



Radiofrequency ablation for gastric antral vascular ectasia

Interventional procedures guidance

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Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the <u>Yellow Card Scheme</u>.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with

those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should <u>assess and reduce the environmental impact of implementing NICE recommendations</u> wherever possible.

1 Recommendations

- 1.1 Current evidence on radiofrequency ablation for gastric antral vascular ectasia raises no major safety concerns; however, evidence on its efficacy is inadequate in quantity. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.
- 1.2 Clinicians wishing to undertake radiofrequency ablation for gastric antral vascular ectasia should take the following actions:
 - Inform the clinical governance leads in their NHS trusts.
 - Ensure that patients understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. In addition, the use of NICE's information for the public is recommended.
 - Audit and review clinical outcomes of all patients having radiofrequency ablation for gastric antral vascular ectasia (see section 7.1).
- 1.3 The procedure should only be done by experienced interventional endoscopists with specific training in the technique.
- NICE encourages further research into radiofrequency ablation for gastric antral vascular ectasia and collaborative publication of data from local audit. Patient selection should be clearly documented, including details of prior treatments. Outcomes should include success and duration of effect in controlling bleeding and the effect of this on the need for blood transfusion. All complications should be reported. NICE may update the guidance on publication of further evidence.

2 Indications and current treatments

- Gastric antral vascular ectasia (GAVE) syndrome, also known as 'watermelon stomach', is a rare but well-recognised cause of chronic upper gastrointestinal blood loss. It is more common in older people. It may lead to iron-deficiency anaemia and transfusion dependence. Rarely, it can cause acute haemorrhage. GAVE is associated with heterogeneous medical conditions, including hepatic, renal, cardiac and autoimmune diseases, but its pathogenesis is unknown. GAVE is characterised endoscopically by diffuse or linear red patches or spots in the antrum of the stomach, which can give a 'watermelon' type of appearance. The classic histopathological findings are vascular ectasia of mucosal capillaries, focal thrombosis, spindle cell proliferation and fibrohyalinosis.
- Initial treatment for GAVE includes endoscopic thermoablation techniques (such as argon plasma coagulation, laser photoablation, cryotherapy) and band ligation. Some patients continue to need blood transfusions despite repeat endoscopic treatments. When endoscopic therapy is not successful, antrectomy may be considered. Surgical resection of the affected part of the stomach is curative, but is associated with risks of morbidity and mortality.

3 The procedure

- The aim of endoscopic radiofrequency ablation for gastric antral vascular ectasia (GAVE) is to ablate the dilated blood vessels and stop internal bleeding.
- 3.2 The procedure is usually done with the patient under conscious sedation. A specially designed radiofrequency catheter is inserted into the gastric antrum under endoscopic guidance. The target area for treatment is identified, and the catheter electrode is positioned by manoeuvring the endoscope. The electrode is in the form of a plate, which allows a broad area to be treated in a few seconds by applying several pulses of radiofrequency energy. The electrode is applied to further areas of GAVE until all have been treated. If necessary, the procedure can be repeated after a few weeks: it is often carried out 2 or 3 times.

4 Efficacy

This section describes efficacy outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the overview.

- A case series of 24 patients with gastric antral vascular ectasia (GAVE) treated by radiofrequency ablation (RFA) reported that 65% (15) of the 23 patients who were transfusion-dependent during the 6 months before RFA did not need any transfusions during the 6 months after RFA. A case series of 21 patients with GAVE refractory to argon plasma coagulation therapy, who were treated by RFA, reported clinical success (defined as complete independence from the need for transfusions during the 6-month follow-up period) in 86% (18 out of 21) of patients, with no evidence of GAVE on follow-up endoscopy.
- The case series of 24 patients reported a significant increase in their mean haemoglobin level from 6.8±1.4 g/dl 6 months before RFA to 9.8±1.8 g/dl 6 months after RFA (p<0.001). The case series of 21 patients reported a significant increase in their mean haemoglobin level from 7.8 g/dl (standard deviation [SD] 1.0) 6 months before RFA to 10.2 g/dl (SD 1.4) 6 months after RFA for the 86% (18 out of 21) of patients in whom there was clinical success (p<0.001).
- 4.3 The specialist advisers listed key efficacy outcomes as eradication of GAVE, resolution of anaemia and reduction in the need for blood transfusion.

5 Safety

This section describes safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the <u>overview</u>.

Ulceration (1 superficial ulcer and 1 bleeding ulcer) was reported in 10% (2 out of 21) of patients in a case series of 21 patients with gastric antral vascular ectasia (GAVE) refractory to argon plasma coagulation therapy. Both ulcers resolved

without intervention. The ulcers occurred in 2 of the first 3 patients in the series who were treated using 4 pulses per location. From the fourth patient onwards, a 2-pulse-per-location protocol was used. A superficial ulcer was detected in 1 patient at endoscopic follow-up 4 to 6 weeks after the last radiofrequency ablation (RFA) session in a case series of 6 patients with GAVE (no further details provided).

- A submucosal tear at the gastro-oesophageal junction was revealed by repeat endoscopy in 1 patient with alcohol-induced cirrhosis and gastrointestinal bleeding from GAVE in a single case report. Dislodgement of the device probe from the endoscope may have caused the tear, which healed within 1 month.
- Gastric inflammatory hyperplastic polyps in the distal body and antrum were detected at a fourth RFA session in 1 patient with hepatitis C and GAVE, in a single case report. The polyps were removed using heat cautery polypectomy (no further details provided).
- In addition to safety outcomes reported in the literature, specialist advisers are asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events (events which they think might possibly occur, even if they have never done so). For this procedure, specialist advisers did not list any anecdotal adverse events. They considered that the following were theoretical adverse events: stricture, perforation, bleeding and abdominal pain.

6 Committee comments

The Committee noted that most of the patients included in the published studies on radiofrequency ablation for gastric antral vascular ectasia (GAVE) had ectasia that had been refractory to other treatments. The procedure has potential for significant benefit to these patients, if further data support its efficacy. Information about the place of radiofrequency ablation for GAVE in treating patients who have not had other interventions would also be useful.

7 Further information

7.1 This guidance requires that clinicians doing the procedure make special arrangements for audit. NICE has identified relevant <u>audit criteria</u> and has developed an audit tool (which is for use at local discretion).

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the overview.

Information for patients

NICE has produced <u>information for the public on this procedure</u>. It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

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Endorsing organisation

This guidance has been endorsed by <u>Healthcare Improvement Scotland</u>.