NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedure consultation document

Radiofrequency ablation for gastric antral vascular ectasia

Gastric antral vascular ectasia is a condition in which enlarged blood vessels in the lower part of the stomach can bleed and cause anaemia. In this procedure, a thin flexible tube with a camera on the end (an endoscope) is passed through the mouth and into the stomach to deliver radiofrequency heat energy to destroy the enlarged blood vessels.

The National Institute for Health and Care Excellence (NICE) is examining radiofrequency ablation for gastric antral vascular ectasia and will publish guidance on its safety and efficacy to the NHS. NICE's Interventional Procedures Advisory Committee has considered the available evidence and the views of specialist advisers, who are consultants with knowledge of the procedure. The Advisory Committee has made provisional recommendations about radiofrequency ablation for gastric antral vascular ectasia.

This document summarises the procedure and sets out the provisional recommendations made by the Advisory Committee. It has been prepared for public consultation. The Advisory Committee particularly welcomes:

- comments on the provisional recommendations
- the identification of factual inaccuracies
- additional relevant evidence, with bibliographic references where possible.

Note that this document is not NICE's formal guidance on this procedure. The recommendations are provisional and may change after consultation.

The process that NICE will follow after the consultation period ends is as follows.

- The Advisory Committee will meet again to consider the original evidence and its provisional recommendations in the light of the comments received during consultation.

- The Advisory Committee will then prepare draft guidance which will be the basis for NICE's guidance on the use of the procedure in the NHS.

For further details, see the Interventional Procedures Programme process guide, which is available from the NICE website.

Through its guidance NICE is committed to promoting race and disability equality, equality between men and women, and to eliminating all forms of discrimination. One of the ways we do this is by trying to involve as wide a range of people and interest groups as possible in the development of our interventional procedures guidance. In particular, we aim to encourage people and organisations from groups who might not normally comment on our guidance to do so.

In order to help us promote equality through our guidance, we should be grateful if you would consider the following question:

Are there any issues that require special attention in light of NICE's duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations between people with a characteristic protected by the equalities legislation and others?

Please note that NICE reserves the right to summarise and edit comments received during consultations or not to publish them at all where in the reasonable opinion of NICE, the comments are voluminous, publication would be unlawful or publication would otherwise be inappropriate.

Closing date for comments: 18 December 2014

Target date for publication of guidance: March 2015

1 Provisional 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 *[[URL to be added at publication]]* is recommended.
- Audit *[URL to audit tool to be added at publication]* and review clinical outcomes of all patients having radiofrequency ablation for gastric antral vascular ectasia (see section 7.2).

1.3 The procedure should only be done by experienced interventional endoscopists with specific training in the technique.

1.4 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 impact 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

2.1 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.

2.2 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

3.1 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 the application of 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 interventional procedure overview.

4.1 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% (18/21) of patients, with no evidence of GAVE on follow-up endoscopy.

4.2 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% (18/21) 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 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 interventional procedure overview.

5.1 Ulceration (1 superficial ulcer and 1 bleeding ulcer) was reported in 10% (2/21) 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 4–6 weeks after the last radiofrequency ablation (RFA) session in a case series of 6 patients with GAVE (no further details provided).

5.2 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.

5.3 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).

5.4 The specialist advisers listed theoretical adverse events as stricture, perforation, bleeding and abdominal pain.

6 Committee comments

6.1 The Committee noted that most of the patients included in the published studies on radiofrequency ablation for gastric antral vascular ectasia 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 gastric antral vascular ectasia in treating patients who have not had other interventions would also be useful.

7 Further information

7.1 For related NICE guidance, see the NICE website.

7.2 This guidance requires that clinicians undertaking the procedure make special arrangements for audit. NICE has identified relevant audit criteria and is developing an audit tool (for use at local discretion), which will be available when the guidance is published.

Bruce Campbell
Chairman, Interventional Procedures Advisory Committee
November, 2014