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RESEARCH PAPER

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The use of Montgomery salivary bypass tubes and pharyngocutaneous fistula following salvage laryngectomy

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Abstract

Objectives: Pharyngocutaneous fistula (PCF) is the most common complication to follow total laryngectomy (TL) and is associated with increases in length of hospital stay and with a need for revision surgery or readmission, as well as with delays in return to oral diet. Patients who require salvage TL (STL) or primary (chemo)radiation therapy are at higher risk for developing PCF. Due to the quality-of-life burden of PCF on patients, limiting this occurrence is crucial.

Methods: We conducted a retrospective cohort study of patients undergoing STL with placement of Montgomery salivary bypass tube (MSBT)™ for at least 2 weeks duration between 2013 and 2017 at a single institution. Our patients all underwent free flap reconstruction. Our primary outcome of interest was development of PCF. Secondary outcomes included demographics, previous treatment, base of tongue (BOT) involvement, extent of defect, concurrent neck dissection (ND), and margin status. Univariate χ^2 analysis was used to evaluate factors associated with PCF.

Results: Forty-four patients underwent STL with Montgomery tube placement and free flap reconstruction. Eight developed PCF (18.2%). The average age was 61.6 years; 36 patients were male (81.8%), whereas eight patients were female (18.2%). There was no association between PCF and previous chemoradiation versus radiation (15.8% vs. 33.3%, $P < 0.30$), BOT involvement versus not (11.1 vs. 22.2%, $P < 0.38$), circumferential versus partial defect (18.8% vs. 17.9%, $P < 0.94$), ND versus none (10% vs. 25%, $P < 0.20$), or margin status.

Conclusion: PCF complicated 18.2% of STL cases at our institution and was not associated with differences in primary treatment modality, presence of concomitant ND, extent of pharyngeal defect, BOT involvement, or positive frozen or permanent surgical margin.

KEYWORDS

free flap reconstruction, Montgomery, pharyngocutaneous fistula, salivary bypass tube, salvage total laryngectomy, total laryngectomy

INTRODUCTION

Pharyngocutaneous fistula (PCF) has long been considered among the most vexing complications to develop following total laryngectomy (TL). This is in part, because it occurs so frequently, complicating up to 65% of all TL postoperative courses.[1] Furthermore, PCF has been associated with increases in length of hospital stay, readmission rates, and overall medical costs while also contributing to decreases in patient quality of life and functional capability.[2–5]

Despite the significant burden to patients, debate remains regarding the many risk factors for PCF as well as universally accepted strategies for prevention. Most studied risk factors are nonmodifiable at the time of surgery and therefore are nonideal targets for prevention at the operative level. Multiple modalities for intra-operative prevention have been described, with some being more widely accepted than others. Free flap reconstruction has been shown to reduce the relative risk of fistula formation and is commonly used in high-risk patients.[6] Montgomery salivary bypass tubes (MSBT)™ have been used in the treatment of PCF since 1978, with varied reports of its effectiveness as a PCF prevention modality.[5,7–9]

In recent years, there has been increasing evidence that the surgeon and hospital volumes and specializations play a key role in postoperative complications, mortality, and survival after cancer surgery. The fundamental goal of radical resection is to obtain adequate exposure that allows good visualization of the entire tumor to ensure resection with wide three-dimensional margins while allowing maximum preservation of normal non-involved tissues.[10] Tassone et al.[11] found that positive initial margins were associated with worse disease-free survival among patients who underwent primary TL despite negative margins on final pathology examination. Aires et al.[12] also found that positive surgical margin was a risk factor for PCF after TL.

In higher-risk populations, such as those requiring salvage TL (STL), there is an increased frequency of PCF occurrence as well as a heightened severity of complication.[2,3] Therefore, it is exceedingly important to identify risks for and limit the occurrence of PCF, especially within this high-risk population. In this study, we sought to determine the incidence of and the risk factors for PCF in patients undergoing STL with free flap and salivary bypass tube (SBT) placement at a single institution.

METERIAL AND METHODS

After approval by the University of Tennessee Health Sciences Memphis Institutional Review Board (#00002301), we reviewed the electronic health records of patients who underwent STL at the institution between 2013 and 2017. Inclusion criteria included history of primary radiotherapy or chemo-radiotherapy and eventual STL. All patients also underwent concomitant free flap reconstruction and MSBT™ placement with tube retention for at least 2 weeks. We excluded patients who underwent primary laryngectomy or received a regional flap reconstruction.

A thorough chart review was performed on the cases of 44 patients who met the inclusion criteria. The following demographic and clinical data were recorded: age, sex, tumor characteristics (primary site and stage, base of tongue (BOT) involvement, and circumferentiality of defect), primary treatment (radiotherapy or chemoradiotherapy), surgical details (surgeon, date, intraoperative frozen section margin status, and permanent margin status), presence or absence of concomitant neck dissection (ND), extent of resection, occurrence of PCF, PCF management (surgical vs. conservative), length of follow-up, functional outcome (time to oral diet), and survival status.

The fistula development rate for the entire cohort was calculated and reported as an incidence of overall fistula occurrence. The population was stratified into cohorts by potential risk factors, and the relative rates of fistula occurrence were calculated for each group of interest. We performed univariate statistical analysis through GraphPad to describe and compare data. Descriptive variables were characterized by mean ± SD for continuous variables and by number percentages for categorical variables. *T*-tests were used to compare means and χ^2 analysis was employed to evaluate the differences between categorical rates.

RESULTS

At a single-center academic institution, 44 consecutive patients underwent STL with free flap reconstruction and MSBT™ placement. The overall incidence of PCF development was 18.2%, occurring in eight of the 44 cases. Development of PCF was not associated with differences in primary treatment modality, presence of concomitant ND, extent of pharyngeal defect, BOT involvement, or margin status.

The average age at the time of STL was 61.64 years old with a SD of 7.44 years. The youngest patient was 49 years and the oldest patient was 79 years. Primary tumor site affected the larynx in 54.5%, hypopharynx in 11.4%, oropharynx in 20.5%, and oral cavity in 9.1% of the study population. The study population included 36 male patients and eight female patients (m∶f ratio of 4.5). Then, 32.5% of patients had early-stage disease (Stage 1 or 2) and 67.5% had late-stage (Stage 3 or 4) based on the American Joint Committee on Cancer 7.[13]

All surgeons performed inverting multilayer closure (Figure 1) and postoperative care was routine for all patients. Two patients expectorated the MSBT™ at different times throughout their postoperative course. One, within the 2-week postoperative window, was surgically replaced; the other occurred later in the postoperative period and was treated conservatively.

The average length of follow-up at the time of the study conclusion was 209 ± 197 days. Some patients were lost to follow-up after surgery, whereas others approached 3-year follow-up timelines. Thirty-nine subjects had documentation of nutritional intake at the last follow-up. Sixteen (41.0%) of these returned to their normal oral

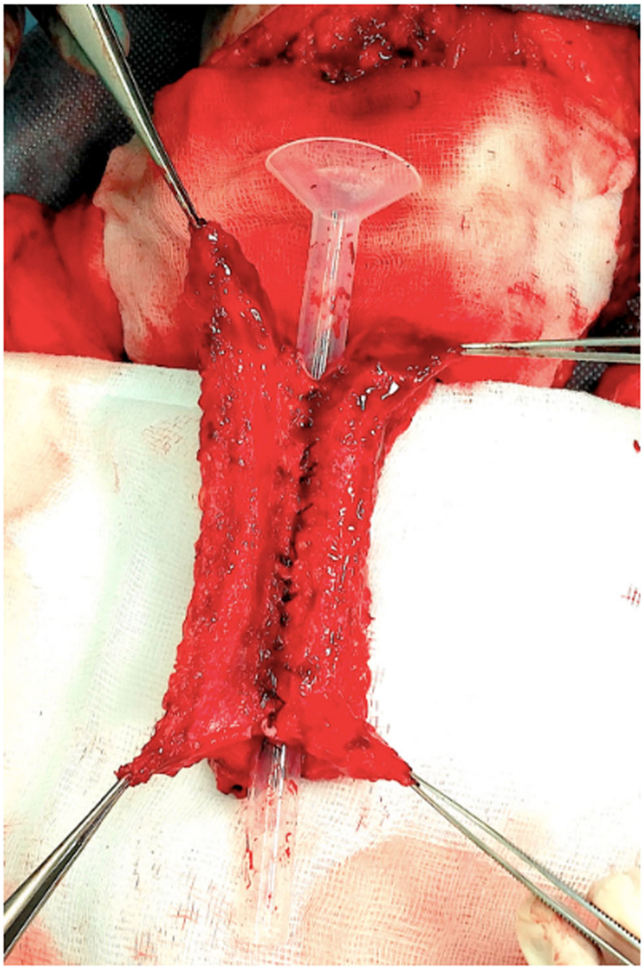

FIGURE 1 Inverting multilayer neopharyngeal closure after placement of the Montgomery salivary bypass tube™ that was employed for all patients in this study.

TABLE 1 Impact of variables on fistula formation.

Variable studied	Total (*n* = 44)	Fistula rate, *n* (%)	*P*
Treatment			0.30
Radiation	6	2 (33.3%)	
Chemoradiation	38	6 (15.8%)	
Neck dissection			0.20
Yes	20	2 (10.0%)	
No	24	6 (25.0%)	
Base of tongue resection			0.38
Yes	17	2 (11.8%)	
No	27	6 (22.2%)	
Circumferential defect			0.94
Yes	16	3 (18.8%)	
No	28	5 (17.9%)	
Initial frozen section margin			0.42
Positive	4	0	
Negative	40	8 (20.0%)	
Permanent section margin			0.32
Positive	2	0	
Close	14	5 (35.7%)	
Negative	28	3 (10.7%)	

diet, while 23 (58.9%) did not return to normal diet or remained reliant on g-tube for nutrition. At the commencement of the study, 35 subjects had known survival information (24 living and 11 deceased).

The incidence of PCF was 18.2% in our cohort, with no significant differences in incidence based on the risk factors investigated. Of those who developed PCF, 62.5% (five of eight) were repaired surgically. This study investigated primary treatment modality (chemoradiotherapy vs. radiotherapy alone), BOT involvement, presence or absence of ND, and extent of resection defect to determine the potential associated risk for PCF development. On univariate analysis, differences in primary tumor site were detected between patients with a history of radiation versus those with chemoradiation, as well as between those with BOT involvement compared with those without ($P < 0.001$ for both). Aside from this, we found no other significant difference in age, primary tumor site, or disease stage between investigated cohorts.

When stratified by primary treatment modality, we noted six patients who received radiotherapy alone and 38 who received radiation and chemotherapy. On χ^2 analysis, there was no significant difference in age ($P = 0.33$) or disease stage ($P = 0.16$) between those with radiation versus those with chemoradiation, though an association existed for differences in primary site ($P < 0.0001$). The rate of PCF among those with primary chemoradiation was 15.8% compared with a PCF rate of 33.3% with primary radiation alone, though no statistical difference was seen on χ^2 analysis ($P = 0.30$) (Table 1).

ND was required or elected for in 20 of the 44 cases and was performed concomitantly during STL. On χ^2 analysis, there was no significant difference in age, primary tumor site, or disease stage between cohorts ($P = 0.75$, $P = 0.89$, and $P = 0.21$, respectively). In these 20 cases with concurrent ND, two patients developed PCF in their postoperative period. When comparing PCF rates between the ND cohort and those without ND, there was an observable, although statistically insignificant, difference in PCF occurrence (10.0% vs. 25.0%, respectively) ($P = 0.20$).

The extent of defect was determined in our study by BOT involvement and classification as a circumferential versus partial defect on excision. Differences in primary site were detected between those stratified by BOT involvement ($P < 0.001$), although there were no significant differences in age or stage of disease between cohorts ($P = 0.15$ and $P = 0.46$, respectively). There was no significant difference in age, primary tumor site, or disease stage between those with circumferential versus partial defects ($P = 0.75$, $P = 0.89$, and $P = 0.21$, respectively).

Then, 38.6% of patients had tumors involving the BOT and the number of BOT surgical resections mirrored this statistic. Here, 11.8% of those with tumors involving the BOT developed PCF compared with 22.2% PCF rate in those without BOT involvement, though this difference did not reach statistical significance on χ^2 analysis ($p = 0.38$). Sixteen patients had circumferential defects, whereas 28 had partial defects (36.4% vs. 63.6%, respectively). Of the 16 afflicted with circumferential defects, 18.8% developed PCF. Of those with partial defects, 17.9% developed PCF. Neither BOT involvement ($p = 0.38$) nor circumferential extent of defect ($p = 0.94$) conferred any significant difference in PCF development within our cohorts.

A total of five different surgeons performed STL on the patients within our cohort. Intraoperative frozen section margins were evaluated by pathology and found to be negative for malignancy in all patients. Four patients required re-resection and a second evaluation of a least one margin intraoperatively. The pathologist either felt the margin was positive or did not feel the specimen was of good quality. The surgeon ultimately achieved a negative frozen section result for these margins. Of the 44 patients, 28 of the patients had negative final margins on permanent evaluation. Fourteen patients had close final margins. Two patients had positive margins on final pathology evaluation of the main specimen.

Nine percent of our patients had positive frozen section margins that required re-resection and 91% of our patients had negative frozen section margins on initial evaluation. None of the patients who required re-resection developed PCF, whereas 20% of patients with initially negative frozen section margins developed PCF. None of the patients with positive margins on permanent section, 35.7% of those patients with close margins on permanent section and 10.7% of those patients with negative margins on permanent section developed PCF. Neither positive initial frozen section margin status ($P = 0.42$) nor positive permanent section margin status ($P = 0.32$) conferred any significant difference in PCF development within our cohorts.

DISCUSSION

The commonality of PCF following TL has been well established, with different rates of PCF occurring in different patient populations. Pooled incidence ranges from 3% to 65%, with most studies reporting an incidence between 10% and 41%.[1,6] As obliterative endarteritis and fibrosis compromise wound healing in patients with a history of radiotherapy or chemoradiotherapy, it is not surprising that PCF complicates post-STL cases more frequently than those who undergo primary laryngectomy. In one meta-analysis, the relative risk of PCF increased to 2.28 ($P < 0.001$) for those with prior radiotherapy compared to those without.[1]

In our cohort of patients undergoing STL with free flap reconstruction and MSBT™ placement, we found an overall PCF incidence of 18.2%. This rate of PCF in laryngectomy patients falls within reported incidences in literature, though it is relatively low considering the high-risk population under investigation. This relatively low complication rate for this high-risk cohort may be due to the operative strategies for fistula prevention applied to all patients who met inclusion for our study (i.e., free flap plus MSBT™). Román et al.[5] found that the use of MSBT™ following TL was associated with a decreased risk of PCF (odds ratio [OR] = 0.185, $P < 0.001$), contributing to the decreased incidence in those with MSBT™ compared to those without (25% vs. 64.3%). In their MSBT™ cohort, they also observed earlier PCF recovery and earlier time to deglutition compared to those without SBT.[5]

Bohlok et al.[14] similarly investigated MSBT™ after TL, with subgroup analysis focusing on those who had undergone STL. They found an incidence of post-STL PCF to be 47% in those without MSBT™, which was significantly higher than the PCF rate of 19% in their MSBT™ subgroup and is comparable to our findings within a similar patient population. They concluded that those with SBT following STL were 41% less likely to develop PCF than those who did not have MSBT™; this effect was only significant on multivariate analysis in cases of salvage (vs. primary) TL.[14]

Because of the lack of consensus, PCF-prevention strategies, personalized operative decisions, and individual clinical judgment become paramount in the care of high-risk cases. The decision to optimize prevention with free flap and MSBT™ placement was supported by independent literature finding risk reduction associated with each, especially in high-risk groups such as our STL population. Despite institutional efforts to optimize prevention, eight out of 44 cases were complicated by PCF postoperatively. This study sought to describe the potential factors that may have influenced post-STL development of PCF despite prevention efforts by way of free flap reconstruction and MSBT™ placement. We assessed the presence of ND, primary chemoradiotherapy versus radiotherapy alone, BOT involvement, extent of defect, and margin status and were unable to demonstrate a statistically significant association between the investigated risk factors and PCF in our study.

As salvage surgery is increasingly employed as a treatment following attempted organ preservation and because chemotherapy employs synergistic toxicity with radiotherapy, it is prudent to consider the complications associated with differences in primary treatment modality. Prior radiotherapy has been well described as one of the most significant and consistent risk factors for the development of PCF.[1,2,6,15,16] Radiotherapy, compared to chemoradiotherapy, is less often investigated and has returned varied reports in the literature. A retrospective study by Busoni et al.[16] showed that for STL, odds ratio of PCF formation was 3.07 with prior radiation, compared to an OR of 7.69 in those with prior chemoradiotherapy ($P = 0.002$ and $P = 0.001$, respectively). Interestingly, a meta-analysis by Sayles et al.[6] found that chemoradiotherapy increases the relative risk of PCF compared to radiotherapy alone in primary but not in STL.

To our knowledge, this study evaluates chemoradiotherapy versus radiotherapy in MSBT™ and STL population. This has significance because in previous literature chemotherapy accounted for some heterogeneity between STL cohorts who experienced better outcomes with MSBT.[14] Ultimately, there was no statistical difference in PCF rate between chemoradiotherapy and radiotherapy in our cohort, supporting the applicability of MSBT™ in salvage cases regardless of primary treatment modality.

BOT involvement and resection become important factors to when considering applicability of MSBT™, because the salivary tube is sutured over the BOT during placement. Another important consideration is the extent of the defect on resection since circumferential resections may lead to tighter pharyngeal mucosa closure, a potentially predisposing environment for PCF formation. In keeping with this, a multivariate analysis by Timmermans et al.[17] identified the extent of pharyngeal resection as a significant risk factor for PCF. In this present study, neither BOT involvement ($P = 0.38$) nor circumferential extent of defect ($P = 0.94$) conferred any significant difference in PCF development within our cohorts. These findings are supported by similar studies, which found no increased risk of PCF associated with BOT involvement or extent of pharyngeal mucosal resection.[18] Our findings contribute to the paucity of literature regarding the extent of resection and suggest that BOT involvement and extent of resection do not preclude patients from benefits of MSBT™.

A consensus opinion regarding risk stratification for the elective ND in the STL has not been universally agreed upon.[19] Whether elective or overtly indicated, ND is not without negative consequence, especially in a previously irradiated neck. Paydarfar and Birkmeyer[1] reported that ND in salvage cases increases the risk of PCF, a result that did not hold true for ND for the entire TL population. Two recent meta-analyses, however, found no significant risk associated with ND for all TL as well as for those specifically undergoing STL, although heterogeneity was high in both.[15,19] In this study, 45.5% of patients underwent ND and eventually went on to have a fistula rate of 10% in their postoperative period. Ultimately, we found no significant difference in PCF rate between cohorts who did versus did not undergo ND.

Saki et al.[20] found that fistula formation after laryngectomy was significantly more common in patients who received previous radiotherapy or who had positive surgical resection margins or had a systemic disease. Tassone et al.[11] found that positive initial margins were associated with worse disease-free survival among patients who underwent primary TL despite negative margins on final pathologic evaluation. Interestingly, our two patients that had positive margins on permanent specimen did not experience PCF. Five of our patients with close margins and 3 of our patients with negative margins on permanent section developed PCF. The four patients in our study that needed re-resection for positive frozen section margins did not develop PCF. Therefore, we did not find that positive margins on frozen or permanent section significantly contributed to the formation of PCF.

This study was conducted at a single institution, with a relatively small cohort size, and is inherently limited by its retrospective and descriptive design. Five different surgeons carried out TL operations, which may have introduced heterogeneity of surgical technique. Despite these limitations, the relative incidence of PCF as well as the findings regarding investigated risk factors in our cohort were comparable to larger combined studies, strengthening the applicability of our conclusions.

CONCLUSION

We found that PCF occurrence complicated STL in 18.2% of our patients that underwent flap reconstruction with placement of MSBT™. There was no association between concomitant ND, extent of pharyngeal defect, BOT involvement, presalvage primary treatment modality, or positive surgical margin and development of PCF in our cohorts. This supports our conclusion that there is applicability for the use of MSBT™ in a wide variety of patients undergoing STL with free flap reconstruction.

AUTHOR CONTRIBUTIONS

Each author contributed to the planning of the article, writing of the article, and editing of the article.

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None.

CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author (CBS) upon request.

ETHICS STATEMENT

The authors obtained approval for this project from our University review board (# 00002301).

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