SELF-EXPANDING NITINOL STENTS FOR THE PALLIATION OF ESOPHAGEAL OBSTRUCTION : SHORT-TERM RESULTS

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SUMMARY :

Purpose : *We studied the short-term results of self-expanding nitinol stents utilized in the palliation of esophageal carcinoma.* ***Methods :*** *The self-expanding metallic stent (SEMS) constructed from nitinol was inserted and released under endoscopic and fluoroscopic control in 16 patients.* ***Results :*** *Correct stent placement was achieved in all patients. No treatment complications were noted. All patients were able to ingest all calories by mouth, and no prosthesis exhibited tumor ingrowth at follow-up examinations (1-112 days).* ***Conclusion :*** *Nitinol stent is a cost-effective and safe alternative to conventional prosthesis in the palliation of strictural esophageal obstructions.*

Key Words : *Esophagus, Stent.*

INTRODUCTION

Although most esophageal cancers are not amenable to cure, they nevertheless require palliation, especially for dysphagia. A variety of therapies are employed in the palliative treatment of esophageal obstruction. Current endoscopic therapeutic modalities include dilation, thermocoagulation, injection of alcohol or chemotherapeutic agents, photodynamic therapy, intra-cavitary irradiation, and placement of plastic or metallic prosthesis (1-5). Unfortunately, no single modality provides effective, safe, inexpensive relief of dysphagia in all cases (6).

This report describes our experience in sixteen consecutive patients with esophageal obstruction palliated with new self-expanding nickel-titanium coil stents.

PATIENTS AND METHODS

Study Design :

All hospitalized patients with malignant or benign dysphagia due to esophageal obstruction were retrospectively analyzed. Only patients treated by esophageal stent implantation were included to the study. All patients gave informed consent following extensive explanation of the risks and the therapeutic alternatives.

Patients :

All patients had dysphagia due to esophageal or esophagogastric obstruction and were considered inoperable because of local tumor extension, distant metastases or severe concomitant disease. The diagnosis was histologically verified in all cases. The clinical characteristics and the other details of the patients are listed in tables 1 and 2. All

No	Age	Sex	Tumor Site	Histologic	Tumor length (cm)	Dysphagia grade before stent placement
1	46	M	Distal	Adeno	4.5	3
2	39	M	Distal	Adeno	4.5	3
3	51	F	Distal	Squamous	5.0	3
4	72	F	Distal	Adeno	4.0	3
5	59	M	GEJ	Adeno	4.0	4
6	49	F	GEJ	Adeno	5.0	4
7	47	F	GEJ	Adeno	5.0	3
8	51	M	Distal	Adeno	6.0	4
9	49	M	Distal	Adeno	6.5	4
10	42	F	Distal	Adeno	4.5	4
11	49	M	Distal	Adeno	4.5	3
12	57	M	Mid	Benign	4.0	3
	"	"	"	"	"	4
13	42	F	Mid	Benign	6.0	3
14	61	M	Mid	Benign	3.5	4
15	49	M	Distal	Adeno	4.5	4
16	37	M	Distal	Adeno	4.5	4

GEJ : gastroesophageal junction.
Distal : distal esophagus.
Mid : Mid-esophagus.
Adeno : Adenocarcinoma.
Squamous : Squamous cell carcinoma.

Table 1 : The clinical characteristics of the patients

required frequent standard endoscopic dilation of the stricture for severe dysphagia. The median grade of dysphagia was 3 (9 patients with grade 4 and 7 with grade 3). Ten men and six women with a mean age of 50 years (range 37 to 72) were included. The histologic diagnosis was squamous carcinoma in 1 case and adenocarcinoma in 12. Three cases had benign esophageal strictures after undergoing surgery for lung or larynx carcinoma.

Stent Implantation :

Following sedation of the patient with midazolam 5 mg (iv) (Dormicum, Roche, Switzerland) the length of the stenosis was determined by endoscopic and fluoroscopic examinations. A guide wire (0.035 inch) was inserted under a 7 mm diameter pediatric endoscope (Olympus UG-FP 7) with fluoroscopic control. We used Savary probe (up to 11 mm) for dilating stenotic section in one case. The self-expanding metallic stent (SEMS), constructed from nickel-titanium allay or "nitinol" (Instent Inc, Eden Proirie, Minn., USA) was inserted over the guide wire. An endoscope was inserted additionally and the stent was released under endoscopic and fluoroscopic control (Fig. 1-3).

Patient Assessment :

Patients were seen on scheduled readmissions or followed up with telephone interviews of weekly intervals. Quality of swallowing was assessed with the aid of a dysphagia score (7); 0: no dysphagia, 1: dysphagia to normal solids, 2: dysphagia to soft solids, 3: dysphagia to solids and liquids, 4: inability to swallow saliva. Tables 1 and 2 reveals dysphagia index before and after stent implantation.

No	No of stents	Open (%)	Dysphagia grade after stent placement	Survival (days)
1	EG 18/7	80	1	50
2	EG 18/8.5	80	1	84
3	EG 18/8.5	100	1	55
4	EG 18/8.5	80	1	63
5	EG 18/7	100	0	84
6	EG 18/8.5	60	2	13
7	EG 18/8.5	100	0	60
8	EG 18/10	60	2	94
9	EG 18/8.5	100	0	112
10	EG 18/8.5	80	1	99 (Alive)
11	EG 18/8.5	80	0	84 (Alive)
12	VR 18/10	80	0	81 (Alive)
	VR 18/10	70	0	39 (Alive)
13	VR 18/15	100	0	59 (Alive)
14	VR 18/7	100	0	40 (Alive)
15	EG 18/8.5	100	?	1
16	VR 18/10	80	1	37 (Alive)

Open (%) : The percentage of the released circumference of the stent.

Table 2 : Results of nitinol stent placement.

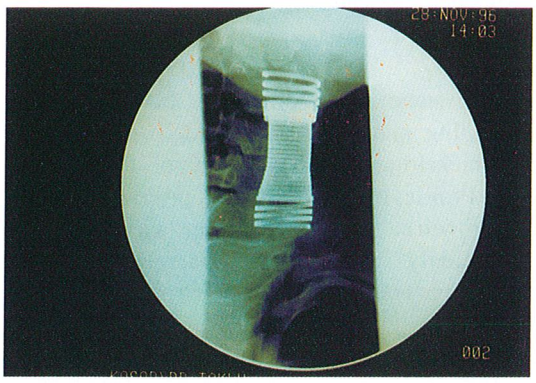

Fig - 1 : Fluoroscopic examinations show the effectiveness of the stent.

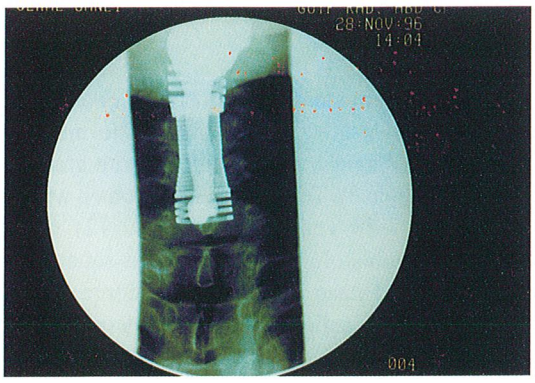

Fig - 2 : Fluoroscopic examinations show the effectiveness of the stent.

RESULTS

Technical Success :

Correct stent placement was achieved in all patients.

Functional Efficacy and Survival :

The functional efficacy is shown in table 2. The mean number of cumulative endoscopic interventions per patient was 4. No treatment complications were noted. Only one death occurred, one day after stent placement due to the

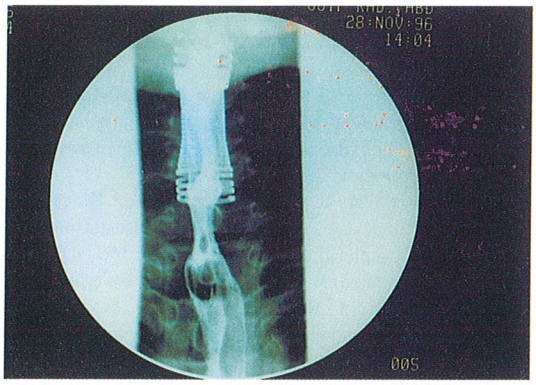

Fig - 3 : Fluoroscopic examinations show the effectiveness of the stent.

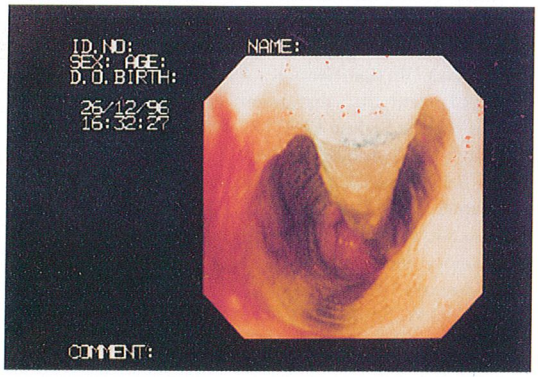

Fig - 4 : Endoscopy reveals a nasogastric tube easily passed into the stent a month after the NITINOL stent placement.

primary disease. All patients were able to ingest all calories by mouth, and at follow-up examinations, no prosthesis exhibited tumor ingrowth. (Fig. 4) In one case, a second stent placement was needed after 81 days because of new occlusion at another location. The average follow-up period was 2 months (range 1-112 days) after stent placement.

DISCUSSION

Carcinoma of the esophagus and gastric cardia causes progressive dysphagia. More than half of these tumors are not amenable to surgical treatment and even after resection about 20 % of these patients will have further dysphagia caused by either recurrence or anastomotic stricture (8-10). Moreover, all operations, which include laryngotracheal and mediastinal regions, can eventually cause of benign strictures in the esophagus (11). Most of the patients are severely malnourished and dysphagia causes deterioration in the quality of life. Palliative treatment methods using repeated dilations, Nd: YAG laser photocoagulation therapy, or insertion of plastic esophageal prosthesis not only have limited effectiveness but also yield a high morbidity and mortality rate (12-17). Expandable metal prostheses have been utilized for esophageal stenoses and palliation of this nature seems to be more effective than other modalities (6,18-21). However, the main problems with these metal stents are tumor ingrowth leading to reobstruction, migration of the stent from its original position, and epithelial trauma by the distal hard edges of the stent. The metallic NITINOL stent used by our group was developed to solve the abovementioned problem (22).

The nitinol expandable stent has been successfully placed in 84 patients previously, 10 reported by Sags and Hagenmuller (23), 60 by Cwikiel and Stridebeck (24) and 14 by Ohta et al (25). The meshed nitinol stent, with its high elasticity, seems to have advantages in relieving dysphagia due to its adaptation to difficult anatomical situations, maneuvrability, and removability (11). As other researchers on the subject, we found that the placement of expandable stents is a relatively easy procedure. It is important to recognize that mastering the technique necessitates a certain amount of time. Our results show that these stents are especially suitable in cases of problematic stenoses, which are difficult to treat using laser or intubation therapy. They can also be successfully applied in cases of "uncomplicated" malignant strictures (11). Gastroesophageal reflux symptoms seem to be the only adverse effect in the long term.

In conclusion, our short-term results suggest that self-expanding metal NITINOL stent is a cost-effective and safe alternative to conventional prostheses in the palliation of either malignant or benign strictural esophageal obstructions.

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