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Does the Surgeon's Caseload Affect the Outcome in Laparoscopic Cholecystectomy for Acute Cholecystitis?

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1	Does the surgeon's caseload affect the outcome in laparoscopic cholecystectomy for acute		
2	cholecystitis?		
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32	the study, contributed to data analysis and revised the manuscript critically. All authors approved the		
33	final version of the manuscript.		
34			

1 Abstract

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3	Background This study investigated how annual caseloads and the surgeon's previous experience
4	influence the outcome in laparoscopic cholecystectomy (LCC) for acute cholecystitis.
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6	Methods Eight-hundred-ninety-two patients treated in Helsinki University Hospital in 2013-2016
7	were retrospectively analyzed. Surgeons were compared regarding volume - over five LCCs for acute
8	cholecystitis a year vs. five or fewer LCCs a year, and experience – attendings vs. residents.
9	
10	Results High-volume surgeons (n=14) operated faster than low-volume surgeons (n=62) (91 min vs.
11	108 min, p. <0.001). Examining only procedures with an attending present, high-volume attendings
12	(n=7) converted less (14.9% vs. 32.0%, p<0.001) and operated faster (95 min vs. 110 min, p<0.001)
13	compared with low-volume attendings (n=41). The results of residents did not significantly differ
14	from the results of attendings.
15	
16	Conclusion Attending surgeons, performing more than five LCCs for acute cholecystitis a year, have
17	shorter operative times and lower conversion rates.
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20	Key words acute cholecystitis – laparoscopic cholecystectomy – surgical experience
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6 Introduction

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8 Laparoscopic cholecystectomy (LCC) is a common procedure performed by gastrointestinal (GI) 9 surgeons, and several reports recommend early cholecystectomy for acute cholecystitis (1-4). LCC 10 for acute cholecystitis is associated with a higher risk of conversion compared with elective LCC, 11 since the inflamed tissues and the distorted anatomy might prove an obstacle too hard to overcome 12 laparoscopically. Conversion is the right choice, when proceeding laparoscopically risks the safety 13 of the patient, but compared with surgeries finished laparoscopically it has been found to result in a 14 longer hospital-stay, more wound complications and pain postoperatively (5,6). In comparison with 15 elective LCC, surgery for acute cholecystitis is also associated with a higher rate of bile duct injuries 16 (BDIs) (5,7).

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Earlier studies have implicated that surgeons with low cumulative and annual caseloads of LCC have higher conversion and complication rates (8-11.) Since LCC for acute cholecystitis is in itself associated with a significantly higher risk of these events, it has been recommended that acute cholecystitis should be operated on only by surgeons, who are well-experienced in the procedure through either high annual caseloads or advanced laparoscopic training (5,6,8-11). The aim of this study was to assess how the annual caseload and surgeon's level of expertise influence the conversion rate and postoperative complications.

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26 Methods

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28 Consecutive patients, who received cholecystectomy for acute cholecystitis in Helsinki University 29 Hospital - a secondary (for 0.6 million inhabitants) and tertiary (for 1.6 million inhabitants) referral 30 centre - in 2013 to 2016 were retrospectively analyzed. Permission to conduct the study was obtained 31 from the institutional review board. Patients were identified from the operating room database using 32 International Classification of Diseases (ICD) codes for acute cholecystitis (K80.0, K80.4 and 33 K81.0), and procedure codes for cholecystectomy (JKA20, JKA21). Conversion to open cholecystectomy was the primary outcome. Complications, length of surgery, and BDIs were
 secondary outcomes.

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Data regarding preoperative factors, intraoperative findings and postoperative course were extracted
from the electronic patient records. BDIs were rated according to the Strasberg classification (12),
and postoperative complications reported within 30 days from surgery were rated using the ClavienDindo classification (13).

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9 Funnel plots were drawn for conversion, postoperative complications, and length of surgery with dots 10 of individual surgeons representing their level of expertise (resident or attending). Surgeons were 11 categorized into high- and low-volume surgeons with five or more LCCs for acute cholecystitis a 12 year or less than five LCCs, respectively. Choosing five procedures a year as a cutoff-limit yielded 13 approximately equally sized groups for volume-comparison. The control limits of the funnel plots 14 used for identification of outliers were set at 95% and 99.8% from the institutional average of the 15 outcomes in 2013-2016 and were obtained using the method of normal approximation (14). Surgeons, 16 who were outliers from the control limits, might have been considered for performing poorer or better 17 than the average. The funnel plots were drawn using Prism, Graphpad Software, Inc, San Diego.

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19 In addition, funnel plots for conversion and postoperative complications were adjusted for case-mix. 20 The adjusted outcomes were calculated from the formula (observed number of events for the 21 surgeon/total predicted probability for the surgeon) × (total observed number of events/total number 22 of LCCs). The predicted probability was obtained using logistic regression. Age over 65 years, 23 diabetes, American Society of Anesthesiologists (ASA) score, previous laparotomy on the upper 24 abdomen, CRP over 150 mg/l, white blood cell count (WBCC) over 13x10⁹/l, gangrene, abscess 25 formation and perforation of the gallbladder (prior to surgery) were included as confounding variables 26 for conversion. The same variables, with the addition of male sex and renal impairment, were used 27 for generating the predicted probability of postoperative complications. We based the variable 28 selection on our previous study regarding risk factors for conversion and complications in LCC for 29 acute cholecystitis (15). Missing data were accounted for using multiple imputations.

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Residents at the institution were in their fourth to sixth year of surgical training and were mainly specializing in GI surgery, with some specializing in urology, vascular or general surgery. The Finnish surgical education system consists of nine months of primary health care rotation, followed by the common trunk period of three years, when the residents works in a central hospital with rotations in different specialties. The last three years are in a university hospital working within just the one specialty the resident has chosen. In our hospital, residents were allowed to perform LCC for acute cholecystitis independently, provided that an attending assessed they possessed the sufficient skills for it. Furthermore, attendings were always available to assist or take over the procedure.

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The statistical analysis was performed with SPSS Statistics v.24 for Mac OS X (IBM, Armonk, NY).
The chi-square test was used for categorical variables and the Mann-Whitney U test for continuous
variables. The tests were carried out two-sided, and a P value of < 0.05 was deemed statistically
significant.

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11 Results

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A total of 1062 patients were identified from the electronic operating room database. Seventy-one patients were excluded due to a primary open approach. Furthermore, 72 patients were excluded due to lacking signs of acute inflammation on the gallbladder during, and 27 patients had already been admitted to hospital and received treatment for another disease prior to cholecystectomy. These exclusion criteria yielded 892 patients for the final analysis.

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19 Over the four-year period, 87 surgeons participated in performing 892 LCCs. Seventy-six surgeons 20 performed 892 LCCs as lead surgeons over the four-year period, resulting in an average of 2.9 21 procedures a year per surgeon. Of these 76 surgeons, 39 were residents, 24 were attendings, and 13 22 surgeons operated both as residents and attendings (i.e. graduated during the study period and are 23 categorized to either resident or attending based on their status at the time of the operation in Figure 24 1). Additionally, 11 attendings acted only as assistants to residents. Residents started out as lead 25 surgeons in 558 (62.6%) LCCs, and they were assisted by an attending in 242 (27.1%) of the 26 procedures.

27

The surgeons' mean age was 40 (in 2013), and 53 (60.9%) of them were women. Of the attendings, all were specialized in GI surgery, but during daily working hours 16 (33.3%) were concentrating on general surgery, 11 (22.9%) on colorectal, six (12.5%) in upper-GI, five (10.4%) in endoscopy, three (6.3%) on bariatric surgery, and two (4.2%) on endocrine surgery. Five (10.4%) attendings worked as full-time acute-care surgeons.

33

1 The basic patient characteristics are presented in Table 1. The outcomes based on procedures by lead surgeon are presented in Figure 1. After case-mix adjustment, seven (9.2%) of 76 had conversion 2 3 rates above the 95% control limit. In regard to complications, four (5.3%) surgeons had rates above 4 the upper 95% limit, and one surgeon's complication rate fell below the lower 95% limit following 5 adjustment. Addressing surgical duration, 11 of 76 (14.5%) surgeons had operating times above the 6 upper 95% limit, and 7 of 76 (9.2%) below the lower 95% limit. 7 8 (Table 1 and Figure 1 here) 9 10 The outcomes based on the presence of an attending are presented in Figure 2. Procedures were 11 categorized to attendings if the attending was the lead surgeon, assisted the resident from the 12 beginning of the surgery, or was called upon to help prior to conversion. Addressing attendings only, 13 11 (22.9%) out of 48 attendings had conversion rates above the upper 95% limit following case-mix 14 adjustment. Two (4.2%) attendings had conversion rates below the lower 95% limit both before and 15 after adjustment. In regard to complications, three (6.3%) out of 48 attendings had complication rates 16 above the upper 95% limit following adjustment, and one (2.1%) attending's complication rate was 17 below the lower 95% limit.

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19 (Figure 2 here)

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21 The results of high-volume (surgeons who performed over five emergency LCCs annually) vs. low-22 volume (who performed five or fewer emergency LCCs annually) are presented in Table 2 and 3 in 23 regard to all surgeons and attendings only, respectively. Surgeons with an annual high-volume of 24 LCCs operated faster but did not differ from low-volume surgeons in regard to conversions and 25 complications. High-volume attendings had lower conversion rates and operated faster compared 26 with low-volume attendings. The results of surgeries performed by attendings only, residents only 27 and residents assisted by attendings only are presented in Table 4. In procedures performed by 28 residents assisted by attendings, the conversion and BDI rates were the highest, and the surgeries 29 lasted the longest. BDIs are presented in Table 5. BDIs occurred significantly more in converted 30 procedures. Of the five type D injuries, two were suspected during LCC, the surgery was converted 31 and the injury was sutured primarily. One injury was discovered after conversion, but it could not be 32 determined, whether it had occurred during the laparoscopic or open phase, and it was sutured 33 primarily over a T-tube, but the patient died of heart failure before definitive treatment could be given.

Two type D injuries were discovered postoperatively on endoscopic retrograde
 cholangiopancreatography (ERCP) and treated with stenting.

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4 (Tables 2,3,4 and 5 here)

5

6 **Discussion**

7

8 Overall, the annual numbers of LCCs for acute cholecystitis per surgeon were notably low, and the 9 funnel plots demonstrated significant variation among the results of individual surgeons. High-10 volume surgeons operated faster than low-volume surgeons but did not have fewer conversions or 11 complications. When looking at just attendings, high-volume attendings converted less and operated 12 faster than low-volume attendings. Residents did not have more adverse outcomes than attendings. 13 The conversion rate of 18% was rather high but fell within rates of 4 - 30 % reported by other studies 14 on acute cholecystitis (6,9,11,16). The high conversion rate might indeed be due to the low annual 15 caseloads, suggesting that surgeons at the institution were not receiving the experience needed for 16 LCC for acute cholecystitis. Other studies have defined high-volume as performing over 10 LCCs a 17 year, but they have included elective LCCs as well (8,17,18).

18

19 The complication rate did not significantly vary with the experience of the surgeon, as concluded by 20 other studies as well (8,9,11,17,18). The impact of the surgeon might, however, not reflect in 21 complications, since they are strongly intertwined with the patient characteristics and the severity of 22 the inflammation itself (6,10,15). With regard to BDIs, the rate of 2.2% was fairly high compared 23 with 0.2-1.0 % noted by other studies (8, 10, 16, 19). Not all of these studies were, however, 24 homogenous for acute cholecystitis, and all excluded minor bile leaks postoperatively, whilst some 25 reported only BDIs that required bile duct reconstruction. In our study, most BDIs were, however, 26 type A cystic duct leaks, and four cases remained undefined. There were no type E injuries, indicating 27 that no BDIs arose from misidentification of the common bile or hepatic duct as the cystic duct. It 28 remains unclear, how the experience of the surgeon alone influences the incidence of BDIs. In a 29 questionnaire-study on surgeons, who had caused BDIs, surgeons reported BDIs throughout all stages 30 of their careers rather than mainly in the beginning (7). However, an Australian study on around 31 35 000 patients stated that surgeons with 1-50 LCCs in the last five years were 2.4 times more likely 32 to cause a BDI compared with surgeons with at least 300 LCCs in the last five years (11), whilst an 33 American study on over 150 000 LCCs did not find a difference in the incidence of BDIs in regard 34 to annual and cumulative caseloads (18).

1

2 Despite the low annual caseloads, residents performed well independently, which might indicate successful case selection, where the risks of conversion and complications are low. The highest 3 4 conversion rates occurred in surgeries started out by residents, in which attendings were called upon 5 to help. These might have been unpredictably difficult, since they were started out by residents alone, 6 but were converted despite the help of an attending. In addition, BDIs seemed to transpire more 7 frequently in procedures where residents were assisted by attendings. These were, as noted, often 8 cystic duct leaks after converted procedures, where the severe inflammation makes the tissues more 9 fragile. In these procedures, a high-volume attending as assistant might have led to lower conversion 10 rates.

11

12 Low-volume attendings had significantly higher conversion rates compared with high-volume 13 attendings. This could result from once mastered skills having been forgotten or never having been 14 properly learnt. A study on hepatectomy stated that the annual volume influences the outcome most 15 in the beginning of a surgeon's career (20), and a study on the learning curve of LCC showed that ca 16 90 LCCs are required for mastering the procedure independently (21). With the low annual caseloads 17 we reported, surgeons might graduate without the proper skills to perform LCC for acute 18 cholecystitis. Once working as an attending, developing this skill further might be challenging, since 19 whilst working on-call there usually is no one more experienced to relieve them in a demanding LCC. 20 Apart from experience, the results of LCC undoubtedly vary due to raw talent, communication and 21 decision-making skills of a surgeon (22). Moreover, surgeons in the early stages of their career might 22 feel more comfortable with a laparoscopic procedure compared with surgeons in the last years of their 23 career, since LCC became the standard technique as late as in the 1990s.

24

25 In this study, we utilized funnel plots to evaluate performance of individual surgeons. In contrast to 26 the crude conversion or complication rate, the funnel plots consider some degree of expected variation 27 by chance. Furthermore, adjusted rates using patient-dependent risk factors in funnel plots make 28 comparison of different surgeons even more reliable. According to the funnel plots, most low volume 29 surgeons with high crude conversion or complications rates stayed within the 95% control limits. On 30 the other hand, as the numbers of surgeries increase, the control limit becomes narrower and the surgeon might be above the 95% control limit despite having a lower crude percentage than some 31 32 low volume surgeons. The hospital administration could use funnel plots to monitor surgeons' 33 performance. Surgeons, who perform worse than the institutional average ie. do not stay within 95% 34 control limits, can then be offered support or further education in order to improve their skills.

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3

How do surgeons learn and maintain sufficient skills of LCCs for acute cholecystitis? Keeping the patient selection in mind, residents should be given enough procedures to perform. An experienced 4 attending should also be available to help when necessary, as we have strived for in our hospital. A study even showed that junior residents in their 2nd to 3rd year of training taught by senior residents 5 in their 4th to 5th year did not achieve worse results compared with junior residents taught by 6 7 attendings (23). Furthermore, allocating severe cases of LCC for acute cholecystitis to fewer 8 attendings would raise the annual caseloads and presumably improve the results. Stable patients, with 9 known risk factors for conversion such as high age, severe inflammation, previous upper abdominal 10 surgery (15), could be performed or supervised by high-volume attendings. Grading systems for the

- 11 severity of inflammation could be utilized to identify patients, who should be operated on by high-12 volume attendings (17,24,25).
- 13

14 Limitations

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16 This study has several limitations. First, due to the retrospective nature of the study, its data is 17 susceptible to misinterpretation, underreporting and missing data. Data on symptoms duration prior 18 to LCC, which has been found to impact the conversion rate significantly (5,6), was missing for 150 19 patients, and was not included in the logistic regression models. Second, we based the classification 20 as lead surgeon and assistant according to the operation report, but the operation report often failed 21 to specify each surgeon's participation- whether for example, the assistant was simply holding the 22 camera and the graspers, or whether they performed small parts of the surgery themselves. 23 Furthermore, we were not able to consider the cumulative caseloads of the surgeons whose operations 24 we evaluated from 2013 to 2016. The electronic operating room database we used is only available 25 from 2010 onwards, and most of the surgeons had experience from work at other hospitals and we 26 were not able to access these records. Neither did we account for the number of elective 27 cholecystectomies performed, which might influence the performance for acute cholecystitis as well. 28 Moreover, the adjustment for risk factors for a difficult procedure might not have accurately 29 considered the differences between the group.

30

31 Conclusions

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33 In conclusion, with the proper patient selection, residents are equipped to perform LCC for acute 34 cholecystitis. An attending, preferably with high annual caseload should be available to call-upon for

1 2 3	help, and patients with risk factors for conversion, such as severe inflammation and several comorbidities, should be operated on by high-volume attendings to lower the conversion rate.		
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6 Figure legends

Fig 1. Outcomes based on surgeon starting out as lead surgeon. Attendings (n=28) performed
334 procedures and residents (n=48) performed 558. Thirteen surgeons operated as both residents
and attendings and are classified into the category in which they had most procedures.
Fig 2. Outcomes based on the presence of an attending. Attendings (n=48) were present in 576
procedures and residents (n=45) performed 316 procedures independently. Thirteen surgeons
operated both as residents and attendings and are represented with two dots.