



and Other Interventional Techniques

Laparoscopic cholecystectomy: quality of care and benchmarking

Results of a single-institution specialized in laparoscopy compared with those of a nationwide study in Switzerland

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Abstract

Background: Quality control is an important issue in surgery. Therefore, we assessed the outcome of laparoscopic cholecystectomies (LC) performed at our institution specialized in laparoscopic surgery in order to do a benchmarking.

Methods: The perioperative courses of the first 1000 LCs performed in Aarberg hospital were recorded, analyzed, and compared with the results of a recent study including 10, 174 patients published by the Swiss Association of Laparoscopic and Thoracoscopic Surgery (SALTS).

Results: The following quality indicators were compared with the corresponding SALTS rates: primary conversion rate 1.5% (SALTS 8.2%; $p < 0.01$); conversion rate for intraoperative complications 6.5% (63.8%; $p < 0.01$); intraoperative complication rate 22.2% (34.4%; $p < 0.01$); postoperative morbidity rate 8.1% (10.4%; n.s.); in-hospital mortality rate 0.1% (0.2%; n.s.); and reoperation rate 0.8% (1.7%; n.s.).

Conclusions: LC has reached a high quality level in its widespread use, but in a small specialized center even a higher quality level can be achieved. Favorable results seem to depend on structural advantages of a surveyable unit in association with a continuously motivated surgical team.

Key words: Laparoscopic cholecystectomy — Laparoscopy — Quality of care — Benchmarking

The first laparoscopic cholecystectomy (LC) in Switzerland was performed in Aarberg on 1 November 1989. The surgical procedure has since then become the gold standard in treatment of symptomatic and even complicated gallstone disease [20]. With the introduction of

a new technique specific measures for quality management are required. This is particularly true in an environment where quality management is a prerequisite of modern health care concerning cost bearers, service providers, and last but not least the patients themselves. Therefore quality management includes not only the control if a new method provides an improvement over traditional procedures, but also the investigation of whether there are differences between various users of the same method [6, 19].

In surgery this means to clarify whether a specific procedure is justified in the treatment of a surgical disorder and further if it is used in the right hands. Such knowledge is important when a new method is confronted with criticism. It can also act as the starting point for quality improvement [24].

The aim of the present study was to assess the achieved quality level of LC in a single institution specializing in laparoscopic surgery, and to compare this with the quality level of LC in widespread use. The definition of quality level was based on several comparable quality indicators such as mortality, intraoperative complications, perioperative morbidity, and reoperation rate, as they are considered to be some of the most important outcome variables in surgery by surgeons as well as patients [6, 15]. In addition the conversion rate was chosen as a quality parameter, since it leads to a larger proportion of open procedures, which are associated with longer hospital stay, more postoperative pain, later return to normal activities, and worse cosmetics, which again are some of the most important endpoints mainly in the patient's opinion [5, 15].

Materials and methods

During the time period of 1 November 1989 to 11 February 1997, 1000 LC were performed at Aarberg hospital. All these operations were done in a modified "French technique" described by Klaiber et al. [9]

Table 1. ASA scores

	Aarberg	SALTS	SALTS ^a	p-value
ASA I	29%	55%	56%	<0.01
ASA II	53%	35%	34%	<0.01
ASA III	17%	4%	3%	<0.01
ASA IV	1%	1%	1%	1.0

^a Corrected by subtraction of Aarberg cases

Table 2. Indications for laparoscopic cholecystectomy

	Aarberg	SALTS	SALTS ^a	p-value
Symptomatic cholecystolithiasis	85.6%	87.9%	88.0%	0.027
Acute cholecystitis	13.3%	11.9%	11.8%	0.16
Suspected common bile duct stones	4.3%	11.8%	12.2%	<0.01
Biliary pancreatitis	2.1%	6.4%	6.6%	<0.01
Chronic scleroatrophic cholecystitis	0.8%	1.8%	1.9%	0.012
Asymptomatic cholecystolithiasis	1.3%	1.3%	1.3%	1.0
Polyp of the gallbladder	0.7%	0.6%	0.6%	0.7
Others	2.5%	2.6%	2.6%	0.84

^a Corrected by subtraction of Aarberg cases

with only little variation over the study time. Initially a intravenous cholangiography was added to the preoperative investigations, which was replaced by routine intraoperative cholangiography (IOC) after the first 398 procedures.

Both surgeons and surgical trainees acted as operators. The latter were always assisted by one of the five staff surgeons. Patient selection was done during the learning period among the first 100 patients presenting with gallstone disease. Subsequently all patients with uncomplicated as well as complicated gallstone disease have at least been evaluated laparoscopically.

Perioperative data was collected prospectively using the computerized datasheet set up by the SALTS. This program was launched on January 1992 to consecutively record all data of LC patients recruited nationwide from 68 hospitals and 14 surgeons with private practices. Because the comprehensive protocol with more than 300 parameters had been developed and in use at our institution since 1989 it was possible to include all our complete LC data in the study. The data was divided into the following categories: individual patient data, demographic variables and risk factors, preoperative workup, indications for LC, position and operative experience of the surgeon, intraoperative findings and intraoperative complications, histopathological findings, postoperative course and complications, and additional treatment within the first 30 days following operation.

Our results were then compared with the recent data of a nationwide multicenter study including 10, 174 patients from 68 institutions, based on the same datasheets and published by the SALTS [28].

Statistical differences between the compared groups were calculated by chi-square tests after SALTS data correction by subtraction of the Aarberg cases. *P* values <0.01 were considered as statistically significant. The differences of operation times could not be statistically analyzed since the standard deviations of the SALTS data were not known.

Results

Demographic findings

In our study group of 1000 LC the female to male ratio was 2:1 with a mean age of 56 years (range 12–98), a mean weight of 77 kg (39–129), and a mean height of 168 (150–200). The distribution of patients into the ASA risk groups is shown in Table 1. Of the Aarberg patients, 4.4% (SALTS 3.3%; *p* = 0.085) had previously under-

gone an upper abdominal operation and 43% (32.7%; *p* < 0.01) had had a lower abdominal operation.

In general, the demographic findings were identical. However, when comparing the previous abdominal operation rate a tendency, and when comparing the ASA scores even a significant difference toward a higher risk group in the Aarberg collective was found.

Indications for LC

Symptomatic uncomplicated cholecystolithiasis was the main indication for LC accounting for 75% of all cases in Aarberg (Table 2). In 1.3% of cases LC was performed on asymptomatic cholecystolithiasis where the discovery of a large gallstone led to the removal of the gallbladder [12]. A stone-free gallbladder was removed in 1.6% of cases; a chronic cholecystitis accounted for 0.8% of all cases. Histopathological findings revealed gallbladder polyps in 0.7% and gallbladder abnormalities in 0.1% of resected gallbladders. In 19.9% of cases the indication for LC was a complicated cholecystolithiasis accounting for 13.3% of acute cholecystitis, 4.3% of choledocholithiasis, and 2.1% of biliary pancreatitis.

In Aarberg 8.9% (SALTS 6.2%; *p* = 0.002) of LC were performed as an emergency procedure within the first 72 hr after onset of symptoms referring to the findings in the literature [10, 27]. Of the patients, 19.3% (18.4%; *p* = 0.49) underwent LC on the first elective list, which means in the regular operation program after pretreatment of acute symptoms with analgetics and antibiotics. Finally, 71.8% (75.4%; *p* = 0.011) of the patients were operated on from a planned elective list after regular admission.

When comparing those results the profile of indications (Table 2) is identical, but nevertheless there are significantly more emergency operations in the Aarberg collective.

Table 3. Intraoperative complications

	Aarberg	SALTS	SALTS ^a	p-value
Gallbladder injury	15.0%	15.4%	15.4%	0.74
Bleeding	5.9%	11.8%	12.1%	<0.01
Lost stones	3.1%	5.7%	5.8%	<0.01
Access-related injury	1.0%	0.4%	0.4%	<0.01
Common bile duct injury	0.1%	0.3%	0.3%	0.24
Others	2.4%	0.8%	0.7%	<0.01

^a Corrected by subtraction of Aarberg cases

Table 4. Reasons for conversion to open procedure

	Aarberg	SALTS	SALTS ^a	p-value
Bleeding	0.6%	2.0%	2.1%	<0.01
Anatomy	0.4%	2.5%	2.6%	<0.01
Acute/scleroatrophic cholecystitis	0.2%	2.5%	2.6%	<0.01
Gallbladder perforation	0.2%	0.7%	0.7%	0.06
Lost stones	0.1%	0.3%	0.3%	0.26
Others	0%	0.2%	0.2%	0.17
Total	1.5%	8.2%	8.5%	<0.01

^a Corrected by subtraction of Aarberg cases

Operation data

The mean operating time for LC in Aarberg was 85 min (range 30–260). In 61.1% of LC an intraoperative cholangiography (IOC) was performed which accounted for an average operating time of 9.8 min. The mean operating time of LC in the SALTS collective was 90.8 min although in only 23.3% of cases was IOC performed.

In Aarberg 91.3% of LC (SALTS 87%; $p < 0.01$) were performed by staff surgeons; the remaining 8.7% (13%; $p < 0.01$) were performed by surgical trainees under assistance.

Intra- and postoperative complications

In 1000 LC at Aarberg hospital there were a total of 275 intraoperative complications registered in 222 patients (Table 3). Of these complication, 93.7% were managed laparoscopically without the need of conversion to an open procedure. The corresponding SALTS data revealed intraoperative complications in 344 patients. However, only 36.2% of these complications were resolved laparoscopically, leading to a significantly higher rate of conversion in the SALTS study group (Table 6).

The major part of the relatively high complication rate is related to minor complications. Gallbladder injuries occurred in 15% of patients (SALTS 15.4%; $p = 0.74$). In 3.1% (5.7%; $p < 0.01$) the gallbladder injury was followed by loss of gallstones into the abdomen. Access-related injuries occurred in 1% (0.4%; $p < 0.01$).

Among the major complications intraoperative bleeding was by far the most frequent-accounting for 5.9% (11.8%; $p < 0.01$) of LC. In addition it was associated with a much higher conversion rate of 10.2% while the overall conversion rate was 1.5% (SALTS 8.2%; $p < 0.01$) (Table 4). Further, in comparison with

the 0.9% conversion rate regarding LC without relevant intraoperative bleeding ($p < 0.01$) there is a highly significant difference. The cause of intraoperative bleeding was mostly associated with injury of the cystic artery or bleeding tears of the liver bed. Other major complications were less frequent. The dreaded lesion of the common bile duct occurred in 0.1% (0.3%; $p = 0.24$) of all cases.

Postoperative complications are shown in Table 5. There were 3.3% (4.8%; $p = 0.02$) local and 4.8% (6.6%; $p = 0.26$) systemic complications resulting in a total postoperative morbidity rate of 8.1% (10.4; $p = 0.02$). In 0.8% (1.7%; $p = 0.03$) of patients a reoperation had to be undertaken. Mortality rate was 0.1% in the Aarberg collective (choledochoduodenostomy and LC for pancreatic carcinoma) and 0.2% in the SALTS patient group, respectively. An overview of the assessed quality indicators is summarized in Table 6.

Discussion

The results of the presented study confirm what made LC the gold standard in the treatment of gallstone disease. LC has reached a high level of quality which at least is comparable to that of open cholecystectomy in terms of morbidity and mortality rates [5, 18, 20, 21, 26]. In terms of patient comfort LC has not only gained wide acceptance but has displaced open cholecystectomy which nowadays is reserved to few indications [5, 8, 17]. The prospective multicenter SALTS study, used as reference for benchmarking in this paper, represents the level of quality which LC has achieved in its nationwide application. It confirms that LC in its widespread use obtains a high level of quality. Furthermore, it allows every single institution to perform a benchmarking and to identify its own position in the quality level spectrum, respectively. For centers specializing in laparoscopic

Table 5. Postoperative morbidity and mortality

	Aarberg	SALTS	SALTS ^a	p-value
Wound hematoma	0.8%	0.1%	0.1%	1.0
Bile leak	0.6%	0.9%	0.4%	0.33
Pancreatitis	0.4%	0.4%	0.9%	1.0
Hemorrhage	0.3%	0.7%	0.7%	0.14
Cholangitis	0.2%	0.2%	0.2%	1.0
Abscess	0.2%	0.3%	0.3%	0.58
Intestinal obstruction	0.2%	0.1%	0.1%	0.36
Wound infection	0.1%	0.1%	0.1%	1.0
Others (local)	0.5%	1.0%	1.0%	0.12
Local morbidity	3.3%	4.8%	4.9%	0.02
Pneumonia/atelectasis	0.7%	n.a.	n.a.	n.a.
Pulmonary embolism	0.2%	0.3%	0.1%	0.58
Cardiac	1.7%	1.8%	1.8%	0.82
Urinary infection	0.6%	0.7%	2.7%	0.71
Others (systemic)	1.6%	2.8%	2.9%	0.02
Systemic morbidity	4.8%	5.6%	5.6%	0.26
Total morbidity	8.1%	10.4%	10.5%	0.02
Mortality	0.1%	0.2%	0.2%	0.49

^a Corrected by subtraction of Aarberg cases

Table 6. Quality indicators: overview

	Aarberg	SALTS	SALTS ^a	p-values
Conversion rate	1.5%	8.2%	8.5%	<0.01
Intraoperative complication rate	22.2%	34.4%	35.1%	<0.01
Conversion rate for intraoperative complications	6.3%	73.8%	77.3%	<0.01
Local morbidity	3.3%	4.8%	4.9%	0.02
Systemic morbidity	4.8%	5.6%	5.6%	0.26
Reoperation rate	0.8%	1.7%	1.7%	0.03
Mortality	0.1%	0.2%	0.2%	0.49

^a Corrected by subtraction of Aarberg cases

surgery this benchmarking is a useful tool to prove whether the self-determination of holding a leading position in laparoscopic performance represents clinical reality.

The evaluation of the first 1000 LC in Aarberg revealed that most intraoperative complications represented minor complications such as perforation of the gallbladder and loss of gallstones without further consequences. What could be demonstrated was the importance of avoiding intraoperative bleeding, as this complication led to a significantly higher conversion rate of 10.2%. Besides intractable bleeding two other main factors influenced conversion rate. An unclear anatomical roadmap caused by an acute or sclerosing cholecystitis and lack of experience of the operating surgeon were also identified as risk factors for conversion to the open procedure. Postoperative morbidity was mostly associated with minor complications that could be treated conservatively. Wound hematomas, urinary tract infections, and pulmonary atelectases accounted for a quarter of the overall morbidity rate. Major postoperative complications were mostly associated to the cardiopulmonary system, especially in patients with higher anesthesiological risk profile.

The fact that in the Aarberg patient group all reoperations were due either to the development of a cholecystitis or to a hematoma underlies the importance of

avoiding the formation of intraoperative bile leaks and of performing meticulous hemostasis in the gallbladder bed, respectively.

Comparison of the Aarberg and SALTS LC group shows an advantage in all investigated quality indicator rates for the single institution specializing in laparoscopic surgery.

The Aarberg conversion rate of 1.5% is 5.5 times lower compared to the SALTS result. Intraoperative complications were 30% less and 10 times more often managed laparoscopically than in the SALTS study. Regarding the postoperative course only slight differences were found in the morbidity and mortality rates. However, in the SALTS group a reoperation after LC had to be performed almost twice as frequently.

Comparing the quality indicators mentioned so far to those from the literature [1, 2, 4, 7, 11, 13, 16, 22, 23, 25] still sets Aarberg among the highest level of quality scale regarding parameters such as conversion rate and reoperation rate. With regard to operation time and mortality, the latter being generally very low, Aarberg positions itself in the middle of the range. As for the intraoperative complications and perioperative morbidity, the rates in the Aarberg as well as in the SALTS collective are relatively high. However, most authors reported only major complications, so only a very limited comparison is possible.

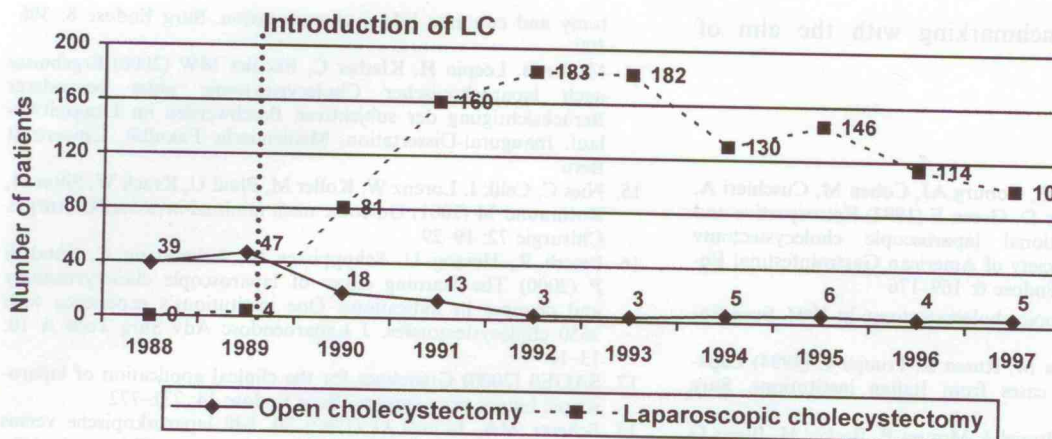


Fig. 1. Evolution of laparoscopic versus open cholecystectomy in Aarberg Hospital.

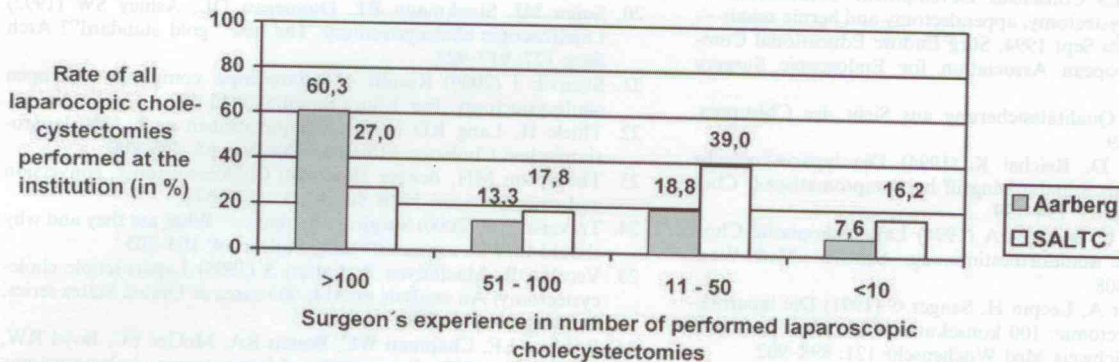


Fig. 2. Surgeons' experience.

The assumption that the good Aarberg results could be explained by patient selection cannot at all be supported for several reasons: (1) one of the lowest open cholecystectomy rates compared to the literature of 5.7% during the overall study period, which dropped to 3.1% during the last 6 years [3, 7, 16, 22, 23]; (2) significantly more patients with higher ASA scores; (3) a significantly higher percentage of emergency procedures; and (4) the tendency for a larger number of cholecystitis specimens at histopathological workup in the Aarberg collective.

Thus, why was a small unit such as Aarberg hospital able to reach a higher quality level on laparoscopic procedures compared to the widespread use?

In Aarberg, we were convinced from the beginning of the laparoscopic era, when the new technique was observed with great skepticism from the majority of the surgical community, that LC would take over the place of open cholecystectomy in the treatment of gallstone disease. This attitude is reflected in the fact that the first LC in Switzerland was carried out at our institution 12 years ago. Since then we have tried to constantly improve our laparoscopic skills and to accept the vulnerable role of being a pioneer in these new techniques. Since excellent results were obtained from the beginning, acceptance for the new method increased rapidly with the patients themselves demanding to have their operations performed the laparoscopic way. But initially laparoscopy

equipment and skills in general were rare, so that patients had to be sent to the centers offering LC. As shown in Fig. 1, a regular boom of LC developed at our institution. Without extension of operative indications, numbers of performed operations increased by more than 350% within 3 years [14]. Thereby experience in laparoscopic surgery and LC increased rapidly. While 60% of LC at our institution were performed by surgeons with an experience of more than 100 laparoscopic interventions, there were only 27% in the SALT group (Figure 2).

In our opinion also the small size of our unit itself was and still is advantageous for reaching a higher quality level performing laparoscopic surgery. The surveyable size simplifies operation modification and adequate changing of equipment when needed, but most importantly the involved team (e.g., anesthesiologists, operating and nursing staff) optimize and close their cooperation faster because fewer people are involved.

In summary, the overall quality of LC has reached a high level even in its widespread use. However, a unit specializing in laparoscopic surgery may still reach a higher level. In our opinion this is particularly explained by a faster increase of operative experience as a consequence of structural advantages. In the context of health care and rationalization, however, the trend goes toward large centralized clinics with the risk of suffering quality loss. Finally, quality control as performed in the present study provides the chance to define standards and to

motivate others for benchmarking with the aim of quality improvement.

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