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Cost-effectiveness of the evaluation of a suspicious biliary stricture

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ABSTRACT

Background: Biliary stricture without mass presents diagnostic and therapeutic challenges because the poor sensitivity of the available tests and significant mortality and cost with operation.
Methods: A decision model was developed to analyze costs and survival for 1) investigation first with endoscopic ultrasound (EUS) and fine needle aspiration, 2) investigation first with endoscopic retrograde cholangiopancreatography (ERCP) and brushing, or 3) surgery on every patient. The average age of someone with a biliary stricture was found to be 62-y-old and the rate of cancer was 55%. Incremental cost-effectiveness ratios (ICER) were calculated based on the change in quality adjusted life years (QALYs) and costs (US$) between the different options, with a threshold of $150,000 to determine the most cost-effective strategy. One-way, two-way, and probabilistic-sensitivity analysis were performed to validate the model.
Results: ERCP results in 9.05 QALYs and a cost of $34,685.11 for a cost-effectiveness ratio of $3832.33. EUS results in an incremental increase in 0.13 QALYs and $2773.69 for an ICER of $20,840.28 per QALY gained. Surgery resulted in a decrease of 1.37 QALYs and increased cost of $14,323.94 (ICER-$10,490.53). These trends remained within most sensitivity analyses; however, ERCP and EUS were dependent on the test sensitivity.
Conclusions: In patients with a biliary stricture with no mass, the most cost-effective strategy is to investigate the patient before operation. The choice between EUS and ERCP should be institutionally dependent, with EUS being more cost-effective in our base case analysis.

1. Introduction

The patient presenting with a biliary stricture without obvious tumor on standard radiographic imaging (ultrasound, computed tomography [CT], or magnetic resonance imaging) presents a difficult diagnostic and therapeutic challenge. The risk of cancer is believed to be approximately 55% [1]. Benign conditions such as chronic pancreatitis, primary sclerosing cholangitis, choledocholithiasis, and postoperative strictures can present in a similar fashion. Furthermore, those with

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Table 1 – Sensitivity and specificity of EUS and ERCP used for the analysis.

Parameter	Best estimate	Low value	High value	Source
EUS sensitivity	0.74 (415/559)	0.30	0.89	[5]
EUS specificity	1.00	0.90	1.00	[6–9,27]
ERCP sensitivity	0.42 (356/861)	0.06	0.64	[1]
ERCP specificity	1.00	0.85	1.00	[1]

benign conditions frequently can be managed without undergoing operative management, such as with endoscopic biliary stenting [2–4]. However, the methods used to evaluate these biliary strictures, which include endoscopic retrograde cholangiopancreatography (ERCP) with bile duct brushings and cytological analysis or endoscopic ultrasound (EUS) with fine needle aspiration (FNA), are highly user dependent and typically have poor sensitivities and negative predictive values [1,5–10]. As a result, patients with negative tests end up with additional tests and upward of 50% undergo an operation anyway [7,10,11]. Extrahepatic biliary strictures typically require a Whipple procedure, which has a significant rate of morbidity and mortality [12–14]. Individuals with benign disease undergoing a Whipple have been shown to have decreased long-term survival [15]. Although operative resection offers the only opportunity for long-term survival for malignant disease, the overall survival rate for patients with malignancy is low regardless of if they undergo resection or not [13,14,16,17].

Therefore, this raises the question of whether it is more cost-effective to proceed straight to the operating room for all patients with suspicious biliary strictures or whether the possibility of avoiding surgery in patients with benign disease necessitates our continued utilization of suboptimal testing methods. This article reports a cost-effectiveness model to address this management question based on the best available information. Based on these data, we provide recommendations for the continued management of these patients and future implications.

2. Methods

We performed a cost-effectiveness analysis using the best estimates of all parameters and probabilities and followed the recommendations of the Panel on Cost-Effectiveness in Health and Medicine [18] using a standard software (TreeAge Pro 2011 Software; TreeAge Software, Williamstown, MA). We limited our analysis to the patient presenting with a suspicious biliary stricture, without evidence of a mass on initial imaging, with the assumption of a resectable lesion and compared three potential scenarios. The first scenario forgoes any further investigation and proceeds to the operating room for resection in every individual. In the second scenario, the stricture is evaluated with ERCP and cytology. If those results are positive, the patient proceeds to the operating room. If those results are negative, further evaluation is pursued until the ultimate decision of whether to manage the stricture operatively or nonoperatively is made. The final scenario is identical to the second scenario except instead of ERCP, EUS and FNA are performed.

The study was conducted using the costs incurred by the health care system. Disease probability, sensitivity, specificity, survival time, and costs were derived from the published literature. Survival values were calculated using the declining exponential approximation of life expectancy (DEALE) method using available data on median or 5-y survival data [19]. The literature regarding quality of life demonstrates minimal difference in quality of life between those before and after Whipple [20–26]. There is a decreased quality of life within the last month of those dying of malignancy. The results are reported in dollars per quality adjusted life year saved. Costs were reported for fiscal year (FY) 2013, and an annual discount rate of 3% was used where appropriate to account for depreciation of costs over time.

The primary outcome measure was the incremental cost-effectiveness ratio (ICER) in dollars per quality adjusted life year (QALY). ICER is calculated by using the cheapest strategy as the reference point. The remaining strategies are listed in the order of costs. The incremental increase in costs from one strategy to the next strategy in the list is divided by the incremental change in QALY. An *a priori* determination was made that a willingness-to-pay up to $150,000 per additional QALY gained as a threshold for determining the most cost-effective strategy. Strategies that were less effective but more costly or strategies that, while more effective, cost more than the $150,000 per QALY would be considered less cost-effective. Confidence intervals for the base case were calculated using 10,000 simulated patients.

Because each variable within the model is an estimation based on published data, the accuracy and robustness of the model is tested by sensitivity analysis. First, each parameter individually was analyzed using a range from low to high value derived from the literature (one-way sensitivity). Then

Table 2 – Cancer prevalence, mortality rate, and operative rates used for the analysis.

Parameter	Best estimate	Low value	High value	Source
Cancer prevalence	0.553 (861/1556)	0.483	1.00	[1]
Surgical perioperative mortality	0.041 (1063/25,930)	0.01	0.12	[12,13]
ERCP negative, malignancy-positive operative rate	0.432 (22/51)	0.25	0.588	[7,10,11]
EUS negative, malignancy-positive operative rate	0.50 (3/6)	0.33	0.67	[7,10,11]
ERCP/EUS negative, malignancy-negative operative rate	0.429 (6/14)	0.00	0.75	[7,10,11]