NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of radiofrequency treatment for haemorrhoids

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

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 January 2017.

Procedure name

- Radiofrequency treatment of haemorrhoids

Specialist societies

- Association of Coloproctology of Great Britain and Ireland
- Royal College of Surgeons of England.

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. Small symptomatic haemorrhoids are classified as grade I. If the haemorrhoids are large, they may prolapse out of the anus. Haemorrhoids that prolapse may reduce spontaneously after defaecation (grade II); they may need to be reduced digitally (grade III); or they may not be reducible, remaining continually prolapsed (grade IV).

Grade I and II haemorrhoids may be managed by changes in diet or using 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 symptomatic grade III and IV haemorrhoids include haemorrhoidectomy, stapled haemorrhoidopexy or haemorrhoidal artery ligation and bipolar electrocoagulation using diathermy.

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

What the procedure involves

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

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

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to radiofrequency treatment for haemorrhoids. The following databases were

searched, covering the period from their start to 22 November 2016: 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	Radiofrequency ablation
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 approximately 880 patients (although there may be some patient overlap between the studies) from 5 RCTs and 2 case series[1–7].

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 radiofrequency treatment for haemorrhoids

Study 1 Gupta PJ (2004)

Details

Study type	**Randomised controlled trial**
Country	India
Recruitment period	2001 to 2002
Study population and number	**n=80 (36 radiofrequency treatment versus 44 rubber band ligation)** Patients with grade II haemorrhoids.
Age and sex	Radiofrequency: mean 29 years (range 18 to 62) Rubber band ligation: mean 31 years (range 19 to 65) 65% (52/80) male
Patient selection criteria	Patients with grade II haemorrhoids (defined as haemorrhoids that prolapse during defaecation, cause bleeding from the rectum and get reduced spontaneously after defaecation) were included. Patients with associated anal fissure, anal spasm or infective anal pathologies, such as cryptitis or proctitis, were excluded from the study.
Technique	All the procedures were done as office procedures, using local anaesthetic. Radiofrequency: the Ellman Dual frequency 4 MHz radiofrequency generator was used (Ellman International Inc., US). Haemorrhoids at all 3 principle positions (that is, at 3, 7 and 11 o'clock) were treated one after the other. The largest haemorrhoid was dealt with first. The mean treatment duration was 3 minutes, ranging from 2 to 5 minutes. Rubber band ligation: patients were sent home 1 hour after the procedure and prescribed a regular dose of laxative. The patients were asked to apply xylocaine 5% ointment locally just before and after defaecation. None of the patients from either group were prescribed analgesics.
Follow-up	**12 months**
Conflict of interest/source of funding	Not reported

Analysis

Follow-up issues: No losses to follow-up were described.

Study design issues: Patients were randomised to 1 of the 2 treatment groups; the method of randomisation is not described. The paper states that postoperative assessment was done by an independent observer who was blinded to the treatment allocation. Pain was measured using a visual analogue scale from 0 (no pain at all) to 10 (the worst pain the patient had ever experienced).

Study population issues: The 2 treatment groups were similar with regard to baseline characteristics. The mean duration of disease was 15 months in the radiofrequency coagulation group and 17 months in the rubber band ligation group.

Other issues: there may be some patient overlap with Gupta PJ, 2005b.

Key efficacy and safety findings

Efficacy	Safety
Number of patients analysed: **80 (36 versus 44)** **Time taken to return to usual activities** • Radiofrequency=2 days • Rubber band ligation=5 days, p=0.051 **Recurrence of bleeding at 1-year follow-up** • Radiofrequency=13.9% (5/36) • Rubber band ligation=6.8% (3/44), p=0.105 **Recurrence of haemorrhoid prolapse at 1-year follow-up** • Radiofrequency=2.8% (1/36) • Rubber band ligation=0% (0/44) **Obliteration of treated haemorrhoids, confirmed by anoscopy, at 1-year follow-up** • Radiofrequency=82% • Rubber band ligation=93%, p=0.004	**Postoperative pain in the first week (visual analogue scale, 0 to 10)** • Radiofrequency=0 to 2 • Rubber band ligation=2 to 4 **Duration of post defaecation pain in the first week** • Radiofrequency=6 minutes • Rubber band ligation=13 minutes, p=0.01 No significant difference was seen after the first week, because pain was negligible in both groups. **Rectal tenesmus at 1-week follow-up** • Radiofrequency=5.6% (2/36) • Rubber band ligation=15.9% (7/44), p=0.019 **Complications** ***Severe pain*** • Radiofrequency=0% (0/36) • Rubber band ligation=4.5% (2/44; both patients returned within 1 day of the procedure complaining about severe pain. The bands were removed.) ***Urinary retention*** • Radiofrequency=0% (0/36) • Rubber band ligation=2.3% (1/44) (The patient was catheterised, which relieved the problem.) ***Post procedure bleeding*** • Radiofrequency=19.4% (7/36) (reported mostly between 5 and 10 days after the procedure, and almost always associated with defaecation) • Rubber band ligation=4.5% (2/44) (reported between 7 and 9 days after the procedure)

Study 2 Filingeri V (2013)

Details

Study type	**Randomised controlled trial**
Country	Italy
Recruitment period	2009 to 2010
Study population and number	**n=27 (12 radiofrequency treatment versus 15 radiofrequency treatment combined with ligation)** Patients with grade II haemorrhoids
Age and sex	Radiofrequency: mean 33 years (range 21 to 43) Rubber band ligation: mean 43 years (range 23 to 49) 59% (16/27) male
Patient selection criteria	Patients with grade II haemorrhoids, confirmed by rectosigmoidoscopy were included. Pregnant women and patients on medications such as anticoagulants or painkillers were excluded.
Technique	All patients had 3 internal haemorrhoidal nodules and a single node was ligated every 15 days, so each patient had 3 procedures in total. A 4 MHz radiofrequency generator was used for the radiofrequency treatment.
Follow-up	**6 months**
Conflict of interest/source of funding	Not reported

Analysis

Follow-up issues: An additional 3 patients were initially randomised but were lost to follow-up (all 3 were assigned to the radiofrequency coagulation group). These patients were not included in the analysis and no details were provided for them.

Study design issues: Primary endpoints were pain, bleeding, patient satisfaction and recurrence. Pain was measured on a scale from 1 (no pain) to 10 (maximum pain). The paper does not describe any power calculations or explain the rationale behind choosing sample size of 30 patients.

Study population issues: All patients had symptoms for at least 6 months before the procedure.

Key efficacy and safety findings

Efficacy	Safety
Number of patients analysed: **27 (12 versus 15)** **Mean satisfaction score during the first 15 days (range 1 to 10)** • Radiofrequency=6.75±2.76 (range 2 to 10) • Radiofrequency combined with ligation=6.08±2.20 (range 3 to 9), p=not significant **Mean satisfaction score at 6 months (range 1 to 10)** • Radiofrequency=6.33±1.96 (range 3 to 10) • Radiofrequency combined with ligation=7.83±2.05 (range 4 to 10), p<0.05 **Complete remission of symptoms at 6 months** • Radiofrequency=66.7% (8/12) • Radiofrequency combined with ligation=86.7% (13/15) Early loss of elastic ligatures (3 days after the procedure)=22.2% (10/45 ligatures); eschars were noted approximately 15 days after the procedure because of the radiofrequency treatment.	**Mean pain score at the end of the procedure (range 1 to 10)** • Radiofrequency=2.08±0.9 (range 1 to 4) • Radiofrequency combined with ligation=2.40±1.5 (range 1 to 7), p=not significant **Mean pain score at the first evacuation (range 1 to 10)** • Radiofrequency=2.16±1.1 (range 1 to 4) • Radiofrequency combined with ligation=2.33±1.17 (range 1 to 5), p=not significant No complications were observed during the study.

Study 3 Filingeri V (2012)

Details

Study type	**Randomised controlled trial**
Country	Italy
Recruitment period	2008 to 2010
Study population and number	**n=75 (39 radiofrequency treatment combined with rubber band ligation versus 36 rubber band ligation alone)** Patients with grade II haemorrhoids
Age and sex	Radiofrequency: mean 41 years (range 23 to 56) Rubber band ligation: mean 37 years (range 21 to 49) 59% (44/75) male
Patient selection criteria	Patients with grade II haemorrhoids, confirmed by rectosigmoidoscopy were included. Pregnant women and patients on medications such as anticoagulants or painkillers were excluded.
Technique	All patients had 3 internal haemorrhoidal nodules and a single node was ligated every 15 days, so each patient had 3 procedures in total. A 4 MHz radiofrequency generator was used for the radiofrequency treatment. All patients were immediately discharged after the procedure.
Follow-up	**6 months**
Conflict of interest/source of funding	Not reported

Analysis

Follow-up issues: An additional 15 patients were initially randomised but were lost to follow-up (6 in the combined radiofrequency treatment group and 9 in the rubber band ligation group). These patients were not included in the analysis and no details were provided for them.

Study design issues: Randomisation was done using sealed envelopes. Primary endpoints were pain, bleeding, patient satisfaction and recurrence. Pain was measured on a scale from 1 (no pain) to 10 (maximum pain). The study did not include a description of any power analysis calculation used to determine the sample size needed to avoid error.

Study population issues: All patients had symptoms for at least 6 months before the procedure.

Key efficacy and safety findings

Efficacy	Safety
Number of patients analysed: **75 (39 versus 36)** **Mean satisfaction score during the first 15 days (range 1 to 10)** • Radiofrequency combined with rubber band ligation=6.72±2.28 (range 3 to 10) • Rubber band ligation=6.61±2.35 (range 3 to 10) **Mean satisfaction score at 6 months (range 1 to 10)** • Radiofrequency combined with rubber band ligation=7.31±2.04 (range 4 to 10) • Rubber band ligation=7.11±2.11 (range 3 to 10) **Complete remission of symptoms at 6 months** • Radiofrequency combined with rubber band ligation=79.5% (31/39) • Rubber band ligation=69.4% (25/36) **Early loss of elastic ligatures (3 days after the procedure)** • Radiofrequency combined with rubber band ligation=18.8% (22/117 ligatures) • Rubber band ligation=17.6% (19/108 ligatures) The authors noted that in these patients at 15 days, eschars were evident in the patients treated by radiofrequency but the procedure was deemed to have failed in those patients treated by rubber band ligation alone.	**Mean pain score at the end of the procedure (range 1 to 10)** • Radiofrequency combined with rubber band ligation=2.13 (range 1 to 7) • Rubber band ligation=2.08 (range 1 to 6) **Mean pain score at the first evacuation (range 1 to 10)** • Radiofrequency combined with rubber band ligation=2.38±1.18 (range 1 to 5) • Rubber band ligation=2.69±1.12 (range 1 to 6) No complications were observed during the study.

Study 4 Gupta PJ (2005a)

Details

Study type	**Case series (retrospective)**
Country	India
Recruitment period	2001–2002
Study population and number	**n=240** Patients with grade I or II haemorrhoids
Age and sex	Mean 34 years (range 19 to 69) 53% (126/240) male
Patient selection criteria	Patients with grade I or II bleeding haemorrhoids, diagnosed by anoscopy were included. Patients with associated anal fissure or infective anal pathologies such as cryptitis or proctitis were excluded.
Technique	An Ellman dual frequency 4 MHz radiofrequency generator was used (Ellman International Inc., US). 5% xylocaine ointment was infused into the anus about 10 minutes before the procedure to reduce the sensitivity of the area. The whole haemorrhoid was treated by rotating the ball electrode of the radiofrequency probe over the haemorrhoid until blanching occurred. Haemorrhoids at all the 3 principal positions were treated 1 after the other, with the largest being treated first. The time taken for each haemorrhoid was 20 to 40 seconds, depending on size. Patients were assessed 1 hour after the procedure and sent home if appropriate. They were advised to apply 5% xylocaine ointment locally just before and after defaecation.
Follow-up	**Mean 18 months (range 15 to 23)**
Conflict of interest/source of funding	Not reported

Analysis

Follow-up issues: 13% (31/240) of patients were lost to follow-up.

Study design issues: An independent observer not belonging to the operating team carried out the assessment of the postoperative findings. Pain was measured using a visual analogue scale from 0 (no pain at all) to 10 (the worst pain the patient had ever experienced).

Study population issues: Of the 240 patients, 197 (82%) had previous conservative treatment, but their symptoms did not respond.

Key efficacy and safety findings

Efficacy	Safety
Number of patients analysed: **240** **Recurrence of bleeding at follow-up (mean 18 months)=15.8% (33/209)** (excluding the patients who were lost to follow-up) On examination, all patients were diagnosed with haemorrhoids. Of the 33 patients, 27 agreed to have repeat radiofrequency treatment. Three of the patients having repeat treatment remained symptomatic and were subsequently treated by band ligation.	**Bleeding in the first 2 weeks=9.6% (23/240)** This occurred most frequently between 5 and 10 days after the procedure and was associated with defaecation. **Heavy bleeding=1.7% (4/240)** The bleeding was spontaneous and not associated with defaecation, occurring in the first week after the procedure. The patients were admitted to hospital and 3 of the 4 had resolution of symptoms after conservative treatment with local compression and haemostatic medication. One patient needed to be examined under general anaesthesia; the active bleeding source was located and secured. **Pain in the anal region=12.1% (29/240)** Intensity of 1 to 2 on the visual analogue scale. The patients were treated with analgesics. **Foul-smelling discharge from the anus=1.7% (4/240)** This resolved without treatment, by the end of the second week after the procedure. **Itching in and around the anal canal=3.8% (9/240)** Resolved spontaneously within a few days. None of the patients developed any infective complications like suppuration in the operated area or perianal inflammation.

Study 5 Gupta PJ (2005b)

Details

Study type	**Randomised controlled trial**
Country	India
Recruitment period	Not reported
Study population and number	**n=60 (28 radiofrequency treatment versus 32 rubber band ligation)** Patients with grade II bleeding haemorrhoids.
Age and sex	Not reported
Patient selection criteria	Patients with grade II bleeding haemorrhoids, diagnosed by anoscopy were included. Patients with associated anal fissure or infective anal pathologies such as cryptitis or proctitis were excluded.
Technique	Radiofrequency treatment: an Ellman dual frequency 4 MHz radiofrequency generator was used (Ellman International Inc., US). The whole haemorrhoid was treated by rotating the ball electrode of the radiofrequency probe over the haemorrhoid until blanching occurred. Haemorrhoids at all the 3 principal positions were treated 1 after the other, with the largest being treated first. The time taken for each haemorrhoid was 20 to 40 seconds, depending on size. Rubber band ligation: done at the 3 principle positions of haemorrhoids. None of the patients from either group were prescribed any analgesics.
Follow-up	**Not reported**
Conflict of interest/source of funding	Not reported

Analysis

Follow-up issues: No losses to follow-up were described.

Study design issues: Blinding was done by sealed envelopes, which were opened by the hospital nurse. The postoperative assessment was done by an independent observer who was not from the operating team. The parameters measured were pain, rectal tenesmus, recurrence of bleeding and patient satisfaction (defined as overall satisfaction with the surgical outcome using a visual analogue scale, 0=dissatisfied, 10=satisfied). The study did not describe any sample size or power calculations.

Study population issues: No details are given with regard to baseline characteristics of patients in the 2 treatment groups.

Other issues: there may be some patient overlap with Gupta PJ, 2004.

Key efficacy and safety findings

Efficacy	Safety
Number of patients analysed: **60 (28 versus 32)** **Recurrence** • Radiofrequency=14.3% (4/28) • Rubber band ligation=6.3% (2/32), p<0.05 **Satisfaction (mean score, visual analogue scale 0 to 10)** • Radiofrequency=9.1 • Rubber band ligation=8.2, p<0.05	**Rectal tenesmus** • Radiofrequency=3.6% (1/28) • Rubber band ligation=18.8% (6/32), p<0.05 **Anal pain (not further described)** • Radiofrequency=7.1% (2/28) • Rubber band ligation=50% (16/32), p<0.05 **Bleeding (not further described)** • Radiofrequency=21.4% (6/28) • Rubber band ligation=12.5% (4/32), p<0.05 **'Vagal' (not further described)** • Radiofrequency, n=0 • Rubber band ligation, n=1

Study 6a Gupta PJ (2002)

Two separate studies were reported in the same paper (study 6a and study 6b)

Details

Study type	**Case series**
Country	India
Recruitment period	1999 to 2000
Study population and number	**n=210** Patients with grade I or II haemorrhoids
Age and sex	Mean 39 years (range 17 to 67) 86% (180/210) male
Patient selection criteria	Patients with grade I or II internal haemorrhoids were selected for inclusion. Patients with grade III or IV haemorrhoids, painful defaecation, associated external haemorrhoids, or associated fissure were excluded.
Technique	An Ellman dual frequency 4 MHz radiofrequency generator was used (Ellman International Inc., US). No anaesthesia was used other than 5% lidocaine ointment for anal canal lubrication. The long ball electrode was applied to the haemorrhoidal masses until shrinkage was achieved. All of the haemorrhoids were treated during a single session. All patients were discharged immediately, except for men older than 55 years or with symptoms of prostatism, who were discharged after ensuring that they had no problem passing urine.
Follow-up	**12 months**
Conflict of interest/source of funding	Not reported

Analysis

Follow-up issues: A total of 17 patients (8%) were lost to follow-up: 6 at 3 months and another 11 at 12 months.

Study design issues: Proctoscopic examination was done at the 3- and 12-month follow-up visits. Data were collected on anal stenosis, anal incontinence, recurrence of haemorrhoids, and degree of relief experienced by patients. Quality of life was assessed by a questionnaire that included parameters such as improvement in general health, increase in appetite, increased sense of well-being, and ease of defaecation.

Study population issues: All patients had rectal bleeding before the procedure, including those with grade I haemorrhoids with bleeding that had not responded to conservative management (n=187). Previous treatment included laxatives, local anaesthetic cream, and drugs such as diosmin. Four female patients were in their second trimester of pregnancy when they were referred for treatment.

Other issues: The paper notes that the radiofrequency device was being used off-label.

Key efficacy and safety findings

Efficacy	Safety
Number of patients analysed: **210** **Return to work** 70% of patients resumed their usual activities after 48 hours; the remaining 30% needed 1 or 2 additional days. **Recurrence of bleeding at 3-month follow-up=1.0% (2/210)** In both patients, the procedure was repeated and symptoms resolved. **Recurrence of bleeding at 12-month follow-up=3.8% (8/210)** In 5 patients, the procedure was repeated and symptoms resolved. The remaining 3 patients refused further treatment. **Asymptomatic recurrence at 12-month follow-up=8.6% (18/210)** On proctoscopic examination, 18 patients had varicosities at the site of treatment, but they were free of any symptoms. No specific treatment was needed. 84% (177/210) of patients experienced near total relief from their symptoms, including anal bleeding, pain and itching. All patients had good faecal continence, which resulted in a perceptible improvement in quality of life.	***Complications within the first 2 weeks of the procedure*** • **Bleeding=8.6% (18/210)** 1 patient had very heavy bleeding, which needed a second procedure. • **Urinary retention=0.5% (1/210)** The patient was 74 years old and had an enlarged prostate; he was catheterised to relieve the symptoms and had no subsequent problems. • **Discharge=16.2% (34/210)** • **Pain=6.7% (14/210)** All patients reported some degree of discomfort in the first 3 days after the procedure, which was relieved by the use of appropriate analgesics. Pain was more commonly reported among patients with larger haemorrhoids or in whom coagulation was done close to the dentate line.

Study 6b Gupta PJ (2002)

Two separate studies were reported in the same paper (study 6a and study 6b)

Details

Study type	**Randomised controlled trial**
Country	India
Recruitment period	Not reported
Study population and number	**n=100 (50 radiofrequency treatment versus 50 infrared coagulation)** Patients with grade I or II haemorrhoids
Age and sex	Not reported
Patient selection criteria	Patients grade I or II bleeding haemorrhoids.
Technique	Radiofrequency treatment: an Ellman dual frequency 4 MHz radiofrequency generator was used (Ellman International Inc., US). Radiofrequency energy was applied directly over the haemorrhoidal masses. Infrared coagulation was done at the pedicle of all 3 principal positions of haemorrhoids (3, 7 and 11 o'clock) in the same session.
Follow-up	**12 months**
Conflict of interest/source of funding	Not reported

Analysis

Follow-up issues: No losses to follow-up were described.

Study design issues: The paper includes very few details of the study. Allocation of patients to each treatment group was randomised, using sealed envelopes that were opened by the surgical nurse upon the patient's arrival for treatment. The paper states that 'results were blinded'.

Study population issues: No details are given with regard to baseline characteristics of patients in the 2 treatment groups.

Key efficacy and safety findings

Efficacy	Safety
Number of patients analysed: **100 (50 versus 50)** **Time off work (days)** • Radiofrequency=2 • Infrared=1 **Overall satisfaction at 1-year follow-up** • Radiofrequency=89% • Infrared=83% **Asymptomatic recurrence at 1-year follow-up** • Radiofrequency=8% • Infrared=16% **Recurrence of bleeding at 1-year follow-up** • Radiofrequency=8% • Infrared=14%	***Outcomes at 2 weeks*** **Pain** • Radiofrequency=8% • Infrared=4% **Bleeding** • Radiofrequency=8% • Infrared=12% **Discharge** • Radiofrequency=10% • Infrared=4% **Retention of urine** • Radiofrequency=2% • Infrared=2%

Study 7a Gupta PJ (2003)

Two separate studies were reported in the same paper (study 7a and study 7b)

Details

Study type	**Case series**
Country	India
Recruitment period	2000 to 2001
Study population and number	**n=50** Patients with grade III (n=30) or IV (n=20) haemorrhoids
Age and sex	Mean 45 years (range 23 to 64) 68% (34/50) male
Patient selection criteria	Patients with grade III or IV haemorrhoids who had been recommended for open haemorrhoidectomy were included.
Technique	An Ellman dual frequency 4 MHz radiofrequency generator was used (Ellman International Inc., US). The procedures were done under general or spinal anaesthesia, depending on the patient. All of the haemorrhoids were treated during a single session. Each procedure was completed in 6 to 8 minutes (with 18 to 46 seconds of radiofrequency treatment for each haemorrhoid). Antibiotics and analgesics were given for the first 10 days after the procedure.
Follow-up	**12 months**
Conflict of interest/source of funding	Not reported

Analysis

Follow-up issues: 12% (6/50) of patients were lost to follow-up at 12 months.

Study design issues: Retrospective case series.

Study population issues: This study focuses on patients with more severe and debilitating haemorrhoids (grade III and IV). The procedure was elective in 45 patients; 5 patients were in the emergency category with acute bleeding and pain. 24% (12/50) of patients had external haemorrhoids as well as internal ones. 8% (4/50) of patients had associated anal fissure. 36% (18/50) of patients had previously been treated by band ligation.

Key efficacy and safety findings

Efficacy	Safety
Number of patients analysed: **50** **Asymptomatic recurrence at 12-month follow-up=9.1% (4/44)** During proctoscopic examination, the patients were found to have varicosities in the treated area. There were no associated symptoms. All of the patients expressed satisfaction with the results of the treatment. 44% (22/50) of patients returned to work within 5 days and the remaining 56% (28/50) returned within 1 week of the procedure. Wound healing was complete in 86% (43/50) of patients by the end of 4 weeks.	***Complications within the first 4 weeks of the procedure*** • **Bleeding=14% (7/50)** (associated with defaecation, no treatment was needed) • **Urinary retention=4% (2/50)** (1 patient had an enlarged prostate, the other had a very large prolapsing haemorrhoid at 11 o'clock that needed coagulation in larger area. It is thought that the treatment may have caused urethral spasm leading to retention of urine. Both patients were catheterised, which relieved the symptoms.) • **Discharge=22% (11/50)** (no treatment needed) • **Pain=100% (50/50)** (subsided within the first 10 postoperative days in 43 patients. No patients complained of pain at the end of 1 month.) None of the patients had sepsis. At 12-month follow-up, 7 patients who had external haemorrhoids had skin tag formation. At 12-month follow-up, there was no anal stenosis or anal incontinence.

Study 7b Gupta PJ (2003)

Two separate studies were reported in the same paper (study 7a and study 7b)

Details

Study type	**Randomised controlled trial**
Country	India
Recruitment period	2001 to 2002
Study population and number	**n=40 (20 radiofrequency treatment versus 20 haemorrhoidectomy by ligation and excision)** Patients with grade III haemorrhoids
Age and sex	Not reported
Patient selection criteria	Patients with prolapsing and bleeding haemorrhoids.
Technique	Radiofrequency: an Ellman dual frequency 4 MHz radiofrequency generator was used (Ellman International Inc., USA). The procedures were done under general or spinal anaesthesia, depending on the patient. All of the haemorrhoids were treated during a single session. Each procedure was completed in 6 to 8 minutes (with 18 to 46 seconds of radiofrequency treatment for each haemorrhoid). Antibiotics and analgesics were given for the first 10 days after the procedure. Comparator: traditional haemorrhoidectomy by ligation and excision (no further details given).
Follow-up	**12 months**
Conflict of interest/source of funding	Not reported

Analysis

Follow-up issues: No losses to follow-up were described.

Study design issues: The paper includes very few details of the study. Allocation of patients to each treatment group was randomised, but there are no further details.

Study population issues: No details are given with regard to baseline characteristics of patients in the 2 treatment groups.

Key efficacy and safety findings

Efficacy	Safety
Number of patients analysed: **40 (20 versus 20)** **Length of hospital stay (hours)** • Radiofrequency=14 • Haemorrhoidectomy=79 **Time off work (days)** • Radiofrequency=5 • Haemorrhoidectomy=21	**Post defaecation pain (days)** • Radiofrequency=6 • Haemorrhoidectomy=13 **Post defaecation bleeding (days)** • Radiofrequency=7 • Haemorrhoidectomy=24 **Secondary haemorrhage** • Radiofrequency, n=0 • Haemorrhoidectomy, n=2 **Incontinence to flatus** • Radiofrequency, n=1 • Haemorrhoidectomy, n=12 **Wound sepsis** • Radiofrequency, n=0 • Haemorrhoidectomy, n=2 **Delayed wound healing** • Radiofrequency, n=1 • Haemorrhoidectomy, n=7 **Stenosis** • Radiofrequency, n=0 • Haemorrhoidectomy, n=5

Efficacy

Length of hospital stay

Most radiofrequency procedures were done as outpatient cases. In a randomised controlled trial (RCT) of 40 patients with grade III or IV haemorrhoids treated by radiofrequency or haemorrhoidectomy, the length of hospital stay was 14 hours and 79 hours respectively[7b].

Resolution of symptoms

In a randomised controlled trial (RCT) of 27 patients with grade II haemorrhoids treated by radiofrequency on its own or combined with ligation, complete remission of symptoms at 6-month follow-up was reported in 67% (8/12) and 87% (13/15) of patients respectively[2].

Time taken to return to usual activities

In an RCT of 80 patients with grade II haemorrhoids treated by radiofrequency or rubber band ligation, the mean time taken to return to work was 2 and 5 days respectively ($p=0.051$)[1]. In the RCT of 40 patients with grade III or IV haemorrhoids, the time off work was 5 days for patients who had radiofrequency treatment and 21 days for patients who had haemorrhoidectomy[7b]. In a case series of 50 patients with grade III or IV haemorrhoids, 44% (22/50) of patients returned to work within 5 days and the remaining 56% (28/50) returned within 1 week of the procedure[7a].

Recurrence of symptoms

In the RCT of 80 patients, recurrence of bleeding at 1-year follow-up was reported in 14% (5/36) of patients who had radiofrequency treatment and 7% (3/44) of patients who had rubber band ligation ($p=0.105$)[1]. Recurrence of haemorrhoid prolapse was reported in 1 patient, who had radiofrequency treatment, in the same study. In an RCT of 60 patients with grade II haemorrhoids treated by radiofrequency or rubber band ligation, recurrence of symptoms was reported in 14% (4/28) and 6% (2/32) of patients respectively ($p<0.05$)[5]. In a case series of 240 patients with grade I or II haemorrhoids, recurrence of bleeding at follow-up (mean 18 months) was reported in 16% (33/209) of patients[4]. In a case series of 210 patients, recurrence of bleeding at 12-month follow-up was reported in 4% (8/210) of patients[6a]. In an RCT of 100 patients who had radiofrequency or infrared coagulation, asymptomatic recurrence was reported in 8% and 16% of patients respectively and recurrence of bleeding was reported in 8% and 14% of patients respectively, at 12-month follow-up[6b]. In the case series of 50 patients with grade III or IV haemorrhoids, asymptomatic recurrence (diagnosed on proctoscopy) was reported in 9% (4/44) of patients at 12-month follow-up[7a].

Shrinkage of visible haemorrhoidal tissue

In the RCT of 80 patients, obliteration of treated haemorrhoids (confirmed by anoscopy) at 1-year follow-up was reported in 82% of patients who had radiofrequency and 93% of patients who had rubber band ligation (p=0.004)[1].

Patient satisfaction

In the RCT of 27 patients, the mean satisfaction score (range 1 to 10, higher scores better) during the first 15 days after the procedure was 6.75±2.76 for radiofrequency treatment alone and 6.08±2.20 for radiofrequency combined with ligation (p=not significant). At 6 months, the mean scores were 6.33±1.96 and 7.83±2.05 respectively (p<0.05)[2]. In the RCT of 60 patients, the mean satisfaction scores (visual analogue scale 0 to 10, higher scores better) were 9.1 and 8.2 respectively (p<0.05; follow-up period not reported)[5] . In the RCT of 100 patients, 89% of patients who had radiofrequency treatment were satisfied compared with 83% of patients who had infrared coagulation[6b]. In the case series of 50 patients, all of the patients expressed satisfaction with the results of the treatment[7a].

Safety

Pain

The postoperative pain score (measured on a visual analogue scale, 0 to 10) in the first week after the procedure ranged from 0 to 2 for patients who had radiofrequency treatment and from 2 to 4 for patients who had rubber band ligation in a randomised controlled trial (RCT) of 80 patients[1]. Duration of post-defaecation pain in the first week was 6 minutes in the radiofrequency treatment group compared with 13 minutes in the rubber band ligation group (p=0.01) in the same study. The mean pain score at the end of the procedure (range 1 to 10) was 2.08±0.9 (range 1 to 4) for patients who had radiofrequency alone and 2.40±1.5 (range 1 to 7) for patients who had radiofrequency combined with ligation (p=not significant) in an RCT of 27 patients[2]. The mean pain scores at the first evacuation (range 1 to 10) were 2.16±1.1 (range 1 to 4) and 2.33±1.17 (range 1 to 5) respectively, p=not significant, in the same study. Pain in the anal region was reported in 12% (29/240) of patients in a case series of 240 patients; the pain intensity was scored 1 to 2 on the visual analogue scale and the patients were treated with analgesics[4]. Anal pain (not further described) was reported in 7% (2/28) of patients who had radiofrequency treatment and 50% (16/32) of patients who had rubber band ligation in an RCT of 60 patients (p<0.05)[5]. Pain was reported in 100% (50/50) of patients in a case series of 50 patients; this subsided within the first 10 postoperative days in 43 patients and no patients complained of pain at the end of 1 month[7a]. Post-defaecation pain continued for 6 days after radiofrequency treatment and 13 days after haemorrhoidectomy in an RCT of 40 patients[7b].

No patients treated by radiofrequency and 2 patients treated by rubber band ligation reported severe pain (both patients returned within 1 day of the procedure complaining about severe pain and the bands were removed) in the RCT of 80 patients[1].

Bleeding

Bleeding after the procedure was reported in 19% (7/36) of patients who had radiofrequency treatment (reported mostly between 5 and 10 days after the procedure, and almost always associated with defaecation) and 5% (2/44) of patients who had rubber band ligation (reported between 7 and 9 days after the procedure)[1]. Bleeding in the first 2 weeks was reported in 10% (23/240) of patients in the case series of 240 patients; this occurred most frequently between 5 and 10 days after the procedure and was associated with defaecation[4]. Heavy bleeding was reported in 2% (4/240) of patients in the same study; the bleeding was spontaneous and not associated with defaecation, occurring in the first week after the procedure. The patients were admitted to hospital and 3 of the 4 had resolution of symptoms after conservative treatment with local compression and haemostatic medication. One patient needed to be examined under general anaesthesia; the active bleeding source was located and secured. Bleeding (not further described) was reported in 21% (6/28) of patients who had radiofrequency treatment and 13% (4/32) of patients treated by rubber band ligation ($p<0.05$) in the RCT of 60 patients[5]. Bleeding within the first 4 weeks of the procedure was reported in 14% (7/50) of patients in the case series of 50 patients; this was associated with defaecation and no treatment was needed[7a]. Post defaecation bleeding continued for 7 days after radiofrequency treatment and for 24 days after haemorrhoidectomy in the RCT of 40 patients[7b]. Heavy bleeding was reported in 1 patient in a case series of 210 patients; the patient had a second procedure[6a].

Urinary retention

Urinary retention was reported in 4% (2/50) of patients in a case series of 50 patients; 1 patient had an enlarged prostate, the other had a very large prolapsing haemorrhoid at 11 o'clock that needed treatment over a larger area. It is thought that the treatment may have caused urethral spasm leading to retention of urine. Both patients were catheterised, which relieved the symptoms[7a]. Urinary retention was reported in 1 patient in the case series of 210 patients; the patient had an enlarged prostate and was catheterised to relieve the symptoms[6a].

Rectal tenesmus

Rectal tenesmus at 1-week follow-up was reported in 6% (2/36) of patients who had radiofrequency treatment and 16% (7/44) of patients who had rubber band ligation ($p=0.019$)[1]. Rectal tenesmus was reported in 4% (1/28) of patients who

had radiofrequency treatment and 19% (6/32) of patients who had rubber band ligation ($p<0.05$) in the RCT of 60 patients[5].

Discharge

A foul-smelling discharge from the anus was reported in 2% (4/240) of patients in the case series of 240 patients[4]. This resolved without treatment, by the end of the second week after the procedure. Discharge was reported in 22% (11/50) of patients in the case series of 50 patients, no treatment was needed[7a]. Discharge was reported in 16% (34/210) of patients in the first 2 weeks after the procedure, in the case series of 210 patients[6a]. This was attributed to the sloughing of the coagulated haemorrhoidal mass.

Itching

Itching in and around the anal canal was reported in 4% (9/240) of patients in the case series of 240 patients[4]. This resolved spontaneously within a few days.

Skin tag formation

Skin tag formation at 12-month follow-up was reported in 7 patients who had external haemorrhoids, in the case series of 50 patients[7a].

Incontinence to flatus

Incontinence to flatus was reported in 1 patient who had radiofrequency treatment and 12 patients who had haemorrhoidectomy in the RCT of 40 patients[7b].

Delayed wound healing

Delayed wound healing was reported in 1 patient who had radiofrequency treatment and 7 patients treated by haemorrhoidectomy in the RCT of 40 patients[7b].

Validity and generalisability of the studies

- Most of the evidence comes from a single centre in India, and there may be some patient overlap between the studies. The results may not be generalisable to other treatment centres. There are no published data on patients treated in the UK.
- Only 2 of the studies include patients with grade III or IV haemorrhoids[7a, 7b].
- Only 1 study included follow-up longer than 12 months[4].

- All of the identified published literature relates to 1 particular device, but there is another device currently in use.

Existing assessments of this procedure

There were no published assessments from other organisations identified at the time of the literature search.

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

- Electrotherapy for the treatment of haemorrhoids. NICE interventional procedure guidance 525 (2015). Available from http://www.nice.org.uk/guidance/IPG525
- 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 up to 8 weeks after birth. NICE clinical guideline 37 (2006, last updated 2015). 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. One Specialist Advisor Questionnaires for radiofrequency treatment of haemorrhoids was submitted and can be found on the NICE website.

Patient commentators' opinions

NICE's Public Involvement Programme will send questionnaires to NHS trusts for distribution to patients who had the procedure (or their carers). When NICE has received the completed questionnaires, these will be discussed by the committee.

Company engagement

A structured information request was sent to 4 companies who manufacture or distribute a potentially relevant device for use in this procedure. NICE received 2 completed submissions. These were considered by the IP team and any relevant points have been taken into consideration when preparing this overview.

Issues for consideration by IPAC

- Radiofrequency is also used in conjunction with other techniques such as suture ligation to treat haemorrhoids and as part of a traditional haemorrhoidectomy. In this overview, studies were only included if the radiofrequency was applied directly to the haemorrhoid itself, with no adjunctive technique such as plication.
- All the published evidence that was identified for this procedure related to a single radiofrequency device.

References

1. Gupta PJ (2004) Radiofrequency coagulation versus rubber band ligation in early haemorrhoids: pain versus gain. Medicina 3: 232–7
2. Filingeri V, Angelico R, Bellini MI et al. (2013) Ambulatory therapy with combined hemorrhoidal radiocoagulation. European Review for Medical & Pharmacological Sciences 17: 130–3
3. Filingeri V, Angelico R, Bellini MI et al. (2012) Prospective randomised comparison of rubber band ligation (RBL) and combined hemorrhoidal radiocoagulation (CHR). European Review for Medical & Pharmacological Sciences 16: 224–9
4. Gupta PJ (2005) Radiofrequency coagulation: a new option in early grades of bleeding hemorrhoids. Bratislavske Lekarske Listy 106: 274–8
5. Gupta PJ (2005) Ambulatory hemorrhoid therapy with radiofrequency coagulation. Clinical practice paper. Romanian Journal of Gastroenterology 14: 37–41
6. Gupta PJ (2002) Novel technique: radiofrequency coagulation--a treatment alternative for early-stage hemorrhoids. Medscape General Medicine 4 (3)
7. Gupta PJ (2003) Radio-ablation of advanced grades of hemorrhoids with radiofrequency. Current Surgery 60: 452–8

Appendix A: Additional papers on radiofrequency treatment for 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
Simillis C, Thoukididou SN, Slesser AA et al. (2015) Systematic review and network meta-analysis comparing clinical outcomes and effectiveness of surgical treatments for haemorrhoids. British Journal of Surgery 102: 1603–18	Systematic review 98 RCTs (7827 patients with grade III or IV haemorrhoids) 11 surgical treatments	Open and closed haemorrhoidectomies resulted in more postoperative complications and slower recovery, but fewer haemorrhoid recurrences. Transanal haemorrhoidal dearterialisation and stapled haemorrhoidectomies were associated with decreased postoperative pain and faster recovery, but higher recurrence rates. The advantages and disadvantages of each surgical treatment should be discussed with the patient before surgery to allow an informed decision to be made.	The systematic review did not include any studies that applied radiofrequency energy directly into or onto the haemorrhoid itself, without any other intervention. Four studies were included that described haemorrhoidectomy done with a radiofrequency device.

Appendix B: Related NICE guidance for radiofrequency treatment for haemorrhoids

Guidance	Recommendations
Interventional procedures	**Electrotherapy for the treatment of haemorrhoids. NICE interventional procedure guidance 525 (2015).** 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 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.
	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).** Stapled haemorrhoidopexy is recommended as a possible treatment for people with prolapsed internal haemorrhoids if: • it is carried out with a circular stapler designed for treating haemorrhoids in this way • surgery is considered to be a suitable treatment for their condition.
NICE guidelines	**Postnatal care up to 8 weeks after birth. NICE clinical guideline 37 (2006, last updated 2015).** 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. [2006] 1.2.51 Women with a severe, swollen or prolapsed haemorrhoid or any rectal bleeding should be evaluated (urgent action). [2006]

Appendix C: Literature search for radiofrequency treatment for haemorrhoids

Databases	Date searched	Version/files
Cochrane Database of Systematic Reviews – CDSR (Cochrane)	22/11/2016	Issue 11 of 12, November 2016
HTA database (Cochrane)	22/11/2016	Issue 4 of 4, October 2016
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane)	22/11/2016	Issue 10 of 12, October 2016
MEDLINE (Ovid)	22/11/2016	1946 to November Week 2 2016
MEDLINE In-Process (Ovid)	22/11/2016	November 16, 2016
EMBASE (Ovid)	22/11/2016	1974 to 2016 Week 47
PubMed	22/11/2016	n/a
BLIC (British Library)	22/11/2016	n/a

Trial sources searched on 18 October 2016

- Clinicaltrials.gov
- ISRCTN
- WHO International Clinical Trials Registry

Websites searched on 18 October 2016

- National Institute for Health and Care Excellence (NICE)
- NHS England
- Food and Drug Administration (FDA) - MAUDE database
- Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP – S)
- Australia and New Zealand Horizon Scanning Network (ANZHSN)
- EuroScan
- 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/ or Hemorrhoidectomy/
2	(hemorrhoid* or haemorrhoid*).tw.
3	pile*.tw.
4	1 or 2 or 3

5	Ablation Techniques/
6	Catheter Ablation/
7	((catheter* or prob* or needle* or electrod* or heat*) adj4 (coagulat* or ablat*)).tw.
8	((radiofrequen* or radio-frequen* or "radio frequen*") adj4 (coagulat* or ablat* or energy)).tw.
9	(RF adj4 (ablat* or coagulat* or energy)).tw.
10	(RFA or RFC or CHR).tw.
11	Radio Waves/ or Radiosurgery/
12	(radiosurger* or radio-surger* or "radio surger*").tw.
13	(thermocoagulat* or thermo-coagulat*).tw.
14	((high-frequenc* or high frequenc* or alternat*) adj4 current*).tw.
15	(current* adj4 coagul*).tw.
16	(radiocoagulat* or radio-coagulat* or "radio coagulat*" or radioablat* or radio-ablat* or "radio ablat*").tw.
17	or/5-16
18	(rafaelo or HPR45i or "HET bipolar" or evrf or ligasure or (ellman* adj3 generat*) or enseal).tw.
19	17 or 18
20	4 and 19
21	animals/ not humans/
22	20 not 21