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The location of bile duct stones may affect intra- and postoperative cholecystectomy outcome: A population-based registry study

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ABSTRACT

Background: Treatment for bile duct stones (BDS) depends largely on anatomical circumstances; yet, whether the outcome of cholecystectomies is impacted by the localization of intraoperatively discovered BDS remains largely unknown.
Methods: A population-based registry study using data from the national Swedish Registry for Gallstone Surgery and Endoscopic Retrograde Cholangiopancreatography (GallRiks). 115,084 cholecystectomies 2006–2016 with the indications gallstone colic or complications were included. The surgical outcome between patients with distal BDS and those with at least one stone above the confluence was compared.
Results: 10,704 met the inclusion criteria. Patients with stones above the confluence had 16% longer operation times and significantly higher rates of intraoperative complications (OR 1.47), gut perforation (OR 4.60), and cholangitis (OR 1.96) compared to patients with distal BDS. The highest clearance rate (96%), as reflected by the need for re-ERCP, was seen after intraoperative ERCP, regardless of the localization of the BDS.
Conclusions: Stones located above the confluence are associated with increased complication risks. These findings stress the importance of carefully considering the optimal methods for BDS removal during surgery.

Introduction

Gallstone disease is very common. In the western world, gallstones are found in 10–15% of the adult population. Each year, 1–4% of prevalent gallstones become symptomatic.[1] The vast majority of patients will only experience biliary colic, but some will also suffer from acute inflammation of the gallbladder (acute cholecystitis), which can prove fatal if the patient develops sepsis.

Approximately 13,000 cholecystectomies are performed in Sweden annually.[2] Laparoscopic cholecystectomy is currently the preferred treatment method in Sweden and the rest of Europe.[3] However, the number of operations that begin as an open cholecystectomy or are intraoperatively converted to open surgery is higher in cases with acute cholecystitis.[2] One-third of all patients undergo acute surgery, according to data from the Swedish Registry for Gallstone Surgery and Endoscopic Retrograde Cholangiopancreatography (GallRiks). In roughly 75% of these cases, the surgical indication was gallstone-related complication including acute cholecystitis, gallstones that have migrated deep into the bile ducts, as well as gallstone-induced pancreatitis.

If the gallstones migrate from the gallbladder to the biliary tree, they can cause obstructive jaundice, cholangitis, or biliary pancreatitis. Bile duct stones are encountered in approximately 10% of all patients undergoing cholecystectomy.[4] There are several ways of managing stones in the biliary tree, including transcystic stone extraction, extraction of the stones through choledochotomy, and endoscopic retrograde cholangiopancreatography (ERCP). The choice of strategy depends on local routines and experience. However, which technique is chosen also depends on the localization of the stones and the efforts required to extract the stones from the anatomical point where the bile ducts are entered. This is of particular importance for ERCP, since this technique depends entirely on endoscopic stone extraction from the most distal end of the biliary tree, without surgically accessing the ducts.

The outcome of different surgical and endoscopic procedures

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and their ensuing complications have been extensively studied.[5–8] However, no large studies have been conducted on the location of intraoperatively-discovered gallstones and their effects on intra- and postoperative outcomes.

The purpose of this study is to investigate whether the position of bile duct stones affects surgical procedure time and intra- and postoperative surgical outcomes as well as to analyze which techniques that are best suited for intraoperatively detected distal and proximal bile duct stones.

Methods

Swedish Registry for Gallstone Surgery and Endoscopic Retrograde Cholangiopancreatography (GallRiks)

GallRiks is a national quality registry that was founded in May 2005. Since 2009 GallRiks has had a national coverage exceeding 80%.[9] The registry serves as a comprehensive and continuously updated database with information on indications, outcomes, and patient satisfaction, all of which are entered online. The registry form consists of two parts. The first section pertains to the cholecystectomy procedure and is completed in conjunction with the performed cholecystectomy online by the responsible surgeon and the second is also completed online but by a local coordinator who administers the 30-day follow-up. Registry data are compared with patient records at regular three-year intervals. The utility of the data was confirmed by independent reviewers (98% validity of registry data compared to the patients' medical records).[10]

Study design

This study was a nationwide, population-based registry study that examined data on all cholecystectomies performed between 1 January 2006 and 31 December 2016 and entered into the GallRiks registry. From this cohort, procedures performed for reasons other than gallstone colic or complications were excluded. From the remaining cohort, cases with successful intraoperative cholangiography (IOC) were identified and these were analyzed after removing the procedures in which no stone/stones were identified with IOC. 10,704 cholecystectomies remained for further analysis (Fig. 1).

Statistical analysis

All statistical analyses were performed with JMP Pro 14.2.0 (SAS Institute Inc., Cary, NC, USA). Comparisons of patient- and procedure-related characteristics are presented in contingency tables. The relationship between stone location and the risk of complications was assessed using multivariate logistic regression. Each variable was tested in univariate and multivariate analyses for statistical significance. In the multivariate analysis, the outcome was adjusted for age, sex, and comorbidity, dichotomized into American Society of Anesthesiologists (ASA) classification 1–2 and ASA ≥ 3. Analyzed associations are presented as odds ratios (ORs) for adverse events with 95% confidence intervals (CIs). A p-value <0.05 was considered statistically significant.

Ethical considerations

The data used in this study were anonymized and all analyses were conducted at the group level. Ethical approval for this study was granted by the regional research ethics committee at Umeå University, Umeå, Sweden (Dnr: 2017/243-31).

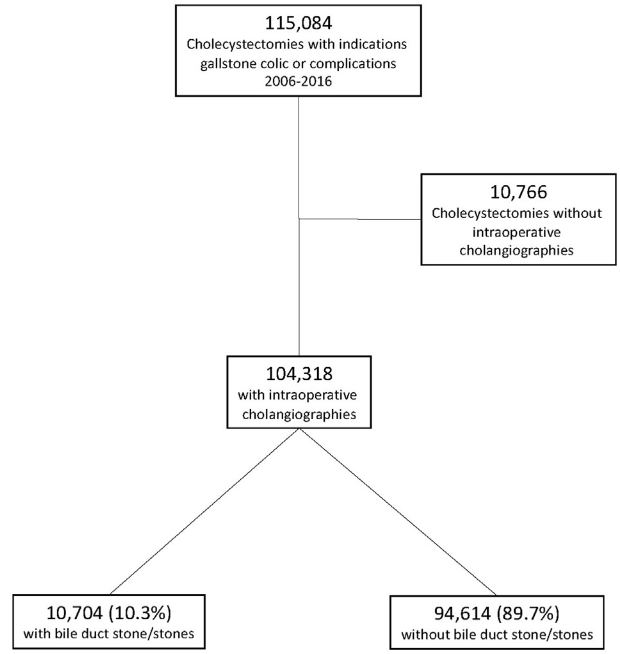

Fig. 1. Flow chart of cholecystectomies included in this study.

Results

Baseline demographics

Between 1 January 2006 and 31 December 2016, 115,084 cholecystectomies were registered in GallRiks of which 10,704 met the inclusion criteria for this analysis (Fig. 1). The baseline demographics of the study population are outlined in Table 1.

Bile duct stone position

Cases were grouped according to stone location as visualized by the intraoperative cholangiography, described as either *low* (stones limited to the common bile duct [CBD] distal to the confluence of the cystic duct) or *high* (at least one stone located above the confluence level) (Fig. 2).

Stone extraction methods

Methods used to extract bile duct stones relative to their position in the biliary tree as well as the corresponding procedure times are given in Table 2. When one or more stones intraoperatively were located above the confluence of the cystic duct, open choledochotomy was the most frequently used surgical method to remove the stones (28.6%). The overall most frequently used method, regardless of location, was intraoperative ERCP (24%) closely followed by preparing for postoperative ERCP (22%). The latter strategy is a procedure undertaken with the intention to perform postoperative ERCP aided by an intraoperatively antegradely inserted guidewire or stent the next possible weekday after completing the cholecystectomy.

As expected, methods primarily designed to clear the distal CBD (e.g., transcystic stone extraction, flushing the bile duct) were around twice as common in the low group (i.e., with stones located below the confluence) (Table 2).

Intraoperative ERCP, open choledochotomy, transcystic stone extraction, and laparoscopic choledochotomy were all significantly more time consuming when one or more stones were located

Table 1
Demographic data.

	Stones limited to the bile duct distal to the confluence (N = 8916)	At least one stone above the confluence (N = 863)	p
Sex			0.3961
Female	5927 (66.5%)	586 (67.9%)	
Male	2989 (33.5%)	277 (32.1%)	
Age (years)			*0.0550*
>53	4348 (48.9%)	451(52.3%)	
≤53	4544 (51.1%)	411 (47.7%)	
ASA			**0.0089**
1-2	8040 (90.2%)	754 (87.4%)	
≥3	876 (9.8%)	109 (12.6%)	

p = Pearson's chi square.

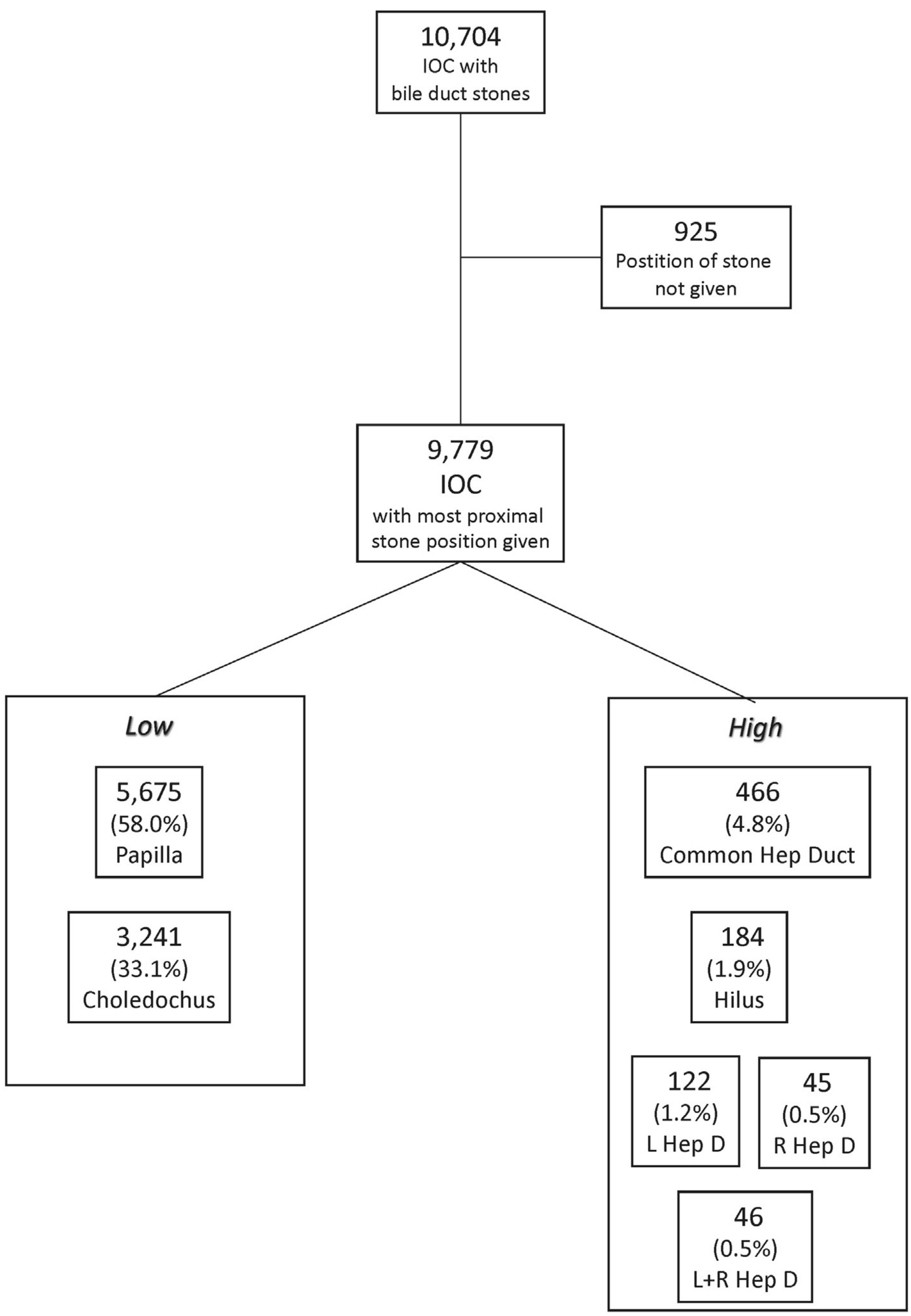

Fig. 2. Localization of bile duct stones discovered upon intraoperative cholangiography during the cholecystectomies included in this study.

Table 2
Methods and procedure time required to extract bile duct stones relative to their position.

	Stones limited to the bile duct distal to the confluence (N = 8916)[a]	At least one stone above the confluence (N = 863)	p*
Intraoperative ERCP	2150 (24.1%)	194 (22.5%)	**<0.0001**
Preparing for postoperative ERCP	1994 (22.4%)	192 (22.3%)	
Open choledochotomy	1127 (12.6%)	247 (28.6%)	
Transcystic stone extraction	1268 (14.2%)	62 (7.2%)	
No intraoperative action	1193 (13.4%)	122 (14.1%)	
Flushing the bile duct	1103 (12.4%)	32 (3.7%)	
Laparoscopic choledochotomy	78 (0.9%)	14 (1.6%)	
	Stones limited to the bile duct distal to the confluence (N = 8916)	**At least one stone above the confluence (N = 863)**	**p#**
	Minutes (Mean ± SEM)	Minutes (Mean ± SEM)	
Intraoperative ERCP	136 ± 1.3	147 ± 4.6	**0.0205**
Preparing for postoperative ERCP	125 ± 1.2	133 ± 4.2	*0.0623*
Open choledochotomy	189 ± 2.2	209 ± 5.5	**0.0009**
Transcystic stone extraction	158 ± 1.7	185 ± 9.4	**0.0064**
No intraoperative action	107 ± 1.3	107 ± 3.8	0.9667
Flushing the bile duct	123 ± 1.6	130 ± 7.5	0.4010
Laparoscopic choledochotomy	192 ± 9.5	264 ± 26.4	**0.0200**
Total time all methods	138 ± 0.7	160 ± 2.7	**<0.0001**

p* = Pearson's chi square.
p# = student's *t*-test.
[a] In three cases, the reason for removal is not listed.

above the confluence. The overall mean surgical procedure time, regardless of the method used to clear the bile ducts, was 16% longer for the patients in the high or proximal group (Table 2).

The majority of bile duct stones (86%) were managed with a laparoscopic and/or endoscopic technique whereas 14% of the patients underwent open choledochotomy (12.6% in the distal stone group and 28.6% in the proximal group) (Table 2). Notably 1319 (96.2%) of these patients got a biliary draining tube placed in the bile duct, thus providing external drainage of bile. This drainage obviously requires additional intervention in order to remove it.

Complication rates

Incidence of complications and 30-day mortality according to the localization of the bile duct stones are given in Tables 3 and 4. In the high group, we found a significantly increased risk for overall intraoperative complications (OR 1.47; 95% CI 1.03–2.09) as well as intraoperative gut perforation (OR 4.60; 95% CI 1.87–11.35). Furthermore, in the multivariate analysis, there was a trend towards increased overall postoperative complications (OR 1.19; 95% CI 1.00–1.42; p = 0.0557) as well as a significantly increased risk of postoperative cholangitis (OR 1.96; 95% CI 1.05–3.66) (Table 4). However, it must be emphasized that one of the limitations of the GallRiks online protocol regarding intraoperative and postoperative complications is that it is only possible to specify the more procedure-specific complications, e.g. perforation of the GI tract, bile duct injury and bleeding whereas other complications can only be registered as free text. Therefore, in Tables 3 and 4 figures are only given for these specified variables as well as for the more unspecified variables *Intraoperative* and *Postoperative complications overall.*

Efficiency of stone extraction techniques

Re-ERCP frequency within 30-days was used as a proxy for retained stones. In Table 5 the incidences of re-ERCPs for each respective stone extraction techniques are given (Table 5). The most effective intervention, regardless if the stone/stones were distal or proximal in the bile duct, seems to be intraoperative ERCP. The rather high success rate for flushing the bile duct is a bit confusing and could perhaps be caused by misinterpreting air bubbles as BDS.

Discussion

The present study shows the importance of the anatomical location of stones in the intraoperative management of stones in the biliary tree. The further the stones were away from the papilla of Vater, the greater the risk of complications. Furthermore, the methods used to remove stones from the biliary tree also seem to be important. In general, all of the intraoperative interventional

Table 3
Incidence of complications and 30-day mortality by localization of biliary tree stones.

		Stones in the bile duct distal to the confluence (N = 8916)	At least one stone above the confluence (N = 863)	p
Intraoperative	**Complications overall**	257 (2.9%)	37 (4.3%)	**0.0210**
	Perforation of the gut	15 (0.2%)	7 (0.8%)	**0.0001**
	BDI	42 (0.5%)	3 (0.4%)	0.6089
	Bleeding	83 (0.9%)	8 (0.9%)	0.9909
Postoperative	**Complications overall**	1503 (16.9%)	170 (19.7%)	**0.0343**
	Cholangitis	62 (0.7%)	12 (1.4%)	**0.0244**
	Pancreatitis	270 (3.0%)	22 (2.5%)	0.4298
	Bile leakage	208 (2.3%)	17 (2.0%)	0.4610
	Re-ERCP within 30 days	680 (7.6%)	76 (8.8%)	0.2153
	30-day mortality	24 (0.3%)	2 (0.2%)	0.8384

p = Pearson's ChiSquare

Table 4
Univariate and multivariate logistic regression analyses of risk for complications in cases where at least one stone is located above the confluence. Stones limited to the bile duct distal to the confluence were treated as reference category. The multivariate models were constructed with adjustment for age, gender and ASA.

		Univariate analyses		Multivariate analyses	
		OR (95% CI)	p	OR (95% CI)	p
Intraoperative	**Complications overall**	1.51 (1.06–2.15)	**0.0219**	**1.47 (1.03–2.09)**	**0.0323**
	Perforation of the gut	4.85 (1.97–11.93)	**0.0006**	**4.60 (1.87–11.35)**	**0.0009**
	BDI	0.74 (0.23–2.38)	0.6103	0.71 (0.22–2.31)	0.5752
	Bleeding	1.00 (0.48–2.06)	0.9909	0.95 (0.46–1.97)	0.8881
Postoperative	**Complications overall**	1.21 (1.01–1.44)	**0.0345**	1.19 (1.00–1.42)	*0.0557*
	Cholangitis	2.01 (1.08–3.75)	**0.0274**	1.96 (1.05–3.66)	**0.0342**
	Pancreatitis	0.84 (0.54–1.30)	0.4304	0.84 (0.54–1.30)	0.4355
	Bile leakage	0.84 (0.51–1.39)	0.4976	0.84 (0.51–1.38)	0.4926
	Re-ERCP within 30 days	1.17 (0.91–1.50)	0.2158	1.17 (0.91–1.50)	0.2226
	30-day mortality	0.86 (0.20–3.65)	0.8386	0.74 (0.17–3.17)	0.6584

methods used to remove stones discovered at IOC (intraoperative ERCP, transcystic stone extraction, and open- or laparoscopic choledochotomy) required longer procedure times when at least one stone was located above the confluence level. However, in intraoperative ERCP, the time difference between the two groups was only 11 min (147 ± 4.6 min vs 136 ± 1.3 min; mean ± SEM) whereas the time difference was 72 min (264 ± 26.4 min vs 192 ± 9.5 min) when a laparoscopic choledochotomy was performed to remove the stones (Table 2). When using re-ERCP within 30 days as a proxy for retained stones, we found low re-ERCP frequencies for both transcystic stone extraction as well as intraoperative ERCP (Table 5). However, intraoperative ERCP had a more consistent stone clearance rate regardless of whether the bile duct stones were located distal or proximal in the bile ducts. Regarding the seemingly favorable outcome when flushing the bile ducts we believe that they should be interpreted with caution since they can be caused by misinterpretation of air bubbles for stones. In a similar fashion the somewhat high re-ERCP rate of "preparing for postoperative ERCP" might be caused by that some scheduled ERCPs have been misinterpreted as unplanned postoperative ERCP by the local coordinators and, thus, the results for this variable must be interpreted with caution.

There are probably some selection mechanisms contributing to the differences described in the present study, yet we believe that these findings are nonetheless relevant to the clinical management of stones in the biliary tree.

The presence of stones located above the confluence level was likely associated with a significantly higher risk of intraoperative complications and gut perforation because, to reach these stones, both the surgeons and endoscopists had to navigate their instruments further through the narrow ducts surrounded by adjacent tissue and organs with a subsequent risk for complications. Moreover, the extended procedure times in the high group could be caused by the same reason. However, further studies are needed to explore why the two groups differ in these respects.

The high group trended toward having slightly higher postoperative complication rates and, together with the significantly higher cholangitis frequency, this suggests that stones higher up in the biliary tree were more difficult to successfully remove. We were unable to find similar studies in the literature, making it difficult to compare our results to previous studies.

A major strength of this study is the vast amount of data made available through the GallRiks database. With a national coverage rate of continuously >80%[9] and data collected from university hospitals as well as county and district hospitals in Sweden, adjustments can be made for hospital-based as well as regional differences. That the GallRiks database has a validity of 98%,[10] and is subject to continuous quality control, are also strengths. Additionally, the responsible surgeon registers the data online immediately after the procedure. However, this can also be a limitation as there is always the possible risk of bias from the interpretation of the intraoperative cholangiography and the registration of intraoperative complications. This is, to some degree, avoided by the 30-day follow-up with the local and independent coordinator. Furthermore, during the study period, 2006–2016, the national coverage rate gradually increased from 73% to 88%.[11] We do not, however, see a systematic reason for the stone location to be associated with the coverage rate.

The main indication for surgery in the elective group was gallstone-related pain, around 70%.[2] In Sweden, complications after cholecystectomy occur in 5–6% of cases and include abscess formation, bleeding, infections, and bile leakage. When comparing elective and acute surgery groups, complications are more common in the latter group.[2]

There are several treatment options (e.g., laparoscopic transcystic common bile duct stone extraction, extraction through choledochotomy, or ERCP) that can be performed either pre-, intra-, or postoperatively, with or without a guidewire, i.e., the "rendezvous" procedure. The transcystic common bile duct technique is, however, not considered feasible if the stones are located above the confluence.

Intraoperative cholangiography (IOC) is mainly used to visualize the anatomy of the biliary tree, identify concrements in the bile ducts, and to identify possible bile duct leaks and injuries.[12] The latter can have severe consequences for the affected patient, including increased morbidity and mortality.[3,13,14] Between 2005 and 2010 some 51,041 patients underwent cholecystectomies in

Table 5
Re-ERCP within 30 days as a proxy for remaining stone/stones with the different techniques Stones distal to the confluence At least one stone above the confluence.

Technique to remove stones	Re-ERCP within 30 days		Re-ERCP within 30 days		p
	N	%	N	%	
Intraoperative ERCP	87/2150	4.1	8/194	4.1	0.9584
Preparing for postoperative ERCP[a]	*298/1994*	*14.9*	*27/192*	*14.1*	0.7428
Open choledochotomy	100/1127	8.9	29/247	11.7	0.1617
Transcystic stone extraction	41/1268	3.2	3/62	4.8	0.4902
No intraoperative action	118/1193	9.9	6/122	4.9	*0.0734*
Flushing the bile duct	33/1103	3.0	1/32	3.1	0.9653
Laparoscopic choledochotomy	3/78	3.9	2/14	14.3	0.1126

p = Pearson's chi square.
[a] In some cases, these figures might be too low due to the fact that the ERCP can be misinterpreted as a complication, when it in fact is the scheduled treatment

Sweden. Of these, 1.5% experienced an iatrogenic bile duct injury.[15] The indications for and extent of the IOC used to identify bile duct injury vary greatly across Europe. Several studies concerning the pros and cons of IOC have been published,[16–21] but no consensus has yet been reached.[3,22] In Sweden, the routine use of IOC is widely accepted, roughly 90% of all cholecystectomies.[23] Bile duct injury is a severe complication of gallstone surgery, patients who are subject to bile duct injury during cholecystectomy have decreased survivability but early detection can improve prognosis. In a large registry-based study using GallRiks data, Törnqvist et al. showed that, even in cases where the IOC was unsuccessful, patients who underwent IOC have a lower mortality risk compared to patients who did not.[15]

In conclusion, both stone localization and removal method influence the outcome of cholecystectomies. Biliary tree stones located above the confluence are associated with a higher risk of intraoperative complications, gut perforation, cholangitis, and prolonged surgery. There is also a tendency for overall postoperative complications to be affected by the localization of the biliary tree stones, with both groups sharing the same risk profile. These findings stress the importance of carefully considering the optimal methods for bile duct stone removal during surgery. However, further studies are called for.

Author contributions

LE and KG conceived of the presented idea.

LE and GS designed the study.

NS and LE collected data from GallRiks and GS verified the analytical methods.

LE and NS wrote the article.

GS and KG reviewed the article.

All of the authors discussed the results and contributed to the final manuscript.

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Declaration of competing interest

Lars Enochsson has no conflict of interest to declare.

Nicholas Sharp has no conflict of interest to declare.

Karolina Gimberg has no conflict of interest to declare.

Gabriel Sandblom has no conflict of interest to declare.

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