ORIGINAL CONTRIBUTIONS





Asymptomatic Cholelithiasis and Bariatric Surgery: a Comprehensive Long-Term Analysis of the Risks of Biliary Disease in Patients Undergoing Primary Roux-en-Y Gastric Bypass

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Abstract

Purpose Currently, there is little consensus on management of the in situ gallbladder of patients undergoing gastric bypass. Our aim was to evaluate outcomes of selective concomitant cholecystectomy (CCY) and long-term biliary outcomes after Roux-en-Y gastric bypass (RYGB).

Materials and Methods We performed a retrospective analysis of patients undergoing laparoscopic RYGB (LRYGB) between 2008 and 2018. Chi-square, Fisher's exact, or Wilcoxon rank-sum tests were used to compare outcomes. Concomitant CCY was performed on a selective basis.

Results Three thousand and four patients underwent a RYGB (LRYGB n = 2458, open RYGB n = 546). Fifty-two percent (n = 1670) of patients had undergone CCY at any stage. Thirty-one percent of patients (n = 933) had CCY prior to RYGB, 13% (n = 403) had a concomitant CCY and 13% (n = 214) of the remainder required interval CCY. In the LRYGB subgroup, 29.9% (n = 735) had a prior CCY; 12.9% (n = 202) of those with an in situ gallbladder required interval CCY. Those who underwent concomitant CCY/ LRYGB (n = 328) were compared with LRYGB alone (n = 1231). The concomitant CCY group was significantly older and had higher percentage of females, higher preoperative BMI, higher Charlson Comorbidity Index, and a higher medication count. There was no significant difference in BMI nadir, length of stay, complications, or mortality. Interval CCY had a higher incidence of CCY-related complications.

Conclusion Our study suggests a higher percentage of bariatric patients with in situ gallbladders will undergo interval CCY than documented in recently published guidelines. Concomitant CCY can be performed without an increase in length of stay or complications. Interval CCY may be associated with a higher complication rate.

Keywords Gastric bypass · Bariatric · Asymptomatic cholelithiasis · Cholecystectomy · Biliary · Complications · MBSAQIP

Introduction

The exponential rise in adult and pediatric obesity rates is rapidly becoming the most pressing public health issue of our time [1]. Recent estimates from the CDC indicate that 39.8% of the US adult population is suffering from obesity [2]. Bariatric surgery is currently the most effective therapy to

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studies have demonstrated that up to 40% of these patients will become symptomatic and require intervention [16], which stands in contrast to the 10–25% reported progression rate from asymptomatic to symptomatic gallstone disease large population studies [17].

In the era of open bariatric surgery, routine concomitant cholecystectomy (CCY) was advocated, regardless of presence of gallbladder symptoms or pathology [18]. In the laparoscopic era, some controversy has persisted regarding the appropriate management of those patients with in situ gallbladders at the time of bariatric surgery. Literature exists to support all approaches including routine concomitant CCY [6, 19], or selective concomitant CCY based on either symptoms/preoperative ultrasound findings [20, 21] or intraoperative findings [10, 22]. Routine postoperative ursodeoxycholic acid (UDCA) administration is used in several bariatric centers but documented poor patient compliance with a significant additional oral medication regimen appears to have somewhat limited more widespread adoption [10, 22, 23]. An additional strategy for patients with an in situ gallbladder after bariatric surgery is to perform CCY only if/when the patient develops symptoms [24, 25]. Several papers have documented increased complications, operative times, and lengths of stay for concomitant CCY [14, 26]. A large population-based study from the USA published in 2011 demonstrated that overall, there was a significant decline in the rate of concomitant CCY between 2001 and 2008, with a small percentage of patients undergoing both procedures more recently [15]. On the other hand, a recent review of the Metabolic and Bariatric Surgery Quality Improvement Project (MBSAQIP) database demonstrated concomitant CCY can be performed safely with laparoscopic sleeve gastrectomy and Roux-en-Y gastric bypass with no increase in length of stay, 30-day mortality, or major complications [27]. A small increase in minor complications was noted, and an average of 27 min was added to operative times. Other authors have shown that while concomitant CCY leads to similar longer operative times and length of stay, it does not lead to higher readmission, reoperation/reintervention, or morbidity and mortality rates [28]. The recent systematic review published by the ASMBS Foregut Committee has recommended against pre- or postoperative screening for gallbladder-related pathology in the absence of symptoms for sleeve gastrectomy and RYGB patients [29]. Additionally, the guidelines recommend against CCY in asymptomatic cholelithiasis. The risk of developing gallstone disease appears to be highest in the first 18 months [14] but appears to be elevated out to 3 years [7].

The aim of this study was to evaluate our experience with a selective approach to concomitant CCY with RYGB. The primary objective was to evaluate the impact of concomitant CCY on standard bariatric surgery outcomes including length of stay and 30-day readmission, as well as biliary-related surgical complications. The primary outcomes of the study were 30-day mortality, 30-day unplanned ICU admission, 30-day reinterventions, and 30-day all-cause readmissions. The secondary objective was to evaluate the incidence surgical indications and morbidity associated with interval CCY after primary RYGB.

Materials and Methods

The institutional setting was a single tertiary-referral MBSAQIP-accredited academic medical center. Institutional review board approval was obtained prior to initiation of the study. All patients undergoing initial RYGB after April 2008 were treated with an evidence-based care pathway for preoperative evaluations, perioperative care, and postoperative follow-up. Adherence to this pathway (ProvenCare Bariatric®) was routinely measured and optimized. The program has been found to provide both significantly reduced length of stay and complications after bariatric surgery [30].

Retrospective analysis of a prospectively maintained database of all patients who underwent RYGB (open and laparoscopic) between January 2008 and December 2018 was utilized. We identified study cohorts defined by the absence or presence and timing of CCY. Patient charts were reviewed using an automated search algorithm to extract the desired variables, and errors/inconsistencies were manually reviewed and corrected where necessary. All patients in our bariatric program undergo routine preoperative right-upper quadrant ultrasound regardless of symptoms or prior CCY (as hepatic steatosis levels are also reported). The previous department chair performed open RYGB and performed an open CCY in all cases unless there was significant technical difficulty (see Table 1), consistent with common practice in the era of open bypass surgery. This surgeon stopped performing this operation in 2012. The open RYGBs were included, which is consistent with the studies included in the current ASMBS guidelines. For the remaining patients undergoing laparoscopic Roux-en-Y gastric bypasses (LRYGB), selective concomitant CCY for symptomatic biliary disease, imaging-confirmed cholelithiasis, or other biliary pathology requiring CCY (e.g., polyps > 1 cm). We do not routinely prescribe ursodeoxycholic acid postoperatively.

Statistical Analysis

Chi-square, Fisher's exact, or Wilcoxon rank-sum tests were used to compare outcomes where appropriate. p value statistical significance was set at < 0.05. Univariate analysis was performed to compare patient demographics and comorbid conditions amongst cohorts. Univariate analysis of categorical variables was performed using the chi-squared test and continuous variables were analyzed using the student t test for normally distributed data or Wilcoxon's rank-sum test for non-normal data. Normally distributed data was reported as mean (SD); non-normally distributed data was reported as

Table 1 Demographics of laparoscopic and open RYGB cohort

	Prior CCY ^a n = 931	Concomitant RYGB ^b /CCY $n = 504$	RYGB only $n = 1569$	Total cohort $n = 3004$	p value
Female (%)	829 (89)	397 (79)	1166 (74)	2392 (80)	0.056
Mean age, years (SD)	47.4 (11.4)	46.2 (11.3)	44.1 (8.1)	45.5 (11.5)	0.001
Medication count (SD)	6.8 (4.2)	6.1 (3.5)	5.5 (3.5)	6.0 (3.8)	0.0001
CCI ^d score (SD)	4.8 (2.4)	4.9 (2.2)	4.4 (2.2)	4.7 (2.3)	0.006
Initial BMI ^c (SD)	47.3 (8.1)	50.7 (10.3)	47.5 (8.1)	48.0 (8.6)	< 0.0001
Most recent BMI (SD)	33.9 (7.2)	36.0 (8.8)	34.7 (8.9)	34.5 (8.4)	0.003
% TWL change (SD)	- 34.6 (13.1)	- 35.5 (13.2)	- 33.4 (12.4)	- 34.7 (12.8)	0.077
Surgical approach					< 0.0001
Laparoscopic (%)	737 (30)	328 (21)	1393 (79)	2458 (81.7)	
Open (%)	212 (36)	195 (60)	139 (40)	546 (17.7)	
Robotic (%)	4 (0.4)	4 (0.8)	8 (0.6)	16 (0.5)	

^a CCY cholecystectomy

^b RYGB Roux-en-Y gastric bypass

^c BMI Body Mass Index, kg/m²

^d CCI Charlson Comorbidity Index

median (IQR). Statistical analysis was performed using SAS® statistical software (SAS Institute, Cary, NC Version 9.4).

Results

Three thousand and four patients who underwent RYGB (2458 laparoscopic, 546 open) between January 2008 and January 2018 were included. We divided the cohort into three groups: patients who had a prior CCY, patients with in situ gallbladder who underwent RYGB only, and patients who had a concomitant RYGB/CCY. In the cohort with an in situ gallbladder after RYGB, we reviewed medical records for interval CCY performed at any institution. Baseline demographics including sex, age, and initial and lowest Body Mass Index (BMI) as well

as comorbidities are compared in Table 1. Thirty-one percent (n = 931) of patients in our overall study cohort had a CCY prior to RYGB and 13% (n = 403) underwent concomitant CCY with RYGB. Of the remaining 1670 patients, 13% (n = 214) underwent an interval CCY. At time of review, 52% (n = 1548) of the entire cohort had undergone a CCY. Duration of follow-up was determined by most recent clinic visit in the patient chart. Of the patients with an in situ gallbladder, 60% had at least 3 years follow-up and 40% of the patients without CCY had at least 5 years of follow-up. Follow-up rates at 1, 3, 5, and 10 years are outlined in Table 4.

In the laparoscopic subgroup, 36% (n = 899) had undergone prior CCY, with a further 21% of patients with an in situ gallbladder undergoing concomitant CCY. The most common indication was symptomatic cholelithiasis. Of those 1231

Table 2Demographics and
comparison of 30-day outcomes
between LRYGB only and con-
comitant LRYGB/CCY

	LRYGB ^a only $(n = 1231)$	Concomitant LRYGB ^{a} /CCY ($n = 328$)	p value
Female (%)	910 (74)	266 (81)	0.008
Age (SD)	43.9 (11.5)	45.9 (11.2)	0.008
BMI, initial (SD)	47.0 (7.7)	48.1 (8.3)	0.032
Comorbidity score (SD)	4.4 (2.2)	4.8 (2.4)	0.025
Medication count (SD)	5.4(3.5)	5.9 (3.6)	0.0279
Length of stay, days (SD)	1.7 (1.2)	1.8 (1.1)	0.116
30-day readmission (%)	126 (10)	43 (13)	0.1368
Reinterventions (%)	40 (3)	14 (4)	0.370
Clavien-Dindo I + II complications (%)	89 (7)	31 (9)	0.180
Clavien-Dindo III+ complication (%)	26 (2)	12 (3)	0.107
30-day mortality	1 (0.1)	1 (0.3)	0.377

^a LRYGB laparoscopic Roux-en-Y gastric bypass

remaining patients, 14% (n = 170) underwent interval CCY. We compared patients who underwent concomitant laparoscopic CCY with RYGB (n = 328) to those who underwent LRYGB alone (n = 1231). There was no significant difference in length of stay, 30-day readmission rate, complications or mortality, or BMI nadir as outlined in Table 2. Operative times were also analyzed. Mean LRYGB operative time was 153 min (SD 44.9) vs 176 min for concomitant LRYGB/ CCY (SD 44.6, p < 0.0001). Average open RYGB operative time was 127 min (SD 36) versus 144 min for concomitant open RYGB/CCY (SD 31, p < 0.0001).

To determine the impact of CCY timing on outcomes between the concomitant and interval CCY groups, overall outcomes as well as CCY-related surgical outcomes were compared between the groups. The median time to CCY for the interval group was 19 months (range 0.62 to 117 months). There was a higher rate of postoperative bile leak and significantly higher rate of reinterventions (including percutaneous abscess drainage, ERCP, and percutaneous biliary drainage) in the interval CCY group. Overall complications directly related to the CCY were significantly higher in the interval group. A comparison of the two groups is found in Table 3. CCY-related complications included percutaneous biliary-tract drainage procedures, percutaneous biloma drainage, gallbladder fossa collections requiring drainage, endoscopic retrograde cholangiopancreatography (ERCP), or superficial skin infections after interval CCY.

	Concomitant $(n = 403)$	Interval $(n = 214)$	p value
Female (%)	320 (79.4)	175 (81.8)	0.482
Age, years (SD)	46.0 (11.3)	44.2 (11.6)	0.086
BMI, initial (SD)	50.8 (10.3)	47.5 (7.9)	0.0003
RYGB approach			0.469
Laparoscopic (% [†])	328 (21)	170 (14)	0.190
Open (% [†])	71 (14)	44 (10)	
Robotic (%)	4 (1)	0	
Indications for CCY			
Symptomatic cholelithiasis (%)	305 (75.7)	67 (31)	n/a
Cholesterolosis (%)	14 (3.5)	0	
Cholecystitis (%)	7 (1.7)	52 (24)	
Gallbladder sludge (%)	9 (2.2)	6 (3)	
Gallbladder polyp (%)	3 (0.7)	3 (1.5)	
Asymptomatic (%)	62 (15.4)	0	
Biliary dyskinesia (%)	3 (0.7)	44 (21)	
Gallstone pancreatitis (%)	0	8 (4)	
Other (%)		22 (15)	
30-day complications			
PBD ^a /percutaneous biloma drainage	0	3 (1.4)	0.041
ERCP ^b (%)	1 (0.3)	12 (5.6)	< 0.0001
Bile duct injury (%)	1 (0.3)	0	1.000
Bile leak (%)	2 (0.5)	4 (1.9)	0.190
Any reoperation/reintervention (%)	82 (20.4)	39 (18.2)	0.527
Related to CCY [*]	3 (0.7)	16 (7.5)	< 0.0001
Clavien-Dindo grade I/II complication (%)	25 (6.2)	13 (6.1)	0.950
Clavien-Dindo grade III+ complication (%)	37 (9.2)	17 (7.9)	0.605
CCY-related complication (%)	3 (0.7)	21 (9.8)	< 0.0001
30-day mortality (%)	2 (0.5)	0	0.546

n/a not available

^a Percutaneous biliary drainage

^b Endoscopic retrograde cholangiopancreatography with stone retrieval via trans-gastric approach

*This includes PBDs, gallbladder fossa collection or abscess drainages, ERCP, and superficial skin infections †Expressed as a percentage of the overall cohort for concomitant RYGB/CCY and as a percentage of those with an in situ gallbladder for interval CCY

 Table 3
 Interval CCY vs

 concomitant RYGB/CCY

Discussion

This is one of the largest studies to evaluate the incidence and outcomes of interval CCY after primary RYGB. In review of the literature, this is the only study to report the percent of patients that followed up at intervals up to 3 years. Our study demonstrates the rate of biliary pathology requiring interval CCY is more than twice the reported rate cited in the ASMBS guidelines. The study demonstrates that concomitant CCY can be performed without a significant increase in perioperative morbidity, mortality, length of stay, or readmissions.

The ASMBS guidelines published this year recommend against concomitant CCY in asymptomatic patients undergoing bariatric surgery [29]. The guidelines were based on higher complication rates associated with concomitant CCY and the low incidence of biliary disease following primary RYGB. The ASMBS guidelines document the risk of developing biliary disease as 6.8% [29]. The manuscripts to support the recommendations included two single institution studies and one meta-analysis. The largest study by Patel et al. [25] reported an interval CCY rate of 4.9% in 1050 patients. This study documented a 78% follow-up rate at 2 years [25]. The second study by Pineda et al. [31] included both primary RYGB and sleeve gastrectomy. This study included 146 patients with an interval CCY rate of 3.4% at 12-month followup. The meta-analysis included the study by Patel and 12 additional studies that were variable in findings and inclusion criteria [14]. The interval CCY rate varied widely from 2.3 to 18.6% in the meta-analysis. The studies included in the metaanalysis were primarily small studies with half of the studies < 200 patients. Most of the studies also had relatively short follow-up with only Patel's study documenting the percent of patients that followed up at 2 years. The risk of biliary disease has previously been demonstrated to be increased for 36 months following primary bariatric surgery [13]. Despite the ASMBS recommendations against concurrent CCY in asymptomatic patients, the meta-analysis included multiple studies (67%) with concomitant CCY in asymptomatic patients. The interval CCY rate may also be underestimated; Altieri et al. [32] reported that 75% of patients in the New

York longitudinal database underwent interval CCY at a different institution than the primary bariatric surgery.

The second justification cited in the ASMBS recommends against concomitant CCY in asymptomatic patients was the higher rate of postoperative morbidity. Previous studies have highlighted an increased incidence of perioperative complications with routine concomitant CCY [15, 33]. More recent evaluations of the MBSAQIP PUF, however, have demonstrated concomitant CCY can be performed without a significant increase in morbidity [27]. Our study similarly demonstrated no significant increase in morbidity, length of stay, or readmissions with concomitant CCY. In addition, this is one of the few studies which have compared biliary-specific complications for interval and concomitant CCY cohorts. While the overall complication rates between the two groups were not significantly different, complications related to CCY were significantly more common in the interval CCY group. This finding is similar to the findings of a Swedish national database review by Wanjura et al. [34] which demonstrated a higher aggregate complication rate with interval CCY. We found a significantly higher percentage of patients in the interval CCY group requiring ERCP to manage leaks and common bile duct stones (5.6% of patients developed choledocholithiasis). We suspect this may be explained in part due to nature of the indications for interval CCY, including significantly higher proportion of acute cholecystitis, cholangitis, and gallstone pancreatitis as the surgical indication, which is outlined in Table 3.

The authors believe the advantages of concomitant CCY include decreasing the risk of developing biliary disease and need for interval CCY, which both previously and in this study has demonstrated a higher risk of perioperative morbidity [34, 35]. Additional advantages include better self-reported quality of life [11], economic advantage in preventing an additional hospitalization [11, 26], and possibly decreasing the need for future complicated biliary access. Disadvantages include higher cost of the index hospitalization [36] and approximately 15–30 min additional operative time in previous studies [20, 34]. In our study, concomitant CCY added a median of 23 min to the operative time for laparoscopic RYGB (Table 4).

Table 4	Follow-up	after	RYGB
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Duration of follow-up (years)	Prior CCY n = 933 (%)	Concomitant RYGB/CCY $n = 403 (\%)$	RYGB only <i>n</i> = 1456 (%)	Interval CCY n = 214 (%)	p value
1	784 (84)	329 (82)	1059 (73)	204 (95.3)	< 0.0001
3	564 (61)	247 (61)	754 (52)	171 (79.9)	< 0.0001
5	383 (41)	176 (44)	542 (37)	131 (61.2)	< 0.0001
10	12 (1)	4 (1.0)	15 (1.1)	6 (2.8)	0.2131

Limitations

This was a single-center, retrospective review of a prospectively maintained institutional database. The authors acknowledge the limitations of retrospective studies. The authors acknowledge that our follow-up was not 100% and a proportion of our cohort may have undergone procedures outside of our health system and may not have followed up with a provider associated with our network.

Conclusions

More than half of Roux-en-Y gastric bypass surgery patients will undergo a CCY during their lifetime. Selective concomitant CCY at the time of the index RYGB can be performed safely without significant increase in morbidity or length of stay. Concomitant can be performed with a modest increase in operative times. The rate of biliary pathology necessitating interval CCY is likely significantly higher than cited in the MBSAQIP position paper, and interval CCY is associated with a higher rate of morbidity compared to concomitant CCY. The authors believe that in patients with preoperative symptomatic or asymptomatic gallbladder disease, a concomitant CCY should be considered.

Compliance with Ethical Standards

Conflict of Interest The authors declare that they have no conflicts of interest.

Ethical Approval Ethical approval for this study was obtained from the local IRB ethics review committee prior to commencement.

Consent This article does not contain any studies with human participants or animals performed by any of the authors. For this type of study, formal consent is not required. Informed consent does not apply.

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