

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedure consultation document

Electrotherapy for the treatment of haemorrhoids

Haemorrhoids (or piles) are swellings containing enlarged blood vessels that are found inside or around the anal canal (back passage). In electrotherapy, a probe is used to apply an electric current to haemorrhoids with the aim of causing them to shrink.

The National Institute for Health and Care Excellence (NICE) is examining electrotherapy for the treatment of 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 provisional recommendations about electrotherapy for the treatment of haemorrhoids.

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- The Advisory Committee will then prepare draft guidance which will be the basis for NICE's guidance on the use of the procedure in the NHS.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: 20 February 2015

Target date for publication of guidance: May 2015

1 Provisional recommendations

- 1.1 Current evidence on the efficacy and safety of electrotherapy for the treatment of grade I to III haemorrhoids is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit.
- 1.2 During the consent process patients should be informed, in particular, about other treatment options, including non-surgical treatments. They should be told that electrotherapy is not always successful and that repeat procedures may be necessary. They

should also be told that the procedure is often painful and may not be tolerated: anaesthesia may be needed for electrotherapy to be used at a level of current that is efficacious.

2 Indications and current treatments

- 2.1 Haemorrhoids occur when the vascular anal cushions become enlarged. Some patients may be asymptomatic, but others have symptoms of bleeding, itching or discomfort (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 dietary modification or use of laxatives, or treated by topical applications (such as corticosteroid creams or local anaesthetics). Interventional treatments include rubber band ligation, sclerosant injections, infrared coagulation or bipolar electrocoagulation using diathermy.
- 2.3 Treatments for grade III and IV haemorrhoids include bipolar electrocoagulation using diathermy, haemorrhoidectomy, stapled haemorrhoidopexy or haemorrhoidal artery ligation.

3 The procedure

- 3.1 Electrotherapy (also called electrocoagulation) aims to provide a treatment for patients with grade I or II haemorrhoids, as an alternative to banding, and for patients with grade III or IV haemorrhoids as an alternative to surgery.

- 3.2 With the patient in the left lateral position, a proctoscope is inserted into the anus to identify a haemorrhoid. A probe with metal contact points is then placed at the base of the haemorrhoid above the dentate line and a direct electric current is delivered. The electric current is controlled by a handpiece attached to the probe. The time for which the electric current is applied depends on the grade of the haemorrhoid and on the dose of direct current. The aim of the direct current application is to cause thrombosis of the feeding vessels and to cauterise the base of the haemorrhoid. More than one haemorrhoid may be treated at each session, depending on the need and tolerance of the patient.
- 3.3 One approach uses a low amplitude direct electric current (between 8 mA and 16 mA) and is used in an outpatient setting. Another approach uses a higher amplitude direct electric current (up to 30 mA) with the patient under general or spinal anaesthesia.

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 randomised controlled trial of 102 patients treated by electrocoagulation with 10–20 mA direct current or injection sclerotherapy reported that, after 8 weeks, 88% (44/50) of patients in the electrocoagulation group had no rectal bleeding and 6% (3/50) had reduced rectal bleeding, while there was no effect on rectal bleeding symptoms in 6% (3/50). In the injection sclerotherapy group, 67% (35/52) had no rectal bleeding and 17% (9/52) had reduced rectal bleeding, while there was no effect on

rectal bleeding symptoms in 15% (8/52) (p value for the overall difference between groups: $p=0.0043$). In a randomised controlled trial of 100 patients treated by electrotherapy with 16 mA direct current ($n=50$) or rubber band ligation ($n=50$), a complete response to the treatment (defined by disappearance of the symptoms and the lack of recurrence during the 1-year follow-up period) was reported for 82% (41/50) of patients in the electrotherapy group and 94% (47/50) in the rubber band ligation group. A relative response (defined as some improvement in severity, duration and interval of symptoms) was reported for 10% (5/50) of patients in the electrotherapy group and 2% (1/50) in the rubber band group, and no response was reported in 8% (4/50) and 4% (2/50) of patients respectively (no significant overall difference between groups, $p=0.2$).

4.2 In a randomised controlled trial of 100 patients treated by electrotherapy (monopolar electrocoagulation with 10–16 mA direct current; $n=50$) or by bipolar electrocoagulation using a probe with 1 positive and 1 negative electrode ($n=50$), the recurrence rates after 1 year were 34% and 29% respectively (absolute numbers and p values not given). Rebleeding was reported after 1 year in 5% and 20% of patients respectively (level of significance not stated). In a case series of 931 patients treated by electrotherapy with 27–30 mA direct current, new grade I or II haemorrhoids were reported in 6% (52/931) of patients during the 1–7 years follow-up period.

4.3 In the randomised controlled trial of 100 patients treated by electrotherapy (monopolar electrocoagulation with 10–16 mA direct current) or bipolar electrocoagulation using a probe with 1 positive and 1 negative electrode, the median times to treatment failure

were 8 months and 2.7 months respectively and the mean numbers of sessions to failure were 6.5 and 3.4 respectively. Treatment failure was defined as the occurrence of a major complication (a painful fissure or ulceration, prolonged rectal spasm, severe persistent bleeding or refusal of further treatment because of discomfort) or persistence of bleeding despite a minimum of 8 treatments without improvement at examination or in symptoms. Treatment failure occurred in 12% of patients in the monopolar electrocoagulation group and in 14% of patients in the bipolar electrocoagulation group (absolute numbers not given).

- 4.4 In the case series of 931 patients treated by electrotherapy with 27–30 mA direct current, 93% of patients went back to work after 2 days, 5% of patients went back to work after 2–6 days and 2% had to stay at home for a maximum of 2 weeks because of pain and discomfort (absolute numbers not given).
- 4.5 In the randomised controlled trial of 102 patients treated by electrocoagulation with 10–20 mA direct current or injection sclerotherapy, 8 weeks after the procedure, 84% (42/50) and 63% (33/52) of patients respectively were fully satisfied with the treatment, 12% (6/50) and 21% (11/52) of patients respectively were moderately satisfied, and 4% (2/50) and 15% (8/52) respectively were not satisfied (p value for overall difference between groups: $p=0.04$).
- 4.6 The specialist advisers listed key efficacy outcomes as resolution of haemorrhoidal symptoms such as bleeding and prolapse.

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 Severe pain during the procedure (measured on a 10-point visual analogue scale, with a higher score indicating more severe pain) was reported in 1 patient (out of 50) in the electrocoagulation group using 10–20 mA direct current and in none of the patients (out of 52) in the injection sclerotherapy group, in a randomised controlled trial of 102 patients. Moderate pain during the procedure was reported in 68% (34/50) of patients in the electrocoagulation group and in 4% (2/52) in the injection sclerotherapy group, and mild pain during the procedure was reported in 30% (15/50) and 96% (50/52) respectively (p value for overall difference between groups: $p < 0.001$).
- 5.2 Procedural pain that resulted in stopping therapy was reported in 20% (5/25) of patients treated by electrotherapy using 16 mA direct current and in none of the patients treated by bipolar electrocoagulation in a randomised controlled trial of 50 patients ($p = 0.05$). Prolonged pain (for more than 1 day following the procedure) was reported in 16% (4/25) of patients in the electrocoagulation group (2 of those patients also reported procedural pain) and in 1 patient in the bipolar electrocoagulation group ($p = 0.35$). In a randomised controlled trial of 408 patients treated by electrotherapy with 16 mA direct current ($n = 136$) or 30 mA direct current ($n = 136$) or Ferguson haemorrhoidectomy ($n = 136$), moderate pain 7 days after the procedure was reported in

7% (10/136) of patients, mild pain was reported in 15% (20/136) of patients and 78% (106/136) of patients had no pain when treated using 16 mA direct current. In the group treated using 30 mA direct current, 15% (20/136) of patients had mild pain and 85% (116/136) had no pain 7 days after the procedure, while all patients (136/136) treated by Ferguson haemorrhoidectomy continued to experience severe pain 7 days after the procedure (p value for overall difference between groups: $p < 0.05$).

5.3 Rectal bleeding 48 hours after the procedure was reported in 16% (8/50) of patients treated by electrotherapy with 16 mA direct current and in 1 patient treated by rubber band ligation in a randomised controlled trial of 100 patients; bleeding 1–48 hours after the procedure was reported in 12% (6/50) and 34% (17/50) of patients respectively, and no bleeding after the procedure was reported in 72% (36/50) and 64% (32/50) of patients respectively (no significant difference observed between groups, $p = 0.5$).

5.4 Rectal ulceration was reported in 1 patient treated by electrotherapy with 16 mA direct current and in 24% (6/25) of patients treated by bipolar electrocoagulation in the randomised controlled trial of 50 patients ($p = 0.10$).

5.5 Retention of urine was reported in 8% of patients in a case series of 931 patients treated by electrotherapy using 27–30 mA direct current; 6% of patients needed catheterisation once and 2% of patients needed catheterisation 2 to 3 times (absolute numbers not given).

5.6 A vasovagal episode with syncope for 10 seconds immediately after electrotherapy with 8–16 mA direct current was reported in 1 patient in the case series of 120 patients; the patient had no

sequelae and subsequently returned for treatment without any adverse effects.

- 5.7 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: burning, perforation, infection, electrocution and thrombosed haemorrhoids.

6 Committee comments

- 6.1 The Committee noted that electrotherapy for the treatment of haemorrhoids is intended to be used as an outpatient procedure without anaesthesia, but that the low power settings which can usually be tolerated without anaesthesia show a greater tendency for haemorrhoid recurrence. It noted that repeat procedures are sometimes needed.

7 Further information

- 7.1 For related NICE guidance, see the [NICE website](#).

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