ANNALS OF SURGERY
Vol. 236, No. 4, 492–501

Paraesophageal Hernias: Operation or Observation?

Nicholas Stylopoulos, MD,* G. Scott Gazelle, MD, MPH, PhD,*†‡ and David W. Rattner, MD*†

*From the *Massachusetts General Hospital, †Harvard Medical School, and ‡Harvard School of Public Health, Boston, Massachusetts*

Objective
To examine the hypothesis that elective laparoscopic repair should be routinely performed on patients with asymptomatic or minimally symptomatic paraesophageal hernias.

Summary Background Data
The management of asymptomatic paraesophageal hernias is a controversial issue. Most surgeons believe that all paraesophageal hernias should be corrected electively on diagnosis, irrespective of symptoms, to prevent the development of complications and avoid the risk of emergency surgery.

Methods
A Markov Monte Carlo decision analytic model was developed to track a hypothetical cohort of patients with asymptomatic or minimally symptomatic paraesophageal hernia and reflect the possible clinical outcomes associated with two treatment strategies: elective laparoscopic paraesophageal hernia repair (ELHR) or watchful waiting (WW). The input variables for ELHR were estimated from a pooled analysis of 20 published studies, while those for WW and emergency surgery were derived from the 1997 HCUP-NIS database and surgical literature published from 1964 to 2000. Outcomes for the two strategies were expressed in quality-adjusted life-years (QALYs).

Results
Analysis of the HCUP-NIS database showed that published studies overestimate the mortality of emergency surgery (17% vs. 5.4%). The mortality rate of ELHR was 1.4%. The annual probability of developing acute symptoms requiring emergency surgery with the WW strategy was 1.1%. For patients 65 years of age, ELHR resulted in reduction of 0.13 QALYs (10.78 vs. 10.65) compared with WW. The model predicted that WW was the optimal treatment strategy in 83% of patients and ELHR in the remaining 17%. The model was sensitive only to alterations of the mortality rates of ELHR and emergency surgery.

Conclusions
If ELHR is routinely recommended, it would be more beneficial than WW in fewer than one of five patients. WW is a reasonable alternative for the initial management of patients with asymptomatic or minimally symptomatic paraesophageal hernias, and even if an emergency operation is required, the burden of the procedure is not as severe as was thought in the past.

The need for surgical correction of asymptomatic paraesophageal hernias is controversial. Many surgeons, citing the influential studies of Belsey[1] and Hill,[2] advocate elective repair of all paraesophageal hernias irrespective of symptoms. The rationale for this approach is prophylactic; that is, prevention of life-threatening complications such as obstruction and strangulation and avoidance of the significant morbidity and mortality of an emergency operation. The perception that laparoscopic techniques offer a less morbid approach to surgical correction of paraesophageal hernias is cited as an additional reason to support the elective repair of paraesophageal hernias. However, beliefs held by the surgical community about the natural history of paraesophageal hernias and the morbidity and mortality of both elective and emergency operations are based on relatively small patient series and anecdotal case reports. Several recent reports suggest that the incidence of catastrophic

Presented at the 122nd Annual Meeting of the American Surgical Association, April 24–27, 2002, The Homestead, Hot Springs, Virginia.
Correspondence: David W. Rattner, MD, Chief, Division of General and Gastrointestinal Surgery, Massachusetts General Hospital, 55 Fruit Street, Boston, MA 02114.
E-mail: drattner@partners.org
Accepted for publication April 24, 2002.

DOI: 10.1097/01.SLA.0000029000.06861.17

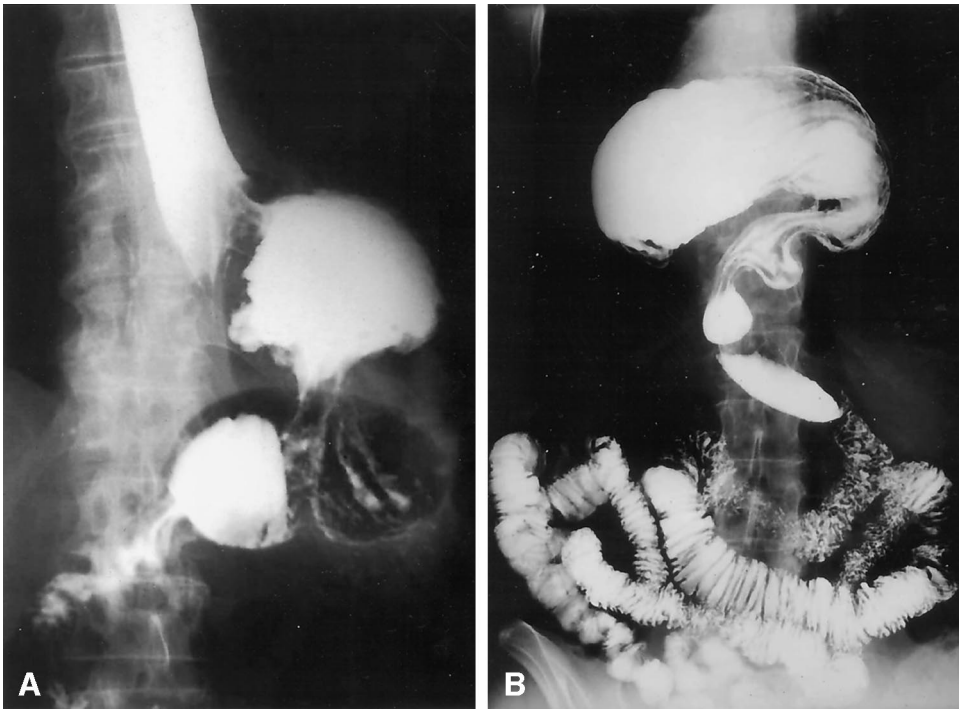

Figure 1. (A) Barium swallow of a type III hiatal hernia with narrowing in the midbody of the stomach as the stomach passes through the hiatus. (B) Barium swallow of a large type III hiatal hernia showing organoaxial volvulus.

complications is less than was previously thought and have argued against elective treatment of asymptomatic paraesophageal hernias.[3,4] In the current study a comprehensive search of the literature and large administrative databases was undertaken, and data from all the available sources were incorporated into a decision analytic model. Using this model, we examined the hypothesis that elective laparoscopic repair should be routinely recommended for patients with asymptomatic or minimally symptomatic paraesophageal hernias.

METHODS

A Markov Monte Carlo decision analytic model[5–7] was developed using DATA 4.0 software (Treeage Software Inc., Williamstown, MA). The model tracks a hypothetical cohort of patients with asymptomatic or minimally symptomatic paraesophageal hernia and reflects the possible clinical outcomes associated with two treatment strategies: elective laparoscopic paraesophageal hernia repair (ELHR) or watchful waiting (WW). Each cycle in the model represents 1 month, and the cohort is followed until all patients have died. The estimates for input variables were based on both the literature and large administrative databases. Employing the Wilson procedure[8] with a correction for continuity, the 95% confidence interval around each probability estimate was calculated, to represent a plausible range of values for the sensitivity analysis.

For this study, paraesophageal hernias were defined as type II and type III hiatal hernias (Fig. 1). From a decision analysis standpoint, minimal symptoms include those symptoms that do not affect the quality of life of a patient. Symptoms such as belching and heartburn were considered minimal symptoms. Severe symptoms were dysphagia, early satiety, postprandial pain, and vomiting. Acute symptoms reflect complete esophageal or gastric obstruction or strangulation of the hiatal hernia. Surgical complications were classified using the grading system proposed by Clavien et al.[9] (Appendix A).

Structure of the Model

Elective Laparoscopic Hernia Repair

Initially, all patients enter the surgery state (Fig. 2). The operation has three immediate outcomes: uneventful recovery, surgical morbidity, and surgical mortality. The postoperative period can be further complicated by the development of persistent symptoms due to the procedure that were not present before the operation (new surgery-related symptoms, see Appendix A). At the end of the first cycle patients in the cohort may die due to age- and sex-related factors, they have hernia recurrence, or they may remain well. Since most of the recurrences are asymptomatic and apparent only on radiographic examinations, it is assumed that patients with recurrence choose not to have another elective operation. The patients then enter the "postsurgery with recurrence" health state, and they remain in this state for the ensuing cycles unless they die or develop symptoms related to hernia recurrence. Similarly, patients without recurrence enter the "postsurgery without recurrence" state, and they remain in this state unless they die or they develop a recurrence.

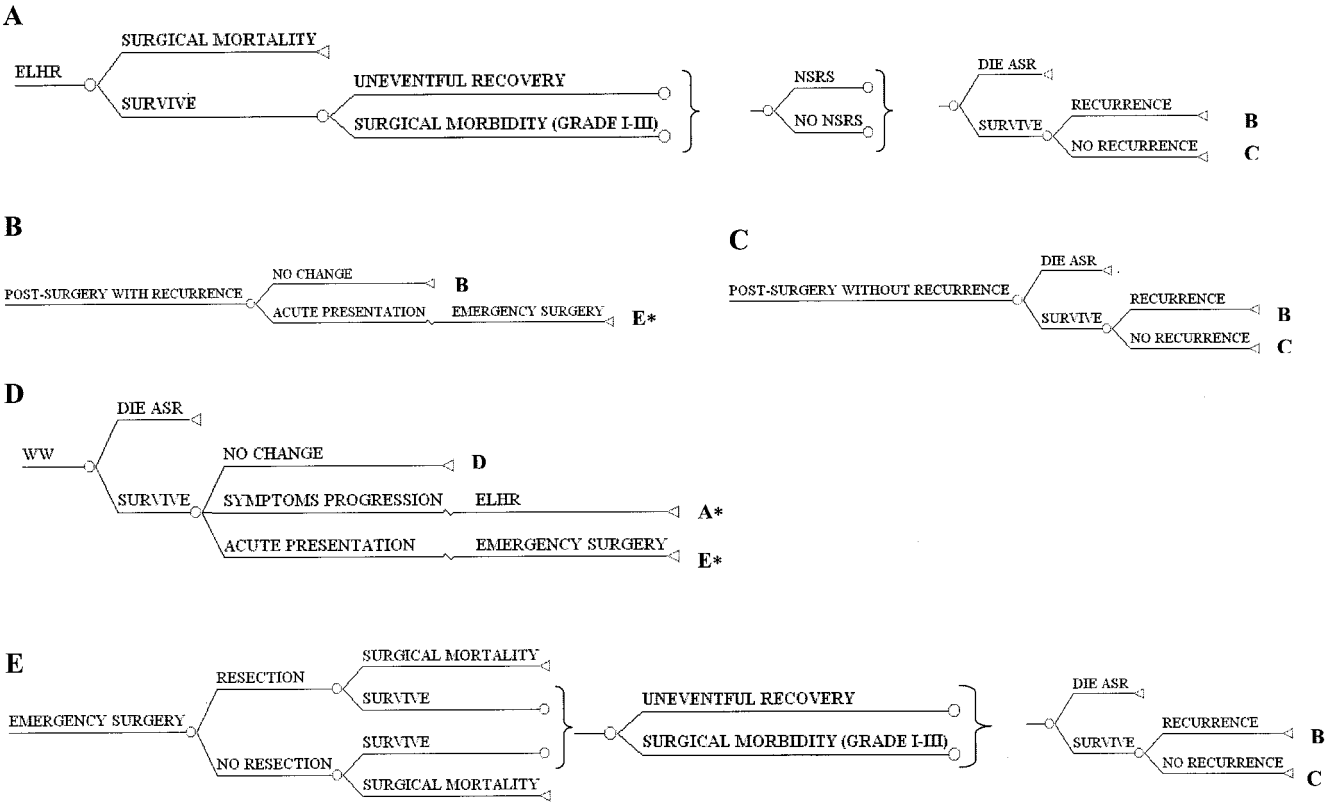

Figure 2. Simplified decision analytic tree for the two treatment strategies: elective laparoscopic hernia repair (ELHR) and watchful waiting (WW). The transitions that are allowed each monthly cycle are shown. ASR Mortality, age- and sex-related mortality. *These transitions occur within the same cycle.

The input variables for elective laparoscopic repair were estimated from a pooled analysis of the published studies reporting results on at least 10 patients.

Watchful Waiting

Initially, all patients enter the WW state (see Fig. 2). A proportion of the cohort, which is determined by the age- and sex-related mortality rate, will die, while three events are allowed to occur for survivors during each cycle they spend in this state. Patients may develop progressive symptoms and ultimately choose to have an elective laparoscopic hernia repair or they may present with acute symptoms that require emergency intervention. If neither of these events occurs, the patients reenter the WW state and the next cycle begins. Emergency surgery is performed through an open approach and may consist of hernia reduction with or without a standard antireflux procedure or may be a more extensive operation (organ resection such as esophagogastrectomy or bowel resection is necessary in 6.4% of cases). The outcomes of an emergency procedure are modeled in a way similar to elective laparoscopic repair. The patients who undergo organ resection are not allowed to develop hernia recurrence in this model.

A comprehensive review of the literature was performed to estimate the probabilities of symptom progression and development of acute symptoms. The input variables for emergency surgery were based on the most recent available data (1997) of the Nationwide Inpatient Sample (NIS) of the Healthcare Cost and Utilization Project (HCUP). This powerful database developed by the Agency of Healthcare Research and Quality (AHRQ) contains information on all inpatient stays (totaling 7,148,420 records in 1997) from over 1,000 hospitals.[10] All patients over 18 years old whose primary diagnosis was coded as ICD-9-CM 552.3 (diaphragmatic hernia with obstruction-hiatal [esophageal] specified as incarcerated, irreducible, strangulated, or causing obstruction-thoracic stomach specified as incarcerated, irreducible, strangulated, or causing obstruction) were included in the analysis. Each individual record was examined and was included in the analysis only if the diagnosis was certain and the patient had an emergency operation. A total of 203 (national weighted estimate for the year 1997, 1,035 patients) emergency hiatal hernia repairs were included in the final analysis.

Data Analysis and Outcome Measures

The endpoints of this study include the probabilities of the important clinical events, which are associated with the two treatment arms under study. These probabilities, as

stated above, are derived from the pooled analysis of the published studies and the NIS-HCUP database. These outcome measures are used as input variables for the Markov Monte Carlo model and are incorporated in the simulation. The simulation ultimately calculates the average quality-adjusted life expectancy of the cohort in quality-adjusted life-years (QALYs). Finally, a sensitivity analysis was performed to assess the robustness of the assumptions used in the model.

Utilities, Quality-of-Life Adjustments, and Risk of Death From Other Causes

No studies have reported utility measures specific to paraesophageal hernia. The available data in the literature, however, allow reliable estimation of the quality-of-life weights for the various health states modeled in the study.[11–17] The details of QALY computations are presented in Appendix B. The age- and sex-related mortality was calculated from standard tables. In addition to age- and sex-adjusted all-cause mortality, the patients with grade III complications were exposed to excess mortality associated with their permanent morbidities. This excess mortality was estimated to be 2% (0%–7%).[18]

RESULTS

Surgical Mortality and Morbidity

Elective Laparoscopic Hernia Repair

Among 21 studies included in the pooled analysis, the mortality rate varied from 0% to 5.2%, with a mean of 1.38%.[19–39] Seventeen studies reported detailed data on postoperative complications. Based on these studies the probability estimates for the different classes of complications were grade I, 8.41% (6.07–11.50%); grade II, 12.42% (9.98–15.34%); grade III, 1.94% (1.13–3.25%); and new surgery-related symptoms, 7.51% (5.33–10.43%).

Emergency Surgery

The analysis of the 1997 NIS database showed that the mortality rate of emergency surgery was 5.4% (CI 4.9–5.8%). This is in contrast to the high mortality rates reported in published series. A pooled analysis of six studies reporting results on at least 10 patients who underwent emergency operation showed a mortality rate of 17% (range 0–40%).[40–45] In Postlethwait's review of the literature published in 1985 a similar mortality rate of 16.9% was identified.[46] Therefore, the value of 17% was used as the upper boundary in the sensitivity analysis. The analysis of the individual records of the 1997 NIS database allowed a thorough classification of the postoperative complications. Only 27.6% of patients who underwent emergency surgery had an uneventful recovery. Organ resection was necessary in 6.4% of patients. The probability estimates for the different classes of complications of emergency surgery were grade I, 32.32% (25.84–39.47%); grade II, 25.51% (19.64–32.4%); and grade III, 3.63% (2.82–5.13%).

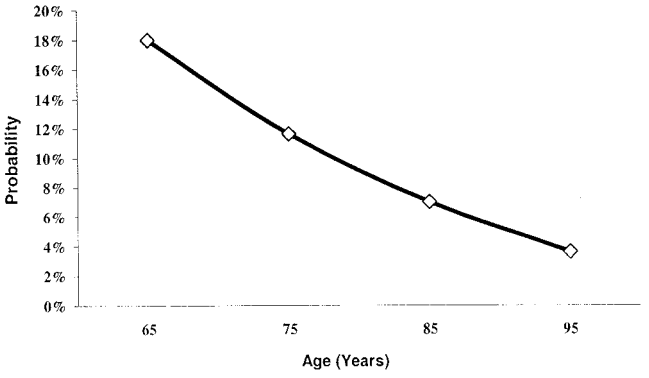

Figure 3. Lifetime risk of developing acute symptoms requiring emergency surgery. The risk decreases significantly as the age of the patient increases.

Watchful Waiting: Progression of Symptoms

There are only a few studies in the literature that provide information regarding the natural course of untreated paraesophageal hernias, and there is only one study with usable statistical data. Treacy and Jamieson[47] conservatively managed 29 patients with paraesophageal hernia. In a follow-up of approximately 87 patient-years, 13 patients required elective operation because of the development of severe symptoms. Assuming a constant hazard rate, the annual probability of symptom progression is estimated to be 13.87% (8.15–21.77%).

Watchful Waiting: Development of Acute Symptoms Requiring Emergency Surgery

The probability of developing acute symptoms requiring emergency surgery was estimated from a pooled analysis of five studies.[3,24,28,48,49] In these studies the authors reported the exact interval for which the hernia had been known to be present before the surgical repair. The highest rate was 7/100 patients per year, reported by Hallisey et al.[48] (approximately 58 patient-years follow-up). Allen et al.[3] reported the longest follow-up in the literature (735 patient-years) and found an incidence rate of 7/1,000 patients per year, 10 times lower than the rate reported by Hallisey et al. Based on these five studies, the pooled annual probability of developing acute symptoms requiring emergency surgery was estimated to be 1.16% per year, ranging from 0.69% to 1.93%. As shown in Figure 3, the lifetime risk of developing acute symptoms is 18% for a 65-year-old patient and decreases exponentially as the patient's age increases.

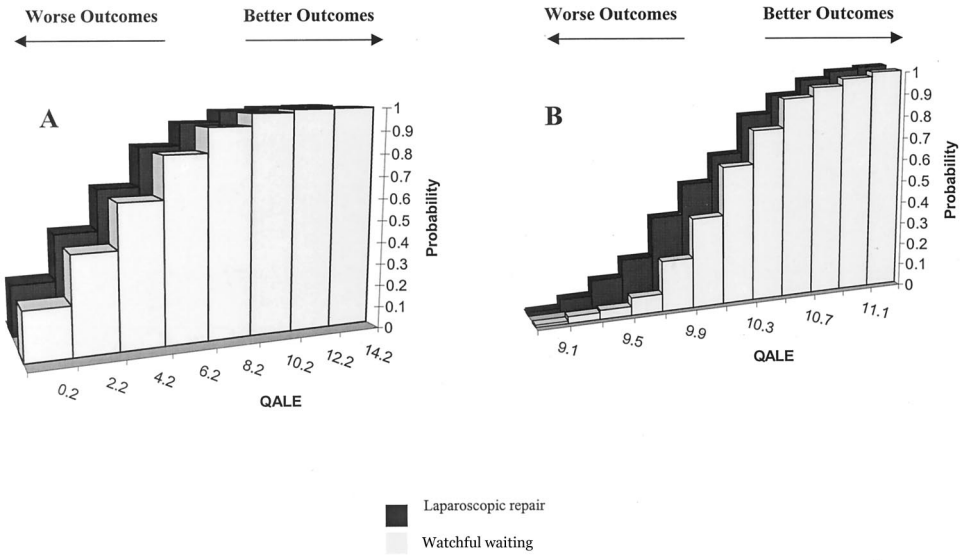

Figure 4. (A) First-order Monte Carlo simulation, distribution of outcomes graph. Watchful waiting (WW) stochastically dominates elective laparoscopic hernia repair (ELHR). For each individual patient and for any value of quality-adjusted life expectancy (QALE) there is a higher chance to get a higher value with WW than with ELHR. For example, for WW there is a 60% chance of getting a QALE of 4.2 years. This means that there is a 100% - 60% = 40% chance of having a QALE value higher than 4.2. With ELHR the chance of having a QALE of 4.2 or less is 70%, meaning that there is only a 30% chance of getting a higher value. This discrepancy is true for any QALE value. (B) Second-order Monte Carlo simulation, distribution sampling: distribution of outcomes graph. For the total number of patients in the cohort and for any value of QALE there is a higher chance to get a higher mean value with WW than with ELHR. For example, for WW there is an 80% chance of getting a mean QALE higher than 9.9 years. With ELHR the chance of having a mean QALE higher than 9.9 years is only 45%.

Recurrence Rate Following Paraesophageal Hernia Repair

Studies with follow-up of more than 5 years are available only for open paraesophageal hernia repair. The published rates of anatomical recurrence for the open repair range between 1/18 patient-years to 1/351 patient-years (pooled estimate 1/52 patient-years).[50–55] Based on these recurrence rates, the annual probability of hernia recurrence was estimated to be 1.9% (0.28–5.4%). The recurrence rate of laparoscopic hernia repair remains unknown and long-term follow-up is not available yet. Additionally, only few reports contain objective radiologic follow-up. One study reported a recurrence rate of 41% (1/4 patient-years),[50] while others reported no recurrence after a follow-up of 21 patient-years.[34] Many authors have stated that the failure rate of repair is the same whether an open or laparoscopic approach is used,[56] and in this model we assumed that the annual probability of recurrence following a laparoscopic repair is 1.9% (0.28–5.4%), the same as in the open hernia repair.

Markov Monte Carlo Model: Quality-Adjusted Life Expectancy

In the base case scenario we examined the impact of the two treatment strategies on the quality-adjusted life expectancy of a hypothetical cohort of 5 million patients aged 65 years old with asymptomatic or minimally symptomatic paraesophageal hernia. The Monte Carlo simulation showed that in this group of patients there is no gain in quality-adjusted life expectancy with ELHR compared to WW. Indeed, ELHR resulted in a reduction of 0.13 QALYs (10.78 vs. 10.65). The risk profiles (probability distributions) of the two treatment strategies are shown in Figure 4. The cumulative risk profile of the WW strategy lies entirely to the right of the corresponding profile of the ELHR treatment arm, demonstrating the presence of first-order stochastic dominance of WW over ELHR.

The model predicts that WW is the optimal treatment strategy in 83% of the patients and ELHR in the remaining 17%. Thus, if laparoscopic repair is recommended routinely to patients with asymptomatic or minimally symptomatic paraesophageal hernias, fewer than one of five 65-year-old patients will benefit more than if WW had been chosen. The difference in the quality-adjusted life expectancy between the two treatment strategies is more pronounced as the age of the patient increases, and according to this model only 1 out of 10 85-year-old patients will benefit from ELHR.

The baseline assumptions of the model were tested in a sensitivity analysis by altering the values of input variables and assessing the impact on the results of the base case scenario. The sensitivity analysis was performed on 24

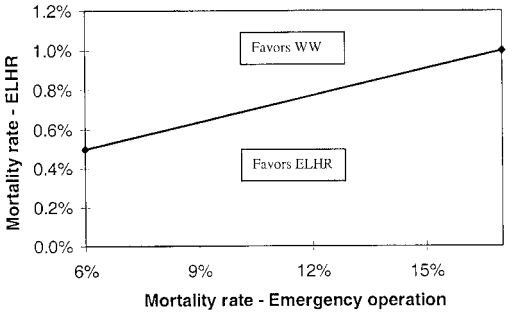

Figure 5. Two-way sensitivity analysis performed by varying the mortality rate of elective laparoscopic hernia repair (ELHR) and emergency operation. Each area represents a combination of mortality rates at which either ELHR or watchful waiting (WW) is the optimal treatment option.

variables (total of probability and utility estimates incorporated in the model). The model was sensitive only to alterations in the mortality rates of the elective and emergency operations (Fig. 5). At the highest value for the mortality rate of emergency surgery (17%), ELHR becomes the optimal treatment, only if the mortality rate for laparoscopic repair is less than 1%. At the lowest value for the mortality rate of emergency surgery (6%), the mortality rate of laparoscopic repair should not exceed 0.5% in order for ELHR to be the optimal treatment option. The alteration of the other important parameters, including the probability of developing acute symptoms, the probability of symptoms progression, the morbidity and recurrence of both ELHR and emergency surgery, and the quality-of-life adjustments did not alter the results of the base case analysis.

DISCUSSION

The majority of published reports suggest that all paraesophageal hernias in good-risk surgical patients should be repaired to prevent the development of potentially life-threatening complications.[19,21,25,28,30,37,42,48,50,56] The capability to perform these repairs laparoscopically with less pain and a more rapid recovery has provided further impetus to those favoring an aggressive surgical approach.[19,28] However, several prominent surgeons have favored a more conservative approach.[3,4,29,38,47] Furthermore, there is growing appreciation that laparoscopic repair of large type III hiatal hernias can be a difficult operation that is associated with a high rate of hernia recurrence as well as other complications, such as vagal nerve injury. Hence, more experience, longer follow-up, and further refinement of the operative technique is indicated before laparoscopic repair of large hiatal hernias can be recommended as the standard approach.[23,38]

The results of the current study do not support the hypothesis that ELHR should be routinely performed on all patients with asymptomatic or minimally symptomatic paraesophageal hernias. The decision analytic model used in this study demonstrated that routine use of ELHR may actually decrease the quality-adjusted life expectancy for patients aged 65 and older. The assessment of the outcomes in symptomatic or other subsets of patients was not in the scope of this report, and these issues will be addressed and evaluated in a future study. The strengths of the current analysis include the large number of patients included and the lifelong time horizon. Most importantly, the values of the input variables were based on recent data derived from a large administrative database and a systematic review of the literature. However, like all models, there are limitations that must be acknowledged. Any working decision model is based on simplifying assumptions, which undoubtedly do not capture all the subtleties of clinical practices. For the probability of hernia recurrence, a constant hazard rate was assumed, since precise estimates of time-dependent long-term failure rates following either open or laparoscopic hernia repairs do not exist. We also assumed that the recurrence rate following ELHR was the same as after open surgery, that most patients with hernia recurrence following surgery were asymptomatic, and that patients with new surgery-related symptoms had quality-of-life scores similar to patients with gastroesophageal reflux and/or achalasia. If these assumptions are changed, the results of the Markov Monte Carlo model may change as well. Another limitation is the fact that the probability estimates for the ELHR are based on retrospective reports, since there are no prospective randomized studies. Unfortunately, there is only one study with usable statistical data that provides information about the annual probability of symptom progression in patients who are managed conservatively.[47] For that reason, this probability was tested in the sensitivity analysis over a wide range of values (8.15–21.77% per year). Within this range of values, the results of the base case scenario do not change, and WW remains superior to ELHR.

While the assumptions used in the model may be questioned, certain facts are apparent that should influence current thinking about the decision to operate on patients with minimally symptomatic paraesophageal hernias. One of the most important findings of our study is that the mortality rate of the emergency paraesophageal hernia repair has been greatly overestimated. Some authors have stated that the mortality rate of emergency surgery is more than 40% or in some cases even 100%.[2,48] The estimated mortality rate of the pooled data available in the literature is 17%. This estimate is based on a relatively small number of patients, since most surgeons do not accumulate a large experience operating urgently on patients with paraesophageal hernias. Indeed, since 1966 there have been only six studies reporting data on 10 or more patients undergoing emergency paraesophageal hernia repair. These reports include 88 patients, and only two of the reports were published after 1990. The analysis of the 1997 NIS-HCUP database provides an updated and more reliable estimate of the mortality rate of the emergency operation. The estimated mortality rate of 5.4% is the nationwide estimate in the United States for the year 1997, based on 203 patients (nationwide esti-

mate 1,035), derived from 1,000 hospitals in 22 states. This represents 20% of a stratified sample of U.S. community hospitals.

Another very important finding is that a patient's risk of needing emergency surgery is much lower than previously believed. The natural history of untreated paraesophageal hernias has been poorly understood. Hill's study[2] is one of the most-cited reports by the advocates of early elective intervention. Hill reported that "incarceration developed in ten of twenty-nine patients with paraesophageal hernia, an incidence of 30.4%." In this study, however, the term "incidence" is misused, since the denominator does not include any information regarding the time period over which the acute symptoms developed in each patient. Instead, 30% is the prevalence of incarceration in this particular series. This is very important, since Hill also stated, "It is striking that the patients had been known to have hiatal hernia for up to twenty years before surgery." Thus, it is evident that the true incidence that should be used to calculate the actual probability of developing acute symptoms is substantially less than 30.4%.

If the incidence rate of symptom progression is constant, the lifetime risk of developing acute symptoms is age-dependent (and can be calculated using the formula: Lifetime risk = 1 - (1 - rate)$^{\text{Life Expectancy}}$. According to our study, the risk of developing life-threatening symptoms is 18% for a 65-year-old patient (rate = 1.1% per year, life expectancy = 17.7 years). Therefore, if the mortality rate of emergency surgery is 5.4%, the overall lifetime risk of death due to paraesophageal hernia in a patient managed by WW is approximately 1% (i.e., 18% risk of developing acute symptoms times 5.4% mortality rate of emergency surgery). If the same patient chooses to undergo an elective laparoscopic repair, he or she is immediately exposed to the risk of surgical death associated with the laparoscopic repair, which is very similar (pooled estimate 1.38%). While the risks of WW approximate the risks of ELHR, clinical decisions must consider much more than just mortality rates. If, however, an emergency procedure is necessary, it is important to bear in mind that the burden on the patient is not as severe as it was thought to be in the past. Additionally, data from the NIS database demonstrate that when emergency surgery is required, the operative procedure is similar to that which would be chosen for an elective operation 93% of the time (i.e., hiatal hernia repair with or without gastropexy). Nevertheless, elective laparoscopic hernia repair is clearly associated with lower morbidity than emergency surgery. Additionally, the likelihood of developing class II and III complications following an emergency operation increases with the age of the patient.

This study demonstrates that currently available data from both the surgical literature and the NIS national database do not support routine elective repair of asymptomatic paraesophageal hernias. A carefully constructed Markov Monte Carlo decision analytic model shows that prophylactic surgery to prevent future complications of a paraesophageal hernia would be more beneficial than WW in only one of five 65-year-old patients. Since progression of symptoms is slow and seldom leads to emergency surgery, WW is the preferred approach for patients with large but relatively asymptomatic paraesophageal hernias. Surgery should be performed for those patients with symptoms of gastric outlet obstruction as well as those with complications of gastroesophageal reflux disease.

APPENDIX

Appendix A

The grading system for surgical complications proposed by Clavien et al.[9]:

Grade I

Non-life-threatening alterations from the ideal postoperative course, with no residual disability, never associated with hospital stay greater than twice the median stay for the procedure (e.g., dysphagia resolved spontaneously, UTI).

Grade II

Potentially life-threatening complications or complications that result in a hospital stay greater than twice the median stay for the procedure. They do not result in residual disability or organ resection (e.g., ARDS, reoperation for early herniation, dysphagia requiring reoperation or dilatation).

Grade III

Complications with residual disability including organ resection or persistence of life-threatening conditions (e.g., acute myocardial infarction, stroke, deep venous thrombosis with or without pulmonary embolism).

All persistent symptoms that developed after surgery and had an impact on the quality of life were classified as new surgery-related symptoms. Patients in this category complained mainly of persistent dysphagia, diarrhea, or symptoms attributable to gastroesophageal reflux.

Appendix B

The Quality of Well Being (QWB) index was used for QALY computations.[11] QWB index ranges from 1.0 (asymptomatic optimum function) to 0.0 (death). Quality-of-life (QOL) weights for patients without hernia were based on the mean of the QWB scores of persons without a medical condition reported in the Beaver Dam Health Outcomes Study (BDHOS) (0.78 for a 65-year-old patient).[12] The patients in the hypothetical cohort are asymptomatic or have minimal symptoms; hence their QOL weight was assumed to be equal to that of patients without hernia (0.78). In the sensitivity analysis, a low boundary was used, corresponding to the upper limit of the utility of the patients with gastroesophageal reflux symptoms (0.75). Similar QOL adjustments were applied to patients with recurrent

paraesophageal hernia. The utilities for patients with postoperative persistent life-threatening conditions (grade III) were also derived from the BDHOS (QOL 0.64 [0.60–0.73]).[12] A quality adjustment factor was assigned to patients whose operation involved esophagectomy and total or partial gastrectomy, based on the study of Young et al. from the Mayo Clinic (QOL 0.71 [0.68–0.74]).[13,14] Patients with new surgery-related symptoms (NSRS) usually complain of heartburn or dysphagia and require chronic drug use. The utility of NSRS state was derived from two studies that reported QOL weights for patients with gastroesophageal reflux disease and achalasia (0.72 [0.64–0.75]).[15,16] According to the time required for recovery, a disutility was assigned to each of the various short-term postoperative health states. The utilities and the total QOL weight for each year a patient undergoes an operation was calculated using the formula: Utility = {[(365 − D)/365] × UHS} + (D × 0.30)/365, where D = the number of days a patient is required to spend in a postoperative state, UHS = the utility of the chronic health state at which the patient is going to return, and 0.30 = the adjustment weight[17] for the diminished QOL during the short-term postoperative states.

The disutilities (D × 0.30) for the short-term postoperative states used in the model are uneventful recovery: ELHR 0.038 (0.019–0.057), emergency surgery 0.057 (0.038–0.077); grade I complications: ELHR and emergency surgery 0.077 (0.057–0.115); grade II and III complications: ELHR and emergency surgery 0.164 (0.115–0.246).

References

1. Skinner DB, Belsey RH. Surgical management of esophageal reflux and hiatus hernia. Long-term results with 1,030 patients. J Thorac Cardiovasc Surg 1967; 53:33–54.
2. Hill LD. Incarcerated paraesophageal hernia. A surgical emergency. Am J Surg 1973; 126:286–291.
3. Allen MS, Trastek VF, Deschamps C, et al. Intrathoracic stomach. Presentation and results of operation. J Thorac Cardiovasc Surg 1993; 105:253–259.
4. Floch NR. Paraesophageal hernias: current concepts. J Clin Gastroenterol 1999; 29:6–7.
5. Beck JR, Pauker SG. The Markov process in medical prognosis. Med Decis Making 1983; 3:419–458.
6. Sonnenberg FA, Beck JR. Markov models in medical decision making: a practical guide. Med Decis Making 1993; 13:322–338.
7. Halpern EF, Weinstein MC, Hunink MG, et al. Representing both first- and second-order uncertainties by Monte Carlo simulation for groups of patients. Med Decis Making 2000; 20:314–322.
8. Newcombe RG. Two-sided confidence intervals for the single proportion: comparison of seven methods. Stat Med 1998; 17:857–872.
9. Clavien PA, Sanabria JR, Strasberg SM. Proposed classification of complications of surgery with examples of utility in cholecystectomy. Surgery 1992; 111:518–526.
10. Healthcare Cost, Utilization Project. Nationwide Inpatient Sample (NIS) Release 6 [CD-ROM]. Rockville, MD: Agency for Healthcare Research and Quality, 1997.
11. Petiti DB. Meta-Analysis Decision Analysis, Cost-Effectiveness Analysis. Methods for Quantitative Synthesis in Medicine, 2nd ed. New York: Oxford University Press, 2000.
12. Fryback DG, Dasbach EJ, Klein R, et al. The Beaver Dam Health Outcomes Study: initial catalog of health-state quality factors. Med Decis Making 1993; 13:89–102.
13. Young MM, Deschamps C, Allen MS, et al. Esophageal reconstruction for benign disease: self-assessment of functional outcome and quality of life. Ann Thorac Surg 2000; 70:1799–1802.
14. Fryback DG, Lawrence WF, Martin PA, et al. Predicting Quality of Well-Being scores from the SF-36: results from the Beaver Dam Health Outcomes Study. Med Decis Making 1997; 17:1–9.
15. Urbach DR, Hansen PD, Khajanchee YS, et al. A decision analysis of the optimal initial approach to achalasia: laparoscopic Heller myotomy with partial fundoplication, thoracoscopic Heller myotomy, pneumatic dilatation, or botulinum toxin injection. J Gastrointest Surg 2001; 5:192–205.
16. Heudebert GR, Marks R, Wilcox CM, et al. Choice of long-term strategy for the management of patients with severe esophagitis: a cost-utility analysis. Gastroenterology 1997; 112:1078–1086.
17. Nord E. Methods for quality adjustment of life years. Soc Sci Med 1992; 34:559–569.
18. Patel ST, Haser PB, Bush HL Jr, et al. The cost-effectiveness of endovascular repair versus open surgical repair of abdominal aortic aneurysms: A decision analysis model. J Vasc Surg 1999; 29:958–972.
19. Oddsdottir M, Franco AL, Laycock WS, et al. Laparoscopic repair of paraesophageal hernia. New access, old technique. Surg Endosc 1995; 9:164–168.
20. Luketich JD, Raja S, Fernando HC, et al. Laparoscopic repair of giant paraesophageal hernia: 100 consecutive cases. Ann Surg 2000; 232: 608–618.
21. Wiechmann RJ, Ferguson MK, Naunheim KS, et al. Laparoscopic management of giant paraesophageal herniation. Ann Thorac Surg 2001; 71:1080–1087.
22. Schauer PR, Ikramuddin S, McLaughlin RH, et al. Comparison of laparoscopic versus open repair of paraesophageal hernia. Am J Surg 1998; 176:659–665.
23. Wu JS, Dunnegan DL, Soper NJ. Clinical and radiologic assessment of laparoscopic paraesophageal hernia repair. Surg Endosc 1999; 13:497–502.
24. Pitcher DE, Curet MJ, Martin DT, et al. Successful laparoscopic repair of paraesophageal hernia. Arch Surg 1995; 130:590–596.
25. Hawasli A, Zonca S. Laparoscopic repair of paraesophageal hiatal hernia. Am Surg 1998; 64:703–710.
26. Perdikis G, Hinder RA, Filipi CJ, et al. Laparoscopic paraesophageal hernia repair. Arch Surg 1997; 132:586–591.
27. Willekes CL, Edoga JK, Frezza EE. Laparoscopic repair of paraesophageal hernia. Ann Surg 1997; 225:31–38.
28. Gantert WA, Patti MG, Arcerito M, et al. Laparoscopic repair of paraesophageal hiatal hernias. J Am Coll Surg 1998; 186:428–433.
29. Horgan S, Eubanks TR, Jacobsen G, et al. Repair of paraesophageal hernias. Am J Surg 1999; 177:354–358.
30. van der Peet DL, Klinkenberg-Knol EC, Alonso Poza A, et al. Laparoscopic treatment of large paraesophageal hernias: both excision of the sac and gastropexy are imperative for adequate surgical treatment. Surg Endosc 2000; 14:1015–1018.
31. Trus TL, Bax T, Richardson WS, et al. Complications of laparoscopic paraesophageal hernia repair. J Gastrointest Surg 1997; 1:221–228.
32. Behrns KE, Schlinkert RT. Laparoscopic management of paraesophageal hernia: early results. J Laparoendosc Surg 1996; 6:311–317.
33. Huntington TR. Short-term outcome of laparoscopic paraesophageal hernia repair. A case series of 58 consecutive patients. Surg Endosc 1997; 11:894–898.
34. Krahenbuhl L, Schafer M, Farhadi J, et al. Laparoscopic treatment of large paraesophageal hernia with totally intrathoracic stomach. J Am Coll Surg 1998; 187:231–237.
35. Medina L, Peetz M, Ratzer E, et al. Laparoscopic paraesophageal hernia repair. JSLS 1998; 2:269–272.

36. Mosnier H, Leport J, Aubert A, et al. Videolaparoscopic treatment of paraesophageal hiatal hernia. Chirurgie 1998; 123:594–599.
37. Edye MB, Canin-Endres J, Gattorno F, et al. Durability of laparoscopic repair of paraesophageal hernia. Ann Surg 1998; 228:528–535.
38. Dahlberg PS, Deschamps C, Miller DL, et al. Laparoscopic repair of large paraesophageal hiatal hernia. Ann Thorac Surg 2001; 72:1125–1129.
39. Athanasakis H, Tzortzinis A, Tsiaoussis J, et al. Laparoscopic repair of paraesophageal hernia. Endoscopy 2001; 33:590–594.
40. Carter R, Brewer LA 3rd, Hinshaw DB. Acute gastric volvulus. A study of 25 cases. Am J Surg 1980; 140:99–106.
41. Haas O, Rat P, Christophe M, et al. Surgical results of intrathoracic gastric volvulus complicating hiatal hernia. Br J Surg 1990; 77:1379–1381.
42. Menguy R. Surgical management of large paraesophageal hernia with complete intrathoracic stomach. World J Surg 1988; 12:415–422.
43. Geha AS, Massad MG, Snow NJ, et al. A 32-year experience in 100 patients with giant paraesophageal hernia: the case for abdominal approach and selective antireflux repair. Surgery 2000; 128:623–630.
44. Ozdemir IA, Burke WA, Ikins PM. Paraesophageal hernia. A life-threatening disease. Ann Thorac Surg 1973; 16:547–554.
45. Beardsley JM, Thompson WR. Acutely obstructed hiatal hernia. Ann Surg 1964; 159:49.
46. Postlethwait RW. Surgery of the Esophagus. Appleton & Lange, 1986.
47. Treacy PJ, Jamieson GG. An approach to the management of paraoesophageal hiatus hernias. Aust NZ J Surg 1987; 57:813–817.
48. Hallissey MT, Ratliff DA, Temple JG. Paraoesophageal hiatus hernia: surgery for all ages. Ann R Coll Surg Engl 1992; 74:23–25.
49. Carlson MA, Condon RE, Ludwig KA, et al. Management of intrathoracic stomach with polypropylene mesh prosthesis reinforced transabdominal hiatus hernia repair. J Am Coll Surg 1998; 187:227–230.
50. Hashemi M, Sillin LF, Peters JH. Current concepts in the management of paraesophageal hiatal hernia. J Clin Gastroenterol 1999; 29:8–13.
51. Ellis FH Jr, Crozier RE, Shea JA. Paraesophageal hiatus hernia. Arch Surg 1986; 121:416–420.
52. Myers GA, Harms BA, Starling JR. Management of paraesophageal hernia with a selective approach to antireflux surgery. Am J Surg 1995; 170:375–380.
53. Maziak DE, Todd TR, Pearson FG. Massive hiatus hernia: evaluation and surgical management. J Thorac Cardiovasc Surg 1998; 115:53–62.
54. Williamson WA, Ellis FH Jr, Streitz JM Jr, et al. Paraesophageal hiatal hernia: is an antireflux procedure necessary? Ann Thorac Surg 1993; 56:447–452.
55. Ackermann C, Bally H, Harder F. Paraesophageal hiatal hernia–risks and surgical indications. Helv Chir Acta 1989; 56:159–162.
56. Oddsdottir M. Paraesophageal hernia. Surg Clin North Am 2000; 80:1243–1252.

DISCUSSION

DR. PHILIP E. DONAHUE (Chicago, IL): This is an important paper, and I appreciate the opportunity to discuss this combined hypothetical and real evidence-based approach to repair of paraesophageal hernias. Watchful waiting, parenthetically, has been used widely in the Midwest for a long time, and we never get to see patients as a rule until they have had minimal symptoms. My concern is that your model, like virtual reality trainers, is programmed to respond to input variables, where you have ascribed significance at the front end; therefore, the outcome is quite predictable. What can't be assessed adequately, I think, is the minimal symptoms. I am not sure how we deal with that, and that troubles me. I am afraid we are going to postpone the repair of these paraesophageal hernias until the patients are 10 to 15 years down the line, when they present with higher risk of tragic outcomes after urgent procedures. There is no question that the risk of perforation or incarceration causing emergency surgery has been overestimated in the past, but I think this report pushes too far. There are a lot of people in managed care groups who will welcome your paper, because this will be yet another hurdle for the patient to cross to qualify for elective surgery.

The second factor that your analysis doesn't include is a factor that is apparent to my patients after repair of paraesophageal hernia: their quality of life, the types of things they eat, ability to travel, all sorts of things, are markedly improved. But, as in many situations wherein patients learn to accommodate to severely chronic conditions and don't recognize them as serious, the true benefit is apparent to all concerned only in retrospect.

Finally, I like your approach very much, since we are acutely reminded that we must start dealing with the facts. The national data sets are extremely valuable, but we cannot ignore the fact that some of the input variables are inadequate or incomplete.

PRESENTER DR. DAVID W. RATTNER (Boston, MA): Dr. Donahue, thank you very much for your comments. Certainly you are one of the pioneers in this field. We, too, in writing the paperwork and constructing the model, grappled with the question of what is minimally symptomatic. And in the manuscript this is laid out as things like belching and mild heartburn. Your premise, however, that the 65-year-old patient with minor symptoms will progress to the point that they must have surgery is what this study shows to be incorrect. In fact, the rate of progression is about 1% per year. And so the lifetime risk for a patient progressing to the point that they have severe symptoms, which we would categorize as postprandial vomiting, postprandial chest pain, and obstructive symptoms, is in the range of 14% lifetime. So I think that inevitable symptom progression is a belief that we are holding onto inappropriately.

In terms of the quality of life, the model does look at quality of life through the utilities. There are well-established utilities for these conditions. And although patients report that they may feel better after surgery, the model was not very sensitive to either morbidity or relatively minor changes in quality of life, at least as you look at this statistically.

There is no question that this is a model, and it is totally dependent on the hypotheses which you generate and the data that you put in. But I think, given the complexity of the problem and the poor quality of the existing surgical literature, I think this is a new way of looking at it.

DR. CARLOS A. PELLEGRINI (Seattle, WA): This is a very important study. You have demonstrated that the risk of complications and the risk of death from emergency treatment of strangulated hernia are less than was previously estimated. Could you please qualify a little bit more what you think symptoms are? Many of these people, as you know, are elderly individuals, and their most common complaint is that they are short of breath when they try to go upstairs or downstairs, and they think that this is from a large hernia. What do you do with that?

The second one is, can you look at the reverse of all of this and say, "What is the benefit in these individuals who have other symptoms, who have other problems?" And have you looked in a similar model to what happens when they are symptomatic? I think this is very important, because today with extensive use of x-rays and other tests we get a significant number of patients coming in from retirement homes who were discovered to have a hernia.

Lastly, is there a difference between the paraesophageal hernias that you showed on the screen there and the rare ones in which the entire stomach appears to be in the chest?

DR. DAVID W. RATTNER (Boston, MA): We did consider the totally intrathoracic stomach. We would consider them to be type III hernias. We agree with you that the study ought to be run in reverse, as you put it, looking at symptomatic patients. It is much more difficult to do this with the data sets that are available, since symptoms are not really defined in the data sets per se.

Your first question was about the elderly patient with shortness of breath. Again, I think this is an individual judgment. I don't think that the data that we present in this study can tell you how to manage every individual situation. But I do think it does give some guidance in the patient with abnormal x-rays who rarely has dyspepsia or other relatively minor complaints that by and large they will not benefit from an elective operation.

DR. JEFFREY H. PETERS (Los Angeles, CA): Dr. Rattner, that was a great study. I think you are to be congratulated for shedding some light on a difficult clinical judgment. Some of the questions I had have already been

asked, but let me just focus on the fact that your analysis used laparoscopic repair versus as the standard operative procedure. Two points. One, some of us have been moving more towards doing these patients open because of the relatively high incidence of recurrence. I wonder if you would comment how an open repair will affect your analysis. Secondly, did you take into account the prevalence of recurrent symptoms? Clearly we don't repair them 100% effectively.

DR. DAVID W. RATTNER (Boston, MA): We chose elective laparoscopic hernia repair because that is a rapidly growing area of this type of surgery. Unfortunately, we are mirroring your experience with large paraesophageal repairs done laparoscopically and also finding that there is a significant recurrence rate. And there are some things—and I hate to say this as a laparoscopic surgeon, but it is true—there are some things you can do open much better than you can do laparoscopically, particularly in regards to the crural closure. So we are swinging back in that direction for some of the larger defects. There is in the manuscript a section which deals with the progression of symptoms. For the purposes of the study, we assigned them utility values that were the same as patients with heartburn or achalasia to mimic dysphagia, and this sensitivity analysis didn't alter the decision making. So I think in terms of the modeling, the recurrent symptoms don't affect the model very much.

DR. JOHN G. HUNTER (Portland, OR): I would just like to echo the group's acclamation for this great study. The trouble with the Markov Monte Carlo stimulation is that it can magnify some very small errors. And if the assumptions plugged into the equations are slightly off, the results may be grossly magnified. I think that you have done a great job in picking appropriate assumptions. I think that the magnifications that often we see in these are not generally present in your paper.

The two questions I have really reflect things that you haven't talked about and one that you have, and that is the issue of iron deficiency anemia. As you know, 30% of patients will be asymptomatic that will have iron deficiency anemia. Should you include this in your decision analysis tree?

The second is really how do you assign utilities? I know that in your model, the utility for the patient with minimally symptomatic was assigned at slightly lower than that of the normal individual. But indeed the quality-of-life studies that you have done and that we have done show that quality-of-life states for individuals with these disorders, especially with gastroesophageal reflux, are terrifically low, and may be as low as those who had MIs and strokes. And I would wonder whether your model would be sensitive to these lower quality-of-life states.

The last thing is that this model tends to hang on several uniquely identified data points. To my reading, the most tenuous one is that the natural history of the untreated paraesophageal hernia was attributed to one study by Glenn Jamieson of 29 patients that were followed for 87 years. What happens if you plug in some of these other studies, the studies of Belzie and the studies of Hill in your decision analysis? Because again, the data in this area is really quite weak.

DR. DAVID W. RATTNER (Boston, MA): I think for the purposes of our model we would not consider iron deficiency anemia to be an asymptomatic patient. Clearly, if it is severe enough to require iron replacement or certainly transfusion, the patient is symptomatic and wouldn't really fall into the category of patients we were talking about in the study.

In terms of the quality-of-life questions, you are right. If we do a GSRS or SF-36, we get pretty significant differences in quality of life between patients with severe GERD and the normal patient. But for most others in the general well-being index, these differences are not of the same magnitude. And that is the index which we used in this study. So the data are what they are. These are standard numbers that were plugged in, they weren't made up.

Lastly, you are right about the Achilles' heel of the study: it is the progression of symptoms rate. It is largely based on Jamieson's study. However, there is a very wide range in other reports of the purported progression of symptoms, and these are cited in one of the tables in the manuscript.

DR. JAMES B. D. MARK (Stanford, CA): I enjoyed the paper. I am sorry the late Dr. Luke Hill is not here to discuss it and perhaps defend some of his positions. There is no question that each of us is influenced by his or her own experience. And many things that are presented are anecdotal. For instance, over a lifetime, I have had experience with two patients who were admitted to the hospital for elective repair of paraesophageal hernia and on the night before operation had incarceration and had to be done in the middle of the night. That obviously affects one's judgment. On the other hand, we have just heard a powerful, statistical presentation. However, we have not heard anything about your own personal experience. I hope you don't leave the podium without telling us if you have done these operations and how they went.

DR. DAVID W. RATTNER (Boston, MA): Yes, I have my battle scars from doing these operations. I must say, dating back to the time when I was a chief resident, which would span nearly 17 years now, I can recall only one case that I had to operate on as a true emergency in the middle of the night. And that is what I would consider an emergency. Someone who is having progressive symptoms and is admitted to the hospital and done 3 or 4 days later would, in my mind, be urgent, and certainly there are a number of those cases. In my own personal experience organ resection is quite rare.