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COST-EFFECTIVENESS ANALYSIS OF CHOLECYSTECTOMY DURING BARIATRIC SURGERY

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COST-EFFECTIVENESS ANALYSIS OF CHOLECYSTECTOMY DURING BARIATRIC SURGERY

By

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Treatise

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The University of Texas Medical Branch, 2011

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ABSTRACT:

Background: Surgeons performing bariatric surgery for morbid obesity vary widely in their use of concurrent cholecystectomy.
Methods: A decision model was developed to evaluate clinical and economic outcomes of current strategies: routine concurrent cholecystectomy, Roux-en-Y gastric bypass (RYGBP) alone with or without postoperative ursodiol therapy, and selective cholecystectomy based on preoperative ultrasound. 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 RYGBP alone without preoperative ultrasound, with a total cost (over the RYGBP cost) of $536.73 per patient. RYGBP with concurrent cholecystectomy had a cost of $631.35. Performing selective cholecystectomy based on preoperative ultrasound was dominated by the other two strategies. Our model was most sensitive to the probability of developing gallbladder-related symptoms after RYGBP alone. When the incidence of gallbladder-related symptoms was lower than 4.6%, the dominant strategy was to perform a RYGBP without cholecystectomy and no preoperative ultrasound. For values above 6.9%, performing concurrent cholecystectomy at the time of the RYGBP was superior to the other strategies. When ursodiol was used, the least expensive strategy was to perform a concurrent cholecystectomy during RYGBP.
Conclusions: The main factor determining the most cost-effective strategy is the incidence of gallbladder-related symptoms after RYGBP. Also, the use of ursodiol was associated with an increase in cost that does not justify its use after RYGBP. Finally, selective cholecystectomy based on preoperative ultrasound was dominated by the other strategies in the scenarios evaluated.

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Chapter 1: Introduction

Obesity in the United States (U.S.) has increased dramatically over the last 30 years.[1] In 2008, it was estimated that 68% of adults in the U.S. were either obese or overweight, an increase from 54.9% in 1994.[1, 2] Surgery is currently considered the best option to achieve sustained weight loss and manage associated comorbidities in patients with morbid obesity.[3-9] Surgery is indicated for patients with a body mass index (BMI) greater than 40 Kg/m^2 or greater than 35 Kg/m^2 with the presence of specific comorbidities such as coronary heart disease, diabetes, sleep apnea, hypertension, and hypercholesterolemia.[10] Roux-en-Y gastric bypass (RYGBP) is considered the gold standard for the surgical treatment of morbidly obese patients due to its durable weight loss and low morbidity.[8, 11]

Open RYGBP surgery was introduced by Mason[12] in 1967 and modified by Alden[12] in 1977 to the current standard. Because of the high incidence of gallstones secondary to the rapid surgically-induced weight loss, cholecystectomy was initially recommended in any patient undergoing open bariatric surgery.[13, 14]

Wittgrove et al.[15] introduced the laparoscopic RYGBP technique in 1994. Concurrent cholecystectomy during laparoscopic gastric bypass surgery is technically difficult due to port placement and is associated with increased operative time.[16] With an increase in the number of RYGBPs done with a laparoscopic approach, cholecystectomy is no longer routinely performed. However, it can be performed safely with minimal additional morbidity and mortality. Recent data on patients who did not undergo cholecystectomy at the time of RYGBP demonstrated that 91-97% of patients remain asymptomatic and never require intervention.[17-21] However, when gallstone-related problems do occur, management after gastric bypass can be more difficult given the altered anatomy and inability to perform endoscopic retrograde cholangiopancreatography (ERCP).[22] This has made the routine use of concurrent cholecystectomy during laparoscopic gastric bypass controversial.

Currently, bariatric surgeons agree that concurrent cholecystectomy is indicated in patients with preoperatively diagnosed with symptomatic gallstone disease. In asymptomatic patients, some surgeons routinely perform cholecystectomy during laparoscopic RYGBP due to the high incidence of gallstone formation postoperatively and the low additional risk of concurrent cholecystectomy.[23, 24] A more selective approach involves preoperative abdominal ultrasound with cholecystectomy at the time of gastric bypass in those with documented gallstones.[8, 16, 25-27] The use of ursodiol in those who do not undergo cholecystectomy can decrease gallstone formation and gallstone-related complications,[28] but cost and patient compliance make the utility of this treatment strategy unclear.[24, 27-29]

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 RYGBP. Specifically, we compared routine concurrent cholecystectomy, RYGBP without cholecystectomy (with or without postoperative ursodiol therapy), and selective cholecystectomy based on preoperative ultrasound. We evaluate 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.

Chapter 2: Methods

Decision model

We developed a decision model that included the three most common strategies for the management of the gallbladder in obese patients undergoing RYGBP: routine concurrent cholecystectomy, RYGBP without cholecystectomy (with or without postoperative ursodiol therapy), and selective cholecystectomy based on preoperative ultrasound, also with or without ursodiol therapy.

The base case scenario for the analysis was a 50-year old obese patient undergoing a RYGBP 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, as the mean time to presentation with gallstone-related complications after bariatric surgery ranges from 7.2 and 18.2 months.[18, 19, 30-32] All possible outcomes for each strategy were entertained over the 2-year time period, from 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 costs less and was more effective (shortest average hospital days) compared to the other two strategies. In contrast, a dominated strategy was the one with higher cost and longer average hospital days compared to any other strategy. In cases where one 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 two strategies. In our study the ICER represents the additional cost required to save an additional hospital day using one strategy when compared to another strategy. The ICER is reported for strategies that are more effective but more costly to quantitate the additional cost necessary to obtain an additional effect when compare to a strategy that is both, less costly and effective.

Costs

Costs are summarized in table 1. The perspective used in this analysis is that of a third-party payer. Costs were adjusted to 2008 dollars when required. Because the Centers for Medicare and Medicaid Services (CMS) represents the national standard followed by most other health care insurers, CMS cost was used as an estimate for reimbursement in the base case scenario. The mean cost for hospitalization was obtained using the Diagnosis Related Groups (DRG) system from the Healthcare Cost and Utilization Project (HCUP) Nationwide Inpatient Sample website (http://www.ahrq.gov/data/hcup/). DRG codes used (DRG codes 414 to 419) include open and laparoscopic cholecystectomy with and without complications. The cost of the RYGBP was excluded because it was the same for all strategies and was estimated to be $10,395. [33] Major and minor complications were reflected in the DRG codes. Discounting (method used to calculate the present value of future costs and benefits) was not necessary due to the short duration of the study period.

Using Medicare reimbursement criteria, the cost of concurrent cholecystectomy during RYGBP was equivalent to 50% of the surgeon fee, as it was considered a secondary procedure. Procedures costs were obtained from the website of the American Medical Association (https://ocm.ama-assn.org/OCM/CPTRelativeValueSearch.do). CPT codes 47562 and 47600 were identified, which correspond to laparoscopic and open cholecystectomy, respectively. National reimbursement fees from the American Medical Association website were also used to determine the cost for an abdominal ultrasound (CPT code 76705).

To obtain the cost of the ursodiol therapy, the average wholesale cost from the Drug Topic Red Book was used.[34]

Probabilities

Probabilities were obtained from a literature review using Pubmed and Ovid MEDLINE® databases. Probabilities required to develop this model include: the probability of complications from cholecystectomy during bariatric surgery, the probability of complications from delayed cholecystectomy after bariatric surgery for gallstone disease, the probability of minor and major complications after cholecystectomy, the probability of developing symptoms with or without post-operative ursodiol, the probability of presenting with complicated gallstone disease in patients who did not receive a cholecystectomy during bariatric surgery (with or without preoperative ultrasound), the probability to undergo laparoscopic or open cholecystectomy for patients presenting with and without complicated gallstone disease, and the probability of having a positive ultrasound during the preoperative evaluation with and without associated gallbladder symptoms.

For patients undergoing intended laparoscopic RYGBP, the conversion rate from laparoscopic to open was estimated at 5%.[8, 35-37] Therefore, we assumed that open cholecystectomy was performed in 5% of the RYGBP group. In the case of development of gallstone disease after RYGBP 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.[38-43] Table 2 lists the base values and range of probabilities used for the base case scenario and sensitivity analysis of the model.

Complications

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

Utilities (Total length of hospital stay)

Total length of hospital stay for each DRG code was obtained from the HCUP Nationwide Inpatient Sample website. Length of stay was considered a proxy for health outcome in this population. For patients undergoing uncomplicated cholecystectomy during RYGBP, no additional length of stay was added, as the length of stay for cholecystectomy is included in the RYGBP recovery time. For patients undergoing cholecystectomy after RYGBP, length 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 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 payoff.

Model assumptions

Assumptions were the same for all strategies to ensure consistent results. The chance of having a complication from the gastric bypass surgery was assumed to be the same for all strategies and, therefore, not included in the model. Patients hospitalized for gallbladder symptoms after bariatric surgery were assumed to receive a 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 ultrasound and biliary symptoms were assumed to have undergone a cholecystectomy during RYGBP. Ursodiol, when prescribed, was assumed to be given for a six-month course and 100% compliance.

Sensitivity analyses

The decision tree was built and analyzed using TreeAge Pro Healthcare (TreeAge Software, Inc., Williamstown, MA – Version 2011). One-way sensitivity analyses were performed on uncertain cost and probabilities. For the sensitivity analyses, costs and probabilities were varied over the range found in current published literature. Sensitivity analyses were not performed for utilities (hospital days) as the uncertainty was minimal in each case.

Table 1. Summary of costs (In US$)

VARIABLE	BASE	LOW	HIGH
CHOLECYSTECTOMY			
During laparoscopic RYGBP	$365.75	Not varied	
During open RYGBP	$528.67		
Post RYGBP, laparoscopic cholecystectomy	$8,191		
Post RYGBP, open cholecystectomy	$10,304		
POST-OPERATIVE COMPLICATIONS – MINOR (In addition to cholecystectomy cost)			
During RYGBP	$3,294	Not varied	
Post RYGBP, after laparoscopic cholecystectomy	$3,294		
Post RYGBP, after open cholecystectomy	$4,152		
POST-OPERATIVE COMPLICATIONS – MAJOR (In addition to cholecystectomy cost)			
During RYGBP	$7,778	Not varied	
Post RYGBP, after laparoscopic cholecystectomy	$7,778		
Post RYGBP, after open cholecystectomy	$14,423		
URSODIOL	$333	$333	$1850
ABDOMINAL ULTRASOUND	$102.51	$50	$200

Table 2. Summary of probabilities

VARIABLE	BASE	LOW	HIGH
GALLBLADDER SYMPTOMS AFTER RYGBP, NO CHOLECYSTECTOMY			
Without ursodiol[18-21]	5.9%	2.0%	10.0%
With ursodiol / Negative preoperative ultrasound[16, 18, 27, 30]	2.6%	2.0%	10.0%
With ursodiol / No preoperative ultrasound*	4.3%	2.0%	10.0%
Complicated gallstone disease (Within patients that develop symptoms).[18, 20, 27, 32]	28%	20%	60%
COMPLICATIONS AFTER CHOLECYSTECTOMY			
Overall for laparoscopic cholecystectomy [44]	4.5%	3%	9%
Minor for laparoscopic cholecystectomy [44]	2.6%	Not varied	
Major for laparoscopic cholecystectomy [44]	1.9%		
Overall for open cholecystectomy[44]	10.0%	5%	20%
Minor for open cholecystectomy[44]	3.8%	Not varied	
Major for open cholecystectomy[44]	6.2%		
SURGICAL TECHNIQUE			
Conversion to open RYGBP[8, 35-37]	2.5%	1%	10%
Laparoscopic cholecystectomy rate for uncomplicated gallstone disease[38-43]	80%	65%	95%
Laparoscopic cholecystectomy rate for complicated gallstone disease[38-43]	70%	65%	95%
ULTRASOUND			
Positive preoperative ultrasound.[32, 45, 46]	12%	20%	60%
Concurrent symptoms (within positive ultrasound)[17, 47]	20%	0%	100%

*Value obtained from pooled data on patients who did and did not received ursodiol/ultrasound.

Table 3. Summary of utilities (in hospital days)

VARIABLE	BASE	LOW	HIGH
CHOLECYSTECTOMY			
During RYGBP	0		
Post RYGBP, after laparoscopic cholecystectomy	2.6	Not varied	
Post RYGBP, after open cholecystectomy	4.2		
POST-OPERATIVE COMPLICATIONS – MINOR (in addition to cholecystectomy LOS)			
During RYGBP	1.9		
Post RYGBP, after laparoscopic cholecystectomy	1.9	Not varied	
Post RYGBP, after open cholecystectomy	2.3		
POST-OPERATIVE COMPLICATIONS – MAJOR			
During RYGBP	4.2		
Post RYGBP, after laparoscopic cholecystectomy	4.2	Not varied	
Post RYGBP, after open cholecystectomy	6.7		

Figure 1-A. Decision model including 3 main strategies to manage the gallbladder during roux-en-y gastric bypass surgery

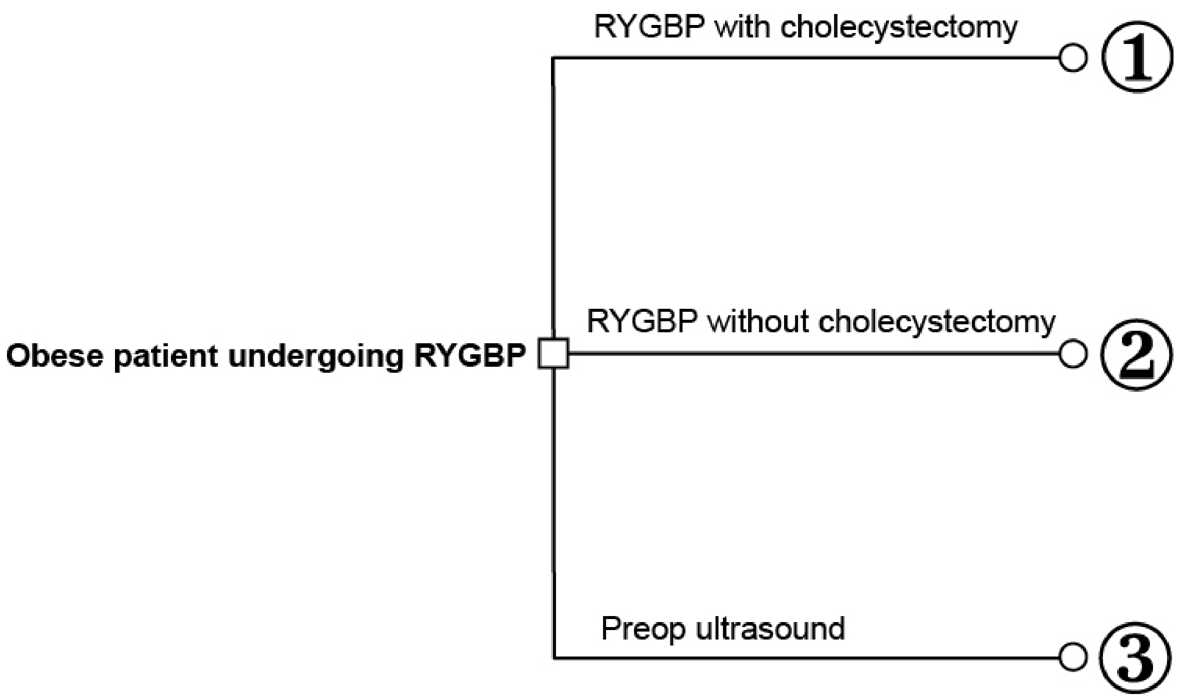


Figure 1-B. Decision model. Roux-e-y gastric bypass with concurrent cholecystectomy

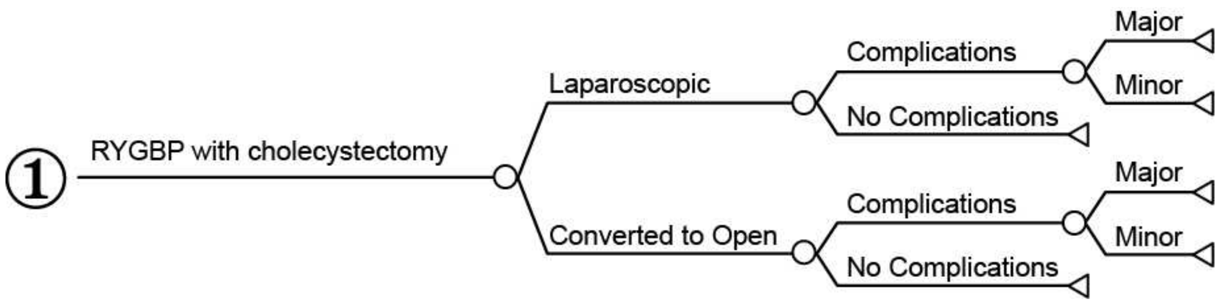


Figure 1-C. Decision model. Roux-en-y gastric bypass alone.

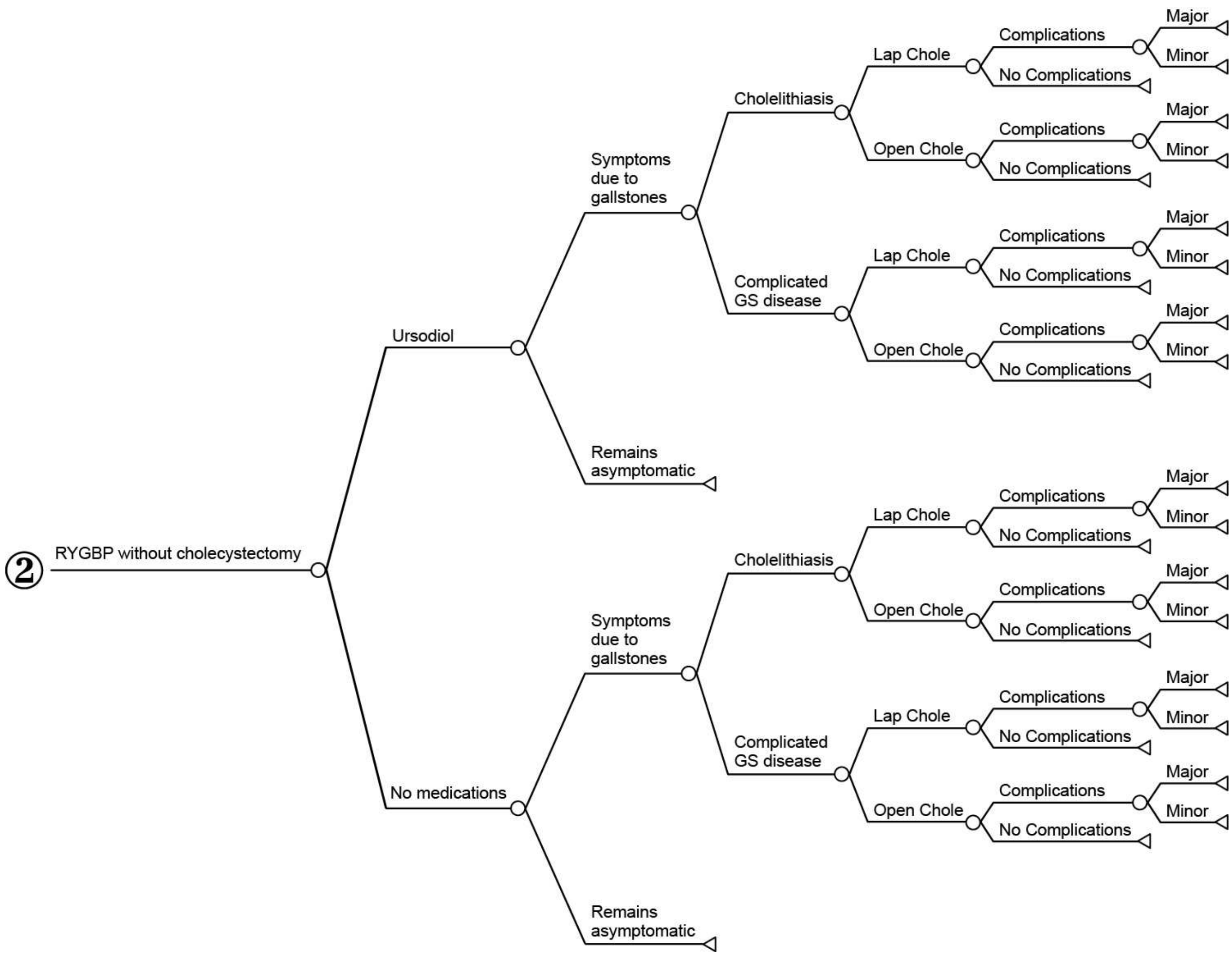
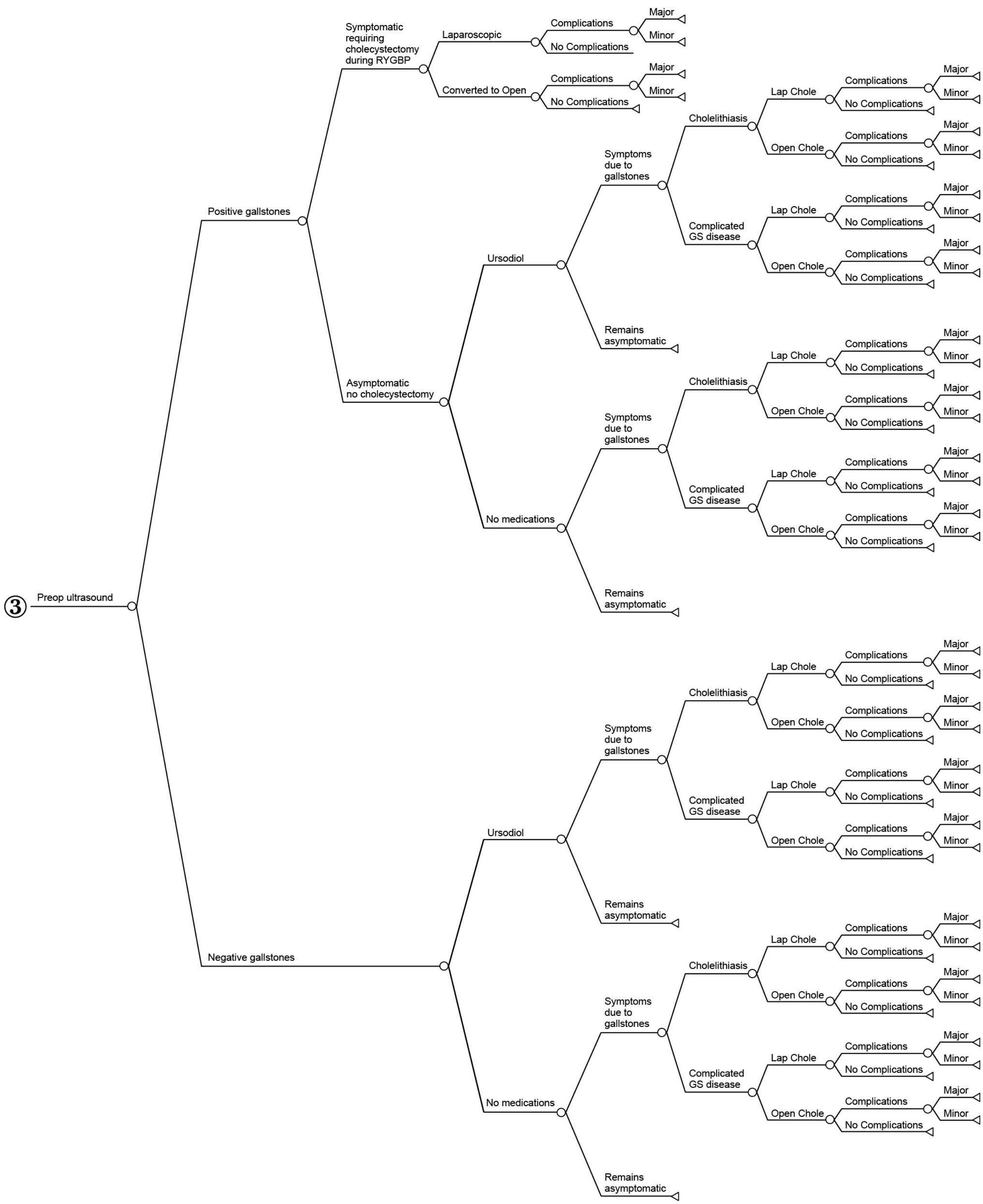


Figure 1-D. Decision model. Selective cholecystectomy during roux-en-y gastric bypass based on preoperative ultrasound



Chapter 3: Results

Base-case analysis

The base case results are shown in Table 4. Over the course of the first 24 months, patients who underwent a cholecystectomy at the time of RYGBP 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 ultrasound, experienced 0.19 hospital days.

The least expensive strategy was to perform RYGBP alone without preoperative ultrasound, with a total cost (over the RYGBP cost) of $536.73 per patient. RYGBP with concurrent cholecystectomy had a cost of $631.35. In cases where selective cholecystectomy based on preoperative ultrasound was performed, gallbladder-related costs rose to $637.95.

Performing selective cholecystectomy based on preoperative ultrasound was dominated (more expensive and more hospital days used) by the other two strategies. Concurrent cholecystectomy, while more costly, was more effective, with lower gallbladder-related hospital days in the 2-year follow-up period. The ICER of performing concurrent cholecystectomy during RYGBP versus RYGBP alone was $2365.50 per hospital day saved.

Sensitivity analysis

A sensitivity analysis was performed on key model parameters, including the probabilities of developing gallbladder-related symptoms after RYGBP, ursodiol use, cost of ursodiol as generic versus brand name, non-selective ultrasound strategy (patients with positive ultrasound undergoing cholecystectomy irrespective of symptoms), incidence of complicated gallstone disease in patients that develop gallbladder-related symptoms after RYGBP alone, conversion rates from laparoscopic to open RYGBP, laparoscopic surgery rates for gallstone disease after RYGBP alone, and incidence of complications after cholecystectomy.

Our model was most sensitive to the probability of developing gallbladder-related symptoms after RYGBP alone. When the incidence of gallbladder-related symptoms was lower than 4.6%, the dominant strategy was to perform a RYGBP without cholecystectomy and no preoperative ultrasound. For values above 6.9%, performing concurrent cholecystectomy at the time of the RYGBP was superior to the other strategies. Selective cholecystectomy based on preoperative ultrasound was dominated by the either of the other 2 strategies at any value range. Table 5 and Figure 2 summarized the sensitivity analysis.

The use of ursodiol also had significant impact on the cost-effectiveness of the different strategies. Without ursodiol, RYGBP without cholecystectomy was the most cost-effective strategy, as shown in the base case. However, once ursodiol or the non-generic Actigall was added, the least expensive strategy was to perform a concurrent cholecystectomy during RYGBP. However, performing a selective cholecystectomy based on preoperative ultrasound was the strategy with the lowest 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 dropped below 40%, concurrent cholecystectomy during RYGBP became the dominant strategy. The use of the brand name drug increased cost without reducing hospital days. Performing RYGBP without cholecystectomy (no preoperative ultrasound) was dominated by the other strategies when ursodiol was used.

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

An increase in the incidence of complicated gallstone disease after RYGBP and higher complication rates after laparoscopic cholecystectomy were associated with a decrease in the incremental cost-effectiveness ratios between RYGBP with cholecystectomy and RYGBP alone. Conversely, an increase in the conversion rate from laparoscopic to open RYGBP, use of laparoscopic cholecystectomy after RYGBP, and higher complications rates after open cholecystectomy were associated with an increase in the incremental cost-effectiveness ratio between RYGBP with cholecystectomy and RYGBP alone. Using a selective approach to perform concurrent cholecystectomy based on preoperative ultrasound results was dominated by at least one of the other strategies in all scenarios. Table 5 summarizes the sensitivity analyses of key model parameters.

Table 4. Base case results

STRATEGY	COST (US$)	LOS (Days)	INCREMENTAL C/E RATIO* (US$/hospital day averted)
RYGBP with concurrent cholecystectomy	$631.35	0.15	$2,365.50
RYGBP without concurrent cholecystectomy, without preoperative ultrasound	$536.73	0.19	Reference
RYGBP without concurrent cholecystectomy, with preoperative ultrasound	$637.95	0.19	Dominated

*Incremental cost-effectiveness ratio represents the additional cost required to save one additional hospital day when comparing different strategies.

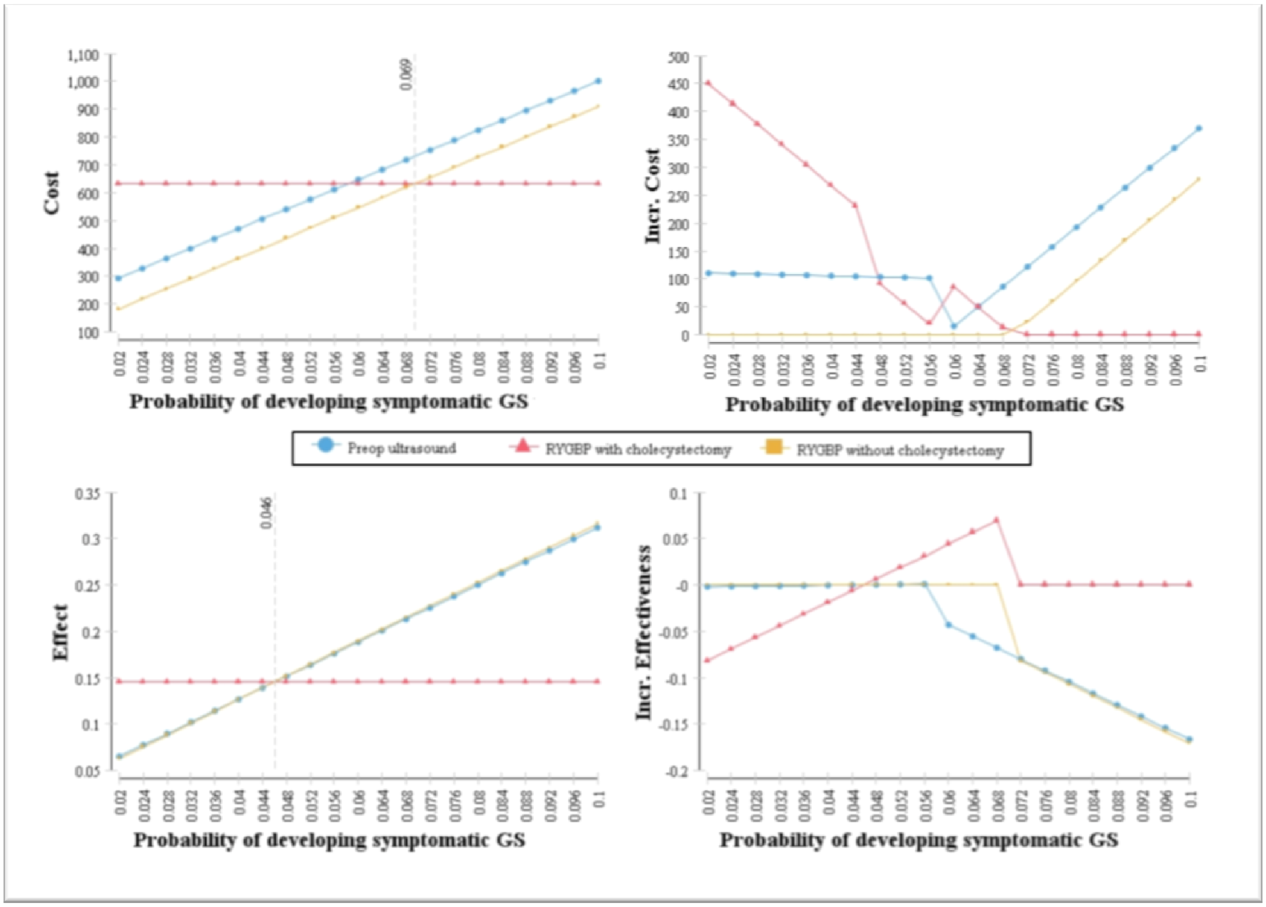
Table 5. Sensitivity analysis.*

VALUE	CONCURRENT CHOLECYSTECTOMY	RYGBP alone	RYGBP alone with preop U/S
INCIDENCE OF GALLBLADDER-RELATED SYMPTOMS AFTER RYGBP			
2%	Dominated	DOMINANT	Dominated
4%	Dominated	DOMINANT	Dominated
6%	$1,938	0	Dominated
8%	REF	Dominated	Dominated
10%	REF	Dominated	Dominated
URSODIOL			
Not prescribed	$2,310	0	Dominated
Generic	0	Dominated	$912
Actigall®	0	Dominated	$27,137
URSODIOL COMPLIANCE			
40%	0	Dominated	Dominated
60%	0	Dominated	$8,250
80%	0	Dominated	$2,951
NONSELECTIVE ULTRASOUND STRATEGY			
Cholecystectomy with positive ultrasound	$2,310	0	Dominated
ULTRASOUND COST			
$50	$2,310	0	Dominated
$150	$2,310	0	Dominated
$200	$2,310	0	Dominated
POSITIVE ULTRASOUND			
20%	$2,310	0	Dominated
40%	$2,310	0	Dominated
60%	$2,310	0	Dominated
INCIDENCE OF COMPLICATED GALLSTONE DISEASE AFTER RYGBP WITHOUT CHOLECYSTECTOMY			
20%	$2,395	0	Dominated
40%	$2,189	0	Dominated
60%	$2,003	0	Dominated
CONVERSION RATE FROM LAPAROSCOPIC TO OPEN RYGBP			
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 RYGBP			
75%	$2,275	0	Dominated
85%	$3,600	0	Dominated
95%	$6,250	0	Dominated
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

*Values are in US$ and represent the incremental cost-effectiveness ratio between strategies

Figure 2. Sensitivity analysis of probabilities of developing symptoms after RYGBP alone.



Chapter 4: Discussion

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

We found that the most cost-effective strategy for managing the gallbladder during RYGBP is sensitive to the incidence of gallbladder-related symptoms after RYGBP. In cases where the incidence of post-operative gallbladder symptoms was lower than 4.6%, the dominant strategy (lower cost and fewer hospital days) was to perform a RYGBP without cholecystectomy. In cases where the incidence of post-operative gallbladder symptoms was over 6.9%, the dominant strategy was to perform concurrent cholecystectomy during RYGBP. Although it was reported that the incidence of symptomatic gallstones during the open RYGBP era was as higher as 28%,[13, 48] recent studies reported an incidence of symptomatic gallstones after laparoscopic RYGBP ranging between 2.3% to 11.5%.[14, 16-21, 49-52] The reasons for this are not completely understood but are likely multifactorial. As RYGBP has gained popularity and laparoscopy became the preferred approach, the indications have expanded. RYGBP is more commonly done in patients with lower BMI 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, though this is rapidly changing.

Classic risk factors for gallstone formation in the general population, have not been proved to be good predictors after bariatric surgery.[49] In an article published by Li et al.[53] patients with an expected weight loss of more than 25% of their original weight were 48% more likely to develop gallstone disease after bariatric surgery compare to those without it. In a recent study by D'Hondt et al.[49] patients with weight loss at 3 months of more than 50% of the extra weight were 2.2 times more likely to develop gallstone after RYGBP compare to those with a less significant weight loss. Furthermore, postoperative hypocaloric diets has also been associated with gallbladder stasis and increase risk of gallstone formation.[54] Therefore, it is imperative to develop validated, individualized risk prediction tools based on preoperative characteristics that can accurately identify the subgroup of patients that are at an increase risk of developing symptomatic gallstone. Strategies can then vary based on individual risk. For example, if and individual risk was estimated to be above 7%, then cholecystectomy at initial operation would be indicated.

Ursodiol is prescribed by a third of the surgeons performing bariatric surgery.[24] A landmark study published by Sugerman et al.[28] reported a 2% rate of gallstone formation in patients receiving ursodiol after gastric bypass compared to 32% in the placebo group with medication compliance above 80% for both groups. However, development of symptoms and the need for cholecystectomy were not reported in the study concluding that ursodiol might be efficacious in preventing gallstone formation. The use of ursodiol also had significant impact on the cost-effectiveness of the different strategies. Based on our results, with ursodiol use, RYGBP without cholecystectomy was no longer the most cost-effective methods. Concurrent cholecystectomy was less costly when ursodiol was used and selective cholecystectomy based on ultrasound findings was shown to have the fewest hospital days with a reasonable increase in cost, assuming a 100% compliance with the medication. However, several studies have shown that compliance with the medication is variable and range between 39% and 85%.[18, 27, 28, 31, 55] Based on our sensitivity analysis, at compliance rates reported in the literature, the additional cost of prescribing ursodiol is prohibitive compared to strategies where ursodiol was not prescribed and should not be recommended after bariatric surgery.

Selective cholecystectomy based on preoperative ultrasound was dominated consistently by the other strategies in the absence of ursodiol use and should not be recommended. Varying the cost of the ultrasound, performing a cholecystectomy in patients with positive ultrasound (irrespective of symptoms), or increasing the incidence of patients with positive ultrasound did not change our results and the selective strategy was always dominated by one of the other two. Others have found similar cholecystectomy rates after RYGBP between asymptomatic patients that did and did not receive an abdominal ultrasound.[18, 21, 32] Based on the data found in the literature and the results from our model, we considered that abdominal ultrasounds 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 timeframes 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 as 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 as no current literature exists about patient preference for gallbladder related symptoms and complications after RYGBP. Our decision model did not include novel endoscopic therapeutic techniques to manage common-bile duct stones after RYGBP such as a transgastric approach or double balloon ERCP as they are only available in specialized centers. Finally, violation of our assumptions will introduce bias to our results. As an example, if patients with gallbladder-related symptoms after RYGBP did not undergo surgery after initial hospitalization or if costs are higher due to the need of additional procedures required to manage gallstone-related complications, cost and hospital days used will increase in those strategies (RYGBP alone and selective cholecystectomy based in preoperative ultrasound) 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 of the management of the gallbladder in patients undergoing RYGBP. We conclude that the main factor determining the most cost-effective strategy is the incidence of gallbladder-related symptoms after RYGBP. Further research should focus on develop individualized risk prediction tools and protocols that accurately identify the subgroup of patients that are at an increase risk of developing symptomatic gallstone. Also, the use of ursodiol was associated with an increase in cost that does not justify its use after RYGBP.

Finally, selective cholecystectomy based on preoperative ultrasound was dominated by the other strategies in the scenarios evaluated.

Chapter 5: Conclusion

Our study provides a unique perspective of the management of the gallbladder in patients undergoing RYGBP. We conclude that the main factor determining the most cost-effective strategy is the incidence of gallbladder-related symptoms after RYGBP. Further research should focus on develop individualized risk prediction tools and protocols that accurately identify the subgroup of patients that are at an increase risk of developing symptomatic gallstone. Also, the use of ursodiol was associated with an increase in cost that does not justify its use after RYGBP. Finally, selective cholecystectomy based on preoperative ultrasound was dominated by the other strategies in the scenarios evaluated.

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Vita

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