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Multicenter retrospective cohort Italian study on elective laparoscopic cholecystectomy performed by the surgical residents

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Abstract

Purpose This retrospective multicenter cohort study aimed to evaluate the clinical outcomes (mortality rate, operative time, complications) of elective laparoscopic cholecystectomy (LC) when performed by a surgical resident in comparison to experienced consultant in the backdrop of Italian academic centers.

Methods Retrospective review of all patients undergoing elective LC between January 2016 and January 2022 at six teaching hospitals across Italy was performed. Cases were identified using the Current Procedural Terminology (CPT) code 5123 (LC without cholangiogram). All cases of emergency surgery, ASA score > 3, or when cholecystectomy was performed with another surgical procedure, were excluded. All suitable cases were divided into 2 groups based on primary surgeon: consultant or senior resident. Main outcome was complication rates (intraoperative and peri/postoperative); secondary outcomes included operative time, the length of stay, and the rate of conversion to open.

Results A total of 2331 cases (1425 females) were included, of which, consultants performed 1683 LCs (72%), while the residents performed 648 (28%) surgeries. The groups were statistically comparable regarding demographics, history of previous abdominal surgery, operative time, or intraoperative complications. The rate of conversion to open cholecystectomy was 1.42% for consultant and none for resident (p=0.02). A statistically significant difference was observed between groups regarding the average length of stay (2.2 ± 3 vs 1.6 ± 1.3 days p=0.03). Similarly, postoperative complications (1.7% vs 0.5%) resulted in statistically significant (p=0.02) favoring resident group.

Conclusions Our study demonstrates that in selected patients, senior residents can safely perform LC when supervised by senior staff surgeons.

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Introduction

Laparoscopic cholecystectomy (LC) is one of the most commonly performed surgeries worldwide as it has become the gold standard approach for both elective and acute scenarios over the years [1–3]. Initially popularized by P. Mouret in 1987 in France and by M. Morino in 1990 in Italy [4], the dissemination and widespread adoption of LC can largely be credited to Eddie J. Reddick and Douglas O. Olsen [5] who led the training program for LC in the USA and to Cuschieri in Europe [6]. Reddick and Olsen [5–7] organized structured courses to teach this technique to surgeons throughout the country and were largely responsible for the rapid spread of laparoscopy in the USA.

LC is the preferred technique for gallbladder removal, whereas the open (OC) approach/conversion is usually performed in selected cases where the anatomy is unclear or in the case of unanticipated intraoperative difficulties/complications. With the widespread adoption of LC in the early 1990s, it soon became apparent that besides the obvious benefits of the laparoscopic approach to most patients, there was an unusually higher incidence of bile duct injury as well [8]. In the early 1990s, Steven Strasberg and others began exploring the mechanism and cause of bile duct injuries that occur during LC [9]. Eventually, in 1995, Strasberg et al. [10] described the Critical View of Safety (CVS) which became the benchmark for ductal identification during LC. Over the years, the total incidence of bile duct injuries (BDI) during LC reduced to about 0.4–1.5% [11].

Despite some authors considering that the involvement of under-training resident surgeons has a negative influence on the procedural outcomes, it is crucial for the new generation who are entering the field of minimally invasive surgery (MIS), where LC is the main adopted procedure. A large retrospective analysis published in 2020, including more than 106,000 MIS procedures performed across multiple academic centers in the USA, reported that LC ranks second out of the 7 most commonly performed MIS procedures during the general surgery residency program [12, 13]. In Italy, despite the large involvement of resident in surgical procedures, no standard training program is routinely adopted by the academic institution, and, at present, no data has been collected about the resident performance in elective LC. The aim of the present retrospective multicenter national study is to evaluate the impact of surgical residency experience on the outcomes of elective LC across our country.

Materials and methods

This is an observational multicenter retrospective cohort study. The Sapienza University-Polo Pontino Research Ethics Committee has confirmed that no ethical approval is required. The data were obtained from routine clinical practice and included, with the relative informed consent for use, into the stored medical chart. We reviewed medical records of all patients who underwent elective LC between January 2016 and January 2022 at 6 teaching hospitals across Italy - two in the north (University of Torino and Ferrara), two in the center (University of Rome 'La Sapienza' Latina and University of Firenze), and two in the south (University of Napoli Federico II and University of Palermo). The primary leading and promoting center was at the Division of General Surgery Polo Pontino-Latina, University of Rome 'La Sapienza'. All these institutions are recognized training centers for academic general surgery residency programs despite that all the Italian Academic centers do not offer a recognized, standard training model in LC.

Inclusion criteria

LC cases were identified using the Current Procedural Terminology (CPT) code 5123 (LC without cholangiogram) with complete resolution of eventual acute events (proven by recent ultrasound and blood analysis). The hospital administrative staff collected data for all LC surgeries performed during the study period from the hospital database, which was then analyzed by a medical researcher involved in the study to evaluate the outcomes.

Exclusion criteria

Patient cases were excluded when cholecystectomy was part of other surgical procedures, patients had an emergency admission and treatment, patients with incomplete data, and those with an American Society of Anesthesiologists (ASA) status > 3.

Elective LC was indicated in case of symptomatic gallbladder disease, microlithiasis, or polyps (exceeding 1 cm) in the absence of clinical and imaging findings suggestive of acute disease as established by the World Society of Emergency surgery (WSES) guidelines [14].

The included cases were divided into 2 groups based on the primary surgeon — senior resident or consultant/ tutor. The resident cohort included only senior residents in their last 2 years of the general surgery residency training program (PGY 4,5) operating under direct (consultant scrubbed in) or indirect (consultant in the operating room, but not scrubbed in) supervision, while the consultant/ tutor group included only surgeons with > 5 years of experience with MIS. Patient's allocations (not randomized) were based on patient's risk, operation's complexity and resident/consultant experience/feeling to respect a "patient's safety-first" policy.

Outcomes

Patient demographics were reviewed — age, gender, status as per ASA classification, history of previous abdominal surgery, intraoperative, peri (30 days) (pain, vomit, surgical site infection (SSI), biliary leak, intrabdominal collection and bleeding) and postoperative (> 30 days) complications (intrabdominal collection, trocar site hernia, retained bile duct stones and SSI) and rate of conversion to open procedure were recorded. The primary outcome of the study was complication rates (intraoperative and peri/postoperative); secondary outcomes included operative time, the length of stay, and the rate of conversion to OC. Peri/postoperative complications were categorized according to the Clavien–Dindo classification [15] and evaluated as Comprehensive Complication Index (CCI), operative time was calculated as the time from the first incision until the skin closure, and the length of stay was calculated from the date of operation to the date of discharge.

Statistical analysis

All outcomes were analyzed using multivariate logistic binomial regression analyses with a set of covariates based on the clinically relevant predictors of postoperative complications, including age, sex, body mass index (BMI), ASA category, and the surgical group (resident/consultant). All data were described as mean \pm standard deviation and range of frequencies and percentages, as appropriate. Numerical variables for different groups were compared using the Student's *t*-test for independent samples. Association between variables was computed using Pearson's product-moment correlation equation or Spearman's rank correlation based on the variable's distribution. A *p*-value of <0.05 was considered statistically significant. All statistical analyses were performed with STATISTICA version 10 (StatSoft, Inc., Tulsa, OK 74,104, USA).

Results

The review initially yielded 2417 cases (1475 females and 942 males). After the first analysis, 86 cases were excluded for the following reasons — incomplete pre, intra, or post-operative data (n = 68) and concomitant surgical procedures not included in CPT codification (n = 18). Finally, 2331 cases (1425 females and 906 males) were eligible for evaluation. The consultants performed 1683 cases (72% - 1029 females and 654 males), while the residents performed 648 cases (28% - 397females and 251 males). The groups were comparable in terms of mean age (Consultant: 55.9 ± 15.4 years; Resident: 54.5 ± 14.7 , p = 1.3). Similarly, no statistically significant differences were recorded between the groups for BMI (28.3 \pm 5 kg/m² vs 27.5 \pm 7 kg/m²; p = 0.9), preoperative ASA score (Consultant: ASA I (40%), ASA II (45%), ASA III (15%); Resident: ASA I (52%), ASA II (35%), ASA III (13%); p = 0.6), and history of previous abdominal operations (Consultant: 347/1683, 21%; Resident: 156/648, 24%; p = 0.9). A summary of patients' demographics is presented in Table 1.

Intraoperative outcomes

There was no statistically significant difference for the recorded operative time between the two groups (p = 0.06) — Consultant = 63.5 ± 35.2 min (range: 25-190 min) vs Resident = 66.8 ± 34.4 min (range: 30-150 min). Intraoperative complications occurred in a total of 94 patients (Consultant: n = 65, 3.8%; Resident: n = 29, 4.5%; p = 0.8) and were reported in the operative chart as bleeding (< 500 mL; n = 22 Consultant; n = 20 Resident) and visceral lesion (n = 19 Consultant; n = 9 Resident) managed intraoperatively. The conversion rate was 1.42% in Consultant Group (n = 24/1683) vs. 0% in Resident Group (p = 0.02). Reasons for conversion were inadequate exposure/traction (n = 15), major intraoperative bleeding (n = 7), and suspicion of a biliary lesion (n = 2).

Table 1Demographiccharacteristics of the studypopulation

	Consultant group	Resident group	Р	
Number of patients (N)	1683	648		
Gender N (%) F/M	1029—61%/654—39%	397-61.3%/251-38.7%	n.s	
Age $(M \pm SD)$	55.9 ± 15.4	54.5 ± 14.7	n.s	
BMI (kg/m ²)	28.3 ± 5	27.5 ± 7	n.s	
ASA score (I-II-III) %	I 40% II 45% III 15%	I 52% II 35% III 13%	n.s	
Previous surgery N (%) Laparoscopic/Open N (%)	347—21% 267—77%/80—23%	156—24% 104—67%/52—33%	n.s	

The complications were classified according to the Clavien-Dindo classification (Table 3).

The mortality rate was nil for both groups. The average hospital length of stay was 2.2 ± 3 days for consultant and 1.6 ± 1.3 days for Resident (p = 0.042). A statistically significant difference was observed for peri (<30 days) and post-operative (> 30 days) complications (p = 0.031). All operative outcomes are reported in Table 2.

Comprehensive Complication Index (CCI) was calculated for single complicated patients of each group with the following formula $CCI = \sqrt{(N RV phys \times MRV pat)/2}$ [16] and reported in Fig. 1.

The risk ratio (RR) with 95% confidence intervals (CIs) revealed a not statistically significant difference between the two Groups (p = 0.67).

	Consultant Group	Resident Group	P	
	N=1683	N=648	1	
Operative time (Min) $(M \pm SD)$	63.5 ± 35.2	66.8 ± 34.4	n.s	
Length of stay (Days)	2.2 ± 3	1.6 ± 1.3	0.042	
Intraoperative complications N (%)	65/3.8%	29/4.5%	n.s	
Conversion rate N (%)	24/1.42%	0/0%	0.02	
Peri-operative complications N (%)	67/3.9%	19/3%		
Pain N (%)	16/0.9%	6/0.9%		
Vomit N (%)	13/0.8%	4/0.6%		
Surgical site infection (SSI) N (%)	8/0.5%	3/0.4%		
Biliary leak N (%)	4/0.2%			
Intrabdominal Collection N (%)	11/0.6%	1/0.1%		
Bleeding N (%)	15/0.9%	5/0.7%		
Post-operative complications N (%)	28/1.7%	3/0.5%	0.031	
Intrabdominal Collection N (%)	4/0.2%			
Trocar site hernia N (%)	11/0.6%	2/0.3%		
Retained bile duct stones N (%)	7/0.4%	1/0.1%		
Surgical site infection (SSI) N (%)	6/0.3%			

 Table 2
 Operative outcomes

Table 3	Summary of peri/
postoper	rative complications
based or	n the Clavien-Dindo
classific	ation

	Grade I	Grade II	Grade IIIa	Grade IIIb	Grade IVa	Grade IVb	Grade V
Consultant Group N (%)	29/1.7%	21/1.2%	15/0.9%	24/1.4%	6/0.3%	0/0%	0/0%
Resident Group N (%)	10/1.5%	6/0.9%	1/0.1%	4/0.6%	1/0.1%	0/0%	0/0%

Fig. 1 Comprehensive Complication Index (CCI) calculation. Consultant Group range 8.7-66.4; Resident Group range 8.7-46.2

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Spearman's rank correlation among all variables revealed a positive and significant correlation between the operative time and the length of stay (p = 0.031), and between the length of stay and the complication rate (p = 0.043).

No other negative or positive correlation was found among the remaining variables (age, sex, BMI, ASA score, previous surgery, and surgeons).

Discussion

Ever since the worldwide dissemination and practice of MIS procedures, it has become essential to train the new generation surgeons in MIS, for which LC is a widely used surgical procedure owing to the plentiful incidence of gallbladder problems. However, with the increased incidence, certain concerns have been raised in literature regarding the operative time and complication rate, which are reportedly higher in the trainees. A variety of reasons have been cited, ranging from a bias in case selection to the resident's experience. Haji et al. (2009) presented a prospective analysis of 835 LCs performed consecutively by consultant surgeons (n=562, 67.3%) and by trainees (n=272, 32%), and reported that no statistically significant difference in the mean operating time, as well as the postoperative complications, were observed between the consultants and trainee surgeons (when no cholangiograms were performed) [17]. In the early 1990s, Schol [18] and Bockler [19] evaluated the integration of new surgical procedures into the general surgery residency training program and concluded that the operator's experience did not affect the conversion or complication rate. Likewise, Koulas et al. [20] analyzed 1370 LCs performed by trainees (33%) and consultants (67%) and reported that a supervised LC performed by trainees did not lead to an increase in surgical morbidity or compromised surgical outcomes. Similarly, a report by the Royal College of Surgeons about 266 consecutive LCs (consultant cohort = 155; trainee cohort = 111) described no statistically significant difference in rate of complications (12.9% consultant vs. 15.3% trainee; p=0.59 [21].

Notably, Nasri et al. retrospectively reviewed 1216 cases and reported that resident participation increases the odds of having longer operation time (odds ratio: 12.54; 95% CI: 7.74–17.34; p < 0.0001) without affecting the morbidity or mortality, conversion rate, or length of stay [22]. Operative time is the only outcome reported to be affected when the surgery is performed by a trainee. For instance, Fahrner et al. showed that surgical residents can perform LC with results comparable to experienced surgeons and only affecting the operative time [23]. Similarly, in 2015, Lavy et al. [24] compared surgical outcomes for resident versus senior surgeons for 180 LCs and reported the only significant difference to be longer operative time, with comparable conversion and complication rates. Ibrahim et al. reported similar findings of comparable rates of conversion, BDI, general complications, and length of stay; however, the total duration of operation was significantly longer for the trainee surgeons compared to senior surgeons [25].

Our results are also based on a large institutional academic cohort (n=2331) which included 1683 cases performed by experienced consultants and 648 cases performed by senior residents under supervision (PGY 4,5). We observed no significant differences in both operative times (Consultant: 63.5 ± 35.2 vs Resident: 66.8 ± 34.4), one of the factors reported to be largely affected by the surgeon's experience, and intraoperative complication rates (Consultant: 3.8% vs Resident: 4.5%). Conversely, peri/postoperative complication rates (p = 0.031), conversion rate (p=0.02), and the consequent hospital length of stay (p=0.042) were significantly different between the two groups; this is probably related to the protective role of the supervisor in performing hardest cases and eventually, converting the at-risk cases to OC. Remarkably, the consultant involved into the study confirmed that they always preferred to be the first surgeon in case of a converted operation, which in turn, affected the data analysis; however, it was impossible to establish how many converted LCs were started by trainees.

Based on this protective approach, coupled with the results of the survey, it can be concluded that a supervised, elective LC can be routinely performed by senior residents without affecting the overall economic and safety outcomes. With proper training and supervision, as guaranteed by recognized academic centers, surgical trainees can achieve a satisfactory level of competence comparable to an experienced surgeon. Furthermore, under supervision, a trainee can perform LC in patients with different BMI, ASA status, or medical and surgical history. Both our groups had > 20% patients with a history of abdominal surgery, open or laparoscopic; however, it did not affect the operative time.

Our study had certain limitations. First, the results come from a retrospective analysis. The comparison was based only on elective cholecystectomy. Additionally, the active presence of an expert supervisor may have affected the outcome in the resident group. Finally, the inclusion of PGY 4–5 resident was based on subjective evaluation of the consultant due to absence of specific training program in the institution involved. Nevertheless, our results are of value owing to the large sample size, besides a comprehensive statistical analysis and an innovative study design reflecting the Italian population for the first time. Future studies on a larger population are needed to further validate our results prospectively.

Conclusion

The results of this novel Italian multicenter retrospective analysis suggest that elective LC represents one of the best procedures to train residents about MIS in general surgery. It can be concluded that senior residents under the supervision of an experienced surgeon can offer comparable surgical outcomes with consultants in terms of patient safety and efficiency.

Authors' contributions A.I.: designed the study, data collection, established group connection, manuscript writing, and data analysis.

M.G., A.M., M.C.C., P.T., F.D.A., C.E.B.: data collection, data analysis.

G.D.B., A.S., M.C., C.A., V.S., A.A., G.A., U.B., F.C., G.C., F.C., M.M.: data collection, critical analysis of the results.

G.S.: Supervisor, data analysis, final revision of the manuscript.

Declarations

Competing interests The authors declare no competing interests.

Conflict of interest The authors declare no competing interests.

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