Intraluminal Negative Pressure Wound Therapy for Optimizing Pharyngeal Reconstruction

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IMPORTANCE Pharyngocutaneous fistula formation after pharyngeal reconstruction is one of the most common and challenging problems to manage. Despite many advances in management, the published success rates indicate a role for any adjuvant therapy that could potentially decrease this complication.

OBJECTIVE To describe the use of intraluminal negative pressure dressings (NPDs) in pharyngeal reconstruction.

DESIGN, SETTING, AND PARTICIPANTS Retrospective case series at a tertiary care academic hospital. Twelve laryngectomy patients underwent pharyngeal reconstruction augmented by placement of an intrapharyngeal NPD in combination with the introduction of vascularized tissue from August 2011 to May 2012. All patients had potential risk factors for compromised wound healing defined as previous radiation therapy, hypothyroidism, diabetes mellitus, compromised nutrition, or established pharyngocutaneous fistula.

INTERVENTIONS An NPD was placed in an intraluminal position spanning the length of the pharyngeal defect as part of the reconstructive procedure. The negative pressure sponge was attached to a standard nasogastric tube to which negative pressure was applied. External closure of the pharynx was then achieved with regional or free tissue transfer.

MAIN OUTCOMES AND MEASURES Pharyngeal closure rates, timing until return to oral diet, identification of wound healing risk factors, and adverse events related to use of the device.

RESULTS Eleven of 12 patients (92%) achieved pharyngeal closure with reconstruction using negative pressure wound therapy. All patients had at least 1 potential risk factor for compromised wound healing, with 11 of 12 (92%) having 2 or more. Seven patients had an established pharyngocutaneous fistula, and 5 patients underwent primary reconstruction after laryngopharyngectomy. In 6 of these 7 patients undergoing fistula repair, pharyngeal closure was achieved, and they resumed an oral diet at 1 week postoperatively. The other had successful leak repair initially, but 1 week later developed a separate area of wound breakdown and a second fistula. All 5 patients in whom an intraluminal NPD was placed at the time of initial vascularized tissue reconstruction were able to resume an oral diet by 3 weeks postoperatively, with 3 of them eating by mouth at 1 week postoperatively. No serious adverse events could be attributed to the use of intraluminal NPDs.

CONCLUSIONS AND RELEVANCE Intraluminal negative pressure wound therapy is feasible and safe. Future research should be conducted to determine its potential in optimizing pharyngeal reconstruction in high-risk patients.
Surgical salvage after chemoradiation therapy for larynx cancer can be complicated by delayed wound healing. Variables contributing to this complication include underlying tissue changes; unfavorable nutritional status from previously compromised enteral feeding access; suppressed thyroid function; bacterial contamination of the wound bed; and tissue dynamics from swallowing, breathing, and coughing. Pharyngocutaneous fistula formation after laryngopharyngectomy is one of the most common and also most challenging problems to manage. The reported incidence of this complication varies widely based on report, with a recent study from our institution describing an overall rate of 21%. Pharyngocutaneous fistula is often complicated by stomal contamination with risk for aspiration pneumonia and great vessel exposure to pharyngeal secretions. To date, there is a lack of high-level evidence on this subject to help guide our decision making, but it has become well recognized that certain strategies, such as the introduction of vascularized tissue into these wounds and optimizing medical comorbidities, aids in management.

Negative pressure wound therapy is a technique that can be used to promote healing. This technology was developed over 15 years ago and has become increasingly valuable in the management of chronic and acute wounds, contaminated wounds, traumatic tissue loss, surgical dehiscence, ulceration from vascular insufficiency, fistulas, and other indications. Current theories on how negative pressure wound therapy is successful include removal of exudate from the wound bed, decrease of interstitial edema, increase in blood flow, increase in granulation formation, decrease in bacterial burden, stimulation of fibroblast and endothelial cell proliferation, mechanical contracture of the wound bed, and mechanical debridement with sponge exchange.

Negative pressure wound therapy generally involves placing a dressing, such as a sponge, into a wound cavity, sealing the area with an adhesive film, and connecting the wound to a vacuum device to deliver a controlled negative pressure to the wound bed. Negative pressure dressings (NPDs) have been previously described in the head and neck in this traditional, externally applied manner. Recently, a system has been devised to apply negative pressure in an intraluminal or intracavitary fashion to heal rectal abscess cavities that developed after colorectal anastomotic leakage. This technology has also been applied to assist healing of anastomotic leaks in the thorax and abdomen after gastrectomy, iatrogenic esophageal perforation, and esophageal rupture from Boerhaave syndrome. Based on these positive reports, we applied this technique in an attempt to potentially optimize pharyngeal reconstruction in high-risk patients, with the major objective of determining safety and feasibility. To our knowledge, this is the first time NPDs have been applied in an intraluminal fashion in the head and neck.

Methods

The institutional review board at the University of Alabama at Birmingham granted approval for the retrospective review of all patients undergoing head and neck reconstruction. Medical records were reviewed for all patients with head and neck cancer in whom intraluminal NPDs were used in combination with the introduction of vascularized tissue for pharyngeal reconstruction. From August 2011 to May 2012, 12 patients met these inclusion criteria.

Demographic and clinical data were recorded, including patient age, sex, medical comorbidities, all previous oncologic therapy, operative details, radiologic findings, and full perioperative course of wound healing. Descriptive variables were assessed as mean (SD) data and categorical variables as percentages with significant digits.

Surgical Technique

Patients in this study underwent concurrent or had previously undergone primary or salvage total laryngectomy with partial or total pharyngectomy. Patients gave written informed consent for surgery, and off-label indications for NPD usage were discussed with them. All procedures were performed in the operating room under general anesthesia with ventilation via cuffed endotracheal tube placed in the tracheostoma. If oncologic ablation was performed at the time of surgery, frozen section pathologic analysis was used to ensure adequate margins. Otherwise, in cases of established pharyngocutaneous fistula, esophagoscopy was performed to ensure that no malignant neoplasm was identified.

We recommend practice with construction of the system before implementation (Figure 1). The typical steps for intraluminal NPD application are illustrated in Figure 2. The nose is topically decongested, and a standard 18F nasogastric tube (NGT) (Kendall) is passed through the nose down into the pharynx and led out of the pharyngeal opening. The defect is measured, and a standard negative pressure wound sponge (VAC Granufoam, KCI) is cut to the appropriate length. We recommend at least 1 cm of intraluminal sponge both superior and inferior to the pharyngeal opening. The sponge diameter should be slightly larger than the diameter of the planned pharyngeal reconstruction at rest but slightly smaller with compression and suction. A stab incision is made in the sponge, and the NGT is inserted, confirming that there are no fenestrations lying outside of the sponge (often the NGT will need to be trimmed). The NGT is then sewn to the sponge with 2-0 silk. Depending on the compliance of the pharynx and the cephalic or caudal location of the pharyngeal repair, often a bolster formed from an occlusive petrolatum gauze dressing, such as Xeroform (Kendall), should be sewn to the cephalic portion of the sponge to maintain adequate suction. The sponge is then withdrawn into an intraluminal position. Closure of the pharynx may then be performed with vascularized tissue (ie, regional or free flap). Suction can be applied intermittently to test the method of closure before final sutures are placed. The NGT should be adequately secured to the nose via tape or transseptal suture. It is important to remember to seal the ventilation port of the NGT. Continuous high-intensity vacuum should be applied to the other port of the NGT, at 125 mm Hg. A canister with less than 100 mL of volume was used to collect secretions from the wound bed. Vacuum tub-
ing can be clamped for patient ambulation, and so forth, similar to techniques for traditional NPDs. Removal of the sponge is performed under general anesthesia in order to reexamine the wound. This is accomplished by flushing the sponge with normal saline and pulling the NGT back until the sponge can be removed orally. The sponge is then disconnected from the NGT, and the remaining NGT is then pulled out through the nose. Postoperatively, an esophagram is recommended to confirm the endoscopic findings (Figure 3).

Results

Application of an intraluminal NPD in combination with the introduction of vascularized tissue resulted in successful pharyngeal reconstruction in 11 of 12 patients (92%). The mean (SD) patient age was 63 (8) years, and 7 of 12 were female (58%). All 12 patients had undergone surgery for malignant neoplasms of the upper aerodigestive tract. Seven patients had an established pharyngocutaneous fistula, and an intraluminal NPD was
placed at the time of the fistula repair in an attempt to optimize pharyngeal closure. Five high-risk patients had an intraluminal NPD placed in a prophylactic fashion at the time of initial reconstruction after laryngopharyngectomy in an attempt to decrease the chance of pharyngocutaneous fistula.

All 12 patients had at least 1 potential risk factor for compromised wound healing (Table), with most (92%) having 2 or more. Nine patients had been previously treated with radiation therapy, 7 were being treated for hypothyroidism, 4 had diabetes mellitus, and 6 had compromised nutrition status (>10% loss of premorbid weight). There was attempt to optimize all comorbidities. The NPD was removed a mean (SD) of 5.8 (1.7) days after placement. The timing of removal was often influenced by access to operating room time, with a goal of 7 days of therapy unless clinically indicated otherwise. One patient had difficulty maintaining an adequate seal and underwent early removal. A second patient’s intraluminal NPD was removed early because the sponge was soiled with stomach contents after an episode of nausea and vomiting. No serious adverse events, however, could be attributed to the use of intraluminal NPDs.

**Optimization of Pharyngocutaneous Fistula Closure With Intraluminal NPD**

Seven patients with potential risk factors for inhibited wound healing and an established pharyngocutaneous fistula underwent reconstruction with vascularized tissue and the use of an intraluminal NPD in an attempt to potentially optimize closure (Table). These patients had failed conservative therapy, with time of failure ranging from 2 weeks to 1 year after pharyngocutaneous fistula diagnosis. Defect measurements ranged from 1 to 6 cm². All 7 of these reconstructions used a regional myofascial pectoralis flap.

All 7 patients (100%) had satisfactory closure of the established pharyngocutaneous fistula based on an esophagram at approximately 1 week postoperatively. Six of these 7 patients (86%) resumed and have maintained an oral diet from that point forward. One of these 7 patients (14%) initially had a successful leak repair but later developed a separate area of wound breakdown and a second fistula.

**Prophylactic Intraluminal NPD**

Five patients at high risk for pharyngocutaneous fistula had an intraluminal NPD placed prophylactically at the time of initial pharyngeal reconstruction with vascularized tissue (Table). Two reconstructions were of complex wounds with pharyngeal violation from cancer ablation in the case of salvage laryngectomy stomal recurrence, 1 requiring a free flap in a tubed fashion. Two other cases were salvage total laryngopharyngectomies requiring free flap reconstruction in a tubed fashion. The fifth reconstruction case was a total laryngectomy patch defect in the setting of a patient who had undergone irradiation twice.

Five of 5 patients (100%) were able to resume an oral diet by 3 weeks postoperatively. Three patients had negative results from esophagrams at 1 week postoperatively and were thus able to immediately resume oral intake. One patient had a negative result from an esophagram at 1 week postoperatively (at the time of NPD removal) but developed a neck infection the following week. A second esophagram was then obtained, which identified a 6-mm pharyngocutaneous fistula; therefore, the wound was washed out and a pathway for drainage was established. This closed without further intervention at the 3-week postoperative mark, at which point he resumed oral nutrition. One patient had an esophagram at 1 week indicating a small contained leak, and therefore a previously placed passive drain was left in place. This leak sealed spontaneously without intervention, and this patient also resumed oral nutrition at the 3-week postoperative time point.

**Discussion**

Herein, we describe the application of intraluminal NPDs to aid in the prevention or closure of pharyngocutaneous fistulas as an adjunct to conventional techniques. Previous re-
ports using NPDs in rectal and esophageal anastomotic leaks or abscess cavities suggested the use of intracavitary NPDs in an attempt to potentially optimize pharyngeal reconstruction.37-40 Although the sample size in this study was small, we feel this novel technique has proven to be feasible after successful application in 12 patients, with a minimum of 6-months’ follow-up. There were no serious adverse events associated with its use. This technique added minimal additional effort to the surgeon or postoperative burden to the patient other than the necessity of a second anesthetic for device removal. Despite advances in managing pharyngocutaneous fistula, with the current published success rates, there is certainly indication for any adjuvant therapy that could potentially decrease this complication.6,9,15,41,42

Patients who underwent intraluminal NPD in combination with the introduction of vascularized tissue experienced a higher than expected rate of successful pharyngeal integrity, allowing them to rapidly return to an oral diet. This retrospective study is prone to selection bias; however, we used this strategy in the “worst of the worst” patients in an attempt to potentially optimize pharyngeal reconstruction.37-40

Table. Comparison of Patients Using Intraluminal Negative Pressure Dressings

<table>
<thead>
<tr>
<th>Patient, No./Sex/Age, y</th>
<th>Fistula Size, cm</th>
<th>Previous Therapy</th>
<th>Wound Healing Risk Factors</th>
<th>Indication</th>
<th>Closure Technique</th>
<th>Tx Length, d</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>1/F/68</td>
<td>2 × 3</td>
<td>Salvage TL, BND 1° Closure</td>
<td>CRT DM Hypothyroidism</td>
<td>Prophylaxis</td>
<td>Tubed RFFF</td>
<td>6</td>
<td>Negative results from esophagram PCF closure PO diet at 1 wk</td>
</tr>
<tr>
<td>2/M/68</td>
<td>1 × 1</td>
<td>Salvage TL RFFF closure, healed. Stomal recurrence = RND/partial pharyngectomy 1° Closure</td>
<td>CRT Hypothyroidism Malnourished</td>
<td>Prophylaxis</td>
<td>Tubed RFFF + PEC</td>
<td>7</td>
<td>Negative results from esophagram PCF closure PO diet at 1 wk</td>
</tr>
<tr>
<td>3/F/71</td>
<td>1.5 × 2.5</td>
<td>TO carbon dioxide laser excisions × 2; salvage TL, BND 1° Closure</td>
<td>XRT DM</td>
<td>Prophylaxis</td>
<td>RFFF</td>
<td>8</td>
<td>Negative results from esophagram PCF closure PO diet at 1 wk</td>
</tr>
<tr>
<td>4/M/68</td>
<td>1 × 2</td>
<td>Salvage TL, BND 1° Closure</td>
<td>XRT</td>
<td>Prophylaxis</td>
<td>Tubed RFFF</td>
<td>3</td>
<td>Negative results from esophagram PCF closure PO diet at 1 wk</td>
</tr>
<tr>
<td>5/F/44</td>
<td>2 × 3</td>
<td>Salvage TL, BND RFFF closure</td>
<td>XRT DM</td>
<td>Prophylaxis</td>
<td>RFFF</td>
<td>7</td>
<td>Negative results from esophagram PCF closure PO diet at 1 wk</td>
</tr>
<tr>
<td>6/F/60</td>
<td>1 × 4</td>
<td>TL, BND RFFF closure</td>
<td>Hypothyroidism Malnourished</td>
<td>Prophylaxis</td>
<td>Tubed RFFF</td>
<td>7</td>
<td>Negative results from esophagram PCF closure PO diet at 1 wk</td>
</tr>
<tr>
<td>7/M/68</td>
<td>2 × 2</td>
<td>TL, BND 1° Closure</td>
<td>DM Malnourished</td>
<td>Prophylaxis</td>
<td>Tubed RFFF</td>
<td>4</td>
<td>Negative results from esophagram PCF closure PO diet at 1 wk</td>
</tr>
<tr>
<td>8/M/60</td>
<td>NA</td>
<td>Salvage TL, BND RFFF closure, healed Stomal recurrence = partial pharyngectomy</td>
<td>XRT Hypothyroidism</td>
<td>Prophylaxis</td>
<td>RFFF</td>
<td>6</td>
<td>Negative results from esophagram PCF closure PO diet at 1 wk</td>
</tr>
<tr>
<td>9/F/73</td>
<td>NA</td>
<td>Salvage TL, BND RFFF closure, healed Stomal recurrence = total pharyngectomy</td>
<td>CRT Hypothyroidism Malnourished</td>
<td>Prophylaxis</td>
<td>Tubed RFFF</td>
<td>5</td>
<td>Negative results from esophagram PCF closure PO diet at 1 wk</td>
</tr>
<tr>
<td>10/F/61</td>
<td>NA</td>
<td>TO carbon dioxide laser excisions × 2; salvage TLP</td>
<td>XRT Hypothyroidism Malnourished</td>
<td>Prophylaxis</td>
<td>Tubed RFFF + PEC</td>
<td>7</td>
<td>Positive results from esophagram Conservative tx PCF closure at 3 wk PO diet at 3 wk</td>
</tr>
<tr>
<td>11/M/55</td>
<td>NA</td>
<td>TLP, BND</td>
<td>Hypothyroidism Malnourished</td>
<td>Prophylaxis</td>
<td>Tubed rectus FF</td>
<td>7</td>
<td>Negative results from esophagram Positive second esophagostomy neck w/o PCF closure at 3 wk PO diet at 3 wk</td>
</tr>
<tr>
<td>12/F/64</td>
<td>NA</td>
<td>Salvage TL</td>
<td>XRT Repeated XRT</td>
<td>Prophylaxis</td>
<td>RFFF</td>
<td>6</td>
<td>Negative results from esophagram PCF closure PO diet at 1 wk</td>
</tr>
</tbody>
</table>

Abbreviations: BND, bilateral neck dissections; CRT, chemoradiation therapy; DM, diabetes mellitus; FF, free flap; NA, not applicable; PCF, pharyngocutaneous fistula; PEC, myofascial pectoralis regional flap; PO, postoperative; RFFF, radial forearm free flap reconstruction; RND, radical neck dissection; TL, total laryngectomy; TLP, total laryngopharyngectomy; TO, transoral; tx, therapy; w/o, washout; XRT, radiation therapy. a Negative pressure dressing removed early.
tempt to optimize their chance at successful pharyngeal closure. Although the introduction of vascularized tissue alone is often sufficient in the management of pharyngeal closure, in these selected patients, most would agree that the rate of pharyngocutaneous fistula is still considerable. It is unknown if this technique could be used to augment primary closure and avoid introduction of vascularized tissue. As previously described, multiple factors likely contribute to limiting the success of the initial wound-healing phase in these cases. In addition to the proposed mechanisms for accelerated healing associated with NPDs, the application of an intraluminal NPD in this fashion theoretically may reduce salivary exposure of the suture lines, decrease positive pressure from swallowing along the closure, and act as a stent.

There were multiple hypothetical concerns with intraluminal NPDs for pharyngocutaneous fistula that have fortunately not proven to be clinically significant. Although 1 patient required a single esophageal dilation postoperatively, we did not notice circumferential scarring from application of the NPD to the entire lumen. Patient discomfort, anecdotally, has been minimal. Depending on the level of the fistula, tissue compliance, and anatomy of prior reconstructions, perhaps the greatest anticipated obstacle was generation of an adequate seal for the wound vacuum cavity. Again, a seal can be maintained with the addition of an occlusive petroleum gauze dressing to the cephalic portion of the wound sponge. Another area of concern when attempting to generate subatmospheric pressure can be if there is a tracheoesophageal prosthesis or a previously created tracheoesophageal puncture with feeding tube inserted through it. Fortunately, these potential sites of failure have not proven to be an issue.

This technique would benefit from additional study to measure both short- and long-term outcomes. Patient-perceived subjective data should be collected, as well as a prospective randomized clinical trial with appropriate controls designed. Such a study should result in a higher likelihood of accurate conclusion in regard to the efficacy of intraluminal NPDs at improving pharyngeal reconstructive outcomes. Safety should be continued to be monitored, because certainly this is an off-label use of technology. Cost analysis for intraluminal NPDs should also be investigated to justify the additional charges associated with the device and a second anesthetic.

Conclusions

Intraluminal negative pressure wound therapy is feasible and safe. Future research should be conducted to determine its potential in optimizing pharyngeal reconstruction in high-risk patients.

REFERENCES

steps toward an international consensus. Injury. 2011;42(suppl 1):S1-S12.