A Novel Obturator Device for Management of Dilated Trachea-esophageal Puncture Tract Fistulas

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Abstract Voice rehabilitation in laryngectomized patients by tracheoesophageal puncture is a time tested technique. In some patients the tracheoesophageal puncture gets inordinately dilated leading to leakage around the prosthesis. Most of these fistulas are managed by a variety of conservative treatments like temporary removal of prosthesis, placement of silastic ring over the prosthesis, placement of nasogastric tube and airway protection by a cuffed tracheostomy tube. Intractable fistulas are tackled by surgical closure but are fraught with failures. We hereby suggest a novel temporary obturator that can be easily made at a very low cost in any hospital having prosthetic rehabilitation services and obviates the need for a tracheostomy tube, nasogastric tube and repeated hospital visits.

Keywords Voice prosthesis ·
Intractable tracheoesophageal fistula · Obturator ·
Medical grade silicone

Introduction

Tracheoesophageal puncture is the most widely used technique for voice rehabilitation following total laryngectomy [1]. The leakage from the trachea-esophageal puncture is a common problem that occurs in 7–42 % cases due to variety

of reasons, such as previous radiotherapy, mechanical trauma, inappropriate size of prosthesis, frequent prosthesis replacements, old age etc [2–4]. In some patients, the fistula tract gets inordinately dilated leading to profuse leakage around the prosthesis and is associated with serious side effects unless treated promptly. Most fistulas normalize with a variety of conservative treatments like downsizing the voice prosthesis length, temporary removal of the prosthesis along with placement of nasogastric tube and tracheostomy tube and placement of silastic ring over the prosthesis [1, 5]. Failure of shrinkage following prolonged conservative therapy is an uncommon but difficult problem that may warrant submucosal purse-string suture or a three layer complete closure of the fistula [6]. Both procedures are not only difficult but are also fraught with failures. We hereby suggest a temporary obturator that can be customized to the need. It obviates the need for a tracheostomy tube, nasogastric tube and repeated hospital visits that hampers patient's quality of life. We have used this device in five patients without any short term complications. The device can be easily made at a low cost in any hospital that has a prosthetic rehabilitation service. Since the conservative treatment of these fistulas always involves avoidance of prosthetic tracheoesophageal voice, the lack of phonation with this device is acceptable (Figs. 1, 2).

Our First Case Summary

A 78 year old male who had undergone a total laryngectomy and primary tracheo-esophageal puncture seven years ago, presented in the casualty with extrusion of the prostheses and a massive salivary leak. On examination the tracheo-esophageal puncture tract was dilated and could not accommodate the prosthesis as well as the silastic

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Fig. 1 The obturator device and its parts

rings. The tracheo-esophageal party wall thickness was 4.5 mm and the diameter of the puncture was 1.2 cm. As per our institutional policy, a nasogastric tube (for feeding) and a cuffed tracheostomy tube (for airway protection) were inserted to allow shrinkage of the dilated fistula tract. The fistula failed to shrink even after 8 weeks. We did consider doing a purse string suture; but realized that the flimsy “party wall” was not suitable for any surgical intervention. We discussed the option of three layered surgical closure of the fistula with the patient, to which he refused. Another 4 weeks of conservative therapy did not help. During this period, the nasogastric feeding and cuffed tracheostomy tube were a source of constant discomfort to

the patient. This prompted us to design a temporary obturator device for this patient. Immediately following the placement of obturator, we removed the tracheostomy tube and the nasogastric tube. On regular follow up for 3 months the patient did not have any device related problems. His only complaint for the first few days, was a foreign body sensation in the throat largely attributable to larger size of the esophageal flange. We have used the obturator device in five patients so far, for similar indications and without any untoward side effects. We have noticed shrinkage in size of fistula in one patient in whom we could reinsert Provox-2 prosthesis (Table 1).

Design

The basic philosophy is that obturator must possess the esophageal and tracheal flanges larger than the dilated fistula tract. The design consists of two circular discs (esophageal and tracheal flanges), connected by a solid cylindrical shaft in the middle. Dimensions are based on the measurements of the fistula tract. In this case the party wall thickness was 4.5 mm and the diameter of the fistula was 12 mm. Based on these measurements we designed an a inner and outer flange diameter 15 mm (larger than the largest diameter of the fistula tract), shaft length of 4.5 mm (in accordance with the party wall thickness of 4.5 mm),

Fig. 2 Insertion of the obturator device (*Left*) and obturator device after insertion (*Right*)

Table 1 Details of patients treated with obturator placement for dilated fistula tract

S. no	Gender	Age	Size of dilated fistula (largest diameter) (cm)	Size of tracheo-esophageal party wall (mm)	Duration of conservative management before obturator insertion (months)	Indication for obturator placement
1.	Male	80	1.4	<4.5	3	Patient refusal for surgery
2.	Male	65	1.2	<4.5	12	Patient unfit for surgical procedure
3.	Female	55	1.1	<4.5	12	Patient refusal for surgery
4.	Male	41	1.2	<4.5	3	Patient refusal for surgery
5.	Male	57	1.3	<4.5	6	Patient refusal for surgery

shaft diameter of 7.5 mm. The shaft diameter of 7.5 mm was designed specifically to allow shrinkage of the fistula up to 7.5 mm, which is approximately the standard shaft diameter of Provox-2 prosthesis. This shaft diameter of obturator can be reduced for other devices with smaller diameters.

Method of Insertion

A linen stitch was taken through the tracheal flange and then tied to the proximal end of the Provox 1 guidewire. Another stitch was taken through the esophageal flange to prevent accidental loss of the device, in case the suture on the tracheal flange breaks. The device was then inserted by retrograde technique similar to the insertion technique of Provox 1.

The Technique of Manufacture

Silicone elastomer medical grade (MED 4515) was used for fabrication of the device. It is a widely used biomaterial; wax pattern of the device was made in modeling wax and processed by flasking in stone plaster. Waxing and packing done with medical grade silicone. The curing cycle of the packed mould is 5 min at 116 °C (24 °F) and post curing cycle is 2 h at 249 °C (480 °C) for minimum 3 h. Device is then finished trimmed, polished with grinding burs, stones, and brushes and autoclaved.

Conclusion

Dilated trachea-esophageal fistula is a frequent problem and there are various methods for treatment. Most patients end up having a nasogastric tube and a cuffed tracheostomy tube for conservative treatment, which is extremely discomforting. Intractable fistulas not amenable to surgery are fewer but challenging for the clinicians. We suggest a temporary obturator device that can be manufactured in

any hospital having prosthetic rehabilitation services. The device is cheap and can be tailored according to the patient's need. Various plugging devices are available today, but most are expensive, come in fixed sizes and are meant for temporary use only. The obturator placement does not hamper shrinkage of fistula, as noticed in one patient in our study. We believe that this novel obturator device can be of considerable benefit to patients with dilated fistula tracts which are not amenable to surgery and if the patient is either unfit for surgery or refuses to undergo a surgical closure. Patients can use electrolarynx for temporary speech rehabilitation when using an obturator and can also receive training for esophageal speech simultaneously.

Conflict of interest We hereby declare that we do not have any conflict of interest.

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