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ORIGINAL CONTRIBUTIONS

Potential Benefits of Prophylactic Cholecystectomy in Patients Undergoing Bariatric Bypass Surgery

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Abstract
Background In patients with morbid obesity, laparoscopic Roux-en-Y gastric bypass (LRYGB) is the treatment of choice. Patients with gallstones routinely undergo cholecystectomy at the same time as LRYGB. Although the risk of developing gallstones afterwards is high, prophylactic cholecystectomy during LRYGB remains controversial. Therefore, we conducted a retrospective study to evaluate the risk associated with prophylactic cholecystectomy and risk factors for developing gallstones after LRYGB.

Methods Data for patients on whom we consecutively performed LRYGB in 2003–2008 were extracted from the prospective bariatric database. The primary endpoint of the study was detection of newly developed gallstones by ultrasonography, and the secondary endpoint was evaluation of the incidence of post-LRYGB cholecystectomy (questionnaire).
Results Of 117 patients who underwent LRYGB, 20 (17 %) had a previous and 26 (22 %) had a concomitant cholecystectomy. Of the 71 LRYGB patients remaining who had not had their gallbladders removed, 22 (34 %) developed gallstones, with 11 (17 %) requiring emergency cholecystectomy before the study began. Seven (10 %) patients were lost to follow-up, and 53 (75 %) underwent abdominal ultrasound during follow-up, which detected stones in another 11 (17 %) patients up to end of the study period.
Conclusions Nearly 50 % of our patients had either experienced gallstones before LRYGB or developed gallstones after LRYGB. In the group with new gallstone development, 50 % required emergency cholecystectomy. These results, together with the reported better quality of life after a combined procedure and the reported economic benefits, support the use of concomitant prophylactic cholecystectomy in patients undergoing LRYGB.

Keywords Bariatric surgery · Roux-en-Y gastric bypass · Gallstones · Gallstone disease · Prophylactic cholecystectomy

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Sébastien Amstutz and Jean-Marie Michel contributed equally to this work.

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Introduction

Obesity is one of the foremost public health challenges of the twenty-first century. Its prevalence has tripled in many countries in Europe over the last three decades [1]. Surgical

treatment is becoming increasingly important [2], and of the many different procedures reported in the literature, laparoscopic Roux-en-Y gastric bypass (LRYGB) is at present considered to be the treatment of choice for patients with morbid obesity [3].

The risk of developing gallstones after LRYGB is estimated to be 35–38 %, probably due to the rapid weight loss and alterations in the enterohepatic cycle after such procedures. Up to 40 % of these patients will become symptomatic due to gallstones, and most of them will undergo a cholecystectomy [4, 5]. However, the importance of prophylactic cholecystectomy (surgery in patients in the absence of gallstones) during LRYGB is controversial. Recently, a Swedish nationwide population-based cohort study that included 13,443 patients undergoing bariatric surgery addressed this question [6]. The authors concluded that there is an increased incidence of cholecystectomy after such interventions, but it is probably due to increased detection of gallbladder disorders as chronic cholecystopathy.

Small gallstones (microlithiasis) may easily migrate into the common bile duct (choledocholithiasis), where they may cause biliary obstruction and potentially biliary pancreatitis. Due to alterations of the anatomy by bariatric surgery, in which there is a bypass of the stomach and the duodenum, standard treatment with endoscopic retrograde choledochopancreaticography (ERCP) and extraction of biliary stones is no longer possible. Newer techniques that employ double-balloon enteroscopy or use a transcutaneous/transgastric approach may still allow access to the common bile duct [7]. However, these newer techniques are technically demanding and combine laparoscopic and endoscopic intervention; as such, they are not performed in all hospitals. On the other hand, concomitant cholecystectomy during the bypass procedure may add time and also increase the risk of intraoperative complications.

Because of the aforementioned reasons, the question of whether to perform prophylactic cholecystectomy during obesity surgery has remained unclear. Therefore, we conducted a retrospective study that evaluated the risk of prophylactic cholecystectomy during obesity surgery, as well as different risk factors associated with the development of gallstones after LRYGB.

Materials and Methods

We extracted data from our prospective bariatric database for consecutive patients who had undergone LRYGB from May 2003 to January 2008 in our surgical department. All patients who had not undergone cholecystectomy in the past or during the LRYGB were included in the study. Written informed consent was obtained from all included patients. The primary endpoint of the study was the detection of newly developed gallstones by ultrasonography in the follow-up. Secondary endpoints were the incidence of post-LRYGB cholecystectomies and the evaluation of potential risk factors for the development of gallstones. The presumed main potential risk factor for gallstone development was the relative weight loss 6 months post-LRYGB.

The included patients were queried by phone with a standardized questionnaire (Supplementary Material 1), which comprised not only questions about symptoms but also questions concerning personal/family history that might possibly be related to gallstones. Patients underwent abdominal ultrasound at follow-up by an experienced radiologist looking for newly developed gallstones, dilated intra- or extrahepatic bile ducts, and the presence of the "radiological Murphy sign."

Patient weight and height data were extracted from the prospective bariatric surgery database preoperatively, as well as 3, 6, 9, 12, and 24 months after, LRYGB. Body mass index (BMI) was calculated as weight (kg) divided by height (meter) squared.

Categorical variables were created and dichotomized according to relative decreases in the BMI of <30 % and ≥30. Continuous variables are described as mean±standard deviation (SD) or range, and categorical variables are described as frequency and relative proportion. The following variables were assessed: gender, age groups, past pregnancy, family history of gallstones, and relative BMI decrease 6 months post-LRYGB. The time between LRYGB and the detection of newly developed gallstones (i.e., the appearance of symptomatic cholecystolithiasis or lithiasic cholecystitis) is described by time-to-gallbladder disorder (TGD). A Cox proportional hazard model was used to evaluate potential associations between variables and TGD, and a multivariable Cox model served to evaluate associations between the presumed potential main predictor (adjusted for age and gender) and TGD. Additionally, the proportional hazard assumptions were tested by using Schoenfeld residuals. Comparisons of surgical complications during and after LYRGB have been performed by the chi-square-test. Otherwise, all statistical tests conducted were two sided and alpha levels of <0.05 were considered significant. Stata 12.0 (Stata Corp, College Station, TX, USA) was used to perform all statistical analyses. The study was approved beforehand by the Intercantonal Ethical Committee of the Cantons of Fribourg, Vaud, and Neuchâtel.

Results

Out of 117 obese patients who underwent LRYGB at our surgery department, 83 had primary LRYGB, 27 had laparoscopic conversion to LRYGB from gastric banding, and seven had laparoscopic conversion from a vertical banded gastroplasty to LRYGB. Transabdominal biliary ultrasonography was routinely performed as part of the standardized

preoperative work-up. Patients with gallstones present at ultrasound underwent LRYGB and cholecystectomy during the same intervention, in agreement with other authors of the bariatric surgical community [8–13].

Of the 117 patients, 20 (17 %) had a previous and 26 (22 %) had a concomitant cholecystectomy. Of the remaining 71 patients, four (6 %) were lost to follow-up, two (3 %) refused to participate in the study, and one (1 %) died following an anastomotic leakage 1 month after LRYGB. Finally, 64 LRYGB patients were further evaluated with a minimum follow-up of 20 months: 47 (73.4 %) women and 17 (25.6 %) men had a mean preoperative BMI of 43 (28–63) and 46 kg/m^2 (37–59), respectively. All 64 patients were contacted after a mean follow-up of 44 (20–86) months following LRYGB. The mean BMI was 36 (23–52), 32 (20–50), and 29 kg/m^2 (20–47), respectively, at 3, 6, and 12 months follow-up. Six (9 %) patients became pregnant, and eight (13 %) presented with a family history of gallbladder disorder. A total of 22 (34 %) patients developed gallbladder stones; 11 (17 %) required an emergency cholecystectomy after 17 (1–54) months follow-up due to acute lithiasic cholecystitis (three patients, 27 %) and symptomatic cholecystolithiasis (eight patients, 73 %) (Fig. 1). The remaining 53 patients (75 %) underwent abdominal ultrasound 44 (20–86) months post-LRYGB. Newly developed gallstones were detected in 11 (17 %) patients, with macrolithiasis in four patients, microlithiasis in four patients, and a combination of both in three patients. All of these patients were offered an elective cholecystectomy; five agreed and six refused the intervention. In summary, of the 117 patients evaluated, 62 (53 %) underwent cholecystectomy: 20 (17 %) before, 26 during (22 %), and 16 (14 %) after LRYGB (Fig. 2). Intra- and postoperative complications of patients undergoing cholecystectomy during and after (elective and emergency operations) LRYGB were not statistically different (Table 1).

Different risk factors potentially associated with TGD were evaluated by univariate analysis (Table 2). Additionally, the presumed main predictor, namely, the relative decrease in BMI at 6 months follow-up (adjusted for gender and age), was added to the evaluation (Table 3). However, none of these variables were significantly associated with TGD, although there was a trend noted for women to have a higher risk of undergoing cholecystectomy compared to men. The hazard ratio for the relative change in BMI at the 6-month follow-up was >1.00 (not statistically significant). The preoperative BMI did not seem to be a risk factor for the development of gallstones. However, rapid weight loss showed a tendency toward being a risk factor, although this finding did not reach the level of statistical significance.

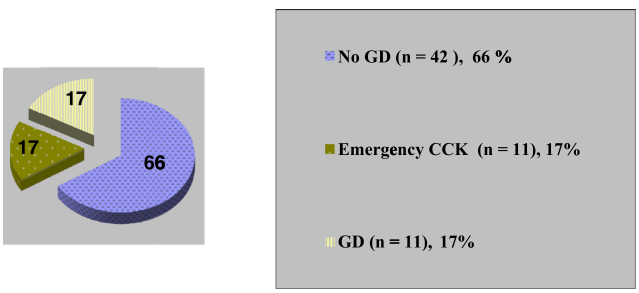

Fig. 1 Gallbladder disease after laparoscopic Roux-en-Y gastric bypass

Discussion

In Western populations, the prevalence of cholecystolithiasis varies from 10–15 % [14], of which 20 % are symptomatic. In obese women, the problem increases to up to 30 %, and it has been reported that those with a BMI >45 kg/m^2 have a sevenfold increased risk of undergoing cholecystectomy compared to those with a lower BMI [15]. In the bariatric surgery population, the estimated incidence of preoperative gallstones varies between 14 and 21 % [12], and up to 93 % of patients undergoing a bariatric intervention will develop cholecystopathy (i.e., cholesterolosis, cholelithiasis, and chronic unspecified cholecystitis), as shown by histological examinations after cholecystectomy [16]. Between 7 and 23 % of all obese patients undergoing bariatric surgery have had cholecystectomies previously [9, 16]. In our study population, 17 % had undergone a cholecystectomy for symptomatic gallstone disease prior to bariatric surgery.

The true incidence of gallbladder disorder is difficult to determine among obese people, since transabdominal ultrasound can yield a high rate of false-negative results due to technical difficulties [17]. Several reports demonstrated a rather low sensitivity of 50–75 % for the detection of gallstones in bariatric patients compared to the general population (97 %) [18, 19]. In our study, ultrasound performed after LRYGB revealed that 17 % of our patients had asymptomatic cholecystolithiasis, most commonly microlithiasis. However, these results are probably too high, since some of the patients may have already had cholecystolithiasis that had not been detected before LRYGB. This is an important confounding variable. To overcome the technical problem of transabdominal ultrasound investigations, some authors have proposed performing intraoperative ultrasound (IOUS), which may markedly improve the detection rate of cholecystolithiasis [20].

The development of gallstones is a well-known complication during and after weight loss and occurs in 22–71 % of patients who have had bariatric surgery [20, 21]. LRYGB may lead to alterations in the enterohepatic cycle, which in turn may increase mucin production, cholesterol

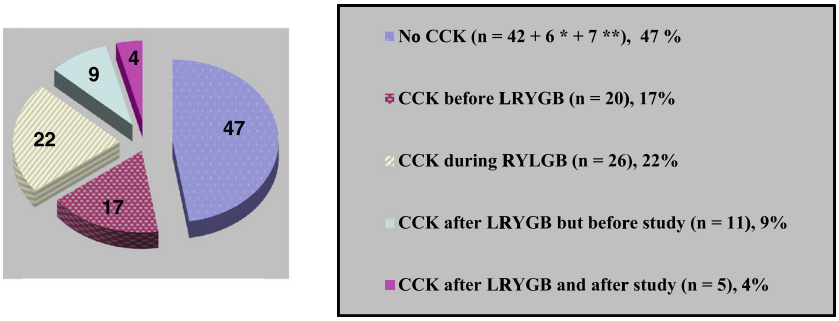

Fig. 2 Cholecystectomy and laparoscopic Roux-en-Y gastric bypass. *Single asterisk* indicates patients with detected gallstones who refused elective cholecystectomy; *double asterisk* indicates patients lost to follow-up.

saturation of bile, and bile acid levels, resulting in gallstone formation [8, 22, 23]. Another important factor for the development of gallstones may be decreased emptying of the gallbladder after bariatric surgery, which has been reported previously [24].

Our results also demonstrate that rapid weight loss postoperatively may be an important factor in the development of gallstones. In order to prevent gallstone formation, high doses of ursodeoxycholic acid for 6 months seems to be effective [25] However, the price and the low compliance [26, 27] make this prophylactic treatment questionable [28].

The incidence of cholecystectomy for symptomatic cholecystolithiasis after LRYGB has been reported to be as high as 18.6 % [29] A meta-analysis including 13 studies [30] found a rate of 6.8 % (95 % confidence interval (CI) 5.0–8.7 %) subsequent cholecystectomies: 5.3 % due to gallbladder dyskinesia or biliary colic, 1 % due to cholecystitis, and 0.2 % due to choledocholithiasis or biliary pancreatitis. However, one limitation of this meta-analysis was the short follow-up time in the included trials. About half of them had a follow-up of <18 months. The time to development of new gallstones after LRYGB is unknown; however, we noted in our study that 17 % of our patients required emergency cholecystectomy after a mean time of 17 (1–54) months follow-up.

Although migration of stones after LRYGB is infrequent (0.2–5.3 % risk), migration and the possible development of biliary pancreatitis is a challenging problem. Standard endoscopy with ERCP is impossible due to the modified anatomy [30, 31]. Some new techniques have been proposed to extract stones from the biliary tree, such as double-balloon enteroscopy and laparoscopic transgastric procedures [7]. However, these techniques are time-consuming and are also associated with significant morbidity; moreover, they are not available at every center that performs standard ERCP.

Based on our study results and considering the aforementioned risks, to patients, we are offering an elective cholecystectomy to patients with newly detected gallstones following LRYGB. However, the main question remains whether prophylactic cholecystectomy should be performed in every patient undergoing LRYGB.

Performing cholecystectomy during LRYGB requires an additional 15–29 min, without any significant additional complications [11, 13]. Most authors report no change in hospital stay if the procedure is done in the same session as laparoscopy [9, 32]. However, Worni et al. [33] analyzed the National Inpatient Sample in the USA, which contains 70,287 patients, and found that concomitant cholecystectomy is associated with a higher rate of early postoperative complications (adjusted odds ratio [OR] 1.59) and in-hospital mortality (unadjusted OR 2.16) and a longer hospital stay of 0.4 days. But he did not find any difference in intraoperative complications (e.g., bile duct or other injuries) when

Table 1 Intra- and postoperative surgical complications in patients undergoing cholecystectomy during and after LRYGB (n=42)

Variables	Cholecystectomy during LRYGB (n=26)	Cholecystectomy after LRYGB (n=16)		p value[a]
		Emergency (n=11)	Elective (n=5)	
Surgical complications	2[b]	0	0	0.256

[a] Chi-square test

[b] One patient with biliary ascites due to injury of the left liver, one with a stenosis of the jejunojenustomy

Table 2 Variables associated with time to gallbladder disease (univariate analyses)

Variables	Hazard ratio	95 % CI	*p* value
Gender			
Male	1.00	–	0.162
Female	2.40	0.70–8.16	
Age group (years)			0.467
<35	1.00	–	–
35–45	0.50	0.16–1.56	0.234
≥45	0.99	0.35–2.85	0.994
Pregnancy following LRYGB			0.193
No	1.00	–	
Yes	1.63	0.78–3.40	
Contraceptive use			0.174
No	1.00	–	
Yes	1.57	0.82–2.99	
Family history of gallbladder disease			0.495
No	1.00	–	
Yes	0.59	0.13–2.65	
Relative BMI at 6 months follow-up			0.357
<30 % relative decrease	1.00	–	–
≥30 % relative decrease	1.58	0.60–4.18	

95 % CI 95 % confidence interval, *LRYGB* laparoscopic Roux-en-Y gastric bypass, *BMI* body mass index

patients undergoing LRYGB with or without concomitant cholecystectomies were compared.

From an economic perspective, concomitant cholecystectomy during LRYGB adds approximately 400–630 USD to the calculated operative costs, whereas delayed cholecystectomy costs have been estimated to be 8000–16,000 USD [11]. Since about 6.9 % of LRYGB patients have to undergo a cholecystectomy later on [11], prophylactic cholecystectomy during LRYGB seems to be cost-effective.

Another argument for performing prophylactic cholecystectomy during LRYGB is based on the fact that the quality of life of such patients seems to be better in the follow-up, since they appear to suffer less from nonspecific gastrointestinal symptoms resulting from chronic cholecystopathy [34].

To date, there is no consensus in the literature regarding prophylactic cholecystectomy during LRYGB. However, the results of this long-term follow-up study emphasize the potential benefits of prophylactic cholecystectomy. A limitation of our study is the small sample size of included patients; therefore, further (multicenter) studies would help to support the evidence reported.

Table 3 Association of relative decrease in body mass index at 6 months follow-up with time to gallbladder disease adjusted for gender and age (multivariable survival analysis)

Variables	Hazard ratio	95 % CI	*p* value
Gender			0.08
Male	1.00	–	
Female	6.19	0.80–47.73	
Age group (years)			0.767
<35	1.00	–	–
35–45	0.65	0.18–2.37	0.512
≥45	1.06	0.27–4.20	0.929
Relative BMI 6 months post-LRYGB			0.618
<30 % relative decrease	1.00	–	–
≥30 % relative decrease	1.32	0.44-3.98	

95 % CI 95 % confidence interval, *LRYGB* laparoscopic Roux-en-Y gastric bypass, *BMI* body mass index

Conclusions

This is the first study to demonstrate that prophylactic cholecystectomy may bring clear benefits to patients undergoing bariatric surgery. Although not statistically significant, weight loss—especially rapid weight loss—seems to be the main risk factor for gallstone formation following LRYGB. Based on our study results regarding the potential complications of newly developed gallstones, together with the reported high incidence of cholecystectomy after LRYGB, the reported better quality of life after a combined procedure, and the reported economic benefits, we propose to perform cholecystectomy in presence of gallstones as well as to consider prophylactic cholecystectomy in absence of biliary concrements for patients undergoing LRYGB.

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Conflict of Interest The authors have no commercial associations that might be a conflict of interest in relation to this article.

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