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Main Article

Tracheoesophageal voice prostheses complications in north Glasgow

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Abstract

The objectives of this study were to determine (1) the rates of complications, admissions to hospital and requirements for further surgery in patients fitted with tracheoesophageal fistula speech valves, and (2) whether any factors were predictive of complications. A case note review was undertaken of all patients undergoing a laryngectomy at Gartnavel General and Stobhill Hospitals over a 10-year period. One hundred patients were identified.

Forty-five patients had complications from their valves, most commonly granulation tissue formation. Thirty-five had a least one admission related to complications and 34 required further surgery. Sixty-seven were vocalizing with the valve.

Radiotherapy and valve type were not statistically significant in predicting complications in this study. Primary puncture was associated with a higher rate of complications, although the numbers undergoing secondary puncture were small.

Key words: Larynx, Artificial; Tracheoesophageal Fistula; Laryngectomy; Complications

Introduction

The use of tracheoesophageal voice prostheses is now routine practice for restoring voice following laryngectomy. Their use was first described more than 20 years ago by Blom and Singer.[1] Success rates in achieving voice have been quoted in the international literature as between 52[2] and 96 per cent.[3] In the UK, the rates of vocalizing have been quoted as between 58[4] and 80 per cent.[5]

Many complications associated with tracheoesophageal valves have been described. These include formation of granulation tissue, enlargement of the fistula, local infection, loss of the prosthesis, loss of speech and dysphagia.[6–10] The rate of these complications ranged from 10[9] to 52 per cent.[10]

There are different types of valves commercially available. The Blom-Singer™ valve (InHealth Technologies, Carpenteria, CA, USA) was first described by Blom and Singer in 1979[1] and the Provox™ valve (Atos Medical, Horby, Sweden) was first described by Hilgers and Schouwenburg in 1990.[11] Both are made of silicone and contain a one-way valve allowing passage of air from the trachea into the neopharynx, enabling the patients to vocalize. The Provox™ valve is most widely used in Europe and the Blom-Singer™ in the USA.

Current practice in north Glasgow is to offer all patients undergoing laryngectomy voice rehabilitation in the form of tracheoesophageal speech valves. Provox™ valves are currently used in Gartnavel General Hospital and Stobhill Hospital, with the Provox™ type one valve inserted as a primary procedure and the Provox™ type two valve used for subsequent changes. Historically, a small number of patients have had a valve insertion as a secondary procedure and Blom-Singer™ valves have been used in a number of patients.

This audit was designed to review all patients with a tracheoesophageal valve (and those who had had their valve removed) in order to determine the rate of complications and also to determine if any factors were predictive of complications.

Methods

A retrospective case note review of medical and speech therapy notes was carried out on all patients undergoing laryngectomy at Gartnavel General and Stobhill Hospitals over a 10-year period between January 1993 and December 2002. Medical records and speech and language therapy notes were reviewed and a proforma used to collect data on: pre- and post-laryngectomy radiotherapy; primary or secondary puncture; type of valve; complications; admissions or further surgery related to

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complications; and whether patients were vocalizing with the valve.

Results

One hundred patients were identified, 74 men and 26 women. The mean age at laryngectomy was 61 years, with a range of 44 to 82 years. One patient was excluded as there were no data available except the patient's age and date of surgery. Therefore, a total of 99 patients was included in the review.

Table I shows the numbers of patients undergoing a primary puncture and the timing of radiotherapy in relation to valve insertion.

Table II shows the type of valve initially used and the type in use at the time of the audit.

Table III summarizes the complications which occurred due to the valves. Patients often had more than one complication. Granulation tissue formation was the most common complication. Many of the complications occurred on multiple occasions.

Table IV shows the number of admissions per patient related to valve complications.

Of the 35 patients requiring admission, 34 required further surgery because of valve-related problems. Many required multiple operations. A variety of operations were performed, including removal and reinsertion of the valve, suturing of the fistula, and creation of a new fistula.

At the time of audit (or the time of death of the patient) 67 patients were vocalizing with the valve, 24 were not and voice status was unknown in eight. Alternative methods of speech were documented in seven patients, with four using an artificial larynx and three using oesophageal speech.

One of the questions we set out to answer was whether there were any factors predictive of complications. Radiotherapy was considered first. Table V summarizes the numbers of complications related to pre- and post-operative radiotherapy; no statistically significant difference was found using a chi-squared test. The total number of patients considered was 95, as we excluded those for whom data on radiotherapy or complications were incomplete.

We looked next at the type of valve being used. Table VI shows the numbers of complications related to the valve being currently used; again, no statistically significant differences were found using the chi-squared test. The total number of patients considered was 90, for the same reasons as above.

The final variable we addressed was primary puncture. Table VII shows the numbers of complications related to primary puncture, compared with secondary puncture. A statistically significant difference was found using Fisher's exact test, although the numbers undergoing a delayed puncture were small, as none of the patients who did not have a primary puncture developed complications.

TABLE I

PATIENTS* RECEIVING PRIMARY PUNCTURE, AND TIMING OF RADIOTHERAPY IN RELATION TO VALVE INSERTION

	Patient treatment (*n*)		
	Primary puncture	Pre-op RT	Post-op RT
Yes	90	29	50
No	8	69	47
Unknown	1	1	2

*$n = 99$. Pre-op = pre-operative; post-op = post-operative; RT = radiotherapy

Discussion

Sixty-seven patients (67 per cent) were vocalizing with their valve at the time of the audit (or at the time of death). This compares well to reported rates of vocalizing in the literature.

The overall complication rate of tracheoesophageal fistula valves in this audit was 45 per cent. This compares with a recorded rate in the literature of between 10[9] and 52 per cent.[10] Granulation tissue formation around the valve site was the most common complication, and this correlates with other results in the literature.[9,10] In many studies of tracheoesophageal valves, the most common complication is described as leakage through the valve.[8,12,13] We chose in this study not to include leakage through the valve as a complication. In our experience, leakage through the valve is an inevitable sequelae of valve use and is the most common reason to change a valve. Therefore, we did not consider it as a complication but more an inevitable consequence of having a valve. Previous studies have shown the median lifetime of a Provox™ valve to be 120 days[13] for a Provox™ type one valve and between 92[13] and 144 days for a Provox™ type two valve.[14] Leakage was recorded as a complication in two patients in our study, in cases in which leakage was persistent despite valve change.

Leakage through the valve has been shown to be due to colonization of the valves with candida,[15–17] and use of antifungals has been shown to increase the lifetime of the valve.[5,17] This problem may be eased by the introduction of the Provox ActiValve™ described by Hilgers *et al*.[18]

As mentioned previously, many patients had multiple complications, with granulation tissue formation in particular being recurrent. Frequently,

TABLE II

PATIENT TRACHEOESOPHAGEAL VALVE TYPE USED,* INITIALLY AND AT TIME OF AUDIT

	Provox™ 1	Provox™ 2	Blom-Singer™	None	Unknown
Initial valve	90	1	7	0	1
Valve at audit	24	59	2	6	8

*In a total of 99 patients

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TABLE III

TRACHEOESOPHAGEAL VALVE COMPLICATIONS*

Complication	Patients (*n*)
Granulations	20
Fistula too large	16
Loss of valve	16
Loss of voice	7
Closure of fistula	2
Dysphagia	6
Infection	1
Leakage	2
Second fistula	1

*In a total of 45 patients

TABLE IV

VALVE COMPLICATION-RELATED ADMISSIONS PER PATIENT*

Admissions (*n*)	Patients (*n*)
1	15
2	9
3	4
4	3
5+	4

*In a total of 35 patients

TABLE V

NUMBER OF PATIENTS WITH COMPLICATIONS RELATED TO PRE- AND POST-OPERATIVE RADIOTHERAPY

Complications	Radiotherapy			
	None	Pre-op	Post-op	Total
Yes	9	11	24	44
No	10	17	24	51
Total	19	28	48	95

$p > 0.05$ (chi-squared test), comparing the number of patients with complications related to pre- and post-operative radiotherapy. Pre-op = pre-operative; post-op = post-operative

this could be dealt with in an out-patient setting with measures such as silver nitrate cautery and temporary removal of the valve and insertion of a stoma gastric tube, allowing the granulations to resolve. However, admission was often required.

Infection did not seem to be a significant problem.

In the 34 patients requiring surgery, the most common procedures were removal and subsequent reinsertion of the valves. Many patients required repeated surgical procedures.

From these results, the only factor predictive of complications appears to be primary puncture. In the earlier years of the audit period, patients only received a primary puncture if the surgery was technically straightforward. Later on, primary puncture was more commonly used and secondary puncture used only in occasional cases where there were specific problems. Age of the patient was not a consideration. Eight patients had a secondary puncture and none of them developed complications. However, the small numbers and the many patient and treatment variables involved make meaningful analysis of these data difficult. Primary puncture has the advantage of avoiding a second general anaesthetic and surgical procedure.

The development of complications was not affected by use of radiotherapy or type of valve. Other studies have agreed that radiotherapy does not increase complication rates;[8,19–22] however, these studies assessed only post-operative radiotherapy.

Garth *et al*. found it impossible to determine whether radiotherapy caused a significant increase in complications.[23] Ayache *et al*. concluded that neither pre- nor post-operative radiotherapy was a statistically significant cause of peri-prosthetic leakage, but they did not assess other complications.[24] Lequeux *et al*. concluded that post-operative radiotherapy actually increased the survival time of Provox™ type two valves[14] but, again, did not address complications. Other studies have suggested that radiotherapy decreases device lifetime.[13]

There are no studies in the literature assessing complication rates following primary or secondary puncture.

The type of valve did not have any statistically significant effect on complication rate. Only a small number of patients had Blom-Singer™ valves, usually employed after patients had experienced problems with their Provox™ valves. Again, these factors make meaningful comparison of complications related to different valve types difficult. Studies comparing Provox™ and Blom-Singer™ valves have shown them to be very similar in terms of voice quality, patient satisfaction and valve lifetime, but complication rates of the two valve types were not compared.[25,26]

Data was incomplete in this study and therefore we did not look at the frequency of valve change. A large number of patients were involved and the dates of valve change, reason for valve change and type of valve used were not always recorded. The purpose

TABLE VI

NUMBER OF PATIENTS WITH COMPLICATIONS RELATED TO VALVE TYPE

Complications	No valve	Provox™ 1	Provox™ 2	Blom-Singer™	Total
Yes	3	10	26	2	41
No	3	13	33	0	49
Total	6	23	59	2	90

$p > 0.05$ (chi-squared test), comparing valve type being currently used

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TABLE VII

NUMBER OF PATIENTS WITH COMPLICATIONS RELATED TO PRIMARY PUNCTURE

Complication	Primary puncture		
	Yes	No	Total
Yes	36	8	44
No	51	0	51
Total	87	8	95

$p = 0.0015$ (Fisher's exact test), comparing complications related to primary and secondary puncture

of this study was to assess valve complications rather than valve lifetime. Many of the complications, such as dysphagia and loss of voice, can occur for other reasons (e.g. stricture formation, or a hyper- or hypotonic pharyngoesophageal segment).[5,23,27] These complications were only included in this study if, on review of the notes, they were felt to be due to the valve rather than to other factors.

Conclusion

Sixty-seven per cent of patients were able to vocalize with their valve. Complications related to tracheoesophageal fistula valves occurred in 45 per cent of patients. Thirty-five per cent of patients required admission and 34 per cent required further surgery due to these complications. These high rates of complication emphasize the need for a multidisciplinary team approach and close follow up of these patients to manage complications and to assist patients in achieving functional speech. It is important when counselling patients to be able to give them information on the problems associated with valves.

- **The objective of this study was to determine the rates of complications, admissions to hospital and requirements for further surgery in patients fitted with tracheoesophageal fistula speech valves, and also to determine if any factors were predictive of complications**
- **A case note review of all patients undergoing a laryngectomy at Gartnavel General and Stobhill Hospitals over a 10-year period is presented. One hundred patients were identified**
- **Forty-five patients had complications from the valves, most commonly granulation tissue formation. Radiotherapy and valve type were not statistically significant in predicting complications**

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