Capstone Project

Measuring the Value of Timely Surgical Care in Underserved Populations:
A Cost-Effectiveness Analysis of Inguinal Hernia Repair

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Abstract

Background

Timely hernia surgery is not accessible for underserved patients. Delayed care can increase the risk of complications and mortality. The objective of this study is to estimate the costs, health benefit, and cost-effectiveness of providing early hernia repair to symptomatic uninsured undocumented populations.

Methods

In this cost-effectiveness study we compared the cost-effectiveness of timely hernia repair to no early hernia repair. A decisions-analysis model was constructed to estimate the cost-effectiveness of the intervention options. We combined peer- review literature and hospital accounting records to gather data for our model inputs. Model inputs included direct costs of treatment, clinical outcome probabilities and health benefit values. Main outcome measures include intervention costs and health benefits, in an incremental cost-effectiveness ratio (ICER). Sensitivity analysis was performed to evaluate the impact of each variable on the ICER outcome. Costs and QALYs were discounted by 3%.

Results

Timely surgery for symptomatic hernias is cost-effective, with an ICER of $747 USD per QALY gained. Surgical repair had a net monetary benefit of $196,022 USD more than the no intervention strategy. Compared to the WHO guidelines for cost-effectiveness analysis, this intervention is “very cost-effective”. This outcome remained robust to variations in model input ranges during sensitivity analysis.

Introduction

Background

There are an estimated 48 million uninsured adults in the United States[1]. Studies have shown that medically uninsured have higher morbidity and mortality than the insured[2 3]. Uninsured patients use primary care services less frequency than those with insurance[3 4]. This reduces the opportunity for prevention and screening[3 4]. They also lack access to specialty services due to the high cost[5]. Limited access to medical care can result in delayed medical presentation of disease and higher hospitalization rate[4 5]. Emergency departments become a system of last resort when medical complaint becomes unmanageable[6 7].

For many uninsured and medically indigent, publicly funded hospitals provide the backbone of the safety-net system[8]. However many of these facilities are overburdened[8]. One in every five Americans has at least one emergency department visit per year[6]. Although there is a general trend in increased emergency department use, the number of emergency room departments has decreased in the United States between 1993 and 2003 [9]. There are now 400 fewer emergency departments resulting in overcrowding and fragmentation of patient care[7,10]. It is estimated that 40% of emergency room visits are from uninsured patients[6]. From 2005 to 2010, uninsured patient visits to the emergency department increased by 25.4% in California[11]. The high cost of service is the primary reason the uninsured delay medical care until an emergency occurs[10–12].

Uncompensated care is defined as medical treatment performed for those that are unable to pay for the bill[13]. A special federal status is given to hospitals providing a disproportionally large share of uncompensated care. These 'Disproportionate Share Hospitals' (DSH) are awarded state and federal grants to cover the shortfall from the uncompensated care. However, for many of these hospitals the DSH funds are not enough to make up for the cost of uncompensated care [13]. The Affordable Care Act will result in a substantial decrease in DSH funding, as many people will become medically insured under the new law[6]. However it is estimated that in 2016 there will be 30 million still uninsured[14]. Importantly, undocumented immigrants are banned from purchasing the subsidized insurance in public health exchanges and will continue to use public and privately funded safety-net hospitals and clinics as the primary source of medical care[6 12]. Uninsured and undocumented patients cite the high cost of service and fear of deportation as the primary reasons they avoid timely medical care[15,16].

Operation Access (OA) is a 501 c 3 non-profit corporation in the San Francisco Bay Area providing uncompensated surgery by volunteer medical and nursing professionals to local uninsured patients[17]. Since its inception in 1993 Operation Access has served 12,000 patients, providing an estimated $100 million USD of uncompensated surgical care[17]. Approximately 80% of OA patients are undocumented immigrants[18]. Patients of Operation Access must be uninsured, meet income guidelines, and be generally healthy with an American Society of Anesthesiologists risk of I or II [18]. Of those surgeries performed by OA, general surgery accounts for 23% of the case load[17].

Inguinal hernia is a common surgical condition and men have a 27% lifetime risk of developing an inguinal hernia [19–21]. An inguinal hernia is defined as a defect in the abdominal wall in the region of the groin through which the intra-abdominal contents protrudes[20,21]. The risk factors of inguinal hernia are not known[20]. Some hernias are asymptomatic, however many result in pain and discomfort due to the groin bulge. Some inguinal hernias can develop life-

threatening complications if a loop of intestine trapped (incarcerated) in the hernia twists, resulting in occlusion of the blood supply to the incarcerated segment of intestine[20,21].

Patients with a reducible (non-incarcerated) hernia that is asymptomatic can be treated by surgical repair or patients can decide to not repair the hernia and monitor its progress. This is called "watchful waiting" in the literature. Many asymptomatic patients however elect hernia repair to avoid future complications. In fact, inguinal hernias are one of the most common elective procedures and are repaired at a rate of 28 per 10,000 people in the United States[20,22]. Clinical guidelines and the scientific literature however show a significant dissonance in the acceptability of the "watchful waiting" approach for asymptomatic inguinal hernias.

Proponents of surgical approach in asymptomatic cases cite that the quality of life of the patient is significantly affected without treatment[22–26]. Thirteen percent of patients reported taking time off work because of their untreated hernia[22]. Waiting to repair a hernia bears the risk of an acute inguinal hernia with a possibility of bowel resection [24,27,28]. For patients that forego early treatment and require surgery in the future, the risk of preoperative, intraoperative, and postoperative mortality with an acute surgery increases significantly[28,29]. Two separate randomized clinical controlled trials have shown that early surgical repair is preferred to watchful waiting and has the best outcomes of morbidity when compared with no surgery [30,31,28]. In another study, 72% of patients randomized to the observation group of no surgery eventually required a hernia repair within an average of 7.5 years [24]. This finding suggests that the majority of asymptomatic hernias will become symptomatic and will eventually need surgery.

Although observation of an asymptomatic hernia is an accepted clinical guideline; for uninsured groups "watchful waiting" is not feasible as they lack regular medical care. For these patients hernia progression cannot be monitored in the clinical setting. In fact, patients who are uninsured do not present asymptomatically as they have no regular medical care to discover the hernia incidentally. Almost all uninsured undocumented patients present to Operation Access as the symptoms become worse. Current clinical guidelines suggest all symptomatic hernias should be surgically repaired[21,23,32]. For undocumented patients this may be more burdensome as they lack the financial assets, access to workman's compensation, or paid sick leave to acquire this operation[15,33–35]. Without treatment this vulnerable patient group runs the risk of high morbidity and mortality[27,36]. Operation Access fills the gap in access to surgical services for this population. Cost-effectiveness studies have not yet assessed the benefit of surgical treatment of symptomatic inguinal hernias.

Research Objective

This study aims to discover the cost-effectiveness of hernia repair in the medically indigent undocumented population that Operation Access serves. We compared the cost and effectiveness of hernia repair for a symptomatic patient to no hernia repair. The aim of this study is to value timely surgical treatment of symptomatic hernias by determining the cost, health benefit, cost-effectiveness, and net monetary benefit of the intervention. We hypothesized that early repair of symptomatic inguinal hernia in uninsured undocumented patients is a cost-effective treatment strategy compared to no timely treatment.

Methods

Overview of Methods

The study is designed to compare the incremental cost-effectiveness of herniorrhaphy for symptomatic inguinal hernias as compared to no surgery for symptomatic hernias, following the consequences over the life span of the patient. The hypothetical study population is based on uninsured and undocumented male adult Operation Access patients who present with a symptomatic inguinal hernia, and are candidates for hernia repair with low risk of surgical complications. We ascertained all medical costs using the Kaiser hospital accounting system, as they are the major provider of charity surgical services for Operation Access. Health probability inputs are based on literature reported values. The cost-effectiveness model was developed in Excel 2011. We calculated the cost and health outcomes of the intervention to estimate the incremental cost-effectiveness ratio (ICER) representing the net cost per quality adjusted life year (QALY) gained. We also calculated the net monetary benefit of the intervention and comparator that takes into account the willingness-to-pay. All future costs and benefits were discounted at a rate of 3%. All costs are reported in 2014 U.S. dollars. We assessed the uncertainty with sensitivity analyses including univariate and bivariate.

Analytic Approach

We developed a decision analysis model to estimate the incremental costs and health benefits of the proposed strategy. The model follows a hypothetical male patient age 35 from the point of presentation with symptoms through their lifetime, assuming an average lifetime of 75 years. The two options in the model are A) the patient undergoes surgical repair of the symptomatic hernia or B) the patient does not receive surgical repair of the symptomatic hernia. The surgery modeled is an open herniorrhaphy procedure as this technique represents the majority of cases hernia repair cases.

The product of this analysis is a decision tree that includes all clinical event outcomes and the probabilities of those events stemming from the two initial options. The main health events considered in the decision tree include probability of acute hernia requiring emergent surgery, the probability of bowel resection, the risks of surgical morbidity, and the risk of surgical mortality.

The major surgical morbidities that contributed to the patient's quality of life and cost of procedure were modeled. These include wound infection, hematoma, and chronic pain. The risk of hernia reoccurrence is also modeled in the decision tree. The risk of acute hernia is presented at the cumulative probability that the hernia will incarcerate or strangulate. The model assumes that if the hernia becomes acute the patient will receive an emergent hernia operation. Bowel resection is a risk in both elective and emergent surgery and carries an additional disability and cost. The full decision tree is shown in Appendix A.

Data Inputs

Data inputs were sourced from the scientific literature and hospital accounting system to determine the value of health benefits, clinical probabilities and intervention costs. Costing information was validated against previous cost-effectiveness literature. Prices are adjusted for inflation to 2014 U.S. dollars. Benefits and costs in the future are discounted at standardized 3% discount rate.

Clinical probability values in the model represent the main findings of systemic reviews and randomized control trials[37 21,25,28,29,38,39 22,24,27,30,36,40,41]. The list of clinical outcomes and model values can be found in Table 1. We included cumulative risk values for inclusion in the model. Papers that reported annual risks were converted over the lifetime with the formula $1-(1-X)^N$, where X represents the annual rate and N compounds the number of years the risk persists. Clinical outcomes not found in systematic reviews were found in individual papers, taking the mean average to determine the value for the model.

Table 1:

Health Input Parameters	Definition	Model Value
Chronic Pain	Probability of chronic pain after hernia repair	11%
Hematoma	Probability of hematoma after hernia repair	7%
Wound Infection	Probability of wound infection after hernia repair	5%
Surgical Mortality	Probability of surgical mortality due to an elective hernia repair	0.2% (0% to 1.8%)
Emergent Surgical Mortality	Probability of surgical mortality due to an emergent hernia repair, no resection	4% (0% to 22.2%)
Emergent Surgical Mortality, and Resection	Probability of surgical mortality due to an emergent hernia repair, bowel resection performed	13.7%
Bowel Resection	Probability of a bowel resection required during an elective hernia repair	0.1% (0% to 0.3%)
Emergent Bowel Resection	Probability of a bowel resection during an emergent hernia repair	10% (5.4% to 15.6%)
Non Surgical Chronic Pain	Probability of chronic pain given the hernia patient has not undergone any surgical treatment	90%
Recurrence	Probability of hernia recurrence after and initial hernia repair	1.4% (0.9% to 4.0%)
Acute Hernia Presentation	Probability of incarceration and/or strangulation that requires emergency surgery	15%

Cost inputs we calculated from the perspective of the provider. These costs were derived from the Kaiser Permanente medical database. Outcomes in the decision tree were matched to relevant ICD-9 diagnostic and procedure codes. The administrative database was searched for actual patient cases that matched the specified ICD-9 codes. Table 2 describes these inputs. Physician of the costing analysis included principal and assisting surgeon, support staff, anesthesiology staff, and hospital attending MD services. Operating room and hospital medical and non-medical supplies and equipment were included. Nursing comprised pre-operative, operative, recovery, and hospital functions. Inpatient therapy, pharmacy, and ancillary laboratory services were also calculated. The reported values do not include administrative overhead, building maintenance, and emergency department visits.

Table 2.

Cost Input Parameters	Definition	ICD-9 Diagnostic Code	Model Value
Elective Hernia Repair	Surgical repair of inguinal hernia	550.90	-
Elective Hernia Repair, Bowel Resection	Surgical repair of inguinal hernia and bowel resection	550.90	-
Emergent Hernia Repair	Surgical repair of Inguinal hernia, obstruction	550.10	-
Emergent Hernia Repair, Bowel Resection	Surgical repair of inguinal hernia, obstruction and gangrene	550.00	-

Health results are reported as quality adjusted life years and table 3 describes the health states variables we measured and the utility value assigned.

We used the Health Utilities Index III measurement system to assign utility values to health outcomes. This system measures 8 attributes of health including ambulation, emotion, and pain, and assigns a disutility for poor outcomes in each category[30]. Health utilities fall on a scale of 0 to 1, where 0 is death and 1 is perfect health. Table 4 gives the utility calculations performed.

Table 3.

Health States	Defininition	Model QALYs
No Morbidity	No surgical morbidity	25.14
No Morbidity + BR	No surgical morbidity; bowel resection performed	24.82
Chronic Pain	Surgical morbidity of chronic pain	19.36
Chronic pain + BR	Surgical morbidity of chronic pain; bowel resection performed	19.04
Hematoma	Surgical morbidity of hematoma	25.09
Hematoma + BR	Surgical morbidity of hematoma; bowel resection performed	24.76
Infection	Surgical morbidity of wound infection	25.12
Infection + BR	Surgical morbidity of wound infection; bowel resection performed	24.80
Hematoma + Infection	Surgical morbidity of hematoma and infection	25.07
Hematoma + Infection + BR	Surgical morbidity of hematoma and infection; bowel resection performed	24.74
Chronic pain + Hematoma	Surgical morbidity of chronic pain and hematoma	19.30
Chronic Pain + Hematoma + BR	Surgical morbidity of chronic pain and hematoma; bowel resection performed	18.98
Chronic Pain + Infection	Surgical morbidity of chronic pain and infection	19.34
Chronic Pain + Infection + BR	Surgical morbidity of chronic pain and infection; bowel resection performed	19.02
Chronic Pain + Hematoma + Infection	Surgical morbidity of chronic pain, hematoma, and infection	19.28
Chronic Pain + Hematoma + Infection + BR	Surgical morbidity of chronic pain, hematoma, and infection; bowel resection performed	18.96

Table 4.

Health Attribute	Classification System	Utility	Disutility
Chronic Pain	Moderate pain that prevents a few activities	0.77	0.23
Hematoma	Moderate pain that prevents a few activities, and somewhat happy	0.88	0.12
Infection	Mild to moderate pain that prevents no activities	0.92	0.08
Bowel Resection	Moderate pain that prevents a few activities, and somewhat happy, and able to walk around the neighborhood with difficulty; but does not require walking equipment or the help of another person	0.64	0.36

Outcomes

In assessing the cost and health benefit of the incremental use of herniorrhaphy this study will result in four outcome measures; the net cost of the intervention, the QALYs gained by the intervention, the incremental cost effectiveness ratio (ICER), and the net monetary benefit. Costs represent the value of resources, not charges. QALYs gained combine the years of life lived and the health status utility of those years. This metric makes it simple to compare the benefit of unrelated interventions.

To compare the incremental costs to the incremental disease averted the ICER value is reported as the net cost per QALY gained. This is calculated by a ratio of the differences in cost (considering costs of surgeries and other hernia-related care) over the differences in health benefit of the two scenarios. The formula used to calculate the ICER is [(Total $Cost_B$-Total $Cost_A$)/(Total $Benefit_B$-Total $Benefit_A$)]. Benefit is measured in QALYs.

The net monetary benefit is employed to incorporate the patient's willingness to pay as a factor in decision analysis. The willingness-to-pay in this model is $50,000 USD. This is derived from the WHO standard of cost-effectiveness threshold. This value is derived for each intervention and then compared against one another. The formula used to calculate net monetary benefit is [(QALYxWTP)-Cost] for each arm of the study.

Analysis

To examine the uncertainty in our base case model parameters from the literature and hospital database, we conducted sensitivity analysis. A tornado analysis was created to determine the most sensitive variables. Clinical outcome probabilities and cost of treatment were varied one at a time and in pairs over plausible ranges found in the literature. Monte Carlo simulations were employed to generate a cost-effectiveness acceptability curve and strategy selection.

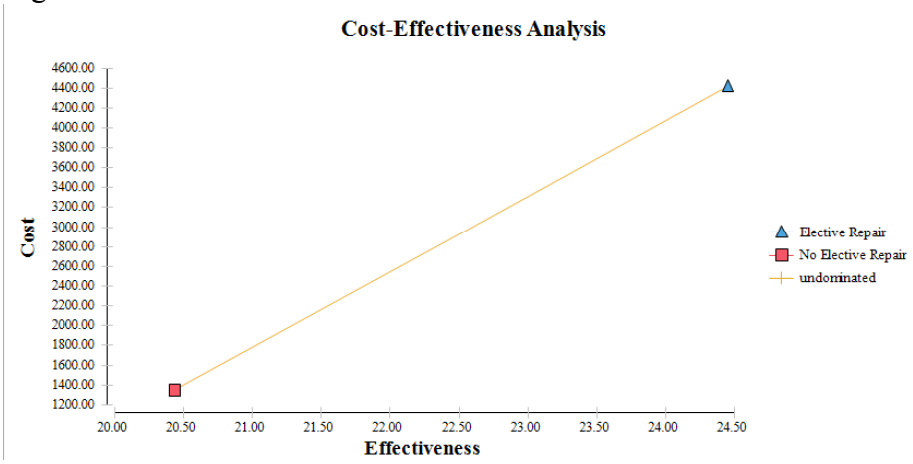
We used the WHO guidelines on cost-effectiveness to analyze the outcome variables of this study. ICER values were compared on a threshold relating to the country's GDP-per capita. The WHO states that an intervention that is "very cost-effective" has an ICER below the GDP per capita[42]. An ICER that is below three times the GDP per capita is considered a "cost-effective" intervention. The GDP per capita in the United States is $53,143 USD.

Results

Base Case

Using the base case health and cost inputs in tables 1 and 2, the QALYs experienced in the intervention arm were 24.45 per patient. The QALYs with no intervention were 20.47. Thus 3.98 quality-adjusted life years were gained in the intervention arm. The cost of the intervention was $4424 USD and $1437 USD for the no intervention arm. The strategy of elective hernia repair was most costly than no repair, at $2977 USD more than the null. This base case yielded an incremental cost-effectiveness ration of $747.54 per QALY gained. The ICER is at the base case decision is represented graphically in Figure 1. Effectiveness in the graph represented the QALYs gained in the strategy.

Figure 1:



The net monetary benefit of the intervention arm was $1,218,085 USD while the no intervention arm was $1022062 USD. This suggests that compared to no intervention, timely hernia repair is cost-effective. The elective hernia repair strategy provides a monetary benefit of $196,022 USD over the no intervention strategy. This base case results are represented in table 5.

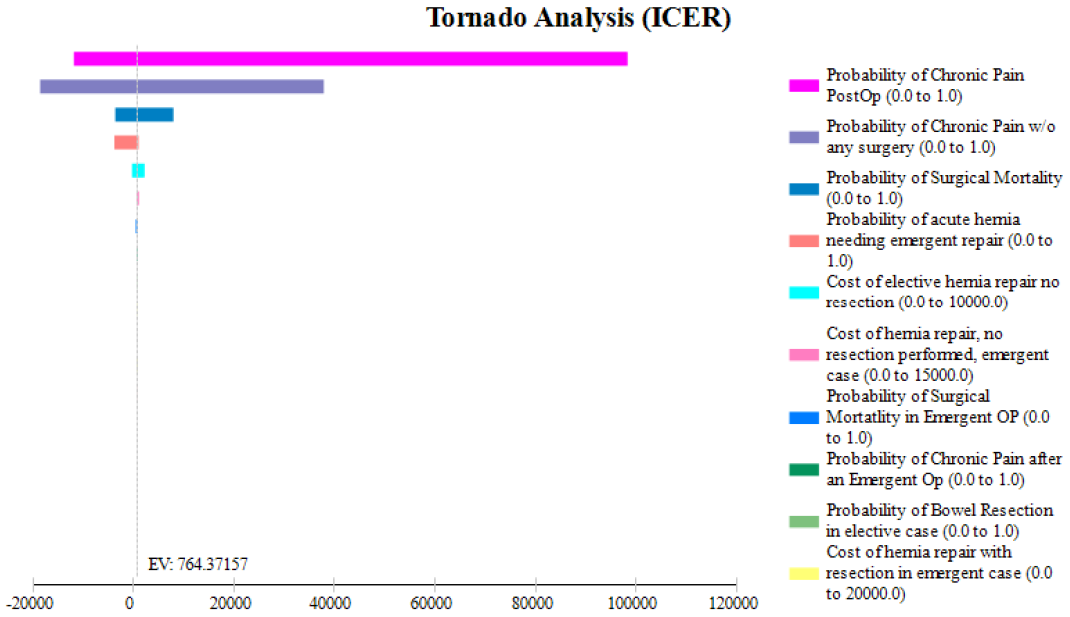
Table 5:

	No Intervention Arm	Intervention Arm
Strategy	No Timely Hernia Repair	Timely Hernia Repair
Cost (USD)	1437.07	4414.12
Incremental Cost (USD)	0	2977.05
QALYs	20.47	24.45
Incremental QALYs	0	3.98
Incremental C/E (USD/QALY)	0	747.54
Net Monetary Benefit (USD)	1,022062.93	1,218085.88

Sensitivity Analysis

The outcome of the base case model remained robust during sensitivity analysis. To assess which variables affected the ICER outcome the most we performed tornado analysis as depicted in graphical form in figure 2.

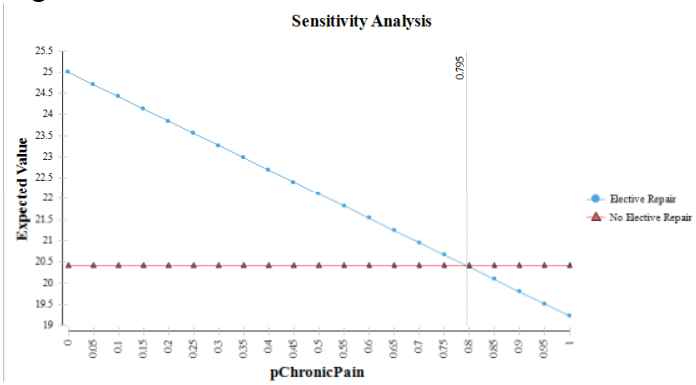
Figure 2.



This graph represents the inputs that contributed the most to the variability of the outcome. We used the results of the tornado analysis to determine the sensitive variables for one-way and two-way sensitivity analysis.

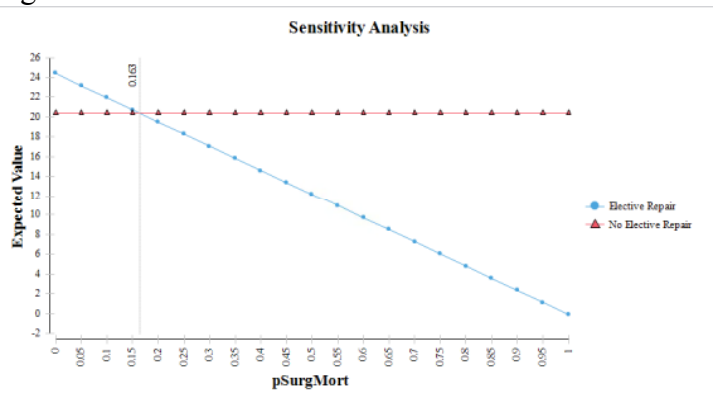
Variations in the majority of health inputs and cost inputs did not affect the ICER result. We took the variables from the tornado analysis and set the range of each at 0% to 1% probability rate, representing the most extreme possible outcomes. We performed a one-way sensitivity analysis on the probability of chronic pain after surgical repair of the hernia (Figure 3). This revealed that for the intervention strategy to be cost-effective, the probability of chronic pain following hernia repair must be less that 79.5%.

Figure 3.



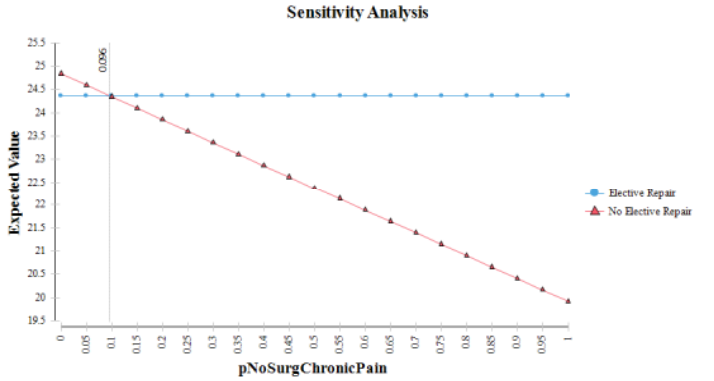
The probability of surgical mortality following an elective repair was also modeled (Figure 4). This analysis showed that below a mortality rate of 16% the intervention strategy is cost-effective.

Figure 4.



The final one-way sensitivity analysis that significantly affected the study result was the probability of a patient, that did not undergo elective or emergent repair, to experience chronic pain. Figure 5 depicts the graphical representation. At a risk of chronic pain greater than 9.6% the model results hold.

Figure 5.



The tornado variables were also used in two-way sensitivity analysis and again we modeled the results using the most extreme scenarios from 0% to 100% probabilities. We tested three pairs of variables to further determine the influence of these model parameters; chronic pain versus the risk of acute hernia (Figure 6), chronic pain versus surgical mortality of elective repair (Figure 7), and surgical morality of elective repair versus the risk of acute hernia (Figure 8). The intervention scenario remained cost-effective within the plausible ranges of all variables tested.

Figure 6.

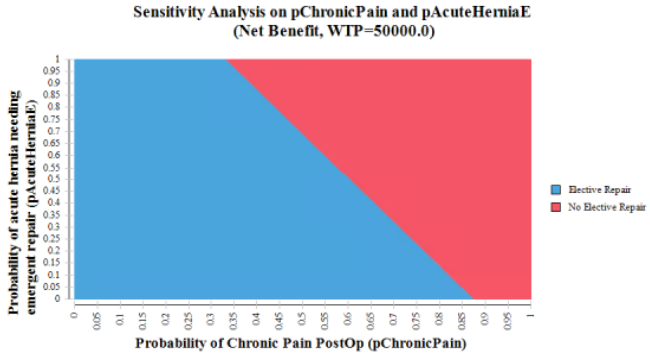


Figure 7.

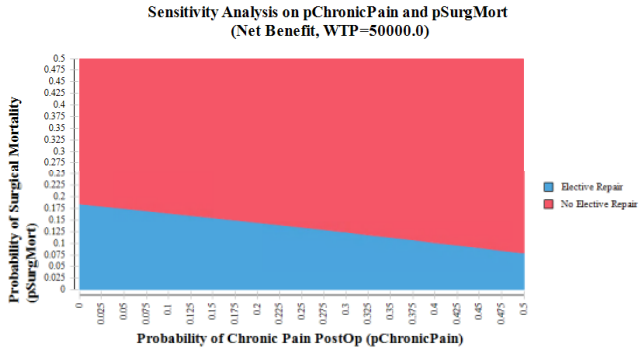
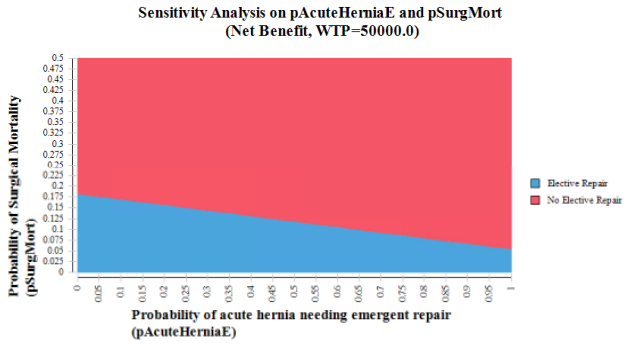
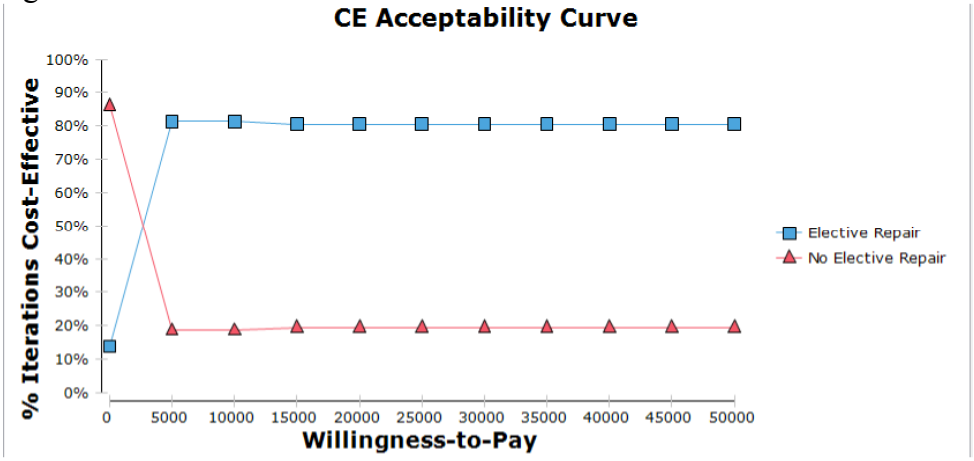


Figure 8.



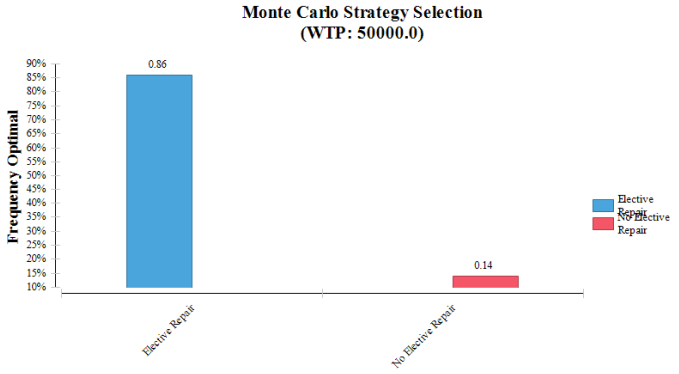
A cost-effectiveness acceptability curve was made to characterize the uncertainty in the base care model. This graph in figure 9 shows that above a willingness-to-pay threshold of $5,000 USD the intervention arm is more likely to be cost-effective.

Figure 9.



A Monte Carlo simulation analysis of 10,000 iterations was performed to analyze the best strategy given the uncertainties in the model (Figure 10). The bar graph shows that elective repair has an 86% chance of being the most cost-effective strategy over 10,000 simulations.

Figure 10.



Discussion

Findings

Our study results suggest that timely hernia repair in symptomatic individuals is cost-effective and the preferred strategy as compared to the no hernia repair strategy. According to the WHO guidelines this intervention is considered “very cost-effective” as the ICER is less than the GDP per capita of the United States. These base case model conclusions remained robust to variations of model parameters in sensitivity analysis. An 86% probability that the model remains cost-effective over all possible scenarios is an acceptable level to make a decision.

Insured patients with access to regular care are treated with hernia repair surgery for symptomatic cases as prescribed by clinical guidelines. Surgery is also indicated in this vulnerable group however; access to care remains to be the only differentiator. This patient population faces disproportionate risk of morbidity and mortality due to lack of access or delay in treatment. Operation Access closes the disparity between the financially protected and undocumented immigrants by providing these necessary services. Other organizations in the United States, such as Surgery on Sundays in Kentucky, have also recognized the gap in access and thus provide free surgery to vulnerable populations. Treatment of symptomatic hernias are not only clinically indicated but are also cost-effective, further promoting the services provided by these organizations. Charity care groups exist for many medical conditions, however specialty services, like surgery, are assumed to be too costly to provide freely to the medically indigent and are therefore more rare. Our results debunk this axiom.

Limitations

A contested topic is the lack of equity incorporated in economic models. For real-life applications, is the cost-effectiveness of the intervention the most important factor to consider? Many similar studies do not address this limitation and suggest that the most cost-effective option should be where resources are directed. The use and relevance of the QALY is also a hotly contested issue, however it has become the imperfect standard for results reporting. Using this metric is important for comparability of our findings with the literature and critical evaluation by others. Another limitation is that we will only included direct medical costs. Our health systems perspective does not incorporate ancillary social costs or other non-medical costs for this specific patient population. Many undocumented patients are employed in physical labor and the effects of an untreated hernia may be more than an individual with an occupation that does not require manual work. Accurately addressing the income loss due to leave from work in the informal economy is difficult due to the paucity of research on this undocumented population. Future studies could extend the costing scheme to include these important perspectives.

Implications

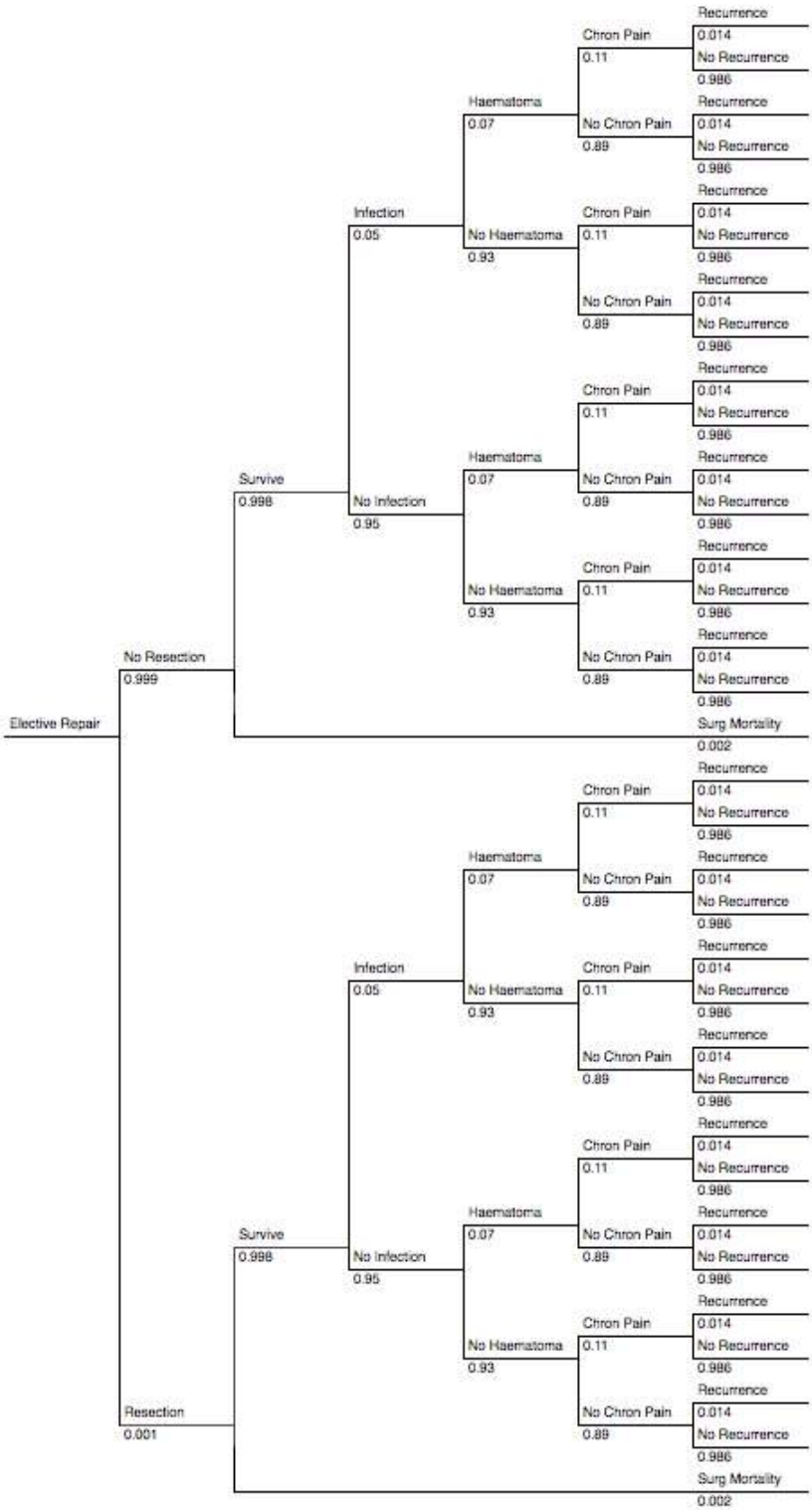
This study is novel in many ways. The research question has not been previously presented in the literature of hernia surgery with the uninsured and undocumented populations. Our specifically targeted undocumented population has broad implications for policy adjustments, public and private health care funding, and future research strategies that focus on the underserved. Proving that the services provided by Operation Access are cost-effective can secure more funding and more hospital partnerships to provide needed services to those on the wait-list. These results may encourage other private hospitals and non-profit organization to consider the donation of surgical services to medically indigent groups.

Conclusion

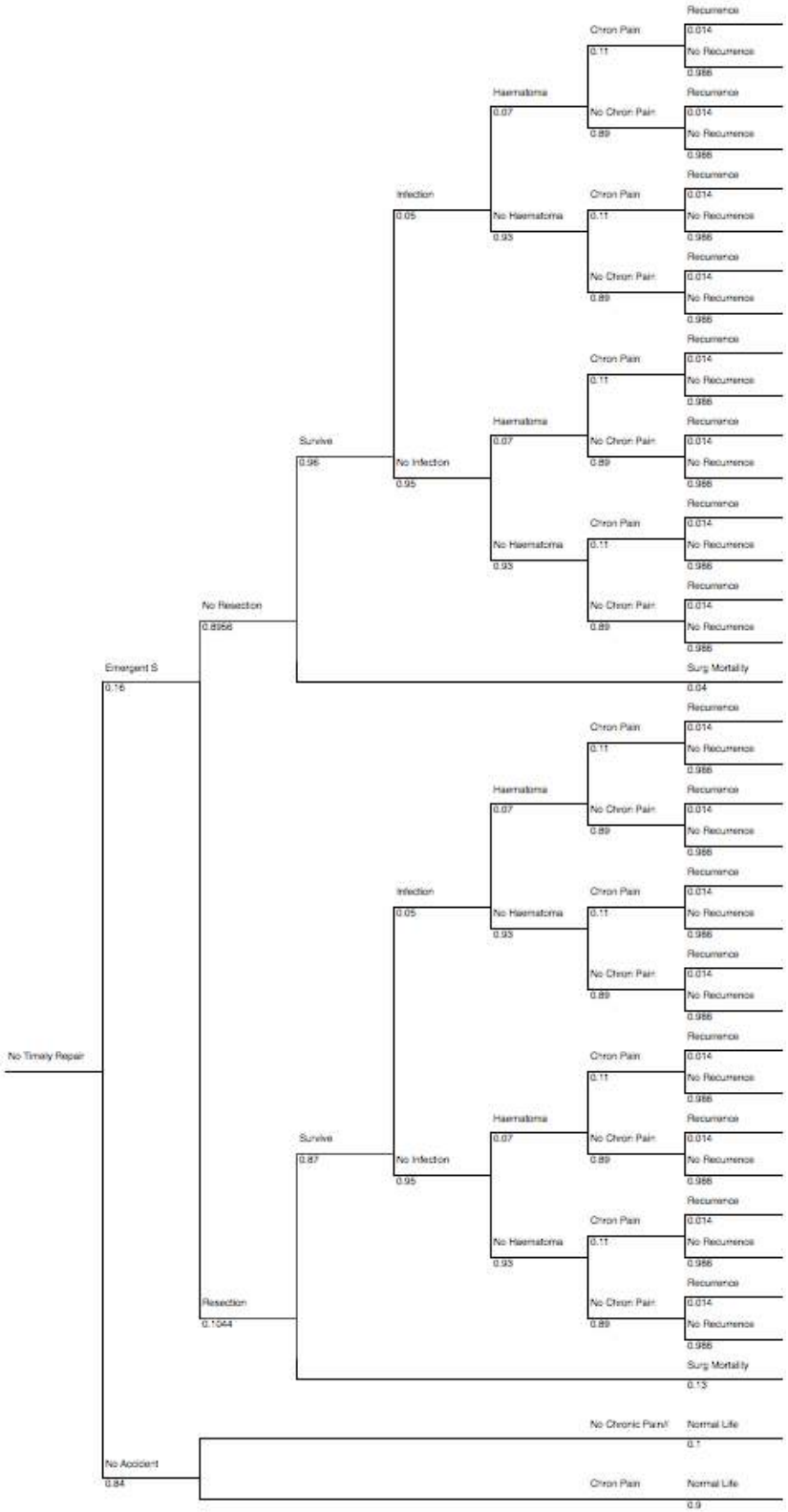
In accordance with clinical guidelines, providing surgical treatment to patients with symptomatic inguinal hernias is very cost-effective. Operation Access is providing a cost-effective service to this medically indigent undocumented population.

Appendix A. : Intervention Arm

All line intersections represent a chance



Appendix A cont.: No Intervention Arm


No Timely Repair
Emergent S
0.16
No Accident
0.84
No Resection
0.8956
Resection
0.1044
Survive
0.96
Survive
0.87
Infection
0.05
No Infection
0.95
Haematoma
0.07
No Haematoma
0.93
Chron Pain
0.11
No Chron Pain
0.89
Recurrence
0.014
No Recurrence
0.986
Surg Mortality
0.04
Surg Mortality
0.13
No Chronic Pain/
Chron Pain
Normal Life
0.1
Normal Life
0.9

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