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Expandable Metal Esophageal Stent Deployment in Patients with Malignant Dysphagia

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Abstract

Background Palliative therapy is the only treatment for inoperable malignant dysphagia. Therapeutic option of self expandable metallic stent has been proven more effective and safest than other conventional palliative therapy like esophageal dilation, plastic stent and laser therapy in malignant dysphagia.

Objectives To study the outcome, efficacy and complications of self expandable metallic stent deployment in patient with malignant dysphagia.

Methods Fifty patients with malignant dysphagia comprised of 38 male and 12 female with malignant dysphagia treated palliativelly with self expandable metallic stent were studied. All the patients were submitted to upper endoscopy and forceps biopsy before self expandable metallic stent deployment. Analysis of stent expansion, mean dysphagia score, complications and mean survival period were carried for the study group.

Results Technical success rate of self expandable metallic stent placement was 86% in first trial and reached to 100% in the second trial. Early technical or patient's complications were negligible. Most important late complication was tumor overgrowth obstructing the stent. The mean dysphagia score point 1.9 and the mean survival period were 3.1 months.

Conclusions Self expandable metallic stent deployment is successful and rewarding procedure for immediate relief of disabling malignant dysphagia with negligible morbidity and zero mortality.

Keyword Self expandable metallic stent, Malignant dysphagia, Esophagus, Iraq

List of Abbreviations: MD = Malignant dysphagia, SEMS = self expandable metal stent, TSR = technical success rate, MDSP = mean dysphagia score points, BICAP = multipolar electrocoagulation, ELT = endoscopic laser therapy, PDT = photodynamic therapy, TTS = through the scope, FNA = fine needle aspiration, EUS = endoscopic ultrasonography, TOF = tracheo-esophageal fistula, PPI = proton pump inhibitor, GERD = gastroesophageal reflux disease, ND = not determine, , MSP = mean survival period,.

Introduction

Malignant dysphagia (MD) in term is given to any difficulty in swallowing due to malignant tumors that arise from the esophagus such as squamous cell carcinoma and adenocarcinoma, or malignant tumors arising from adjacent structures and infiltrating the esophagus. Squamous cell carcinoma represents 90% of primary esophageal cancer. There are many risk factors for this tumor; smoking, excess alcohol intake is most important acquired and avoidable risk factors [1-4]. The product of tobacco which is nitrosamine [5] is found to be cancerous to the esophagus.

Adenocarcinoma is less than 10% which is usually in the lower third of esophagus, since more than 90% for the patients with adenocarcinoma occurs as sequel to the Barrett's disease which is considered the most important risk factor for development of this type of tumor. The other rare non epithelial primary malignant tumors represent about 1%

arise from muscles of the esophagus, i.e., liomomyosarcoma [4,5].

Secondary esophageal tumors infiltrating the esophagus lead to MD. The commonest adjacent organs that the malignant tumors arise from are the lung, stomach especially the cardia, mediastinum and breast. Carcinoma of cardia cause sever dysphagia *per se* or due to infiltration to lower third of esophagus but in most of the time it is impossible to differentiate the primary site of adenocarcinoma whether arise from the esophagus or cardia even by endoscopic and histopathological examination [1,4,5].

Dysphagia grade was described by Stoller et al in 1977 and Atkinson et al in 1979 as follow: [1]

0 = no dysphagia, 1 = able to swallow most foods, 2 = able to swallow a soft diet, 3 = able to swallow liquids only and 4 = unable to swallow saliva.

The aim of stent placement is to improve dysphagia score points. The prognosis is dismal, at the time of diagnosis and the overall 5-year survival is 5%. More than 60% of patients are inoperable at the time of diagnosis, and because of debilitation or advanced age patients with comorbid diseases and metastasis at the time of presentation, so the palliation is the only realistic therapeutic option for these patients [4].

Self expandable metallic stent (SEMS) invented in 1980 by Boston scientific/microvasive in USA, but the placement of the SEMS for the first time by Doctor Frimberger in 1983 by per oral method [5] (Fig. 1 and 2). SEMS is promising and rapidly developing medical branch. Complications may include migration and perforation, occlusion, recurrent dysphasia, chest pain and bleeding [1,5].

The intention of this study is to study the outcome, efficacy and complications of SEMS deployment in patient with MD.

Methods

Eighty five patients with MD referred during Jan. 2004 to Jan. 2006 to the Gastroenterology and Hepatology Teaching Hospital in Baghdad for palliative therapy and were candidates for stent. They comprised 64 males and 21 females with an age range between 38 and 82 years (mean 62 years).

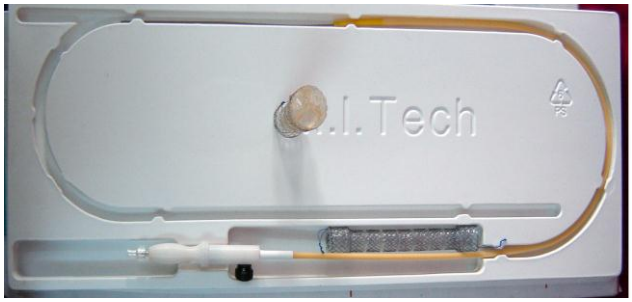

Fig. 1. Choostent Covered Esophageal; Diameter 18mm Total Length 140mm and its Delivery Device; Diameter is 6mm and usable length is 70 cm.

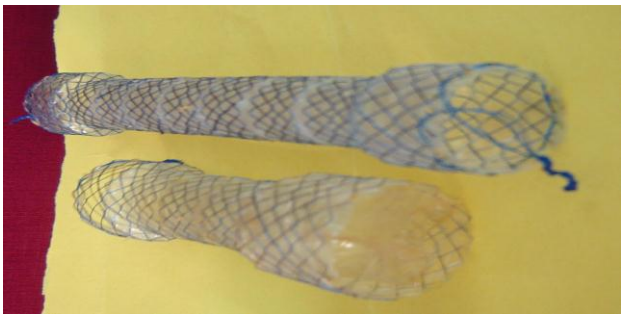

Fig. 2. Choostent SEMS with full expansion without anti reflux valve (upper), with tricuspid anti reflux valve (lower).

Fifty one males were smokers versus thirteen females and fourteen were alcoholics versus none of the females. Out of the total number, 35 patients were not fit for stent because of upper esophageal tumor (16 patients), tumor extent to fundus and body of stomach (7 patients) and complete obstruction to esophageal lumen (12 patients). We failed to identify the distal edge of the tumor and thus referred for another palliative treatment.

The rest fifty patients were inoperable (38 male and 12 female); were reevaluated thoroughly with biochemical, serological, hematological assessment with special concerns to viral screening, thrombin and partial prothrombin times. In addition, imaging studies including abdominal ultrasonography,

chest radiology, computed tomography scanning, and barium swallow when feasible. All the patients underwent endoscopy and biopsy was taken from the esophageal tumor.

Trial of SEMS was done to all patients using the following materials:

a. Olympus scope (GIFQ 160) or (GIF XP 120) used as upper endoscopy of the patients.
b. Choostent (cover, uncover), M.I. Tech, Seoul, Korea with (delivery device; guide wire 0.038 inch, diameter 6mm, usable length 70 cm).
c. Fluoroscope machine model 9800 C-arm.
d. Piano guide wire (metallic stainless steel floppy)
e. Contrast used (Omnipaque 240 mg/ml) equal to lohexol 518 mg + tromtamol 1.2 mg + sodium. Calcium editate 0.1mg/ml.
f. Savary-Guilliard polyvinyl dilator (wilsoncock)

We used the per oral rout method under complete aseptic technique in the theater. Covered stent was selected for those patients with tracheoesophageal fistula or with risk of perforation of esophageal wall by tumor. Uncovered stent was used when the tumor was in the cardia or when there was invasion to the mucosa and submucosa. All the patients sedated with intravenous 50-100 mg of pethidine.

The patients were kept in the hospital for two days and they were allowed to take clear liquid diet within 6 hours. Dysphagia score was recorded after 24 hours and the endoscopy repeated in the next day for the assurance of proper placement and expansion of the stent. The patients then discharged when there was no complication. If the patients tolerated the liquid diet well they were instructed to take soft food in the second week with dysphagia score (Fig. 3).

Result

The technical success rate (TSR) was 86% (43 out of 50) as 1 patient with migration and 6 patients there with high suspicion of perforation and the procedure postponed to the next day after the perforation had been excluded.

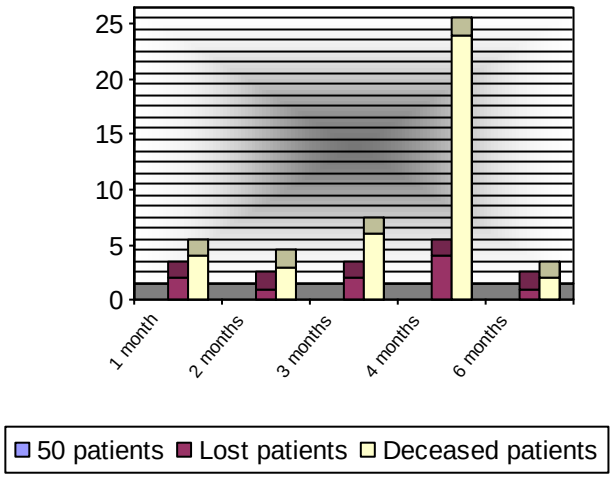

Fig. 3. Follow up period of 50 patients with malignant dysphagia after stent deployment

The criteria of technical success were expansion of the distal flange of stent 2-3 cm from distal edge of tumor and proximal flange of the stent 2-3 cm from proximal edge crossing the tumor with endoscopic and radiologic follow (Fig. 4-6).

Chest pain occurred in 24 out of 50 patients (48%) after stent placement, 12 patients with uncovered SEMS and 12 patients with covered SEMS. This was the commonest immediate complication after stent deployment in patients with malignant dysphagia (Fig. 4-6).

Recurrent dysphagia occurred in 6 patients in the first 2 weeks and the cause in all the case was food impaction and they were treated by excessive wash through the endoscope.

Migration occurred in 2 patients in the first two weeks of placement both with covered stent and another stent was re-inserted.

Perforation, sudden death, and sepsis were not recognized in any patients. Two weeks later, chest pain was seen in 6 patients (gave history of retrosternal discomfort) out of the 24 patients.

Late complications started to appear after first month includeing recurrent dysphagia by tumor obstruction and were increasing proportionally with duration of stent

deployment (Table 4). The mean dysphagia score points (MDSP) had been measured twice (24 hours 1 week later). The MDSP score was 3.3 before the stent and became 1.4 after stent deployment.

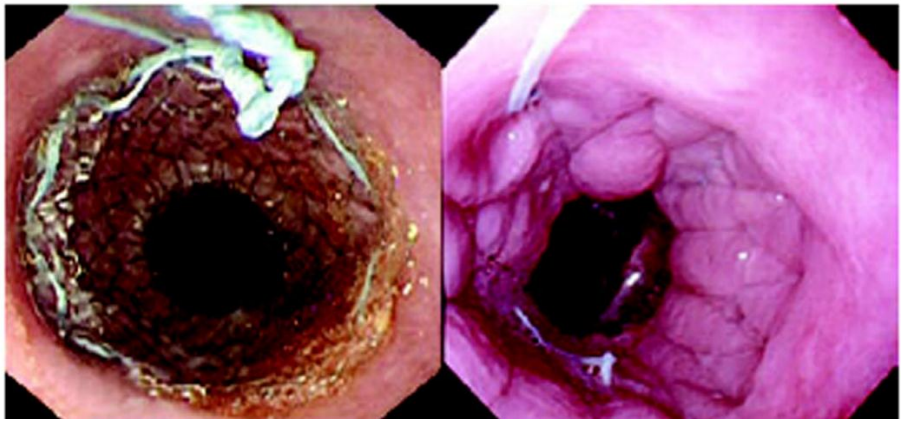

Fig. 4. Endoscopy shows fully expanded flange of covered stent after deployment (Left); shows firmly fixed flange of stent into the esophageal mucosa after insertion of uncover stent (Right)[7]

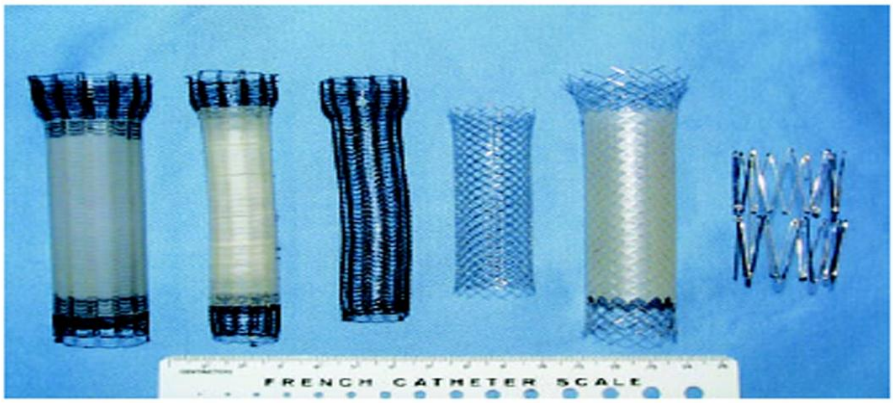

Fig. 5. Esophageal SEMS (Left to right): Ultraflex, large diameter, covered; Ultraflex, covered; Ultraflex uncovered; wallstent, uncovered; wallstent, large diameter, covered, Z-stent [15,16]

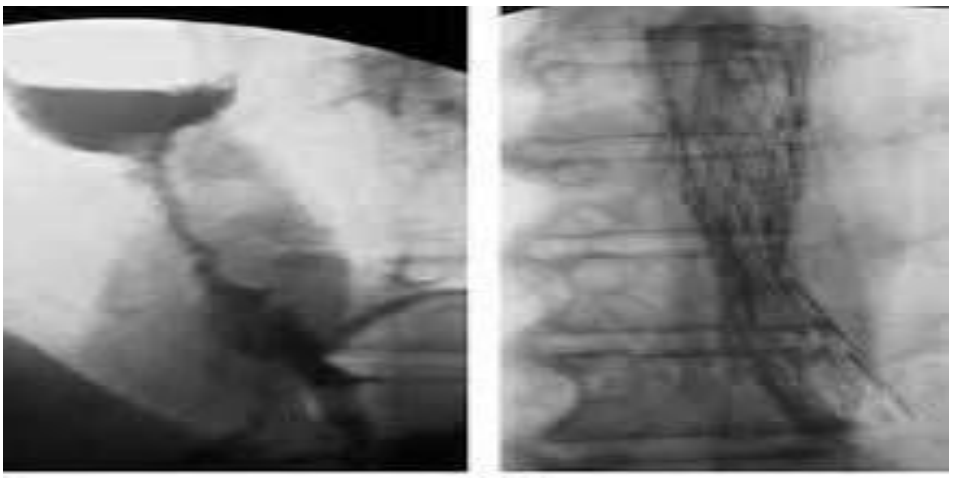

Fig. 6. Radiological view for SEMS before and after deployment

Discussion

The range of age (36-82 years) in this study and mean age of 56 years is lower compared to U.S.A, S. Korea mean age 62 and 65 years respectively [6,7]. Male:female ratio was 3:1, which is similar to other centers in USA and South Korea (3:1 and 4.1:1; respectively) [6,7].

Duration of dysphagia was 3-6 months, Ginsberg and Fleischer [4], mentioned in their review that dysphagia is rarely present for more than one year.

The TSR was 86 % in the first trial and reached 100% in the second trial next day of the study. This was similar to study conducted by Gukovsky-Reicher et al [5] where ultraflex stent was used in 44 patients and the TSR was 95 %. Similar TSR is reported by Chan Sup Shim in 61 patients with covered Choostent SEMS. The results of TSR in most centers with variant stents are nearly equal or slightly different (Table 1). Analysis of success evaluated as relieve of dysphagia was assessed by calculating the MDSP. The score of our study was in close proximity to that of many different centers and variants stents (Table 1).

Table 1. TSR, MDSP and MSP Comparative results in different centers and variant stents

Worker	Country	Stent deployed	No. of patients	TSR	MDSP	MSP
Our study	Iraq	Choostent	50	86%	1.9	3.1
Gukovsky-Reicher et al [5]	USA	Ultraflex	44	95%	1.5	3
Shim and Jung [6]	Korea	Choostent	61	95.5%	1.8	4.2
Raijman et al [10]	USA	Wallstent	101	96%	2.2	5.2
Doo et al [12]	Korea	Choostent	17	100%	2.0	4.8
Cwikiel et al [15]	USA	Ultraflex	106	97%	1.8	6

TSR = technical success rate, MDSP = mean dysphagia score points, MSP = mean survival

Kozarek and colleagues [8] analyzed data from 75 SEMSs deployment and found no correlation between complication rate and patient's age, sex or stent location it was very close to this study.

In this study 12 patients had complete obstruction of the esophageal lumen who were excluded from study which is similar to the work of Barr et al on 80 patients in which 16 of them had complete obstruction of the lumen and were treated by four sessions of laser therapy before stent deployment [2].

Early technical complications in this study were rather low. Migrations were seen in 2%, failure of insertion in first trial was 12%. No failure in expansion or perforation. These results are nearly similar to Gukovsky-Reicher *et al* [5], Cwikiel and colleagues [15] and Shim and Jung [6] in which migration were reported as 2%, 1% and 1% respectively.

Early complications it is rather higher. Chest pains were reported as 36%. In half of those patients uncovered SEMS were deployed. This is not comparable with Gukovsky-Reicher *et al* [5], Cwikiel *et al* [15] or Raijman *et al* [10] where chest pain occurred in 4%, 8% and 13% respectively. Recurrent dysphagia due to food impaction was 12% which is higher than the compared centers. This is explained by failure of compliance of the patients to special fluid diet. Bleeding occurred in 4% which is similar to USA, South Korea's centers (Table 2).

Delayed technical complications increased proportionally with duration of stent deployment. In this study, obstruction of stent is reported in 36% by tumor overgrowth mainly, with in the follow up period, while obstruction by food impaction is seen in 6% which is higher than other center. In three American centers the results were 8%, 19%, and 5 % [6], while in South Korea it was 17% [7] (Table 3).

Table 2. Early complications in different centers and variant stent

Complications	Our study	Gukovsky-Reicher et al [5]	Cwikeil et al [15]	Raijman et al [10]	Doo et al [12]	Shim and Jung [6]
Food impaction	12%	0%	0%	0%	0%	0%
Migration	2%	0%	0%	0%	1%	0%
Failure of expansion	0%	0%	6%	1%	2%	4.8%
Stent misplacement	0%	0%	1%	0%	0%	1.5%
Fracture	0%	0%	0%	0%	0%	0%
Chest pain	46%	5%	8%	13%	10%	8%
Recurrent dysphagia	12%	0%	0%	0%	3%	0%
Bleeding	4%	0%	0%	5%	4%	0%
Perforation	0%	2%	1%	0%	0%	0%
Sudden death	0%	0%	0%	0%	0%	ND

Table 3. Late complications in different centers and variant stents

Complications	Our study	Gukovsky-Reicher et al [5]	Cwikeil et al [15]	Raijman et al [10]	Doo et al [12]	Shim and Jung [6]
Food impaction	6%	5%	5%	0%	2%	0%
Tumor obstruction	36%	13%	19%	6%	17%	1%
Migration	4%	8%	3%	3%	4%	0%
Stent kinking	2%	2%	0%	0%	2%	0%
Chest pain	12%	0%	0%	ND		0%
Recurrent dysphagia	48%	38%	23%	15%	16%	3.3%
GERD	30%	8%	ND	ND	6%	8%
Bleeding	6%	0%	3%	2%	2%	0%
Perforation	ND	0%	5%	0%	0%	0%
Sepsis	ND	0%	0%	0%	0%	ND

This could be explained on the basis that patients received proper chemotherapy. Migration of stent occurred in 4% and the stent kinking in 2%. All these results nearly similar to the USA and South Korea centers [6-8].

Recurrent dysphagia was reported in 48%. This is slightly higher than three American centers in which the results were 38%, 23%, and 15% [6] and in the South Korea was 16 % [7-9].

GERD was recognized in 24% which represent all patients with uncovered non anti-reflux stents and in 6% with covered anti-reflux. The clinical features were used for diagnosis of GERD and not 24 hours PH monitoring as it is not available in the center of this study.

Doo et al, in 17 patients treated with anti-reflux Choostent had only one patient complicated by GERD, this proved by 24 hours monitoring of PH [10].

The mean survival period in this study is 3.1 months which is comparable to four American centers 3, 6, 5.2, 4, 4 months [6,12-15], however in the South Korea experience the mean survival period is 4.6 months.

Dormann *et al* [16] and Costamagna *et al* [17] used the poly flex plastic stent in state of metallic stent and found there is less complications.

In conclusion, most of inoperable patients with MD have rather prolonged period of dysphagia range from 3-6 months, SEMS deployment resulted in immediate relief of dysphagia, because of high technical success rate of stent deployment, low morbidity related to this

procedure and no mortality, all these results are encouraging causes for using this type of palliative therapy, most of late recurrent dysphagia results from distal tumors overgrowth which obstruct the distal part of stent, and decrease mean dysphagia score point from 3.3 to 1.4 lead to improve in dysphagia and quality of life.

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Author contribution

Dr. Saadoon selects the cases, follows up them and participates in stent deployment in some cases and Dr. Shubbar arranges the study and gives the instructions throughout the study.

Conflict of Interest

None.

Funding

None.

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