Title Page

Full Title: The Incidence of Symptomatic Remnant Gall Bladder: A Population Study.

Running Title: Symptomatic Remnant Gall Bladder

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Abstract

Background:

Subtotal cholecystectomy is utilised in conditions of high risk to critical structures, like the common bile duct. However, the remnant gall bladder may become symptomatic and require a completion cholecystectomy for treatment. This second procedure can itself be a risk to critical structures.

Aims:

To establish the incidence of redo-cholecystectomy and identify risk factors that lead to subtotal cholecystectomy and repeat operation in a review of state-based practices for cholecystectomy.

Method:

A search of state coding records relating to cholecystectomy from 1998 to 2016. Patients who were coded for cholecystectomy-related procedures on different dates were identified. Patients who underwent the procedures within 6 months were excluded to avoid acute post-operative complications and gall bladder malignancy.

Results:

210,719 cholecystectomies were performed. 1133 required repeat procedure. 616 were excluded, leaving 516 (0.25%) cholecystectomy patients requiring a second cholecystectomy. The subsequent operation was more likely to be an emergency procedure; involve transcystic bile duct exploration, adhesiolysis and require ICU admission post-operatively. A repeat cholecystectomy was more likely to occur after having the primary procedure at a public hospital and when an intra-operative cholangiogram was not performed. Over the study period, the rate of repeat cholecystectomy increased from 0.02% to 0.6%. Incidentally, the rate of intra-operative cholangiogram during a primary cholecystectomy increased from 43% to 73%.

Conclusions:

Repeat cholecystectomy is an uncommon procedure. A second cholecystectomy is a more complex and likely to require ICU support. Referral to a tertiary hepatobiliary unit is recommended.

Keywords: Hepatopancreaticobiliary Surgery, General Surgery, Subtotal Cholecystectomy, Gall bladder

Introduction

Cholecystectomy is one of the most common general surgical procedures performed. As a laparoscopic procedure, it has evolved into a safe operation and is widely utilised in general surgical training. The most significant intra-operative complication is common bile duct injury, with an incidence of 0.4-1.4%^{1,2}. This injury is associated with significant long term morbidity to the patient, including stricturing and recurrent cholangitis. Key to performing a laparoscopic cholecystectomy safely is establishing the critical view of safety, dissection of Calot's triangle, and correctly identifying the cystic duct, prior to transection¹. In this way, common bile duct injury can be minimised. With evidence supporting early cholecystectomy in the management of acute cholecystitis, surgeons are increasingly exposed to a hostile Calot's triangle, with significant inflammation and scarring³. This makes achieving a critical view more difficult and hazardous. In this setting, several alternative procedures may be performed, including cholecystostomy, sub-total cholecystectomy and conversion to an open cholecystectomy.

A subtotal cholecystectomy is utilised in conditions where risk to critical structures is high when attempting to obtain a critical view of safety¹. Two broad techniques have been described⁴. The reconstituting method closes Hartman's pouch to create a gall bladder remnant, using sutures or stapler. The fenestrating method leaves Hartman's pouch open, and the cystic duct opening is closed from within. Both of these procedures rely on clearance of calculi from Hartmann's pouch prior to closure. Significant morbidity occurs with both of these techniques. This includes a bile leak rate of 18% for fenestrating and 7% for reconstituting, recurrent biliary events of 9% fenestrating and 18% reconstituting⁵. In a systematic review, the most common indications for subtotal cholecystectomy were severe cholecystitis (72.1%), cirrhosis and portal hypertension (18.2%), then gall bladder empyema or perforation (6.1%)⁶. 72.9% of these procedures were completed laparoscopically. The bile duct injury rate was 0.08% in this review.

The true incidence of symptomatic gall bladder remnant is somewhat unknown. This may be in part be due to a failure of patient disclosure to the outcome of their procedure, and awareness that a gall bladder remnant remains⁷. The diagnosis of a symptomatic gall bladder remnant is dependent on proving that the remnant exists using axial biliary imaging. Once established, the decision to proceed to a completion cholecystectomy weighs the risk of surgery against the impact of the patient symptoms. Redo or completion cholecystectomy is a complex procedure, requiring division of adhesions, high likelihood of conversion to an open procedure, and increased risk of common bile duct injury^{7,8}.

In this review of state-based operative practices for cholecystectomy, the primary aim was to establish the incidence of redo-cholecystectomy and secondly identify risk factors that lead to subtotal cholecystectomy and completion surgery.

Methods

Victoria is the second most populous state in Australia, with an approximate population of 6.264 million people over 237,629 sq kilometres⁹. Surgical care is provided in regional hospitals, with tertiary specialised hepatobiliary centres in Melbourne. Surgical procedures are also performed in the private and public hospital sector. To enable funding, cholecystectomy is assigned a specific CMBS code, which includes open procedure (30443), laparoscopic procedure (30445), conversion to open procedure (30446), associated trans-cystic exploration (30448) and choledochotomy (30449). An intra-operative cholangiogram is coded separately (30439). There is no code for completion or revision cholecystectomy.

A de-identified search of the Victorian Department of Health coding records for the above procedural codes were performed from 1998 to 2016. The start date of 1998 was selected due to the widespread competency and popularity of the laparoscopic approach in the local environment. Of these, patients who were coded for

a cholecystectomy-related procedure on separate dates were identified as having had a redo-procedure. Patients who underwent two procedures within six months of the index procedure were excluded. This was to avoid including return to theatre for acute post-operative complications (like bleeding or bile leak) and further surgery related to gall bladder malignancy.

Data was collected for all patients with a cholecystectomy-related code. This included demographics, indications, emergency/elective, procedure location (public/private, regional/metropolitan, tertiary/non-tertiary hepatobiliary centre) and cholangiography use. Statistical analysis was performed using SPSS¹⁰ with Chi-squared test for significance of risk factors for requiring a completion cholecystectomy.

Results

210,719 cholecystectomies were performed from 1998 to 2016. 1133 (0.53%) required a repeat procedure. 616 patents were excluded, leaving 516 (0.25%) cholecystectomy patients requiring a second cholecystectomy. Demographics for all cholecystectomies are listed in table 1, alongside the 516 patients with repeat cholecystectomies. Of all the cholecystectomies, 38% were performed in a rural setting, 19.7% were performed in tertiary hepatobiliary centres, and 42.4% in private hospitals. 90.5% of all cholecystectomies were completed laparoscopically, with 0.25% requiring conversion to an open procedure, and the remainder commenced as an open procedure. Intraoperative cholangiogram was used in 62.86% of all cases.

Redo-Cholecystectomy

516 patients required a second procedure. 92.83% of patients had the first procedure as a laparoscopic procedure, with none having been converted to open procedure. This was statistically significant when compared to the total number of cholecystectomies ($p=0.04$). An intraoperative cholangiogram at the first procedure,

was less frequently performed, when compared to the overall cohort, at 58.53% ($p=0.049$). The first procedure indication was more likely to be chronic cholecystitis (65.69%, $p=0.0001$). Compared to the overall cohort, the patients requiring a repeat cholecystectomy were more likely to be female (81.4% vs overall 70.4%, $p<0.0001$) and younger (41.83 yo vs overall 49.12 yo, $p<0.0001$). A repeat cholecystectomy was less likely to occur if the patient had their initial operation performed in a rural setting, 0.20% vs 0.27% for metropolitan patients ($p=0.009$), or in a private institution (0.21% vs 0.27%, $p=0.008$). There was no difference for emergency or elective presentation. There was a non-statistically significant trend towards more repeat procedures occurring at a tertiary hepatobiliary centre, 0.28% to 0.24% ($p=0.09$).

Regarding the second cholecystectomy, the procedure occurred approximately 6 years after the initial procedure, extrapolating from the age difference in first and second procedures. The cholecystectomy was completed laparoscopically in 87.40% of patients. 72.87% of patients had an intraoperative cholangiogram performed ($p<0.0001$ when compared to overall). The second procedure was more likely to require division of adhesions — laparoscopic adhesiolysis 21.71% vs. 16.26% (overall), $p=0.008$, or extensive adhesiolysis (up to 2 hrs) 7.17% vs. 2.83% (overall), $p<0.0001$. A transcystic bile duct exploration was required in 3.10% repeat procedures. Patients were more likely to require an ICU admission (>1 hour) after their second cholecystectomy, 7% compared to 4.5% overall, but reporting in this group was incomplete. The indication for a second cholecystectomy was mostly chronic cholecystitis, in keeping with the overall cohort. However, 7.49% of patients had cholelithiasis without cholecystitis, higher than the overall rate of 5.42% ($p=0.021$). The second procedure was more likely to be performed in a metropolitan setting (75% vs 61%, $p<0.0001$), and proportionally more in tertiary hepatobiliary centres.

Repeat cholecystectomy and intraoperative cholangiogram over time

Over the study period from 1998 to 2016, there had been an increasing incidence of repeat cholecystectomy and utilisation of intraoperative cholangiogram. Figure 1 demonstrates the rate of repeat cholecystectomy on

an annual basis. The first incidence of a repeat cholecystectomy was in 2000, with a rate of 0.03% for that year. This had increased to 0.67% by 2016. Figure 2 demonstrates intraoperative cholangiogram usage rates, with a gradual increase from 42.75% in 1998 to 73.06% in 2016.

Discussion

The true incidence of the symptomatic remnant gall bladder is unknown. However, as a surrogate marker, those symptoms that can be attributed to and correspond with a remnant gall bladder will undergo a redo-cholecystectomy. Persistence of biliary symptoms following cholecystectomy has historically been labelled post-cholecystectomy syndrome with a reported incidence of around 10%¹¹. With increasing availability and use of high resolution axial imaging modalities such as CT and MRI, it is increasingly recognised that these symptoms may be attributable to a remnant gallbladder. In two case series presented by Singh et al⁷ and Concors et al⁸, diagnosis of the remnant gall bladder is often challenging. Furthermore, Singh et al identified that reporting and disclosure of a subtotal cholecystectomy was absent 71% of these cases⁷. Both of these case series place particular weight on imaging, CT and MRI, to confirm the existence of the remnant and to define the anatomy prior to proceeding.

In our patient cohort, the incidence of repeat cholecystectomy is 0.25%, for the period of 1998 to 2016. However, throughout this time period, the trend for redo-cholecystectomy increased, from 0.03% in 2000 to 0.67% in 2016. This rate increase may be due to the greater awareness of symptoms occurring from the remnant gall bladder, with these patients being investigated and identified. Given the average time between procedures is approximately 6 years, a considerable lag time exists in either symptom occurrence or recognition of the problem. Alternatively, the rate increase may be a reflection of operative practices, with a reluctance to convert to an open procedure. In the 516 patients who required a redo-cholecystectomy, none were listed as a laparoscopic converted to open procedure. As the laparoscopic procedure has become the standard of

care, exposure to and competence with an open procedure may have decreased in surgeons ⁸ The reluctance to convert may also reflect the patient's expectation to receive a laparoscopic procedure.

A redo-cholecystectomy was more likely to be required in younger female patients, with chronic cholecystitis as the indication for the initial surgery. Consider each demographic risk factor in turn. Women have a higher incidence of cholelithiasis ¹² and younger patients will have a longer period of time to form calculi. In a reconstituting sub-total cholecystectomy technique, a "mini-gall bladder" is created, retaining stones or recreating the conditions where stones are formed ⁴. In this series, 7.49% of patients had stones without cholecystitis, suggesting the possibility of stones being trapped or reformed. Lastly, chronic cholecystitis leads to dense scar within Calot's triangle and difficulty in safely dissecting the critical view of safety, a common indication for subtotal cholecystectomy ⁶.

This review identified that patients requiring a redo-cholecystectomy were more likely to have the initial procedure performed in a metropolitan centre and a public hospital setting. There may be several reasons for this. Firstly, the case selection bias of more complex cases being transferred to tertiary centres (both metropolitan and public) for management. This selection bias is demonstrated by the majority of second cholecystectomies, a more complex procedure, being performed in a metropolitan setting. Secondly, public hospital accounts for more training than private institutions, where the decision by trainees or junior surgeons to perform a subtotal cholecystectomy may reflect their own ability or lack of supervision.

The second (redo) cholecystectomy procedure typically occurred 6 years from the first, with a higher likelihood of adhesiolysis, transcystic bile duct exploration and an ICU admission. Overall, this reflects the complexity of the procedure. The rate of bile duct injury in redo-cholecystectomy has been reported by Concors et al as 1 in 14 via an open approach ⁸. This is significantly higher than the 0.4-1.4% bile duct injury rates for laparoscopic cholecystectomy ¹.

An intraoperative cholangiogram has not been shown to prevent bile duct injury, but does facilitate early identification of bile duct injury ¹. In the redo-cholecystectomy group, an IOC was less likely to be performed at the initial operation. The necessity of performing a cholangiogram is often debated, citing the need to perform a ductotomy as the source of bile duct injury ⁸. However, the cholangiogram provides the benefit of confirming duct anatomy, including the length of the cystic duct, and identifying duct calculi, including the cystic duct. In this cohort, the trend of practice is to perform a cholangiogram as standard, demonstrated by the increasing rate of cholangiogram over the time period to 73%. This may reflect the perceived benefits and the training received in standard rather than selective cholangiography.

There are several limitations with this cohort study. The first is the generalised nature of the data collected. Individual cases were unable to be interrogated more closely to examine the symptoms and investigations leading toward the repeat procedure, or the circumstances leading to sub-total cholecystectomy.

Secondly, by excluding repeat cholecystectomies within the first 6 months, there is the potential to miss a small number of early redo-procedures. However, published case series of repeat cholecystectomies show an average 18 to 24 month time interval from first and second procedure ^{7,8}. Thirdly, the data collected is limited by the completeness of the state-based records, where incomplete coding and recording (ie. ICU stay) was unable to be tracked and collected.

The incidence of redo-cholecystectomy in this cohort is 0.25% for the time period of 1998 to 2016. However, the incidence is rising annually. The second cholecystectomy is likely to occur 6 years later than the primary procedure; in a metropolitan hospital and with an increased likelihood of adhesiolysis, bile duct ex-

ploration and ICU admission. The procedure may be avoided if an initial complete cholecystectomy is performed, which may require conversion to an open procedure. If a second procedure is required, transfer to specialist hepatobiliary unit is recommended.

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Nil

Disclosure Statement

The authors have no conflicts of interest or financial ties to disclose.

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Figure Legend**Figure 1. Initial and repeat cholecystectomy over time.**

Number of first and second cholecystectomies annually. Rate of second cholecystectomy as a percentage of all cholecystectomies, demonstrating an increasing annual trend.

Figure 2. Cholangiography over time

Number of cholecystectomy and cholangiograms per annum, and percentage of cholangiograms occurring with cholecystectomies.

Table 1. Key Features

Key features of the cases, grouped as demographic, procedural, geographical location and operative indication. P-values represent single-tailed chi-square test for significance in the redo-cholecystectomy group when compared to all cholecystectomies.

	All Cholecystectomies	Redo-Cholecystectomy	
		1st Cholecystectomy	2nd Cholecystectomy
Number	210719	516	516
Age (years) — mean	49.12+/-17.2(0-85)	41.83+/-15.52(5-85)	47.6+/-15.52(10-85)
(range)		p<0.0001	
Female	148330 (70.4%)	420 (81.4%)	420 (81.4%)
		p<0.0001	
Private	89617 (42.5%)	353 (38.7%)	191 (37%)
		p=0.081	P=0.012
Elective	168677 (80.0%)	415 (80.4)	379 (73.4%)
		p=0.8205	P=0.0002
ICU Admission	9435 (4.5%)	10 (1.9%)	36 (7%)
		P=0.0044	p=0.006
<u>Procedure</u>			
Laparoscopic	191330 (90.53%)	479 (92.83%)	451 (87.40%)
		P=0.04	P<0.0001
Open	14938 (7.07%)	30 (5.81%)	44 (8.53%)
		P=0.26	P=0.2
Lap to Open	532 (0.25%)	0 (0%)	1 (0.19%)
			P=0.79

	All Cholecystectomies	Redo-Cholecystectomy	
		1st Cholecystectomy	2nd Cholecystectomy
With CBDE	2980 (1.41%)	5 (0.97%)	16 (3.10%)
		P=0.4	P=0.0012
Cholangiogram	132857 (62.86%)	302 (58.53%)	376 (72.87%)
		P=0.049	P<0.0001
Adhesiolysis	34369 (16.26%)	69 (13.37%)	112 (21.71%)
		p=0.076	p=0.0008
Location			
Metropolitan	127528 (61%)	341 (66%)	389 (75%)
		p=0.20	p<0.0001
Tertiary Hepatobiliary Unit	41543 (19.7%)	117 (22.7%)	127 (24.6%)
		p=0.019	p<0.0001
<u>Indications</u>			
Acute Cholecystitis	34223 (12.81%)	81 (14.78%)	61 (9.93%)
		p=0.168	p=0.03
Chronic Cholecystitis	153103 (57.31%)	360 (65.69%)	353 (57.49%)
		p=0.0001	p=0.928
Cholelithiasis without cholecystitis	14372 (5.38%)	27 (4.93%)	46 (7.49%)
		p=0.641	p=0.21

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