Sphincter Preserving Fistula Management: A Value Analysis

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Abstract

Introduction: The goals in the treatment of anal fistulas are to eliminate the primary fistula opening and any associated tracts and secondary openings without a change in fecal continence. This study was performed to determine the outcomes and costs for patients who selected sphincter preserving techniques compared to those who opted for traditional methods of management of transsphincteric fistulas.

Methods: Patients presenting with a transsphincteric fistula where prospectively enrolled in a database. All patients were managed using a standardized algorithm. Fecal continence was assessed preoperatively and at 12 months postoperatively using Fecal Incontinence Severity Index and Staining of Undergarment questionnaires. The hospital records were reviewed for the Diagnosis Related Groups (DRG), Computerized Procedure Terminology (CPT) codes and Medicare reimbursements.

Results: On average, patients who selected sphincter preservation had a 92% chance that their fistula could be managed using sphincter preserving techniques. They underwent 1.25 more surgical procedures with an increased cost of $8081. However they also had significantly less detriment in fecal continence.

Conclusion: Transsphincteric anal fistulas can be effectively managed using sphincter preserving techniques. Use of these techniques is associated with less detriment in fecal continence but does result in more surgical procedures and higher costs. A value judgment is required to determine if the benefit is worth the cost.

KEYWORDS: Fistula, sphincter preservation
Introduction
Fistulas-in-ano are the sequelae in up to 50% of perianal abscesses. The goals in the treatment of anal fistulas are to eliminate the primary fistula opening and any associated tracts and secondary openings without a change in fecal continence. No single technique exists that is appropriate for the treatment of all fistulas. With this in mind, an algorithm for the surgical management of anal fistulas was developed (Figure 1). The purpose of this study was to determine the outcomes and costs of sphincter preserving techniques when compared to traditional methods for the management of transsphincteric fistulas.

Methods
With Institutional Review Board (IRB) approval, patients presenting with a transsphincteric fistula were prospectively enrolled in a database which included patient demographics (age, race, gender), comorbidities (diabetes, inflammatory bowel disease, immunosuppression, body mass index), social history (tobacco use), past surgical history (anorectal surgical procedures), fistula characteristics (location, anatomy) and treatment modalities selected. All patients were managed using a standardized algorithm (Figure 1). Continence was assessed preoperatively and at 12 months postoperatively using Fecal Incontinence Severity Index (FISI) and Staining of Undergarment (SU) questionnaires (Figure 2). Patients excluded from this study were those with intersphincteric, extraspincteric, or rectovaginal fistulas and those whose fistula was associated with active inflammatory bowel disease, Human Immunodeficiency Virus (HIV) infection or anal irradiation. Fistula healing was determined by a single colon and rectal surgeon (CNE) using clinical examination 12 months after the final treatment for the patient’s fistula. Healing was defined as no complaint of perianal pain, swelling or drainage within the previous 6 months, no history of additional treatment for a fistula and no evidence of an anal fistula on physical examination. No radiographic or ultrasound studies were performed to confirm fistula healing.

Patients underwent a standardized informed consent process. Those who selected sphincter preserving techniques underwent a second standardized informed consent process to select between either an anal fistula plug or ligation of the intersphincteric fistula tract reinforced with a bioprosthetic (BioLIFT). The techniques for these procedures have been previously described. The prosthetics used in this study were the Anal Fistula Plug (anal fistula plug) and the 4 by 7 centimeter Biodesign graft (BioLIFT); both purchased from Cook Surgical Inc., Bloomington, IN.
The hospital records for patients in this study were reviewed for the Diagnosis Related Groups (DRG), Computerized Procedure Terminology (CPT) codes utilized and Medicare reimbursement for the various procedures.

An intent to treat analysis was performed comparing outcomes of patients who selected sphincter preserving techniques to those who opted for traditional methods of management of transsphincteric fistulas. Average values of the variables (age, continence scores) were compared using chi squared analysis with p values less than 0.05 considered significant.

**Results**

Between April, 2007 and August, 2009, 63 patients with transsphincteric fistulas agreed to participate in this study. There were 44 men and 19 women with an average age of 48 years (range 24-59). A history of diabetes was present in 12 patients, Crohn’s disease in 4 patients and tobacco smoking in 37 patients. Fistulotomy was selected by 12 patients; all male. No patients were lost to follow up and all questionnaires and clinical examinations were performed. The DRG and CPT codes used with the Medicare reimbursements and the costs of the bioprosthetics are shown in Table 1. Table 2 gives a breakdown of the outcomes, costs per healed fistula, and change in continence with the various techniques selected by the participants. Overall, when compared to patients who selected a traditional fistulotomy, those who selected sphincter preserving techniques underwent 1.25 more procedures and had an increased cost of $8081 per healed fistula (Table 3). However, patients who selected sphincter preservation also had a significant decrease in the negative effects on continence associated with surgery for an anal fistula.

**Discussion**

This study design was selected for 2 reasons. First, initial attempts to randomize patients to either sphincter preserving or traditional techniques of surgical management was not possible due to poor enrollment related to the risk of incontinence after fistulotomy and the poor long term results of sphincteroplasty. Attempts to randomize patients who selected sphincter preservation to either the anal fistula plug or BioLIFT were also unsuccessful because of poor enrollment related to the different morbidity and outcomes of the two procedures in the literature.

The second reason this methodology was selected is because this approach allows evaluation of the complete “episode of care”; a concept that has been the focus of
recent attention by third party payers. This methodology allows a more complete 
evaluation of the cost and outcomes of the various modalities available for the 
treatment of transsphincteric anal fistulas. This methodology accounts for staged 
procedures, the impact of multiple perianal septic episodes on sphincter function 
and other unknown variables related to the surgical management of 
transsphincteric anal fistulas. Most importantly, this methodology allows for the 
evaluation of cost, outcomes and safety of the different approaches. Patients, 
surgeons and payers can use these data to determine the value of each technique. 
This methodology is not comprehensive; it does not capture the relevant costs 
related to time lost from work because multiple procedures or the lifetime costs 
related to fecal incontinence; i.e. continence garments, etc.

Lastly, the role of the various techniques in this algorithm will almost certainly be 
the topic of much debate. The algorithm was meant to represent the “state of the 
art” at the time this study had begun, but there is no doubt that this algorithm will 
be modified as new techniques for the surgical management of anal fistulas are 
described and new data is published regarding current methods.

The incidence of fistula recurrence with the various techniques in this series is 
consistent with the published results with these techniques in the literature.\textsuperscript{4-8} The 
impact of these techniques on continence has not been as extensively or 
consistently studied in the literature. The data regarding continence obtained with 
this study does suggest that less than perfect continence is more prevalent than 
suspected in patients with fistula disease. The difference in mean preoperative 
FISI and staining of undergarment scores between the traditional and sphincter 
preserving groups, while not reaching statistical significance, may be a reflection 
of the fact that no women, with their unique risk of obstetric sphincter injury, 
chose fistulotomy. The FISI and staining of undergarment scores of the 4 patients 
who ultimately had their fistula successfully managed using a cutting seton were 
included in the sphincter preservation group. This is appropriate as this study 
employs an intent to treat analysis and it is not possible to determine if the 
sphincter dysfunction in this group is related to the multiple surgical procedures, 
the recurrent anorectal sepsis or the subsequent fistulotomy.

As stated earlier, this study does provide data which patients and surgeons can use 
to determine the value of the currently available techniques for the surgical 
management of anal fistulas. In this study patients who select sphincter 
preservation have a 92% chance that their fistula can be managed using sphincter 
preserving techniques, undergo 1.25 more surgical procedures, have a greater 
morbidity and an increased cost. These increased costs will ultimately result in 
higher premiums for the patient with private insurance and higher taxes for all to
support public insurance programs. However, for this increase in morbidity and cost, patients were found, on average, to have significantly less detriment in their sphincter function.

The increase in the number of surgical procedures and cost were primarily related to the requirement that patients undergoing sphincter preservation have a 9-12 week period of seton drainage. While controversial, it was felt that a period of seton drainage allows any acute inflammation of the fistula tract to resolve and potential side branches to close and would improve the outcomes with sphincter preserving fistula. This requirement also prolonged the period of morbidity from the fistula.

There is a large volume of literature concerning anal fistulas. This study, incorporating multiple techniques for the management of transsphincteric fistula, fistula recurrence, evaluation of continence and the costs for the entire episode of care is the most complete assessment of the surgical management of transsphincteric anal fistulas in the literature.

Conclusions
Management of transsphincteric anal fistulas by sphincter preservation is effective but costs $8081 more per healed fistula when compared to traditional fistulotomy. Use of these techniques also results in a significant decreased detriment in FISI and staining of undergarment scores. A value judgment is required by the surgeon, patient and the public to determine if the benefit is worth the cost.

Conflict of Interest
CNE; Cook Surgical Inc.’ Bloomington IN, Honorarium, Paid Consultant, Research Grant
AJS; none
References
**Figure 1.** Algorithm for the management of transsphincteric fistulas

Fistula-in-ano

→ Eligible for study

Yes (n=63) → Informed Consent → Draining seton (n=51) → Anal Fistula Plug (n=12) → Healing (n=8) → LIFT/BioLIFT (n=4) → Healing (n=3) → Follow-up

No → Exclude from study → Fistulotomy (n=12) → Healing → BioLIFT (n=39) → Healing (n=36) → Follow-up

Recurrence (n=4)

→ Repeat BioLIFT → Advancement Flap → Cutting Seton (n=4)

→ Healing → Recurrence → Healing (n=4) → Cutting Seton → Follow-up

→ Informed Consent → Follow-up
Thank you for completing this questionnaire on incontinence. Incontinence is defined as the inability to have full control over the passage of stool or gas. Please answer the questions as honestly as you can. Your answers will remain strictly confidential.

Fecal Incontinence Severity Index
For each of the following, please indicate how often in the last month, on average, you have experienced any amount of accidental bowel leakage. *Please select only one answer per row.*

<table>
<thead>
<tr>
<th></th>
<th>Never</th>
<th>1 to 3 times a month</th>
<th>Once a week</th>
<th>2 or more times a week</th>
<th>Once a day</th>
<th>2 or more times a day</th>
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</thead>
<tbody>
<tr>
<td>Gas</td>
<td>(+0)</td>
<td>(+2)</td>
<td>(+4)</td>
<td>(+6)</td>
<td>(+8)</td>
<td>(+9)</td>
</tr>
<tr>
<td>Mucus</td>
<td>(+0)</td>
<td>(+5)</td>
<td>(+7)</td>
<td>(+7)</td>
<td>(+9)</td>
<td>(+11)</td>
</tr>
<tr>
<td>Liquid stool</td>
<td>(+0)</td>
<td>(+10)</td>
<td>(+13)</td>
<td>(+14)</td>
<td>(+16)</td>
<td>(+18)</td>
</tr>
<tr>
<td>Solid stool</td>
<td>(+0)</td>
<td>(+11)</td>
<td>(+14)</td>
<td>(+16)</td>
<td>(+17)</td>
<td>(+19)</td>
</tr>
</tbody>
</table>

**Total ______** (to be calculated by your doctor)

Staining of Undergarment
Do you have

1. Staining of underwear ______(+1) ______(+2) ______(+3) ______(+4)
2. The need to wear a pad ______(+1) ______(+2) ______(+3) ______(+4)

**Total ______** (to be calculated by your doctor)
**Table 1.** DRG and CPT codes with the Medicare reimbursement and the cost of the bioprosthetics.

<table>
<thead>
<tr>
<th>DRG code</th>
<th>n (patients)</th>
<th>Reimbursement</th>
</tr>
</thead>
<tbody>
<tr>
<td>348</td>
<td>26</td>
<td>$ 6,914</td>
</tr>
<tr>
<td>349</td>
<td>37</td>
<td>$ 4,003</td>
</tr>
<tr>
<td><strong>Average (per procedure)</strong></td>
<td></td>
<td><strong>$ 5,204</strong></td>
</tr>
</tbody>
</table>

**CPT code**

<table>
<thead>
<tr>
<th>CPT code</th>
<th>Description</th>
<th>Reimbursement</th>
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</thead>
<tbody>
<tr>
<td>46020</td>
<td>Placement of seton</td>
<td>$ 214</td>
</tr>
<tr>
<td>46280</td>
<td>Treatment of fistula submuscular</td>
<td>$ 430</td>
</tr>
<tr>
<td>46707</td>
<td>Placement of anal fistula plug</td>
<td>$ 454</td>
</tr>
<tr>
<td>57267</td>
<td>Placement of prosthetic (add on)</td>
<td>$ 537</td>
</tr>
<tr>
<td>Hospital</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physician</td>
<td></td>
<td>$ 264</td>
</tr>
</tbody>
</table>

Cost of bioprosthetics (Cook Surgical Inc., Bloomington IN)

- Anal fistula plug: $ 850
- Bioprosthetic graft (Biodesign, 4x7 cm): $ 550
**Table 2.** Outcomes and costs for surgical management of transsphincteric anal fistulas (*NS* = not significant)

**Fistulotomy (12 patents)**

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Healed fistulas</th>
<th>12</th>
</tr>
</thead>
<tbody>
<tr>
<td>Continence</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FISI pre</td>
<td>4.3</td>
<td></td>
</tr>
<tr>
<td>post</td>
<td>19.6</td>
<td></td>
</tr>
<tr>
<td>p</td>
<td>&lt; .05</td>
<td></td>
</tr>
<tr>
<td>SU pre</td>
<td>1.7</td>
<td></td>
</tr>
<tr>
<td>post</td>
<td>2.9</td>
<td></td>
</tr>
<tr>
<td>p</td>
<td>&lt; .05</td>
<td></td>
</tr>
</tbody>
</table>

**Costs**

- Hospital (avg) $ 5,204
- Physician $ 430
- **Per healed fistula** $ 5,634

**Placement of seton (51 patents)**

**Costs**

- Hospital (avg) $ 5,204
- Physician $ 214
- **Total** $ 5,414

**Anal fistula plug (12 patents)**

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Healed fistulas</th>
<th>8</th>
</tr>
</thead>
<tbody>
<tr>
<td>Continence</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FISI pre</td>
<td>6.7</td>
<td></td>
</tr>
<tr>
<td>post</td>
<td>7.1</td>
<td></td>
</tr>
<tr>
<td>p</td>
<td>NS*</td>
<td></td>
</tr>
<tr>
<td>SU pre</td>
<td>1.8</td>
<td></td>
</tr>
<tr>
<td>post</td>
<td>1.7</td>
<td></td>
</tr>
<tr>
<td>p</td>
<td>NS</td>
<td></td>
</tr>
</tbody>
</table>

**Costs**

- Seton $ 5,414
- Hospital (avg) $ 5,204

http://services.bepress.com/wjcs/vol5/iss2/art2
Physician $ 454
Bioprosthetic $ 850
**Per healed fistula** $17,883

**BioLIFT (44 patents)**

**Outcomes**

- Healed fistulas: 40
- Continence
  - FISI
    - pre: 7.6
    - post: 9.4
    - p: NS
  - SU
    - pre: 2.3
    - post: 1.8
    - p: NS

**Costs**

- Seton $ 5,414
- Hospital (avg) $ 5,204
  - add on $ 537
- Physician $ 430
  - add on $ 264
- Bioprosthetic $ 550
**Per healed fistula** $13,639

**Cutting seton (4 patents)**

**Outcomes**

- Healed fistulas: 4
- Continence
  - FISI
    - pre: 7.0
    - post: 28.3
    - p: <.05
  - SU
    - pre: 2.1
    - post: 3.2
    - p: <.05

**Costs**

- Hospital (avg) $ 5,204
- Physician $ 214
**Per healed fistula** $ 5,414
Table 3. Comparison of outcomes and costs of patients with fistulotomy and sphincter preserving techniques for the surgical management of transsphincteric fistulas

<table>
<thead>
<tr>
<th></th>
<th>Fistulotomy</th>
<th>Sphincter preserving</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>12</td>
<td>51</td>
<td></td>
</tr>
<tr>
<td>Healed fistulas</td>
<td>12</td>
<td>47 (92%)</td>
<td></td>
</tr>
<tr>
<td>Change in continence</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FISI</td>
<td>15.3</td>
<td>1.2</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>SU</td>
<td>1.2</td>
<td>-0.7</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Costs per healed fistula</td>
<td>$5,634</td>
<td>$13,715</td>
<td></td>
</tr>
</tbody>
</table>