Multidimensional Analysis of the Learning Curve of Laparoscopic Colorectal Surgery in a Regional Hospital. The Implementation of a Standardised Surgical Procedure Counterbalances the Lack of Experience.

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Abstract

Background: Although in the last few years a larger proportion of colorectal surgeries have been performed laparoscopically, a steep learning curve prevents us from considering laparoscopic colorectal surgery as the gold standard technique for treating disease entities in the colon and rectum. The purpose of this single center study is to determine, using various parameters and following a well structured and standardised surgical procedure, the adequate number of cases after which a single surgeon qualified in open surgery but with no previous experience of laparoscopic colorectal surgery and without supervision, can acquire proficiency in this technique.

Methods: From 2012 to 2019, 112 patients with pathology in the rectum and colon underwent a laparoscopic colorectal resection by a team led by the same surgeon. The patients were divided into two groups (Group A:50 – Group B:62) and their case records and histopathology reports were examined for predefined parameters, statistically analyzed and compared between groups.

Results: There was no significant difference between groups in the distribution of conversions (p=0.635) and complications (p=0.637). Patients in both groups were operated for the same median number of lymph nodes (p=0.145) and stayed the same number of days in hospital (p=0.109). A statistically important difference was found in operation duration both in total (p=0.006) and for each different type of colectomy (sigmoidectomy: p=0.026, right colectomy: p=0.013, Extralevator abdominoperineal resection: p=0.050, low anterior resection: p=0.083).

Conclusions: Taking into consideration all the parameters, it is our belief that a surgeon acquires proficiency in laparoscopic colorectal surgery after performing at least 50 diverse cases with a well structured and standardised surgical procedure.

Background

Although the feasibility and oncologic efficacy of laparoscopic surgery for the treatment of inflammatory, benign and malignant disease entities in the colon and rectum have been demonstrated in randomized controlled trials [1–4], still many surgeons are skeptical and avoid performing colorectal surgeries laparoscopically [5]. Four large prospective, randomized controlled trials, from North America, Canada and Europe, have been completed and have demonstrated that laparoscopic treatment of colon cancer has oncologic results similar to open surgery, with no increased morbidity or mortality, and offers patients all the advantages of laparoscopic surgery [6–9]. Despite the fact that a greater adoption of laparoscopic colorectal surgery has been observed in the last years [10], the implementation of this technique is still progressing slowly [11]. According to the recent statistical data, in England equal numbers of patients with pathology in the colon and rectum undergo open and laparoscopic surgery [12]. In other countries, the percentage of colorectal surgeries performed laparoscopically is much lower [13, 14]. The main reason for that is the steep and long-term learning curve of laparoscopic colorectal surgery [15, 16].

The term learning curve, which was firstly introduced by Hermann Ebbinghaus in 1885 in the study of Psychology of Learning and Theodore Paul Wright in 1936 for the aircraft industry in order to express the
graphic representation of the mean rate of learning for a procedure, is imported into laparoscopic colorectal surgery and is under investigation by several studies [17–21]. It is completed when the predefined variables reach a steady state and the outcomes are comparable with those in literature [22, 23].

Despite the fact that multiple parameters and numerous criteria are taken into consideration in order to determine the adequate number of cases to achieve proficiency, a consensus has not yet been reached among surgeons [24–26]. No reliable framework for case selection during training is available and as a consequence the learning curve for laparoscopic colorectal surgery has not been conclusively analyzed [27].

The aim of this study is to determine the safety and clinical outcomes of laparoscopic resection for colorectal disease entities performed by a single surgeon with no previous experience of laparoscopic colorectal surgery and to analyze the learning curve of a well structured and standardised surgical procedure followed by a standardised postoperative protocol [28], using various parameters.

**Methods**

From October 2012 to January 2019, 112 patients with pathology in the rectum and colon submitted to laparoscopic colorectal resection at a regional general hospital (Venizeleio General Hospital of Heraklion in Crete) by a team led by the same surgeon (M.C.) who was qualified in open surgery (> 300 colectomies) but had no previous experience with advanced laparoscopic procedures. Furthermore, the laparoscopic colorectal operations were performed without the attendance or supervision of an experienced in laparoscopic colectomies surgeon. Before beginning to perform colorectal resections laparoscopically, the surgeon (M.C.) became familiar with the cognitive aspects of this new procedure by watching operative videos, attending to seminars and assisting during laparoscopic colorectal surgeries at specialized hospitals in this field. He obtained the necessary for advanced laparoscopic surgery skills by training in animal models and virtual reality simulators.

Patients with locally advanced disease (T4 or bulky tumors), previous operations with a midline incision and BMI > 35 were excluded from the study. The study population was organized chronologically according to the date of surgery and it was divided into two groups. The first group contained the initial 50 interventions and the second the following 62 patients. The case records and histopathology reports were examined for predefined parameters such as patient demographic data, location of the tumor, type of surgical procedure, conversion to open surgery, surgical time, distal and circumferential margins, number of harvested lymph nodes and total hospital stay. Mortality, surgical complications and oncological outcome were also examined. The data collected was then statistically analyzed and compared between these two groups.

The time of surgery was calculated from the time of the first port placement to the time of closure of the wound and the data for all the laparoscopic surgeries was collected from the formal surgery records. The surgeries which were converted to open were excluded from surgical time analysis. The distal and circumferential margins and the number of harvested lymph nodes were obtained from the histopathology reports. Circumferential resection margins (CRMs) were defined as positive if malignant cells were found at microscopy at a distance of less than 2 mm.
Preoperative preparation

All patients included in the present study underwent a preoperative preparation with extended medical report, physical examination, rectal exam, blood level of cancer markers, chest X-ray, thoracic and abdominal computerized tomography and total colonoscopy with biopsy. The patients with a tumor in the rectum had in addition a rigid rectoscopy and a nuclear magnetic resonance imaging (MRI) of the rectum. If a preoperative chemoradiotherapy was conducted for the patients with a tumor in the rectum, a repetitive MRI was performed.

Surgical notes

All the surgical procedures were performed by a team led by the same surgeon (M.C.) without the supervision of any surgeon specialized in laparoscopic colorectal surgery. The rest of the team consisted of two trainees, one responsible for the camera and the other as a surgical assistant, and a single scrub nurse. The role of each member of the team was precisely defined in order to make everything work correctly.

General anesthesia with epidural analgesia was the preferred mode of anesthesia. A well structured and standardised surgical procedure was implemented following oncological criteria, according to the principle of the Complete Mesocolic Excision (CME) and Total Mesorectal Excision (TME) with Central Vascular Ligation (CVL) [29–31]. For patients with a tumor at the lower rectum unsuitable for low anterior resection, the chosen surgical technique was Extralevator abdominoperineal resection (ELAPE) with the patient at a jacknife position [32, 33].

Postoperative protocol

All the patients of this study underwent a “fast track” postoperative protocol. Specifically, mobilization of the patients took place the next morning after the day of surgery. None of the patients had a nasogastric tube so they were encouraged to drink liquids from the first postoperative day. The urinary catheter was removed the morning after the operation, with the exception of the patients submitted to a low rectal resection or Extralevator abdominoperineal resection. In these cases, the catheter was maintained for at least four days.

Statistical Methods

Mean, median and standard deviation SD were used to describe the continuous variables like operation hours and days of hospitalisation, while frequencies and %frequencies for discrete data. Independent samples t-test and the corresponding non-parametric Mann-Whitney were used for two groups comparisons. For more than two groups comparisons, one-way ANOVA followed by Tukey HSD post hoc test were used. Pearson chi-square test was assessed to examine possible association between two discrete variables. Box plots and scatter plots were used for graphical representation of data. IBM SPSS Statistics 24.0 was used for statistical analysis of data and a = 0.05 limit was set for accepting the null hypotheses.

Results
From October 2012 to January 2019, a total of 112 patients underwent laparoscopic colectomies at Venizeleio General Hospital of Heraklion in Crete (Greece). Patients were formally divided into two groups named as A and B. Group A can be characterised as training group and Group B as post-training group. In Table 1, the demographics of patients -age and sex- are shown. There is no significant difference in patients’ sex between the two groups A and B (p = 0.546) and the age distribution (p = 0.634).

| Group | n   | %     | n   | %     | p   |
|-------|-----|-------|-----|-------|-----|
| Sex   | 1   | (n = 48) | 23  | 47.9% | 25  | 52.1% | 0.546 |
|       | 2   | (n = 64) | 27  | 42.2% | 37  | 57.8% |       |
| Age   | <= 50 | (n = 13) | 5   | 38.5% | 8   | 61.5% | 0.634 |
|       | 51–60 | (n = 20) | 8   | 40.0% | 12  | 60.0% |
|       | 61–70 | (n = 30) | 11  | 36.7% | 19  | 63.3% |
|       | 71–80 | (n = 36) | 19  | 52.8% | 17  | 47.2% |
|       | 81+   | (n = 13) | 7   | 53.8% | 6   | 46.2% |

Of a total of 112 patients, who were initially selected for pre and post training laparoscopic surgery, nine of them (8.0%) were excluded due to conversion from laparoscopic to open surgery.

| Group | Total | n   | %     | n   | %     | n   | %     | p   |
|-------|-------|-----|-------|-----|-------|-----|-------|-----|
|       | Conversion | No | 46  | 92.0% | 57  | 91.9% | 103 | 92.0% | 0.99 |
|       |         | Yes | 4   | 8.0%  | 5   | 8.1%  | 9   | 8.0%  | 0.635 |

Patient’s diagnoses and operation types

The distribution of operation types in groups A and B are shown in Fig. 1. There is a higher number of sigmoidectomies in group B (n = 22) in comparison to group A (n = 12), while the opposite pattern was shown in ELAPE operations, n = 3 for group B vs n = 10 for group A (Fig. 1). A significant difference in the frequencies of operation types was found for group A and B patients (p = 0.045).
Number of lymph nodes, days of Hospitalization, duration of operation and clinical characteristics between pre and post training period

In Table 3 the distribution of operation margins and complications during operation in pre (A) and post (B) training group, are shown. Only 1 patient had positive margins, and this was recorded in A group. There is no significant difference in type of margin proportions between groups (p = 0.301). Operational complications were observed in 7 cases in total number of patients (6.8%). The distribution of complications were 4 cases in group A (8.0%) and 3 cases in group B (5.7%) which is not significantly different between groups (p = 0.637).

|                | Group   | A            | B            | n  | n  | %  | p   |
|----------------|---------|--------------|--------------|----|----|----|-----|
| Margins        | Free    | 49 98.0%     | 53 100.0%    | 0  | 0  | 0.301 |
|                | Positive| 1 2.0%       | 0 0.0%       |    |    |     |     |
| Complications  | No      | 46 92.0%     | 50 94.3%     | 0  | 0  | 0.637 |
|                | Yes     | 4 8.0%       | 3 5.7%       |    |    |     |     |

For each of these 7 patients with complications, a laparotomy was performed after the initial laparoscopic colorectal operation. In addition, the patient of Group B with anastomotic leak after sigmoidectomy, died the postoperative period of the second surgery due to deterioration of the respiratory system. No other death reported, neither during the laparoscopic colorectal surgeries nor the immediate postoperative period.

| Complications       | Group   | A | B |
|---------------------|---------|---|---|
| Anastomotic leak    | A       | 2 | 1 |
| Stenosis of anastomosis | A | 1 | 0 |
| Ligature of ureter  | A       | 1 | 0 |
| Lesion of urinary bladder | A | 0 | 1 |
| Lesion of the iliac vein | A | 0 | 1 |
| TOTAL NUMBER        |         | 4 | 3 |
Table 5
Description of complications for each type of surgery

| Complications                  | Type of Surgery          | Right colectomy | Sigmoidectomy | Low anterior resection | ELAPE |
|--------------------------------|--------------------------|-----------------|---------------|------------------------|-------|
| Anastomotic leak               |                          | -               | 1             | 2                      | -     |
| Stenosis of anastomosis        |                          | -               | 1             | -                      | -     |
| Ligature of ureter             |                          | 1               | -             | -                      | -     |
| Lesion of urinary bladder      |                          | -               | 1             | -                      | -     |
| Lesion of the iliac vein       |                          | -               | 1             | -                      | -     |
| TOTAL NUMBER                   |                          | 1               | 4             | 2                      | 0     |

Patients in both groups were operated for the same median number of lymph nodes. Median and quartile range of lymph nodes for group A were 20 (14–28), while for group B were 26 (16–34) showing no statistically significant differences (p = 0.145). Hospitalization days were not significantly different in both groups (p = 0.109) showing a median of 7 (5–8) for group A and 6 (5–7) for group B. Operation duration was less in post training group (group B) (median 4.0, 3.5–4.0) vs pre-training group (group A) (median 4.5, 3.5–5.5) (p = 0.006) (Table 6).

Table 6
Number of lymph nodes, days of hospitalization and operation duration between training (group A) and post-training group (group B)

| Group          | A                     | B                     | p*  |
|----------------|-----------------------|-----------------------|-----|
|                | Mean | SD | Quartiles | Mean | SD | Quartiles |      |
| Operation duration (hours) | 4.5  | 1.2 | 3.5 | 4.5 | 5.5 | 4.0 | 1.4 | 3.5 | 4.0 | 4.0 | 0.006 |
| Hospitalization (days)      | 7.9  | 4.7 | 5.0 | 7.0 | 8.0 | 6.2 | 1.9 | 5.0 | 6.0 | 7.0 | 0.109 |
| Lymph Nodes (number)        | 22.3 | 12.2 | 14.0 | 19.5 | 28.0 | 26.8 | 15.1 | 16.0 | 26.0 | 34.0 | 0.145 |

* Mann-Whitney test
Operation characteristics between training group (A) and post training group (B) per type of operation

When type of operation was considered during A vs B group comparison, although the median duration of operations were lower in group B than A, significance was present only in Low anterior resection 4.5 (4.0-4.5) for group B vs 5.5 (4.5–5.5) for group A (p = 0.036). A tendency for significance was found for sigmoidectomy (p = 0.059). Group B showed a median of 3.5 (3.5-4.0) vs 4.5 (3.5-5.0) for group A (Table 7).

| Operation                          | Group A | Group B | Quartile | Quartile | Quartile | Quartile | P    |
|-----------------------------------|---------|---------|----------|----------|----------|----------|------|
| Duration (hours)                  |         |         | 1st      | 2nd      | 3rd      | 1st      | 2nd  | 3rd  |
| Sigmoidectomy                     | 3.5     | 3.5     | 3.5      | 3.5      | 4.0      | 0.059    |      |      |
| Right colectomy                   | 3.5     | 3.5     | 3.5      | 3.5      | 4.0      | 0.286    |      |      |
| ELAPE                             | 4.5     | 6.0     | 6.0      | 4.3      | 5.0      | 0.937    |      |      |
| Low anterior resection            | 4.5     | 5.5     | 5.5      | 4.0      | 4.5      | 0.036    |      |      |
| Hospitalization (days)            |         |         |          |          |          |          |      |      |
| Sigmoidectomy                     | 6       | 5       | 5        | 5        | 7        | 0.557    |      |      |
| Right colectomy                   | 5       | 7       | 8        | 5        | 6        | 7        | 0.697|      |
| ELAPE                             | 7       | 8       | 9        | 7        | 9        | 10       | 0.371|      |
| Low anterior resection            | 6       | 7       | 8        | 6        | 6        | 7        | 0.713|      |
| Lymph nodes (number)              |         |         |          |          |          |          |      |      |
| Sigmoidectomy                     | 14      | 17      | 27       | 12       | 23       | 33       | 0.901|      |
| Right colectomy                   | 18      | 22      | 28       | 20       | 28       | 36       | 0.240|      |
| ELAPE                             | 7       | 14      | 16       | 16       | 18       | 37       | 0.077|      |
| Low anterior resection            | 15      | 25      | 29       | 20       | 28       | 34       | 0.713|      |

Timeline of operation duration

An alternative approach was shown in Fig. 2. The timeline of operation duration in hours was presented vs consecutive patients’ number for each of the operation types. Independently on group (A or B), there is a significant decrease in operation time for sigmoidectomies (rs=-0.382, p = 0.026) as operation duration vs patients’ consecutive series showed. The same declining pattern was found for right colectomy operations (rs=-0.389, p = 0.013) and ELAPE (rs=-0.554, p = 0.050). A tendency for declining was found for low anterior resection (rs=-0.446, p = 0.083).

Discussion
Laparoscopic colorectal surgery is demanding as it requires an elevated level of technical skills. Despite the fact that the feasibility and oncologic efficacy of laparoscopic colorectal surgery have been proved [1–4], its implementation in daily surgical practice is still limited [11, 13, 14]. The main factor contributing to this is the steep and long term learning curve [15, 16]. In literature, the number of cases needed in order to achieve proficiency in laparoscopic colorectal surgery, varies enormously. Simons et al. reported a learning curve of 11–15 cases in a series of 144 patients in 1995 [34], whereas Tekkis et al. demonstrated a learning curve of 55 cases for right-sided colectomies versus 62 cases for left-sided resections [17]. In a multicenter analysis of 4852 cases, the learning curves varied from 87 to 152 procedures [27]. In other studies [15, 25–26, 35–36], the adequate number of laparoscopic resections ranges from 30 to 70 cases. As can easily be understood, there is no consensus among the surgeons [24–26]. The aim of this study is to evaluate the learning curve based on the initial outcomes of our first 112 operations using various parameters.

The present study demonstrates that conversion rates do not differ significantly as the surgeon gains more experience. Our overall 8% conversion rate is in accordance with the 5–20% reported in the literature [37–39] and there was no significant change between the first 50 and the next 62 cases. Furthermore, no significant difference in the rate of surgical complications was identified between the two groups. Operational complications were observed in 7 cases in total number of patients (6.8%) and their distribution was 4 cases in group A (8.0%) and 3 cases in group B (5.7%). Other reported series have concluded that at least 40–50 procedures are necessary to lower the complication rate significantly [20, 26, 34]. In addition, the 0.8% overall mortality rate and the 2.9% anastomotic leak rate in laparoscopic surgeries (3 cases of low anterior resection), which were detected in our study, are comparable with those in multicenter trials [37–39].

A very important parameter is the oncologic efficacy of the laparoscopic colorectal procedure. That goal, as represented by negative surgical distal and circumferential margins and adequate number of harvested lymph nodes, can be reached early in the learning curve as demonstrated in our research. The median and quartile range of lymph nodes for training and post training group were comparable, showing no statistically significant difference. Furthermore, only one patient of the post training group with a bulky tumour in the rectum locally expanded, despite the neoadjuvant chemotherapy and radiotherapy, had positive surgical circumferential margins. These results can be easily explained by taking into consideration the ample knowledge of anatomy and the respect of the rules of chirurgical oncology, credentials of the surgeon obtained by experience in open surgery. An inappropriate resection is not justifiable even in the training period and oncological outcomes should not be compromised. For that reason, the completion of the operation laparoscopically does not constitute a purpose in itself.

The increasing number of cases performed laparoscopically, does not alter the overall hospitalization of the patients between the two groups. The implementation of a well structured and standardised surgical procedure followed by a standardised postoperative protocol, ensure that all patients take advantage of the benefits of laparoscopic surgery [6–9]. COLOR II and Ivanov P et al. reported reduced hospitalization as a result of faster recovery in laparoscopically operated patients versus those who had an open surgery [40, 41].

The surgical time in laparoscopic colorectal surgery is longer than in open surgery even if the resections are performed by surgeons with experience in advanced laparoscopic procedures [42]. In our experience, the
operating time decreases with the surgeon's increasing experience and it is a useful criterion for evaluating the learning curve. Specifically, there was a significant decrease in operation time for sigmoidectomies, right colectomy operations and ELAPE, and a tendency for declining was found for low anterior resections. Our results are similar to those of Choi et al., who demonstrated a decline in the time of laparoscopic sigmoidectomy after 30–42 cases [35].

Conclusions

The key factor for accomplishing adequate oncologic resections laparoscopically and shortening the learning curve, is the implementation of a well structured and standardised surgical technique followed by a standardised postoperative protocol. From our perspective, a surgeon acquires proficiency in laparoscopic colorectal surgery after performing at least 50 diverse cases. It is our belief that the results of this study will encourage and enable a larger number of surgeons to adopt laparoscopic surgery in the daily clinical practice as the gold standard technique for treating diseases in the colon and rectum.

Abbreviations

- C. = Manousos Christodoulakis
- CRM = Circumferential resection margins
- MRI = Magnetic resonance imaging
- CME = Complete Mesocolic Excision
- TME = Total Mesorectal Excision
- CVL Central Vascular Ligation
- ELAPE = Extralevator abdominoperineal resection

Declarations

Ethics approval and consent to participate: This study was in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. The study was approved by the Ethics Committee of Scientific Board of Venizeleio General Hospital of Heraklion (Decision No.128/Meeting 17/18-12-2019). Informed consent was obtained from all patients. The consent was either written or verbal. From some patients verbal consent was taken due to either low level of educational attainment or better understanding of the scientific protocol of the study using oral language. The Ethics Committee of Scientific Board of Venizeleio General Hospital of Heraklion with the same decision (Decision No.128/Meeting 17/18-12-2019) accepted both ways (written or verbal) for the information and consent of the patients.

Consent for publication: Not applicable

Availability of data and material: The datasets generated and analysed during the current study are included in this manuscript and its supplementary information files.
Competing interests: The authors declare no conflicts of interest.

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**Figures**
Figure 1

Distribution of operation types in group A and B
Figure 2

Timeline of operation duration in hours vs patient's consecutive series for each operation type

**Supplementary Files**

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