NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of superior rectal artery embolisation for haemorrhoids

Haemorrhoids (piles) are enlarged blood vessels inside or around the anal canal (back passage). In this procedure, a tube (catheter) is used to place small coils or particles into blood vessels supplying the area. This blocks them and reduces blood supply to the haemorrhoids. The aim is to shrink them, so relieving symptoms such as pain and bleeding.

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Introduction

The National Institute for Health and Care Excellence (NICE) prepared this interventional procedure 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 overview was prepared in January 2018.

Procedure name

• Superior rectal artery embolisation for haemorrhoids.

Specialist societies

- Association of Coloproctology of Great Britain and Ireland
- British Society of Interventional Radiology
- Pelvic Floor Society
- Royal College of Radiologists.

Description of the procedure

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. Goligher's classification is commonly used to grade haemorrhoids from I to IV. Small symptomatic haemorrhoids are classified as grade I and they do not prolapse. Larger haemorrhoids may prolapse out of the anus. Prolapsed haemorrhoids 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 electrocoagulation.

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

What the procedure involves

Superior rectal artery embolisation for haemorrhoids is done under local anaesthesia. A catheter is passed into the inferior mesenteric artery through an introducer sheath in a large artery (usually the femoral artery). A microcatheter is then passed into the superior rectal arteries using X-ray fluoroscopy to confirm correct placement and to identify the branches of the superior rectal artery. Small

IP overview: superior rectal artery embolisation for haemorrhoids Page 2 of 15 coils (about 2 mm to 3 mm in diameter) and/or particles are placed into the most distal branches of the superior rectal arteries, to occlude the blood supply to the haemorrhoids.

The aim is to occlude permanently the branches that feed the haemorrhoidal plexuses and relieve the symptoms associated with haemorrhoids, such as pain and bleeding.

Efficacy summary

Symptom improvement

In a case series of 30 patients, there was a statistically significant improvement in the median French bleeding severity score (range 0 to 9, lower scores better), from 7 before the procedure to 4 after the procedure (p<0.0001; median follow-up 5 months). The general symptoms score improved from 12 to 6 (p<0.0001). The clinical success rate (defined as improvement of at least 2 points on the French bleeding severity score) was 72% (21/29).¹

In a case series of 40 patients, bloody discharge stopped in 75% (30/40) of patients on the first day after embolisation and in 15% (6/40) of patients on the second day; 10% (4/40) of patients (all with grade III haemorrhoids) continued to have some bloody smearing for 5 to 7 days after the procedure. General patient satisfaction (with regard to resolution of irritation, discomfort, bloody discharge and pain) was 94% (32/34) for patients with grade I or II haemorrhoids and 83% (5/6) for patients with grade III haemorrhoids.²

In a case series of 14 patients, clinical success at follow-up (mean 192 days) was 72% (10/14). Of the first 6 patients, who had only partial embolisation, rebleeding was reported in 4. Two patients had additional embolisation of the posterior rectal arteries and 2 patients declined additional treatment. Of the 2 patients who had additional treatment, 1 had clinical success and the other had rebleeding at 1 month. A third embolisation was done on 2 small remaining arteries leading to complete cessation of rectal bleeding.³

Quality of life

In the case series of 30 patients, there was a statistically significant improvement in median quality of life score from 4.0 before the procedure to 2.0 after the procedure (p<0.0001).¹

Changes in haemorrhoid size

In the case series of 40 patients, there was a statistically significant decrease in nodal size from 0.9 cm, 1.4 cm and 2.0 cm for grade I, II and III haemorrhoids respectively before embolisation to 0.5 cm, 0.8 cm and 1.2 cm at 1-month follow-up (p<0.05 for all grades).²

Safety summary

Painful, oedematous, perianal reaction was reported in 1 patient, who had 3 embolisation procedures, in a case series of 14 patients. The symptoms resolved within 2 weeks after treatment with non-steroidal anti-inflammatory drugs.³

Anecdotal and theoretical adverse events

In addition to safety outcomes reported in the literature, specialist advisers are asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events (events which they think might possibly occur, even if they have never happened). For this procedure, specialist advisers did not describe any anecdotal adverse events. They considered that the following were theoretical adverse events: colonic ischaemia, mucosal injury, pain, and bleeding or vessel damage at the arterial puncture site.

The evidence assessed

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to superior rectal artery embolisation for haemorrhoids. The following databases were searched, covering the period from their start to 9 January 2018: 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 <u>literature search strategy</u> for details). 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.

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	Superior rectal embolisation.
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.

 Table 1 Inclusion criteria for identification of relevant studies

List of studies included in the IP overview

This IP overview is based on 84 patients from 3 case series, although there may be some patient overlap between the studies.^{1–3}

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 the <u>appendix</u>.

Table 2 Summary of key efficacy and safety findings on superior rectal artery embolisation for haemorrhoids

Study 1 Moussa N (2016)

Details

Study type	Case series
Country	France (2 centres)
Recruitment period	2014 to 2015
Study population and	n=30
number	Patients with chronic bleeding associated with haemorrhoids.
Age and sex	Mean 58 years; 63% (19/30) male
Patient selection criteria	All patients had contraindications for surgery. All patients were referred for severe and incapacitating bleeding.
Technique	Coils (2 to 3 mm) were used to occlude the distal branches of the superior rectal arteries, using a percutaneous femoral approach. The aim was to close all branches of the superior rectal artery just above the pubic ramus. During the intervention, patients were given a bolus of intravenous heparin. No specific sedation or prophylactic antibiotics were given. Patients were discharged after 3 hours of monitoring by a specialist nurse.
Follow-up	Median 5 months
Conflict of interest/source of funding	None

Analysis

Follow-up issues: No losses to follow-up were described, although some results were only reported for 29 of the 30 patients.

Study design issues: Small, prospective case series of consecutive patients. Bleeding was assessed using the French bleeding severity scale (range 0 to 9, with lower scores indicating less severe bleeding), which was developed by the authors and has not yet been validated. Technical success was defined as the occlusion of all visible branches of the superior rectal artery above the public ramus. Clinical success was defined as improvements in clinical scores (by at least 2 points for the French bleeding score) after embolisation, with no complications. Quality of life was measured using a score from 1 (no discomfort) to 5 (permanent discomfort).

Study population issues: Thirteen patients were on oral anticoagulant treatment, 4 had an acquired or genetic coagulation disorder, and 3 had chronic inflammatory disease of the colon. In another 7 patients a surgical approach was not possible because of previous unsuccessful surgery. Most patients (67%; 20/30) had grade II haemorrhoids before embolisation, 4 patients had grade I haemorrhoids, 3 patients had grade 3 haemorrhoids and 3 patients had grade 4 haemorrhoids.

Key efficacy and safety findings

Efficacy					Safety
Number of patients analysed: 30					There were no clinical complications in the early postoperative period.
Immediate technical success=93% (embolisation of all branches was not possible in 2 patients because of vasospasm)					There were no cases of rectal ulceration, anal fissure or puncture
Clinical success with an improvement of at least 2 points on the French bleeding score=72% (21/29) (17 patients had a single embolisation, and 4 patients had 2 embolisation sessions)					One patient had an episode of acute
No clinical success was seen in 28% (8/29) of patients, including 1 patient who had 3 embolisation sessions.					diarrhoea 1 week after the procedure, which spontaneously resolved. This was not attributed to the embolisation.
Mean number of arteries em	bolised per patient	t=3.1±1.3			
Mean number of coils per pa	atient=7.6±4.4				
Clinical scores before and	Clinical scores before and after embolisation; median (interquartile range)				
	Before	After	Change	p value	
French bleeding severity score (0 to 9)	7.0 (6.0; 8.0)	4.0 (2.0; 5.0)	-3.0 (-5.0; -1.0)	<0.0001	
General symptoms score (0 to 20)	12.0 (9.0; 15.0) n=30	6.0 (5.0; 7.0) n=30	-4.0 (-9.0; -2.0)	<0.0001	
Goligher's prolapse stage	2.0 (2.0; 2.0) n=30	2.0 (2.0; 2.0) n=29	0.0 (0.0; 0.0) n=29	1.00	
Quality of life (range 1 to 5)	4.0 (3.0; 4.0)	2.0 (1.0; 2.0)	-1.0 (-2.0; -1.0)	<0.0001	
The general symptoms scor pain, and impact on quality once per year), 2 (at least o movement. Impact on qualit (severe) or 4 (very severe).	e included bleeding of life. The first 4 sy nce per month), 3 (y of life was scored	g, prolapse, mar ymptoms were s at least once pe l 0 (not at all), 1	nual reduction, disc cored 0 (never), 1 (r week) or 4 (with e (minimal), 2 (mode	omfort or at least every bowel rate), 3	

Study 2 Zakharchenko A (2016)

Details

Study type	Case series
Country	France
Recruitment period	2005 to 2010
Study population and	n=40
number	Patients with symptomatic haemorrhoids (grade I to III).
Age and sex	Mean 35 years (range 25 to 65); 38% (15/40) male
Patient selection criteria	Grade I to III chronic internal haemorrhoids according to Goligher's classification. Exclusion criteria included contraindication to conventional angiography, such as allergies to iodinated contrast medium, medications or renal function impairment.
Technique	Embolisation was done through a catheter that was installed exactly above the point of division of the superior rectal artery (SRA) into distal branches. Non-lysing synthetic polyvinyl alcohol (PVA) particles and standard metallic coils were used. Small diameter (0.3mm) PVA particles were used to occlude the distal branches of the SRA. Embolisation was completed with 3 to 5 mm metallic coils that were placed in the SRA trunk. Endovascular intervention was done until the 'end point' was achieved (no flow in the SRA distal branches and no opacification of terminal branches in the projection of the haemorrhoids). After the procedure, a compression bandage was applied to the puncture site and bed rest was prescribed for 8 to 12 hours.
Follow-up	1 month
Conflict of interest/source of funding	None

Analysis

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

Study design issues: Small, prospective case series. The same experienced proctologic surgeon did the initial clinical evaluation, haemorrhoidal and overall staging, and subsequent follow-up evaluations. A single-blinded histopathological analysis was done of rectal mucosa samples taken at the 1 day and 1 month examinations. At 1 month follow-up, a Doppler probe introduced via a rectoscope was used to assess blood flow; anal sphincter function was assessed with an electromyographic recording and anal tone was assessed using a sphincterometer.

Study population issues: Most patients had grade II haemorrhoids (n=28, 69%), 6 (15%) patients had grade I and 6 (15%) patients had grade III.

Key efficacy and safety findings

Efficacy							Safety
						Salety	
Number of patients analysed: 40						There were no immediate complications.	
Symptom relief							
Bloody discharge stopped in 75% (30/40) of patients on the first day after embolisation and in 15% (6/40) on the second day. 10% (4/40) of patients (all with grade III haemorrhoidal disease) continued to have some bloody smearing for 5 to 7 days after the procedure.						There were no haematomas, infections or pseudoaneurysms at the puncture site and no patients complained of anal pain syndrome.	
General patient a discharge and p • Grade II • Grade I	satisfacti ain) I=83% (5/ and II=94	on (regardin 6) % (32/34)	ig resolution of i	rritati	ion, disco	mfort, bloody	
Mean length of ho	ospital sta	y=2.5±0.5 da	ays				
General disability	period la	sted 5 to 7 da	ays (6.2±0.9)				
Changes in dime (mean±standard	ension of deviatio	[;] internal hae n)	emorrhoids at 1 n	nontl	h follow-u	ıp	
Internal	Nodal si	ze before	Nodal size 1 mo	nth	n value	Dimension	
haemorrhoid	treatmen	at (cm)	after treatment (cm)	p value	decrease	
arade	acathor			,,,,,		(%)	
$\int (n=6)$		0 9+0 4	0.5-	⊦0 1	<0.05		
I(n=28)		1 4+0 5	0.0	L0.1	<0.00	-43	
$\frac{11}{11-20}$		2.0+0.5	1.2-	<u>⊧0.∠</u>	<0.00	-40	
Anal sphincter to	one (mea	nternal sof	deviation)	Fyte	ernal snhir	octer	
		tone (a)	intotor resting	stre	nath of co	ntraction (a)	
		Men	Women	0110	Men	Women	
Normal range		400 to 450	350 to 400	600	0 to 650	550 to 600	
Refore embolisa	tion	481+1 1	397+8 7	6	641+9.4	569+2 1	
1 month follow-	in	423+11.2	381+9.8	6	14+16 7	551+7.2	
	4P	<0.05	<0.05		<0.05	<0.05	
p value		<0.00	0.05		~0.05	<0.03	
Results of anal e	electromy	ography (m	ean±standard de	viati	on)		
		Resting mv	oelectric activity	Acti	ve contrac	tion	
		(mkV)	1	myc	pelectric a	ctivity (mkV)	
		Men	Women		Men	Women	
Before embolisa	ition	45±0.78	42.6±1.06	18	85±0.77	184±1.07	
1 month follow-u	цр	44±0.76	6 41.4±1.13	18	84±0.79	182.6±1.41	
Results of recto	sigmoid	Dopplerome	try				
		Duplex Dop	pler quantification	n (ml/	min)]
Flow in haemorrhoidal Flow in sigmoid colon							
nodes mucosa (inter-nodal							
space)							
Before embolisa	Before embolisation 109.5±9.2 58.4±4.1						
1 day follow-up		60.2±4.4* 59.1±4.3					
1 month follow-u	lb		59.6±4.3*			59.4±4.1	
*p<0.05							
-							

Study 3 Vidal (2015)

Details

Study type	Case series
Country	France
Recruitment period	Not reported
Study population and	n=14
number	Patients with severe chronic rectal bleeding caused by haemorrhoids (grade II to IV).
Age and sex	Mean 57 years (range 41 to 83); 79% (11/14) male
Patient selection criteria	Patients were selected by a multidisciplinary team (proctologist, visceral surgeon, and radiologist). Other medical or surgical treatments were not suitable. All treatment was considered to be 'compassionate'.
Technique	The inferior mesenteric artery was catheterised and the superior rectal arteries were then catheterised with a rapid transit microcatheter. Coils (2 and 3 mm in diameter and 3 cm long) were used for the embolisation. Partial embolisation (only right and left superior rectal artery) was done in the first 6 patients and complete embolisation (right, left and posterior superior rectal artery) was done in the remaining 8 patients.
Follow-up	Mean 192 days (2 to 13 months)
Conflict of interest/source of funding	None

Analysis

Study design issues: Small case series. Clinical success was defined as lack of bleeding or insignificant amounts of bleeding that was well tolerated by the patients.

Study population issues: Most patients had stage II haemorrhoidal disease (n=10), 3 patients had stage III disease and 1 patient had stage IV disease. Seven patients had previously had unsuccessful proctological surgery and the surgeons decided that redo surgery would be associated with a high risk of complications. Ten patients had severe coagulation disorders (6 were taking anticoagulants and 4 had cirrhosis) and the surgeons decided that surgery would be associated with a high risk of haemorrhage.

Key efficacy and safety findings

Efficacy	Safety
Number of patients analysed: 14	One patient, who had 3 embolisation
Technical success=100% (14/14)	procedures, had a painful, oedematous, perianal reaction. The patient was treated with non-steroidal anti-
Clinical success at follow-up=72% (10/14)	inflammatory drugs and symptoms resolved within 2 weeks.
Of the first 6 patients, who had only partial embolisation, rebleeding was reported in 4. Two patients (stage II and stage III) had additional embolisation of the posterior rectal arteries and 2 patients refused additional treatment. Of the 2 patients who had additional treatment, 1 had clinical success and the other had rebleeding at 1 month. A third embolisation was done on 2 small remaining arteries leading to complete cessation of rectal bleeding.	There were no other pain or ischaemic complications in the other 13 patients.
Mean procedure time=69 minutes (range 39 to 18)	
Mean dose of contrast agent injected=112 ml (range 88 to 143)	
Mean Dose-Area Product=62 Gy cm ² (range 22 to 149)	

Validity and generalisability of the studies

- No randomised studies were identified.
- All of the case series were based in France.
- There may be some patient overlap between the studies.
- Two of the studies only included patients for whom surgery was unsuitable. ^{1,3}
- Most patients had grade II haemorrhoids before embolisation.
- One study only included patients with grade II to IV haemorrhoids. ³ The other studies also included patients with grade I haemorrhoids.
- One study only included patients who had chronic, disabling bleeding and improvement in bleeding was the main clinical outcome.¹
- There is a lack of long-term follow-up data.

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.

Interventional procedures

- Radiofrequency treatment for haemorrhoids. NICE interventional procedures guidance 589 (2017). Available from <u>http://www.nice.org.uk/guidance/IPG589</u>
- Electrotherapy for the treatment of haemorrhoids. NICE interventional procedures guidance 525 (2015). Available from <u>http://www.nice.org.uk/guidance/IPG525</u>
- Haemorrhoidal artery ligation. NICE interventional procedures guidance 342 (2010). Available from http://www.nice.org.uk/guidance/IPG342
- Circular stapled haemorrhoidectomy. NICE interventional procedures 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

Additional information considered by IPAC

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. Three Specialist Advisor Questionnaires for superior rectal artery embolisation for haemorrhoids were submitted and can be found on the <u>NICE website</u>.

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.

Issues for consideration by IPAC

- A few additional studies have been published in languages other than English.
- Studies that describe the use of artery embolisation to treat acute lower gastrointestinal haemorrhage are not included.
- Ongoing trial: NCT02303925 Feasibility of Superior Rectal Artery Embolization for the Treatment of Hemorrhoidal Disease (EMBORRHOID); single group assignment; estimated enrolment 26; estimated study completion date November 2017.

References

- Moussa N, Sielezneff I, Sapoval M et al. (2017) Embolization of the superior rectal arteries for chronic bleeding due to haemorrhoidal disease. Colorectal Disease: the official journal of the Association of Coloproctology of Great Britain and Ireland 19: 194–9
- Zakharchenko A, Kaitoukov Y, Vinnik Y et al. (2016) Safety and efficacy of superior rectal artery embolization with particles and metallic coils for the treatment of hemorrhoids (Emborrhoid technique). Diagnostic and Interventional Imaging 97: 1079–84
- Vidal V, Sapoval M, Sielezneff Y et al. (2015) Emborrhoid: a new concept for the treatment of hemorrhoids with arterial embolization: the first 14 cases. Cardiovascular and Interventional Radiology 38: 72–8

Literature search strategy

Databases	Date searched	Version/files
Cochrane Database of Systematic	09/01/2018	Issue 1 of 12, January 2018
Reviews – CDSR (Cochrane)		
HTA database (Cochrane)	09/01/2018	Issue 4 of 4, October 2016
Cochrane Central Database of Controlled	09/01/2018	Issue 12 of 12, December 2017
Trials – CENTRAL (Cochrane)		
MEDLINE (Ovid)	09/01/2018	1946 to Present with daily update
MEDLINE In-Process (Ovid)	09/01/2018	January 08, 2018
MEDLINE Epubs ahead of print (Ovid)	09/01/2018	January 08, 2018
EMBASE (Ovid)	09/01/2018	1974 to 2018 Week 02
BLIC (British Library)	09/01/2018	n/a

Trial sources searched

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

Websites searched

- 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	Embolization, Therapeutic/
2	((Arter* or catheter* or cannula*) adj4 (emboli* or embolus)).tw.
3	Surgical Procedures, Minimally Invasive/
4	(Mini* adj4 invasive* adj4 (surg* or procedure* or tech* or intervent* or treat* or
therap)*)).tw.
5	Emborrhoid*.tw.
6	or/2-5
7	1 or 6
8	Hemorrhoids/ or Hemorrhoidectomy/
9	(hemorrhoid* or haemorrhoid*).tw.
10	pile*.tw.
11	or/8-10
12	7 and 11

Appendix

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
Vidal V, Louis G, Bartoli JM et al. (2014) Embolization of the hemorrhoidal arteries (the emborrhoid technique): a new concept and challenge for interventional radiology. Diagnostic and Interventional Imaging 95: 307–15	Case reports n=3	Observations show that the technique is feasible and reproducible, with no ischaemic complications or pain. Additional studies are needed to evaluate the efficacy of the procedure for treating haemorrhoidal disease.	A larger case series from the same centre is included.This appears to include the 3 patients described in this article.

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