TECHNIQUE

Indigenous Silicone Rubber Endoprosthesis for Malignant Esophago-Pulmonary Fistula

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Abstract

Endoscopic placement of an esophageal endoprosthesis is the most rational therapy for relieving the distress of malignant esophago-pulmonary fistula. The commercial prostheses are very expensive for widespread use in India. We have indigenously prepared silicone rubber endoprostheses. The wall of the prosthesis was hardened in a graded manner until the desired resistance to compression with flexibility is achieved. This prosthesis was placed successfully in five patients with malignant esophago-pulmonary fistula. Dysphagia and aspiration were relieved in all the patients. One patient had delayed esophageal perforation and died of massive bleeding 3 weeks after the placement of prosthesis. The indigenous endoprosthesis is cost-effective and safe. (Indian J Gastroenterol 1992; 11: 132-135)

Key Words: Aspiration, cancer esophagus, palliation, trachea.

Introduction

Esophageal cancer is one of the commonest gastrointestinal cancers in India.1 Upto 5% of the patients may develop esophago-pulmonary fistula (EPF), which is a devastating terminal complication.2 These patients are usually debilitated, malnourished and have a short life expectancy.3 The role of surgery in the form of a bypass or prosthesis placement by traction is limited and is associated with high morbidity and mortality.4 Endoscopic endoprosthesis placement is the most commonly used method for palliation of EPF.5-10 The endoprosthesis restores the pleasure of oral food intake and palliates aspiration in a majority of patients.5,9

Although the results of several studies reveal the commercial prosthesis to be safe and effective, the cost of these endoprostheses is a strong reason against their routine use in India. Less expensive home made prostheses from polyvinyl (Tygon) tubing have proved to be safe and effective.5

Silicone rubber is a good biocompatible and non-degrading materials and is used in prostheses and implants in tissues such as breast, cartilage, blood vessel, penis, dura, trachea, esophagus, etc. A silicone rubber esophageal endoprosthesis was devised by Atkinson to overcome tube degradation during long term use.7 We present our initial experience with an indigenous, low-cost, silicone rubber endoprosthesis for the palliation of EPF.

Technique

Prosthesis preparation: The endoprostheses were made from opaque silicon rubber of food grade standard. Silicon rubber retains its properties (tensile strength, elongation characteristics, hardness, tear strength, resistance to compression, resilience and non-stick property) against a wide variety of physical and chemical stresses. Under conditions of clinical usage, silicon rubber can withstand enzymes, oils, acids, chemicals, foods, fungi and radiation over long periods of time. It is odorless and does not harden, dissolve or crack with use. It is used in commercial endoprostheses which are to remain in situ for many months.5,6 It is radio-opaque.

Endoprostheses were made by the moulding method using a precast die. Our initial endoprosthesis was 6 cm long with an internal diameter of 12 mm and wall thickness of 2 mm. The proximal end was shaped into a soft funnel having a maximum outer diameter of 28 mm. The distal end was truncated and cone shaped by increasing the wall thickness, having an outer diameter of 20 mm to prevent migration, as recommended in previous reports (Fig 1A). The hardness of the silicone rubber was gradually increased from 50 to 80 durometer until the desired resistance to compression (up to 300 mmHg) and adequate flexibility was achieved. The effect of radiation (15,000 cGy), heat (100°C) and cold (0°C) on the hardness and flexibility of the endoprosthesis was tested prior to its clinical use.

The cost of casting each die was Rs 2,500 and that of moulding each prosthesis Rs 35 for a 6-cm long and Rs 50 for a 9-cm long prosthesis.
Fig 1: (A) Guidewire (G), 10 mm Savary-Gilliard dilator (D), endoprosthesis (E), pusher tube (P) and nylon line (arrow). (B) Prosthesis and introducer assembly ready for use. Note the inner nylon line.

Prosthesis Placement: The endoprosthesis was inserted using a modification of the Dumon-Gilliard technique, after obtaining an informed consent. The intubation was performed in the fluoroscopy suite using intravenous sedation (diazepam 5 to 15 mg and pentazocine 15 to 45 mg). After endoscopic placement of a Savary-Gilliard guidewire, the stricture containing the fistula was dilated up to 16 mm or more using Savary-Gilliard dilators (SGD). Endoscopically, we repeated to assess the extent of the stricture and fistula and for the placement of a radiopaque marker on the chest wall corresponding to the upper level of the stricture. A nylon fishing line was passed through two holes punctured in the funnel of the endoprosthesis; the latter was then loaded on to a 100 cm long and 10 mm thick SGD (Fig 1A). The pusher tube was then loaded on to the SGD. The expanded end of the pusher tube was introduced into the funnel of the endoprosthesis and kept in place by pulling the nylon line taut (Fig 1B). The nylon line also helps to reposition the endoprosthesis if required. The distance between the upper level of the stricture to the inner level was marked on the pusher tube. The whole assembly (10 mm SGD, endoprosthesis and pusher tube) with the nylon line held taut (Fig 1B) was introduced as a single unit after adequate lubrication over the previously placed SGD guidewire under fluoroscopic control. Once the endoprosthesis was well positioned, the guidewire and 10 mm SGD were removed, followed by the pusher tube.

An esophagogram using water soluble contrast was performed 18 hours later to confirm the closure of the EPF (Figs 2 and 3). Peroral feeding was resumed thereafter. Intravenous fluids, antibiotics, analgesics and chest...
physiotherapy were used in the periprocedural period. The diet and precautions to be observed during eating were explained. The nylon line was removed before the patient was discharged from the hospital.

The endoprosthesis was successfully placed in 5 consecutive patients with EPF (Table). Peroral feeding could be resumed within 24 hours of the procedure in all the patients. One patient had delayed esophageal perforation into the right bronchus 1 week after intubation; she died of massive hematemesis 3 weeks after intubation. Four patients had adequate relief of aspiration symptoms for 4 weeks or more. The patients were followed up for 1 to 3 months. One patient died of esophageal carcinoma 3 months after intubation.

Discussion

Patients with a malignant EPF are doubly cursed – both by dysphagia and by incessant cough. Most patients die within weeks to months after developing EPF regardless of therapy, from aspiration pneumonia, lung abscess, mediastinitis or hemorrhage. When left untreated, EPF is uniformly fatal within one month. Endoprosthesis placement is the most rational therapy for a majority of these patients. However, an ideal endoprosthesis must be flexible, incompressible, non-traumatic, must have an adequate lumina and should not migrate.

The authors with the most experience and the best results continue to favor home-made endoprosthesis from Tygon, which are tailor made to the patient’s need. The Tygon tubes are not freely available in India and are often not practical for widespread use, as considerable time and skill are required to make a good endoprosthesis on the spot. The latex and tygon endoprostheses can deteriorate and result in tube fracture or pressure necrosis of the esophagus during prolonged use.

In vitro studies show that silicone rubber is a better material for endoprosthesis. Silicone rubber is presently used for two popular commercial (Keymed and Wilson Cook) endoprostheses. The commercial endoprostheses are extremely expensive for widespread use in India. Incorporation of a nylon or steel spring is necessary in very soft tubes to prevent collapse or compression in vivo. As this technology is not easily available in India, we increased the hardness of the silicon rubber by trial and error until an adequate flexibility and resistance to withstand compression was achieved. As there is no spring in the wall of this prosthesis, grinding can be performed to decrease the outer diameter of various regions by a few millimeters as and when required. Our endoprosthesis may however be insufficient for a small percentage of acutely angulated strictures and EPF located in the cervical esophagus.

The standard endoprosthesis provides adequate palliation in a majority of the patients with EPF. An extra large funnel, self expandable prosthesis, injection of collagen around the prosthesis and wrapping the funnel with a felt sponge have been used as second line modifications for those patients who do not improve with standard endoprostheses.

The procedure-related mortality in experienced hands is 4% to 10%. The overall 30-day mortality is 20% to 35% following endoscopic endoprosthesis placement. Although these figures are high, they are acceptable and considerably less than those of surgical placement by traction. The median survival following intubation of esophageal cancer is 2 to 3 months and somewhat shorter for patients with EPF.

The major advantage of the indigenous endoprosthesis is the reduction in cost to less than one percent. A variety of prostheses can therefore be prepared and stocked to be used as per the patients’ requirements. This would help us avoid feeding gastrostomy/jejunostomy as the only therapy for patients with EPF.

References


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**ISG News**

**Young Clinicians (investigators) Attendance Awards**

for

10th World Congresses of Gastroenterology, Los Angeles (USA), October 2-7, 1994

World Congresses of Gastroenterology will offer Attendance Scholarships to selected Young Clinicians/Investigators in the fields of Coloproctology, GI Surgery, Hepatology, GI Endoscopy and Gastroenterology.

The Indian Society of Gastroenterology therefore invites applications from interested candidates provided they are members of the Society and aged 37 years or less on October 2, 1994. Applications with following information should reach the Honorary Secretary (Dr S L Broor, Professor & Head, Department of Gastroenterology, G B Pant Hospital, New Delhi).

1. Curriculum vitae; this should include:
   i) age and date of birth (with a proof), ii) mailing address, iii) qualifications year wise, iv) national & international academic awards (mention criteria and nature of these awards), v) experience in gastroenterology or related field as specified above, iv) academic and research affiliations (mention whether full time or part time; if part time, number of hours/week), vi) whether ordinary or life member of ISG, and vii) the applicant's own appraisal (not more than 250 words) with regards to his/her research activities and suitability of attending the World Congress.

2. i) List of publications, and ii) five photocopies each of 5 best papers/published in the above mentioned fields in indexed medical journals.

3. List of papers presented by the candidate, i) at annual conferences of ISG, and ii) at other national or international conferences.

4. A 250-word Abstract of an original unpublished basic or clinical research paper relating to the field of gastroenterology, coloproctology, surgery of alimentary tract, hepatology or endoscopy.

Candidates will be required to present their paper during the forthcoming annual conference of Indian Society of Gastroenterology at Delhi.

S L BROOR
Secretary

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