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Research Article

Incidence of Cholelithiasis Following Bariatric and Metabolic Surgery - A Retrospective Study

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Received: March 20, 2020; **Published:** April 30, 2020

Abstract

Introduction: Metabolic syndrome is now a recognized surgical problem and can be treated with a wide range of surgeries. The occurrence of gallstone formation following rapid weight loss after various bariatric surgeries has been studied.

Aim: The purpose of this study was to evaluate the incidence of gallstone formation after undergoing various bariatric and metabolic procedures and to assess whether it is necessary to perform concomitant cholecystectomy, to prevent major problems caused due to gallstone formation.

Materials and Methods: A retrospective study was done among patients who underwent bariatric and metabolic surgery between February 2008 and December 2019. The patients were then grouped into two: group A (those who developed gallstones or sludge) and group B (those who did not). The time and weight at which the patient developed gallstones was noted.

Results: Of 753 patients who underwent bariatric and metabolic surgery, 662 patients were included in this study. We observed that 42 (6.34%) developed gallstones or sludge (group A), while 620 (93.66%) remained free of gall bladder disease (group B). 35.72% of group A developed stones or sludge within 1yr, which can be attributed to weight loss following surgery, whereas 64.26% developed stones after 1 year.

Conclusion: Prophylactic use of Ursodeoxycholic acid (UDCA) for the first 6 months should be implemented to reduce the incidence of gall stone formation after metabolic surgery. Concomitant cholecystectomy should be reserved for cases with preoperative finding of gallstones.

Keywords: *Cholelithiasis; Bariatric Surgery; Gallstones*

Introduction

The prevalence of Metabolic Syndrome has been on the rise in the past few decades, encompassing chronic diseases such as obesity, diabetes, hypertension, cardiovascular diseases, dyslipidemia and obstructive sleep apnea. Various modalities of combatting this syndrome have been introduced; ranging from lifestyle measures such as diet (keto diet, intermittent fasting, low calorie, high protein diets) and exercise; medical treatment including drugs like Orlistat, Phentermine and Topiramate, Liraglutide, Dulaglutide; and bariatric and metabolic surgery which includes a wide range of procedures.

Lifestyle measures and medical treatment have been ineffective in controlling the progression of the disease in the long run, only leading to an increase in the financial burden and various complications associated with these diseases. Bariatric and Metabolic surgery has been proven to be the most effective way of achieving and maintaining control of this disease.

However, drastic weight loss, achieved by any of these means, is likely to increase the occurrence of gallstones and sludge. A few studies have been done, which reported these findings.

Various Bariatric and Metabolic surgeries have come into practice: ranging from Roux-en-Y Gastric Bypass (RYGB), Bilio-Pancreatic Diversion-Duodenal Switch (BPD-DS), One Anastomosis Gastric Bypass-Mini-Gastric Bypass (OAGB-MGB) to Gastric Bands (LAGB), Sleeve Gastrectomy (SG) and sleeve plus procedures like Duodeno-jejunal Bypass (DJB), Single Anastomosis Duodeno-Ileal - Sleeve (SADI-S), Transit (TB) or Loop Bipartition (LB) and Ileal Interposition (IISG). With marked weight loss following surgical management of obesity, a higher incidence of gall stone formation has been expected.

Prevalence of gallstones has been estimated to be around 5.9 to 21.9% in USA [1] and Europe [2] and around 4.15 - 9.6% in India [3].

Gallstone disease has been reported to be more prevalent in the obese population [4]. Those undergoing bariatric surgeries are more prone to developing cholelithiasis following rapid weight loss after surgery. This is attributed to an increase in cholesterol concentration in bile, decreased motility of the gallbladder or disruption of the enterohepatic circulation of biliary salts. Management of gallstones in patients who have undergone bypass procedures involving exclusion of the duodenum, becomes challenging, as endoscopic access to the biliary tract is lost and special skills and equipment are required to go through the remnant stomach to access the biliary tree in such cases. The ideal approach towards management of gallstones in the bariatric population continues to be debatable.

Aim of the Study

This study aims to document the incidence of gallstone formation, following Bariatric and Metabolic surgery in spite of using Ursodeoxycholic acid prophylaxis and to assess if this is adequate and justifies avoiding concomitant cholecystectomy or if a change in management is warranted.

Literature Review

Over the decades, Bariatric surgery has developed into Metabolic surgery with many procedures being introduced - either new procedures or new approaches or modifications made to old procedures. Procedures with greater bowel exclusion, like BPD-DS, SADI-S, Loop or Transit Bipartition, usually lead to more malabsorption than other bypass procedures like OAGB, RYGB, Sleeve Plus group like DJB, Ileal interposition; which in turn cause more malabsorption than purely restrictive procedures like Sleeve and Gastric Banding.

Gallstone or sludge formation has been reported following weight loss after bariatric procedures. It was initially thought of as a complication due to the bypass but newer studies challenge this view with increased incidence in purely restrictive procedures as well.

Routine cholecystectomy was performed along with BPD-DS in the initial days because of high incidence of gallstone formation in those patients [5], however, studies later challenged this concept. Bardaro., *et al.* showed an 8.7% incidence of gallstones in the postoperative period following BPD-DS, in spite of prophylactic usage of UDCA for 6 months after surgery [6]. In the 219 patients studied, 19.6% underwent cholecystectomy which included 12.7% prior to the bariatric procedure, 4.5% at the same time as the BPD-DS and 8.7% in the postoperative period. They suggested that this low incidence rate did not justify routine cholecystectomy in patients undergoing BPD-DS, which was in contrast to older beliefs.

Another study done by Sucandy., *et al.* showed that avoiding routine cholecystectomy in BPD-DS was associated with an acceptable risk of biliary problems [7]. They found biliary symptoms in 22.7% of patients after undergoing BPD-DS, of which 5.4% occurred in the first year following surgery, 11% in the second postoperative year and 6.1% thereafter.

Various studies have been done to assess gallstone formation after RYGB. Li., *et al.* observed that 8.7% developed symptomatic gall stones after RYGB, of which 1.8% developed complications [8]. Maria., *et al.* noticed a 9.7% incidence of gall stones after RYGB which occurred around 2.6 years after surgery [9]. Mishra., *et al.* observed that 13.39% developed gallstones of which 33.92% became symptomatic [10], while a study done by De Oliveira [11] showed a much higher rate of 52.8%.

Reported rates after sleeve gastrectomy range from 3.8% symptomatic stones with 1.9% presenting as complications as noted by Li., *et al.* [8] to 47.9% gallstones and 22.9% symptomatic gallstones in a study done by Manatsathit [12]. Other rates are 10.26% symptomatic gallstones reported by Shaer., *et al.* [13] 10.1% noted by Maria., *et al.* [9] and 8.42% observed by Mishra., *et al* [10].

A rate of 6.8% of symptomatic gallstones was noted by O'Brien., *et al.* [14] in patients undergoing LAGB with similar rates of 6.5% noted by Maria., *et al*. Incidence rates after OAGB-MGB ranged from 12.76% to 54.6% [10,13]. A study done by Mahdy., *et al.* did not observe any gallstone formation in the first year after SASI [15].

Different theories have been put forth to understand the mechanism of development of gallstones and sludge. Bennion., *et al.* proposed that reduced oral intake and diversion of food from the upper small bowel may reduce cholecystokinin, causing bile stasis in the gall bladder which may cause supersaturated bile to form cholesterol crystals [16]. However, this was opposed by Bastouly., *et al.* who hypothesized that the exclusion of duodenum does not play a role in the formation of sludge or gall stones in patients who have undergone RYGB and suggested that alteration in neuronal pathways and metabolic alterations contribute to gallstone or sludge development in a bigger way when compared to alterations in enteric hormone secretions [17].

Shiffman., *et al.* suggested that an increased bile calcium concentration, elevated bile mucin concentration and bile cholesterol supersaturation, were responsible for formation of gallstones after rapid weight loss following RYGB [18]. Various factors leading to an increase in the risk of gallstone formation following a bariatric procedure include rapid loss of weight, increased saturation of cholesterol in bile, loss of gall bladder emptying stimulated by the duodenum and changes in motility of the gallbladder caused by dividing the hepatic branch of the vagus nerve [19-22].

Some studies done by Li., *et al.* [22] and Shaer., *et al.* [13] show that weight loss of more than 25% increased the risk of gallstone formation following bariatric surgery. Some studies observed a higher incidence of gallstones in patients with higher body mass index (BMI) [13].

Chen., *et al.* compared incidence of gallstone in obese patients undergoing bariatric surgery and obese people who did not undergo surgery and found similar rates (2.89% vs 2.79%). They also observed an increased rate in the bariatric population when compared to the general population (2.89% vs 1.15%). Amongst those who underwent bariatric surgery, an increased incidence was noted in females and in those who underwent restrictive procedures. They found that 33% occurred within 2 years after surgery and 82% occurred within 5 years following bariatric surgery [24].

The ideal approach towards gallstone management in the bariatric population has been a dilemma. Many differing views exist in approaching such cases. While some authors believe in performing routine cholecystectomy without the presence of gallstones in patients undergoing bypass [BPD-DS, RYGB], others argue that the low incidence of gallstone formation and a relatively higher rate of complications from concomitant cholecystectomy does not justify this. Some carry out routine preoperative ultrasound scanning and concomitant cholecystectomy in those diagnosed with gallstones even when asymptomatic, while others prefer to wait and observe asymptomatic cases and intervene only if they become symptomatic.

Prophylactic measures include concomitant cholecystectomy (in the absence of gallstones) [even with asymptomatic gallstones) or postoperative use of UDCA. Routine use of UDCA as prophylaxis in the postoperative period is practiced by many, ranging from a period of 6 - 12 months; while others reserve it for only specific cases, owing to problems such as nausea, diarrhoea and abdominal pain, which reduces the compliance among patients. The recommended dosage and duration of UDCA is 300 mg twice a day after meals, for the first 6 months after bariatric surgery. Miller., *et al.* noticed a decreased rate of gallstone formation with daily oral administration of UCDA for 6 months [25].

While there have been many studies conducted on this topic, to our knowledge, there has been no study, encompassing a wide variety of procedures such as the ones described here, including the ileal interposition.

Research Methodology

We conducted a retrospective analysis of prospectively collected data of patients who underwent bariatric and metabolic surgery between February 2008 and December 2019. Data was collected before the surgery and also up to the last follow up after the surgery.

All patients were subjected to ultrasound scan of the abdomen, apart from other routine investigations, to complete the preoperative assessment. Those diagnosed with stones or sludge in the gallbladder underwent laparoscopic cholecystectomy along with the planned surgery.

All patients are advised to take UDCA for 6 months postoperatively. They are followed up at 1, 3, 6, 9 and 12 months; and at 6-monthly intervals thereafter. Ultrasound of the abdomen is done routinely at 6 monthly intervals for all patients or at any time in case of any symptoms such as abdominal, flank or back pain, dyspepsia, vomiting, jaundice or fever. If diagnosed with cholelithiasis, either incidentally on follow up or during evaluation of symptoms, if a patient had previously undergone a procedure with any form of bypass of the duodenum (biliary access lost), a laparoscopic cholecystectomy was carried out. In non-bypass cases (biliary access intact), only symptomatic patients were operated, while asymptomatic patients were observed with repeated follow ups.

Patients presenting with sludge were given a trial of UDCA for 3 months. In case of no resolution or increase in symptoms, they were subjected to surgery.

The patients in this study group underwent different types of procedures. These include: Endoscopic placement of intragastric balloon (IGB), SG, RYGB, OAGB-MGB, SG with LB, diverted/duodenal ileal interposition [D-IISG] and non-diverted/jejunal ileal interposition [J-IISG].

Inclusion criteria:

- Patients with preoperative ultrasound.

Exclusion criteria:

- h/o cholecystectomy prior to bariatric surgery
- Preoperative ultrasound showing gallbladder stones
- Lost to follow up.

After excluding the above, the remaining patients were studied and then grouped into two: group A (those who developed gallstones or sludge postoperatively) and group B (those who did not). The postoperative timing at which the patient developed gallstones or sludge, along with the weight loss of the patient at that time was noted.

During the study period, 753 patients underwent Bariatric and Metabolic procedures. 91 were excluded from the study, of which 25 (3.32%) had undergone cholecystectomy previously, while 38 (5.05%) were found to have gallstones on ultrasound scanning during the clinical evaluation before surgery and underwent concomitant cholecystectomy along with the bariatric/metabolic procedure. All the procedures were completed safely without any complications, however it did increase the postoperative time and led to added difficulty due to altered port placements. 28 (3.72%) were lost to follow up. Finally, 662 (87.91%) were included in this study; demographics of groups A and B are listed in table 1.

	Group A 42 (6.34%)	Group B 620 (93.66%)	Significance
Age	46.05	41.97	NS
Gender [M/F]	22/20	304/316	NS 'p' value = 0.674; Chi square = 0.176
Weight	109.9	109.81	NS
BMI	39.7	40.9	NS
Diabetes	29/42 (69%)	309/620 (49.8%)	'p' value = 0.016 (S); Chi square = 5.808

Table 1: *Demographics*

The primary outcome of this study was to evaluate the incidence of gallstone formation after Bariatric and Metabolic surgery. The secondary outcome was evaluation of weight loss and the timing at which gallstones developed after surgery.

Statistical analysis

Analysis of data was done using the Chi square test as a test of significance for categorical data. All the 'p' values < 0.05 were considered as statistically significant. Paired 't' test was used to analyze descriptive statistics. Unpaired 't' test was used as a test of significance for continuous data.

Results

Of the 662 patients included in this study, 42 patients (6.34%) developed gallstones or sludge during follow up assessment (group A), while 620 patients (93.66%) did not develop gallstones or sludge (group B). Overall, in this cohort of 753 patients, prevalence of gallstones or sludge was observed in 105 (13.95%). Of the 42 who developed gallstones or sludge, the incidence and procedure distribution is shown in table 2.

Surgery	No. of Patients	Group A	Group B
IGB	7	0	7
LAGB	4	0	4
SG	326	11 (3.37%)	315
RYGB	12	2 (16.67%)	10
MGB-OAGB	65	5 (7.69%)	60
SG+LB	42	6 (14.29%)	36
D-IISG	144	15 (10.42%)	129
J-IISG	62	3 (4.84%)	59

Table 2: *Incidence of gallstone/sludge formation after different procedures.*
IGB: Intra-Gastric Balloon; LAGB: Laparoscopic Adjustable Gastric Band; SG: Sleeve Gastrectomy;
RYGB: Roux-en-Y Gastric Bypass; OAGB-MGB: One Anastomosis Gastric Bypass-Mini-Gastric Bypass;
SG+LB: Sleeve Gastrectomy+Loop Bipartition; D-IISG: Duodenal Ileal Interposition with Sleeve Gastrectomy;
J-IISG: Jejunal Ileal Interposition with Sleeve Gastrectomy.

This study showed lower incidence rates in patients undergoing Sleeve Gastrectomy (3.37%) compared to OAGB-MGB (7.69%) and other bypass procedures like RYGB (16.67%) or Loop Bipartition (14.29%). Of the 14.29% who developed stones after Loop Bipartition, half developed in the first year after surgery, while the other half developed around 1.5 to 3 years after surgery. 10.42% developed stones after the diverted ileal interposition and 4.84% after non-diverted ileal interposition (more akin to the SG numbers), showing a higher incidence with exclusion of the duodenum. In this study, no stone formation was seen after IGB (n = 7) or LAGB (n = 4).

As shown in table 3, 69.05% of those developing gallstones were diabetic, while 30.95% were not [p value = 0.016 (S)]. Surprisingly, only 8.58% of diabetics developed gallstones while 91.42% of diabetics did not.

	Group A (42) with stones	Group B (620)
Diabetics	29/42 (69.05%)	309/620 (49.84%)
Non-diabetics	13/42 (30.95%)	311/620 (50.16%)

Table 3: *Presence of diabetes in patients with/without gallstones. Chi square = 5.808, p value = 0.016 (S).*

In group A, i.e. those who developed gallstones, 22 patients (52.38%) were male and 20 patients (47.62%) were female. Mean pre-operative weight was 109.91 ± 35.15 kg, while mean weight at which gallstones or sludge developed was 77.34 ± 19.70 kg. This group showed a mean weight loss of 32.57 ± 23.13 kg, while the mean percentage of weight lost was 27.93 ± 11.55% (Table 4).

	N	Minimum	Maximum	Mean	Std. Deviation
Pre Op Weight (kg)	42	61.2	273.0	109.905	35.1471
Weight at which gallstones/sludge formed (kg)	42	51.0	130.0	77.338	19.7028
Weight loss at the time of Gallstone/Sludge Formation (kg)	42	-2.00	143.00	32.5667	23.13408
Percentage of Total Weight Lost (%)	42	-2.10	52.38	27.9349	11.55163
Time of Gallstone/Sludge formation (Yr)	42	0.25	10.00	2.7576	2.59127

Table 4: *Secondary Outcomes in Group A = 42 with gallstone formation.*

Mean time of development of gallstones or sludge after bariatric and metabolic surgery was found to be 2.76 ± 2.59 years in this study. As depicted in table 5, an incidence of 4.76% was seen during the first 3 months after surgery, 9.52% during 3 - 6 months, 21.43% during 6 - 12 months and 64.26% more than 1 year after surgery. In spite of routine use of UDCA in the postoperative period, 14.28% developed stones or sludge in the first 6 months following surgery.

Timing of gallstone/sludge development	Number of patients	Incidence (%)
< 3 Months	2	4.76
3 - 6 Months	4	9.52
6 - 12 Months	9	21.43
> 12 Months	27	64.26

Table 5: *Timing of postoperative gallstone formation.*

We observed that the majority, 27 of 42 patients (64.26%), developed stones more than 1 year after surgery. In this group, the mean time of development of gallstones was 4 years (range 1.33 to 10 years).

As shown in table 6, we did not find a reduction in gallstone formation after increasing the duration of UDCA prophylaxis from 3 months to 6 months [5.93% vs 6.43%; p value = 0.839].

UDCA Prophylaxis	3 months	6 months
Number	7/118	35/544
%	5.93%	6.43%

Table 6: *Duration of UDCA prophylaxis.*
Chi square = 0.0411, p value = 0.839 (NS).

36 patients developed gall stones and 6 had sludge. 21 patients underwent subsequent laparoscopic cholecystectomy which was completed safely in all patients without any complications, while 14 patients were not operated as they did not follow up in spite of being advised surgery.

18 patients were symptomatic of which 2 had CBD stones along with gallstones and 1 patient developed acute biliary pancreatitis. CBD exploration with successful clearance of stones was done using a ureteroscope to gain access via the cystic duct opening during laparoscopic cholecystectomy in both patients. The patient with pancreatitis was treated conservatively and is awaiting surgery.

Sludge was seen in 6 patients, which disappeared after treatment with UDCA, but recurred in 1 who is currently on UDCA again.

Discussion

The management of cholelithiasis in bariatric cases has always been a controversial topic. Whether concomitant prophylactic cholecystectomy is justified, is debatable. Various studies have been done in this area, discussing the incidence and mechanism of formation of gall stones following various procedures, prophylaxis like ursodeoxycholic acid after bariatric surgery, drawbacks and difficulties of concomitant cholecystectomy along with bariatric surgery, and problems when gallstones are left untreated.

Incidence

In this study, we observed that 6.34% developed gall stones or sludge, while 93.66% remained free of gall bladder disease.

An incidence of 3.37% was found in patients undergoing Sleeve gastrectomy, which was comparable to findings in a study done by Li., *et al*. (3.8%) [8]. However, other studies have reported higher rates of 8.42% (Mishra., *et al*.); 10.1% (Maria., *et al*.); 10.26% (Shaer., *et al*.) and 47.9% (Manatsathit., *et al*.) [8-13]. We found a rate of 14 - 16% in bypass surgeries like SG+LB or RYGB, but surprisingly only 7.69% after OAGB-MGB; 10.42% after duodenal ileal interposition and 4.84% after jejunal ileal interposition. A higher incidence was observed in patients undergoing the diverted ileal interposition with exclusion of the duodenum as opposed to the non-diverted jejunal ileal interposition.

In this study, 14.29% of patients undergoing Sleeve Gastrectomy with Loop Bipartition developed gallstones or sludge, of which half developed in the first year after surgery, while the other half developed around 1.5 to 3 years after surgery. In contrast, Mahdy., *et al*. did not find any gallstone development in the first year following this procedure [15]. This study showed a lower incidence of gallstone development in patients undergoing OAGB-MGB. 7.69% was observed here, in contrast to 12.76% [10] and 54.6% [13] as reported by other authors.

Of the patients undergoing RYGB, 16.67% developed gallstones or sludge. Other studies have reported rates ranging from 8.7% to 71% [8,26]. Hoy., *et al*. found 30% of patients developing gallstones 12 months following surgery [27], while Maria., *et al*. found 9.7% forming gall stones around 2.6 ± 2.3 years after surgery [9]. Wattchow observed a third of patients forming gallstones [28], De Oliveira [11] noted a rate of 52.8% and Mishra., *et al*. found a rate of 13.39%, a third of which became symptomatic [10]. Around 3 - 16% were shown to become symptomatic in other studies [29,30].

Gallstone formation following LAGB was shown to be 6.5% by Maria., *et al*. [9] and 6.8% by O'Brien., *et al* [14]. Kiewiet., *et al*. observed a higher incidence of gallstones after LAGB (26.5%) [31]. Gallstone formation following weight loss with calorie restriction was noted to be around 10 - 20% [32].

In contrast to some studies, we observed a lower incidence rate after restrictive procedures like Sleeve gastrectomy or non-diverted ones, like the jejunal ileal interposition with sleeve (no bowel exclusion) when compared to other procedures. In our patients, a higher rate of gallstone formation was observed in cases with duodenal exclusion.

In this study, 3.32% of patients had a history of cholecystectomy prior to bariatric/metabolic surgery, while 5.05% had concomitant cholecystectomy at the time of the metabolic procedure. Overall, in this patient cohort, 13.95% prevalence of gallstone or sludge was observed which was lower than that observed by Mishra., *et al*. (21.76%) [9].

Association with weight loss

The mean percentage weight loss in this study is 27.93 ± 11.55%.

Yang., *et al*. noted an incidence of gallstones by 16 weeks of rapid weight loss at 10.9%, showing that loss of BMI predicts gallstone formation [33]. Hoy., *et al*. observed that absolute weight loss is a risk factor for formation of gallstones following calorie restriction [27]. Li., *et al*. carried out an analysis of risk factors for gallstones among patients undergoing RYGB, LAGB, and SG and found that weight loss more than 25% was the only significant risk factor [23]. This was supported by Shaer., *et al*. who observed a similar correlation between weight loss in excess of 25% and gallstone formation. They also noted a correlation between BMI and gallstones, with higher incidence noted in BMI greater than 40 kg/m^2 (42.1% vs 6.45%) [13]. Mishra., *et al*. found a slightly higher percentage of weight loss in patients who developed symptomatic gallstones (30.99%) [10].

On the contrary, Shiffman., *et al*. did not find an association between gallstone formation and percent weight loss or percent excess weight loss [34]. While an increase in incidence of gallstones was observed in morbidly obese patients and in those experiencing rapid weight loss, De Oliveira., *et al*. found no association between weight loss and formation of gallstones [11]. Manatsathit., *et al*. reported similar findings [12].

Timing of development

In this study 15 patients (of the 42) or 35.71% developed gallstones or sludge in the first year after metabolic surgery. 6 (14.29%) in the first six months and 9 (21.43%) in 6 - 12 months. This can be attributed to weight loss following surgery. On the other hand, 27 patients (64.26%) developed stones more than 1 year after surgery.

The mean time of development of gallstones or sludge in the postoperative period was observed to be 2.76 ± 2.59 years.

In the group that developed gallstones more than 1 year following surgery the mean time of development was 4 years, ranging from 1.33 to 10 years. This suggests the need for repeated ultrasound scans during long term follow ups of patients after bariatric surgery to pick up any development of gallstones or sludge.

Majority of patients seemed to develop gallbladder disease later than 1 year following surgery which showed that metabolic surgery did not play an important role in the development of gallbladder disease for most of these patients.

This was in contrast to Li., *et al*. who found symptomatic gallstones developing at a mean of 10.2 months following surgery (2 - 37 months) [8]. Mishra., *et al*. found that all patients who developed gallstones were diagnosed within 2 years after surgery [10]. Maria., *et al*. found gallstones developing around 3.2 years after LAGB, 2.6 years after RYGB and 2.7 years after Sleeve Gastrectomy [9].

On the other hand, Manatsathit., *et al*. showed that the majority (95.8%) of the patients developed stones in the first 6 months following surgery [12], while Shaer., *et al*. showed that 33.3% gallstone formation was noted in the first 6 months and 10.3% in 6 - 12 months after surgery [13].

UDCA prophylaxis

In spite of routine use of UDCA in the postoperative period, the incidence in our study was 4.76% in the first 3 months and 9.52% in 3 - 6 months following surgery.

Between 2008 and 2012, UDCA was prescribed for only 3 months postoperatively which was subsequently changed to 6 months. Incidence of gallstones or sludge noted is 5.93% in those operated in the first five years and 6.43% in the subsequent 8 years. This shows us that there was no significant benefit, in increasing the duration of prophylaxis to 6 months.

A meta-analysis done by Dimitrios., *et al*. suggested that administration of 500 - 600 mg of UDCA for a period of 6 months following surgery was associated with reduced incidence of gallstone formation. They also observed that patients who received the UDCA prophylaxis had a lesser need for urgent cholecystectomy [35].

This was supported by Penna., *et al*. who followed 61 patients with asymptomatic gallstones who were treated with UDCA for 6 months after bariatric surgery. They observed that 96.8% continued to be asymptomatic, while 1 developed symptoms and was managed conservatively and another underwent surgery for chronic cholecystitis after 6 months. They suggested UDCA therapy instead of prophylactic concomitant cholecystectomy in those with asymptomatic gallstones [36].

Concomitant cholecystectomy

Fobi., *et al*. conducted a study in 761 patients undergoing banded RYGB along with prophylactic cholecystectomy irrespective of the preoperative ultrasound findings. They found 86.2% prevalence of gall bladder pathology. 12.35% of patients with negative ultrasound findings were found to have gallstones [37].

Worni., *et al*. reported a significantly higher mortality rate in laparoscopic RYGB surgery with concomitant cholecystectomy when compared to RYGB surgery alone (0.2% vs. 0.1%). They also observed a 1.1% increase in overall perioperative complication rate (6.2% vs. 5.1%) [38].

A meta-analysis conducted by Warschkow., *et al*. showed a low rate of subsequent cholecystectomy following laparoscopic RYGB (6.8%); majority presenting with uncomplicated biliary disease and only 1 - 5% becoming symptomatic [39].

O' Brien., *et al*. found that concomitant cholecystectomy was technically difficult to perform due to alterations in the port placements and also increased operating time by 30 minutes [14].

Maria., *et al*. found a 0.12% injury of the common bile duct in cases undergoing concomitant cholecystectomy [9].

Doulamis., *et al*. found that patients undergoing concomitant cholecystectomy with gastric bypass had a higher rate of anastomotic leak or stricture when compared to those who underwent gastric bypass alone [40].

In contrast, Hanaa., *et al*. showed that concomitant cholecystectomy during Sleeve gastrectomy seems to be a safe procedure but with slightly higher risk of bleeding and pneumonia when compared with LSG alone. They suggested concomitant cholecystectomy for established gallbladder disease [41].

In this study, patients who had preoperative detection of gallstones, concomitant cholecystectomy was done along with the metabolic procedure to avoid complications arising in the future, like gallstones slipping into the CBD and causing greater complications, especially in bypass procedures making ERCP access difficult.

Advantage

Avoids need for ERCP which is difficult to perform after bypass surgery (access through the gastric remnant), due to altered anatomy of gastrointestinal tract.

Drawbacks

Increased postoperative complications, intraoperative time, altered port placement adding difficulty in performing the surgery.

In this series, 5.05% had concomitant cholecystectomy at the time of the metabolic procedure. The procedures were completed safely without any complications, however it did increase the postoperative time and led to added difficulty due to altered port placements.

The patients who developed sludge in this study were given a trial with UDCA for 3 months if asymptomatic, which led to disappearance of sludge in all 6 patients, but sludge recurred in 1 patient after discontinuing UDCA which has again been restarted.

2 of the 42 patients developed sludge within 3 months following surgery in spite of having lost 18.46% and 25.21% of their total body weight at that time. 4 of the 42 patients developed sludge or stones between 3 - 6 months after surgery even after experiencing a weight loss of 15.21%, 18.96%, 33.1% and 39.81%.

One of the patients achieved 15.79% weight loss by 6 months after surgery, maintained this for 3 years, but started regaining weight from the fourth postoperative year. Gallstones developed at 8.5 years after surgery when the patient increased weight, beyond the original preoperative weight.

Conclusion

Postoperative development of gallstones was observed in 6.34% patients in this study; of which 4.76% developed gallstones in the first 3 months and 9.52% in the 3 - 6 month period, in spite of the use of UDCA prophylaxis for 6 months. While this supports our use of prophylactic UDCA postoperatively, it does not justify routine cholecystectomy in bariatric procedures (as shown by the low incidence of gallstone formation). However, we found that there was no significant difference in increasing the duration of UDCA prophylaxis from 3 months to 6 months; currently, usage for 6 months is still advocated.

While concomitant cholecystectomy can be carried out safely as shown in our study where there were no complications observed, it should be reserved for patients who are diagnosed with gallstones or sludge during the preoperative workup (that too in experienced teams), due to disadvantages of added intraoperative time and struggle with access due to altered port placements.

We found that the extent of weight lost in the first 6 months did not correlate with gallstone formation as the majority of the gallstones developed more than 1 year after surgery.

We observed a lower incidence rate after Sleeve gastrectomy and Jejunal ileal interposition, when compared to other procedures. A higher rate was observed in cases with duodenal exclusion in this study.

This study found incidence rates of gallstone formation after bariatric surgery to be comparable to that of the general population.

Majority of gallstones were found more than 2 years after surgery, occurring most commonly around the 4th postoperative year, showing that rapid post-surgery weight loss did not play a major role in the development of gallstones in our patients; it could be mainly due to altered entero-hepatic circulation of biliary salts.

Continued surveillance with 6 - 12 monthly ultrasound scans, would be useful for early diagnosis and treatment.

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