



Incidence of Gallstone Formation and Cholecystectomy 10 Years After Bariatric Surgery

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Published online: 15 January 2015
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Abstract

Purpose Rapid weight loss is a risk factor for gallstone formation, and postoperative treatment options for gallstone formation are still part of scientific discussion. No prospective studies monitored the incidence for gallstone formation and subsequent cholecystectomy after bariatric surgery longer than 5 years. The aim of the study was to determine the incidence of gallstone formation and cholecystectomy in bariatric patients over 10 years.

Materials and methods One hundred nine patients were observed over 10 years after laparoscopic gastric banding or gastric bypass/gastric sleeve. The incidence of gallstone formation and cholecystectomy was correlated to longitudinal changes in anthropometric parameters.

Results In total, 91 female and 18 male patients were examined. Nineteen patients had postoperative gallstone formation, and 12 female patients required cholecystectomy. The number needed to harm for gallstone formation was 7.1 and 2.3 cases in the banding group and gastric bypass/gastric sleeve group, respectively. The number needed to harm for cholecystectomy was 11.6 and 2.5 cases in the banding group and the gastric bypass/gastric sleeve group, respectively. Weight loss was higher in patients requiring subsequent cholecystectomy.

Mean follow-up to cholecystectomy was 21.5 months with the latest operation after 51 months.

Conclusion Female gender and rapid weight loss were major risk factors for postoperative cholelithiasis. Ultrasound examinations within 2 to 5 years are recommended in every patient, independent of bariatric procedure. Pharmacologic treatment should be considered in high risk patients within 2 to 5 years to prevent postoperative cholelithiasis. This helps to optimize patient care and lowers postoperative morbidity.

Keywords Gallstone formation · Bariatric surgery · Cholecystectomy · Obesity · Weight loss

Introduction

Despite the beneficial effects of bariatric surgery, bariatric patients are prone to the formation of gallstones with a postoperative cumulative risk of 30–53 %—an observation that still gives rise to concern in the scientific community [1]. The estimated prevalence for gallstones in the general population varies between different ethnicities, whereas higher rates have been observed in Caucasian, Hispanic, and Native American origin [2, 3]. In Europe, the overall prevalence for cholelithiasis was 19 % in women and 9 % in men, respectively [4].

Gallstone formation itself depends on several risk factors [5]. In the general population, several risk factors for gallstone formation are known to increase with age with a cut-off of 40 years, female gender, obesity, and rapid weight loss as the most important contributors [2–4, 6, 7]. According to a former study, the risk for gallstone formation during active weight loss increases dramatically above a weight loss of 1.5 kg per week [8]. The mechanisms why weight loss periods—due to very low calorie diet or bariatric surgery—actually promote gallstone formation is poorly understood, although changes in

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gallbladder bile composition with increased content of bile mucin have been reported [7, 9].

Most of the present studies investigating postoperative gallstone formation are retrospective and focus on a follow-up period from months to 5 years after bariatric surgery [10].

The aim of the present study is to investigate the long-term effect of bariatric surgery on gallstone formation and the frequency of cholecystectomy (CHE) as well as to identify associated risk factors. We therefore investigated the incidence of gallstone formation and CHE in patients undergoing either laparoscopic adjustable gastric banding (LAGB=banding group) or procedures other than LAGB (gastric bypass (GB)/gastric sleeve (GS) group) over a mean follow-up period of 10 years.

Methods and Procedures

A total of 109 patients (91 females, 18 males) with a BMI >35 kg/m² and at least one comorbidity or a BMI >40 kg/m² was examined within a 2-month period pre-operatively and 10 years after bariatric surgery.

Exclusion criteria were type 1 and type 2 diabetes mellitus, uncontrolled hypertension, a history of cardiovascular disease (CVD), secondary cause of obesity, pregnancy, medication-influencing coagulation, lipid lowering or antipsychotic medication, and alcohol consumption of more than 20 g alcohol per day. Acute infectious disease and inflammation was excluded by medical history, physical, and laboratory examinations. No patient received ursodeoxycholic acid and/or other drugs known to influence gallstone formation during the study. Written informed consent was obtained from all subjects. The authors certify that all applicable institutional and governmental regulations concerning the ethical use of human volunteers were followed during this study. The local ethical committee approved the study.

Surgical Procedure

The surgical procedures were performed at the Department of Visceral, Thoracic and Transplant Surgery, Innsbruck Medical University, as described elsewhere [11].

Anthropometric Measures

Anthropometric parameters included body weight, total body adipose tissue mass, lean mass, abdominal subcutaneous adipose tissue (aSAT), visceral adipose tissue (VAT), body mass index (BMI), and waist circumference (WC). Electrical body impedance analysis (BIA, including lean mass, total body adipose tissue mass) were determined by impedance analysis using InBody 3.0 Body Composition Analyzer from Biospace Europe (Deitzenbach, Germany) with an integrated scale

using the software Lookin Body 3.0. Follow-up measurements were done using InBody 720 Body Composition Analyzer from Biospace Europe with an integrated scale using the software Lookin Body Version 3.2, Body Composition Analysis Management System.

Body height was measured to the nearest 0.1 cm, and body weight was measured to the nearest 0.1 kg using an electronic scale. BMI was calculated dividing body weight by body height in meters squared. WC was measured using a tapeline at the level midway between the lateral lower rib margin and iliac crest.

The diameter aSAT and VAT were determined in a morning fasting state as described by Pontiroli et al. [12]. An Acuson Sequoia 512 System with 3.0 MHz curved array transducer (Siemens-Acuson, Mountain View, CA, USA) was placed along the xypho-umbilical line next to the umbilicus, and both aSAT and VAT were measured after smooth expiration. VAT was measured from the internal surface of the musculus rectus abdominis to the near wall of the aorta. Abdominal subcutaneous adipose tissue was measured at the same position as the distance between the external surface of the muscle and the skin. The thickness of the muscle and skin was excluded.

Excess weight loss was calculated according to the following formula: ((difference in BMI/(BMI baseline–25)) \times 100 [13].

Ultrasound Measurements

Each patient underwent abdominal ultrasonography using an Acuson Sequoia 512 System with 3.0 MHz curved array transducer (Siemens-Acuson, Mountain View, CA, USA) in supine and left lateral position. Imaging studies of the liver were performed using the Native TEQ (Tissue Equalisation)TM Ultrasound technology, which automatically responds to patient-specific information with continuous, hands-free, and voice-free gain adjustment. Native TEQTM is based on a real time monitoring function that checks the image for tissue and interface changes. The system then calculates new optimal settings for all and depth-dependent gain, immediately distinguishing between soft tissue, artifacts, noise, and specular reflectors. Both axial and lateral gain is adjusted before the image is formed. We used Native TEQTM technology in this study to obtain automatically optimized, user-independent images of the liver and the biliary system including the gall bladder and the common bile duct. All ultrasound examinations were performed by one experienced investigator. Although technical limits may exist in obese subjects, adequate visualization of the gall bladder and the common bile duct was possible in all patients.

Statistical Analyses

The Shapiro-Wilk test was assessed for determination of Gaussian distribution of all analyzed parameters; skewed data were log-transformed to achieve an approximately normal distribution. Dependent and independent Student's *T* test was used to estimate significant changes in parametric data over the different follow-up period. Chi² test was used to calculate significant changes between categorical data. A two sided *p* value smaller or equal to 0.05 was considered statistically significant. All analyses were performed using SPSS version 21 (IBM Cooperation, Armonk, New York, USA).

Results

Table 1 illustrates differences between the LAGB group and GB/GS group over the observation period. Table 2 illustrates differences between patients with and without subsequent CHE. Mean follow-up time of patients was 125.5±17.8 months. A cohort of 109 patients was included in this study. Of these, 94 patients (86.2 %) underwent LAGB at baseline (banding group) and 15 patients (13.8 %) had bariatric procedures other than LAGB (GB/GS group). Mean age of the study cohort was 55.3±10.5 years. Mean body weight loss was 17.4±34.2 kg (15 %) in the LAGB group and 21.2±31.9 kg (16 %) in the GB/GS-group, representing a BMI excess weight loss of 59.9±85.2 and 58.9±69.5 % in the LAGB and GB/GS group, respectively.

During the observation period, no patient was lost to follow-up. Nineteen patients (22.2 %, excluding patients who were already diagnosed with gallstone formation or CHE prior to bariatric surgery (*n*=28)) were newly diagnosed with gallstone formation (11 female and 8 male patients). Of these, 13 gallstone formations (16.3 %) occurred in the LAGB group (80 patients) and 6 (42.9 %) in the GB/GS group (14 patients), calculating a number needed to harm (NNH) of 7.1 cases in the LAGB group and 2.3 cases in the GB/GS group. The number needed to harm indicates how many patients experience bariatric surgery until one patient develops a complication (cholelithiasis or cholecystectomy). Chi² test indicated a significant difference in the incidence of gallstone formation between the LAGB and GB/GS-group (*p*=0.023).

Twelve female patients (14.1 %, excluding patients who had CHE prior to bariatric surgery (*n*=24)) had CHE after bariatric surgery due to symptomatic gallstone formation. Of these, 6 CHE (8.6 %) occurred in the LAGB group (70 patients) and 6 (40 %) in the GB/GS-group (15 patients), calculating a number needed to harm of 11.6 cases in the LAGB group and 2.5 cases in the GB/GS group. Chi² test

Table 1 Differences between the LAGB and GB/GS group at baseline and after a mean follow-up of 10 years, *N*=109

	LAGB group	GB/GS group	<i>p</i> value ^a
Lost to follow-up	0	0	n.a.
Sex	80 female, 14 male	11 female, 4 male	n.a.
Age (years)	53.2±11.3	50.7±8.9	0.272
Body weight (kg)	115.9±20.9	116.3±23.4	0.685
Difference VAT (cm)	-4.6±2.6	-5.1±2.6	0.594
Difference aSAT (cm)	-1.4±1.3	-1.7±1.4	0.601
Difference lean body mass (kg)	-6.9±7.6	-10.3±9.6	0.160
Difference total body fat mass (kg)	-15.1±15.7	-21.7±18.1	0.170
Weight loss (kg)	17.4±34.2	20.1±31.9	0.418
Weight loss (%)	15	16	0.418
Prior gallstone formation	5	1	n.a.
Prior cholecystectomy	24	0	n.a.
Gallstone formation ^b	13 (16.3 %)	6 (42.9 %)	0.023
Cholecystectomy ^b	6 (8.6 %)	6 (40 %)	0.013
Excess weight loss (%) ^c	54.8 (17.3–92.6)	87.7 (66.4–114.2)	0.992
Follow-up to CHE (months)	24.4±18.6	19.0±16.2	0.662

Mean±standard deviation is shown for parametric distributed data, median and interquartile range for non-parametric data, an alpha-level of 0.05 was considered as statistically significant

LAGB laparoscopic adjustable gastric banding, GB gastric bypass, GS gastric sleeve, n.a. not applicable, VAT visceral adipose tissue, aSAT abdominal subcutaneous adipose tissue, CHE cholecystectomy, kg kilograms

^a Chi² test for comparison of categorical variables; independent student's *T* test for comparison of continuous variables

^b Number of cases during the observation period. Only in patients without gallstone formation or cholecystectomy prior to bariatric surgery

^c ((Difference in BMI/(BMI baseline–25))×100

indicated a significant difference in the incidence of subsequent CHE between the LAGB and GB/GS-group (*p*=0.013).

Mean follow-up time until CHE was 21.6±16.6 months with a range from 5 to 51 months and was generally shorter in patients treated with GB/GS (Table 1).

Mean weight loss significantly differed between patients who had postoperative CHE compared to non-CHE patients (38.6±17.1 kg for CHE patients and 15.2±37.3 kg for non-CHE patients; *p*=0.016; see Table 2).

Discussion

The question how to manage gall bladder disease that occurs after bariatric surgery remains controversial. At present, three different strategies are discussed that address the issue of postoperative gallstone formation: first, patients undergoing laparoscopic GB—the known most effective option

Table 2 Differences between patients with and without concomitant cholecystectomy over a follow-up observation period of 10 years

	CHE	No CHE	<i>p</i> value ^a
Age (years)	49.6±11.1	50.9±10.1	0.667
Body weight (kg)	118.2±22.9	119.9±14.9	0.864
Difference VAT (cm)	−5.6±0.2	−4.6±2.7	0.084
Difference aSAT (cm)	−1.2±0.5	−1.5±1.4	0.691
Difference lean body mass (kg)	−9.9±5.6	−7.2±8.1	0.314
Difference total body fat mass (kg)	−27.9±12.7	−14.6±15.9	0.013
Weight loss (kg) ^b	38.6±17.1	15.2±37.0	0.016
Weight loss (%) ^b	32.7	12.8	0.016
Excess weight loss (%) ^b	81.4 (66.4–93.0)	55.3 (17.4–99.1)	0.143

Mean±standard deviation is shown for parametric distributed data, median and interquartile range for non-parametric data; an alpha-level of 0.05 was considered as statistical significant

CHE cholecystectomy, VAT visceral adipose tissue, aSAT abdominal subcutaneous adipose tissue, kg kilograms

^aIndependent student's *T* test for continuous variables; chi²-test for categorical variables. Alpha-level of 0.05 was considered as statistically significant

^bIndicates an observation period of 10 years. Excess weight loss was calculated according to the formula: ((difference in BMI / (BMI baseline–25))×100

concerning pronounced weight loss—are treated with concomitant CHE [14]. Second, patients are re-evaluated for selective laparoscopic CHE after the bariatric surgical procedure is finished and (symptomatic) gallstones or other biliary symptoms are present [15]. Third, patients are treated with ursodeoxycholic acid, a substance which inhibits gallstone formation, after the bariatric surgical procedure is finished [16, 17].

Recent studies estimated a current prevalence of gallstone formation in the general population in industrialized nations of 10–20 %, while only 1–5 % of these patients require CHE due to symptomatic gallstone formation. Former observations indicated a significantly higher incidence of gallstone formation and/or gall sludge of 28–71 % in bariatric surgery patients. Hereby, the incidence for gallstone formation is influenced by the rapid weight loss and an increased disposition for biliary stone formation [4, 18]. Still, the incidence of CHE due to symptomatic gallstone formation in GB patients approximates 6.8 % after the bariatric procedure, which makes the risk for gallstone formation requiring CHE comparable to the risk in the general population [10].

The present study illustrates a gallstone formation rate of approximately 20 % detected by ultrasound measures. The NNH approximates five LAGB and three GB/GS patients undergoing bariatric surgery for one CHE to occur.

A recent study indicated that patients with gallstone formation due to rapid weight loss were found to have a higher

rate of symptomatic cholelithiasis [19]. According to the actual guidelines for Perioperative Nutritional, Metabolic, and Nonsurgical Support of the Bariatric Surgery Patient (AACE/TOS/ASMBS) in 2013, ultrasound measurements should be utilized conventionally for the detection of gallstone formation in postbariatric surgery patients, without postulating a precise time frame [20]. A recent study indicated that weight loss ≥25 % was the only predictive factor for postoperative gallstone formation and could therefore help to select patients for subsequent ultrasound measures after bariatric surgery [21]. According to this and the present results, ultrasound measurements should be performed in the period of pronounced and rapid weight loss, namely during the first 24 months but not later than 5 years after bariatric surgery. Though, asymptomatic gall stones are not an indication to treat and the risk and costs of cholecystectomy do not warrant its prophylactic use in asymptomatic patients [22]. Nevertheless, clinicians and patients can get conscious about the presence of cholelithiasis through ultrasound measurements and this may help to facilitate diagnostic decisions if a patient shows abdominal colic symptoms.

Endoscopic access to the common bile duct is not applicable after GB in every patient [23]. Therefore, the treatment of symptomatic choledocholithiasis has to be performed with more complex endoscopic retrograde cholangiopancreatography (ERCP) techniques including gastrostomy or gastric stents or even with laparoscopy, which may result in longer hospital stays and mortality rates for the patients [24]. In regard to prevention of gallstone formation, pharmacological treatment with ursodeoxycholic acid has been shown to be a safe and effective treatment option during rapid weight loss, although its effects depend on patients' compliance [18, 25]. Ursodeoxycholic acid can therefore be used to prevent cholelithiasis in periods of rapid weight loss and to reduce asymptomatic cholesterol gallstones in the long-term, which are not radiopaque and therefore not calcified.

A CHE rate of approximately 10 % occurred in the present study, the NNH approximates nine patients in the LAGB group and five patients in the GB/GS group for one CHE to occur. Only female patients required subsequent CHE with the highest incidence during the first 2 years after bariatric surgery while the latest CHE was conducted after 5 years. The incidence of CHE was higher in the GB/GS group compared to the banding group and correlated to the amount of total body weight lost during the follow-up period. This result is in contrast to a recent study of Moon et al., who determined a postoperative gallstone formation frequency of 0 % after LAGB [26]. Hypothetically, if the present study investigated GB/GS patients only, the rate of postoperative cholelithiasis and CHE would have been presumably higher. Rapid weight loss, which is more likely to be experienced by GB/GS patients compared to LAGB patients, is one of the most important risk factor for cholelithiasis. As a practical consequence, patients undergoing bariatric surgery

techniques with a presumably high and rapid weight loss should be considered for prophylactic treatment against cholelithiasis—namely ursodeoxycholic acid—within the first 24 months up to 5 years after surgery.

Our results are in line with a recent meta-analysis conducted by Warschkow et al., whose calculations comprised 13 retro- and prospective intervention studies with concomitant CHE after GB as their primary outcome variable [10]. The mean incidence for subsequent CHE was 6.8 % with a per year risk of 3.1 %, respectively. The authors conclude that the selective approach should be recommended in contrast to concomitant CHE in GB patients. Another recent study including over 70,000 patients undergoing GB surgery illustrated significantly lower rates of mortality, morbidity, re-interventions, and shorter hospital stays in patients who were treated with selective rather than concomitant CHE [27].

Besides the meta-analytical model of Warschkow et al., which—as the author's state could have been influenced by individual follow-up periods—some of the 13 studies analyzed illustrated an incidence of subsequent CHE of approximately 10 %, which is in line with our study results.

Though the prevalence of CHE after bariatric surgery is comparable to the general population, the NNH for both gallstone formation and CHE are low and increase the burden of disease and duration of hospital stay in obese patients undergoing rapid weight loss.

The question remains, whether pronounced and sustained weight loss induces or even protects from gallstone formation in obese patients, as the present results in bariatric patients were not compared to obese patients not undergoing bariatric surgery. The finding that no CHE was necessary between 5 and 10 years after bariatric surgery in the present study gives rise to discussion, as the mean BMI after 10 years still was $32.5 \pm 6.7 \text{ kg/m}^2$, representing obese and therefore high risk patients per se. The present study compares results of a bariatric intervention cohort with observations in the general population, whose anthropometric characteristics are unknown, therefore only giving an estimate of the main effect of pronounced and sustained weight loss on the incidence of gallstone formation. In the optimal case, the present studies' design would be a prospective and controlled, recruiting an equally sized, obese non-intervention cohort. However, withholding surgery from a patient fulfilling medical indication for bariatric intervention for years is contradictory to the ethical standards of the institutional research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Further limitations of the present study are its small sample size, which may have biased the results at a given event rate of 10–20 % due to statistical limitations. No a priori power-analysis was performed.

The strength of the present study is its naturalistic, prospective design, a participant's follow-up rate of 100 %, and its investigation period of over 10 years.

In conclusion, rapid weight loss and female gender are the major risk factors for CHE in patients undergoing bariatric surgery.

The clinical relevance of this study emphasizes the necessity of ultrasound examinations as well as the pharmacological prevention of cholelithiasis in high risk bariatric patients as suggested by the revised AACE/TOS/ASMBS guidelines in 2013, during the period of pronounced and rapid weight loss within the first 2 years up to 5 years postoperatively. Ultrasound examinations should be performed independently of the bariatric procedure, as LAGB was also found to cause postbariatric gallstone formation. The development of gallstone formation later than 5 years after bariatric surgery is unlikely. The most important finding of the present study is the time frame of five postoperative years for the development of cholelithiasis. Therefore, in high risk patients with rapid weight loss or planned bariatric procedures that lead to massive expected weight loss, the a priori application of pharmacological treatment against gallstone formation should be recommended for at least 24 months up to 5 years after surgery while longer postoperative treatment seems unnecessary. This could result in optimized care and lower morbidity in these vulnerable patients.

Acknowledgments The expert technical assistance of Dr. Karin Salzmann is gratefully acknowledged. This study was supported by the Austrian Science Fund (FWF) KLI 348 and by the Austrian Science Fund ZFP 266730.

The corresponding author, Prof. Dr. Christoph Ebenbichler, had full access to all data in the study and had the final responsibility for the decision to submit for publication.

Authors Contributions Andreas Melmer was involved in manuscript preparation, data analysis, patients' recruitment, and clinical examination. Wolfgang Sturm performed the ultrasound examinations; Bernhard Kuhnert was involved in manuscript preparation and data analysis; Julia Engl-Prosch was involved in manuscript preparation, patients' recruitment and clinical examination; Claudia Ress was involved in patients' recruitment and clinical examination; Alexander Tschoner was involved in manuscript preparation; Elisabeth Laimer performed the bariatric surgery; Matthias Biebl performed the bariatric surgery; Johann Pratschke performed the bariatric surgery; Herbert Tilg was involved in manuscript preparation; and Christoph Ebenbichler is the principal investigator of the study and was involved in manuscript preparation, patients' recruitment, and clinical examination.

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

Informed Consent Informed consent was obtained from all individual participants included in the study.

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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