#### **ORIGINAL CONTRIBUTIONS**





# Concomitant Cholecystectomy for Asymptomatic Gallstones in Bariatric Surgery—Safety Profile and Feasibility in a Large Tertiary Referral Bariatric Center

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#### Abstract

**Background** Obesity is a risk factor for gallstone formation, which can be exacerbated by bariatric surgery-induced rapid weight loss. Current guidelines do not recommend concomitant cholecystectomy (CC) for asymptomatic gallstones during the bariatric surgery procedure. However, long-term follow-up studies have shown that the incidence of post-bariatric surgery symptomatic gallstones necessitating therapeutic cholecystectomy increases to 40%. Therefore, some surgeons advocate simultaneous cholecystectomy during the bariatric surgery for asymptomatic individuals. This study aims to evaluate the safety of performing cholecystectomy for asymptomatic gallstones during the bariatric procedure.

Methods Data from a consecutive series of patients that underwent primary laparoscopic sleeve gastrectomy (LSG), laparoscopic Roux-en-Y gastric bypass (LRYGB) or conversion of LSG to a LRYGB with or without concomitant cholecystectomy for asymptomatic gallstones between Jan 2010 and Dec 2017 were retrieved from the database. The primary endpoint was the complication rate. Secondary endpoints were the surgical operating room time (ORT) and the length of hospital stay (LOS). Results Out of the 2828 patients who were included, 120 patients underwent a concomitant cholecystectomy during their bariatric procedure (LSG or LRYGB) for asymptomatic gallbladder stones and were compared to the 2708 remaining patients who only had bariatric surgery. None of the concomitant cholecystectomy patients developed a gallbladder-related complication. There was no significant increase in the rate of minor or major complications between the CC groups and the non-CC groups (LSG: 6.7% vs. 3.2%, p=0.132; LRYGB: 0% vs. 2.3%, p =0.55; and conversion of LSG to LRYGB: 20% vs. 7.1%, p = 0.125, respectively). In addition, there was no significant increase in the length of hospital stay (1.85  $\pm$ 4.19 days vs. 2.24  $\pm 1.82$ , p=0.404) for LSG group and (1.75  $\pm 2.0$  vs. 2.3  $\pm 2.1$ , p=0.179) for LRYGB group. Adding the cholecystectomy to the bariatric procedure only added an average of 23 min (min) (27 min when added to LSG and 18 min when added to LRYGB). Conclusion As one of the largest series reviewing concomitant cholecystectomy in bariatric surgery, this study showed that in skilled laparoscopic bariatric surgical hands, concomitant cholecystectomy during bariatric surgery is safe and prevents potential future gallstone-related complications. Long-term large prospective randomized trials are needed to further clarify the recommendation of prophylactic concomitant cholecystectomy during bariatric surgery.

Keywords Concomitant cholecystectomy  $\cdot$  Asymptomatic Gallbladder stones  $\cdot$  Gallstones  $\cdot$  Bariatric surgery  $\cdot$  LSG  $\cdot$  LRYGB  $\cdot$  Sleeve gastrectomy  $\cdot$  Gastric bypass

**Key Points** 

• Current guidelines do not recommend concomitant cholecystectomy (CC) for asymptomatic gallstones during the bariatric surgery.

• There was no significant increase in hospital stay or the rate of minor or major complications between the CC groups and the non-CC groups.

• Combining the 2 procedures deemed safe and feasible.

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## Introduction

It is known that obesity can lead to gallstone formation [1]. Although gallstones can potentially become symptomatic, many surgeons do not perform concomitant cholecystectomy (CC) for asymptomatic individuals at the same time as the bariatric surgery, which is identical to the management of asymptomatic stones in the non-obese population [2]. It is stipulated that only a small proportion of post-bariatric

surgery patients will develop symptomatic stones, and if so, simple cholecystectomy can then be performed. Moreover, CC at the time of the bariatric surgery is technically challenging due to sub-optimal port placement and excessive visceral obesity, which prolongs the surgical time and potentially can increase the complication rate. However, the studies recommending the conservative approach over CC were based on short-term follow-up data [2, 3]. On the other hand, long-term post-bariatric surgery follow-up studies, which are few in number, showed an increase in the incidence of gallbladder symptoms over time [4, 5]. Furthermore, some studies have shown that CC performed during the bariatric surgery does not lead to an increase in severe complication rates (Clavien-Dindo,  $CD \ge IIIa$ ) [6–8] and that it is cost-effective [9], thus supporting the recommendation of performing CC during bariatric surgery.

This study was conducted to evaluate the safety of performing CC for patients with asymptomatic gallstones undergoing bariatric surgery.

# **Materials and Methods**

Data was extracted from our database of bariatric patients operated in Bariatric center comparing those who had CC for asymptomatic stones with those who had only their primary bariatric surgery procedures. The criteria for having bariatric surgery were consistent with the international guidelines: a body mass index (BMI) of 35 kg/m<sup>2</sup> or greater with at least one obesity-related comorbidity or a BMI of 40 kg/m<sup>2</sup> or greater [10]. This study was approved by the scientific board of Bariatric center, Al Ain, The United Arab Emirates (AAMDHREC Protocol No. MF2058-2021-786).

The primary endpoint of this study was the safety of CC during bariatric surgery for patients with asymptomatic gallstones in terms of complications, which were graded according to the Clavien-Dindo classification. Secondary endpoints were the length of stay (LOS) and surgical operating room time (ORT)). A postoperative follow-up period of 30 days for complications was used in this study.

The study included patients who had LSG, LRYGB, or LSG conversion to LRYGB. All patients were screened by an abdominal ultrasound as a part of the routine work-up. In case of asymptomatic gallstones detected on US, patients were given the choice to have a CC. Patients were explained that the current guidelines do not advocate CC, but that the future chances of having future gallbladder-related issues or even complications in the decades to come are not unlikely, while CC in our hands can be performed with a very low risk of additional complication.

Those who underwent a simultaneous other procedure (i.e., an umbilical hernia repair), or other types of revision were excluded from this study. The cohort of patients who underwent CC was compared to a control group of patients that had a LSG or LRYGB procedure without CC.

Analysis was performed using SPSS (PASW) 18.0 software. Categorical data were described as percentage of the total cohort. Continuous variables were presented as mean standard deviation (SD). The differences in categorical data were analyzed using the chi-squared test. The independent t test was used to compare continuous variable groups. A p < 0.05 was considered to be statistically significant.

## **Surgical Technique**

All procedures are performed with the surgeon standing between the patient's legs (French position): the assistant standing on the patient's left side and the scrub nurse on the patient's right side.

The standardized surgical technique for the LSG is performed using three 12-mm ports placed in a horizontal line at 12 cm below the sternum and when combined with a cholecystectomy, an additional 4<sup>th</sup> (5 mm) port is placed in the right flank. The standardized linear stapled LRYGB (with or without cholecystectomy) is performed through three similarly placed 12-mm ports plus two 5-mm ports placed in both flanks (see Fig. 1).

After completing the bariatric surgery procedure, the laparoscope (scope: 10mm/30-degree angle) is moved from the 12 mm midline port to the 12-mm port in the right upper quadrant to perform the cholecystectomy (see Fig. 1). The gallbladder fundus is grasped by the assistant using an atraumatic 5-mm grasper through the left upper quadrant 12-mm trocar and pulled over the liver. The surgeon uses a 5-mm atraumatic grasper introduced through the right flank 5 mm port with his left hand and an ultrasonic energy device through the 12-mm midline port (former scope port) with his right hand.

With regard to the cholecystectomy, we prefer the traditional CVS approach [8], while some other bariatric surgeons prefer the Glissonian approach (fossa first) as the gallbladder lies deeper within its fossa in obese patients [11].

We prefer to do the bigger bariatric procedure first as placement of a liver retractor for the bariatric procedure following a CC could potentially cause a bleeding of the liver bed as well as dislocation of the cystic duct/artery clips.

## Results

Between Jan 2010 and Dec 2017, 2828 patients had either a primary LSG (n=2335) or LRYGB (n=379), or conversion of LSG to LRYGB (n=114) at Bariatric center, which is the tertiary center in the city of AL Ain, UAE. One hundred and twenty patients (78 LSG, 27 LRYGB, and 15 conversions to LRYGB) agreed to have to a CC for asymptomatic

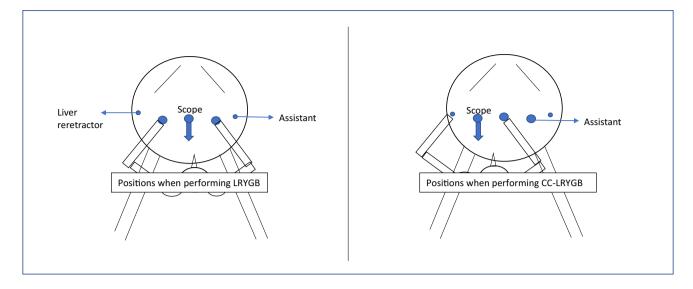


Fig. 1 Ports, instruments placement, and surgeon's position

gallbladder stones simultaneously with their bariatric surgery. Baseline characteristics including BMI, gender, and age were identical for the two surgical subgroups (see Table 1). The rate of detected preoperative gallstones was 3.3% in the LSG group, 7.1% in the LRYGB group, and 13.2% in the conversion of LSG to LRYGB group.

In this trial, significant differences were found in the gender in both the LSG and LRYGB comparative groups: mean age and height (see Table 1). Moreover, there were more patients suffering from type 2 diabetes, hypertension, or GERD in the LSG with CC (LSG-CC) subgroups. There were no significant statistical differences in the other base-line characteristics between those who had a CC and those who had a bariatric procedure only.

#### Complications

None of the 120 patients who underwent CC were found to have a postoperative gallbladder-related complication. The serious complications (CD  $\geq$  IIIa) rate was not significantly different between the CC groups and the non-CC groups for the three defined surgical groups (LSG: 6.7% vs. 3.2%, p=0.132; LRYGB: 0% vs. 2.3%, p=0.55; and conversion of LSG to LRYGB: 20% vs. 7.1%, p=0.125). Even for minor complications (CD  $\leq$  II), these figures were not significantly different (LSG: 30.8% vs. 24.5%, p=0.967; LRYGB: 14.8% vs. 25.3%, p=0.162; and conversion of LSG to LRYGB: 6.7% vs. 19.2%, p=0.212)

#### Surgical Time and Length of Hospital Stay

The overall mean additional time of adding a cholecystectomy to the bariatric surgery was 23 min. For the LGS, the time difference was 27 min (0:56  $\pm$  0:26 vs. 1:23  $\pm$  0:27, *p*=0.000). In the LRYGB, it was 18 min (1:32  $\pm$  0:37 vs. 1:50  $\pm$  0:33, *p* =0.212). The mean LOS was 1.85 ( $\pm$  4.19) for LSG group versus 2.24 ( $\pm$  1.82) days for CC-LSG (*p*=0.404). In the LRYGB, it was 1.75 ( $\pm$  2.0) versus 2.3 ( $\pm$ 2.1) days for CC-LRYGB group (*p*=0.179).

## Discussion

Obesity is a major risk factor for the development of gallstones. Stones are found during the preoperative work-up in 6.3–43.6% of the patients with morbid obesity undergoing bariatric surgery [1-3, 12, 13]. Our patients demonstrated a similar incidence of gallstones (3.3–13.2%). Additionally, significant weight loss is a risk factor for gallstone formation with an incidence of about 35% (range of 28-71%) of post-bariatric surgery patients [5, 14-21]. This is most likely caused by the rapid weight reduction of more than 1.5 kg per week which induces an increase in biliary cholesterol concentrations, gallbladder hypokinesia, an increase in the secretion of calcium, arachidonic acid derivatives, biliary mucin, and a disturbed enterohepatic circulation of biliary salts [6, 14, 15]. During the open surgery era, most surgeons performed a prophylactic cholecystectomy during the bariatric surgery to prevent possible future complex dissections should the patient requires an open cholecystectomy afterward [22, 23]. However, with the development of the laparoscopic approach, the need for prophylactic cholecystectomy was doubtful with consensus gradually shifting away from CC.

Several approaches have been advocated for the ideal management of gallbladder disease in bariatric surgery

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|              | LSG                 |  |  |         | LRYGB                |   |                     |         | Conversion LSG to LRYGB | G to LRYGB                 |                    |         |
|--------------|---------------------|--|--|---------|----------------------|---|---------------------|---------|-------------------------|----------------------------|--------------------|---------|
|              | LSG 2257<br>(96.7%) | $\begin{array}{ccc} LSG + CC 78 & Total 2335 \\ (3.3\%) & (100\%) \end{array}$ | Total 2335<br>(100%)                   | P value | LRYGB 352<br>(92.9%) | LRYGB + CC<br>27 (7.1%)                                     | Total 379<br>(100%) | P value | R-LRYGB 99<br>(86.8%)   | R-LRYGB +<br>CC 15 (13.2%) | Total<br>114(100%) | P value |
| Age          | 29.43 (±9.8)        | 35.26 (±10.47) 29.6 (±9.84)  | 29.6 (±9.84)                           | 0.000   | 37 (±11.2)           | 39.8 (±11.7)  | 37.3 (±11.28) 0.221 | 0.221   | 38.23<br>(±10.34)       | 33.21 (±7.52)              | 37.61<br>(±10.14)  | 0.083   |
| Male         | 834 (37%)           | 12 (15.4%)   | 846 (36.2%)                            | 0.000   | 80 (22.7%)           | 2 (7.4%)  | 82 (21.6%)          | 0.043   | 26 (26.3%)              | 8 (53.3%)                  | 34 (29.8%)         | 0.037   |
| Female       | 1423 (63%)          | 66 (84.6%)   | 1489 (63.8%)                           |         | 272 (77.3%)          | 25 (92.6%)  | 297 (78.4%)         |         | 73 (73.7)               | 7 (46.7%)                  | 80 (70.2%)         |         |
| Height (cm)  | 163.76<br>(±8.88)   | 159.86 (±7.62)   | $159.86 (\pm 7.62)$ $163.6 (\pm 8.87)$ | 0.000   | 161.6 (±9.1)         | 160.2 (±6.0)  | 161.5 (±8.9)        | 0.432   | 162.33<br>(±9.24)       | 168.03<br>(±10.87)         | 163.08<br>(±9.61)  | 0.032   |
| Weight (kg)  | 120.05<br>(±21.11)  | 115.97<br>(±20.19)   | 119.91<br>(±21.09)                     | 0.093   | 113.3 (±18.1)        | 113.3 ( $\pm$ 18.1) 113.1 ( $\pm$ 12.7) 113.3 ( $\pm$ 17.8) |                     | 0.952   | 111.24<br>(±20.90)      | 124.33<br>(±27.62)         | 112.96<br>(±22.20) | 0.033   |
| BMI          | 44.42<br>(±6.068)   | 45.21 (±7.29)  | 44.45<br>(±6.113)                      | 0.260   | 43.2 (±5.4)          | 43.9 (4.5±)   | 43.2 (±5.4)         | 0.463   | 42.07 (±7.86)           | 43.47 (±5.65)              | 42.25 (±7.61)      | 0.509   |
| DM type II   | 316 (14%)           | 20 (25.6%)   | 336 (14.4%)                            | 0.005   | 120 (34.1%)          | 8 (29.6%)   | 128 (33.8%)         | 0.404   | 23 (23.2%)              | 2 (13.3%)                  | 25 (21.9%)         | 0.312   |
| NTH          | 363 (16.1%)         | 19 (24.4%)   | 382 (16.4%)                            | 0.042   | 106 (30.1%)          | 7 (25.9%)   | 113 (29.8%)         | 0.415   | 29 (29.3%)              | 4 (26.7%)                  | 33 (28.9%)         | 0.551   |
| Dyslipidemia | 311 (13.8%)         | 16 (20.5%)   | 327 (14.0%)                            | 0.069   | 101(28.7%)           | 8 (29.6%)   | 109 (28.8%)         | 0.539   | 25 (25.3%)              | 1 (6.7%)                   | 26 (22.8%)         | 0.095   |
| OSA          | 218 (9.7%)          | 10 (12.8%)   | 228 (9.8%)                             | 0.225   | 46 (13.1%)           | 4 (14.8%)   | 50 (13.2%)          | 0.489   | 12 (12.1%)              | 2 (13.3%)                  | 14 (12.3%)         | 0.582   |
| Asthma       | 243 (10.8%)         | 10 (12.8%)   | 253 (10.8%)                            | 0.335   | 39 (11.1%)           | 4 (14.8%)   | 43 (11.3%)          | 0.367   | 15 (15.2%)              | 4 (26.7%)                  | 19 (16.7%)         | 0.506   |
| GERD         | 277 (12.3%)         | 20 (25.6%)   | 297 (12.7%)                            | 0.002   | 95 (27%)             | 8 (29.6%)   | 103 (27.2%)         | 0.459   | 47 (47.5%)              | 6(40%)                     | 53 (46.5%)         | 0.398   |

patients. It ranges from (1) routine prophylactic CC during all bariatric surgery procedures, (2) cholecystectomy only in patients with preoperatively ultrasound proven gallbladder stones, (3) cholecystectomy only in patients with symptomatic stones, (4) or the routine administration of urodeoxycholic acid (ursodiol) for 6 months postoperatively to all patients. The last option has shown to decrease the incidence of gallstone formation from 27.7 to 8.8% [24–26]. However, the high costs of this oral medication and its adverse effects (constipation, headache, dizziness, diarrhea, and upper respiratory tract infections) resulted in poor compliance to this medical treatment [26–28].

Those who plead against a CC raised concerns about the following: (1) sub-optimal trocar placement with visceral obesity and a gallbladder engulfed by a steatotic liver might increase the risk of complications; (2) it prolongs the surgical time; (3) the incidence of postoperative complications from gallstones is low (7–16%) [3, 18, 20, 21]; (4) and that in most cases, post-bariatric surgery symptomatic gallstone patients can be treated easily by a simple interval cholecystectomy.

Although relatively low rate of symptomatic gallstones post-bariatric surgery is the main argument for those against routine cholecystectomy, the internationally published data supporting this approach was obtained from retrospective studies with relatively short-term follow-up of only 1–3 years [6]. There are only few long-term post-bariatric surgery follow-up studies, and they showed that the incidence of post-bariatric surgery symptomatic gallstones increases with time. Melmer A. et al. revealed from a series of 109 patients (number needed to harm 2.5) [5], which within a 10-year period following bariatric surgery, there was an impressive 40% chance of developing symptomatic gallstones necessitating a cholecystectomy. Gracie et al., following 123 non-bariatric patients with asymptomatic stones for 15 years found that gallstones become more symptomatic by 5% each 5 years of follow-up [4]. In addition, Brockmeyer et al. reported an incidence of 8% of patients with asymptomatic gallstones developing biliary symptoms requiring cholecystectomy after 11.6 years follow-up [29]. Moreover, other longer term data from non-bariatric surgery patients have shown that up to 50% of asymptomatic stones will become symptomatic within 10-20 years of their initial diagnosis [30]. Since most patients undergoing bariatric surgery are between their 2<sup>nd</sup> to 4<sup>th</sup> decade of life, the rates of symptomatic gallstones in post-bariatric patients are very likely to increase. Furthermore, only about 20% of bariatric surgery patients had a cholecystectomy prior to their bariatric surgery [1, 3, 18]. Studies have reported that over 75% of routinely removed gallbladders had some sort of pathology despite negative preoperative abdominal ultrasounds [1]. Additionally, gallstone-related issues might interfere with the diagnosis of other possible post-bariatric

surgery problems such as intussusception, recurrent abdominal pain, food intolerance, or internal herniation. Moreover, gallstone migration into the common bile duct, which has an incidence of 0.2–5.3% [31, 32], is a difficult condition to manage, especially after LRYGB because of the anatomic alterations hindering the performance of an ERCP.

Therefore, some surgeons [33] advocate concomitant removal of the gallbladder during the bariatric surgery for the following facts: (1) the surgeon is already performing an abdominal surgery and an additional cholecystectomy can be performed through the same ports without additional scars and with an average of half an hour extra surgical OR time; (2) CC during bariatric surgery does not increase the rate of severe (CD  $\geq$  IIIa) complications [6–8, 34]; (3) laparoscopic surgery has become safer due to better technical visualization and expert high volume bariatric surgeons; (4) cholecystectomy complications in the bariatric population are significantly higher when the cholecystectomy is performed at a later stage due to the fact that around 36.2% of the post-bariatric surgery cholecystectomies are performed for complicated gallbladder diseases such as cholecystitis or migrated stones [33, 35]; (5) patients may benefit from a better quality of life by eliminating the non-specific chronic cholecystopathy-related symptoms; (6) additionally, there is no need for ultrasonic gallbladder surveillance or readmissions due to gallstones; (7) lastly, and from costeffectiveness stand point, CC is more cost-effective as it adds only around 400-600 USD to the bariatric procedure, whereas delayed cholecystectomy has an estimated cost of 8000–16,000 USD [9, 31] (see Table 2).

Our series of 120 patients receiving CC for asymptomatic gallstones during bariatric surgery demonstrated that in trained surgical hands using a CVS cholecystectomy approach, CC is very safe. However, an unclear higher rate of CD 3–4 complications was observed in the revision of sleeve to bypass group, which was not significant due to the smaller numbers in this subgroup analysis. The three CD 3–4 cases consisted of 2 hematomas and 1 respiratory

 Table 2
 Advantages and disadvantages of concomitant cholecystectomy in bariatrics

| Advantages CC  | Disadvantages CC   |
|--|--|
| No additional trocars                                    | Sub-optimal trocar placement                                     |
| It is safe with no<br>increase of complica-<br>tions     | Potential increase of complications during surgery               |
| Avoid future high-risk<br>gallbladder interven-<br>tions | Alternatively future cholecystectomy has a low complication rate |
| Better quality of life                                   | Prolonged surgical time  |
| No need for future US                                    |  |
| Cost-effective   |  |

failure. Adding the CC to the bariatric procedure resulted in significant more surgical time (mean 27 min) in the LSG, and non-significant more time (mean 18 min) to the LRYGB, which is similar or lower than the average of 33 min needed for the additional cholecystectomy reported in other studies [6, 9, 36]. The reason why the additional ORT for CC in LSG was longer than in in LRYGB remains unclear, but could be explained by the higher performed CC ratio in the LRYGB-CC group by the more senior surgeon in our group and partially by the fact that an additional port needs to be placed in the LSG-CC group. Moreover, our study showed that CC in bariatric surgery does not lead to longer LOS, which was similar to the results reported by other studies [6]. Limitations to our study are related to the fact that it is a retrospective review of a bariatric database and not a randomized controlled trial, and that it was a single institutional analysis. Moreover, the relative disproportion between the size of the study group and the control group could potentially lead to a type II error.

## Conclusion

The question whether to perform a prophylactic cholecystectomy during bariatric surgery remains unclear. However, evidence that gallstone problems are likely to increase with time, in addition to the proven safety of CC when done by experienced laparoscopic surgeons, should revive interest in considering CC. Future large-sized randomized controlled trials with a long-term follow-up are needed to address the efficacy of CC during bariatric surgery.

#### Declarations

Conflict of Interest The authors declare no competing interests.

**Ethical Approval** All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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