Title: **Radiofrequency ablation for Barrett's oesophagus with dysplasia**

Agency: Medical Services Advisory Committee (MSAC)
MDP 853
Commonwealth Department of Health and Ageing
GPO Box 9849 Canberra ACT 2601
http://www.msac.gov.au

Reference: MSAC Application 1143
First printed May 2011
ISBN (print) 978-1-74241-402-7 ISBN (online) 978-1-74241-403-4

Aim

To assess the safety, effectiveness and cost-effectiveness of radiofrequency ablation (RFA) in (a) patients with Barrett's oesophagus (BO) with low grade dysplasia (LGD), (b) patients with Barrett's oesophagus with high grade dysplasia (HGD) and (c) patients with early intra-mucosal cancer (IMC).

Results and Conclusions

Safety

The limited literature available suggests RFA is safe for the treatment of patients with BO with LGD, HGD or early IMC. No comparative evidence was available for the assessment of the safety of RFA compared to surveillance with acid suppressive medication (conservative therapy), argon plasma coagulation (APC) or oesophagectomy. No deaths resulted from treatment with RFA, and a total of 23 reported complications occurred in 411 patients, following multiple treatment sessions. Most adverse events were minor in nature and resolved without additional intervention. The most common adverse event was gastrointestinal haemorrhage (4/411, 1 percent) and dysphagia (4/411, 1 percent). The incidence of non-transmural lacerations, superficial mucosal lacerations and stricture following treatment with RFA appeared to be linked to prior endoscopic mucosal resection (EMR).

Effectiveness

The limited literature suggests RFA is effective for achieving histological eradication of intestinal metaplasia (IM) and dysplasia at a mucosal level. One randomised controlled trial was available to assess the effectiveness of RFA versus a sham procedure for patients with BO with LGD and HGD. However, no comparative evidence was available contrasting RFA to surveillance with acid suppressive medication (conservative therapy) or APC or oesophagectomy. When compared to a sham procedure RFA was found to be more effective with the complete eradication of intestinal metaplasia (CR-IM) and complete eradication of dysplasia (CR-D) higher in the RFA group (98% and 99% respectively) than the control group (57% and 59%) ($P<0.001$). Evidence of subsquamous IM was found in five (of 411) patients (1.2 percent). The rate of CR-IM across all included studies ranged from 54 percent to 91 percent. Escape EMR due to failure of RFA to achieve CR-IM was performed in 20 (of 411) patients, with results reported in 15 of the 20 patients. Of those reported all achieved CR-IM on long-term follow-up (24 months). Additional RFA treatment sessions were required in five (of 411) patients.

Cost-effectiveness

The cost-effectiveness for patients with BO with LGD and HGD was assessed separately. For LGD, replacing surveillance with RFA would yield an additional benefit of 0.129 quality adjusted life years (QALYs) at an additional cost of $10,175. This gave an incremental cost effectiveness ratio (ICER) for RFA compared to surveillance of $78,975 per QALY. The main drivers of the cost-effectiveness result was the probability of eradication of LGD after treatment with RFA, the probability of progressing to cancer from LGD and the cost of RFA. In the sensitivity analysis, if the frequency of surveillance is reduced after eradication of LGD or HGD, the resulting ICER is $71,075.

There was insufficient comparative evidence to undertake a full cost-effectiveness analysis of RFA for the treatment of BO with HGD. Therefore, a cost analysis was conducted to compare the annual cost of treating HGD with RFA, oesophagectomy, EMR or APC.
Based on an estimated prevalence of 100 cases of HGD, if direct replacement of RFA occurred for oesophagectomy the overall cost savings would be $1,214,588. If RFA was used to treat 100 patients instead of EMR or APC, there would be a total additional cost of $778,156 or $606,155, respectively.
The cost analysis assumes that RFA, EMR, APC and oesophagectomy are identical in terms of effectiveness and does not take into account any reduction in quality of life that may occur post-surgery with oesophagectomy. Individual patient characteristics may mean that all four treatment options are not interchangeable.

Methods
The evidence assessing the use of RFA in patients with BO with LGD, HGD and early intra-mucosal cancer was systematically assessed. PubMed, EMBASE, the Cochrane Library, Current Contents and York CRD were searched for relevant literature from database inception to April 2010.
Studies were included in the review using pre-determined selection criteria and reasons for exclusion were documented. The quality of studies was assessed, data were extracted in a standardised manner, and results were reported narratively.