

Ultraflex Stent Placement for Palliation of Esophageal Cancer

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Nine patients with malignant esophageal obstruction were treated with non-covered or covered Ultraflex stents. All patients achieved palliation, six of nine patients showed improvement of at least one dysphagia grade, and five patients could tolerate a normal or near-normal diet. Major (massive bleeding) and minor complications (ingrowth, overgrowth, stent migration, and bleeding) were encountered during follow-up in 2 and 4 patients, respectively. Ultraflex stents for esophageal cancer offer effective palliative treatment and quickly improve dysphagia. However, care should be exercised particularly of potentially serious life-threatening complications such as massive bleeding.

Key words: ultraflex stent, esophageal cancer, palliative therapy

Introduction

Most patients with carcinoma of the esophagus present with progressive, unrelenting dysphagia, malnutrition, and weight loss (1). Palliative therapy is the primary form of treatment, since these patients are not candidates for curative surgical resection (2). Laser surgery, radiotherapy and conventional plastic prostheses are well-established modes of treatment, and highly effective methods of palliation for the dysphagia that usually

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accompanies esophageal cancer (3-5). Laser therapy is not suitable for tumors causing extrinsic compression or long stenosis (6), while radiotherapy requires a long course extending at least for two months (7). Furthermore, the use of rigid plastic endoprotheses is plagued by high complication rates (8, 9).

Recently, self-expanding metal stents have provided a new option for the palliative treatment of malignant stenotic esophageal tumors (10-13). These stents have proved to be effective in reducing morbidity and mortality (10, 11). Several studies have examined the therapeutic benefits of various self-expanding metal esophageal stents for esophageal neoplasia, but few have compared different self-expanding metal stents (12, 13).

The aim of the present study was to evaluate the effectiveness and complications of non-covered and/or covered Ultraflex stents for palliation of dysphagia due obstructive esophageal cancer.

Patients and Methods

Patients

From January 1995 to December 1997, nine patients with malignant dysphagia due to esophageal carcinomas were treated with non-covered or covered Ultraflex stents (Boston Scientific Corporation, Watertown, MA, USA) after informed consent. The mean age was 65 years (range, 46 to 85 years) and patients included four men and five women. All nine patients had esophageal squamous carcinomas. The tumor was located in the upper, middle and lower esophagus in 1, 6, and 2

patients, respectively. Chemotherapy was performed in 3 patients, radiotherapy in 2 patients, and both in 1 patient (Table 1).

Table 1. Patient demographics

Cases	Age	Sex	Location	Prior treatment
1	60	M	Middle	Chemotherapy
2	62	M	Middle	Chemotherapy
3	70	M	Middle	Chemotherapy
4	72	F	Lower	None
5	46	M	Lower	None
6	56	F	Upper	Chemotherapy and radiation
7	74	F	Middle	Radiation
8	85	F	Lower	None
9	85	F	Lower	Radiation

Stents placement technique

After guidewire insertion (Jegwire; 0.035 inch; Boston Scientific Corporation) esophageal dilation was performed twice each for 2 min using 8-10 atm Endoscopy Dilators (diameter 8 mm, length 50 mm, Boston Scientific Corporation). The stent was then pushed out of the delivery catheter and delivered. Five non-covered and six covered Ultraflex stents were implanted in these patients. The body of the stent ranged in length from 10 to 15 cm (Fig. 1A and B). The stents were placed fluoroscopically under local anesthesia. Patients underwent a follow-up endoscopic examination immediately, 3 days, 1 week and 4 weeks later, and as needed thereafter.

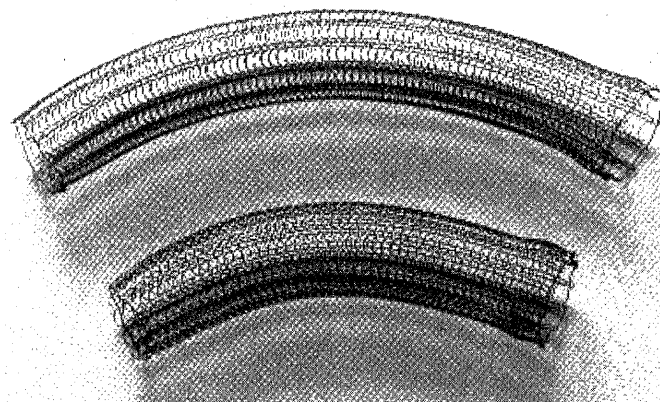
Severity of dysphagia and complications

The severity of dysphagia was quantified with a 0 to 4 dysphagia scale as follow: grade 0, normal, no dysphagia; grade 1, unable to swallow solid food; grade 2, unable to swallow semi-solids; grade 3, unable to swallow liquids; grade 4 unable to swallow own saliva. All nine patients had severe grade 3 or 4 dysphagia, and none were suitable candidates for operative surgery.

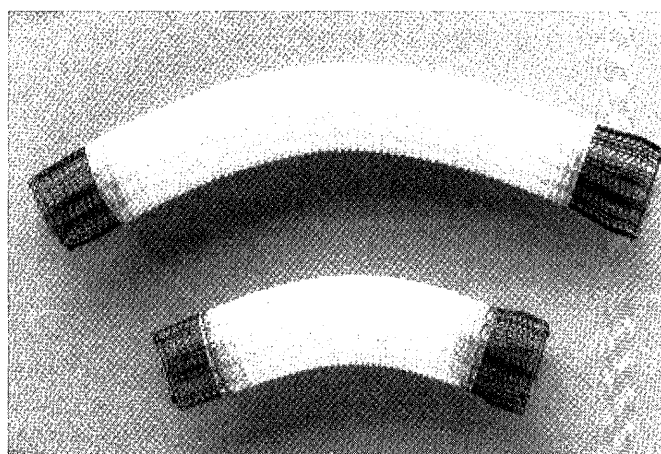
The major stent-related complications were defined as life-threatening complications, such as bleeding requiring blood transfusion, while minor complications were defined as non-life-threatening complications, such as tumor ingrowth, overgrowth, stent migration, and bleeding without requiring blood transfusion.

Results

Stent placement was successful in all nine patients, however two patients required a second stent because of migration, and tumor ingrowth or overgrowth. After one week of stenting, all five patients with non-covered stent and five of six patients with covered stent showed



A



B

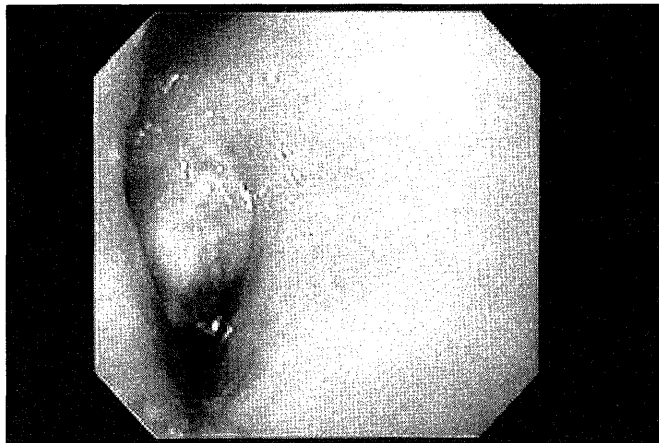
Fig 1. Ultraflex stents. A; non-covered type, B; covered type

improvement of at least one dysphagia grade. After one month, three patients with non-covered stent and three patients with covered stent became able to swallow a normal or near-normal diet. There was no difference in improvement of grades of dysphagia between non-covered and covered Ultraflex stents.

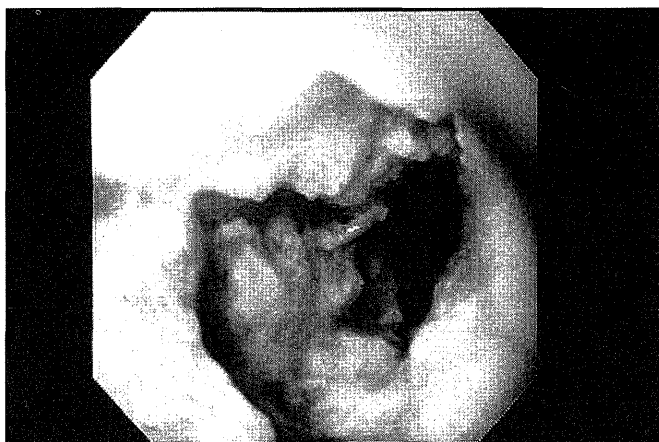
Five patients were discharged from the hospital after 2 to 4 weeks, however all nine patients died during the follow-up period; the mean survival after the procedure was 12 weeks (range 1 to 56 weeks). Severe complications, such as massive bleeding occurred in two patients who received non-covered and covered Ultraflex stents. Both (Case 3; non-covered and Case 9; covered) died due to massive esophageal bleeding, one and three months later, respectively. Three types of minor problems were encountered: ingrowth and overgrowth (1 patient; non-covered type), stent migration (1 patient; covered type), and bleeding (2 patients; non-covered type). One patient (Case 8) underwent an additional non-covered Ultraflex stent because of stent migration 10 days after stenting of the covered type. Another

patient (Case 2) had recurrent dysphagia due to tumor ingrowth and overgrowth, one after 2 months. In this patient, an additional overlapping covered Ultraflex stent was successfully placed.

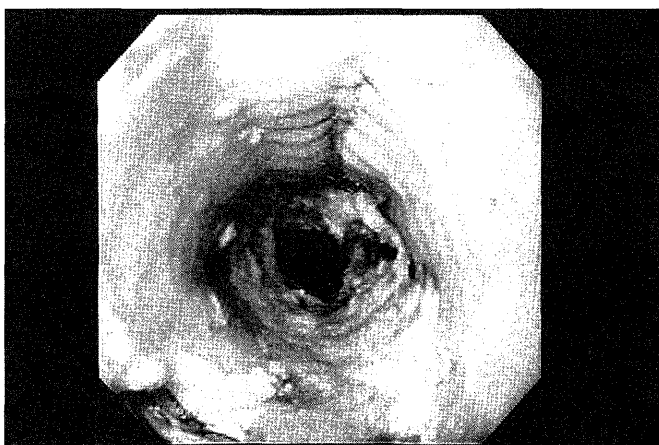
Fig. 2 represents a 70-year old man with squamous cell



A



B



C

Fig. 2. Endoscopic photographs. A; Nodular tumors with near-total obstruction. B; Proximal view of non-covered Ultraflex stent with massive fibrin exudate after 3 days of insertion. C; View of non-covered Ultraflex stent with full expansion after 7 days of application.

carcinoma of esophagus and thoracic aortic aneurysm (Case 3, Tables 1 and 2). Dysphagia was of grade 3. The patient was treated palliatively with Ultraflex stent. After stenting, the severity of dysphagia improved and the patient was able to swallow a semi-solid diet. Improvement was sustained for 1 month but he suddenly died because of a massive hematemesis probably due to rupture of an aortic aneurysm. Unfortunately, autopsy was not performed.

Discussion

A variety of esophageal endoprosthesis ranging from rigid plastic devices to the newer self-expandable metallic stents (e.g., Z-stent, Wall-stent, Ultraflex-stent) have been used (4, 8-33). Despite the good results, complications are common, and further therapeutic interventions are necessary in a considerable number of patients. Thus, the ideal stent is not yet available. Self-expanding metallic stents offer a number of advantages, including small delivery systems and large lumen diameter, less operative sedation, ease of insertion, immediate relief of obstruction, and long patency rates (14, 15). Despite these favorable results, there are still considerable number of complications including stent migration, tumor ingrowth and overgrowth, and bleeding. The rate of complications is reported at 31-49% in patients treated with Z-stent and/or Wall stent (16-18).

Recent reports have indicated the long-term effectiveness of Ultraflex stents and that these stents provide a safe method of palliative therapy for patients with obstructive esophageal neoplasms (12, 19). Ultraflex stents seem to offer a lower force of expansion (20), and Ell et al. (21) reported that the expansile force of Ultraflex stent is sufficient even for very firm strictures. However, in our experience, one of nine patients showed an insufficient degree of spontaneous expansion.

The most common cause of recurrent dysphagia is ingrowth or overgrowth of non-covered stents by the tumor tissue (22, 23). Knyrim et al. (24) indicated that non-covered stents are associated with fewer complications. Non-covered stents are associated with tumor ingrowth and overgrowth which may further reduce the size of the available lumen, and sometimes require a second stent (stent in stent) or laser therapy (15, 25). Covered metallic stents offer effective treatment for perforations and fistulas in patients with esophageal malignancies (26, 27), and might prevent tumor ingrowth allowing treatment of digestive-respiratory fistulas (28). However, preliminary studies indicate that migration of stent or disruption of the membrane by tumor ingrowth may occur even in these stents (29, 30). We presented

two cases of tumor overgrowth after stenting in patients with inoperable esophageal cancers that were managed by placement of a second stent. The frequency of distal migration of covered stents (5-25%) is relatively higher than that of non-covered stents (0-1%) (12, 21, 31-33). In our series, one case treated with covered stent later showed stent migration.

den Hartog et al. (34) and Kinsman et al. (35) reported that chemoradiotherapy increased the incidence of stent-related complications in the management of malignant esophageal strictures. However, Raijman et al. (5) reported that the same therapy was not associated with increased risk of life threatening complications. In our series, chemotherapy and/or irradiation before stent application were not associated with increased risk of complications (Table 2).

Issues related to the palliative therapy for esophageal cancer are complex. Whereas the tendency is to focus on technical aspects of therapy and the relief of dysphagia,

broader aspects related to quality of life cannot be ignored (23). In our departments, patients were actively encouraged to take optimal oral nutrition, before and after discharge from hospital. Prolonged cachexia reduces appetite and restoration of a normal diet may require more than simply the restoration of the esophageal lumen.

Further investigation in a large series of patients treated by stent insertion have to be performed before a general conclusion can be drawn regarding the clinical efficacy of Ultraflex stents for endoscopic palliation of esophageal carcinoma.

In summary, Ultraflex stents for esophageal cancer offer a quick improvement of dysphagia in patients with non-operable esophageal tumors. Tumor ingrowth and overgrowth are problems associated with noncovered stent. Covered stent are associated with markedly less tumor ingrowth and overgrowth, but stent migration of covered stent is inferior to that of non-covered stents.

Table 2. Results and complications of Ultraflex stent

Cases	Stent type	Dysphagia grade			Complications	Follow up
		Pre-stent	Post(1w)	Post(1mo)		
1	N	4	3	3	Bleeding	Died(2mo)
2	N	4	2	1	Ingrowth, Overgrowth	Died(13mo)
	C	3	1	1		
3	N	3	1	1	Massive bleeding	Died(1mo)
4	N	4	3	3	Bleeding	Died(4mo)
5	C	4	3		None	Died(3w)
6	C	4	4		None	Died(1w)
7	C	3	3	1	None	Died(9mo)
8	C	4	2		Stent migration	Died(5mo)
	N	2	1	1		
9	C	3	3	2	Massive bleeding	Died(4mo)

N : non-covered type, C : covered type

Acknowledgement

We gratefully acknowledge the skillful technical assistant of Mr. Kawazoe.

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