Oesophageal self expanding metal stents
Preliminary report about covered and non-covered types

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Abstract

Objective : **The aim of this study was to evaluate the effectiveness and complications rate of covered and non-covered self expanding metal stents in the palliative treatment of oesophageal dysphagia.**

Design : **In this retrospective non-randomized study, we evaluated 11 non-covered and 17 covered stents of different types.**

Results : **Grade of dysphagia and improvement after treatment were similar in both groups, all the seven fistulas were sealed by covered stents.**

Covered stents seem to be safer regarding the rate of life-threatening complications and reinterventions.

In contrast to published studies, bleeding was our major complication with death related in half of these patients. Aorto-Oesophageal fistula was proved by autopsy in two of them.

Conclusions : **Covered stents lead to less drawbacks than non-covered ones and seem to be recommended in the palliation of oesophageal dysphagia even in the absence of fistula.** (Acta gastroenterol. belg., **2000**, 63, **331-335**).

Key words : oesophageal carcinoma, oesophageal fistula, oesophageal stent, oesophageal stricture.

Introduction

From their initial introduction in 1990, more than 800 Self-Expandable Metal Stents (SEMS) have been implanted in the oesophagus for palliation of malignant strictures or fistula (1,2). Owing to their easy and safe placement, they are now considered as the method of choice compared to conventional plastic endoprosthesis (3) or YAG laser therapy (4).

The first designed SEMS were non-covered, covered ones able to seal fistulas having been developed secondarily (5).

A few reports comparing different types of SEMS are available (6,7) most concerning non-covered Wallstents® and Ultraflex®.

We report here our retrospective data about 28 covered and non-covered SEMS, their efficiency and complication rate.

Patients and methods

Patients and lesions characteristics

Demographic data and lesions' characteristics are shown in Table I and II, respectively. We used the Dysphagia Score reported by Dorta *et al.* (6) : o = no dysphagia, 1 = dysphagia for certain solids, 2 = dysphagia for all solids, 3 = dysphagia also for semisolids, 4 = dysphagia for all solids and liquids. The median dysphagia score was 4 [3-4].

Malignant strictures included six oesophageal squamous carcinomas, twelve oesophageal adenocarcinomas, one mesothelioma, two mediastinal metastatic adenopathies (ovary and larynx) and four lung cancers. The three benign affections were two cicatricial strictures after laryngeal and gastric surgery and one tuberculous tracheo-oesophageal fistula.

The seven oesophago-respiratory fistulas occurred in oesophageal squamous cell carcinoma in two cases, non small cell lung carcinoma in two, oesophageal adenocarcinoma in one, epidermoid lung carcinoma in one and tuberculosis in one.

Stent material

Between May 1992 and June 1997, we have placed 28 oesophageal SEMS : 11 non-covered and 17 covered ones. Their own characteristics have been described elsewhere (8). The first available stents (AV shunt and Strecker Stent) were adapted from vascular stents ; some improvement was carried out, leading to the actual stents, but the main characteristics did not change.

We have implanted four non-covered Wallstents® (Schneider) including two 9F AV shunt® and two 11.5F Unistep®, seven non-covered nitinol stents (Boston Scientific) including four Strecker Stent® and three Ultraflex®, five covered Wallstents® (Schneider) including four 18.5F Telestep® (and one 22F Telestep®, eight covered Ultraflex® with distal release (Boston Scientific), three covered Gianturco-Rösch Z stents® (Wilson Cook) with one ring-shaped row of barbs and one covered Song Stent® (Sooho Medi Tech).

Stent implantation

All procedures were performed according to manufactories' recommendations (7). Savary bougienage was required in 12 patients (mean maximal diameter 12.8 mm) and balloon dilatation in 1 (inflated diameter 18 mm).

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Table I. — **Patient data**

	Total	**Non- covered : 11**		**Covered : 17**			
		Wallstent®	Ultraflex®	Wallstent®	Ultraflex®	Gianturco®	Song®
No of patients (n)	**28**	4	7	5	8	3	1
Sex M/F	**20/8**	2/2	7/0	4/1	6/2	1/2	0/1
Mean age ± SD(yr)	**67 ± 11**	70 ± 14	68 ± 7	62 ± 7	63 ± 12	80 ± 9	73
(extremes)	**(44-87)**	(57-85)	(58-77)	(52-70)	(44-74)	(70-87)	–
Median dysphagia score before stenting	**4**	4	3	4	4	4	4
(extremes)	**(2-4)**	**(3-4)**	(2-4)	(3-4)	(3-4)	–	–
Prior treatment							
CT	**2**			2			
RT	**2**	1				1	
CT + RT	**7**		1	1	5		
surgery	**1**					1	
Nd YAG laser	**6**	1	4			1	
bougienage	**12**	3	1	4	1	3	

CT = chemotherapy (5-FU, cisplatin), RT = external radiotherapy.

Table II. — **Lesion's characteristics**

	Total	**Non- covered**		**Covered**			
		Wallstent®	Ultraflex®	Wallstent®	Ultraflex®	Gianturco®	Song®
Malignant	**25**	4	7	4	7	2	1
oesophagus	18	2	7	3	4	1	1
lung or others	7	2		1	3	1	
Benign	**3**			1	1	1	
Mean length ± SD (cm)	**6.2 ± 2.3**	6.5 ± 2.1	7.4 ± 1.9	7.2 ± 2.6	4.4 ± 2.0	5.3 ± 1.2	8
(Range)	**(1.5-10)**	(4-9)	(5-10)	(3-10)	(1.5-7)	(4-6)	–
Location							
upper third	**3**			1	2		
middle third	**14**	2	2	3	4	2	1
lower third	**10**	2	5	1	1	1	
Oesojejunal anastomosis	**1**				1		
Fistula	**7**			2	4	1	

All stents were inserted under mild sedation (midazolam) and fluoroscopic control ; the site of insertion was determined by external paper clips for the first nine patients and by local submucosal injections of Lipiodol® for the others ; there were no endoscopic controls during stent's deployment.

After 24 or 48 h, we checked stents' patency by water soluble contrast or barium ingestion in 21 patients ; three patients underwent endoscopy within 2 days after placement.

Statistical analysis

Numerical variables are expressed as mean ± SD or by medians.

Dysphagia scores were compared before and after stenting by Wilcoxon signed rank test. As mentioned, our study was retrospective and non-randomized ; the choice of stent was influenced by the patient's characteristics (e.g. fistula) and by the coming of new devices. For all these reasons, we had to give up statistical comparison between types of stents, regarding dysphagia scores, complications and survival.

Results

Median follow-up was 54 days (10-889).

Dysphagia score and sealing of fistulas

The median dysphagia score was 1[extremes 0-1]after stenting, meaning statistically significant improvement of 3 points, ($p < 0.001$) ; there were no differences between stents.

All oesophago-respiratory fistulas were sealed by covered stents as showed by contrast ingestion in 5 cases, and by the disappearance of cough when swallowing in the 2 others.

Technical complications

The positioning was correct in all cases and we had no further migration. X Ray control performed at 24 or 48h revealed incomplete opening of three non-covered nitinol SEMS : wires of the upper part of two Strecker Stents® were protruding into the lumen of the oesophagus, which could be alleviated by balloon dilatation in one out of two cases ; incomplete opening of the

Table III. — **Late complications**

	Total	Non- covered		Covered			
		Wallstent®	Ultraflex®	Wallstent®	Ultraflex®	Gianturco®	Song®
Ingrowth	**4**	1	1	2			
Overgrowth	**2**			1	1		
Bleeding*	**10**	2	5	2	1		
Mediastinal Fistulas°	**2**	1				1	
Food impaction	**2**		1		1		

* including 2 Aorto-oesophageal fistulas proved by autopsy.
° mediastinal fistulas proved by oral contrast ingestion.

Table IV. — **Life-threatening complications and deaths related to stents**

	Total	Non- covered			Covered			
		Total	Wallstent®	Ultraflex®	Total	Wallstent®	Ultraflex®	Gianturco®	Song®
	28	**11**	4	7	**17**	5	8	3	1
Life-threatening complications	**11**	**7**	2	5	4	1	2	1	
– bleeding	**9**	**6**	1	5	**3**	1	2		
– perforation	**2**	**1**	1		**1**			1	
Stent-related deaths	**7**	**5**	2	3	**2**		1	1	
– bleeding	**5**	**4**	1	3	**1**		1		
– perforation	**2**	**1**	1		**1**			1	

medium part of a non-covered Ultraflex® occurred in a third patient with predominant extraluminal development of oesophageal adenocarcinoma, correct opening was obtained after balloon dilatation.

Early complications (within 7 days)

One patient with covered Walllstent® developed a mediastinal fistula proved by water soluble contrast ingestion on day 2.

In two patients with non-covered Wallstent®, we observed one food impaction on day 7 and one mucosal necrosis on day 3 concomitant to radiotherapy, both required endoscopic desobstruction.

Survival and late complications (after 7 days)

Median survival time was 1.7 month (95% confidence interval 1.2-2.3) and the 30-days mortality was 18% (5/28). It was equivalent for all the stents.

The late complications are listed in Table III. Eighteen of them occurred in 15 patients, three presented two complications : consecutive in two cases and simultaneous in one.

Among these complications, 11 were considered as life-threatening : 2 perforations and 9 bleedings, either acute and massive, either chronic and requiring more than 2 units of packed red blood cells transfusion.

We observed 5 deaths related to massive bleeding including 2 aorto-oesophageal fistulas proved by autopsy and 2 deaths related to oesophageal perforation.

Details of these cases are listed in Table IV.

Bleeding occurred in four cases of middle-third stent's implantation and in five cases of lower-third implantation. The 2 autopsy-proved aorto-oesophageal fistulas occurred in middle-third stenting. They were observed at the upper part of the stent through normal mucosa in one case, and in the middle part through post-radiotherapy fibrosis in the other.

Bleeding and life-threatening complications were less frequent with non-covered stents.

Post-stenting endoscopy and rate of reintervention

Endoscopic reinterventions were mandatory in 9/28 cases (32%). Covered stents showed a lower rate of reintervention than non-covered ones. Details are given in Table V.

Table V. — **Endoscopic reinterventions**

	Total	Non- covered	Covered
Reintervention rate/ n of stents	9/28	8/11	1/17
Indications for reintervention			
Incomplete deployment	3	3 (nitinol)	–
Ingrowth	2	2	–
Overgrowth	1	–	1
Food impaction	2	2	–
Mucosal necrosis	1	1	–

Role of radiotherapy

Nine of our patients underwent external radiotherapy (mean 40 Gy (30-60)) prior or concomitant to stenting. Among them, we noted one massive bleeding at day 147, one aorto-oesophageal fistula at day 33 and one obstructive mucosal necrosis during concomitant radiotherapy. These three patients died from stent-related complications, but the six other patients did not have life-threatening complications.

Discussion

In our retrospective, non randomized study, the choice of the stent was partially influenced by the characteristics of the oesophageal lesions (9) : we chose covered stents in presence of fistulas whatever the type of stents, and according to the flexibility and the smooth edges of the nitinol made stents, we preferred Ultraflex® in presence of sinuous lesion or in high upper third localisation. However, even if nitinol stents have a less expansion force than stainless steel ones, our choice was not influenced by the stiffness of the stenosis. We used mainly bare and covered Wallstents® or Ultraflex®, and also a few Gianturco-Rösch® and Song stents®.

Our median overall survival was1.7 month, similar to the results of Nelson *et al.* (57 days), but lower than in other European series (73-75 days) (5), probably because of too late stenting in the course of patient's disease. The 30-day mortality rate was 18% (5/28), slightly higher than in other published results (0-14%) (5).

There were a three points improvement in the Dysphagia Score after stenting ($p < 0.001$). All oesophago-respiratory fistulas were sealed by covered SEMS using 2 Wallstents®, 4 Ultraflex® and 1 Gianturco-Rösch®.

Incomplete deployment occurred only in non-covered nitinol stents (3 out of 7), due to their weak radial force compared to the stainless steel stents as noted by Dorta *et al.* (6).

One of the relevant results of this study is the high rate of life-threatening bleeding compared to published data. They occurred mainly in patients with non-covered stents.

Acunas *et al.* (10) did not mention any bleeding in 59 patients treated with non-covered nitinol stents. Ramirez *et al.* (2) reported immediate and delayed bleeding in 4.5% of 353 patients in compiled series ; in the same way, Siersema *et al.* (1) noted 3.7% of life-threatening hemorrhage in a survey of the literature including 804 patients. By contrast, in our experience there were globally 32% of patients with severe bleeding (9/28) and 5 deaths related, 3 of them directly caused by massive bleeding (1 non-covered Wallstent®, 1Strecker stent® and 1 covered Ultraflex®). Autopsy was performed in the first two patients and revealed aorto-oesophageal fistula through normal oesophageal wall in the first case and through post radiotherapy fibrosis in the other. As mentioned by Siersema *et al.* (1) the 3 acute massive bleedings, including the proved aorto-oesophageal fistulas occurred in mid-oesophagus stent's insertion where the aortic arch causes physiological compression.

Globally we observed 7/28 deaths (25%) clearly related to œsophageal stenting ; the same result was obtained by Bethge *et al.* (11) in 17 patients. Therapeutic reinterventions were necessary in 9 patients (32%). Four of them (14%) were required within 7 days owing to incomplete deployment of 3 non-covered nitinol stents, or stents' obstruction by food or severe mucosal necrosis secondary to radiotherapy . Five delayed reinterventions (18%) were performed after a median time of 99 days (range 30-110) for ingrowth in two patients, overgrowth in one and food impaction in one. The majority of these adverse events and reinterventions occurred with non-covered stents. Difficulties in stent's deployment occurred only with bare nitinol stents (2 Strecker stents® and 1 Ultraflex®), owing to their weak radial force and probably to their need to detorsion for opening. Dorta *et al.* (6)and Grund *et al.* (12) also noted this problem even in spite of balloon dilation immediately after stenting. We no longer faced this problem with the covered Ultraflex®.

Oesophageal injury, vasculitis and tumor necrosis induced by chemo- and/or radiotherapy may potentiate the pressure necrosis caused by metal stents, but it is not known if it really enhances the risk of bleeding and perforation. Kinsman *et al.* (13) found a statistically increased risk among 59 patients treated by Gianturco-Rösch Z stents®, the same results were obtained by Segalin *et al.* (9) and Bethge *et al.* (11).Vermeijden *et al.* (14) noted that 6/7 fistula formations occurred in patients previously treated by radiotherapy. However, other retrospective studies (3,5,15,16) failed to show any statistical difference.

In conclusion, metal stents are effective in palliation of dysphagia and sealing fistulas ; as observed in the more recent literature, even if not statistically assessable in our non-randomized study, covered stents seem to be safer than non-covered ones regarding the rate of life-threatening complications and reinterventions and the induced mortality. Among these complications, fatal bleeding, notably caused by aorto-oesophageal fistulas are more frequent in our experience than previously reported.

References

1. SIERSEMA P.D., TAN T.G., SUTORIUS F.F.J.M., DEES J., VAN BLANKENSTEIN M. Massive hemorrhage caused by a perforating Gianturco-Z stent resulting in an aortoesophageal fistula. *Endoscopy*, 1997, **29** : 416-20.
2. RAMIREZ F.C., DENNERT B., ZIERER S.T., SANOWSKI R.A. Esophageal self-expandable metallic stents — indications, practice, techniques and complications : results of a national survey. *Gastrointest. Endosc.*, 1997, **45** : 360-4.

3. KOZAREK R.A., BALL T.J., BRANDABUR J.J., PATTERSON D.J., LOW D., HILL L. *et al.* Expandable versus conventional esophageal prostheses : easier insertion may not preclude subsequent stent-related problems. *Gastrointest. Endosc.*, 1996, **43** : 204-8.
4. ELLUL J.P.M., WATKINSON A., KHAN R.J.K., ADAM A., MASON R.C. Self-expanding metal stents for the palliation of dysphagia due to inoperable oesophageal carcinoma. *Br. J. Surg.*, 1995, **82** : 1678-81.
5. NELSON D.B., AXELRAD A.M., FLEISCHER D.E., KOZAREK R.A., SILVIS S.E., FREEMAN M.L. *et al.* Silicone-covered Wallstent prototypes for palliation of malignant esophageal obstruction and digestive-respiratory fistulas. *Gastrointest. Endosc.*, 1997, **45** : 31-7.
6. DORTA G., BINEK J., BLUM A.L., BÜLHER H., FELLEY C.P., KOELZ H.R. *et al.* Comparison between esophageal Wallstent and Ultraflex stents in the treatment of malignant stenoses of the esophagus. *Endoscopy*, 1997, **29** : 149-54.
7. MAY A., HAHN E.G., ELL C. Self-expanding metal stents for palliation of malignant obstruction in the upper gastrointestinal tract. Comparative assessment of three stent types implemented in 96 implantations. *J. Clin. Gastroenterol.*, 1996, **22** : 261-6.
8. ELL C. , MAY A. Self-expanding metal stents for palliation of stenosing tumors of the oesophagus and cardia : a critical review. *Endoscopy*, 1997, **29** : 392-98.
9. SEGALIN A., BONAVINA L., CARAZZONE A., CERIANI C., PERACCHIA A. Improving results of esophageal stenting : a study on 160 consecutive unselected patients. *Endoscopy*, 1997, **29** : 701-9.
10. ACUNAS B., ROZANES I., AKPINAR S., TUNACI A., TUNACI M., ACUNAS G. Palliation of malignant esophageal strictures with self-expanding nitinol stents : drawbacks and complications. *Radiology*, 1996, **199** : 648-52.
11. BETHGE N., SOMMER A., VON KLEIST D., VAKIL N. A prospective trial of self-expanding metal stents in the palliation of malignant esophageal obstruction after failure of primary curative therapy. *Gastrointest. Endosc.*, 1996, **44** : 283-6.
12. GRUND K.E., STOREK D., BECKER H.D. Highly flexible self-expanding meshed metal stents for palliation of malignant esophagogastric obstruction. *Endoscopy*, 1995, **27** : 486-94.
13. KINSMAN K.J., DE GREGORIO B.T., KATON R.M., MORRISON K., SAXON R.R., KELLER F.S. *et al.* Prior radiation and chemotherapy increase the risk of life-threatening complications after insertion of metallic stents for esophagogastric malignancy. *Gastrointest. Endosc.*, 1996, **43** :196-203.
14. VERMEIJDEN J.R., BARTELSMAN J.F.W.M., FOCKENS P., MEIJER R.C.A., TYTGAT G.N.J. Self-expanding metal stents for palliation of esophagocardial malignancies. *Gastrointest. Endosc.*, 1995, **41** : 58-63.
15. RAIJMAN I., SINICROPE F., LEVERITT S., NARANJO K., AHMED M., GLOBER G. *et al.*. Does chemo-radiation therapy (ChXRT) increase the incidence of complications after self-expanding coated stents (cEES) in the management of malignant esophageal strictures ? *Gastrointest. Endosc.*, 1996, **43** : 343.
16. SCHEIDER D.M., HABER G.B., COHEN J., DORAIS J.A., ROSS C.F., KANDEL G. *et al.*. Covered-expandable esophageal stents (CES) : problems associated with new designs. *Gastrointest. Endosc.*, 1996, **43** : 345.