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A 3-Year MBSAQIP propensity-matched analysis of Roux-en-Y gastric bypass with concomitant cholecystectomy: Is the robotic or laparoscopic approach preferred?

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Abstract

Background The primary objective of this study was to compare outcomes of patients undergoing minimally invasive RYGB (MIS/RYGB) versus MIS/RYGB with concomitant Cholecystectomy (CCY). A secondary objective was to compare the outcomes for laparoscopic RYGB (LRYGB) and robotic RYGB (RRYGB) with concomitant CCY.

Methods Outcomes of 117,939 MIS/RYGB with and without CCY were propensity-matched (Age, Gender, BMI, Comorbidities), 10:1, using the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) database from 2015–2017. The MIS/RYGB with CCY were then separated into LRYGB and RRYGB cases for comparison. Exclusion criteria included emergency cases, conversions to open, and age less than 18.

Results The operative time and length of stay (LOS) was significantly increased with addition of concomitant CCY. There was no significant difference in readmission, reoperation, intervention, morbidity, or mortality. The RRYGB with CCY approach was associated with a significantly longer operative times compared to the LRYGB with CCY (177 vs. 135 min, $p < 0.0001$). The laparoscopic and robotic groups demonstrated no significant difference LOS, readmission, reoperation, intervention, morbidity, or mortality rates.

Conclusions Our study demonstrates that concomitant cholecystectomy increased the operative time and length of stay. However, concomitant CCY was not associated with any increased morbidity. The study demonstrated no significant difference in morbidity between robotic and laparoscopic approach. The robotic approach, however, was associated with a significantly longer operative time compared to the laparoscopic approach. While the indications for CCY remain controversial, concomitant CCY does not convey additional risk regardless of operative approach.

Keywords Roux-en-y gastric bypass · Bariatric · Concomitant cholecystectomy · Laparoscopic · Robotic · Biliary disease

There are several known risk factors for gallstone formation in the general public, such as age, female gender, obesity, and parity [1, 2]. One well known risk factor for the development of gallstones and subsequent biliary disease is the period of rapid weight loss found in the first three years following roux-en-y gastric bypass (RYGB) [3–5]. The incidence of gallstone formation after RYGB is as high as 38%. Unfortunately, the mechanism of stone formation in bariatric patients is not fully understood but multiple theories have been proposed such as: increased cholesterol saturation as a result of mobilization from adipose tissue, gallbladder stasis, increased secretion of mucin and calcium, and increased presence of prostaglandins and arachidonic acid promoting cholesterol crystal precipitation [6].

The optimal management of biliary disease in bariatric patients has remained controversial. In the current era of minimally invasive bariatric surgery, the trend has been to avoid prophylactic or concomitant asymptomatic cholecystectomy (CCY) due to the low rate of biliary disease following bariatric surgery [7]. A recent review by the ASMBS (American Society of Metabolic and Bariatric Surgeons) Foregut Committee recommends concomitant CCY only in symptomatic patients undergoing primary RYGB [8].

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These recommendations were based on the increased risk associated with interval cholecystectomy and the low risk of developing biliary disease [8]. Previous studies have been inconsistent on the risk of concomitant CCY [9]. The largest study of the NSQIP (American College of Surgeons National Quality Improvement Program) database demonstrated a higher rate of major adverse outcomes in patients undergoing RYGB with concomitant CCY [10]. A recent study evaluating a single year of the MBSAQIP database, however, demonstrated no increase in morbidity in patients undergoing concomitant CCY [11].

Advancements in robotics have significantly increased the utilization of robotic bariatric surgery. The safety and efficacy of robotics in bariatric surgery has been previously demonstrated [12–14]. On the other hand, studies, including Pokala et al. have evaluated the perioperative outcomes of robotic assisted CCY, finding an increase in the 30 day morbidity and length of stay [15, 16]. In review of the literature, the short-term outcomes of laparoscopic compared to robotic bariatric surgery with concomitant CCY have not been previously evaluated. The primary objective of this study was to compare 30 day outcomes of patients, in a propensity-matched cohort, undergoing minimally invasive (MIS)/RYGB versus MIS/RYGB with concomitant CCY. A secondary objective was to compare the 30-day outcomes for laparoscopic RYGB (LRYGB) versus robotic RYGB (RRYGB) with concomitant CCY.

Materials and methods

Prior to the initiation of research, this project was exempt by the Geisinger Institutional Review Board. This study uses the de-identified data from the MBSAQIP database, without the need for individual written consent. The Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) database participant use files from 2015–2017 were queried for primary procedure CPT codes for laparoscopic and robotic RYGB (43,644, 43,645) alone and with the addition of laparoscopic and robotic CCY (47,562, 47,563). Emergency, revision procedures, and records missing data relevant for analysis were excluded. A total of 117,939 patients were identified as undergoing a MIS/RYGB from 2015–17. After matching 10:1 a SMD (Standard Mean Difference) below 0.01 was considered well matched for all variables. Variables selected for matching included Age, Body Mass Index (BMI), Sex, Race, first assist training level, American Society of Anesthesiologists (ASA) Score, and comorbidities included in the MBSAQIP database. After propensity matching 36,260 patients with MIS/RYGB and 3626 MIS/RYGB with concomitant CCY are identified in Table 1.

The 30-day outcomes of MIS/RYGB with and without CCY were compared, and these individual outcomes are noted in Table 2 and Table 3. The post matched cohort of MIS/RYGB with CCY was then separated into 213 LRYGB and 413 RRYGB cases for a second comparison. Outcomes were compared using the Chi-squared or Fisher's exact test for categorical variables and the Wilcoxon rank-sum test for continuous variables. Results are reported as frequency (%) and median and interquartile range unless otherwise specified.

Results

Query of the MBSAQIP participant use date file from 2015–2017, a total of 117,939 patients were identified as having a MIS/RYGB. A total of 36,260 patients who underwent an MIS/RYGB and 3,626 who underwent a MIS/RYGB with concomitant CCY were compared after propensity matching demonstrated in Table 1. As seen in Table 4, the mortality rate was low in both groups (0.2% vs. 0.1%; $p = 0.209$). Both groups had similar morbidity rates (4.6% vs. 4.6%; $p = 0.892$) as well as need for reoperations or interventions. The length of stay (LOS) and readmission rates were similar for both groups. The addition of concomitant CCY did, however, significantly increase the operative time (111 min vs. 139 min; $p < 0.0001$).

When comparing the surgical approach, the laparoscopic group was associated with significantly shorter operative times compared to robotic group (135 min vs. 177 min; $p < 0.0001$) demonstrated in Table 5. The robotic and laparoscopic groups demonstrated no significant difference in LOS, readmission, reoperation, or intervention. The morbidity and mortality were similar between the laparoscopic and robotic approach.

Discussion

The rapid development of gallstones after bariatric surgery is well documented in over one-third of patients. Previous studies have demonstrated concomitant CCY is safe; however, the perioperative morbidity has been inconsistently documented in published studies [9, 11, 17]. The current recommendations are to avoid cholecystectomy in bariatric patients with asymptomatic cholelithiasis. The ASMBS recommendations were based on 1. low incidence of biliary disease following MIS/RYGB and 2. the increased morbidity of interval cholecystectomy [8].

The NSQIP study is currently the largest published series of bariatric patients undergoing concomitant cholecystectomy demonstrated a higher morbidity with concomitant cholecystectomy group [10]. Our study is the largest and

Table 1 Pre- and post-propensity match variables

Variable	Pre-match			Post-match		
	MIS/RYGB $n=114{,}285$	MIS/RYGB + CCY $n=3654$	SMD	MIS/RYGB $n=36{,}260$	MIS/RYGB + CCY $n=3626$	SMD
Age	45.3 ± 11.8	46.3 ± 11.8	0.088	46.3 ± 12.0	46.3 ± 11.8	0.002
BMI	46.1 ± 8.0	46.5 ± 8.2	0.042	46.5 ± 8.3	46.5 ± 8.2	0.002
Female sex	91,596 (80.15%)	2957 (80.93%)	0.020	29,336 (80.9%)	2936 (81%)	0.002
Race			0.148			0.009
White	86,145 (75.38%)	2917 (79.83%)		29,076 (80.2%)	2899 (80%)	
Black or African American	16,074 (14.06%)	499 (13.66%)		4932 (13.6%)	494 (13.6%)	
Other, Unknown	12,066 (10.56%)	238 (6.51%)		2252 (6.2%)	233 (6.4%)	
First assist training level			0.182			0.013
General surgeon	5749 (5.03%)	118 (3.23%)		1197 (3.3%)	116 (3.2%)	
Weight loss surgeon	14,602 (12.78%)	430 (11.77%)		4205 (11.6%)	425 (11.7%)	
MIS fellow	14,127 (12.36%)	570 (15.6%)		5708 (15.7%)	563 (15.5%)	
None	13,639 (11.93%)	554 (15.16%)		5530 (15.3%)	548 (15.1%)	
PA/NP/RNFA	44,987 (39.36%)	1445 (39.55%)		14,244 (39.3%)	1442 (39.8%)	
Resident (PGY 1–5 +)	21,181 (18.53%)	537 (14.7%)		5376 (14.8%)	532 (14.7%)	
Diabetes	40,119 (35.1%)	1332 (36.45%)	0.028	13,289 (36.7%)	1322 (36.5%)	0.004
Pre-Op GERD requiring medication	43,700 (38.24%)	1470 (40.23%)	0.041	14,554 (40.1%)	1458 (40.2%)	0.001
Pre-Op hypertension requiring medication	60,527 (52.96%)	1957 (53.56%)	0.012	19,424 (53.6%)	1942 (53.6%)	< .001
Pre-Op hyperlipidemia	33,098 (28.96%)	1107 (30.3%)	0.029	10,872 (30%)	1098 (30.3%)	0.006
Pre-Op obstructive sleep apnea	49,840 (43.61%)	1635 (44.75%)	0.023	16,108 (44.4%)	1617 (44.6%)	0.003
Pre-Op history of COPD	2235 (1.96%)	84 (2.3%)	0.024	811 (2.2%)	84 (2.3%)	0.005
Pre-Op oxygen dependent	1019 (0.89%)	42 (1.15%)	0.026	388 (1.1%)	42 (1.2%)	0.008
History of MI	1776 (1.55%)	55 (1.51%)	0.004	541 (1.5%)	55 (1.5%)	0.002
Previous PCI/PTCA	2742 (2.4%)	99 (2.71%)	0.020	968 (2.7%)	98 (2.7%)	0.002
Previous cardiac surgery	1238 (1.08%)	60 (1.64%)	0.048	574 (1.6%)	59 (1.6%)	0.004
History of DVT or PE	1417 (1.24%)	69 (1.89%)	0.052	632 (1.7%)	69 (1.9%)	0.012
Pre-Op therapeutic anticoagulation	3036 (2.66%)	136 (3.72%)	0.061	1350 (3.7%)	135 (3.7%)	< .001
Pre-Op venous stasis	1438 (1.26%)	81 (2.22%)	0.073	758 (2.1%)	81 (2.2%)	0.010
Pre-Op renal insufficiency	741 (0.65%)	34 (0.93%)	0.032	334 (0.9%)	34 (0.9%)	0.002
Pre-Op Steroid/Immunosuppressant use for chronic condition	1740 (1.52%)	58 (1.59%)	0.005	578 (1.6%)	58 (1.6%)	< .001
Previous foregut surgery	1953 (1.71%)	47 (1.29%)	0.035	481 (1.3%)	46 (1.3%)	0.005
Current smoker within 1 year	9526 (8.34%)	318 (8.7%)	0.013	3088 (8.5%)	317 (8.7%)	0.008
Patient's ambulation limited most or all of the time pre-op	2238 (1.96%)	98 (2.68%)	0.048	954 (2.6%)	98 (2.7%)	0.004
Pre-Op functional health status			0.039			0.004
Independent	113,083 (98.95%)	3613 (98.88%)		35,867 (98.9%)	3585 (98.9%)	
Partially dependent	842 (0.74%)	35 (0.96%)		335 (0.9%)	35 (1%)	
Totally dependent	360 (0.32%)	6 (0.16%)		58 (0.2%)	6 (0.2%)	
ASA class			0.083			0.009
I	228 (0.2%)	6 (0.16%)		62 (0.2%)	6 (0.2%)	
II	19,565 (17.14%)	519 (14.22%)		5177 (14.3%)	515 (14.2%)	
III	89,329 (78.26%)	2947 (80.74%)		29,308 (80.8%)	2927 (80.7%)	
IV	5016 (4.39%)	178 (4.88%)		1713 (4.7%)	178 (4.9%)	
V	8 (0.01%)	(0%)		0	0	
Missing = 143						
Pre-Op requiring or on dialysis	184 (0.16%)	11 (0.3%)	0.029	96 (0.3%)	11 (0.3%)	0.007

Table 2 Pre-match complications

Complication	MIS/RYGB $n = 114{,}285$	MIS/RYGB + CCY $n = 3654$
Unplanned admission to ICU within 30 days	1,283 (1.1%)	42 (1.2%)
Post-Op superficial incisional SSI occurrence	1002 (0.9%)	34 (0.9%)
Post-Op deep incisional SSI occurrence	160 (0.1%)	5 (0.1%)
Post-Op Organ/Space SSI occurrence	405 (0.4%)	15 (0.4%)
Wound disruption	97 (0.1%)	2 (0.1%)
Post-Op vein thrombosis requiring therapy	196 (0.2%)	7 (0.2%)
Pulmonary embolism	177 (0.2%)	8 (0.2%)
Post-Op pneumonia	442 (0.4%)	12 (0.3%)
On ventilator > 48 h	170 (0.2%)	9 (0.3%)
Intra-op or post-op myocardial infarction	58 (0.1%)	0
Intra-Op or post-Op cardiac arrest requiring CPR	68 (0.1%)	1 (0%)
Stroke/CVA	9 (0%)	0
Coma > 24 h	2 (0%)	0
Unplanned intubation	278 (0.2%)	8 (0.2%)
Acute renal failure	140 (0.1%)	6 (0.2%)
Progressive renal insufficiency	119 (0.1%)	4 (0.1%)
Post-Op urinary tract infection	581 (0.5%)	13 (0.4%)
Transfusion intra-op/Post-Op (72 h of surgery start time)	1221 (1.1%)	51 (1.4%)
Peripheral nerve injury	15 (0%)	0
Post-Op sepsis	203 (0.2%)	11 (0.3%)
Incisional hernia noted on exam	87 (0.1%)	3 (0.1%)
Post-Op septic shock	133 (0.1%)	6 (0.2%)

most comprehensive study on the perioperative outcomes of concomitant cholecystectomy in patients undergoing primary MIS/RYGB. The authors believe using the MBSAQIP PUF (Participant user files) has several advantages over the previous NSQIP study. The MBSAQIP PUF is a comprehensive database of all cases performed at MBSAQIP centers as opposed to NSQIP, which relies on random patient sampling. In addition, MBSAQIP centers are required to follow patients for 1 year so admissions and procedures performed at outside institutions should be captured during routine follow-up.

The current study demonstrates that the addition of concomitant CCY did significantly increase the operative time as would be expected. The length of stay was also increased by 0.3 days in the concomitant cholecystectomy group; however, the authors believe this is not clinically significant. Unlike the NSQIP data, our study demonstrated concomitant CCY was not associated with a significant increase in readmission, reoperation, or intervention [17].

The ASMBS guidelines also cited the low incidence of biliary disease as the second justification against asymptomatic cholecystectomy. The ASMBS guidelines document the risk of developing biliary disease as 6.8% [8]. In review of the supporting articles for the recommendation, there were two studies and one meta-analysis cited. One study reported an interval cholecystectomy rate of 4.9% in 1050 patients, which reported that 78% were followed up at 2 years [18]. The other study included both RYGB and Sleeve gastrectomy patients. The study included 146 patients with an interval cholecystectomy rate of 3.4% at 12-month follow-up [19]. The meta-analysis was more varied in findings. The interval cholecystectomy rate was between 2.3–18.6% [18, 20–31]. The studies included in the meta-analysis were small studies with half the studies less than 200 patients. The studies also had relatively short follow-up with only one study reporting the percent of patients followed up at 2 years [18, 20–31]. The risk of biliary disease, however, has been previously demonstrated to be increased for 3 years after bariatric surgery (5). In addition, most (67%) of the studies included in the meta-analysis performed concurrent cholecystectomy in asymptomatic patients with cholelithiasis. The interval cholecystectomy rate may also be underestimated since up to 75% of patients may have their interval cholecystectomy at a different institution [32].

The optimal technical approach for primary MIS/RYGB with concomitant CCY has not been previously studied. The robotic platform for primary bariatric surgery has demonstrated similar perioperative outcomes to the laparoscopic approach [12–14]. Robotic CCY has also been shown to be safe, however, with a potentially higher overall complication

Table 3 Post-match complications

Complication	MIS/RYGB $n=36{,}260$	MIS/RYGB + CCY $n=3{,}626$
Unplanned admission to ICU within 30 days	436 (1.2%)	42 (1.2%)
Post-Op superficial incisional SSI	335 (0.9%)	33 (0.9%)
Post-Op deep incisional SSI	56 (0.2%)	5 (0.1%)
Post-Op organ/space SSI	134 (0.4%)	15 (0.4%)
Wound disruption	30 (0.1%)	2 (0.1%)
Post-Op vein thrombosis requiring therapy	69 (0.2%)	7 (0.2%)
Pulmonary embolism	64 (0.2%)	8 (0.2%)
Post-Op pneumonia	149 (0.4%)	12 (0.3%)
On ventilator > 48 h	53 (0.2%)	9 (0.3%)
Intra-op or post-op myocardial infarction	23 (0.1%)	0
Intra-Op or post-Op cardiac arrest requiring CPR	22 (0.1%)	1 (0%)
Stroke/CVA	4 (0%)	0
Coma > 24 h	0	0
Unplanned intubation	90 (0.3%)	8 (0.2%)
Acute renal failure	56 (0.2%)	6 (0.2%)
Progressive renal insufficiency	34 (0.1%)	4 (0.1%)
Post-Op urinary tract infection	213 (0.6%)	13 (0.4%)
Transfusion intra-op/post-Op (72 h of surgery start time)	397 (1.1%)	51 (1.4%)
Peripheral nerve injury	4 (0%)	0
Post-Op sepsis	64 (0.2%)	11 (0.3%)
Incisional hernia noted on exam	25 (0.1%)	3 (0.1%)
Post-Op septic shock	49 (0.1%)	6 (0.2%)

Table 4 Minimally invasive RYGB with concomitant cholecystectomy versus alone

Outcomes	MIS/RYGB $n=36{,}260$	MIS/RYGB + CCY $n=3626$	*p* value
Operative time (Minutes)	111 (82, 145)	139 (107, 183)	< .0001
LOS, mean ± sd (Days)	2.0 ± 1.7	2.3 ± 2.5	< .0001
Readmission	2207 (6.1%)	206 (5.7%)	0.329
Reoperation	823 (2.3%)	85 (2.3%)	0.774
Intervention	867 (2.4%)	91 (2.5%)	0.657
Complication	1662 (4.6%)	168 (4.6%)	0.892
Mortality	62 (0.2%)	3 (0.1%)	0.209

Table 5 Laparoscopic versus Robotic RYGB with concomitant cholecystectomy

Outcomes	LRYGB + CCY $n=3213$	RRYGB + CCY $n=413$	*p* value
Operative time (Minutes)	135 (103, 176)	177 (138, 248)	< .0001
Post-op LOS (Days)	2 (2, 2)	2 (1, 2)	0.282
Readmission	181 (5.6%)	25 (6.1%)	0.729
Reoperation	76 (2.4%)	9 (2.2%)	0.814
Intervention	78 (2.4%)	13 (3.2%)	0.379
Any complication	148 (4.6%)	20 (4.8%)	0.830
Mortality	3 (0.1%)	0 (0%)	0.999

rate [16]. Our study demonstrates RRYGB with concomitant CCY can be safely performed with similar perioperative outcomes to the laparoscopic approach. The robotic platform, however, had a significantly longer operative times compared to the laparoscopic approach. Prior studies have also found significant cost differences in the two techniques [15, 16]. Strosberg et al. not only demonstrated increased cost with robotic CCY but also decreased hospital revenue when compared to the laparoscopic approach [15].

We recognize that this study is a retrospective review of a prospectively maintained national database which has inherent limitations of observer and reporter bias. The MBSAQIP PUF does not collect information regarding preoperative biliary symptomatology or clinical decision making on the technical approach to MIS/RYGB. Furthermore, we do not have long-term outcomes outside of 30 days postoperatively.

To date this is the largest and most comprehensive study comparing perioperative outcomes of primary MIS/RYGB with concomitant CCY. The current study demonstrates that concomitant cholecystectomy is associated with minimal impact to morbidity, mortality, readmissions or interventions compared to primary MIS/RYGB. The authors believe the current recommendations against cholecystectomy in asymptomatic patients is too strongly worded given the low risk and poor evidence on the rate of interval cholecystectomy. The authors believe the laparoscopic and robotic platform have similar perioperative outcomes, however, the robotic platform is limited by the significant increase in operative time and cost.

Compliance with ethical standards

Disclosures Drs Falvo, Vacharathit, Daouadi, Gabrielsen, Horsley, Petrick and Parker, and Mr. Dove and Fluck have nothing to disclose.

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