




ORIGINAL ARTICLE

Modified vacuum-assisted closure (EndoVAC) therapy for treatment of pharyngocutaneous fistula: Case series and a review of the literature

Teresa Bernadette Steinbichler MD¹  | Dolores Wolfram MD² |
Annette Runge MD¹ | Roland Hartl MD¹ | Daniel Dejaco MD¹  |
Tina Rauchenwald MD² | Claus Pototschnig MD¹ | Herbert Riechelmann MD¹ |
Volker Hans Schartinger MD¹ 

¹Department of Otorhinolaryngology, Head and Neck Surgery, Medical University of Innsbruck, Innsbruck, Austria

²Department of Plastic, Reconstructive and Aesthetic Surgery, Medical University of Innsbruck, Innsbruck, Austria

Correspondence

Volker Hans Schartinger, Department of Otorhinolaryngology, Head and Neck Surgery, Medical University of Innsbruck, Anichstr.35, A-6020 Innsbruck, Austria.
Email: volker.schartinger@i-med.ac.at

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Abstract

Background: Pharyngocutaneous fistula is a potential life-threatening complication following head and neck surgery. There is only limited evidence about the efficacy of vacuum-assisted closure (VAC) therapy and endoscopic vacuum-assisted closure (EndoVAC) therapy for the treatment of pharyngocutaneous fistulas.

Methods: In this article, we report on a consecutive case series of six male patients with pharyngocutaneous fistula treated with a modified outside-in EndoVAC technique. We also present a review of the current related literature.

Results: EndoVAC therapy alone was successful in five of the six patients (83.3%) with a median duration of EndoVAC therapy of 18.5 days (range: 7 to 32 days) and a median number of EndoVAC sponge changes of 4 (range: 1 to 9 changes). One patient needed additional reconstructive surgery after prior radiochemotherapy and jejunal transfer. No treatment-related complications were observed.

Conclusion: EndoVAC therapy is an easy-to-perform, safe procedure for the treatment of pharyngocutaneous fistulae.

KEYWORDS

head and neck cancer, laryngectomy, negative-pressure wound therapy, radiochemotherapy, salvage surgery

1 | INTRODUCTION

Pharyngocutaneous fistula is one of the most common complications in laryngeal and pharyngeal surgery, particularly in cases where the mucosal membranes cannot be kept intact and must be closed again. In various studies,¹⁻⁴ the incidence of pharyngocutaneous fistula has been reported to be approximately 14% after primary total laryngectomy, and the incidence significantly increases up to 36% after prior radiochemotherapy.^{1,2,5,6} In addition to unfavorable factors, such as prior radiochemotherapy, several general patient conditions, such as malnutrition, diabetes mellitus, and low preoperative hemoglobin, can affect wound healing and increase the risk of pharyngocutaneous fistula formation.³ Pharyngocutaneous fistulae severely affect a patient's quality of life as they prohibit oral intake, prolong the hospital stay, and might cause the need for repeated surgical interventions.^{1,2} The occurrence of fistulae was found to increase the length of a hospital stay by more than 18 days in comparison an average non-complicated case.⁷ Furthermore, Parikh et al.⁷ demonstrated that 57% of patients required secondary reconstructive surgery, whereas 43% were treated with conservative wound care. Patients who require surgical repair are best treated using regional myocutaneous flaps or free tissue transfers.⁷ Fistulae are often associated with extensive overlying skin loss and mucosal dehiscence. Unless a critical structure is exposed, flap reconstruction should not be undertaken until the process of secondary healing and the development of healthy granulation tissue has occurred.¹ However, it is often difficult to achieve healthy granulated recipient tissue in pharyngocutaneous fistula patients because the saliva further degrades the recipient tissue, independent of the use of anticholinergic drugs.

Endoscopic vacuum-assisted closure (EndoVAC) therapy is a recent innovation described for use in luminal perforations and post-surgical leaks after gastrointestinal surgery. Vacuum-assisted closure (VAC) therapy is an established technique for managing superficial wounds by applying negative pressure through a polyurethane sponge. It promotes healing through enhanced formation of granulation tissue, increasing vascularity and decreasing stasis.⁸ In head and neck surgery, conventional VAC therapy has been reported to have high success rates in multiple indications with a low evidence level.⁹ In pharyngocutaneous fistulae, the mean response was reported to be 90% in a summary of 51 cases.^{9,10} In 2008, Weidenhagen et al. reported the use of an endoscopically-placed VAC system for the treatment of anastomotic leaks after gastric resection.¹¹ EndoVAC therapy has since been described for a range of upper gastrointestinal indications. It was initially used for leaks following gastro-esophageal resections.¹²⁻¹⁴ However, other indications have included iatrogenic

esophageal perforations,¹⁵ sleeve gastrectomy leaks,¹⁶ or pancreatic pseudocysts.¹⁷ EndoVAC is minimally invasive and provides an alternate treatment modality in difficult situations.¹⁸ Very high success rates of 80–90% have been reported in small case series, with around 100 cases in total.^{15,16,19} In head and neck pharyngocutaneous fistulae, limited information is available from case reports using endoluminal application.²⁰

In this article, we report on the novel and successful use of modified outside-in EndoVAC therapy as a technique for the treatment of pharyngocutaneous fistulae in a series of six patients.

2 | MATERIALS AND METHODS

A retrospective analysis of all six of the patients treated with modified outside-in EndoVAC therapy at the Department of Otorhinolaryngology, Medical University of Innsbruck between 2018 and 2020 was performed. Various patient and disease parameters were analyzed, including sex, age, and the American Society of Anesthesiologists (ASA) score, as a simple instrument to assess general health status,¹⁵ length of hospital stay, number of surgical interventions, total surgical procedure time, and functional impairment.

2.1 | Surgical procedure

Modified outside-in EndoVAC sponge insertions were performed under general anesthesia with an endotracheal tube. The patient was placed in the supine position. A thorough assessment of the pharyngocutaneous fistula was performed (Figure 1A), if necessary, with the help of 0° or 30° endoscopes. This included the diameter of the defect, the size of the cavity, and the use of a pharyngoscopy to visualize the luminal end of the fistula. Microbiological samples are acquired to evaluate bacterial wound contamination. Moreover, a histological sample was obtained to exclude tumor recurrence as cause of the fistula. Afterwards, the EndoVAC sponge (EndoSponge®, Braun Melsungen Corp., Melsungen, Germany) was matched to the defect size and inserted into the fistula using the outside-in technique (Figure 1B). To seal the system, Tachosil® (Takeda, Berlin, Germany) and Opsite Transparent Waterproof Films (Smith+Nephew, Baar, Switzerland) were used (Figure 2). Then, a negative pressure of 100–125 mm Hg was applied (V.A.C. Therapy®, KCI, Vienna, Austria). The pharyngeal side of the modified outside-in EndoVAC was not sealed but collapsed due to the applied negative pressure. Therefore, it is mandatory that the length of the EndoVAC sponge does not exceed

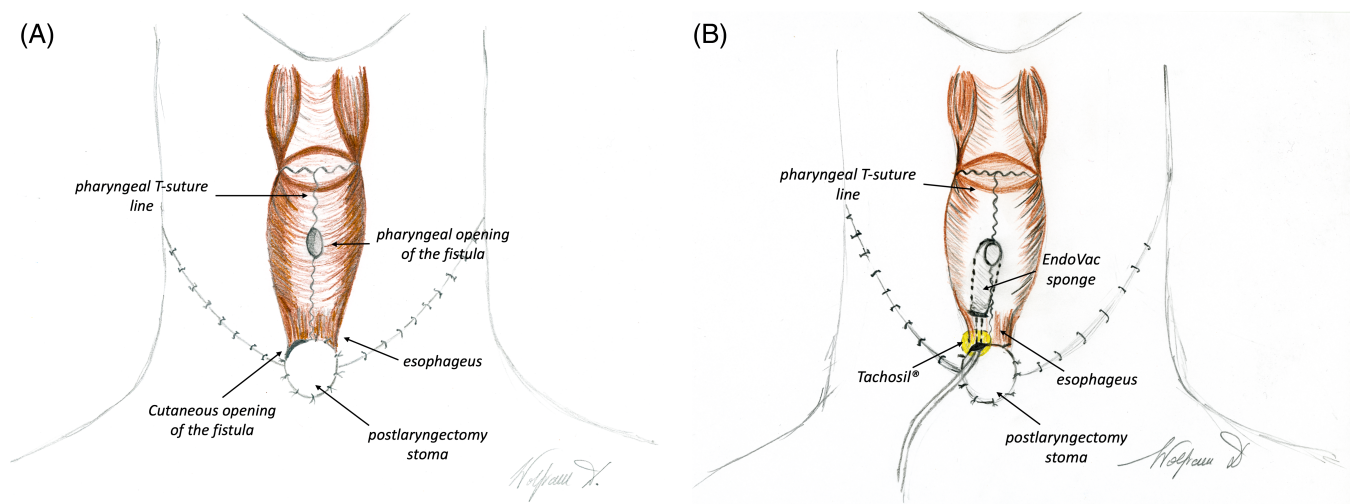


FIGURE 1 (A) Graphical illustration of pharyngocutaneous fistula after laryngectomy. The pharyngeal opening of the fistula is typically localized around the T-suture of the pharyngeal mucosa. The cutaneous opening of the fistula is typically localized in close proximity to the postlaryngectomy stoma. (B) Graphical illustration of pharyngocutaneous fistula after laryngectomy with the EndoVac sponge in situ. The EndoVac sponge is placed into the fistula in an outside-in technique and shortened during each change to allow subsequent closure of the fistula. Printed with permission from © Medical University of Innsbruck [Color figure can be viewed at wileyonlinelibrary.com]



FIGURE 2 Materials required for modified EndoVac treatment. Besides standard surgical equipment, the EndoVAC sponge (EndoSponge®, Braun Melsungen Corp., Germany), Tachosil® (Takeda, Berlin, Germany) and Opsite Transparent Waterproof Films (Smith+Nephew, Baar, Switzerland) are used [Color figure can be viewed at wileyonlinelibrary.com]

the mucosal lining of the pharyngeal wall. The EndoVAC sponge was changed every 2–4 days to clear the exudate that may block the system; this was done either under general anesthesia or under mild sedation. If the sponge is left for a prolonged period of time, it can become fixed to the surrounding structures. To change the sponge, it is first disconnected from the suction. If the sponge cannot be removed easily by using gentle traction, saline should be infused to gently manipulate it out.¹⁸ During each change, the EndoVAC sponge is slightly shortened to allow

subsequent closure of the fistula. Successful treatment is achieved when the luminal end of the fistula is closed, which can also be verified using blue dye swallow examinations prior to the EndoVAC sponge change. Postoperatively, the fistula closure is confirmed with video fluoroscopic studies before resuming oral nutrition. Secondary wound healing is achieved for the remaining fistula canal, when possible.

3 | RESULTS

3.1 | Study population

Six male patients with a median age of 60 years (range: 52–77 years) undergoing modified EndoVAC therapy for pharyngocutaneous fistula between 2018 and 2020 at the Department of Otorhinolaryngology, Medical University of Innsbruck, were consecutively included in the study. Five of the six patients suffered from pharyngocutaneous fistula after laryngectomy; one patient was referred to our department after surgical treatment for Zenker's diverticulum at another center. The clinical and demographic data are summarized in Table 1.

3.2 | Clinical presentation and history

All but one of the six patients ($n = 5$) developed pharyngocutaneous fistula after prior laryngectomy (Figures 1A and 3). Three of these patients received salvage laryngectomy ± pharyngectomy due to the failure of

TABLE 1 Overview of the study population

No. Diagnosis	Pathology	Risk factors systemic ^a	Risk factors local ^a	First-line surgical procedure	ASA Age score demarcation	Day of fistula EndoVAC treatment	Definitive wound closure	Total number of inpatient days	Swallowing outcomes (follow-up time)
1	Laryngeal cancer	Hypertension Anticoagulation Atrial fibrillations	—	Total laryngectomy with bilateral neck dissection	77 3 17	16	Primary wound closure	59	No gastrostomy tube, diet slightly restricted (11.5 months)
2	Esophageal cancer	Hypertension	Prior RCTH (laryngeal cancer 5 years ago)	Total laryngopharyngectomy, esophageal resection and reconstruction with free jejunal transfer	55 3 28	21	Pectoralis major flap	88	No gastrostomy tube, diet slightly restricted (20 months)
3	Oropharyngeal cancer	Hypothyroidism. Hypertension	Prior RCTH	Total laryngopharyngectomy, bilateral neck dissection and reconstruction with free forearm flap transfer	71 2 25	11	Primary wound closure	57	Gastrostomy tube needed; some oral feeding possible (8 months) ^b
4	Zenker's diverticulum	—	—	Open surgery for Zenker's diverticulum	56 1 19	7	Primary wound closure	21	Normal oral intake (15 months)
5	Hypopharyngeal cancer	Hypothyroidism. Hypertension, Hepatitis C	Prior RCTH	Total laryngopharyngectomy bilateral neck dissection and reconstruction with pectoralis major flap	52 2 11	32	Primary wound closure	143	Normal oral intake (21 months)
6	Laryngeal cancer	—	—	Total laryngopharyngectomy bilateral neck dissection	65 3 18	23	Primary wound closure	52	Normal oral intake (18 months)

Abbreviations: RCTH, radiochemotherapy; SCC, squamous cell carcinoma.

^aFor impaired wound healing.

^bPatient had a locoregional and distant relapse 2 months after EndoVAC treatment and received palliative immunotherapy+ systemic therapy. The local relapse is located at the base of the tongue.



FIGURE 3 Case presentation of a male patient presenting with pharyngocutaneous fistula after salvage laryngectomy. (A) Endoscopic view of the pharyngocutaneous fistula 1 week after fistula demarcation and unsuccessful treatment with parasympatholytic drugs (scopolamine patch, glycopyrroniumbromid), intravenous antibiotics, local administered medical honey (MediHoney®, DermaScience Inc., Ontario, CA, USA) and a salivary by-pass tube. (B) Overview of the same patient 1 week after fistula demarcation. The cutaneous opening of the fistula is localized at approximately one o'clock of the post-laryngectomy stoma. (C) Endoscopic view of the pharyngocutaneous fistula after 2 weeks of modified EndoVac treatment. Besides significant shrinkage of the fistula and closure of the pharyngeal opening of the fistula, the fistula was lined with healthy granulation tissue allowing secondary wound healing [Color figure can be viewed at wileyonlinelibrary.com]

first-line radiochemotherapy ($n = 3$). The median day of fistula demarcation was 18 days after laryngectomy (minimum 11 days, maximum 28 days). Oral diet is usually started in our center 10–14 days after (salvage) laryngectomy and after regular findings in blue dye swallows and video fluoroscopic studies. The fistula was demarcated in five of the six patients after the start of oral intake and after an initial normal X-ray examination ($n = 5$). One patient had an open resection of a Zenker's diverticulum at another center. He was transferred to our department 42 days after the initial surgery and after failure of the conservative fistula treatment and failure of surgical fistula closure without any reconstructive flaps 4 days earlier. In all cases, the fistula was visualized with blue dye swallows and video fluoroscopic studies. The initial conservative treatment approaches consisted of no oral nutrition, parasympatholytic drugs to inhibit salivary gland function (scopolamine patch, glycopyrroniumbromid), intravenous antibiotics, and local administered medical honey (MediHoney®, DermaScience Inc., Ontario, CA, USA) over 4–7 days. Additionally, a silicone, salivary bypass tube was inserted under general anesthesia in all of the patients; however, the bypass tube was not well tolerated by four of the patients.^{21,22} After the failure of these initial treatments, EndoVAC sponges were inserted into the fistula as described above under general anesthesia (Figures 1 and 2). The total surgical procedure time for the first EndoVAC application was 33–55 min (median: 50 min). The EndoVAC system was placed against a salivary bypass tube if it was tolerated by the patient ($n = 2$). Four of the patients ($n = 4$) did not tolerate the salivary bypass tube due to a strong gag reflex, which could not be controlled with medication. The EndoVAC sponge was changed every 2–4 days to clear the

exudate that could block the system. Furthermore, if the sponge is left for a longer period of time, it can become fixed to the surrounding structures due to the formation of granulation tissue. The total surgical procedural time for the subsequent changes of the EndoVAC sponge ranged from 9 to 78 min (median: 28 min). The number of EndoVAC sponge changes ranged from 1 to 9 (median: 4), and the overall duration of EndoVAC therapy ranged from 7 to 32 days (median: 18.5 days). The total surgical procedure time for the removal of the EndoVAC system after fistula closure ranged from 13 to 190 min (median: 34 min). In one patient, removal of the EndoVAC system was combined with reconstruction with a myocutaneous pectoralis major flap, requiring a total surgical procedure time of 190 min. Enteral nutrition was routinely achieved with gastrostomy tubes during EndoVAC treatment. Two of the salvage laryngectomy patients already had a gastrostomy tube because of first-line radiochemotherapy, which could be used during EndoVAC therapy ($n = 2$). Three patients received a gastrostomy tube for enteral nutrition during the first EndoVAC application ($n = 3$). The patient who developed pharyngocutaneous fistula after open resection of a Zenker's diverticulum at another center received a nasogastric tube during the first EndoVAC application for enteral nutrition.

Median hospital stay of the patients was 58 days (range: 21–143 days).

Modified EndoVAC monotherapy led to a closure of the pharyngocutaneous fistula in all but one case; thus, the procedure had a success rate of 83.3%. The patient who required combined therapy had undergone an initial total laryngopharyngectomy, esophageal resection and reconstruction with free jejunal transfer due to esophageal cancer. Prior to this treatment, he had received

locoregional radiochemotherapy in 2013 due to laryngeal cancer (Table 1). In this case, modified EndoVAC therapy was combined with a myofascial pectoralis major flap for definitive fistula closure.²³ Five of the six patients were able to continue an oral diet. No pharyngeal stricture was observed (median follow-up time: 15 months). One patient had a locoregional and distant relapse 2 months after the end of the EndoVAC treatment. The local relapse was located at the base of the tongue. This patient is not able to swallow and is dependent on a gastrostomy tube (Table 1).

4 | DISCUSSION

The development of pharyngocutaneous fistula represents a complication of total laryngectomy and other head and neck surgeries where mucosal defects are an integral part of the surgical procedure. Potentially life-threatening complications may occur, such as erosion of large blood vessels, especially the carotid artery, and further surgical interventions are frequently necessary.¹⁻³ The incidence of pharyngocutaneous fistula has been reported to be 14.3% (95% confidence interval [CI] 11.7–17.0) after primary total laryngectomy, increasing significantly to 22.8% (95% CI 18.3–27.4) and 34.1% (95% CI 22.6–45.6) in cases of previous radiotherapy or previous radiochemotherapy.⁴ In addition to prior radiotherapy and radiochemotherapy, a previous bilateral neck dissection, including a level VI dissection, is associated with a higher risk for fistula formation.³ Malnutrition is reported to be present in 35% to 50% of all patients with head and neck cancer, and the affected patients are at a greater risk for major surgical complications. A preoperative albumin value <3.5 g/dl is also associated with an increased risk for postoperative fistula formation and a postoperative hemoglobin level < 12.5 g/dl has been reported to carry a 9-fold increase in the risk of fistula development.³ Other patient factors favoring fistula formation are tobacco use, tumor stage, tumor site (especially hypopharyngeal cancer), diabetes mellitus, chronic pulmonary diseases, and chronic hepatopathy.^{24,25} In our case series, five of the six patients had at least one local or systemic risk factor and had an ASA score II or score III as rated by the anesthesiologist (Table 1).²⁶

Pharyngocutaneous fistulae are classified into major and minor pharyngocutaneous fistulae. Major pharyngocutaneous fistulae are defined as fistulae lasting longer than 1 month, or requiring surgical treatment for repair, or if the fistula leads to death.^{25,27} In high-risk patients, fistula-preventive therapies, such as salivary bypass tubes, myocutaneous pectoralis major flaps, and intraluminal negative pressure wound therapy with EndoVAC, have been suggested.^{21,23,28} However, despite all efforts to prevent pharyngocutaneous fistula, its development

cannot always be avoided and it remains a common problem in head and neck surgery. In this article, we describe a novel use of EndoVAC therapy for direct pharyngocutaneous fistula closure and for preparing the recipient cervical tissue prior to flap reconstruction by generating healthy granulation tissue (Figure 2). EndoVAC was not used endoscopically; we prefer the use of the term modified outside-in EndoVAC therapy. However, the tubular shape of the EndoVAC sponge was used for contraction and cleaning of the pharyngocutaneous fistula with the help of continuous negative pressure suction (Figure 1).

This modified EndoVAC therapy was found to be a safe and feasible procedure, as none of the patients in this study had any complications related to its use. In general, VAC wound therapy is contraindicated whenever large blood vessels are exposed²⁹; thus, in pharyngocutaneous fistula, modified EndoVAC therapy should only be used in the case of median defects or if the defect is not situated in close proximity to the carotid artery and jugular vein. The first EndoVAC application took nearly 1 h; however, this surgical procedure time also included a pharyngoscopy to visualize the luminal end of the fistula and the histological probes of the fistula and surrounding tissue to exclude tumor recurrence. Subsequent EndoVAC sponge changes took less than 30 min, and could also be performed under mild sedation instead of general anesthesia. The surgical technique was easy to perform and could be done by all surgeons regardless of their education level, after the first demonstration. An air tight covering of the EndoVAC system was mandatory for achieving continuous negative pressure suction. This was the most difficult part of the entire procedure, but it could be managed with Tachosil, a fibrin- and thrombin-coated matrix, and with transparent foils (Figure 2). The use of this modified EndoVAC therapy led to a closure in all patients except one, and in that patient, it helped prepare the recipient cervical tissue for myofascial pectoralis major flap reconstruction.

Five of the six patients were able to continue an oral diet after modified EndoVAC therapy ($n = 5$). No patient developed a pharyngeal stricture. According to Sweeny et al., the incidence of pharyngeal stricture is not increased after pharyngocutaneous fistula formation.³⁰ However, an increased risk of stricture formation after negative pressure wound therapy was described for anastomotic leakage after rectum and esophageal resections.^{11,12} We were unable to find a positive correlation, as none of the presented patients suffered from pharyngeal stricture (Table 1), which is also supported by a case series presented by Asher et al.¹⁰ The median follow-up time was 18 months, which might be sufficient as the majority of pharyngeal strictures occur within the first year after total laryngectomy.^{30,31}

5 | CONCLUSION

Modified outside-in EndoVAC therapy should be considered as a therapeutic option in major pharyngocutaneous fistula. It is an easy-to-perform and safe procedure especially for median fistulae or when the fistula does not develop in close proximity to larger blood vessels. It can be used alone or it can be combined with reconstructive flaps. Furthermore, the proposed modified EndoVAC therapy was found to have good swallowing function results as no pharyngeal stricture was observed, and five of the six patients were able to continue oral intake.

DATA AVAILABILITY STATEMENT

Data available on request from the authors.

ORCID

Teresa Bernadette Steinbichler  <https://orcid.org/0000-0002-2666-226X>

Daniel Dejaco  <https://orcid.org/0000-0001-9176-7415>

Volker Hans Schartinger  <https://orcid.org/0000-0002-5887-7644>

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