

I. Introduction

Implantation of a self-expanding nitinol stent in a case of stenosing squamous cell carcinoma of the middle esophagus uT3N+M1 UICC stage IV.

Rechannelling stenoses is an essential part of treatment of inoperable esophageal and cardiac carcinoma. Implantation of endoprotheses has long been the realm of endoscopy. While rigid silicon tubes were once customary in this procedure, self-expanding metallic stents (SEMS) are almost exclusively used today. The correct stent must be selected from a range of stent lengths and diameters (shaft and bulb), coatings (fully and partly coated, uncoated) and release types (distal vs. proximal release). This case study describes implantation of a CibuFlex ePTFE-coated nitinol esophageal stent with stent length of 150 mm (length of coating 120 mm), stent diameter of 26/20/26 mm and distal release.

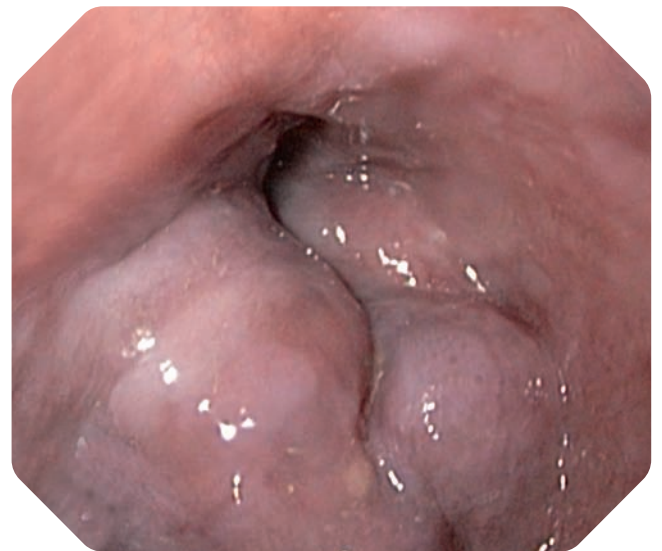
2. Case study

A 73-year-old male patient reported unintentional weight loss of 10 kg and progredient dysphagia for the previous 2 months. An ambulant esophago-gastro-duodenoscopy showed a stenosing esophageal carcinoma which was just passable with a standard gastroscope. No solid organ metastases were seen in a CT scan performed at another institution. However, a large lymph node conglomerate was detected adjacent to the tumor.

The patient was hospitalized for the completion of the diagnostic workup and treatment. In a repeated gastroscopy the esophageal tumor showed stenosing growth from 24 to 34 cm. An external histology had already confirmed SSC. A bronchoscopy was performed to exclude an esophago-tracheal fistula with normal result.

Since the patient complained of new difficulty in swallowing and dysarthria, a cerebral computer tomography was performed showing a space-occupying lesion of the left frontoparietal lobe. A head MRI showed further suspected metastatic lesions in the supratentorial region with central necrosis and perifocal oedema. Slight compression of the left posterior horn of the lateral ventricle was seen.

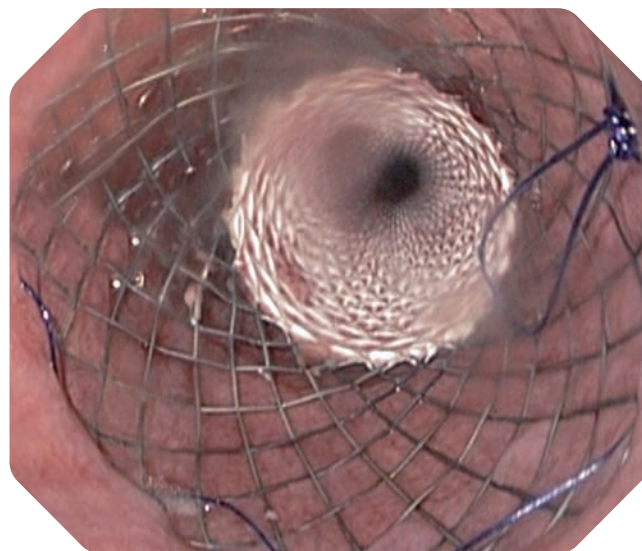
The interdisciplinary tumor conference recommended implantation of an esophageal stent followed by palliative full brain radiation (20 Gy). Successively systemic palliative chemotherapy with 5-FU and a platinum derivative was suggested.



Esophago-gastro-duodenoscopy (EGD) with view of cranial periphery of tumor at 26 cm from bite block (BB)

3. Therapy

The patient was placed on his left side on the X-ray table and sedated with a continuous propofol drip after an initial bolus of 60 mg Propofol. A standard OLYMPUS brand gastroscope was used to view the circular tumor, extending from 26 to 34 cm from the bite block with overt exophytic and exulcerating growth. The distance of the upper esophageal sphincter from the bite block was 18 cm, the gastro-esophageal junction was localized at 42 cm. First step the proximal and distal edges of the tumor were marked by injecting contrast medium into the esophageal wall and attaching radiopaque markers ('ampoule files') to the skin in the area of the right lateral thoracic wall. After endoscopic passage of the stenosing tumor an anti-kink guide wire (nitinol wire 0.035 inch, 260 cm) was introduced and the endoscope was removed. Bouginage of the tumor stenosis was not performed as sufficient residual lumen was present. The selected CibuFlex ePTFE-coated nitinol esophageal stent measured 150 mm x 20 mm, with coating length at 120 mm. The stent was introduced via the guide wire in situ after the inner lumen had been flushed with saline solution and the exterior sheath coated with lubricant for easy passage. To facilitate introduction of the stent the patient's head was slightly reclined and the hypopharyngeal passage was splinted using a finger. The stent, pre-loaded in the application device, was positioned in such a way that the ePTFE coating extended safely beyond the proximal and distal edges of the 8-cm tumor stenosis. Markers at the upper and lower edge of the stent facilitated precise positioning. A second operator now re-introduced the endoscope along the application device in situ to monitor optimal positioning of the upper stent edge during stent release. Stent release was prepared by turning the locking screw through 1/2 to 1 turn counter-clockwise. The stent was then released by continuously retracting the sheath / supporting sheath over the stabilizer under radiographic and endoscopic monitoring of the procedure. The proximal end of the application device was additionally fixed in position as an easily operated two-hand system by supporting it on the chest of the first operator releasing the stent. After a brief pause to allow the stent shaft to self-expand and increase its diameter, the application device with radiopaque soft tip and stent extended beyond the stenosis by around 3 - 4 cm on each side. Correction of the position by simply pulling the extraction loop on the proximal end of the stent proved unnecessary. After radiological verification of the rapid but still incomplete expansion of



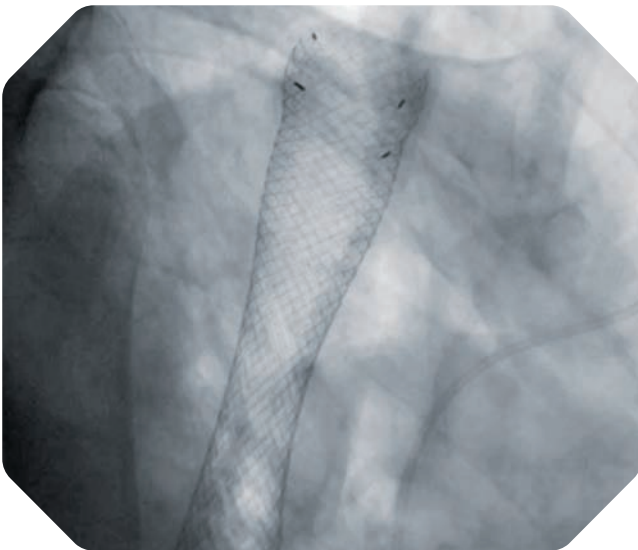
Stent implantation with view of the fully expanded proximal bulb at 22 cm from BB



Endoscopic passage through the expanded SEMS (view of the coated section in the stent mid-section)

the stent, passage of the endoscope was not forced owing to the risk of stent dislocation. The efficiency of decompression was tracked by instilling contrast medium via the working channel of the endoscope compressed onto the proximal stent edge under X-ray monitoring. After a 30-minute observation period in the recovery room, the pain-free patient was moved to the ward. The patient was able to take fluids two hours after stent

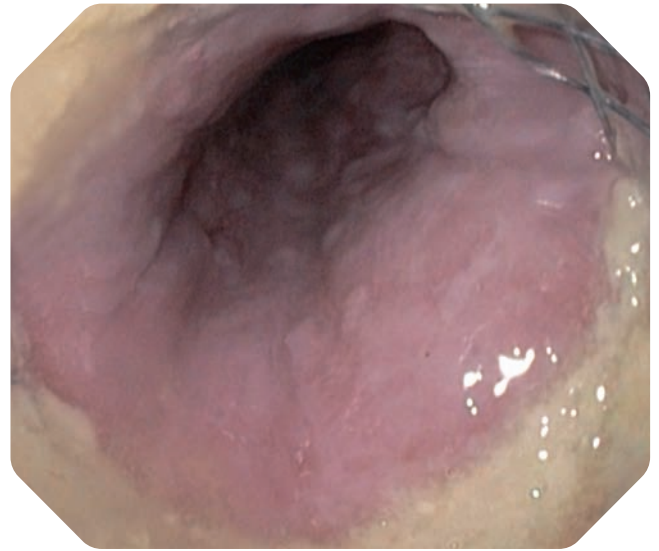
implantation; feeding was reintroduced, initially in the form of clear soup, on the same evening. The patient did not make use of the on-demand analgetics provided for the next 48 to 72 hours. Dietary advice (e.g. avoidance of fibrous foods, plentiful fluid intake with meals etc.) was ordered for the following day. The markers integrated into the proximal and distal stent ends allowed for radiological control of correct stent position after 48 hrs.



X-ray view

4. Summary and critical evaluation

In this case of a patient with symptomatic severe esophageal stenosis resulting from exophytic and exulcerating growth of esophageal squamous cell carcinoma located at 26 to 34 cm from bite block, patency was rapidly and effectively restored by the implantation of a CibuFlex ePTFE-coated nitinol esophageal stent (150 x 20 mm, 120 mm coating length). The radiopaque soft tip of the application device enabled atraumatic passage of the tumor to be effected. The markers integrated into the proximal and distal stent ends enabled the stent to be positioned precisely. The application device is designed as an easy-to-operate coaxial two-hand system which enables continuous controlled release of the stent to be effected in a pull-back system. The high expansion force of the CibuFlex esophageal stent used here guarantees migration-free precise positioning of the stent and effective stent implantation in the relevant tumor stenosis.



View of the distal stent opening at 37 cm from bite block after endoscopic passage of the expanded stent (48 hrs. after stent implantation)



Stent implantation with view of the fully expanded stent bulb at 22 cm from bite block (48 hrs. after stent implantation, with food residue)

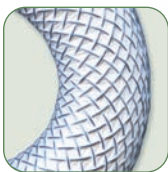
CibuFlex in "dog-bone" design

The combination of nitinol wire and ePTFE covering makes this esophageal stent highly durable offering an ideal balance between flexibility and radial force



Woven nitinol structure

- Self-expanding stent
- High radial force
- Maximal flexibility



ePTFE covering

- Sandwich technique (ribbed outer surface for ideal fixation and smooth inner surface for optimal food passage)
- Resistant to gastric acid, durable and extremely hard-wearing
- Prevents tumor ingrowth
- Occludes esophageal fistulae reliably



Safety

- Atraumatic stent ends
- Retrieval loop for repositioning and stent removal
- 8 Platinum-Iridium markers at the stent ends and the end of the covering provide excellent visibility



Navigation

- Radiopaque soft tip
- Proximal and distal markers
- Adapted to .035/.038 inch guide wire

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