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TECHNIQUES

MA-NOS radical sigmoidectomy: report of a transvaginal resection in the human

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Abstract
Background With available laparoscopic and endoscopic instruments/technology a standard radical sigmoid resection is feasible and safe using transvaginal minilaparoscopic-assisted natural orifice surgery (MA-NOS).
Methods The intervention was a transvaginal MA-NOS sigmoidectomy in a 78-year-old woman with a sigmoid adenocarcinoma. Maintaining triangulation the surgeon positioned himself at the right side of the patient and used the transvaginal trocar for dissection and stapling of both the inferior mesenteric vessels and the upper rectum. The colonic resection was performed extracorporeally in the conventional fashion and was followed by an intra-abdominal endoscopically assisted stapled anastomosis.
Results Advantages of minimally invasive surgery seemed to be enhanced with this hybrid laparoscopic approach. Postoperative course was uneventful. All oncological principles governing resection and management were accomplished and the pathology examination confirmed a T3N1 lesion. The patient was discharged on the fourth postoperative day.
Conclusion Transvaginal MA-NOS radical sigmoidectomy is a feasible and oncologically safe procedure. MA-NOS is a realistic option for avoiding the need of assisting incisions and related morbidity in the laparoscopic resection of large intra-abdominal lesions. Combined hybrid laparoscopic NOS in humans (MA-NOS) currently provides a safe and reliable way of defining future clinical applications and advantages of NOS and NOTES. Additionally, it stimulates the active development and evaluation of the underpinning technologies and instrumentation.

Keywords NOS · MA-NOS · NOTES · Transvaginal · Sigmoidectomy · MIS · MAS

Surgical treatment has been in constant evolution over the last 20 years in the quest for minimising incisions irrespective of the complexity of the operation. The trend that began with minimally invasive cholecystectomy first described by Mühe in 1985 [1] rapidly progressed to include other more technically challenging abdominal procedures. More recently, minimally invasive colorectal procedures such as laparoscopic-assisted colectomy have become more popular as prospective randomised trials have demonstrated their safe clinical application in malignant disease [2–4]. Parallel to the move of surgery towards the minimally invasive surgery (MIS) approach, ongoing advances in interventional gastrointestinal flexible endoscopy (submucosal resection, stenting, endoscopic suturing) have ushered in new alternative therapeutic approaches with the potential to reduce further the invasiveness of surgical treatment.

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It was predictable and a question of time before these two interventional approaches (minimally invasive surgery and interventional endoscopy) would come together as an operative platform enabling the performance of major intraperitoneal operations without the need of skin incisions. To this effect, two approaches have emerged in the last five years: natural orifice surgery (NOS) and natural orifice transluminal endoscopic surgery (NOTES), the difference between the two being the way the peritoneal cavity is accessed. In NOS, the peritoneal cavity is accessed *directly* from the natural orifice/cavity, e.g., vaginal and rectal (TEM), whereas in NOTES, after passage through a natural orifice (mouth or anus), the peritoneal cavity is approached *indirectly* at a considerable distance from the natural orifice (mouth or anus) through a perforation in the gastrointestinal tract (stomach or colon) to enable access of the flexible endoscope to the peritoneal cavity.

Transgastric abdominal exploration and liver biopsy first reported by Kalloo et al. in 2004 [5] was soon followed by multiple additional procedures including oophorectomy, partial hysterectomy, tubal ligation and gastrojejunal anastomosis [6–9]. Several technical issues undoubtedly make this approach to upper abdominal compartment organs difficult and are stimulating considerable technical research and development. Thus with the transgastric access, the operating surgeon faces the added challenge of having to dissect with the scope in a retroflexed position. To avoid this limitation, some researchers have considered the per anal transcolonic approach for procedures in the upper abdominal compartment: the first transcolonic experimental NOTES procedures were reported by Pai et al. [10]. They successfully performed cholecystectomies in a surviving porcine model. The transcolonic approach was considered easier and faster than the transgastric approach. Since then, the safety and feasibility of other access routes such as the vagina have been described in porcine animal models for the gall bladder, peritoneoscopy and the resection of small organs [11, 12]. Ryou and Fong et al. reported a more aggressive combined transvaginal and transcolonic approach for NOTES distal pancreatectomy [13].

The transvaginal access to the abdominal cavity is a well-established route for many gynaecological procedures (hysterectomy, myomectomy, adnexectomy) and has been used for extraction of large specimens [14]. Recently, Whiteford et al. described complete sigmoid colon mobilization, high vascular ligation, en bloc lymphadenectomy and stapled end-to-end anastomosis performed by a single operator using transanal endoscopic microsurgery instrumentation in three male cadavers. They concluded that standard sigmoid resection, en bloc lymphadenectomy and primary anastomosis without any incisions are feasible and highlight the potential for TEM instrumentation as a portal to the peritoneal cavity for NOS procedures [15]. Young-Fadok et al. investigated the feasibility of a NOTES right hemicolectomy in a female human cadaver [16]. Critical steps of this operation such as dissection and control of the ileocolic vessels, dissection of the caecum, creation of the anastomosis and transaction of the bowel could all be accomplished using a bidirectional approach (transcolonic and transgastric).

With this background, institutional review board approval was obtained for us to proceed with the use of MA-NOS approach in a female patient requiring sigmoid resection. To our knowledge, this is the first clinical report of this hybrid transvaginal radical sigmoidectomy. The operation was performed in a 78-year-old woman with a partially obstructing sigmoid adenocarcinoma. The potential risks and benefits of the operation were discussed with the patient, who gave informed consent. All the principles of laparoscopic sigmoidectomy for cancer were strictly adhered to.

Methods

Preoperative work-up and bowel cleansing were standard as for minimally invasive colorectal resection. The patient was placed in the lithotomy position and the peritoneal cavity was entered through a small incision in the posterior vaginal vault. Transvaginal access to the peritoneal cavity with introduction of a long 12-mm trocar was performed under laparoscopic guidance with a needle scope placed at the right lower quadrant (RLQ). It was through this port that pneumoperitoneum was insufflated, maintained and monitored. With the patient now in steep Trendelenburg position, a flexible tip endoscope (Videolaparoscope HD EndoEYE flexible tip Olympus Europe) was then introduced through the trocar in the vaginal wall for anatomic inspection and to guide the introduction of two more 2-mm needle ports on the right flank 2 cm below the navel and another at the umbilical scar needed for retraction and exposure (Fig. 1).

To maintain the principle of triangulation for the approach to the operative field, the surgeon positioned himself at the right side of the patient using the grasper in the RLQ for traction, with his right hand holding the dissecting hook through the transvaginal trocar (Fig. 1). The quality of exposure of the operative field obtained was excellent and was improved as needed by the introduction of an anal dilator through the rectum for further traction on the rectal–sigmoid junction by a second assisting surgeon (Figs. 2 and 3).

Standard steps of a laparoscopic sigmoid cancer resection were then followed. First the inferior mesenteric artery and vein were exposed, dissected and, once skelotonised,

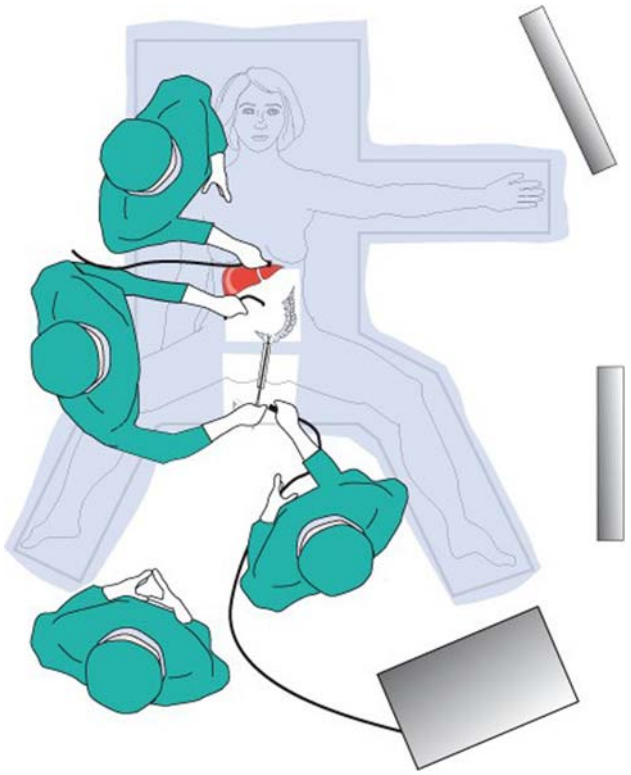

Fig. 1 Operating room setup. Position of surgeon for operative field triangulation

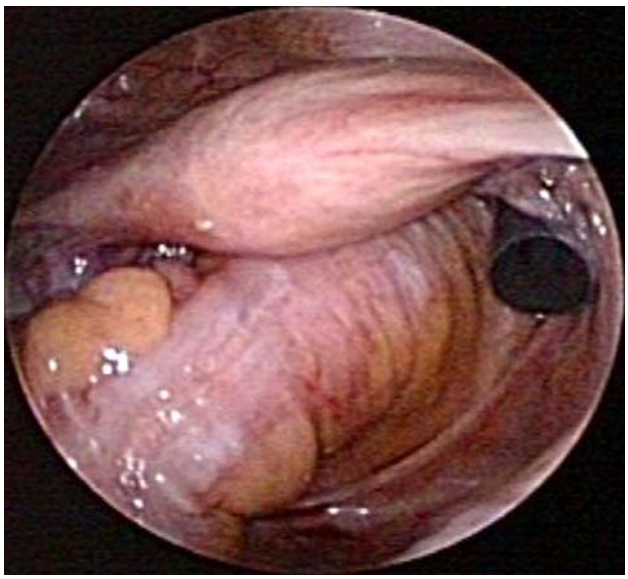

Fig. 2 Pelvic organs anatomic view and relations obtained with the laparoscopic miniscope. Transvaginal trocar in situ

transected with a 45-mm Endo GIA stapler (Covidien, AutoSuture, Endo GIA Universal Roticulator 45-2-0) that was introduced through the transvaginal trocar (Fig. 4). After identifying the left ureter and completing medial dissection with total sigmoid mobilization, a 45-mm Endo GIA

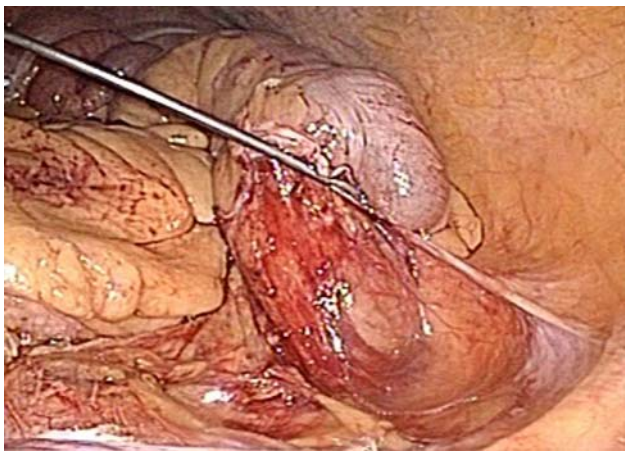

Fig. 3 Intraoperative view with the flexible tip endoscope introduced through the transvaginal trocar

Fig. 4 Inferior mesenteric artery transection with stapler through transvaginal trocar

(Covidien, AutoSuture, Endo GIA Universal Roticulator 45–3.5) stapler was introduced through the transvaginal trocar for transection of the upper rectum (Fig. 5). Following oncological principles, a wound edge protector (3M Steridrape Wound Protector 1073, ring diameter 12.1 cm) was introduced through the incision in the posterior vaginal wall. Iodine solution lavage of the pelvis and rectum was performed. Adequate positioning of the wound edge protector around the vaginal wall was monitored under laparoscopic guidance. The mobilised colon was carefully extracted through the vagina. The proximal colonic resection was performed extracorporeally in the conventional fashion with placement of a purse-string suture (Covidien, AutoSuture Purstring 45) and insertion of the circular stapling anvil into

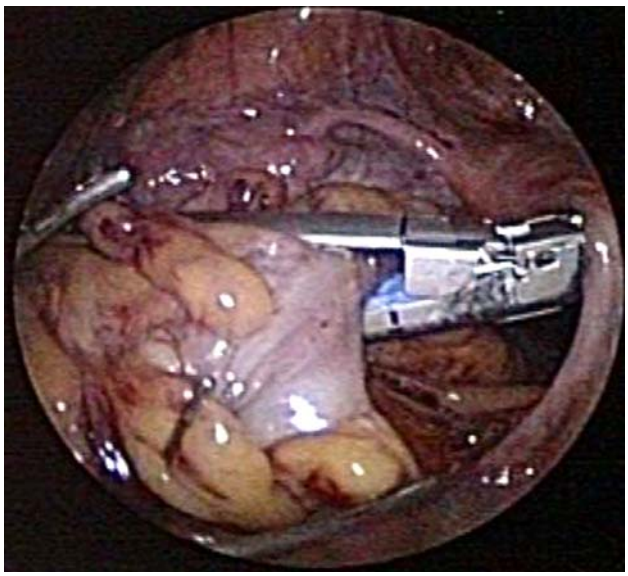

Fig. 5 Rectal transection with stapler through transvaginal trocar

the proximal end of the bowel. The bowel was then replaced into the abdominal cavity. A circular stapler (Covidien, AutoSuture DST series EEA 31 mm) with a bio-absorbable staple line reinforcement membrane (GORE SEAM-GUARD Bioabsorbable Staple Line Reinforcement, Ref. 1BSGC31) was inserted transanally. A grasper was inserted through the transvaginal trocar to attach the anvil in position and perform an end-to-end anastomosis under direct visual control with the laparoscope. The operative site was checked to ensure haemostasis. Finally the colpotomy was closed with interrupted 2–0 polyglactin sutures. The operative time was 150 min.

Results

The basic advantages of minimally invasive surgery seemed to be enhanced with this hybrid laparoscopic and natural orifice endoscopic approach. The abdominal scars have been difficult to notice and postoperative pain was minimal and responded readily to oral paracetamol and ketoprofene in usual doses. Oral intake was initiated as soon as passage of flatus was described at the second postoperative day. The patient was active and walking at 48 h with no discharge, bleeding or discomfort from vaginal access site. She was discharged on the fourth postoperative day. At the follow-up visit 10 days after surgery, the patient had completely resumed full activity. Pathology reported a moderately differentiated adenocarcinoma infiltrating through the muscularis propia into the subserosa, with 2 out of 16 lymph nodes being positive (T3N1 lesion). Size of specimen was adequate with wide and negative resection margins.

Discussion

The Gastrointestinal Surgery Unit of Hospital Clínic is a national and local referral centre for advanced laparoscopic procedures where more than 1500 minimally invasive colorectal resections for malignancy have been performed [2, 3]. Our service is committed to constant research in minimally invasive surgical procedures, through both randomized control trials and experimental animal laboratory work. All procedures are included in our database with a separate registry for experimental operations. Activities are monitored by the Institutional Review Board and Ethical Committee.

NOS and NOTES constitute attractive areas of research and interest to colorectal surgeons as their basic components: advanced endoscopy, endoluminal surgery and peritoneal entry via a natural orifice, are all part of colorectal practice. The first hybrid NOS transvaginal radical sigmoidectomy in a human being was performed after extensive experimental surgery with transgastric NOTES cholecystectomy in live pig models and after having performed our first clinical NOTES transgastric cholecystectomy last November (unpublished data). This experience and the constant interaction with our multidisciplinary team of specialists have allowed us to identify and become familiar with the technical limitations and difficulties of the NOTES approach.

Since the first presentation on NOTES at DDW 2000, research interest in NOTES and NOS has grown steadily. An obvious advantage of both approaches is the elimination of the need for abdominal wall incisions and their related complications. Other potential advantages result from the further reduction of surgical trauma when using the NOS approach as distinct from laparoscopic and open surgery, including reduction of adhesion formation, lower stress response and faster recovery. From a review of abstracts and animal studies reported to date, it is clear that these have addressed the efficacy of individual components of NOTES rather than the NOTES or NOS intervention as a whole [17], e.g. efficacy/safety of access wound and its closure, problems concerning imaging and optics, manoeuvrability and grasping. Up to now the common denominator has been the definition of feasibility of different types of procedures with identification and management of technical limitations of instruments. Consequently, the potential benefits of both NOTES and NOS remain largely theoretical.

The first clinical NOTES procedure was a transgastric appendectomy, performed by Rao and Reddy in India in 2005 [18]. Last year, there were three case reports of clinical transvaginal NOS cholecystectomies performed successfully without complications [19–21]. All of these procedures were hybrid, in which two or at least one additional 2–5-mm port was used for additional exposure or traction.

Della Flora et al. in their review of NOTES for intra-abdominal surgery described a total of 34 studies of intra-abdominal NOTES procedures until September 2007. Only four of the reviewed studies were performed in humans and only one of these was comparative. One of the few clinical studies consisted of three transvaginal appendectomies using minilaparoscopy-assisted natural orifice surgery (MA-NOS) [22]. Although not strictly NOTES, MA-NOS is to be seen as a precursor of NOTES providing an interim solution to safe clinical practice [17]. Pearl et al. performed nine human hybrid transgastric peritoneoscopies in patients requiring a gastrotomy for resection of gastrointestinal stromal tumour (GIST) or removal of foreign bodies. The gastrotomy was subsequently closed laparoscopically [11]. The only other human study is a report of NOTES transvesical peritoneoscopy [12]. The remaining 30 animal studies have been experimental pilot feasibility procedures, 20 of which included survival as part of the outcome evaluation. To date, three human trials have been registered with the Clinical Trials Register (JW Hazey at the Center for Minimally Invasive Surgery, University of Ohio; L. Swanstrom at Oregon Clinic, Portland; J. M. Marks at University Hospitals Cleveland Case Medical Centre), and are yet to be completed [17].

Current NOTES procedures with flexible endoscopes are technically limited by the inability to manipulate tissue effectively or to retract organs. There are two basic considerations when considering distal force exertion: firstly, force diminishes over the course of a long and flexible endoscope; secondly, the forces are mainly applied along the same axis as the visual axis because the instrument channels are oriented parallel to one another. Endoscopes only allow limited force transmission, minimal traction-counter traction, and they buckle away from target organ when force is exerted [23].

The ideal scenario would consist of a stable platform for both optics and mechanical forces (traction, counter-traction), that would allow passage of effectors or instruments. The future application of NOTES for large-organ intra-abdominal surgery (colorectal, gastric, spleen) depends not only on the improvement of endoscopes, but also on the invention and development of a range of new devices for flexible endosurgery instrumentation and a safe and efficient form of tissue approximation for defect closure [24].

With these limitations in mind and the available technology/instrumentation, combined hybrid laparoscopic NOS procedures are presently the safest and most reliable way to define future clinical applications and advantages of NOTES. At the Hospital Clinic in Barcelona, we used minilaparoscopy-assisted natural orifice surgery (MA-NOS) to perform a radical sigmoidectomy in a 78-year-old female with colon cancer. Beyond demonstrating feasibility, we strictly adhered to oncological principles governing resection and management. Consequently, we are certain that neither long-term survival nor local recurrence were compromised in this particular patient. Nevertheless, it is obvious that long-term follow-up is needed to confirm this observation. Postoperative course was uneventful. We did not consider that baseline operative morbidity or mortality is likely to be influenced by our approach. Complications associated with incision and closure of the posterior vaginal wall are extremely rare. Furthermore, the risk-prone steps such as anastomosis and colon/tumour resection were done outside the vagina under direct vision.

The possibility of avoiding an assisting incision and its potential complications in laparoscopic colorectal resections is of great clinical value. Though small, assisting incisions (Pfannenstiel, transverse minilaparotomy, hand-port incision) are still laparotomies. Incisional hernias are experienced by 4–18% of US patients submitted to open surgery, with surgical wound infections occurring in 2–25% of patients undergoing laparotomies in the US. Both complications translate into additional healthcare costs [25, 26].

From the technical viewpoint, a few issues need to be highlighted: firstly, the proximity of the access route (transvaginal) to the target organ clearly facilitates not only final extraction but also the step-by-step dissection, with easier traction and counter-traction; secondly, the introduction of an anal dilator through the rectum as an additional manoeuvre proved useful in the exposure of the surgical field (additional second-orifice assistance); thirdly, it is important to have a preoperative colonic transit series that provides some indication for the need or otherwise of splenic flexure mobilization; and fourthly, we were able to reproduce step by step the standard laparoscopic sigmoid resection. From our experience, it seems that the ideal tumour locations for this approach are upper rectum and sigmoid.

The complexity of the scientific, technical and ethical challenges that need to be overcome demands coordination and collaboration between the different scientific working groups to identify the barriers to development of NOS and NOTES and to provide a series of steps and guidelines to progress this concept. In response to this need, a group of expert laparoscopic surgeons and endoscopists representing both SAGES and ASGE teamed up in Chicago, July 2005 to create a guide for the development of NOTES. The working group, known as the Natural Orifice Surgery Consortium for Assessment and Research (NOSCAR), identified potential barriers to performing NOTES that would require resolution before this approach could be performed safely in humans in the resulting white paper [27]. The European scientific experts in this field have created a similar scientific monitoring society, EURO-NOTES.

Surveys presented at the SAGES 2007 meeting where patients were asked about their perceptions of NOTES

technology indicate what risks are considered acceptable. Complications, recovery time and postoperative pain were considered to be more important than cosmesis, cost and length of hospital stay, but there was no tolerance for higher risk or worse outcome for NOTES regardless of expected benefits. This indicates that safety and efficacy need to be adequately addressed before performance of NOTES in the clinical setting becomes acceptable [28]. Furthermore well-designed well-conducted studies are needed to define clinical applications. The results obtained from the different experimental studies indicate that NOTES can in fact be used to perform selected intra-abdominal procedures. However, the most evident need is for further development of these procedures and detailed studies comparing NOTES to current surgical alternatives before NOTES may be seriously considered for routine clinical use.

Conclusions

Transvaginal MA-NOS radical sigmoidectomy is a feasible and oncologically safe procedure. Clinical results in this patient were comparable to those obtained with laparoscopic-assisted sigmoid resection. MA-NOS is an option which avoids the need for assisting incisions and their related complications during resection of large intra-abdominal organs. Amid the excitement for potentially scar-free surgery and the abolishment of skin-wound-related complications lies a distinct need to develop more robust safe technologies to achieve reliable closure and overcome technical challenges, thus bridging the gap between potential applicability and clinical reality. With these limitations in mind and the available technology/instrumentation, combined hybrid laparoscopic approaches are presently the safest and most reliable way to define future clinical applications of NOTES. Appropriate clinical indications for these new procedures are yet to be defined. As NOTES/MA-NOS are still in a developmental stage, it is difficult to compare the safety and efficacy of using such approaches for intra-abdominal surgery with current surgical interventions. Our patients' main concern with this even less invasive procedure is safety and similar efficacy with acceptable risk. Our huge challenge is to provide this in the context of evidence-based clinical practice. We, as many other surgical groups, have begun our journey.

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