

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedure consultation document

Radiofrequency treatment for haemorrhoids

Haemorrhoids (or piles) are enlarged blood vessels inside or around the anal canal (back passage). In this procedure, a special probe that uses radiofrequency energy is inserted into or moved over the surface of the haemorrhoid. The treatment may need to be repeated. The aim is to shrink the haemorrhoid.

The National Institute for Health and Care Excellence (NICE) is examining radiofrequency treatment for haemorrhoids 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 draft recommendations about radiofrequency treatment for haemorrhoids

This document summarises the procedure and sets out the draft recommendations made by the advisory committee. It has been prepared for public consultation. The advisory committee particularly welcomes:

- comments on the draft 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 draft 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- The advisory committee will then prepare draft guidance which will be the basis for NICE's guidance on the use of the procedure in the NHS.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: 10 May 2017

Target date for publication of guidance: August 2017

1 Draft recommendations

1.1 Current evidence on the safety and efficacy of radiofrequency treatment for haemorrhoids is inadequate in quantity and quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.

1.2 Clinicians wishing to do radiofrequency treatment for haemorrhoids should:

- Inform the clinical governance leads in their NHS trusts.

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- 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 treatment for haemorrhoids (see section 7.1).

1.3 NICE encourages further research into radiofrequency treatment for haemorrhoids, preferably randomised controlled trials. It may update the guidance on publication of further evidence. Outcomes should include pain, secondary haemorrhage, recurrence rate, the need for repeat procedures and quality-of-life measures. Details of patient selection should also be reported.

2 Indications and current treatments

2.1 Haemorrhoids happen when the vascular anal cushions become enlarged. Some patients may be asymptomatic, but others have symptoms of bleeding, itching or discomfort. Small symptomatic haemorrhoids are classified as grade I. If the haemorrhoids are large, they may prolapse out of the anus. Haemorrhoids that prolapse may reduce spontaneously after defaecation (grade II); they may need to be reduced digitally (grade III); or they may not be reducible, remaining continually prolapsed (grade IV).

2.2 Grade I and II haemorrhoids may be managed by changes in diet or using laxatives, or treated with topical applications (such as corticosteroid creams or local anaesthetics). Established interventional treatments include rubber band ligation, sclerosant

injections, infrared coagulation or bipolar electrocoagulation using diathermy.

2.3 Established treatments for symptomatic grade III and IV haemorrhoids include haemorrhoidectomy, stapled haemorrhoidopexy or haemorrhoidal artery ligation and bipolar electrocoagulation using diathermy.

2.4 Electrotherapy is another treatment option, which is used for grade I to IV haemorrhoids.

3 The procedure

3.1 Radiofrequency treatment for haemorrhoids is usually done under local anaesthetic. A lubricated proctoscope is inserted into the anus to allow good visualisation of the anal canal and to expose the haemorrhoids. Local anaesthetic is injected into tissue surrounding the haemorrhoid. Details of the procedure vary according to the specific device being used. A specially designed probe connected to a radiofrequency generator is inserted into the haemorrhoid, or a ball electrode is rolled over the surface of the haemorrhoid. The tissue within the haemorrhoid heats up and the haemorrhoid shrinks. The haemorrhoids may be treated in several sessions, each taking up to 20 minutes.

3.2 Radiofrequency treatment for haemorrhoids is claimed to be faster and less painful than other treatment methods, with a shorter recovery time.

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
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detailed information on the evidence, see the [interventional procedure overview](#).

- 4.1 In a randomised controlled trial (RCT) of 80 patients with grade II haemorrhoids treated by radiofrequency or rubber band ligation, the mean time taken to return to work was 2 and 5 days respectively ($p=0.051$). In an RCT of 40 patients with grade III or IV haemorrhoids, the time off work was 5 days for patients who had radiofrequency treatment and 21 days for patients who had haemorrhoidectomy. In a case series of 50 patients with grade III or IV haemorrhoids, 44% (22/50) of patients returned to work within 5 days and the remaining 56% (28/50) returned within 1 week of the procedure.
- 4.2 In the RCT of 80 patients, recurrence of bleeding was reported in 14% (5/36) of patients who had radiofrequency treatment and 7% (3/44) of patients who had rubber band ligation ($p=0.105$) at 1-year follow-up. Recurrence of haemorrhoid prolapse was reported in 1 patient, who had radiofrequency treatment, in the same study. Recurrence of symptoms was reported in 14% (4/28) and 6% (2/32) of patients respectively ($p<0.05$) in an RCT of 60 patients with grade II haemorrhoids treated by radiofrequency or rubber band ligation. Recurrence of bleeding was reported in 16% (33/209) of patients in a case series of 240 patients with grade I or II haemorrhoids treated by radiofrequency, at a mean follow-up of 18 months. Recurrence of bleeding was reported in 4% (8/210) of patients in a case series of 210 patients with grade I or II haemorrhoids treated by radiofrequency, at a mean follow-up of 12 months. In an RCT of 100 patients who had radiofrequency or infrared coagulation, recurrence of bleeding was reported in 8% and 14% of patients respectively, at 12-month follow-up.

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- 4.3 In the case series of 50 patients with grade III or IV haemorrhoids, asymptomatic recurrence (diagnosed on proctoscopy) was reported in 9% (4/44) of patients at 12-month follow-up. In the RCT of 80 patients, obliteration of treated haemorrhoids (confirmed by anoscopy) was reported in 82% of patients who had radiofrequency and 93% of patients who had rubber band ligation ($p=0.004$) at 1-year follow-up.
- 4.4 In the RCT of 60 patients, the mean satisfaction scores (using a visual analogue scale of 0 to 10, where higher scores show more satisfaction) were 9.1 for radiofrequency treatment and 8.2 for rubber band ligation ($p<0.05$; follow-up period not reported). In the RCT of 100 patients, 89% of patients who had radiofrequency treatment were satisfied compared with 83% of patients who had infrared coagulation (p value not reported). In the case series of 50 patients, all of the patients expressed satisfaction with the results of the treatment.
- 4.5 The specialist adviser listed the key efficacy outcomes as symptomatic and clinical resolution of haemorrhoids.

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 The postoperative pain score (measured on a visual analogue scale of 0 to 10, where higher scores show more pain) in the first week after the procedure ranged from 0 to 2 for patients who had radiofrequency treatment and from 2 to 4 for patients who had

rubber band ligation in a randomised controlled trial (RCT) of 80 patients. Duration of post-defaecation pain in the first week was 6 minutes in the radiofrequency treatment group compared with 13 minutes in the rubber band ligation group ($p=0.01$) in the same study. Pain in the anal region was reported in 12% (29/240) of patients in a case series of 240 patients. The pain intensity was scored 1 to 2 on the visual analogue scale and the patients were treated with analgesics. Anal pain (not further described) was reported in 7% (2/28) of patients who had radiofrequency treatment and 50% (16/32) of patients who had rubber band ligation in an RCT of 60 patients ($p<0.05$). Pain was reported by all patients in a case series of 50 patients; this subsided within 10 days after surgery in 43 patients and no patients complained of pain at the end of 1 month. Post-defaecation pain continued for 6 days after radiofrequency treatment and 13 days after haemorrhoidectomy in an RCT of 40 patients.

- 5.2 Bleeding after the procedure was reported in 19% (7/36) of patients who had radiofrequency treatment (reported mostly between 5 and 10 days after the procedure) and 5% (2/44) of patients who had rubber band ligation (reported between 7 and 9 days after the procedure) in the RCT of 80 patients. Bleeding, associated with defaecation, in the first 2 weeks was reported in 10% (23/240) of patients in the case series of 240 patients. Heavy bleeding in the first week after the procedure was reported in 2% (4/240) of patients in the same study; the bleeding was spontaneous and not associated with defaecation. The patients were admitted to hospital and 3 of the 4 had resolution of symptoms after conservative treatment. One patient needed to be examined under general anaesthesia; the active bleeding source was located and secured.

Bleeding (not further described) was reported in 21% (6/28) of patients who had radiofrequency treatment and 13% (4/32) of patients who had rubber band ligation ($p < 0.05$) in the RCT of 60 patients. Bleeding within 4 weeks of the procedure was reported in 14% (7/50) of patients in the case series of 50 patients; this was associated with defaecation and no treatment was needed. Post-defaecation bleeding continued for 7 days after radiofrequency treatment and for 24 days after haemorrhoidectomy in the RCT of 40 patients. Heavy bleeding, treated by a second procedure, was reported in 1 patient in a case series of 210 patients.

- 5.3 Urinary retention was reported in 4% (2/50) of patients in the case series of 50 patients; 1 patient had an enlarged prostate, the other had a large prolapsing haemorrhoid. It is thought that the treatment may have caused urethral spasm, leading to retention of urine. Both patients were catheterised, which relieved the symptoms. Urinary retention was reported in 1 patient in the case series of 210 patients; the patient had an enlarged prostate and was catheterised to relieve the symptoms.
- 5.4 Rectal tenesmus was reported in 6% (2/36) of patients who had radiofrequency treatment and 16% (7/44) of patients who had rubber band ligation ($p = 0.019$) at 1-week follow-up in the RCT of 80 patients. Rectal tenesmus was reported in 4% (1/28) of patients who had radiofrequency treatment and 19% (6/32) of patients who had rubber band ligation ($p < 0.05$) in the RCT of 60 patients.
- 5.5 Skin tag formation at 12-month follow-up was reported in 7 patients who had external haemorrhoids, in the case series of 50 patients.
- 5.6 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, the specialist adviser did not list any additional anecdotal adverse events. They considered that the following were theoretical adverse events: infection and abscess.

6 Committee comments

- 6.1 There have been changes to the procedure, in particular to the design of the radiofrequency probe. The majority of published evidence considered by the committee came from studies which used a ball-shaped electrode.

7 Further information

- 7.1 For related NICE guidance, see the [NICE website](#).
- 7.2 This guidance requires that clinicians doing the procedure make special arrangements for audit. NICE has identified relevant audit criteria and is developing an audit tool (which is for use at local discretion). This tool will be available when the guidance is published.

Tom Clutton-Brock
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