NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of 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.

Introduction

The National Institute for Health and Care Excellence (NICE) has prepared this interventional procedure (IP) overview to help members of the Interventional Procedures Advisory Committee (IPAC) make recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This IP overview was prepared in September 2014 and updated in February 2015.

Procedure name

- Electrotherapy for the treatment of haemorrhoids

Specialist societies

- Association of Coloproctology of Great Britain and Ireland.

Description

Indications and current treatment

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).

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). Established interventional treatments include rubber band ligation, sclerosant injections, infrared coagulation or bipolar electrocoagulation using diathermy.

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

What the procedure involves

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. 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. 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.

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to electrotherapy for the treatment of haemorrhoids. The following databases were searched, covering the period from their start to 4 February 2015: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches (see appendix C for details of search strategy). Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

The following selection criteria (table 1) were applied to the abstracts identified by the literature search. Where selection criteria could not be determined from the abstracts the full paper was retrieved.

Table 1 Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies were included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, or a laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising study methodology, unless they reported specific adverse events that were not available in the published literature.
Patient	Patients with haemorrhoids.
Intervention/test	Electrotherapy.
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

List of studies included in the IP overview

This IP overview is based on 2826 patients from 6 randomised controlled trials (RCTs)[1–6], 1 non-randomised comparative study[7] and 2 case series[8–9].

Other studies that were considered to be relevant to the procedure but were not included in the main extraction table (table 2) have been listed in appendix A.

Table 2 Summary of key efficacy and safety findings on electrotherapy for the treatment of haemorrhoids

Study 1 Izadpanah A (2005)

Details

Study type	**RCT**
Country	Iran
Recruitment period	1999–2002
Study population and number	n=**408 (136 electrotherapy with 16 mA direct current versus 136 electrotherapy with 30 mA direct current versus 136 Ferguson haemorrhoidectomy)** patients with symptomatic haemorrhoids grade I, II and III
Age and sex	Mean 43 years; 57% (232/408) male
Patient selection criteria	Patients with haemorrhoids grade I, II, III who had not responded to medical therapy with symptoms of fresh rectal bleeding, itching or prolapse. Exclusion criteria: patients with other anorectal disease (including fissure, fistula, inflammatory bowel disease).
Technique	Ferguson haemorrhoidectomy: spinal or general anaesthesia. No more than 2 haemorrhoids were excised per session. Patients were prescribed meperidin 50 mg IV after the procedure. Electrotherapy using 16 mA: no anaesthesia. Current increased from 0 to 16 mA over 1 min. Duration of electrotherapy maintained for 10 min or until gas bubbles from needle penetration site ceased. Electrotherapy using 30mA: spinal or general anaesthesia. Current increased from 0 to 30 mA in seconds. Duration of electrotherapy: grade I haemorrhoids, 3.5 min; grade II haemorrhoids, 4.5 min; grade III haemorrhoids, 6 min. Patients were prescribed meperidin 50 mg IV after the procedure. All patients were prescribed metronidazole 500 mg, 3 times per day for 5 days and diclofenac 25 mg, 3 times per day to take if they had pain after the procedure.
Follow-up	**36 months**
Conflict of interest/source of funding	Office of Vice Chancellor for Research of Shiraz University of Medical Sciences. (financial support)

Analysis

Follow-up issues: All patients were asked to return to the clinic 1 week, 2 weeks and 2 months after the procedure. After 2 months, patients were told to return to the clinic if they had any complications. If no complications occurred, patients were asked to come back for regular visits every 6 months, for up to 24 months.
Study design issues: Systematic block randomisation. Student's t-test, 1-way and 2-way ANOVA, and Kolmogorov–Smirnov test were used for statistical analysis when appropriate.
Study population issues: No significant difference in the distribution of grades among the 3 groups.
Other issues: None.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **408 (136 electrotherapy with 16 mA direct current versus 136 electrotherapy with 30 mA direct current versus 136 Ferguson haemorrhoidectomy)**

Recurrence rate for the 3 groups and need for haemorrhoidectomy in the electrotherapy groups (up to 36-month follow-up)

	16 mA direct current (n=136)	30 mA direct current (n=136)	Ferguson haemorrhoidectomy (n=136)
Recurrence rate after 1st treatment session	36% (49/136)	7% (9/136)	8% (11/136)
Haemorrhoidectomy rate or treatment failure after further treatment sessions	12%* (6/49)	44%** (4/9)	N/A

*Rate after 2 or 3 treatment sessions with 16 mA direct current
** Rate after 2 treatment sessions with 30 mA direct current

Duration of the procedure

	16 mA direct current (n=136)	30 mA direct current (n=136)	Ferguson haemorrhoidectomy (n=136)
Mean duration of the procedure for 1 haemorrhoid (min)	9.7±1.5	6.1±1.4	23±8

Length of hospital stay

	16 mA direct current (n=136)	30 mA direct current (n=136)	Ferguson haemorrhoidectomy (n=136)
1 day hospital stay (% of patients)	0	98% (133/136)	82% (111/136)
2 days hospital stay or more (% of patients)	0	2% (3/136)	18% (25/136)

Safety

- Electrotherapy using 16mA: 21% of patients who were treated without anaesthesia could not tolerate the procedure because of pain during insertion of the probe in the haemorrhoid and initiation of current.
- Severe bleeding after the procedure requiring reoperation occurred in 3% of patients from the Ferguson haemorrhoidectomy group. No patients in the other 2 groups developed such bleeding requiring surgical control.
- Prolonged non-healing ulcer (6%) and anal stricture (2%) developed in patients from the Ferguson haemorrhoidectomy group. These complications were not reported in the other 2 groups.

Pain score[a] 1 day after the procedure (% of patients)

	16 mA direct current (n=136)	30 mA direct current (n=136)	Ferguson haemorrhoidectomy (n=136)
No pain (score=0)	35% (48/136)	17% (23/136)	0
Mild (score 1-3)	65% (88/136)	0	0
Moderate (score 4-7)	0	48% (65/136)	0
Severe (score 8-10)	0	35% (48/136)	100% (136/136)[b]

[b] p<0.05

Pain score[a] 7 days after the procedure (% of patients)

	16 mA direct current (n=136)	30 mA direct current (n=136)	Ferguson haemorrhoidectomy (n=136)
No pain (score=0)	77.5% (106/136)	85% (116/136)	0
Mild (score 1–3)	15% (20/136)	15% (20/136)	0
Moderate (score 4-7)	7.5% (10/136)	0	0
Severe (score 8-10)	0	0	100% (136/136)[b]

[b] p<0.05

Pain score[a] 14 days after the procedure (% of patients)

	16 mA direct current (n=136)	30 mA direct current (n=136)	Ferguson haemorrhoidectomy (n=136)
No pain (score=0)	100% (136/136)	100% (136/136)	0
Mild	0	0	24% (33/136)

	(score 1-3)			
	Moderate (score 4-7)	0	0	57% (78/136)
	Severe (score 8-10)	0	0	19% (26/136)
	[a]Pain score measured on a 10-point visual analogue scale, with a higher score indicating more severe pain.			
Abbreviations used: CI, confidence interval; RCT, randomised controlled trial; SD, standard deviation				

Study 2 Khan N (2006)

Details

Study type	**RCT**
Country	Pakistan
Recruitment period	2004–2005
Study population and number	n=**102 (50 electrocoagulation (direct current of about 10–20 mA) versus 52 injection sclerotherapy)** patients with grade I or II haemorrhoids.
Age and sex	Mean 44 years; 84% (86/102) male
Patient selection criteria	Only patients entitled to free treatment were included in the study for better follow-up, aged 20–80 years, and with grade I or II haemorrhoids. Exclusion criteria: pregnancy, local infection, immune deficiency, grade III or IV haemorrhoids, haemorrhagic diathesis, patients with pacemakers, history of arrhythmias.
Technique	Electrocoagulation group: direct current of about 10–20 mA applied with a bipolar probe for 5–7 minutes for each haemorrhoid using an electrocoagulation machine (Wieda, China). Injection sclerotherapy group: 1–2 ml of 5% phenol in almond oil injected in the submucosal plane of each haemorrhoid core above the dentate line. After the procedure, all patients had metronidazole for 2 days and bulk laxatives for 1 week, and were advised to increase vegetable intake in diet.
Follow-up	**8 weeks**
Conflict of interest/source of funding	Not reported.

Analysis

Follow-up issues: History taking and proctoscopic examination were done during follow-up visits. At 8-week follow-up, overall patient satisfaction was measured.

Study design issues:

- After the recruitment, patients were randomised into 2 groups (lottery method) and were called 1 by 1, on the given date to the outpatient department for the procedure.
- Chi square test and Fisher's exact test were used.

Study population issues:

- 67% (68/102) of patients had symptoms for more than 6 months; 30% (30/102) of patients for the last 1–3 months; 4% (4/102) of patients, for the last 4-6 months.
- 34% (35/102) of patients had associated local pain, 66% (67/102) of patients had no pain before the procedure.
- All patients had rectal bleeding and 30% (31/102) of patients had associated mucus discharge.
- 79% (81/102) of patients had grade II haemorrhoids and 21% (21/102) had grade I haemorrhoids.

Other issues: None.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **102 (50 versus 52)**

Overall patient satisfaction after 8 weeks

	Electrocoagulation (n=50)	Injection sclerotherapy (n=52)
Not satisfied	4% (2/50)	15% (8/52)
Moderate satisfaction	12% (6/50)	21% (11/52)
Fully satisfied	84% (42/50)	63% (33/52)

Significant difference was observed between groups (p=0.04)

Reduction in bleeding per rectum after 8 weeks

	Electrocoagulation (n=50)	Injection sclerotherapy (n=52)
No effect	6% (3/50)	15% (8/52)
Reduced bleeding	6% (3/50)	17% (9/52)
Fully cured	88% (44/50)	67% (35/52)

Significant difference was observed between groups (p=0.043)

Safety

Pain score during procedure

	Electrocoagulation (n=50)	Injection sclerotherapy (n=52)
Mild* (score 0-3)	30% (15/50)	96% (50/52)
Moderate* (score 4-6)	68% (34/50)	4% (2/52)
Severe* (score 7-10)	2% (1/50)	0

*****Pain score measured on a 10-point visual analogue scale, with a higher score indicating more severe pain.
Significant difference was observed between groups (p<0.001)

Abbreviations used: CI, confidence interval; RCT, randomised controlled trial; SD, standard deviation

Study 3 Azizi R (2010)

Details

Study type	**RCT**
Country	Iran
Recruitment period	2003–2005
Study population and number	n=**100 (50 electrotherapy with 16 mA max direct current versus 50 rubber band ligation)** patients with haemorrhoids.
Age and sex	Range 25–75 years old; 59% (59/100) male
Patient selection criteria	Patients with haemorrhoids. Exclusion criteria: patients with grade IV prolapsed haemorrhoids; presence of pathology in patients over 45 years old; patients who were inaccessible for any reason.
Technique	Patients were prescribed 1 Bisacodyl suppository 1 day before the procedure and on the morning of the day of the procedure. Electrotherapy using 16 mA max direct current (Ultroid): the current intensity was gradually increased until the patient felt discomfort. Then, the intensity was decreased by 1 degree and the current was maintained constant until the end of the procedure. Rubber band ligation: 1–2 rings were used during the procedure. After the procedure, cefixime 400 mg once daily was prescribed for 3 days.
Follow-up	**1 year**
Conflict of interest/source of funding	Not reported.

Analysis

Follow-up issues: Patients were followed-up 1 week and 1 month after having treatment.
Study design issues: Prospective study. Patients were informed about each procedure and 1 procedure was assigned randomly to each patient. Mann–Whitney U and chi-square tests were used.
Study population issues: Major referring symptoms: bleeding, 94% (47/50) of patients in both groups; prolapse, 18% of patients in the electrotherapy group versus 30% in the rubber band ligation group; pain,18% versus 30%; itching, 2% versus 8%; and constipation, none versus 6%. Grades of haemorrhoids in the electrotherapy group: grades I and II, 70% (35/50) of patients; grade III, 30% (15/50) of patients. Grades of haemorrhoids in the rubber band ligation group: grades I and II, 76% (38/50) of patients; grade III, 24% (12/50) of patients (not significant difference between both groups). Mean±SD number of treated haemorrhoids: 2.6±0.5 in the electrotherapy group versus 2.2±0.4 in the rubber band ligation group ($p<0.01$).
Other issues: Two patients with grade IV haemorrhoids were treated by electrotherapy; 1 had a complete response and 1 had no response. Both cases were excluded from the study. Discrepancies were identified in the paper, related to the data on pain after the procedure.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **100 (50 electrotherapy with 16 mA direct current versus 50 rubber band ligation)**

Response to the treatment

	Electrotherapy (n=50)	Rubber band ligation (n=50)
No response (no change in severity, duration, and interval of symptoms)	8% (4/50)	4% (2/50)
Relative response	10% (5/50)	2% (1/50)
Complete response (symptoms disappeared and no recurrence during the follow-up period)	82% (41/50)	94% (47/50)

No significant difference was observed between groups (p=0.2)

Mean treatment time

	Electrotherapy (n=50)	Rubber band ligation (n=50)
Mean treatment time (min)	18±4.1	14.6±1.9

Significant difference was observed between groups (p<0.01)

Safety

Bleeding after the procedure

	Electrotherapy (n=50)	Rubber band ligation (n=50)
No bleeding	72% (36/50)	64% (32/50)
Bleeding 1–24 h after the procedure	6% (3/50)	22% (11/50)
Bleeding 24–48 h after the procedure	6% (3/50)	12% (6/50)
Bleeding 48 h after the procedure	16% (8/50)	2% (1/50)

No significant difference was observed between groups (p=0.5)

Pain during the procedure

	Electrotherapy (n=50)	Rubber band ligation (n=50)
Mild to moderate intraoperative pain (patients felt pressure and pain, but did not have any pain reflex in the area)*	92% (46/50)	62% (31/50)
Painful procedure and retraction of perineal area during the procedure, but the procedure was tolerable	8% (4/50)	38% (19/50)

***Significant difference was observed between groups (p=0.00)**

Pain after the procedure

The results for pain after the procedure, and the tests for statistical significance of this, are described inconsistently in this paper. The figures in this table are the ones in the abstract and main text of the paper.

	Electrotherapy (n=50)	Rubber band ligation (n=50)
No pain	74% (37/50)	72% (36/50)
Mild (if relieved with paracetamol and sitz bath) to moderate pain (if relieved with a nonsteroidal anti-inflammatory drug)	24% (12/50)	26% (13/50)
Severe (if hospitalisation and use of opioid)	2% (1/50)	2% (1/50)

Abbreviations used: RCT, randomised controlled trial; SD, standard deviation.

Study 4 Randall GM (1994)

Details

Study type	**RCT**
Country	USA
Recruitment period	Not reported
Study population and number	n=**100 (50 direct current electrocoagulation 10–16 mA versus 50 bipolar electrocoagulation)** patients with chronic bleeding from internal haemorrhoids
Age and sex	Mean 50 years; 79% (79/100) male
Patient selection criteria	Patients with lower gastrointestinal chronic bleeding from internal haemorrhoids, failure of prior medical management, and availability to be followed as an outpatient. Exclusion criteria: active proctitis, inflammatory bowel disease, rectal wall prolapse, pregnancy, rectal malignancy, prothrombin time greater than 2 seconds above normal, acute hepatitis, abnormal bleeding time, severe thrombocytopenia, thrombocytosis, any other coagulopathy, and severe immunosuppression.
Technique	Electrotherapy of 10-16 mA: Current gradually increased from 0 to 10-16 mA in 2-mA increments. Ultroid. Duration of electrotherapy maintained for 8-10 min. Up to 2 haemorrhoid segments were treated per session. Bipolar probe – BICAP probe. Standard 50-W generator set on a power of 4 to 5. Delivery of 1-second pulses. Four to 6 coagulation pulses per haemorrhoid segment were needed. Two to 3 haemorrhoid segments were treated per session. Patients were prepared with 1 or 2 Fleet enemas before the procedure. No sedation was used. Patients were prescribed suppositories or rectal ointments for 1-2 weeks after each treatment session, bulk agents daily, and stool softeners as needed for constipation. Patients were re-evaluated and treatments were done every 3–4 weeks until treatment success (defined as resolution of haemorrhoidal symptoms and reduction of internal haemorrhoid grade to 0 or 1).
Follow-up	**1 year**
Conflict of interest/source of funding	Research supported in part by research personnel of an NIH NIDDK Grant to CURE and equipment grants from CIRCON-ACMI (BICAP), Microvasive and Cabot (direct current probe).

Analysis

Follow-up issues: Patients were followed-up 3–4 weeks after each session until treatment success. After treatment success was achieved, patients were followed-up with anoscopy every 6 months. If patients could be followed, those with treatment failures (defined as the occurrence of a major complication or persistence of bleeding despite multiple treatments [8 treatments or more without improvement in examination or symptoms]) were offered the other anoscopic treatment or surgery.
Study design issues: Prospective, multicentre study. Patients randomised to direct current or bipolar treatment at the time of the initial anoscopy by opening a sealed envelope.
Study population issues:

- Each study group was comparable for age, sex, years of bleeding, anaemia at presentation, years of medical treatment, prior haemorrhoid treatment or surgery and haemorrhoidal symptoms.
- Maximum haemorrhoid grade that the patients in each group presented with: grade I, 4% of patients in the direct current group and none in the bipolar group; grade II, 36% of patients in the direct current group and 43% in the bipolar group; grade III, 60% of patients in the direct current group and 57% in the bipolar group.
- Percentage of patients with significant anaemia: 19–25%.
- More men were included in the study because 1 of the centres was a Veterans Administration hospital.
- Mean number of years of bleeding before treatment was 12–15 years.
- Mean number of years of medical treatment was 5–6 years.
- Almost 25% of patients had had prior haemorrhoidectomies or other invasive treatments with laser, rubber band ligation, or infrared coagulation.

Other issues: None.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **(50 direct current electrocoagulation 10–16 mA versus 50 bipolar electrocoagulation)**

Mean treatment time

	Direct current (n=50)	Bipolar electrocoagulation (n=50)
Treatment of 2 haemorrhoid segments	16 min	24 s

Significant difference between groups

Number of treatment sessions

	Direct current (n=50)	Bipolar electrocoagulation (n=50)
Mean (±SE) number of sessions for clinical success*	3.1±0.3	3.4±0.4
Range of sessions	2–13	2–8
Mean (±SE) number of sessions to alleviate bleeding	3.0±0.4	3.0±0.4

*****Resolution of haemorrhoidal symptoms and reduction of internal haemorrhoid size to grade 0 or I.

Overall success rate

	Direct current (n=50)	Bipolar electrocoagulation (n=50)
Overall success rate	88% (44/50)	86% (43/50)

Haemorrhoidal symptoms after 1 year

	All patients (n=100)
No symptoms	69%
Mild symptoms	23%
Severe symptoms	8%

Recurrence of symptoms after 1 year

	Direct current (n=50)	Bipolar electrocoagulation (n=50)
Symptom recurrences	34%	29%
Rebleeding	5%	20%

Median time to failure

	Direct current (n=50)	Bipolar electrocoagulation (n=50)
Median time to	8 months	2.7 months

Safety

Complications

	Direct current (n=50)	Bipolar electrocoagulation (n=50)
Mild discomfort (In all patients, mild discomfort resolved immediately after the procedure and was described as tolerable.)	73% (absolute number not given)	88% (44/50)
Major complications (Painful fissure or ulceration, prolonged rectal spasm, severe persistent bleeding, or refusal of further treatment because of discomfort.)	12% (6/50) 3/6 patients were crossed over and had bipolar electrocoagulation with success, 1/6 had surgery with success, and 2/6 refused further treatment.	14% (7/50) 4/7 patients were crossed over with success, 2/7 had surgery with success, 1/7 had persistent bleeding and refused surgery.
Urgent surgery	0	4% (2/50) The 2 patients with very severe bleeding (included in the patients who had major complications) needed transfusions. They had fewer than the mean number of treatments found to relieve bleeding. One had severe angina.

failure		

Mean number of sessions to failure

	Direct current (n=50)	Bipolar electrocoagulation (n=50)
Mean number of sessions to failure	6.5	3.4

99% of patients who completed the course of treatments said they would accept further treatment with the same device if they had a recurrence or were asked again to participate.

Abbreviations used: CI, confidence interval; RCT, randomised controlled trial; SE, standard error.

Study 5 Yang (1993)

Details

Study type	**RCT**
Country	USA
Recruitment period	Not reported
Study population and number	n=**50 (25 direct current 16 mA versus 25 bipolar electrocoagulation)** patients with internal haemorrhoids
Age and sex	Mean 44 years versus mean 53 years; % males not reported.
Patient selection criteria	Patients with bleeding internal haemorrhoids unresponsive to medical therapy.
Technique	Direct current (Microvasive) was gradually increased to a maximum tolerable limit or 16 mA. It was continued for 10 min or until the patient's discomfort became intolerable. Three haemorrhoid segments at most were treated per session. Bipolar electrocoagulation (Circon-ACMI): a maximum of 3 haemorrhoid segments were treated at each session. Settings ranging from 4 to 6 on a standard 50W generator were used.
Follow-up	**Mean 3.6 months**
Conflict of interest/source of funding	Not reported

Analysis

Follow-up issues: Patients were followed-up and treated every 2 to 4 weeks. Length of follow-up in the direct current group: mean 3.6 months. Length of follow-up in the bipolar electrocoagulation group: mean 2.4 months.
Study design issues: Patients with symptomatic haemorrhoids first had medical therapy (including a high-fibre diet, fibre supplementation, topical therapy, and stool softeners). If patients had persistent rectal bleeding after 6 weeks of medical therapy, they were randomly assigned to either group. Patients continued medical therapy throughout the study period. Fisher's exact test was used to analyse proportional data and Wilcoxon's non-paired rank sum test was used to evaluate quantitative data.
Study population issues: Patients treated by bipolar coagulation were significantly older ($p<0.01$). Mean duration of rectal bleeding: 14.1 months versus 19.2 months (p value not reported). Initial haemorrhoid grading did not differ between both groups.
Other issues: None.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **50 (25 direct current 16 mA versus 25 bipolar electrocoagulation)**

Treatment parameters (mean± standard error)

	Direct current (n=25)	Bipolar electrocoagulation (n=25)	p
Treatment time (min)	8.8±0.2	0.1±0.03	<0.001
Number of treatment sessions	3.1±0.6	2.5±0.5	0.40

Treatment success[a]

	Direct current (n=25)	Bipolar electrocoagulation (n=25)	p
Success rate	88%	92%	NS

[a]Obliteration of the haemorrhoids or reduction of the haemorrhoids to a size of grade I without further bleeding

Treatment failures****

	Direct current (n=25)	Bipolar electrocoagulation (n=25)	p
Uncontrollable bleeding necessitating blood transfusions and eventual surgical intervention	4% (1/25)**	8% (2/25)***	1
Refusal to continue therapy due to pain	8% (2/25)	0	0.49

**Patient had grade III haemorrhoids
***Patients had grade II haemorrhoids
****Patients who continued to bleed despite 6 treatment sessions, who had uncontrollable bleeding requiring blood transfusions or surgical intervention, or who refused to continue the study because of intolerable procedural pain.

Recurrence

	Direct current (n=25)	Bipolar electrocoagulation (n=25)	p
Number of patients with recurrent rectal bleeding	1 patient after 4 months. He had further treatment twice at 2-	1 patient after 12 months. He had further treatment. No recurrence was reported after 2 months of additional	NS

Safety

Complications

	Direct current (n=25)	Bipolar electrocoagulation (n=25)	Difference	p
Ulcerations	4% (1/25)	24% (6/25)	20% (95% CI, 2% to 38%)	0.10
Procedural pain terminating therapy	20% (5/25)	0	20% (95% CI, 4% to 36%)	0.05
Prolonged pain (>1 day after therapy)	16% (4/25)*	4% (1/25)	12% (95%CI, -4% to 28%)	0.35

*2 of those patients noted procedural pain.

	weeks intervals. No recurrence was reported after 3 months of additional follow-up.	follow-up.			

Abbreviations used: CI, confidence interval; NS, not significant; RCT, randomised controlled trial.

Study 6 Hinton CP (1990)

Details

Study type	**RCT**
Country	Australia
Recruitment period	Not reported
Study population and number	n=**50 (26 direct current therapy of 16 mA max versus 24 bipolar diathermy)** patients with symptomatic haemorrhoids of at least third degree
Age and sex	64% (32/50) male; age not reported
Patient selection criteria	Patients with symptomatic haemorrhoids of at least third degree.
Technique	Direct current therapy: Ultroid. Current was increased slowly to the maximum tolerable level up to 16 mA and treatment was continued for up to 10 minutes. One haemorrhoid was treated per session. Remaining haemorrhoids were treated at successive sessions and, if necessary, any haemorrhoid that had not resolved after 1 treatment was retreated. Haemorrhoids not successfully treated after 2 sessions were considered treatment failures. Successful treatment was defined by the resolution of symptoms and shrinkage of visible haemorrhoidal tissue. Bipolar diathermy: Bicap. All visible haemorrhoidal tissue was treated at each session, but care was taken to avoid circumferential injury.
Follow-up	**None**
Conflict of interest/source of funding	Not reported

Analysis

Follow-up issues: None.
Study design issues: Consecutive patients randomised to have 1 or the other treatment.
Study population issues: None
Other issues: None

Key efficacy and safety findings

<table>
<tr><td>Efficacy</td><td>Safety</td></tr>
<tr><td>Number of patients analysed: 50 (26 direct current therapy of 16 mA max versus 24 bipolar diathermy)

Treatment success
<table>
<tr><td></td><td>Direct current therapy (n=26)</td><td>Bipolar diathermy (n=24)</td></tr>
<tr><td>Successful treatment
(% of patients)</td><td>76% (20/26)*</td><td>83% (20/24)*</td></tr>
<tr><td>Successful treatment after crossover (n=10)
(% of patients)</td><td>25% (1/4)**</td><td>50% (3/6)**</td></tr>
</table>
*p=not significant
** The remaining 6 patients were treated by conventional surgical methods.
Mean number of treatments and mean treatment time
<table>
<tr><td></td><td>Direct current therapy (n=26)</td><td>Bipolar diathermy (n=24)</td></tr>
<tr><td>Mean number of treatments</td><td>2.5</td><td>2</td></tr>
<tr><td>Mean treatment time</td><td>8.5 min</td><td><1 min</td></tr>
</table></td><td>No significant complications in either group.</td></tr>
<tr><td colspan="2">Abbreviations used: RCT, randomised controlled trial</td></tr>
</table>

Study 7 Zinberg SS (1989)

Details

Study type	**Non-randomised comparative study**
Country	USA
Recruitment period	Not reported
Study population and number	n=**758 (192 direct electric current [8–16mA] versus 302 infrared coagulation versus 264 heater probe coagulation)** patients with symptomatic haemorrhoids
Age and sex	Not reported
Patient selection criteria	Symptomatic haemorrhoids not responsive to conservative therapy with a high-fibre diet. Only internal haemorrhoids were treated. Exclusion criteria: colonic disease such as inflammatory bowel disease, colon polyps, or colon malignancies.
Technique	Outpatient basis. Some patients were sedated. Number of treatment sessions/patient for the 3 procedures: 1–5 (most patients needing 2–3). Infrared coagulation: 1.5 s pulse. 3–5 applications/session, depending on the size of the haemorrhoids. Sessions done at 2-week intervals. Heater probe: 25 joules/pulse. Mean 5 pulses applied/patient (range 2–7). Session intervals: 10 days to 2 weeks. Direct current therapy: 8–16 mA for a period of 8–10 min using the Ultroid device. Sessions done at 2-week intervals.
Follow-up	**Range 4–24 months**
Conflict of interest/source of funding	Not reported

Analysis

Follow-up issues: Follow-up varied according to the procedures (12–24 months for infrared coagulation; 6–12 months for heater probe; 4–8 months for direct current therapy).
Study design issues: Consecutive patients.
Study population issues:

- 90% (682/758) of patients were sedated with meperidine and midazolam intravenously; 10% (76/758) had no medication.
- Grade of haemorrhoids for patients treated by infrared coagulation: I, 50% (152/302) of patients; II, 45% (136/302) of patients; III, 4% (13/302) of patients; IV, 1 patient.
- Grade of haemorrhoids for patients treated by heater probe coagulation: I, 67% (178/264) of patients; II, 26% (69/264) of patients; III, 6% (17/264) of patients; IV, none.
- Grade of haemorrhoids for patients treated by electrotherapy: I, 30% (58/192) of patients; II, 57% (109/192) of patients; III, 11% (21/192) of patients; IV, 2% (4/192) of patients.

Other issues: None.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **758 (192 versus 302 versus 264)**

Complete resolution of symptoms (good results)

Haemorrhoid grade	Electrotherapy (n=192)	Infrared photocoagulation (n=302)	Heater probe coagulation (n=264)
Grade I	100% (58/58)	97% (148/152)	95.5% (170/178)
Grade II	93% (101/109)	96% (131/136)	88% (61/69)
Grade III	85% (18/21)	23% (3/13)	6% (1/17)
Grade IV	0 (0/4)	0 (0/1)	0 (0/0)

Improvement in symptoms but minor discomfort or occasional spotting left (fair results)

Haemorrhoid grade	Electrotherapy (n=192)	Infrared photocoagulation (n=302)	Heater probe coagulation (n=264)
Grade I	0 (0/58)	3% (4/152)	4.5% (8/178)
Grade II	7% (8/109)	3% (4/136)	12% (8/69)
Grade III	9.5% (2/21)	70% (9/13)	88% (15/17)
Grade IV	75% (3/4)	100% (1/1)	0 (0/0)

Number of patients requiring surgery

Haemorrhoid grade	Electrotherapy (n=192)	Infrared photocoagulation (n=302)	Heater probe coagulation (n=264)
Grade I	0 (0/58)	0 (0/152)	0 (0/178)
Grade II	0 (0/109)	1 patient (1/136)	0 (0/69)
Grade III	1 patient (1/21)	1 patient (1/13)	1 patient (1/17)
Grade IV	1 patient (1/4)	0 (0/1)	0 (0/0)

Safety

Pain

Haemorrhoid grade	Electrotherapy (n=192)	Infrared photocoagulation (n=302)	Heater probe coagulation (n=264)
Grade I	2% (1/58)	20% (31/152)	10% (17/178)
Grade II	3% (3/109)	38% (52/136)	9% (6/69)
Grade III	33% (7/21)	38.5% (5/13)	12% (2/17)
Grade IV	100% (4/4)	100% (1/1)	0 (0/0)
All grades	8% (15/192)	29% (89/302)	9% (25/264)

Bleeding

Haemorrhoid grade	Electrotherapy (n=192)	Infrared photocoagulation (n=302)	Heater probe coagulation (n=264)
Grade I	2% (1/58)	19% (29/152)	9% (16/178)
Grade II	2% (2/109)	20% (27/136)	10% (7/69)
Grade III	9.5% (2/21)	31% (4/13)	12% (2/17)
Grade IV	25% (1/4)	100% (1/1)	0 (0/0)
All grades	3% (6/192)	20% (61/302)	9% (25/264)

Study 8 Izadpanah (2004)

Details

Study type	**Case series**
Country	Iran
Recruitment period	1995–2002
Study population and number	n=**931 (27–30 mA direct current)** patients with symptomatic haemorrhoids not responding to medical treatment.
Age and sex	41% (382/931) male Age not reported.
Patient selection criteria	Patients with fresh rectal bleeding or reducible prolapsed haemorrhoid with no response to medical treatment. Exclusion criteria; patients with grade IV haemorrhoids, anal fissures, previous anorectal operations or any other anorectal diseases.
Technique	Under general or spinal anaesthesia upon anaesthesiologist's preference, direct current of 27–30 mA was used. Treatment duration for grade I haemorrhoids: 4.5 min, grade II: 5.5 min, grade III: 7 min. All haemorrhoids were attempted to be treated in the 1st session. If a skin tag was present, it was excised. Patients were discharged a few hours after the procedure except for those who had surgical or medical problems. No antibiotic was prescribed. All patients had 1 injection of 50 mg pethidine after the procedure.
Follow-up	**Mean 4 years**
Conflict of interest/source of funding	Office of Vice Chancellor for Research of Shiraz University of Medical Sciences. (financial support)

Analysis

Follow-up issues: Two weeks and 2 months later, patients had follow-up. After 2 weeks, if symptoms resolved, patients were asked to refer to the clinic if any signs or symptoms were present.
Study design issues: Patient satisfaction assessed with non-standard composite score of other measures.
Study population issues: In total 2015 haemorrhoids were treated; 16% (319/2015) grade I, 57% (1158/2015) grade II, 27% (538/2015) grade III.
Other issues: None.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **931**

Treatment response

	Direct current therapy (n=931)
% of patients with good response	97% (904/931)
% of patients with no response (patients who returned with fresh rectal bleeding or prolapsed haemorrhoid 2 weeks to 2 months after the procedure)	3% (27/931)*

*89% (24/27) patients had further treatment by electrotherapy and 11% (3/27) were treated by haemorrhoidectomy. Out of 24, 9 patients continued bleeding or the haemorrhoids did not disappear and therefore were treated by haemorrhoidectomy.

Hospital length of stay

	Direct current therapy (n=931)
% of patients discharged on the day of the procedure	96% (890/931)
% of patients who stayed in hospital for 2–5 days (mean 2.7 days) due to surgical complications	4% (41/931)*

Recurrence (follow-up 1–7 years)

	Direct current therapy (n=931)
% of referrals due to anal pain, bleeding and itching	8% (71/931)
% of patients with new grade I–II haemorrhoids	6% (52/931)
% of patients with anal fissures	2% (17/931)
% of patients with nonspecific colitis	0.2% (2/931)

Return to normal activity

	Direct current therapy (n=931)
% of patients who went back to work after 2 days	93%
% of patients who went back to work after 2–6 days	5%
% of patients who had to stay at home up to 2 weeks due to pain and discomfort	2%

Patient satisfaction*

Score	Direct current therapy (n=931) % of patients
Score 4 (1–4=very poor satisfaction)	1%
Score 5–8 (poor satisfaction)	3%
Score 9–12 (good satisfaction)	18%

Safety

Pain after the procedure

	Direct current therapy (n=931) % of patients
No pain and no need for analgesia 6h after the procedure	52%
No pain and no need for analgesia 24h after the procedure	92%
Mild pain* for the first 24h	40% (372/931)
Mild pain* for 2-8 days	8% (82/931)
Mild pain* at day 2	8% (82/931)
Mild pain* at day 3	4%
Mild pain* at day 7	1%
Moderate to severe pain requiring a repeated injection of pethidine in the first 24h	1%

*Pain relieved with 2–3 diclofenac 25 mg tablets or sitz bath)

Bleeding after the procedure

	Direct current therapy (n=931) % of patients
% of patients who reported a few drops of bloody discharge after 5–7 days	43%

Other complication after the procedure

	Direct current therapy (n=931) % of patients
Urine retention	8% (6% of patients needed1 time catheterisation and 2% needed 2–3 times catheterisation).

Score 13–16 (excellent satisfaction)	78%	
* Determined using the criteria of pain, bleeding, status of haemorrhoid and recurrence of the symptoms after the procedure.		

Study 9 Norman DA (1989)

Details

Study type	**Case series**
Country	USA
Recruitment period	Not reported
Study population and number	n=**120** patients with symptomatic internal and mixed haemorrhoid disease treated by direct current electrotherapy (8–16 mA)
Age and sex	Mean 48 years; 62% (74/120) male
Patient selection criteria	Symptomatic haemorrhoids. Exclusion criteria: patients with other disease than haemorrhoids accounting for symptoms.
Technique	Current was increased over a 1–2 minute period to a maximum of 16 mA or to patient tolerance. One or more haemorrhoid segments were treated per session. The highest grade(s) of disease was treated first. If, on evaluation, a previously treated segment revealed any grade of haemorrhoid disease, additional treatment was applied and the data incorporated into that segment. Patients returned for evaluation of prior and additional treatment after 10–14 days. Ultroid system.
Follow-up	**Mean 23 months.**
Conflict of interest/source of funding	Not reported.

Analysis

Follow-up issues: Follow-up data obtained by direct contact. Anoscopy was only performed for diagnosis if patients had symptoms at follow-up.
Study design issues: Consecutive patients.
Study population issues:

- Number of patients with grade of haemorrhoids as maximal disease: I, 9% (11/120) of patients; II, 22% (26/120) of patients; III, 38% (46/120); IV, 31% (37/120).
- Mean duration of symptoms before treatment by electrotherapy: 119 months± 134 months (SD).
- Prior therapy: surgical haemorrhoidectomy, 12.5% (15/120) of patients; medical therapy including topical cream, suppository, or stool bulking agent, 73% (85/120) of patients; injection sclerotherapy, 2% (2/120) of patients; cryosurgery, 1 patient (1/120); rubber band ligation, 1 patient (1/120).

Other issues: None.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **120**

Symptoms and number of treatments required for symptom resolution:

Symptom	Bleeding	Protrusion	Pain	Pruritus
% patients	85	58	52	49
Number of treatments (±SD) for symptom resolution	4.0±3.3	3.9±2.9	3.6±2.3	3.9±2.5

All patients were successfully treated and remained symptom-free after mean 23-month follow-up.

- 82.5% (99/120) of patients had ablation of all haemorrhoid disease

- 17.5% (21/120) of patients had asymptomatic with residual grade I haemorrhoids in 1 or more segments

Safety

- No major complications.
- 1 patient had a vasovagal episode with syncope for 10 s immediately after direct current therapy without sequelae. He subsequently returned for treatment without adverse effects.
- 1 patient had rectal pain after the procedure, relieved in hours with a sitz bath. Subsequent treatment was not associated with post-procedure pain.

Abbreviations used: SD, standard deviation

Efficacy

Treatment success

An RCT 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)[2].

In an RCT 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) of patients 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)[3].

An RCT 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) reported overall treatment success (defined as the resolution of haemorrhoidal symptoms and reduction of internal haemorrhoid grade to 0 or 1) in 88% (44/50) and 86% (43/50) of patients respectively (no significant difference)[4].

An RCT of 50 patients treated by electrotherapy with 16 mA direct current (n=25) or bipolar electrocoagulation (n=25) reported treatment success rates of 88% and 92% respectively (p value not significant). In the electrotherapy group, 8% (2/25) of patients refused to continue therapy due to pain and 1 patient had uncontrollable bleeding and needed blood transfusions and a surgical intervention. In the bipolar electrocoagulation group, 8% (2/25) of patients had uncontrollable bleeding and needed blood transfusions and a surgical intervention[5].

An RCT of 50 patients treated by electrotherapy with 16 mA direct current (n=26) or bipolar diathermy (n=24) reported treatment success in 76% (20/26) and 83% (20/24) of patients respectively (p value not significant). After crossover, 4 additional patients were successfully treated: 1 in the electrotherapy group and 3 in the bipolar diathermy group. The remaining 6 patients were treated by conventional surgical methods[6].

In a non-randomised comparative study of 758 patients treated by either electrotherapy with 8–16 mA direct current (n=192), infrared coagulation (n=302) or heater probe coagulation (n=264), the symptoms completely resolved in 100% (58/58), 97% (148/152) and 96% (170/178) of patients with grade I haemorrhoids respectively; in 93% (101/109), 96% (131/136) and 88% (61/169) of patients with grade II haemorrhoids respectively; in 85% (18/21), 23% (3/13) of patients and 1 patient (1/17) with grade III haemorrhoids respectively; and in none of the patients with grade 4 haemorrhoids. Two patients (out of 192) in the electrotherapy group needed surgery: 1 with grade III and 1 with grade IV haemorrhoids; 2 patients (out of 302) from the infrared coagulation group needed surgery: 1 with grade II and 1 with grade III haemorrhoids; 1 patient (out of 264) in the heater probe coagulation with grade III haemorrhoids needed surgery[7].

A case series of 931 patients treated by electrotherapy with 27–30 mA direct current reported that 97% (904/931) of patients had a good response to the treatment (no symptoms of haemorrhoids up to 2 months after the procedure). Among patients with no response, 89% (24/27) had further treatment by electrotherapy and 11% (3/27) were treated by haemorrhoidectomy; 9 patients out of 24 were still bleeding or still had haemorrhoids and therefore were further treated by haemorrhoidectomy[8].

A case series of 120 patients treated by electrotherapy with 8–16 mA direct current reported that 100% of patients were successfully treated and remained symptom-free after mean 23-month follow-up; 83% (99/120) of patients had ablation of all haemorrhoid disease and 18% (21/120) of patients were asymptomatic with residual grade I haemorrhoids in 1 or more segments[9].

Recurrence of haemorrhoids

An RCT of 408 patients treated by either electrotherapy with 16 mA direct current (n=136), electrotherapy with 30 mA direct current (n=136) or Ferguson haemorrhoidectomy (n=136) reported recurrence rates after the first treatment session of 36% (49/136), 7% (9/136) and 8% (11/136) respectively. The patients with recurrence in the 2 electrotherapy groups had further treatment sessions and 12% (6/49) of these patients in the 16 mA direct current group and 44% (4/9) of these patients in the 30 mA direct current group needed haemorrhoidectomy after 2 or 3 treatment sessions because of treatment failure (no p value reported)[1].

In the RCT 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).[4]

The RCT of 50 patients treated by electrotherapy with 16 mA direct current or bipolar electrocoagulation reported recurrent rectal bleeding in 1 patient in each

group. The patient in the electrotherapy group had recurrent rectal bleeding after 4 months; he had further treatment twice at 2-week intervals and had no recurrence after 3 months of additional follow-up. The patient in the bipolar electrocoagulation group had recurrent rectal bleeding after 12 months; he had further treatment and there was no recurrence after 2 months of additional follow-up[5].

In the 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[8].

Median time to failure

In the RCT of 100 patients treated by electrotherapy (monopolar electrocoagulation with 10–16 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].

Return to normal activity

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 (level of significance not stated and absolute numbers not given)[8].

Patient satisfaction

In the RCT 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: $p=0.04$)[2].

In the case series of 931 patients treated by electrotherapy with 27–30 mA direct current, 78% of patients reported an excellent satisfaction with the procedure, 18% of patients reported a good satisfaction, 3% of patients were poorly satisfied, and 1% were very poorly satisfied. Patient satisfaction was rated from 1 to 16, 1 indicating no satisfaction and 16 an excellent satisfaction, and determined using the criteria of pain, bleeding, status of the haemorrhoid and recurrence of the symptoms[8].

Safety

Pain

Intolerance to the procedure was reported in 21% of patients who were treated by electrotherapy using 16 mA direct current without anaesthesia in an RCT of 408 patients treated by either electrotherapy with 16 mA direct current (n=136), electrotherapy with 30 mA direct current (n=136) or Ferguson haemorrhoidectomy (n=136); insertion of the probe in the haemorrhoid and initiation of current were listed as the causes of the pain. Inconsistent reporting related to the intolerance of the procedure was identified. 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: $p<0.05$)[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 an RCT 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: $p<0.001$)[2].

The procedure was considered painful (with retraction of the perineal area) but tolerable for 8% (4/50) of patients in the electrotherapy group using 16 mA direct current and for 38% (19/50) of patients in the rubber band ligation group in an RCT of 100 patients; 92% (46/50) and 62% (31/50) of patients respectively had mild-to-moderate pain during the procedure (patients felt pressure and pain but did not have pain reflex in the area, $p<0.01$). Severe pain after the procedure was reported in 1 patient in each group; mild-to-moderate pain was reported in 24% (12/50) of patients treated by electrotherapy with 16 mA direct current and 26% (13/50) of patients treated by rubber band ligation, and no pain was reported in 74% (37/50) and 72% (36/50) of patients respectively[3].

Mild discomfort was reported in 73% of patients treated by electrotherapy using 10–16 mA direct current (n=50) and in 88% of patients treated by bipolar electrocoagulation (n=50) in a second RCT of 100 patients[4].

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 an RCT 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)[5].

Pain was reported in 8% (15/192), 29% (89/302) and 9% (25/264) of patients treated by electrotherapy with 8–16mA direct current, infrared coagulation or heater probe coagulation respectively in a non-randomised comparative study of 758 patients[7].

Moderate-to-severe pain needing a repeated injection of pethidine in the first 24 hours after the procedure was reported in 1% of patients in a case series of 931 patients treated by electrotherapy using 27–30 mA direct current (no further details provided)[8].

Rectal pain after the procedure was reported in 1 patient in a case series of 120 patients treated by electrotherapy with 8–16 mA direct current; the pain was relieved in hours with a sitz bath. Further treatment was not associated with pain after the procedure[9].

Rectal bleeding

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 the RCT 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)[3].

Rectal bleeding was reported in 3% (6/192), 20% (61/302) and 9% (25/264) of patients treated by electrotherapy with 8–16 mA direct current, infrared coagulation or heater probe coagulation respectively in the non-randomised comparative study of 758 patients[7].

Rectal bleeding 5–7 days after the procedure (defined as a few drops of bloody discharge) was reported in 43% of patients in the case series of 931 patients treated by electrotherapy using 27–30mA direct current[8].

Rectal ulceration

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 RCT of 50 patients (p=0.10)[5].

Retention of urine

Retention of urine was reported in 8% of patients in the 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)[8].

Vasovagal episode

A vasovagal episode with syncope for 10 seconds immediately after the procedure was reported in 1 patient in the case series of 120 patients treated by electrotherapy with 8–16 mA direct current; the patient had no sequelae and subsequently returned for treatment without any adverse effects[9].

Validity and generalisability of the studies

- Studies using 16 mA direct current and studies using 30 mA direct current were included in the overview.
- Some studies had no follow-up data at all.
- The longest available follow-up was 4 years.
- Some studies had discrepancies in the reported data.
- Not many recent studies were retrieved by the literature search.

Existing assessments of this procedure

Clinical practice guidelines for the treatment of haemorrhoids from the French Health Authority were published in 2001 and are not available in English[10].

Related NICE guidance

Below is a list of NICE guidance related to this procedure. Appendix B gives details of the recommendations made in each piece of guidance listed.

Interventional procedures

- Haemorrhoidal artery ligation. NICE interventional procedure guidance 342 (2010). Available from http://www.nice.org.uk/guidance/IPG342
- Circular stapled haemorrhoidectomy. NICE interventional procedure guidance 34 (2003). Available from http://www.nice.org.uk/guidance/IPG34

Technology appraisals

- Stapled haemorrhoidopexy for the treatment of haemorrhoids. NICE technology appraisal 128 (2007). Available from http://www.nice.org.uk/guidance/TA128

NICE guidelines

- Postnatal care. NICE clinical guideline 37 (2014). Available from http://www.nice.org.uk/guidance/CG37

Specialist advisers' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College. The advice received is their individual opinion and is not intended to represent the view of the society. The advice provided by Specialist Advisers, in the form of the completed questionnaires, is normally published in full on the NICE website during public consultation, except in circumstances but not limited to where comments are considered voluminous, or publication would be unlawful or inappropriate. Six Specialist Adviser Questionnaires for electrotherapy for the treatment of haemorrhoids were submitted and can be found on the NICE website.

Patient commentators' opinions

NICE's Public Involvement Programme sent 50 questionnaires to 1 private practice for distribution to patients who had the procedure (or their carers). NICE received 23 completed questionnaires.

The patient commentators' views on the procedure were consistent with the published evidence and the opinions of the specialist advisers.

Issues for consideration by IPAC

- IPAC may wish to note that differing levels of direct current have been applied in the studies of this technique.
- No ongoing trials.

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8. Izadpanah A, Hosseini SV, Mehrabani D et al. (2004) Assessment of electrotherapy in treatment of hemorrhoids in Southern Iran. Saudi Medical Journal 25:1896-1899.
9. Norman DA, Newton R, and Nicholas GV. (1989) Direct current electrotherapy of internal hemorrhoids: an effective, safe, and painless outpatient approach. American Journal of Gastroenterology 84:482-487.
10. Abramowitz L, Godeberge P, Staumont G et al. (2001) Clinical practice guidelines for the treatment of hemorrhoid diseases. [French] OT - Recommandations pour la pratique clinique sur le traitement de la maladie hemorroidaire. Gastroenterologie Clinique et Biologique.25 (6-7) (pp 674-702), 2001.Date of Publication: 2001. 674-702.

Appendix A: Additional papers on electrotherapy for the treatment of haemorrhoids

The following table outlines the studies that are considered potentially relevant to the IP overview but were not included in the main data extraction table (table 2). It is by no means an exhaustive list of potentially relevant studies.

Article	Number of patients/follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Izadpanah A, Hosseini S, and Mahjoob M. (2010) Comparison of electrotherapy, rubber band ligation and hemorrhoidectomy in the treatment of hemorrhoids: a clinical and manometric study. Middle East Journal of Digestive Diseases 2:9-13.	RCT n=150 (52 electrotherapy with 30mA direct current versus 47 Ferguson haemorrhoidectomy versus 51 rubber band ligation) patients with symptomatic grade II and III haemorrhoids Follow-up =3 months	No significant change in manometric indexes after rubber band ligation and electrotherapy. Patients treated by haemorrhoidectomy had more postoperative pain and itching compared to patients treated by rubber band ligation and electrotherapy.	Main findings of the study are manometric changes which are not clinical outcomes.
Olatoke S, Adeoti M, Agodirin O et al. (2014) Direct current electrotherapy for internal haemorrhoids: Experience in a tertiary health institution. Pan African Medical Journal.18, 2014.Article Number: 145.Date of Publication: 2014.	Case series n=57 Follow-up= mean 16 months	•% of patients who had a successful treatment in 1 session: 86% (49/57) •% of patients with symptomatic residual grade I disease needing more than 1 treatment session: 14% (8/57) •Treatment failure: none •Some patients had dull non-localised rectal aching sensation during the procedure which resolved upon depression of the current. •No other complications occurred during the procedure or follow-up period (16 months).	Larger case series included.
Varma JS, Chung SC, and Li AK. (1991) Prospective randomised comparison of current coagulation and injection sclerotherapy for the outpatient treatment of haemorrhoids. International Journal of Colorectal Disease 6:42-45.	RCT n=51 (23 electrocoagulation 16mA versus 28 sclerotherapy) Follow-up=6 weeks	Sclerotherapy was found significantly less tedious than electrocoagulation by the surgeon ($p<0.001$). More patients complained of discomfort during electrocoagulation but no significant difference in tolerance scores between the 2 groups was reported. Significant benefits reported in both groups after 6 weeks but	Studies with more patients or longer follow-up already included.

		no significant differences in bleeding or prolapse scores between the 2 groups. 3 patients in the electrocoagulation group versus none in the sclerotherapy group refused to have the same treatment again. Patient satisfaction rates of 83% (electrocoagulation) versus 75% (sclerotherapy).	
Wright RA, Kranz KR, and Kirby SL. (1991) A prospective crossover trial of direct current electrotherapy in symptomatic hemorrhoidal disease. Gastrointestinal Endoscopy 37:621-623.	RCT n= 16 (electrotherapy using Ultroid but maximum current amplitude used not stated versus sham) Follow-up= none	No significant difference in the improvement of symptoms between the 2 groups.	Studies with more patients or longer follow-up already included. No detail on the amount of milliamps used in the electrotherapy group.

Appendix B: Related NICE guidance for electrotherapy for the treatment of haemorrhoids

Guidance	Recommendations
Interventional procedures	**Haemorrhoidal artery ligation. NICE interventional procedure guidance 342 (2010)** 1.1 Current evidence on haemorrhoidal artery ligation shows that this procedure is an efficacious alternative to conventional haemorrhoidectomy or stapled haemorrhoidopexy in the short and medium term, and that there are no major safety concerns. Therefore this procedure may be used provided that normal arrangements are in place for clinical governance, consent and audit. **Circular stapled haemorrhoidectomy. NICE interventional procedure guidance 34 (2003)** 1.1 Current evidence on the safety and efficacy of circular stapled haemorrhoidectomy appears adequate to support the use of the procedure, provided that normal arrangements are in place for consent, audit and clinical governance. 1.2 Clinicians wishing to learn circular stapled haemorrhoidectomy should be trained, mentored and monitored, as described in the Association of Coloproctology's consensus document on the procedure (see the Association's website).
Technology appraisals	**Stapled haemorrhoidopexy for the treatment of haemorrhoids. NICE technology appraisal 128 (2007)** This technology appraisal examined the currently available devices for stapled haemorrhoidopexy. The evidence considered refers to the HCS33 circular stapler (models PPH01 and PPH03, Ethicon Endo-Surgery). At the time of the technology appraisal, there was no evidence to make recommendations for the Autosuture stapler with the STRAM kit adaptor. 1.1 Stapled haemorrhoidopexy, using a circular stapler specifically developed for haemorrhoidopexy, is recommended as an option for people in whom surgical intervention is considered appropriate for the treatment of prolapsed internal haemorrhoids.
NICE guidelines	**Postnatal care. NICE clinical guideline 37 (2014).** Physical health and well-being *Haemorrhoids* 1.2.50 Women with haemorrhoids should be advised to take dietary measures to avoid constipation and should be offered

	management based on local treatment protocols. 1.2.51 Women with a severe, swollen or prolapsed haemorrhoid or any rectal bleeding should be evaluated (urgent action).

Appendix C: Literature search for electrotherapy for the treatment of haemorrhoids

Databases	Date searched	Version/files
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	04/02/2015	Issue 2 of 12, February 2015
Database of Abstracts of Reviews of Effects – DARE (Cochrane Library)	04/02/2015	Issue 1 of 4, January 2015
HTA database (Cochrane Library)	04/02/2015	Issue 1 of 4, January 2015
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	04/02/2015	Issue 1 of 12, January 2015
MEDLINE (Ovid)	04/02/2015	1946 to January Week 4 2015
MEDLINE In-Process (Ovid)	04/02/2015	February 03, 2015
EMBASE (Ovid)	04/02/2015	1974 to 2015 Week 05
PubMed	04/02/2015	n/a
JournalTOCS	04/02/2015	n/a

Trial sources searched on 17/09/2014

- National Institute for Health Research Clinical Research Network Coordinating Centre (NIHR CRN CC) Portfolio Database
- Current Controlled Trials *meta*Register of Controlled Trials – *m*RCT
- Clinicaltrials.gov

Websites searched on 17/09/2014

- National Institute for Health and Care Excellence (NICE)
- NHS England
- Food and Drug Administration (FDA) - MAUDE database
- French Health Authority (FHA)
- Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP – S)
- Australia and New Zealand Horizon Scanning Network (ANZHSN)
- Conference websites <<add details>>
- General internet search

The following search strategy was used to identify papers in MEDLINE. A similar strategy was used to identify papers in other databases.

1	Hemorrhoids/
2	(hemorrhoid* or haemorrhoid*).tw.
3	pile*.tw.

4	1 or 2 or 3
5	Electric Stimulation Therapy/
6	Electric Stimulation/
7	Electrocoagulation/
8	(electrotherap* or electrostimul* or electrocoagul*).tw.
9	((electric* or electro*) adj4 (stimul* or current* or coagul* or treat* or therap*)).tw.
10	(direct* adj4 current*).tw.
11	(current* adj4 coagul*).tw.
12	(Hemorrhoidolys* or haemorrhoidolys*).tw.
13	ultroid.tw.
14	5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13
15	4 and 14
16	animals/ not humans/
17	15 not 16