

## Reduction of Cholelithiasis after Bariatric Surgery

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### Abstract

**Background:** Gallstones are common in the Bariatric patients and may be formed during rapid weight loss period. A rational approach to the management of the gallbladder should be incorporated into bariatric surgical practice. It has been recommended that patients undergoing roux-en-y gastric bypass have routine cholecystectomy regardless of gallstone status. A combined prospective and retrospective study to evaluate the outcome of cholecystectomy rates in Bariatric patients have one of three bariatric procedures (LRYGB, LSG, and LGB), evaluated with a median follow-up 24 months. The highest cholecystectomy rate was found in LRYGB group (10.6%) and the frequency was highest within the first 6 months (3.7%).

**Aim of Study:** To evaluate the prophylactic measures for prevention of gallstone formation after bariatric surgery and to identify risk factors.

**Patients and Methods:** A total of 120 obese patients were included in the study. Pre-operative assessment was performed, including: History, examination, obesity evaluation (body weight, BMI, waist circumference), full laboratory study, gastroscopy, and abdominal ultrasonography. After laparoscopic sleeve gastrectomy, patients were divided randomly into: Group 1 (control), Group 2 (urso-deoxycholic acid), and Group 3 (ezetimibe) and Group 4 (combined drug therapy). Patients were scheduled for 3, 6, and 12 month visits for assessment.

**Results:** A significant reduction in gallstone formation was found in group 3 "ezetimibe" (5.5%) and group 4 "combined medication" compared with the group 1 "control" (17.6%). A statistically significant increase in % excess weight loss was observed in patients with gallstones (38.5%) versus patients without gallstones (28.2%). Percentage of gallstone formation during first 6 months post-operatively was double that during the next 6 months in both the control and treatment groups.

**Conclusions:** The rapid weight loss after bariatric surgery is the most important predisposing cause for gallstones formation. These can cause serious problems such as acute cholecystitis, choledocholithiasis and pancreatitis. Clinicians should be cautious in terms of cholelithiasis in patients with complaints of abdominal pain during the post-operative follow-

up period. In such a case, the abdominal ultrasound should definitely confirm.

**Key Words:** Obesity – Co-morbidity – Gallstone disease – Risk factors – Prophylactic measures.

### Introduction

**OBESITY** is related with many chronic diseases as (hypertension, type 2 diabetes, dyslipidemia, cardio-vascular diseases, sleep apnea and etc). Other modalities for weight reduction (diet, exercise); usually result in regaining weight differently from bariatric surgery. Obesity related morbidities both shorten life time and cost expensive. Bariatric surgery has recently become one of the most common treatment modality in maintaining long-term weight reduction and improving obesity-related conditions. Therefore; bariatric surgery is a cost-effective treatment modality [1].

**Risk factors:** Obesity, female gender, age >40 years, and white races, rapid weight gain or weight loss (after bariatric surgery), pregnancy, use of oral contraceptives, estrogen replacement therapy, diabetes, and family history are increases the incidence of cholelithiasis [2,3].

Rapid weight loss after Bariatric surgery activates multiple physiologic factors affects gallstones formation. Hyper saturation of bile with cholesterol, raised mucin production and hypo-motility of gallbladder contribute to gallstone formation [4].

Division of hepatic branch of the vagus nerve causes gallstone formation as well [5].

Obese persons are at risk for cholesterol gallstones due to high saturation of cholesterol in their bile. About 75% of gallstones are of cholesterol type. The risk increases during rapid weight loss using low-calorie diets and after bariatric surgery [6].

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The mechanism of gallstone formation during rapid weight loss is noted; completely under several mechanisms have been suggested including increased bile cholesterol saturation and gallbladder stasis, increased secretion of mucin and calcium, and increased prostaglandins [7].

Gallstones are common surgical diseases in the community and a greater problem in the obese population. It was estimated >30 years ago that 15% of the population had gallstones [8]. The peak incidence of gallstones occurring the western world in the 1960s [9]. It remains a common disease; the risk of developing gallstones is directly related to the level of obesity [10]. A relative risk above a body mass index of 40 (calculated as weight in kilograms divided by the square of height in meters) being 5 to 6 times that of the background population [11].

The risk of gallstone formation increases 8-fold in patients with BMI >40kg/m<sup>2</sup> [12], and increases 5-fold in patients who are underwent bariatric surgery compared with normal population [13].

According to the actual clinic practice guidelines for the Peri-operative Nutritional, Metabolic, and Non-surgical Support of the Bariatric Surgery Patient (2013 update, American Association of Clinical Endocrinologists, The Obesity Society and American Society for Metabolic & Bariatric Surgery), hepat-obiliary ultrasound is not recommended as a routine screen for liver disease but this knowledge has grade-C evidence level. If the patient complains symptomatic biliary disease and laboratory investigations reveal elevated liver function tests (2-3 times the upper limit of normal) abdominal US is indicated In post-operative period, if the patient has right upper quadrant pain, ultrasound should be performed for evaluation of acute cholecystitis [14].

#### *Incidence of cholelithiasis in bariatric surgery patients:*

The relation-ship between obesity and cholelithiasis has been widely studied, some issues remain controversial. Roux-en-Y gastric bypass (RYGBP) is associated with gallstone formation, and the incidence of cholelithiasis after RYGBP ranges from 6.7% to 52.8% [15].

It is controversial whether cholecystectomy should be performed routinely during the bariatric gastric bypass or only if cholelithiasis is present [16].

#### *Drugs commonly used for prevention of gallstone:*

Urso-deoxycholic acid enhances the conversion of cholesterol to bile acids; and enhances cholesterol transport as liquid crystals [17].

*Urso-deoxycholic acid (UDCA):* Is generally used to dissolve gallstones in patient's how un-like surgery. It is indicated also in patients at high risk for recurrent cholecystitis. UDCA is a bile acid and normally it is produced by the body that is stored in the gallbladder. It decreases the production of cholesterol and increases dissolving cholesterol in bile. So; it prevents gallstone formation [18].

*Ezetimibe:* Is a cholesterol-lowering agent that inhibits intestinal cholesterol absorption [19].

A long-term study is needed to observe whether ezetimibe can reduce gallstone prevalence [20].

## Patients and Methods

From February 2015 to January 2020, a total of 120 consecutive patients underwent Laparoscopic bariatric surgery at General Surgery Department, Al-Azhar University Hospitals. All procedures were performed for the management of morbid obesity (BMI >35kg/m<sup>2</sup> with or without significant co-morbidities related to obesity).

All patients were subjected to follow-up abdominal ultrasonography (US) obtained pre-operatively and at 3, 6, and 12 months post-operative.

Eligible patients were between 20 and 46 years of age and had a BMI of at least 40kg/m<sup>2</sup> or BMI of at least 35kg/m<sup>2</sup> with co-morbidities according to the guidelines of the National Institutes of Health Consensus Development Conference Statement.

Informed consent was obtained from each patient before initiation of the study, and hospital ethical committee approval was obtained for the protocol of the study (Table 1).

Table (1): Baseline characteristics of patients involved in the study.

Variable	Point of variation	Mean	p-value
<i>Gender:</i>			
Men (n, %)	56 (46.6%)	23	(10.5)
Women (n, %)	64 (53.3%)	26	34 (89.5)
Mean age (yr)	20-46	43.16	±10.11
Mean weight (kg)	110-220	123.02	123.02±19.70
Mean BMI (kg/m <sup>2</sup> )	40-54	47.86±	±4.92

**Exclusion criteria:**

History of cholecystectomy, presence of gallstones, pregnancy or inadequate use of contraceptive methods.

All patients were subjected to pre-operative clinical examination with obesity evaluation and laboratory evaluation performed before surgery, including fasting blood sugar, lipid profile, ECG and echo-cardiography, chest radiography and spirometry, abdominal US, gastroscopy, hormonal level (thyroid function test and serum cortisol) and vitamin D assays, and other basic pre-operative work was performed. Laparoscopic sleeve gastrectomy and gastric bypass surgery was performed by one operator and two assistants for all the cases.

We divided patients randomly into four groups: group 1 (control group); group 2, using (urso-deoxycholic acid group) at a dose of 4-5mg/kg/day in divided oral doses; and group 3, (ezetimibe group) at a dose of 10mg/day orally and group 4 (combined drug therapy "urso-deoxycholic acid and ezetimibe" group).

All treatments initiated 10 days after surgery and continued for 12 months or until gallstone development.

Patients agreed to take the trial medication for 12 months or until gallstones developed. Medication compliance was monitored at every visit.

There were no serious or significant adverse effects experienced during the study. EWL was recorded and abdominal US was performed by radiologists for all patients at every visit (at 3, 6, and 12 months).

Each patient was evaluated with pre-operative abdomino-pelvic ultrasonography. Patients who were found to have gallstones (cholecystectomy was performed at the same time) and those who had undergone cholecystectomy before bariatric surgery were excluded.

**Results**

Three months after bariatric surgery all of the patients in the study are free of biliary diseases, 6 months after surgery 3 of the 30 patients (9.5%) in control group had developed cholelithiasis; 9 months after surgery in control group, 5 patients had formed gallstones (16.6%) in control group; and 12 months after surgery, 6 of the 30 patients (18 %) had presented with cholelithiasis. No additional patients developed cholelithiasis during the last year of follow-up.

Table (2) reveals the number and percentage of gallstone formation in the four groups at 6 month follow-up post-operative period. It shows that 3 (10%) of 10 patients developed gallstones in group 1 and 4 (13.3%) of 30 patients developed gallstones in group 2, whereas only 4 (13.3%) of 10 patients developed gallstones in group 3 and only 2 (6.6%) of 30 patients developed gallstones in group 4.

Table (2): Percentage of gallstone formation in the treatment groups versus control.

Group	Total (n)	Number with gallstones (%)				p-value
		3 mo.	6 mo.	9 mo.	12 mo.	
Group 1 (Control group)	30	0	3 (10%)	5 (16.6%)	6 (20%)	0.03
Group 2 (urso-deoxycholic acid group)	30	0	4 (13.3%)	4 (13.3%)	5 (16.6%)	0.01
Group 3 (ezetimibe)	30	0	4 (13.3%)	4 (13.3%)	3 (10%)	0.01
Group 4 (combined group)	30	0	2 (6.6%)	3 (10%)	2 (6.6%)	0.01
Total	120 (100%)	0	13 (10.8%)	16 (13.3%)	16 (13.3%)	<0.05
		45 (37.5%)				

Table (2) shows no significant difference in gallstone formation between the urso-deoxycholic acid groups and ezetimibe group, whereas a statistically significant reduction in gallstone formation was observed in the ezetimibe group and combined drug therapy group compared to control group.

All patients who underwent cholecystectomy had their gallbladders removed laparoscopically

with no conversions or significant complications. No patient presented with acute cholecystitis, choledocho-lithiasis, or bile duct dilation.

**Discussion**

The risk of gallstones is directly related to the level of obesity with the relative risk above a body mass index of 40 being 5 to 6 times that of the background population [9].

Cholecystectomy, generally performed laparoscopically, is the accepted approach for symptomatic gallstones with few exceptions [21].

Obesity is considered an independent risk factor for cholelithiasis, and a large proportion of the obese patients have gallstones [19].

Cholelithiasis is common in obese patients because of elevated biliary cholesterol secretion, incremented nucleation factors, and impaired gallbladder contractility [22].

Gallstone disease in the present study developed rapidly in the first six months after surgery. In this period, weight loss and cholesterol saturation of bile increased because of the reduced output of bile acids and phospholipids as well as the mobilization of cholesterol from adipose stores.

The surgeons enabled to use urso-deoxycholic acid (Ursodiol, Actigall) in patients during the first 6 months after bariatric operations [23].

Urso-deoxycholic acid is a bile acid that prevents lithiasis by acting on cholesterol and mucin levels in the bile (thereby decreasing the saturation of bile) and improving gallbladder emptying [24].

Kielani et al., proposed that; the incidence of gallstone formation is highest during the first 6 months after surgery showing 33.8% in the first 6 months versus 21.6% in the next 6 months post-operatively [25].

In our study, the percentage of patients with gallstones in the treatment group was 4.7% during the first 6 months versus 2.04% in the next 6 months. However, in the control group, it was 11.76 versus 5.88% in the first 6 months versus next 6 months, which supports the hypothesis that gallstone formation is highest during the first 6 months following surgeries due to rapid weight loss during that period.

Melmer et al., observed 109 patients who underwent bariatric surgery (gastric banding, gastric bypass, or sleeve gastrectomy) over 10 years and gallstone formation after surgery was detected as 17.4% and it was detected more frequent in gastric bypass and sleeve groups (42.9%) than gastric banding group (16.3%). This result was correlated with the amount of weight loss. They also reported that need for cholecystectomy was higher in bypass and sleeve group [26].

Abdallah et al., investigated that the influence of the UDCA in the prevention of cholelithiasis after LSG and they reported that UDCA reduced

the incidence of the cholelithiasis after LSG. They also realized that dyslipidemia and rapid EWL caused to the tendency of gallstone formation 3 months after LSG [27].

The reduction rate in performance of cholecystectomies in bariatric patients is due to many reasons, including; increased operative time, duration of hospitalization, potential complications, and surgeon's concern about removal of a normal organ [28].

The base of such combination was suggested by De Bari et al. who stated that the cholelitholytic mechanism of ezetimibe is totally different from that of hydrophilic bile acids such as urso-deoxycholic acid; it has been proposed that a combined therapy of ezetimibe and urso-deoxycholic acid could be a faster means to promote the dissolution of cholesterol gallstones. This can be due to the two distinct mechanisms: the formation of unsaturated micelles by ezetimibe and a liquid crystalline mesophase by urso-deoxycholic acid [29].

#### *Conclusion:*

The gallstone related complications are relatively common after LSG. Most of the patients with gallstones are symptomatic, and some have potentially severe conditions. If urso-deoxycholic acid is unavailable, it may be appropriate to perform cholecystectomy not only during bariatric surgery (if cholelithiasis is present), but also during the post-operative period if gallstones develop, even in the absence of symptoms. Laparoscopic cholecystectomy is effective and safe in the latter situation.

The reduction in the performance of cholecystectomies in bariatric patients is due to many reasons, including increased operative time, duration of hospitalization, potential complications, and surgeon's concern about removal of a normal organ.

We suggest a combination of urso-deoxycholic acid and ezetimibe in prevention of gallstone formation after laparoscopic sleeve gastrectomy.

We determine the duration of post-operative UDCA use according to the pre-operative BMI of the patient. UDCA is recommended as 30mg twice a day for 3 months in patients with BMI less than 40kg/m<sup>2</sup>, for 4 months in patients with BMI between 40-50kg/m<sup>2</sup>, and for 6 months in patients with BMI greater than 50kg/m<sup>2</sup>.

If urso-deoxycholic acid is unavailable, it may be appropriate to perform cholecystectomy. Laparoscopic cholecystectomy is effective and safe in the latter situation.

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## دراسة تقليل حدوث الحصوات المرارية بعد عمليات جراحة السمنة

ترتبط السمنة بالعديد من الأمراض المزمنة مثل (ارتفاع ضغط الدم، السكري من النوع ٢، اعتلال نسبة الدهون، أمراض القلب والأوعية الدموية، توقف التنفس أثناء النوم وغيرها).

أصبحت جراحة السمنة مؤخراً واحدة من أكثر طرق العلاج شيوفاً في الحفاظ على تقليل الوزن على المدى الطويل وتحسين الأمراض المرتبطة بالسمنة. وبالتالي، جراحة لعلاج البدانة هي طريقة علاج فعالة من حيث التكلفة.

حصوات المرارة من المشاكل الجراحية شائعة الحدوث في مرضى السمنة ويمكن تشكيلها خلال فترة فقدان الوزن السريعة. إنقاص الوزن السريع بعد جراحة السمنة ينشط عوامل فسيولوجية متعددة تؤثر على تكوين حصاة المرارة.

التشبع المفرط للصفراء مع الكوليسترول، وإنتاج الميوسين المرتفع، وقلة الحركة في المرارة تسهم في تكوين الحصوة. الأشخاص الذين يعانون من السمنة المفرطة معرضون لخطر حصوات المرارة في الكوليسترول بسبب تشبع الكوليسترول المرتفع في الصفراء حوالي ٧٥٪ من حصى المرارة من نوع الكوليسترول. يزداد الخطر خلال فقدان الوزن السريع باستخدام الوجبات منخفضة السعرات الحرارية وبعد جراحة لعلاج البدانة. يزيد خطر تكوين الحصوة ٨ أضعاف في المرضى الذين يعانون من مؤشر كتلة الجسم < ٤٠ كجم/م<sup>٢</sup>، ويزيد ٥ أضعاف في المرضى الذين خضعوا لجراحات لعلاج البدانة مقارنة بالسكان العاديين.

موضوع البحث: دراسة مشتركة مستقبلية ذات أثر رجعي لتقييم نتائج معدلات استئصال المرارة لدى مرضى علاج البدانة لديها واحد من ثلاثة إجراءات لعلاج البدانة (LRYGB، LSG، LGB)، تم تقييمها بمتابعة متوسطة لمدة ٢٤ شهراً. وتم العثور على أعلى معدل لاستئصال المرارة في مجموعة LRYGB 10.6% وكان التردد أعلى خلال الأشهر الستة الأولى (٣.٧٪).

هدف البحث: تقييم التدابير الوقائية للحد من تشكيل الحصوات المرارية بعد جراحات السمنة لعلاج البدانة وتحديد المخاطر.

المرضى وطرق البحث: تم تضمين الدراسة إجمالاً ١٢٠ مريضاً ممن يعانون من السمنة المفرطة، تم إجراء تقييم ما قبل الجراحة، بما في ذلك (التاريخ المرضي، الفحص، تقييم السمنة ووزن الجسم، مؤشر كتلة الجسم، محيط الخصر، إجراء المعامل الكاملة، منظار ضوئي للمريء والمعدة، عمل الموجات فوق الصوتية في البطن. بعد استئصال المعدة بالمنظار، تم تقسيم المرضى عشوائياً إلى: المجموعة ١ (السيطرة)، المجموعة ٢ (حمض أوروكسيكوليك والمجموعة ٣ (ezetimibe) والمجموعة ٤ (العلاج بالعقاقير مجتمعة).

النتيجة: تم العثور على إنخفاض كبير في تكوين الحصوة في المجموعة ٣ (ezetimibe 5.5%)، والمجموعة ٤ (الجمع بين الدواء مقارنة مع المجموعة ١ السيطرة (١٧.٦٪). لوحظت زيادة معتد بها إحصائياً في النسبة المئوية لفقدان الوزن الزائد في المرضى الذين يعانون من حصى في المرارة (٣٨.٥٪) مقابل مرضى بدون حصى في المرارة (٢٨.٢٪). كانت النسبة المئوية لتشكيل الحصوة خلال ٦ أشهر الأولى بعد الجراحة ضعف ذلك خلال ٦ أشهر القادمة في كل من مجموعات المراقبة والعلاج.

الاستنتاجات: إن فقدان الوزن السريع بعد جراحة علاج البدانة هو السبب الأكثر أهمية المسبب لتشكيل حصوات المرارة. ومن الممكن أن تسبب مشاكل خطيرة مثل التهاب المرارة الحاد، انسداد صفراوي، التهاب البنكرياس. يجب أن يكون الأطباء حذرين من حدوث انسداد صفراوي في المرضى الذين يعانون من شكاوى من آلام في البطن خلال فترة المتابعة اللاحقة للعمليات الجراحية. في مثل هذه الحالة، يجب بالتأكيد تأكيد الموجات فوق الصوتية في البطن، وفقاً للمبادئ التوجيهية للممارسة العيادية الفعلية للدعم الجراحي والتغذوي وغير الجراحي لمرضى جراحة السمنة تحديث ٢٠١٣، الجمعية الأمريكية لأطباء الغدد الصماء الإكلينيكيين وجمعية السمنة والجمعية الأمريكية لجراحة الأيض والسمنة والكبد ينبغي دمج نهج طبي وقائي في المعاملة مع المرارة أثناء التدخل الجراحي لعلاج البدانة لقد تم التوصية بأن يخضع المرضى الذين يخضعون لتجاوز مسار المعدة في عمليات تحويل المسار لاستئصال المرارة الروتيني بغض النظر عن حالة الحصوات.