ORIGINAL ARTICLE

Self Expandable Metallic Stent Endoscopic Insertion In Esophageal Cancer

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ABSTRACT

Objective: To determine the safety of self expandable metallic stent (SEMS) placement under endoscopic guidance without fluoroscopy.

Study Design: Quasi experimental study.

Place and Duration of Study: Section of Gastroenterology and Hepatology, Departments of Medicine, Isra University Hospital and Liaquat University of Medical and Health Sciences (LUMHS), Hyderabad, from April 2006 to March 2009.

Methodology: In 80 patients with inoperable carcinoma of esophagus, SEMS made-up of nickel titanium alloy and mesh shaped with distal release system were placed without the use of fluoroscope under endoscopic guidance. Patients with proximal location of tumour in esophagus were excluded. They were followed at one week after deployment. All the complications were recorded. Dysphagia score was assessed before and after stent placement. Mean pre- and post-stenting scores were compared using t-test.

Results: Fluoroscopy was needed in only 2 patients. In 75 patients the stent was successfully placed with endoscope control only, without fluoroscope. Dysphagia score improved significantly from 4.26$\pm$1.07 before stenting to 1.02$\pm$0.57 later, ($p < 0.001$). Minor complications like retrosternal pain occurred in 30 (37.5%) patients and major complications in 8 (10.0%) patients amongst which 4 (5.0%) developed upper gastrointestinal bleeding and 4 patients (5.0%) had aspiration.

Conclusion: Insertion of self expandable metallic stent in esophageal carcinoma without fluoroscope was safe and effective in relieving dysphagia at short term follow-up.

Key words: *Self expandable metallic stent. Esophageal carcinoma. Dysphagia.*

INTRODUCTION

Esophageal cancer is not uncommon in Pakistan, being seventh common cancer in men and sixth most common in women in Karachi.[1] The five years survival rate for esophageal cancer varies from 5 to 10%, despite therapeutic progress.[2] Weight loss and poor quality of life (QOL) are mainly due to dysphagia which is the main presenting feature of esophageal cancer. Palliative treatment of dysphagia with self expanding metal stent (SEMS) is considered to be the procedure of choice improving of QOL until death.[3] Fluoroscopy is routinely used to guide the placement of SEMS for the palliative treatment of patients with esophageal malignancy. The access to fluoroscopy is limited in many centres and one of the main reason for delay in the treatment and transfer to other centres for SEMS insertion. However, there are reports regarding safety and efficacy of a simple procedure of SEMS insertion under endoscopic guidance alone, without using fluoroscopy.[4-7]

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Local experience is rich in safety and efficacy of esophageal stricture dilatation without fluoroscopy.[8-11] The aim of this study was to evaluate the safety and efficacy of endoscopic guided SEMS insertion for inoperable esophageal carcinoma without the use of fluoroscopy.

METHODOLOGY

From April 2006 to March 2009, patients with dysphagia secondary to inoperable esophageal cancer with advanced stage III or IV were enrolled in this observational, non-randomized prospective study. All the consecutive patients were first seen by the oncologist and surgeon (Liaquat University of Medical and Health Sciences) and after deciding on the inoperability of esophageal cancer were referred to (Section of Gastroenterology and Hepatology, Department of Medicine, Isra University Hospital) for self expandable metallic stent (SEMS) placement. Patients with proximal location of tumour 15-16 cm from incisor teeth, where placement of SEMS was not possible, and the patients who did not consent for stenting were excluded. In all patients the SEMS placement occurred as a primary treatment. All the SEMS were 20 mm in diameter, made-up of nickel-titanium alloy and mesh shaped covered and designed for distal release pre-loaded into a delivery system. All the patients were explained the limitations of SEMS placement without fluoroscopy guidance prior to consent. Baseline demographic data

and the histology of the cancer were recorded. This study was approved by the Human Research Review Committee of the Isra University Hospital, Hyderabad and the Medical Ethical Committee, LUMHS, Jamshoro, Pakistan. In patients under conscious sedation, the endoscope was passed into the esophagus and the guidewire was placed through the stricture, enabling Savary Gilliard dilatation up to 11 mm. After inserting the tip of the guidewire into the antrum, the scope (8.9 mm in diameter) was pulled back slowly, allowing the estimate of the tumour length and its proximal extension. The SEMS were selected, with a deployed length at least 4 cm longer than the stricture, and was loaded onto the guidewire and passed through the esophagus. Re-intubation with the endoscope was performed to accurately place, the proximal white marker of the stent at 2 cm above the tumour edge during releasing of stent. After 24 hours, all the patients were rescoped to confirm the accuracy of placement of SEMS. Technical difficulties in SEMS placement and complications were recorded.

Patients were followed at one week after deployment. Pre- and post-stenting dysphagia score were graded as grade 0: no dysphagia, able to tolerate normal food; (1) able to swallow all but with sticking of food retrosternally; (2) able to swallow only some solid food; (3) able to swallow only semisolid food; (4) able to swallow liquid only; (5) unable to swallow anything.

The data were evaluated in statistical program SPSS 16. Qualitative data regarding tumour histopathology, minor and major complications etc. are presented as frequencies and percentage. Numerical parameters i.e. age in years, duration of dysphagia, dysphagia score (pre- and post-) were expressed as mean ± standard deviation; t-test was applied to compare the mean pre- and post-stenting dysphagia scores. A p-value ≤ 0.05 was considered as statistically significant.

RESULTS

Eighty patients were included in the study. The mean age was 52.33±14.53 years ranging from 28-85 years. Majority were females (56,70%). Mean duration of dysphagia was 3.86 months. Squamous cell carcinoma was seen in 85% patients (Table I). SEMS placement under endoscopic control alone was successful in 75 (93.75%) out of 80 patients. No technical problem occurred during placement of the SEMS. Pre-SEMS placement, dilatation of stricture was needed in 37 patients (48.0%).

There was significant improvement in the dysphagia score (pre-stent mean score = 4.26+1.0, post-stent mean score = 1.02±0.5, p < 0.001, Table II).

Major early complications (within 24 hours) occurred in 8 (10.0%) patients. Four (5%) patients developed upper gastrointestinal bleeding and in another 4(5%) aspiration of gastric contents occurred. All of them were treated conservatively. No major complications like perforation, esophageal respiratory fistula, tracheal compression or death occurred during or immediately after the procedure. Minor complications like retrosternal pain needing opiod analgesia occurred in 30 (37.5%) patients. No stent migration was seen at the time of upper GI endoscopy performed 24 hours after the SEMS placement (Table I).

Table I: Demographic characteristics and complications of stenting.

Parameters	n (%)
Age in years (mean)	52.33 ± 14.53
Gender	
Male	24 (30.0%)
Female	56 (70.0%)
Duration of dysphagia (in month)	3.86 ± 3.25
Tumour histopathology	
Well differentiated sq. cell carcinoma	32 (40.0%)
Poorly differentiated sq. cell carcinoma	16 (20.0%)
Moderately differentiated sq. cell carcinoma	20 (25.0%)
Well differentiated adenocarcinoma	6 (7.5%)
Moderately differentiated adenocarcinoma	6 (7.5%)
Minor complications	
Retrosternal pain	30 (37.5%)
Stent migration	0
Major complications	
Upper GI bleeding	4 (5.0%)
Perforation	0
Aspiration	4 (5.0%)
Respiratory arrest	0
Tracheal compression	0
Death occurred during procedure	0

Table II: Pre- and poststenting dysphagia score.

Dysphagia (score)	
Dysphagia score (pre-stent) mean ± SD (range):	4.26±1.07 (0-5) (n=80)*
No dysphagia, able to tolerate normal food (0)	3 (3.87%)
Able to swallow all but with sticking of food retrosternally (1)	1 (1.3%)
Able to swallow some solid food (2)	0
Able to swallow only semisolid food (3)	2 (2.5%)
Able to swallow liquid only (4)	36 (45.0%)
Unable to swallow anything (5)	38 (47.5%)
Dysphagia score (post stent) at 1 week mean ± SD (range):	1.04 ± 0.53 (0-2) (n=75)*
No dysphagia, able to tolerate normal food (0)	12 (16.0%)
Able to swallow all but with sticking of food retrosternally (1)	54 (72.0%)
Able to swallow some solid food (2)	9 (12.0%)
Able to swallow only semisolid food (3)	0
Able to swallow liquid only (4)	0
Unable to swallow anything (5)	0

** P value = < 0.001 is highly significant statistically calculated by non-parametric Wilcoxon signed ranks test*

DISCUSSION

The placement of SEMS under endoscopic guidance without the use of fluoroscopy has the following limitations. It is not feasible in tight stricture. It is not

possible in upper esophageal malignant stricture. Wire insertion across the stricture is under endoscopic guidance only and should be done carefully. Dilatation is required which is generally not required if fluoroscopic guidance is used.

Four previous studies have shown safety and efficacy of SEMS insertion without fluoroscopy under the endoscopy control alone. The success rate of SEMS placement was 77-100%. The success rate in this study was more or less the same as mentioned in above studies.

Whether the SEMS is distal release or proximal one, has no impact on success rate. Similarly, the types of SEMSs also has no impact on success rate.

Use of nasogastroscope or ultra thin scope during SEMS placement did not improve the success rate but it may provide some comfort to patients and endoscopist during the procedure.

The success rate of SEMS placement under endoscopy alone is indeed comparable with those published by institutions that use fluoroscopy control.[12-14] A comparision with other studies is given in Table III.[5,7,13,15]

In this study, 3 patients were excluded because of very proximal tumour and even fluoroscopy-guided stent placement was technically not feasible. However, in 2 patients, fluoroscopy was found necessary to guide through the tight stricture for stent placement. Dilatation of malignant esophageal stricture through Savary Gilliard dilatation was also performed. These results are comparable with previous local studies on esophageal dilatation without fluoroscopy.

There was no malposition or migration of SEMS either during the procedure or 24 hours later when repeat endoscopy was done.

The majority of esophageal cancers in Pakistan are squamous cell in origin. In this study, 85% of cases are squamous cell carcinoma which is nearly the same as reported 80% by Shariyar *et al.*[14] The mean age of these patients was 52.33±14.5 matched with local literature (51.0±14.25 years) as reported earlier.[14] However, these patients were quite young compared with Western population where mean age for esophageal is reported as 70 years.[15]

In this study, covered SEMS were used for the palliative treatment of dysphagia in esophageal cancer but a major drawback is the risk of stent migration, which occurs in up to 20% of patients.[16] In this study, no patient had stent migration. This could be due to the short follow-up of patients, minimal dilation of the stricture and that the proximal end of each stent was broader and tulip-like in shape.

Major complication in this study was upper GI bleeding which was mild to moderate in severity and occurred within 3-6 hours of stent placement. All were treated expectantly. This is consistent with both the local and the international studies.[14,17]

There was a very high frequency (37%) of post-stent placement chest pain compared to previously reported 3-22%. All of those patients required narcotic analgesics for relief. This could be due to the stretching effect of the SEMS. This high frequency may also be due to short follow-up period; it is reported that prolonged chest pain occurs in fewer than 13% of the patients who undergo SEMS placement.[18,19]

The main draw back in this study is the short duration of follow-up so that in-growth of tumour and long-term palliation could not be assessed. However, the larger number of patients is rather a favourable point regarding the safety of this technique.

Table III: Comparison between procedures, results and complications of stent insertion under endoscopic control alone.

Author	n	Scope diameter	Type of stent		Dysphagia score		Complications
					Pre-stent	Post-stent	
White RE *et al.*[4]	70	12.8 mm	Wall stent (n=30) Ultraflex (n=40) distal or proximal release	100%	3.3	0.5	2 perforations 2 tumour in-growth 1 tumour over growth
Ben Soussan *et al.*[6]	33	5.9 mm	Ultraflex with proximal release	90%	3.1	1.2	1 death (pulmonary embolism) 2 severe retrosternal pain 1 GERD 1 Food impaction 5 obstruction of stent 1 esophago-respiratory fistula
Wilkes EA *et al.*[7]	98	8.9 mm	Uncovered Ultraflex with proximal release	92%	3.1	1.0	25 Tumour overgrowth and stricture 13 Food impaction 6 Hemorrhage 5 Tracheoesophageal fistula
Austin AS *et al.*[5]	30	8.9 mm	Uncovered Ultraflex with proximal release	77%	NA	NA	No complication
Ali Akbar *et al.* (present study)	80	8.9 mm	Covered nitinol stent with distal release	93.75%	4.26	1.04	4 Upper GI bleeding 4 Aspiration 30 Retrosternal pain

NA = Not available.

CONCLUSION

This study re-emphasizes that endoscopic guidance SEMS placement is a safe and efficacious method for dysphagia palliation due to esophageal malignancies in resource-poor settings where fluoroscopy is not available.

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