

Clinical Techniques: Downstate Fistula Formula Update

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Received on: 27 June 2021; Accepted on: 09 November 2022; Published on: 21 January 2023

ABSTRACT

Aim: Review our case series of salvage total laryngectomies (STL) after 2010 using the downstate fistula formula (DFF) for the incidence of postoperative (post-op) pharyngocutaneous fistulas (PCF).

Background: Pharyngocutaneous fistulas (PCF) remains the most common complication after STL, even with the use of vascularized flaps at a rate of 30%. The DFF is a multipronged approach to prophylactically address risk factors contributing to PCF formation.

Technique: The DFF incorporates a watertight two-layer closure, pectoralis major myocutaneous flap reconstruction, antibiotic prophylaxis, delayed oral intake using a G-tube, salivary diversion, and an anti-reflux regimen.

Conclusion: Initial results of 11 patients treated by the DFF published in 2009 showed a 0% failure rate. A review of patients treated by DFF from 2010 continued to maintain a 0% failure rate.

Clinical significance: The use of the DFF in STL patients has reduced the incidence of PCF to zero with a reduced length of stay.

Keywords: Fistula formula, Pharyngocutaneous fistula, Salvage laryngectomy.

International Journal of Head and Neck Surgery (2022); 10.5005/jp-journals-10001-1539

BACKGROUND

Results of the Veterans Administration trial in 1991, followed by the Radiation Therapy Oncology Group 91-11 trial in 2003, revolutionized first-line treatment for advanced laryngeal cancer. These studies demonstrated the efficacy of chemoradiation in eradicating cancer while preserving laryngeal function and leading to concurrent chemoradiation (CCRT), largely replacing total laryngectomy as the primary treatment for T3 and select T4 cancers.¹ Despite near equivalent survival rates, larynx preserving therapy comes at the cost of increased local failure rates, with subsequent STL required in 16–36% of patients.^{1–3} As is well documented in the literature, STL following CCRT is associated with up to three times the risk of post-op wounds and systemic complications in comparison to primary surgical treatment.⁴

A systematic review by Hasan et al. found an overall complication rate of 65.7% following STL, and consistent with prior studies, the most common complication is the formation of a PCF.⁵ Furthermore, STL was shown to have two times the risk of PCF formation with increased duration and severity of PCF compared to primary surgery.⁶ Development of PCF is associated with increased morbidity secondary to delay in initiation of adjuvant treatment as well as prolonged hospitalization and the occasional need for reoperation. Despite tremendous research investigating surgical techniques to reduce rates of PCF and recent studies demonstrating the success of pectoralis major muscle flap (PMMF) in lowering PCF rates following STL, the overall incidence remains unchanged at about 30%.^{1,3–5,7,8} It is, therefore, essential that we develop a reliable, reproducible method for preventing this complication and the associated morbidity it portends.

As described previously in the literature, the DFF⁹ is a multipronged approach integrating the most promising PCF prevention techniques described consistently and prophylactically in every STL. Prior to the development of the DFF, the senior author had an unplanned PCF occurrence rate of 67% following STL. This calculation is based on historical controls composed of nine cases where one

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How to cite this article: Irizarry R, Sukato D, Sundaram K. Clinical Techniques: Downstate Fistula Formula Update. *Int J Head Neck Surg* 2022;13(4):99–101.

Source of support: Nil

Conflict of interest: None

or more components of the formula were not used. Following the implementation of the formula, the first 11 cases performed by the senior author all healed successfully without unplanned fistula formation. Now, 10 years following implementation, outcomes performed by the same senior author are reported.

Technique

The fistula reduction formula includes early gastrostomy, anti-reflux therapy (histamine type 2 blockade and proton pump inhibitor), broad-spectrum triple antibiotic therapy (cephalexin, metronidazole, and ciprofloxacin), a watertight two layer closure, PMMF interposition, and a controlled diverting pharyngostomy (Fig. 1).

Pharyngeal Closure

Reconstruction is performed in two tension free layers by either a horizontal or T closure based on available mucosa. The inner layer is closed by simple 3-0 submucosal continuous vicryl sutures with inverted mucosal edges. The second layer of serosa and remaining pharyngeal musculature is closed with simple interrupted 3-0 vicryl sutures. The third layer is a pectoralis major interposition muscle flap. The flap is held in place by Prolene sutures secured in place to the upper skin flap with retention buttons and removed 4 weeks later.

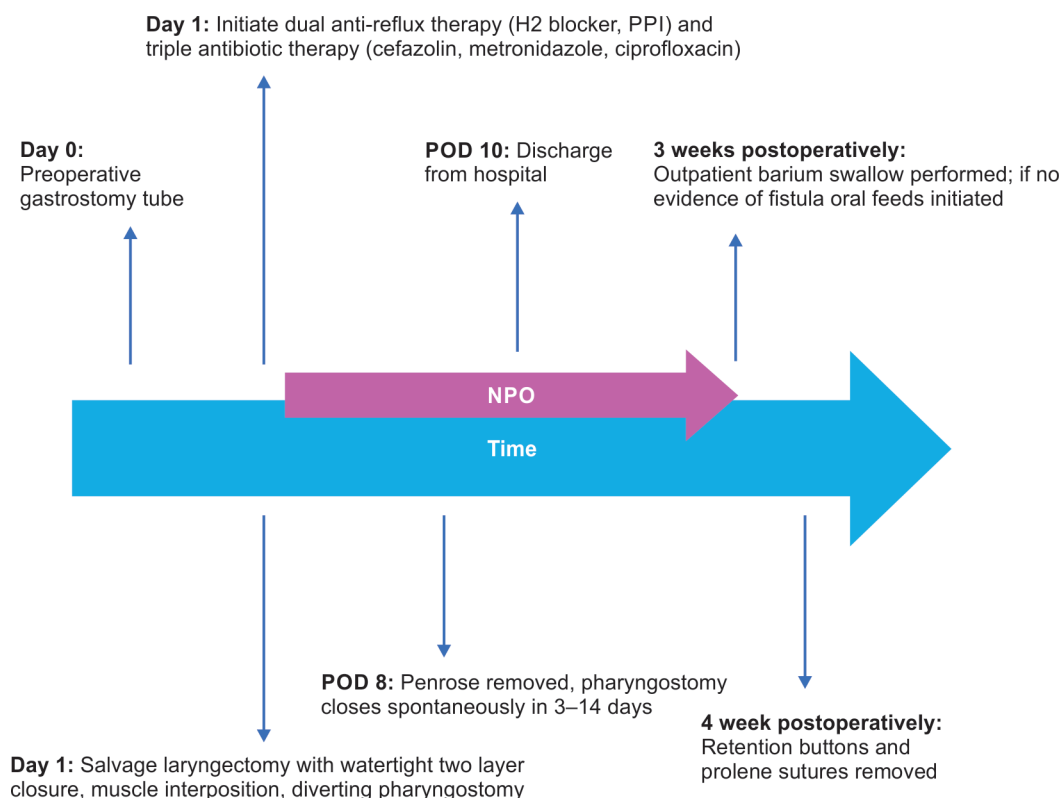


Fig. 1: DFF timeline

Updates

A total of 10 new cases were performed over the past 10 years, each using the DFF, none of which developed a PCF. All patients underwent salvage total laryngectomy. Seven of these cases were treated primarily with the DFF. All of these cases healed as expected with no unexpected complications or extended length of stay. Two patients were initially treated by another surgeon and underwent initial reconstruction with a radial forearm free flap. Both cases were complicated by post-op PCF. Subsequently, both then underwent DFF reconstruction with a senior author and healed without complications or extended length of stay. The last patient underwent primary treatment with DFF, and the post-op course was complicated by wound infection and dehiscence of the stomal suture line without fistula formation. Wound cultures grew methicillin-resistant *Staphylococcus aureus* (MRSA) and *Pseudomonas aeruginosa* (*P. aeruginosa*). Following the initiation of appropriate antibiotic therapy and local wound care with daily packing changes, this patient healed appropriately and was discharged. Wound infection prolonged hospital stays by 1 week.

DISCUSSION

Salvage total laryngectomy (STL) has surpassed primary total laryngectomy in frequency despite the increased risk of post-op complications ranging from 59 to 64%.¹⁰ As seen in initial outcome studies, PCF remains the most common complication of STL and is seen in about 30%^{1,3,5,7,8} of patients, though significant institutional variation exists with rates ranging between 14 and 61%. Development of post-op PCF is associated with delay in adjuvant treatment, prolonged hospital stays, reoperation in a highly comorbid patient group, and mortality from carotid blowout or aspiration pneumonia.³ Unchanged rates of PCF following STL

indicate we have yet to develop a technique or intervention to consistently reduce the morbidity of this essential salvage surgery.

Studies examining vascularized flaps in salvage laryngectomy strongly support the standardized use of the pectoralis major myocutaneous flap. Single institutional studies report an 18–22% absolute risk reduction of fistula formation with the use of this flap. A meta-analysis including 33 studies suggests a reduction in fistula rates from 28% without flap coverage to 10% with onlay flap-reinforced closure.⁴ A second meta-analysis by Sayles et al. demonstrated that PCF rates following salvage surgery prophylactically performed with PMMF were equivalent to those for primary laryngectomy (10–14%).¹¹ Yet persistent PCF formation and wide-ranging institutional variation suggest the presence of other influencing factors.¹²

Our outcomes using the DFF support the prophylactic use of PMMF as the foundation of fistula prevention. Using the DFF, the senior author was able to obtain a 0% rate of PCF, which has remained consistently at 0% over the past 10 years. Although PMMF is an essential component of healthy healing, it is independently insufficient to obtain 0% rates of PCF, as evidenced by the literature. To augment the use of vascularized onlay flaps, the DFF aims to preemptively address additional risk factors and thereby lower the PCF rate even further. Other factors influencing the formation of PCF remain controversial, with conflicting evidence in the literature. Conclusive findings are limited by the retrospective nature and heterogenous reporting variables in existing studies. Some potential variables that warrant consideration include antibiotic prophylaxis, the timing of oral feeds, and salivary diversion interventions.

Wound infection remains the second most common post-op complication seen in about 14% of patients. Infection likely potentiates the impaired wound healing observed in radiated

tissue, making an immature stoma vulnerable to breakdown. Initially, our triple antibiotic regimen appeared sufficient to prevent post-op infection. Our last patient, however, demonstrates the importance of understanding microbial evolution and adjusting antibiotic regimens appropriately. Given the recent propensity for immature tracheostomas to harbor organisms such as MRSA and *P. aeruginosa*, the continued success of the DFF will likely require an alteration in the antibiotic regimen. Our continued success will likely require the incorporation of clindamycin into ciprofloxacin and flagyl, and therefore address MRSA coverage.

Another concept of the DFF is to “protect” the pharyngeal closure from acidity and saliva, which involves the use of a prophylactic gastrostomy tube, anti-reflux therapy, and a controlled diverting pharyngostomy. This concept of “protecting” the surgical site is supported by the observation that our DFF was successful despite the failure of free-flap reconstruction. These findings suggest that viable vascularized tissue alone is insufficient to prevent PCF formation. By implementing our multipronged approach, we have shown evidence that our formula can be used not only prophylactically to prevent PCF but also to treat cases of initial reconstructive failure.

CONCLUSION/SIGNIFICANCE

Our findings are limited by a small sample size, but provide support for incorporating a multipronged approach for preventing fistula formation. Although single institution protocols published in the literature may approach our fistula rate of 0%, we believe the prophylactic and targeted multifactorial nature of DFF is critical for achieving and maintaining a 0% rate of PCF over the past 10 years.

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