Laparoscopy Versus Open Colorectal Surgery: How Strong Is the Evidence?

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Introduction and Rationale

The original concept of laparoscopic colectomy was to minimize the surface impact on the abdominal wall, while the same extent of resection was being performed on the colon, as might be accomplished through an open large incision. Since that concept was proposed and started in 1991 with the first case report of a laparoscopic right colectomy, the ability of laparoscopic surgeons has increased to the point that almost all operations on the entire gastrointestinal tract can be accomplished laparoscopically. It is remarkable that laparoscopic technique and instrumentation have not changed much from the initial explosion of long straight instruments inserted through the abdominal wall access ports which mirrored most of the instruments used in open operations. Laparoscopy is considered standard of care for most general surgical procedures, and the same can be said for colorectal operations, even though some surgeons lag behind in adoption of the approach. The evidence is mature and fills the surgical literature with solid evidence that laparoscopic techniques can be utilized for almost all routine and even some advanced colorectal procedures.

Levels of Evidence and Data Quality

As we consider recent publications on outcomes from laparoscopic operations, we should only accept Level 1 or 2 evidence to make our decisions and adhere to the principles of evidence-based practice. The early reports of laparoscopic techniques and outcomes were in the form of case reports or small, single-institution, retrospective

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P. Sylla et al. (eds.), *The SAGES Manual of Colorectal Surgery*,
https://doi.org/10.1007/978-3-030-24812-3_6

reviews of consecutive patient series with, at best, a case-matched retrospective historical control group of patients treated with open technique. This barely qualified as Level 4 evidence on the literature quality scale, where randomized controlled trials (RCTs) are considered Level 2 and systematic meta-analysis of data from similar-design, RCTs is considered Level 1 evidence (e.g., Cochrane Database Systematic Reviews) [1, 2]. In the early days of laparoscopic general surgery, very few randomized controlled trials for comparison of outcomes between minimally invasive and open procedures were performed. Fortunately, comparison of large retrospective series with historic outcomes measures was able to detect a rise in complication rates (e.g., bile duct injury during cholecystectomy). Efforts were redirected to make the minimally invasive approach as safe as the open approach while maintaining the benefits of minimally invasive access to abdominal organs (e.g., development of the critical view of the portal structures and cystic duct in cholecystectomy). Meta-analysis of these retrospective series reviews, without case matching or propensity score-controlled adjustment, does not improve the quality of the data because the biases of selection and partial follow-up persist. Combining data simply increases the number of subjects to make a comparison statistically significant.

Fortunately, colorectal surgeons have learned that RCTs will answer specific questions without controversy in most circumstances. The area of laparoscopic resection for colorectal cancer has been the most studied [3–13]. The complexity of designing an RCT is based on selecting a homogeneous population with as few confounding factors as possible and applying a consistent approach to the disease and patient to achieve predetermined primary and secondary outcomes. Randomization can remove almost all selection bias from the process, and prospectively collected data are usually more complete and less likely to be manipulated. Colon and rectal cancers have been the focus of most RCTs in colorectal surgery and continue to populate the literature. As mentioned above, the meta-analysis of the combined data from RCTs can provide the clearest answer to a major question like cancer treatment. It is important to try to standardize the confounding factors in each trial to make the combined analysis meaningful. For example, the definition of the rectum or the segments of the colon used in the study will make a difference in the ability to draw a conclusion. Dr. Lars Pahlmann took the data from the early RCTs studying laparoscopic colectomy for cancer to provide a meta-analysis of combined trials and confirmed equivalence of laparoscopic and open approaches to colon cancer [14]. It is hoped that combined data analysis of the recently published rectal cancer trials will give us the same confidence in the use of laparoscopy in patients with rectal cancer.

Reviews of large administrative databases (e.g., National Inpatient Sample [15] and Premier Prospective Database [16] and California Cross Section Database [17]) provide adequate numbers of patients to result in statistical significance for even small differences in outcomes across a wide spectrum of patients, hospitals, and surgeons. It is important to remember that these large databases are usually reservoirs of data from hospitals and insurance companies that utilize relatively untrained personnel to enter the data at the patient interface. The data are collected with

limited filters, other than the fact that the patient had a procedure or a disease process based on codes. Some databases are able to include severity of illness information and enhance comparison of patients based on comorbidities and other individual features of the patient. The integration of disease codes, procedure codes, and billing codes can sometimes be faulty and give a false sense of security and accuracy based on large numbers alone.

The best technique for managing retrospective data is achieved by educated, specifically trained, data abstractors and entry personnel focused on a set of definitions, rules, and criteria for specific conditions and outcomes. The National Surgical Quality Improvement Project (NSQIP) [18], the Society of Thoracic Surgery (STS) database, and the National Cancer Database (NCDB) at the American College of Surgeons are examples of trustworthy databases that can give a reliable answer even within the limitations of retrospective data. The quality of the data needs to be considered when evaluating outcomes of different techniques. Each database has its own limitations based on the comprehensiveness of the data collected, which is constrained by time, resources, and storage capacity. Fortunately, the newest data collection effort in colorectal surgery is supported by the NCDB with prospective rectal cancer-specific data collection through the National Accreditation Program in Rectal Cancer (NAPRC) managed by the American College of Surgeons. These data elements were collaboratively defined by consensus within the multidisciplinary OSTRiCh (Optimizing Surgical Treatment of Rectal Cancer) Consortium during the design phase of the NAPRC. As the NAPRC functions, data points will be changed to answer new questions relevant to clinical practice.

If laparoscopic colorectal surgery is to be considered as standard of care over open surgery, we need contemporary data and reports from the literature to confirm ongoing safety and quality of outcomes from the laparoscopic approach. A search of the surgical literature back to 2006 yielded a large number of reports (134) comparing open and laparoscopic colorectal surgery. A selection process that focused on resection of the colon and rectum and comparison of the 2 approaches yielded 25 articles that deserve discussion. Comparison of different aspects of the procedure and a range of outcomes have been reported in the past decade in large database reviews, systematic meta-analysis, randomized controlled trials, and prospective non-randomized series. The bottom line reflects the ability of laparoscopic colorectal surgery to achieve excellent outcomes and improve on some of the aspects of recovery over the open approach.

Outcomes

The benefit of laparoscopy is most realized in the short-term outcomes of length of stay and postoperative pain. These are uniformly superior to the open technique. Mortality after a laparoscopic colorectal procedure has been reported to be less than after an open resection (0.52% vs 1.24%) (relative risk = 0.69) (0.4% vs 2.0%) [15, 19–28]. Length of stay is always shorter by multiple days for laparoscopic

resections compared to open [6, 15–28]. Complications over a broad spectrum of definitions are always fewer for laparoscopic procedures [16, 19–28]. Laparoscopy acts in conjunction with protocols for enhanced recovery after surgery to improve outcomes after colectomy [6, 23].

The cost of laparoscopic procedures to the system, while higher in the operating room, has been shown to be lower overall, due to reduced complications and length of stay [15, 16]. Cost comparisons warrant further investigation as the application of technologic advances including robotic-assisted surgery increases in colorectal surgery. Cancer outcomes after laparoscopic surgery have been shown to be the same as for open operation including survival, recurrence, lymph node harvest, and ability to resect locally advanced, emergently operated, obstructed tumors from all sections of the colon and the rectum and in elderly and high-risk patients [4–6, 15, 20, 22, 24–30]. Several rectal cancer trials have developed the concept of the composite pathologic assessment as an immediate oncologic outcome. Long-term outcomes of 3- or 5-year overall survival, disease-free survival, and local recurrence are considered non-inferior and therefore acceptable as a preferred standard owing to its short-term benefits.

Hand-assisted laparoscopic techniques have been shown to provide equivalent outcomes to open and straight laparoscopic colorectal resections with a lower conversion rate and shortened learning curve [19, 31, 32]. Sexual and bladder function may be impacted by laparoscopic techniques used in low rectal resection; otherwise, quality of life is similar to open results [3, 5]. Conversion from laparoscopic to open operation has been shown to impact outcomes adversely [3, 32, 33]. Conversion is associated with longer length of stay, higher rates of readmission, and higher rates of postoperative complications. Studies have reported negative oncologic outcomes following conversion; however, when adjusting for other factors, perioperative outcomes and pathologic features are more predictive of oncologic endpoints such that conversion may be a proxy for more biologically aggressive disease or a more susceptible patient [34].

Laparoscopy for the management of benign disease including inflammatory bowel disease and diverticulitis is well studied and is extensively covered in several subsequent chapters. In the two available randomized controlled trials that consider laparoscopic over open ileocolic resection for Crohn's disease, despite a longer operative time with laparoscopy, laparoscopy was found to be feasible, safe, and with low conversion rate provided procedures were performed with proper patient selection and by experienced surgeons. There is strong evidence that laparoscopic sigmoid resection offers the benefit of reduction in major complications and shorter hospital stay over open resection [35–37]. There are no randomized data for laparoscopic treatment of small intestinal obstruction [2].

See Table 6.1.

Table 6.1 Summary of best quality evidence for laparoscopic colorectal surgery

Study	Type	N	Indications	Endpoint	Conclusion
COST (2007) Fleshman et al. [7]	RCT non-inferiority	872	Colon cancer Stage I–III	Time to recurrence	"Laparoscopic colectomy for curable colon cancer is not inferior to open surgery based on long-term oncologic endpoints"
COLOR (2005) Veldkamp et al.[a]	RCT non-inferiority 7% margin	1248	Colon cancer Stage I–IV	3-yr DFS	"…the difference in disease-free survival between groups was small and, we believe, clinically acceptable, justifying the implementation of laparoscopic surgery into daily practice" "Laparoscopic surgery [has]…similar rates of disease-free survival, overall survival and recurrences as open surgery at 10-year follow-up"
CLASICC[b,c] (2005, 2012)	RCT	794	Colon and rectal cancer Stage I–IV	Multiple OS, DFS, LR	"…impaired short-term outcomes after laparoscopic-assisted anterior resection for cancer of the rectum do not yet justify its routine use" "Long-term results…support the use of laparoscopic surgery for both colonic and rectal cancer"
ALCCaS (2018) McCombie et al. [5]	RCT	601	Colon cancer Stage I–III	5-year OS, DFS, freedom from recurrence	"… laparoscopic colorectal resection was not inferior to open colorectal resection in direct measures of survival and recurrence"
COREAN (2014) Jeong et al. [4]	RCT non-inferiority 15% margin	340	Rectal cancer Stage II–III	3-year DFS	"…laparoscopic resection for locally advanced rectal cancer after preoperative chemoradiotherapy provides similar outcomes for disease-free survival as open resection, thus justifying its use"
COLOR II (2015) [13]	RCT non-inferiority 5% margin	1044	Rectal cancer Stage I–III	3-year LR	"…laparoscopic surgery is as safe and effective as open surgery in patients with rectal cancers without invasion of adjacent tissues"
Z6051 (2015, 2018) Fleshman et al. [8, 9]	RCT non-inferiority 6% margin	486	Rectal cancer Stage I–III	Composite pathology 2-year DFS, recurrence	"Laparoscopic assisted resection of rectal cancer was not found to be significantly different to OPEN resection of rectal cancer based on the outcomes of DFS and recurrence"

(continued)

Table 6.1 (continued)

Study	Type	N	Indications	Endpoint	Conclusion
AlaCaRT (2018) Stevenson et al. [11]	RCT non-inferiority 8% margin	475	Rectal cancer (0–15 cm) Stage I–IV	Composite pathology 2-year LR, DFS	"Laparoscopic surgery for rectal cancer did not differ significantly from open surgery in effects on 2-year recurrence or DFS and OS"
Maartense et al. (2006)[d]	RCT	60	Ileocolic Crohn's disease	3-month QoL	"QoL …was not different for laparoscopic-assisted compared with the open ileocolic resection, morbidity, hospital stay, and costs were significantly lower"
Milsom et al. (2001) [35] Stocchi et al. (2008)[e]	RCT	60	Ileocolic Crohn's disease	Recurrence Postoperative complications	"Laparoscopic ileocolectomy is at least comparable to open ileocolectomy…"
Sigma trial Klarenbeek et al. [f] (2009)	RCT	104	Diverticulitis	Mortality Postoperative complications	"Laparoscopic surgery was associated with a 15.4% reduction in major complication rates, less pain, improved quality of life, and shorter hospitalization at the cost of a longer operating time"
Gervaz et al. (2010, 2011)[g,h]	RCT	113	Diverticulitis	Postoperative pain Duration of ileus duration of LOS	"Laparoscopic sigmoid resection is associated with a 30% reduction in duration of postoperative ileus and hospital stay"

DFS disease-free survival, *OS* overall survival, *LR* local recurrence, *RCT* randomized controlled trial, *QoL* quality of life, *LOS* length of hospital stay

[a]Veldkamp et al. [38]
[b]Guillou et al. [39]
[c]Green et al. [40]
[d]Maartense et al. [41]
[e]Stocchi et al. [42]
[f]Klarenbeek et al. [37]
[g]Gervaz et al. [36]
[h]Gervaz et al. [43]

Conclusion

In summary, there is high-quality evidence the supports laparoscopic treatment of most colorectal diseases. Outcomes are generally equivalent if not better than open operation in almost all parameters. Laparoscopy for both benign and malignant colorectal diseases should be considered whenever possible, and surgeons should now

consider laparoscopy as standard of care. As technological advances in the field of minimally invasive surgery continue to evolve, surgeons must continue to validate the safety and feasibility of these newer technologies with high-quality evidence.

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