

## Is a Metallic Stent Useful for Non Resectable Esophageal Cancer?

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**A flexible nitinol stent was inserted to treat malignant stricture of the esophagus in 28 patients. Stenting was successful in all 28 patients, leading to an improved oral intake that was maintained for >80% of the survival period in 26 patients. Patients with tumors arising in the esophagus (n=24) were divided into two groups to compare complications and prognosis: patients who underwent stenting only (n=10); and patients who underwent stenting after radiochemotherapy (n=14). Fatal complications associated with stenting were seen in four patients (28.6%) who underwent stenting after radiochemotherapy and in one patient (10.0%) who underwent stenting only. Although survival was significantly longer for patients who underwent prior radiochemotherapy than for patients who did not, the incidence of fatal complications tended to be higher. No significant differences in background factors other than radiochemotherapy before stenting were observed between patients with fatal and non-fatal complications. Stenting was shown to represent a useful treatment for malignant stricture of the esophagus, as oral intake improved and was maintained for a long period of time in most patients. However, incidence of fatal complications was high among patients who underwent radiochemotherapy, and caution must be exercised due to the difficulty in predicting fatal complications. (Ann Thorac Cardiovasc Surg 2004; 10: 224–8)**

**Key words:** esophageal carcinoma, esophageal stent, metallic stent, radiochemotherapy

### Introduction

The esophageal stent has been recognized as effective for palliative treatment of advanced esophageal cancer associated with severe stricture or tracheoesophageal fistula.<sup>1-3</sup> Recently, insertion of a self-expanding mesh stent has been demonstrated as a safe and easily performed palliative procedure with a low rate of complications.<sup>4,5</sup> The increasing use of radiochemotherapy for esophageal cancer has led to an increase in the number cases in which stenting is performed after this therapy. Combined stenting

and radiotherapy is associated with improved survival,<sup>6</sup> although some authors have commented that prior radiotherapy is significantly associated with increased risk of complications after stenting.<sup>7</sup> The present study aimed to evaluate both the utility and complications associated with esophageal stenting for esophageal cancer, focusing particularly on cases in which stenting was performed after radiochemotherapy for esophageal cancer presenting with severe stricture or fistula formation.

### Patients and Methods

Between 1995 and 2001, a total of 28 patients (24 males, 4 females) with malignant stricture of the esophagus (n=26) or tracheoesophageal fistula (n=2) underwent stent insertion. Median age of subjects was 69 years (range, 42-85 years). In most cases, the primary tumor site was the esophagus, although tumors originated in the lung in

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Received September 22, 2003; accepted for publication April 29, 2004.

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**Table 1. Clinical characteristics of 28 patients**

Age (yrs)	68.2±10.6
Sex (M/F)	24/4
Tumor histology (no. of patients)	
Esophageal squamous cell carcinoma	22
Esophageal adenocarcinoma	2
Pulmonary adenocarcinoma	3
Metastatic mediastinal tumor	1
Location of tumor (no. of patients)	
Upper-third	11
Mid-third	12
Lower-third	5
Prior radiochemotherapy (no. of patients)	14
Tumor length (cm)	6.21±2.25

three patients and in the mediastinum in one patient. Tumors were located in the proximal third of the esophagus (n=11), middle third (n=12), or distal third (n=5). All tumors in these patients were considered inoperable at the time of stent insertion due to the extent of disease, advanced age, or poor clinical status. Before stent insertion, intravenous hyperalimentation was utilized in all patients, and no enteral feeding was performed in any of the patients.

A total of 14 patients had previously received combined radio- (total irradiation dose, 60 Gy) and chemotherapy (cisplatin and 5-FU), with stent insertion becoming necessary in these patients when dysphagia and tracheoesophageal fistula failed to improve. Clinical characteristics of patients and tumors are described in Table 1.

Flexible nitinol stents (Ultraflex™, Boston Scientific Corporate, Natick, MA, USA) were used in all patients. Details of this stent have been described elsewhere.<sup>8)</sup> All stents were inserted endoscopically under fluoroscopic guidance to monitor positioning and expansion of the stent after release. In cases in which the endoscope could not be advanced through the stricture, balloon dilation was performed prior to stent insertion. Endoscopic examination was repeated at three days after insertion to monitor position and patency of the stent. Oral intake of patients was restricted to water immediately after stent insertion, with a semi-soft or normal diet introduced two days after the procedure.

Dysphagia scores assigned to each patient were based on a standard scoring system (Table 2) and tumor staging was performed in accordance with the 5th edition of the UICC system. All patients were followed up until death, using endoscopic examinations initially carried out four weeks after stent insertion, and subsequently at two-month

**Table 2. Dysphagia score**

0 - Taking normal diet
1 - Unable to swallow certain solids
2 - Limited to a semi-soft diet
3 - Liquids only, but enough
4 - Unable to swallow adequate liquids

intervals. Patients were also asked about relief of dysphagia, presence of pain or any other stent-related symptoms. In addition, endoscopy was performed at any stage when dysphagia appeared during follow-up.

Statistical analyses were performed using the Mann-Whitney test or Fisher's exact test, with values of p<0.05 regarded as statistically significant. Overall survival was calculated according to the Kaplan-Meier method and the log-rank test was used to determine statistical differences.

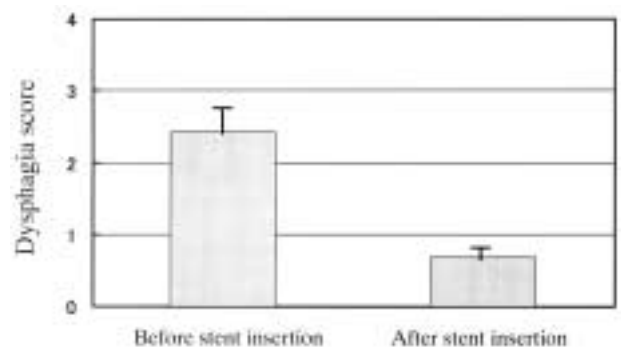
**Results**

**Improvement of dysphagia**

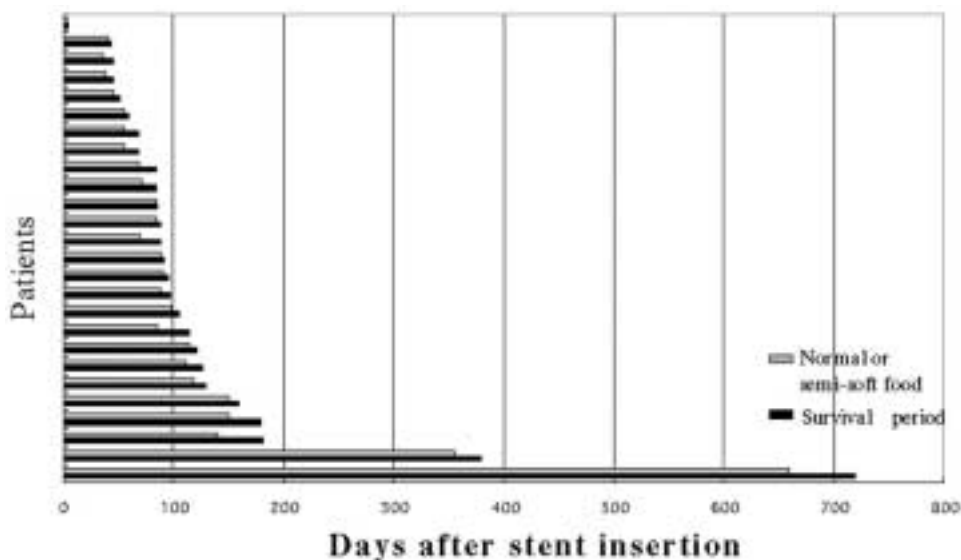
Insertion was successful in all patients. Dysphagia improved in 26 of the 28 patients (92.9%), with the median dysphagia score decreasing from 2.4 prior to insertion to 0.8 following insertion (p<0.01; Fig. 1). Most patients (n=20; 71.4%) were able to be discharged from hospital.

**Survival after stent insertion**

Mean survival of the 28 patients was 123 days after stent insertion (range, 3-720 days). Although most patients died as a result of primary disease, stent-related complications caused five deaths. Apart from two patients who could not eat, patients were able to consume normal or semi-



**Fig. 1.** Dysphagia scores before and after stent insertion. Results are expressed in mean values ± standard deviation. Dysphagia score decreasing from 2.4 prior to insertion to 0.8 following insertion (p<0.01).



**Fig. 2.** Survival and oral intake after stent insertion. All patients could take normal or semi-soft food over 80% of survival period.

soft food for >80% of the survival period (Fig. 2). During follow-up, repeat stenting was required in three cases for treatment of tumor overgrowth, which was diagnosed at 45, 68, and 134 days after initial insertion.

**Complications**

Stent-related complications were observed in 10 patients. Complications occurred during the early phase ( $\leq 7$  days) in five patients, and during the late phase (>2 months) in five patients. In five patients, complications proved fatal (esophageal perforation, penetration of the aorta, hemorrhage and tracheal stenosis; Table 3).

**Patient outcomes in relation to prior radiochemotherapy**

Outcomes of patients with respect to prior radiochemotherapy are described in Table 4. This analysis was confined to patients with primary esophageal cancer (n=24). Although patients who had received prior radiochemotherapy (n=14) were slightly younger, the subgroups showed no other differences in terms of gender, tumor size, or extension at primary staging. Patients who had received prior radiochemotherapy showed prolonged survival after stent insertion (Fig. 3). Of the five patients who experienced fatal complications, four had previously undergone radiochemotherapy. Fatal complications occurred in four of 14 patients (28.6%) who had undergone prior radiochemotherapy, and in one of 10 patients (10.0%) who had not received this treatment. Fatal complications thus tended to occur more frequently in patients with prior radiochemotherapy, although this difference did not achieve statistical significance. Of the 10 patients with complications, there were no marked differences in age,

biochemical findings and peripheral blood data between the five patients with fatal complications and the five patients with non-fatal complications (data are not shown).

**Discussion**

Palliation of dysphagia represents a major therapeutic challenge in patients with non-resectable esophageal tumor. Although placement of conventional, plastic esophageal stents is a well-known strategy,<sup>9</sup> recent reports have described various advantages for metallic stents over plastic stents.<sup>10,11</sup> In particular, the small diameter delivery system used in the placement of metallic stents has led to reduced stent-related complication rates compared with conventional stents.<sup>4,12,13</sup> The present study demonstrated a high rate of success in stent placement with improvement of dysphagic symptoms in 92.9% of patients. Moreover, symptom improvement was maintained for >80% of the survival period in all patients.

Half of the patients in this study had already received

**Table 3. Stent related complications**

Fatal complications (n=5)	
$\leq 7$ days	Tracheal stenosis (n=1) Esophageal perforation (n=2)
>2 months	Massive hemorrhage (n=1) Esophageal perforation (n=1)
Non-fatal complications (n=5)	
$\leq 7$ days	Stent migration (n=1) Aspiration pneumonia (n=1) Reflux esophagitis (n=1)
>2 months	Tracheal stenosis (n=2)

**Table 4. Outcome of patients treated with or without prior radiochemotherapy**

	Rc+	Rc-	p
Age (yrs)	65.9±10.7	72.5±11.2	N.S.
Sex (M/F)	11/3	9/1	N.S.
Tumor length (cm)	6.71±1.68	6.70±2.54	N.S.
Tumor staging (n)	II: 1	II: 1	N.S.
	III: 1	III: 0	
	IV: 12	IV: 9	
Median survival after stent insertion (days)	166	65	<0.01
Fatal complications (n)	4	1	N.S.

RC+, with prior radiochemotherapy; RC-, without prior radiochemotherapy; N.S., not significant.

previous radiochemotherapy, a therapy that usually involves delayed onset of symptom palliation. However, stenting had become necessary in these patients because dysphagia or tracheoesophageal fistula had failed to respond to radiochemotherapy after an appropriate period of time.

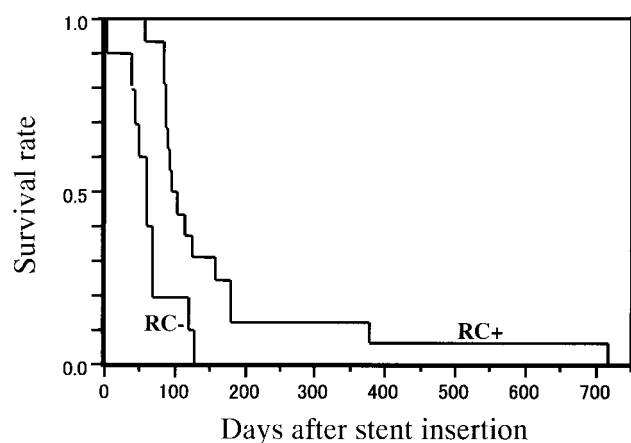
Fatal complications occurred in five patients, four of whom had undergone radiochemotherapy. Only one fatal complication was observed in a patient who had not received radiochemotherapy. Although survival was significantly longer for patients in the present study who underwent stenting after radiochemotherapy compared to patients who underwent stenting only, incidence of fatal complications was high (28.6%) in patients with prior radiochemotherapy. No marked differences in background factors were noted between patients with fatal and non-fatal complications. In other words, at this point of time, predicting fatal complications is difficult before stent in-

sertion. As the incidence of fatal complications was high among patients who underwent radiochemotherapy, stenting should not necessarily be performed in patients with esophageal stricture. Stenting should only be performed in consenting patients who have received sufficient explanation about the risks involved. Otherwise, treatments such as esophageal bypass or intestinal fistulation should be considered.

Regarding nutrition before stenting, intravenous hyperalimentation was utilized for all patients. This needs to be changed: enteral nutrition should be selected for long-term nutritional management. Re-evaluation of the results with enteral nutrition is necessary.

Optimal timing of stent insertion has not been discussed. Among the patients who underwent radiochemotherapy, stenting was performed after radiochemotherapy in all cases. When stenting is done before radiochemotherapy, assessing therapeutic effects becomes difficult, and numerous problems could be expected if surgery were to be performed later. Since no reports have documented that stenting before radiochemotherapy lowers the incidence of complications, we believe that stenting should be performed after radiochemotherapy.

In conclusion, stenting for the treatment of malignant esophageal stricture represents a useful treatment for improving and maintaining oral intake over a long period of time. However, among patients who have undergone radiochemotherapy, incidence of fatal complications is high, and because predicting fatal complications is difficult, caution must be exercised.



**Fig. 3.** Survival curves after stent insertion. RC, prior radiochemotherapy. There is a significant difference in survival rate between the patients with RC and those without RC ( $p < 0.01$ ).

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