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Ali Siddiqui
Thomas Jefferson University

Pradnya Mitroo
Thomas Jefferson University

Thomas E. Kowalski
Thomas Jefferson University

David Loren
Thomas Jefferson University, david.loren@jefferson.edu

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Endoscopic sphincterotomy with or without cholecystectomy for choledocholithiasis in high-risk surgical patients: a decision analysis

A. SIDDIQUI, P. MITROO, T. KOWALSKI & D. LOREN

Division of Gastroenterology and Hepatology, Thomas Jefferson University Hospital, Philadelphia, PA, USA

Correspondence to: Dr A. A. Siddiqui, University of TexasSouthwestern Medical Center, 4500 S.Lancaster Road (111B1), Dallas, TX75216, USA. E-mail:ali.siddiqui@utsouthwestern.edu

Abstract

Background

Laparoscopic cholecystectomy (LC) is recommended for patients with choledocholithiasis after ERCP with sphincterotomy (ES) and stone extraction.

Aim

We designed decision model to address whether ES alone versus ES followed by LC (ES + LC) is the optimal treatment in high-risk patients with choledocholithiasis.

Methods

Our cohort were patients with obstructive jaundice who have undergone an ES with biliary clearance. Recurrent biliary complications over 2-year period stratified by gallbladder status (in/out) and age-stratified surgical complication rates were obtained from the literature. Failure of therapy was defined as either recurrent symptoms or death attributed to biliary complications.

Results

For age 70–79 years, ES failed in 15% whereas ES LC failed in 17% of cases. Mortality in the EC LC group was 3.4 times that of the ES alone cohort. For age 80+ years, ES was dominant with an incremental success rate of 8%. Mortality in the ES LC was 7.6 times that of ES. For age <70, ES LC was the dominant strategy with an incremental success rate 5%. Sensitivity analysis in the groups confirmed our conclusions.

Conclusions

Management of choledocholithiasis by ES and stone clearance, but without cholecystectomy, should be considered for patients aged 70+. For low-risk patients, ES LC should be performed to prevent recurrent biliary complications.

INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) with endoscopic sphincterotomy (ES) is accepted as the therapy of choice for patients with stones in the bile duct.^{1–3} Endoscopic stone extraction is successful in over 96% of patients^{3–5} with a low procedure-related morbidity (5.8%) and mortality (0.2%). Subsequent laparoscopic cholecystectomy (LC) is the standard treatment in those patients with concomitant gall-bladder stones. The rationale for

cholecystectomy is to prevent biliary complications such as acute cholecystitis, biliary colic, recurrent biliary stones, cholangitis and biliary pancreatitis. Many patients with biliary stones are elderly and have multiple comorbid conditions and are thus poor surgical candidates. Postoperative mortality and morbidity increase with age and associated comorbid diseases.^{6,7} Several groups have proposed that endoscopic extraction of bile duct stones, with the gall-bladder left in situ, could be an option in high surgical risk patients presenting with jaundice secondary to choledocholithiasis.⁸ Although endoscopic therapy may carry lower immediate morbidity or mortality, late biliary complications are not uncommon. The decision whether to proceed to surgery is further complicated by the fact that the morbidity and mortality of LC have declined with greater surgical experience.^{9,10} Additionally, some of the studies that advocate use of ES in high-risk patients do not agree with the definition of high surgical risk.^{11,2} We designed decision analysis to address whether ES alone vs. ES followed by LC (ES + LC) is the optimal treatment modality in high-risk patients with choledocholithiasis.

PATIENTS AND METHODS

Literature review

A Medline research looking at English language articles from 1990 to the present was performed for variation of the following terms: ERCP, ES, LC, elderly, gallstones, cholelithiasis, morbidity and mortality. Bibliographies of accepted articles were reviewed and we searched recent issues of peer-review journals of gastroenterology and surgery. Only studies that had more than 10 patients and outcome data that could be abstracted were used. Updated series took precedence over older studies from the same institution. Some variability was noted in the studies reporting testing characteristics and complications rates for the different variables. Weighted mean values for each parameter were calculated from the usable trials and applied to our decision tree. All probabilities for clinical inputs in the model, as well as the range tested in the sensitivity analysis, are summarized in Tables 1 and 2.

Decision analytical model

Using a decision analysis software program, DATA 3.5 (TreeAge Software Inc., Williamstown, MA, USA), we evaluated the clinical outcomes and recurrent biliary complications in patients with cholelithiasis within 2-year period in three different age groups: (i) patients younger than 70 years. (ii) patients of age 70–79 years (base cohort). (iii) patients of age 80 years or more. The decision tree used in the analysis is illustrated in Figure 1.

For each of the age groups, the analysis started with cohort of 100 hypothetical patients with intact gallbladders presenting with obstructive jaundice because of

cholelithiasis. All patients underwent successful ERCP with ES and biliary clearance without complications. Patients were then assigned to two groups: group I (ES + LC), in which patients were treated with LC to remove the gall-bladder following ES and group II (ES only), in which the gall-bladder was left *in situ* after ES.

Patients in group I underwent an ES followed by an LC. The decision model was divided into that subset of patients who had immediate complications following LC and those patients who had no surgical complications. In the group of patients who had immediate surgical complications, the mortality and morbidity of LC were modeled based on published rates in the literature. Those patients who did not die because of surgical complication nor had post-operative complications were then assessed for long-term recurrent biliary complications and mortality within 2-year period.

Patients in group II underwent an ES and the gallbladder was left *in situ*. These patients were then assessed for long-term recurrent biliary complications and mortality within 2-year period.

Appraisal of clinical outcomes

The decision tree was used to evaluate the preferred treatment strategy for management of choledocholithiasis in patients in each of the three different age groups. Short-term operative mortality and morbidity were assessed. Failure of therapy was defined as either recurrent symptoms or death attributed to biliary complication.

Sensitivity analysis

The performance characteristics were varied to determine the threshold patient age and complication rates that would alter treatment strategies using one-way and multiple-way sensitivity analyses so as to detect its effect on the ultimate results.

It is not realistic to rely upon one value for probabilities, as there is marked variability in outcomes seen in the literature. In doing sensitivity analysis, we can see whether changing the mortality and mortality rate alters the favored decision strategy. If it does not, this proves the robustness of the model. If it does alter the strategy, the model is considered to be sensitive to changes in the probability of that particular test. In the final analysis, this helps determine the most optimal treatment modality for patients with choledocholithiasis, who are at increased surgical risk.

One-way sensitivity analyses were done by varying single variable baseline probabilities over credible range and then interpreting their effect on final

outcomes. For each scenario, one-way sensitivity analysis was performed, plotting success of therapy against surgical complications, to determine the optimal strategy to follow (ES + LC vs. ES alone). Three-way sensitivity analysis of recurrent complications in ES, ES LC and surgical morbidity was then performed to further validate the strength of the decision model.

RESULTS

Decision tree analysis

Age less than 70 years

In patients who were less than 70 years of age, the ES + LC was the dominant strategy. Patients with choledocholithiasis who underwent an ES followed by LC had a 90% overall success rate with 2-year mortality rate of 0.05 per 100 patients. In comparison, patients with choledocholithiasis who underwent only an ES had an 85% overall success rate. The ES-only group had 2-year mortality rate of 0.1 per 100 patients, which was twice that of the ES + LC group. A one-way sensitivity analysis identified threshold surgical complication rate of 9.8% (Figure 2), above which ES was the dominant strategy and further validated that in patients less than 70 years of age with biliary obstruction because of choledocholithiasis, ES followed by LC should be the treatment of choice. Patients who underwent only ES had lower overall success rate and higher mortality.

Age 70–79 years (base cohort)

In patients aged 70–79 (base cohort), ES alone was the dominant strategy when compared with ES + LC. The ES-alone group had an overall success rate of 85% when compared with the ES + LC group that had an 83% success rate. The ES-alone group thus has an incremental success rate of 2%. The ES-alone group had 15% failure rate when compared with 17% in the ES + LC group. The 2-year mortality in the EC + LC group was 3.4 times that of the ES-alone cohort. One-way sensitivity analysis determined threshold surgical complication rate of 10% (Figure 3), above which ES was the dominant strategy; therefore in patients of age 70–79 years with biliary obstruction because of choledocholithiasis, ES alone should be the treatment of choice. ES + LC have higher failure rates and mortality in this age group.

Age 80 years and above

For the cohort of age 80 years or more, ES was dominant with an overall success rate of 86% when compared with 78% in the ES + LC group. The ES-only group, therefore, had an incremental success rate of 8% over ES + LC. Three-way sensitivity analysis of recurrent complications in ES, ES + LC and

surgical morbidity, identified ES as the dominant strategy in all cases except when biliary complications for ES exceeded 22.2% (range 6–24%). Mortality in the ES + LC group was 7.6 times that of the ES cohort. ES-alone group had an overall greater success rate and lower mortality rate compared with the ES + LC group.

The decision analysis results are summarized in Table 3.

DISCUSSION

We constructed a decision analysis, attempting to simulate the clinical scenario of patient presenting with obstructive jaundice because of an obstructed common bile duct stone. Patients were stratified into three different age groups, and the model was used to determine the optimal management strategy. We found that ERCP with sphincterotomy (ES) and stone clearance, but without cholecystectomy, should be strongly considered for patients aged 70–79 (base cohort). In patients of age 80 years and above, ERCP with ES alone was the dominant strategy, largely because of increased surgical complication rates. For low-risk patients (less than 70 years of age), ES followed by LC should be performed to prevent recurrent biliary complications and decrease overall morbidity and mortality.

Decision modeling uses complex clinical situation and is based on previously published data. It helps serve as an adjunct to clinical decision making. It should be remembered that decision modeling is subject to several limitations. The influences of factors such as patient preferences that may impact the choice of clinical approach are difficult to access. Our decision model has several limitations. The model has level of uncertainty when looking at the clinical assumptions. Like all decision models, the limitations may affect the validity and generalizability of our findings. Therefore, sensitivity analysis allows us to address this uncertainty by giving range of values to inputs prone to uncertainty. We have made number of simplifying assumptions so as to create working decision model that may not capture many of the subtleties that happen in clinical practice.

Patients who present with obstructive jaundice secondary to bile duct stones usually undergo an ES followed by LC. Procedure complication rates from both elective and emergency ERCPs in the elderly are similar to those of the younger age groups, despite the geriatric population having more comorbidities.^{12, 13} A study by Clarke et al.¹⁴ showed that post-ERCP pancreatitis occurred in 5% of patients aged 85 or above. This was similar rate to younger patients.¹³ Although it is well documented that patients undergoing endoscopy can experience hypoxaemia, it is not clear whether this contributes to any associated complications.^{15, 16}

As opposed to endoscopy, there is an increase in incidence of post-operative mortality and morbidity after cholecystectomy with advancing age. The elderly are at an increased risk for surgery because of concurrent comorbidities, decreased functional reserve and greater chance that surgery will be done on an emergency basis.¹⁰ Several studies have looked at the results of LC in the elderly population.¹⁷⁻²⁰ The majority of these studies are comprised of small number of patients, and there are only two reports that focused out outcomes in octogenarians.^{21, 22} These studies have reported that when compared with younger patients, the elderly have more complications, higher rates of conversion to an open cholecystectomy, and longer post-operative hospitalization. Maxwell et al.²² compared 105 octogenarians to control group of 210 patients who were younger than 80 years. His study showed that patients older than 80 years required more emergency surgery (11% vs. 4.8%), had higher intra-operative complications (13% vs. 3.3%) and greater incidence of conversion to an open cholecystectomy (16% vs. 8.6%). The overall complication rate was also higher in octogenarians.

Elective cholecystectomy after ES is still arguable. Certain surgical reports suggest that the presence of cholelithiasis is an indication for elective cholecystectomy after ES.²³ Surgical sphincterotomy has been shown to prevent gallstone formation in prairie dogs.^{24, 25} In humans, ES stimulates gall-bladder motility and was thought to prevent further gallstone formation.²⁶

Boerma et al.²⁷ did prospective, randomized trial in 120 patients with gall-bladder stones, who underwent an ES for common bile duct stones. Patients were then randomly allocated to wait-and-see for LC. The primary outcome was recurrence of biliary events during a 2-year follow-up. The mean age in this group of patients was 60 years. Of the patients allocated to wait-and-see, 47% had recurrent biliary complications over 2 years when compared with 2% in patients who underwent an LC. In this group of patients, ES alone was an inadequate therapy compared with ES + LC because of high recurrent biliary complications. Young patients tended to develop recurrent biliary complications the most. These findings were compatible with the conclusions in our study for low-risk patients (younger than 70 years), for which we recommended ES followed by LC to prevent recurrent biliary complications. It should be noted that the biliary complication rate in the wait-and-see group (47%) was significantly higher when compared with other similar trials. Several other trials²⁸⁻³⁰ have also suggested ES LC as treatment of choice in younger low-risk patients with choledocholithiasis.

Lai et al.³¹ looked at 140 patients (mean age 69 years) with intact gall-bladder, who underwent ES for clearance of stones in the bile duct. Of the 140 patients, 46 underwent elective LC soon after sphincterotomy and 94 did not. There was no statistically significant difference in recurrent complications between patients without gall-bladders vs. the patients with intact gall-bladders. Therefore, elective

cholecystectomy after ES did not prevent the recurrent biliary complications in patients with cholelithiasis or nonfunctional or normal gall-bladder. Similar conclusions were drawn by Boytchev,³² in which late biliary complications after ES for choledocholithiasis in patients with gall-bladder *in situ* were rare (2% per year) in patients with mean age of 78 years.

A recent study by Lau³³ looking at patients with mean age of 71 years advocated ES + LC for choledocholithiasis. The authors stated that these patients should undergo ES + LC because of greater long-term morbidity and mortality in the ES-alone group. However, closer look at this study reveals that the authors do not specifically mention immediate surgical mortality in patients undergoing cholecystectomy. Furthermore, the authors state that long-term mortality was higher in the ES-alone group. The long-term mortality rate estimates for ES-alone group vs. ES + LC group reveals that this is an estimation of 'all causes of death' rather than death caused by recurrent biliary complications. When one looks at long-term mortality from biliary complications alone among the two groups, the mortality rates are essentially the same.

Hammarstrom et al.³⁴ retrospectively evaluated 184 patients (mean age = 81 years) to see whether ES with common bile duct calculi and the gall-bladder *in situ* should be followed by routine cholecystectomy. These patients were followed for median duration of 69 months. Cholecystectomy was required in only 35 because of acute cholecystitis or biliary colic. The rest of patients who underwent ES alone were relatively asymptomatic. The findings in this study confirmed that endoscopic treatment alone in this group of patients was feasible treatment principle. Several other studies^{1, 35-37} have further confirmed that octogenarians with common bile duct calculi do well with ES alone on long-term follow-up.

Targarona et al.³⁸ carried out prospective trial of comparing ES + LC with that of ES for treatment of bile duct stones in patients with mean age of 80 years. Patients undergoing ES + LC had higher immediate morbidity when compared with the ES-alone group (23% vs. 16%). During mean follow-up of 17 months, the probability whether patients being free of biliary symptoms was higher in the ES + LC group than in the ES-alone group (85% and 61%, respectively). These findings contradict the findings of our decision analysis and the previously mentioned studies. It is important to understand that our decision analysis is predictive model that utilizes data from multiple clinical trials rather than just one trial. The conclusions of our model are hence based upon data compiled from various studies and hence may not always agree with an individual study mentioned above. Furthermore, our conclusions recommending the ES-alone strategy in patients more than 80 years of age have been validated by sensitivity analysis that accounts for the marked variability in outcomes seen in the literature.

The data analysis in our study indicates that for younger, relatively healthy patients, ES LC is the dominant strategy with an overall success rate of 90%. This result was further validated by sensitivity analysis. The mortality for the ES + LC group was also half that of the ES-alone group. ES alone is safe and effective procedure for most elderly patients with symptomatic cholelithiasis, including the extreme elderly, 80 years of age or older. When compared with other groups, elderly patients have much higher rate of conversion to an open cholecystectomy, more complications and mortality. Factors that account for these adverse outcomes include more comorbidities, especially coronary artery disease.

In conclusion, on the basis of these observations, we recommend that in younger patients (age <70 years) with choledocholithiasis, ES followed by elective LC should be encouraged before the development of biliary complications. Such an approach may serve to lower complications and mortality. More elderly patients (age >70 years) with multiple comorbidities are at greatly increased risk for surgical morbidity and mortality and should be considered for ES alone.

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TABLES & FIGURES

TABLE 1

Decision analysis baseline values for endoscopic sphincterotomy (ES) + laparoscopic cholecystectomy (LC) group.

Age (years)	Immediate complications (%)	Immediate post-surgical mortality (%)	Long-term complications (%)	Long-term mortality (%)
Complications/mortality in ES + LC group				
<70 ^{27, 30, 39, 40}	4 (2-7)	0.2	5.8 (0.5-8)	0.7
70-79 ^{31, 39-46}	11 (10-14)	2.2	5.8 (0.5-8)	0.7
>80 ^{21, 31, 39, 40, 43-49}	17 (16-19)	4.25	5.8 (0.5-8)	0.7

TABLE 2

© 2006 The Authors. This is the authors' version prior to publication in *Alimentary Pharmacology & Therapeutics* 24(7):1059-1066, October 2006. The definitive version is available at [www.blackwell-synergy.com](http://dx.doi.org/10.1111/j.1365-2036.2006.03103.x) (<http://dx.doi.org/10.1111/j.1365-2036.2006.03103.x>) Journal compilation © 2006 Blackwell Publishing.

Decision analysis baseline values for endoscopic sphincterotomy (ES)-alone group.

Age (years)	Long-term complications (%)	Long-term mortality (%)
Complications/mortality in ES-alone group		
<70 ^{27, 30, 34, 41, 47, 50-54}	15 (5-24)	0.7
70-79 ^{7, 31-35, 38, 41, 42, 47, 50-55}	15 (11-20)	0.7
>80 ^{7, 31, 32, 34, 45, 38, 41, 47, 50-54}	15 (6-25)	0.7

TABLE 3
Decision model analysis results

Age (years)	ES success	ES mortality (%)	ES + LC success	ES + LC mortality (%)
<70	85	0.1	90	0.05
70-79	85	0.1	83	0.34
80+	86	0.1	78	0.76

FIGURE 1
Decision model tree used in our analysis.

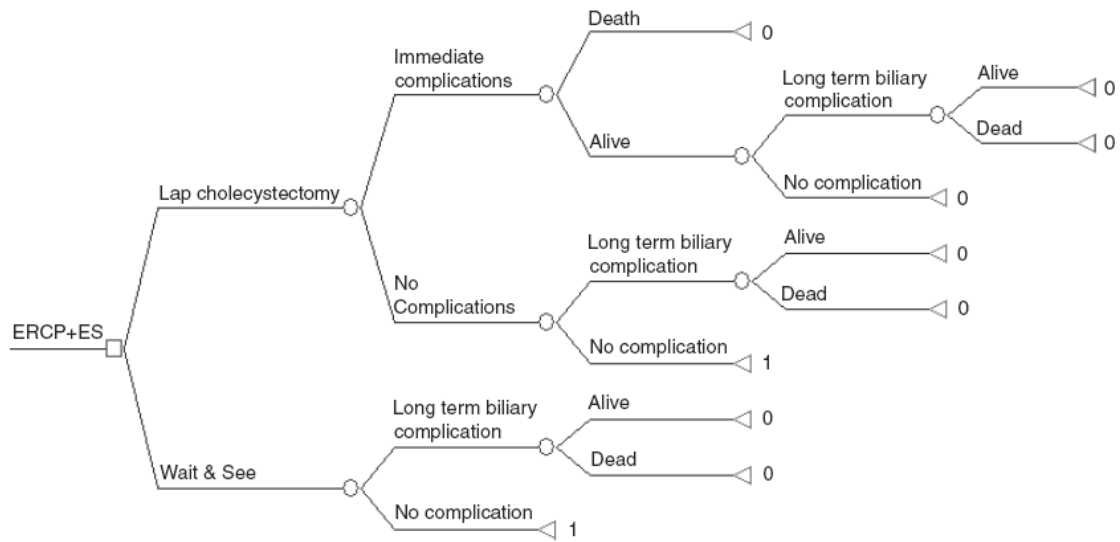


FIGURE 2

Results of sensitivity analysis showing a threshold surgical complication rate of 9.8%, above which ES was the dominant strategy.

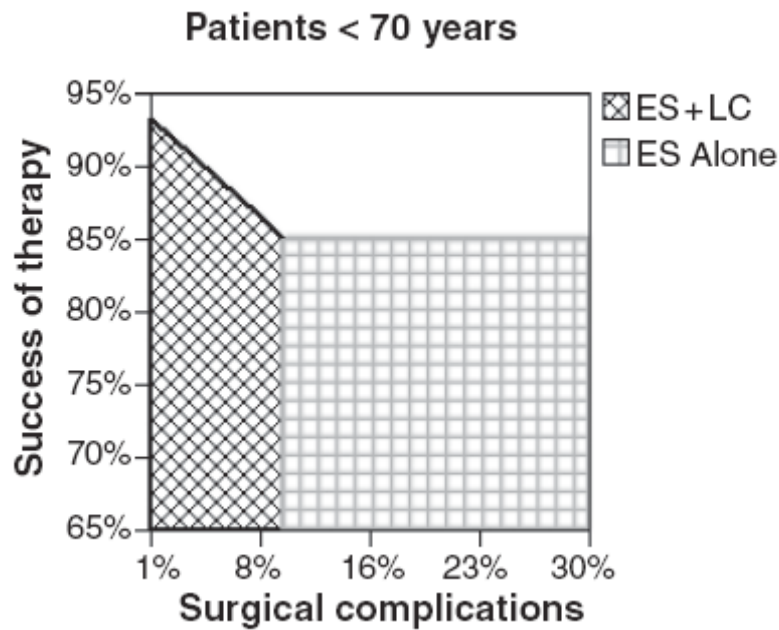


FIGURE 3
 Results of sensitivity analysis showing a threshold surgical complication rate of 10%, above which ES was the dominant strategy.

