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Original article

Fluoroscopically guided insertion of self-expandable metal esophageal stents for palliative treatment of patients with malignant stenosis of esophagus and cardia: comparison of uncovered and covered stent types

Dj. Saranovic,[1] A. Djuric-Stefanovic,[1] A. Ivanovic,[1] D. Masulovic,[1] P. Pesko[2]

[1]*Institute for Radiology and* [2]*First Surgical Clinic, Institute for Diseases of the Digestive System, Clinical Center of Serbia, Beograd, Serbia and Montenegro*

SUMMARY. **The aim of this retrospective study was to present and compare the results of using two different types of esophageal self-expanding stents (uncovered and covered) for palliative treatment of patients with inoperable malignant stenosis of the esophagus and cardia. Over a period of 8 years, 152 patients underwent fluoroscopically guided insertion of metal esophageal stents. We inserted uncovered esophageal nitinol Strecker stents in 54 patients (group I) and covered esophageal Ultraflex stents in the remaining 98 patients (group II). The stent insertion procedure was successively performed in all patients. Closure of esophageal fistula by covered stents was achieved in 8/8 patients. Mean dysphagia score was significantly decreased in both patient groups at 4 weeks follow-up: from 2.73 before stent insertion to 0.15 in group I, and from 2.67 to 0.05 in group II (on 0–4 scale). Eighty-eight per cent of patients with covered stents and 54% with uncovered type were free of symptoms during follow-up. Complications occurring during follow-up and their comparative frequency in the two groups of patients were as follows (group I: group II%): stent migration (0 : 10%); tumor or granulation tissue ingrowth (100 : 53%); overgrowth at the ends of stents (17 : 30%); restenosis causing recurrent dysphagia (37 : 8%); and appearance of esophageal fistulas (8 : 6%). In conclusion, fluoroscopically guided insertion of self-expandable esophageal stents is a safe and comfortable method of palliation for patients suffering with malignant dysphagia. In selection of a stent, covered types should be given priority for prevention of restenosis.**

KEY WORDS: **esophagus, stenosis or obstruction, esophagus, neoplasms, esophagus, grafts and prostheses, stents and prostheses.**

INTRODUCTION

Malignant stenosis of the esophagus could be caused by tumor ingrowth by esophageal cancer or by extrinsic compression by metastatic neoplasm. The consequence of both processes is diminishing of esophageal lumen width, which leads to progressive dysphagia.

At the time of diagnosis, a high percentage of patients with esophageal cancer have an advanced stage of disease, when the tumor is not operable and only palliative treatment is applicable, primarily to manage dysphagia.[1–4] Chemoradiation protocols, palliative radiotherapy and palliative by-pass surgical interventions are methods that require a good general condition of the patient.[1,4] In patients with advanced disease and in poor general condition, which accounts for a large number of those affected by esophageal cancer, the aim of palliative therapy is to restore the esophageal lumen. Two basic therapeutic approaches for restoring the esophageal lumen are: insertion of endoprosthesis that will mechanically broaden the lumen at the site of stricture, and intraluminal tumor destruction under control of endoscopy. Various methods of intraluminal tumor destruction are available: laser ablation, photodynamic therapy, electro-coagulation, and chemical necrolysis.[1,4,5] Two basic types of esophageal prostheses are available: plastic tubes and self-expandable stents.[2,3,6]

Address correspondence to: Dr Aleksandra Djuric-Stefanovic, First Surgical Clinic – Department of Radiology, Institute for Diseases of Digestive System, Clinical Center of Serbia, Koste Todorovica 6, 11000 Beograd, Serbia and Montenegro.
Email: avstefan@eunet.yu

Self-expandable esophageal stents were introduced into clinical practice in 1990.[7] These are metal endoprostheses, constructed in such a way that they can be 'packed' by compression and extension into a system of flexible delivery catheters only a few millimeters in diameter.[7,8] This stent-system, owing to its small diameter and flexibility, can be passed through strictures of very narrow lumen. Upon deployment of the stent from the stent-system, it expands the lumen width to near regular lumen size.[8,9] The tubular shaped esophagus is easily accessible and a very suitable organ for simple and safe stent insertion. For this reason, and owing to good results in dysphagia management, the use of self-expandable metal stents is today widely accepted as one of the leading methods of palliative treatment of patients with malignant esophageal tumors.[10–12]

In the last 15 years of metal esophageal stent utilization, the basic design has been modified to prevent complications that have been reported in monitoring the patients treated by this method.[13–17]

PATIENTS AND METHODS

One hundred and fifty-two patients with inoperable malignant esophageal stenosis or stenosis of cardia were treated by fluoroscopically guided placement of self-expandable metal esophageal stents in the Department of Radiology in the Institute for Diseases of Digestive System (First Surgical Clinic), Clinical Center of Serbia, over an 8-year period (February 1996 to January 2004).

The patients were divided into two groups, according to the type of the stent inserted: group I consisted of 54 patients undergoing the placement of an uncovered stent (from February 1996 until April 1998), and group II consisted of 98 patients with the inserted covered stent (from May 1998 until January 2004).

We analyzed the following features of patients before the stent insertion: sex, age and severity of dysphagia; while the following characteristics of malignant stricture were considered prior to intervention: etiology of stricture, histological type of the growth, stricture length and minimal diameter. We illustrated the distribution of patients in relation to these characteristics, observed in each group individually, and in the total population, and this information is summarized in Table 1.

Grade 3 dysphagia was found in the majority of patients (63%), meaning they were able to swallow liquid only (Table 1).

Esophageal carcinoma was the most frequent cause of stricture in our patients (74%) (Table 1), and the middle third of the esophagus was the most frequent location of stricture (53%). Advanced bronchial carcinoma was the cause of all cases of extrinsic compression of esophagus and was present in 9% of patients (Table 1). In all patients with extrinsic compression of the esophagus, esophageal mucosa was intact before insertion of the stent, which was verified by endoscopy.

Squamous cell esophageal carcinoma was the more frequent histological finding (Table 1).

Eight patients in group II had fistula of the esophagus and underwent placement of a covered stent to close the fistula. Four of these patients had esophago-bronchial fistula and the remaining four had esophago-mediastinal fistula, localized in the thoracic segment of the esophagus.

We measured the length and minimal diameter of stricture prior to intervention by esophagography, performed with focus-film (Fo-Fi) distance of 115 cm. Mean length of stricture was 7.6 cm, and mean minimal diameter was 4 mm (Table 1).

The indication for insertion of a self-expandable stent was inoperability. These patients could not be operated on for the following reasons: unresectable

Table 1 Distribution of patients in relation to their sex, age, degree of dysphagia, etiology of stricture, histological type of tumor, stricture length and minimal diameter, before insertion of stent

	Total (n = 152)	Uncovered stent (n = 54)	Covered stent (n = 98)
Sex: (M : F)	135 : 17	52 : 2	83 : 15
Mean age (years)	64	61	65
Mean dysphagia score†	2.70	2.73	2.67
Etiology of stricture:			
Esophageal cancer	113 (74%)	45 (76%)	68 (72%)
Cancer of cardia	25 (16%)	3 (6%)	22 (22%)
Extrinsic esophageal compression	13 (9%)	5 (15%)	8 (5%)
Recurrence in esophago-jejuno anastomosis	1 (1%)	1 (1%)	0
Histological type of tumor:			
Squamous cell carcinoma	117 (77%)	43 (79%)	74 (76%)
Adenocarcinoma	22 (14%)	6 (12%)	16 (15%)
Bronchial carcinoma	13 (9%)	5 (9%)	8 (9%)
Mean length of stricture (cm)	7.1	7.7	6.7
Mean minimal diameter of stricture (mm)	4.3	3.5	4.7

†Dysphagia was ranked from 0 to 4 according to modified Atkinson's scale: Grade 0 – normal swallowing; Grade 1 – impaired, but possible swallowing of solid food; Grade 2 – swallowing of soft food and liquid; Grade 3 – swallowing of liquid only; Grade 4 – difficult or impossible swallowing of liquid and saliva.

tumor (102 patients), poor general condition (21) and distant metastases (29).

We employed two types of self-expandable esophageal stents: Nitinol esophageal Strecker stent (Boston Scientific Corp.) in 54 patients (group I) and covered esophageal Nitinol Ultraflex stent (Boston Scientific Corp.) in 98 patients (group II).

The Nitinol esophageal Strecker stent is made of thin (0.15 mm) elastic nitinol (alloy of nickel and titanium) wire, which is interwoven in a mesh cylinder. It is interwoven in such a way that the stent has a wrinkled surface. The diameter of a fully expanded stent is 18 mm in its mid-distal portion, with the most proximal 5 mm segment diameter of 20 mm. Available lengths of stents are: 7, 10 and 15 cm. This stent is not covered. The stent-system is 8 mm in diameter and consists of the internal Teflon catheter with lumen for guide-wire, having, at its front, the compressed stent immersed in water-soluble gel, overlain by a protective transparent Teflon catheter which covers the compressed stent. The internal catheter of the Strecker stent has two impressed radio opalescent markers which shows the ends of completely expanded stents. When the protective catheter is removed, the stent is 'released', and, upon contact with saliva at body temperature, dissolves the gel and is expanded within a few minutes which makes it possible to pull out the internal catheter.

The covered esophageal Nitinol Ultraflex stent is a new generation nitinol esophageal stent. It is made of interwoven nitinol fibers similar to the Strecker stent. Lumen diameter of a maximally expanded stent is 18 mm, with the most proximal 15 mm segment measuring 20 mm in diameter. The stent is partially covered by polyurethane lining on its external surface, leaving segments both proximal and distal uncovered to the length of 15 mm each. Stents are 10 cm (7 cm covered part) and 15 cm long (12 cm covered part). The Ultraflex stent-system is different from the nitinol Strecker stent-system in that the former has no external protective catheter filled with gel, but firmly interwoven silk threads covering the compressed stent. The end (either proximal or distal) of the interwoven thread is pulled through the catheter lumen to the opposite end of the catheter and tied to a plastic ring. During placement of the stent, this ring pulls the thread, which releases the stent. The stent is available with distal and proximal release. The internal catheter is the same as the esophageal Strecker stent-system, differing only in the position of markers. The internal catheter of the covered Ultraflex stent has four impressed radio opalescent markers: the internal pair shows the ends of the covered segment, while the external pair shows the ends of the completely expanded stent.

We inserted stents under control of fluoroscopy. After the ingestion of water-soluble contrast medium for visualization of malignant stenosis, the patients were administered two sublingual tablets of 2% xylocaine for local anesthesia of pharyngeal mucosa. Patients who did not tolerate the procedure using xylocaine were intravenously injected with 2–5 mg of midazolam during the intervention. We passed deflated balloon-catheters through the mouth across the stricture or to the proximal margin of stricture, and then advanced a guide-wire (Super Stiff Guidewire 0.35-inch or 0.38-inch, 260 cm long, with soft straight distal tip) through the stricture to the gastric lumen. Before we placed the stent, we performed balloon dilatation to 10–15 mm to allow ease of insertion of the stent-system through the strictured segment. The stent-system was positioned in such a way that the internal markers are found at the same distance from the stricture ends. The stent is released by pulling the protective sleeve (Strecker stent), or by pulling the ring to which the thread is tied (Ultraflex stent). After 1–2 minutes, the stent is suitably expanded to allow the internal catheter to be pulled out safely.

Immediately upon the completion of stent intervention, we performed esophagography with water-soluble contrast medium to evaluate the position of the stent, patency of the new lumen, and assess for perforation. If no extra luminal breakthrough of contrast medium was identified, we advised patients to consume liquids.

Control esophagography using barium contrast medium was performed 24 hours after intervention, to observe stent position, the degree of expansion in stricture segment and the rate of contrast medium passage through the lumen of the stent. If these parameters were satisfactory, the patients were advised to consume well-chopped food. If a stent passed through the cardia, with its lower part in the gastric lumen, the patients were administered antireflux therapy (Omeprazole 20 mg/day) to abate symptoms of gastroesophageal reflux.

We placed stents 5–8 cm longer than the stricture to prevent subsequent overgrowth. In five patients from group I and eight patients from group II, two stents were overlapped due to stricture length.

The patients were subsequently followed-up by monthly X-ray controls (esophagography), and in some cases by endoscopy.

In addition to descriptive methods including arithmetical mean, SD, maximum and minimum, the χ^2 test (contingency tables 2×2), Wilcoxon's paired test and Mann–Whitney test were used for statistical analysis.

RESULTS

There were no clinically significant complications during the insertion of stents. Some technical complications did occur including: distal partial migration of stents during release in six patients (2 Strecker stents, 4 Ultraflex stents) and wedging

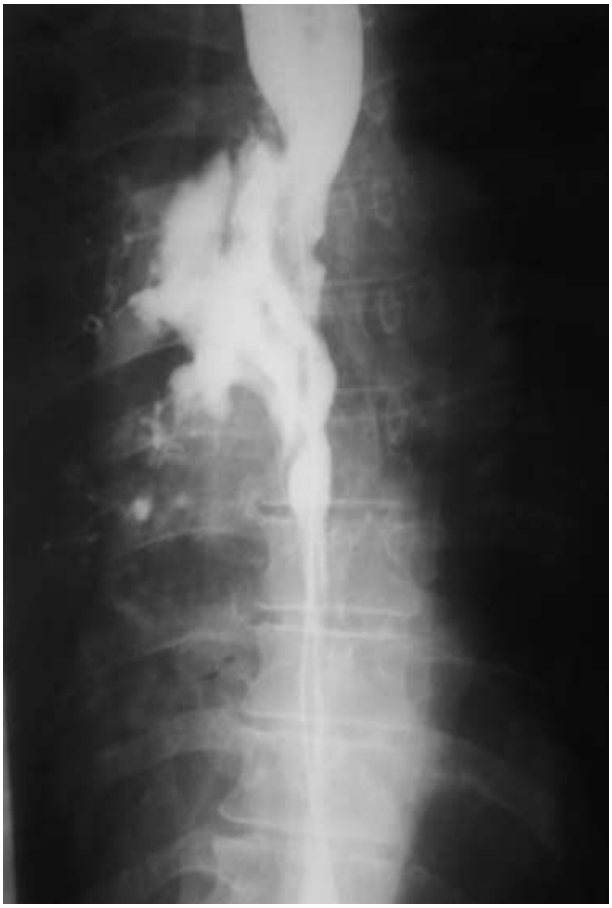

Fig. 1 Esophago-bronchial fistula in the middle esophageal segment, caused by cancer of the esophagus.

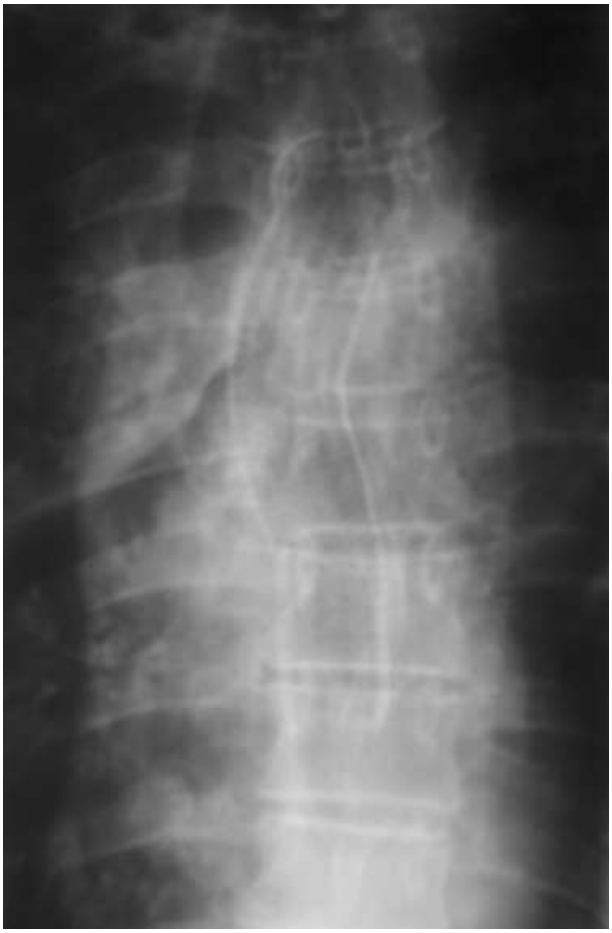

Fig. 2 Control radiography 1 day after insertion of the covered Ultraflex stent.

of the Strecker stent in one patient. As the protective sleeve was pulled too slowly, the distal end expanded, while the proximal part remained unexpanded and became wedged between the external and internal catheter. Upon withdrawal of the catheter with a semireleased stent, we placed the protective 'sleeve' back in the initial position and another insertion attempt was completed successfully. In cases of partial migration, stents were pulled up to the correct position by grasper forceps under control of endoscopy immediately after intervention.

All patients who had esophageal fistula documented by esophagography and endoscopy and had the covered stents implanted, manifested complete closure of their fistulas immediately after the stent insertion. This was documented by esophagography using water-soluble contrast medium, which was then verified by barium contrast examination 1 day after the intervention (Figs 1, 2 and 3). Immediately upon the control barium esophagography, they started with oral consumption of food, which was completely impossible before the intervention.

After insertion of the stent, the lumen of esophagus or cardia in the segment of stenosis widened significantly in every patient (Figs 4 and 5).

We compared the smallest diameter of stricture before and 1 day after insertion of the stent. The average smallest diameter of lumen was increased from 3.5 mm to 15 mm in group I patients ($Z = -5.101$, $P = 0.000$), and from 4.7 mm to 17.5 mm in group II ($Z = -6.640$, $P = 0.000$) which is a highly significant difference in both groups.

During the follow-up period we evaluated the patients with implanted stents on a monthly basis (first control was 1 month after the intervention). The condition of patients (anamnesis: presence and severity of dysphagia, body weight), and behavior of stents (barium study) were monitored. Out of 152 patients, eight died in the first month after intervention from sequelae of advanced malignant disease (five with uncovered and three with covered stents). A total of 131 patients were followed up; of these 41 patients had uncovered stents (group I), and 90 patients had covered stents (group II). Thirteen patients were lost for follow-up.

An average degree of dysphagia on first monthly control was 0.15 in group I and 0.05 in group II, compared with 2.73 in group I and 2.67 in group II before stent insertion ($Z_{\text{Group I}} = -5.187$, $P = 0.000$; $Z_{\text{Group II}} = -6.866$, $P = 0.000$;).

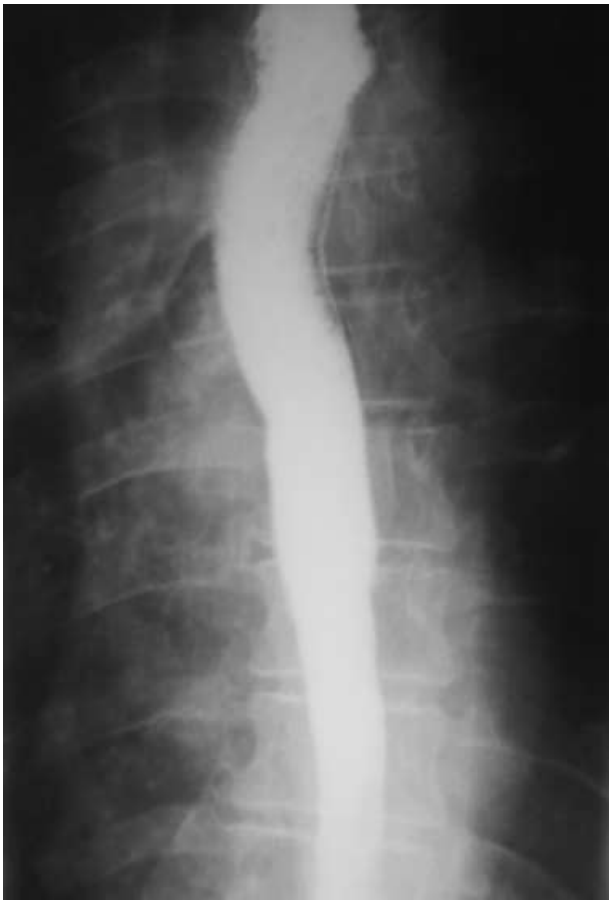

Fig. 3 Control esophagography of the same patient: absence of extra luminal penetration of contrast medium – complete closure of fistula.

Twenty-two of the 41 patients with uncovered stents (54%) and 79 of the 90 patients with covered stents (88%) had no dysphagia or other difficulties in the follow-up period ($\chi^2 = 14.908$, $P = 0.000$).

Complications that occurred during the follow-up of patients were as follows: migration of stent, ingrowth of tumor or granulation tissue in the stent lumen, overgrowth of the ends of stents, recurrent dysphagia due to restenosis, blocking of food in the lumen of the stent, and appearance of esophageal fistulas (Table 2).

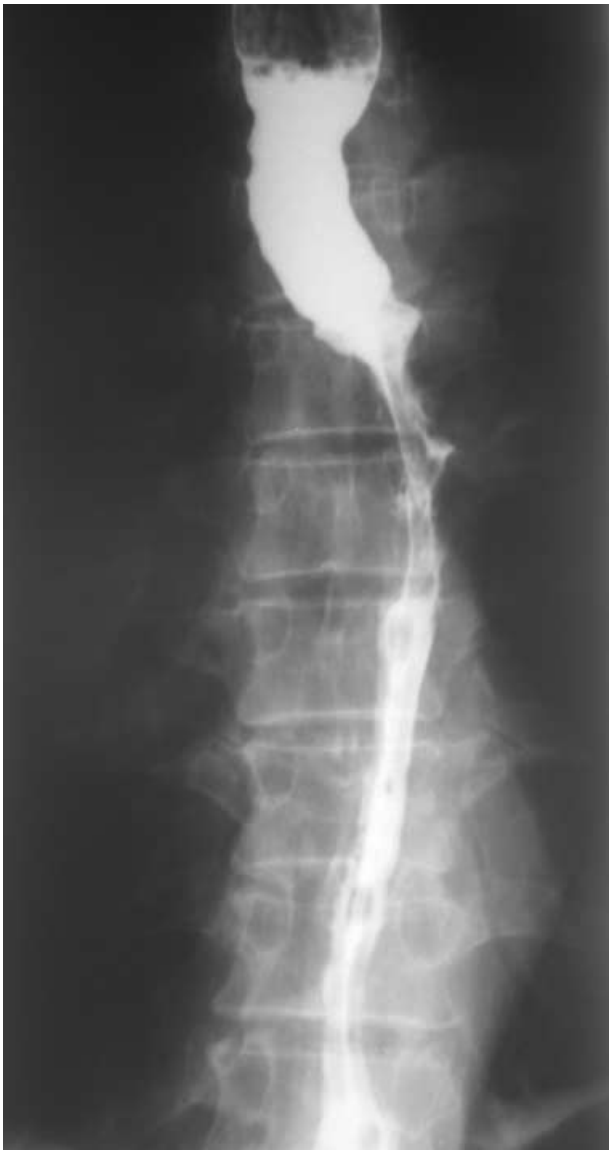

Fig. 4 Esophagography before insertion of stent: malignant stenosis of the middle part of the thoracic esophagus.

Late migration of the stent was diagnosed if the stent was out of position at the time of 4-week follow-up. Late migration occurred in nine patients (10%) with implanted Ultraflex covered stent, while

Table 2 Complications recorded in follow-up period

	Group I – Uncovered stent ($n = 41$)	Group II – Covered stent ($n = 90$)	Difference
Migration of stent	0/41 (0%)	9/90 (10%)	$\chi^2 = 4.402$ $P = 0.036$
Ingrowth	41/41 (100%)	48/90 (53%)	$\chi^2 = 28.163$ $P = 0.000$
Overgrowth	7/41 (17%)	27/90 (30%)	$\chi^2 = 2.449$ $P = 0.118$
Restenosis – recurrent dysphagia	15/41 (37%)	7/90 (8%)	$\chi^2 = 16.729$ $P = 0.000$
Blockage of stent lumen by food	2/41 (5%)	0/90 (0%)	$\chi^2 = 4.458$ $P = 0.035$
Esophageal fistula	4/41 (8%)	4/90 (6%)	$\chi^2 = 1.1386$ $P = 0.239$

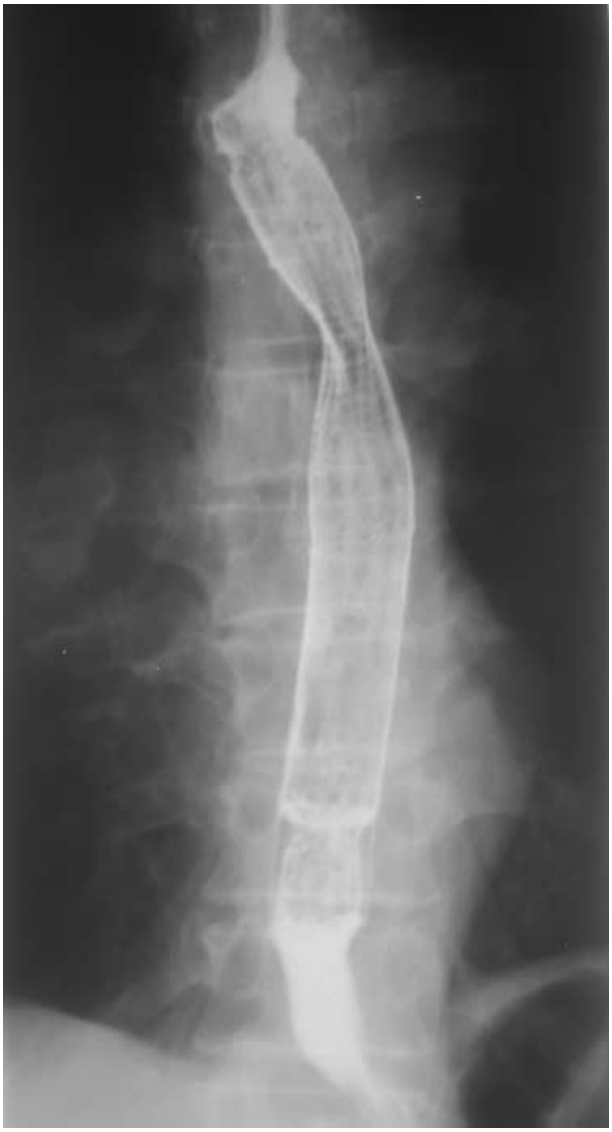

Fig. 5 Esophagography 1 day after placement of the covered esophageal Ultraflex stent: lumen of esophagus in segment of stenosis widened significantly: unobstructed contrast medium passage.

none of the uncovered Strecker stents migrated in the late follow-up period. Migration was identified in eight patients on the first monthly reassessment and in one patient 3 months following the insertion. In six of the nine patients, stents passed through the cardia with the distal end projecting into the gastric lumen. In all nine patients, the stent migrated partially and distally, meaning that the proximal part was left in the stricture segment. Four of the nine patients who had distal stent migration subsequently developed stenosis due to proximal overgrowth, while a fifth patient had proximal restenosis associated with esophago-mediastinal fistula. New covered Ultraflex stents were placed in these five patients.

Ingrowth of tumor or granulation tissue within the stent lumen was evident in all patients (100%) with uncovered stents during follow-up. Ingrowth was recorded in 53% of patients with covered stents, which is a highly significant difference in frequency of ingrowth between the two types of stents used (Table 2).

In patients with uncovered stents, ingrowth of tumor vegetations were visualized only in some parts of the stent in the early follow-up period, while subsequently the ingrowth expanded throughout the whole length of the stent.

Pattern of ingrowth in patients with partially covered Ultraflex stents was that tumor tissue grows into the uncovered segments – the ends of the stents (Fig. 6).

Ingrowth of granulation tissue within the stent lumen occurred in eight of the 13 patients with extrinsic compression of the esophagus (5 from group I and 3 from group II).

Overgrowth of stent borders by tumor tissue was seen in seven patients with uncovered stents and in 27 patients with covered stents (Table 2). Although a higher percentage of overgrowth was noted in patients having covered stents, no significant difference was found in relation to the type of stent (Table 2).

Twenty-two of the 131 patients (15 with the uncovered, and 7 with covered stents) had secondary stenosis resulting from ingrowth or overgrowth (restenosis) to such an extent that it caused recurring dysphagia (Table 2). Mean time from stent insertion to the manifestation of secondary dysphagia was 5 months in patients with uncovered stents, and 7 months in patients with covered types. We placed a new stent in patients with restenosis.

Food impaction within the stent lumen occurred in two patients with Strecker stents inserted in cardia. Deposits of food were cleared away under by endoscopy and patency was restored.

Esophageal fistula formation was a late complication, which developed in four patients with uncovered stents and four patients with covered types (Table 2). In patients with esophageal fistula, we placed the covered second stent (except in one patient from group I who underwent gastrostomy because at the time of appearance of the fistula we did not have covered stents available).

Within the period of observed follow-up, all patients in group I died, while 84 patients in group II died. Duration of follow-up was 1–11 months for group I and 1–15 months for group II. Mean survival time was 4.5 months for group I and 4.8 months for group II ($Z = -0.841$, $P = 0.401$).

DISCUSSION

The majority of studies have reported only technical complications in the insertion of self-expandable stents, as follows: difficulties during stent release; migration during positioning; and incomplete

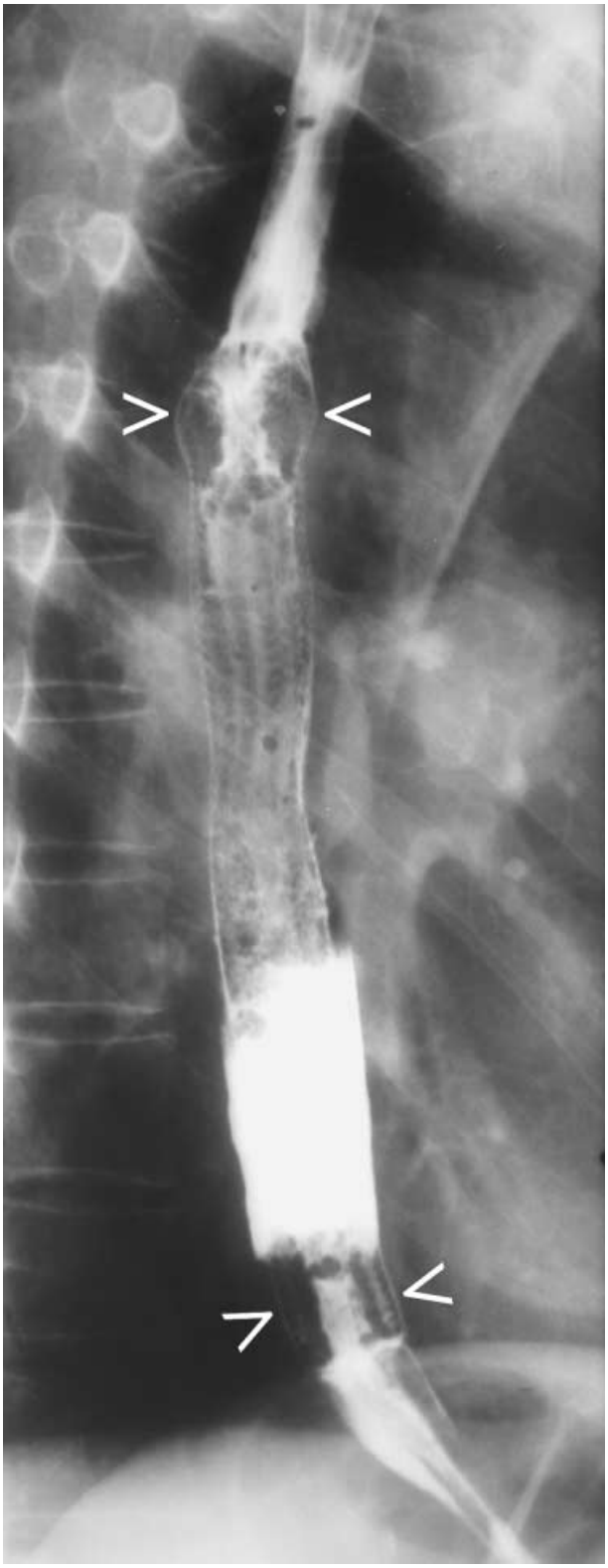

Fig. 6 Ingrowth in the partially covered stent: tissue grows into the uncovered segments – ends of stent – arrowheads (esophagography 4 months after stent placement).

expansion of stent immediately after insertion.[11,18–23] Life-threatening complications, such as esophageal perforation, occur very rarely during the insertions of self-expandable esophageal stents.[11,21,24–26] Small diameter and high pliability of the stent system allow safe passage through the very narrow strictures, without previous aggressive dilatation.[25] The feasibility of insertion of stents in patients with very narrow stricture segments represents, together with the absence of procedural morbidity and mortality, a major advantage of this technique over other palliative methods.

Comparison of the smallest diameter of stricture before and after stent insertion clearly shows large improvement in both groups of patients immediately after implantation of the stent, which is confirmed statistically. The Strecker stent has a smaller radial force than the Ultraflex stent. Thus, the average diameter of a Strecker stent immediately after insertion was 15 mm, or approximately 83% of its maximal diameter (18 mm).[21] This type of stent gradually expands to its maximal diameter approximately 7 days after placement.

Closure of an esophageal fistula by the covered stent is instantaneous and complete, and so far severe complications have not been identified.[24,27] In addition, patients with fistulas could not be managed by other palliative methods such as laser ablation of tumor or radiotherapy. Survival over 30 days is rare in these patients, unless they undergo an occluding procedure using a plastic endoprosthesis or covered stent.[21,27–31] Placement of covered esophageal stents is the method of choice for treatment of patients with esophageal fistula.

Enlargement of the esophageal lumen in segments of stenosis after stent implantation was associated with a corresponding lowering of the degree of dysphagia. Thus, in the majority of our patients, the degree of dysphagia, which was most commonly grade 3 before the procedure, dropped to 0–1 after the stent implantation, meaning that the patients were able to swallow soft, mushy and well-chopped food, which is in agreement with other studies.[11,21,32,33] There was no significant difference in improvement of swallowing in relation to the type of stent used.[11,20,21,34] Compared to other palliative methods, the fastest and most significant improvement in swallowing is achieved in patients undergoing implantation of esophageal self-expandable metal stents.[11,28,29,33,35]

Late migration of stents occurred only in group II patients with the covered Ultraflex stent, while none of the uncovered Strecker stents migrated (Table 2). According to the authors' opinion, higher propensity of covered Ultraflex stent towards migration is caused by the design of the stent, which is superficially covered by a smooth polyurethane lining. It prevents the stent being implanted longitudinally in the esophageal mucosa, since only 15 mm-long ends of the stent are not covered. The uncovered stent alternatively is completely implanted lengthwise in the mucosa by its relief surface, thus reducing the

possibility of its migration. Hyperplasia of epithelium covers the inner surface of the stent, thus embedding it in the esophageal wall.[20] Data from the literature are compatible with our results: a higher incidence of late migration of all types of covered stents compared to the uncovered types.[11,21,27,36–38] Studies have reported the incidence of late migration from 0% to 58% for different types of covered stents.[11,21,27,37] Although not so common, migration of uncovered stents is possible.[34] Studies have shown a higher incidence of migration if the stent passes through the cardia, which was confirmed in our series.[11,21,27] In an attempt to prevent the migration of covered stents, suggestions related to stent design refinement have been made.[16,17,39–42]

As the malignant tumor continues to grow after stent implantation, the growth of tumor tissue through the stent lumen and extension over the stent borders are two major late complications.[43–45] Ingrowth was evident in all patients with implanted uncovered stents and in half of patients with covered stents (Table 2). Authors who used the esophageal Strecker stents reported lower percentage of patients with ingrowth compared with our results: Adam *et al.*, 26%; Acunas *et al.*, 32%; Cwiekel *et al.*, 20%.[11,19,20] This difference between their and our results could be explained by the fact that they controlled their patients only if dysphagia recurred, and consequently, the ingrowth could not be noted unless it caused critical secondary stenosis of the esophagus.[11,20] Covered stents have been designed to prevent ingrowth. Except for rupture of the plastic stent cover, ingrowth is possible only in uncovered ends of the stent. Authors who used partially covered stents reported the incidence of growth in the uncovered ends of stents from 2% to 25%.[43–45]

Although we placed stents 5–8 cm longer than the stricture, the overgrowth of stent borders by tumor tissue occurred in both groups of patients (Table 2). Other authors' results are similar: the frequency of overgrowth ranges from 2% to 25% in different series.[11,20,46–48]

The esophageal fistula was another late complication, which developed in 6% of all patients, without any significant difference in relation to the type of stent (Table 2). Our results were compatible with other authors': the incidence of fistula after the insertion of different types of metal esophageal stents ranged from 0% to 10%, without significant difference among different types of the stents that were used.[11,19–21]

Although the ingrowth of tumor tissue in the stent lumen occurred in the majority of patients during follow-up, 17% of all patients had restenosis that caused recurring dysphagia. Significantly higher percentage of patients with uncovered stents suffered recurrent dysphagia in the follow-up period, compared with groups of patients with covered stents (Table 2).

We may conclude that the insertion of self-expandable esophageal stents is the technique appropriate for all patients with malignant stenosis of the esophagus and cardia. The procedure is safe and provides fast, complete and permanent management of dysphagia in the majority of patients, rendering it the method of first choice for palliation of dysphagia in patients with inoperable malignant stenosis of the esophagus and cardia. In selection of a stent, covered types should be given priority for prevention of restenosis.

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