PALLIATIVE TREATMENT OF OESOPHAGEAL CARCINOMA — EFFICACY OF PLASTIC VERSUS SELF-EXPANDABLE STENTS

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Objectives. A prospective randomised study of patients with irresectable oesophageal carcinoma treated with self-expandable covered metal Wallstent and plastic Procter Livingstone tubes was performed. The purpose was to compare the efficacy, cost effectiveness, ease of implantation, long-term patency and complications of the two different stents.

Methods. Data recorded included dysphagia score (0 - 4) the day before and after stent placement, location and length of stricture, procedural time and complications, and stent patency at 1 and 3 months' follow-up. A comparative costing of materials, theatre and anaesthetic time and hospital stay was undertaken.

Results. Forty patients were studied over 12 months (20 in each group). Strictures were located most commonly in the middle third of the oesophagus (75%), followed by the upper third (12.5%) and lower third (12.5%). Mean stricture length was 6 cm (2 - 12 cm); 10 patients (25%) had strictures 8 cm or longer. Five patients had tracheo-oesophageal fistulas (3 Wallstent; 2 Procter Livingstone tube). There was effective fistula sealing in all 3 Wallstent patients, and non-sealing in 1 of the Procter Livingstone patients. The mean pre-operative dysphagia score in both groups was 3, and immediately postoperatively the score was 0 in the Wallstent group and 2 in the plastic tube group. Initial stent placement was satisfactory in all Wallstent patients, with 2 patients requiring 2 stents each for adequate tumour coverage, and in 15 patients (75%) having plastic stents. Immediate complications were chest pain in 2 patients with Wallstents and oesophageal perforation in 2 patients (10%) with plastic stents. Wallstent patency at 1 and 3 months was 90% and 88%, respectively, and plastic stent patency was 66% and 50%. Four patients (10%), 2 in each group, died during the study from massive tumour load or metastatic disease. Comparative costing of the Wallstent versus the plastic tube

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stent was R4 123 versus R2 146 or a factor of 1.9.

Conclusion. Palliation with the Wallstent is effective, with excellent 1- and 3-month patency. The Wallstent is superior to the conventional plastic stent in terms of ease of implantation, better long-term patency and fewer complications. It is particularly useful for the treatment of patients with fistulas and long strictures. Accurate placement is critical in order to prevent stent migration and tumour overgrowth. However, it costs almost twice as much to implant the Wallstent as it does to implant the plastic tube.

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Oesophageal cancer has its highest incidence in developing countries such as South Africa and China where patients present late with inoperable cancer requiring palliation. Annual admissions to King Edward VIII Hospital, the major teaching hospital in KwaZulu-Natal, have shown a fivefold increase in each decade since 1955, in which year only 21 patients were admitted. At present more than 600 patients annually are admitted to the specialised unit at King George V Hospital in Durban, which was established to deal with this major therapeutic and logistic problem.[1]

However, adequate palliation of dysphagia is difficult to achieve with a low morbidity.[2] A plastic stent placed through a rigid oesophagoscope has been the only form of palliation available for many years.[3] However, there is significant morbidity and mortality associated with stent insertion.[4] During the first 10 years of our experience in the oesophageal cancer unit at King George V Hospital, a total of 2 446 and 339 patients, respectively, were treated by pulsion and traction intubation using a Procter Livingstone or Celestin tube.[5] The mortality rate for the traction technique was 21% and that for the pulsion technique 15%.[6] Use of the Atkinson method of insertion has dramatically decreased our overall perforation rate to 1%.

Self-expandable metal stents have demonstrated a number of advantages over conventional plastic stents. However, only two studies comparing the different stents prospectively have been performed, namely in the USA[7] and Italy.[8] A major limitation with regard to their use has been the cost of stents in developing countries. The purpose of our study was to compare prospectively the efficacy of the two different stents in black African patients with inoperable oesophageal carcinoma.

MATERIALS AND METHODS

Patients with dysphagia from oesophageal carcinoma were randomised (simple random sampling without replacement) on admission to hospital into two groups, one treated with covered expandable metal stents (Wallstent; Schneider, Switzerland) and the other with plastic stents (Procter Livingstone tube; Roynhardt, South Africa). Criteria for admission to the study included biopsy confirmation of carcinoma (all were squamous cell type), evidence of irresectability of the lesion clinically, and informed consent in writing by the patient. The study protocol was approved by the Natal Medical School ethics committee.

All patients had a lateral thoracic barium swallow examination the day before the procedure to assess the location and length of the stricture as well as the presence or absence of a tracheo-oesophageal fistula. Dysphagia was scored by one of the authors (CS) from 0 to 4 (0 = normal diet, 1 = only small solids, 2 = semi-solids / semi-liquids, 3 = only liquids, 4 = not even saliva), and scoring was repeated the day after the procedure.

The Wallstent was inserted under fluoroscopic guidance in theatre using a C-arm under sedation (midazolam 5 - 10 mg intravenously). Stents were 20 mm or 25 mm in diameter with an effective length of 10 cm. A standard procedure was used: the pharynx was anaesthetised with 1% lignocaine and a 5F catheter was passed orally into the proximal oesophagus. Five millitres of water-soluble non-ionic contrast (iohexol / Omnipaque 300 mg iodine / ml) was used to identify the level and extent of the stricture. The 5F angiographic catheter with a hydrophilic-coated 0.35-inch guide wire (Terumo, Japan) was used to probe the opening of the stricture and then carefully to traverse the stricture into the gastric fundus under fluoroscopic guidance. The hydrophilic wire was exchanged for a 260 cm Amplatz (Cook, USA) wire with a floppy tip ensuring sufficient length in the gastric fundus. Predilatation of the stricture with a 12 mm diameter angioplasty balloon (Schneider, Switzerland) was routinely used followed by stent insertion using the telestep 22F delivery system.[9] Non-ionic contrast was used to confirm the correct stent position and stent patency. The plastic Procter Livingstone stent was implanted under general anaesthetic via rigid oesophagoscopy with measurement of the stricture length and dilatation of the stricture with bougies up to 25 mm diameter. The plastic stent (inner diameter 12 mm, length 11 - 19 cm) was inserted under direct vision.[3]

In both groups of patients procedural time was measured and any immediate complications were noted. The implant position was noted as being good, acceptable or poor. A follow-up barium swallow and repeat dysphagia score were performed the following morning. Patients were asked to return for follow-up at 1 month and 3 months, when a barium swallow was repeated.

Costing of the procedures was calculated using standard costs worked out by the Department of Health for hospital stay, theatre time and nursing time in public hospitals. Material costs, including the costs of the stent, the guide wire, catheter and angioplasty balloon, were based on provincial hospital

tender prices. Anaesthetic materials were itemised and costed as per provincial hospital tender prices. In the comparative cost analysis the total number of stents and procedures per patient were calculated over the initial hospital stay. Costing did not include later stent placement after hospital discharge.

RESULTS

The mean dysphagia score before the procedure was 3 in both groups (able to swallow only liquids), with a score range from 1 to 4. The strictures were located most commonly in the middle third of the thoracic oesophagus (75%), followed by the upper and lower thirds. The mean stricture length as measured from the barium swallow was 6 cm, with a range from 2 to 12 cm. There were 10 patients (25%) — 6 Wallstent, 4 Procter Livingstone tube — with a stricture length more than 8 cm. Five patients (12.5%) — 3 Wallstent, 2 Procter Livingstone tube — had tracheo-oesophageal fistulas demonstrated on barium swallow.

The results for the two groups are set out in Table I. The mean procedure time for Wallstent implantation was 25 minutes (range 20 - 35 minutes) compared with 30 minutes for plastic stent insertion, excluding anaesthetic time (range 25 - 45 minutes). Stricture dilatation was used in both groups; 12 mm in the Wallstent group and 25 mm in the plastic stent group. Wallstent placement was satisfactory in 18 patients but unsatisfactory in the other 2, with proximal shortening resulting in inadequate tumour coverage. The complication was immediately noted and second stents were implanted at

Table I. Covered self-expandable (Wallstent) versus plastic stents

	Wallstent	Plastic stent
No. of patients	20	20
Procedure time (min.)	25	30
		(+10 - 20 min. anaesthetic time)
Position		
Satisfactory	20	15
Poor	—	5
Complications		
Perforation	0	2
Haemorrhage	0	2
Pain	2	5
Migration	1	5
Mean dysphagia		
Pre-operative score	3	3
Postoperative score	0	2
Mean hospital stay	24 h	3 d
Patency		
1 mo.	90% (18/20)	66% (12/18)
3 mo.	88% (16/18)	50% (8/16)
Mortality	2	2

the same time with good results. In the plastic stent group two contained perforations were detected at the time of implantation. These were managed conservatively (nasogastric feeds, antibiotics). In the first 24 hours after the procedure 2 patients who had Wallstents implanted complained of central chest pain, which settled within 3 days of using simple analgesia. Five patients who received plastic stents complained of persistent pain despite analgesia. The Wallstents occluded fistulas in all 3 patients, but the plastic stent was unsuccessful in 1 of the 2 patients, who was then managed by the standard conservative methods. The mean dysphagia score within 24 hours after the procedure was 0 for Wallstent-implanted patients and 2 for plastic stent-implanted patients. Patency was confirmed in all 20 patients with Wallstents and in only 15 patients with plastic stents. In the 5 patients (25%) with occluded plastic stents this was due to proximal stent migration. The mean hospital stay for Wallstent patients was 24 hours, and that for the Procter Livingstone tube group 3 days. At 1 month's follow-up Wallstent patency was confirmed in 18 out of 20 patients (90%) (dysphagia score 0 - 1) and plastic stent patency in 12 out of 18 (66%) (dysphagia score 1 - 2). In 1 patient Wallstent occlusion was due to tumour overgrowth that warranted implantation of a second stent with good results, and in the other it was due to Wallstent migration into the stomach. In the latter case obstruction was due to distal oesophageal carcinoma and was managed by oesophageal dilatation, with the malpositioned stent left *in situ*. In the plastic stent group, stent obstruction was due to proximal stent migration, tumour overgrowth, or food bolus impaction. Management involved tube replacement with a longer tube, oesophageal dilatation (when the plastic stent could not be retrieved due to proximal tumour overgrowth), or removal of the food bolus via a rigid endoscope. Four patients (10%), 2 from each group, died from massive tumour load or metastatic disease. At 3 months' follow-up, 16 of 18 patients (88%) (dysphagia score 0 - 2) had patent Wallstents, 2 patients having died in the interval. Only 8 (50%) of 16 patients who returned for follow-up had patent plastic stents (dysphagia score 1 - 3) at this time (2 died, 2 lost to follow-up). Management of occluded stents was the same as at 1-month follow-up.

Table II is a comparative cost analysis of the procedures, including anaesthetic, nursing, theatre time and daily bed costs during the initial hospital admission. The Wallstent cost R4 123 to implant compared with R2 146 for plastic tube placement. The Wallstent itself costs 100 times the cost of the plastic tube. These implantation cost elements ignore issues of long-term patency after the end of the hospital stay. It would be difficult to calculate long-term costing because many patients were lost to follow-up after 3 months.

DISCUSSION

Our results demonstrate the superiority of self-expandable covered metal stents over plastic stents in the palliation of

Table II. Comparative costing of Wallstents v. Celestin plastic stents during first admission (in rands)

Materials	Wallstent	Procter Livingstone
Cost per stent	3 000	30
Stent/procedure	3 300	30
Guidewire/catheter	150	—
Anaesthesia		
Materials		
Dormicum 15 mg	15	—
Lignocaine spray	5	5
Propofol	—	35
Mivacurum	—	20
Glycopyrrolate	—	4
Neostigmine	—	1
Oxygen/nitrous oxide for 30 min.	—	142
Anaesthetic time	—	250
Theatre time	250	450
Hospital stay @ R403/day	403	1 209
Total	4 123	2 146

oesophageal carcinoma. There are less procedural complications and improved 3-month patency with metal stents. This confirms the findings of other prospective studies from Italy and the USA.[8,9] In our study 25% of patients presented late with long strictures (> 8 cm), and 12.5% presented with tracheo-oesophageal fistulas. This is a common problem in black African patients. These two subgroups of patients did considerably better with Wallstent implantations.

Plastic stent implantation via endoscopy has been the main form of palliation for inoperable oesophageal cancer for the past 20 years.[10] This stent is relatively inexpensive compared with the Wallstent, by a factor of 1 to 100. However, the delivery system is bulky and stent implantation requires a general anaesthetic. A survey of the surgical literature showed morbidity of up to 36% and mortality from 2% to 16%.[3] The main complications are haemorrhage (5%) and perforation (10%).[3] Perforation is a serious complication, more common with long (> 8 cm) strictures. Stent dislodgement is common, occurring in 20% of patients. Stent obstruction is also a common problem owing to the narrow internal diameter of the stent, which means that patients can only swallow a semisolid diet.

In our study Wallstent patency at 3 months' follow-up was far better than plastic stent patency. Wallstent obstruction was usually due to tumour overgrowth above the proximal edge of the stent rather than to food bolus obstruction, which was more common in patients with plastic stents. A disadvantage of the Wallstent is that accurate placement of the stent is critical in a long stricture as the stent shortens on deployment and the whole stricture may not be adequately covered, as seen in 2 of

our patients who required second co-axial stent placements. We found Wallstent migration to be very uncommon except for our first case. This is possibly due to the fact that most of our patients had mid-oesophageal strictures, as opposed to other studies where most cancers involved the distal oesophagus where stent migration is more likely.[4]

The major limitation to the effective use of expandable metal stents is their relative cost compared with plastic stents, especially in developing countries. A critical comparison of the costs involved is required as expandable metal stents may prove to be more cost-effective in the long term. In our study the actual Wallstent device was 100 times more expensive than the plastic tube; however, the total cost, including hospital stay, was R4 123 compared with R2 146, which is 1.9 times more expensive. Despite any increased implantation costs subsequent to this study, and even if there are no lower unit costs per Wallstent arising from its wider adoption, there is still a case to be made for its superiority. We envisage that patency over periods longer than the observed 3 months will show further reduction in plastic tube patency and minimal reduction in Wallstent patency. As soon as the ratio of patencies (here 88% v. 50%, or 1.76) reaches or exceeds the cost ratio (R4 123/2 146, or 1.91) there is strong evidence for further long-term relative economies arising from the Wallstent. Extrapolating from the observed patency trends, we confidently expect the Wallstent to be vindicated.

In patients with fistulas and strictures more than 8 cm in length the advantages of using metal stents are considerable; we believe that their use in these two subgroups constitutes the optimal treatment.

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