

Development of single-port cholecystectomy: results of a case-control study matched to one surgeon

Nikolaus Wawra
Alexander Buia
Ernst Hanisch

Department of Visceral and Thoracic Surgery, Asklepios Klinik Langen, Academic Teaching Hospital, Goethe-University Frankfurt, Langen, Germany

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Correspondence: Ernst Hanisch
Department of Visceral and Thoracic Surgery, Asklepios Klinik Langen, Academic Teaching Hospital, Goethe-University Frankfurt, Röntgenstrasse 20, D-63225 Langen, Germany
Tel +49 610 3912 1309
Email e.hanisch@asklepios.com

Background: Single-port laparoscopic cholecystectomy is an evolving technique which is now widely established. Up until now, the safety of the procedure and a respective learning curve have not been adequately reported in most studies. The aim of this study was to demonstrate that single-port cholecystectomy is a safe procedure, with a positive learning curve from a case-control study matched to one surgeon.

Methods: One hundred single-port cholecystectomies performed by one surgeon (AB) were retrospectively matched to 100 patients who underwent conventional laparoscopic cholecystectomy carried out by the same surgeon. The two groups were matched in respect of surgical indication, gender, age, and body mass index. The groups were compared with respect to operation time, use of additional trocars, analgesics required in the post anesthesia care unit, postoperative complications, and duration of hospital stay.

Results: No significant difference was found between the two groups with respect to postoperative complications and stay in hospital. The operation time increased slightly in the single-port group. Directly after the operation, the analgesic use required in the post anesthesia care unit was higher in the single-port group. Consumption of analgesics on the surgical ward was very similar in each group. In respect to the learning curve, the operation time and use of additional trocars showed a positive trend, starting with the thirtieth operation.

Conclusion: Single-port cholecystectomy is a feasible and safe procedure in a specialist setting. The procedure can be done under the same safety rules as those for conventional laparoscopic cholecystectomy. Considering the learning curve, starting with the thirtieth operation, a positive trend was seen. Long-term studies will be needed to establish the incidence and rate of incisional hernias.

Keywords: single-port cholecystectomy, postoperative complications, conventional laparoscopic, cholecystectomy, procedural safety, learning curve

Introduction

After development of conventional laparoscopic surgery in the early 1980s and its adoption as the golden standard in the treatment of gallbladder disease, single-port surgery was the next step in reducing the surgical trauma suffered by the patient to a minimum, with the beneficial effect of more rapid convalescence, a shorter stay in hospital, less pain, and better cosmetic results.^{1,2} By 1999, Piskun and Rajpal had already described the method of laparoscopic cholecystectomy via a single incision at the navel.³ However, it took ten years before serious attempts were made to establish the method, owing to a lack of technological prerequisites, eg, 5 mm camera optical systems. Since 2008, the number of publications on the topic of single-port cholecystectomies has been rising exponentially.

These are mainly feasibility studies and reports on experience, mostly in small numbers of cases. In 2009, Hernandez et al and Rivas et al published the first large-scale studies including 100 patients. In 2010, Curcillo et al reported the largest study published so far, comprising 297 patients.⁴⁻⁶ In 2011, Phillips et al showed a comparable complication rate for both procedures in a prospective randomized clinical study of 200 patients.⁷ Unfortunately, no study has been able to refute convincingly the doubts with regard to intraoperative and postoperative safety so far, owing to the lack of a means of adequate triangulation in single-port cholecystectomy. In July 2012, Hall et al published a systematic review regarding single-port cholecystectomy that criticizes the real benefit of this new technique and a lack of studies reporting the learning curve.⁸

Our paper aims to demonstrate that single-port cholecystectomy can be performed in a comparable patient population with intraoperative and postoperative safety that is equivalent to that achieved with conventional laparoscopic cholecystectomy and that a positive learning curve exists, as documented by this matched case-control study (Figure 1).

Materials and methods

Patients

We prospectively gathered patient data for 100 laparoscopic single-port cholecystectomies carried out by one surgeon (AB) from January 2009 until April 2012. A study assistant documented the basic demographic data, including patient age, gender, and body mass index. The duration of surgery, port system used, intraoperative complications, additional trocars, drainages, and operating surgeon were also recorded, along

with postoperative stay in hospital, requirement for analgesics in the post anesthesia care unit, intraoperative complications, and secondary wound healing. The data obtained were then compared retrospectively with 100 conventional laparoscopic cholecystectomies performed from 2006 to 2008 and matched with regard to patient age, gender, body mass index, indication for surgery, and the operating surgeon. Patients with chronic symptomatic cholelithiasis and acute cholecystitis who underwent single-port cholecystectomy in our hospital from 2009 to 2011 (100 of 571 cholecystectomized patients) and those who underwent conventional laparoscopic cholecystectomy in our hospital from 2006 to 2008 and who fulfilled the above inclusion criteria with regard to patient age, gender, body mass index, and indication, and operating surgeon (100 of 706 cholecystectomized patients) were included in the comparison. Contraindications to single-port cholecystectomy were a previous laparotomy, liver cirrhosis, bile duct obstruction, and an American Society of Anesthesiologists score > 2.

Procedure

The patients are placed in the French position. Single-port cholecystectomies are performed via a roughly 20 mm incision at the navel. After opening the fascia of the rectus abdominis muscle and incision of the visceral peritoneum, a single-port system is introduced into the abdomen, and a pneumoperitoneum of 12 mmHg is set up. With a 5 mm camera introduced via the port system, an orientation inspection of the abdomen is performed. The camera is guided by the surgical assistant standing left-lateral to the patient (Figure 2). Afterwards, the surgeon introduces bent-tipped forceps into

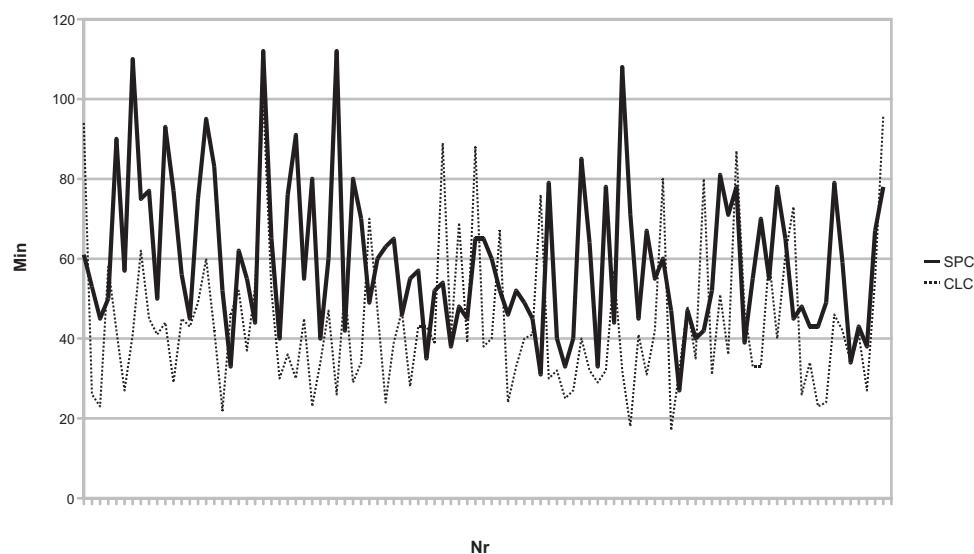


Figure 1 Graph showing the graphic trend of all 100 single-port cholecystectomies with a harmonization of the curve to shorter operation times versus conventional laparoscopic cholecystectomies.

the abdomen, then uses these to retract the gallbladder in the right laterocranial direction (Figure 3). Using likewise bent-tipped or straight monopolar surgical scissors, Calot's triangle is exposed (Figure 4). If there is no lateralization of the gallbladder because of special anatomical features, an additional 5 mm accessory trocar introduced into the right upper abdomen is used. No intraoperative cholangiography was performed in any case.

Port systems

Four port systems were used, including the Tri-Port 73 and its further development, the Tri-Port-Plus 2 (Olympus, Hamburg, Germany). This is a multichannel port via which three or four instruments can be introduced simultaneously into the abdomen using special gel valves of 10 mm and 5 mm diameter.⁹ The other systems used were one Quad Port (Olympus Germany, Hamburg), two X cones (Karl Storz, Tuttlingen, Germany), one GelPoint (Applied Medical, Düsseldorf, Germany), and one Uno-Point (Ethicon Endo Surgery, Norderstedt, Germany).

Statistical analysis

The statistical analysis was performed using the Statistical Package for Social Sciences (IBM) software program (SPSS Inc, Chicago, IL). Gaussian distribution was confirmed for all data, and they were analyzed for differences using the paired *t*-test. Data are presented as the mean with the 95% confidence interval.

Results

A single-port cholecystectomy was carried out in 100 patients and a conventional laparoscopic cholecystectomy in

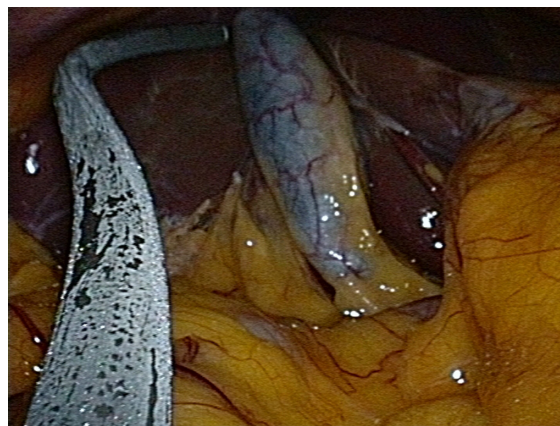


Figure 3 Lateralization of the gallbladder with a long bent-tipped instrument to expose Calot's triangle.

100 patients, all by one surgeon. Each patient population contained 66 women and 44 men. The average age of the patients in the single-port cholecystectomy group was 49.3 years and that in the conventional laparoscopic cholecystectomy group was 49.6 years. The body mass index in the single-port cholecystectomy group averaged 27.6 and in the conventional laparoscopic cholecystectomy group was 28.11. The mean duration of surgery was longer in the single-port cholecystectomy group (59.57 minutes) than in the conventional laparoscopic cholecystectomy group (44 minutes). An additional dextralateral 5 mm trocar was used 31 times, and a pronounced learning curve is discernible at both points. Thus, the average duration of surgery was 68 minutes in the first 30 single-port cholecystectomies as compared with 55 minutes in the last 30 operations, and use of an additional 5 mm trocar in the first 30 single-port cholecystectomies was 47% as compared with 23% in the

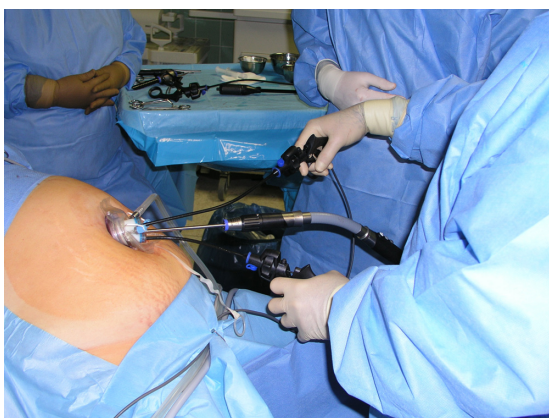


Figure 2 The typical surgical paradigm, whereby the surgeon is positioned between the lower extremities of the patient, who is placed in the French position, while the assistant is standing on the left lateral side of the patient, guiding the optical instrument.



Figure 4 Standardized intraoperative visualization of the gallbladder infundibulum and relevant structures within Calot's triangle to minimize the risk of bile duct injury.

last 30 operations. Altogether, 91 cases of symptomatic cholecystitis and nine cases of acute cholecystitis were operated on. The Tri-Port system was used in 93 cases, and the Tri-Port-Plus was used twice. Abdominal wound drainage sites were created less frequently in the single-port cholecystectomy group (27 times) than in the conventional laparoscopic cholecystectomy group (48 times). Analgesic requirement (piritramide) in the post anesthesia care unit was 7.20 mg in the single-port cholecystectomy group and 4.23 mg in the conventional laparoscopic cholecystectomy group. There was no damage to the gallbladder in either group. In one case, there was biliary pancreatitis owing to a prepapillary concretion 14 days after single-port cholecystectomy; this concretion was removed without problems by endoscopic retrograde cholangiopancreatography. Temporarily elevated hepatic enzymes returned to normal after surgery and the patient was completely asymptomatic. The average stay in hospital was 3.84 days in the single-port cholecystectomy group and 4.12 days in the conventional laparoscopic cholecystectomy group. Tables 1–2 show an overview of the most important results.

Discussion

The objective of developing laparoscopic surgery was to reduce surgical trauma. The advantages of this, including a lower incidence of wound infections and incisional hernias and fewer cases of paralytic ileus following gastrointestinal

Table 1 Demographic and clinical characteristics

	SPC (95% CI)	CLC (95% CI)	P value
Male (n)	34	34	
Female (n)	66	66	
Indication			
Chronic (n)	91	91	
Acute (n)	9	9	
BMI	27.60 (26.73–28.47)	28.11 (27.17–29.06)	0.875
Age (years)	49.27 (46.23–52.31)	49.57 (46.57–52.57)	0.971
Duration of operation (min)	59.57 (55.78–63.35)	44.0 (40.02–47.58)	0.202
Additional trocar (n)	31	na	
Drainages (n)	27	48	0.023
Complications			
Biliary tract damage (n)	0	0	
Wound infection (n)	0	1	
Stay in hospital (days)	3.84 (3.6–4.08)	4.12 (3.87–4.37)	0.096

Note: Data are presented as the mean and 95% CI.

Abbreviations: BMI, body mass index; CI, confidence interval; SPC, single-port cholecystectomy; CLC, conventional laparoscopic cholecystectomy; na, not applicable.

Table 2 Results for the learning curve

	First 30 SPC (CI)	Last 30 SPC (CI)	P value
Duration of operation (minutes)	68.2 (55–77)	54.84 (45–65)	0.012
Additional trocar (n)	14	7	0.089
Drainages (n)	11	6	0.231
Stay in hospital (days)	4.2 (3–5)	3.71 (3–4)	0.146

Note: Data are presented as the mean and 95% CI.

Abbreviations: CI, confidence interval; SPC, single-port cholecystectomy.

operations, more rapid mobilization owing to less pain, and better cosmetic results, have been documented by numerous studies. Today, many conditions that can be treated by surgery, eg, colon resection, can be undertaken laparoscopically.¹⁰

In addition, the aim of single-port laparoscopic surgery is to reduce the surgical trauma on the abdominal wall and to improve the cosmetic outcome. However, owing to inadequate triangulation and the lack of freedom for the hands of the surgeon and the assistant, using the single port entails new technical difficulties in dissection.

In a systematic review by Antoniou et al published in 2011, data for all studies published up to now were compared with those for conventional laparoscopic cholecystectomy.¹¹ No significant increase in intraoperative or postoperative risk was shown. However, the studies compared were not homogeneous and a comparative patient population was not available. Hall et al⁸ came up with a similar result in the latest systematic review published in July 2012, and also criticized the lack of studies reporting a learning curve.

In February 2011, Joseph et al published a case-control study comparing 185 single-port cholecystectomies with 108 conventional laparoscopic cholecystectomies, all performed by the same surgeon. However, there was no matching of the data with regard to age, indication, gender, or body mass index. The patient population was relatively inhomogeneous, so comparability of the data was limited.¹²

In May 2012, Arrezo and Morino posed the same question after a prospective randomized clinical trial.¹³ In November 2011, Phillips et al showed a comparable complication rate for both procedures in a prospective randomized clinical trial of 200 patients.⁷ This led to the conclusion that both procedures have a similar complication rate. Certainly the patient population was not homogeneous, especially body mass index (28.9 versus 31.0). In addition, the operations were done by different surgeons in 10 different surgical wards, and a learning curve was not constructed.

In our case-control study, in which all patients were treated by the same experienced surgeon, we were able to document the safety of single-port cholecystectomy. The most dreaded complication, ie, injury to the choledochus, did not occur in any case, and has been observed in only two cases out of a total of 1277 operations carried out at our hospital from 2006 to 2011. We have always endorsed the view of Way et al that a major reason for bile duct injuries is the anatomical illusions to which everyone is exposed, and surgical experience does not protect from these illusions. This makes safety of pre-eminent importance in the development of our single-port cholecystectomy technique.¹⁴ Especially in the early phase of our study, due to the lack of bent instruments, adequate triangulation was not always possible.

We consider that safety with complete visualization of Calot's triangle and dissection of the gallbladder infundibulum is the most important factor in intraoperative prevention of choledochal injury (Figure 4). For this reason, a 5 mm additional trocar was used in 31 cases mainly in the initial phase of implementation of the technique.

In addition to that, our data show a learning curve with a positive trend starting from the thirtieth operation with respect to operation time and use of an additional 5 mm dextralateral trocar. The average duration of surgery was 68 minutes in the first 30 single-port cholecystectomy as compared with 55 minutes in the last 30 procedures. This difference is significant ($P = 0.012$). Compared with the conventional laparoscopic cholecystectomy group, the operation time in the single-port cholecystectomy group was still higher for the last 30 operations. Moreover, the use of an additional trocar decreased from 47% in the first 30 operations to 23% in the last 30 operations. We consider that the learning curve could be much steeper in the future. We started our single-port cholecystectomies without any experience of this procedure. If an experienced single-port surgeon is able to support the trainee with advice, the learning curve will be much shorter. Table 2 shows the most important results regarding the learning curve. Figure 1 shows the graphic trend of all 100 single-port cholecystectomies, with more harmonization of the curve towards shorter operation times than with the conventional laparoscopic cholecystectomies.

Surprisingly, there were higher analgesic requirements in the post anesthesia care unit for the single-port cholecystectomy group (piritramide 7.20 mg) than for the conventional laparoscopic cholecystectomy group (piritramide 4.23 mg), which was statistically significant

($P < 0.001$). We attribute this result to the larger fascial incision required for single-port cholecystectomy. A higher analgesic requirement could not be demonstrated during the postoperative hospital stay on the ward, which was slightly shorter in the single-port cholecystectomy group (3.84 days) than in the conventional laparoscopic cholecystectomy group (4.12 days).

Our data show that single-port cholecystectomy can be performed just as safely as conventional laparoscopic cholecystectomy in a specialist setting by one experienced surgeon. We will have to wait for the long-term results with regard to incisional hernias. Using this new technique will entail a shorter and steeper learning curve.

Disclosure

NW, AB, and EH have no conflicts of interest or financial ties to report.

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