## CLINICAL RESEARCH

# Is Routine Cholecystectomy Justified in Severely Obese Patients Undergoing a Laparoscopic Roux-en-Y Gastric **Bypass Procedure? A Comparative Cohort Study**

Ignazio Tarantino · Renè Warschkow · Thomas Steffen · Philipp Bisang · Bernd Schultes · Martin Thurnheer

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#### **Abstract**

Background The aim of the present study was to evaluate the risks and benefits of concurrent prophylactic cholecystectomy (CPC) during laparoscopic Roux-en-Y gastric bypass (LRYGB).

Methods From December 2000 to November 2006, CPC during LRYGB was only performed in the presence of gallbladder pathology (n=140). Beginning in December 2006, CPC was performed during all LRYGB procedures (n=134). Exclusion criteria were open bypass procedure, previous bariatric surgery other than gastric banding, and previous cholecystectomy (CCE) or necessary concurrent CCE due to gallbladder pathology.

Results During a median follow-up of 3.1 years, 26 (18.6%; 95% CI, 12.9-25.9%) of 140 patients without CPC subsequently required a CCE, leading to a gallbladder disease-free survival rate at 5 years of 77.4% (95% CI, 67.3-87.6%). Multivariate analysis identified a distal LRYGB and excess weight loss of >75% at 2 years to be significant risk factors for the development of biliary complications while a preoperative BMI>50 m<sup>2</sup>/kg was protective. In the second series, prophylactic CCE was not associated with prolonged hospitalization or operative time. The postoperative complications were not related to the CPC.

Conclusions The present data indicate that a substantial number of patients develop gallbladder complications after LRYGB. Furthermore, CPC can safely be performed during

Ignazio Tarantino and Renè Warschkow contributed equally to this work.

I. Tarantino (⋈) · R. Warschkow · T. Steffen · P. Bisang · B. Schultes · M. Thurnheer Department of Surgery, Kantonsspital St. Gallen,

e-mail: Ignazio.Tarantino@kssg.ch

9007 St. Gallen, Switzerland



LRYGB. Based on these findings, CPC should be considered a reasonable approach in severely obese patients undergoing LRYGB.

Keywords Laparoscopic Roux-en-Y gastric bypass · Symptomatic cholelithiasis · Bariatric surgery · Morbid obesity

## Introduction

The increasing worldwide prevalence of severe obesity and associated co-morbidities has resulted in a substantial rise in the number of bariatric procedures performed every year [1–3]. Gallbladder pathologies such as biliary stones are frequently found in obese patients [4-6]. Of note, rapid weight loss following bariatric surgery and altered gallbladder function due to postoperative anatomical changes [7] are key pathophysiological factors that further increase the risk of biliary stone formation [8-10]. Supporting this finding, multiple observational studies [3, 5, 9, 11, 12] have reported high incidences of gallbladder stones, ranging between 28% and 71%, after Roux-en-Y gastric bypass (RYGB) surgery, currently the most frequently performed bariatric procedure [13]. Increased cholesterol saturation in the bile and the gallbladder mucin concentration, the most important pronucleating factor, are important pathophysiological features of the enhanced biliary stone formation associated with rapid weight loss [14]. Additionally, gallbladder emptying has been shown to be significantly compromised after RYGB procedures, also predisposing patients to gallstone development [15].

Despite the well-documented high risk of gallbladder complications after bariatric surgery, there is still no commonly accepted therapeutic approach to this problem. While some bariatric surgeons' advocate routine concurrent prophylactic cholecystectomy (CPC) at laparoscopic Rouxen-Y gastric bypass (LRYGB) surgery, others call for a more selective approach, i.e., performing cholecystectomy (CCE) only in the presence of gallbladder pathology. Arguments supporting routine CPC include the overall low morbidity rates associated with the additional procedure [16] and the rather high rate of pathologic findings of the specimens [12, 17–20]. CPC may also spare patients from a second procedure should gallbladder disease develop. However, there is a broad consensus that bariatric candidates should be routinely screened by ultrasonography for gallbladder pathology before the operation and that CCE should be performed in patients with pathological findings [21–24].

At the authors' institution, gastric bypass surgery was introduced in December 2000. Until November 2006, CCE was performed during LRYGB only in patients with preoperative ultrasonographic pathological gallbladder findings. Beginning in December 2006, CPC was established as a standard procedure during all LRYGB operations. This background of two consecutive relatively large series of LRYGB procedures, with the first series being carried out without and the second series being carried out with CPC, enabled us to evaluate the risks and benefits of different gallbladder management in LRYGB surgery in our prospectively collected data set.

#### **Materials and Methods**

## Study Design and Endpoints

This was a comparative cohort study based on a retrospective review of a prospectively maintained database and medical chart review of all severely obese patients presenting at our institution for LRYGB from December 2000 to March 2008. From December 2000 to November 2006, CCE was only performed concurrently with LRYGB in patients with ultrasonographically confirmed cholecystolithiasis, sludge, and/or gallbladder polyps. From December 2006 to March 2008, a routine CPC was performed in all patients receiving an LRYGB. The endpoints of the study were the following: the incidence of biliary complications and the necessity of subsequent CCE following LRYGB in patients not undergoing CPC (first series); morbidity related to the CPC with LRYGB in the second series; and the difference in duration of hospital stay and operative time between the two cohorts.

## Study Outcome Measures and Definitions

The study outcome measures included the following: incidence of biliary long-term complications such as

symptomatic cholecystolithiasis, cholecystitis, biliary pancreatitis necessitating a CCE, and a required choledochus revision in patients not receiving a CPC during an LRYGB procedure; morbidity related to the CPC, defined as bleeding, infection, bile leakage, or common bile duct injury in the second series; operation time (minutes) calculated from the first skin incision to the application of dressing; and length of hospital stay (number of days) recorded from hospital admission to the discharge date in both series. In contrast to a primary LRYGB, a secondary LRYGB was defined as an LRYGB procedure in patients who had previously undergone gastric banding.

## Eligibility Criteria for Patients

All patients who underwent an LRYGB procedure during the time interval were included in the study. The indication for surgery was based on the guidelines of the consensus development conference panel of the National Institutes of Health and the consensus on obesity treatment in Switzerland [25, 26]. Exclusion criteria included the following: previous CCE, the need for open gastric bypass procedure, previous bariatric procedure other than gastric banding, and being lost during follow-up.

## Preoperative Evaluation and Management

All patients were evaluated preoperatively for the presence of biliary symptoms. Abdominal ultrasonography was performed in all patients. In addition, all patients underwent an upper gastrointestinal endoscopy to exclude gastroduodenal lesions and detect *Helicobacter pylori* (HP) infections. In cases of positive HP findings, eradication by the use of classical antibiotic regimes was performed before surgery. Furthermore, all patients underwent esophageal manometry preoperatively to exclude severe esophageal dysfunction.

# Surgical Procedure

All procedures were carried out by one surgeon (MT). The LRYGB procedure was performed using six ports. An additional 5-mm trocar was placed in the right lateral abdominal wall in patients receiving CPC. Before CPC, the gallbladder was punctured, and bile was aspirated. CPC was performed using a conventional technique beginning with the exposure of the triangle of Calot followed by the identification of the cystic artery and the cystic duct. Both structures were sectioned between clips (Ligaclip® 12 mm, Ethicon Endo-Surgery, Cincinnati, USA or EndoClipL, 10 mm, Covidien). Afterwards, a conventional retrograde CCE was performed using an ultrasonic dissector (Harmonic ACE, Ethicon Endo-Surgery). CPC was always



performed before the LRYGB procedure. In all patients, a 15–20-ml gastric pouch was created as the restrictive component of the LRYGB procedure. Gut limb lengths were systematically varied according to the patients' BMI, co-morbidities, eating habits, and psycho-social situation, thereby establishing a "proximal" and a "distal" variant of the LRYGB procedure. The proximal LRYGB comprised an alimentary limb of 150 cm (i.e., the distance between the upper gastro-jejunal anastomosis and the lower jejuno-jejunal anastomosis) and a biliopancreatic limb approximately 60 cm distal to the ligament of Treitz. The distal LRYGB comprised a common channel (i.e., the distance between the lower anastomosis and Bauhin's valve) that was 10% (60–100 cm) of the total small bowel length and a biliopancreatic limb that was between 60 and 100 cm long.

## Postoperative Management and Follow-up

Ursodeoxycholic acid was not prescribed to any patients throughout the study period. Routine follow-up visits at the outpatient clinic took place at 2 weeks; 1, 2, 6, 9, 12, 18, and 24 months after surgery; and at least annually thereafter. Postoperative ultrasound scans were obtained only when patients developed biliary symptoms or abnormal liver function tests.

#### Statistics and Authorization

Statistical analyses were performed using SPSS 17 software (SPSS Inc., Chicago, IL, USA). A two-sided *p* value<0.050

Fig. 1 Trial flow diagram

was considered statistically significant. Continuous data are expressed as the means ± standard deviations. For comparing proportions, chi-squared tests were applied. For comparisons of continuous data, Mann–Whitney tests were used. For univariate survival analyses, log-rank tests were performed. For multivariate survival analyses, full Cox regression models and backward variable selection were applied. The R statistical software (www.r-project.org) using the bootStepAIC package was used for bootstrapping the backward variable selection process from the full Cox regression model [27]. The study was approved for retrospective data analysis by the Swiss Federal Expert Commission for Physician Confidentiality and the Institutional Review Board. The study was registered on www. ClinicalTrials.gov (NCT01219166).

#### Results

During the entire study period, 437 patients underwent RYGB surgery at the authors' institution. The patient selection process is illustrated in Fig. 1. After exclusion of patients according to the exclusion criteria, 140 patients remained in the first series and did not receive CPC, and 134 patients remained in the second series, in which CPC was performed.

Baseline characteristics of included patients and relevant information about their previous and concurrent abdominal operations are shown in Table 1. Follow-up was significantly shorter in the group of patients receiving CPC. Due to the evolution of distinct surgical strategies at the authors'

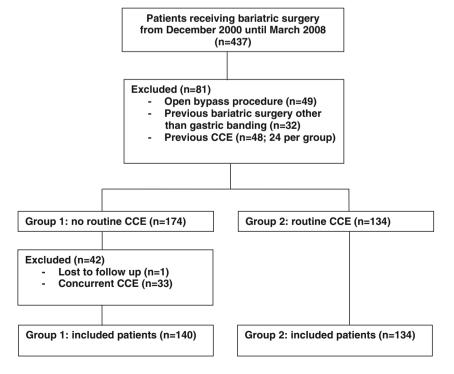




Table 1 Patient characteristics

	Total $(n=274)$	No prophylactic CCE (n=140)	Prophylactic CCE (n=134)	$p^{a, b}$	
Age (years)	41.8±10.1	43±10.2	40.7±9.8	$0.070^{a}$	
Follow-up (years)	$2.7 \pm 1.0$	$3.3 \pm 1.0$	$2.1 \pm 0.5$	<0.001 <sup>a</sup>	
Preoperative BMI (kg/m <sup>2</sup> )	$46.9 \pm 6.1$	$47.7 \pm 6.4$	$46.1 \pm 5.6$	0.073 <sup>a</sup>	
Preoperative BMI categories				$0.111^{b}$	
Morbidly obese [<50 kg/m <sup>2</sup> ]	190 (69.3%)	91 (65%)	99 (73.9%)		
Superobese [>50 kg/m <sup>2</sup> ]	84 (30.7%)	49 (35%)	35 (26.1%)		
Gender				$0.544^{b}$	
Female	202 (73.7%)	101 (72.1%)	101 (75.4%)		
Male	72 (26.3%)	39 (27.9%)	33 (24.6%)		
Bypass procedure				<0.001 <sup>b</sup>	
Proximal LRYGB	86 (31.4%)	72 (51.4%)	14 (10.4%)		
Distal LRYGB	188 (68.6%)	68 (48.6%)	120 (89.6%)		
Previous gastric banding				$0.747^{b}$	
No	165 (60.2%)	83 (59.3%)	82 (61.2%)		
Yes	109 (39.8%)	57 (40.7%)	52 (38.8%)		
Previous abdominal procedure				$0.467^{b}$	
No	247 (90.1%)	128 (91.4%)	119 (88.8%)		
Yes	27 (9.9%)	12 (8.6%)	15 (11.2%)		
Additional procedures					
Hiatoplasty	53 (19.3%)	17 (12.1%)	36 (26.9%)	$0.002^{b}$	
Adhesiolysis	103 (37.6%)	46 (32.9%)	57 (42.5%)	$0.098^{b}$	
Partial gastrectomy	88 (32.1%)	28 (20%)	60 (44.8%)	<0.001 <sup>b</sup>	
Hernia repair	5 (1.8%)	2 (1.4%)	3 (2.2%)	$0.616^{b}$	
Others	27 (9.9%)	10 (7.1%)	17 (12.7%)	$0.124^{b}$	

n (%); mean  $\pm$  standard deviation

institution, distal LRYGB procedures were performed significantly more often in the second series. Additionally, hiatoplasties and partial gastrectomies were more frequently performed in patients of the second series.

Biliary Complications After LRYGB in the First Series

During a median follow-up period of  $3.1\pm1.0$  years, 10 (13.9%) patients after a proximal LRYGB and 16 (23.5%) patients after a distal LRYGB required a CCE because of symptomatic cholelithiasis. In total, 26 (18.6%; 95% CI, 12.9–25.9%) patients required a CCE because of the occurrence of a symptomatic cholelithiasis. Of these patients, 23 (88.5%) patients were operated on laparoscopically, while 3 (11.5%) patients underwent CCE using an open technique. Two of these three patients had their surgeries in a small peripheral hospital, and the open technique was chosen because of suspected adhesions due to the previous LRYGB procedure. The third patient who received an open CCE (at the authors' institution) displayed acute cholecystitis and a concurrent epigastric hernia.

Here the open approach was used to avoid the pre-peritoneal implantation of a mesh in an infectious state. Biliary pancreatitis was not observed in any of the patients. However, choledocholithiasis was found in 3 (11.5%) patients, and acute cholecystitis was diagnosed in 16 (61.5%) patients. In all of the three patients with a choledocholithiasis, an intra-operative choledochus revision with extraction of the stones by a Fogarty catheter was successfully performed. The biliary complication-free survival after LRYGB was 85.5% (95% CI, 79.6–91.4%) at 2 years, 84.3% (95% CI, 78.1–90.5%) at 3 years, 81.3% (95% CI, 74.0–88.6%) at 4 years, and 77.4% (95% CI, 67.3–87.6%) at 5 years (Fig. 2). As calculated with the absolute risk reduction, the number needed to treat by means of prophylactic CCE was seven after two postoperative years and four after 5 years [25].

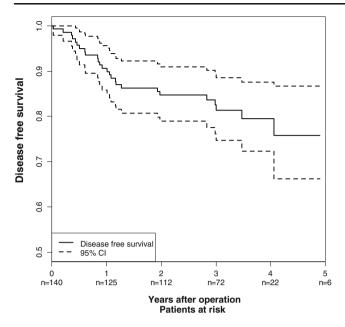
Risk Factors for Biliary Complications

In a full model Cox regression, excess weight loss (EWL) exceeding 75% at 2 years was a statistically significant risk



a Mann-Whitney test

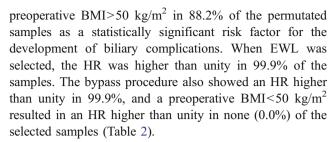
<sup>&</sup>lt;sup>b</sup> Chi-square test



**Fig. 2** Kaplan–Meier analysis of biliary complications. Kaplan–Meier analysis of patients subsequently requiring a CCE after LRYGB due to symptomatic cholelithiasis. The biliary complication-free survival rates were 85.5% (95% CI, 79.6–91.4%) at 2 years, 84.3% (95% CI, 78.1–90.5%) at 3 years, 81.3% (95% CI, 74.0–88.6%) at 4 years, and 77.4% (95% CI, 67.3–87.6%) at 5 years

factor (p=0.021), with a hazard ratio (HR) of 2.99 (95% CI, 1.18–7.58), for the development of biliary complications. In the same model when calculating with excess BMI (EBMI) loss instead of EWL, EBMI loss exceeding 75% at 2 years was also a statistically significant risk factor (p=0.044), with HR of 2.58 (95% CI, 1.03-6.69) for the development of biliary complications. Furthermore, with an HR of 2.76 (95% CI, 1.06-7.20), the distal variant of LRYGB significantly increased the risk of development of biliary complications (p=0.038). A BMI above 50 kg/m<sup>2</sup> was determined to be a significant (p=0.018) protective factor against the development of biliary complications (HR= 0.28; 95% CI, 0.10-0.81), while age, gender, previous gastric banding, excess weight loss at 6 months exceeding 50%, and excess BMI loss at 6 months exceeding 50% had no significant influence on the risk of biliary complications (Fig. 3). Confirming the results of the full Cox regression model, the sensitivity analysis (Cox regression model with backward variable selection; Table 2) also revealed that weight loss of more than 75% (p=0.039) and the distal variant of LRYGB (p=0.018) were significant risk factors for the development of biliary complications, with HRs of 2.30 and 2.61, respectively. Again, this analysis showed that a preoperative BMI above 50 kg/m<sup>2</sup> was significantly protective against the development of biliary complications (HR=0.33; p=0.017).

In a bootstrap analysis, EWL was selected in 80.9%, the bypass procedure (proximal vs. distal) in 77.5% and a



Operative Outcome and Hospital Stay in the First and Second Cohorts

Data on operative outcome and hospital stay of the two consecutive cohorts are summarized in Table 3. Neither operative time (p=0.247) nor the rate of conversion to open surgery (p=0.435) differed significantly between the two cohorts. Patients receiving CPC had significantly shorter hospital stays (p<0.001). EWL [percent] at 2 years was similar among the patients in the first and the second series. The postoperative complications in the patients of the second cohort were not related to the additionally performed CPC.

#### Discussion

To the authors' knowledge, this is the first study comparing two cohorts with a clearly predefined treatment algorithm "prophylactic vs. no prophylactic CCE" in patients undergoing LRYGB procedures. During the median follow-up period of 3.1 years, 18.6% of the patients who did not have a CPC at the time of LRYGB surgery subsequently required a CCE. The 5-year gallbladder disease-free survival was only 77.4%, reflecting that, in the first series, almost one fourth of the patients developed symptomatic cholecystolithiasis after LRYGB. With this history, it is important to note that CPC in the second series was not associated with an increased conversion rate to open surgery, operative time, duration of hospital stay, and postoperative morbidity, indicating that routine CPC is a safe approach in LRYGB surgery.

Previous reports of the incidence of gallstone formation after RYGB have varied between 28% and 71% [3, 5, 9, 11, 12]. Compared to the general population, the diagnostic accuracy of ultrasound examination for the detection of cholecystolithiasis is much lower in obese patients [22]. Given this limited diagnostic accuracy, the diagnosis of cholecystolithiasis may be missed preoperatively in some patients undergoing LRYGB, which may bias both present and previous results. However, gallstone formation per se does not represent a clinically relevant outcome because it can be asymptomatic over many years; thus, cholecystolithiasis was not an outcome variable in our study. Reported



**Fig. 3** Full model Cox regression for risk factors for biliary complications. Full model Cox regression with caseload per group, events, hazard ratio (HR) with 95% confidence interval (95% CI), multivariate Wald statistic *p* value, and graphical representation HR with 95% CI

n	Events	HR	95% CI	p Wald				
57	13 (22.8%)	1.00	ref	0.173				
83	13 (15.7%)	0.58	(0.26-1.28)					
101	18 (17.8%)	1.00	ref	0.249				
39	8 (20.5%)	1.72	(0.68-4.33)					
	,		,					
91	21 (23.1%)	1.00	ref	0.018				
49	5 (10.2%)	0.28	(0.10 - 0.81)					
	,		,					
83	14 (16.9%)	1.00	ref	0.918				
	,		(0.37-2.44)					
	( , , ,		( /					
72	10 (13.9%)	1.00	ref	0.038				
				0.000				
	(====,=,		(,					
84	14 (16.7%)	1.00	ref	0.239				
	` ,		(0.24-1.42)		<del></del>			
00	12 (211170)	0.00	(0.2 1 1.12)					
71	9 (12 7%)	1 00	ref	0.021				
	,			0.021				
00	17 (24.070)	2.00	(1.10 7.50)					
					0.1 0.2 0.5 1.0 2.0 5.0 10.0			
					Hazard ratio			
	57 83 101 39 91 49 83 57 72 68 84 56	57 13 (22.8%) 83 13 (15.7%) 101 18 (17.8%) 39 8 (20.5%) 91 21 (23.1%) 49 5 (10.2%) 83 14 (16.9%) 57 12 (21.1%) 72 10 (13.9%) 68 16 (23.5%) 84 14 (16.7%) 56 12 (21.4%) 71 9 (12.7%)	57 13 (22.8%) 1.00 83 13 (15.7%) 0.58 101 18 (17.8%) 1.00 39 8 (20.5%) 1.72 91 21 (23.1%) 1.00 49 5 (10.2%) 0.28 83 14 (16.9%) 1.00 57 12 (21.1%) 0.95 72 10 (13.9%) 1.00 68 16 (23.5%) 2.76 84 14 (16.7%) 1.00 56 12 (21.4%) 0.59 71 9 (12.7%) 1.00	57 13 (22.8%) 1.00 ref 83 13 (15.7%) 0.58 (0.26-1.28) 101 18 (17.8%) 1.00 ref 39 8 (20.5%) 1.72 (0.68-4.33) 91 21 (23.1%) 1.00 ref 49 5 (10.2%) 0.28 (0.10-0.81) 83 14 (16.9%) 1.00 ref 57 12 (21.1%) 0.95 (0.37-2.44) 72 10 (13.9%) 1.00 ref 68 16 (23.5%) 2.76 (1.06-7.20) 84 14 (16.7%) 1.00 ref 56 12 (21.4%) 0.59 (0.24-1.42) 71 9 (12.7%) 1.00 ref	57 13 (22.8%) 1.00 ref 0.173 83 13 (15.7%) 0.58 (0.26-1.28)  101 18 (17.8%) 1.00 ref 0.249 39 8 (20.5%) 1.72 (0.68-4.33)  91 21 (23.1%) 1.00 ref 0.018 49 5 (10.2%) 0.28 (0.10-0.81)  83 14 (16.9%) 1.00 ref 0.918 57 12 (21.1%) 0.95 (0.37-2.44)  72 10 (13.9%) 1.00 ref 0.038 68 16 (23.5%) 2.76 (1.06-7.20)  84 14 (16.7%) 1.00 ref 0.239 56 12 (21.4%) 0.59 (0.24-1.42)  71 9 (12.7%) 1.00 ref 0.021			

incidence rates of symptomatic cholelithiasis after RYGB have also varied widely in previous studies [3, 9, 23, 24, 28-30], ranging from 3% to 28%. In particular, those surgeons who found a rather low incidence rate of symptomatic cholecystolithiasis in their series do not recommend routine CPC with LRYGB [3, 9, 23, 24, 28-30]. However, most of the cited studies were retrospective in nature and, in contrast to the present study, did not rely on prospectively collected data, which may have biased their results. Moreover, none of the previous studies used adequate statistical methods to calculate time-dependent gallbladder disease-free survival rates. Lastly, in the previous studies, in contrast to the present study, no comparison between two cohorts with predefined treatment algorithms, e.g., "prophylactic vs. no prophylactic CCE," was performed, implying an inherent substantial degree of selection bias [23, 24, 28-32].

According to our Kaplan–Meier analysis, almost one fourth of the patients in the first series required a CCE within the first 5 years after LRYGB due to symptomatic cholelithiasis, of which almost three fourths were complicated by means of either cholecystitis or choledocholithiasis. In this context, after RYGB, performing an endoscopic retrograde cholangiopancreatography (ERCP) to evaluate the bile duct and remove stones is difficult or even impossible due to the profound anatomical changes established by the surgery. While transgastric and retrograde ERCP through the alimentary limb have been described in a few RYGB patients [33, 34], these procedures are very difficult to perform and frequently fruitless. Together, these points argue for the routine performance of CPC during RYGB surgery.

When considering CPC in patients receiving LRYGB, its putative benefits have to be weighed against the potential

**Table 2** Backward variable selection Cox regression model with bootstrapping

aBackward variable selection
Cox regression model
bBootstrapping procedure for
backward variable selection
process with 9,999 samples.
Column selection expresses the
proportion of the time the
variable was selected in the
backward variable selection
process, and column HR>1
expresses the proportion of
hazard ratios above 1.0

	Cox regression model <sup>a</sup>				Bootstrap <sup>b</sup>		
	p	HR	95% CI f	for HR	Selection (%)	HR>1 (%)	
BMI	0.017				88.2		
Morbidly obese [ $<$ 50] ( $n$ =91)		1	Ref			Ref	
Superobese [ $>50$ ] ( $n=49$ )		0.33	(0.13	-0.90)		0.0	
Bypass procedure	0.018				77.5		
Proximal RYGB (n=72)		1	Ref			Ref	
Distal RYGB (n=68)		2.61	(1.16	-5.83)		99.9	
EWL 24 months	0.039				80.9		
<75% (n=71)		1	Ref			Ref	
>75% (n=69)		2.30	(1.02	-5.21)		99.9	



Table 3 Operative and postoperative outcome

	Total ( <i>n</i> =274)	No prophylactic CCE (n=140)	Prophylactic CCE (n=134)	p <sup>a, b</sup>
Operative time [min]	227.9±65.2	234.8±70.7	220.7±58.4	0.247 <sup>a</sup>
Conversion to open	9 (3.3%)	4 (2.9%)	5 (3.7%)	$0.435^{b}$
Hospital stay [days]	8.5±5.5	$10.8 \pm 6.0$	$7.3 \pm 4.7$	<0.001 <sup>a</sup>
Excess weight loss 2 years [%]	77.3±26.8	76.3±30.6	$78.4 \pm 22$	0.111 <sup>a</sup>

n (%); mean  $\pm$  standard deviation

morbidity associated with this procedure. CPC in morbidly obese patients is commonly considered technically difficult [11] and hazardous because it was associated with serious complications in up to 2–3% of the patients in early studies [35]. In line with more recent studies [2, 22, 23], the results obtained in our second cohort demonstrate that, in experienced hands, CPC can be safely performed during LRYGB. In fact, in our second series, none of the postoperative complications were related to the CPC, and the conversion rate was not affected by this additional procedure. This surprisingly positive result may be based upon some technical specifics regarding the performance of CPC at the authors' institution. First, the falciform ligament is routinely divided in order to improve the access to the upper abdomen. Second, the CPC is always performed at the beginning of the operation when the level of patience is still high and the surgeon is not exhausted by the highly demanding LRYGB procedure. Third, an additional 5-mm trocar is routinely placed in the right lateral abdominal wall to perform the CPC. All of these measures may contribute to the safety of the procedure.

In contrast to Hamad et al. [16], who reported a significantly longer operating time and also a longer hospital stay associated with CPC in RYGB surgery, the present study, in accordance with several recently published studies [2, 7, 21], did not find such negative effects of CPC. On the contrary, the mean duration of surgery was significantly shorter in the second series, in which patients received a CPC. This at first glance surprising finding is most likely explained by the larger experience and the learning curve of the surgeon. Previous studies reported that concurrent CCE prolongs LRYGB surgery by approximately 20-30 min [2, 7, 21]. However, considering the time required for other additional procedures such as hiatoplasties and adhesiolysis, which had to be performed in a high proportion of our patients, the time necessary for CPC appears to be negligible. Regarding the relatively long median duration of the hospital stay, 8.5 days, in our study, reimbursement is not based on diagnosis-related groups but on the length of the hospital stay according to the current policy in Switzerland. Therefore, a direct comparison of our data with that of other studies reporting a much shorter average hospital stay will clearly be severely biased. Most importantly, however, the present results show that CPC with LRYGB does not prolong the hospital stay, which is a finding that is in agreement with the results of several previous studies [2, 7, 23].

The present study also allowed for the identification of risk factors for the development of biliary complications after LRYGB surgery. At first glance, it seems surprising that a rapid weight loss reflected by an EWL or EBMI loss of more than 50% within the first six postoperative months was not identified as a risk factor for developing symptomatic cholelithiasis. While there is no doubt that rapid weight loss promotes the formation of cholesterol cholelithiasis [5, 8], gallstone formation per se does not inevitably lead to symptomatic cholelithiasis [24], the outcome variable in our study. This may explain why the 6-month EWL>50% did not reach significance in the computed multivariate models. An EWL or an EBMI loss of more than 75% at 2 years, however, was identified as a statistically significant independent risk factor. The clinical relevance of this finding appears doubtful because the 2year EWL or EBMI loss cannot safely be predicted before the operation, precluding any clinical decision relevant to this issue. As indicated by our multivariate analyses, the distal LRYGB variant clearly yielded a greater risk for developing symptomatic cholelithiasis than the proximal LRYGB. Representing a form of biliopancreatic diversion, the distal RYGB partly interrupts the enterohepatic circulation, leading to distinct bile acid loss and subsequently enhanced gallstone formation [36]. This mechanism may explain the increased risk of symptomatic cholethiasis after distal in comparison to proximal gastric bypass surgery. In fact, as early as 1980, Scopinaro et al. had already reported a high incidence of gallstones after their famous biliopancreatic diversion procedure and recommended the routine performance of prophylactic CCE [36]. More surprisingly, a preoperative BMI>50 kg/m<sup>2</sup> was a significant protective factor against the development of symptomatic cholelithiasis. One possible explanation for this finding may be that, in the present series, the EWL



<sup>&</sup>lt;sup>a</sup> Mann-Whitney test

<sup>&</sup>lt;sup>b</sup>Chi-square test

(percent) as well as the EBMI over time was lower in patients with a BMI above than below 50 kg/m<sup>2</sup> (data not shown), especially in patients with a proximal LRYGB procedure.

In conclusion, severely obese patients who undergo LRYGB surgery are at high risk for the development of symptomatic biliary complications after the operation. Performing a CPC with LRYGB does not significantly increase the conversion rate to open surgery, the postoperative morbidity, or the operative time or hospital stay. With one fourth of the patients developing symptomatic cholelithiasis requiring CCE after LRYGB surgery, the number needed to treat with CPC is seven at 2 years and four at 5 years. Based on these findings, we conclude that CPC should be considered in LRYGB surgery, particularly for those variants that establish a biliopancreatic diversion.

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

#### References

- 1. Uy MC, Talingdan-Te MC, Espinosa WZ, et al. Ursodeoxycholic acid in the prevention of gallstone formation after bariatric surgery: a meta-analysis. Obes Surg. 2008;18:1532–8.
- Nougou A, Suter M. Almost routine prophylactic cholecystectomy during laparoscopic gastric bypass is safe. Obes Surg. 2008;18:535–9.
- Wudel Jr LJ, Wright JK, Debelak JP, et al. Prevention of gallstone formation in morbidly obese patients undergoing rapid weight loss: results of a randomized controlled pilot study. J Surg Res. 2002;102:50-6.
- 4. Dittrick GW, Thompson JS, Campos D, et al. Gallbladder pathology in morbid obesity. Obes Surg. 2005;15:238–42.
- Amaral JF, Thompson WR. Gallbladder disease in the morbidly obese. Am J Surg. 1985;149:551–7.
- Shiffman ML, Sugerman HJ, Kellum JH, et al. Gallstones in patients with morbid obesity. Relationship to body weight, weight loss and gallbladder bile cholesterol solubility. Int J Obes Relat Metab Disord. 1993;17:153–8.
- Ahmed AR, O'Malley W, Johnson J, et al. Cholecystectomy during laparoscopic gastric bypass has no effect on duration of hospital stay. Obes Surg. 2007;17:1075–9.
- Iglezias Brandao de Oliveira C, Adami Chaim E, da Silva BB. Impact of rapid weight reduction on risk of cholelithiasis after bariatric surgery. Obes Surg. 2003;13:625–8.
- Shiffman ML, Sugerman HJ, Kellum JM, et al. Gallstone formation after rapid weight loss: a prospective study in patients undergoing gastric bypass surgery for treatment of morbid obesity. Am J Gastroenterol. 1991;86:1000–5.
- Everhart JE. Contributions of obesity and weight loss to gallstone disease. Ann Intern Med. 1993;119:1029–35.
- Sugerman HJ, Brewer WH, Shiffman ML, et al. A multicenter, placebo-controlled, randomized, double-blind, prospective trial of prophylactic ursodiol for the prevention of gallstone formation

- following gastric-bypass-induced rapid weight loss. Am J Surg. 1995;169:91–6. discussion 6–7.
- Schmidt JH, Hocking MP, Rout WR, et al. The case for prophylactic cholecystectomy concomitant with gastric restriction for morbid obesity. Am Surg. 1988;54:269–72.
- Buchwald H, Avidor Y, Braunwald E, et al. Bariatric surgery: a systematic review and meta-analysis. JAMA. 2004;292:1724–37.
- Worobetz LJ, Inglis FG, Shaffer EA. The effect of ursodeoxycholic acid therapy on gallstone formation in the morbidly obese during rapid weight loss. Am J Gastroenterol. 1993;88:1705-10.
- 15. Bastouly M, Arasaki CH, Ferreira JB, et al. Early changes in postprandial gallbladder emptying in morbidly obese patients undergoing Roux-en-Y gastric bypass: correlation with the occurrence of biliary sludge and gallstones. Obes Surg. 2009;19:22–8.
- Hamad GG, Ikramuddin S, Gourash WF, et al. Elective cholecystectomy during laparoscopic Roux-en-Y gastric bypass: is it worth the wait? Obes Surg. 2003;13:76–81.
- Calhoun R, Willbanks O. Coexistence of gallbladder disease and morbid obesity. Am J Surg. 1987;154:655–8.
- Aidonopoulos AP, Papavramidis ST, Zaraboukas TG, et al. Gallbladder findings after cholecystectomy in morbidly obese patients. Obes Surg. 1994;4:8–12.
- 19. Seinige UL, Sataloff DM, Lieber CP, et al. Gallbladder disease in the morbidly obese patient. Obes Surg. 1991;1:51–6.
- Fobi M, Lee H, Igwe D, et al. Prophylactic cholecystectomy with gastric bypass operation: incidence of gallbladder disease. Obes Surg. 2002;12:350–3.
- Villegas L, Schneider B, Provost D, et al. Is routine cholecystectomy required during laparoscopic gastric bypass? Obes Surg. 2004;14:206–11.
- Escalona A, Boza C, Munoz R, et al. Routine preoperative ultrasonography and selective cholecystectomy in laparoscopic Roux-en-Y gastric bypass. Why not? Obes Surg. 2008;18:47–51
- 23. Tucker ON, Fajnwaks P, Szomstein S, et al. Is concomitant cholecystectomy necessary in obese patients undergoing laparoscopic gastric bypass surgery? Surg Endosc. 2008;22:2450–4.
- 24. Swartz DE, Felix EL. Elective cholecystectomy after Roux-en-Y gastric bypass: why should asymptomatic gallstones be treated differently in morbidly obese patients? Surg Obes Relat Dis. 2005;1:555–60.
- NIH conference. Gastrointestinal surgery for severe obesity. Consensus Development Conference Panel. Ann Intern Med. 1991;115:956–61.
- Consensus sur le traitment de l'obésité en Suisse. Schweiz Med Wochenschr. 1999;129:4–205.
- Austin PC, Tu J. Bootstrap methods for developing predictive models. Am Stat. 2004;131–7.
- Papasavas PK, Gagne DJ, Ceppa FA, et al. Routine gallbladder screening not necessary in patients undergoing laparoscopic Roux-en-Y gastric bypass. Surg Obes Relat Dis. 2006;2:41–6. discussion 6–7.
- Patel KR, White SC, Tejirian T, et al. Gallbladder management during laparoscopic Roux-en-Y gastric bypass surgery: routine preoperative screening for gallstones and postoperative prophylactic medical treatment are not necessary. Am Surg. 2006;72:857–61.
- Taylor J, Leitman IM, Horowitz M. Is routine cholecystectomy necessary at the time of Roux-en-Y gastric bypass? Obes Surg. 2006;16:759–61.
- 31. Portenier DD, Grant JP, Blackwood HS, et al. Expectant management of the asymptomatic gallbladder at Roux-en-Y gastric bypass. Surg Obes Relat Dis. 2007;3:476–9.



- 32. Caruana JA, McCabe MN, Smith AD, et al. Incidence of symptomatic gallstones after gastric bypass: is prophylactic treatment really necessary? Surg Obes Relat Dis. 2005;1:564–7. discussion 7–8.
- Martinez J, Guerrero L, Byers P, et al. Endoscopic retrograde cholangiopancreatography and gastroduodenoscopy after Rouxen-Y gastric bypass. Surg Endosc. 2006;20:1548–50.
- 34. Mosler P, Fogel EL. Massive subcutaneous emphysema after attempted endoscopic retrograde cholangiopancreatography in a
- patient with a history of bariatric gastric bypass surgery. Endoscopy. 2007;39 Suppl 1:E155.
- 35. Fuller W, Rasmussen JJ, Ghosh J, et al. Is routine cholecystectomy indicated for asymptomatic cholelithiasis in patients undergoing gastric bypass? Obes Surg. 2007;17:747–51.
- Scopinaro N, Gianetta E, Civalleri D, et al. Two years of clinical experience with biliopancreatic bypass for obesity. Am J Clin Nutr. 1980;33:506–14.

