

Electrotherapy for the treatment of haemorrhoids

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 [Yellow Card Scheme](#).

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 assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

1 Recommendations

- 1.1 Current evidence on the efficacy and safety of electrotherapy for the treatment of grade 1 to 3 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 for lower-grade haemorrhoids. 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 can be painful, and general or regional anaesthesia may be needed to deliver electrotherapy at higher levels of current.

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 1). If the haemorrhoids are large, they may prolapse out of the anus. Haemorrhoids that prolapse may reduce spontaneously after defaecation (grade 2); they may need to be reduced digitally (grade 3); or they may not be reducible, remaining continually prolapsed (grade 4).
- 2.2 Grade 1 and 2 haemorrhoids can be managed by dietary modification or use of laxatives, or treated by 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 grade 3 and 4 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 1 or 2 haemorrhoids, as an alternative to banding, and for patients with grade 3 or 4 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 cause the haemorrhoid to shrink. The precise mechanism of action is not known. More than 1 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 described in the literature 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 [overview](#).

- 4.1 A randomised controlled trial of 102 patients treated by electrocoagulation with 10 mA to 20 mA direct current or injection sclerotherapy reported that, after

8 weeks, 88% (44 out of 50) of patients in the electrocoagulation group had no rectal bleeding and 6% (3 out of 50) had reduced rectal bleeding, while there was no effect on rectal bleeding symptoms in 6% (3 out of 50). In the injection sclerotherapy group, 67% (35 out of 52) had no rectal bleeding and 17% (9 out of 52) had reduced rectal bleeding, while there was no effect on rectal bleeding symptoms in 15% (8 out of 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 out of 50) of patients in the electrotherapy group and 94% (47 out of 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 out of 50) of patients in the electrotherapy group and 2% (1 out of 50) in the rubber band group, and no response was reported in 8% (4 out of 50) and 4% (2 out of 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 mA to 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 mA to 30 mA direct current, new grade 1 or 2 haemorrhoids were reported in 6% (52 out of 931) of patients during the 1 to 7 years' follow-up period.

4.3 In the randomised controlled trial of 100 patients treated by electrotherapy (monopolar electrocoagulation with 10 mA to 16 mA direct current) or bipolar electrocoagulation, 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 (level of significance not stated and absolute numbers not given).

- 4.4 In the case series of 931 patients treated by electrotherapy with 27 mA to 30 mA direct current, 93% of patients went back to work after 2 days, 5% of patients went back to work after 2 to 6 days and 2% had to stay at home for a maximum of 2 weeks because of pain and discomfort (level of significance not stated and absolute numbers not given).
- 4.5 In the randomised controlled trial of 102 patients treated by electrocoagulation with 10 mA to 20 mA direct current or injection sclerotherapy, 8 weeks after the procedure, 84% (42 out of 50) and 63% (33 out of 52) of patients respectively were fully satisfied with the treatment, 12% (6 out of 50) and 21% (11 out of 52) of patients respectively were moderately satisfied, and 4% (2 out of 50) and 15% (8 out of 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, and pain after the procedure.

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 [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 mA to 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 out of 50) of patients in the electrocoagulation group and in 4% (2 out of 52) in the injection sclerotherapy group, and mild pain during the procedure was reported in 30% (15 out of 50) and 96% (50 out of 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 out of 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 out of 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 out of 136) of patients, mild pain was reported in 15% (20 out of 136) of patients and 78% (106 out of 136) of patients had no pain when treated using 16 mA direct current. In the group treated using 30 mA direct current, 15% (20 out of 136) of patients had mild pain and 85% (116 out of 136) had no pain 7 days after the procedure, while all patients (136 out of 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 out of 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 to 48 hours after the procedure was reported in 12% (6 out of 50) and 34% (17 out of 50) of patients respectively, and no bleeding after the procedure was reported in 72% (36 out of 50) and 64% (32 out of 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 out of 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 mA to 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 the procedure was reported in 1 patient in a case series of 120 patients treated by electrotherapy with 8 mA to 16 mA direct current; 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, and that patients treated by the low power settings often need repeat procedures.
- 6.2 The Committee noted that there was little evidence about the use of this procedure for grade 4 haemorrhoids.

7 Further information

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the [overview](#).

Information for patients

NICE has produced [information for the public on this procedure](#). 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 [Healthcare Improvement Scotland](#).