Techniques in Minimally Invasive Rectal Surgery

Alessio Pigazzi
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Chapter 1
Training and Learning Curve in Minimally Invasive Rectal Surgery

Deborah S. Keller and Eric M. Haas

Introduction to Learning Curves in Minimally Invasive Surgery

The learning curve is a graphical demonstration of the number of cases a surgeon must perform to become proficient.

When learning a new procedure, performance is expected to improve with experience, and graphically plotting performance against experience produces a learning curve [1–3]. The concept of a learning curve, where inexperienced clinicians improve with increasing experience, is particularly fitting for minimally invasive surgery, which requires a high degree of special dexterity and technical skills, and learning has potentially dramatic implications [4, 5]. The learning curve is a graphic representation of the individual surgeon's experience performing a procedure versus outcome variables of clinical interest, such as operative time, postoperative complications, and conversion rates [6–9] (Fig. 1.1). A technically demanding technique, such as minimally invasive rectal resection, is often termed as having a "steep learning curve." This term has been described as a misnomer, as complex techniques are more likely to have gradual learning curves, with small improvements in outcome associated with each case, and expertise possible only after significant experience [4].

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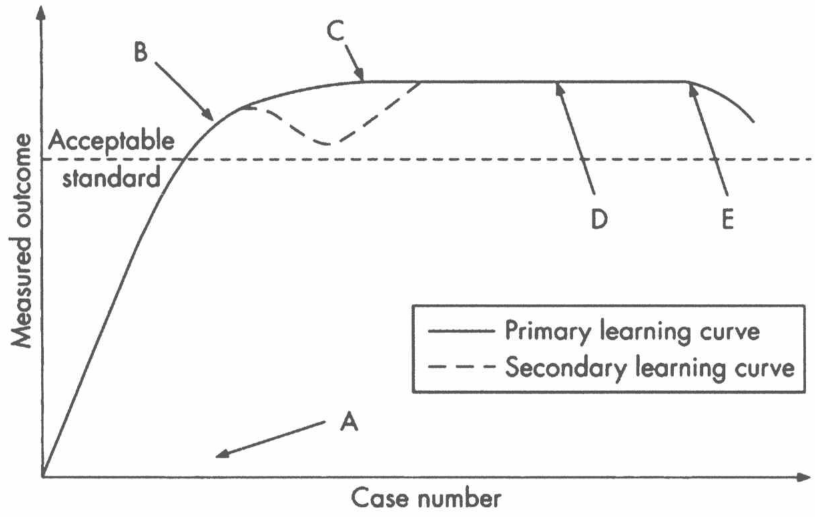

Fig. 1.1 Idealized learning curve

Defining a learning curve for minimally invasive surgery is complex but necessary to identify the number of cases for competence, facilitate more effective training, and integrate minimally invasive rectal surgery into practice [10]. Measuring the learning curve also has benefits for patient safety and surgical education, as teaching is centered on techniques and outcomes [11, 12]. Progress along the learning curve for surgical technique is measured by surgical process and patient outcomes [4]. In minimally invasive surgery, ascent up the learning curve is based on a decline in operating time, intraoperative complications, conversion rate, and length of stay [13]. An initial training period is required for all surgeons to become proficient in these complex procedures by continuous repetition of the tasks [5]. However, the learning curve is individualized and variable, as different biases and laparoscopic experiences of each surgeon limit the generalizability of comparable curves [14].

Creating a Learning Curve

The cumulative summation (CUSUM) method, a practical tool for creating a learning curve, plots a defined outcome variable against the surgeon's experience to define the point where proficiency and independence are reached.

As a surgeon learns a new technique, constructing a learning curve to measure outcomes and estimate their location on the curve is helpful. Most studies describing the learning curve in minimally invasive colorectal surgery fail to properly define the curve, have poor descriptions of mentorship/supervision, and have variable definitions of successfully attaining proficiency [15]. Several statistical methods can be used to create a learning curve, including simple graphs, splitting the data chronologically, and performing a *t* test or chi-squared test, curve fitting, or other model fitting [1, 15, 16]. For continuous variables, such as operative time, the moving average method is useful. For binary outcomes, which may or may not happen, such as conversion and complications, the cumulative summation (CUSUM) method is the most practical tool [14]. CUSUM uses sequential analysis technique to allow a surgeon to judge whether the variation observed in performance is acceptable or outside outcomes expected from random variation [17]. More simply, CUSUM is the running total of differences between the individual data points for a defined outcome variable and the sum of all data points [18]. To plot the CUSUM curve, the outcome of interest is selected and the cases are listed chronologically. Then, CUSUM (SN) is calculated as $SN = \sum (X_i - X_0)$, where X_i is the individual case's value and X_0 is the mean for all cases. After each case, the variable is sequentially added to the cumulative scores for that variable and then plotted graphically [10]. The CUSUM variable is plotted on the *y*-axis against the procedure attempt on the *x*-axis [19]. At acceptable levels of performance, the CUSUM curve is flat, while at unacceptable levels of performance, the curve slopes upward and eventually crosses a decision interval [16]. The surgeon's proficiency can be extrapolated from the graph by the peak or plateau for that outcome variable. This graphical representation allows an individual surgeon training to determine when they can efficiently and effectively perform a certain procedure, as well as facilitating more effective training, and integrating the technique into practice [10].

Differences in Minimally Invasive Colon and Rectal Surgery

The learning curves for minimally invasive colon resections are well defined, as the safety and efficacy was proven in early controlled trials, giving surgeons greater experience than with rectal resections.

Minimally invasive colorectal surgery was introduced in the early 1990s and remains an evolving technique. The safety and feasibility of minimally invasive surgery for colon cancer was proven in early controlled trials [20–26]. With widespread acceptance and utilization, the learning curve for laparoscopic colon resections has been well defined. Previous studies suggested laparoscopic colon resections require approximately 50 cases to gain proficiency, with reports ranging from 30 to 150 cases for independence and improved surgical process and patient outcomes [27–32]. Procedure-specific learning curves are estimated at 70–80 cases for sigmoid colectomy [2], 55 cases for right colectomy, and 62 cases for left colectomy [5].

The comparative effectiveness of laparoscopy for rectal cancer was less clear, as early controlled trials concentrated on the oncologic safety of *colon* cancer [22, 24, 33, 34]. Initial high-level rectal cancer data stemmed from the UK MRC-CLASICC trial, which raised concerns of adequate total mesorectal excision (TME), positive circumferential resection margins, increased rates of erectile dysfunction, and worse overall outcomes in converted patients [24–26, 35]. These concerns hindered general acceptance [36]. Since the initial studies, long-term outcomes from the COLOR II and CLASICC randomized controlled trials supported use of laparoscopic surgery for rectal cancer [37, 38]. The Comparison of Open versus laparoscopic surgery for mid- and low REctal cancer After Neoadjuvant chemoradiotherapy (COREAN) trial furthered these findings, demonstrating laparoscopic rectal resection after preoperative chemoradiotherapy was safe, oncologically equivalent to open surgery, and offered improved short-term outcomes [39]. Multiple additional studies and meta-analyses have found affirmed the equivalent oncologic outcomes and superior patient outcomes of laparoscopic rectal resection, even in converted cases [24, 39–53].

The Learning Curve for Specific Minimally Invasive Rectal Surgery Techniques

Laparoscopic Rectal Resection

While pelvic surgery is technically difficult, proficiency can be reached after performing 16–75 multiport laparoscopic cases. Fewer cases are required for experienced laparoscopic surgeons to reach competence.

With safety and oncologic equivalency proven, studies sought to define the specific learning curve for laparoscopic rectal resection. Laparoscopic surgery for rectal cancer is more technically demanding than laparoscopic colectomy [54]. The narrow confines of the bony pelvis, standard practice of autonomic nerve-sparing TME, and limitation of available stapling devices make laparoscopic surgery even more challenging [55]. Further, the inherent differences in case complexity warrant a specific analysis of the laparoscopic rectal resection learning curve [56]. The long curve has been cited as a major factor limiting growth [57–60].

Despite the inherent difficulties, studies on the learning curve for laparoscopic rectal resections found lower case numbers were needed for proficiency than with colon resections. Schlachta et al. reviewed a prospective database over 8 years at a single center, finding the learning curve for performing colorectal resections was approximately 30 cases; after that point, the "experienced" surgeons performed significantly more rectal resections, had significantly shorter operative time (180 vs. 160 min, $p<0.001$) and length of stay (6.5 vs. 5 days, $p<0.001$), and trended toward lower intraoperative complications and conversion rates [30]. Li et al. had similar results, finding the learning curve of laparoscopic rectal resections was approximately 35 cases; further, surgeons without previous basic laparoscopic experience could ascend the learning curve at the same rate by performing 2.1 laparoscopic rectal resections per month [61]. Kayano et al. evaluated 250 consecutive laparoscopic low anterior resections, split into 5 groups of 50, to determine the learning curve with the moving average method [54]. They found the learning curve stabilized at 50 cases, the conversion rate decreased significantly by group 4 (151–200 cases), and postoperative complication rate decreased significantly by group 5 (201–250 cases). Additionally, they found the risk factors affecting the learning curve were T stage and male sex [54]. Liang et al. cited the lowest number needed for proficiency [62]. In evaluating 160 laparoscopic-assisted rectal cancer resections based on lymph node harvest, length of distal margin, blood loss, complications, conversion rate, and length of stay over 2 years, Liang et al. found a surgeon may be proficient after performing only 16–20 rectal cancer cases [62]. Conversely, Son et al. cited the highest number of cases needed for proficiency in the current literature [56]. They retrospectively evaluated 431 patients over a 12-year period for conversion to laparotomy, complications, reoperations, operative time, and intraoperative transfusion using the CUSUM method, moving average method, and analysis of variance (ANOVA) tests. The authors found the learning curve was at case 61 for conversion, case 79 for complications, and cases 61–75 for operative time and intraoperative transfusion. Overall, the authors concluded the learning curve for laparoscopic rectal surgery was approximately 60–80 procedures [56]. Experience in laparoscopic colon resections has facilitated ascension up the learning curve for rectal resection. A prospective, single-center observational study by Bottger et al. reported a surgeon experienced in open colorectal surgery, with basic laparoscopic experience, needs to perform 35laparoscopic rectal resections within 200laparoscopic colon resections before operating time and complication rates plateau [63]. While these studies give a range of cases needed to ascend up the learning curve, all reports were based on single-center, non-randomized studies.

Park et al. added another dimension to the learning curve, evaluating economic outcomes along the curve between laparoscopic and open management of rectosigmoid cancer [64]. The authors analyzed operating room (OR) costs, OR-related hospital profit, total hospital charge, and patient payment during early (initial 37 laparoscopic cases) and experienced (subsequent 79 laparoscopic cases) learning periods. OR costs remained significantly higher with laparoscopy during the two periods, but by the experienced period, the OR-related hospital deficit improved (–\$1072 to –\$840), total hospital charges were similar (\$7983/patient versus \$7045/patient, $p > 0.05$), and patients paid a lower surcharge for laparoscopy (\$1885–\$1118) [64]. Given the current financial pressures, defining and shortening the learning curve is critical for making minimally invasive rectal surgery cost-effective and viable in today's healthcare environment (Table 1.1).

Table 1.1 Data on the learning curve for multiport laparoscopic rectal resections

Year	Author	*n*	Learning curve
2001	Schlachta et al.	461	30 cases
2006	Li et al.	105	35 cases
2010	Son et al.	431	60–80 cases
2011	Kayano et al.	250	50 cases
2011	Liang et al.	160	16–20 cases
2011	Bottger et al.	200	35 cases

Single-Incision Laparoscopic Surgery

The learning curve for single-incision laparoscopic surgery (SILS) in rectal resections is yet to be defined. With the unique skill sets and ergonomic demands, defining the SILS learning curve could benefit training and implementation.

With emerging technology in colorectal surgery, studies on the learning curve addressed new minimally invasive techniques. Single-incision laparoscopic surgery (SILS) has proven benefits over multiport laparoscopy, reducing the number of incisions, tissue trauma, perioperative pain, postoperative narcotics, port-site-related complications, and, in some studies, length of stay [65–69]. SILS has been shown safe and feasible specifically in rectal resections [70]. Small single-institution studies found SILS safe in slim patients with small tumors [65]. However, use is recommended only for skilled laparoscopic surgeons. While safety and feasibility have been established, all learning curve and training studies to date have focused on colectomy [71, 72]. Thus, studies evaluating the learning curve for SILS rectal resections are needed and, from the current literature, can be performed without increasing risk to the patient. Knowing the unique skill sets and ergonomic demands of SILS, the implementation of an evidence- and competency-based SILS training curriculum could facilitate efficient and effective training of SILS surgeons [73].

Hand-Assisted Laparoscopic Surgery

Hand-assisted laparoscopic surgery (HALS) is a bridge between open and laparoscopic surgery, allowing more complex procedures to be performed with minimally invasive benefits. Limited research in HALS rectal resection have conflicting outcomes, ranging from no distinct learning curve to higher case volumes for proficiency compared to multiport laparoscopy, Thus, further study is needed.

Hand-assisted laparoscopic surgery (HALS) was developed to bridge the learning curve between open and laparoscopic surgery. HALS retains the benefits of minimally invasive surgery while allowing surgeons to perform more complex procedures that would have otherwise been performed open or with great difficulty laparoscopically [74]. HALS has been reported especially advantageous for rectal resections and patients with higher BMI and comorbidity profiles [75]. Outcomes for HALS are comparable to multiport laparoscopy [74, 76–78]. Further, HALS has similar patient outcomes between colon *and* rectal surgery. In a 5-year review of a prospective database at the Mayo Clinic in Minnesota, short-term outcomes of 323 patients undergoing HALS for colon (194) or rectal cancer (129) were evaluated. Operative time was significantly less for colon than rectal cases (157 vs. 204 min; $p<0.0001$), but conversion to laparotomy (14 % vs. 10 %; $p=0.38$), lymph node yield (18 vs. 18; $p=0.45$), and postoperative complications were similar (28 % vs. 30 %; $p=0.72$) [79]. Proponents of HALS claim the tool can restore the tactile sensation lacking in laparoscopic procedures, improve hand-eye coordination, allow the hand to be used for blunt dissection or retraction, and rapidly control unexpected bleeding [80–84]. These features can significantly reduce operative time, a major variable on the minimally invasive surgery learning curve [83]. A virtual reality training simulator comparing HALS with multiport laparoscopy for sigmoid colectomy confirmed HALS accelerated the mobilization and anastomosis steps [85]. Advocates of HALS claim it is also easier to learn than multiport laparoscopy; however, there is limited published literature on the learning curve for HALS in rectal resections [81]. Ozturk et al. sought to define the learning curve for HALS procedures including total proctocolectomy [86]. A retrospective review of a single surgeon's operative time, conversion rate, complications, length of stay, reoperations, and readmissions was compared for 2 consecutive cohorts of 25 HALS procedures. They found no changes in outcomes or the operative time for proctocolectomy as experience was gained, concluding there was no learning curve for HALS [86]. When evaluating rectal resections exclusively, higher case volumes were reported for proficiency with HALS compared to multiport laparoscopy. Pendlimar et al. used CUSUM analysis to determine the cases required to attain technical proficiency and effect improvement in operative time with HALS [87]. The change point occurred between 105 and 108 total cases, with decrease in mean operative time for low anterior resection at 70 min ($p<0.001$), coloanal anastomosis at 52 min ($p=0.003$), and total proctocolectomy with ileal reservoir at 80 min ($p<0.001$) [87]. With increasing use of HALS, more studies focused on rectal resections are needed to objectively define the learning curve using this technology.

Robotic-Assisted Laparoscopic Surgery

Robotic-assisted laparoscopic surgery (RALS) for rectal surgery has a multiphasic learning curve, with initial proficiency, integration of more challenging cases, and mastery of the technique between 25 and 72 cases. With the addition of more complex cases with increasing experience, operative time is not the optimal measure of proficiency.

Of the new technologies, the most robust learning curve data for minimally invasive rectal surgery is with RALS. Bokhari et al. evaluated the learning curve for RALS using the CUSUM method in 50 consecutive rectal resections [9]. They found the learning curve had three unique phases: (1) the initial learning curve (15 cases), (2) the plateau with increased competence (10 cases), and (3) mastery with more challenging cases (after 25 cases). For RALS rectal surgery, the authors concluded the learning curve occurred at 25 cases [9]. Sng et al. also found a multiphase learning curve for RALS rectal cases [88]. The authors performed a retrospective review of operative times in 197 consecutive patients over a 4-year period to define the learning curve using the CUSUM technique; they note the curve described an experienced laparoscopic colorectal surgeon [88]. Sng et al. found docking time had a learning curve of 35 cases, while the learning curves for total operative, robot, and console had three phases: (1) the initial learning curve (35 patients), (2) more

Table 1.2 Data on the learning curve for robotic-assisted rectal resections

Year	Author	*n*	Initial competence	Mastery
2011	Bokhari et al.	50	15 cases	25 cases
2012	Jimenez-Rodriguez et al.	43	9–11 cases	21–23 cases
2013	Sng et al.	197	35 cases	69 cases
2014	Kim et al.	167	32 cases	72 cases

challenging cases (93 patients), and (3) the concluding phase (69 patients). In addition, increased case complexity and subsequent longer hospital lengths of stay were seen in the latter two phases [88].

The three distinct phases were again seen when looking specifically at RALS for rectal cancer. Jimenez-Rodriguez et al. used CUSUM methodology to analyze the learning curve in 43 consecutive rectal cancer resections over a 2-year period [89]. The authors created two curves, operating time and success, and both had three well-differentiated phases: (1) initial learning (9–11 cases); (2) consolidation of skills, with increased competence (12 cases); and (3) mastery with more complex cases (after 21–23 cases). The authors found significantly reduced docking time ($p<0.001$) but increased operative time ($p=0.007$) in phase 3 [89]. Thus, the estimated learning curve for RALS in rectal cancer is achieved after 21–23 cases. To analyze the learning process in robotic TME, Kim et al. performed a retrospective review of 167 patients who underwent robotic TME for rectal cancer over a 5-year period [90]. The moving average and CUSUM methods were used to create learning curves based on operative time, conversion, complications, and circumferential margin. The authors found the learning curve for all outcomes was reached after 32 cases, while operative time had 2 plateaus: after 32 cases and then again after 72 cases. More complicated cases were performed in later phases, but complications remained constant throughout the series ($p=0.82$). Therefore, the learning process for robotic TME is most prominent after the initial 32 cases [90]. While present evidence on RALS shows comparable feasibility, safety, and patient outcomes to multiport laparoscopic surgery, operative time and total cost are greater; surgeons should keep this in mind when considering embarking on a new learning curve for RALS [91] (Table 1.2).

Future Direction

Transanal Approaches

While the learning curve for proficiency in TEM is brief, other factors have limited widespread use. New methods for transanal excision of rectal lesions, such as TAMIS and NOTES, are emerging, but further research is needed to develop formal learning curves with these techniques.

Transanal endoscopic microsurgery (TEM), a minimally invasive technique for a full-thickness resection of rectal tumors with highly specialized instruments, was originally described by Gerhard Buess in the early 1980s [92, 93]. TEM was the initial progression of local excision for benign and well-selected malignant rectal tumors [94]. TEM offered the benefits of minimally invasive local excision with access higher in the rectum, offering comparable oncologic outcomes, greater exposure than transanal excision, and less morbidity than transabdominal approaches [95–97]. TEM alone was sufficient for "favorable" T1 tumors, while unfavorable T1 or T2 tumors required adjuvant treatment, and use in T3 or greater was only for palliation [96]. Studies demonstrated reductions in operation time, length of stay, and complication rates with increasing experience [98]. Barendse et al. evaluated outcomes of 4 colorectal surgeons performing 555 TEM resections, finding a learning curve affected conversion rates, procedure time, and complication rates but not recurrence rates [99]. Maya et al. evaluated the learning curve in 23 patients over a 3-year period using the CUSUM method [92]. The authors found two phases: initial stabilization of the learning curve after the first four cases and then an additional rising and leveling after the first ten cases [100]. While proficiency may be achieved after four cases, widespread acceptance of TEM has remained slow for several reasons, including technical demands, costly equipment, cumbersome setup, limited indications, and perceived difficulty [97, 100, 101].

Transanal minimally invasive surgery (TAMIS) is a popular, emerging tool for resection of benign and carefully selected, early-stage malignancies of the mid- and distal rectum [102]. TAMIS is a feasible alternative to local excision and transanal endoscopic microsurgery, providing its benefits at a fraction of the cost [103–105]. TAMIS has expanded the bounds of local excision, making transanal resection of upper rectal/rectosigmoid lesions possible [106]. Continued expansion of this technique, including using the robotic platform for transanal access surgery, is underway [107–109]. The TAMIS technique has also evolved to a full TME. Transanal mini-laparoscopy-assisted natural orifice transluminal endoscopic surgery (NOTES) or TAMIS-TME is a new approach to performing minimally invasive rectal resection. For locally advanced mid- and distal-rectal cancer with curative intent, it is a rapidly expanding approach with significant promise. The "bottom-up" approach to en bloc rectal cancer resection is especially advantageous in obese male patients with a narrow pelvis [110]. Short-term outcomes have shown oncologic adequacy [110–112]. While promising, careful patient selection, a specialized team, and long-term outcome evaluation are required before widespread use of this technique [112]. While the popularity and applications of TAMIS continue to grow, larger case series and controlled trials are needed to develop formal learning curves with this platform.

Training in Minimally Invasive Rectal Surgery

During the learning process, patient safety and outcome are not adversely affected. Virtual reality simulators and colorectal fellowship training may help surgeons ascend learning curve.

The generalizability of current learning curve studies is limited from inconsistent data quality and individual variations [32]. One consistent finding across all studies is that training patient safety and oncological outcomes are not adversely affected