Gallbladder Management During Laparoscopic Roux-en-Y Gastric Bypass Surgery: Routine Preoperative Screening for Gallstones and Postoperative Prophylactic Medical Treatment are Not Necessary

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In the bariatric surgery literature, the optimum approach to the gallbladder is controversial. Recommendations range from concomitant cholecystectomy to selective screening and postoperative medical prophylaxis. At our institution, we have taken a highly selective approach where patients are not routinely screened for gallstones, nor are they medically treated postoperatively with bile salts. We have reviewed our experience with this approach. From January 2003 to January 2005, 407 laparoscopic Roux en Y gastric bypasses were performed at UCLA and postoperative outcomes were collected into a prospective database. Exclusion criteria included previous cholecystectomy, a follow-up period less than 6 months, or incomplete records. One hundred ninety-nine patients were included in the study. With a mean follow up period of 17.8 months, 12 (6%) patients required cholecystectomy for gallstone-induced pathology. Laparoscopic removal was performed in 11 (92%) patients. Indications for surgery included acute cholecystitis in five (2.5%) patients, gallstone pancreatitis in two (1%) patients, and biliary colic alone in another five (2.5%) patients. The incidence of symptomatic gallstones requiring cholecystectomy after laparoscopic Roux en Y gastric bypass is low. These results are similar to those from institutions where routine preoperative screening and prophylactic postoperative medical therapy is used. Routine preoperative screening or medical prophylaxis may not be necessary.

MORBID OBESITY, DEFINED as a body mass index (BMI) greater than 40, is rapidly approaching tobacco as the number one cause of preventable mortality in the United States. In 2002, 5.1 per cent of the United States population was considered morbidly obese, quadruple the rate from 1986.[6] This change in the U.S. population is mirrored by a similar increase in the number of bariatric surgeries performed each year. An estimated 13,365 weight loss surgeries were performed in 1998, with that number increasing to 72,177 in 2002,[9] and over 130,000 in 2004 (American Society of Bariatric Surgery data).

Obesity and the rapid weight-loss associated with bariatric surgery have long been associated with cholelithiasis. Recent studies have demonstrated gallstone formation in up to 36 per cent of patients that have undergone weight loss surgery.[13] It is believed that higher cholesterol concentrations within the gallbladder may be the inciting factor for stone development. Bile sampled from patients at the time of gastric bypass surgery compared with those taken from patients that developed stones postsurgery seem to support this conclusion.[13, 15, 18] Other potential factors include the division of the hepatic branch of the vagus nerve during gastric pouch formation and decreases in cholecystokinin (CCK) levels after surgery from enteric food stream diversion. The latter results in decreased

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gallbladder emptying and increased stasis, promoting stone formation.[1, 18]

Despite the increasing number of bariatric surgeries performed, no consensus exists with regard to gallbladder management in these patients. The spectrum ranges from routine cholecystectomy to prophylactic medical therapy or no intervention. Many institutions perform routine cholecystectomy at the time of gastric bypass surgery, quoting an 11 per cent incidence of discovering preexisting stones and a 32 per cent to 40 per cent incidence of postoperative gallstone formation.[3, 10] However, this adds operative time and risk to an already complicated surgery. Some will only remove the gallbladder if stones are present at the time of surgery and treat postoperatively with ursodiol, quoting a low symptomatic biliary disease rate in compliant patients.[11, 14, 16] Other studies, however, have shown poor compliance (41%), with the incidence of stone formation at 28 per cent.[11] Finally, others require neither screening nor prophylactic therapy for gallstones. In agreement with the last strategy, at our institution, concurrent cholecystectomy is only performed in symptomatic cases. The purpose of our study was to determine the incidence of postgastric bypass biliary disease requiring operative intervention in this setting.

Materials and Methods

From January 2003 to January 2005, 407 patients underwent a laparoscopic Roux en Y gastric bypass (LRYGB) at our institution. Data pertaining to preoperative comorbidities, and perioperative and postoperative outcomes were collected into a prospective database. Exclusion criteria included previous cholecystectomy, a follow-up period less than 6 months, or incomplete records that could not be accessed through the Kaiser Permanente Patient Data Computer System. The 6-month minimum follow-up period was chosen as it represented the period of greatest weight loss and highest likelihood of stone development. Only patients that were members of the Kaiser Permanente Health System were included in the study. Any care received by these patients in the Southern California area is documented in a regional computer system. The computer system was used not only to determine patient follow-up, but to also verify that patients remained Kaiser Members at the time of data retrieval. Institutional Review Board approval was obtained and 199 patients were included in the study. As part of our routine protocol, no screening or intervention for asymptomatic biliary disease was performed, nor was prophylactic postoperative bile salt therapy given to the patients. Only clinical suspicion for symptomatic biliary disease dictated whether patients were evaluated for the presence of gallstones. Study endpoints included any hospital admissions for biliary disease (biliary colic, acute cholecystitis, cholangitis, or gallstone pancreatitis) or cholecystectomy. All variables were examined for comparability using contingency tables, χ^2 test, or Student's t test, depending on the level and distribution of the data.

Results

Four hundred seven consecutive patients underwent LRYGB surgery at UCLA Medical Center during the time period from January 2003 to January 2005. Of these patients, 85 (21%) were excluded for having previously undergone a cholecystectomy, including 1 patient that underwent concurrent cholecystectomy at the time of gastric bypass for gallstone-related symptoms. An additional 108 patients (27%) were members of other insurance health systems and were excluded for not having documented follow-up that could be accessed from the Kaiser Permanente Data Collection System. The remaining 15 excluded patients (3.7%) had left the Kaiser Permanente Health System before the 6-month minimum follow-up period. Table 1 shows a comparison of the study population and the eligible patients. No statistically significant differences with respect to gender, weight, BMI, or medical comorbidities are noted.

In the end, 199 patients (49%) met the inclusion criteria. Of the 199 patients included within the study, six patients (3%) were lost to follow-up and were assumed to have left the Kaiser Permanent Health System before the time of data retrieval. The average follow-up for the group that left the Kaiser system was 7.5 months (range, 7–10 months). The average follow-up for the entire study population was 14.5 months (range, 7–31 months).

In the study population, 12 (6%) patients developed symptomatic biliary disease and underwent a cholecystectomy. As demonstrated in Table 2, a comparison

TABLE 1. *Comparison of Patient Populations Included and Excluded from the Study*

	Excluded Patients	Included Patients	*P*
Total patients	218	199	
Age in years	44 (15–67)	43 (20–60)	ns
Percentage of women	89%	86%	ns
Height in inches	65 (59–75)	65 (59–73)	ns
Weight in pounds	297 (205–490)	301 (202–561)	ns
Initial BMI (kg/m^2)	49.9 (38–72)	50.1 (38–85)	ns
Comorbidities			
Hypertension	48%	49%	ns
Diabetes mellitus	24%	21%	ns
Hyperlipidemia	45%	45%	ns
Gastroesphogeal reflux disease	48%	48%	ns

TABLE 2. *Comparison of Symptomatic and Asymptomatic Patients*

	Nonsymptomatic	Symptomatic	*P*
Total patients	187	12	
Age in years	44 (20–66)	39 (26–56)	0.0924
Percentage of women	85.6%	91.7%	0.8718
Height in inches	65.2 (59–73)	65.3 (59–71)	
Weight in pounds	302 (209–561)	305 (205–387)	
BMI (kg/m^2)	50 (38–85.3)	50.6 (41–60)	0.7744
Comorbidities			
Hypertension	50%	33.3%	0.2554
Diabetes mellitus	21.4%	8.3%	0.4740
Hyperlipidemia	46.5%	25%	0.1464
Gastroesophageal reflux disease	48.1%	41.7%	0.6640
Postoperative			
30-day weight loss (lbs)	33.4 (13–63)	33.4 (17–47)	
Follow-up in months	14.5 (7–31)	17.8 (10–23)	0.0512

of the two groups did not reveal any statistically significant differences with respect to gender, weight, BMI, or medical comorbidities. Patient follow-up, however, tended to be longer for the cholecystectomy group (17.8 months *vs* 14.5 months); however, this was not statistically significant. This trend was also not observed after adjusting the inclusion criteria to a minimum of 10 months of follow-up (Table 3).

Operative indications included acute cholecystitis in five (2.5%) patients, gallstone pancreatitis in two (1.0%) patients, and biliary colic in the other five (2.5%) patients. Symptoms prompting a medical visit typically occurred around 9.5 months post-LRYGB (range, 4–15 months), and cholecystectomy was performed approximately 6 weeks later (range, 5–17 months post-LRYGB). One patient had to be converted from laparoscopic to open surgery for extensive gallbladder inflammation.

Discussion

The overall incidence of gallstones in the general population has been estimated to be around 10 per cent to 20 per cent with variations based on age, gender, and ethnicity.[17] Obesity is a known risk factor for the development of gallstones. Using preoperative and intraoperative screening methods, a baseline prevalence of 34 per cent to 43 per cent has been reported in the bariatric surgery literature.[3, 11] In addition, multiple studies have also demonstrated the association between rapid weight loss and the development of gallstones. Although the higher incidence of gallstone formation in this select patient population is accepted, the best approach to this problem is widely debated.

TABLE 3. *Comparison of Symptomatic and Asymptomatic Patients with at Least 10 Months of Follow-Up*

	Nonoperative Patients	Operative Patients	*P*
Total pts	150	12	
Age in years	44 (20–66)	39 (26–56)	0.0960
Percentage of women	86.67%	91.67%	0.9604
Initial BMI (kg/m^2)	49.5 (38–65)	50.6 (41–60)	0.5455
Comorbidities			
Hypertension	50%	33.3%	0.2664
Diabetes mellitus	21.33%	8.33%	0.4817
Hyperlipidemia	47.33%	25%	0.1351
Gastroesophageal reflux disease	46.67%	41.67%	0.7382
Follow-up in months	16.1 (10–31)	17.8 (10–23)	0.2873

Some advocate routine cholecystectomy on all patients undergoing a gastric bypass.[5, 10] This recommendation is based on the theory that these patients are at a higher risk for developing stones not only from their preexisting obesity, but also from the rapid postoperative weight loss. In addition, medical prophylactic therapy with bile salts is not 100 per cent effective. Poor patient compliance because of side effects and high cost are cited as potential reasons. However, adding a cholecystectomy to gastric bypass surgery has been shown to significantly increase operative time and hospital stay in institutions that advocate it.[5] Routine prophylactic cholecystectomy in this group can be technically demanding secondary to body habitus, hepatomegaly, and the large amount of intra-abdominal fat, potentially increasing the incidence of complications. Therefore, a significant number of patients may be placed at unnecessary operative risk for a problem that may never develop.

Other bariatric surgery centers use a selective approach. Patients are routinely screened by preoperative or intraoperative ultrasound. A cholecystectomy is performed in all patients who have gallstones, regardless of the presence or absence of symptoms. Bile salt therapy is then given to those that do not undergo cholecystectomy in an attempt to prevent the development of stones from the rapid postoperative weight loss. Medical therapy focuses on the finding that cholesterol concentration in the bile increases in the obese

and in those with rapid weight loss.[13, 15, 18] Ursodiol is used to increase bile salt concentration and to decrease cholesterol saturation. Some have also postulated that it may even improve gallbladder emptying.[19] Studies with excellent compliance have demonstrated a reduction in the incidence of stones from 30 per cent to 2–3 per cent.[12] Prophylactic bile salt therapy is effective, but applicability to the general population may be a problem if the majority of patients are not compliant because of taste, high cost, or side effects such as diarrhea and nausea. This would negate any benefit that prophylactic medical therapy would have. Other studies have not been able to duplicate this high level of compliance, and in those studies where compliance is poor (41% of study population), gallstone formation occurred in 28 per cent of patients, a rate similar to those not treated with ursodiol.[11] In these studies, overall symptomatic biliary disease (10% with a mean follow-up of 10 months) occurred at a similar rate to the patients in our study (6% with a mean a follow-up of 14.5 months) that were not treated with ursodiol. Although patients in both groups may still develop symptoms at a much later date beyond our follow-up period, it still compares favorably within the study period.

The third strategy used by many institutions, including ours, centers on the belief that not all patients that develop stones will become symptomatic. Gracie and Ransohoff[4] followed 123 University of Michigan faculty members with gallstones for 21 years: only 1 per cent to 2 per cent per year developed symptoms. Other studies suggest that the longer the stones remain quiescent, the less likely that symptoms are to develop.[2] In institutions that screen all bariatric surgery patients with intraoperative ultrasound, up to an additional 20 per cent are found to have silent cholelithiasis.[3, 11] Therefore, prophylactic cholecystectomy in this setting may subject a large number of patients to unnecessary operative risk with the likelihood of benefiting only a small number of patients.

A recent survey of the American Society of Bariatric Surgery that performed a standard Roux-en-Y gastric bypass showed that only 30 per cent removed normal-appearing gallbladders, and only one-third placed their patients on bile-salt therapy postoperatively.[7] At our institution, a concurrent cholecystectomy is only performed for symptomatic disease. In our study, this was only performed once out of a potential 322 patients. Postoperatively, biliary symptoms typically developed 9.5 months after the gastric bypass. At this point, most have already lost a significant portion of their preoperative weight, and obesity related comorbidities such as diabetes and hypertension had improved or even resolved completely. The cholecystectomy itself is probably technically easier and the perioperative complication rate may be lower in these "healthier" patients. In our study, 91 per cent of the symptomatic patients underwent a successful laparoscopic cholecystectomy. The only open conversion was in a patient with acute cholecystitis who presented 5 days after her symptoms had begun. No postcholecystectomy complications were noted in these 12 patients.

However, our study leaves many questions unanswered. Because we do not screen patients preoperatively for the presence of gallstones, it is unknown if those with silent cholelithiasis are more or less likely to develop symptomatic biliary disease compared with others who develop stones *de novo* from the rapid weight loss. In addition, as follow-up weights were not always recorded beyond 30 days, a relationship between the amount of long-term weight loss and the development of symptomatic biliary disease could not be determined.

Conclusion

The incidence of symptomatic gallstones requiring cholecystectomy after LRYGB is low. Our results are similar to those from institutions where routine preoperative screening and/or prophylactic postoperative medical therapy are used. Laparoscopic biliary surgery can be safely performed in the small population that does develop symptomatic cholelithiasis after LRYGB. Therefore, routine preoperative screening or postoperative medical prophylaxis may not be necessary. Long-term follow-up and further maturation of our data will determine whether these results continue beyond the 18-month follow-up period.

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