Cost benefit analysis of mesh reinforcement of stapled left pancreatectomy

Kamran Idrees1, Joshua R. Edler2, David C. Linehan1,2, Steven M. Strasberg1,3, David Jacques1, Nicholas A. Hamilton1, Ryan C. Fields1,3, Dennis Lambert2, Steven Kymes2 & William G. Hawkins1,3,4

1Department of Surgery and 2Center for Economic Evaluation in Medicine, Washington University School of Medicine, St Louis, MO, USA, 3Siteman Cancer Center, St Louis, MO, USA and 4Department of Surgery, St Louis Veterans Affairs Medical Center, St Louis, MO, USA

Abstract

Objectives: Pancreatic leak is a morbid complication following left pancreatectomy, which results in prolonged hospitalization, additional diagnostic testing and invasive procedures. The present authors have previously demonstrated that mesh reinforcement of stapled left pancreatectomy results in fewer pancreatic leaks. This study was conducted to investigate whether mesh reinforcement also results in cost benefits for the health care system.

Methods: A cost benefit model was developed to estimate net cost savings from the payer’s perspective. The model is based on the results of a randomized, single-blinded trial of mesh versus no mesh reinforcement of the pancreatic remnant after left pancreatectomy. A two-way sensitivity analysis was conducted to determine the model’s sensitivity to fluctuations in the cost of mesh and the effectiveness of the mesh in reducing clinically significant leaks.

Results: Average total costs for an episode of care were US$13 337 and US$15 505 for patients who did and did not receive mesh, respectively, which indicates savings of US$2168. Two-way sensitivity analysis showed that, given a probability of 1.9% for developing a clinically significant leak in patients in whom mesh reinforcement was used, the strategy would continue to save costs if mesh were priced at ≤US$1804.

Conclusions: Mesh reinforcement decreases clinically significant pancreatic leaks. Despite the additional cost of mesh reinforcement, the use of mesh reinforcement results in overall cost savings for the health care system because of the resultant decrease in the occurrence of clinically significant leaks.

Received 18 September 2012; accepted 20 December 2012

Correspondence

William G. Hawkins, Washington University Medical Center, Department of Surgery, 660 South Euclid Avenue, Campus Box 8108, St Louis, MO 63110, USA. Tel: +1 314 362 7046. Fax: +1 314 367 1943. E-mail: hawkinsw@wustl.edu

Introduction

Pancreatectomy is performed to excise known malignancy, prevent malignant transformation or relieve symptoms. Left pancreatectomy (resection of the pancreas left of the superior mesenteric vein), whether performed via an open or a laparoscopic technique, is frequently associated with complications caused by the postoperative leakage of pancreatic fluid from the occluded stump of the pancreas (pancreatic leak). Although pancreatic leak may be asymptomatic in a minority of patients, it more often leads to morbid complications and alters patient care. As a result, pancreatic leak is one of the most intensely studied surgical complications.1–3 The reported rates and definitions of pancreatic leak have varied widely in the past. The recent consensus conference and standardization of a classification schema have helped to facilitate comparisons among data from different studies.4 The best estimate of the magnitude of the current problem is from prospective studies which use the modern consensus definition and focus on pancreatic leak as the principle endpoint. The
largest of these is the DISPACT cooperative trial, which compared stapling and hand-sewing techniques for closure of the pancreatic remnant. This showed no significant difference in leak rates between hand-sewn (28%) and stapled (32%) closures, but, more importantly, demonstrated that this problem remains an important challenge. Clinically significant pancreatic leaks burden patients adversely, as can be gauged by increases in hospital stay, rates of readmission, and requirements for additional interventional and diagnostic procedures, and intensive care unit (ICU) transfers. Retrospective analyses have demonstrated that this complication translates into increased health care costs for patients amounting to tens of thousands of dollars.

In an effort to understand and reduce the rate of pancreatic leak, the present group performed a single-blinded randomized controlled trial (RCT) of mesh reinforcement for stapled left pancreatectomy in both laparoscopic and open procedures. Complete details on this trial were published in 2012, but are briefly summarized here. The mesh reinforcement group showed a reduction in the planned primary endpoint of clinically significant leaks categorized as Grade B and C leaks according to the International Study Group on Pancreatic Fistula (ISGPF) classification system. Rates of clinically significant leak (Grades B and C) were 24.4% (11 of 45 patients) in the control group and 1.9% (one of 53 patients) in the mesh reinforcement group ($P = 0.0007$). The patients in this trial serve as a basis for the cost benefit model explored here. If all grades of leak (Grades A, B and C) were to be included in the model, no difference would be seen in this cost benefit approach because by definition Grade A leaks cannot result in a change in clinical management and therefore cannot incur costs.Leaks originally coded as Grade A leaks which eventually incurred costs are upgraded to the appropriate B or C category. The present authors hypothesized that the observed reduction in the frequency of clinically significant pancreatic leak would provide significant benefit to patients and hence result in cost savings for the health care system. However, not all patients develop clinically significant pancreatic leaks and only a limited number of patients would benefit from this intervention. The objective of this study was to determine if the additional cost of using mesh in all patients undergoing stapled left pancreatectomy would justify the benefit gained and hence result in overall cost savings for the health care system.

**Materials and methods**

An evaluation of the use of mesh reinforcement in patients undergoing left pancreatectomy was conducted. This employed a simple decision model and took a cost benefit approach from the payer’s perspective.

The randomized clinical trial was approved by the internal review board of the Washington University School of Medicine and registered on clinicaltrials.gov (NCT01359410). The study began on 1 July 2007 and ended on 30 November 2010. The study was stopped ahead of full recruitment because it met early stopping criteria at interim analysis.

**Model construction**

A simple decision model was constructed comparing two simulated cohorts of patients undergoing left pancreatectomy with and without mesh reinforcement (Fig. 1). The model replicated the post-surgical experience of patients for 100 days following index...
surgery. Costs considered in the model include initial surgical costs (hospital and physician fees for surgery and the cost of mesh reinforcement) and potential post-surgical costs of care, including but not limited to costs of hospital and physician fees, subsequent drain replacement and cross-sectional imaging. The result of the model is the expected total net cost of the post-surgical management of a patient who underwent surgical extirpation. The statistical result of the model represents the net benefit of the management strategy; the strategy that results in the lowest net cost is considered to provide the highest net benefit to the payer. The model was constructed and evaluated using TreeAge 2011 (TreeAge Software, Inc., Williamsport, MA, USA), a software specifically designed to create and evaluate decision trees and models.9

The design incorporates important cost determinants derived from the present group’s recent randomized clinical trial.8 Each patient’s perioperative history was known as these data points were collected as secondary endpoints in the clinical trial. In addition, the hospital provided data on all captured billing events for 100 days following the surgery date, including initial length of stay and emergency room visits, radiologic tests, admissions to and duration of any ICU stay, and interventional procedures. This incomplete list gives examples of the types of event captured but is not inclusive of all data in the paper. A few patients incurred billing events at outside hospitals in the surrounding area. Patients who were admitted to outside facilities were included in the present model and it is likely that all events at outside hospitals were captured in this trial. The Medicare cost estimates used for the cost benefit model were identical to those used for events at outside hospitals in the surrounding area. Costs considered in the model include initial surgical costs (hospital and physician fees for surgery and the cost of mesh reinforcement) and potential post-surgical costs of care, including but not limited to costs of hospital and physician fees, subsequent drain replacement and cross-sectional imaging. The result of the model is the expected total net cost of the post-surgical management of a patient who underwent surgical extirpation. The statistical result of the model represents the net benefit of the management strategy; the strategy that results in the lowest net cost is considered to provide the highest net benefit to the payer. The model was constructed and evaluated using TreeAge 2011 (TreeAge Software, Inc., Williamsport, MA, USA), a software specifically designed to create and evaluate decision trees and models.9

The probabilities of events in Table 1 were combined with the cost data in Table 2 to determine that the expected cost of post-

<table>
<thead>
<tr>
<th>Probability</th>
<th>Baseline (no mesh)</th>
<th>Mesh reinforcement</th>
<th>Reduction (baseline – with mesh)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any leak</td>
<td>56.5%</td>
<td>38.4%</td>
<td>17.6%</td>
</tr>
<tr>
<td>Clinically significant leak</td>
<td>23.8%</td>
<td>1.9%</td>
<td>22.0%</td>
</tr>
<tr>
<td>Upgrade leak status</td>
<td>7.7%</td>
<td>0.0%</td>
<td>7.7%</td>
</tr>
<tr>
<td>Replace drain</td>
<td>23.8%</td>
<td>1.9%</td>
<td>22.1%</td>
</tr>
</tbody>
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Sensitivity analysis
The robustness of the cost benefit decision to assumptions concerning parameter values was evaluated using one-way sensitivity analysis.11 Given uncertainty in model parameters, a two-way sensitivity analysis was conducted to determine the model’s sensitivity to fluctuations in the cost of mesh and the effectiveness of the mesh in reducing the occurrence of clinically significant leaks. Variables that change the cost benefit decision are reported.

Results
Utilizing the decision model (Fig. 1) and the clinical outcome data, patients were assigned to each limb of the decision model. Costs to the health care system were determined for each patient and assigned to the respective group. Average costs were determined for each breakpoint along each respective limb of the decision model.

Table 1 lists the probabilities used for the cost benefit and sensitivity analyses of the model. Probabilities were obtained from the results of the trial. Model probabilities for each group (no mesh reinforcement versus mesh reinforcement) include those for the following categories: any leak; clinically significant leak; upgrade in leak status, and replacement of drain. ‘Any leak’ includes all leaks (i.e. both clinically relevant ISGPF Grade B or C leaks and clinically asymptomatic ISGPF Grade A leaks). Clinically significant leaks include only leaks of Grades B and C. The upgrade leak category was necessary to capture Grade A leaks that became Grade B or C leaks. This occurred in several patients. For example, this type of event occurred when a drain capturing a Grade A leak became accidently dislodged and a new drain was required. As need for an interventional procedure is one of the defining factors in determining leak grade, this category of upgrade leak was helpful in determining cost analysis.

Table 2 presents cost estimates for significant patient events in 2012 Medicare dollars. These are the costs utilized for the subsequent sensitivity analysis. Costs were determined utilizing the Medicare database and published data on specific institutional costs. Costs varied slightly over the duration of the trial, but for modelling purposes all monetary values of earlier events were adjusted for inflation to 2010 US dollars using the Consumer Price Index for medical care (derived from the US Bureau of Labor Statistics).

The probabilities of events in Table 1 were combined with the cost data in Table 2 to determine that the expected cost of post-

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Table 1 List of probabilities used in the model

<table>
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<td>22.1%</td>
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operative management of a patient who underwent left pancreatectomy was US$13 337 if mesh was placed intraoperatively and US$15 505 if no mesh was used. This indicates that, on average, the use of mesh resulted in a saving of US$2168 per patient (from the payer’s perspective).

One-way sensitivity analysis (Fig. 2) showed that at a mesh price of US$165 (the cost at the study institution) mesh reinforcement will produce a cost saving if the probability of the occurrence of pancreatic leak is ≤52.7%. Two-way sensitivity analysis demonstrated that mesh reinforcement would be expected to provide cost savings over a clinically relevant range of values for effectiveness and cost of mesh (Fig. 3). An analysis using data on leakage rates in patients who were given mesh reinforcement (Table 1) in the present clinical trial showed that mesh priced at ≤US$1804 would still result in a cost saving. Other sensitivity analyses completed did not contraindicate the cost savings to be obtained by the use of mesh reinforcement.

**Discussion**

Pancreatic leaks remain a clinically significant problem and as a result impact on costs to the health care system. The present authors and others have demonstrated that mesh reinforcement of stapled pancreatectomy reduces the occurrence of clinically significant leaks. The present study explored a simplified decision model which looked at the major determinants of health system costs and applied this to patients undergoing left pancreatectomy with and without mesh reinforcement. Mesh reinforcement resulted in an average cost benefit to the health care system of US$2168 per patient. The present data were also able to show that this benefit would be expected to be maintained over a clinically relevant range of leaks and mesh costs. This cost saving was more modest than had been hoped, but even modest health care savings can become substantial when applied across the large number of patients who undergo left pancreatectomy each year.

The present study should be interpreted in the light of several limitations. Firstly, although the model is based on the results of an RCT, not all of the data elements on resource use that are required to obtain a true estimation of costs were captured. Nonetheless, in the light of the superior clinical outcomes seen with mesh reinforcement, it is likely that the inclusion of such costs would have increased the extent of the cost savings derived in patients who were given mesh reinforcement and would thus have

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### Table 2 List of costs

<table>
<thead>
<tr>
<th>Factor</th>
<th>Cost, US$</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost of surgery</td>
<td>$11 850</td>
<td>Cost for surgery. Physician 48140; hospital DRG 192</td>
</tr>
<tr>
<td>Mesh reinforcement</td>
<td>$165</td>
<td>Cost for mesh during surgery</td>
</tr>
<tr>
<td>Readmit patient</td>
<td>$5248</td>
<td>Cost to readmit patient. No physician charge; hospital DRG 192</td>
</tr>
<tr>
<td>Install drain</td>
<td>$433</td>
<td>Cost to install drain. Physician 43267; no hospital charge</td>
</tr>
<tr>
<td>Laboratory test</td>
<td>$110</td>
<td>Cost to test for pancreatic leak</td>
</tr>
<tr>
<td>Replace drain</td>
<td>$433</td>
<td>Assumed to be same as first installation</td>
</tr>
<tr>
<td>Drain management (no mesh)</td>
<td>$30 (average: 35 days)</td>
<td>Cost to maintain drain with no mesh</td>
</tr>
<tr>
<td>Drain management (with mesh)</td>
<td>$30 (average: 17 days)</td>
<td>Cost to maintain drain with mesh</td>
</tr>
</tbody>
</table>

DRG, diagnosis-related group code.
strengthened the present findings. Secondly, it is important to recognize that primary quality-of-life data were not collected from trial participants. Lastly, it is typically recommended that evaluations of health care programmes should be conducted from the societal perspective, as well as from that of a cost–utility analysis. Cost–utility analyses are not typically accepted in the USA for making coverage decisions and therefore a cost–utility analysis is unlikely to influence US decision makers. Conversely, payers in Canada and the European Union typically require that the societal perspective be taken along with a cost–utility analysis. However, it must be noted that as the findings of the present study demonstrate a positive net benefit from the payer’s perspective, an analysis from the societal perspective would result in similar findings because such an analysis would take a broader perspective of benefit from the payer’s perspective by applying societal willingness to pay for the benefit of the intervention. In addition, clinically significant leaks impact patients in very diverse ways and thus it could be speculated that the avoidance of leaks would result in an earlier return to work and earlier initiation of chemotherapy in some patients.

Health care costs have escalated, often driven by innovation and progress. It is increasingly important to look for innovations that save health care dollars while benefiting patients. Therefore, it is reasonable to utilize this study of cost benefit as further evidence to justify the use of mesh reinforcement in left pancreatectomy. Further innovations are needed to limit the impact of pancreatic leak. Including cost benefit analyses in future study designs may aid in selecting the best and most cost-effective options for patients.

Acknowledgements
The study was supported by the Department of Surgery and the Center for Economic Evaluation in Medicine, Washington University School of Medicine.

Conflicts of interest
None declared.

References

Figure 3 Two-way sensitivity analysis depicting the mesh price required for mesh reinforcement to remain cost saving over a range of mesh effectiveness in reducing clinically significant leaks


