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Symptomatic biliary lithiasis after bariatric surgery: results of supra-selective management

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**SYMPTOMATIC BILIARY LITHIASIS AFTER BARIATRIC SURGERY: RESULTS OF
SUPRA-SELECTIVE MANAGEMENT**

THÈSE

PRÉSENTÉE POUR L'OBTENTION DU TITRE DE DOCTEUR EN MÉDECINE

DIPLÔME D'ÉTAT

Adrian MANCINI

[Données à caractère personnel]

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A mon frère Bruno

A mes parents. Merci d'avoir toujours cru en mon parcours, pour votre aide quotidienne. J'espère vous rendre fiers chaque jour.

A Daddy. Pour m'avoir soutenu à chaque instant depuis tant d'années et pour avoir été là quand j'ai eu besoin de toi. J'espère que tu es fière toi aussi. Rien n'aurait été possible sans toi.

A Hélène

Merci pour l'amour que tu m'apportes au quotidien. Tu es la rencontre la plus importante de ma vie. Ta présence, ton soutien, ton intelligence, tes conseils et la bêtise dont tu sais aussi faire preuve me sont extrêmement précieux et indispensable. Merci pour nos échanges permanents sur à peu près tous les sujets. *La vie est beaucoup trop douce à tes côtés.*

We can be heroes, just for one day

David Bowie.

Introduction : Les patients bénéficiant d'une chirurgie bariatrique sont à haut risque de présence préopératoire de lithiase biliaire et de développement postopératoire. La réalisation d'une cholécystectomie dans le même temps opératoire reste controversée. Le but de ce travail est d'analyser le résultat de l'approche supra-sélective de la vésicule biliaire, c'est-à-dire la cholécystectomie concomitante uniquement chez les patients porteurs d'une lithiase vésiculaire symptomatique.

Matériels et Méthodes : Il s'agit d'une étude monocentrique rétrospective de tous les patients ayant bénéficié d'une chirurgie bariatrique coelioscopique ou robotique entre 2010 et 2018.

Résultats : 520 patients ont été inclus avec un suivi médian de 37.5 mois. La procédure était un bypass gastrique chez 328 patients (63.1%) et une sleeve gastrectomie dans 192 cas (36.9%). Soixante et un patients étaient déjà cholécystectomisés (13.6%). Soixante-quatre patients avaient une lithiase vésiculaire préopératoire (14.2%). Quatre patients ont bénéficié d'une cholécystectomie concomitante. Quatorze patients (2.7%) ont nécessité une intervention pour prise en charge d'une lithiase biliaire symptomatique : 12/445 patients (2.7%) ont nécessité une cholécystectomie secondaire, parmi lesquelles 11/12 (91.7%) ont été réalisées par coelioscopie et 9/12 (75%) en chirurgie ambulatoire, et sans aucune complication. Deux patients (0.4%) ont nécessité un abord de la voie biliaire principale après bypass gastrique par voie trans hépatique avec 100% de succès et sans complication.

Conclusion : Les taux de lithiase symptomatique après chirurgie bariatrique et de cholécystectomie secondaire dans le cadre de l'approche supra sélective sont faibles, chacun de 2.7%. Après chirurgie bariatrique, tous les patients avec vésicule biliaire en place doivent recevoir de l'acide Ursodésoxycholique pendant 6 mois.

Introduction: Patients undergoing bariatric surgery are at high risk for both the prevalence of preoperative cholelithiasis as well as their postoperative development. The question of whether cholecystectomy should be performed during bariatric surgery remains controversial. The aim of this work is to study the results of the supra-selective approach for gallbladder management, involving concomitant cholecystectomy only in patients with gallstones-related symptoms.

Material & Methods: This is a retrospective review of a prospective database of all patients who underwent laparoscopic or robotic bariatric surgery between 2010 and 2018 in a single institution.

Results: Five hundred twenty patients were included with a median follow-up of 37.5 months. The procedure was Gastric Bypass in 328 patients (63.1%) and sleeve gastrectomy in 192 (36.9%). Seventy-one patients had a history of cholecystectomy (13.6%). Sixty-four patients had preoperative lithiasis (14.2%). Four patients underwent concomitant cholecystectomy. Fourteen (2.7%) patients required an intervention for symptomatic lithiasis: 12/445 (2.7%) patients required subsequent cholecystectomies and 11/12 (91.7%) were performed through a laparoscopic approach as outpatient surgery in 9/12 (75%) without complication. Two patients (0.4%) required access to the biliary tree for the treatment of choledocolithiasis after RYGBP and were managed through percutaneous transhepatic approach with a success rate of 100% and no complication.

Conclusion The rate of symptomatic lithiasis after bariatric surgery is low. The need for a subsequent cholecystectomy in the setting of the supra-selective approach is rare, 2.7%. This second procedure is safe and easy. All patients with gallbladder left in-situ should receive Ursodeoxycholic acid prophylaxis for 6 months.

1. Introduction

A. Epidemiology of obesity

The World Health Organization defines obesity as a condition of excessive fat accumulation in the body adversely affecting health and well-being [1]. The most used parameter to define this condition is the Body Mass Index (BMI), which is determined by weight and height in square meters. Thus, obesity is defined as $BMI > 30\text{kg/m}^2$, and it can further be subdivided by subclasses of BMI based on Garrow's classification, as demonstrated in Table 1 [2].

The prevalence of obesity is currently increasing worldwide: in 2016, 650 million people were obese [3]; consequently, obesity is now considered an epidemic. Forecasts suggest a dramatic increase in the years ahead: by 2030, an estimated 51% of the worldwide population will suffer from obesity [4]. In France, the prevalence of obesity was 8.5% in 1997 and reached 15% in 2012 [5]. Children and teenagers are also concerned: in 2016, 20.6% of teenagers and 13.9% of children between 2 and 5 years old were obese in the United States [6]. While comparisons in France are lower, with 4% obesity in children ages 6 to 17 years, the numbers continue to increase more quickly each year [5].

B. Associated diseases and disabilities

In addition to excess body weight, obesity is associated with several chronic diseases and disabilities. One of the most frequently related diseases is Type II diabetes mellitus because of low quantities of insulin production from pancreatic β -cells as well as peripheral insulin resistance [7]. Obstructive Sleep Apnea Syndrome (OSAS) is also commonly associated with obesity. The prevalence of OSAS within the general population is 2 to 7% [8] but reaches 22 to 77% in the population of patients undergoing bariatric surgery [9,10]. This disease is responsible for augmented cardiovascular risk and metabolic syndrome [11]. Liver diseases

are also associated with obesity, regrouped as Non-Alcoholic Fatty Liver Disease (NAFLD), which encompasses a wide spectrum of stages of severity, from Non-Alcoholic Steatohepatitis (NASH) to dysmetabolic cirrhosis and even end-stage liver disease [12–14]. Additionally, lipid disorders are commonly associated with obesity, including increased fasting plasma triglycerides, high LDL cholesterol, and low HDL cholesterol [15]. Obesity and associated diseases are responsible for a dramatic diminution of life expectancy, with life loss ranging from 5 to 20 years, especially among younger white men ages 20 to 30 years with severe levels of obesity (BMI > 45) [16].

Beyond a medical viewpoint, obesity is also associated with negative social considerations in both children and adults. For example, the literature demonstrates that obesity in children and teenagers is negatively associated with academic performance [17–19]. Moreover, in adults, empirical evidence demonstrates that obesity discrimination is openly reported by both employers and employees in workplace and recruitment scenarios, especially among women [20–22].

C. Surgical management of obesity

Bariatric surgery has proven to be an effective intervention for the treatment of obesity and obesity-related diseases, resulting in improved weight loss outcomes and associated comorbidities as compared to non-surgical interventions [23]. Bariatric surgery can also address social issues and unemployment [24]. In 2016, more than 680,000 bariatric procedures were performed worldwide, mainly comprised of two types of intervention [25]. The first intervention is the Sleeve Gastrectomy (SG). As a purely restrictive procedure, SG reduces caloric oral intake and causes satiety through limited gastric volume by surgically resizing the stomach. It consists in the transection of the greater gastric curvature, resulting

in a sleeve. The second most performed procedure is the Roux-en-Y Gastric Bypass (RYGBP). As a mixed procedure, it first involves the creation of a gastric pouch with a volume of 30 mL, which is responsible for a restrictive component. Next, the creation of a 150 cm Roux-en-Y gastrojejunostomy is responsible for a malabsorptive component [26]. The final configuration after these two procedures is shown in Figure 2.

D. General considerations about biliary lithiasis

Biliary lithiasis, or gallstone disease, occurs when solid calculi are formed by precipitation of supersaturated bile composed of cholesterol monohydrate crystals or by “black pigment” of polymerized calcium bilirubinate [27]. The prevalence of cholelithiasis ranges from 6 to 22% in the general population of developed countries [28,29]. Generally, gallstones remain clinically insignificant, and only 10 to 20% of patients with known lithiasis develop symptomatic diseases requiring cholecystectomies, such as biliary colic, acute biliary pancreatitis, cholecystitis, and choledocolithiasis [30–32].

E. Link between gallstones, obesity, and bariatric surgery

Obesity is a well-known risk factor in the formation of cholesterol gallstones, and it exposes patients to a 5- to 7-fold increased risk of gallstone-related complications that require cholecystectomies than in the general population [33–35]. Moreover, rapid weight loss after bariatric surgery has also been proven to be a risk factor for gallstone formation due to cholesterol hyper-saturation of bile and crystallization, decreased secretion of biliary acids, increased mucin production (enhancing crystallization), and gallbladder hypomotility secondary to decreased cholecystokinin [36]. Moreover, in the case of RYGBP, additional mechanisms could produce potential intraoperative injuries to the hepatic branches of the vagus nerves during the dissection of the lesser omentum, which is responsible for

hypomotility of the gallbladder [37,38]. In the existing literature, the estimated median time for the development of gallstones ranges from 6 to 16 months after bariatric surgery [39–45].

The question of whether cholecystectomy should be performed during bariatric surgery represents one of the oldest controversies in the field of bariatric surgery. Indeed, patients undergoing bariatric surgery are at high risk for both the prevalence of preoperative cholelithiasis as well as their postoperative development after rapid weight loss. Thus, Concomitant Cholecystectomy (CC) at the time of bariatric surgery could decrease the need for a potentially challenging secondary cholecystectomy, avoiding the difficult management of common bile duct stones and access to the biliary tree in patients with duodenal exclusion after RYGBP. However, CC has been associated with increased operative time, length of stay, rate of complications, mortality, and potential bile duct injury [40,44,46–51]. Based on these associations, different strategies to manage the gallbladder in patients undergoing obesity surgery are currently described in the literature, especially in the case of RYGBP.

The first strategy is the prophylactic approach, involving systematic CC for all patients undergoing RYGBP with or without preoperative cholelithiasis [52–54]. The second strategy is the selective approach, involving CC for patients with pre- or intra-operative Ultra-Sound (US) proof of cholelithiasis [38,55–63]. With the third approach, CC is performed only if the patient experiences symptomatic cholelithiasis (biliary colic, cholecystitis, or acute biliary pancreatitis), regardless of the findings of the US [41,44,48,64–70]. In the existing literature, this strategy is described as “elective” [71], “expectant” [69], “conservative” [72], and even wrongly, as the “selective” approach: it results in confusion among comprehension and comparison of the different approaches [65,66]. To resolve this issue, we purpose to describe

it as the “supra-selective approach ” by analogy with the selective one, involving CC only in the case of symptomatic cholelithiasis.

The aim of this work is to study the incidence of symptomatic biliary lithiasis and the results of the supra-selective approach for gallbladder management in all patients undergoing laparoscopic bariatric surgery, including SG and Gastric Bypass, and to discuss its effectiveness and relevance in comparison to others strategies presented in the existing literature.

2. Material & Methods

Design of the study

We performed a retrospective review of all patients who underwent laparoscopic bariatric surgery between 2010 and 2018 at Grenoble University Hospital, France (prospective database from the Severe Obesity Outcome Network SOON, clinical trial NCT02264431). Criteria for inclusion were the following: all patients undergoing laparoscopic or robotic bariatric surgery, including primary Gastric Bypass (GBP), which includes RYGBP or Omega-Loop Gastric Bypass (OLGB), and SG. Revisional procedures were also studied but only in the case of weight loss failure, including RYGBP and SG after Laparoscopic Adjustable Gastric Band or Mason’s Vertical Banded Gastroplasty. Patients undergoing two procedures during the follow-up were analyzed after the revisional one.

Preoperative baseline characteristics of all patients were collected as follows: age, sex, weight, BMI, associated diseases, previous cholecystectomy or bariatric surgery, and the result of preoperative abdominal US. Postoperative data were collected through medical records as follows: measure of individual follow-up time, symptomatic cholelithiasis requiring cholecystectomy (including biliary colic, cholecystitis, and acute biliary pancreatitis), delay, surgical approach (open or laparoscopy), day-case surgery or conventional hospitalization and

associated complications, or choledocolithiasis requiring an interventional procedure in order to access the biliary tree after GBP, approach, associated complication, and success.

Current management of gallbladder

All patients are routinely screened for cholelithiasis by preoperative abdominal US and are asked for a history of symptomatic biliary disease (abdominal pain suggesting biliary colic, acute biliary pancreatitis). According to the supra-selective approach, only patients with a history of symptomatic biliary disease undergo CC during laparoscopic bariatric surgery. All other patients, regardless of the findings of the preoperative US or the procedure (including GBP and SG) with in situ gallbladder, receive ursodeoxycholic acid (UDCA), 500 mg/day for 6 months.

Endpoints

The main endpoint was the rate of patients who required surgical or interventional procedures for symptomatic biliary lithiasis, including biliary colic, biliary pancreatitis, acute cholecystitis, or choledocolithiasis during the follow-up. Secondary endpoints were the following: rate of patients who required a subsequent cholecystectomy within a follow-up of at least 12 months, indication, open or laparoscopic approach, rate of day-case surgery, and outcomes. Approach for the management of choledocolithiasis after GBP and associated complications were analyzed. Comparisons between patients with and without preoperative cholelithiasis were performed and subgroup analysis according to the type of surgery.

Statistical analysis

Quantitative data are presented as the mean and standard deviation for normally distributed data or the median and interquartile range for non-normal distributed data after assessment

of the normal distribution of the data using the Shapiro-Wilk Test. Comparison between subgroups of patients was performed using chi-square test for independent samples or Fisher's exact test if assumptions of chi-square were not met. The statistical analysis was performed using the software XLSTAT (Addinsoft, Paris, France). A p value < .05 was considered statistically significant.

Compliance with ethical standards

According to the law in our country, all patients included in this study signed a written consent to be included in the prospective database from the Severe Obesity Outcome Network SOON, clinical trial NCT02264431.

3. Results

Population

Five hundred and twenty patients were included and analyzed with a median follow-up of 37.5 months (IQR 23 - 60.25). The median age was 43 years. There were 396 females (76.2%) and 124 males (23.8%). The median BMI was 44.6 kg/m². The main associated diseases were OSAS in 229 patients (44%), hypertension in 177 patients (34%), and diabetes in 144 patients (27.7%). The bariatric procedure was Gastric Bypass in 328 patients (63.1%) and sleeve gastrectomy in 192 (36.9%). Seventy-one patients had a history of a previous cholecystectomy (13.6%). Sixty-four patients had preoperative lithiasis (14.2%). Three patients underwent CC because of preoperative symptomatic biliary disease and one because of gallbladder injury during liver biopsy. After the procedure, 445 patients (85.6%) had in situ gallbladder and 61 had lithiasis among these patients (13.7%). The preoperative characteristics of the population and details of the procedures are outlined in Table 1.

Endpoints

During the follow-up, 14/520 patients (2.7%) required a surgical or interventional procedure for symptomatic biliary lithiasis. Among them, 12 patients required subsequent cholecystectomies and 2 patients required access to the biliary tree for the treatment of choledocolithiasis after RYGBP (Table 2).

Concerning access to the biliary tree, 2/520 patients (0.4%) required this procedure for choledocolithiasis, 20 to 35 months after RYGBP. Both patients had previous cholecystectomies before bariatric surgery. Percutaneous transhepatic cholangiography under local anesthesia associated with balloon dilation of the sphincter of Oddi were performed for these two patients. Then, a balloon was used to push the gallstone through the papilla. Success rate was 100%, and no complications were associated (Figure 3).

Concerning subsequent cholecystectomies, 12/445 patients (2.7%) required such a procedure at a median time of 25 months (IQR 16.5 – 44.2), including 9/278 patients (3.2%) in the GBP subgroup (RYGBP and OLGB) and 3/167 in the SG subgroup (1.8%) without statistical difference ($p = 0.54$). There was no difference between patients with and without preoperative lithiasis, as 3/61 (4.9%) and 9/384 (2.3%) respectively required subsequent cholecystectomies ($p = 0.21$). Indication for subsequent cholecystectomy was biliary colic in 9 patients, cholecystitis in 2, and acute biliary pancreatitis in 1. Most were performed through a laparoscopic approach ($n = 11/12$, 91.7%) in the setting of outpatient surgery ($n = 9/12$, 75%). Two patients were excluded from an outpatient surgery program because of social contraindications and were hospitalized only 1 night. The median length of stay (LOS) after the subsequent cholecystectomy was 1 day (IQR 1 – 1.25), and there were no related surgical complications.

4. Discussion

Main endpoint

In our study, the global rate of surgical or interventional procedures for symptomatic biliary lithiasis after bariatric surgery was 2.7%. Among these, 12 required a subsequent cholecystectomy, and 2 required access to the biliary tree for treatment of choledocolithiasis after RYGBP. This does not compare to current literature as most published studies excluded patients with previous cholecystectomies. This issue seems to be important as in our study, 2 patients with previous histories of cholecystectomies required access to the biliary tree.

Subsequent cholecystectomies in the supra-selective and selective approaches

In our study, the global rate of subsequent cholecystectomies after all procedures (including GBP and SG) in the setting of the supra-selective approach is 2.7% at a median time of 25 months, with a median follow-up of 37.5 months. This rate is low in comparison to the current literature, which ranges from 6.2% to 8.4% with a median follow-up ranging from 8 to 49 months [41,64,66,70,73].

Concerning analysis by procedure subgroup, we found a rate of 3.2% in the GBP subgroup, contrasting with most rates reported in the literature, from 8 to 14.5% [41,66,68–71,74]. Only one study reported a similar low rate of 3.3% within 12 months [65]. Concerning the SG subgroup, the rate of subsequent cholecystectomy was 1.8% in our study, in accordance with the 1.6% found by Brockmeyer et al. [41], but the rate was higher in 4 others studies, ranging from 3.5 to 7.5% [44,66,67,70]. Compared with the selective approach, CC for patients with US-proven cholelithiasis regardless of symptoms shows a global high rate of subsequent cholecystectomies ranging from 6 to 17% after RYGBP [38,56,57,60,63] and 6.1% after SG [60]. Only one study reported a low rate of 2.3% after RYGBP [55]. Surprisingly, the rate of

subsequent cholecystectomies in the setting of the supra-selective approach in our study is one of the lowest in the literature compared to studies describing the same approach and is similar to the lowest rate in a study describing selective approach at approximately 3% [54].

The first possible explanation of this result could be postoperative prophylaxis with UDCA: all our patients routinely receive this medication for 6 months regardless of the presence of cholelithiasis or the type of procedure, unlike most other studies finding a higher rate of subsequent cholecystectomies where patients do not receive UDCA after the selective [38,56,57,60] or supra-selective approach [44,64,67,69]. Two studies have reported a higher rate of subsequent cholecystectomies despite the use of UDCA, but the compliance was low, approximately 25 to 48% [71,74]. There is current evidence in the literature, including Randomized Controlled Trials, systematic review, and meta-analysis, for the protective role of UDCA, not only for the formation of US cholelithiasis [75–78] but also and mainly for the decrease of symptomatic ones requiring subsequent cholecystectomies in patients with or without preoperative cholelithiasis [42,79–83]. Moreover, few authors and societies recommend this prophylactic therapy, including the European Association for the Surgery of Liver (EASL), the American College of Surgeons (ACS), the International Federation of Surgery for Obesity (IFSO), the Obesity Society, and the American Society for Metabolic and Bariatric Surgery (ASMBS) [79,84–86].

The second explanation is the current contradicting rate of patients with preoperative cholelithiasis requiring subsequent cholecystectomies. In our study, only 4.9% of patients with preoperative cholelithiasis required a subsequent cholecystectomy, and there is no difference in comparison to patients without cholelithiasis. This finding correlates with most of the literature as the rate of subsequent cholecystectomies in patients with known

cholelithiasis ranges from 1.5 to 9% [64,68,72,87,88]; however, it contradicts 2 studies which reported a higher rate up to 17% where as a nuance, UDCA was not used [63,89]. Moreover, Morais et al. reported that none of their patients with known cholelithiasis developed postoperative symptoms requiring a cholecystectomy [65]. Therefore, the presence of preoperative cholelithiasis does not seem to be a predictive factor of the need for a second procedure. These findings argue that CC based on US preoperative proof of cholelithiasis should be avoided.

Concerning the delay of subsequent cholecystectomies, the estimated median time for the development of postoperative gallstones ranges from 6 to 16 months [39–45]. In our study, the median time was longer, approximately 25 months (IQR 16.5 – 44.2). We argue that this difference is probably due to the small size of our population, resulting in a statistical bias.

Safety of CC and subsequent cholecystectomies

Current literature notes a controversy concerning the difficulty and safety of performing a CC or subsequent cholecystectomy in a patient with previous bariatric surgery. CC was historically recommended at the time of open gastric bypasses, but the trend toward laparoscopic surgery has change the rules, especially concerning the risk of biliary duct injury, which has increased in comparison to open surgery, approximately 0.5% [90–92]. In our study, we found that a subsequent cholecystectomy is easy and safe, as 91.7% were performed through a laparoscopic approach and 75% through outpatient surgery. Available literature reported a similar rate of successful laparoscopic approaches, from 95 to 97.5% [41,64,73]. We are convinced that it is easier to perform a cholecystectomy as a stand-alone procedure in a patient after weight loss and a lesser BMI. Concerning association of RYGBP and CC, a number of studies demonstrated that this association is responsible for an increased operative time of

approximately 20 to 60 minutes [55,58,61,74,89], increased LOS [49,50,55], complications including major adverse events [45,49–51,55], reoperation, and even in-hospital mortality [49]. Concerning SG, CC is associated with a significant increased risk of postoperative bleeding [44]. As a nuance, Tustumi et al. reported in a meta-analysis that the risk for postoperative complications and reoperation was lower in CC than in subsequent cholecystectomies [45], and Wanjura et al. showed a higher risk for 30-day postoperative complications when a cholecystectomy was performed after RYGB, compared with before [51]. This is a normal finding because indications are not the same before or during bariatric surgery (uncomplicated gallstones), while after bariatric surgery, up to 40% of indications were acute cholecystitis or involved common bile duct exploration in the study of Tustumi et al., which are known to be more difficult procedures [45].

One cost-effectiveness analysis has been reported in the literature by Benarroch et al., concluding the main factor that determines the most cost-effective strategy is the incidence of gallbladder-related symptoms after RYGB. When the incidence of gallbladder-related symptoms is low (<4.6%), the most cost-effective approach is to perform RYGB alone without preoperative ultrasonography, but for higher incidence (>6.9%), performing a CC at the time of the RYGB is superior to other strategies. Selective cholecystectomies based on preoperative ultrasonography remain the least cost-effective approach [93].

Prophylactic approach and CC

The prophylactic approach, consisting of a systematic CC for all patients undergoing RYGBP, was initially described in the setting of open-RYGBP [54,57,89,94] based on two major arguments. The first argument was the high rate of abnormalities found during the pathology exam of the gallbladder, ranging from 42 to 99.3% [53,55,94,95]. Most of these abnormalities,

however, had no clinical relevance, such as chronic cholecystitis found in up to 65% of patients [53,94] or uncomplicated gallstones found in up to 51% of patients [53]. Moreover, Fobi et al. found that 33% of resected gallbladders had no abnormalities according to pathology exams [94].

The second argument is the issue of access to the biliary tree after RYGBP. In our study, 2 patients with choledocolithiasis after RYGBP were successfully treated by the percutaneous transhepatic approach without any complications. Although not widely published after RYGBP, this approach is described after the failure of an endoscopic approach or in patients with duodenal exclusion. The percutaneous transhepatic approach appears to be a less invasive procedure to manage choledocolithiasis in such patients and is associated with a high rate of success in the current literature, up to 100% [96–98] with a low rate of complication of 6.8% in the largest study [99]. Other approaches have been more widely studied after RYGBP, such as the Laparoscopic Trans-Gastric ERCP (LTG-ERCP) that involves endoscopic access through a laparoscopic gastrostomy performed in the gastric remnant [100,101]. Despite being technically demanding, this procedure is considered to be successful in the literature, up to 80 – 100% safe and reliable when performed by a trained team [41,102–108]. As a nuance, some specific and major complications can occur, such as gastrostomy leak or a gastric or duodenal perforation. In the current literature, the rate of complication ranges from 16% in the study of Grimes et al. related to the access site [105] to 36% in the study of Frederiksen et al., including 14% of major complications (classified as Clavien-Dindo > IIIb), which mainly include bleeding, hematoma, and intra-abdominal abscesses [109]. Finally, in a systematic review of the literature involving 509, Banerjee et al. found a rate of success of 98.5%, associated with 14% of adverse events, mainly wound infections [110].

Arguments for the supra-selective approach

To summarize the discussion, we are convinced that the prophylactic approach should not be recommended regarding associated morbidity, mortality, and increased LOS. Moreover, most of the abnormalities found during pathology exams have no clinical relevance. Finally, different approaches for access to the biliary tree after RYGBP are described and considered as safe and successful.

The selective approach appears to be unreliable because most patients who require subsequent cholecystectomies have no cholelithiasis on preoperative US. The best argument against reliability is that the rate of subsequent cholecystectomies remains the same as in the supra-selective approach. Consequently, the supra-selective approach appears to be the most reasonable way to manage gallbladders in patients undergoing bariatric surgery.

Limitations of this study

Limitations of our study include a retrospective analysis. Additionally, our study population was small in comparison to larger studies published in the literature. However, the median follow-up time was acceptable, 37.5 months (IQR 23 - 60.25). Moreover, we sought to avoid potential bias by including all patients who underwent bariatric procedures, including SG and revisional procedures, which are less widely studied in the literature than RYGBP.

5. Conclusion

The rate of symptomatic lithiasis after bariatric surgery is low and concerns patients with or without previous cholecystectomies. The need for a subsequent cholecystectomy after a Gastric Bypass or Sleeve Gastrectomy in the setting of the supra-selective approach is rare, respectively 3.2% and 1.8%. This second procedure is safe and easy, as most are performed

through a laparoscopic approach in a day-case surgery setting. Regarding the present study and the most recent literature, there are no arguments for a cholecystectomy at the time of bariatric surgery except in patients with cholelithiasis-related symptoms. All other patients with gallbladder left in-situ, and regardless of the procedure, they should receive UDCA prophylaxis for 6 months.

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Figures and tables

Body Mass Index	Classification
Normal Weight	20 - 24.9
Overweight	25 - 29.9
Class I obesity	30 - 34.9
Class II obesity	35 - 39.9
Class III obesity - Morbid obesity	> 40

Figure 1. Classification of obesity following Garrow.

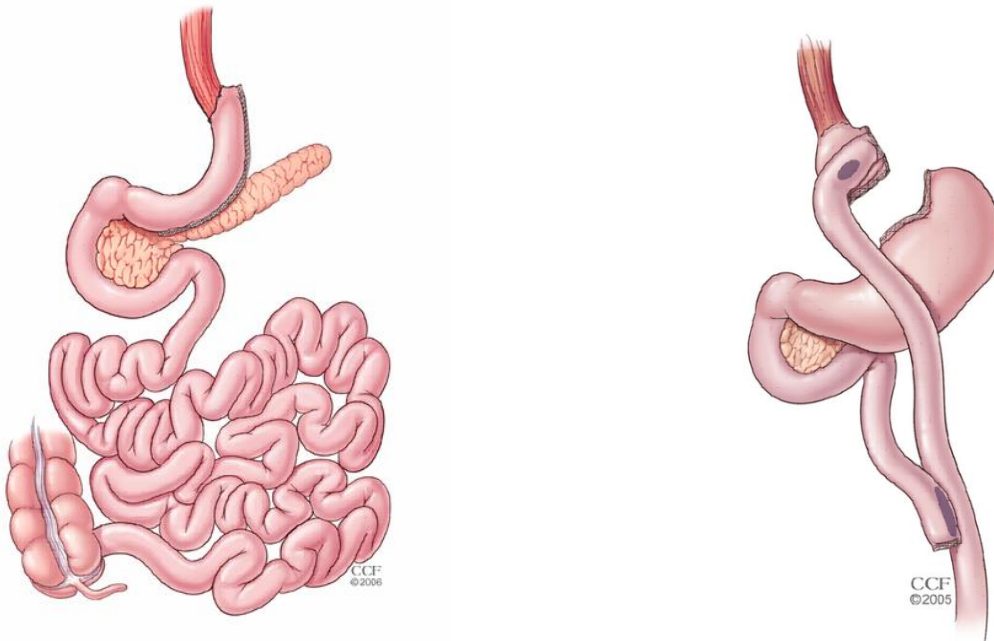


Figure 2. Sleeve Gastrectomy (Left) and RYGBP (Right). (ASMBS website).

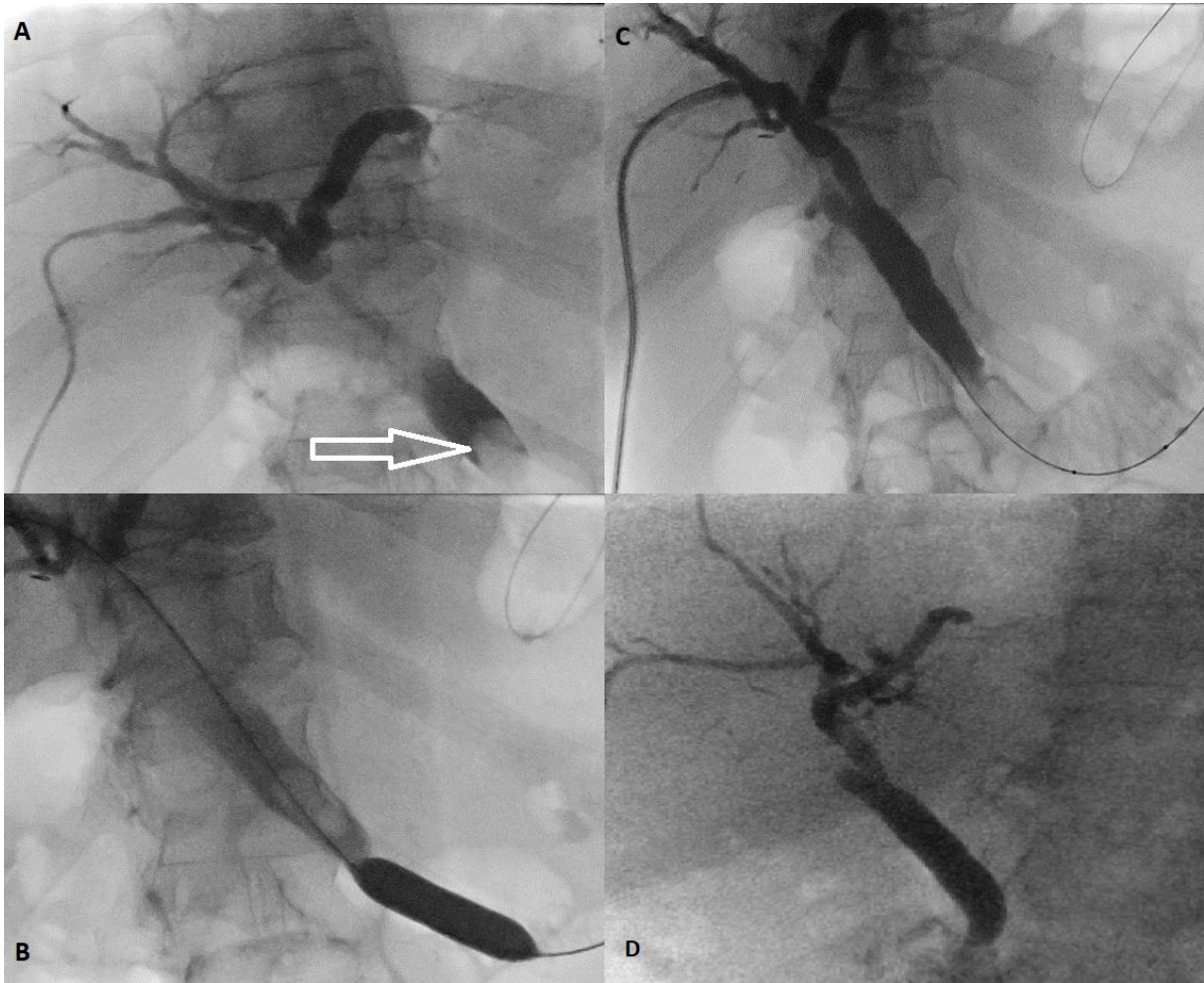


Figure 3. Percutaneous transhepatic cholangiography procedure. A = Cholangiography showing common bile duct stone (white arrow). B = Trans hepatic dilatation of the sphincter of Oddi. C = Final cholangiography showing clearance of the common bile duct. D = Transhepatic cholangiography 24 hours after the procedure showing no abnormalities.

Table 1. Preoperative baseline characteristics of the population (n=520)

Age (Median, IQR)	43 years	35 - 52
Sex		
<i>Male (n)</i>	124	23.8%
<i>Female (n)</i>	396	76.2%
Weight (Median, IQR)		
	120 kg	108 - 137.7
BMI (Median, IQR)		
	44.6 kg/m ²	41 - 50
Associated disease		
<i>OSAS</i>	229	44.0%
<i>HT</i>	177	34.5%
<i>Diabetes</i>	144	27.7%
<i>Previous cholecystectomy</i>	71	13.7%
Procedure		
<i>Primary GBP</i>	266	51.1%
<i>RYGBP</i>	260	50.0%
<i>OLGBP</i>	6	1.1%
<i>Revisionnal GBP</i>	62	11.9%
<i>RYGBP</i>	61	11.7%
<i>OLGBP</i>	1	0.2%
<i>Primary SG</i>	184	35.4%
<i>Revisionnal SG</i>	8	1.6%

OSAS: Obstructive Sleep Apnea Syndrom. HT: Hypertension. GBP: Gastric By Pass. RYGBP:

Roux-en-Y Gastric By Pass. OLGBP: Omega-Loop Gastric By Pass

Table 2. Result for main endpoint

Biliary complications	14/520	2.7%
<i>Access to the biliary tree</i>	2/520	0.4%
<i>Subsequent cholecystectomy</i>	12/445	2.7%

Table 3. Results for subsequent cholecystectomy

Number (rate)	12/445	2.7%
Median Time (months, IQR)	25	16.5 – 44.2
Procedure (rate) *		
<i>GBP</i>	9/278	3.2%
<i>SG</i>	3/167	1.8%
Indication (rate)		
<i>Biliary colic</i>	9/12	75%
<i>Cholecystitis</i>	2/12	16.7%
<i>Acute biliary pancreatitis</i>	1/12	8.3%
Preoperative cholelithiasis (rate) **		
<i>With</i>	3/161	4.9%
<i>Without</i>	9/384	2.3%

* *p-value* = 0.54. ** *p-value* = 0.21.

SYMPTOMATIC BILIARY LITHIASIS AFTER LAPAROSCOPIC BARIATRIC SURGERY: RESULTS OF SUPRA-SELECTIVE MANAGEMENT

Abstract (247 words)

Introduction: Patients undergoing bariatric surgery are at high risk for both the prevalence of preoperative cholelithiasis as well as their postoperative development. The question of whether cholecystectomy should be performed during bariatric surgery remains controversial. The aim of this work is to study the results of the supra-selective approach for gallbladder management, involving concomitant cholecystectomy only in patients with gallstones-related symptoms.

Material & Methods: This is a retrospective review of a prospective database of all patients who underwent laparoscopic or robotic bariatric surgery between 2010 and 2018 in a single institution.

Results: Five hundred twenty patients were included with a median follow-up of 37.5 months. The procedure was Gastric Bypass in 328 patients (63.1%) and sleeve gastrectomy in 192 (36.9%). Seventy-one patients had a history of cholecystectomy (13.6%). Sixty-four patients had preoperative lithiasis (14.2%). Four patients underwent concomitant cholecystectomy. Fourteen (2.7%) patients required an intervention for symptomatic lithiasis: 12/445 (2.7%) patients required subsequent cholecystectomies and 11/12 (91.7%) were performed through a laparoscopic approach as outpatient surgery in 9/12 (75%) without complication. Two patients (0.4%) required access to the biliary tree for the treatment of choledocolithiasis after RYGBP and were managed through percutaneous transhepatic approach with a success rate of 100% and no complication.

Conclusion The rate of symptomatic lithiasis after bariatric surgery is low. The need for a subsequent cholecystectomy in the setting of the supra-selective approach is rare, 2.7%. This second procedure is safe and easy. All patients with gallbladder left in-situ, they should receive Ursodeoxycholic acid prophylaxis for 6 months.

KEYWORDS: Bariatric surgery; Gastric bypass; Sleeve gastrectomy; cholecystectomy;
cholelithiasis

FILIÈRE : [DES Chirurgie Générale](#), [DESC Chirurgie viscérale](#)

THÈSE SOUTENUE PAR : Adrian MANCINI

TITRE :

SYMPTOMATIC BILIARY LITHIASIS AFTER LAPAROSCOPIC BARIATRIC SURGERY:
RESULTS OF SUPRA SELECTIVE MANAGEMENT

CONCLUSION :

The rate of symptomatic lithiasis after bariatric surgery is low and concerns patients with or without previous cholecystectomies. The need for a subsequent cholecystectomy after a Gastric Bypass or Sleeve Gastrectomy in the setting of the supra-selective approach is rare, respectively 3.2% and 1.8%. This second procedure is safe and easy, as most are performed through a laparoscopic approach in a day-case surgery setting. Regarding the present study and the most recent literature, there are no arguments for a cholecystectomy at the time of bariatric surgery except in patients with cholelithiasis-related symptoms. All other patients with gallbladder in-situ, and regardless of the procedure should receive Ursodeoxycholic acid prophylaxis for 6 months.

VU ET PERMIS D'IMPRIMER

Grenoble, le : 210912

LE DOYEN



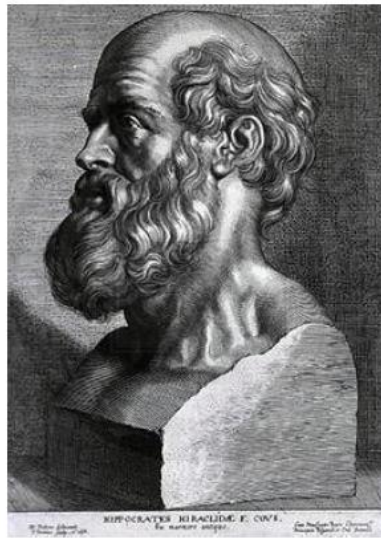
Pr. Patrice MORAND

Pour le Président
et par délégation
—
Le Doyen de Médecine
Pr. Patrice MORAND

LE PRÉSIDENT DE LA THÈSE



Pr. Anne-Laure BOREL



SERMENT D'HIPPOCRATE

En présence des Maîtres de cette Faculté, de mes chers condisciples et devant l'effigie d'HIPPOCRATE,

Je promets et je jure d'être fidèle aux lois de l'honneur et de la probité dans l'exercice de la Médecine.

Je donnerai mes soins gratuitement à l'indigent et n'exigerai jamais un salaire au dessus de mon travail. Je ne participerai à aucun partage clandestin d'honoraires.

Admis dans l'intimité des maisons, mes yeux n'y verront pas ce qui s'y passe ; ma langue taira les secrets qui me seront confiés et mon état ne servira pas à corrompre les mœurs, ni à favoriser le crime.

Je ne permettrai pas que des considérations de religion, de nation, de race, de parti ou de classe sociale viennent s'interposer entre mon devoir et mon patient.

Je garderai le respect absolu de la vie humaine.

Même sous la menace, je n'admettrai pas de faire usage de mes connaissances médicales contre les lois de l'humanité.

Respectueux et reconnaissant envers mes Maîtres, je rendrai à leurs enfants l'instruction que j'ai reçue de leurs pères.

Que les hommes m'accordent leur estime si je suis fidèle à mes promesses.

Que je sois couvert d'opprobre et méprisé de mes confrères si j'y manque.