ORIGINAL CONTRIBUTION

Asymptomatic Gallstones Revisited

Is There a Role for Laparoscopic Cholecystectomy?

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Objective: To compare the mortality effects of prophylactic laparoscopic cholecystectomy with that of expectant management in persons with asymptomatic gallstones.

Design: Decision analytic models of the two clinical strategies using input data from a review of the published medical literature pertaining to the epidemiology, natural history, and treatment outcomes related to gallstone disease.

Patients: Cohorts of men and women aged 30 and 50 years with asymptomatic gallstones.

Intervention: Prophylactic laparoscopic cholecystectomy performed at the time of diagnosis of asymptomatic gallstones or expectant management, defined as therapeutic intervention delayed until gallstone symptoms or complications spontaneously develop.

Main Outcome Measures: Gallstone-related deaths and gallstone-related life-years lost for each age and gender cohort, by strategy. Models were subjected to rigorous sensitivity analysis to test the robustness of the results to changes in individual input variables. Outcomes were calculated with and without discounting nonfinancial benefits.

Results: The prophylactic laparoscopic cholecystectomy strategy led to fewer gallstone-related deaths than the expectant management strategy, but all of the deaths in the prophylactic laparoscopic cholecystectomy group occurred earlier in life. In cohorts older than age 30 years, the expectant management strategy resulted in fewer undiscounted gallstone life-years lost than the prophylactic laparoscopic cholecystectomy strategy. Discounting favored expectant management further because life-years lost were delayed compared with prophylactic surgery. Sensitivity analysis demonstrated the superiority of expectant management over a wide range of input assumptions.

Conclusions: Prophylactic laparoscopic cholecystectomy should *not* be routinely recommended for individuals with asymptomatic gallstones.

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ALTHOUGH laparoscopic cholecystectomy was introduced in the United States in 1989, it is now considered the treatment of choice for individuals with symptomatic gallstones.[1] Rapid provider adoption and intense patient demand for this less invasive treatment has precluded the performance of controlled trials necessary to definitively establish the clinical indications, safety, and efficacy of its use.[2]

However, most people with gallstones are asymptomatic and remain that way. Fewer than 5% of the 20 million individuals with gallstones in the United States experience symptoms in any year.[3-5] Earlier studies have concluded that open cholecystectomy is not indicated for patients with asymptomatic gallstones.[4,6,7] The advent of laparoscopic cholecystectomy has reopened the debate regarding the appropriate clinical strategy in this patient population. The objective of this study was to compare the mortality effects of prophylactic laparoscopic cholecystectomy with those of an expectant management strategy in persons with asymptomatic gallstones.

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METHODS

DECISION MODEL

The goal of our analysis was to quantify life-years lost due to alternative management strategies of asymptomatic gallstone disease and its related complications. Computer simulation allows the quantification of outcomes associated with gallstones, a clinical state in which observable events may occur repeatedly, irregularly, or not at all, over time. A multistate transition model was constructed to reflect the potential flux in these events (SMLTREE software, Jim Hollenberg, MD, New York, NY, 1989).

Two strategies were evaluated: (1) expectant management, defined as surgical intervention delayed until the initial episode of biliary symptoms or the spontaneous development of gallstone complications; and (2) prophylactic laparoscopic cholecystectomy, defined as performance of laparoscopic cholecystectomy at the time of gallstone diagnosis.

STUDY POPULATION

Hypothetical cohorts of 100 000 subjects, including women aged 30 years, men aged 30 years, women aged 50 years, and men aged 50 years, each with the diagnosis of gallstones and no associated symptoms, were entered into the two strategies described above.

STUDY DURATION

The model was run in 1-year cycles until all members of the cohort died of gallstone disease (and related surgical intervention) or of other causes.

MODEL INPUT PROBABILITIES

A search was conducted for English-language articles on MEDLINE (National Library of Medicine) to obtain pertinent input data for the simulation model. Bibliographies of accepted articles were reviewed to identify reports published before 1966 (MEDLINE dates to 1966) and those not included in the computerized database.

Appropriate studies were pooled into the following areas related to gallstone disease: epidemiology, natural history, and treatment outcomes. Since laparoscopic surgery is a new procedure (first performed in the United States in 1989), and results from large, randomized trials have not yet been reported, a formal meta-analysis was not performed. Weighted averages were used to calculate input values when studies used a similar method (eg, case series).

Base case input probabilities and acceptable ranges about the point estimates of each event in the model are shown in the **Table**. Age- and sex-specific life expectancy values were drawn from the *Vital Statistics of the United States*.[66] Base case inputs were constructed with a slight bias to underestimate the potential benefits of expectant management in light of the earlier findings that found this strategy to be superior to prophylactic open cholecystectomy in asymptomatic patients.[4,7]

MODEL EQUATIONS

The gallstone-related mortality rate (r) was calculated by multiplying the probabilities for individual events leading to a gallstone-related death (**Figures 1** and **2**). The number of gallstone-related deaths (d) was determined by multiplying the gallstone-related mortality rate (r) by the number of people who entered that cycle year (n). For the $_i$th cycle:

$$d_i = r_i \times n_i$$

where d_i is the number of gallstone-related deaths, r_i is the gallstone-related mortality rate, and n_i is the number of cohort members alive at the beginning of cycle i.

Gallstone-related deaths (d) were then multiplied by the years of life expectancy lost (l), conditional on age (a) and gender (g) at time of death, to yield the gallstone-related life-years lost (y). For the $_i$th cycle:

$$y_i = d_i \times l_{ag}$$

where y_i is the number of gallstone-related life-years lost, d_i is the number of gallstone-related deaths, and, l_{ag} is the life expectancy for age (a) and sex (g).

Thus, the total number of gallstone-related life-years lost for the cohort was then a function of the following:

$$(y)t = \sum_{i=0}^{N} y_i$$

where N is all cohort members who died.

EXPECTANT MANAGEMENT STRATEGY

In any cycle, individuals in the expectant management strategy group may remain asymptomatic (and reenter the next cycle 1 year older), die of a non–gallstone-related cause (determined by life tables), or develop gallstone symptoms or complications (Figure 1, A).

The annual gallstone symptom rate was derived from population-based natural history studies,[3,4,67-74] which have been extensively described elsewhere.[75,76] Studies of asymptomatic patients with long-term follow-up have found that the symptom rate declines over time after the initial gall-

The development and diffusion of laparoscopic cholecystectomy has taken general surgery by storm.[8,9] Since its first performance by Mouret in Lyon, France, in 1987, more than half the general surgeons in the United States have learned the technique.[10] Advantages of laparoscopically guided surgery include reduced postoperative pain, shorter hospitalization, faster return to a baseline level of activity, and a better cosmetic result.[1] Academic- and comstone diagnosis.[3,69,74] Although the prevalence of gallstonesis more common in women than in men, differences in symptom incidence between the sexes have not been demonstrated.[76]

We made the conservative assumption that surgery was indicated in all symptomatic individuals after the initial presentation of biliary pain, an assumption that favors the prophylactic surgery strategy. Natural history studies show that the first symptomatic episode is usually reversible and benign.[5,67-74] Serious events infrequently complicate the initial attack, and these life-threatening complications have been shown to occur more often as age increases.[77-81] Because a complicated presentation is associated with a higher rate of adverse outcomes, surgery may be performed in either elective (eg, for chronic cholecystitis) or urgent (eg, for acute cholecystitis) circumstances in this model (Figure 1, B).

Regardless of clinical presentation, all surgical candidates were initially considered for laparoscopic cholecystectomy. There are clinical characteristics that contraindicate the performance of cholecystectomy using the laparoscopically guided approach (eg, carcinoma of the gallbladder, cirrhosis of the liver).[1] Open cholecystectomy was therefore reserved for patients in whom laparoscopic cholecystectomy was preoperatively contraindicated and for those requiring an intraoperative conversion to the open technique once the laparoscopic procedure had begun. This conversion rate was determined by the clinical presentation (Figure 1, C). Since conversion to open cholecystectomy can occur in either controlled (eg, failure to visualize anatomy) or emergent (eg, uncontrollable bleeding) circumstances, separate outcomes paths were modeled for each (Figure 1, D).

Adverse events related to surgical intervention were modeled according to patient age, clinical presentation, and type and timing of surgery (Figure 1, E). Only those complications that had a direct effect on mortality were represented in the survival function (Figure 1, F). Because increasing age is an independent risk factor of operative mortality, an age adjustment has been incorporated into the model. Available laparoscopic surgery data were not sufficient to incorporate mortality adjustments for sex and race into the base case. However, since historical studies of open surgery report a decreased operative mortality rate for women,[82] it was examined in the sensitivity analysis.

Follow-up studies of cholecystectomy reveal that not all individuals are fully relieved of their symptoms after successful surgery.[83-86] However, we assumed in our models that persisting symptoms or new symptoms arising after cholecystectomy were not due to gallstones and, therefore, had no differential mortality effect between treatment groups.

For cholecystectomy survivors, life expectancy was modeled using an annual two-state process (Figure 1, G). Individuals either survived (and reentered this process 1 year older) or died of a non–gallstone-related cause, based on vital statistics.[66] We made the assumption that, for cholecystectomy survivors, life expectancy rates were independent of the presence of gallstone symptoms and their treatment.

PROPHYLACTIC LAPAROSCOPIC CHOLECYSTECTOMY STRATEGY

By definition, gallbladder surgery was performed in all members of the prophylactic laparoscopic cholecystectomy cohort at the age of entry (index year). Since these individuals were all free of symptoms and/or spontaneous gallstone complications at the time of intervention, surgery was always performed in elective clinical circumstances (Figure 2, A). Laparoscopic cholecystectomy was the initial procedure performed in each case. The conversion rate to open cholecystectomy (Figure 2, B), type of conversion (Figure 2, C), and operative complications (Figure 2, D) were modeled in a similar fashion to those in the expectant management strategy.

Since each member of the prophylactic laparoscopic cholecystectomy cohort was operated on in the index year, all gallstone-related deaths occurred at the same age (Figure 2, E). For surgery survivors, life expectancy was modeled using the same two-state process used in the expectant management strategy. Individuals either survived (and reentered the model in the subsequent cycle, 1 year older) or died of a non–gallstone-related cause (Figure 2, F). Since all surviving cohort members were presumed to be gallstone free, there were no gallstone-related symptoms possible in this strategy.

DISCOUNTING

Many individuals are not indifferent to the timing of benefits and costs: to account for the preference that benefits are received early and adverse events (or costs) are delayed into the future, both the benefits and cost outcomes of an analysis should be discounted.[87] Owing to the controversy surrounding the discounting of nonfinancial benefits,[87-90] life-years lost due to gallstones are reported with and without discounting. In the calculation of the discounted results, an annual discount rate of 5% was used in the base case.

SENSITIVITY ANALYSIS

To test the robustness of the discounted and undiscounted results with regard to changes in values of the input probabilities, sensitivity analyses were performed about the point estimates used in the base case, reflecting the ranges reported in the published literature (Table).

munity-based case series of laparoscopic cholecystectomy[11-55] had, for the most part, equivalent surgical outcomes as did those of historical open cholecystectomy controls.[56-62] Several studies reported a higher rate of bile duct injuries among patients who received laparoscopic cholecystectomy than among those who received open cholecystectomy. However, these adverse events may have been a function of a lack of surgeon experience and might

Model Input Probabilities

Input	Estimate	Range
Annual gallstone symptom rate (expectant management strategy only)[3-5,67-74]	...	.001-.10
Years 0-5	.020	...
Years 6-10	.015	...
Years 11-15	.010	...
Years ≥16	.005	...
Rate of surgery if symptomatic	1.00	...
Elective clinical presentation rate, % of cholecystectomies[4,67-74,77-81]		
Prophylactic laparoscopic cholecystectomy	1.00	1.00
Expectant management		
Aged 30-60 y	.900	.50-.95
Aged >60 y	.800	.50-.95
Urgent clinical presentation rate (expectant management strategy only)		
Aged 30-60 y	.100	.05-.50
Aged >60 y	.200	.05-.50
Rate conversion to open cholecystectomy, % of laparoscopic cholecystectomies[11-55]		
Elective clinical presentation	.050	.01-.10
Urgent clinical presentation	.200	.05-.40
Type of conversion to open cholecystectomy, % of conversions[11,13,42,46]		
Controlled circumstances	.750	.50-.90
Emergent circumstances	.250	.10-.50
Laparoscopic cholecystectomy mortality before age adjustment[11-55]		
Elective clinical presentation	.001	.0005-.005
Urgent clinical presentation	.004	.001-.10
Open cholecystectomy mortality[56-61,77-81]		
Controlled open cholecystectomy		
Elective clinical presentation	.002	.0005-.005
Urgent clinical presentation	.004	.005-.250
Emergent open cholecystectomy		
Elective clinical presentation	.004	.001-.010
Urgent clinical presentation	.008	.005-.250
Operative yearly mortality adjustment[7,82,92-94]	.085	.008-.100

be offset by reductions in other serious complications (eg, pulmonary embolism, stroke) that result from laparoscopic cholecystectomy's decreased morbidity and shortened recovery period.[11-14,20,23,50]

Given the clinical advantages and patient preferences as well as the mass media's positive portrayal of laparoscopic cholecystectomy, there is concern that its use may soon be advocated for those individuals with asymptomatic gallstones.[63,64] The impact on the health care system of broadening the indications for laparoscopic cholecystectomy would be substantial in terms of clinical outcomes and resource use, especially since long-term studies of risks, benefits, and costs of this procedure have yet to be performed.

Unfortunately, there have been no controlled trials comparing surgery with expectant management of asymptomatic gallstones. Although some surgeons support the performance of clinical studies,[65] none are likely, given the logistical difficulties and expense of conducting such investigations. Using decision analysis, Ransohoff and colleagues[7] found expectant management to be as clinically effective and more cost-effective than prophylactic open cholecystectomy in patients with asymptomatic gallstones. We used similar computer simulation techniques to update this work and expanded it to include laparoscopic cholecystectomy.

RESULTS

GALLSTONE-RELATED DEATHS

In the four cohorts examined, there were fewer gallstone-related deaths in the prophylactic laparoscopic cholecystectomy group than in the expectant management strategy group (**Figure 3**). However, in each of the prophylactic laparoscopic cholecystectomy cohorts, all of the gallstone-related deaths occurred during the index year (eg, 117 deaths in 30-year-old men). This differs markedly from the expectant management cohorts, in which the ages at gallstone-related death were widely distributed. More than half the gallstone-related deaths in the cohort of 30-year-old

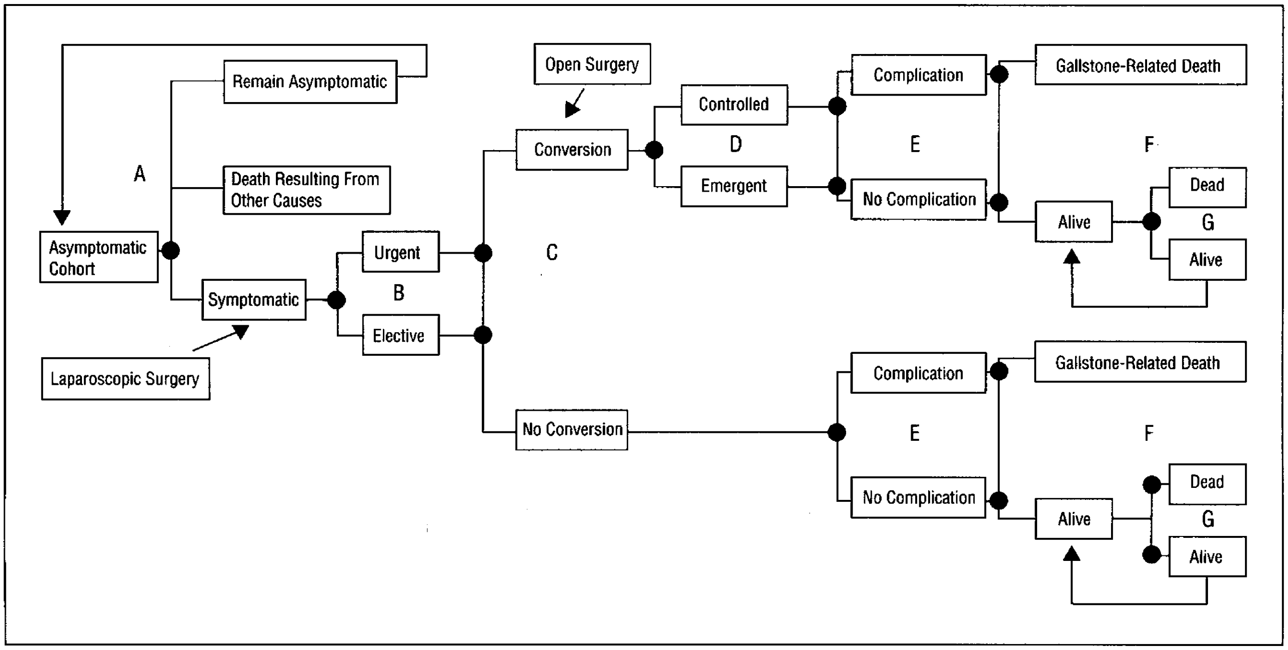

Figure 1. *Decision model for the expectant management strategy.*

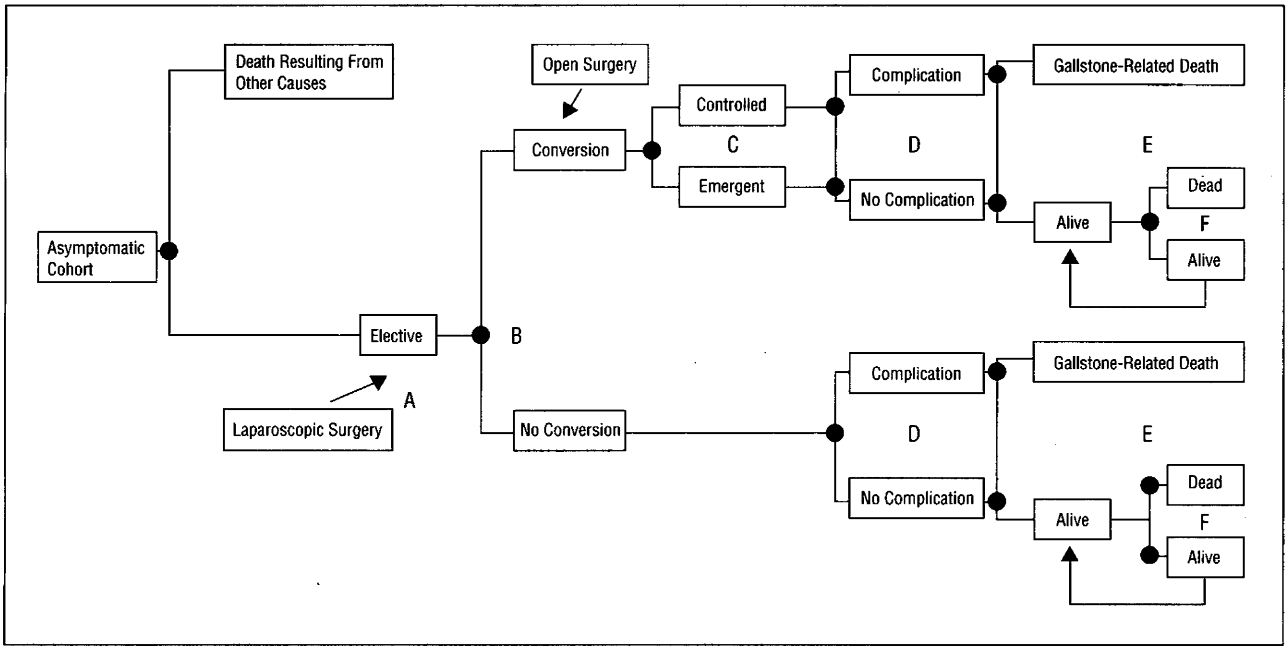

Figure 2. *Decision model for the prophylactic cholecystectomy strategy.*

women managed expectantly occurred after the age of 65 years (**Figure 4**). This bimodal age distribution in gallstone-related deaths was seen in each of the expectant management cohorts, affecting directly the calculation of life-years lost as a result of gallstone disease.

UNDISCOUNTED LIFE-YEARS LOST

Gallstone-related life-years lost in the 30-year-old cohorts were nearly equivalent in both strategies when analyzed by sex (**Figure 5**). However, in the 50-year-old cohorts, there were fewer life-years lost in both sexes in the expectant management strategy group than in the prophylactic laparoscopic cholecystectomy group.

DISCOUNTED LIFE-YEARS LOST

Discounting enhances the advantage of the expectant management strategy in every instance, in that gallstone-related deaths in this strategy are delayed relative to deaths in the prophylactic laparoscopic cholecystectomy strategy, which all occur in the index year (**Figure 6**). For

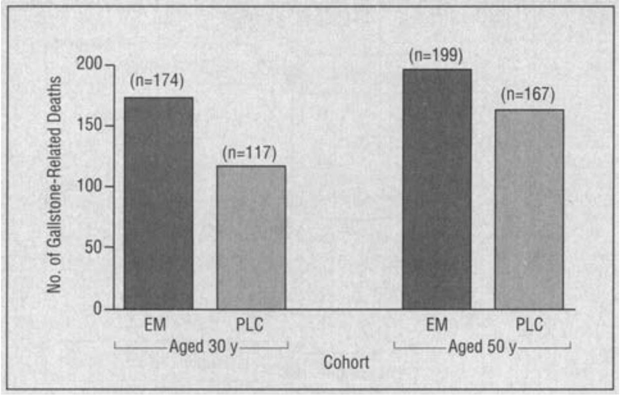

Figure 3. *Gallstone-related deaths per 100 000 population, by age and clinical strategy. EM indicates expectant management; PLC, prophylactic cholecystectomy.*

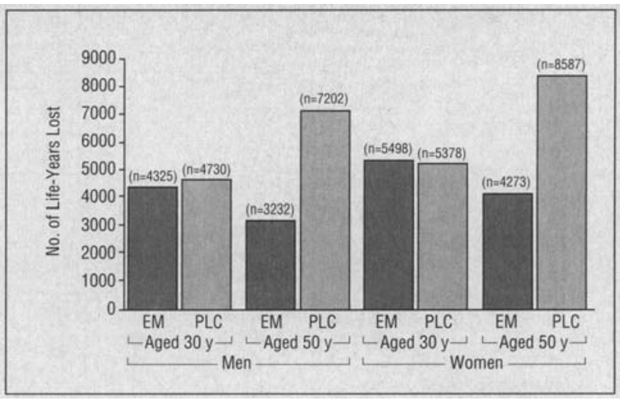

Figure 5. *Undiscounted gallstone-related life-years lost per 100 000 population, by age, sex, and clinical strategy. EM indicates expectant management; PLC, prophylactic cholecystectomy.*

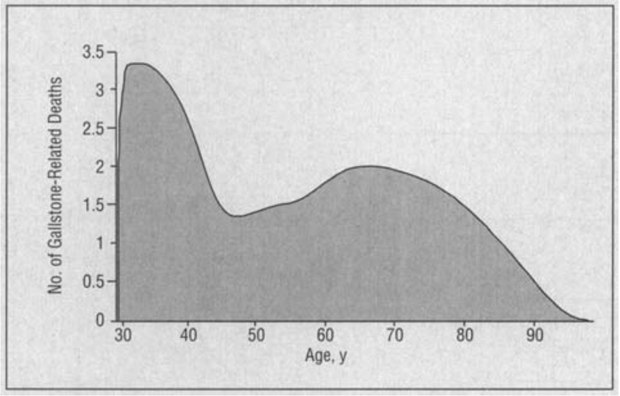

Figure 4. *Gallstone-related deaths per 100 000 population in the 30-year-old female expectant management cohort, by age.*

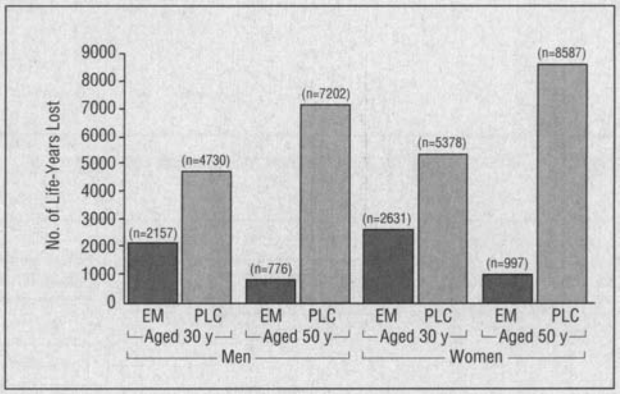

Figure 6. *Discounted gallstone-related life-years lost per 100 000 population, by age, sex, and clinical strategy. EM indicates expectant management; PLC, prophylactic cholecystectomy.*

the cohorts examined, the expectant management strategy resulted in fewer discounted life-years lost as a result of gallstone disease compared with the prophylactic laparoscopic cholecystectomy strategy.

UNDISCOUNTED SENSITIVITY ANALYSES

Sensitivity analyses performed on the input ranges found in the Table revealed that the total undiscounted gallstone-related life-years lost were sensitive to two variables: annual gallstone symptom/surgery rate and elective laparoscopic cholecystectomy mortality rate. Threshold analyses were performed to determine the values at which these inputs would change the outcomes sufficiently enough to alter the preferred strategy.

30-Year-Old Cohorts

Undiscounted life-years lost in the 30-year-old cohorts were nearly equivalent for the two management strategies examined (Figure 5). Increasing the annual gallstone symptom/surgery rate to greater than 2.5% per year resulted in a slight advantage for the prophylactic laparoscopic cholecystectomy strategy. Decreasing the laparoscopic cholecystectomy mortality rate to near the lowest acceptable value (one of 1500 patients) resulted in a similar effect. Reversing the direction of change in each of the two value adjustments yielded a similarly slight advantage for expectant management.

50-Year-Old Cohorts

In the 50-year-old cohorts, a doubling of the annual symptom/surgery rate to 4% was necessary to yield an equivalent number of undiscounted gallstone-related life-years lost in both strategies. The laparoscopic cholecystectomy mortality rate must fall to one of 2000 patients (half the base case estimate) for prophylactic surgery to equal gallstone-related survival outcomes with that of expectant management in this age group.

DISCOUNTED SENSITIVITY ANALYSES

In each scenario tested, sensitivity analyses performed about the base case estimates (Table) confirmed the advantage of expectant management over prophylactic laparoscopic cholecystectomy in minimizing discounted gallstone life-years lost. After broadening the sensitivity analyses, the only variable with potential to justify a prophylactic surgery strategy was the elective laparoscopic cholecystectomy mortality rate. Only when the surgical mortality rate was below three of 100 000, did the prophylactic surgery strategy yield a small advantage in terms of discounted gallstone-related life-years lost.

ALTHOUGH SOME case series report a zero mortality rate, the statistical power of each of these studies is questionable owing to the small sample sizes. Moreover, the absence of operative mortality has not been substantiated in large databases or in centers in which laparoscopic cholecystectomy experience is not well established. Cholecystectomy-related morbidity and mortality rates in hospitals in New York State exceed those found in case series from centers with established experience with this new procedure.[91]

Gallstone-related death is very uncommon in either strategy of the simulation (lifetime risk less than 0.2%). In the ideal scenario of zero operative mortality, the life expectancy gained per person in a prophylactic surgery strategy ranged from a maximum of 3 weeks (in 30-year-old women, undiscounted) to a minimum of 2 days (in 50-year-old men, discounted).

COMMENT

LIMITATIONS

Computer-based health simulations have a number of shortcomings related to the difficulties in specifying a model and obtaining accurate input estimates that realistically reflect the clinical problem under examination. Our simulation of individuals with asymptomatic gallstones focused on a single outcome measure—mortality—for which model inputs were available from the published literature. We used a large number of published studies, which were not exactly equivalent in patient demographics, clinical care settings, specific medical interventions, and measurement of outcomes. Sensitivity analyses were used to explore the robustness of the simulation results using ranges found in these dissimilar studies.

Mortality is only one of many factors of interest to physicians and patients in deciding whether to undergo gallbladder surgery. Other relevant elements of this decision, such as the removal of painful symptoms, improvement in patient function, and cost-effectiveness ratio, were not included in this analysis because reliable and valid data for these variables do not exist.

Laparoscopic cholecystectomy is still evolving, a characteristic that makes formal assessment difficult. This point should not be underestimated, since inputs used in this model were drawn from the published literature, which often dealt with the early use of laparoscopic cholecystectomy. Additional clinical experience with this technique may affect the results of the simulation. We attempted to assess and test the impact of this and other factors with the greatest potential to alter the model outcomes through the use of rigorous sensitivity analyses.

BIASES

Our base case inputs had inherent biases. The most sensitive input, annual gallstone symptom rate, was biased against expectant management, since we assumed surgery was always indicated after a single symptomatic episode. Although a 2% annual symptom rate for the first 5 years (Table) can be found in the literature,[3-5] the rate of cholecystectomy modeled for these symptomatic patients (100%) is higher than rates found in most natural history studies.[3,4,67-73] For example, only one in five patients with gallstone symptoms in the placebo population from the National Cooperative Gallstone Study underwent cholecystectomy during a 2-year period.[5] The impact of this assumption is to favor prophylactic surgery, in that it overestimates the number of cholecystectomies performed in the expectant management cohorts, and, therefore, most likely increases the rate of adverse surgical events contributing to life-years lost. This bias in favor of prophylactic surgery is, however, partially offset since early surgical intervention will decrease the number of urgent (and riskier) cholecystectomies performed (eg, for acute cholecystitis), since past biliary symptoms are a risk factor for later complications.[76]

In addition, symptoms persisting after cholecystectomy may impel a costly diagnostic and treatment cascade. There are no data that suggest that postcholecystectomy syndromes occur more frequently in patients who are symptomatic before the procedure. However, symptoms leading to cholecystectomy that are not related to the biliary tract may occur more frequently in the expectant management cohort. This finding would bias our results against prophylactic surgery. Conversely, postcholecystectomy syndromes related to the surgery itself (eg, bile leaks, retained stones) would be more prevalent in the prophylactic surgery group, since every member of the cohort was exposed to a procedure, as opposed to only one quarter of the cohort managed expectantly.

Adjustments of operative mortality for age were based on a formula derived from the results of the National Halothane Study,[82] which has been used in other gallstone disease decision models.[7,92-94] The use of an age-related mortality factor also biased our results against the expectant management strategy. Age-associated increases in surgical mortality are applicable only to the expectant management model because all surgery in the prophylactic laparoscopic cholecystectomy groups occurs at the age of cohort entry. If reductions in fatal complications result from the use of minimally invasive surgery, then the use of this adjustment overestimates death rates in the expectant management cohorts. These reductions in mortality were estimated by the model through the use of sensitivity analyses. (Data are lacking since the National Halothane Study [1969] predates the advent of laparoscopic general surgery.)

We made the assumption that life expectancy rates were independent of the presence of gallstone symptoms and their treatment. Although comorbid relationships with gallstones have been described (eg, sickle cell anemia, cirrhosis of the liver), there are no data to suggest that gallstone duration or related symptoms are significantly associated with these comorbid states. This association would tend to bias the analysis toward the use of prophylactic cholecystectomy. The natural history literature[3,4,68-72] does not suggest that a difference in comorbid illnesses exists between symptomatic and asymptomatic groups.

.POLICY IMPLICATIONS

This model showed a steadily growing gallstone-related survival advantage for expectant management as the age of the cohort increased above 30 years, the age at which the clinical simulation found equivalent survival between the two management strategies when gallstone-related life-years lost were not discounted. However, this finding should not suggest that a policy of prophylactic laparoscopic cholecystectomy is desirable in patients aged 30 years. In the case of equal survival outcomes, it is necessary to assess how such a policy decision would affect outcomes other than patient survival. Nonclinical effects, such as patient function and resource use (increased demand for screening tests, larger surgical caseloads, and shifting resources away from other interventions), are important to consider from the perspective of the health care provision system, already burdened with the problems of patient dissatisfaction and escalating costs.

Economic evaluations of laparoscopic cholecystectomy report that the direct medical costs of this new procedure are lower or similar to those of open cholecystectomy, owing primarily to decreased length of hospital stay.[27,39,95] Additional indirect cost advantages of laparoscopic surgery, such as faster return to employment, also have been reported.[96] Unfortunately, other parameters needed to accurately estimate the cost-effectiveness of laparoscopic cholecystectomy are unavailable: adoption of same-day surgery,[97] use of disposable and more sophisticated (and more expensive) instrumentation, and expanded use of intraoperative cholangiography.[98] When these data become available, the model can be expanded to incorporate these factors.

After a decade of stability of the per-capita cholecystectomy rate,[99] clinical leaders and surgical industry representatives now estimate large increases in the numbers of cholecystectomies performed. This expansion in caseload parallels the diffusion of laparoscopic cholecystectomy. It is doubtful that these additional cholecystectomy cases are a result of increases in gallstone incidence or annual symptom rate. More likely, this growth is due to the increased use of laparoscopic surgery in symptomatic patients who deferred an open, invasive procedure. This one-time effect on cholecystectomy rates should dissipate in a few years. However, the degree to which increased cholecystectomy rates are a result of the broadening of surgical indications is uncertain. This model indicates that expansion of laparoscopic cholecystectomy indications to include individuals with asymptomatic gallstones is not generally indicated.

TO DATE, indications for the use of laparoscopic cholecystectomy have not been established by formal studies of the largest population with gallstones, ie, those without symptoms (20 million people in the United States). The driving forces behind the use of this minimally invasive therapy in this group of patients include the following: expanded use of advanced diagnostic imaging modalities (eg, ultrasonography, computed tomography, magnetic resonance imaging) revealing silent gallstones, public awareness of laparoscopic cholecystectomy as positively presented in the mass media, and favorable hospital reimbursement policies that currently exist for this procedure. It is unlikely that any further data from controlled clinical trials will become available to formally answer the questions at hand. Thus, decision models will need to be increasingly relied on to integrate the multiple complex factors that influence management strategies to help guide clinical decision making.

CONCLUSION

Using life-years lost from gallstone disease as the principal outcome, a formal decision analysis revealed that a strategy to perform prophylactic laparoscopic cholecystectomy should not be routinely recommended for individuals with asymptomatic gallstones. This conclusion is further strengthened by the fact that the model was biased slightly to underestimate the benefits of expectant management. Using input values derived from the published literature, prophylactic laparoscopic cholecystectomy was not superior to expectant management in terms of gallstone-related survival in any clinical circumstances. These results thus concur with, and extend, earlier research that favored expectant management compared with prophylactic open cholecystectomy in this same population.[4,7]

Based on the best available data, the advent of laparoscopic cholecystectomy should not alter the current consensus, which recommends expectant management for individuals with asymptomatic gallstones.[1]

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Reprints not available.

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