

A new design fully covered metal stent (SX-ELLA stent Esophageal HV) for the palliation of malignant dysphagia: a prospective follow-up study

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Background: Self-expandable metal stents (SEMS) are frequently used for the palliation of malignant dysphagia. Recurrent dysphagia due to stent migration in covered stents and non-tumoral or tumoral tissue growth in uncovered stents is the main cause of stent failure and occurs in 15-30% and 10-30% of patients, respectively.

Aim: We aimed to determine efficacy, recurrent dysphagia, particularly due to migration and tissue growth, and complications of the SX-ELLA stent Esophageal HV (Ella-CS, Hradec Kralove, Czech Republic). This novel design is fully covered to resist tissue ingrowth and has an anti-migration ring to resist migration. Furthermore, it is braided in one piece to improve flexibility and expected to resist hyperplastic tissue reaction.

Methods: Between February 2007 and May 2008, 45 patients with malignant dysphagia from inoperable or metastatic esophageal or gastric cardia cancer (n=43) or lung cancer (n=2) underwent placement of an SX-ELLA stent Esophageal HV in two tertiary referral centers. Patients were followed by scheduled telephone calls at 14 days after stent placement, and then monthly until death. Outcome measures were dysphagia score, recurrent dysphagia, complications, endoscopic reinterventions and mortality.

Results: At 4 weeks, dysphagia score improved from a median of 3 (liquids only) prior to stent placement to a median of 1 (ability to eat some solid food) ($p < 0.001$). Twelve of 45 (27%) patients developed recurrent dysphagia, in 6 (13%) patients due to stent migration and in 2 (4%) due to tissue overgrowth. Others causes of recurrent dysphagia were food obstruction, stent fracture and partial stent deployment. Major complications (severe pain,

hemorrhage, fistula and fever) occurred in 10/45 (22%) patients. Minor complications, i.e., mild pain and gastro-esophageal reflux were observed in 12/45 (27%) patients. In total, 26 endoscopic reinterventions were performed in 18 patients (40%) for recurrent dysphagia or complications. Until November 2008, 39 patients died of whom 5 (11%) due to hemorrhage after a median of 107 days, most likely due to a combination of tumor progression and/or stent compression.

Conclusions: The use of the SX-Ella stent Esophageal HV is effective and relatively safe for the palliation of malignant dysphagia. Recurrent dysphagia due to tissue growth and stent migration was reduced compared with other currently available covered stents, although still 40% of patients needed a reintervention for recurrent dysphagia or complications.