Systematic literature review of the complications of primary and secondary tracheoesophageal punctures in patients with laryngectomies for voice restoration

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INTRODUCTION

The aim of this study is to provide a critical evaluation of the current literature on the complications of primary and secondary tracheoesophageal puncture (TEP) in laryngeal cancer patients who have had total laryngectomy (TL). This will be achieved by reviewing and collecting data from trials. The study also hopes to provide recommendations for future studies in order to help improve current guidance on management of voice restoration(VR) to maximise success rates and minimise complication rates.

Anatomy and physiology of voice. Figure 1 illustrates the anatomy of key structures involved in creating voice. Voice is made of two components; these are phonation and articulation. Phonation refers to "sound production at the larynx"[2] whereas the latter describes the process by which clear speech is formed.[2] Vocal folds are known to control the pitch of the sound. Figure 2 illustrates the glottis where the vocal folds can be found. Air flows from lungs (source) through the vocal cords (vibration) and then amplified and modified by the paranasal sinuses, pharynx, oral and nasal cavities. The production of distinct sounds is achieved by voluntary movements of the tongue, lips and cheeks.[2]

Laryngeal carcinoma. Cancer of the larynx is the most common form of head and neck cancers.[4] In Europe there has been a slight decline in the incidence of laryngeal cancers in both males and females.[5] Studies have shown that primary prevention strategies such as elimination

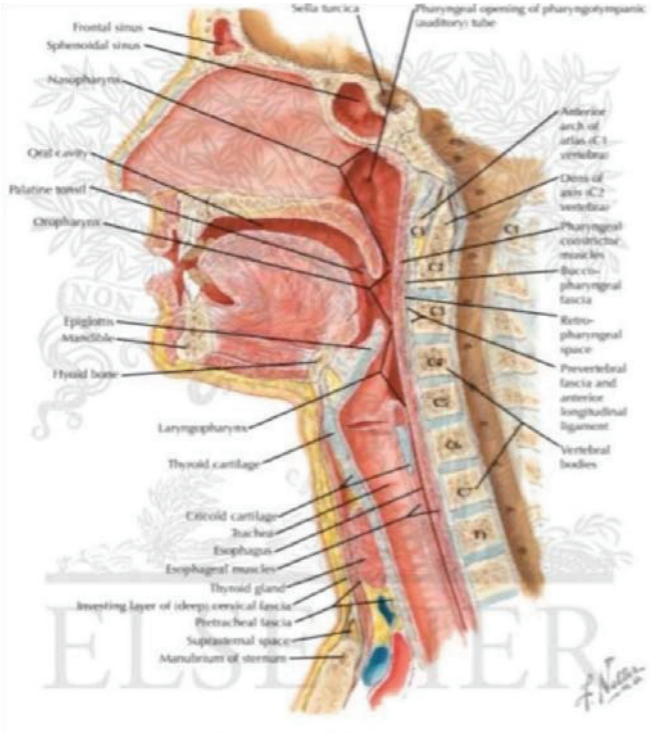

Figure 1: Anatomy of mouth and throat adapted from Netter images[1]

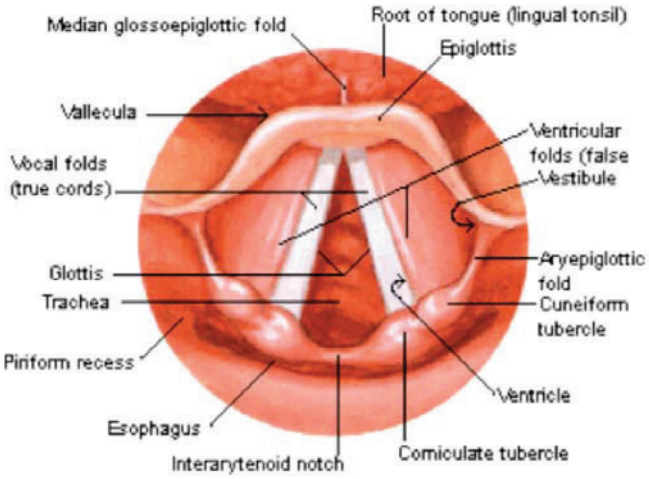

Figure 2: Entrance to glottis (cited from aboutcancer)[3]

of tobacco and reduction of alcohol have been the most effective methods of reducing the incidence of laryngeal cancers.[6] There has also been a decline in the mortality rate of patients with laryngeal cancer. This is due to improvements in both the diagnostic and management aspects of laryngeal carcinoma. NICE pathways on upper aerodigestive tract cancers suggest that T4a squamous cell carcinoma of the larynx is an indication for surgery with adjuvant radiotherapy with or without concomitant chemotherapy.[7]

Current guidance on laryngeal cancer. With recent advancements in surgical techniques organ preservation has become possible through methods such as partial laryngectomy, transoral laser microsurgery and transoral robotic surgery.[4] Despite such advancements TL is still performed in advanced cases. TL was first done in 1873 by Christian Billroth however the current practice of the surgery follows the technique done by Bottini in 1875.[8] TL involves the complete removal of the larynx thus preventing natural air flow. In order to maintain an adequate flow of air the trachea is connected to a tracheal stoma which is located in the cervical region. The upper portion of the airway becomes disconnected with the lower hence leading to a loss of smell and voice. Indications for a TL include advanced laryngeal cancer, tumours of adjacent organs as well as post-traumatic laryngeal stenosis.[9] The loss of speech presents numerous challenges to the patient and can have a detrimental effect on their quality of life.[10]

Tracheoesophageal punctures. Voice restoration (VR) is a key aspect of post-operative management in patients who have undergone TL. Non-surgical methods include electro larynx and oesophageal speech whereas surgical methods involve TEP followed by the placement of voice prosthesis. The latter has become the gold standard method of VR in patients.[10] Thirty years following its introduction, TEP has become the first choice for voice restoration in patients who have undergone TL. Evidence

has proved that this method of voice restoration leads to better speech intelligibility, longer phonation time and voicing.[11, 12] The procedure can be done at the time of TL (primary) or as a procedure separate from TL (secondary). TEP involves making a puncture through the posterior aspect of the trachea and anterior wall of the oesophagus. It is important that at the time of the procedure that the party wall has not been separated as this is a major contraindication to this procedure.[11] Once the fistula has been created in the tracheoesophageal wall one-way valve prosthesis (VP) can be placed.[10] This allows the air to be directed from the lungs into the oesophagus thus allowing vibrations in the wall to create sound. The VP also limits the entry of oesophageal contents in the trachea.[13]

Voice prosthesis. The mechanism of action largely revolves around the idea of shifting pulmonary air from the trachea and into the pharyngoesophagus allowing vibrations to create sound. This is achieved by the occlusion of the tracheostoma. VP can be divided into indwelling and non-indwelling. Non-indwelling VP are easier to manage and replace from the perspective of the patients.[14] When deciding which one to place, factors such as ease and quality of speech, device life, the ability of VP to alleviate complications and cost of VP are all considered.[14] Current data suggests that indwelling VPs are widely preferred in practice, this is due a longer device life, reduced prosthesis-related complications and better speech quality.[15]

Complication	No. of patient (out of 22)	%
Leakage around/ through prosthesis	14	64
Prosthesis displacement	7	32
Intractable aspiration of secretions or oral intake	5	23
Bronchial aspiration of prosthesis	4	18
Granulation tissue	4	18
Tracheostomal stenosis	11	50
Widening of tracheoesophageal fistula	3	14

Table 1: Specific complications as reported by Dayangku Norsuhazenah *et al* (retrospective study in Malaysia looking at the complications and success rates of patients of patients undergoing TEP over a 10 year duration)[19]

Primary TEP has recently gained greater popularity. This is associated with earlier voice recovery which can be explained by the lack of need for nasogastric feeding following the procedure.[16] Evidence shows that patients undergoing primary TEP can begin voice rehabilitation within 14 days of the procedure.[16] Patients opting for primary TEP have the benefit of undergoing one less surgery. This leads to greater cost effectiveness. Even though these advantages provide a justification for setting primary TEP as the gold standard for voice restoration there is no guideline or set recommendation regarding the optimal time for carrying out this procedure.[17] Certain evidence has shown that primary TEP is known to have a greater risk of complications. These include increased risk of infection, stomal stenosis, fistula and leakage from the prosthesis.[17] Whereas secondary TEP involves greater costs it has been suggested that it may lead to fewer complications and greater patient satisfaction with the voice attained, especially after a period of aphonia.[18]

RESULTS

Tables 1 through to 11 are of results reported by the seven studies that have been selected for the purpose of this research. Tables 12 through to 14 have been created in order to provide a more meaningful comparison of the results observed across all seven selected studies.

Surgical	Number of reported cases	
Type of complication	Primary	Secondary
Widening of fistula	10	3
Stomal stenosis	10	3
Pharyngoesophageal strictures	6	1

Table 2: Surgical complications in primary and secondary TEP reported By Cheng *et al* (retrospective study looking at patients undergoing TEP over a 16 year period. Patients who had a TL and TEP done between 1987 and 2002. Aim of study was to observe three common surgical complications mentioned above and three common prosthesis related complications mentioned below[17]

Prosthesis related	Percentage of patients (%)	
Type of complication	Primary (n=51)	Secondary (n=51)
Prosthesis leakage	39.2	23.5
Prosthesis dislodgement	11.8	5.9

Table 3: Prosthesis-related complications in primary and secondary TEP reported by Cheng *et al*[17]

Prosthesis-related complications	Overall percentage (%)
Leakage through valve	51.8
Obstruction of prosthesis	14.2

Table 4: Prosthesis related problems across primary and secondary TEP as reported by Makitie *et al* (retrospective review of patients over 10 year duration. Patients between December 1992 and December 2002 with total laryngectomies and laryngopharyngectomies were selected for this trial)[20]

Fistula-related complications	Overall percentage (%)
Inadequate size of prosthesis	12.4
Granulation tissue in fistula	9.2
Leakage around prosthesis	7.3
Puncture site too high or too low	4.1
Extrusion of prosthesis	0.5
Stricture of tracheostoma	0.5

Table 5: Fistula-related complications across primary and secondary TEP as reported by Makitie *et al*[20]

	Number of cases	
	Primary TEP	Secondary TEP (observed after TL)
Pharyngocutaneous fistula	11	3
Microstoma	3	1
Peritracheostomal infection	4	0
Abscess	2	0

Table 6: Long term complications in primary and secondary TEP as reported by Boscolo-Rizzo *et al* (retrospective study evaluating patients who underwent the procedures between June 1998 and December 2004. Patients undergoing TL after May 1998 were given primary TEP whereas those having TL between January 1996 and May 1998 were given a secondary TEP. Patients received an indwelling Blom-Singer prosthesis followed by Provox 2 during rehabilitation)[21]

Surgical complication	Secondary TEP (%)
Tracheoesophageal fistula enlargement	19.1
Mediastinitis	3.1
Para oesophageal abscess	3.1

Table 7: Surgical complications in patients with secondary TEP as reported by Imre *et al* (retrospective study of patients undergoing secondary TEP and VP only insertion between January 2006 and June 2011. All patients received a Provox indwelling VP)[22]

Prosthesis-related complication	Secondary TEP (%)
Deglutition of prosthesis	12.7
Leakage around prosthesis	19.1
Granulation tissue formation	4.2

Table 8: Prosthesis-related complications in patients with secondary TEP and VP insertion only as reported by Imre *et al*[22]

Complication	Provox 1	Provox 2	Blom-Singer	No Valve	Total
Yes	10	26	2	8	41
No	13	33	0	0	49
Total	23	59	2	8	90

Table 9: Complications in different VP used as reported by Calder *et al* p value > 0.005 (retrospective review over a 10 year duration on patients with TL and TEP with VP insertion from January 1993 to December 2002 at Gartnavel General and Stobhill Hospitals)[23]

Complication of TEP	Number of patients
Granulations	20
Enlarged fistula	16
Loss of valve	16
Voice loss	7
Closure of fistula	2
Dysphagia	6
Infection	1
Leakage	2
Second fistula	1

Table 10: Complications of TEP as reported by Calder *et al*[23]

Complication	Primary TEP (%)	Secondary TEP (%)	P–Value
PCF	50	0	0.006*
PE stenosis	10	2	0.31
Wound/stomal breakdown	35	3	0.49
Wound infection	15	1	0.59
TEP site leakage	5	1	0.46
CP spasm	5	1	0.46
Stomal stenosis	0	0	1.00

Table 11: Percentage of complications in primary and secondary TEP (PCF, p value 0.06) as reported by Emerick *et al* (retrospective review of a prospective cohort of patients. Patients were selected from the University of Michigan organ preservation protocols taken place between 1998 and 2005. Study focused on the complications of patients with primary and secondary TEP following induction and concurrent chemoradiation).[24]

Tables 12-15 provide a meaning full comparison of the selected studies

Study	Number of participants	Mean age	Age range (Years)	Males (%)	Females (%)
Dayangku Norsuhazenah *et al*	22	62.1	41-79	95.5	4.5
Cheng *et al*	68	59	31-82	75.0	25.0
Makitie *et al*	95	63.5	38-88	93.0	7.0
Boscolo-Rizzo *et al*	93	63	39-86	93.5	6.5
Imre *et al*	47	62.8	41-80		
Calder *et al*	100	61	44-82	74.0	26.0
Emerick *et al*	30	62.2 - Primary TEP 64.1 - Secondary TEP	-	90.0	10.0

Table 12: Retrospective study information for the seven selected studies

	Percentage of patients undergoing procedure (%)	
Study	Primary	Secondary
Dayangku Norsuhazenah *et al*	18.0	82.0
Cheng *et al*	75.0	25.0
Makitie *et al*	81.0	18.0
Boscolo-Rizzo *et al*	80.6	19.3
Imre *et al*	0.0	100.0
Calder *et al*	90.0	8.0
Emerick *et al*	66.7	33.3

Table 13: Number of patients undergoing primary or secondary TEP in each of the seven studies

	Overall complications across primary and secondary TEP (%)	
Study	Surgical complication	Prosthesis-related complication
Dayangku Norsuhazenah *et al*	32.7	77.3
Cheng *et al*	39.7	42.6
Makitie *et al*	-	66.0
Boscolo-Rizzo *et al*	25.8	-
Imre *et al*	42.0	
Calder *et al*	45.0	
Emerick *et al*	43.0	-

Table 14: Reported percentages of surgical and prosthesis-related complications

Study	Primary		Secondary	
	Surgical (%)	Prosthesis related (%)	Surgical (%)	Prosthesis related (%)
Dayangku Norsuhazenah *et al*	Equal incidence	50.0	Equal incidence	38.9
Cheng *et al*	43.1	47.1	29.4	29.4
Boscolo-Rizzo *et al*	20.3	-	16.7	-
Imre *et al*	-	-	25.3	36.0
Calder *et al* *Fisher's exact test p =0.0015	41.4		0.0	0.0

Table 15: Reported complications in primary and secondary TEP groups

DISCUSSION

From the selected studies we can see that they are all retrospective in nature. This study has reported the results and findings of seven reviews in order to ascertain any trends or patterns amongst the complications in primary and secondary TEP. More importantly grouping the studies and using similar parameters has allowed us to create a more holistic and representative picture regarding the complications thus providing a more accurate comparison of the effect of the timing of TEP on complications. Additionally, the number of participants across all trials was small with the maximum being 100 (Table 12). Mean age across all seven studies ranged from 59-64.1 years. Males made up the larger percentage of participants across the trials, with all seven studies recruiting 74% or more males. This is reflective of the higher incidence of laryngeal cancers amongst men; however might not be reflective of the general population. Additionally, the percentage of patients undergoing primary TEP versus secondary TEP varied depending on the criteria of each study. Some studies had higher percentages of primary TEP whereas others had the opposite. In total five out of the seven studies had higher percentages of primary TEP, since these studies were retrospective this finding supports the recent increase over the last decade in a preference amongst ENT surgeons in opting for primary TEP. More importantly selection bias (preference) has led to an inconsistency in numbers when comparing both procedures. This has made it increasingly difficult to properly assess and compare both procedures as there are more patients undergoing primary TEP rather than secondary.

From the results we can see that the complications of TEP are best divided into two separate categories, each one representing the origin of the problem (surgical and prosthesis related). Identifying the complication in such a manner allows the clinician to manage the patient appropriately. Surgical and prosthesis related complications occurred in both primary and secondary TEP groups. The nature of complications was similar across both types of TEP. When looking at surgical complications, problems with the fistula (enlargement, closure, secondary) were commonly reported on, with Imre et al recording an occurrence of 19.1% in patients with secondary TEP[22] (Table 7). This was similar to Calder *et al*[23] who reported that an enlarged fistula occurred in 20 patients (16.8%) undergoing either TEP and by Dayangku Norsuhazenah *et al*[19] who suggested an occurrence in three patients (14%). Tracheostomal stenosis was another common surgical complication of TEP regardless of the timing with Dayangku Norsuhazenah *et al*[19] reporting an occurrence of 50%. Among the other surgical complications included mediastinitis, cervical spine fractures, cervical cellulitis, peritracheostomal infection and abscesses. Similarly, the timing of the procedure did not have any effect on the type of prosthesis related complications suffered across both groups. Leakage around the prosthesis was reported in six out of the seven studies with the Dayangku Norsuhazenah *et al*[19] reporting an occurrence of 64% followed by Makitie *et al*[20] who suggested a 51.8% occurrence across both groups. Granulation tissue was reported in four out of the seven studies with the highest percentage of occurrence being 21.1% of in Calder *et al*[23] followed by 18% as suggested by Dayangku Norsuhazenah *et al.*[19] Lastly, displacement/obstruction of prosthesis was also mentioned across the studies with a 32% occurrence across both groups noted by Dayangku Norsuhazenah *et al*.[19] Rarer complications included dysphagia and voice loss as reported by Calder *et al*.[23]

When looking at surgical and prosthesis-related complications, there seemed to be some inconsistencies present in the reporting of each, as some studies presented an overall complication of TEP whereas others categorized them. Dayangku Norsuhazenah *et al*[19] and Makitie *et al*[20] suggest that prosthesis-related complications have a higher incidence as compared with surgical, however such an assumption cannot be made on the basis of such a small number of studies. More importantly Imre *et al*[22] and Calder *et al*[23] show an overall complication rate of 42% and 45% respectively (Table 14). These numbers are in line with what has been recorded in literature between 10 and 52 percent.[25, 26] Such high numbers of post-operative complications suggest that addressing these should be among the primary aims of assessing the quality of surgical

voice restoration attained. This finding emphasizes the notion that earlier voice restoration should not be the sole factor deciding the outcome of this intervention, rather a combination of both.

Similarly when trying to compare the complication rate between primary and secondary TEP there seems to be variation present. Table 15 shows an equal incidence of surgical complications between the two groups as reported by Dayangku Norsuhazenah *et al*.[19] This is not the case when looking at the prosthesis related complications as Table 15 shows a higher percentage in primary TEP as compared with secondary TEP in the same study. This can further be supported by the other results which show a general trend towards a higher percentage of complications among primary TEP patients. Boscolo-Rizzo *et al*[21] had remarkable results, with no patients undergoing secondary TEP suffering from complications as compared with 41% receiving a primary TEP. Such results further support the claim that secondary TEP provides a lesser chance of suffering from complications as compared with primary. This was supported statistically by Calder *et al*[23] as they found a significant difference in complication rates between primary and secondary TEP (p=0.0015, Table 15). Alongside this, Emerick *et al*[24] have statistically confirmed a significant difference between the groups with regards to complications of pharyngocutaneous fistula (PCF) (p=0.006, Table 11). It is important to note that PCF increase the morbidity of patients.[24] They can lead to increased hospitalisations, delay in oral intake and life threatening complications such as a carotid blowout.[24] Additionally the study concluded that co morbidities did not have any effect on the rate of complications of both groups. This was found to be contradicted by a study published in 1985[27] which concluded that diabetes and documented oesophageal strictures are risk factors which increase the risk of post-operative complications.

Interestingly when looking at VP and their effects on the rates of complication Calder *et al*[23] compared three popular valves commonly used in the market (Provox 1, Provox 2 and Blom Singer). It concluded that the use of each of these did not create a significant difference in the rate of complications (p>0.05, Table 9). This is an important finding with regards to post-operative complications and therefore stresses on other factors such as longevity, voice quality etc to be the judge of the success rates of these valves.

It is important to note several limitations faced by us when conducting this systematic review. In order to provide a more accurate and better understanding of the complication rates it is worth carrying out a meta-analysis of the current literature. This will provide more reliable results and help solidify risk factors as well as common complications in order to create an individualised care pathway for each patient opting for surgical voice restoration. Having suggested this, it is also important to stress the lack of similarity in criteria used between previous studies thus making it harder to easily compare the findings. In order to tackle this issue it might be worth carrying out prospective randomized control trials on this topic rather than retrospective reviews. Even though they might be a costlier option they will provide more accurate data, larger number of patients and can adopt similar parameters hence making a meta-analysis more plausible. There also seems to be some inconsistencies present in the classification of problems between the studies (surgical or prosthesis-related). This has led to some confusion and has made it increasingly difficult to compare studies. A universally accepted classification can help solve this issue and provide better comparisons.

Even though there has been extensive research done on the complications of primary and secondary TEP, there is no clear cut evidence suggesting which one leads to fewer problems. Studies so far have been contradicting and a lack of similar parameters amongst them has made it hard to apply a meta-analysis. It could be argued that results are leaning more towards the idea that secondary TEPs produce fewer complications however the difference is not significant enough to gain enough weighting to challenge the benefits of early voice restoration achieved by primary TEP. Alongside this, an absence of recommendations regarding the optimal time for performing TEP suggests that more work needs to be done on this topic. A lack of clarity in the complications has meant that the weight of early voice restoration and speech quality is seen as more than that of the complications. This might explain why primary TEP has become more fashionable in recent times however this might not be the best choice, as one might be sacrificing long term gains for short term benefits. It is imperative that a greater understanding of the similarities and differences in complications between the two procedures is gained as this will lead to improvements in the post-operative results of these procedures. After having conducted this study our recommendations for future research on this topic include carrying out prospective studies with similar parameters, applying meta analyses and trying to create a universally accepted classification of which complications can be considered surgical or prosthesis-related.

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