

Comparison of covered and uncovered self-expanding metallic stents used in the palliative treatment of inoperable malignant esophageal strictures

İnoperabl malign özefageal darlığın palyatif tedavisinde kullanılan kaplı ve kapsız kendiliğinden genişleyen metalik stentlerin karşılaştırılması

Eyüp ŞENOL^{1,2}, Fahrettin KÜÇÜKAY¹, Mehmet YURDAKUL¹, Rıza S. ÖKTEN¹, Muharrem TOLA¹, Murat Bülent KÜÇÜKAY³, Adnan KARAN¹, Mustafa ÖZDEMİR¹, Fatma Ayça EDİS ÖZDEMİR¹

¹Department of Radiology, Türkiye Yüksek İhtisas Hospital, Ankara

²Department of Radiology Aksaray State Hospital, Aksaray

³Department of Intense Medicine, Lokman Hekim Hospital, Ankara

Background and Aims: The aim of this study is to evaluate the efficacy of self-expanding metallic stents used in the palliative treatment of inoperable malignant esophageal stenosis, and comparing covered vs. uncovered self-expanding metallic stent types. **Materials and Methods:** In our study, 62 patients seen in our clinic for palliative treatment, received covered or uncovered self-expanding metallic stents under fluoroscopic (Philips Integris Allura, Holland) guidance for malignant esophageal strictures. The study was a retrospective analysis of the records of these 62 patients who were treated between February 2008 and November 2013. Clinic ephicasis, complications related to the procedure, and data related with morbidity and mortality were collected retrospectively. **Results:** A total of 81 self-expanding metallic stents, including secondary attempts, were successfully placed. Dysphagia scores decreased significantly after treatment in both covered and uncovered stent types compared to pre-procedure scores. A procedure-related mortality rate of 3.2% was observed. Secondary intervention rate was 25.8%, and a statistically insignificant relationship was found between covered vs. uncovered stent types and secondary interventions. No statistically considerable differences were observed in survival rates among patients with covered and uncovered self-expanding metallic stents, and among patients receiving and not receiving chemotherapy-radiotherapy. Mortality and morbidity were higher in patients who experienced complications in the early period following self-expanding metallic stent implantation and in patients with major complications. However, no statistically significant relationship was observed between covered vs. uncovered self-expanding metallic stent type, complication type or time period. **Conclusion:** Self-expanding metallic stent is an effective and reliable method in the palliative treatment of malignant esophageal stricture. Additionally, self-expanding metallic stent type as well as chemotherapy and radiotherapy have no considerable effect on mortality or morbidity in these patients.

Key words: Malignant esophageal stricture, palliative treatment, self expanding metallic stent

INTRODUCTION

Esophageal cancers are generally diagnosed in advanced stages and portend to a poor prognosis and high mortality. Five years life expectancy is between 10-15%

Giriş ve Amaç: Bu çalışmanın amacı, inoperabl malign özefageal darlığın palyatif tedavisinde kullanılan, kendiliğinden genişleyen metalik stentlerin (self-expanding metal stent) etkinliğinin araştırılması ve kullanılan kaplı ve kapsız kendiliğinden genişleyen metalik stent tiplerinin karşılaştırılmasıdır. **Gereç ve Yöntem:** Non-curable malign özefageal striktür tanısı olan, palyatif tedavi için kliniğimize başvuran 62 hastaya, Şubat 2008 ve Kasım 2013 tarihleri arasında, floroskopi (Philips Integris Allura, Holland) kılavuzluğunda, kaplı ve kapsız kendiliğinden genişleyen metalik stent uygulandı. Klinik etkinlik, işleme bağlı komplikasyonlar ve sağ kalım ile ilgili veriler retrospektif olarak toplandı **Bulgular:** Sekonder girişimler dahil 81 adet kendiliğinden genişleyen metalik stent %100 başarı ile implante edildi. İşlem öncesine oranla işlem sonrası disfaji skoru, her iki stent tipinde de belirgin azalmıştır. İşleme bağlı mortalite oranı %3,2 bulunmuştur. Sekonder girişim oranı %25,8 olup kaplı-kapsız stent tipi ile sekonder girişimler arasında istatistiksel anlamlı bir ilişki saptanmamıştır. Sağ kalım açısından, kaplı ve kapsız kendiliğinden genişleyen metalik stent uygulanan hastalar arasında; ayrıca kemoterapi-radyoterapi alan ve almayan hastalar arasında, istatistiksel anlamlı farklılık saptanmadı. Kendiliğinden genişleyen metalik stentlerin implantasyonundan sonra erken dönemde komplikasyon görülen hastalarda ve majör komplikasyonlar görülen hastalarda mortalite ve morbidite-nin daha yüksek olduğu izlendi. Ancak komplikasyon tipi ve dönemi ile uygulanan kaplı-kapsız kendiliğinden genişleyen metalik stentlerin tipi arasında istatistiksel anlamlı bir ilişki saptanmadı. **Sonuç:** Malign özefageal darlıkların palyatif tedavisinde kendiliğinden genişleyen metalik stentlerin, etkili ve güvenilir bir yöntem olduğunu söyleyebiliriz. Ancak uygulanan kaplı veya kapsız kendiliğinden genişleyen metalik stent tipinin, kemoterapinin ve radyoterapinin, mortalite ve morbiditeye anlamlı bir etkisinin olmadığını görmekteyiz.

Anahtar kelimeler: Malign özefageal darlık, palyatif tedavi, kendiliğinden genişleyen metalik stent

for these patients. The most frequently seen symptom of esophagus and gastro-esophageal junction's malignant obstructions is dysphagia. Thus, the reduction of

Correspondence: Eyüp ŞENOL

Türkiye Yüksek İhtisas Hospital, Department of Radiology

Kızılay Sokak No: 4 06100 Sıhhiye-Ankara-Turkey

Phone: +90 312 306 16 19 • E-mail: dreyupsenol@hotmail.com

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dysphagia has an important role in palliative treatment of non-curable advanced stage esophageal cancers that do not offer the opportunity for surgical intervention. Palliative treatment is the only suitable therapeutic option since metastasis is seen in most of the cases during diagnosis. The primary treatment endpoint for these patients is to reduce dysphagia and prevent co-morbidities that hasten mortality (1-3).

Various therapeutic approaches are used to achieve an acceptable level of the ability to swallow in these patients, which includes, self-expanding metallic stent (SEMS) intubation, laser therapy, intraluminal radiotherapy (brachithery), chemotherapy, bipolar diathermy coagulation and alcohol injection. Three of them come one step forward: Laser therapy, intraluminal radiotherapy and SEMS intubation (4).

Laser therapy provides effective palliation and the complication rate is low; however, it is not suitable for treatment of extrinsic compressions. It is also difficult in patients whose stricture segment is long and tortuous. Finally, equipment is expensive and various sessions are required for treatment (5). Intraluminal radiotherapy provides palliation in less than 40% of patients and the timeframe to for relief of dysphagia is nearly 2 months (6). SEMSs are easy-to-apply and offer a reliable palliation method. Complication rates related with the procedure are low and it considerably decreases dysphagia in a short period following application as well as increasing quality of life. Since the life expectancy of these patients is short, SEMS intubation has become the commonly preferred palliative treatment option. However, SEMS intubation is not without problems, and sometimes, secondary attempts are required (7,8).

In our study, two different types of SEMS (covered and uncovered) were placed under the guidance of fluoroscope in patients with malignant esophageal stricture. Some patients received chemotherapy-radiotherapy before and/or after the operation. Our aim was to compare covered vs. uncovered SEMSs used in the treatment of malignant esophageal strictures on patient survival rates, quality of life and complications.

MATERIALS and METHODS

A total of 62 patients suffering from swallowing problems due to malignancies, seen between February 2008 and November 2013, were included in the study. Of those 62 patients 52 (83.8%) were male, and 10 (16.2%) female. The average age was 63.6 +/- 12.3 (range, 41-86). Covered or uncovered SEMSs were placed under guidance

of fluoroscopy in patients who were deemed inoperable due to local invasion, metastasis or recurrent disease, as diagnosed by esophagography, computed tomography (CT) and ultrasonography (USG). Patients receiving partially covered stents were not included in the study.

A total of 21 patients had primary esophageal carcinoma, 25 gastric cardia or gastroesophageal junction tumors, and 16 patients had esophageal stenosis due to a metastatic situated mass. Stenosis localization prior to operation was at 1/3rd proximal section in 2 patients, at 1/3rd middle section in 14 patients and at 1/3rd distal section in 46 patients.

Patients with esophageal obstruction based on malignant reasons were included in the examination group. Patients who received SEMS due to dysphagia based on trauma-fistula or post-operative benign stenosis were excluded.

Prior to the procedure all patients were informed of treatment options and complications, and patient consents were obtained.

On the day before the operation, esophagography, taken with barium sulfate or iodine opaque material, was performed to determine lesion localization and length. Oropharyngeal local anesthesia was provided with lidocaine (Xylocaine pump spray %10, AstraZeneca, İstanbul) before the operation followed by SEMS placement under guidance of fluoroscopy (Philips Integris Allura, Holland) and what was suitable based on the lesion's localization and length.

Dysphagia score was assessed and recorded pre- and post-operatively using the dysphagia scoring scale of Mellow and Pinkas (9). Accordingly, the score was: 0 - Normal diet; 1 - Dysphagia with certain solid foods; 2 - Able to swallow semi-solid soft foods; 3 - Able to swallow liquids only, and 4 - Unable to swallow liquids or saliva (complete dysphagia).

Patients who were allowed only fluid foods up to 24 hours following the operation were given a diet consisting of soft foods later. At discharge, they were counseled on not eating certain solid and particle foods, refraining from sleep until 3-4 hours after consuming a meal and sleeping with their head at a 45o vertical position. They were also warned to return to the hospital immediately if they suffered bleeding from the mouth, excessive nausea-vomiting, severe chest pain or inability to swallow what they ate. They were also told to come to hospital for routine checkups in 1-3 months periods. If a patient could not return for a follow up visit, information on

progress and general health status was taken with them or their family doctors by telephone.

According to the classification determined in the study performed by Baron TH (10), complications seen during the operation or in the first week after the procedure were recorded as early complications; those seen after this time period were recorded as late complications. Complications seen during and after the operation were categorized and recorded based on the classification determined by Turkyilmaz *et al.* (11). Accordingly, bleeding, perforation, tracheoesophageal fistula, esophagopleural fistula, delivery system entrapment, aspiration pneumonia, tracheal compression and airway compromise were recorded as major complications. Chest pain, nausea-vomiting, the sensation of having a foreign substance that made it hard to swallow, tumor, overgrowth/ingrowth, bolus food obstruction, gastro esophageal reflux, granulation tissue formation, stent migration, stent malposition and intractable hiccups were recorded as minor complications.

Wilcoxon, Mann Whitney U, Chi-square, Kaplan Meier and Kruskal Wallis tests were used for the statistical analysis of the data.

RESULTS

A total 62 patients, 52 (83.9%) males and 10 (16.1%) females received either covered SEMS (n=31) or uncovered (n=31) SEMS. Diameters of the covered SEMS varied between 18-24 mm and between 70-180 mm in length. Uncovered SEMS diameter varied between 18-22 mm and between 70-180 mm in length. The follow up period for patients in this study ranged from 1 to 690 days.

Cardiac arrest occurred during placement of a covered SEMS in a 57 years old male who had obstruction in the esophagus 1/3 proximal section. Cardio-pulmonary resuscitation was attempted but the patient did not respond to treatment. The patient died before SEMS implantation could be performed. The patient was excluded from the study group. A covered SEMS implanted in a 64 years old male patient migrated and was removed. The patient died from cardio-pulmonary arrest while a balloon expansion operation was being performed. Esophago-pelural fistula and affiliated empyema table development was detected 20 days after an uncovered SEMS was implanted in a 47 years old female patient. Infection, which did not respond to treatment, occurred in one patient due to a fistula. Sepsis table developed and the patient died on the 27th day following the operation.

As a result, procedure related mortality occurred in 2 of

the 62 patients (3.2%) in the study group. One of these patients (50%) received a covered SEMS and the other (50%) an uncovered SEMS.

Secondary attempts were required for 16 (25.8%) of the 62 patients, including 11 (35.5%) of 31 patients with covered SEMS and 5 (16.1%) of 31 patients with uncovered SEMS. Secondary SEMS implantations were done once for each of 14 patients, twice on one patient and three times on another patient. Thus, a total of 19 pieces of secondary SEMS implantation were performed on 16 patients. In this manner, including secondary attempts, a total of 81 SEMS implantations were performed on 62 patients.

The reasons why secondary attempts were required include: restenosis related to tumor tissue growth in 15 of 19 cases (78.9%), stent migration in 2 (10.5%) cases, and one (5.3%) case each of tumor tissue growth observed synchronously with stent migration and trachea-esophageal fistula observed synchronously with stent migration.

A total 81 SEMS implanted in 62 patients were successfully implanted. Pre-surgery dysphagia scores were 3 and 4, mean value 4. After the operation, dysphagia scores were between 2-4, mean value 3. Dysphagia scores of patients after the operation were statistically significant and considerably lower than pre-operation ($P=0.000$).

Patency duration of 31 pieces of covered SEMS varied between 1-360 days ($M = 60$). Patency duration of 31 pieces of uncovered SEMS varied between 7-450 days ($M=60$). No meaningful statistical difference was detected between patency durations in covered vs. uncovered stents ($P=0.447$).

The average survival period for 31 patients who received covered SEMS was 198.24 days, with 25 (80%) deaths observed in the follow-up. Average survival period of 31 patients with uncovered SEMS was 117.52 days; 29 (93.5%) deaths were observed in the follow-up. No meaningful statistical difference was detected in the survival periods of patients with covered and uncovered SEMS ($P=0.132$).

A total of 47 (75.8%) of the 62 patients received radiotherapy (RdT) before and/or after operation, with an average survival time of 139.21 days. Average survival time of 15 (24.8%) patients who didn't receive RdT was 214.28 days. Death was observed in 44 (93.6%) of 47 patients who received RdT, and in 10 (66%) of 15 patients who didn't receive RdT. No statistically meaningful difference was observed in survival periods of patients who did or did not receive RdT ($P=0.312$).

Forty-eight (77.4%) of the 62 patients received chemotherapy (ChT) before and/or after the operation, with an average survival period of 136.62 days. 14 (22.6 %) of the 62 patients did not receive ChT, with an average survival period of 228.52 days. Death was observed in 45 of 48 patients (93.7%) who received ChT, and in 9 of 14 patients (64.3%) who did not receive ChT. No statistically meaningful difference was observed in survival periods of patients who did or did not receive ChT (P=0.198).

No statistically meaningful relationship was detected between stent patency duration and gender (P=0.555) or between stent patency duration and tumor localization (esophageal, esophagus external and gastro-esophageal junction) (P=0.051). No statistically meaningful relationship was detected between age of patients and stent patency duration (P=0.650). Also, no statistically meaningful relationship was found between stent patency duration and whether or not a patient received chemotherapy (P=0.993) or radiotherapy (P=0.727) (Table 1).

Among the 62 SEMS patients, 2 (3.2%) had SEMS implanted in the esophagus 1/3 proximal section, 14 (22.6%) to 1/3 middle section, and 46 (74.2%) were implanted to 1/3 distal section. Patency duration of 14 SEMS that were implanted to esophagus 1/3 middle section varied between 1-360 days (M=30); patency dura-

tion of 46 SEMS implanted to 1/3 distal section varied between 7-450 days (M=75). No statistically meaningful differences was detected between patency duration and localization of SEMS. (P=0.188).

Localization area was in the esophagus 1/3 middle section in 22.6% of patients who received covered SEMS. Localization area in 24.1% of patients who received uncovered SEMS was in the esophagus 1/3 middle section. No statistically meaningful relationship was detected between SEMS localization and type of SEMS, covered or uncovered. (P=0.887).

Complications seen in early and late period for the 62 patients are described in Table 2. Accordingly, the most frequent complications in both covered and uncovered SEMS were nausea in the early period and recurrent dysphagia caused by tumor growth or food obstruction in the late period.

Early complications were seen in 17 (27.4%) of the 62 patients who received SEMS, with an average survival time of 102.76 days. Complications were seen in the late period in 31 of 62 patients (50%) who received SEMS, with an average survival time of 194.21 days. Survival times of patients having complications in the early period were meaningfully shorter than ones having complications in late period (P=0.020).

Covered SEMS were placed in 6 of 17 patients (35.3%) who experienced early period complications and uncovered SEMS were placed in 11 (64.7%) patients with early complications. Covered SEMS were placed in 17 of 31 patients (54.8%) having late period complications and uncovered SEMS were placed in 14 (45.2%) of them. No statistically meaningful difference was detected between complication period and type of SEMS (covered-uncovered) (P=0.402).

Stent patency durations in patients with minor complications were meaningfully higher than stent patency duration in patients with major complications (P=0.026) (Table 1). While covered stent were placed in 50% of patients who had major complications, 47.8% of patients who had minor complications received uncovered stents. No statistically meaningful difference was detected between covered and uncovered SEMS in regard to major or minor complications (P=1.000).

Table 1. Examination of differences between stent patency duration and gender, tumor type, SEMS type, radiotherapy status, chemotherapy status and complication types

	Stent patency duration (day) Median (Min. - Max.)	p
Gender		
Male	60 (1-450)	0.555
Female	45 (1-360)	
Tumor type		
Esophageal	60 (7-450)	0.051
Gastro-esophageal junction	75 (7-360)	
Esophageal external	30 (1-180)	
SEMS type		
Covered	60 (1-360)	0.447
Uncovered	60 (7-450)	
Radiotherapy		
Yes	60 (1-450)	0.727
No	60 (7-180)	
Chemotherapy		
Yes	60 (1-450)	0.993
No	90 (7-180)	
Complication		
Major	22.5 (1-30)	0.026*
Minor	60 (7-450)	

Min: minimum, Max: Maximum, P: Statistical p value.

DISCUSSION

SEMS is an accepted therapeutic approach in the palliative treatment of esophageal stricture and dysphagia due to malignant reasons. It is simpler, more reliable and

Table 2. Complications based on operation following esophageal SEMS implantation

Complication Period	Encountered Complications	Covered SEMS (n=31)	Uncovered SEMS (n=31)
Immediate (at the time of placement)	Aspiration	-	-
	Airway compromise	-	-
	Malposition	-	-
	Delivery system entrapment	1 (3.2%)	-
	Stent dislocation	1 (3.2%)	-
	Perforation	-	-
Early (up to 1 week after stent placement)	Bleeding	3 (9.6%)	2 (6.4%)
	Chest pain	1 (3.2%)	1 (3.2%)
	Nausea	9 (29%)	11 (35.4%)
Late (beyond 1 week of successful stent placement)	Recurrent dysphagia due to reobstruction from tumor or food impaction	7 (22.5%)	11 (35.4%)
	Migration	5 (16.1%)	2 (6.4%)
	Esophagorespiratory fistula	1 (3.2%)	1 (3.2%)
	Bleeding	2 (6.4%)	2 (6.4%)
	Gastroesophageal reflux and aspiration	2 (6.4%)	3 (9.6%)

n: Number of patients

better tolerated than other methods. It has low mortality and morbidity rates and allows for swallowing ability to reach an acceptable level rapidly after the operation, and generally, after a single procedure. Mortality rates related with the operation vary between 0.5% and 7% in the literature (12-14).

In our study, SEMS were implanted in 62 patients under guidance of fluoroscopy with a 100% technical success rate. A meaningful decrease in post-operative dysphagia scores were detected in patients with both covered and uncovered SEMS, compared to pre-operative scores. Mortality rates occurred in 3.2% of patients due to complications related to the surgery.

However, SEMS is not a perfect method, and major and minor complications are observed in the early and late post-operative period. For this reason, factors affecting treatment success and quality of life should be examined after the operation.

Regarding major life threatening complications-bleeding rates after SEMS implantation were seen in 1-12% of cases reported in previous studies in the literature. Perforation is one of the most frightening complications in esophageal malignant patients receiving SEMS implantation, although reports in the literature put the rate at lower than 5%. SEMS related tracheal compression, esophagopelural-esophago-tracheal fistula development and aspiration pneumonia are rarely seen serious complications (15-19).

In our study, hemorrhage was seen in 7 of 62 (11.3%) patients in the early and late period following SEMS implantation. One of 62 (1.6%) patients who received SEMS encountered an esophagopelural fistula and sepsis table in the late period, following successful uncovered SEMS implantation. Tracheoesophageal fistula development was detected in the late period following operation in one (1.6%) patient who received a covered SEMS. Neither tracheal compression nor perforation were not seen in any of the 62 patients in our study.

One minor complication that is not a life-threatening danger is chest pain, which is reported in many patients in the early follow up period after SEMS implantation; in previous reports in the literature extended chest pain was reported in 13% of cases. In previous reported series, stent migration was reported in up to 35% of patients receiving covered stents and up to 6% in those receiving uncovered stents. It has been reported that recurrent dysphagia rates seen due to tumor overgrowth/ingrowth in previous literature reports were anywhere between 5-50%. Additionally, it was reported that the tumor ingrowth rate was between 17-36% in uncovered stents and at a lower rate in covered stents; additionally, it was reported that tumor overgrowth rates reach up to 15% in covered stents (20-24).

Extended chest pain was experienced by 2 of 62 (6.4%) patients in our series. Stent migration was detected in 2 of 31 (6.4%) patients who received uncovered SEMS

and 5 of 31 (6.4%) patients implanted with covered SEMS. Tumor overgrowth-ingrowth was seen in 10 of 31 (32.2%) patients who received uncovered SEMS and 4 of 31 (12.9%) patients receiving covered SEMS.

When we consider major and minor complications as a group, stent patency duration in patients with major complications following SEMS implantation was found to be shorter than in patients with minor complications. However, no statistically meaningful relationship was detected between covered vs. uncovered SEMS type and major or minor complication type.

It has been reported in previous studies that the survival time was shorter for patients with complications in the early period until one week following operation. In various series it was reported that early period complications were more frequent in covered stents, while other publications reported a greater complication frequency in uncovered stents (25-27). In our study, survival times of patients having early period complications were found to be shorter than ones with late period complications. However, no statistically meaningful relationship was detected between early and late period complications after operation or in covered vs. uncovered stent types.

It was reported in previous studies in the literature that mortality rates related to malignant strictures in the esophagus 1/3 proximal and 1/3 middle section with SEMS were higher and survival times were shorter (28, 29). In our study, no statistically meaningful relationship was found between SEMS localization and survival, and between SEMS localization and stent patency duration.

Conflicting results were reported in previous studies in the literature regarding the effect of chemotherapy and radiotherapy on morbidity and mortality in the malignant esophageal stricture treatment (30-32). In our study, chemotherapy and radiotherapy treatment had no meaningful effect on survival.

Another factor affecting quality of life in patients is the need for secondary stent placement attempts, which varies in reported cases in the literature between 22% and 50% (33-35). In our study, the secondary stent placement rate was 25.8%. Also, no statistically meaningful difference in the need for secondary attempts was detected between covered and uncovered SEMS.

No statistically meaningful difference was found regarding survival periods or stent patency duration in patients receiving covered and uncovered stents in our study.

In our study, no statistically meaningful relationship was found between the gender of patients and stent patency duration, and between age of patients and stent patency duration. Also, no statistically meaningful relationship was found between tumor localization (esophageal, esophagus external, gastro-esophageal junction) and stent patency duration.

Only patients with esophageal obstructions due to malignant reasons were included in our study. Patients who received SEMS due to fistula, trauma or post-operative benign stenosis were not included. Also, it is not a randomized prospective research but a retrospective examination. These are limitations of our study.

In light of the findings of our study, we can say that SEMSs are simple, easy-to apply and offer a reliable method for the palliative treatment of patients suffering from malignant esophageal strictures. We can also say that it is an effective method in reducing dysphagia and increasing quality of life, and which have low fatal complication rates. Finally, in our study we see that that chemo-radiotherapy and whether a patient receives a covered or uncovered SEMS has no significant impact on mortality and morbidity.

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