

The Swedish Registry of Gallstone Surgery and Endoscopic Retrograde Cholangiopancreatography (GallRiks)

A Nationwide Registry for Quality Assurance of Gallstone Surgery

Lars Enochsson, MD, PhD; Anders Thulin, MD, PhD; Johanna Österberg, MD, PhD; Gabriel Sandblom, MD, PhD; Gunnar Persson, MD, PhD

Objectives: To describe the process of initiating and organizing a nationwide validated web-based quality registry of gallstone surgery and endoscopic retrograde cholangiopancreatography (ERCP) and to present some clinical data and the impact the registry has had on the clinical treatment of gallstones.

Design: Observational, population-based registry study.

Setting: Data from the nationwide Swedish Registry of Gallstone Surgery and ERCP (GallRiks).

Patients: From May 1, 2005, to December 31, 2011, 63 685 cholecystectomies (laparoscopic and open) and 37 860 ERCPs have been prospectively registered in GallRiks.

Interventions: Cholecystectomies, laparoscopic or conventional, as well as ERCP in a population-based setting.

Main Outcome Measures: Registrations of all cholecystectomies and ERCPs are performed online by the surgeon or endoscopist. Thirty-day follow-up of both gallstone surgery and ERCP is mandatory, as is an additional 6-month follow-up of the cholecystectomies. Scores

on the 36-Item Short Form Health Survey are registered preoperatively and 6 months postoperatively in elective cholecystectomies at selected units.

Results: The 30-day overall complication rate is 6.1% in elective cholecystectomy, 11.2% in urgent cholecystectomy, and 12.0% following ERCP. The use of antibiotic and thromboembolic prophylaxis in elective laparoscopic cholecystectomy in Sweden has decreased by 8.7% and 17.8% (2006-2011), respectively, mainly owing to presentation of GallRiks data both at meetings and published in peer-reviewed publications. The large database has also enabled several research projects, including one demonstrating that the intention to perform intraoperative cholangiography reduced the risk of death after cholecystectomy. The database has reached greater than 90% national coverage and is continuously validated.

Conclusions: GallRiks is a validated national quality registry for gallstone surgery and ERCP, serving as a base for audit of gallstone disease treatment. It also provides a database for clinical research.

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Author Affiliations: Division of Surgery, CLINTEC, Karolinska Institutet and Department of Surgical Gastroenterology, Karolinska University Hospital (Drs Enochsson and Sandblom) and Swedish Association of Local Authorities and Regions (Dr Thulin), Stockholm, Department of Surgery, Mora Hospital, Mora (Dr Österberg), and Department of Surgery, County Hospital Ryhov, Jönköping (Dr Persson), Sweden.

SYMPTOMATIC GALLSTONE DISEASE is common throughout the world. The prevalence, however, varies. Ultrasonographic and cholecystographic surveys have shown that gallstones are rare in Asian countries (3%-6%),^{1,2} whereas they are quite common in the Western world. In the United States, prevalences of 5% to 22% have been reported.³ In Europe, high prevalences are reported but with regional differences (Germany, 19.7%⁴; Norway, 21.9%⁵; Sweden, 15%⁶). For patients with symptomatic gallstones, the only evidence-based treatment available today is surgery.⁷

However, the fact that about one-fifth of the patients undergoing surgery are not relieved of their symptoms emphasizes the importance of careful symptom assessment and establishing the right indications for surgery.⁸

The postoperative complication rate following gallstone surgery is low but not negligible. Furthermore, patients with iatrogenic common bile duct injuries are found to be almost 3 times as likely to die during the first 5 postoperative years compared with those without bile duct injury.⁹ Despite high expectations, the introduction of laparoscopic gallstone surgery (laparoscopic cholecystectomy

[LC]) has neither reduced the complication rates nor eliminated the risk of bile duct injuries.³

Because gallstone disease is widespread and may be present concurrently in patients with abdominal symptoms of other causes, incorrect indications for surgery may lead to overtreatment with the risk of iatrogenic morbidity as well as unnecessary costs to society. The only way of ensuring an accurate selection of patients suitable for gallstone surgery is a careful evaluation of the symptoms and health-related quality of life prior to surgery as well as postoperatively.

A national registry for quality assurance with good compliance among the participating hospitals gives the opportunity to analyze regional and interhospital differences in the management of gallstone disease and the postoperative outcome. Furthermore, a national registry may provide a study population large enough to obtain statistical power for scientific research that would be difficult to achieve in prospective randomized controlled trials. Whereas randomized controlled trials in general are considered to provide data of the highest degree of evidence, data from a registry reflect the actual outcome of the treatment as it is practiced in the community at large, without the exclusion criteria of randomized studies and not limited to centers of excellence. The large number of patients also makes it possible to study rare events, eg, bile duct injuries, with sufficient statistical power.

The aims of this article are to describe the process of how a validated nationwide quality registry for gallstone surgery and endoscopic retrograde cholangiopancreatography (ERCP) was established in Sweden and to present some data from the 7 years it has existed as well as the impact the registry has had in Sweden on the treatment of gallstone disease.

METHODS

INITIATION PHASE

The idea of introducing a national registry was originally presented to the Swedish Surgical Society in 2003. The board approved and an introductory meeting was held in March 2003. An inquiry regarding interest in participating in the registry was sent to all surgical departments in Sweden. If a responding department already had a local registry for gallstone surgery, it was encouraged to submit its protocol to be considered for use in GallRiks. To get a complete assessment of both the surgical and endoscopic treatments of gallstone disease as well as complications following cholecystectomy, all ERCP procedures are also included in the registry. The boards of the Swedish Surgical Society, the Swedish Association of Upper Abdominal Surgery, and the Swedish Association of Innovative Surgical Technology appointed members to a working committee with the assignment to define the parameters to be used in the registry. A prototype was presented at the Swedish Surgical Week and the registry officially opened on May 1, 2005. The start and organization of the registry were made possible by financial support from the Swedish National Board of Health and Welfare. This support facilitated GallRiks becoming well accepted by the Swedish surgical community.

ONLINE REGISTRATION

There was a general consensus among the board members that the registry should be accessible online by all the participating surgeons and endoscopists for them to immediately be able to register the procedures (cholecystectomies and ERCPs). Another important goal was to make it possible for all the participating hospitals to access updated reports online so they could compare their results with the rest of the participating departments. The board commissioned the Uppsala Clinical Research Centre (<http://www.ucr.uu.se>) to deliver and support the Internet-based software solution as well as to host the database.

There were, however, several issues to address when introducing an online registration of patient data: the online registration had to be performed in a digitally secure environment to protect the integrity of the patients; the registry needed to aim at getting good compliance from both patients and doctors; and the patients had to be fully informed and any wish of the patient not to participate had to be respected and immediately executed.

COMPLIANCE AND PUBLIC RESULTS

Several problems must be solved when organizing a prospective registration of benign diseases. Highly specialized surgery for a malignant disease is usually performed at academic referral centers, whereas surgery for benign disease is more decentralized. For the registry to be population based, a large number of very small units have to be included for the registry to be complete. To achieve good compliance in quality registers for benign surgery, the number of parameters to obtain a complete picture of the quality must be balanced against an abundance of parameters with the concomitant risk of reduced registration compliance. Therefore, during the first 2 years (2005-2006), we mainly focused on getting the registry as balanced as possible, on one hand making the registry as complete as possible and on the other hand having as few parameters as possible to achieve good compliance. There are also annual meetings with the GallRiks board to continuously update the variable set.

Whereas transparency and public presentation of all registered data are encouraged in Sweden, this policy of making data from each unit available to the public may cause conflicts. In a quality registry, the following must be dealt with to achieve good registration compliance: apprehension that an unfavorable outcome becomes known to the public, and apprehension that unfavorable results impair the prestige either individually or for the participating hospital in relation to the rest of the surgical community.

These factors must be taken into account to maintain a high level of credibility within the registry. Thus, during the initial building phase of the registry, only names of the participating hospitals and the number of registered procedures at each department were made public. However, from 2007, the number of outcome parameters being made publicly available has increased. So far, this has proven not to have any major negative effect regarding registration compliance by the participating clinics.

QUALITY MEASURES

Cholecystectomies

For cholecystectomies, several outcome variables are used as quality measures. Procedures completed with a minimally invasive approach are noted. Most of these operations are LCs. In Sweden, although some clinics have used the minimally invasive open technique with small skin incisions, they are in-

cluded in the minimally invasive group in GallRiks but constitute only a small part (2.6%) of the database. Operative time, postoperative length of stay in days, and intraoperative and postoperative complications are also included in the registry.

After the operation, the surgeon makes an immediate on-line registration of the operation and completes the web-based form. The surgeon can register in general terms if there was an intraoperative complication and also specify the complication in free text. However, some complications are considered to be more specifically related to surgery and thus are specified under separate headings, such as perforation of the gut, intraoperative bleeding that demands intervention, and intraoperatively discovered bile duct injury. Postoperative complications are registered after 30 days by the local coordinator at the clinic who, in a similar manner, registers the complications that have occurred within 30 days after the operation.

Also, health-related quality of life is measured with the 36-Item Short Form Health Survey (SF-36) preoperatively and postoperatively (elective cholecystectomies). However, until recently, the SF-36 has been used by only a few pioneering clinics.

Endoscopic Retrograde Cholangiopancreatographies

Several outcome variables are used as quality measures for ERCP, including successful deep cannulation of the bile duct, pancreatitis (the Cotton criteria are used, with the S-amylase level increased >3 times and abdominal pain lasting >24 hours), and intraoperative and postoperative complications, which are registered in much the same way as described for cholecystectomies. The outcome measures are made available to each reporting unit as reports online or as summaries sent to the coordinator at each unit.

REGISTRATION OF PATIENT-RELATED OUTCOME

Patient-related outcome is a crucial outcome measure for treatment of diseases with low mortality. As the ultimate goal of treating gallstones is to relieve symptoms and improve quality of life rather than to prevent lethal outcome, measuring patient-related outcome preoperatively and postoperatively is essential to achieve good quality assurance. The SF-36 score is recorded preoperatively and 6 to 9 months postoperatively in patients undergoing elective cholecystectomy at selected units with sufficient resources to reach a good response rate.

OBJECTIVE VALIDATION

For both the medical profession and the public to have confidence in a quality registry, it is necessary for the registry to submit to independent objective validation. Therefore, the GallRiks board continually performs an external validation of all the participating hospitals. The medical records of 25 randomly selected procedures registered in GallRiks at each participating unit are thoroughly scrutinized by independent observers. Data from the respective GallRiks registration are compared with the corresponding medical record of each procedure. The results are assembled in a database and immediate feedback is given to the head of the surgical department as well as to the people responsible for the registry at the department. Following the validation, there is a discussion regarding any problems encountered at registration and how to solve them. On average, each hospital is visited once every third year. The results of the validations are published in the annual reports and are available on the GallRiks website (<http://www.ucr.uu.se/gallriks/index.php/arsrapporter>). The validation has

shown a complete match between the medical records and the database in more than 95%.¹⁰

COVERAGE

To assess the accurate number of all cholecystectomies and ERCPs performed in Sweden each year, there is a central database search of the Swedish National Patient Registry (<http://www.socialstyrelsen.se/register/halsodataregister/patientregistret/inenglish>). The results of this database search and how well each participating clinic is able to register all their cholecystectomies and ERCPs in GallRiks are presented to the public with the aim of stimulating and increasing the registration efforts.

STATISTICAL ANALYSIS

Statistical methods and data analysis were carried out using JMP version 9.0 statistical software (SAS Institute, Inc) for Mac OS X version 10.7.4 (Apple Inc). All the variables were tested for normality. For descriptive statistics, continuous data are presented as mean (standard error of the mean) for normal distribution. To compare groups, the *t* test and Mann-Whitney *U* test were used as appropriate. The differences in complication rates among patients with urgent vs elective surgery were analyzed using Pearson χ^2 test. The material was analyzed in total and stratified according to type of surgery. *P* < .05 was considered to be statistically significant.

RESULTS

PARTICIPATING HOSPITALS AND REGISTERED PROCEDURES

At the end of the first year, 36.1% of the Swedish hospitals had joined the register. The number of hospitals participating in GallRiks, however, increased rapidly from 26 in 2005 to 72 in 2011, which constitutes 98.6% of all hospitals. The number of registered cholecystectomies and ERCPs has also increased during this period. Presently, approximately 90% of all cholecystectomies and ERCPs registered in the Swedish National Patient Registry are being registered in GallRiks. During the study period, GallRiks included 63 685 cholecystectomies and 37 860 ERCPs. A 30-day follow-up was completed in 60 850 cholecystectomies (95.5%) and in 36 299 ERCPs (95.9%). In parallel, the number of hospitals included in the registry and the number of included interventions have increased, whereas complete 30-day follow-up has decreased somewhat (**Table 1**).

QUALITY MEASURES

Procedures Completed With Minimally Invasive Technique

The first quality parameter published by GallRiks in 2007 was the percentage of cholecystectomies performed with the laparoscopic technique. Since the official start of GallRiks in 2005, the percentage of urgent cholecystectomies performed with the laparoscopic technique has increased from 44.3% in 2005 to 74.6% in 2011. During the same period, the percentage of converted urgent LCs decreased from 15.8% to 11.9%. The number of urgent

Table 1. Overall Annual Numbers of Cholecystectomies and Endoscopic Retrograde Cholangiopancreatographies in GallRiks as Well as Completed 30-Day Follow-up

Year	No.		Complete 30-d Follow-up, %
	Patients	Hospitals	
Cholecystectomy			
2005 ^a	1113	26	100
2006	7689	51	99.7
2007	8953	63	98.8
2008	10 440	69	96.7
2009	12 030	72	95.8
2010	11 632	71	93.4
2011	11 828	72	92.9
ERCP			
2005 ^a	466	14	100
2006	4288	35	99.8
2007	5154	39	99.7
2008	6480	51	93.3
2009	6754	50	96.8
2010	7173	49	96.2
2011	7545	52	91.9

Abbreviation: ERCP, endoscopic retrograde cholangiopancreatography.
^aMay 1 to December 31.

operations initiated as open cholecystectomies decreased from 39.8% to 13.5%. Elective LCs have shown a similar but less steep gradual increase from 87.1% in 2006 to 91.9% in 2011. In 2005, however, the percentage of elective LCs was rather high (90.9%), probably because the first hospitals to join the registry were those with a special interest in laparoscopic surgery (**Table 2**). There is a wide span in the percentage of urgent cholecystectomies being performed with the laparoscopic technique between different hospitals in Sweden (42.4%-97.5% in 2011).

Operative Time

There have been no dramatic changes in operative time throughout the years. The mean operative time in urgent LC is significantly longer compared with elective LC, although the differences are moderate—approximately 15 minutes. Open elective LC takes approximately 15 minutes longer compared with open urgent LC. When there is a conversion from laparoscopic to open surgery, the operative time is significantly extended (**Table 3**).

Length of Postoperative Hospital Stay

The mean postoperative stay is just longer than 2 days for urgent LCs in Sweden, whereas it is approximately 1 day for elective LCs. The differences are small but significant. The mean postoperative stay for open cholecystectomies is 5 to 6 days, and there are virtually no differences between urgent and elective operations; however, probably due to outliers or mass significance because of the huge database, significant differences were noted in 2006. The LCs that are converted have a postoperative stay of 5 to 7 days (**Table 4**). Although the mean postoperative stay has remained fairly constant throughout the years (with the exception of 2005, which was the

start-up year with few hospitals included in the registry), there are large variations in the length of hospital stay between hospitals, probably owing to different case-loads.

Successful Cannulations for ERCPs

The overall rates of successful bile duct cannulation have remained stable throughout the years. The success rate is approximately 92%.

Intraoperative and Postoperative Complications

Intraoperative cholecystectomy complications have remained rather constant, with the exception of the first 2 years. In urgent cholecystectomy, the intraoperative bleeding rate is significantly higher in acute cholecystectomy. The overall postoperative complication rate in urgent cholecystectomy is double that of elective cholecystectomy (11.2% vs 6.1%, respectively), a ratio that has been fairly constant throughout the years (**Table 5**). In ERCP, the overall intraoperative (2.8%) and postoperative (12.0%) complications have remained rather constant throughout the years, with the exception of a slight increase in the pancreatitis frequency of elective ERCP (**Table 6**).

Patient-Related Outcome

Since 2011, the outcome of SF-36 score registration for patients undergoing planned surgery has been reported by 11 units with response rates of at least 50%. The reports are focused on the difference between the preoperative and postoperative outcomes of the bodily pain subscale and physical composite score. The responsiveness of the SF-36 score in patients undergoing cholecystectomy has been assessed,¹¹ confirming SF-36 as an appropriate patient-related outcome measure for patients undergoing gallstone surgery.

Antibiotic and Thromboembolic Prophylaxis in Gallstone Surgery

Antibiotic prophylaxis in elective LC has decreased from 21.0% in 2006 to 12.3% in 2011, whereas approximately half of the patients get antibiotic prophylaxis in open elective cholecystectomy—a figure that has remained fairly constant throughout the years (**Table 7**). Thromboembolic prophylaxis has decreased from 2005 to 2011 in both urgent and elective LC, from 58.4% to 31.3% in urgent LC and from 50.8% to 28.6% in elective LC. In both urgent and elective open cholecystectomy, approximately 70% of the patients get thromboembolic prophylaxis (**Table 8**).

COMMENT

Since its start in May 2005, GallRiks has gradually grown to become a nationwide registry that provides data on quality outcome of gallstone surgery and ERCP. Continuous validation ensures the validity of the data in the

Table 2. Laparoscopic, Open, and Converted Cholecystectomies in Urgent and Elective Surgery

Year	Patients, %					
	Urgent			Elective		
	Laparoscopic	Open	Converted	Laparoscopic	Open	Converted
2005 ^a	44.3	39.8	15.8	90.9	3.4	5.7
2006	62.7	24.6	12.8	87.1	6.7	6.2
2007	60.4	25.1	14.5	88.3	4.8	6.9
2008	61.3	23.5	15.1	89.9	4.1	6.1
2009	67.5	19.1	13.5	91.1	3.8	5.1
2010	69.6	16.3	14.1	91.9	3.5	4.6
2011	74.6	13.5	11.9	91.9	3.2	5.0

^aMay 1 to December 31.

Table 3. Operative Time for Laparoscopic, Open, and Converted Cholecystectomies

Year	Laparoscopic			Open			Converted		
	OT, Mean (SEM), min			OT, Mean (SEM), min			OT, Mean (SEM), min		
	Urgent	Elective	P Value	Urgent	Elective	P Value	Urgent	Elective	P Value
2005 ^a	96 (4.1)	83 (1.5)	.003	87 (5.1)	113 (14.9)	.12	135 (12.8)	144 (10.7)	.49
2006	103 (1.4)	87 (0.6)	<.001	104 (3.0)	111 (4.3)	.25	158 (5.1)	149 (3.6)	.16
2007	103 (1.2)	88 (0.6)	<.001	101 (2.2)	113 (4.5)	.01	150 (3.8)	152 (3.7)	.74
2008	101 (1.0)	87 (0.5)	<.001	102 (2.1)	120 (4.3)	<.001	146 (3.4)	155 (3.5)	.06
2009	99 (1.0)	86 (0.5)	<.001	103 (2.3)	117 (4.1)	.002	152 (3.6)	162 (3.7)	.046
2010	100 (1.1)	86 (0.5)	<.001	103 (2.5)	117 (4.3)	.005	150 (3.8)	167 (4.2)	.002
2011	104 (1.0)	89 (0.5)	<.001	106 (2.8)	123 (5.3)	.006	159 (4.4)	166 (3.8)	.19

Abbreviation: OT, operative time.

^aMay 1 to December 31.

Table 4. Length of Postoperative Stay Following Laparoscopic, Open, and Converted Cholecystectomies

Year	Laparoscopic			Open			Converted		
	LOS, Mean (SEM), d			LOS, Mean (SEM), d			LOS, Mean (SEM), d		
	Urgent	Elective	P Value	Urgent	Elective	P Value	Urgent	Elective	P Value
2005 ^a	2.6 (0.5)	1.7 (0.1)	.09	5.7 (0.8)	7.5 (1.3)	.24	6.6 (1.3)	7.3 (2.4)	.78
2006	2.4 (0.1)	1.8 (0.1)	<.001	6.6 (0.3)	5.3 (0.5)	.03	5.5 (0.4)	4.9 (0.3)	.26
2007	2.5 (0.3)	1.4 (0.1)	<.001	5.9 (0.3)	5.8 (0.5)	.84	6.5 (0.6)	4.6 (0.4)	.003
2008	2.2 (0.1)	1.3 (0.1)	<.001	5.8 (0.3)	5.4 (0.6)	.58	5.3 (0.3)	5.0 (0.4)	.58
2009	2.2 (0.1)	1.1 (0.1)	<.001	5.2 (0.3)	6.6 (0.7)	.07	5.4 (0.4)	5.1 (0.4)	.53
2010	2.2 (0.1)	1.2 (0.1)	<.001	5.6 (0.4)	6.1 (0.9)	.61	5.0 (0.3)	6.6 (0.9)	.10
2011	2.2 (0.1)	1.0 (0.1)	<.001	6.5 (0.4)	5.2 (0.6)	.07	6.7 (1.3)	4.9 (0.4)	.26

Abbreviation: LOS, length of stay.

^aMay 1 to December 31.

registry. The included data are also the base of several studies, the results of which can hopefully contribute to improvement in the treatment of patients with gallstone disease.

In a study by Lundström et al¹² with GallRiks data of 10 927 elective cholecystectomies, no benefit of prophylactic antibiotics was found. Although the authors did not exclude that the results might have been obscured by confounding factors since this was not a randomized trial, the low incidence of postoperative infections does not advocate the use of prophylactic antibiotics in elective cholecystectomy due to all the negative effects of such a strategy, including increased resistance and increased cost.

In the first study of 11 074 ERCPs with descriptive data from GallRiks, Enochsson et al¹⁰ found that the technical quality and complication rates of ERCPs in Sweden were well within international standards.

Because the registry contains so much data, it has become possible to answer questions that surgeons have long discussed but where the material in previous studies often has been too small and where randomized studies would take far too long to answer the specific questions with adequate statistical power. One such issue is whether it is beneficial to provide thromboprophylaxis in patients undergoing LC. In a study of 48 010 cholecystectomies, Persson et al¹³ found that intraoperative bleeding complica-

Table 5. Intraoperative and Postoperative Cholecystectomy Complications in Urgent and Elective Surgery

Complication by Year	Cholecystectomies, %		P Value
	Urgent	Elective	
2005^a			
Intraoperative	12.8	13.4	.82
Bleeding	2.6	1.7	.39
Perforation	0.0	0.4	.39
Bile duct injury	0.0	0.0	
Postoperative	7.7	4.9	.13
2006			
Intraoperative	11.6	11.7	.92
Bleeding	1.9	1.0	.004
Perforation	0.2	0.1	.78
Bile duct injury	0.7	0.4	.06
Postoperative	9.6	5.5	<.001
2007			
Intraoperative	2.8	2.2	.11
Bleeding	1.0	0.6	.04
Perforation	0.1	0.1	.83
Bile duct injury	0.2	0.2	.87
Postoperative	9.5	5.8	<.001
2008			
Intraoperative	3.2	2.6	.13
Bleeding	1.4	0.8	.01
Perforation	0.1	0.2	.34
Bile duct injury	0.3	0.3	.90
Postoperative	11.5	6.2	<.001
2009			
Intraoperative	2.9	2.2	.04
Bleeding	1.3	1.0	.20
Perforation	0.2	0.1	.38
Bile duct injury	0.2	0.3	.53
Postoperative	12.4	6.2	<.001
2010			
Intraoperative	2.1	1.7	.16
Bleeding	1.0	0.6	.03
Perforation	0.2	0.1	.53
Bile duct injury	0.2	0.2	.99
Postoperative	12.3	6.4	<.001
2011			
Intraoperative	2.5	1.6	.004
Bleeding	1.3	0.4	<.001
Perforation	0.2	0.2	.93
Bile duct injury	0.3	0.2	.59
Postoperative	11.4	6.4	<.001

^aMay 1 to December 31.

tions occurred in 1.9% when thromboprophylaxis was administered vs 0.7% in those without prophylaxis. Postoperative bleeding complications also increased: 1.4% with thromboprophylaxis vs 0.7% without thromboprophylaxis. However, there was no significant reduction in thromboembolic events when thromboprophylaxis was given. Another question that has long been debated is whether routine intraoperative cholangiography is good in cholecystectomy.¹⁴⁻¹⁶ In a study with data from 51 041 cholecystectomies from the GallRiks database, it has been shown that the intention to perform intraoperative cholangiography reduced the risk of death after cholecystectomy.¹⁷ There are ongoing studies with GallRiks data to determine whether the intention to perform intraoperative cholangiography can reduce the number of intraoperative bile duct injuries and whether intraoperative ren-

Table 6. Intraoperative and Postoperative Endoscopic Retrograde Cholangiopancreatography Complications in Urgent and Elective Procedures

Complication by Year	ERCPs, %		P Value
	Urgent	Elective	
2005^a			
Intraoperative	2.0	0.7	.34
Bleeding	0.0	0.0	
Postoperative	10.6	11.6	.77
Pancreatitis	1.6	3.6	.20
2006			
Intraoperative	3.1	2.1	.10
Bleeding	0.9	0.7	.46
Postoperative	10.3	10.0	.75
Pancreatitis	2.3	3.8	.009
2007			
Intraoperative	2.7	2.4	.57
Bleeding	0.7	0.6	.80
Postoperative	12.1	10.1	.05
Pancreatitis	2.4	3.6	.03
2008			
Intraoperative	2.7	1.9	.10
Bleeding	0.6	0.5	.48
Postoperative	12.5	13.1	.56
Pancreatitis	3.0	4.2	.03
2009			
Intraoperative	2.5	2.1	.27
Bleeding	0.8	0.3	.02
Postoperative	12.3	11.3	.27
Pancreatitis	2.9	3.8	.06
2010			
Intraoperative	3.8	2.2	.001
Bleeding	0.8	0.5	.26
Postoperative	13.0	12.5	.58
Pancreatitis	2.9	4.5	.002
2011			
Intraoperative	3.8	3.1	.14
Bleeding	0.8	0.4	.11
Postoperative	12.2	12.5	.68
Pancreatitis	3.1	5.6	<.001

Abbreviation: ERCPs, endoscopic retrograde cholangiopancreatographies.
^aMay 1 to December 31.

dezvous ERCP in conjunction with LC can reduce the rate of post-ERCP pancreatitis.

By the results from published studies using GallRiks data as well as the annual reports presented both at the Swedish Surgical Week and at the annual national meetings organized by the GallRiks board, we hope that GallRiks will be able to minimize complications as well as regional differences that still exist in Sweden regarding the treatment of patients with gallstone disease to meet international standards and produce the best possible care for the patient.

The results of this study show significant decreases of 8.7% in the administration of prophylactic antibiotics and 17.8% in thromboembolic prophylaxis from 2006 to 2011 in elective LC, which we believe may be related to the results of the studies performed on GallRiks data and presented both at the annual meetings and later published in the literature.^{12,13} The 11.9% increase in urgent gallstone operations started with the laparoscopic technique from 2006 to 2011 may be the result of introduc-

Table 7. Antibiotic Prophylaxis in Laparoscopic, Open, and Converted Cholecystectomy

Year	Prophylactic Antibiotics								
	Laparoscopic			Open			Converted		
	Urgent	Elective	P Value	Urgent	Elective	P Value	Urgent	Elective	P Value
2005 ^a	26/101 (25.7)	105/732 (14.3)	.003	17/67 (25.4)	8/16 (50.0)	.05	9/27 (33.3)	16/41 (39.0)	.63
2006	425/1138 (37.4)	921/4378 (21.0)	<.001	110/381 (28.9)	92/184 (50.0)	<.001	54/193 (28.0)	111/269 (41.3)	.003
2007	467/1449 (32.2)	844/4823 (17.5)	<.001	139/504 (27.6)	87/185 (47.0)	<.001	69/268 (25.8)	98/313 (31.3)	.14
2008	545/1707 (31.9)	806/5696 (14.2)	<.001	164/572 (28.7)	79/175 (45.1)	<.001	84/321 (26.2)	122/311 (39.2)	<.001
2009	568/1984 (28.6)	839/6787 (12.4)	<.001	117/462 (25.3)	92/167 (55.1)	<.001	80/323 (24.8)	127/302 (42.1)	<.001
2010	514/1848 (27.8)	765/6617 (11.6)	<.001	75/360 (20.8)	80/166 (48.2)	<.001	71/289 (24.6)	100/255 (39.2)	<.001
2011	677/2164 (31.3)	809/6602 (12.3)	<.001	103/334 (30.8)	61/138 (44.2)	.01	87/291 (29.9)	121/286 (42.3)	.002

^aMay 1 to December 31.**Table 8. Thromboembolic Prophylaxis in Laparoscopic, Open, and Converted Cholecystectomy**

Year	Thromboembolic Prophylaxis								
	Laparoscopic			Open			Converted		
	Urgent	Elective	P Value	Urgent	Elective	P Value	Urgent	Elective	P Value
2005 ^a	59/101 (58.4)	372/732 (50.8)	.15	49/67 (73.1)	10/16 (62.5)	.40	22/27 (81.5)	33/41 (80.5)	.92
2006	548/1138 (48.2)	2030/4378 (46.4)	.28	277/381 (72.7)	137/184 (74.5)	.66	138/193 (71.5)	203/269 (75.5)	.34
2007	636/1149 (43.9)	2104/4823 (43.6)	.86	359/504 (71.2)	141/185 (76.2)	.19	187/268 (69.8)	219/313 (70.0)	.96
2008	634/1707 (37.1)	2048/5696 (36.0)	.37	398/572 (69.6)	125/175 (71.4)	.64	195/321 (60.8)	219/311 (70.4)	.01
2009	686/1984 (34.6)	2279/6787 (33.6)	.41	324/462 (70.1)	126/167 (75.5)	.19	199/323 (61.6)	206/302 (68.2)	.08
2010	606/1848 (32.8)	2047/6617 (30.9)	.13	272/360 (75.6)	125/166 (75.3)	.95	182/289 (63.0)	161/255 (63.1)	.97
2011	678/2164 (31.3)	1889/6602 (28.6)	.02	240/334 (71.9)	100/138 (72.5)	.89	195/291 (67.0)	173/286 (60.5)	.10

^aMay 1 to December 31.

ing the parameter of percentage of cholecystectomies with the minimally invasive technique as a quality indicator. Furthermore, it is important for a quality registry to indicate whether something that can affect patient safety changes. One such observation from this study is that the pancreatitis rate in elective ERCP has increased from 3.8% in 2009 to 5.6% in 2011 ($P = .007$), which has to be analyzed further.

For the registry to stay vital and to develop, it is necessary to continue to have high validity and good national coverage. If these conditions are met, the registry can continue to be a solid database for future research that hopefully will improve the quality of treatment of gallstone disease. Furthermore, for participants from both small hospitals and large academic centers to cooperate in research projects, there is a possibility to add variables specific for each unit to the registry. To meet the gradually increasing demand to use data from the registry for research projects, to keep the research projects at a high level, and to avoid conflicts between research groups, a research committee has been assigned by the board to evaluate the applications. GallRiks may also serve as a base for prospective randomized multicenter trials. We thus expect that GallRiks will play a significant role in the future of improving the procedural technique, the safety, and the outcome for the patient.

CONCLUSIONS

A validated quality registry may provide unique opportunities to study the effectiveness of benign surgery. It can also be a valuable tool for quality improvement of the health care delivered and has the potential to yield new knowledge from which national guidelines on management of gallstone disease can be formed. This article describes the process of organizing such a registry as well as the problems and possibilities it provides. A necessary condition for success is that the national surgical community and societies support such a process and realize the benefits from it.

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Correspondence: Lars Enochsson, MD, PhD, Division of Surgery, CLINTEC, Karolinska Institutet and Department of Surgical Gastroenterology, Karolinska University Hospital, SE-141 86 Stockholm, Sweden (lars.enochsson@ki.se).

Author Contributions: Study concept and design: Enochsson, Thulin, Österberg, Sandblom, and Persson. Acquisition of data: Enochsson, Österberg, and Persson. Analysis and interpretation of data: Enochsson, Thulin, Österberg,

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