Successful endoscopical sealing of malignant esophageotracheal fistulae by using a covered self-expandable stenting system

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Abstract

Objective: Any treatment of tracheo–esophageal fistulae in end-stage malignant stenosis of the esophagus must be weighed against associated morbidity and mortality. In a prospective study we investigated benefits and risks of the use of one type of coated, self-expandable stent.

Patients and methods: We treated four male and two female patients, (mean age 68.3 years, range: 38–90 years), with malignant esophago–tracheal fistula non-resectable due to advanced tumour stage and/or functional reasons. All were in a poor general condition suffering from aspiration pneumonia and malnutrition. Four out of the six patients had had one or multiple extra- or endoluminal palliative treatments at a mean interval of 191 days (range: 7 days–15 ms) since the last intervention. The fistulae were sealed by using a covered, self-expandable stent (ULTRAFLEX esophageal stent system, Microinvasive, Boston Scientific Corporation, Boston, MA).

Results: Stenting did not cause any technical problems and all fistulae were successfully sealed in a one-step procedure. The median hospital stay was 4.6 days (range: 3–9 days). Except for one late stent induced recurrent fistula treated by re-stenting and tracheostomy, we did not observe any stent associated complications. Five patients died of tumour generalization. The median survival of the patients who died was 78 days (range: 35–129 days). One patient is alive and well at 120 days after stenting.

Conclusion: In spite of the small number of patients the results suggest that this type of stent represents a safe and efficient approach for palliative endoscopic treatment of this high risk group. Local pretreatment does not preclude the successful use of the self-expandable coated stent. © 2001 Elsevier Science B.V. All rights reserved.

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1. Introduction

Esophageotracheal fistulae (Fig. 1) are relatively uncommon in malignant diseases of the esophagus, occurring in about only 5–15% of patients with esophageal cancer or other mediastinal malignancies [1,2]. Nevertheless, the clinical implications for these patients are dramatic due to recurrent aspiration with subsequent, eventually lethal infections.

Any type of endoluminal palliation of dysphagia due to malignant tumour stenosis may increase the incidence of esophago–respiratory fistulae: Laser desobliteration [3], local hyperthermia [4], endoluminal high-dose afterloading [5,6] and photodynamic therapy [7] are as well effective as commonly used methods for recanalisation. Therapeutically induced necroses of the esophageal wall at the tumour bearing site may promote the formation of a transmural leakage. In this context it has been reported, that stenting, if used as a secondary line treatment after endoluminal tumor debulking and recanalisation, carries a higher risk for stent-induced esophageal rupture than stenting without local pretreatment [8].

Once an esophageotracheal fistula has developed, the general condition of the patient declines rapidly due to aspiration pneumonia and malnutrition. As tumour stage is generally advanced and life expectancy is short, the major interest of any therapeutic procedure in these cases must be a rapid and successful palliation, reducing the duration of in-hospital stay at low cost and a low rate of therapy-induced complications.

The significant morbidity and mortality of formerly used cuffed plastic stents [9] and the inherent difficulties with the insertion of rigid stents has been overcome by the new coated expandable stents [10–12].

In this prospective study we evaluated the use of one type of a self-expandable coated stent (covered ULTRAFLEX...
esophageal stent system, Microinvasive, Boston Scientific Corporation, Boston, MA) regarding efficiency, complications and quality of life in six patients suffering from advanced, non-resectable stenosis of the esophagus and symptomatic esophageotracheal fistula. Furthermore we investigated the implications of local pretreatment in the context of stenting for tracheoesophageal fistulae.

2. Patients and methods

2.1. Patients

From November 1996 to July 2000 we treated four men and two women (mean age 68.3 years, range from 38 to 90 years), suffering from malignant stenosis of the esophagus non-resectable due to either advanced tumour stage and/or functional reasons, who had developed symptomatic esophageotracheal fistula. Histologically, four squamous-cell carcinomas of the esophagus, one adenocarcinoma of the esophagogastric junction and one metastasis of renal cell carcinoma to the esophagus and to paraesophageal lymph nodes were documented.

Five fistulae were localized in the proximal and one in the middle third of the esophagus, extending to the cardia. In this case of involvement of the gastro–esophageal junction the fistula was located in the left main bronchus.

In all cases the tumour showed a circumferential involvement of the esophageal wall. The mean length of the stenosis was 6.7 cm (range: 1–15 cm). The length of the esophago–respiratory fistula ranged from 0.5 to 2.0 cm (mean: 1.2 cm).

Four out of the six patients had had one or multiple palliative treatments for the tumour stenosis. The mean interval between the last endo- or extraluminal treatment to the development of the fistula was 191 days (range: 7 days–15 months). No fistula appeared during the hospital stay. Four patients had undergone photodynamic therapy (PDT) by using a hematoporphyrin derivative (Photosan-3, Seehof Laboratory, Wesselburenkoog, Germany) as photosensitizer preceding endoluminal high-dose brachytherapy (fraction dose: 5 Gy, total dose: 15 Gy) In one patient this regimen had been followed by external beam radiation (total dose: 60 Gy).

All patients suffered from aspiration pneumonia and attacks of coughing, presenting with a reduced general condition (mean Karnofsky index: 63.5). The dysphagia score was 3.2 corresponding to severe dysphagia with intermittent inability to swallow their saliva in four of them. The mean time between development of symptoms and diagnosis/treatment was 4.2 days (from 1 to 11 days).

The diagnostic work-up comprised flexible tracheo-broncho- and esophagogastroscopy as well as fluoroscopy, using water soluble contrast medium and the patients were supported by standardized, high caloric parenteral nutrition.

2.2. Stenting

The intervention was done under short-time anesthesia. In case of tumour stenosis (2/6) dilatation to a lumen of 12.5 mm by using Savary Bougies preceded the stenting procedure. The oral and aboral margins of the tumour and/or the fistula were identified and marked by hypodermic needles on the surface of the thorax/neck with the help of simultaneous endoscopic and fluoroscopic control. After insertion of a guidewire the endoscope was removed.

The length of the stent was chosen in a way ensuring that the total length of the tumour and the fistula were well within the covered segment of the stent, the latter overlapping the preset margins by at least 2 cm.

The covered Ultraflex system delivery catheter was passed over the guide wire and the stent was positioned in a way ensuring the abovementioned overlap of the marker needles and the two radiopaque markers indicating the length of the stent. Once in position, the stent was deployed, beginning at its distal end.

Correct positioning and the sealing of the fistula were confirmed by tracheo–broncho and esophagoscopy inspection and by endoscopic instillation of water soluble contrast medium under fluoroscopic control.

One day after stent implantation both the position and functional result were controlled by a swallow of contrast medium before reestablishing an enteral nutrition protocol. All patients had broad-spectrum antibiotic treatment as well a physiotherapy.
3. Results

3.1. Stent insertion procedure and quality of sealing

No technical problems were met during stent insertion. The immediate endo- and fluoroscopic control as well as the esophagogram on day one showed complete sealing of the fistula and no sign of stent dislocation. Because of distinct extrinsic tumour compression the stent did not satisfactorily expand in one case. A single pneumatic dilatation was done on day one, ensuring full stent deployment as documented by another esophagogram.

3.2. Dysphagia, fistula associated symptoms and quality of life

Within 2 days after implantation the swallowing function was satisfactory in all cases. The pretreatment dysphagia score (mean 3.2) was significantly reduced (mean 1.1, \( P < 0.001 \)). Stent related chest pain was observed in all patients. The pain was characterized as severe by one, moderate by two and mild by three patients but easily controlled by NSAR. Gastroesophageal reflux was present in the one patient who had a tumour in the middle third extending to the cardia and with the aboral end of the stent protruding into the stomach. Heartburn was controlled by proton-pump inhibitors. Nocturnal regurgitation was prevented by avoiding late meals and by sleeping with the thorax slightly elevated.

Within 2 weeks after the implantation of the stent, the performance status improved significantly (pretreatment Karnofsky index mean 65.3 versus 71.3, after stenting \( P < 0.001 \)). Fistula induced symptoms, as severe coughing and aspiration pneumonia subsided within one day and within at least 1 week, respectively.

The mean hospital stay was 4.6 days (range: 3–9 days). With the exception of one patient who developed a major complication no further hospitalization was required up to this time or until death.

3.3. Major complications

Sixty days after successful sealing of a fistula in the middle of the trachea, one patient was re-admitted for recurrent symptoms. The endoscopical and fluoroscopic reevaluation showed a stent induced fistula caused by penetration of the upper edge of the stent into both esophagus and trachea (Figs. 2 and 3). Telescopic proximal re-stenting was done, but the extrinsic pressure of the stent caused subtotal tracheal stenosis requiring median tracheostomy. The patient died 43 days later of metastatic disease, without any evidence of aspiration.

3.4. Minor complications

Forty-one days after successful sealing of the fistula, a patient noticed progressive dysphagia caused by tumour regrowth at the distal end of the stent. Endoscopical recanalisation was performed by endoluminal photodynamic therapy. Endoscopy 4 weeks later showed a complete desobliteration of the tumor stenosis without any clinical sign of dysphagia. Another patient who had ignored the diet prescriptions presented with aphagia due to food impaction in the stent. Endoscopical removal of the obstacle was done.

3.5. Survival

Five out of the patients died of tumour generalisation. The median survival of the patients who died was 78 days (range: 35–129 days). One patient is still alive and well at 120 days.

4. Discussion

Treatment of esophageotracheal fistula in advanced malignant disease of the esophagus still represents a chal-
lence for any physician. The associated symptoms, such as heavy coughing, aspiration pneumonia, dysphagia and malnutrition are very compromising for these patients the performance status of whom declines rapidly.

Successful sealing of the fistula ensuring an acceptable quality of life must be the goal of any treatment for these patients. Because of the short life expectancy palliation must be done quickly, efficiently and at low morbidity and mortality rates.

Due to the advanced tumour stages in these patients routine surgical procedures, like muscle flap repair or palliative resection are reserved to a minority of selected cases.[13].

During the last 10 years different stent types have been developed and modified according to the requirements in clinical practice. The formerly used semirigid push-through tubes [9, 14] carried a high risk of perforation, as their positioning required a dilatation of the esophageal lumen up to 18 mm while the buttresses on the outside caused a rough passage trough the stenosis.

The newly developed coated and self expandable stenting systems [10–12, 15, 16] are less dangerous, as a lumen of no more than 12 mm is required to enable the insertion of the folded stent. Thus the otherwise risky, extensive presenting dilatation can be reduced to a minimum and a possible enlarging of a preexisting fistula can be prevented [17].

In this study using the covered Ultraflex stent, no technical problem was observed during positioning, as there is no shortening of the stent in relation to the radiopaque markers after deployment. A further advantage is the rapid expansion to the full diameter, enabling all patients to ingest well chewed food on day two after the intervention. Postinterventional secondary dilatation of the stent was only necessary in one case with exceptionally rigid extrinsic stenosis. The rapid expansion also caused both an immediate and complete sealing of the leakage and a tight fixation to the esophageal wall without any tendency for dislocation [11, 12].

In spite of explicit advantages, the use of this stent can also be associated with side effects, significant morbidity and even mortality [10–12, 15, 16]. In spite of the necessity for dilatation in 2/6 cases and in spite of the fact that four patients had had local pretreatment with possible weakening of the esophageal wall we did not observe any case of perforation. Tumour regrowth at one or both ends of a coated stent has been described and was equally found in one of our patients. Desobliteration or telescopic re-stenting, however, is never a problem in such cases [18, 19].

As in other types of stents, patients complained about slight to severe pain at the site of stenting. In the absence of signs of perforation postinterventional retrosternal pain is easily treated by analgetics. Reflux occurred in case of distal stent, but it was efficiently controlled by conservative measures.

In one patient who ignored diet prescriptions, food impaction caused complete obliteration of the stent requiring endoscopic desobliteration on an outpatient basis.

Only in one patient we observed the serious complication of a stent-induced fistula occurring two months after implantation. Though the leakage could be sealed by proximal telescopic re-stenting, another problem evolved: the pressure of the proximal stent caused significant narrowing of the tracheal lumen which could only be treated by tracheostomy, as the patient would have been too weak to expectorate sufficiently if a tracheal stent would have been inserted.

The four patients who had had local palliative treatment of their esophageal malignancies did not worse than those after stent implantation than those who had stenting as the first and only measure. This might be due to the relatively long time interval between the last local treatment and the formation of the fistula.

Considering the severity of the condition the mean hospital stay was very short. With one exception all further interventions could be done on an outpatient basis, thus the relatively high costs of this stent type (1210 euro in Austria) is justified. The patients retained their ability to swallow until death or throughout the whole observation period, respectively.

5. Conclusion

Tracheo–esophageal fistula in advanced, malignant stenosis of the esophagus represents a fatal complication, associated with a rapidly decreasing performance status of the patient.

Stenting by using a self-expandable, covered device is a safe and easily applicable technique for successful sealing of these fistulae, ensuring a good quality of the remaining span of life. Due to the low rate of complications and the quick relief from symptoms a marked reduction of the duration of in-hospital stay is achieved. Palliative local pretreatment of the esophagus does not negatively effect the application of a covered expandable stent in case of a fistula provided the leakage does not occur immediately after the intervention.

References


