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REVIEW ARTICLE

Routine use of salivary bypass tubes in laryngectomy patients: systematic review

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Abstract

Background: Pharyngocutaneous fistula is a cause of significant morbidity following laryngectomy. Routine use of salivary bypass tubes during laryngectomy has been proposed to reduce the incidence of fistulae and neopharyngeal strictures.

Method: Following a systematic search of Embase, Medline and Cochrane databases (1946 – current), included articles were assessed for bias according to the *Cochrane Handbook for Systematic Reviews of Interventions*.

Results: Three case–control trials showed reduced pharyngocutaneous fistula rates with the use of salivary bypass tubes; six case series reported widely varied fistula rates. With regards to stricture rates, the largest case–control trial found no improvement with salivary bypass tube use. No fatal adverse events were observed among the 204 patients who received a salivary bypass tube.

Conclusion: Low-level evidence suggests salivary bypass tubes may reduce the incidence of fistula in high-risk patient groups. A robust randomised controlled trial, or large, multicentre cohort studies, are needed to further examine this intervention.

Key words: Laryngectomy; Saliva; Stents; Cutaneous Fistula; Stricture; Morbidity

Introduction

Surgical resection of laryngeal malignancies and reconstruction of the subsequent defects in the aerodigestive tract are among the most challenging of oncological procedures; they are associated with substantial morbidity and mortality.

Pharyngocutaneous fistula formation, the most common complication following laryngectomy, has adverse effects on post-operative rehabilitation, adjuvant therapy and overall survival.[1] Neopharyngeal stricture, another common complication, negatively impacts patients' quality of life by impeding speech and swallow.[2]

Several surgical strategies have been proposed to reduce the incidence of these complications. This systematic review summarises the evidence available for the routine use of salivary bypass tubes and the effect on fistula and stricture rates.

Materials and methods

Search strategy

A systematic search was conducted, on the 5th July 2016, of the Embase, Medline, and Cochrane Library databases, from 1946 – current. The following search terms were used: 'salivary bypass tube', 'salivary tube', 'salivary stent', 'Montgomery tube' and 'Montgomery stent'. Only articles written in the English language and comprising human subjects were included. The reference lists of relevant articles were also searched.

Study selection

Included were all peer-reviewed published studies in which salivary bypass tubes were placed routinely during laryngectomy. No randomised controlled trials were found. Individual case reports, letters and conference abstracts were excluded.

Study evaluation

The included studies were graded according to the Oxford Centre for Evidence-based Medicine scheme. They were then assessed independently by the first two authors for risk of bias, according to the *Cochrane Handbook for Systematic Reviews of Interventions*.[3] Discrepancies were referred to the senior author.

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Results

The systematic search yielded 99 studies. Ninety of these studies were excluded; 30 were duplicates, and 60 were case reports, conference abstracts or letters (Figure 1). The included studies consisted of six case series (level 4 evidence) and three retrospective case–control studies (level 3b evidence). In total, 383 patients were investigated, of whom 204 received a salivary bypass tube.

Within most of the studies, there was heterogeneity of type and extent of surgical resection; however, the majority of patients had either total or partial pharyngectomy, in addition to total laryngectomy.

The findings of the authors' risk of bias assessment for each included study are shown in Table I.[4–12] Overall, the included studies had a moderate-to-high risk of bias, because of the retrospective design and the heterogeneity of study populations. Confounding factors included prior chemoradiotherapy, use of flap versus primary closure, flap type, and primary versus secondary surgery.

Fistula rate

Of the three retrospective case–control studies, Bondi *et al.*[5] ($n = 53$) reported a significantly lower fistula rate with salivary bypass tube use (45 per cent *vs* 9 per cent). Of note, the salivary bypass tube group had a higher proportion of flap repairs (i.e. inherently higher fistula risk). Punthakee *et al.*[4] ($n = 103$) found a significant reduction in fistula rates with salivary bypass tube use on univariate analysis; however, the effect was not significant once multivariate analysis was used to account for potential confounding factors. The study was substantially underpowered to detect the treatment effect. León *et al.*[6] ($n = 61$) reported a non-significant reduction in fistula rate with salivary bypass tube use. The results are summarised in Table II.[4–6]

Data from the six case series were categorised according to the type of flap used; López *et al.*[10] utilised two flap types. Two case series,[7,10] comprising 44 patients, used a radial free forearm flap and salivary bypass tube; 18 per cent developed fistulae. Two case series[9,10] (total $n = 45$) used an anterolateral thigh flap and salivary bypass tube; 2 per cent developed fistulae. Three case series[8,11,12] (total $n = 77$) used a pectoralis major myocutaneous flap and salivary bypass tube; a total of 15.6 per cent developed fistulae. These results are summarised in Table III, and compared with quoted rates for fistulae in the wider literature.[7–18] Study heterogeneity prevented meaningful meta-analysis.

Stricture rate

Only one case–control study, by Punthakee *et al.*,[4] assessed the effect of salivary bypass tube use on neopharyngeal stricture rates; they found no association. Two case series[7,10] ($n = 44$) reported an average stricture rate of 9 per cent using a radial free forearm flap and salivary bypass tube. Two case series[9,10] ($n = 45$) reported an average stricture rate of 6.6 per cent using an anterolateral thigh flap and salivary bypass tube. Three case series[8,11,12] ($n = 77$) reported an average stricture rate of 14 per cent using a pectoralis major myocutaneous flap and salivary bypass tube. Table IV summarises these results.[7–13,15,16,19,20]

Safety

Of the 204 patients covered in this review, who received a salivary bypass tube during laryngectomy, there were 2 arterial bleeds, 4 distal migrations and 7 proximal migrations. None of these events were fatal; the arterial bleed rates were similar between patients

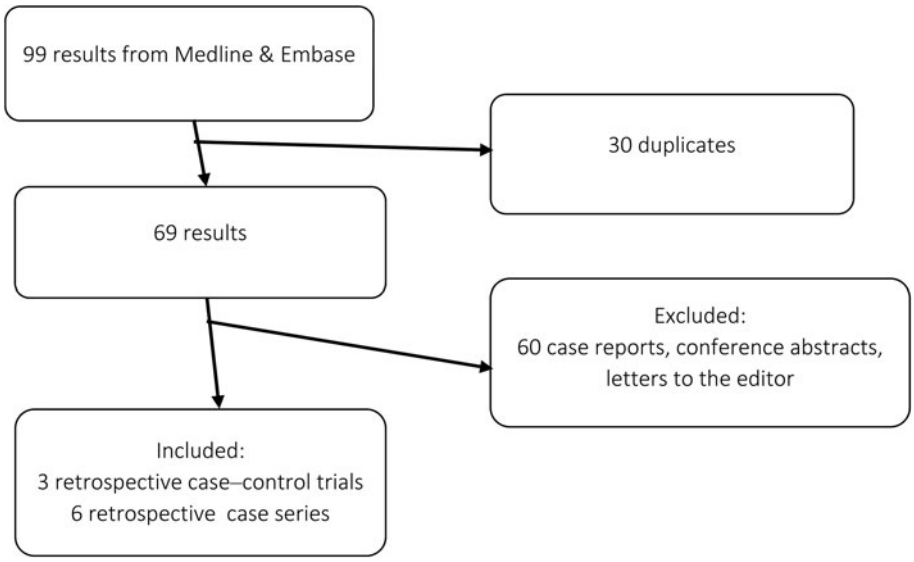

FIG. 1
Results of the systematic search.

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TABLE I
AUTHORS' RISK OF BIAS ASSESSMENT FOR EACH INCLUDED STUDY*

Study (year)	Selection bias	Blinding	Attrition rates	Selective reporting	Other bias
Punthakee *et al.*[4] (2013)	High risk	High risk	Low risk	Low risk	1. Confounding variables not controlled for
Bondi *et al.*[5] (2013)	High risk	High risk	Low risk	Medium risk (strictures not reported)	2. Technique variation between surgeons or with time
León *et al.*[6] (1999)	High risk	High risk	Low risk		
Varvares *et al.*[7] (2000)	High risk	High risk	Low risk	Low risk	
Spriano *et al.*[8] (2002)	High risk	High risk	Low risk	Low risk	
Murray *et al.*[9] (2007)	High risk	High risk	Low risk	Low risk	
López *et al.*[10] (2013)	High risk	High risk	Low risk	Low risk	
Fabian[11] (1998)	High risk	High risk	Low risk	Low risk	
Jegoux *et al.*[12] (2007)	High risk	High risk	Low risk	Low risk	

*Assessment of the key domains, as set out in the Cochrane Handbook for Systematic Reviews of Interventions.[3]

with and without a salivary bypass tube. As a result of the stent migrations, several authors reported securing the salivary bypass tube to a nasogastric tube sutured at the nasal septum.

Three case reports of salivary bypass tube related adverse events exist, all fatal. One arterioesophageal fistula occurred following laryngectomy due to a retro-esophageal subclavian artery.[21] A distal migration of salivary bypass tube caused intestinal perforation following laryngectomy.[22] An aortoesophageal fistula occurred in a paediatric patient following the long-term use of a salivary bypass tube to reconstruct oesophageal atresia.[23]

Discussion

Summary of main results

The largest case–control study[4] ($n = 103$) showed a reduction in fistula rates with salivary bypass tube use. This finding was significant on univariate analysis, but not on multivariate analysis that attempted to correct for confounding factors, such as flap type and prior chemoradiotherapy. This could indicate a true lack of an effect for salivary bypass tube treatment or reflect the underpowered nature of the study (188 participants were required to achieve 80 per cent power). All patients in this study had flap reconstruction, and thus were, arguably, at greater risk of fistulae. A second case–control study[6] found no significant effect; this study reported a high incidence of fistulae overall in both groups (54 per cent). The third case–control study[5] showed a significant reduction in the fistula rate with salivary bypass tube use. The salivary bypass tube group had higher rates of pre-operative radiotherapy and higher rates of flap repair. It is important to note that in this study, the authors selected patients they considered at high risk for fistula development (based on the extent of the tumour and prior radiotherapy). This may explain the large treatment effect observed with salivary bypass tube use in that cohort.

Two case series[7,10] (total $n = 44$), focusing on salivary bypass tube use with a radial free forearm flap, reported an average fistula rate of 18 per cent, as compared to quoted rates in the literature of 20–53 per cent.[13–15] Two case series,[9,10] investigating salivary bypass tube use with an anterolateral thigh flap, reported that 2 per cent of 45 patients developed fistulae, compared to quoted rates of 9–30 per cent[15–17] for anterolateral thigh flaps without a salivary bypass tube. This could suggest some treatment benefit. However, the heterogeneity of the patients included in these studies and in the wider literature prevents any meaningful comparison via meta-analysis. The average rate of fistula found with a pectoralis major myocutaneous flap and salivary bypass tube in three studies[8,11,12] was 15.6 per cent, similar to that reported in a large meta-analysis of a pectoralis major myocutaneous flap series (19.4 per cent).[18]

With regard to the effect of salivary bypass tube use on stricture formation, the largest and most robust study included in this review, by Punthakee *et al.*,[4] found no

TABLE II
SUMMARY OF CASE–CONTROL STUDY* RESULTS

Study (year)	Patients (n)	Flap type	Fistula rates (%)		P-value
			No SBT	SBT	
León *et al.*[6] (1999)	61	PMMF	61	47	Not significant
Punthakee *et al.*[4] (2013)	103	Mixed	18	7.8	0.048† (0.21‡)
Bondi *et al.*[5] (2013)	53	Mixed & non-flap repairs	45	9	<0.01

*Level 3b evidence. †On univariate analysis. ‡On multivariate analysis, performed to account for potential confounding factors. SBT = salivary bypass tube; PMMF = pectoralis major myocutaneous flap

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TABLE III
FISTULA RATES IN CASE SERIES* USING SALIVARY BYPASS TUBES VERSUS RATES IN WIDER LITERATURE WITHOUT SALIVARY BYPASS TUBES, BY TYPE OF FLAP

Study (year)	Patients (*n*)	Flap type	Fistula rates (%)	Fistula rates in literature (without SBT) (%)
López *et al.*[10] (2013)	24	RFFF	16	20–53[13–15]
Varvares *et al.*[7] (2000)	20	RFFF	20	
López *et al.*[10] (2013)	31	ALT	3	9–30[15–17]
Murray *et al.*[9] (2007)	14	ALT	0	
Spriano *et al.*[8] (2002)	37	PMMF	13.5	19.4[18]
Fabian[11] (1998)	22	PMMF	32	
Jegoux *et al.*[12] (2007)	18	PMMF	0	

*Level 4 evidence. SBT = salivary bypass tube; RFFF = radial free forearm flap; ALT = anterolateral thigh flap; PMMF = pectoralis major myocutaneous flap

association. Seven case series reported stricture rates with salivary bypass tube use ranging from 3 to 16 per cent. In comparison, the rates in the literature are: 20–36 per cent for a radial free forearm flap,[13,19,20] 6–24 per cent for an anterolateral thigh flap[15,16] and 12 per cent for a pectoralis major myocutaneous flap.[16] The wide range of stricture rates without salivary bypass tube use precludes direct statistical comparison, but the rates seem broadly similar with or without salivary bypass tube use.

Level of evidence

The level of evidence found for this review was at best level 3b (three studies) and otherwise level 4 (six studies). The included studies are all of relatively weak design, and at high risk of bias, because of factors such as: retrospective data collection; lack of blinding of surgeons, patients or data analysts; and small patient groups with multiple confounding factors. In particular, cases and controls were non-contemporaneous, with the salivary bypass tube patients being operated on later than the non-salivary bypass tube patients, such that the salivary bypass tube groups could have benefited from technical and surgical advances.

Quality and completeness of evidence

The heterogeneity of the patient populations within each study significantly limits the ability to draw any firm conclusions regarding the effect of salivary bypass tubes. In particular, the variation within and between studies in regard to the extent of surgical resection limits direct comparison. Conversely, these relatively small and diverse patient cohorts could be argued to reflect the reality of advanced laryngeal cancer populations, and as such provide practical and relevant information.

Strategies to reduce the risk of bias in this review included the use of a robust search strategy, in conjunction with a medical librarian, which was then run twice to ensure reproducible results. However, because of practical constraints, the search was limited to articles written in the English language. Two authors independently assessed the included studies for risk of bias according to the criteria specified in the *Cochrane Handbook for Systematic Reviews of Interventions*. However, as the included studies themselves had a high risk of bias because of their design, this review will inherently carry a risk of bias. To our knowledge, there are no other reviews on this topic with which to compare.

Implications for practice and research

The data in this review are not sufficiently robust to support recommendations in clinical practice. However, the findings suggest that salivary bypass tube use in laryngectomy might benefit certain patients who are at high risk of fistula formation, and this may

TABLE IV
STRICTURE RATES IN CASE SERIES* USING SALIVARY BYPASS TUBES VERSUS RATES IN WIDER LITERATURE WITHOUT SALIVARY BYPASS TUBES, BY TYPE OF FLAP

Study (year)	Patients (*n*)	Flap type	Stricture rates (%)	Stricture rates in literature (without SBT) (%)
López *et al.*[10] (2013)	24	RFFF	8	20–36[13,19,20]
Varvares *et al.*[7] (2000)	20	RFFF	10	
López *et al.*[10] (2013)	31	ALT	3	6–24[15,16]
Murray *et al.*[9] (2007)	14	ALT	14	
Spriano *et al.*[8] (2002)	37	PMMF	0	12[16]
Fabian[11] (1998)	22	PMMF	23	
Jegoux *et al.*[12] (2007)	18	PMMF	16.7	

*Level 4 evidence. SBT = salivary bypass tube; RFFF = radial free forearm flap; ALT = anterolateral thigh flap; PMMF = pectoralis major myocutaneous flap

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inform surgical decision making in individual challenging cases. A large, multicentre cohort or, ideally, randomised controlled trial, is needed. This is warranted by the existing evidence, to examine salivary bypass tube use in patients stratified into different risk categories.

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