International Journal for Quality in Health Care 2008; **Volume 20, Number 2:** pp. 144–151
Advance Access Publication: 24 January 2008
10.1093/intqhc/mzm073

Outcome measurement in laparoscopic cholecystectomy by using a prospective complication registry: results of an audit

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Abstract

Objective. The aim was to assess and discuss the utility of a complication registry for determining outcome and delivered care in surgery.

Method. All patients with Laparoscopic Cholecystectomy between 1998 and 2006 were analysed. Complications were prospectively documented and evaluated according to outcome measures mentioned in literature (bile duct injury, morbidity, mortality and conversion rate) for Laparoscopic Cholecystectomy. In addition, all patient files were evaluated for possible risk factors and non-registered complications.

Results. One thousand two hundred fifty four Laparoscopic Cholecystectomies were performed, with 207 complications in 152 (12%) patients. Eighteen (9%) events were additionally found after evaluating all medical files. Thirteen (1%) bile duct injuries occurred, 7% (n = 91) morbidity, no mortality and 18% (n = 226) conversion rate. The probability of complications was significantly higher in patients diagnosed with complicated gallstone disease, ASA 3/4, > 70 years, acute and converted procedures. Thirty % (n = 63) of all documented adverse events reflected issues other than traditionally mentioned outcome measures, categorised as hospital-provider errors or miscellaneous.

Conclusion. Ninety % of all complications in laparoscopic cholecystectomy were documented in our registry. Factors associated with a high probability of complications were identified and 30% of all events reflected issues other than traditionally mentioned outcome measures for Laparoscopic Cholecystectomy. The registry can be used for outcome measurement, however differences in case mix and data collection methods should be taken into account.

Keywords: complication registry, quality of care, outcome measurement, laparoscopic cholecystectomy

Introduction

In Western society, gallstone disease presents as a clinical problem with major morbidity. For the last 20 years, there has been a shift in the surgical management of this disease from an open surgical approach to laparoscopic cholecystectomy. Since the introduction of laparoscopic cholecystectomy much effort has been put in measuring outcome, primarily due to an apparent increase in bile duct injuries [1–7]. A review comparing laparoscopic versus open cholecystectomy showed a shorter hospital stay and a quicker convalescence in favour of the laparoscopic group, and no significant differences in traditional outcome measures [8]. Small incision cholecystectomy was equivalent to the laparoscopic procedure, with no differences in mortality, complications and post-operative recovery [9].

Morbidity and mortality rates have been traditionally used to measure the outcome in a surgery, with much concern about the quality of these data [10–12]. In the Netherlands, as in many other countries, current practice emphasizes healthcare quality and the development of performance indicators (process and outcome measures). The outcome of laparoscopic cholecystectomy in literature has been assessed by many different outcomes measures: 'bile duct injuries, conversion rates, morbidity and mortality'. However, there remains considerable debate which measures should be used to reflect surgical quality, as the various measures have strengths and weaknesses [13, 14]. In our clinic, we register complications prospectively and patient-centred, implying that the registry puts attention on the whole process of care [15]. The intention of this registry was to act as an instrument for quality assurance and to provide an objective

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evaluation of delivered healthcare. The aim of this study was to assess the utility of our complication registry in judging the provided care in cholecystectomy and to discuss its role in measuring outcome and quality of care.

Patient and methods

Patients

All patients ($n = 1254$) in whom laparoscopic cholecystectomy was performed between 1 January 1998 and 1 January 2006 were included. On indication, an open cholecystectomy (e.g. upper abdominal surgery in history) was performed. Small incision cholecystectomy was not routinely performed. Data were collected prospectively in an electronical medical file. The following patient, disease and treatment characteristics were included age, gender, ASA (*American Society of Anaesthesiologists Physical Status*) classification [16], hospital stay, primary diagnosis (symptomatic gallstone disease; cholecystolithiasis/choledocholithiasis or complicated gallstone disease; biliary pancreatitis/cholecystitis), acute or elective procedure, type of surgeon, (consultant/resident) and duration of the procedure.

Patient and treatment subgroups were analysed for the probability of complications.

In patients suspected for bile duct stones, without spontaneous duct clearance, ERCP (Endoscopic Retrograde Cholangio Pancreaticography) was pre-operatively performed. Intraoperative cholangiography was not routinely performed during laparoscopic cholecystectomy.

Methods

Registration of complications. We used the definition of a complication developed by the Association of Surgery of the Netherlands: 'Any state or event, unfavourable to the patient's health that arose during admission or 30 days after discharge that either causes unintentional injury or requires additional treatment'. The registration methods and classifying systems used have been described in detail elsewhere [15, 17]. In brief when a complication was identified by one of the physicians in the surgical team, he or she documented the complication in an electronical medical file. This file is operational all over the hospital and the outpatient clinic that makes recording simple. All complications were discussed in the daily surgical conference. The electronic database consists of two systems for classifying complications: one developed by the Association of Surgery of the Netherlands and the other by the Trauma Registry of the American College of Surgeons. Both systems do not inform about severity of complications. The system of the Association of Surgery of the Netherlands uses four denominators to classify an event: nature of the complication, anatomic localization, specification and additional description. The Trauma Registry of the American College system was originally developed as a complication list to record the morbidity in trauma patient populations [18]. The list explicitly defines complications and uses four-digit-codes. Although the latter list was developed for trauma populations, its design is rather broad and consequently encompasses complications applicable to general surgery.

The registered events were categorized into six groups: (i) surgery/intervention-related, (ii) infection-related, (iii) organ dysfunction (cardiopulmonary, renal, neurological and gastrointestinal), (iv) hospital–provider errors, (v) drug-related and (vi) miscellaneous group.

To asses the quality of the data, we additionally evaluated all patient files for non-registered complications, performed by two authors who were blinded for the complications primary documented in the registry. At the time of evaluation, they were not affiliated with the surgical department. In the past, both worked at the surgical department of the St Elisabeth Hospital and consequently were familiar with the registry and attitude of registration. These additional events were taken along in the total analysis. All patients were seen within 30 days at the outpatient clinic after discharge and if a complication had occurred it was recorded and discussed at the daily team session.

Measuring outcome. The outcome of laparoscopic cholecystectomy is primarily qualified to bile duct injury (0–1%), in-hospital mortality (death during the admission in which the procedure is performed; 0–0.1%), conversion rate (1.5–8.2%), and peri-operative morbidity (2.3–10%) [1–8].

These outcome measures were analysed and compared with the results mentioned in literature. We did not define conversion as a complication. The conversion rate was therefore recorded retrospectively by evaluating all surgical procedures. Bile duct injuries were classified according to the Strasberg classification (Table 1) [19].

Statistical analysis

Statistical analyses were performed through a computerized software package, using Excel (Office XP from Microsoft) and Graph Pad Prism 4. Analysing the probability of complications by group was performed with the chi-square statistic.

Table 1 Strasberg classification of bile duct injuries [19]

Type A: bile leak from cystic duct or liver bed without further injury
Type B: partial occlusion of the biliary tree, most frequently of an aberrant right hepatic duct
Type C: bile leak from duct (aberrant right hepatic duct) that is not communicating with the common bile duct
Type D: lateral injury of biliary system, without loss of continuity
Type E: circumferential injury of the biliary tree with loss of continuity

The analysis of the two group's open and laparoscopic cholecystectomy was performed with the unpaired independent Student's *t*-test, chi-square test and the Mann–Whitney test for non-parametric data.

Results

Between 1 January 1998 and 1 January 2006, 1254 laparoscopic cholecystectomies and 113 primarily open procedures were performed (Table 2). In 152 (12%) patients 189 complications were documented in the registry. After evaluating all patient files, 18 (9%) complications were additionally found (Table 3). The median hospital stay in patients with complications was twice as long compared to the group without 6 (1–36) versus 3 days (1–64). The probability of complications was significantly higher in ASA 3/4 patients; patients with complicated gallstone disease, acute procedures, conversion and patients aged >70 years. Moreover, this probability was also higher when a procedure took longer than 120 min (Table 4). The incidence of adverse events and the number of procedures fluctuated over the years (Table 5). No differences in the investigated characteristics (age, gender, ASA classification, surgeon, diagnosis, acute or elective procedure, blood-loss and duration of the procedure) were found over the years. Surgery/intervention-related complications ($n = 51/25\%$), infection-related ($n = 53/26\%$) and hospital–provider errors ($n = 50/24\%$) were most frequently documented.

Outcome measures

There was no mortality, a morbidity rate (organ dysfunction and Infection-related events) of 7% ($n = 91$), a conversion rate of 18% ($n = 226$) and 13 (1.0%) occurrences of bile duct injury; eight classified as Strasberg Type A, four as Type D and one as Type E. One bile leak from the cystic duct, identified by Endoscopic Retrograde Cholangio Pancreaticography, which was performed for a retaining bile duct stone after cholecystectomy and a per-operative identified lateral injury of the common bile duct, was not recorded in our registry.

Additional evaluation of the converted cholecystectomy group, showed significant more ASA 3/4 patients, acute procedures, complicated gallstone disease and higher age (Table 6).

In the category hospital–provider errors ($n = 50/1254$ (4%)) 32% ($n = 16$) of the events were related to an insufficient pre-operative work up/medication, which resulted in a delay of the procedure. Nine (18%) times an event was found to be a judgement error, e.g. missing abdominal dehiscence during clinical stay; performing an Endoscopic Retrograde Cholangiopancreaticography post-operative as one was not confident with the clip's placed for the cystic duct; continuing a laparoscopic procedure for 3 h; performing a laparoscopic cholecystecyomy in a 85-year-old patient without complaints, giving a urine catheter to a patient on haemodialysis with no remaining diuresis; postponing a procedure resulting in a biliary pancreatitis or performing a procedure in a patient with bronchitis.

Table 2 Number and characteristics of all surgical cholecystectomies (laparoscopic and open) performed between 1 January 1998, and 1 January 2006

	Laparoscopic cholecystectomy ($n = 1254$)	Open cholecystectomy ($n = 113$)	*P*-value
No. of patients with complications	$n = 152$ (12%)	$n = 40$ (35%)	<0.001[a]
No. of complications	$n = 207$	$n = 93$	
Hospital admission (median days + range)	3 (1–64)	11 (2–87)	<0.001[b]
Age (median years + range)	51 (10–91)	64 (27–89)	<0.007[c]
Gender			
Male	318 (25%)	46 (41%)	<0.004[a]
Female	936 (75%)	67 (59%)	
Type of procedure			
Acute	197 (16%)	54 (48%)	<0.001[a]
Elective	1057 (84%)	59 (52%)	
Diagnosis			
Symptomatic gallstone disease	986 (79%)	38 (34%)	<0.001[a]
Complicated gallstone disease	268 (21%)	75 (67%)	
ASA classification			
ASA 1/2	1162 (93%)	83 (73%)	<0.001[a]
ASA 3/4	92 (7%)	30 (27%)	

[a]Chi-square test.
[b]Mann–Whitney test.
[c]Unpaired independent *t*-test.

Table 3 Type and number of registered and non-registered complications in laparoscopic cholecystectomy between 1 January 1998 and 1 January 2006

Category	Registered	Non-registered
Surgical related	$n = 51$	$N = 5$
Post-operative haemorrhage	12	
Abdominal wall dehiscence	7	
Bile leakage–Cystic duct	8	1
Bile duct injury	5	1
Iatrogenic bowel injury	7	
Peritonitis	2	
Pre-operative bleeding subumbilical wound	1	
Galbladder injury with pus excretion—antibiotics started	1	
Iatrogenic injury spleen	1	
Post-operative Ileus	1	
Avulsion cystic duct/cystic artery/haemorrhage (conversion)	5	3
Wound seroma	1	
Organ related	$N = 38$	$N = 2$
Cardiac arrest	2	
Arrhytmia	5	1
Other cardiovascular	1	
Respiratory failure	9	
Congestive heart failure	7	
Post-operative liver function disorders, E.R.C.P.* performed	3	
Peroneus paresis	1	
Myocardial infarction	1	
Transient ischaemic attack/Cerebro Vascular Accident	3	
Pleural effusion	1	
Urinary retention	4	1
Haemorrhage upper Gastro Intestinal	1	
Hospital–provider errors	$n = 50$	$n = 5$
Pre-operative medication	16	1
Procedure postponed due to logistical problems	9	2
Uncertainty of clipped structure; post-operative ERCP[a] performed	1	
Error in diagnosis—pneumonia instead of cholecystitis	1	
Error in judgement	9	
Drain removed without cutting pig tail	1	
No follow up after conservative treatment cholecystitis	1	
Delay in MD response	1	
Cholecystectomy performed in patient without stones	1	
Error in technique (gauze left in situ for > than 5 days)	1	
Medication given to wrong patient	1	
Ascites liquor brought to the wrong laboratory	1	
Dysfunction laparoscopic equipment, conversion necessary	2	2
No follow up in patient with a stent in common bile duct	1	
Incomplete hospital record	2	1
Blood lost during transport to laboratory	1	
Haematoma pharynx after oral intubation	1	
Infection related	$n = 53$	$n = 6$
Pneumonia	11	2
Thromboflebitis	5	1
Intra-abdominal abscess	9	
Wound infection	19	2
Sepsis/SIRS (Systematic Inflammatory Response Syndrome)	5	
Urinary tract infection	4	1

(*continued*)

Table 3 Continued

Category	Registered	Non-registered
Miscallenous	$n = 13$	$N = 0$
Procedure postponed due to cardiac complaints	1	
Pre-operative pulmonary function disturbed	1	
Patient left the hospital without making follow up appointment	1	
Re-admission directly after procedure because of abdominal pain	2	
Procedure postponed while patient was ill	1	
Cicatrical hernia after gynaecological laparoscopy	1	
Unable to contact patient about date surgical procedure	1	
Bad communication between anaesthesiologist and patient, prior to intubation	1	
Post-operative common bile duct stones	2	
Technical difficulties to intubate the patient	1	
Post-operative leucopenia with unknown etiology	1	
Drug related	$n = 2$	$N = 0$
Hypoglycaemia	1	
Morfine induced respiratory failure	1	
Total	207	18 (9%)

[a]ERCP: Endoscopic Retrograde Cholangio Pancreaticography

Table 4 Patient and treatment characteristics of 1254 laparoscopic cholecystectomies and the proportion of complications, between 1 January 1998 and 1 January 2006

	No. of patients ($n = 1254$)	No. and rate of patients with complications ($n = 152$)	*P*-value[a]
Gender			
Male	318	56 (18%)	<0.003
Female	936	96 (10%)	
ASA Classification			
ASA 1/2	1162	125 (11%)	<0.002
ASA 3/4	92	27 (29%)	
Diagnosis:			
Symptomatic gallstone disease	986	103 (10%)	<0.002
Complicated gallstone disease	268	49 (18%)	
Resident	973	110 (10%)	0.1482
Consultant	281	42 (15%)	
Type of procedure:			
Acute	197	41 (21%)	<0.003
Elective	1057	111 (10%)	
Conversion			
Yes	226	55 (24%)	<0.001
No	1028	97 (9%)	
Age (years):			
<30	91	5 (5%)	<0.001
30–39	208	17 (6%)	

(*continued*)

Table 4 Continued

	No. of patients ($n = 1254$)	No. and rate of patients with complications ($n = 152$)	*P*-value[a]
40–49	241	24 (10%)	
50–59	271	17 (6%)	
60–69	219	34 (16%)	
> 70	224	55 (25%)	
Time of procedure			
<60 min	495	45 (9%)	<0.001
60–120 min	710	93 (13%)	
>120 min	49	14 (29%)	

Total of all registered events and additional events found in the medical files.
[a]Chi-square test.

In the category Miscellaneous, 13 different events were found, ranging from rude communication between physician and patient, to postponement of a procedure due to illness and non-specific post-operative abdominal complaints of the patient.

Discussion

Healthcare systems have given attention to develop quality measures with the aim for quality improvement. Measuring complications has been the most suggested tool to assess outcome in surgery. By evaluating 1254 laparoscopic cholecystectomies, the present study analysed the usefulness of a complication registry to measure the outcome and provided care.

Validity

The usefulness of a clinical database depends strongly on the quality of the collected data. The accuracy of documenting complications and identifying true frequency is crucial when used as outcome measurement tool [20]. Therefore, we tried to identify the true frequency by analysing all patient files for non-registered complications. Although there inevitably will be slight inaccuracies in the electronic medical patient file this is the most valid way to achieve appropriate information. Eighteen additional complications were found after analysing all medical files, resulting in 189 (91%) correctly documented events. However, significant complications were missing, as post-operative haemorrhage, bile leak from the cystic duct and pre-operative bile duct injury. A regular quality control of the data is needed for preventing such data errors [21].

Outcome measures

Bile duct injury. We found 1% ($n = 13$) bile duct injury's, which is relatively high comparing literature.

However, after classifying our leaks according to Strasberg, 8 of 13 cases were recorded as Type A (bile leak from cystic duct or liver bed without further injury), with

Table 5 Number of patients and complications in laparoscopic cholecystectomy between 1 January 1998 and 1 January 2006

Type	1998	1999	2000	2001	2002	2003	2004	2005	
Surgery/ intervention	3	5	9	3	4	5	13	9	51
Infection-related	6	9	8	4	3	3	10	10	53
Organ-dysfunction	4	2	11	3	4	4	4	6	38
Hospital–provider errors	3	1	7	4	5	4	9	17	50
Drugs-related	0	0	0	0	1	0	1	0	2
Miscellaneous	0	2	0	3	5	0	0	3	13
Total	16 (15%)	19 (13%)	35 (25%)	17 (15%)	22 (16%)	16 (10%)	37 (19%)	45 (17%)	207
No. of patients	13	13	22	15	19	11	24	35	152
No. of procedures	105	148	138	117	138	155	192	261	1254

Total of all registered events and additional events found in the medical files.

Table 6 Characteristics of patients with laparoscopic cholecystectomy and conversion, performed in the period between 1 January 1998 and 1 January 2006

	Conversion cholecystectomy ($n = 226$)	Laparoscopic cholecystectomy ($n = 1028$)	*P*-value
ASA			
1/2	$n = 189$ (84%)	$n = 973$ (95%)	<0.001[a]
3/4	$n = 37$ (16%)	$n = 55$ (5%)	
Procedure			
Acute	$n = 103$ (46%)	$n = 94$ (9%)	<0.001[a]
Elective	$n = 123$ (54%)	$n = 934$ (91%)	
Age (median + range)	62 (16–91)	49 (10–86)	<0.001[b]
Diagnosis			
Symptomatic gallstone disease	$n = 92$ (41%)	$n = 858$ (83%)	<0.001[b]
Complicated gallstone disease	$n = 134$ (59%)	$n = 170$ (17%)	

[a]Chi-square test.
[b]Unpaired independent *t*-test.

minor consequences. Comparison with other centres is rather difficult, because not all specify their injuries [2–4, 7].

Mortality and morbidity. There was no mortality. All organ dysfunction and infection-related events, were defined as morbidity ($n = 91/1254$, 7%). Keus *et al*. found a total of 63 (5.4%) complications in a review comparing laparoscopic cholecystectomy versus open cholecystectomy. If we analyse their results for organ dysfunction and infection-related complications, the incidence will be 2.6% ($n = 30$) [8]. However, these results were very heterogeneous making comparisons rather difficult.

Conversion. Two hundred and twenty-six (18%) procedures were converted, which is high. A recent report of Ishizaki *et al*. showed a 7.5% conversion rate [6]. They found that the incidence of complicated gallstone disease and acute procedures were significantly higher in the converted group, which was also seen in our study. Our protocol in complicated gallstone disease follows the guidelines for optimal surgical timing as mentioned in literature [22].

However, with this conversion rate we could question ourselves if the timing of the intervention has been most optimal chosen and the guidelines will be re-discussed in our surgical team. This brings us to the point whether conversion should be documented as a complication, because it could be an important choice in the prevention of major complications. In the Netherlands, the use of conversion rate as a performance indicator has been heavily discussed. In the end, it was discarded as conversion to open surgery was seen as a sign of experience that enables the avoidance of duct injury. Conversion informs about the procedure and is influenced by several factors, such as advanced patient age, male sex, acute cholecystitis, common bile duct stones with previous endoscopic sphincterotomy, which is also seen in our study [6, 22]. Diverse adverse events, not directly related to surgical procedures, were categorized as hospital–provider error and miscellaneous ($n = 63/30\%$). These events enclose, for instance, errors in the logistic process, judgement or diagnosis and are not reported in surgical literature.

The registry's role in measuring outcome

Using outcome measures for evaluating quality of care requires risk adjustment, to control for case-mix [5]. In our study, the probability of complications was significantly higher in patients diagnosed complicated gall stone disease, ASA 3/4, age > 70 years, acute procedures, conversion and procedures lasting more than 2 h. Differences found in outcome measures should be applied with great care since there are many pitfalls when using such data in quality assessment. For instance, vulnerable patients for cholecystectomy are often excluded in randomization and have worse outcome than a standard population [23].

Quality of surgical practice has been improved by a local audit [24]. Continuous monitoring and discussion of all adverse events, as in our daily surgical conference, will form a base for consistent data. The registry, however, lacks a regular local audit, which is necessary for quality monitoring. Therefore, we intend to introduce a three-monthly audit of all procedures and documented adverse events in our clinic. A major issue, and difficult to answer, will be to define what reflects good quality of care and how to measure it for different surgical procedures? Diversity in outcome, as analysed here for laparoscopic cholecystectomy, will probably be the case for any other procedure. Also a limitation of the study is the small numbers of events over the years, which has been mentioned as a pitfall for quality monitoring, especially in low risk procedures as laparoscopic cholecystectomy [13].

Improving and discussing the quality of quality measurement deserves full priority and physicians should be increasingly involved in developing outcome evaluation programs [25].

Nowadays, the approaches to surgical quality and safety ask for a much wider assessment of factors relevant for surgical

outcome; so-called operations profile. Strictly necessary is a systematic approach, in which the outcomes of surgical care are determined by structural aspects of the system (personnel, environment and infrastructure) as well as the process (what is actually done in providing and receiving care) [26].

Conclusion

Ninety percent of all complications in laparoscopic cholecystectomy were recorded correctly in our database. Factors associated with a high probability of complications were identified and 30% of all events reflected issues distinctive from traditionally mentioned outcome measures in laparoscopic cholecystectomy. A high conversion rate (18%) was found, considerably in acute procedures and patients with complicated gallstone disease.

Using the registry for outcome measurement can be done on the condition that adjustment for differences in case mix and data collection methods will be incorporated. The registry's role for monitoring and improving quality is limited in its current form, which has resulted in the introduction of a local regular audit.

Acknowledgements

We would like to make an acknowledgement to prof. Dr. G.L.M. van Heck, University of Tilburg, who critically reviewed the manuscript once.

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Accepted for publication 09 December 2007