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## Cost-effectiveness analysis of cholecystectomy during Roux-en-Y gastric bypass for morbid obesity

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### Abstract

**Background**—Controversy exists regarding the use of concurrent cholecystectomy during Roux-en-Y gastric bypass performed for morbid obesity.

**Methods**—A decision model was developed to evaluate the cost-effectiveness of current strategies: routine concurrent cholecystectomy, Roux-en-Y gastric bypass alone with or without postoperative ursodiol therapy, and selective cholecystectomy based on preoperative findings on ultrasonography. Probabilities were obtained from a comprehensive literature review. Costs and hospital days were obtained from the Healthcare Cost and Utilization Project Nationwide Inpatient Sample. One-way sensitivity analyses were performed.

**Results**—The least expensive strategy was to perform RYGB alone without preoperative ultrasonography, with an average cost (over RYGB costs) of \$537 per patient. RYGB with concurrent cholecystectomy had a cost of \$631. Selective cholecystectomy based on preoperative ultrasonography was dominated by the other 2 strategies. Our model was most sensitive to the probability of developing gallbladder-related symptoms after RYGB alone. When the incidence of gallbladder-related symptoms was <4.6%, the dominant strategy was to perform a RYGB alone without preoperative ultrasonography. For values >6.9%, performing concurrent cholecystectomy at the time of the RYGB was superior to other strategies. When ursodiol was used, the least expensive strategy was to perform a concurrent cholecystectomy during RYGB.

**Conclusion**—The main factor determining the most cost-effective strategy is the incidence of gallbladder-related symptoms after RYGB. The use of ursodiol was associated with an increase in cost that does not justify its use after RYGB. Finally, selective cholecystectomy based on preoperative ultrasonography was dominated by the other strategies in the scenarios evaluated.

Obesity in the United States has increased dramatically over the last 30 years.<sup>1</sup> Bariatric surgery is considered currently the best option to achieve sustained weight loss and manage associated co-morbidities in patients with morbid obesity.<sup>2–8</sup> Roux-en-Y gastric bypass (RYGB) is the current criterion standard because of its durable weight loss and low morbidity.<sup>7,9,10</sup>

Concurrent cholecystectomy during laparoscopic gastric bypass surgery is difficult technically because of port placement and is associated with increased operative time.<sup>11</sup> With an increase in the number of RYGBs performed with a laparoscopic approach,

cholecystectomy is no longer performed routinely. Recent data on patients who did not undergo cholecystectomy at the time of RYGB revealed that 91% to 97% of patients remain asymptomatic and never require intervention.<sup>12–16</sup> When gallstone-related problems do occur, however, management after gastric bypass can be more difficult given the altered anatomy and inability to perform endoscopic retrograde cholangiopancreatography (ERCP).<sup>17</sup> This consideration has made the routine use of concurrent cholecystectomy during laparoscopic gastric bypass controversial.

Currently, bariatric surgeons agree that concurrent cholecystectomy is indicated in patients diagnosed preoperatively with symptomatic gallstone disease. In asymptomatic patients, few surgeons still perform cholecystectomy routinely during laparoscopic RYGB.<sup>10,18,19</sup> Many favor a more selective approach, with preoperative abdominal ultrasonography and cholecystectomy at the time of gastric bypass in those with documented gallstones.<sup>7,10,11,20–22</sup> The use of ursodiol in those who do not undergo cholecystectomy can decrease gallstone formation and gallstone-related complications,<sup>23</sup> but cost and patient compliance make the utility of this treatment strategy unclear.<sup>19,22–24</sup>

The cost-effectiveness of different strategies for the management of the gallbladder in patients undergoing gastric bypass surgery has not been examined. The goal of this study was to use a decision model to evaluate the most cost-effective strategy for gallbladder management in patients undergoing RYGB. Specifically, we compared routine concurrent cholecystectomy, RYGB without cholecystectomy (with or without postoperative ursodiol therapy), and selective cholecystectomy based on preoperative findings of gallstones on ultrasonography. We evaluated cost-effectiveness from the third-party payer perspective and report additional gallbladder-related costs, health outcomes, and incremental cost-effectiveness ratios expressed as additional costs per hospital days saved.

## METHODS

### Decision model

We developed a decision model that included the 3 most common strategies for the management of the gallbladder in obese patients undergoing RYGB: routine concurrent cholecystectomy, RYGB without cholecystectomy (with or without postoperative ursodiol therapy), and selective cholecystectomy based on findings of gallstones on ultrasonography, also with or without ursodiol therapy. These models are summarized in Fig 1.

The base case scenario for the analysis was a 43-year-old morbidly obese patient (body mass index,  $>40 \text{ kg/m}^2$ ) undergoing a RYGB as part of his/her weight loss plan. In our model, the patient was considered to be at risk for gallstone-related complications for a 2-year time period because the mean time to presentation with gallstone-related complications after bariatric surgery ranges from 7.2 to 18.2 months.<sup>13,14,25–27</sup> In the current literature, accurate estimates of 10-year gallstone-related complication rates are not available. Therefore, extension of the analysis beyond the 2-year time point would have introduced substantial uncertainties in our estimates, lessening the validity of our study. All possible outcomes for each strategy were entertained over the 2-year time period, from the development of gallstone-related complications and subsequent surgical outcomes to patients remaining asymptomatic for the entire time period. Ursodiol use was not included in the base case scenario. Additional gallbladder-related costs, health outcomes, and incremental cost-effectiveness ratios (expressed as additional cost per hospital days saved) were reported.

A strategy was considered to be dominant when it cost less and was more effective (shortest average hospital days) compared to the other 2 strategies. In contrast, a dominated strategy was one with a higher cost and a greater duration of average hospital stay compared to any

other strategy. In cases where 1 strategy costs less but another is more effective, our results were expressed as incremental cost-effectiveness ratio (ICER). The ICER is used to compare the difference in cost and outcomes between 2 strategies. In our study, the ICER represents the additional cost required to save an additional hospital day using 1 strategy when compared to another strategy.

## Costs

Costs are summarized in Table I. The perspective used in this analysis is that of a third-party payer. Costs were adjusted to 2008 dollars when required. The mean cost for hospitalization was obtained using the Diagnosis-Related Group (DRG) system from the Healthcare Cost and Utilization Project (HCUP) Nationwide Inpatient Sample web site.<sup>28</sup> The HCUP is sponsored by the Agency for Healthcare Research and Quality (AHRQ) and represents the greatest collection of longitudinal hospital care data in the United States, with all-payer, encounter-level information. Mean annual costs by DRG for any given year can be queried. DRG codes 414 to 419 include open and laparoscopic cholecystectomy and are classified as cholecystectomy without complications, cholecystectomy with minor complications, and cholecystectomy with major complications (listed separately for laparoscopic and open). The cost of the RYGB was excluded, because it was the same for all strategies and was estimated to be \$10,395.<sup>29</sup> Discounting (the method used to calculate the present value of future costs and benefits) was not necessary because of the short duration of the study period.

Using Medicare reimbursement criteria, the cost of concurrent cholecystectomy during RYGB was equivalent to 50% of the surgeon fee because it was considered a secondary procedure. Procedures costs were obtained from the CodeManager web site of the American Medical Association.<sup>30</sup> Current Procedural Terminology (CPT) codes 47562 and 47600 were identified, which correspond to laparoscopic and open cholecystectomy, respectively. National reimbursement fees from the American Medical Association web site<sup>30</sup> were also used to determine the cost for an abdominal ultrasound (CPT code 76705).

The cost of ursodiol therapy was based on the average wholesale price from the Drug Topic Red Book.<sup>31</sup>

## Probabilities

Table II lists the base values and range of probabilities used for the base case scenario and sensitivity analysis of the model. Probabilities were obtained from a literature review using PubMed and Ovid MEDLINE databases. Model probabilities include those for the following: complications from cholecystectomy during bariatric surgery, complications from delayed cholecystectomy after bariatric surgery for gallstone disease, minor and major complications after cholecystectomy, developing symptoms with or without postoperative ursodiol, presenting with complicated gallstone disease in patients who did not undergo a cholecystectomy during bariatric surgery (with or without preoperative ultrasonography), undergoing laparoscopic or open cholecystectomy for patients presenting with and without complicated gallstone disease, and having a positive ultra-sonographic examination during the preoperative evaluation with and without associated gallbladder symptoms.

For patients undergoing intended laparoscopic RYGB, the conversion rate from laparoscopic to open was estimated at 5%.<sup>7,32–34</sup> Therefore, we assumed that open cholecystectomy was performed in 5% of the RYGB group. In the case of development of gallstone disease after RYGB without cholecystectomy, 80% of patients with uncomplicated gallstone disease (biliary colic without cholecystitis, common bile duct stones, or acute pancreatitis) were considered to have a laparoscopic cholecystectomy, while 70% of patients with complicated

gallstone disease were considered to have had a laparoscopic procedure based on published rates in the literature.<sup>35–40</sup>

## Complications

Patients may develop postoperative complications after cholecystectomy regardless of timing or cause. Minor complications include wound infection or hematoma not requiring operative drainage, urinary tract infection, phlebitis, ileus managed conservatively, and readmission for nonspecific abdominal pain requiring nonoperative management. Major complications include common bile duct injury, a retained common bile duct stone, bleeding requiring blood transfusion or reoperation, intra-abdominal abscess requiring drainage, biliary fistula, pneumonia, respiratory insufficiency, septic shock, cardiac complications, cerebrovascular accidents, and upper gastrointestinal bleeding. Death was a rare event and included in the major complication group.

## Utilities (total duration of hospital stay)

Table III summarizes the utilities. Total duration of hospital stay for each DRG code was obtained from the HCUP Nationwide Inpatient Sample website.<sup>28</sup> Duration of stay was considered a proxy for health outcome in this population.<sup>41</sup> For patients undergoing uncomplicated cholecystectomy during RYGB, no additional duration of stay was added, because the duration of stay for cholecystectomy is included in the RYGB recovery time. For patients undergoing cholecystectomy after RYGB, duration of stay was equivalent to the mean hospital days for patients undergoing laparoscopic (DRG code 419) or open (DRG code 416) cholecystectomy. When patients developed complications, additional hospital days for complications were obtained by subtracting the mean hospital stay of patients without postoperative complications from the mean hospital stay of patients with either minor (DRG codes 415 and 418) or major (DRG codes 414 and 417) complications. All values were included in the duration of stay outcome.

## Model assumptions

Assumptions were the same for all strategies to ensure consistent results. The chance of having a complication from RYGB was assumed to be the same for all strategies and was therefore not included in the model. Patients hospitalized for gallbladder symptoms after bariatric surgery were assumed to have undergone cholecystectomy during the same hospitalization, regardless of the cause or severity. It was assumed that patients undergoing concurrent cholecystectomy during bariatric surgery had the same gallbladder-related complication rates as patients undergoing cholecystectomy for uncomplicated gallstone disease. The rate of minor and major complications was the same for all patients undergoing a laparoscopic cholecystectomy regardless of the timing of or the reason for surgery. The same was true for open cholecystectomy, but rates differed from that of laparoscopic cholecystectomy. Patients with a positive ultrasonographic examination and biliary symptoms were assumed to have undergone cholecystectomy during RYGB. Ursodiol, when prescribed, was assumed to be given for a 6-month course, and 100% compliance was also assumed.

## Sensitivity analyses

The decision tree was built and analyzed using TreeAge Pro Healthcare (version 2011; TreeAge Software, Inc, Williamstown, MA). One-way sensitivity analyses were performed on uncertain cost and probabilities. For the sensitivity analyses, costs, utilities, and probabilities were varied over the range found in current published literature.

## RESULTS

### Base-case analysis

The base case results are shown in Table IV. Over the course of the first 24 months, patients who underwent a cholecystectomy at the time of RYGB required, on average, 0.15 hospital days for gallbladder-related conditions. Patients who did not undergo a concurrent cholecystectomy, either with or without a preoperative ultrasonography, experienced 0.19 hospital days.

The least expensive strategy was to perform RYGB alone without preoperative ultrasonography, with an average cost per patient (over the RYGB cost) of \$537. RYGB with concurrent cholecystectomy had a cost of \$631. In cases where selective cholecystectomy based on preoperative ultrasonography was performed, gallbladder-related average costs increased to \$638.

Performing selective cholecystectomy based on preoperative ultrasonography was dominated (more expensive and more hospital days used) by the other 2 strategies. Concurrent cholecystectomy, while more costly, was more effective, with fewer gallbladder-related hospital days in the 2-year follow-up period. The ICER of performing concurrent cholecystectomy during RYGB versus RYGB alone was \$2,366 per hospital day saved.

### Sensitivity analysis

Table V summarizes the sensitivity analyses of key model parameters. Our model was most sensitive to the probability of developing gallbladder-related symptoms after RYGB alone. When the incidence of gallbladder-related symptoms was <4.6%, the dominant strategy was to perform a RYGB without cholecystectomy and no preoperative ultrasonography. For values >6.9%, performing concurrent cholecystectomy at the time of the RYGB was superior to the other strategies. Selective cholecystectomy based on preoperative ultrasonography was dominated by the either of the other 2 strategies at any value range. Table V and Fig 2 summarized the sensitivity analysis.

Additional sensitivity analyses found that an increase in hospital stay or postoperative complications with concurrent cholecystectomy will decrease its effectiveness (because of an increase in the average hospital days used for this strategy), making RYGB alone the dominant strategy. In contrast, an increase in costs for patients with gallbladder-related symptoms after RYGB because of difficult management of common bile duct stones requiring the use of novel endoscopic techniques (such as transgastric or laparoscopic-assisted ERCP) would decrease the ICER of concurrent cholecystectomy versus RYGB alone, further favoring the use of concurrent cholecystectomy. If the additional cost of managing gallstone-related complications after RYGB exceeded \$1,603, RYGB with concurrent cholecystectomy dominated the other strategies.

The use of ursodiol also had a significant impact on the cost-effectiveness of the different strategies. Without ursodiol, RYGB without cholecystectomy was the most cost-effective strategy, as shown in the base case. Once ursodiol or the nongeneric Actigall (Watson Pharmaceuticals, Inc, Corona CA) was added, however, the least expensive strategy was to perform a concurrent cholecystectomy during RYGB. Performing a selective cholecystectomy based on preoperative ultrasonography was the strategy with the fewest hospital days for gallbladder-related conditions (0.08 hospital days) with an ICER of \$912 per hospital day saved, assuming 100% compliance with the medication. When compliance with ursodiol decreased to <40%, concurrent cholecystectomy during RYGB became the dominant strategy. The use of the brand name drug increased cost without decreasing

hospital days. Performing RYGB without cholecystectomy (no preoperative ultrasonography) was dominated by the other strategies when ursodiol was used.

In cases where concurrent cholecystectomy was performed at the same time as the RYGB in patients with a positive ultrasonography (regardless of symptoms), no additional benefit was obtained and the strategy was dominated by the others. The cost of ultrasound and increasing the percentage of patients with positive ultrasonographic findings did not affect this pattern.

An increase in the incidence of complicated gallstone disease after RYGB and greater complication rates after laparoscopic cholecystectomy were associated with a decrease in the ICERs between RYGB with cholecystectomy and RYGB alone. Conversely, an increase in the conversion rate from laparoscopic to open RYGB, the use of laparoscopic cholecystectomy after RYGB, and higher complication rates after open cholecystectomy were associated with an increase in the incremental cost-effectiveness ratio between RYGB with cholecystectomy and RYGB alone. Using a selective approach to perform concurrent cholecystectomy based on preoperative results of ultrasonography was dominated by at least one of the other strategies in all scenarios.

## DISCUSSION

Our study used a decision model to evaluate the most cost-effective strategy for the management of gallbladder in patients undergoing RYGB. Our model compares the benefits of avoiding future gallbladder-related complications with concurrent cholecystectomy during RYGB at the expense of performing unnecessary cholecystectomy in the majority of the patients versus deferring the cholecystectomy and exposing patients that are known to be at greater risk to develop gallbladder-related complications with subsequent additional costs and hospitalization requirements. Specifically, we compared routine concurrent cholecystectomy, RYGB without cholecystectomy (with or without postoperative ursodiol therapy), and selective cholecystectomy based on preoperative ultrasonography.

We found that the most cost-effective strategy for managing the gallbladder during RYGB is sensitive to the incidence of gallbladder-related symptoms after RYGB. In patients in whom the incidence of postoperative gallbladder symptoms was <4.6%, the dominant strategy (that offered lower costs and fewer hospital days) was to perform a RYGB without cholecystectomy. In patients in whom the incidence of postoperative gallbladder symptoms was >6.9%, the dominant strategy was to perform concurrent cholecystectomy during RYGB. Although it was reported that the incidence of symptomatic gallstones during the open RYGB era was as high as 28%,<sup>42,43</sup> recent studies reported an incidence of symptomatic gallstones after laparoscopic RYGB ranging from 2.3% to 11.5%.<sup>11–16,44–48</sup> The reasons for this are not completely understood but are likely multifactorial. As RYGB has gained popularity and laparoscopy became the preferred approach, the indications have expanded. RYGB is performed more commonly in patients with a lower body mass index and less expected weight loss than those initially chosen for open procedures. In addition, techniques have changed (length of the Roux limb, etc) and weight loss rates may be less drastic. Finally, given the limitations of the laparoscopic instrumentation, the very heaviest patients may be approached open, although this is changing rapidly.

Classic risk factors for gallstone formation in the general population have not proven to be good predictors after bariatric surgery.<sup>44</sup> In an article published by Li et al,<sup>49</sup> patients with an expected weight loss of >25% of their original weight were 48% more likely to develop gallstone disease after bariatric surgery compared to those without it. In a recent study by D'Hondt et al,<sup>44</sup> patients with weight loss at 3 months of >50% of the extra weight were 2.2



times more likely to develop gallstone after RYGB compared to those with a less substantial weight loss. In addition, postoperative hypocaloric diets have also been associated with gallbladder stasis and increase risk of gallstone formation.<sup>50</sup> Therefore, it is imperative to develop validated, individualized risk prediction tools based on preoperative characteristics that can identify accurately the subgroup of patients that are at an increased risk of developing symptomatic gallstones. Strategies can then vary based on individual risk. For example, if an individual's risk was estimated to be >7%, then cholecystectomy at initial operation would be indicated.

Our findings complement the findings of a recent population-based study by Worni et al.<sup>10</sup> Using the National Inpatient Sample database, they reported that concurrent cholecystectomy was associated with a longer duration of hospital stay, higher rates of postoperative complications, and greater mortality. Our study provides cost-effectiveness data that further support this management strategy. After accounting for the impact of future gallbladder-related complications in patients who undergo RYGB alone, this strategy remains cost-effective.

Ursodiol is prescribed by one-third of surgeons performing bariatric surgery.<sup>19</sup> A landmark study published by Sugerman et al<sup>23</sup> reported a 2% rate of gallstone formation in patients receiving ursodiol after gastric bypass compared to 32% in the placebo group, with medication compliance >80% for both groups. The development of symptoms and the need for cholecystectomy, however, were not reported in the study. The authors concluded that ursodiol might be efficacious in preventing gallstone formation. The use of ursodiol also had a significant impact on the cost-effectiveness of the different strategies. Based on our results, with ursodiol use, RYGB without cholecystectomy was no longer the most cost-effective method. Concurrent cholecystectomy was less costly when ursodiol was used, and selective cholecystectomy based on ultrasonographic results was shown to have the fewest hospital days with a reasonable increase in cost, assuming 100% compliance with the medication; however, several studies have shown that compliance with the medication is variable and ranges between 39% and 85%.<sup>13,22,23,26,51</sup> Based on our sensitivity analysis, the additional cost of prescribing ursodiol at compliance rates reported in the literature is prohibitive compared to strategies where ursodiol was not prescribed and should not be recommended after bariatric surgery.

Selective cholecystectomy based on preoperative ultrasonography was dominated consistently by the other strategies in the absence of ursodiol use and should not be recommended. Varying the cost of the ultrasonography, performing a cholecystectomy in patients with positive ultrasonographic findings (irrespective of symptoms) or increasing the incidence of patients with positive ultrasonography did not change our results, and the selective strategy was always dominated by 1 of the other 2 strategies. Others have found similar cholecystectomy rates after RYGB between asymptomatic patients that did and did not undergo abdominal ultrasonography.<sup>13,16,27</sup> Based on the data found in the literature and the results from our model, we considered that abdominal ultrasonographic examinations should only be obtained for diagnostic purposes in patients complaining of right upper quadrant symptoms during the preoperative evaluation.

Our study has several limitations. Using a third-payer perspective does not take into account patient-related costs and preferences. Probabilities were obtained from an extensive literature review using multiple sources accounting different time-frames and location. To diminish the influence of the variation in sources, sensitivity analyses were performed including the range of values found in the literature. Also, this study might not have validity in countries other than the United States because cost and hospital days were obtained using DRG codes, which are an exclusive disease classification/ payment system for the United

States. Health state utilities were not included because no current literature exists about patient preference for gallbladder-related symptoms and complications after RYGB. Our decision model did not include novel endoscopic therapeutic techniques to manage common bile duct stones after RYGB, such as a transgastric approach or double balloon ERCP, because they are only available in specialized centers. To account for this, we performed an additional sensitivity analysis varying the cost of the management of post-RYGB gallstone-related problems. Our analysis was sensitive to the cost of managing gallstones after gastric bypass. When the additional cost of managing gallstone-related complications after RYGB exceeds \$1,603, RYGB with concurrent cholecystectomy dominates the other strategies. Finally, violation of our assumptions will introduce bias to our results. For example, if patients with gallbladder-related symptoms after RYGB did not undergo cholecystectomy after initial hospitalization or if costs are greater because of the need for additional procedures required to manage gallstone-related complications, cost and hospital days used will increase in those strategies (RYGB alone and selective cholecystectomy based on pre-operative ultrasonographic results) with different results. Also, if use of laparoscopic techniques or incidence of complications differs between strategies, cost and hospital days used will change leading to different cost-effectiveness ratios.

Our study provides a unique perspective on the management of the gallbladder in patients undergoing RYGB. We conclude that the main factor determining the most cost-effective strategy is the incidence of gallbladder-related symptoms after RYGB. Our findings---in conjunction with the conclusions of Worni et al<sup>10</sup>---support a recommendation against routine cholecystectomy during RYGB in asymptomatic patients. Additional research should focus on developing individualized risk prediction tools and protocols that identify accurately the subgroup of patients that are at an increased risk of developing symptomatic gallstone. Also, the use of ursodiol was associated with an increase in cost that does not justify its use after RYGB. Finally, selective cholecystectomy based on preoperative ultrasonography was dominated by the other strategies in the scenarios evaluated.

## References

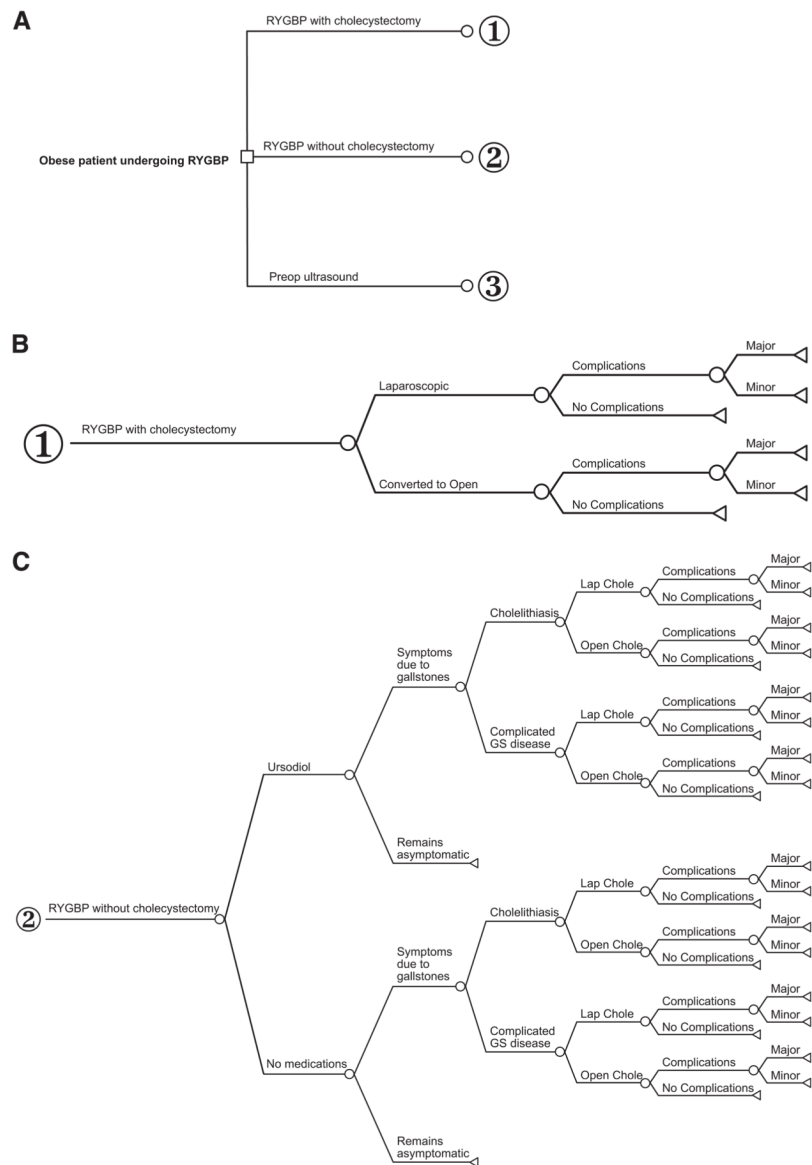
1. Flegal KM, Carroll MD, Kuczmarski RJ, Johnson CL. Overweight and obesity in the United States: prevalence and trends, 1960–1994. *Int J Obes Relat Metab Disord*. 1998; 22:39–47. [PubMed: 9481598]
2. Brolin RE, Bradley LJ, Wilson AC, Cody RP. Lipid risk profile and weight stability after gastric restrictive operations for morbid obesity. *J Gastrointest Surg*. 2000; 4:464–9. [PubMed: 11077320]
3. Carson JL, Ruddy ME, Duff AE, Holmes NJ, Cody RP, Brolin RE. The effect of gastric bypass surgery on hypertension in morbidly obese patients. *Arch Intern Med*. 1994; 154:193–200. [PubMed: 8285814]
4. Choban PS, Onyejekwe J, Burge JC, Flancbaum L. A health status assessment of the impact of weight loss following Roux-en-Y gastric bypass for clinically severe obesity. *J Am Coll Surg*. 1999; 188:491–7. [PubMed: 10235576]
5. Foley EF, Benotti PN, Borlase BC, Hollingshead J, Black-burn GL. Impact of gastric restrictive surgery on hypertension in the morbidly obese. *Am J Surg*. 1992; 163:294–7. [PubMed: 1539761]
6. Pories WJ, Swanson MS, MacDonald KG, Long SB, Morris PG, Brown BM, et al. Who would have thought it? An operation proves to be the most effective therapy for adult-onset diabetes mellitus. *Ann Surg*. 1995; 222:339–50. [PubMed: 7677463]
7. Schauer PR, Ikramuddin S, Gourash W, Ramanathan R, Luketich J. Outcomes after laparoscopic Roux-en-Y gastric bypass for morbid obesity. *Ann Surg*. 2000; 232:515–29. [PubMed: 10998650]
8. Brolin RE. Bariatric surgery and long-term control of morbid obesity. *JAMA*. 2002; 288:2793–6. [PubMed: 12472304]
9. Kellum JM, DeMaria EJ, Sugerman HJ. The surgical treatment of morbid obesity. *Curr Probl Surg*. 1998; 35:791–858. [PubMed: 9745619]

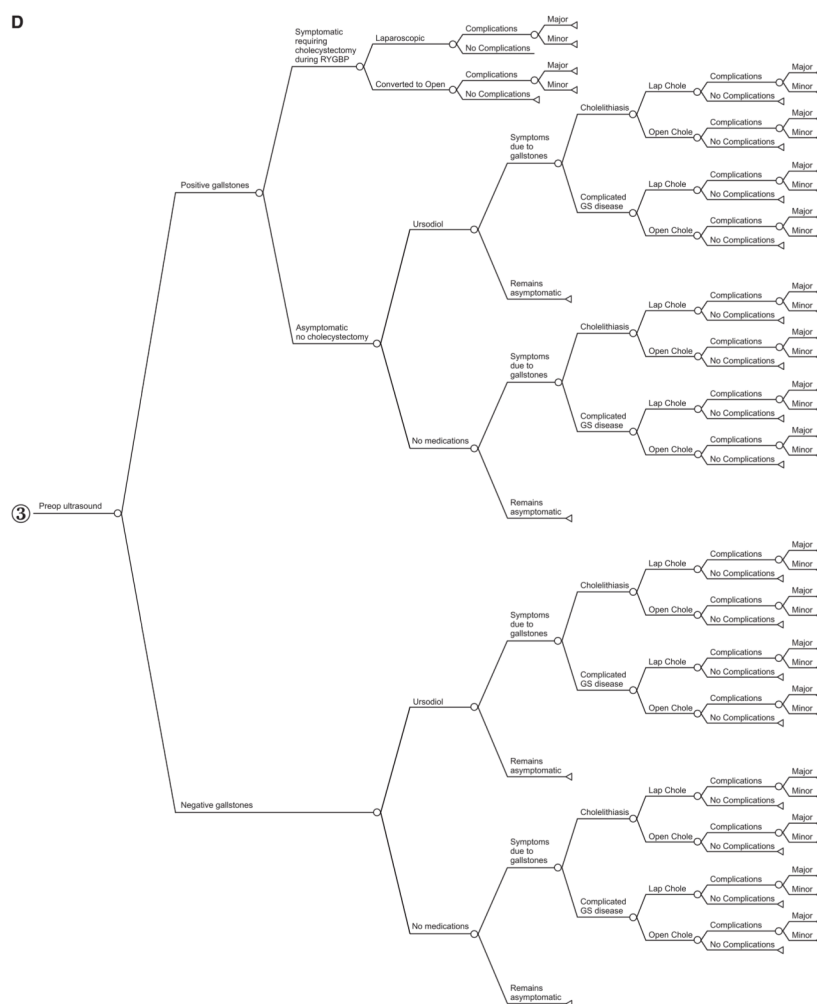


10. Worni M, Guller U, Shah A, Gandhi M, Shah J, Rajgor D, et al. Cholecystectomy concomitant with laparoscopic gastric bypass: a trend analysis of the nationwide inpatient sample from 2001 to 2008. *Obes Surg.* 2012; 22:220–9. [PubMed: 22183984]
11. Hamad GG, Ikramuddin S, Gourash WF, Schauer PR. Elective cholecystectomy during laparoscopic Roux-en-Y gastric bypass: is it worth the wait? *Obes Surg.* 2003; 13:76–81. [PubMed: 12630618]
12. Ellner SJ, Myers TT, Piorkowski JR, Mavanur AA, Barba CA. Routine cholecystectomy is not mandatory during morbid obesity surgery. *Surg Obes Relat Dis.* 2007; 3:456–60. [PubMed: 17442623]
13. Papasavas PK, Gagne DJ, Ceppa FA, Caushaj PF. Routine gallbladder screening not necessary in patients undergoing laparoscopic Roux-en-Y gastric bypass. *Surg Obes Relat Dis.* 2006; 2:41–6. [PubMed: 16925315]
14. Patel JA, Patel NA, Piper GL, Smith DE III, Malhotra G, Colella JJ. Perioperative management of cholelithiasis in patients presenting for laparoscopic Roux-en-Y gastric bypass: have we reached a consensus? *Am Surg.* 2009; 75:470–6. [PubMed: 19545094]
15. Patel KR, White SC, Tejirian T, Han SH, Russell D, Vira D, et al. Gallbladder management during laparoscopic Roux-en-Y gastric bypass surgery: routine preoperative screening for gallstones and postoperative prophylactic medical treatment are not necessary. *Am Surg.* 2006; 72:857–61. [PubMed: 17058721]
16. Portenier DD, Grant JP, Blackwood HS, Pryor A, McMahon RL, DeMaria E. Expectant management of the asymptomatic gallbladder at Roux-en-Y gastric bypass. *Surg Obes Relat Dis.* 2007; 3:476–9. [PubMed: 17442625]
17. Fobi MA, Chicola K, Lee H. Access to the bypassed stomach after gastric bypass. *Obes Surg.* 1998; 8:289–95. [PubMed: 9678196]
18. Fobi M, Lee H, Igwe D, Felahy B, James E, Stanczyk M, et al. Prophylactic cholecystectomy with gastric bypass operation: incidence of gallbladder disease. *Obes Surg.* 2002; 12:350–3. [PubMed: 12082886]
19. Mason EE, Renquist KE. Gallbladder management in obesity surgery. *Obes Surg.* 2002; 12:222–9. [PubMed: 11975217]
20. Higa KD, Boone KB, Ho T. Complications of the laparoscopic Roux-en-Y gastric bypass: 1,040 patients---what have we learned? *Obes Surg.* 2000; 10:509–13. [PubMed: 11175957]
21. Iglesias Brandao de Oliveira C, Adami Chaim E, da Silva BB. Impact of rapid weight reduction on risk of cholelithiasis after bariatric surgery. *Obes Surg.* 2003; 13:625–8. [PubMed: 12935366]
22. Villegas L, Schneider B, Provost D, Chang C, Scott D, Sims T, et al. Is routine cholecystectomy required during laparoscopic gastric bypass? *Obes Surg.* 2004; 14:60–6. [PubMed: 14980035]
23. Sugerman HJ, Brewer WH, Shiffman ML, Brolin RE, Fobi MA, Linner JH, et al. A multicenter, placebo-controlled, randomized, double-blind, prospective trial of prophylactic ursodiol for the prevention of gallstone formation following gastric-bypass-induced rapid weight loss. *Am J Surg.* 1995; 169:91–6. [PubMed: 7818005]
24. Miller K, Hell E, Lang B, Lengauer E. Gallstone formation prophylaxis after gastric restrictive procedures for weight loss: a randomized double-blind placebo-controlled trial. *Ann Surg.* 2003; 238:697–702. [PubMed: 14578732]
25. Kim JJ, Schirmer B. Safety and efficacy of simultaneous cholecystectomy at Roux-en-Y gastric bypass. *Surg Obes Relat Dis.* 2009; 5:48–53. [PubMed: 19161934]
26. Swartz DE, Felix EL. Elective cholecystectomy after Roux-en-Y gastric bypass: why should asymptomatic gallstones be treated differently in morbidly obese patients? *Surg Obes Relat Dis.* 2005; 1:555–60. [PubMed: 16925290]
27. Tucker ON, Fajnwaks P, Szomstein S, Rosenthal RJ. Is concomitant cholecystectomy necessary in obese patients undergoing laparoscopic gastric bypass surgery? *Surg Endosc.* 2008; 22:2450–4. [PubMed: 18288531]
28. US Department of Health and Human Services, Agency for Healthcare Research and Quality web site. Healthcare Cost & Utilization Project (HCUP). Available from <http://www.ahrq.gov/data/hcup/>

29. Zhao, Y.; Encinosa, W. Healthcare Cost and Utilization Project (HCUP) statistical briefs. Rockville (MD): Agency for Health Care Policy and Research; 2006. Bariatric surgery utilization and outcomes in 1998 and 2004: statistical brief #23.
30. American Medical Association CodeManager web site. CPT code/relative value search [subscription required]. Available from <https://ocm.ama-assn.org/OCM/CPTRelativeValueSearch.do>
31. Red Book. Montvale (NJ): PDR Network, LLC; 2010. Physician's Drug Reference. (Red Book Drug Topics)
32. Lujan JA, Frutos MD, Hernandez Q, Liron R, Cuenca JR, Valero G, et al. Laparoscopic versus open gastric bypass in the treatment of morbid obesity: a randomized prospective study. *Ann Surg.* 2004; 239:433–7. [PubMed: 15024302]
33. Nguyen NT, Goldman C, Rosenquist CJ, Arango A, Cole CJ, Lee SJ, et al. Laparoscopic versus open gastric bypass: a randomized study of outcomes, quality of life, and costs. *Ann Surg.* 2001; 234:279–89. [PubMed: 11524581]
34. Podnos YD, Jimenez JC, Wilson SE, Stevens CM, Nguyen NT. Complications after laparoscopic gastric bypass: a review of 3464 cases. *Arch Surg.* 2003; 138:957–61. [PubMed: 12963651]
35. Carbonell AM, Lincourt AE, Kercher KW, Matthews BD, Cobb WS, Sing RF, et al. Do patient or hospital demographics predict cholecystectomy outcomes? A nationwide study of 93,578 patients. *Surg Endosc.* 2005; 19:767–73. [PubMed: 15868259]
36. Hannan EL, Imperato PJ, Nenner RP, Starr H. Laparoscopic and open cholecystectomy in New York State: mortality, complications, and choice of procedure. *Surgery.* 1999; 125:223–31. [PubMed: 10026758]
37. McMahon AJ, Fischbacher CM, Frame SH, MacLeod MC. Impact of laparoscopic cholecystectomy: a population-based study. *Lancet.* 2000; 356:1632–7. [PubMed: 11089821]
38. Riall TS, Zhang D, Townsend CM Jr, Kuo YF, Goodwin JS. Failure to perform cholecystectomy for acute cholecystitis in elderly patients is associated with increased morbidity, mortality, and cost. *J Am Coll Surg.* 2010; 210:668–77. [PubMed: 20421027]
39. Shea JA, Healey MJ, Berlin JA, Clarke JR, Malet PF, Staroscik RN, et al. Mortality and complications associated with laparoscopic cholecystectomy. A meta-analysis. *Ann Surg.* 1996; 224:609–20. [PubMed: 8916876]
40. Wolf AS, Nijse BA, Sokal SM, Chang Y, Berger DL. Surgical outcomes of open cholecystectomy in the laparoscopic era. *Am J Surg.* 2009; 197:781–4. [PubMed: 18926519]
41. Brown LM, Rogers SJ, Cello JP, Brasel KJ, Inadomi JM. Cost-effective treatment of patients with symptomatic cholelithiasis and possible common bile duct stones. *J Am Coll Surg.* 2011; 212:1049–60. [PubMed: 21444220]
42. Amaral JF, Thompson WR. Gallbladder disease in the morbidly obese. *Am J Surg.* 1985; 149:551–7. [PubMed: 3985293]
43. Shiffman ML, Sugerman HJ, Kellum JM, Brewer WH, Moore EW. Gallstone formation after rapid weight loss: a prospective study in patients undergoing gastric bypass surgery for treatment of morbid obesity. *Am J Gastroenterol.* 1991; 86:1000–5. [PubMed: 1858735]
44. D'Hondt M, Sergeant G, Deylgat B, Devriendt D, Van Rooy F, Vansteenkiste F. Prophylactic cholecystectomy, a mandatory step in morbidly obese patients undergoing laparoscopic Roux-en-Y gastric bypass? *J Gastrointest Surg.* 2011; 15:1532–6. [PubMed: 21751078]
45. Fakhry SM, Herbst CA, Buckwalter JA. Cholecystectomy in morbidly obese patients. *Am Surg.* 1987; 53:26–8. [PubMed: 3800160]
46. O'Brien PE, Dixon JB. A rational approach to cholelithiasis in bariatric surgery: its application to the laparoscopically placed adjustable gastric band. *Arch Surg.* 2003; 138:908–12. [PubMed: 12912752]
47. Schmidt JH, Hocking MP, Rout WR, Woodward ER. The case for prophylactic cholecystectomy concomitant with gastric restriction for morbid obesity. *Am Surg.* 1988; 54:269–72. [PubMed: 3364862]
48. Shiffman ML, Sugerman HJ, Kellum JH, Brewer WH, Moore EW. Gallstones in patients with morbid obesity. Relationship to body weight, weight loss and gallbladder bile cholesterol solubility. *Int J Obes Relat Metab Disord.* 1993; 17:153–8. [PubMed: 8385075]

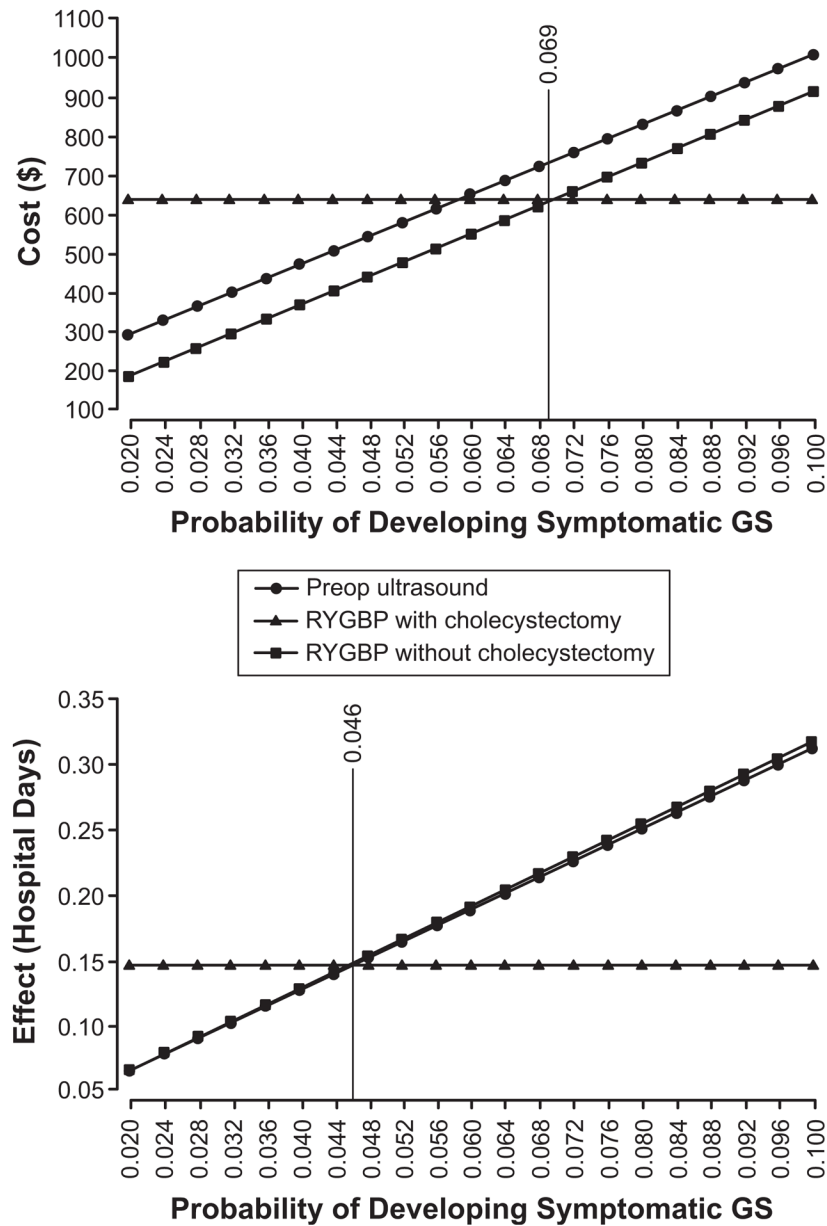
49. Li VK, Pulido N, Fajnwaks P, Szomstein S, Rosenthal R, Martinez-Duarte P. Predictors of gallstone formation after bariatric surgery: a multivariate analysis of risk factors comparing gastric bypass, gastric banding, and sleeve gastrectomy. *Surg Endosc.* 2009; 23:1640–4. [PubMed: 19057954]
50. Worobetz LJ, Inglis FG, Shaffer EA. The effect of ursodeoxycholic acid therapy on gallstone formation in the morbidly obese during rapid weight loss. *Am J Gastroenterol.* 1993; 88:1705–10. [PubMed: 8213711]
51. Wudel LJ Jr, Wright JK, Debelak JP, Allos TM, Shyr Y, Chapman WC. Prevention of gallstone formation in morbidly obese patients undergoing rapid weight loss: results of a randomized controlled pilot study. *J Surg Res.* 2002; 102:50–6. [PubMed: 11792152]
52. Keus F, de Jong JA, Gooszen HG, van Laarhoven CJ. Laparoscopic versus open cholecystectomy for patients with symptomatic cholecystolithiasis. *Cochrane Database Syst Rev.* 2006; 4:CD006231. [PubMed: 17054285]
53. Fuller DN, Rickgauer JP, Jardine PJ, Grimes S, Anderson DL, Smith DE. Ionic effects on viral DNA packaging and portal motor function in bacteriophage phi 29. *Proc Natl Acad Sci U S A.* 2007; 104:11245–50. [PubMed: 17556543]
54. Nougou A, Suter M. Almost routine prophylactic cholecystectomy during laparoscopic gastric bypass is safe. *Obes Surg.* 2008; 18:535–9. [PubMed: 18369687]
55. Simopoulos C, Polychronidis A, Botaitis S, Perente S, Pitiakoudis M. Laparoscopic cholecystectomy in obese patients. *Obes Surg.* 2005; 15:243–6. [PubMed: 15802068]





**Fig 1.**  
 (A) Decision model including 3 main strategies to manage the gallbladder during Roux-en-Y gastric bypass. (B) Decision model for Roux-en-Y gastric bypass with concurrent cholecystectomy. (C) Decision model for Roux-en-Y gastric bypass alone. (D) Decision model for selective cholecystectomy during Roux-en-Y gastric bypass based on preoperative ultrasound.





**Fig 2.**  
Sensitivity analysis of probabilities of developing symptoms after Roux-en-Y gastric bypass alone.

**Table I**

## Summary of costs

Variable	Cost in US dollars		
	Base	Low	High
Cholecystectomy			
During laparoscopic RYGB	366	Did not vary	
During open RYGB	529		
After RYGB, laparoscopic	8,191		
After RYGB, open	10,304		
Postoperative complications, minor (in addition to cholecystectomy cost)			
During RYGB	3,294	Did not vary	
After RYGB, after laparoscopic cholecystectomy	3,294		
After RYGB, after open cholecystectomy	4,152		
Postoperative complications, major (in addition to cholecystectomy cost)			
During RYGB	7,778	Did not vary	
After RYGB, after laparoscopic cholecystectomy	7,778		
After RYGB, after open cholecystectomy	14,423		
Ursodiol	333	333	1,850
Abdominal ultrasonography	103	50	200

*RYGB*, Roux-en-Y gastric bypass.

**Table II**

## Summary of probabilities

Variable	Probability (%)		
	Base	Variable	Base
Gallbladder symptoms after RYGB, no cholecystectomy			
Without ursodiol <sup>13–16</sup>	5.9	2.0	10.0
With ursodiol/negative preoperative ultrasonography <sup>11,13,22,25</sup>	2.6	2.0	10.0
With ursodiol/no preoperative ultrasonography *	4.3	2.0	10.0
Complicated gallstone disease (within patients that develop symptoms) <sup>13,15,22,27</sup>	28.0	20.0	60.0
Complications after cholecystectomy			
Overall for laparoscopic cholecystectomy <sup>52</sup>	4.5	3.0	9.0
Minor for laparoscopic cholecystectomy <sup>52</sup>	2.6	Did not vary	
Major for laparoscopic cholecystectomy <sup>52</sup>	1.9		
Overall for open cholecystectomy <sup>52</sup>	10.0	5.0	20.0
Minor for open cholecystectomy <sup>52</sup>	3.8	Did not vary	
Major for open cholecystectomy <sup>52</sup>	6.2		
Surgical technique			
Conversion to open RYGB <sup>7,32–34</sup>	2.5	1.0	10.0
Laparoscopic cholecystectomy rate for uncomplicated gallstone disease <sup>35–40</sup>	80.0	65.0	95.0
Laparoscopic cholecystectomy rate for complicated gallstone disease <sup>35–40</sup>	70.0	65.0	95.0
Ultrasonography			
Positive preoperative ultrasonography <sup>27,53,54</sup>	12.0	10.0	60.0
Concurrent symptoms (within positive ultrasonography) <sup>12,55</sup>	20.0	0	100.0

\* Value obtained from pooled data on patients who did and did not received ursodiol/ultrasonography. *RYGB*, Roux-en-Y gastric bypass.

**Table III**

## Summary of utilities

	No. of hospital days		
Variable	Base	Variable	Base
Cholecystectomy			
During RYGB	0	0	1
After RYGB, after laparoscopic cholecystectomy	2.6	Did not vary	
After RYGB, after open cholecystectomy	4.2		
Postoperative complications, minor (in addition to cholecystectomy DOS)			
During RYGB	1.9	Did not vary	
After RYGB, after laparoscopic cholecystectomy	1.9		
After RYGB, after open cholecystectomy	2.3		
Postoperative complications, major			
During RYGB	4.2	Did not vary	
After RYGB, after laparoscopic cholecystectomy	4.2		
After RYGB, after open cholecystectomy	6.7		

*DOS*, Duration of stay; *RYGB*, Roux-en-Y gastric bypass.

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Table IV

Base case results

Strategy	Cost (USD)	Incremental cost	DOS (days)	Incremental DOS	ICER* (USD/HD averted)
RYGB without concurrent cholecystectomy, without preoperative ultrasonography	537	Reference	0.19	Reference	Reference
RYGB with concurrent cholecystectomy	631	+94	0.15	-0.04	\$2,366
RYGB without concurrent cholecystectomy, with preoperative ultrasonography	638	+101	0.19	0	Dominated

\* Represents the additional cost required to save 1 additional hospital day when comparing different strategies.

HD, Hospital day; ICER, incremental cost-effectiveness ratio; DOS, duration of stay; RYGB, Roux-en-Y gastric bypass; USD, US dollar.



Table V

Sensitivity analysis<sup>\*</sup>

Value	Concurrent cholecystectomy	RYGB alone	RYGB alone with preoperative US
Incidence of gallbladder-related symptoms after RYGB			
2%	Dominated	Dominant	Dominated
4%	Dominated	Dominant	Dominated
6%	1,938	0	Dominated
8%	Reference	Dominated	Dominated
10%	Reference	Dominated	Dominated
Ursodiol			
Not prescribed	2,310	0	Dominated
Generic	0	Dominated	912
Actigall <sup>†</sup>	0	Dominated	27,137
Ursodiol compliance			
40%	0	Dominated	Dominated
60%	0	Dominated	8,250
80%	0	Dominated	2,951
Nonselective ultrasonography strategy			
Cholecystectomy with positive ultrasonography	2,310	0	Dominated
Ultrasonography cost			
\$50	2,310	0	Dominated
\$150	2,310	0	Dominated
\$200	2,310	0	Dominated
Positive ultrasonography			
20%	2,310	0	Dominated
40%	2,310	0	Dominated
60%	2,310	0	Dominated
Incidence of complicated gallstone disease after RYGB without cholecystectomy			
20%	2,395	0	Dominated
40%	2,189	0	Dominated
60%	2,003	0	Dominated
Conversion rate from laparoscopic to open RYGB			
0%	1,255	0	Dominated
2%	1,608	0	Dominated
4%	2,048	0	Dominated
6%	2,609	0	Dominated
8%	3,685	0	Dominated
10%	4,039	0	Dominated
Laparoscopic rates for cholecystectomy after RYGB			
75%	2,275	0	Dominated
85%	3,600	0	Dominated
95%	6,250	0	Dominated

Value	Concurrent cholecystectomy	RYGB alone	RYGB alone with preoperative US
100%	13,400	0	Dominated
Incidence of complications after laparoscopic cholecystectomy			
1%	Dominant	Dominated	Dominated
3%	279	0	Dominated
7%	Dominated	Dominant	Dominated
9%	Dominated	Dominant	Dominated
Incidence of complications after open cholecystectomy			
5%	1,794	0	Dominated
20%	3,694	0	Dominated
Additional hospital stay with concurrent cholecystectomy (days)			
0.2	Dominated	Dominant	Dominated
0.4	Dominated	Dominant	Dominated
0.6	Dominated	Dominant	Dominated
0.8	Dominated	Dominant	Dominated
1.0	Dominated	Dominant	Dominated
Additional cost to manage gallbladder complications after RYGB			
\$500	1,590	0	Dominated
\$1,000	870	0	Dominated
\$1,500	149	0	Dominated
\$2,000	Dominant	Dominated	Dominated

\* Values are in US dollars and represent the incremental cost-effectiveness ratio between strategies.

<sup>†</sup> Manufactured by Watson Pharmaceuticals (Corona, CA).

RYGB, Roux-en-Y gastric bypass; US, ultrasonography.