetted tract to the external opening. The overall success rate was 95 % (20/21) with a median healing time of 2 weeks for external fistula opening and 4 weeks for intersphincteric groove incision. Other modifications include concomitant endorectal advancement flap (LIFT-EARF procedure) to prevent infection at the residual tissue [20] and additional partial fistulotomy for complex fistula (LIFT-PLUS procedure) [21]. Definitely, further studies may be required to determine whether this modification of the LIFT procedure is necessary.

Conclusion

The LIFT procedure is a new sphincter-sparing procedure for cryptoglandular fistulas with acceptable success rates and can effectively preserve continence. Its main indication is for transphincteric fistulas in patients with/without previous surgery and with short fistula tracts. Its efficacy and long-term outcome should be further investigated, preferably with randomized controlled trials. There is a lack of evidence to recommend the combined use of prosthetic materials or the LIFT procedure against other traditional techniques for anal fistulas.

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20 Video-Assisted Anal Fistula Treatment

Piercarlo Meinero

20.1 Introduction

The VAAFT (video-assisted anal fistula treatment) is a new technique for the surgical treatment of complex anal fistulas and their recurrences. Until now, all technical procedures were performed "blindly," even if supported by good preoperative diagnostic images. Moreover, the use of the metallic probe during the first consultation or at the beginning of the operation can cause false tracts. VAAFT works on the principle of "putting an eye" on the probe and exploring the tract from the inside under direct vision. This allows precise identification of possible secondary tracts and abscess cavities and minimizes the risk of creating false passages on the way to reaching the internal opening. In other words, the "fistuloscopy" can be considered as the diagnostic phase of VAAFT technique. After this, the diatermocoagulation of the fistula internal walls, its cleaning, and the hermetic closure of the internal opening are performed, always visually. An ideal technique should define the fistula anatomy, drain possible associated abscesses, destroy the fistula tracts, preserve sphincter integrity, and close the internal opening. VAAFT respects all of these principles. This technique comprises two phases: a diagnostic one and an operative one.

20.2 Materials

Karl Storz GmbH tower video system (Tuttlingen, Germany) is used. The VAAFT kit includes a Meinero's fistuloscope, a unipolar electrode (Fig. 20.1), an endobrush (Fig. 20.2), and forceps. The fistuloscope has an 8° angled eyepiece, and its diameter is 3.3 × 4.7 mm. It has an optical channel and also a working and irrigation channel. The sheath is 18 cm long, but it reduces its length to 14 cm with a removable handle. The fistuloscope has two taps, one of which is connected to a 3,000 ml bag of glycine–mannitol 1 % solution. A semicircular or linear stapler and 0.5 ml of synthetic cyanoacrylate (Glubran 2—GEM, Viareggio, Italy) can be used to close the internal opening. Normally, the patient is placed in the lithotomic position; spinal or general anesthesia are required.

20.2.1 The Diagnostic Phase

Its purpose is to correctly locate the internal fistula opening and any possible secondary tracts or abscess cavities. Before starting the procedure, we inject some milliliters of saline solution through the

P. Meinero, MD
Department of General Surgery – Colorectal Surgery, Sestri Levante Hospital (Italy),
Via Arnaldo Terzi, 43, 16039 Sestri Levante, Italy
e-mail: pimeine@libero.it

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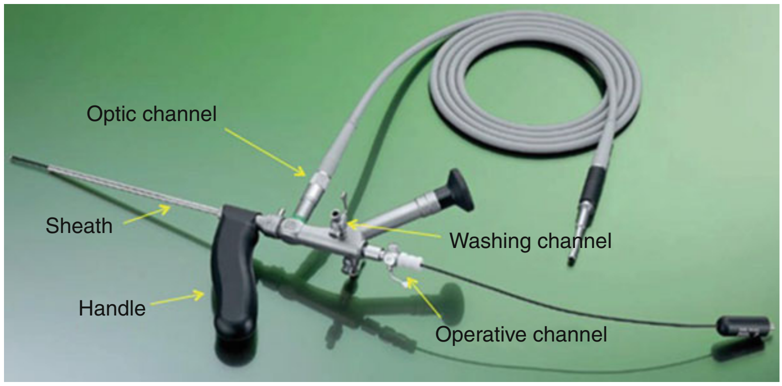

Fig. 20.1 The Meinero fistuloscope

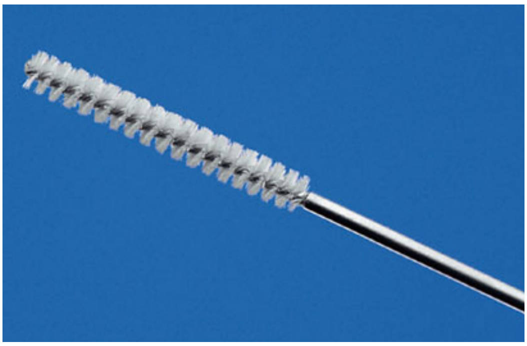

Fig. 20.2 The endobrush

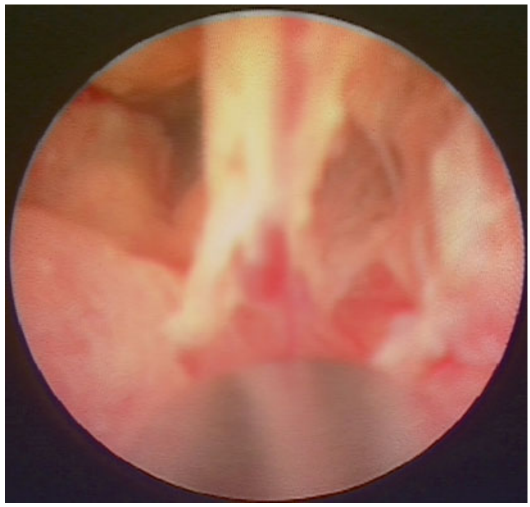

Fig. 20.3 The insertion of the fistuloscope while the glycine–mannitol 1 % solution is running; in the box the fistula pathway appears on the screen

external opening by a syringe in order to dilate the fistula lumen. The external opening skin is removed in order to better introduce the fistuloscope. The obturator is inserted into the fistuloscope-operating channel. It appears as a crescent shape in the lower part of the screen, and thanks to its blunt tip, it ensures a good orientation in the fistula tract. The fistuloscope is inserted through the external opening, and the glicine-mannitol solution opens the fistula tract. So the fistula pathway clearly appears on the screen (Fig. 20.3). The finger in the anus helps to straighten the fistula tract by combined movements between the finger and the fistuloscope. Finally, we arrive at the end of the fistula tract, which is the internal opening. In about 70 % of cases, the fistuloscope goes out of the internal opening, but when the patient is operated several times, the internal opening might be very narrow or completely closed. In that case, its location is found by viewing the fistuloscope light behind the rectal mucosa. We put two or three stitches on the internal opening in order to isolate and don't lose it during the operative phase. If the internal opening is closed, the stitches are put in any case on the mucosa illuminated by the fistuloscope light. Sometimes, the waste tissue in the tract can be removed using the forceps passing through the operative channel of the fistuloscope. The surgeon follows the fistula pathway using slow left-right and up-down movements. Any force used at this stage may lead to the fistuloscope entering the fatty tissue of the buttock and rupturing the fistula, causing severe edema, and the procedure may have to be abandoned. These maneuvers are aided by the complete relaxation of the surrounding tissue induced by the spinal anesthesia. At this point, the

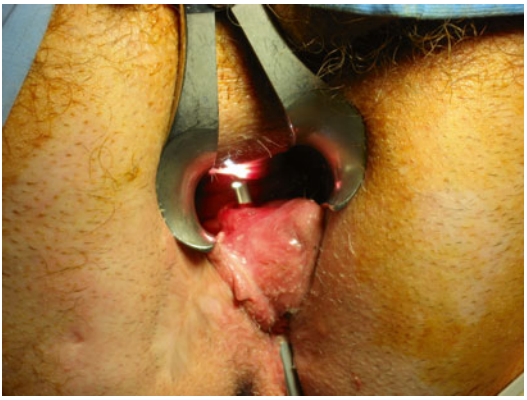

Fig. 20.4 The fistuloscope has reached the internal orifice and the tip is in the rectum

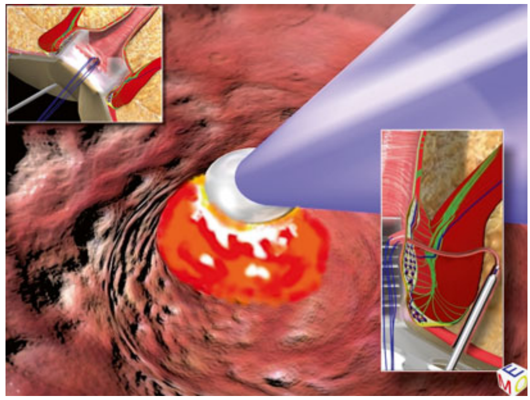

Fig. 20.5 The rectal wall is cauterized under vision by a unipolar electrode

finger in the anus helps to straighten the fistula tract by combined movements between the finger and the fistuloscope. Optimum vision of the inside of the fistula is assured by the continuous jet of the washing solution to the point where you reach the end of the fistula pathway which is the internal fistula opening (Fig. 20.4). Dimming the lights in the operating theater enables an easy localization of the fistuloscope light in the rectum or in the anal canal. The assistant can insert an anal retractor in order to localize the internal fistula opening by looking for the light of the telescope in the rectum or anal canal. When the fistuloscope exits through the internal opening, the rectal mucosa clearly appears on the screen. As we said before, the fistuloscope usually goes out through the internal opening, but sometimes it is not so easy, as the internal opening might be very narrow: in that case, its location is found by viewing the fistuloscope light behind the rectal mucosa. At this point, it's useful to put two or three stitches in two opposite points of the internal opening margin in order to isolate and, above all, not to lose it. The stitches must not be knotted because the internal opening must remain open to allow the flowing out of the waste material during the operative phase.

20.2.2 The Operative Phase

Purposes are the fistula destruction from the inside, the fistula cleaning, and finally the internal opening closure. We leave the rectum and start from the internal opening to the external opening. We remove the obturator, change the tap, and insert the electrode through the operative channel of the fistuloscope. The electrode is connected to the electrosurgical power unit (Fig. 20.5). We start destroying the fistula always visually, not forgetting any possible secondary tracts or possible abscess cavities. Once the destruction is completed, we remove the electrode and insert the endobrush through the operative channel, always visually, in order to clean the main tract and any possible branches. If the fistula is straight, a Volkmann spoon could be used. The last step is the internal opening closure. If the patient has never been operated, we lift the stitches on the internal opening in order to obtain a sort of volcano, and we put a semicircular stapler at the volcano's base (Fig. 20.6). We can use also a linear stapler, roticulator or not: it depends on the internal opening position. The final result is simply a short scar in the anal canal or in the rectum (Fig. 20.7). If the patient has been operated several times, the internal opening could be too tough and sclerotic. In this case, we make an incision on the mucosa and close the internal opening on the internal muscle plan by one or two vicryl 2/0 stitches and a mucosa running suture. Once the internal opening closure is completed, we inject a half milliliter of synthetic cyanoacrylate (GLUBRAN 2) immediately behind the suture by a tiny catheter inserted

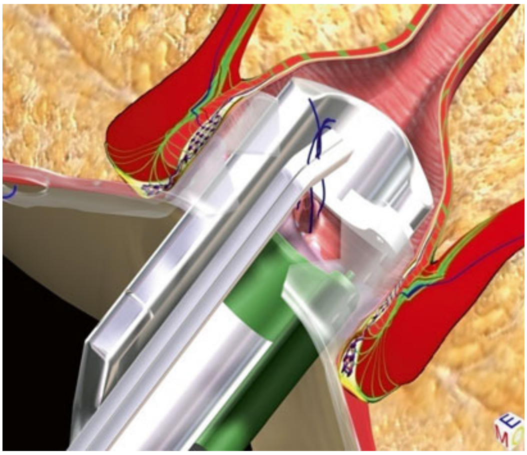

Fig. 20.6 Closure of the internal opening by a semicircular stapler

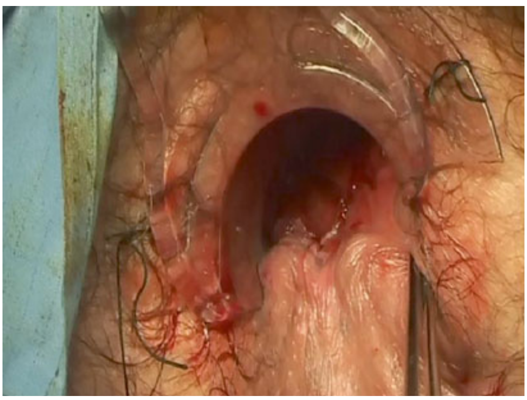

Fig. 20.7 Vertical suture after linear stapler closure

through the main fistula tract. The aim is just to reinforce the suture, above all when we make a flap. Indeed, the fistula pathway must not be filled by the cyanoacrylate, in order to allow the flowing out of the secretions during the postoperative time. So, the cyanoacrylate excess is removed by a forceps at the end of the operation.

20.3 Results

From May 2006 to December 2013, 443 patients with a complex anal fistula were managed with this technique. Any fistula that could not be adequately treated by simple fistulotomy was considered "complex." Our series consisted of 242 males and 201 females, with a median age of 42 years (range 21–77 years). Exclusion criteria included Crohn's disease and cases of simple fistulas. Preoperative assessment included blood tests, virtual or traditional colonoscopy, and a chest X-ray where appropriate. Approval was obtained from the Ethics Committee of our Institution, and all patients provided informed consent. One hundred and three patients did not require any additional diagnostic investigations, and preoperative assessment of the fistula anatomy was based on clinical grounds alone. Some 152 patients underwent magnetic resonance imaging (MRI) or endoanal ultrasonography at our institution, while 188 underwent fistula imaging (MRI, ultrasonography, or CT) prior to referral and did not require further testing. Some 331 patients had already undergone prior surgery for complex anal fistula. Some 17 patients had a diverting colostomy. Follow-up was conducted at 2, 6, and 12 months after VAAFT and subsequently once per year. Some 62 patients were contacted by phone interview after the first year of follow-up. Some 379 out of the 443 patients were followed up for a minimum of 6 months with a median duration of follow-up of 19 months (range 6–84 months). In 256 cases (57.8 %), secondary tracts and abscesses were found. In 144 cases (32.5 %), the internal fistula opening was located in the anal canal, in 247 cases (55.8 %) at the level of the dentate line, and in 52 cases (11.7 %) in the rectum. In 329 patients (74.2 %), the internal opening of the fistula was founded. In the other 114 (25.8 %), it was found by viewing the fistuloscope light in the rectum. The operative time was progressively reduced (from 2 h to 30 min) following improvement in the learning curve. No major complications occurred, and no infection or bleeding was observed; however, there were 16 cases of postoperative urinary retention. In one case, scrotal edema was observed caused by the infiltration of the irrigation solution after rupture of the fistula wall. Four cases of allergy to the synthetic cyanoacrylate were reported. One patient was discharged after 6 days because of headache related to the spinal anesthesia; all the other patients were discharged within 24 h. Most patients reported that postoperative pain was acceptable both in the early and in the later postoperative period. Pain control was based on the visual analog scale (VAS) score with a mean value of 4.0 (on a scale of 1–10) during the first 48 h. None of the patients reported pain after the first postoperative week. Some 121 patients (27.3 %) did not require analgesics, whereas 277 patients (62.5 %) needed Ketorolac trimetamine for 3–4 days and 45 (10.2 %) needed Ketorolac trimetamine for a week. In the group of 379 patients with a follow-,up>6 months primary healing was achieved in 285 patients (75.2 %) within 2–4 months after surgery. In 94 patients (24.8 %) the procedure was unsuccessful: in 70 patients (18.5 %) no wound healing was observed, and in 24 patients (6.3 %) a true recurrence after temporary healing was observed. Some 77 patients underwent VAAFT once more, and 48 of them healed after 2 months from the operation. Finally in the group of 25 patients unhealed after re-VAAFT, 13 patients underwent fistulotomy and 6 fistulectomy, always before fistuloscopy. Overall (first VAAFT and successive VAAFT retreatment) healing was obtained in 333/379 patients (87.9 %). Some 246 patients were followed up for at least 24 months, of which 239 (97.1 %) were still healed: these data show that if there is no recurrence for 2 years the percentage of healing is very high. We did not formally evaluate anal continence in our patients with a validated score before and after surgery. Our aim was only to determine whether the operation might have worsened patients' continence, and this was evaluated by simply asking the patients about continence problems. All patients denied worsening of fecal continence postoperatively. Among those who had an active job, the longest time off work was 3 days.

20.4 Comments

In the last few years the traditional seton treatment of complex anal fistulas has been associated with a risk of anal sphincter impairment, and a recent review reports an incontinence rate as high as 12 % [1]. Many alternative attempts have been made to treat high anal fistulas [2], and in all cases the blind probing of the tract was the first step in order to define the fistula course and to locate the internal opening. Therefore the probe introduction and the progression maneuver remained a difficult technique that a coloproctologist had to sharpen thanks to his progressively wider experience. Every surgeon knows that correct location of the internal opening offers the best opportunities to successfully cure anal fistulas; on the other hand the accidental creation of false passages is a sure sign that the fistula will not heal. VAAFT's main innovation is the possibility to explore the fistula tract from the inside: the blind "burglar-like" probing is replaced by a complete endoluminal "under vision" evaluation that includes, in addition to the main tract, secondary tracts and abscess cavities. The fistuloscopy minimizes the risk of rupture of the fistula and plays a fundamental role in understanding the course of a complex fistula. The effectiveness of this approach is emphasized when patients have been operated on many times and many unpredictable pathways and multiple orifices have to be located. Sometimes in these types of fistulas there is no longer a single internal orifice, and the chronic suppuration is supported by large, undrained, abscess cavities and secondary tracts: the operation of the fistuloscope allows the surgeon to find them and to directly cauterize their walls under vision. In the VAAFT operative phase all tracts can be treated by the monopolar electrode and the brush in order to destroy pyogenic tissue and to stimulate the processes of fibrosis and regeneration. This treatment is optimal to prepare the closure of the internal orifice. As regards this step VAAFT describes different options, a semicircular or a linear stapling or an advancement flap reinforced by a half ml of synthetic cyanoacrylate immediately behind the suture. We must consider that the closure could also be achieved by other techniques, i.e., ligation of the intersphincteric tract (LIFT), plugs of different shape and materials, fibrin glue, and there is an unexplored field of potential association with our video-assisted approach. The true revolutionary concept of VAAFT procedure is it being carried out visually,

Fig. 20.8 The scar resulting at the end of the procedure

and it can be considered compatible with instead of alternative to other different recent sphincter-sparing techniques. Recently many authors report experience of treating high anal fistulas by many different associated techniques [3, 4]. We believe that our published results [5–7] will be improved and the endoluminal video-assisted approach will be a winning choice. These considerations are confirmed by the preliminary VAAFT experience of other authors on cryptoglandular complex anal fistulas [8, 9]. Schwandner adopted VAAFT to treat 11 patients with perianal Crohn's disease suffering from complex fistulas and reported an 82 % success rate after a mean follow-up of 9 months [10]. These results on complex fistula treatment in Crohn's disease are confirmed in our preliminary experience in few cases: the cauterization and cleaning of fistula tracts allows even its closure or, however, obtains a temporary healing and drainage and avoids the insertion of a seton. The advantages of the VAAFT technique are evident: surgical wounds on the buttocks or in the perianal region are very small (Fig. 20.8), there is complete certainty in the localization of the internal fistula opening (a key point in all fistula surgical treatments), and the fistula can be completely destroyed from the inside. There is no requirement to preoperatively know the kind of fistula because operating from the inside no damage is caused to the anal sphincters. Therefore, no preoperative examination is necessary. The risk of postoperative fecal incontinence is excluded. Moreover, the patients have no need for dressing and can start working again after a few days since the VAAFT technique can be performed in day surgery. The patients' quality of life after VAAFT is so much better than after traditional techniques that even in case of recurrence they request VAAFT again.

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21 Stapled Haemorrhoidopexy and Stapled Transanal Rectal Resection (STARR) in the Treatment of Symptomatic Rectoanal Prolapse

Dott. Antonio Longo

21.1 Introduction

The goal of this chapter is to explain the rational basis of two procedures indicated to correct the symptomatic internal rectal prolapse. Both techniques, based on the same principle, should be used in relation to the entity of the prolapse that needs resection. In particular, I will try to explain why the haemorrhoidal prolapse, the internal or external rectal prolapse, and the rectocele aren't distinct pathologies but only different dynamic morphological aspects of a unique basic anatomical and structural alteration of the rectum. All studies and subsequent developments began through some thoughts and considerations on haemorrhoids. From the understanding of the pathogenesis of this pathology start to develop many other studies to the understanding of the nature of other pathologies, especially the obstructed defecation, whose frequent association with haemorrhoidal disease was clinically evident but escaped the pathogenetic correlation.

Haemorrhoidal disease has been known for thousands of years for its high incidence among the human species and the relative ease with which it is diagnosed. In the course of millennia, countless theories have followed one another trying to clarify the anatomical and physiological nature of haemorrhoids and the dynamics of their causes and pathogenesis. It seems appropriate to briefly report some concepts of anatomy and physiopathology to better understand the rationale of the various therapeutic options for the haemorrhoidal disease.

Today it is widely recognised that the haemorrhoidal cushions play a role in anal continence because of their ability to inflate and deflate rapidly [1]. This ability to adjust their volume is due to the anatomical nature of the cushions, with their numerous arterial and venous shunts that produce vascular lacunar spaces. The blood supply to the haemorrhoidal cushions through the superior, middle, and inferior haemorrhoidal arteries, which undoubtedly exceeds the sole biological needs, has the ultimate purpose of allowing the haemorrhoids to quickly fill with blood to optimise, in synergy with the anal sphincters, the anal continence. It is thus a case of "hypervascularisation" that supports the functional role to optimise the anal continence.

The haemorrhoidal cushions are kept in their position by connective tissue and smooth muscle fibres [2] and are covered with anal mucosa. The anal mucosa overlying the haemorrhoids, besides being arranged in longitudinal folds that provide for an adequate aperture of the anal canal during defecation, is specialised in the discrimination of rectal contents and therefore plays a fundamental role regarding the anorectal reflexes and thus

D.A. Longo, MD
Director of European Center of Coloproctology and Pelvic Diseases, Vienna Chief Consultant Coloproctology and Pelvic Diseases, Cliniche Gavazzeni, Humanitas, Bergamo
e-mail: alongo@neomedia.it

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regarding anal continence. These simple considerations have led important reflections:

The first is that "hypervascularisation" is physiological, then can't be blamed as pathogenetic cause.

The second reflection is that ablation or destruction of the haemorrhoids, regardless of the methods, ends up in weakening – in various degrees – anal continence and dilatability.

Among the many theories on the pathogenesis of the haemorrhoidal disease that have followed one another in centuries, some have obviously left such a long-lasting impression that they are still evoked nowadays, often wrongly, in therapeutic decisions. Among these theories, we find the so-called theory of the varicose veins, dating from age of Galen and Hippocrates [1]. Going back to the observation of the frequent association between dilation of the haemorrhoidal plexuses and symptoms, this theory, although identifying different causative factors for haemorrhoidal dilation, ended up equating haemorrhoidal disease to rectal varices, like the ones following portal hypertension. Subsequently it has well been clarified that rectal varices caused by portal hypertension are a rare pathology and distinct from that of the haemorrhoids. As the dilation of the haemorrhoidal veins is often associated with a prolapse, it is fundamental to understand the pathogenetic correlation between these two phenomena. Angiographic studies have demonstrated that haemorrhoidal prolapse causes a venous kinking between the middle and inferior haemorrhoidal veins and a stretching of the superior haemorrhoidal vessels that obviously obstruct outflow. This obstacle is worsened by sphincter hypertone. These factors can create a venous dilation with blood stagnation, thrombosis and oedema. It is therefore evident that venous dilation is a complication following prolapse and not a primary cause of haemorrhoidal pathology.

Although nowadays this theory is no longer supported among proctologists, the idea that the haemorrhoidal pathology is similar in some way to varicose veins continues to be widespread. This is proved by the fact that many drugs prescribed for haemorrhoidal pathology are the same used for lower limb varices. The theory of *vascular hyperplasia* has its origin in a histological similarity between the prolapsed haemorrhoidal cushions and angiomatous tissues. Although it has been abandoned, this theory deserves to be remembered here as many of the studies performed to prove its validity have contributed to clarify the anatomical structure of the haemorrhoids. In any case it has been clearly demonstrated histologically that haemorrhoidal specimens show no signs of tissue hyperplasia.

The theory nowadays largely accepted by proctologists is the one proposed by Gass and Adams in 1950 [3], *the sliding anal lining theory*. This theory assumes the prolapse of the anal lining as the pathogenetic cause of haemorrhoidal disease. It is based on the concept that "fragmentation" of the ligaments of Treitz and Parks, which support the haemorrhoidal cushions, causes prolapse of haemorrhoids and of anal mucosa. The prolapse is considered a predisposing cause of all the haemorrhoidal symptoms and complications.

It is useful making some considerations on Goligher's classification [4] that, as is known, is the most widespread tool to assess haemorrhoidal pathology. Although this classification, which divides haemorrhoidal prolapse into four grades, is accepted unanimously, some of its elements have to be viewed critically. The definition of the first degree of prolapse is not entirely clear, as it includes haemorrhoids that are "not prolapsing, but increased in volume, and projecting into the anal canal and bleeding". It is evident that this definition of first degree is bound to be considered critically for several reasons: (a) it is not very clear why you would include non-prolapsed haemorrhoids in a classification based on prolapse itself; (b) besides the fact that projection into the lumen of the anal canal is a normal anatomical condition, the concept of "increased volume" appears unclear as no reference is made to either what a normal volume is or to a range of normality, and it is well-known that haemorrhoidal volume is very variable in the population at large and even in the same subject depending on physiological conditions; and (c) in order to define this first-degree prolapse a symptom like bleeding is being used which is illogical in a classification otherwise based on the clinical behaviour of the prolapse (whether reducible spontaneously, manually or non-reducible). This incongruence in classification is probably due to the fact that in the way it was formulated, the theory of prolapse is not able to sufficiently explain the clinical events and, in a certain way, the true essence of haemorrhoidal pathology.

The three pathological theories outlined, even if conceptually different, have some elements in common. Varices, vascular hyperplasia and prolapse generated by wearing of supportive tissue are considered irreversible anatomical and histological alterations. Moreover, all the variations in pathogenesis delineated so far tend to indicate haemorrhoidal pathology as a primary disease, with cause and effect limited to the anal canal. Because of these convictions, the elimination of haemorrhoidal tissue was considered, until recent times, the only logical and effective therapeutic treatment.

Since 1993, through clinical observations and anatomical and radiological studies, we have revolutionised the concept of haemorrhoidal disease and pathogenetic causes. We have shown the correlation, clinical and pathogenetic, between haemorrhoidal prolapse, internal rectal prolapse and/or rectocele, obstructed defecation syndrome and anatomical and functional pathologies of the pelvic organs and structures. We have revolutionised the treatment of these diseases overcoming the initial skepticism of many surgeons. We have created incontrovertible scientific evidence, except for the usual interest to maintain some old concepts. To better express our thought, we should report briefly the evolution of our ideas to the formulation of the unitary theory of rectoanal prolapse.

21.2 Unitary Theory of Rectoanal Prolapse

In order to introduce the principles of stapled haemorrhoidopexy (SH) and stapled transanal rectal resection (STARR), I think it is useful to briefly present the considerations, clinical observations and original studies which form the rational basis of these techniques, and at the beginning of the 1990s, after performing hundreds of Milligan and Morgan, Ferguson, Whitehead and other procedures, I realised that the postoperative period was a very painful experience for patients and that the sad notoriety of these procedures induced many patients to refuse surgery.

Our results of follow up in patients underwent to haemorrhoidectomy using any method and whatever energy (laser, ligasure, diathermy, ultracision, etc.,) show an enormous difference with the results published in literature, mostly in terms of postoperative pain, stenotic complications and days needed for heal. I became convinced that a haemorrhoidectomy, whether closed, open, semi-closed or other, did not represent an adequate therapeutic response to the problem. Through the simple analysis of and extensive reflections on the literature, I sensed that the very essence of haemorrhoidal pathology had still not been captured. I came across some incoherencies and contradictions that represented a stimulus for me to study of the problem more in depth. Thomson [1] thought that the disruption of the haemorrhoids' supportive tissue caused prolapse. Haas [2], in 1984, demonstrated that haemorrhoidal supportive tissue disintegrates in all subjects after the age of 30, but not everyone has symptomatic haemorrhoids or prolapse.

This information matches the clinical observation that haemorrhoidal prolapse is always associated with rectal mucosal prolapse, which can protrude into the anal canal and then outside the anus. The external prolapse of rectal mucosa is permanent in the so-called fourth-degree prolapse, and so it is clinically comparable to an ectropion.

Non-reducible rectal mucosa prolapse is thus certainly the cause of soiling which in turn causes perianal dermatitis and hence pruritus. Where and how does rectal mucosa, which prolapses together with the haemorrhoids, return to within the rectum at the end of evacuation in the case of second- and third-degree prolapses? To answer this question, we performed a defecography in all patients with haemorrhoidal prolapse of grades II, III and IV in addition to routine proctoscopy. The result was that all patients with any degree of haemorrhoidal prolapse presented a rectoanal invagination whose size could not be correlated with the size and grade of the external prolapse.

Moreover, in women a rectocele was almost always associated with rectoanal invagination. Rectoanal invagination and rectocele associated with haemorrhoidal prolapse explain the previously unclear correlation between haemorrhoidal disease, straining and obstructed defecation (OD). If we consider the constant association of haemorrhoidal prolapse and rectal prolapse, we can exclude that this is just an occasional concomitance of two distinct pathologies as has always have been thought and written. Clearly this must be a clinical and pathological picture of its own. What still had to be determined was a cause-effect relationship: is it the haemorrhoids that, when prolapsed, draw the rectal mucosa down or is it the rectal prolapse that pushes the haemorrhoids out of the anus? There was no doubt for us that the second hypothesis had to be correct. In fact it is impossible to find a haemorrhoidal prolapse without rectal prolapse, while the opposite is frequently observed. We came up with the theory that rectoanal invagination causes a kinking in the superior haemorrhoidal veins which hampers haemorrhoidal venous outflow and leads to dilatation of the haemorrhoids. This dilatation and stretching of the haemorrhoids can cause increased friction and mechanical trauma to the overlying mucosa during the passage of faeces, with subsequent de-epithelisation and bleeding. We think that this clinical condition constitutes what it is defined rather fuzzily as first-degree haemorrhoidal prolapse.

Subsequently rectal invagination extends to the anal canal during evacuation, causes its obstruction and induces increased straining. It is easy to imagine but also demonstrable in dynamic cinedefecography how the faecal bolus pushes both rectal prolapse and haemorrhoids out of the anal canal with force. In fact, only once the prolapse is expelled freeing the anal canal allowing the evacuation.

The above-mentioned clinical studies have led us to a revolutionary conclusion that is in conflict with all the traditional ideas on the pathogenesis of haemorrhoidal disease: haemorrhoidal prolapse and all its related symptoms constitute a pathology secondary to the internal rectal prolapse; the rupture of the supportive tissue of the haemorrhoids is a necessary but not sufficient precondition because a prolapse occurred. In fact, the rupture of supporting fibres is a physiological phenomenon typical of aging (Haas [2]), and it does not necessarily imply haemorrhoidal prolapse. Seemingly, in young subjects the rupture of the Treitz fibres is caused when the rectal prolapse repeatedly pushes against the haemorrhoidal cushions. Haemorrhoidal prolapse is therefore only one of many of possible clinical manifestations of an internal rectal prolapse.

This new theory explains the correlation between haemorrhoidal disease and obstructed defecation. In fact, rectoanal invagination is also the main cause of the obstructed defecation syndrome.

The limited scope of this chapter does not allow us to go into detail about all the clinical aspects related to rectoanal prolapse and the studies that led us to some conclusions. It is however necessary to give at least a short summary in order to explain the rational basis and goal of the techniques stapled haemorrhoidopexy and STARR. Internal rectal prolapse (whether associated or not with anal, mucous and haemorrhoidal prolapse) can be a mucosal rectal prolapse (about 10 % of our cases) or a full-thickness rectal prolapse.

In fact when performing a baseline two-view X-ray of the empty rectum with barium contrast (Fig. 21.1), we can see that some patients present with a rectum the shape of which, especially distally, indicates a detachment from the sacral-coccygeal plane; this type of rectum is usually folded on itself, with unnatural loops lying on the perineum, and is longer than usual. We have called this conformation “rectal redundancy”.

Performing a varied dynamic rectal videodefecography in patients with rectal redundancy, i.e. with only the sigmoid filled with barium and potato starch, we note that such redundancy often

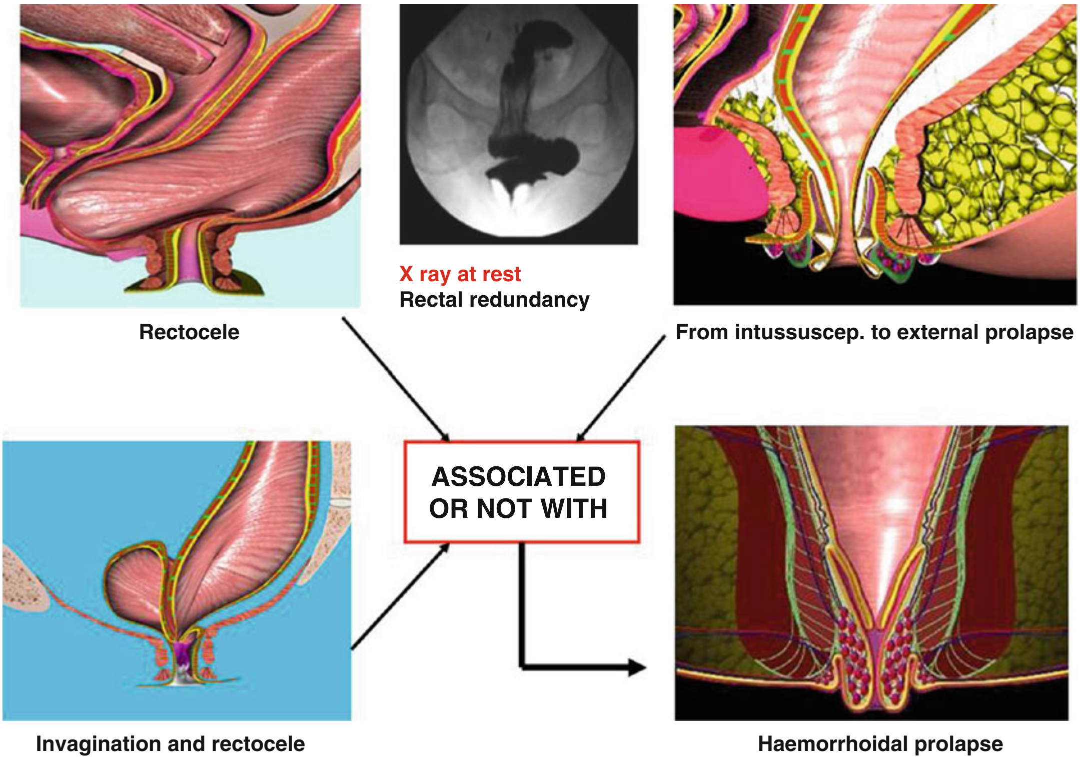

Fig. 21.1 The rectal redundancy is the baseline alteration, detectable at rest, that during evacuation transforms into rectocele, loop rectocele, intussusception and external rectal prolapse. All these dynamic alterations may occur associated among them or even with haemorrhoidal prolapse

causes an obstacle or difficulty to the transit of barium into the rectal lumen, causing more intense straining and repeated attempts at evacuating.

During straining, it is possible to observe how this rectal redundancy can assume different morphological aspects including various combinations (Fig. 21.1): simple or multiple invagination, rectocele caused by rectal dilatation or by formation of a loop, and partial or total outward expulsion of the rectum.

In patients with haemorrhoidal prolapse, a good impregnation of the anal canal allows to visualise how a rectoanal invagination pushes haemorrhoids and anal mucosa outside (Fig. 21.1). It is also interesting to observe that in some patients, a descent of the Douglas pouch or formation of an enterocele can be seen during straining; by compressing the rectum from above and pushing it towards the sacrum, this facilitates emptying of the rectal contents.

Enterocele and deep Douglas pouch are always associated with a descending perineum. These pelvic alterations can disappear completely and partially or can persist at the end of straining. With regard to their behaviour, we have divided these pelvic alterations into stable and dynamic ones. They are indeed caused by excessive straining because of rectal obstacle to evacuate. Therefore, in our opinion these pelvic alterations must be considered supporting mechanisms compensating for the incapacity of a prolapsed rectum to empty physiologically. Obviously, these same pelvic alterations, becoming stable even at rest, may instead hinder the evacuation.

With regard to the nature of the rectocele, we would like to point out that cadaveric studies and ultrasonographic mapping of the rectum in patients with a similar clinical and defecographic picture have clearly demonstrated that the only perceivable alteration is the thinning or disappearance of the muscular layer of the rectum. This type of defect begins just above the anal canal and extends variably upwards. As the rectal ampulla is no longer supported by the muscular layer, it can expand anteriorly and, after occupying the perineal body, push into the posterior vaginal wall, causing a colpocele. Large rectoceles can dilate the vaginal wall abnormally causing secondary structural damage. In any case, a rupture of the famous rectovaginal septum – the definition, function and existence of which has always been controversial – cannot be considered a primary cause of rectocele. In numerous cadaveric dissections, we have actually never been able to detect such septum, and we therefore think that this is probably a wrong definition given by gynaecologists (out of self-interest?). We have recently received a clear confirmation of this theory by pathologists who never detected such "septum" in specimens of full-thickness vaginal wall. We thought that these – rather detailed – preliminary remarks were necessary to make the following conclusion understandable: haemorrhoidal prolapse is a pathology secondary and consequent to upon rectal prolapse, mucosal or full thickness.

We therefore consider the clinical and pathological distinction between haemorrhoidal disease, rectal prolapse and rectocele an artificial one. Although the haemorrhoidal prolapse is the pathological alteration that causes the typical symptoms of haemorrhoidal disease, it must be considered a simply consequence of an internal rectal prolapse that progressively causes a prolapse of the anal mucosa, the haemorrhoidal cushions and the anoderma. Not always does an internal rectal prolapse cause a mucous and haemorrhoidal prolapse associated with it, but all haemorrhoidal prolapses are invariably associated with rectal prolapse. For this reason, a more correct definition of haemorrhoidal prolapse would be that of a rectoanal prolapse which would provide a more correct description of the anatomical and pathological condition. An in-depth revision of these pathologies and a clinical reclassification based on a new theoretical foundation are therefore necessary. We have proposed a single combined classification of these pathologies termed "unitary theory of rectoanal prolapse" (Fig. 21.2).

Based on the results of our studies and our observations, we came to the conclusion that a treatment consisting of the correction of internal rectal prolapse could represent a rational treatment for haemorrhoidal prolapse, for obstructed defecation if present, both because it would eliminate the mechanical obstacle and because resection of the distal rectum would include removing any rectoceles present, leading to improved of rectal compliance. Regarding the haemorrhoidal prolapse, we want to underline the fact that bleeding, thrombosis and haemorrhoidal oedema are only a few of the possible symptoms of the prolapses defined as rectoanal, and therefore obstructed defecation and continence disorders have to be taken into consideration when taking the history of these patients.

The rectal prolapse associated with a haemorrhoidal prolapse can present with different sizes, and there is no correlation in terms of size between haemorrhoidal and rectal prolapse. For this reason, the simple clinical evaluation of an external haemorrhoidal prolapse is not predictive of the size of the rectal prolapse that has to be removed, and so it does not allow us to determine the technique that needs to be chosen. Histologically, a simple mucosal prolapse is a detachment of mucosa and submucosa from the muscular layer of the rectum, and given their increased length, it presents as a redundancy. Full-thickness prolapse is generally characterised by a lengthening of the rectum because of structural alterations of the muscular layers. The rectum tends to form multiple loops that fold on themselves. In other cases rectal prolapse can be due to slippage of the whole rectum-sigmoid. In this case the natural evolution is a complete external rectal prolapse. Mucous rectal prolapses can be resected with the stapled anopexy technique. STARR is reserved to large mucosal prolapses or to full-thickness prolapses. STARR can be performed by means of two PPH devices or with the more recently introduced curved stapler that goes by the (senseless) name of TRANSTAR.

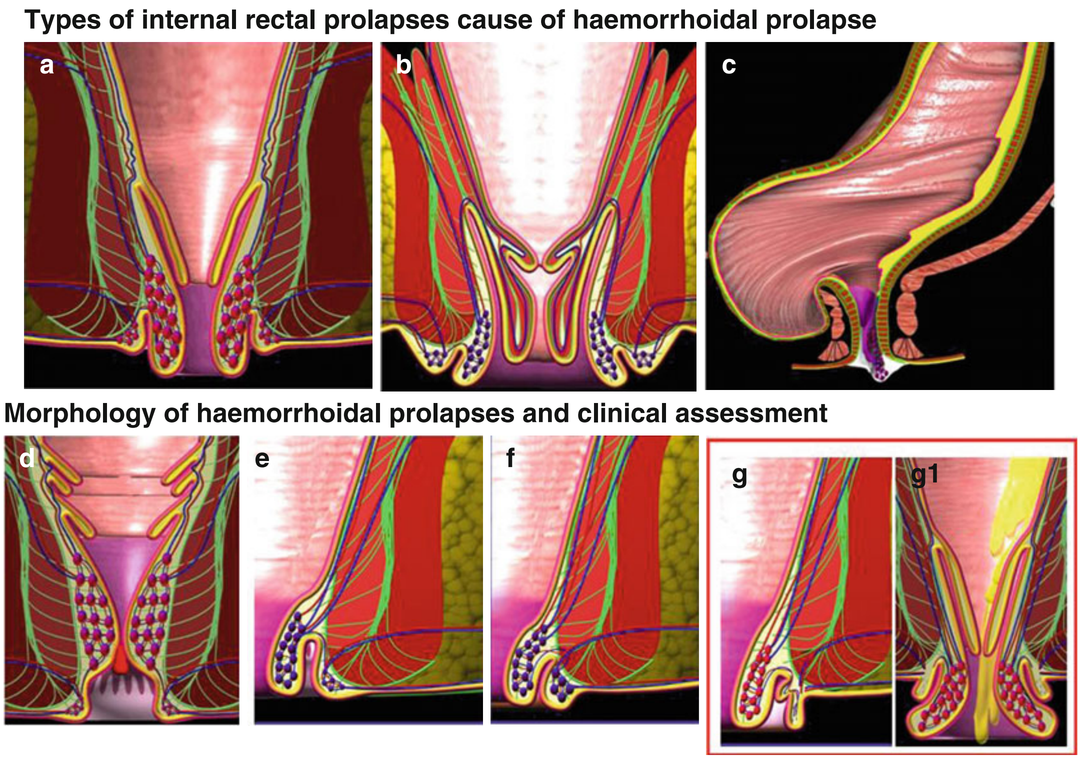

Fig. 21.2 The haemorrhoidal prolapse can be caused from a mucosal (**a**) or full-thickness rectal intussusception (**b**) and/or dilation (rectocele) (**c**). The occult internal rectal prolapse can cause, because of compression of haemorrhoidal veins, a haemorrhoidal swelling and bleeding without prolapse (**d**). The prolapse could be limited to the internal haemorrhoids (**e**) or extended to the external ones and to the anoderma (**f**). All the types of these prolapses could be spontaneously reducible, manually reducible and irreducible. The skin tags (**g**) often are associated with moist anus (**g1**)

21.3 Stapled Haemorrhoidopexy (SH)

21.3.1 Technique

Also known as the PPH procedure, Longo procedure, stapled anopexy and circumferential mucosectomy, PPH is a technique developed in 1993 that reduces the prolapse of haemorrhoidal tissue by excising a doughnut-like ring of the prolapsed rectal mucosa with a circular stapling device: with this the haemorrhoidal cushions, anal mucosa and anoderma are lifted and permanently fixed in their anatomical position [5], and a haemorrhoidal prolapse during defecation is prevented. The procedure can be performed under subarachnoid anaesthesia; the patient is placed in lithotomic position. A PPH-01 or PPH-03 kit (Ethicon Endo-Surgery, Cincinnati, Ohio) is necessary. The introduction of the circular anal dilator (CAD) causes the reduction of the anal prolapse into the rectum. After removing the obturator, the prolapsed rectal mucosa falls into the lumen of the dilator. The purse-string anoscope (PSA) is then introduced through the dilator. This anoscope will push the prolapsing mucosa back against the rectal wall along a 270° circumference, while the mucous membrane that protrudes through the anoscope window can be easily captured with a stitch (Prolene TM 00, Ethicon). By rotating the anoscope, it will be possible to complete a purse-string suture around the entire rectal circumference, 2–3 cm above the haemorrhoidal apex.

A PPH-01/PPH-03 stapler is opened to its maximum position. Its head is introduced until crossing the purse-string which is then tied with a knot. The ends of the suture are knotted externally. Then the stapler is partially tightened while keeping the casing outside. Once half the casing is inserted into the CAD, it is pushed against the purse-string, and while exerting moderate traction on the ends of the suture, the instrument is tightened. Keeping the stapling device in the maximum closed position, for approximately 30 s, may improve the haemostasis. Firing the stapler releases a double staggered row of titanium staples through the tissue. The circular stapler knife excises the tissue. A circumferential column of mucosa is removed. Finally, the staple line is examined using the anoscope. Additional haemostasis can be achieved by stitches (Vicryl TM 2-0, Ethicon).

21.4 Results

A recent systematic review [6] has allowed us to document the fact that a huge number of scientific publications are available in the literature about the PPH procedure: there are 29 publications [7–35] on 25 randomised clinical trials comparing PPH stapled haemorrhoidopexy with conventional haemorrhoidectomy. They included a total of 1,918 patients, of whom 971 underwent stapled haemorrhoidopexy (PPH procedure) and 947 had surgical haemorrhoidectomy. The main results are reported here:

Procedure Time. In the 23 trials [7, 9, 11, 13, 14, 16–35] in which it was possible to calculate, it was found that the PPH procedure stood out for its significantly shorter operating time compared with conventional haemorrhoidectomy [mean operating time, 17.55 vs. 28.90 min; weighted mean difference (WMD) – 11.35 min; $P=0.006$].

Pain. The PPH procedure caused significantly less postoperative pain than conventional surgery. Twenty-three trials [7, 9, 11, 13–19, 21–23, 25, 28–35] reported significantly less pain after PPH as evidenced by reduction of the pain scores at rest and on defecation by 42.3 %.

Recovery. There was a faster surgical and functional recovery after stapled haemorrhoidopexy. The PPH haemorrhoidopexy allowed a faster functional recovery with shorter time off work (WMD – 8.45 days; $P<0.00001$) and earlier return to normal activities (WMD – 15.85 days; $P=0.03$).

Patient Satisfaction. Significantly more patients in the PPH than in the conventional haemorrhoidectomy group rated the procedure as satisfactory [93.3 vs. 86.4 %; odds ratio (OR) 2.33; $P=0.003$] [9, 13, 16, 17, 23, 30, 34].

Re-intervention. The PPH procedure did not increase the overall need of surgical (OR, 1.27; $P=0.4$) and nonsurgical (OR, 1.07; $P=0.82$) re-intervention compared with conventional haemorrhoidectomy [7, 9, 11, 14–16, 18–21, 25, 27–30, 32–34].

Bleeding. There was no significant difference in the amount of intraoperative bleeding ($P=0.26$) or the incidence of early postoperative bleeding (bleeding within 24 h of surgery; $P=0.11$). At more than 1 day after surgery, the PPH procedure was associated with significantly less risk of bleeding (9.8 vs. 15.1 %; OR, 0.52 $P=0.001$) [7, 11, 13, 17, 19–22, 25–27, 29, 35]. There was no difference between the groups regarding the need for readmission as a result of bleeding (OR, 0.63; $P=0.67$), blood transfusion (OR, 0.64; $P=0.54$) or further non-operative (OR, 4.06, $P=0.08$) or operative interventions for bleeding (OR, 1.02; $P=0.95$).

Perianal Complications. There was no significant difference between the two procedures regarding early (OR, 1.82; $P=0.52$) [36–40] or late anal stenosis (OR, 0.69; $P=0.33$) [7, 9, 11, 14, 16, 18, 19, 22, 23, 26, 27, 35], anal fissure (OR, 0.93; $P=0.88$) [7, 16, 23, 25–27, 34, 35] or perianal fistula (OR, 0.25; $P=0.23$) [18, 21, 23, 27, 28].

Early Recurrence. There was no significant difference between the two groups with regard to early postoperative recurrence (within 6 months) or persistence of symptoms from haemorrhoids: 24.8 and 31.7 % after PPH procedure and conventional haemorrhoidectomy, respectively (OR, 0.68; $P=0.08$) [9, 19, 22, 25, 28, 33, 35]. There was no difference in the need for further operation for early recurrent haemorrhoids (OR, 0.71; $P=0.69$).

Late Recurrence. The incidence of recurrent haemorrhoids at 1 year or more after surgery was higher after stapled haemorrhoidopexy (5.7 vs. 1 %; OR, 3.48, $P=0.02$). However, the overall incidence of recurrent or persistent symptoms from haemorrhoids was similar in the groups (PPH vs. conventional: 25.3 vs. 18.7 %; OR, 1.57; $P=0.07$) [9, 17–19, 22, 25, 28].

Quality of Life. Three trials [7, 11, 20] addressed the quality of life after surgery. There was no significant difference in quality of life after either surgical procedure, as both the Short-Form 36 Quality of Life questionnaires [8, 20] and the Eypasch Gastrointestinal Quality of Life instrument [11] showed. However, there was a tendency towards higher median physical and mental scores after PPH procedures.

Cost-Effectiveness. Four trials [11, 14, 20, 31] investigated the cost-effectiveness of stapled haemorrhoidopexy compared with conventional surgery. When both the operating cost and hospital stay charges were taken into account, conventional haemorrhoidectomy was more expensive than the PPH procedure, although the differences were not statistically significant [14, 20]. Thus, the cost of the disposable stapler was offset by a shorter hospital stay. In an Asian study [11], where hospital charges are less expensive than in the West, the total medical cost was higher after the PPH procedure (U.S. $1,283.09±T 31.59 vs. U.S. $921.17±16.85).

In light of all the above-mentioned considerations, PPH stapled haemorrhoidopexy is safe with many short-term benefits, and long-term results are similar to the conventional procedure.

21.5 STARR Technique

21.5.1 The Rationale for the STARR Approach

Various surgical techniques have been devised which we would like to discuss in the context of our studies: rectopexy corrects invagination, but does not repair rectocele. Moreover the rectal fixation impedes the physiological dynamic rectal movement. We believe that this is the reason for the high percentage of faecal impaction after rectopexy. Posterior colpoperineoplasty corrects abnormal dilation of the rectocele, but since it is not effective on invagination, it does not correct the main cause of mechanical obstruction. In accordance with our pathophysiologic view of ODS, we conceived that a circumferential resection of the prolapsing distal rectum could provide a rational and effective treatment for ODS. Removal of the prolapsed rectum means to remove the rectocele and intussusception thus the anatomical substrate of mechanical obstruction. The affected portion of the rectal ampulla is replaced by structurally healthy rectum with normal compliance and capacity to sustain adequate endoluminal pressure. The rectum does not dilate anymore and will not protrude towards the vagina. The rectocele and posterior colpocele will be corrected. Removal of the obstacle will allow defecation with normal straining. The effect is a reduction of the dynamic and morphological alterations caused by excessive straining: dynamic enterocele, deep Douglas, descent of the perineum, etc.

21.5.2 Technique

STARR was proposed by Longo in 1998. We suggest performing the procedure under subarachnoid anaesthesia with the patient in lithotomic position. The lithotomic position is mandatory. Spinal anaesthesia is advantageous because it achieves a constant sphincter relaxation. Two PPH-01 or PPH-03 kits (Ethicon Endo-Surgery, Cincinnati, Ohio) are necessary. The CAD introduction manoeuvre is similar to the stapled haemorrhoidopexy (Fig. 21.3). The edge of the prolapsing rectal cylinders must be captured by three stitches passed at 10 – 12 – 2 h. The tail end of the central stitches is tied together with the right and left ones. In order to avoid the inclusion of posterior prolapse in the anterior resection, a spatula, 2 cm large, must be carefully inserted 8–10 cm through the posterior hole in the flange of the CAD. A PPH 01 stapler head, at

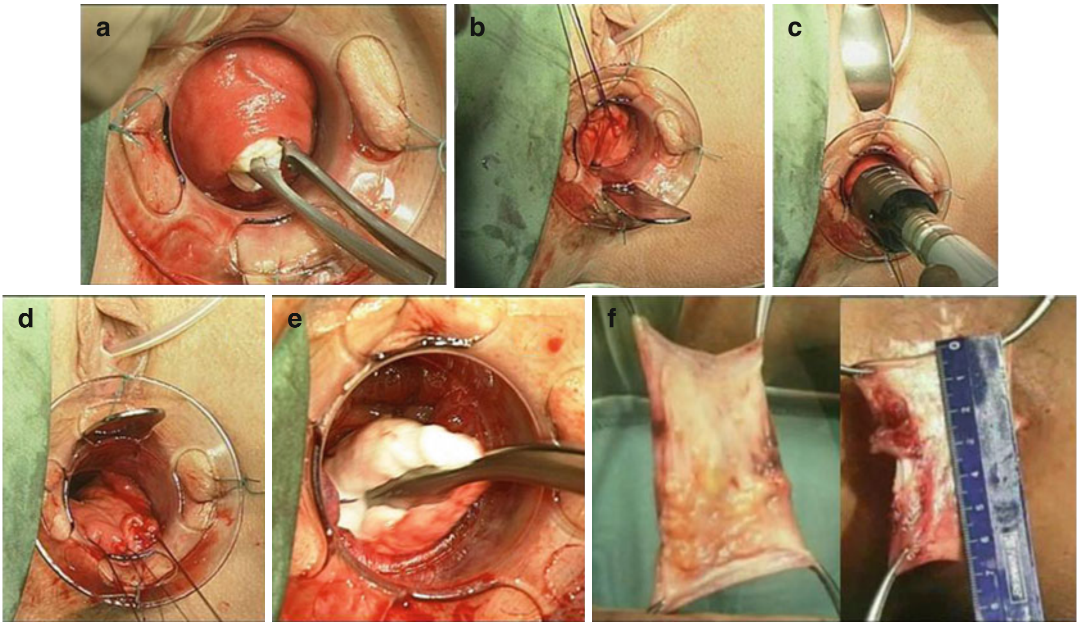

Fig. 21.3 Steps of STARR. The STARR procedure achieves the resection of the full-thickness internal prolapses. 1° step consist in the resection of the anterior prolapsed cylinder by PPH and 2° step in the resection of the residual posterior prolapse by one more PPH. (**a**) Evaluation of internal prolapse using a wad of gauze. (**b**) Three stitches are applied to the anterior edge of the prolapse; a spatula, 10–12 cm long and 2 cm wide, is inserted through the rear hole of the CAD to protect the posterior rectal wall. (**c**) Introducing a spatula into the vagina, before to firing, the posterior wall of vagina must be checked with the finger in order to avoid his entrapment. (**d**) Three stitches are applied to the posterior prolapse and the spatula introduced into anterior hole of CAD. Using the second PPH, the posterior prolapse is resected. (**e**) Postoperative evaluation of the rectal prolapse. (**f**) The STARR procedure permits to resect till 10 cm of prolapse

its maximum opening, is inserted and positioned just beyond the sutures. The suture threads are pulled through the casing holes and knotted together. Keeping the head of the stapler just above the stitches, start to close the stapler. Before the complete closure, in women, a vaginal valve is placed in the posterior fornix, and with two fingers, it is checked that the vaginal wall isn't trapped in the stapler. After having fired, the stapler is removed.

Normally, two dog ears, connected with a mucous bridge, will be observed. After removing the spatula and interrupting the mucosal bridge, one stitch for each dog ear is passed through and one more in the middle of the edge of the posterior prolapse (they are the lateral end of the posterior prolapse). Having introduced the spatula in the anterior window of the CAD flange, the posterior resection is made as well the anterior one. At the end of the procedure, two small dog ears can be observed; it can be removed or sutured using Vicryl 00.

A strip of Vaseline gauze tied to a suture should be introduced to prevent the formation of submucosal haematomas and to facilitate diagnosis of postoperative bleeding. To apply a urinary catheter for 24 h is useful to prevent urinary retention.

21.6 Results

Recently, in an attempt to prevent the incidence of failures after SH caused by incomplete resection of the prolapsed tissue (due to the limited volume of the stapler casing), the STARR procedure was adopted successfully for those patients in which a large prolapse was associated with the haemorrhoidal disease. Boccasanta [41] stated that, in patients with an association of prolapsed haemorrhoids and large rectal prolapsed, STARR results in a more complete resection of the prolapsed tissue than SH, with equal morbidity and a significantly lower incidence of residual disease and skin tags. The author used the circular anal dilator, CAD, in order to determine the appropriate surgical technique.

Furthermore, as reported in a recent randomised multicentre trial involving more than 400 patients, even if both the PPH-01 and PPH-03 kit can be used, the use of the PPH-03 stapler instead of the PPH-01 ensures a statistically significant reduction of intraoperative bleeding and a significant decrease of operative time.

21.6.1 Comment on SH and STARR

What emerges clearly from a review of the available literature on stapled haemorrhoidopexy and STARR is that many surgeons consider stapled haemorrhoidopexy a procedure indicated for haemorrhoidal prolapse and STARR an operation exclusively indicated in cases of obstructed defecation due to internal rectal prolapse and rectocele. Others consider that in case of haemorrhoidal prolapse, indications for STARR should be limited to patients with associated OD. It is fundamental to revise and adjust these ideas regarding indications for SH and STARR in order to obtain optimal results. As said before, haemorrhoidal prolapse is always a consequence of an internal rectal prolapse of variable size and not correlated to the degree and dimensions of muco-haemorrhoidal prolapse. This implies that a modest external prolapse can be associated with a significant internal prolapse. If we perform SH in these kinds of patients, we will certainly leave a residual internal rectal prolapse behind. We believe that this may predispose for a higher rate of recurrences and may also be the reason why a possibly associated OD is not cured or, worse, even aggravated as the residual prolapse can be jammed inside the anastomosis, especially if a fibrotic ring forms.

It is therefore important to state clearly that for haemorrhoidal prolapses, whether symptoms of obstructed defecation are associated or not, STARR is the procedure of choice whenever an important mucosal prolapse is detected and in all the cases in which there is a full-thickness prolapse or a rectocele. I hope not to shock anyone by confessing that in the last few years, I have myself performed STARR in about 95 % of patients with muco-haemorrhoidal prolapse. Thanks to this decision, the rate of recurrences has dropped, at 3 years of follow-up, from 4.9 to 0.4 %. Also with regard to curing OD as one of the complications of this procedure, the results are much more satisfactory. Paradoxically postoperative pain and bleeding have also decreased. In any case, the key aspect is that after so many years, the theory has been proven that haemorrhoidal prolapse is secondary to rectal prolapse and that it can be effectively cured by rectal prolapsectomy sparing the haemorrhoids.

Generally, with regard to the advantages of SH and STARR reduced postoperative pain and faster return to work are frequently highlighted. In my personal opinion, the main advantages are resolution of OD (which is often associated), efficient outcome regarding soiling and continence and the rare incidence of stenosis and, if they occur, the relatively easy treatment of stenosed anastomoses. Now that initial scepticism about SH and STARR as a cure for haemorrhoids has been overcome, the usual detractors insist on a supposedly higher rate of recurrences following these procedures, which has been proven absolutely incorrect, and on supposed severe complications. Obviously complications can occur, but after three million procedures, only very few cases have been reported and overemphasised with the support of some compliant journal that has published a number of articles without the necessary verifications on the trustworthiness of results. In fact, if some of the articles that report on severe and frequent complications were reliable, one would have to suspect a sadomasochistic tendency among thousands of surgeons performing this technique and an inclination to economical failure on the part of the five new companies that have copied the original PPH.

This whole chapter can be summarised by saying that prolapsed and hence symptomatic haemorrhoids are only an epiphenomenon of an internal rectal prolapse which is the primary pathology. Therefore, by adequately treating the internal rectal prolapse, haemorrhoidal disease and all the other symptoms caused by rectoanal prolapse are cured.

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22 Endoscopy in Coloproctology

Yiu Wing Luk and Paul Ho Ng

22.1 Introduction

More than 14 million colonoscopies are performed in the USA annually [1]. It is one of the most important diagnostic modalities in coloproctology, providing direct visualization of the entire colonic mucosa, histological specimens through biopsies and allowing therapeutic manipulations such as polypectomy.

A well-performed colonoscopy should be accurate, safe and well tolerated. Safety is especially important as the current most common indication for colonoscopy is screening. This requires appropriate steps to be taken before, during and after the procedure.

22.2 Preparing for the Procedure

22.2.1 Bowel Preparation

Bowel preparation is a commonly overlooked, yet extremely important facet for performing high-quality colonoscopy. Good bowel preparation improves rate of polyp-detection, reduces procedure time and increases rate of complete colonoscopies [2]. Most endoscopists would agree that a well-prepared colon is easier to work on.

While examination of the distal colorectum using flexible sigmoidoscopy can be performed with per rectal bowel preparation, a complete colonoscopy is usually performed following a period of dietary fibre restriction and intake of an oral bowel preparatory agent. Patients should be provided written instructions on dietary fibre restriction along with a direct verbal advice. The bowel preparation agents listed in Table 22.1 are currently available in Hong Kong.

Isotonic agents are safe in most patients and reliable in obtaining a good flushing effect. Their main drawbacks are the poor palatability and the need to ingest a large volume. Anti-emetics taken before ingestion of these agents may facilitate completion of the bowel preparation. The authors give ondansetron to patients with previous experience of bowel preparation-associated severe vomiting.

Hyperosmotic agents are smaller in volumes and usually more palatable but are contraindicated in patients with significant cardiac or renal comorbidities to avoid the hazards following significant third-space fluid shift. Significant amount of water needs to be consumed following the administration of these agents.

It must be noted that sodium phosphate preparations is increasingly recognized to be associated

Y.W. Luk
Honorary Consultant, Department of Medicine, Pamela Youde Nethersole Eastern Hospital, Chai Wan, Hong Kong
e-mail: ywluk@premiermedical.com.hk

P.H. Ng (✉)
Suite 708, Champion Building, 301-309 Nathan road, Kowloon
e-mail: Dr@paulng.clinic

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Table 22.1 Types of bowel preparation agents in Hong Kong

	Agents (brand name)	Pros	Cons
Isotonic	Polyethylene glycol (Klean-Prep®) Sodium sulphate anhydrous (Peglyte®)	No significant fluid or electrolyte shift into third space Suitable for patients with comorbidities such as renal or cardiac diseases	Large volume Poor palatability
Hypertonic	Sodium picosuphfate (Picolax®) Sodium phosphate (Fleet®)	Better palatability Smaller volume consumed	May result in significant third space fluid or electrolyte shift Not suitable for elderly patients (>60-year-old), patients with cardiac, renal or liver failure Acute phosphate nephropathy (sodium phosphate preparations)

Table 22.2 Sedating agents commonly used in colonoscopy

Class	Drug	Effects	Typical dose	Onset of action (min)	Duration of action (min)	Reversal agent
Benzodiazepines	Class property: sedative, anxiolytic, non-analgesic, amnesic					Flumazenil
	Midazolam	Excellent amnesic effect	0.02–0.03 mg/kg repeat in 2–5 min	1–2	15–80	
	Diazepam emulsion	Prolonged action	0.03–0.1 mg/kg repeat in 2–5 min	2–5	360	
	Lorazepam	Prolonged onset and action; slow recovery	0.011 mg/kg repeat 15–20 min	15–20	360–480	
Opioids	Class property: sedative, analgesic, non-amnesic					
	Pethidine	Prolonged action; significant hypotensive effect	25–50 mg over 3–5 min	5	60–180	Naloxone
	Fentanyl	Fast onset and short action; minimal hypotensive effect	0.5–1 mcg/kg repeat 2–5 min	2–3	2–5	
Propofol	Cardiopulmonary depression; rapid onset; amnesic, sedative		25 mcg/kg/min	<1	3–10	Nil

with acute phosphate nephropathy even in individuals with normal baseline renal function.

A split dose regime in which two separate doses of bowel preparation, one given the day before and one given on the morning of the procedure, may improve the overall quality of bowel preparation [3]. Its feasibility depends on the timing of the colonoscopy so that enough fasting can still be achieved after completion of consumption of the bowel preparation.

22.2.2 Sedation and Monitoring

Colonoscopy is usually performed under moderate sedation. A typical regime contains a benzodiazepine and an opiate. Commonly used agents are listed in Table 22.2.

Midazolam is used by many endoscopists for its fast onset and short duration of action and excellent retrograde amnesic effect. Its potency can vary significantly between patients, and as a result should be given with extreme caution in elderlies, patients with organ failure or risk of respiratory depression.

Propofol is useful in selected patients who are "difficult to sedate" including chronic alcoholics and chronic sedative users. It has a rapid onset of action, and its effect is rapidly reversed after cessation of administration. When used appropriately, typically in anaesthetists' hands, it provides maximum patient comfort. However, it must be noted that due to the potent suppression of gag reflex and potential of respiratory suppressive effect, airway compromise can occur. In previous experiences, 0.01 % of patients undergoing colonoscopy under propofol required bag-mask ventilation [4].

Pethidine and fentanyl are the commonly used opiates and offer both sedative and analgesic properties. Fentanyl has a more rapid onset of action and a shorter recovery time.

Cardiopulmonary complications can be induced by all of these agents. It is therefore important to monitor the vital signs of the patients closely. A pulse oximeter should be attached at all times. Blood pressure should be recorded at regular intervals. It is important that an experienced person monitors the airway patency and provides suctioning of saliva and secretions regularly.

In selected patients with high risk from sedation, such as in people in age extremes, those with multiple comorbidities and anticipated prolonged procedures, it is appropriate to consider additional monitoring with electrocardiogram and capnography, which would detect early cardiac arrhythmia including bradycardia and hypoventilation, respectively. Monitored anaesthetic care (MAC) should be considered in this group of patients. A sedation-free colonoscopy can be performed to avoid the use of sedatives and analgesics in selected patients [5].

22.3 During the Procedure

22.3.1 The Colonoscope

"Standard" colonoscopes have a diameter of about 13 mm. Paediatric scopes have a diameter of about 11 mm. Length of these scopes can vary from 1330 to 1700 mm. Modern colonoscopies use an external light source transmitted to the tip by optic fibre. Image acquisition is with a CCD at the tip. Typical field of view is 140°, with exceptions (see the following section), and angle of bend 180°, with exceptions (see the following sections). A working channel with diameter of 3.7 mm allows passage of accessories and instruments such as biopsy forceps and the apparatus described below.

22.3.2 Insufflation

The colonic lumen needs to be distended for visualization to facilitate intubation and examination. Typically only partial distension is performed during scope insertion and full distension needs to be performed during scope withdrawal. Three agents are currently used for such purposes, namely, air, carbon dioxide and water. It has been estimated that the volume required for colonic distension for a routine colonoscopy ranges from 8.2 to 17.8 L [6].

Air insufflation comes as a standard feature with all modern colonoscopy setups, providing flow rates of 1.8–2.7 L/min to undistended colon. The flow rate drops as the colon becomes pressurized (distended). Air insufflation is the most commonly used distending agent. It requires no additional equipment, adds no extra cost and does not require additional manipulation. However, occasionally patients may develop significant abdominal distension following air-filled procedure if suctioning was not carried out adequately. Inadvertently, over-insufflating the colon during intubation can pose difficulty for completing the examination.

CO_2 insufflation employs cylindered pressurized CO_2 released at controlled rate through insufflation channel. CO_2 is reabsorbed 13 times more quickly than oxygen into the blood stream, thus is dissipated from the colon much more quickly. This property, together with the innate vasodilatatory effect of CO_2, improves parietal blood flow during the procedure. Clinically, these translate into less post-colonoscopy pain and bloating [7]. Its universal use is mainly limited by the additional cost from cylinder CO_2 and the additional arrangements on transporting and storing these cylinders. It is contraindicated in patients with chronic pulmonary conditions who are at risk of CO_2 retention.

Water instillation facilitates passage of the colonoscopy. It has been demonstrated that water immersion technique straightens and opens the sigmoid colon, reduces spasm and avoids elongation of the colon commonly associated with air insufflation. It has thus been advocated as a way to improve patient tolerance without sedation and as a way to overcome difficult intubation [8]. Once caecal intubation is achieved, standard air or CO_2 insufflation resumes. A water pump is usually required for using this technique. It is best avoided in patients susceptible to hypothermia, fluid overload and electrolyte disturbances.

It is important to note that insufflation should be kept minimal during scope intubation to avoid over-distension of and "lengthening" of colon leading to difficulty in completing the procedure; and generous during scope withdrawal to facilitate adequate examination. Suctioning to remove insufflated gas towards the end of the procedure reduces abdominal distension post-procedure and improves patient comfort.

22.4 Improving Polyp Pickup Rate

Advances in colonoscopy have focused on improving polyp detection rate and in situ histological prediction, especially in differentiating adenomas from non-adenomatous polyps.

Some polyps are inherently more difficult to detect, namely so-called flat polyps and polyps behind folds. Differentiating minute mucosal changes including dysplasia associated with chronic inflammatory bowel diseases may also pose difficulties with standard endoscopy. A number of strategies have been developed to aid the detection of flat polyps, including chromoendoscopy, magnifying endoscopy and non-white light endoscopy or software processing/enhancement. In practice, turnover time and tight schedule are limitations in implementing routine use of these on all patients.

22.4.1 Withdrawal Time and Manoeuvre

After successful intubation to the caecum, examination of the colonic mucosa is performed during withdrawal. Length of withdrawal time is associated with polyp detection rate [9]. It is important that all solid and liquid residues be removed by flushing and suctioning during scope withdrawal. A circular movement should be adopted to look between and behind colonic folds. Additional devices may be used to facilitate this (see below). Repeated withdrawal and intubation around turns are encouraged, until every part of the colonic mucosa is confidently examined.

22.4.2 Improving Field of View, Cap Colonoscopy and Retro Examination

Improving the field of view and manipulating folds are two accepted strategies in improving polyp pickup rate.

The field of view of most modern colonoscopes is 140°, and is postulated to contribute to the missing of polyps at the peripheries of endoscopic view. One CT virtual colonoscopy simulation study estimated that by improving the field of view fewer polyps would be missed [10].

The 180 series of colonoscopes produced by Olympus Medical possess a wider field of view, 170°. However, in clinical studies this has not translated into higher polyp detection rate [11]. A prototype 210° scope is being evaluated for potentially better polyp pickup rate [12].

To further extend the view, retroflex scopes and third-eye colonoscopy were developed. RetroView range of endoscopes produced by Pentax has an extended range of flexion and smaller bend radius allowing retroflexion in colonic lumen. The operation of a retroflexed scope is the same as a standard colonoscopy. The Third Eye colonoscope is a through-the-channel baby scope, which conforms into a "J" shape after being passed into the lumen. Third eye colonoscopy requires the application of a special cap to the "mother" scope, a single-used catheter and a second set of image generator, which uses light filter to block off light emitted from the mother scope, avoiding the blinding effect.

Each has its merits – a retroflexed scope can perform therapeutic procedures on detected polyps readily, while third eye endoscopy has lower potential of being jammed in the colon. Since the Third Eye endoscope occupies the working channel of a standard endoscope, polypectomy needs to be performed after removal of the Third Eye, i.e. loss of retrograde vision, unless when dual channel mother scope is used.

Mucosal fold can be manipulated with a colonoscopy cap. Cap colonoscopy is performed by applying a transparent cap to the tip of a standard endoscope. It can be used to manipulate folds and help visualize polyps situated behind folds. Previous studies have shown a better polyp pickup rate. It has the advantage of being low cost, easy to apply and requires little additional learning [13].

22.5 Advances in Technology and Technique

22.5.1 Chromoendoscopy and Magnifying Endoscopy

Chromoendoscopy was commonly performed to suspicious areas before newer technologies emerged. Unlike upper chromoendoscopy, in which the choice of staining materials is wide, lower chromoendoscopy almost invariably employs indigo carmine or methylene blue.

It is important to clear the mucosal surface of any fluid or residue before dying. A spraying catheter is then passed down the working channel of a standard endoscope, through which the staining agent is injected with a standard syringe.

The endoscopist should be familiar with different kinds of mucosal pit pattern for this technique to be useful (Table 22.3).

When used properly, chromoendoscopy has a sensitivity of 92–98 % and specificity of 91–95 % for differentiating neoplastic from non-neoplastic lesions.

22.5.2 Narrow-Band Imaging

Narrow-band imaging (NBI), instead of white light, employs specific light spectrums of 440–460 nm (blue) and 540–560 nm (green). As these spectrums are absorbed by haemoglobin, vascular patterns are highlighted.

There is no convincing evidence to show that NBI yields better polyp detection rates than white light colonoscopy [14], but it may be useful in differentiation between different types of lesions. Several classification systems have been proposed for NBI examination of the colorectal region. Under the NBI international colorectal endoscopic classification (NICE), lesions detected in the colon are classified into three types (Table 22.4 and Fig. 22.1)

NBI is less promising in detecting colonic dysplasic in long-standing inflammatory bowel disease. In previous studies, NBI did not demonstrate a benefit in the detection of dysplasia comparing to white light endoscopy [16], and detected significantly fewer lesions as compared with chromoendoscopy in tandem examinations [17].

22.5.3 Software Processing

FICE and iScan are post-processing techniques marketed by Fujinon and Pentax, respectively.

In the limited number of trials, FICE has not demonstrated differences in adenoma detection rate. No clinical data for iScan is available at the moment.

22.5.4 Endorectal Ultrasound

Is useful for staging of rectal cancer (T and N) and follow-up, perianal diseases of inflammatory bowel disease and faecal incontinence. Please refer to relevant chapters of this book.

22.5.5 Endocystoscopy

This adopts highly magnifying optical endoscope (Olympus) with the ability to magnify up to

Table 22.3 Kudo's classification of chromoendoscopy (With permission from Elsevier)

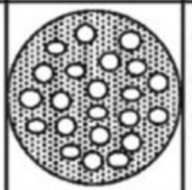
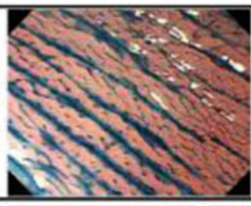
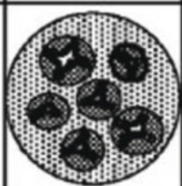
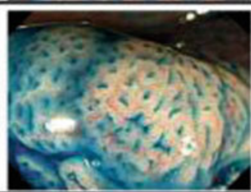
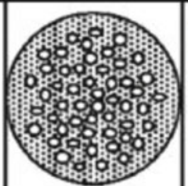
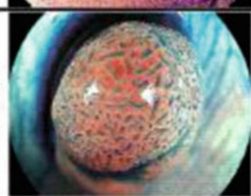
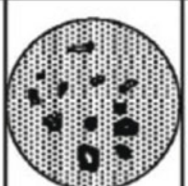
Type	Schematic	Endoscopic	Description	Suggested Pathology	Ideal Treatment
I			Round pits.	Non-neoplastic.	Endoscopic or none.
II			Stelllar or papillary pits.	Non-neoplastic.	Endoscopic or none.
III$_S$			Small tubular or round pits that are smaller than the normal pit	Neoplastic.	Endoscopic.
III$_L$			Tubular or roundish pits that are larger than the normal pits.	Neoplastic.	Endoscopic.
IV			Branch-like or gyrus-like pits.	Neoplastic.	Endoscopic.
V$_I$			Irregularly arranged pits with type III$_S$, II$_L$, IV type pit patters.	Neoplastic. (invasive).	Endoscopic or surgical.
V$_N$			Non-structural pits.	Neoplastic (massive submucosal invasive).	Surgical.

Table 22.4 NBI international colorectal endoscopic (NICE) classification

	Type 1	Type 2	Type 3
Colour	Same or lighter than background	Browner than background	Brown to dark brown relative to background; sometimes patchy white areas
Vessels	None, or isolated lacy vessels may be present coursing across the lesion	Brown vessels surrounding white structures	Has areas of disrupted or missing vessels
Surface pattern	Dark or white spots of uniform size, or homogenous absence of pattern	Oval, tubular or branched white structures surrounded by brown vessels	Amorphous or absent surface pattern
Most likely pathology	Hyperplastic	Adenoma	Deep submucosal-invasive cancer
Suggested action	Follow-up[a]	Polypectomy[a]/EMR/ESD	Surgery

[a]It has been suggested that lesions might be discarded after resection (resect-and-discard approach) or left in situ if confidently classified by NBI [15]. However, due to the high variation in sensitivity and specificity, this approach should not be adopted universally

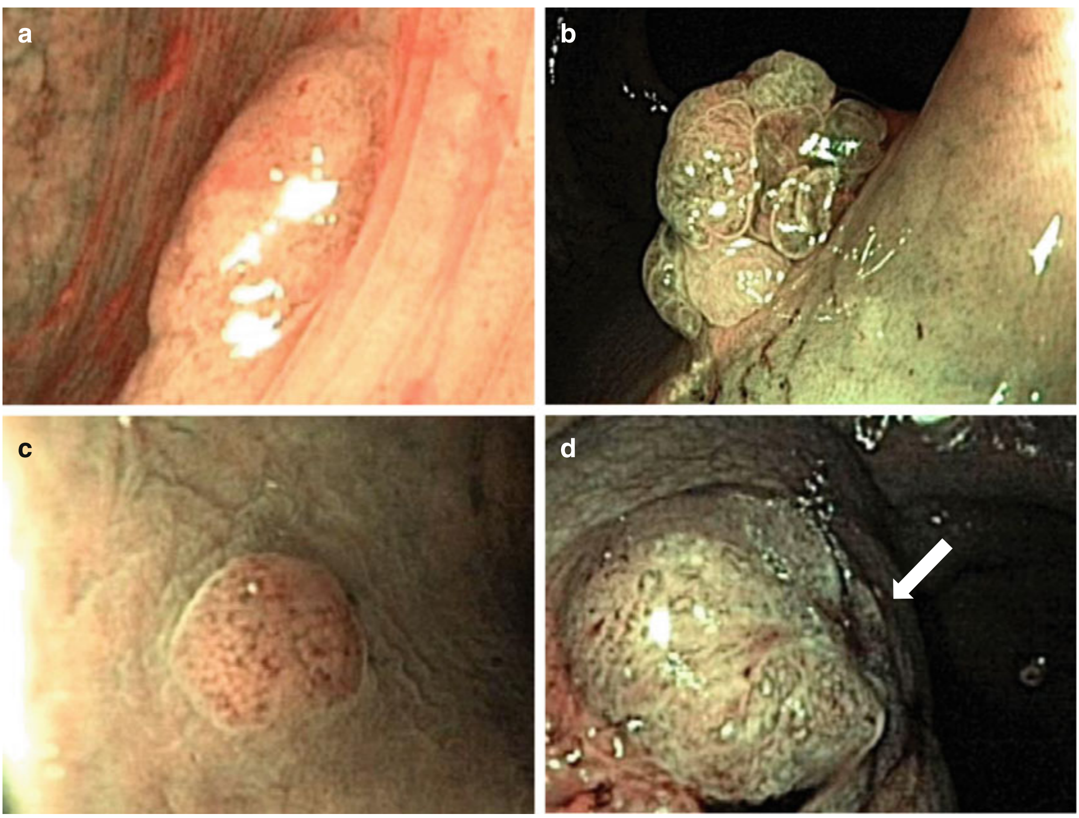


Fig. 22.1 NBI images. (**a**) A typical hyperplastic polyp (NICE Type 1); (**b**) A villous adenoma (NICE Type 2); (**c**) Another hyperplastic polyp with more visible vessels (NICE Type 1, note the lacy and dotted pattern of vessels); (**d**) Adenocarcinoma in situ, note the arrowed dimpled and darkened area representing deeper invasion (NICE Type 3)

1400×. Its shortcomings are that the lens must be placed in close contact with the area of interest and lacks the power to penetrate beyond the most superficial layer of tissue plane.

22.5.6 Confocal Laser Endocystoscopy (CLE)

The only currently commercially available system is a laser scanning microprobe which can be passed down the working channel of standard microscopes. Area of interest needs to be stained with topical contrast agents such as acriflavine and cresyl violet, or intravenous fluorescein.

Advantages of CLE over endocystoscopy are that endoscopic view is not sacrificed during the examination with CLE miniprobe, the depth of penetration can be adjusted and that the resolution is higher.

22.5.7 Optical Coherence Tomography

This new technology relies on the backscattering of light to obtain cross-sectional images of tissue. Its working principle is similar to ultrasonography, except that a near-infrared light is used instead of sound waves. Linear or radial two-dimensional images can be obtained.

It has a resolution of 20 μm, required no tissue contact nor water interface, allowing more flexible use than endorectal ultrasound. However, because the penetration is up to 3 mm into the mucosa, it is only useful for examining the full thickness of colon wall but not surrounding structures such as lymph nodes.

Clinical studies have demonstrated that hyperplastic and adenomatous polyps appear differently on OCT [18] and transmural inflammation can be identified allowing Crohn's disease to be distinguished from ulcerative colitis [19].

22.6 Advances in Polypectomy

Polypectomy has become an integral part of modern colonoscopy, and is an important way to prevent colorectal cancer. Large (>2 cm) or broad-based polyps are sometimes dealt with in a second session, and/or by endoscopic submucosal dissection (ESD), which is described in a separate chapter of this book.

Most detected polyps are otherwise resected in the same screening session. A good polypectomy is one which removes all polyp tissues without inducing deep colonic wall injuries or bleeding.

Snares and hot biopsy forceps are used for polypectomy. These are monopolar devices in which a current passes from the point of intervention, through the colonic wall, soft tissue, and back to the generator through a conductor placed over patient's skin. The amount of tissue injury is determined by the current and apparatus used, the contact point and the condition of the soft tissue in immediate contact with the point of intervention.

A snare delivers more localized tissue burn effect, avoiding excessive collateral damage, and is suitable for pedunculated lesions or sessile lesions after submucosal pre-injection (see below).

A hot biopsy forcep has a higher risk of inducing transmural injury if inadequate tension is applied to pull the polyp away from the colonic wall before applying the electrocautery current, and is mainly used for smaller polyps. Extreme caution must be exercised if it were to be used on polyps located in right-sided colon. The authors routinely apply pre-injection to even small polyps in these locations.

Modern endoscopic generators are capable of delivering either a pure cut, pure coagulation or a "blend" mode current. "Blend" currents result in less post-polypectomy bleeding.

Other ways to improve polypectomy performance include the following:

1. Pre-injection to the base of the polyp to "raise up" the polyp
2. Placing the polyp at the opening of the accessory channel
3. Positioning the patient such that the poly "hangs" down from the non-dependent side of the colonic wall
4. Using auxiliary devices such as loops and clips

22.6.1 Preinjection Technique

A solution is injected into the submucosal layer of the polyp base, to thicken the colonic wall. This serves several purposes:

– The fact that the lesion can be "raised" indicates likely absence of involvement of deeper colonic wall by the lesion – the raise test
– Lower chance of transmural thermal injury, due to the cushioning effect of expanded colonic wall
– Lower chance of bleeding, due to tamponade effect, and to a lesser extent vasoconstrictive effect (if adrenaline is used)
– Higher chance of complete removal of the polyp base

Commonly used solutions are normal saline and diluted adrenaline (1:10,000). Other agents such as dextrose solution, succinylated gelatin, hyaluronic acid and hydroxyethyl starch are rarely used in Hong Kong.

The authors routinely employ submucosal saline pre-injection to larger lesions and/or lesions in right-sided colon, or to facilitate removal of polyps from difficult areas such as behind folds or around turns. Adrenaline injection to stalk of pedunculated polyps is given to reduce chance of immediate post-polypectomy bleeding.

22.6.2 Patient Positioning

Colonoscopy is usually performed with the patient in left decubitus position. In some situations, turning the patient to a different position may facilitate a smooth polypectomy to be performed. By placing a polyp at the anti-dependent side of the colonic lumen:

- It "hangs down" from the colonic wall, facilitating identification and snaring of the stalk.
- Avoiding endoscopic view to relevant area being obscured by pooled liquid residue or blood, shall bleeding occur.
  (The dependent side of the colonic lumen can be readily identified as the side which water pools; the "anti-dependent" side refers to the opposite side).

22.6.3 Auxillary Devices

Hemoclips, Nylon loops are sometimes used during removal of large polyps to avoid or treat post-polypectomy complications.

Nylon loop application prior to polypectomy decreases rate of bleeding and should be considered in high risk cases (bleeding tendency, broad stalk). It should be placed close to the base of the polyp, while the resection should be performed so that a portion of the stalk is left as margin for further cutting and coagulation, if bleeding does occur. It can be difficult to apply a nylon loop to polyps with short stalks or to those located between sigmoid loops.

Hemoclip can be used to clip bleeding or exposed vessels, or to close entire mucosal defect following polypectomy (photos) to reduce risk of bleeding and perforation. Closure of the mucosal defect should only be performed when complete removal of the polyp is ascertained, as any subsequent endoscopic polypectomy at same site may be difficult after hemoclip placement.

22.7 Disease-Specific Approach

22.7.1 Polyps and Colorectal Carcinoma

Colorectal carcinoma is the second commonest cancer in Hong Kong [20]. It is now known that regular colonoscopy surveillance reduces colorectal cancer deaths. It is important that clinicians understand the follow-up interval for different findings detected during surveillance. Follow-up duration for colon polyps is guided by the number, type and characteristics of polyps detected. National polyp study has provided insight into the exact follow-up scheme. Table 22.5 summarizes current recommendations for polyp follow-up. Base of large resected polyps should be tattooed to facilitate future surveillance.

22.7.2 Inflammatory Bowel Disease

Endoscopic examination has a major impact on establishing the diagnosis and monitoring of inflammatory bowel diseases.

Table 22.5 Polyp follow-up strategy

Baseline colonoscopy: Most advanced findings	Recommended surveillance interval (years)	Quality of evidence
No polyps	10	Moderate
Small (<10 mm) hyperplastic polyps in rectum or sigmoid	10	Moderate
Adenomatous polyps		
1–2 small (<10 mm) tubular adenomas	5–10	Moderate
3–10 tubular adenomas	3	Moderate
>10 adenomas	<3	Moderate
One or more tubular adenomas > 10 mm	3	High
One or more villous adenomas	3	Moderate
Adenoma with high-grade dysplasia	3	Moderate
Serrated lesions		
Sessile serrated polyps < 10 mm with no dysplasia	5	Low
Sessile serrated polyp with dysplasia	3	Low
Traditional serrated adenoma	3	Low
Serrated polyposis syndrome	1	Moderate

Lieberman et al. [21] (With permission from Elsevier)

22.7.2.1 Diagnosis

The diagnosis of inflammatory bowel disease, in addition to relevant clinical features, requires compatible endoscopic appearance and histological examination. In suspected IBD patients, it is vital to intubate the terminal ileum and carefully examine the anal canal and perianal region.

Biopsy should be taken from the entire examined mucosa at regular intervals even if endoscopic appearance is normal. Any suspicious areas should also be biopsied. It is important to clearly label biopsy specimen from different areas, to assess the exact extent of disease involvement.

22.7.2.2 Surveillance

Surveillance of the colon in ulcerative colitis and Crohn's colitis with the aim to detect dysplasia is advocated in patients with long-standing diseases. White light endoscopy is performed first, with chromoendoscopy or one of the other advanced non-white light modalities used on suspicious areas. Biopsy should be taken at regular intervals from the colonic mucosa with clear labelling of biopsy site. Additional targeted biopsy is taken from suspicious areas, including irregular mucosae, ulcers or frank outgrowths. Different associations have issued different recommendations regarding screening intervals, and are summarized in Table 22.6.

Low Risk

- Left-sided ulcerative colitis (or Crohn's colitis involving less than 50 % of the colon)
- Extensive colitis with no active inflammation

Intermediate Risk

- Extensive colitis with mildly active inflammation
- Post-inflammatory polyps
- Family history of colorectal cancer in a first-degree relative who was at least 50 years of age

Higher Risk

- Extensive colitis with moderately active inflammation
- A stricture in the preceding five years
- Unresected dysplasia within 5 years
- Associated with primary sclerosing cholangitis
- A family history of colorectal cancer in a first-degree relative younger than 50 years of age

Table 22.6 Inflammatory bowel disease surveillance recommendations

	Ulcerative colitis		Crohn's disease
	Starting	Interval	
AGA	8 years after pancolitis 15 years after left-sided colitis	Repeated every 2 years	Same as UC
ACG	8–10 years	Annual surveillance	Insufficient evidence to provide guidelines
ASGE	8 years of pancolitis 15 years of left-sided colitis	Repeat every 1–3 years	Insufficient evidence to provide guidelines
BSG	10 years after onset of symptoms	Low risk: every 5 years Intermediate risk: every 3 years Higher risk: annually	Same as UC

AGA American Gastroenterology Association, *ACG* American College of Gastroenterology, *ASGE* American Society for Gastroenterology Endoscopy, *BSG* British Society of Gastroenterology

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23 Updates in Adjuvant Therapy

Wai Man Sze

23.1 Introduction

Colorectal cancer is the third most common cancer worldwide. In 2008, there were 1.2 million new cases and 609,000 deaths from the disease [1].

Colorectal cancer is a highly treatable disease. However, recurrence after curative surgery is still a major problem and often causes major morbidity and mortality. In recent years, major advances have been achieved in molecular biology, surgery, radiotherapy, and drug treatment. These have contributed to improvements in early detection, prediction of prognosis, cure rate in early stage, and survival in advanced disease.

23.2 Staging

The two most important prognostic factors of colorectal cancer, namely, depth of tumor invasion and degree of nodal involvement, have long been incorporated into the UICC/AJCC staging systems [2, 3]. New subgroups were added to the 7th edition of the UICC/AJCC staging convention (Table 23.1). T4 lesions were subdivided into T4a (defined as tumor penetrating the surface of the visceral peritoneum) and T4b (as tumor directly invading or histologically adherent to other organs or structures). Stage II tumors were subdivided into IIA (T3N0), IIB (T4aN0), and IIC (T4bN0).

23.3 Adjuvant Treatment for Stage II and III Colon Cancer

23.3.1 Stage II Colon Cancer

The prognosis for patients with stage II colon cancer is good, with a 70 % 5-year overall survival rate and 85 % 5-year disease-specific survival [4]. The use of systemic adjuvant chemotherapy for stage II colon cancer remains controversial. The majority of randomized studies have not shown conclusive evidence of an overall survival benefit when treating stage II colon cancer patients with adjuvant chemotherapy (Table 23.2). The study by the QUick and Simple and Reliable (QUASAR) collaborative group [10] reported a significant survival benefit to treatment with 5-fluorouracil-(5FU)-based chemotherapy in patients who underwent complete resection of colon or rectal cancer. The QUASAR study included mainly stage II colon cancer patients, but 9 and 29 % of the study population were non-stage II and rectal cancer patients, respectively. The authors estimated a 3.6 % (1.0–6.0) absolute improvement in survival

W.M. Sze
Cancer Care Centre, Private Practice, Room 1303, 26 Nathan Road, Kowloon, Hong Kong, SAR China
e-mail: szewm@netvigator.com

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Table 23.1 UICC/AJCC TNM staging (7th edition) of carcinoma of colon and rectum [3]

T – Primary tumor			
Tx	Primary tumor cannot be assessed		
T0	No evidence of primary tumor		
Tis	Carcinoma in situ		
T1	Tumor invades submucosa		
T2	Tumor invades muscularis propria		
T3	Tumor invades through muscularis propria into subserosa or into non-peritonealized pericolic or perirectal tissues		
T4a	Tumor penetrates to the surface of the visceral peritoneum		
T4b	Tumor directly invades or is adherent to other organs or structures		
N – Regional lymph nodes			
Nx	Regional lymph nodes cannot be assessed		
N0	No regional lymph node metastasis		
N1	1–3 regional lymph nodes		
N2	4 or more regional lymph nodes		
M – Distant metastasis			
M0	No distant metastasis		
M1	Distant metastasis		
Group stages			
Stage	**T**	**N**	**M**
0	Tis	0	0
I	T1–2	0	0
IIA	T3	0	0
IIB	T4a	0	0
IIC	T4b	0	0
IIIA	T1–2	N1	0
IIIB	T1–2	N2b	0
	T2–3	N2a	0
	T3–4a	N1	0
IIIC	T3–4a	N2b	0
	T4a	N2a	0
	T4b	N1-2	0
Iva	Any	Any	M1a
IVb	Any	Any	M1b

of stage II colorectal cancer patients after adjuvant chemotherapy treatment. The Adjuvant Colon Cancer Endpoints Group (ACCENT) analyzed individual data of 20,898 stage II–III colon cancer patients from 18 randomized trials. Of these 20,898 patients, 33 % had stage II disease. The ACCENT group reported a 5.4 % benefit in 8-year overall survival (OS) using 5FU-based chemotherapy treatment in stage II colon cancer patients (OS for surgery alone was 66.8 % vs 72.2 % for surgery and 5FU-based chemotherapy; $p = 0.026$) [11]. Current evidence suggests that adjuvant chemotherapy confers only a modest benefit to unselected stage II colon cancer patients. Therefore, the use of adjuvant chemotherapy for stage II colon cancer patients requires thorough discussion with patients concerning the associated risks and benefits. Recent guidelines have recommended that adjuvant treatment should not be routinely given to unselected patients and should only be considered in cases of high-risk stage II disease [12]. Traditional high-risk factors include T4 disease, high-grade tumor, lymphovascular or perineural invasion, obstruction, perforation, and inadequate nodal sampling on colectomy specimen [12, 13].

Several new molecular prognostic and predictive factors have been investigated, the most promising of which is microsatellite instability (MSI). Tumors can be classified as microsatellite stable (MSS), microsatellite instability low (MSI-L), or microsatellite instability high (MSI-H) depending on the presence or absence and extent of microsatellite instability. Nearly all studies have shown MSI to be prognostic in stage II colon cancer. Patients with MSI-H tumors had more favorable outcomes. In addition, a majority of studies have demonstrated that stage II patients with MSI-H tumors did not derive any benefit from adjuvant fluoropyrimidine chemotherapy [14–16]. Although a few studies did not confirm the predictive value of MSI in cases of adjuvant chemotherapy using fluoropyrimidine [17] or additional irinotecan [18], MSI testing is currently recommended to assist in the decision of whether to treat T3N0 colon cancer patients using chemotherapy. Chemotherapy may not be necessary for T3N0 patients with MSI-H disease. Multigene assays such as Oncotype DX [19–21], ColDx [22], and ColoPrint [23, 24] have been investigated for their ability to provide better prognostic and predictive information. The

Table 23.2 Randomized studies of systemic adjuvant chemotherapy for stage II colon cancer

			Stage II		
Study	Stage and site	Treatment	Patient no.	Recurrence-free	Overall survival
NCCTG [5]	Stage II and III Colon and rectum	Surgery alone	36[a]	58 %[d]	78 %[d]
		5FU/levamisole	33[a]	75 %[d] $p=0.1$	78 %[d] $p=0.26$
INT-0035 [6]	Stage II Colon	Surgery alone	159	71 % (7 years)	72 % (7 years)
		5-FU/levamisole	159	79 % (7 years) $p=0.1$	72 % (7 years) $P=0.83$
IMPACT [7]	Stage II Colon only (Pooled results from 5 separate studies)	Surgery alone	509	73 %	80 %
		5FU/LV	507	76 % $p=0.06$ (one-sided)	82 % $p=0.057$ (one-sided)
NSABP [8]	Stage II and III Colon	Control arms of C01–C04[e]	793		
	(Pooled results from C01–C04)	Experimental arms of C01–C04	772	HR 0.75[d]	HR 0.7[c]
NCCAP [9]	Stage II and III Colon and rectum	Surgery alone	235[a]	–	70 %
		5FU/levamisole	233[a]	–	78 % p value not reported
QUASAR [10]	Stage I, II, and III Colon and rectum	Surgery	1622[b]		
		5FU-based	1617[b]	HR 0.78 95 % CI 0.64–0.95 (Stage II colon HR 0.82 99%CI 0.63–1.08)	HR 0.82 95%CI 0.67–0.99 (Stage II colon HR 0.86 99%CI 0.66–1.12)

5-FU 5-fluorouracil, *LV* leucovorin, *CI* confidence interval, *HR* hazard ratio, *IMPACT* International Multicenter Pooled Analysis of Colon Cancer Trials, *NCCTG* The North Central Cancer Treatment Group, *NCCAP* The Netherlands Adjuvant Colorectal Cancer Project, *NSABP* National Surgical Adjuvant Breast and Bowel Project, *QUASAR* QUick and Simple and Reliable

[a]% of rectal cancer patients among stage II patients not reported

[b]9 % non-stage II and 29 % rectal cancer patients included

[c]$P \leq 0.05$

[d]Estimated from the survival curve or graph

[e]Patients in control arms of NSABP C03 and 04 had adjuvant chemotherapy

potential clinical use of these assays for deciding whether chemotherapy is appropriate is still under active investigation.

Oxaliplatin-based adjuvant chemotherapy has been widely used in stage III colon cancer patients. The use of oxaliplatin in stage II patients has not been supported by randomized studies [25, 26]. Recently, preliminary data [27] has demonstrated that the effectiveness of adjuvant oxaliplatin might be related to p53 and MSI status. Further studies are needed to address this issue. The new pT4bN0 patient subgroup in the AJCC 7th edition had a much worse 5-year relative survival rate (58.4 %) than pT4aN0 patients (79.6 %) [28]. Some clinicians may treat pT4bN0 patients using oxaliplatin because of the poor prognosis in this substage.

23.3.2 Stage III Colon Cancer

Adjuvant chemotherapy has consistently been shown to improve survival and decrease recurrence in stage III colon cancer patients [5, 29–32]. The use of 5-fluorouracil-based chemotherapy [33] can reduce the recurrence rate by 40 % and cancer-related deaths by 33 %. Adjuvant chemotherapy is currently regarded as the standard treatment for stage III colon cancer patients, unless the treatment is contraindicated because of coexisting medical conditions.

Three randomized studies [25, 34–37] have demonstrated that adding oxaliplatin to a fluoropyrimidine-based chemotherapy backbone can improve overall survival by 4–5 %. The 5-year overall survival rate of stage III patients treated with oxaliplatin-based adjuvant chemotherapy has been reported as 70–75 % (Table 23.3). Surprisingly, medications that are useful in treating metastatic colorectal cancer have not been beneficial as part of adjuvant therapy. Irinotecan has been shown to have the same efficacy as oxaliplatin for metastatic colorectal cancer. However, irinotecan did not confer an additional benefit in an adjuvant setting [38, 39]. Similarly, studies using chemotherapy and targeted drugs such as bevacizumab [40, 41] or cetuximab [42, 43] have suggested that the drugs had no benefit in an adjuvant setting. Therefore, adjuvant treatment with irinotecan, bevacizumab, or cetuximab is not recommended in routine clinical practice. The benefit of adjuvant treatment using fluoropyrimidine-based chemotherapy is similar in both the elderly [44, 45] and in the general population. However, data from subset analyses of MOSAIC [26] and NSABP C-07 [25] have suggested that oxaliplatin may not be beneficial for patients older than 70. Unlike fluoropyrimidine, the benefit of oxaliplatin in patients older than 70 remains unproven.

23.3.3 Adjuvant Treatment for Stage II and III Rectal Cancer

The management of rectal cancer involves a multidisciplinary team including surgeons, diagnostic radiologists, pathologists, radiation oncologists, and medical oncologists [46]. The best outcomes can only be achieved using a multidisciplinary approach with stringent quality control [47].

Unlike colon cancer, local failure was once a major problem in rectal cancer. In the past, the local failure rate was reported to be nearly 50 % [48] after surgery alone. The local failure rate has improved dramatically [49] in recent decades due to improved imaging, surgical techniques, pathology standards, radiation technology, and chemotherapy treatment.

Radical surgery remains the essential component for curative treatment. Total mesorectal excision [50] is regarded as the standard surgical technique for resectable mid or low rectal cancer [51–53]. The reported local failure rate after total mesorectal excision is in the range of 10 % [54, 55]. The most important prognostic factor in predicting local recurrence is circumferential resection margin (CRM) [56, 57]. The predictive value of CRM for local recurrence is even more powerful in the neoadjuvant treatment setting [56]. Therefore, it is imperative that treatment and patients are appropriately selected before surgery

Table 23.3 Randomized studies of adjuvant treatment for stage III colon cancer

Study	Treatment arm		Patient no.	5-year disease-free survival	5-year overall survival
	Control	Experimental	Control vs experimental		
Oxaliplatin-based adjuvant chemotherapy					
MOSAIC [35]	LV5FU2	FOLFOX4	675 vs 672	58.9 % vs 66.4 %	68.7 % vs 72.9 %[a]
				$p=0.005$	$p=0.023$
NSABP C-07 [25]	FU/FA	FLOX	860 vs 854[b]	57.8 % vs 64.4 %	73.8 % vs 76.5 %
				$p<0.001$	$p=0.052$
XELOXA [37]	FU/FA	XELOX	942 vs 944	59.8 % vs 66.1 %	74.2 % vs 77.6 %
				$p=0.0045$	$P=\text{NS}$
Irinotecan-based adjuvant chemotherapy					
CALGB 89803 [38]	FU/FA	Irinotecan/FU/FA	629 vs 635	0.61 vs 0.59	0.71 vs 0.68
				$p=0.74$ (1 sided)	$p=0.85$ (1 sided)
PETACC-3 [39]	LV5FU2	Irinotecan and LV5FU2	1050 vs 1044	54.3 % vs 56.7 %	71.3 % vs 73.6 %
				$p=0.106$	$p=0.094$
Adjuvant chemotherapy and targeted drugs					
NSABP C-08 [40]	mFOLFOX6	mFOLFOX6 + bev	1006 vs 2006	72.4 % vs 74.2 %[c]	NR
				$p=0.25$	
AVANT [41]	FOLFOX	FOLFOX + bev or XELOX + bev	955 vs 960 vs 952	HR 1 vs 1.17 vs 1.07	HR 1 vs 1.27 vs 1.15
				p insignificant	p insignificant
NO147 [42]	mFOLFOX6	mFOLFOX6 + cetuximab	909 vs 954[d]	74.6 % vs 71.5 %[c]	87.3 % vs 85.6 %
				$p=0.08$	$p=0.15$
PETACC8 [43]	FOLFOX4	FOLFOX4 + cetuximab	811 vs 791[d]	75.5 % vs 72.4 %[e]	HR 1.09
				$p=0.66$	$p=0.55$

MOSAIC Multicenter International Study of Oxaliplatin/5-Fluorouracil/Leucovorin in the Adjuvant Treatment of Colon Cancer, *NSABP* National Surgical Adjuvant Breast and Bowel Project, *XELOXA* XELOX in Adjuvant Colon Cancer Treatment, *CALGB* Cancer and Leukemia Group B, *PETACC* Pan European Trial Adjuvant Colon Cancer, *NCCTG* North Central Cancer Treatment Group, *NCI* National Cancer Institute, *FU* 5-fluorouracil, *FA* folinic acid, *LV* leucovorin, *Bev* bevacizumab, *NR* not reported, *HR* hazard ratio, *NS* nonsignificant

[a]6-year

[b]Subset analyses

[c]3-year

[d]k-ras wild type patients

[e]4-year

to avoid positive CRM. With advances in MRI technology, we can now more precisely predict CRM in a clinical setting. The Mercury Study Group reported a 94 % accuracy rate in predicting negative surgical margin [58]. MRI, if available, is the preferred imaging modality for determining the need for and type of preoperative treatment.

Adjuvant treatment for rectal cancer is a controversial subject. The data from randomized studies have not been totally consistent, and the optimal approach is still to be defined. Adjuvant radiotherapy reduced the pelvic failure rate by approximately 50 % irrespective of whether the primary surgery was total mesorectal excision [59, 60]. However, the overall survival benefit conferred by adjuvant radiotherapy is still uncertain. The Swedish Rectal Cancer Trial demonstrated an 8 % improvement in the overall survival rate with a 13-year median follow-up time [61, 62]. This benefit to overall survival was not demonstrated in the subsequent preoperative radiotherapy study by the Dutch Colorectal Cancer Group [49, 60].

Preoperative radiotherapy is preferred because it provides better pelvic control and less toxicity [63, 64] than postoperative radiotherapy. Both short-course radiotherapy (25 Gy in 5 fractions over 5 days) with immediate surgery and long-course radiotherapy (45–50.4 Gy in 25–28 fractions over 5–5.5 weeks) have been used in clinical practice. Studies comparing short-course and long-course radiotherapy have not demonstrated any difference in overall survival [65, 66]. Short-course radiotherapy is efficient and requires fewer radiotherapy resources. However, the downsizing effect may not be adequate to alter the surgical approach. Studies comparing short-course radiotherapy with long-course radiotherapy have shown no differences in sphincter-preservation rate between the two approaches [67, 68]. Short-course radiotherapy in combination with delayed surgery has also been explored. The initial results of Lyons R90-01 revealed a trend of more frequent sphincter-preservation surgery [69]. Long-term follow-up showed no difference in anal function between the two approaches [70]. Another study addressing this issue, Stockholm III, reported that short-course radiotherapy with immediate surgery had higher postoperative complication rates compared to short-course radiotherapy with delayed surgery [71, 72]. Other clinical outcomes of Stockholm III are pending.

Preoperative concurrent chemoradiotherapy has been investigated by several randomized studies (Table 23.4) [65, 66, 73–78]. In general, local control was better when using concurrent chemoradiotherapy. However, the improvement in local control did not translate into an overall survival benefit and acute toxicity increased when using chemoradiotherapy treatment. There was no difference in late toxicity. More intensive chemoradiotherapy (Table 23.5), such as the use of oxaliplatin as a concurrent agent, conferred a higher pathological complete regression rate. Preliminary results of this approach have suggested it was more toxic and did not result in better local control, disease-free survival, or overall survival rate.

Although the role of postoperative adjuvant chemotherapy in colon cancer is well established, the role of postoperative adjuvant chemotherapy in rectal cancer is still controversial. Individual randomized studies have not conclusively confirmed any survival benefit. A recent systematic review [84] included 21 randomized controlled trials and 9785 rectal cancer patients, with 11 randomized trials performed in Western countries and 10 in Japan. Adjuvant chemotherapy reportedly provided benefits to both overall survival (hazard ratio 0.83, confidence interval 0.76–0.91) and disease-free survival (hazard ratio 0.75, confidence interval 0.68–0.83).

Table 23.4 Randomized studies comparing preoperative radiotherapy (RT) with preoperative chemoradiotherapy (CRT) for stage II–III rectal cancer

Study	CRT	RT	Patient no.	Local control	Overall survival	Acute toxicity	Late toxicity
			RT vs CRT				
Boulis-Wassif et al. [73]	FU	34.5 Gy/15 fr	121 vs 126	85 % vs 85 %	59 % vs 46 %	3/121 vs 6/126	NR
				NR	$p=0.06$	NR	
EORTC 22921 [74, 75]	FU/LV with RT+adjuvant 4 courses FU/LV	45 Gy/25 fr	505 vs 506	17.1 % vs (8.7 %[a] and 7.6 %[b])	65.8 % vs 64.8 %	37.7 % vs 54.3 %	No difference
				$p=0.002$	$P=0.84$	$p<0.005$	
Buiko et al. [65]	RT: 50.4 Gy/28 fr+FU/LV	25 Gy/5 fr	155 vs 157	9 % vs 14.2 %	66.2 % vs 67.2 %	3.2 % vs 18.2 %	7.1 % vs 10.1 %
				$p=0.17$	$p=0.96$	$p<0.001$	$p=0.36$
FFCD 9203 [76]	FU/LV	45 Gy/25 fr	367 vs 375	8.1 % vs 16.5 %	67.9 % vs 67.4 %	2.7 % vs 14.6 %	NR
				$p<0.05$	$p=0.684$	$p<0.05$	
Brandengen et al. [77]	FU/LV with RT+adjuvant FU/LV for 16 weeks	50 Gy / 25 fr	109 vs 98	67 % vs 82 %	53 % vs 66 %	6 % vs 29 %	37 % vs 41 % (same)
				$p=0.03$	$p=0.09$	$p=0.001$	NR
TROG 01.04 [66, 78]	RT: 50.4 Gy/28 fr+FU[c]	25 Gy/5 fr[c]	162 vs 161	7.5 % vs 4.4 %	74 % vs 70 %	1.9 % vs 28 %	9/155 vs 13/158
				$p=0.24$	$p=0.62$	$p<0.001$	$p=0.53$

EORTC European Organization for Research and Treatment of Cancer, *FFCD* Federation Francophone de Cancerologie Digestive, *TTROG* Trans-Tasman Radiation Oncology Group, *RT* radiotherapy, *CRT* chemoradiotherapy, *FU* 5-fluorouracil, *LV* leucovorin

[a]Patients treated without postoperative chemotherapy

[b]Patients treated using postoperative chemotherapy

[c]Both RT and CRT arms received adjuvant chemotherapy

Table 23.5 Randomized studies comparing preoperative chemoradiotherapy (CRT) with or without oxaliplatin for stage II–III rectal cancer

Study	No oxaliplatin	With oxaliplatin	Patient no.	pCR rate	Local control	Overall survival	Acute toxicities
			Control vs experimental				
STAR-01 [79]	RT 50.4 Gy/28 fr Infusional 5-FU	RT 50.4 Gy/28 fr Weekly oxaliplatin + infusional 5-FU	379 vs 368	16 % vs 16 %	NR	NR	8 % vs 24 %
				$p=0.904$			$p<0.001$
ACCORD 12/0405 Prodige2 [80, 81]	RT 45 Gy/5 weeks Capecitabine	RT 50 Gy/5 weeks Weekly oxaliplatin + capecitabine	299 vs 299	13.9 % vs 19.2 %	93.9 % vs 95.6 %	87.6 % vs 88.3 %	10.9 % vs 25.4 %
				$p=0.008$	NR	$p=$NS	$p<0.001$
CAO/ARO/AIO-04 [82]	RT 50.4 Gy/28 fr Concurrent infusional 5FU + adj 5FU	RT 50.4 Gy/28 fr Concurrent oxaliplatin + infusional 5FU + adj oxaliplatin + 5FU	623 vs 613	13 % vs 17 %	NR	NR	20 % vs 23 %
				$p=0.04$			NR
NSABP R-04 [83]	RT 50.4–55.8 Gy Gy/25–28 fr Infusional 5FU or capecitabine	RT 50.4–55.8 Gy Gy/25–28 fr Weekly oxaliplatin + infusional 5FU or capecitabine	924 vs 643	17.8 % vs 19.5 %	87.9 % vs 88.8 %	79 % vs 81.3 %	7 % vs 16 %[a]
				$p=0.42$	$p=0.7$	$p=0.38$	$P<0.0001$

STAR Studio Terapia Adiuvante Retto network, *ACCORD* Actions Concertees dans les Cancers Colorectaux et Digestifs, *NSABP* National Surgical Adjuvant Breast and Bowel Project, *pCR* pathological complete response, *RT* radiotherapy, *5FU* 5-fluorouracil, *NR* not reported, *NS* nonsignificant

[a]Grade 3–4 diarrhea

Conclusions

Surgery is the key treatment component in resectable colorectal cancer. Adjuvant chemotherapy is indicated for stage III colon cancer and selectively for high-risk stage II patients. Preoperative short-course radiotherapy or chemoradiotherapy for rectal cancer can improve local control, though the impact of such treatment on overall survival is still uncertain. Oxaliplatin is beneficial as an adjuvant treatment in stage III colon cancer, though the benefit for patients older than 70 or as part of chemoradiotherapy for rectal cancer remains unproven.

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Informed Consent in Colorectal Surgery

24

David Tzit Yuen Lam

24.1 Introduction

The professional requirement for surgeons performing colorectal surgery is no different from those performing other branches of surgery. Two recent cases heard by the Medical Council of Hong Kong are of particular relevance to consent in colorectal surgery. The judgement handed down illustrated in practical details what is expected of surgeons before performing certain colorectal surgical operations.

24.2 Case I [1]

Mr. A visited Dr. R for haemorrhoid problem. Dr. R explained that haemorrhoid can be treated conservatively or operatively and further advised Mr. A to undergo conservative treatment first. Dr. R also explained to Mr. A that in case he considered surgery, the choices would lie between conventional hemorrhoidectomy (CH) and stapled haemorrhoidopexy (SH). Dr. R mentioned that SH has the advantages of less pain, shorter recovery time, less need for wound care and not much risk involved. The patient was given conservative treatment.

Mr. A returned 3 months later when he decided to undergo surgical treatment. Dr. R advised SH and gave a detailed explanation of the procedure without much referral to CH. Surgical risks were explained, but the risk of rectal perforation and recurrence rate were not discussed.

Surgery was subsequently performed in a private hospital. To cut the story short, surgery was unfortunately complicated by rectal perforation. The patient developed lower abdominal pain and urinary retention the day after surgery and progressed to peritonitis after a couple of days. He was admitted to a public hospital through the Emergency Department, and he received Hartmann's operation.

Mr. A launched a complaint against Dr. R to the Medical Council, and the Medical Council laid charges against Dr. R, amongst other charges, for failing to obtain an informed consent before SH.

After hearing evidences from expert witnesses appointed by the Defendant and the Prosecution, the Medical Council was of the view that

(a) Both CH and SH were equally suitable treatment options for Mr. A
(b) Dr. R had the responsibility to discuss the pros and cons of each surgical option to Mr. A in order for him to make an informed choice

D.T.Y. Lam
City Surgical Center,
Room 833, 8/F, 639 Nathan Road,
Kowloon, Hong Kong, China
e-mail: lamtydavid@gmail.com

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(c) Dr. R failed to mention that SH has a higher recurrence rate
(d) A higher recurrence rate is a significant difference between CH and SH
(e) Dr. R failed to mention that SH carries the low but serious risk of rectal perforation
(f) By nature, CH does not come with the risk of rectal perforation
(g) Rectal perforation is the defining difference between CH and SH, which must be explained to the patient

The Medical Council contended that Dr. R did not provide a balanced explanation of CH and SH. Instead, Dr. R had been promoting SH to Mr. A, emphasising the pain of conventional haemorrhoidectomy and the relatively less pain and few risks of SH. The consent was therefore not an informed consent.

The Medical Council found Dr. R guilty of failing to obtain an informed consent from Mr. A before SH.

24.2.1 Lesson Learned from Case I

Section 2 of the Code of Professional Conduct (2009) promulgated by the Medical Council of Hong Kong (the Code) sets out a doctor's requirement on obtaining patients' consent to medical treatment. A few observations from the above case are worth discussing.

The Medical Council relied heavily on expert witnesses. With regard to whether or not CH and SH were equally suitable for this patient, the Defendant's opinion carried little if any weight in spite of the fact that he was the only surgeon (and specifically not the expert witnesses) who had examined the patient at the material time.

The Code provides that "consent is valid only if (ii) the doctor has provided proper explanation of the nature, effect and risks of the proposed treatment and other treatment options (including the option of no treatment) (2.7)."

The Code further requires that "the explanation should be balanced and sufficient to enable the patient to make an informed decision. (2.10.2)"

Since the Medical Council has in this case decided that both CH and SH were equally suitable for Mr. A, Dr. R has the responsibility to give a balanced view with regard to the nature, effect and risks of each of the options.

Systematic Cochrane reviews of CH and SH were published only in late 2006 (updated in 2010), by which time the higher recurrence rate of SH was convincingly demonstrated. The incidence happened in late 2009 to 2010. The Medical Council expects doctors to keep themselves abreast of advances when providing treatment for patients.

While it is understandable that a comparison of recurrence rate between the two procedures should form part and parcel of an informed consent, how much to explain with regards to potential complications can be somewhat elusive.

The Code requires that "the explanation should cover not only significant risks, but also risks of serious consequence even though the probability is low. (2.10.3)"

24.2.2 The Right to Choose and Not the Actual Choice

In Chester v Afshar [2004] UKHL 41, nNeurosurgeon Dr. Afshar, while obtaining consent for surgery, failed to explain to Miss Chester a 1–2 % risk of cauda equina syndrome stemming from the surgical treatment of her low back pain. Unfortunately, Miss Chester developed this complication. The judge at the Court of First Instance found that Miss Chester would have sought further advice or made alternative treatment decisions had the risk of cauda equina syndrome been explained to her. The failure of Dr. Afshar to explain was therefore causal to Miss Chester's suffering.

Dr. Afshar appealed. The Court of Appeal judges upheld the decision of the Court of First Instance and pointed out that a doctor has the duty to obtain consent from a patient on a fully informed basis, with the patient aware of all risks. It would be unnecessary for the patient to prove that she (in this case) would have chosen another option but for the information missed. Rather, by not fully informing, the doctor would be violating her right to choose [2].

24.2.3 Is Any Complication Rare Enough to Not Mention?

The risk of rectal perforation will be far below 1–2 %. No one will argue that it comes with serious consequences. We should take note, however, that reported complications that are serious also include severe rectal bleeding, severe chronic pain, rectal stenosis, recto-vaginal fistula and Fournier gangrene. Apart from recto-vaginal fistula, all these complications do occur rarely with traditional haemorrhoidectomy as well.

For the same token, putting up an intra-venous catheter can lead to septic thrombophlebitis, life-threatening cellulitis requiring amputation and ICU care and cutting off the catheter tip that ends up anywhere between the periphery and the pulmonary artery requiring surgical or radiological intervention. While these complications are rare, no one will brush them away as trivial. Should these be mentioned always? Who does?

24.2.4 Back to Bolam?

In Montgomery v Lanarkshire Health Board [2015] UKSC 11, Dr. McLellan, the Obstetrician taking care of Mrs. Montgomery who has diabetes, did not mention to her the possibility of shoulder dystocia. Dr. McLellan explained that he would not routinely inform his patients of shoulder dystocia because the risk of a grave problem related to shoulder dystocia was very small to the baby, but if advised of the risk of shoulder dystocia women would opt for a caesarean section, which was not in the maternal interest. Unfortunately, Mrs. Montgomery's baby was born with serious disability.

On appeal, the Supreme Court held that the willingness of a doctor to discuss with his patients the risk of a proposed surgery is a reflection of his attitude, and how much respect he has for his patient. It is not determined by medical knowledge or schools of thought. Bolam [3] test will not therefore be the correct test to use.

The principle of self-determination is highlighted. Patients should determine for themselves what treatment they will choose and what risks they are willing to undertake. The doctor has the duty to provide adequate information for patients to make an informed decision. Adequate information means any material risks inherent to a surgical procedure and reasonable alternatives. According to Lord Kerr and Lord Reed, "A risk is 'material' if a reasonable person in the patient's position would be likely to attach significance to it" [5].

24.3 Case II [2]

In another recent Medical Council inquiry case, two charges were laid against Dr. S. Charge 1 was for failing to properly and adequately inform a patient, Mr. B, of possible complications of fistulectomy before surgery. Charge 2 was for failing to properly and adequately explain to Mr. B the alternative treatment, viz. seton, before surgery.

On MRI performed a day before surgery, a Y-shaped fistula with two internal openings and one external opening was found. The upper limb of the Y represented a tract ending in a high internal opening. From my personal experience of over 20 years, I have seen numerous complex tracts with one internal opening and multiple external openings and complex tracts with one internal opening and a rostral extension of a typically blind tract ending either as an intersphincteric or supra-sphincteric abscess. What the MRI finds here (two internal openings ending up in one common external tract) is way off my understanding, but let us assume it exists for discussion sake.

Surgery was performed as planned. Dr. S excised the low fistula tract by fistulectomy. The upper tract broke while he was dissecting rostrally, and Dr. S backed off. Unfortunately, Mr. B developed solid anal incontinence after surgery. After a few days, he was referred to a public hospital, where he underwent defunctioning colostomy, seton placement, overlapping sphincteroplasty and finally closure of colostomy. He was cured of his fistula eventually.

Any explanation related to fistulectomy, if it had been given by Dr. S, was not documented. Defence would be very difficult without documentation, and Dr. S was advised by his lawyers not to contest. He pleaded guilty on both charges.

24.3.1 Lesson Learned from Case II

It was still up to the Medical Council to judge whether or not the conduct of Dr. S amounted to professional misconduct. It is this deliberation that sheds light on yet another expectation the Medical Council has on doctors. Charge 1 involves the doctor's failure to explain potential faecal incontinence after fistulectomy. This is straightforward, and we shall not discuss further. We focus on charge 2, i.e. alternative treatment of seton insertion.

The Medical Council found that Dr. S never advised Mr. B of the alternative treatment of seton insertion and that he neither advised the patient nor documented a treatment plan of multiple staged operations. The Medical Council held the view that for high-type fistula, seton insertion is a widely accepted treatment which is less likely to lead to incontinence. Dr. S had the responsibility to properly advise Mr. B of the applicable treatment option, which he failed to do. He was therefore convicted on both charges.

Not only are doctors expected to explain the proposed operation and its alternatives, but doctors are also expected to explain the treatment plan to patients. In the case of anal fistula, it will be the intra-operative decision of seton placement and staged operation. While as surgeons we may see this as a technical consideration, patients will reasonably expect the doctor to paint to them the whole picture, including treatment plans ahead.

24.3.2 Basic Principles of Informed Consent

Medicine is not a simple consumer product. The patient, or customer, as some would put it, often does not have an understanding of his health need sufficient for him to make a decision to his best interest. The doctor, on the other hand, knows more about the patient's health condition, his medical need and treatment options available. Doctors and patients are not on level grounds when a medical decision is called for.

By virtue of the right to self-determination, any adult of a sound mind may determine for himself the medical treatment (or no treatment) that he considers best for him. In this regard, the doctor has the responsibility of explaining to his patients his medical condition and treatment options available, including the option of no treatment.

The doctor has to explain to the patient the nature and severity of a medical condition he is suffering from, how it will affect his health and how his life may be affected. The doctor should put before his patients the treatment options available, explaining in a balanced manner the pros and cons of each type of treatment. The doctor should not exaggerate the benefit of one treatment and the disadvantages of another in order to bias a patient's decision. The patient should reasonably expect to understand what might happen if he chooses not to undergo treatment at all.

The risks involved in a treatment should be clearly explained, especially common complications, and those, albeit rare, come with serious consequences. The doctor should depict to his patient what he can reasonably expect after undergoing treatment.

Understandably, not all patients are intelligent enough to understand complicated medical concepts. Doctors should not rush to push a decision out of his patients. Enough time and opportunity for discussion should be given.

When the above are fulfilled, a patient should be in a position to make an informed decision for himself. The doctor may proceed to obtain an informed consent from his patient.

24.3.3 The Code in Brief

Let us now quickly run through what doctors in Hong Kong are required to do in obtaining an informed consent (see section 2 of the Code) [4].

First and foremost, if a doctor performs surgery on a patient who does not consent to such treatment, he has committed a crime. He is liable to be charged with battery or wounding and assault, occasioning actual bodily harm. Exception is allowed for emergency treatment.

Consent has to be given voluntarily. The doctor bears the responsibility to properly explain, in order that the patient has a reasonable understanding of the nature, effect and risk of surgery.

Such explanation has to be balanced, and sufficient to enable the patient to make an informed decision. It should cover not only significant risks but also risk of serious consequences even though the probability of occurrence is low.

Consent may be implied or expressed. Implied consent is applicable only for minor and non-invasive treatment. For expressed consent, it may be given orally or in writing. Oral consent is acceptable for minor invasive procedures. Even for consent given orally, doctors are encouraged to document the oral consent in the case record.

Informed consent obtained in writing is required for major surgical procedures and all those involving general, parenteral, spinal or epidural anaesthesia and major regional blocks.

Contents of the explanation should be included on the consent form. The consent form has to be signed by the doctor, the patient and (if present) the witness at the same time. It should be obtained well ahead of surgery so that the patient has reasonable time to consider adequately.

Specific provisions are given for consent relating to under-aged patients and those with advanced directives. These topics are beyond our scope of discussion.

Conclusion

Days are gone when patients fully confided in their doctors to make for them the best decisions and asked no questions. By upholding the principle of self-determination, doctors today are expected to provide adequate information to their patients to help them make for themselves the best decision.

The Medical Council relies heavily on opinions made by expert witnesses, who should provide the Medical Council with fair and accurate information in a disinterested manner. Personal, biased opinion not backed by evidence-based medicine harms not only the defendant doctor in a most unfair manner but gives the public a wrong impression as to the proper conduct expected of doctors.

(The author is a member of the Medical Council of Hong Kong.)

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