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Retrospective Study

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Change point analysis validation of the learning curve in laparoscopic colorectal surgery: experience from a non-structured training setting

Learning curve in laparoscopic colorectal surgery

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Abstract

BACKGROUND

The introduction of minimal invasive principles in colorectal surgery was a major breakthrough, resulting to multiple clinical benefits; at the cost, though, of a notably steep learning process. The development of structured nation-wide training programs led to the easier completion of the learning curve; however, these programs are not, yet, universally available, thus prohibiting the wider adoption of laparoscopic colorectal surgery.

AIM

The present study displays our experience in the learning curve (LC) status of laparoscopic colorectal surgery, under a non-structured training setting.

METHODS

We analyzed all laparoscopic colorectal procedures performed in the 2012-2019 period, under a non-structured training setting. Cumulative sum (CUSUM) and change-point analysis (CPA) was introduced.

RESULTS

Overall, 214 patients were included. In terms of operative time, CPA analysis identified the 110th case as the first turning point. A plateau was reached after the 145th case. Subgroup analysis estimated the case n:58 for colon and case n:52 for rectum as the respective turning points. A learning curve pattern was confirmed for pathology outcomes, but not in the conversion to open surgery and morbidity endpoints.

CONCLUSION

The learning curves in our setting validate the comparability of the results, despite the absence of National or Surgical Society driven training programs.

Key Words: Colorectal; Education; Gastrointestinal; Laparoscopy; Outcomes

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Core Tip: In terms of operative time, the learning curve of a dedicated colorectal surgical team consists of 3 phases. Change point analysis (CPA) identified the 110th case as the separation key-point of the first two phases. A plateau was reached after the 145th case. Although we were able to confirm the presence of a learning curve pattern in the histopathological endpoints, this was not the case for the open conversion and morbidity outcomes. Formal training program initiatives are necessary for the safe and efficient implementation of laparoscopic colorectal operations.

INTRODUCTION

The introduction of minimal invasive principles in colorectal surgery, during the last two decades, was a major breakthrough [1]. Multiple studies confirmed the advantages of a minimal invasive approach, including reduced analgesic requirements, fewer complications, and a shorter recovery period [2].

Nonetheless, the accrual of these benefits depends on the completion of an elongated learning process [3-5]. Due to the complexity of laparoscopic colorectal operations and the innate dexterity requirements, the accumulation of the respective surgical skills is quite demanding [6-9]. Thus, like other multi-leveled procedures, learning curves were universally adopted for the assessment of surgical competency [10-13].

Although there is a remarkable heterogeneity in the turning points of laparoscopic colorectal learning curves, current evidence suggests that, at least, 100 consecutive operations are needed to obtain proficiency [14-17]. During the initial phase, an analogous variation in endpoints, such as morbidity and open conversion rates, is expected [3,18-24].

The determination of the individual elements that contribute to the elongation of the learning curve was a major step towards the establishment of a safety and training culture in laparoscopic colorectal surgery [14,23,25]. Subsequently, the development of structured nation-wide training programs expedited the completion of the respective learning curves [26–28]. Among the various components of these programs are the formation of specialized colorectal surgical groups, the conduction of hands-on courses and the introduction of mentor guidance during the first cases [26–29]. Unfortunately, these initiatives are not, yet implemented in all health systems, thus restraining the efficient dissemination of the minimal invasive principles in colorectal surgery [9,24,30].

Therefore, we designed this study, to analyze the laparoscopic colorectal surgery learning curves, outside a formal national or surgical society driven training program.

MATERIALS AND METHODS

This study is a retrospective analysis of a prospectively collected database. Between January 2012 and December 2019, data from all laparoscopic colorectal resections performed by a specialized colorectal surgical team, were recorded in an institutional database. All patients, prior to their inclusion, provided informed consent for data recording, analyses, and future publication. This study report follows the STROBE guidelines [31].

The surgical team consisted of two consultant surgeons with previous experience in laparoscopic general surgery (G.T., I.B.). Six months prior to the onset of the study, the surgeons attended both national and international specialized formal courses and performed their initial operations under proctoring. However, this learning process was not based on any national or scientific society training program, due to the absence of such initiatives in Greece. The surgical team was also supported by a dedicated pathology team responsible for the evaluation of the resected specimens.

All operations were performed with 4 or 5 trocars. Dissection was completed using an energy source. A medial to lateral approach was implemented in all patients. In case of malignancy, the appropriate oncological principles (Complete mesocolic excision/

Total mesorectal excision CME/TME and Central vascular ligation CVL) were followed. Splenic flexure mobilization was always performed in left sided tumors. A structured pathology report was, also, provided.

All adult patients (age>18 years) submitted to elective or semi-elective laparoscopic colorectal surgery for benign or malignant disease were deemed as eligible. The following exclusion criteria were considered: 1) age<18 years, 2) American Society of Anesthesiologists (ASA) score>III, 3) emergency surgery, i.e. peritonitis, perforation, 4) cases not performed by the above-mentioned surgical team.

The primary endpoint of our study was to identify the learning curve status of the operation duration in patients submitted to laparoscopic colorectal operations (LCRO). Subgroup analysis for colon (LCO), and rectal operations (LRO) were, also, performed. Secondary endpoints included operative characteristics (complication and open conversion rate), and specimen pathology quality outcomes. Postoperative complications were any Clavien Dindo ≥ 2 adverse events. The complexity of each operation was graded on the basis of the Miskovic *et al* [23] classification system. Data extraction was completed by a group of senior researchers (I.M., G.V. and A.V.).

Statistical Analysis

Prior to any statistical analysis, a Shapiro-Wilk normality test was applied to all continuous variables. Since normality was not proven, a non-parametric approach was implemented. Mann-Whitney U test was used for the comparison of continuous variables. Kruskal Wallis H test was applied in multiple comparisons of continuous data. Categorical variables were analyzed with Pearson chi square test, while proportions were evaluated by the Z test. Correlation was assessed through a Spearman's Rank-Order correlation test.

To identify variations in the changing rate of the studied variables and plot the respective learning curve (LC), cumulative sum (CUSUM) analysis was performed. CUSUM analysis was applied to all above-mentioned endpoints.

The CUSUM analysis plots that confirmed a significant LC pattern, were further evaluated by change-point analysis (CPA). CPA allows the identification of even small

trend shifts and provides the respective statistical significance of each change. The CPA analysis incorporated the application of 1000 bootstraps, and a 50% Confidence Level (CL) for candidate changes.

The acceptable rate of missing values was <10%. Missing data were handled with the multiple imputation technique. Continuous data were reported in the form of Median (Interquartile Range), whereas categorical variables were provided as N(Percentage). Significance was considered at the level of $P < 0.05$. Statistical analyses were completed by STATA v.13 and SPSS v.23 software.

RESULTS

Patient characteristics are summarized in Table 1. Overall, 214 Laparoscopic colorectal operations were included in the study. More specifically, 76 (35.5%) right colectomies, 31 (14.5%) left colectomies, 26 (12.2%) sigmoidectomies, 72 (33.6%) low anterior resections (LAR), 7 (3.3%) ultra-low anterior resections (ULAR), and 2 (2.4%) abdominoperineal resections (APR) were performed. Most of the cases displayed a level 1 (54.2%) and 2 (38.2%) complexity. Mean operation duration was 180 and 200 minutes for LCO and LRO, respectively. The results of the correlation analyses are reported in Supplementary Material Tables. The overall complication rate was 22.9%. Negative resection margins were confirmed in 95.3% of the patients. A mesocolic and a mesorectal resection plane was achieved in 86.4% and 88.8% of cases, respectively.

Figure 1 illustrates the LCRO learning curve, in terms of operation duration. A declining trend of the CUSUM plot, until the 109th case was noted, followed by an upwards shift and a maximum value at the 176th case. CPA analysis confirmed the 110th (CL: 100%) and 145th (CL: 99%) case turning points. On the basis of these findings (Table 2), the LCRO LC was subdivided in three distinct phases (Phase I: 1 to 109 operations, Phase II: 110 to 144 operations and Phase III: 145 to 214 operations).

Figures 2 and 3 display the learning curve plots of LCO and LRO, correspondingly. Both LC patterns were comparable. First successive cases resulted to a gradual decrease and the reach of a minimum, followed by a consequent increment of the LC line. We

confirmed that the 58th (CL: 99%) and the 52nd (CL: 100%) case were the corresponding turning points of colon and rectal resections. Hence, we identified two phases of the LCO and LRO learning curve (LCO Phase I: 1 to 57 operations, Phase II: 58 to 133 operations and LRO Phase I: 1 to 51 operations, Phase II: 52 to 81 operations).

Table 2 summarizes the eligible patient data and the study outcomes between the various LC phases. LCRO Phase III displayed a significant improvement in the specimen length ($P < 0.001$), the resection distal margin ($P < 0.001$) and the lymph node yield ($P = 0.016$).

Subgroup analyses of the LC phases showed that surgical experience was correlated with the specimen length in both LCO and LRO ($P = 0.001$ and $p < 0.001$, respectively). However, dexterity in laparoscopic surgery increased the distal resection margin ($p < 0.001$) and number of excised lymph nodes ($P = 0.002$) only in LCO.

Postoperative complication analysis (Supplementary Material Figures) in LCRO ($P = 0.48$), LCO ($P = 0.419$) and LRO ($P = 0.521$), did not identify a LC pattern. Similarly, open conversion was not associated with a learning curve pattern, in any of the study subgroups ($P = 0.3$, $P = 0.8$, $P = 0.19$, correspondingly).

Finally, the diagrams of the pathology endpoints are provided in Supplementary Material Figures. The 64th case (CL: 100%) was estimated as the turning point of the specimen length in colon resections. A plateau was reached after the 99th case (CL: 94%). The respective turning point of the LRO was the 47th case. There were no significant CPA turning points in the resected lymph node yield.

DISCUSSION

LC is defined as the schematic depiction of the fluctuation of an efficiency outcome, plotted over a successive number of repetitions [27,29]. Among the various statistical methodologies that have been employed for the LC evaluation are the group splitting, moving average and CUSUM analysis [3,17,32,33]. Following an introductory learning phase, the trainee is gradually performing operations of higher complexity and difficulty [34,35]. Finally, once the iteration of the process does not affect the measured

variable, mastery is achieved [16,17,32]. As a result, estimation of the LC turning points is of paramount importance in trend analysis [26].

The inherent divergence of the learning efficiency, alongside the discrepancy in the estimated LC endpoints, resulted to a significant heterogeneity in the published LC outcomes [4,36]. To be more specific, recent studies in laparoscopic colorectal surgery, suggested that LC turning points fluctuate between 10 [32] and 200 cases [37].

Operation duration has been frequently introduced as the LCRO LC estimated variable [27,29,32]. Nonetheless, surgical expertise assessment, based solely upon operation duration may result to biased conclusions [27,29]. This is due to the fact that, the overlapping surgical skills and the efficient collaboration between the assisting theater personnel, can also impact the duration of a procedure [27,38,39]. Initial studies suggested that 23 operations may suffice for the standardization of operative time [9,24]; however, this was not validated in subsequent trials, where a 96-cases margin was reported [23]. Our results estimated the first LC cut-off point at the 110th case, which is in parallel with the previous evidence.

Interestingly, we identified lower LC turning points during the individual assessment of both colon and rectal operations (LCO: 58 cases, LRO: 52 cases). This discrepancy may be the result of the combination of the two study subgroups. In particular, the estimated LC of a specific operation subtype, is, usually, shorter, since it incorporates fewer surgical steps. Despite the fact that previous surgical competence, in either LCO or LRO, may accelerate the transposition of skills to the other, completion of LCRO LC prerequisites the attainment of mastery in both operations. Therefore, LCRO LC is equal to the summation of the two subgroup CUSUM plots.

The narrow working space, the lack of three-dimensional vision and the fixed port positions, further enhance the LCRO surgical complexity and the risk of critical intraoperative events [29]. Consequently, the learning curve status may have a direct impact on perioperative morbidity [7,17,22,23]. Previous reports estimated that a plateau in LCRO complication rate is achieved after 140 to 200 operations [23,37]. However, we were not able to validate a LC pattern in perioperative morbidity. Similarly, MacKenzie *et al*,

suggested the absence of fluctuation in the perioperative complications rate during the LC period [4]. Nonetheless, these results may be due to an inadequate sample size, since larger cohorts confirmed the presence of an LC pattern in perioperative morbidity [7,17,22,23,37].

Open conversion is considered in the case of a critical event, that is not amendable by the ongoing approach [17,19,32]. Typical examples include an intraoperative complication or the compromise of the oncological principles [15,19,24,25]. Although not widely accepted, conversion turning point is estimated at 61 successive operations [18,26,40]. A structured training program, though, may further reduce the above-mentioned LC margin [18,26,40]. Even though our results were in accordance with previously published reports [23], we did not confirm the presence of a LC trend in the open conversion rate.

Specimen-related endpoints are of paramount importance when evaluating the oncological efficacy of an operation [6,14,36]; lymph node yield is the most prominent among them [6,14,36]. However, this can be misleading since lymph node harvest can be affected by anthropometric and disease-related characteristics [41]. Despite these, we confirmed the presence of a significant LC trend in the number of the resected lymph nodes. Additionally, change point analyses validated the increase of the specimen length after the 64th and 47th LCO and LRO case, respectively. We did not introduce positive resection margin and non-CME/ TME dissection plane as an LC outcome, due to the scarcity of these events. Moreover, in case of CME/ TME violation, an open conversion was performed, to secure adherence to oncological principles.

A swift completion of the learning curve is needed, in order to capitalize on the LCRO advantages [29]. Modular training enables the partitioning of the procedure in successive steps, each with its own optimization requirements [18]. The introduction of advanced LCRO courses, mentor guidance and large operational volume exposure results to a considerable downgrade of the LC cut-off points [18,27]. These methods have been successfully enrolled in multiple national structured training programs, with promising results [17,26]. Nonetheless, surgeons in healthcare systems that have not included LCRO in their official guidelines, do not have access in similar training

modules [22]. Therefore, the implementation of LCRO in such settings, is based on the individual training efforts of the involved surgeons, with questionable, though, results.

In this study we analyzed the pooled learning curve of two senior colorectal surgeons. LCRO training was not structured and included course attendance and proctor guidance. Despite this, previous experience in laparoscopic surgery and open colorectal resections could have impacted the pooled LCRO LC turning points. Therefore, our results may not reflect the typical LC pattern of an average surgical trainee.

Several limitations should be acknowledged, prior to the appraisal of our findings. First, despite the statistical significance of several LC turning points, our study incorporated a, relatively, small sample size. This prohibited further explanatory analyses, including risk-adjustment of the learning curves. Moreover, the innate discrepancy in terms of patient and surgical characteristics, degraded the significance of our results. Furthermore, another major source of bias could be the retrospective design of our study. Finally, the fact that only two consultants were included in this study, prohibited the safe extrapolation of these findings to a wider pool of colorectal surgeons and surgical trainees.

CONCLUSION

Overall, our study reported that the LCRO operation duration learning curve consists of 3 distinct phases. CPA analysis estimated that the 110th case is the cut-off point between the first two phases. Stabilization of operative time is achieved after the 145th case. LCO and LRO subgroup analysis estimated the 58th and 52nd case as the respective turning points. In contrast to the open conversion and morbidity outcomes, a learning curve pattern was confirmed in pathology endpoints. The learning curves in our settings validate the comparability of the results, despite the absence of National or Surgical Society driven training programs. However, the initiation of a formal LCRO training policy is necessary for the safe and efficient implementation of these procedures.

ARTICLE HIGHLIGHTS

Research background

The introduction of structured training programs results to an enhanced learning process in laparoscopic colorectal surgery.

Research motivation

National training programs are not widely available, thus constraining the efficient adaptation of minimal invasive techniques in colorectal surgery.

Research objectives

The objective of this study was to analyze the learning curve patterns in ¹laparoscopic colorectal operations, under a non-structured training setting.

Research methods

A retrospective analysis of a prospectively collected database was performed. Cumulative sum and change point analysis were introduced for the evaluation of learning curve patterns.

Research results

In terms of operation duration, three learning curve phases were identified. A learning curve pattern was also confirmed in pathology endpoints, but not in the open conversion and complications outcomes.

Research conclusions

Laparoscopic colorectal operations under a non-structured training setting, resulted to similar learning patterns with the respective structured training curves.

Research perspectives

The introduction of formal training programs in laparoscopic colorectal surgery is necessary for the safer and wider adoption of these techniques.

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