Competence Acquisition for Single-Incision **Laparoscopic Cholecystectomy**

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ABSTRACT

Background and Objectives: Within the past few years, there has been a push for an even more minimally invasive approach to biliary disease with the adoption of single-incision laparoscopic cholecystectomy. We sought to compare 4 individual surgeon experiences to define whether there exists a learning curve for performing single-incision laparoscopic cholecystectomy.

Methods: We performed a retrospective review 290 single-incision laparoscopic cholecystectomies performed by a group of general surgeons, with varying levels of experience and training, at 3 institutions between May 2008 and September 2010. The procedure times were recorded for each single-incision laparoscopic cholecystectomy, ordered chronologically for each surgeon, and subsequently plotted on a graph. The patients were also combined into cohorts of 5 and 10 cases to further evaluate for signs of improvement in operative efficiency.

Results: Of the 4 surgeons involved in the study, only 1 (surgeon 4, laparoscopic fellowship trained with <5 years' experience) confirmed the presence of a learning curve, reaching proficiency within the first 15 cases performed. The other surgeons had more variable procedure times, which did not show a distinct trend. When we evaluated the cases by cohorts of 5 cases, surgeon 4 had a significant difference between the first and last cohort. Increased body mass index resulted in a slightly longer

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operative time (P < .0063). The conversion rate to multiport laparoscopic surgery was 3.1%.

Conclusions: Our results indicate that among experienced general surgeons, there does not seem to be a significant learning curve when transitioning from conventional laparoscopic cholecystectomy to single-incision laparoscopic cholecystectomy. The least experienced surgeon in the group, surgeon 4, appeared to reach proficiency after 15 cases. Greater than 5 years of experience in laparoscopic surgery appears to provide surgeons with a sufficient skill set to obviate the need for a single-incision laparoscopic cholecystectomy learning curve.

Key Words: Single-incision laparoscopic surgery, Laparoscopic cholecystectomy, Learning curve, Education, Proficiency.

INTRODUCTION

Once primarily performed by an open technique, cholecystectomy has become a standard laparoscopic procedure over the past 2 decades. The major advantages of the laparoscopic approach include reduction of postoperative pain, shorter recovery time, and improved cosmesis, while maintaining an acceptable complication rate.1-7 Within the past few years, there has been a push for an even more minimally invasive approach to biliary disease with the adoption of single-incision laparoscopic cholecystectomy (SILC). Many investigators believe that by reducing the combined incision length, surgeons can attain equivalent results with improved postoperative pain and patient satisfaction.8 Although rigorous scientific data are sparse at this time, preliminary experiences have been quite promising.9,10

One of the major barriers to entry is the "learning curve" thought to accompany the implementation of the modality of SILC, specifically the modified instruments, an unfamiliar visual perspective, and an increased incidence of instrument collision in an operative field with restricted degrees of freedom. For single-port laparoscopic surgery to achieve wider acceptance, a surgeon must show safety, efficacy, and reproducibility of technique across a complete range of patient and clinical scenarios. To determine the approximate learning curve, 2 main surgical endpoints should be evaluated: (1) decrease in time to complete the procedure and (2) decreased incidence of conversion to multiport laparoscopic surgery or open surgery.

Recent studies have attempted to quantitatively assess the number of cases needed to achieve proficiency.^{11,12} However, they have been limited to mostly individual operator reports. We set out to compare 4 individual surgeon experiences to determine whether a learning curve exists in performing SILC.

METHODS

We performed an institutional review board–approved (IRB No. 10–361A) retrospective review of 290 SILCs performed by a group of general surgeons at 3 institutions between May 2008 and September 2010. SILCs were performed in a standardized, reproducible manner based on the Consensus Statement of the Consortium for Laparo-Endoscopic Single Site (LESS) Cholecystectomy. None of the cases involved robotic assistance. The 4 surgeons training and experience levels were classified as follows: surgeon 1, no laparoscopic fellowship with >15 years' laparoscopic experience; surgeon 2, no laparoscopic fellowship with >10 years' laparoscopic experience; surgeon 3, laparoscopic fellowship with >5 years' laparoscopic experience; and surgeon 4, laparoscopic fellowship with <5 years' laparoscopic experience.

All of the study surgeons performed their first SILC during the same period. Patient demographic data and operative details, including indications for surgery and other concomitant procedures, were collected by chart review. The procedure times (incision to skin closure) were recorded for each SILC, ordered chronologically starting with the first SILC performed by each surgeon, entered into a spreadsheet, and subsequently plotted on a graph. The patients were also split into cohorts of 5, 10, and 25 cases to further evaluate for signs of improvement in operative efficiency. Patients were excluded from the study if they underwent other concomitant procedures (intraoperative cholangiogram, endoscopic retrograde cholangiopancreatography, ventral hernia repair, and so on) that significantly lengthened the operative time.

Descriptive statistics for total procedure time were calculated for each cohort by surgeon. Because total procedure time does not follow a Gaussian distribution, the Kruskal-Wallis test was used to compare each of the cohorts. A graph of the ranks was then plotted. We defined a learn-

ing curve as a downward trend in procedure times across cases. If there was no learning curve, we expected the procedure times to vary in a random way over time (ie, null hypothesis). The runs test is a nonparametric method for determining whether a sequence of values exhibits a random or nonrandom pattern. In the context of this example, a nonrandom pattern indicating the existence of a learning curve would occur when procedure times in the earlier cases would tend to be above the median procedure time and procedure times would tend to be below the median procedure time for later cases (ie, alternative hypothesis). A "run" was defined as a series of consecutive points that were either all above (n1) or all below (n₂) the median procedure time for the specific surgeon (ie, maximal subsequence of like elements). A very small number of runs would indicate nonrandomness consistent with the learning-curve hypothesis (alternative hypothesis). Because n_1 and n_2 were both large (>10) for each surgeon, the Z statistic was calculated. At a significance level of $\alpha = .05$, the rejection region for this 1-tailed test was Z < 1.64.

RESULTS

Patient demographic data are shown in **Table 1**. The mean age of the patients in our study was 47 years (range, 32–62 years), with female patients comprising 72% and with a mean body mass index (BMI) of 28.6 (maximum, 35). In 77.9% of cases, surgery was performed in an elective setting, and 19.3% of cases were performed for a diagnosis of acute cholecystitis. The median procedure times for surgeons 1, 2, 3, and 4 were 70.5, 113, 79, and

Table 1. Study Population Demographic Data				
	Data			
Age (y)	47.0 ± 15.1			
Sex	28.0% male and 72.0% female			
BMI^a	28.6 ± 6.3			
Length of stay (d)	Mean, 0.8; median, 0.0			
ASA ^a score	2.0 ± 0.6			
Elective cases	77.9%			
Pathology				
Symptomatic cholelithiasis	76.9%			
Acute cholecystitis	19.3%			
Other	3.8%			

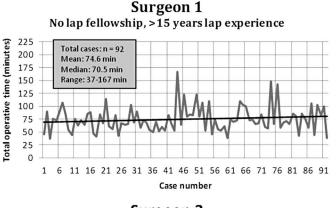
^aASA = American Society of Anesthesiologists; BMI = body mass index.

113 minutes, respectively. As shown in **Figure 1**, the procedure times were randomly scattered above and below the median procedure time for surgeons 1, 2, and 3. However, for surgeon 4 (laparoscopic fellowship trained and <5 years' experience), most of the procedure times that were above the median were before case 15 and most of the procedure times below the median were observed after that time. The runs test showed that the number of runs (6 runs) was significantly lower than expected by chance (Z = -3.20). When we subdivided the operative times into cohorts of 5 cases, the same findings held true. Surgeons 1, 2, and 3 had no appreciable learning curve, whereas surgeon 4 had a significant drop-off in procedure time during the fourth cohort (P < .0071) (**Figure 2**). When we further subdivided the results into cohorts of 10 and 25 cases, none of the surgeons had a significant decrease in operative times from one cohort to the next. Lastly, when we compared a surgeon's first and last 5-case cohorts, there was no significant difference in operative times (Table 2). Surgeon 4 showed a trend toward decreased operative times, but this did not reach statistical significance (P < .0542).

Irrespective of surgeon, there was a small positive correlation between BMI and total procedure time ($\rho = 0.16$, P < .0063). When we controlled for differences in BMI and divided each surgeon's operative experience into 3 groups (normal, overweight, and obese), there was no significant difference between operative times for surgeons 1 and 2. However, surgeon 3 ($\rho = 0.24$, P < .0169) and surgeon 4 ($\rho = 0.34$, P < .0031) had a significantly positive correlation between their case times and increasing BMI. All complications are listed in **Table 3**. The most common complication involved conversion to a multiport laparoscopic cholecystectomy, occurring in 2.8% patients (n = 8). Only 1 patient required a transition to open cholecystectomy for severe adhesions and inadequate visualization. There was no significant relationship between the complication or conversion rate and the relative experience of the surgeon at the time of the complication.

DISCUSSION

Our results suggest that there does not seem to be a significant learning curve for experienced laparoscopic general surgeons (>5 years' experience) when transitioning from traditional laparoscopic surgery to SILC. Initial studies of single-incision laparoscopic surgery on animals indicated that transitioning from traditional multiport lapa-



Surgeon 3 Lap fellowship, >5 years lap experience fotal operative time (minutes) 250 Total cases: n = 99 225 Mean: 83.4 min 200 Median: 79.0 min 175 Range: 42-201 min 150

Surgeon 2 No lap fellowship, > 10 years lap experience 300 fotal operative time (minutes) Total cases: n = 72 275 Mean: 118.3 min 250 Median: 113.0 min 225 Range: 38-250 min 200 175 125 100 75 50 25 11 16 21 26 31 36 41 46 51 56 61 66 71

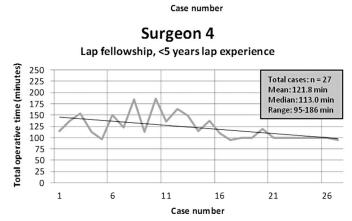


Figure 1. Total operative times listed chronologically by surgeon 1–4 (trendline shown for each).

3

6 11 16 21 26 31 36 41 46 51 56 61 66 71 76 81 86 91

Case number

125

100

75

50

25

0

Surgeon 1 No lap fellowship, >15 years lap experience Surgeon 3 Lap fellowship, >5 years lap experience Pr > ChiSq 0.5410 Statistical score Statistical score 40 -**\rightarrow** 20 20 10 11 12 13 14 15 16 12 13 14 15 16 17 18 19 Cohort number Cohort number Surgeon 4 Surgeon 2 Lap fellowship, <5 years lap experience No lap fellowship, >10 years lap experience Pr > ChiSq 0.0793 60 Statistical score Statistical score 15 11 12 13 14 15

Figure 2. Operative times by 10-case cohorts evaluated by the runs test. ChiSq = χ^2 ; lap = laparoscopic; Pr = probability of runs test.

Table 2. Operative Times by 5-case Cohort							
	Operative Time	P Value					
	First Cohort	Last Cohort					
Surgeon 1	63.6 ± 21.8	77.0 ± 26.9	.4116				
Surgeon 2	101.4 ± 21.4	110.6 ± 28.1	.5762				
Surgeon 3	92.0 ± 27.2	85.0 ± 23.3	.6739				
Surgeon 4	122.6 ± 22.4	100.0 ± 19.1	.0542				

Cohort number

Table 3. Operative Complications				
Complication	Total Events (%)			
Conversion to multiple port or open/repositioning of port	9 (3.1)			
Cystic duct leak	2 (0.7)			
Retained CBD ^a stone	5 (1.7)			
Significant bleeding/postoperative hematoma	2 (0.7)			
Significant spillage	2 (0.7)			
^a CBD = common bile duct.				

Cohort number

Table 4. Prior Studies								
Study	No. of Surgeons	No. of SILC ^a Patients	Learning Curve	No. of Cases	Conversion Rate (%)			
Kravetz et al ¹⁹ (2009)	1	20	Yes	5	10.0			
Solomon et al ¹² (2010)	1	56	Yes	10	3.6			
Hernandez et al ¹¹ (2010)	3	150	Yes	75	7.3			
Qiu et al (2011)	1	80	Yes	20	0			
Joseph et al (2012)	7 (residents)	49	Yes	5	10.2			
Chaudhary et al (2012)	1	70	Yes	20	14.3			
Spinoglio et al ¹⁶ (2012)	1	25	Yes	<25	0			
Feinberg et al ¹⁵ (2012)	2	50	Yes	25	10			

^aSILC = single-incision laparoscopic cholecystectomy.

roscopic cholecystectomy might require a specific training program.¹⁴ Previous experiences in humans have indicated anywhere from a 5- to 75-case learning curve with SILC (Table 4). 12,15-17,20,21 These studies did not differentiate surgeons based on their previous level of training and laparoscopic experience. Our results did not show a significant time drop-off after the first 5 to 10 cases for experienced general surgeons performing laparoscopic surgery. In surgeon 4, who had the least experience, it appeared as though technical proficiency was achieved after 15 cases. There was no statistically significant difference in operative times between the first and last 5 cases, when we analyzed each surgeon independently. However, when we compared times between surgeons, there were statistically significant differences in all 3 cohorts evaluated (first, middle, and last). This finding may represent disparities in surgeon operative and varying levels of resident involvement. Lastly, BMI may have played a role in some of the cases, though only significantly affecting operative times for 2 surgeons. Future studies are needed to further evaluate this relationship.

Our study population accurately represents what a typical experienced laparoscopic surgeon may encounter in his or her daily practice. The study operators have different years of experience, have diverse training backgrounds, and operate at various hospitals, thereby eliminating any possible surgeon-related bias. Our study has several limitations. The cases were performed at 2 large academic tertiary-care institutions and 1 smaller community-based hospital. There was heavier resident involvement at the 2 former hospitals, which may have skewed the data toward increased operative times. However, there are some recent data to suggest that resident involvement in single-incision surgery does not significantly affect operative times. Residents with experience in standard laparoscopic surgery are expected to have a short

learning curve. ^{17,18} Individual surgeons chose eligible patients in a nonrandomized fashion, and as a result, there may be some element of selection bias. In addition, as a surgeon's experience grew, more difficult cases (obese patients, acute cholecystitis, and so on) were undertaken. We believe these factors may have had a differential impact on operative times for some surgeons but not for others, accounting for some of the variability. If simple and straightforward cases continued to be selected for SILC throughout, times may have actually improved, albeit unlikely. Each surgeon performed other single-incision operations during the study period, contributing to additional experience and potentially affecting the learning curve.

The complication rate was relatively low and in line with previous reports of SILC. In the approximately 3% of cases that required the placement of additional ports, most were for suboptimal retraction. The addition of 1 or more ports allowed the operating surgeon to achieve better visualization. The patients who required conversion were not negatively affected by the additional incisions.

The number of cases required for acquiring proficiency in performing SILC varies from 5 to 25 cases in the literature. Hernandez et al¹¹ reported on 150 SILC patients operated on by 3 different surgeons with 75 cases for skill acquisition, with a conversion rate of 7.3%, whereas Kravetz et al¹⁹ reported on 20 SILC patients with 5 cases for skill acquisition and a conversion rate of 10%. Our results indicate no measurable learning curve for experienced general surgeons, with a low conversion rate of 3.1%. Total surgical experience level may be the most important factor in achieving competence in SILC. Future studies should standardize indications and concurrent single-incision surgery to eliminate these potential sources of bias.

CONCLUSION

Previous studies have indicated anywhere from a 5- to 75-case learning curve for SILC cases. Our results indicate that among experienced general surgeons, there does not seem to be a significant learning curve when transitioning to SILC, irrespective of fellowship training. Although the most experienced surgeon in the group, surgeon 1, achieved the best operative times, the other laparoscopists reached their baseline performance almost immediately. Surgeon 4, the least experienced surgeon, reached technical proficiency after 15 cases. In light of these findings, we do not believe that general surgeons require a laparoscopic fellowship to perform SILC, especially recently trained graduates who have had laparoscopic techniques more integrated into their training. To confirm these results and avoid potential biases, prospective randomized studies are required.

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