Prospective Analysis of Laparoscopic Cholecystectomies Based on Postgraduate Resident Level

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Background: Few studies have attempted to ascertain the safety of laparoscopic cholecystectomies (LC) based on resident postgraduate year. We hypothesize that there is no difference in complications based on resident level in LC.

Methods: We prospectively gathered data from 200 LC. Residents were classified as surgeon chief (SC), surgeon junior (SJ), or teaching assistant (TA/SJ). Outcomes included surgical complications and operative time based on resident level or ambulatory status.

Results: Average operating time was 65.17, 69.38, and 63.91 minutes for SC, SJ, and TA/SJ, respectively. Average operative time in the elective group was 62 versus 70.67 minutes in the emergent group ($P = 0.037$). Five, 2, and 6 major complications occurred in the TA/SJ, and SC groups, respectively, ($P = 0.937$). Major complications occurred in 9 of 97 emergent and 4 of 70 elective cases ($P = 0.396$).

Conclusion: With respect to time and morbidity in LC, we found all level of residents to be safe.

Key Words: minimally invasive, laparoscopy, cholecystectomy, surgical education

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Since its implementation in 1987 by Eric Muhe, laparoscopic cholecystectomy (LC) has quickly become one of the most frequently performed surgeries in the United States. Approximately 750,000 LCs are performed annually in the United States, whereas another 80,000 are performed in an open fashion.[1] The rise in the number of cases completed laparoscopically can be attributed to tremendous growth in operative experience leading to shorter operative time, as well as advancements in the technology used in the operating room, such as better laparoscopes leading to increased visualization and improved instruments. The most commonly feared complication associated with the laparoscopic approach is ductal injury; however, early studies show that ductal injury rates are equivocal to the traditional open approach.[2]

Numerous education courses, such as the Fundamentals of Laparoscopic Surgery, were designed to increase the proficiency and test the competency of operator skills in laparoscopy. The skills obtained by taking Fundamentals of Laparoscopic Surgery have been shown to increase proficiency in both resident and attending physicians.[3,4] Work hour restrictions and changing technology, such as robotics and increased expertise in endoscopy, have changed the overall training experience for residents. Some have even suggested implementing short curricula for topic-specific procedures. These curricula would include didactic as well as virtual reality simulation to help aid trainees in this new era of surgical resident education.[5] In fact, many centers have already set up larger simulation facilities geared toward academics and teaching those already in practice.[6]

Studies have examined resident participation in laparoscopic cases, and specifically LC, but few have looked into the level of training as well as the resident's year in training as they potentially relate to intraoperative and postoperative complications. We hypothesize that there is no statistically significant difference in complications based on resident participation. These outcomes will help define the adequacy of current teaching models, and efficacy and safety of intraoperative resident teaching.

METHODS

The study was performed at the St. Josephs Regional Medical Center in Paterson, New Jersey. The hospital is a 700-bed, level 2 trauma center in an urban setting. It provides medical care for the predominantly underserved area of Paterson, New Jersey. All care was performed under the supervision of core faculty surgeons. LC performed by 9 staff surgeons over a 1-year period between January 2013 and January 2014 were evaluated. Of 200 patients enrolled, a total of 167 patients completed the study after 33 were disqualified. All patients were seen preoperatively in either the general surgery clinic or were admitted through the emergency department. Patients were categorized as elective or emergent depending on their ambulatory status at presentation. The operative time and any intraoperative deviations from usual course were also recorded, including gallbladder perforation, bile spillage, bleeding from the gallbladder fossa, nearby structural injuries, and if intraoperative cholangiogram (IOC) was performed including the results of the IOC.

Patients were excluded if they were under the age of eighteen, were lost to follow-up, or were found to have other pathology not consistent with biliary tract disease. Follow-up included being seen and examined in the surgery clinic or in the emergency department, and having received a phone call at one month postoperatively.

Each resident recorded his or her role as teaching assistant (TA/SJ), surgeon chief (SC), or surgeon junior

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TABLE 1. Center for Disease Control Definition of Postoperative Infection Used in Study

Credit roles for surgery residents:

Only 1 resident may take credit as a surgeon for each operation and only for 1 procedure in an operation. On same patient a senior resident may take credit as surgeon while another resident takes credit as a First Assistant, or a senior resident may take credit as a Teaching Assistant while a more junior resident takes credit as a surgeon.

SC = Surgeon Chief Year-Predominate role in case. PGY 4/5 only.

SJ = Surgeon Junior Years-Predominate role in case. PGY 1, 2, 3 only.

TA = Teaching Assistant (more senior resident working with junior resident who takes credit as surgeon)

FA = First Assistant (any instance in which a resident assists at an operation with another surgeon—an attending or more senior resident—responsible for the operation).

Available at: http://www.acgme.org/acgmeweb/tabid/377/ProgramandInstitutionalAccreditation/SurgicalSpecialties/Surgery/CaseLoginformation.aspx. Accessed November 21, 2012.

Definitions of surgical site infections:

A *superficial incisional SSI* must meet one of the following criteria.

Infection occurs within 30 d after the operative procedure and involves only skin and subcutaneous tissue of the incision and patient has at least one of the following:

(a) Purulent drainage from the superficial incision.

(b) Organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision.

(c) At least one of the following signs or symptoms of infection: pain or tenderness, localized swelling, redness, or heat, and superficial incision are deliberately opened by surgeon, and are culture-positive or not cultured. A culture-negative finding does not meet this criterion.

(d) Diagnosis of superficial incisional SSI by the surgeon or attending physician.

A *deep-incisional SSI* must meet one of the following criteria.

Infection occurs within 30 d after the operative procedure if no implant is left in place or within 1 y if implant is in place and the infection appears to be related to the operative procedure and involves deep soft tissues (eg, fascial and muscle layers) of the incision and patient has at least one of the following:

(a) Purulent drainage from the deep incision but not from the organ/space component of the surgical site.

(b) A deep incision spontaneously dehisces or is deliberately opened by a surgeon and is culture-positive or not cultured and the patient has at least one of the following signs or symptoms: fever (> 38°C), or localized pain or tenderness. A culture-negative finding does not meet this criterion.

(c) An abscess or other evidence of infection involving the deep incision is found on direct examination, during reoperation, or by histopathologic or radiologic examination.

(d) Diagnosis of a deep-incisional SSI by a surgeon or attending physician.

An *organ/space SSI* must meet one of the following criteria.

Infection occurs within 30 d after the operative procedure and infection involves any part of the body, excluding the skin incision, fascia, or muscle layers, that is opened or manipulated during the operative procedure and patient has at least one of the following:

(a) Purulent drainage from a drain that is placed through a stab wound into the organ/space.

(b) Organisms isolated from an aseptically obtained culture of fluid or tissue in the organ/space.

(c) An abscess or other evidence of infection involving the organ/space that is found on direct examination, during reoperation, or by histopathologic or radiologic examination.

(d) Diagnosis of an organ/space SSI by a surgeon or attending physician.

Reporting instructions:

Do not report a stitch abscess (minimal inflammation and discharge confined to the points of suture penetration) as an infection.

"Cellulitis," by itself, does not meet the criteria for superficial incisional SSI.

If the incisional site infection involves or extends into the fascial and muscle layers, report as *deep-incisional SSI.*

Classify infection that involves both superficial and deep incision sites as *deep-incisional SSI.*

Classify infection that involves both superficial and deep incision sites as *deep-incisional SSI.*

Occasionally, an organ/space infection drains through the incision. Therefore, classify it as *an organ/space SSI.*

Available at: http://www.cdc.gov/nhsn/PDFs/pscManual/9pscSSIcurrent.pdf. Accessed November 21, 2012.

PGY indicates postgraduate year; SSI, surgical site infection.

(SJ) depending on the level of participation in the operation. SC was assigned to postgraduate year (PGY) 4, or 5 level residents. SJ was assigned to residents at the PGY 1 to 3 level. SJ/TA/SJ was assigned when a senior level resident was the first assistant to a SJ. During TA/SJ cases, an attending was present throughout the case but did not lead the residents unless help was asked. Participation was based on 2 segments of the operation: (1) ductal and arterial dissection; and (2) dissection of the gallbladder from the gallbladder fossa. Upon completion of > 50% participation, a resident could take credit for the above-mentioned roles as SJ or SC and the case was included in the study.

All patients were given appointments to be seen in the surgery clinic 2 weeks postoperatively. At the patients were screened by residents for evidence of wound infection, ductal injury, pain, and other operative-related complaints. Wound infection was classified as follows: superficial incisional site infection, deep-incisional site infection, or organ space site infection. Definitions for each category were based on the wound classifications from the Center for Disease Control (Table 1). Major ductal injuries included those that required operative intervention, interventional radiology, or hospital admission until resolution of symptoms.

Patients were also contacted by telephone at 1 month postoperatively and asked a standard questionnaire. They were queried about visits or admissions to our institution or any other doctor/hospital, signs of infection, signs of bleeding, or deviation from a normal postoperative course. On the phone and in person, the patients were spoken to in their native tongue. Emergency department records were also reviewed to ensure that patients' records were assessed if they presented to the emergency department in the postoperative period. If patients were not seen and examined postoperatively as well as contacted by telephone they were excluded from the study results.

All information was collected and entered into a secure Excel database for further analysis. Statistical analysis was performed using SPSS software. Difference was regarded as significant if P values were <0.05. Univariate analysis of variance and Student-Newman-Keuls test were used to compare operative time. Pearson χ^2 and Mantel-Haenszel tests were used to compare major complications. The protocol was reviewed and approved by the Institutional Review Board of St. Joseph's Regional Medical Center.

RESULTS

Of the original 200 patients, 167 completed the study. Thirty-three were excluded due to primarily to lack of follow-up. Sixty-two (37%), 32 (19%), and 73 (44%) of the LC were performed by resident SJ, TA/SJ/SJ, and SC, respectively. A total of 97 (53%) cases were defined as emergent and 70 (47%) cases were defined as elective. Of the 73 SC cases, 46% were elective. The TA/SJ group comprised of 55% elective cases and 39% elective cases in the SJ group.

The average length of operation for all groups was 67.04 minutes (range, 25 to 180 min). SC average operative time was 65.18 minutes [SD = 24.6; 95% confidence interval (CI), 5.99]. TA/SJ average operative time was 66.72 minutes (SD = 21.9; 95% CI, 5.17). SJ average operative time was 69.39 minutes (SD = 17.11; 95% CI, 4.13). A Student-Newman-Keuls analysis of average operative time between SJ, TA/SJ, and SC showed no significant difference in average operative length ($P = 0.621$) (Fig. 1). Average operative time in the elective group was 62 minutes (SD = 18.46; 95% CI, 4.6). Average operative time in the emergent group was 70.67 minutes (SD = 24.18; 95% CI, 5.66). The average length of operation between emergent and elective cases in total were significantly different ($P = 0.037$) based on univariate analysis of variance (Fig. 2).

A comparison was done with the 2 independent variables (resident level and ambulatory status of the patient) versus major or no complication. These results showed no statistical significance (odds ratio = 0.587; 95% CI, 173-1.986; $P = 0.391$). Further comparisons were then done to look at the individual independent variables and any correlation to major surgical complications.

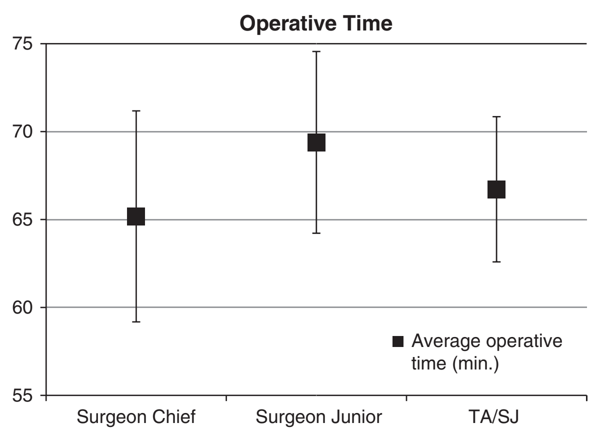

FIGURE 1. Average operative time based on resident level. Includes 95% confidence intervals for each data point. TA/SJ indicates teaching assistant.

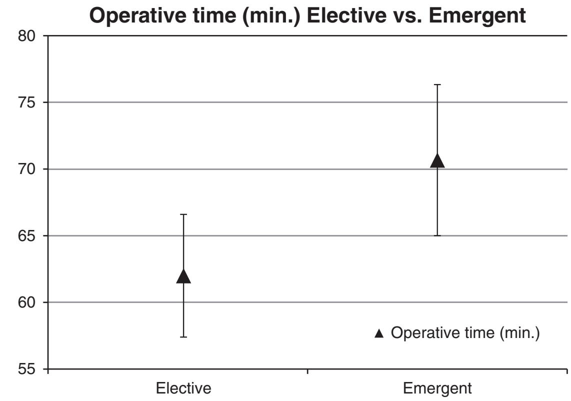

FIGURE 2. Average operative time based on ambulatory status. Includes 95% confidence intervals for each data point.

There were a total of 13 (7.8%) major surgical complications across all 3 resident-level groups. Five major complications occurred in the SJ group, 2 major complications occurred in the TA/SJ group, and 6 major complications occurred in the SC group (Fig. 3). A Pearson χ^2 analysis showed no significant difference between the 3 groups ($P = 0.937$). The 13 major complications included bleeding (38%), ductal injury (31%), infection/abscess (23%), and bowel injury (8%). As per the Methods section, all major injuries included in the study required operative intervention, interventional radiology, or hospital admission until resolution of symptoms. The 4 major ductal injuries included 2 cystic duct leaks, 1 common bile duct injury, and 1 right hepatic duct injury. There was 1 death of the 167 patients (0.6%), because of a postoperative myocardial infarction.

Nine of 97 (9.3%) emergent cases had a major complications, and 4/70 (5.7%) elective cases had a major complication. Pearson χ^2 test of major surgical complications in emergent and elective cases showed no correlation between both the factors ($P = 0.396$).

Minor complications were seen in 67/167 (40%) cases. The vast majority of these complications were accounted for by minor intraoperative bleeding (controlled with application of a hemostatic agent), or bile spillage from iatrogenic perforation of the gallbladder. These complications did warrant further operative intervention and also did not add any significant morbidity such as length of stay, or need for further diagnostic or therapeutic modalities. A Mantel-Haenszel test of minor surgical complications in emergent and elective cases and based on resident level showed no correlation between both factors (odds ratio = 0.955; 95% CI, 0.505-1.807; $P = 0.888$) (Table 2).

DISCUSSION

The acquisition of knowledge in the medical profession has evolved from an apprenticeship type model to an evolving curriculum. Changes in weekly and daily work hour regulations have decreased the total exposure of surgical residents to operative experience. Hope et al[7] estimates that residents cover 15% fewer cases at their community teaching hospital since the implementation of the

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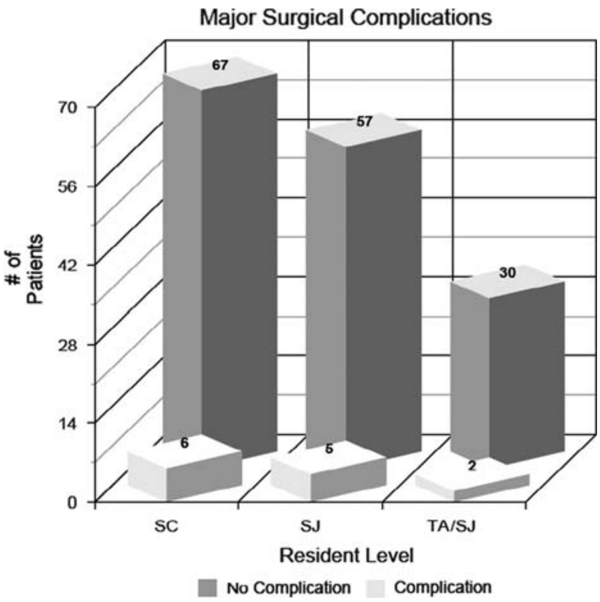

FIGURE 3. Major complications based on resident level of participation.

80-hour work week. With these changes comes a need to reassess the current training standards; however, it is certain that resident participation plays a key and safe role. Numerous studies have proven the safety of resident participation in surgical cases. Raval et al[8] were able to show, in a selected procedural range, a slightly higher morbidity rate with a lower mortality rate, neither of which were statistically significant. Meanwhile, Davis et al[9] found that resident participation in laparoscopic cases increased morbidity, but found it unlikely to be clinically significant. Recently, the national surgical quality improvement program found a small overall increase in surgical complications, likely attributable to superficial wound infections.[10]

Outside of morbidity and mortality, operative cost has been examined with regards to resident participation. Bridges and Diamond[11] found that each resident added approximately $49,000 throughout residency to the overall cost of patient care due to extraoperative time. Similar to this, Hosler and colleagues looked at resident cost from an ophthalmologic perspective. He found that residents added about $8293 a year. Interestingly, the cost was all accrued during the first half of the year. As the residents became more experienced, their operative time decreased from 63 minutes in July to 27 minutes the following June.[12]

Our institution allows an active role from an early postgraduate year level in LC. Once an attending believes a senior resident is competent to operate independently, they will allow the resident to become a TA/SJ to a more junior resident. The current literature does not look at the actual experience of the resident involved, solely the resident level and expectations of that postgraduate year. Bosker et al[13] were able to show that in laparoscopic sigmoidectomies, resident training level mattered and the experience within that level was a factor in associated complications. They determined that a set number of cases were necessary to achieve an acceptable rate of complications. No major studies have applied this model to morbidities associated with LC.

Bariatric surgery has also attempted to look at the effects of resident participation. Krell and colleagues looked at 17,000 patients with laparoscopic Roux-En-Y gastric bypasses (LRYGB). The results of the study showed that surgical residents' participation in LRYGB resulted in longer operative times, higher rates of wound infections, and more thromboembolic events. They argue that more time spent outside of the operating room, on simulation and teaching, could help mitigate the complication rate.[14] In a similar fashion, Fanous and Carlin compared resident and physician assistant participation in LRYGB in 2012. The operative time was approximately 40 minutes longer in the resident index cases. The rates of complications were similar; therefore, the authors deemed residents' participation to be safe and effective.[15] Although the 2 papers seem to differ, Fanous and Carlin only used senior level residents for their cases, which may account for the differences in morbidity. This again highlights the importance of experience within the resident year in determining overall outcomes.

Data for all LC was compiled from the year before our study. The occurrence of major complications was 5.9%. The current years' complication rate of 7.7% is comparable. Although the only statistically significant finding dealt with the ambulatory status of the patient, we found nonsignificant yet interesting results in many aspects. As expected, operative time was lowest in the resident level with the most experience (65.18 min in the SC group). Operative time with regards to minor complications showed similar results with the SC group having the shortest operative time when a minor surgical complication occurred. Overall and major complications were similar in the

TABLE 2. Number of Complications and Operative Time Based on Resident Year, Ambulatory Status, and Type of Major Complication

	Major Complications	Minor Complications	Operative Time (min)	Minor Complications—Operative Time (min)	Major Complications—Operative Time (min)
Surgeon chief	6/73	33/73	65.18	74.09	102.5
Surgeon junior	5/62	26/62	69.39	77.5	69
Teaching assistant	2/32	8/32	66.72	86.25	90
Elective	4/70	28/70	62	73.04	67.5
Emergent	9/97	39/97	70.67	79.62	96.67
All	13/167	67/167	67.04	76.87	87.69
Bleeding	5/167	—	—	—	96
Infection	3/167	—	—	—	75
Bowel injury	1/167	—	—	—	105
Ductal injury	4/167	—	—	—	82.5

SC/SJ level. Of importance, cases done with TA/SJ had a lower percentage of major and minor complications alike. Operative time in this group was also shorter than the SJ group, although TA/SJ cases were more likely to be selected preoperatively as a suitable teaching case.

Our study had numerous limitations in its design and outcomes. We only enrolled patients who were unisured, on Medicaid, or state-assisted insurance; hence our patient population was skewed to the indigent. This allowed residents to be involved in the postoperative assessment of all patients as opposed to those who would follow-up with a nonhospital employed surgeon. There is no definition for bile spillage or negligible spillage, no definition for significant bleeding, and all complications were self-reported. Postoperative complications were noted by surgical clinic or emergency room physical examinations; however, these were subjective to residents or surgical attendings' interpretations. Finally, resident selection for cases was likely based on projected difficulty of the case. For example, a patient with signs of gangrenous cholecystitis was more likely to be assigned to an SC than an SJ. This may have caused an overestimate of operative time and complications in the SC group.

The model for training surgeons in laparoscopic surgery has drastically changed over the past 25 years. In the early 1990s, residents would graduate with approximately 100 laparoscopic cases, and those without such training were deemed trained after a 2- to 3-day course.[16] Our recent graduates have approximately 250 LC alone; however, laparoscopic cases have become standard for many different types of operations. The key to reducing operative time and morbidity may lie in simulated training and feedback. During their advanced laparoscopic cases, Lin et al[17] found that operative time, length of stay, and conversion to open was acceptable after about 3 years in their program. The program involved laboratory sessions, tutorials, and feedback.

CONCLUSIONS

We believe that this study highlights the importance of further resident education and simulation laboratory training in the new era of surgical residency. Increased exposure to simulated laparoscopy could be the key in shortening the learning curve from that of a junior to senior resident, thereby decreasing operative time while maintaining safety. As an advanced skill set, a tandem simulation machine (with junior and senior residents) would allow senior residents the opportunity to learn to assist without the aid of an attending surgeon. Although operative times were higher in the junior resident and TA/SJ groups, they did not show statistical significance. Because of this finding and equivalent major complication rates among surgical residents regardless of their postgraduate level, we believe that residents of all levels are appropriate for safe participation in LC.

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