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Watchful waiting versus elective repair for asymptomatic and minimally symptomatic paraesophageal hernias: A cost-effectiveness analysis

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A R T I C L E I N F O

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A B S T R A C T

Objective: To evaluate the decision of watchful waiting (WW) versus elective laparoscopic hernia repair (ELHR) for minimally symptomatic paraesophageal hernias (PEH) with respect to cost-effectiveness.
Background: The current recommendation for minimally symptomatic PEHs is watchful waiting. This standard is based on a decision analysis from 2002 that compared the two strategies on quality-adjusted life-years (QALYs). Since that time, the safety of ELHR has improved. A cost-effectiveness study for PEH repair has not been reported.
Methods: A Markov decision model was developed to compare the strategies of WW and ELHR for minimally symptomatic PEH. Input variables were estimated from published studies. Cost data was obtained from Medicare. Outcomes for the two strategies were cost and QALY's.
Results: ELHR was superior to the WW strategy in terms of quality of life, but it was more costly. The average cost for a patient in the ELHR arm was 11,771 dollars while for the WW arm it was 2207.
Conclusion: This study shows that WW and ELHR both have benefits in the management of minimally symptomatic paraesophageal hernias.

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Introduction

Prior to 2002, the standard of care for a paraesophageal hiatal hernia was surgical repair after diagnosis, irrespective of symptoms.[1–3] This decision was based on the reported high rates of progression to acute gastric volvulus, strangulation, bleeding, or obstruction.[2] However, in 2002, Stylopoulos et al. performed a decision analysis using a Markov model comparing elective laparoscopic hernia repair (ELHR) and watchful waiting (WW) for patients with asymptomatic or minimally symptomatic paraesophageal hernias (PEHs).[4] He found that WW was superior to elective repair for patients older than 65 years of age with a minimally symptomatic PEH. As a result, the pendulum swung in favor of WW for minimally asymptomatic PEHs.

Today, the management of asymptomatic and minimally symptomatic PEHs remains controversial, even among experts.[5] Although many paraesophageal hernias cause symptoms that are attributable to them on careful history taking, some may produce minimal symptoms. Minimal symptoms are those that are not bothersome to the patient, or are well controlled by non-surgical means such as antacid medications. Dietary modification can also be employed.

In his analysis, Stylopoulos found the mortality rate of ELHR and the annual probability of developing acute symptoms requiring emergency surgery with WW to be 1.4% and 1.1%, respectively.[4] Since 2002, the morbidity and mortality of elective PEH repair have decreased significantly. Over the last 15 years, a number of studies have been published that could change Stylopoulos's findings.[1,6,7] Spaniolas et al. analyzed two years of data (2010–2011) and looked specifically at elderly patients' risk.[6] They found that in the entire cohort there was a 0.5% mortality rate. Kaplan et al. also

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published PEH repair data from NSQIP for repairs performed between 2005 and 2012.[1] The mortality rate in their cohort was 0.65% for elective repair, and 5.5% for emergency repair.

Decreases in surgical morbidity and mortality may be due to improved healthcare systems in general, or due to an improvement in the results of laparoscopic PEH repair in particular. Furthermore, it is possible that the learning curve for this technically challenging operation was still occurring at the time of the Stylopoulos analysis. The current mortality rates for ELHR are close to those that may have changed the decision outcome in the Stylopoulos model. Another decision analysis was produced recently, however, that replicated these results.[8]

We hypothesized that the medical community may have reached the threshold for a change in the management strategy of minimally symptomatic PEHs, when cost was also considered. To test this hypothesis, we conducted a cost-effectiveness analysis using updated estimates of morbidity and mortality for elective PEH repair to more accurately characterize the outcomes of minimally symptomatic PEHs.

Methods

A comprehensive literature search was performed in PubMed, Web of Science, EMBASE, and regional databases on PEH and natural history of PEHs. Keywords included “paraesophageal hernia repair,” “risk,” “laparoscopic,” “quality of life,” and “outcomes.” Relevant studies in the English language were thoroughly reviewed. More recent studies utilizing large national data sets were favored when creating the base-case estimates. These studies were primarily reviewed by two authors (EM and JC) and the final base-case estimates for the model were chosen by EM.

Pooled estimates were calculated for elective and emergent surgical morbidity and mortality. These are the first four variables shown in Table 1. We estimated the probability of converting from WW to elective repair in the model based on the available data on symptom progression (13.87% annually). We also accounted for redo surgery in the case of symptomatic recurrence in this arm (0.9%). For emergent cases, we assumed that many patients would require placement in a skilled nursing facility after their hospitalization for ongoing rehabilitation. These costs were incorporated in the model.

Quality of life estimates were taken from the Stylopolous study.[4] These utility values were used to construct quality-adjusted life-years (QALYs), a metric commonly used in cost-effectiveness analyses that incorporates both the duration and quality of life in certain health states.

Cost data was obtained from Medicare data via the AHRQ website using ICD9 codes. The ICD9 codes we used included: 553.3 diaphragmatic hernia without mention of obstruction or gangrene, 553.9 recurrent, 551.3 gangrene, 552.3 obstructed, 537.89 obstruction/torsion of cardia/stomach, 536.1 acute. The median costs of elective repair from the National Inpatient Sample in 2013 was $11,018. For emergent repair the median costs was between $15,639–33,675 depending on the presence of obstruction alone or gangrene.[9] The cost of additional diagnostic tests for symptomatic states and complications were estimated based on expert opinion and Medicare data. The cost of SNF stay is approximately $10,000 based on published literature.[10]

Using TreeAge ™ software (TreeAge Software, Inc., Williamstown MA), a Markov model was developed to track a hypothetical cohort of patients with asymptomatic or minimally symptomatic PEHs managed either expectantly (i.e. WW) or with ELHR. The model was developed by one surgeon primarily (EM), with consultation with two other surgeons (RG, RN) and two experts in cost-effectiveness analysis (RN, RN). A bifurcated model was created (Fig. 1) for the two strategies above branching off of the decision node. The time horizon was 20 years, which in most cases should be equal to lifetime, since the average age of a patient with PEH is 61. The cycle length was one year. Standard discounting was applied at 3% for future costs and utilities. The analysis was performed from a payer perspective.

Pooled estimates as above were used as input variables. Variables with their base-case values and references are shown in Table 1. The parameters in this table determine the likelihood of hypothetical patients in our model transitioning to different health states in the model (probabilities), the quality of life in each health states (utilities), and costs. The Markov model included the following health states in the ELHR arm: death, immediate post-operative state, recurrent PEH, well post-surgery or symptomatic post-surgery. Potential health states for the hypothetical patient in the WW arm began with the minimally symptomatic state. In this state patients could have progression of symptoms and subsequent elective repair, or emergency repair. If they had surgery, their possible postoperative health states paralleled those in the ELHR arm.

Outcomes for the two strategies were cost and QALYs, which were combined to calculate an incremental cost-effectiveness ratio (ICER). One-way sensitivity analyses were performed for multiple variables. These were the variables for with the largest probability ranges, i.e. the lowest quality estimates available in the literature.

Table 1
Input parameters for the Markov model.

Variable name	Description	References	Base-case parameter value	Range for sensitivity analysis
ELSMR	Elective Laparoscopic surgery serious morbidity risk	Spaniolas[6]	4.1%	
ELSDR	Elective Laparoscopic Surgery Death Risk, all patients	Kaplan[1]	0.46%	
EMSMR	Emergent surgery morbidity risk	Kaplan[1]	21%	
EMSDR	Emergent Surgery Death Risk, overall	Kaplan[1]	5.5%	
ELSMRE	Elective Laparoscopic surgery serious morbidity risk in the elderly (age>80)	Spaniolas	5.8%	
ELSDRE	Elective Laparoscopic surgery mortality risk in the elderly (age>80)	Spaniolas	1%	
REC	Risk of recurrent symptomatic paraesophageal hernia	Lidor[11] Oelschlager[12] Stringham[13]	1/111 = 0.9%	0–30%
OBSR	Risk of obstruction and emergent surgery	Stylopoulos[4]	1.16% per year	.69–1.93%
PSXR	Risk of progressive symptoms, leading to elective repair	Treacy and Jamieson[14] Stylopoulos	Annual probability 13.87%	8.15–21.77%
QOLPR	Quality of life post-elective repair	Stylopoulos	(0.78)	
QOLPER	Quality of life post-emergent repair	Stylopoulos	(0.71)	.68–.74
QOLMSH	Quality of life with minimally symptomatic hernia	Stylopoulos	(0.78)	
QOLSH	Quality of life with symptomatic hernia	Stylopoulos	(0.72)	.64–.75

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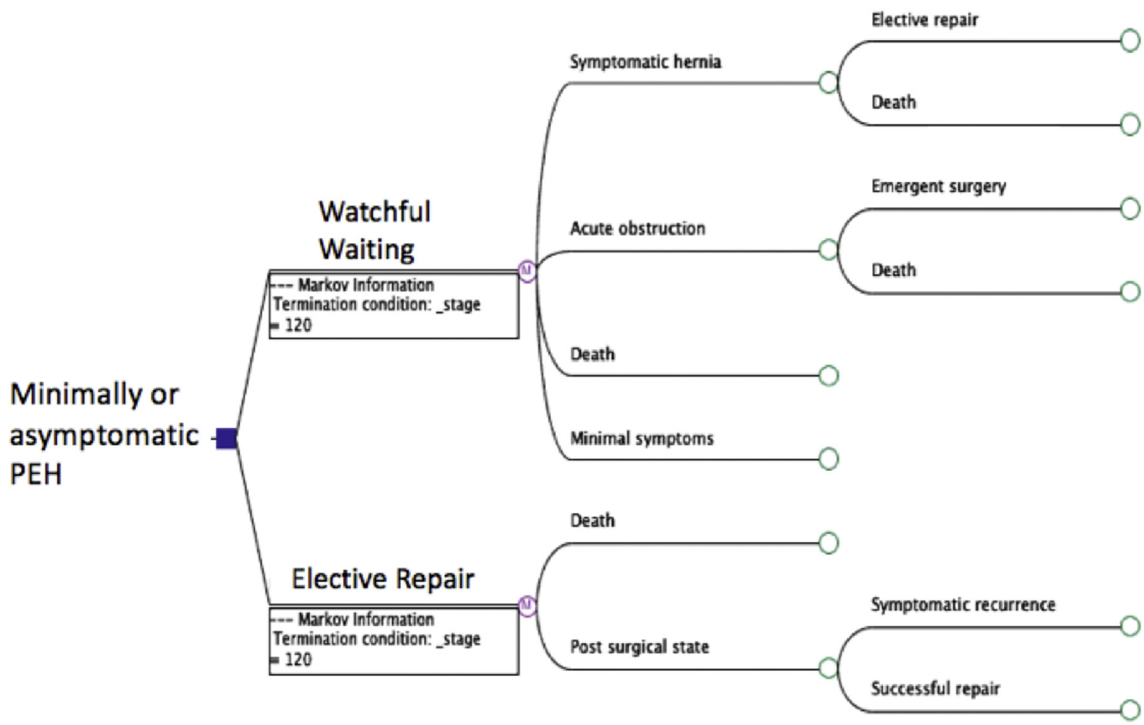

Fig. 1. Simplified Markov model produced in Tree Age ™.

Results

ELHR was superior to the WW strategy in terms of quality of life, but more expensive (Fig. 2). The average cost for a patient in the ELHR arm was $11,771 while for the WW arm it was $2207 (Table 2). The QALY's accrued were 13.0 for the WW arm and 14.3 for the ELHR arm. The ICER was $7303 per QALY. This is far below standard willingness-to-pay thresholds of $50,000 or $100,000 per QALY. Major costs accrued in the model were elective surgery (accrued in the initial postop health state in the elective surgery arm) and emergent surgery (accrued as a transition in the watchful waiting arm).

One-way sensitivity analyses were performed for the variables with the largest estimated ranges based on the literature, i.e. the most uncertainty in terms of natural history of disease. These were the risk of a recurrent symptomatic PEH and risk of progressive symptoms leading to elective repair (crossover) in the WW arm. These sensitivity analyses did not lead to a different result as the probability estimates were ranged. The ICER ranged from $5302 to $12,368 per QALY in these analyses.

Discussion

In this study we revisited the current standard of care for minimally symptomatic PEH. This standard was established in 2002 with the decision analysis by Stylopoulos et al. Their analysis showed that WW was the preferred approach. Since then, the morbidity and mortality of elective repair have been significantly reduced, actually to the threshold levels that they reported in their analysis. In reconstructing our own model, we showed that ELHR was the more effective strategy, although more costly. This study improves the existing literature by using modern rates of morbidity

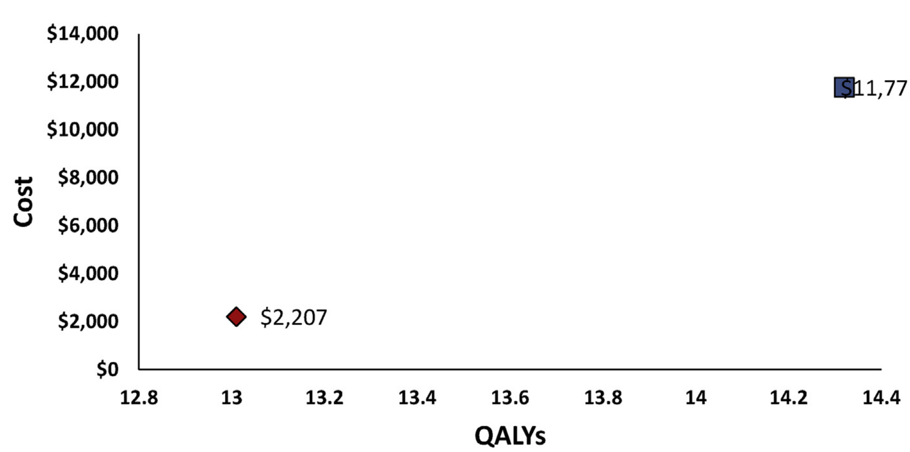

Fig. 2. The base-case cost-effectiveness plane for WW (diamond) and ELHR (square).

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Table 2
Results of Cost-Effectiveness analysis for WW and ELHR strategies.

Strategy	Cost	Effectiveness (QALYs)	Incremental Cost-Effectiveness Ratio
Watchful waiting	$2207	13.01	-
Elective repair	$11,771	14.32	$7303

and mortality for paraesophageal hernia repair, and by adding the dimension of cost.

This study has a different conclusion regarding quality of life for the two strategies as compared to another recent decision analysis by Jung et al.[8] The two types of models were performed in somewhat different ways, but many of the input values appear quite similar. One important difference in assumptions may have been regarding symptomatic recurrent hernias. In our study, we assumed that the rate of symptomatic recurrence was not well defined, and that many symptomatic hernias would progress to surgery. This is based on available estimates of reoperation from Lidor [11]and Oelschlager.[12] In the Jung study, they assumed that 55% of recurrent hernias are symptomatic. A recent study by Stringham and colleagues[13] also points to a higher rate of symptomatic recurrences; at one year postoperatively 71% of their patients were satisfied with their condition, although this was a relatively high-risk cohort. It may be, then, that our model underestimates the prevalence of symptoms after PEH repair. In sensitivity analysis, however, even when we ranged the rate of symptomatic recurrence to 30% annually, the overall result did not change.

The strengths of this type of analysis include the ability to simulate many person-years using probabilities published in the existing literature. This can aid in clinical decision making by providing data that would be prohibitive to obtain through an actual prospective trial. In using probabilities that have been published from national surgical databases, and costs from Medicare, this analysis should be broadly applicable to patients across the U.S.

The limitations of this analysis are that it relies on the available published data for probabilities, utilities and costs. Many of the estimates were taken from retrospective studies out of necessity. The available data on probabilities of progression of this disease in particular may not be reliable.[14] Patients who do not undergo surgery for this problem are not reliably captured by administrative data. It is, therefore, hard to know what the course of their disease is. Like other hernia types, it may be that the rationale for repair is more supported by the rate of progression of symptoms, rather than the need for emergent repair, but this rate of progression is not well defined.

In addition, quality of life data or utilities may not be accurate. They have been estimated in this study from previous literature based on other disease processes, but are not well defined specifically for PEH. There are specific quality of life data available for PEH, but they have not yet been converted to utilities. We were not able to obtain the raw data necessary to perform these conversions.

There are undoubtedly costs that have not been captured in this analysis. For example, emergency department visits for both non-operatively managed patients as well as post-operative patients are not captured here. Some costs have been estimated, such as the cost of complications and skilled nursing facility stays, as well as preoperative testing. In addition, while medicare cost data were the best available estimates for this study, they may not accurately reflect the actual cost of care.

This study shows that both strategies of watchful waiting and elective repair have benefits for minimally symptomatic paraesophageal hernias. While elective repair produced more QALYs in our model, it was the more costly strategy. Physicians and patients should feel comfortable choosing either strategy on an individualized basis, since they both offer benefits. Patients' individual priorities and health status should be considered when choosing the most appropriate strategy for management of a minimally symptomatic paraesophageal hernia.

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