Journal of Investigative Surgery

ISSN: 0894-1939 (Print) 1521-0553 (Online) Journal homepage: https://www.tandfonline.com/loi/iivs20

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To cite this article: Nina Odelberg, Yücel Cengiz, Arthur Jänes & Joakim Hennings (2020) The Impact of a Surgical Unit's Structure and Operative Technique on Quality in Two Swedish Rural Hospitals, Journal of Investigative Surgery, 33:10, 924-929, DOI: 10.1080/08941939.2019.1579277

To link to this article: https://doi.org/10.1080/08941939.2019.1579277

Journal of Investigative Surgery, 33: 924–929, 2020

ISSN: 0894-1939 print / 1521-0553 online
DOI: 10.1080/08941939.2019.1579277

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ORIGINAL RESEARCH

The Impact of a Surgical Unit's Structure and Operative Technique on Quality in Two Swedish Rural Hospitals

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ABSTRACT

Introduction: Laparoscopic cholecystectomy (LC) is a commonly performed surgical procedure with a low complication rate. It is performed either as an acute or as an elective procedure. Most elective LCs are performed on nonlethal diseases and this is why good quality is important. Our study compared the quality of LC in two surgical units in northern Sweden (Sundsvall and Östersund) which use different clinical structures (subspecialised vs. general surgery) and surgical techniques (ultrasound fundus first vs. conventional diathermy). The study aimed to investigate whether these differences affected the quality of outcomes after LC. *Materials and methods:* This is a registry-based study which included 607 elective LCs from January 2014 to May 2016. There were 286 from Sundsvall and 321 from Östersund. Primary outcomes were operative time and the percentage of day surgeries. The secondary outcome was the presence of postoperative complications within the first 30 days in terms of bile duct injury, bleeding that necessitated reoperation, bile leakage and abscesses treated with drainage and mortality. *Results:* The time length of surgery was shorter in Sundsvall (mean 48.3 min) compared to Östersund (mean 108.6 min, $p < 0.001$. The percentage of day care surgeries was 94% in Sundsvall and 23% in Östersund, $p < 0.001$. Six patients (2.1%) had a complication in Sundsvall compared to seven patients (2.2%) in Östersund, $p = 1.00$. *Conclusion:* There is a significant difference between the two hospitals regarding operative time and the percentage of day surgeries. Complication rates in both units were equal and low.

Keywords: laparoscopic cholecystectomy; operative technique; day surgery; complications; quality

INTRODUCTION

The first LC was performed in Germany in 1985 by Professor Dr. Erich Mühe [1]. At first, it was met with criticism, but its popularity grew [2]. It is now the treatment of choice for benign gallbladder disease [3] and used in both acute and elective operations. The procedure is technically more demanding than traditional open cholecystectomy. The risk of damaging the common bile duct and surrounding viscera is higher and this is why good surgical skills are important.

Elective surgery is a procedure that corrects nonlife-threatening medical problems. The most common reason for elective gallbladder surgery is pain due to gallstones, which is a benign condition. Postoperative complications after surgery for a benign condition are considered less acceptable than after surgery for a potentially lethal disease. Therefore, it is important to provide high quality elective LCs. Hospitals in Sweden have chosen different ways to achieve this.

New surgical techniques have been developed since the first LC was performed in 1985. In a conventional LC, the dissection is made with monopolar diathermy. It starts at the triangle of Calot and the gallbladder is subsequently dissected from the liver and extracted. This technique is used by most clinics, among them Östersund. In Sundsvall, however, an alternative technique is used, namely ultrasonic fundus-first, where the gallbladder is dissected

Received 20 October 2018; accepted 10 December 2018.
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from the liver before approaching the triangle of Calot. Several studies and a review have recognized the value of ultrasonic devices with shorter operative time, better postoperative parameters with less pain and nausea, and shorter sick leave [4–6], without adversely affecting the total cost [5,7].

The laparoscopic approach is the standard method for many interventions. Thus, surgical residents and specialists must develop laparoscopic skills. There are indications that a more structured education, as well as a refined operative technique, leads to higher quality of care for the patients as well as a more efficient use of healthcare resources [8]. Several studies have also recognized the importance of incorporating simulator training in the curriculum, as this improved both learning and outcomes [8–12] without compromising safety [10].

Hospitals in Sweden have chosen various ways to pursue the training of surgeons. They differ not only in their educational programs but also in the organization of their surgical units. The surgical department in Sundsvall has a section that specializes in the upper gastrointestinal tract (UGI). The UGI unit is responsible for gallbladder surgery and the curriculum, combining simulation training along with structured surgical training. Clinical placement within the section is divided into blocks of 3 to 6 months with a total of around 18 months. During these time blocks, the residents practice LC. In Östersund, gallbladder surgery is spread amongst different sections and surgeons, with no one section having the overall responsibility. This also applies to LC training, which is interspersed within all clinical placements, during the 5-year surgical residency. In both clinics, simulation training was introduced at the end of our study period. A formal "cholecystectomy driver's license" has been utilized in both departments. It is issued when the surgeon is considered to be independent. Both hospitals use peroperative cholangiography as routine and it was successfully conducted in >90% in both hospitals during the study period.

There is a patient hotel available in Sundsvall as well as in Östersund.

Our study intended to evaluate the quality of LCs in two rural hospitals. By using a validated national register (GallRiks), our aim was to identify whether different structures within a surgical unit, in terms of organization and education, and different operative techniques, affected quality.

MATERIAL AND METHODS

GallRiks

The Swedish National Registry for Gallstone Surgery and Endoscopic Retrograde Cholangiopancreatography (GallRiks) was founded in 2005 [13], is validated and covers approximately 90% of all cholecystectomies in Sweden [14]. The surgeon responsible for the operation registers the surgical data, and the local coordinator at each surgical unit reviews patient notes to register the incidence of any postoperative complications within 30 days of the surgery. The register is validated once a year.

Study Design

This was a registry-based study. Data were gathered from the register (GallRiks) between 1 January 2014 and 30 May 2016 for the two participating clinics with about 400 cases per clinic divided into elective and acute LCs. The data were compared to two of GallRiks' surrogate markers for quality, operative time and percentage of day surgeries. Day surgery is defined in this study as a procedure where the patient comes to the hospital and is discharged the same day, normally within 6 hours after the operation. The study was approved by the Regional Ethics Committee and adheres to the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

Study Population

Only elective operations were included in the study to ensure basic procedures. Primary exclusion criteria were acute operations, primary open operations, converted operations, and peroperative ERCP. Secondary exclusion criteria were subtotal cholecystectomy, and the presence and treatment of choledochal stone. A total of 100 operations were excluded, 45 in Sundsvall, and 55 in Östersund. No account was taken of the surgeon's level of training in order to reflect clinical routines. Both surgical residents and specialists were included in the study cohorts. In total, 607 LCs were included, 286 from Sundsvall, and 321 from Östersund.

Preoperative and Surgical Parameters

Chosen preoperative parameters were gender, age, and body mass index (BMI). Surgical parameters included the percentage of day surgeries, operative time, and postoperative complications within the first 30 days. The postoperative complications comprised bile duct injury, bleeding, bile leakage, abscess, and mortality. Amongst these complications, with the exception of mortality, we analyzed the ones that needed intervention: reoperation for bile duct injury or bleeding, and drainage for bile

leakage and abscesses. Both preoperative and surgical parameters were evaluated and compared between the two hospitals.

Statistical Analysis

Statistical analysis was performed using IBM SPSS version 24. Continuous variables were compared using the Mann-Whitney *U*-test. The χ^2 test or Fisher's exact test were used for comparison of categorical variables when appropriate. The data are presented as means, standard deviation (SD) and proportions. A two-tailed $p < 0.05$ was considered statistically significant.

RESULTS

Sundsvall and Östersund were compared regarding the baseline characteristics of patients in terms of gender, age, and BMI. The results showed no significant difference between the two groups (Table 1). The mean age was 47.8 years in Sundsvall and 48.6 years in Östersund. The majority of patients were women in both hospitals. According to mean BMI, the patients who underwent elective LC were overweight.

Surgical parameters included operative time and type of surgery, and outpatient or inpatient surgery. The results are summarized in Table 2. Mean operative time for Sundsvall, where the ultrasonic fundus-first method is used, was 48.3 minutes, SD 19.2. In Östersund, where the conventional technique with diathermy is used, the mean operative time was 108.6 minutes, SD 35.5. The difference was statistically significant, $p < 0.001$. The national average found in GallRiks for elective LC due to pain from gallstones (2014–2016) was 83.5 minutes, SD 36.8.

In six of the included elective LCs performed in Sundsvall, the dissection was made with an ultrasonic dissector from the triangle of Calot instead of fundus-first. In Östersund, dissection with diathermy from fundus-first was used in 29 of the included cases. This could have affected the mean surgery time for the two departments. However, after subanalysing these cases no significant differences neither in operative time nor in the other studied parameters were noted for these groups and the impact on the result deemed insignificant concerning our outcome measures and we chose to include these data as they were within clinical routine.

The proportion of elective LCs performed in day surgery differed between the two surgical units. In Sundsvall, 94% (270 of 286) of the operations were day surgeries, compared to Östersund where the proportion was 23% (75 of 321), $p < 0.001$.

TABLE 1 Baseline characteristics of patients

Variable	Sundsvall ($n = 286$)	Östersund ($n = 321$)	p value
Age (yr)	47.8 ± 14.9	48.6 ± 16.9	0.671[a]
Sex			0.563[b]
Male	96 (34%)	116 (36%)	
Female	190 (66%)	205 (64%)	
BMI (kg/m^2)	27.9 ± 4.4	28.7 ± 4.8	0.669[a]

Continuous data are presented as mean ± SD. Proportion as %.
[a]Mann-Whitney *U* test.
[b]Chi-square test for independence.

Postoperative complications during the first 30 days are presented in Table 3. It includes both 30-day morbidity and a specification of which kinds of complications we chose to investigate. Data concerning postoperative complications were missing for one patient in both hospitals.

In Sundsvall, six patients (2.1%) had an adverse event while in Östersund there were 7 (2.2%), $p = 1.00$. When comparing each one of these complications between the two hospitals, no significant difference was demonstrated and the numbers were low. No patient died in either hospital within the first 30 days.

According to GallRiks, the national average for postoperative complications after elective LC due to pain from gallstones was 4.7% (2014–2016).

DISCUSSION

Our study showed a significant difference in operative time between the two surgical departments. In Sundsvall, where the ultrasonic fundus-first technique was used, the surgery time was significantly shorter (mean 48.3 minutes) compared to Östersund (mean 108.6 minutes) indicating (in the absence of increased complications) a good surgical technique. The national average for elective LC due to pain from gallstones during the study period was 83.5 minutes. One possible explanation for the difference in operative time between the two hospitals might be the use of different dissecting techniques and/or instruments. Previous work has shown faster operative time for ultrasonic fundus-first dissection compared to conventional LC with diathermy from Calot's triangle [4,5,7]. Discussions suggest that this is due to better hemostasis, which allows a more exact and faster dissection. However, two recent randomized studies have shown similar operative time for the two techniques [15,16].

Since the duration of the operation is dependent on the individual surgeon's training and expertise

TABLE 2 Surgical data

Variable	Sundsvall ($n = 286$)	Östersund ($n = 321$)	p value	National average
Operative time (min)	48.3 ± 19.2	108.6 ± 35.5	< 0.001[a]	83.5 ± 36.8[c]
Type of surgery			< 0.001[b]	
Outpatient surgery, n (%)	270 (94%)	75 (23%)		
Inpatient surgery, n (%)	16 (6%)	246 (77%)		

Continuous data are presented as mean ± SD. Proportion as %.
[a]Mann-Whitney U test.
[b]Chi-square test for independence.
[c]Elective LC due to pain from gallstones between 2014 and 2016. Approximate values.

TABLE 3 Postoperative complications within the first 30 days

Variable	Sundsvall ($n = 285$)	Östersund ($n = 321$)	p value	National average
30-day morbidity, n (%)	6 (2.1%)	7 (2.2%)	1.00[a]	4.7%[b]
Bile duct injury, reoperated	1 (0.3%)	0 (0%)	0.471[a]	
Bleeding, reoperated	2 (0.7%)	0 (0%)	0.221[a]	
Bile leakage, percutaneous drainage	1 (0.3%)	5 (1.6%)	0.221[a]	
Abscess, percutaneous drainage	2 (0.7%)	2 (0.6%)	1.00[a]	
Mortality	0 (0%)	0 (0%)	–	

Proportions are presented as %.
[a]Fisher's exact test.
[b]Proportion of surgical complications after elective LC due to pain from gallstones, 2014–2016.

[4,8–10], the difference in structure of the surgical units is an important aspect to consider when discussing the difference in operative time [3,4]. Most of the LCs in Sundsvall are performed by a UGI specialist or in the presence of a UGI specialist. Meanwhile, the procedure in Östersund is performed by any surgical specialist (i.e. general surgeon), which could prolong the surgery time because they have less specific procedure experience. Furthermore, some of the operations at both clinics are performed by residents and the structured surgical training in Sundsvall might improve the learning curve for the residents (and also make them better trained when they become specialists), which could affect the outcome of the operation and decrease the operative time for them as compared to Östersund trained residents [8–11]. Additionally, the logistics within the operating room for the two surgical units might differ. Good logistics in the OR can increase operational efficiency and, hence, the duration of the surgery. Because the study period spanned 1.5 years, it was deemed to extend across temporary logistic problems and reflect the clinical setting and situation well in the two units.

The proportion of outpatient surgeries differed between the two hospitals. In Sundsvall, 94% of the operations performed were outpatient surgeries compared to 23% in Östersund. There could be several reasons for this [7]. Logistics such as a more active use of the patient hotel in Sundsvall might contribute. Both hospitals have access to a patient hotel which provides accommodation to those who do not need a hospital bed but who, for some reason, cannot go home, for example, if they suffer from postoperative pain or nausea or have a long journey home. The hotel in Sundsvall is adjacent to the hospital. In Östersund the hotel lies beyond the hospital. In the vast majority, though, patients at both hospitals defined as day surgery patients were discharged and sent home the same day as the operation after approximately 6 hours surveillance.

Furthermore, the use of different surgical techniques and/or instruments could be the cause. This was shown in an earlier study where hospitalization was more common in patients who underwent diathermy from the triangle of Calot, compared to ultrasound dissection [3,4]. The main reason for hospitalization was postoperative pain and nausea [7].

Any operation is a trauma and the longer the operative time, the more trauma the patient is exposed to [3–5]. Hence, the recovery might be longer and the risk higher for the patient to be hospitalized. This could perhaps partly explain the low percentage of day surgeries in Östersund where the operative time was twice as long.

Postoperative complications are rare [13]. Both outpatient and inpatient LCs can be performed with few complications [17–19]. The most common are bile leakage, bleeding, and abscess [20–23]. Bile duct injury in elective laparoscopic cholecystectomy is a rare complication (0.2%) and the one injury in the Sundsvall material (the only one in their overall series according to cumulative data) is noted but deemed insufficient to base further conclusions on.

Thirty-day morbidity was similar in Sundsvall and Östersund, 2.1% vs. 2.2%, and was considered low, as the national average for elective LC due to pain from gallstones between 2014 and 2016 according to GallRiks was 4.7%. The 30-day mortality rate in both hospitals was zero. This is in line with the low mortality rate reported in studies [24,25] and the 30-day mortality reported for gallbladder surgery in Sweden in 2016 (0.1%) [22].

Patient characteristics at the two hospitals that we compared were the same. Hence, no difference in age, gender, or BMI has influenced the results. However, the ASA classification system for assessing the physical status of the patient before surgery was not included in our study. Considering that a patient's physical status can complicate an operation, resulting in longer operative time and more complications, the ASA classification could have been included. However, since we only studied elective procedures i.e. patients with low ASA, we considered the ASA classification to be of less importance for the results.

Our study showed that higher quality LCs were performed in Sundsvall. For this analysis, we used two of GallRiks' surrogate markers for quality, namely operative time and percentage of outpatient surgery. The frequency of postoperative complications was, though and importantly, equal in both hospitals and lower than the national average. One strength of the study was the use of a validated database where most gallbladder procedures in Sweden are registered. However, a limitation was the use of more than one variable: a surgical unit's structure (organization and education) and surgical techniques. This made it difficult to conclude whether the results were due to the differences in structure, surgical technique and instruments or, very plausibly, a combination of the two. Thus, further studies need to be conducted to separate the impact of each parameter.

Further studies including the more complex acute cholecystitis operations are planned as well as to try to study the impact of each parameter (clinical organization and technique) in the elective laparoscopic cholecystectomy setting.

CONCLUSION

There is a significant difference regarding operative time and the percentage of outpatient surgeries between the two surgical units. Further studies are needed to better determine the cause of these results.

DECLARATION OF INTEREST

N. Odelberg, Y. Cengiz, and J. Hennings have nothing to disclose. A. Jänes is in the advisory board, Verb Surgical since 2017.

FUNDING

This work was supported by The Swedish National Quality Registry for Gallstone Surgery and Endoscopic Retrograde Cholangiopancreatography (Gallriks).

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