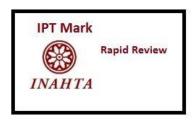


# INFORMATION BRIEF (RAPID REVIEW) TRUMPET ART STENT

Malaysian Health Technology Assessment Section (MaHTAS)
Medical Development Division
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## TITLE: TRUMPET ART STENT

#### **PURPOSE**

To provide brief information on the efficacy/effectiveness, safety, and cost-effectiveness of Trumpet Anti-reflux TATA (ART) stent for cardioesophageal junction carcinoma (COJ).

#### **BACKGROUND**

Oesophageal cancer is one of the most fatal malignancies worldwide. Despite improvements in the management and treatment of cancer, the prognosis in oesophageal cancer remains very poor due to high rate of metastasis at initial presentation.<sup>1,2</sup> Palliative chemotherapy, brachytherapy, radiation therapy, surgery, and ablation therapy are the available treatment modalities for oesophageal cancer.<sup>1</sup>

Dysphagia is one of the most common presenting symptoms of oesophageal cancer. Placing a stent across the tumor is one of the palliative options to relieve dysphagia, and to improve quality of life.<sup>3</sup> Self-expanding metal stent (SEMS) is the most frequently chosen method for dysphagia. Nevertheless, oesophageal stent placement is associated with several complication such as stent migration, bleeding, perforation and severe acid reflux.<sup>4</sup> Various modification has been made to the traditional stents to reduce the complications, one of it is the development of anti-reflux oesophageal stents. Trumpet ART stent is an anti-reflux stent specifically designed for COJ. It is invented by Dr Mahadevan Deva Tata, a local upper gastrointestinal surgeon in collaboration with medical device manufacturer, M.I.tech Korea. It was claimed to be the first COJ stent in the world.

#### **EVIDENCE SUMMARY**

A total of 57 titles were retrieved from the scientific databases such as Medline, EBM Reviews, EMBASE via OVID, PubMed and from general search engines [Google Scholar and US Food and Drug Administration (USFDA)], using the search term; "Trumpet ART stent", "anti-reflux stent", "oesophageal stent", "cardioesophageal junction", and "gastroesophageal carcinoma". Last search was conducted on 20 April 2022. Two studies were found to be relevant and included in this review.

### **EFFICACY/ EFFECTIVENESS**

There was no retrievable evidence on the effectiveness of Trumpet ART stent for COJ from databases. Based on Medical Device Authority (MDA) website, there was one study conducted on Trumpet ART stent in Hospital Tuanku Jaafar, Seremban.<sup>5</sup> However, the

results from the study were not published. Nevertheless, there was one study retrieved on the effectiveness of anti-reflux stents for oesophageal cancer.

Pandit et al. conducted a systematic review with meta-analysis to compare the effectiveness between anti-reflux stents and standard stents. A total of eight randomised controlled trials (RCTs) (n=395 oesophageal cancer patients) were included in this study. Compared to the standard stent, the anti-reflux stent showed a trend towards reduction in the dysphagia score without reaching a statistical significance [Standardized mean difference (SMD): -0.33 (-0.71, 0.05); p=0.09,  $I^2$ :37%]. There was no statistical difference in the gastrointestinal reflux (GER) scores between the two types of stents [SMD: -0.17 (-0.78, 0.45); p=0.008,  $I^2$ : 74%].

#### **SAFETY**

A systematic review with meta-analysis by Pandit et al. reported that compared to standard stent, anti-reflux stent showed no difference in the risk of stent migration [Odd ratio (OR): 1.37 (0.66, 2.83); p=0.40,  $I^2$ : 0%], bleeding [OR: 1.43 (0.40, 5.13); p=0.59,  $I^2$ : 0%], and obstruction [OR: 1.66 (0.60, 4.60); p=0.33,  $I^2$ : 0%].

Doosti-Irani et al. compared the complications of palliative treatments including stents in patients with oesophageal cancer. In this network meta-analysis (n=24 RCTs), open stent and Ultraflex stent plus omeprazole was compared with anti-reflux stent. The relative risk (RR) for treatment related deaths were higher in open stent and Ultraflex stent plus omeprazole (RR=3.00, 95%CI: 0.13-70.23) and (RR=2.55, 95%CI: 0.11-59.49), respectively.<sup>7</sup>

#### **COST-EFFECTIVENESS**

There was no retrievable evidence on the cost-effectiveness of Trumpet ART stent.

#### CONCLUSION

There was very limited evidence to suggest the effectiveness and safety of Trumpet ART stent for patients with COJ. Both anti-reflux stent and standard stent were comparable in terms of efficacy and safety in patients with oesophageal cancer, while the risk of treatment related death were lower with anti-reflux stent.

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