

A Rational Approach to Cholelithiasis in Bariatric Surgery

Its Application to the Laparoscopically Placed Adjustable Gastric Band

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Background: Gallstones are more common in the obese population and may be formed during rapid weight loss. 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. We analyzed the outcomes of a noninterventionist policy on 1000 patients undergoing laparoscopic adjustable gastric banding.

Hypothesis: Patients scheduled for adjustable gastric banding should undergo investigation for and treatment of gallbladder disease regardless of symptoms.

Methods: Patients were screened preoperatively for symptoms of gallstones. Ultrasound examination was performed only in those with symptoms and, if stones were present, cholecystectomy was performed with gastric banding. The remaining patients were followed up clinically and outcomes were noted.

Results: A total of 1000 patients were followed up for 12 to 96 months, a total of approximately 3500 patient-years. Cholecystectomy was performed in 181 patients before and 10 at gastric banding surgery. Of the 809 patients at risk, 55 (6.8%) presented with symptomatic disease during follow-up and proceeded to undergo elective cholecystectomy without complications from the disease or the treatment.

Conclusions: The incidence of cholecystectomy after gastric banding surgery was not different from the expected rate for a nonsurgical obese population. In contrast, after Roux-en-Y gastric bypass, a median of 40% of patients form stones in the postoperative period, and prophylactic cholecystectomy may be justified. Our data indicate that a noninterventionist approach to the gallbladder is appropriate for patients undergoing adjustable gastric banding surgery.

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GALLSTONES ARE a common problem in the community and a greater problem in the obese population. It was estimated more than 30 years ago that 15% of the US population had gallstones.¹ Although we have evidence of the peak incidence of gallstones occurring the Western world in the 1960s,² it remains a common disease. The risk of developing gallstones is directly related to the level of obesity,³ with the relative risk above a body mass index (calculated as weight in kilograms divided by the square of height in meters) of 40 being 5 to 6 times that of the background population.⁴ Cholecystectomy, generally performed laparoscopically, is the accepted approach for symptomatic gallstones with few exceptions.

The optimal approach to asymptomatic gallstones ("the silent gallstone") has been the subject of considerable debate.

Although higher figures can be derived from postmortem analyses, the prevalence of asymptomatic gallstones in the general community was estimated at 17% by an Italian epidemiologic study of 4751 unselected adults who were assessed by means of ultrasound.⁵ On the basis of data from the 1980s indicating that the onset of symptoms was infrequent and the prognosis if symptoms did arise was benign, it is now broadly accepted that, for the general population, the silent gallstone does not need to be treated. Gracie and Ransohoff⁶ followed up 123 staff members of the University of Michigan who had asymptomatic gallstones. The 15-year cumulative probability of developing biliary symptoms was 18%. Similarly, McSherry and colleagues⁷ followed up 135 middle-income Americans with asymptomatic gallstones for 58 months. During this time, only 10% developed symptoms and 7% came to operation. Schwesinger and Diehl⁸ brought together these and 4 additional

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studies of the natural course of gallstones to indicate that the mean likelihood of symptoms occurring by 5 years is 17%. However, there continues to be debate regarding subgroups for whom the standard rule should possibly not be applied.⁸ These include patients with diabetes mellitus, transplant recipients, young children, and the patient undergoing bariatric surgery.

Each bariatric surgeon needs to establish a policy regarding the investigation and management of gallstones as a part of the routine assessment and care of the bariatric patient. The recent report by Fobi and coworkers⁹ has renewed the focus on the optimal treatment of these patients. They have followed a policy of prophylactic cholecystectomy in all of their patients who undergo Roux-en-Y gastric bypass (RYGB) and thereby have provided us with valuable data on the prevalence of gallstones in this group of patients. Of a total of 761 patients studied, 178 (23.4%) had prior cholecystectomy. Another 207 (27.2%) had asymptomatic gallstones detected either on ultrasound (20.2%) or after examination of the gallbladder after removal (7.0%). Apart from the disappointing observation that gallbladder ultrasound showed a sensitivity of only 74%, their data provide an important measure of the prevalence of silent gallstones in severely obese patients undergoing bariatric surgery.

For this group of patients, a number of valid reasons can be advanced for approaching their possible biliary problems differently. These patients have a higher prevalence of cholelithiasis and are therefore more likely to harbor silent gallstones. As they are already having an operation in the upper abdomen for obesity, the addition of cholecystectomy might incur less cost or morbidity than would be expected with 2 separate procedures. Rapid weight loss is known to facilitate the formation of new gallstones; thus, such patients would be considered to be at greater risk of subsequent biliary problems than the background population.

There are 3 options. First, and perhaps most common, is the practice of investigating for gallstones as a routine part of the preoperative assessment and proceeding to cholecystectomy if stones are present, even in the absence of symptoms. This was the approach of Hamad et al in their recent report.¹⁰ Second is the approach of Fobi and colleagues,⁹ who performed cholecystectomy in all patients as a routine part of the bariatric procedure. Preoperative investigation of the gallbladder was not required. The third policy, which we have been following, is of not investigating the gallbladder unless symptoms are present, and then treating only symptomatic patients. The aim of this report is to examine the consequences of this "noninterventionist" policy, which was followed in 1000 patients who underwent laparoscopic placement of an adjustable gastric banding system (Lap-Band system; BioEnterics Corp, a division of INAMED Corp, Santa Barbara, Calif).

METHODS

As a part of the routine preoperative assessment of severely obese patients for entry into the adjustable gastric banding program, all patients were screened for possible biliary symptoms by a medical consultation with the surgeon, consultations with 3

physicians, completion of a standardized medical profile, and performance of liver function tests. Ultrasound of the gallbladder was not performed routinely, but was performed if the patient had symptoms that were at least suggestive of biliary disease. If the results of ultrasound were negative, no further tests for biliary disease were conducted in any of these patients. The identification of gallstones on ultrasound was followed by a recommendation that cholecystectomy be performed at the time of gastric banding.

All patients were then followed up permanently at our follow-up clinic. The rate of loss to follow-up is currently at 3.6%, thus enabling us to monitor the health outcomes of more than 96% of our patients. All patients underwent an annual comorbidity review at which changes in the clinical history were noted and the liver function tests were repeated.

Patient data were maintained on a patient management database (LapBase; AccessMed, Melbourne, Australia) and on a research-oriented comprehensive comorbidity database (Microsoft Access; Microsoft Corp, Redmond, Wash). Weight loss was expressed principally as percentage of excess weight lost (EWL). The ideal weight used for these calculated values was the median value of the 1983 edition of the Metropolitan Life Insurance tables.

The demonstration of gallstones in symptomatic patients during this follow-up led in all cases to cholecystectomy.

Binary regression analysis was used to assess for factors that were associated with the need for cholecystectomy either before or after surgery. Differences in proportions were assessed with the χ^2 test, with odds ratios calculated for some 2×2 tables. A *P* value of less than .05 was considered statistically significant. All analysis was performed with SPSS for Windows software, version 10.0.5.¹¹

RESULTS

INCIDENCE OF CHOLECYSTECTOMY

The first 1000 consecutive patients undergoing adjustable gastric banding were treated between July 1, 1994, and October 31, 2001. The follow-up ranged from 12 to 96 months, with a median of 42 months. A total of 3500 patient-years of follow-up were recorded. Weight loss followed the characteristic pattern after gastric banding of a steady progression of weight loss to 52% of EWL at 2 years, followed by stability at this level during the next 4 years.¹²

A total of 191 patients (19.1%) had symptomatic cholelithiasis at or before surgery (181 [18.1%] before banding and 10 [1.0%] during banding). This is in keeping with the prevalence of published series. Of the 809 patients with intact gallbladders, 55 (5.5% of total; 6.8% of those at risk) subsequently had cholecystectomy. Based on the number of patient-years of follow-up, this represents 1 cholecystectomy for every 64 patient-years. The mean \pm SD rate of weight loss after adjustable gastric band placement was not significantly different in those who presented subsequently with symptomatic gallstones ($48.4\% \pm 16.9\%$ of EWL) compared with the remainder ($45.8\% \pm 18.4\%$ of EWL; *P* = .31). Readmission for cholecystectomy generally required a 24- to 48-hour stay. One patient (1.8%) of the 55 required conversion from a laparoscopic to an open procedure. No complications occurred in association with the procedure. Cholecystectomy as a part of adjustable gastric band placement added approximately 30 minutes to the duration of the opera-

Table 1. Actual Compared With Estimated Cholecystectomy Incidence in Years After Adjustable Gastric Banding

Years (No. of Patients)	Actual Cholecystectomy, No.	Estimated Cholecystectomy,* No.	P Value (χ^2 Test)
1 (809)	18	15	.59
2 (632)	20	12	.15
3 (506)	9	9	>.99
4 (364)	5	7	.56
5 (230)	2	4	.41
6 (103)	1	2	.56
Total	55	49	.55

*Estimated cholecystectomy numbers were based on 2% of women¹³ and 1% of men developing symptomatic gallstones each year.

tion. Port placement was generally not ideal, as we attempted as far as possible to use the port sites of the initial procedure. Thus, both the position and the angle of the ports were compromised, making the performance of the cholecystectomy component more difficult than would be expected with optimal port placement.

OBSERVED VS EXPECTED CHOLECYSTECTOMY RATE

Is the cholecystectomy rate that we have noted above the expected rate if this group of patients had not had surgery? This question can be approached in 2 ways, either by extrapolating from the natural course data for the non-obese community with adjustment for the increased prevalence of stones in obese people or by comparison with observational data from case series of obese patients presenting with symptomatic disease. The former approach carries the unproved assumption that obesity does not increase the likelihood of acute cholecystitis occurring if stones are present.

Approach 1

The findings of Fobi et al⁹ (27% prevalence of gallstones) and the pooled natural course data as summarized by Schwesinger and Diehl⁸ (17% become symptomatic within 5 years) provide us with values for calculating reasonable predictions. Of the 809 patients at risk, 27% (218 patients) may be expected to have been harboring gallstones. If 17% of these developed symptoms, 37 patients would be expected to come to cholecystectomy. The observed frequency was 55 patients. This difference is not significant on χ^2 test ($P = .053$), supporting the view that patients undergoing adjustable gastric banding are not at added risk of biliary disease because of the procedure. However, the difference nears significance, and additional data need to be collected to be sure that there is not a modest effect.

Approach 2

Approximately 2% of women and 1% of men with a body mass index of 45 can be expected to develop symptomatic gallstones each year.¹³ **Table 1** shows an estimated

cholecystectomy rate based on this expectation for our patients had they not proceeded to gastric surgery and compares those values with the actual cholecystectomy rate after surgery for adjustable gastric banding. There is no difference between the number requiring cholecystectomy and the number estimated to require this procedure, during any 1-year period of follow-up or for the whole follow-up period.

From the combined outcomes of these 2 approaches, we are not able to show that the rate of cholecystectomy after adjustable gastric banding is different from the expected rate for this group of patients.

NEGATIVE EFFECTS OF DELAYED CHOLECYSTECTOMY

There were 2 cases among the 55 in whom the development of symptomatic gallstones caused some concern, as both occurred during pregnancy. One woman developed symptomatic gallstones with frequent attacks of biliary colic and an episode of pancreatitis during the last trimester. Fluid was removed from the band on diagnosis of the biliary colic, but despite this she had a net weight loss of 7 kg for the pregnancy. She had an uncomplicated delivery of a 3560-g healthy male infant after induction at 38 weeks' gestation. An uneventful laparoscopic cholecystectomy was performed 6 weeks post partum. A second woman developed symptomatic gallstones at 32 weeks' gestation. She had regular attacks of biliary colic during the subsequent 5 weeks. She had normal delivery of a male infant at 41 weeks. Uneventful laparoscopic cholecystectomy was performed 9 weeks after delivery. All others have had uneventful laparoscopic cholecystectomies. No acute admissions for acute cholecystitis and no septic complications of the adjustable gastric banding system occurred.

PREDICTORS OF HIGHER RISK

Can we predict a subgroup who are at higher risk? Binary regression analysis was used to look for predictors of risk of needing subsequent cholecystectomy. The group who underwent cholecystectomy were not found to be different from the noncholecystectomy group with respect to age, initial weight or body mass index, or percentage of EWL at 1 or 2 years as continuous variables, and sex and family history of gallstones as categorical variables.

COMMENT

The protocols of Fobi et al⁹ and our group represent the extremes, being cholecystectomy for all ("do not let problems arise") vs cholecystectomy for symptomatic disease only ("do not look for problems"). In the middle are the groups who will treat asymptomatic gallstones found on a routine preoperative ultrasound ("treat the test").¹⁰

In formulating policy regarding the investigation and management of the gallbladder in bariatric surgery, we must incorporate recognition of the likelihood of disease in the future and the health consequences of that

Table 2. Incidence of Gallstones Either Treated or Present at the Time of RYGB (Preoperative) or Appearing as New Gallstones After Operation (Postoperative)

Study, y	No.	Preoperative, %	Postoperative, %	Follow-up, mo
Amaral and Thompson, ¹⁵ 1985	87	28	28	36
Schmidt et al, ¹⁶ 1988	NA	30	40	24
Shiffman et al, ²⁰ 1993	230	35	47	24
Sugerman et al, ¹⁸ 1995	56	NA	32	6
Wudel et al, ¹⁹ 2002	41	NA	71	12

Abbreviations: NA, not available; RYGB, Roux-en-Y gastric bypass.

disease balanced against the costs and risks of the treatment, much of which will be unnecessary.

In this study, the delayed treatment of symptomatic gallstones has not led to any serious negative consequences and has avoided the increased risks and use of resources of the more interventionist approaches. We have found that need for a cholecystectomy arose once in approximately 64 patient-years of follow-up. This rate was not different from the background expectation. On this basis, we have been comfortable in continuing with the policy of not looking for gallstones by preoperative ultrasound unless symptoms were present and of not removing the gallbladder unless symptomatic cholelithiasis exists. In other words, we do not modify the routine approach to the patient because of their obesity or the planned surgery.

Under the "cholecystectomy for all" approach, an additional 744 cholecystectomies would have been performed. The cost for this, as a minimum, would have been an additional 300 to 400 hours of operating time, almost certainly some increased length of stay, and possible complications of the procedure. Our data do not indicate a benefit that would accrue to these 744 patients to make up for the increased costs and risks.

The "treat the test" approach would have generated an additional 809 biliary ultrasound examinations (26% of which may have been falsely negative⁹) and a 20.1% (163 patients) cholecystectomy rate for asymptomatic gallstones. Again, the costs are greater, and yet there would be 107 patients who may not show evidence of defined benefit by the additional surgery.

The planned form of bariatric surgery (adjustable gastric banding or RYGB; open or laparoscopic) is an important variable, as patients undergoing RYGB are known to be at high risk. In 1983, Wattoo and coworkers¹⁴ first defined an increased likelihood of gallstone formation after RYGB and advocated oral treatment with chenodiol as an option for prevention or treatment. Subsequent reports¹⁵⁻¹⁹ have defined the risk of new stone formation after RYGB at between 28% and 71%, with a median value of 40%. These data are summarized in **Table 2**.

Although the very rapid early weight loss with RYGB has been thought to be an important factor in generating this problem, the cited studies generally did not show that the extent of weight loss was a predictor of new gallstone formation,²⁰ indicating that RYGB may predispose to gallstones through other mechanisms, related to duodenal bypass or malabsorption. Whatever the mecha-

nism, patients undergoing RYGB are clearly at much higher risk than patients undergoing adjustable gastric banding. It would appear that, with a median likelihood of forming new gallstones of 40%, the expected presence of stones already in 27%, and a more than 70% failure of full compliance with preventive programs with ursodiol,¹⁹ a more interventionist approach is appropriate as a part of RYGB.

The surgical approach is also relevant. Open surgery lends itself more readily to concomitant cholecystectomy than laparoscopic procedures. Whereas the upper midline incision gives equal access to the left upper quadrant and the gallbladder, port placement for one laparoscopic procedure is rarely ideal for another, and probably the best approach is to defer the second procedure or to replace all ports rather than compromise access. We have not used either modification so far, but we are aware that potential for contamination of the band or tubing with biliary bacteria during cholecystectomy is a serious consideration.

There are significant costs associated with the concomitant cholecystectomy. We have estimated that there is an additional 30 minutes of operating time. Hamad et al¹⁰ reported an additional 48 minutes of operating time when laparoscopic cholecystectomy was added to laparoscopic RYGB, and they found that the length of stay was increased from a mean of 2.7 days to a mean of 4.4 days. There is also the potential for the full range of complications that may occur with cholecystectomy, but few have so far been reported.²¹

On balance, therefore, it would appear that, for the patient undergoing RYGB, 1 of the 2 forms of interventionist approach is indicated. Whether all patients undergoing RYGB should have routine cholecystectomy, or only those showing stones on preoperative ultrasound, needs to be tested directly by a randomized controlled clinical trial of cost-effectiveness.

In contrast, we recommend a noninterventionist approach for patients receiving the adjustable gastric banding system. As only 6.8% of those at risk have presented with symptomatic disease at a median follow-up of 42 months (1 cholecystectomy for every 64 patient-years of follow-up), the risk is markedly lower after adjustable gastric banding than after RYGB (median of 40% shown to have new gallstones at 24 months) and is probably not different from the expected rate for the non-surgically treated obese people in the community. We conclude that the data support our current approach of not looking for gallstones unless symptoms occur and dealing with them

on their merit, independent of the adjustable gastric band placement.

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