NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of haemorrhoidal arterial ligation

Haemorrhoids (also known as piles) are enlarged blood vessels in or around the lower part of the bowel. They can cause itching, bleeding or pain, and may protrude outside the anus.

This procedure is carried out on an area of the lower part of the bowel that is relatively less sensitive to pain. It does not involve tissue removal. Blood vessels are stitched to reduce the blood supply to the haemorrhoids, which relieves symptoms of bleeding and discomfort, and can help them to shrink. If they are large, the tissue overlying the haemorrhoids may also be folded up and stitched.

Introduction

The National Institute for Health and Clinical Excellence (NICE) has prepared this 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 September 2009.

Procedure name

- Haemorrhoidal arterial ligation

Specialty societies

- Association of Coloproctology of Great Britain and Ireland.

Description

Indications and current treatment

Haemorrhoids (also known as piles) 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 rectum. Haemorrhoids that prolapse may reduce (return into the anal canal) 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 or II haemorrhoids may be managed by diet modification or treated by topical applications. Interventional treatments include rubber band ligation and scleroscant injections.

Treatments for Grade III and IV haemorrhoids include surgical excision of the haemorrhoids (haemorrhoidectomy) or 'non-excisional' stapled haemorrhoidopexy.

What the procedure involves

Haemorrhoidal arterial ligation is a non-excisional procedure that aims to reduce symptoms of discomfort and bleeding by removing the blood flow to the haemorrhoids.

The procedure is usually performed with the patient under general anaesthesia and is usually carried out after an enema. Using a proctoscope, the haemorrhoidal arteries are ligated with sutures (above the dentate line) to remove the flow of blood to the haemorrhoids. A Doppler probe may be used to help locate the haemorrhoidal arteries. For larger prolapsing haemorrhoids, an adjunctive mucosal plication procedure is done. The prolapsing mucosa is plicated up to the level of the dentate line where it is fixed by ligation of the plicating sutures (haemorrhoidopexy).

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to haemorrhoidal arterial ligation. Searches were conducted of the following databases, covering the period from their commencement to 1 October 2010: 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 grades II to IV haemorrhoids.
Intervention/test	Haemorrhoidal arterial ligation.
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 overview

This overview is based on approximately 3061 patients from 1 systematic review, 3 randomised controlled trials (RCTs), 1 non-randomised trial and 4 case series.

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 haemorrhoidal arterial ligation

Abbreviations used: CI, confidence interval; DGHAL, Doppler-guided haemorrhoidal arterial ligation; GI, grade I; GII, grade II; GIII, grade III; GIV, grade IV; HAL, haemorrhoidal arterial ligation; NS, not significant; RCT, randomised controlled trial; THD, transanal haemorrhoidal dearterialisation; VAS, visual analogue scale

Study details

Giordano P (2009)[1]

Systematic review

UK

Recruitment period: literature search from 1995 onwards

Study population: patients with haemorrhoids: 2% GI (6/305), 36.3% GII (482/1329), 57.4% GIII (912/1589), and 14.6% GIV (189/1295).

n = **1996 (from 16 case series and 1 RCT)**

Age: 21 to 93 years

Sex: 58.4% male

Patient selection criteria: not stated

Technique: THD with or without mucosopexy; various forms of anaesthesia used (general, local, general and local).

Morinaga 1995
Sohn 2001
Arnold 2002
Shelygin 2003
Charúa Guindic 2004
Bursics 2004
Lienert and Ulrich 2004
Narro 2004
Vavra 2004
Ramirez 2005
Felice 2005
Scheyer 2006
Greenberg 2006
Wallis de Vries 2007
Abdeldaim 2007
Dal Monte 2007

Key efficacy findings

Number of patients analysed: **1996** with an average of 6 arteries ligated

Results overall

Outcome	% of patients
Itching	10.6 (27/254)
Prolapse	9.0 (96/1065)
Bleeding	7.8 (89/1145)
Pain on defaecation	4.7 (53/1123)

In the 6 studies with ≥ 1-year follow-up:

Outcome	% of patients
Prolapse	10.8 (46/427)
Bleeding	9.7 (49/507)
Pain on defaecation	8.7 (18/206)

Recurrence: 27 patients required a second procedure for recurrent haemorrhoidal prolapse.

Return to normal activity: this occurred between 2 and 3 days after the procedure for most studies (but at a mean of 3.5 days in Dal Monte[6]).

Comparison of studies with ≥ 1-year (n = 6) and < 1-year (n = 9) follow-up*

Outcome	< 1-year follow-up	≥ 1-year follow-up	p value

Key safety findings

3 patients developed significant haemorrhage requiring blood transfusion:

- 1 patient lost 1.3 litres postoperatively requiring transfusion and surgical intervention.
- 1 patient bled on the 8th day postoperatively and required 2 transfusions.
- 1 patient who had coagulopathy (no more details given)

Early postoperative events

	% of patients
Fever	3.9 (15/383)
Thrombosed haemorrhoids	1.8 (25/1386)
Anal fissure*	0.8 (14/1695)
Urinary retention	0.7 (10/1468)
Incontinence	0.4 (3/693)
Anal fistulas	0.4 (3/815)
Proctitis	0.2 (2/909)
Stool retention	0.1 (1/711)

* The study later states that anal fissure occurred in 2.3% (4/177) of patients overall. It is unclear why this figure is less than the early postoperative occurrence of this event.

Comments

Follow-up issues:

- 1540 patients completed follow-up (average follow-up of patients not given).

Study design issues:

- Data collection and analysis was performed by two researchers independently of each other.
- Included non-English articles; excluded abstracts, studies without the use of a Doppler and any studies reporting on patients already reported on.

Study population issues:

- Some of the patients (563) had undergone previous procedures (rubber-band ligation, 223; sclerotherapy, 322; stapled haemorrhoidopexy, 2; open haemorrhoidopexy, 3).
- 23 patients had concurrent procedures (such as fissurectomy, skin tag resection, herniorrhaphy).
- The study stated that results by grade of haemorrhoids were given

Abbreviations used: CI, confidence interval; DGHAL, Doppler-guided haemorrhoidal arterial ligation; GI, grade I; GII, grade II; GIII, grade III; GIV, grade IV; HAL, haemorrhoidal arterial ligation; NS, not significant; RCT, randomised controlled trial; THD, transanal haemorrhoidal dearterialisation; VAS, visual analogue scale

Study details	Key efficacy findings				Key safety findings	Comments
Cantero 2008 Follow-up: **mean follow-up not stated (range 1 to 79 months)** Conflict of interest/source of funding: not reported	Bleeding	6.3% (40/638)	9.7% (49/507)	< 0.05		by 2 studies. These 2 studies are included in this table so this detail is not included here[5,6]. **Other issues**: • Type of anaesthesia was not described in 10 studies. The others used general (1), local (5) or both general and local anaesthesia (1). • It appears that only one study performed mucosopexy after dearterialisation[6].
	Pain on defaecation	3.8% (35/917)	8.7% (18/206)	< 0.01		
	Prolapse	7.8% (50/638)	10.8% (46/427)	Not significant		
	* 1 study did not report follow-up. **Pre-operative outcomes** The pre-operative proportion of patients with bleeding, pain and prolapse ranged from 45%-100%, 12%-83% and 12%-100% respectively across the studies.					

Abbreviations used: CI, confidence interval; DGHAL, Doppler-guided haemorrhoidal arterial ligation; GI, grade I; GII, grade II; GIII, grade III; GIV, grade IV; HAL, haemorrhoidal arterial ligation; NS, not significant; RCT, randomised controlled trial; THD, transanal haemorrhoidal dearterialisation; VAS, visual analogue scale

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Bursics A (2004)[2]

RCT
Hungary
Recruitment period: not stated
Study population: patients with haemorrhoids (GI 1, GII 13, GIII 19, GIV 27); presenting with bleeding (49), pain (26), prolapse (3) and discharge (2) (some presented with more than one symptom).
n = 60 (30 closed scissor haemorrhoidectomy [group A] vs 30 DGHAL [group B])
Mean age: 47.5 years
Sex: 45% male
Patient selection criteria: patients underwent clinical exam, rigid sigmoidoscopy and anoscopy for diagnosis and staging; those with underlying pathologies were excluded by barium enema or colonoscopy, if necessary.
Technique: DGHAL; mode of anaesthetic varied (see comments section).

Mean follow-up: 11.7 months

Conflict of interest/source of funding: not reported</td>
<td>Number of patients analysed: 60 (30 vs 30) with an average of 6 arteries ligated
Early postoperative period
<table>
<tr><th></th><th>Group A</th><th>Group B</th><th>p-value</th></tr>
<tr><td>Doses of minor analgesics</td><td>11.7</td><td>2.9</td><td>< 0.005</td></tr>
<tr><td>Patients requiring opioid analgesics</td><td>9</td><td>0</td><td>NS</td></tr>
<tr><td>Patients not requiring pain relief</td><td>2</td><td>23</td><td>NS</td></tr>
<tr><td>Return to normal activities*</td><td>24.9 days</td><td>3 days</td><td>< 0.0005</td></tr>
</table>
* Defined as return to job or no longer needing help taking care of themselves
Longer term symptom status
<table>
<tr><th></th><th>Group A</th><th>Group B</th></tr>
<tr><td>Symptoms at 6 weeks</td><td>5/26[a]</td><td>5/26[b]</td></tr>
<tr><td>Symptoms during remaining follow-up</td><td>5/26[c]</td><td>3/26[d]</td></tr>
</table>
[a] 1 patient had bleeding diverticulosis but this resolved with conservative treatment; 1 had symptoms which resolved after 3 sessions of rubber band ligation; 2 did not have further therapies; 1 patient with no problems had prolapsing secondary haemorrhoid in one direction.
[b] 3 patients had perianal fullness and/or pain and had</td>
<td>Postoperative complications
<table>
<tr><th>Outcome</th><th>Group A</th><th>Group B</th></tr>
<tr><td>Fever[a]</td><td>9</td><td>0</td></tr>
<tr><td>Nausea[b]</td><td>6</td><td>2</td></tr>
<tr><td>Urinary retention requiring catheterisation</td><td>1</td><td>0</td></tr>
<tr><td>Anal fissure[c]</td><td>0</td><td>3</td></tr>
<tr><td>Overall[d]</td><td>14</td><td>2</td></tr>
</table>
[a] These occurred during the first postoperative week; 2 were given antibiotics and the others resolved spontaneously.
[b] All cases required intravenous fluid replacement.
[c] These occurred during the follow-up of 11.5 months; 1 healed with conservative therapy, and the other 2 healed after fissurectomy or lateral sphincterotomy before the end of the follow-up period.
[d] The difference in complications between the groups was statistically significant ($p < 0.05$) (except for anal fissure for which the significance was not reported).
Late complications
There were no reports of stricture formation, incontinence or evacuation</td>
<td>Follow-up issues:
Follow-up occurred 6 weeks after the operation and then every 3 months afterwards. It involved a rectal digital examination and also rigid sigmoidoscopy if the patient had complaints.
3 patients in group A and 1 in group B were lost to follow-up after 3 months (it is not stated whether or not these were the patients who presented with symptoms at 6 weeks). These patients were contacted by letter and by phone.
Study design issues:
Inadequate randomisation (completed based on the date the patients attended the outpatient clinic).
Methods used to recruit patients and whether or not blinding was attempted was not stated.
Intention to treat analysis not described.
The study did not state which underlying pathologies were excluded.</td>
</tr>
</table>

Abbreviations used: CI, confidence interval; DGHAL, Doppler-guided haemorrhoidal arterial ligation; GI, grade I; GII, grade II; GIII, grade III; GIV, grade IV; HAL, haemorrhoidal arterial ligation; NS, not significant; RCT, randomised controlled trial; THD, transanal haemorrhoidal dearterialisation; VAS, visual analogue scale			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
	prolapse on straining but bleeding stopped and no further therapy was required; 2 (with bleeding and pain, not prolapse) were successfully treated with suppositories. [c] 2 were patients with problems at 6 weeks; 3 were patients with newly reported recurrences (the study reported that these were bleeding in 3 instances, pain in 4, discharge in 1 and prolapse in 1, but it is not clear if these are for all 5 patients or just those with new symptoms). [d] 2 were patients with problems at 6 weeks; 1 reported recurrent bleeding requiring a second DGHAL which was successful. At the end of the follow-up period 28 patients treated by DGHAL were complaint free and 25 patients in the haemorroidectomy group were complaint free (not significant).	problems at 1 year follow-up.	**Study population issues**: • There were no statistically significant differences between the groups in grades of the disease, sex, age and length of follow-up. **Other issues**: • This is included in the systematic review[1]. • The authors state that the first 10 patients treated by DGHAL had a general anaesthetic and the remaining 20 were treated under local anaesthetic after the surgeons had more experience (15 of these had infiltration and the last 5 had surface anaesthesia). All patients in group A (except 3) were treated under general anaesthesia.

Abbreviations used: CI, confidence interval; DGHAL, Doppler-guided haemorrhoidal arterial ligation; GI, grade I; GII, grade II; GIII, grade III; GIV, grade IV; HAL, haemorrhoidal arterial ligation; NS, not significant; RCT, randomised controlled trial; THD, transanal haemorrhoidal dearterialisation; VAS, visual analogue scale

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Khafagy W (2009)[3]

RCT
Egypt
Recruitment period: 2002 to 2004
Study population: patients with GIII or GIV haemorrhoids presenting with anal discomfort (all), post-defaecation bleeding (41) and prolapse (26).
n = 45 (15 each treated by stapled haemorrhoidectomy [group A], open haemorrhoidectomy [group B] and DGHAL [group C])
Age: 21 to 61 years
Sex: 71% male
Patient selection criteria: patients with thrombosis, acute irreducible prolapse, coexisting anorectal disease (such as anal fissure, faecal incontinence or perianal fissure) or pregnancy were excluded.

Technique: DGHAL (each procedure was carried out with spinal or general anaesthesia).

Follow-up: not reported

Conflict of interest/source of funding: not reported</td>
<td>Number of patients analysed: 45 (15 vs 15 vs 15) with 5 to 6 arteries ligated for each patient.
Pain
Determined on 10-cm VAS score
<table>
<tr><th>Follow-up</th><th>Group A</th><th>Group B</th><th>Group C</th><th>p value (between groups A and C)</th></tr>
<tr><td>1st 24 hours</td><td>2.75</td><td>7.99</td><td>2.9</td><td>NS</td></tr>
<tr><td>At 1st motion range</td><td>1.23</td><td>7.01</td><td>2.1</td><td>NS</td></tr>
<tr><td>1 week</td><td>0.39</td><td>2.51</td><td>0.42</td><td>NS</td></tr>
</table>
(The difference between group B and groups A and C was significant at each period; p < 0.01.) (the study authors appear to have made an error and reported p > 0.01)
Improvement of symptoms
<table>
<tr><th></th><th>Group A</th><th>Group B</th><th>Group C</th><th>p value</th></tr>
<tr><td>Bleeding</td><td>60.0%</td><td>73.0%</td><td>53.0%</td><td>NS</td></tr>
<tr><td>Prolapse</td><td>66.7%</td><td>100.0%</td><td>60.0%</td><td>< 0.01</td></tr>
<tr><td>Pain</td><td>33.3%</td><td>46.7%</td><td>53.0%</td><td>NS</td></tr>
<tr><td>Pruritus</td><td>20.0%</td><td>33.3%</td><td>46.7%</td><td>NS</td></tr>
<tr><td>Incontinence</td><td colspan="3">100.0%</td><td>NS</td></tr>
</table>
(Follow-up for these outcomes not stated.)</td>
<td>Early postoperative complications
<table>
<tr><th></th><th>Bleeding</th><th>Urine retention</th></tr>
<tr><td>Staple</td><td>1 (6.7%)</td><td>1 (6.7%)</td></tr>
<tr><td>Open</td><td>0</td><td>5 (33.3%)</td></tr>
<tr><td>DGHAL</td><td>0</td><td>0</td></tr>
</table>
(There was no significant difference between groups.)</td>
<td>Follow-up issues:
All patients were assessed 12 weeks postoperatively (included symptom questionnaire, measurement of postoperative stenosis and postoperative incontinence, anorectal manometry).
Study design issues:
Randomisation was through a computer-generated table and put into an envelope for patient selection.
Patients were blinded.
Patient recruitment not described.
Study population issues:
There was no significant difference between groups for age, sex or presenting symptoms.
Other issues:
The authors state that grade IV patients were included in the study but then state that those with irreducible prolapsed haemorrhoids were excluded. It is uncertain</td>
</tr>
</table>

Abbreviations used: CI, confidence interval; DGHAL, Doppler-guided haemorrhoidal arterial ligation; GI, grade I; GII, grade II; GIII, grade III; GIV, grade IV; HAL, haemorrhoidal arterial ligation; NS, not significant; RCT, randomised controlled trial; THD, transanal haemorrhoidal dearterialisation; VAS, visual analogue scale			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
	Functional outcomes (from anorectal manometry) There was no significant difference between anal pressure and rectal volumes between the 3 groups.		which criteria they used for staging since irreducible prolapse is a criterion for grade IV according to the Goligher scale.

Abbreviations used: CI, confidence interval; DGHAL, Doppler-guided haemorrhoidal arterial ligation; GI, grade I; GII, grade II; GIII, grade III; GIV, grade IV; HAL, haemorrhoidal arterial ligation; NS, not significant; RCT, randomised controlled trial; THD, transanal haemorrhoidal dearterialisation; VAS, visual analogue scale

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Festen S (2009)[9]

RCT
The Netherlands
Recruitment period: 2006 to 2007
Study population: patients with GIII or GIV haemorrhoids with a history of rubber band ligation
n = 41 (23 THD vs 18 stapled haemorrhoidopexy)
Mean age: 50 years
Sex: 75% male
Patient selection criteria: patients below 18 years, unavailable for follow-up (because of language or residence), inflammatory bowel disease and history of haemorrhoidal or anal surgery were excluded.

Technique: THD under general or spinal anaesthesia including additional ‘reefing of mucosa’ with same suture used for ligation.

Follow-up: 6 weeks

Conflict of interest/source of funding: not reported</td>
<td>Number of patients analysed: 41 (23 vs 18)
Pain
This was assessed 1 day and 1 and 3 weeks after the procedure on a VAS.

<table>
<tr><th></th><th>Stapled haemorrhoidopexy</th><th>THD</th><th>Difference (95% CI)</th><th>p value</th></tr>
<tr><td></td><td colspan="3">VAS (range)</td><td></td></tr>
<tr><td>Day 1</td><td>5.1</td><td>3.1</td><td>1.98 (1.02 to 2.94)</td><td>0.00</td></tr>
<tr><td>Day 7</td><td>3.2</td><td>1.6</td><td>1.66 (0.70 to 2.62)</td><td>0.00</td></tr>
<tr><td>Day 21</td><td>1</td><td>0.2</td><td>0.78 (–0.18 to 1.74)</td><td>0.06</td></tr>
</table>
(The scale and direction of VAS was not described. According to the discussion, a higher score meant higher pain.)

Resolution of symptoms after 6 weeks.
Stapled haemorrhoidopexy – 83% (15)
THD – 78.3% (18)
(p = 0.648)
Of those with continuing symptoms in the stapled haemorrhoidopexy: 1 had persistent anal blood loss treated by haemorrhoidectomy, 2 had persistent prolapse.
The 5 patients with persistent problems in the THD group had persistent prolapse.</td>
<td>Complications
<table>
<tr><th></th><th>Stapled haemorrhoidopexy</th><th>THD</th></tr>
<tr><td>Bleeding</td><td>11% (2)*</td><td>4.3% (1)**</td></tr>
<tr><td>Postop mild bladder dysfunction resolving spontaneously in 6 weeks.</td><td>5.6% (1)</td><td></td></tr>
<tr><td>Soiling</td><td></td><td>4.3% (1)***</td></tr>
</table>
* both patients were treated by intra-anal application of a gauze soaked in lidocaine and adrenaline
** treated with haemostatic stitch to control bleeding
*** treatment with fibre supplements</td>
<td>Follow-up issues:
Patients were assessed for postoperative pain at 1 day and 1, 3 and 6 weeks after the procedure.
Study design issues:
This was a pilot study.
Patient recruitment not described.
Randomisation was completed with the use of opaque envelopes (not otherwise described).
Blinding not described.
Study was performed by 2 experienced surgeons.
The size and scale of the VAS was not described.
Study population issues:
All patients had a history of rubber band ligation.
There was no significant difference between groups for age, sex, grade of haemorrhoids, or number of previous rubber band ligations.
Other issues:
The authors stated that the persistence of prolapse in those treated with the</td>
</tr>
</table>

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Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
			stapled procedure is higher than previous reported. They propose that the stapler may have been positioned too high. • The authors also suggest the high rate of persistent prolapse (in relation to previous literature) may be due to the high grade of haemorrhoids in study patients.

Abbreviations used: CI, confidence interval; DGHAL, Doppler-guided haemorrhoidal arterial ligation; GI, grade I; GII, grade II; GIII, grade III; GIV, grade IV; HAL, haemorrhoidal arterial ligation; NS, not significant; RCT, randomised controlled trial; THD, transanal haemorrhoidal dearterialisation; VAS, visual analogue scale

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Hajdarevic B (2009)[4]

Non-randomised trial
Bosnia and Herzegovina
Recruitment period: not reported
Study population: patients who presented at a hospital or private specialists who had confirmed grade II or III haemorrhoids.
n = 70 (35 treated by DGHAL [group A] vs 35 control [group B])
Age: not stated
Sex: not stated
Patient selection criteria: patients with frequent heavy bleeding in at least 4 of the last 12 months, verification with secondary anaemia and previous treatment were included.

Technique: DGHAL with the use of a sedative and local anaesthesia.

Follow-up: 12 to 13 months

Conflict of interest/source of funding: not reported</td>
<td>Number of patients analysed: 70 (35 vs 35) with 6 arteries ligated for each patient on average.

Treatment success
This was determined to be successful based on no recurrence of bleeding or prolapse at 12 to 13 months' follow-up.
<table>
<tr><th></th><th>% of patients</th></tr>
<tr><td>Group A</td><td>91.4 (32)*</td></tr>
<tr><td>Group B</td><td>22.9 (8)</td></tr>
</table>
* The 3 patients without 'success' had recurrence of bleeding but there was no further description of these patients.
Patients deemed to be 'unsuccessful' in the control group were not described.</td>
<td>Complications
<table>
<tr><th></th><th>% at 8 days after treatment</th><th>% at 25 days after treatment</th></tr>
<tr><td>Group A</td><td>11.4 (4)</td><td>2.8 (1)</td></tr>
<tr><td>Group B</td><td>74.2 (26)</td><td>11.4 (4)</td></tr>
</table>

It is not stated what the complications were, though the authors state that complications usually arose after thrombosis of external haemorrhoids.
Postoperative complications were detected at 15-day follow-up examinations.
The difference between occurrence of complications 8 days after treatment was statistically significant between the groups ($p < 0.01$), but the difference after 25 days was not significant.
</td>
<td>Follow-up issues:
The study stated that patients were examined after 12 to 13 months but did not state if any patients were lost to follow-up.
Study design issues:
The study was described to be retrospective-prospective but it was not explicitly explained what this meant. Questionnaires appear to have been sent to patients, but how many questionnaires were sent out or the response rate was not described. The follow-up exam at 12 to 13 months appeared to be performed (including anorectal pressure measurement and an overview of HAL proctoscopy).
The comparator procedure was not well described so it is not clear what procedure was performed on these patients.
Study population issues:
The authors stated that there was no significant difference between age and</td>
</tr>
</table>

Abbreviations used: CI, confidence interval; DGHAL, Doppler-guided haemorrhoidal arterial ligation; GI, grade I; GII, grade II; GIII, grade III; GIV, grade IV; HAL, haemorrhoidal arterial ligation; NS, not significant; RCT, randomised controlled trial; THD, transanal haemorrhoidal dearterialisation; VAS, visual analogue scale			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
			gender between groups but these were not reported. **Other issues**: • This study was not written clearly so was difficult to read.

Abbreviations used: CI, confidence interval; DGHAL, Doppler-guided haemorrhoidal arterial ligation; GI, grade I; GII, grade II; GIII, grade III; GIV, grade IV; HAL, haemorrhoidal arterial ligation; NS, not significant; RCT, randomised controlled trial; THD, transanal haemorrhoidal dearterialisation; VAS, visual analogue scale

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Gupta (2008)[8]

Case series
India
Recruitment period: 1997 to 2007
Study population: patients with symptomatic, prolapsing haemorrhoids for mean 6.3 years; GII 76, GIII 441, GIV 99
n = 616
Mean age: 11–93
Sex: 58.6% male

Patient selection criteria: patients with acute thrombosed piles or concurrent anal pathology (such as fistula or fissures) were excluded (some patients with GII were included if they had severe refractory symptoms).

Technique: ligation and mucosopexy (no Doppler guidance – see ‘comments’ section); use of general, spinal or local anaesthesia based on decision of anaesthetist

Mean follow-up: not stated

Conflict of interest/source of funding: ‘no competing interests’ declared</td>
<td>Number of patients analysed: 616 (4 weeks), 523 (12 months) with average 3.12 haemorrhoids ligated for each patient.
Postoperative pain
Mean analgesics required: 14 ± 4 tablets over mean 9 ± 3 days

Symptomatic resolution at 4 weeks
<table>
<tr><th></th><th>% with resolution (no.)</th></tr>
<tr><td>Bleeding</td><td>95.6 (589)</td></tr>
<tr><td>Prolapse</td><td>98</td></tr>
<tr><td>Pain on defaecation</td><td>96</td></tr>
</table>
*patient numbers not reported
Of the 93% of patients who completed 1-year follow-up, 89 were asymptomatic at 1-year follow-up (total figure of those who completed 1-year follow-up was not reported; 93% of patients is around 523 patients so patients with no symptoms at 1-year follow-up was around 17% [89/523]).

Patient satisfaction (n = 523)
This was assessed on a 10-cm VAS (10 being most satisfied) at a visit at 12-month follow-up. The mean patient score was 8.2 (based on 93% [probably 523] patients).
(the paper this was written as ‘8.2%’ which is presumably incorrectly written).

‘Inquiry’ in 2007 (n = 307)
The following results were based on 307 patients treated by May 2006 (485 had been treated by this date but only</td>
<td>Complications
Complications occurred in 9% (56/616) of patients
<table>
<tr><th></th><th>No. patients</th></tr>
<tr><td>Perianal thrombosis</td><td>12</td></tr>
<tr><td>Bleeding*</td><td>4</td></tr>
<tr><td>Pain*</td><td>2</td></tr>
<tr><td>Urinary retention</td><td>9</td></tr>
<tr><td>Pruritus ani</td><td>2</td></tr>
<tr><td>Mucosal prolapse</td><td>6</td></tr>
<tr><td>Skin tag</td><td>13</td></tr>
<tr><td>Constipation</td><td>4</td></tr>
<tr><td>Tenesmus</td><td>4</td></tr>
</table>
* requiring readmission</td>
<td>Follow-up issues:
• 93% completed 1-year follow-up (number of patients not reported and reason for loss of follow-up not reported)
• Postoperative pain was assessed on a VAS by patients at home and they also recorded analgesics used each day for the first 14 days after surgery. Patients were then followed up at 4 weeks, 6 months and 1 year and later if they had complaints.
• Patients in the study were recruited up until the end of 2007, however, the authors completed an ‘inquiry’ at the beginning of 2007 which included 485 patients who were treated up until May 2006. It was not stated how these patients were contacted. Only 63% (307) of these patients responded.
Study design issues:
• Unlike the other studies in this table, this study did not use Doppler-guidance. The study described the use of artery forceps to retract the haemorrhoidal cushions and visualise the</td>
</tr>
</table>

Abbreviations used: CI, confidence interval; DGHAL, Doppler-guided haemorrhoidal arterial ligation; GI, grade I; GII, grade II; GIII, grade III; GIV, grade IV; HAL, haemorrhoidal arterial ligation; NS, not significant; RCT, randomised controlled trial; THD, transanal haemorrhoidal dearterialisation; VAS, visual analogue scale

Study details	Key efficacy findings	Key safety findings	Comments
	63% [307] responded). **% with resolution** Bleeding and pain during defaecation: 94* Prolapse: 89** (total number and mean follow-up not reported) *Those who still had bleeding were treated conservatively but some not responding to these measures were treated with band ligation or infrared coagulation (number of patients treated by this means not stated) ** The remaining 11% completed rectal examination. 4% of these had skin tags which the patients considered to be prolapse; all patients were offered a 'redo' procedure (it was not reported how many had another procedure)		haemorrhoids.

Abbreviations used: CI, confidence interval; DGHAL, Doppler-guided haemorrhoidal arterial ligation; GI, grade I; GII, grade II; GIII, grade III; GIV, grade IV; HAL, haemorrhoidal arterial ligation; NS, not significant; RCT, randomised controlled trial; THD, transanal haemorrhoidal dearterialisation; VAS, visual analogue scale

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Walega P (2008)[5]

Case series
Poland and Austria
Recruitment period: 2000 to 2006
Study population: patients treated at 2 centres with grades II to IV haemorrhoids (GII 144, GIII 319, GIV 44).
n = 507 (308 phase 1 in Austria, 199 phase 2 in Poland)
Mean age: 50.1 years (Austria) and 41 years (Poland)
Sex: 61% male (Austria) and 65% male (Poland)

Patient selection criteria: physical examination confirming stage and medical history which included stinging in anal canal, pruritus, pain and bleeding; those with neoplastic changes in the anal canal were excluded.

Technique: DGHAL; first group had sedation and the second group a local anaesthetic with sedation.
Follow-up: 1 year

Conflict of interest/source of funding: not reported</td>
<td>Number of patients analysed: 507 with 3 to 7 arteries ligated for each patient.

Patient-reported success
The following was given by patients at 1-year follow-up:
• 69.2% (351) had ‘good’ results (significant symptom relief).
• 14.8% (75) had ‘acceptable’ results (the reported success by the other 81 patients was not reported).
By grade status group: 92.4% (133/144) of patients with grade II and 84.0% (272/324) of patients with grade III had ‘very good’ or ‘good’ results (‘very good’ – free of the disease, ‘good’ – when patients had significant symptom relief). Of those with grade IV disease, only 40.9% (18/44) of patients were satisfied with the operation.

Effects on symptoms
<table><tr><th></th><th>Phase 1 group</th><th>Phase 2 group</th></tr><tr><td>Recurrence</td><td>15.6% (48)</td><td>20.6% (41)</td></tr><tr><td>Pain on defaecation</td><td>0.97% (3)</td><td>1.0% (2)</td></tr><tr><td>Bleeding</td><td>5.2% (16)</td><td>7.5% (15)</td></tr></table>The number of patients with each outcome by grade were:<table><tr><th>Outcome</th><th>Grade 2</th><th>Grade 3</th><th>Grade 4</th></tr><tr><td>Recurrence</td><td>11</td><td>52</td><td>26</td></tr><tr><td>Pain on defaecation</td><td>1</td><td>3</td><td>1</td></tr><tr><td>Bleeding</td><td>4</td><td>20</td><td>7</td></tr></table></td>
<td>There were no intraoperative or immediate postoperative complications.

18.1% of patients needed analgesics for 1 to 2 days (number of patients not reported)
Postoperative complications
<table><tr><th>Complication</th><th>Phase 1 group</th><th>Phase 2 group</th></tr><tr><td>Thrombosis</td><td>2.9% (9)</td><td>4.5% (9)</td></tr><tr><td>Fistula</td><td>0.3% (1)</td><td>0% (0)</td></tr><tr><td>Fissure</td><td>1.3% (4)</td><td>3.5% (7)</td></tr></table></td>
<td>Follow-up issues:
• Anorectal manometry tests were performed before treatment and at 1, 3 and 12 months after treatment.
• Completeness of follow-up not reported.

Study design issues:
• This study was complete in two phases: the first in Austria and the second in Poland.
• The purpose of the study was to determine clinical effectiveness and functional results by anorectal manometry.

Study population issues:
• Some patients may have been included in Scheyer which is in the systematic review[1].
• In the first group, 23 patients also had fissurectomy, resection of skin tags, and herniorraphies; in the second group, 32 patients also had anorectal folds excised and 4 patients had anal polyp excision.</td>
</tr>
</table>

Abbreviations used: CI, confidence interval; DGHAL, Doppler-guided haemorrhoidal arterial ligation; GI, grade I; GII, grade II; GIII, grade III; GIV, grade IV; HAL, haemorrhoidal arterial ligation; NS, not significant; RCT, randomised controlled trial; THD, transanal haemorrhoidal dearterialisation; VAS, visual analogue scale			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
	Functional outcomes There were no significant differences in basal anal pressure, squeeze pressure or vector volume after the procedure. In 5 patients, a recto-anal inhibitory reflex was observed 1 month after DGHAL.		

Abbreviations used: CI, confidence interval; DGHAL, Doppler-guided haemorrhoidal arterial ligation; GI, grade I; GII, grade II; GIII, grade III; GIV, grade IV; HAL, haemorrhoidal arterial ligation; NS, not significant; RCT, randomised controlled trial; THD, transanal haemorrhoidal dearterialisation; VAS, visual analogue scale

Study details

Dal Monte PP (2007)[6]

Case series

Italy and UK

Recruitment period: 2000 to 2006

Study population: patients with symptomatic grades II, III or IV haemorrhoids (GII 138, GIII 162, GIV 30) presenting with bleeding (212) or prolapse (192).

n = **330**

Mean age: 52.4 years

Sex: 55% male

Patient selection criteria: not reported

Technique: THD with general anaesthesia in the first patients and spinal anaesthesia (or perineal block) in later patients, depending on patient preference followed by mucosopexy or figure-of-8 stitch.

Follow-up: **not reported**

Conflict of interest/source of funding: not reported

Key efficacy findings

Number of patients analysed: **330**

Return to normal activities

In 276 patients, this was 3.5 days on average.

Postoperative pain (on VAS – 0 being no pain)

This was not reported by 150 patients. Of those who reported pain, mean VAS score was 1.32:

	% of patients
Mild pain (VAS < 2)	35.5% (117)
Moderate pain (2 < VAS < 8)	16.% (54)
Severe pain (VAS > 8)	2.7% (9)

Analgesia was not required in 56.4% (186) of patients, needed for no more than 2 days in 38.8% (128) and for up to 7 days in 4.9% (16) of patients.

Short-term resolution of symptoms (n = 330, 1 month)

Outcome	**% of patients with resolution**
Bleeding	91.9% (204/222)*
Prolapse	95.8% (184/192)**

***** Of those who did not respond, 4 were GII, 3 GIII, and 1 GIV; minor oozing was observed from ligation sites in some patients but this stopped once the sutures were absorbed.

****** 111 of these patients were treated with anopexy; of those who did not respond, 3 were GIII and 5 GIV.

Key safety findings

There were 23 postoperative complications (6.9% complication rate).

	Number of patients
Fissure	2
Thrombosis	5
Urinary retention needing catheterisation	2
Submucosal haematoma	4
Haematuria	1
Immediate bleeding*	4
Delayed bleeding**	3
Needle rupture***	2

* 1 was due to laceration of a rectal polyp when the device was introduced (the patient had refused preoperative colonoscopy).

** 1 required an operation to stop the bleeding.

*** needle tip chipped and was left in the submucosa with no consequence

Comments

Follow-up issues:

- Patients were followed up at 1 week, 1 month and 6 months (this involved an interview, physical exam and anoscopy or rectosignoidoscopy).
- Only 219 patients were followed up for 46 months. Further details were not given.

Study population issues:

- Of the patients treated, 177 had already undergone rubber band ligation (96), sclerotherapy (64), cryotherapy (13), stapled haemorrhoidopexy (2) or open haemorrhoidectomy (2).

Other issues:

- This study is included in the systematic review[1].
- Use of anaesthetic was general for the first patients. Spinal anaesthesia was also offered to patients later in the series if they preferred it (numbers of patients treated by each not reported).

Abbreviations used: CI, confidence interval; DGHAL, Doppler-guided haemorrhoidal arterial ligation; GI, grade I; GII, grade II; GIII, grade III; GIV, grade IV; HAL, haemorrhoidal arterial ligation; NS, not significant; RCT, randomised controlled trial; THD, transanal haemorrhoidal dearterialisation; VAS, visual analogue scale

Study details	Key efficacy findings	Key safety findings	Comments
	Long-term resolution of symptoms (n = 219, 46 months) Of these 100 were GII, 104 were GIII and 15 were GIV. **Outcome** / **% of patients with resolution** Bleeding: 92.9 (132/142)* Prolapse: 92.4 (110/119)** * Of those with recurrence of bleeding, 7 patients were GII, 2 were GIII and 1 was GIV. ** Recurrence occurred in 5 patients with GIII and 4 with GIV. **Patients also treated with anopexy** Of the 219 patients, 63 were treated with running suture anopexy and 56 with a figure-of-8 stitch. Only prolapsed haemorrhoids were treated with anopexy. The relapse rate of those treated with anopexy by grade was: **% of patients with running suture (n = 63)** / **% of patients with figure-of-8 stitch (n = 56)** GIII: 6 (3/50) / 3.7 (2/54) GIV: 50 (3/6) / 11.1 (1/9) (These figures were not statistically significant.)		

Abbreviations used: CI, confidence interval; DGHAL, Doppler-guided haemorrhoidal arterial ligation; GI, grade I; GII, grade II; GIII, grade III; GIV, grade IV; HAL, haemorrhoidal arterial ligation; NS, not significant; RCT, randomised controlled trial; THD, transanal haemorrhoidal dearterialisation; VAS, visual analogue scale

Study details	Key efficacy findings	Key safety findings	Comments
Faucheron J-L (2008)[7] **Case series** France Recruitment period: 2002 to 2004 Study population: patients with grades II to IV haemorrhoids (GII 1, GIII 78, GIV 21) presenting with bleeding (87) and pain (77) (58 also had skin tags). n = **100** Mean age: 45 years Sex: 46% male Patient selection criteria: patients with thrombosis, uncertain diagnosis, associated infections, anal fissure, pregnancy and less than 18 years old were excluded. Technique: DGHAL with local or spinal anaesthesia. Mean follow-up: **3 years** Conflict of interest/source of funding: not reported	Number of patients analysed: **100** with an average of 8.4 ligatures placed in each patient. ***Return to normal activities*** 79 patients were discharged and returned to normal activities on the same day as surgery. ***Recurrence*** There were 12 recurrences at mean 12.6-month follow-up (7 GIII, 5 GIV). These were treated by DGHAL (1), stapled haemorrhoidopexy (7) or haemorrhoidectomy (4) (recurrence not defined).	There were 6 early and 6 late complications (12%). ***Early complications*** **No. of patients** Acute fissure (day 9, 10, 15): 3 Bleeding (day 11): 1* Dyschezia (painful defaecation) lasting 6 days but not requiring treatment: 1 (GIV) Requirement of analgesia for 4 days: 1 ***** This patient later presented with anal fissure at 11-month follow-up. ***Late complications*** **No. of patients** Anal pain: 1 Anal fissure (at 8, 11 months): 2 Thrombosis (at 4, 7, 17 months): 3* * These patients were treated with thrombectomy (2) or haemorrhoidectomy (1); all had GIII haemorrhoids and one also had skin tag resection.	**Follow-up issues**: • This was completed at 1 month and 3 years; there was no reported loss to follow-up. **Study population issues**: • 18 had previous surgery (12 sclerosis or rubber band ligation, 4 stapled anopexy, 2 haemorrhoidectomy). • 19 patients had simultaneous procedures: fissurectomy (7), skin tags (12). **Other issues**: • The mode of anaesthetic used depended on patient preference (47 pudental block, 47 spinal anaesthesia, 6 general anaesthesia).

Efficacy

Symptom resolution

A systematic review of 17 studies including 1996 patients reported recurrence of bleeding, pain on defaecation and prolapse in 6% (40/638), 4% (35/917) and 8% (50/638) of patients respectively in 9 studies with follow-up of less than 1 year; these figures were 10% (49/507), 9% (18/206) and 11% (46/427) respectively in the 6 studies with follow-up of 1 year or more[1]. In general the proportion of patients with preoperative bleeding, pain and prolapse ranged from 45% to 100%, 12% to 83% and 12% to 100% respectively across the studies[1].

A case series of 100 patients reported that in the 3 years of follow-up, there were 12 recurrences (7 grade III, 5 grade IV) of haemorrhoids which occurred at a mean of 12.6 months of follow-up[7].

A randomised controlled trial (RCT) of 45 patients reported that significantly more patients treated with open haemorroidectomy had an improvement in prolapse symptoms than those treated by staple haemorrhoidectomy and arterial ligation (100% vs 67% and 60% respectively; $p < 0.01$; follow-up not stated)[3].

An RCT of 41 patients reported resolution of symptoms in 78% (18/23) of the 23 patients treated with haemorrhoidal ligation and 83% (15/18) of the 18 patients treated with stapled haemorrhoidopexy, but this difference was not significant[9].

A non-randomised trial of 70 patients reported that 91% (32/35) of patients treated with Doppler-guided arterial ligation had treatment success (with no recurrence of bleeding or prolapse) compared with 23% (8/35) of patients treated with the comparator (not described) at 12 to 13 months of follow-up[4].

A case series of 616 patients treated with the procedure without the use of Doppler guidance reported symptom resolution in 96%, 98%, and 96% of patients who presented with bleeding, prolapse, and pain on defaecation, respectively, at 4-week follow-up. A study of the 485 patients treated from 1997 until early 2007 reported that among the 307 patients who responded (63%), 94% had resolution of bleeding or pain on defaecation and 89% had resolution of prolapse (mean follow-up of these patients not reported)[8].

A case series of 330 patients reported 93% (132/142) of patients who presented with bleeding and 92% (110/119) of patients who presented with prolapse had a resolution of symptoms at mean 46-month follow-up (80 and 73 patients respectively were lost to follow-up; no reason given). Of those with recurrence of bleeding, 7 patients had grade II, 2 had grade III and 1 had grade IV haemorrhoids. Of those with recurrence of prolapse, 5 patients had grade III and 4 had grade IV haemorrhoids[6].

Postoperative pain and recovery period

An RCT of 60 patients reported significantly less requirement for analgesics (3 compared with 12 doses) and a faster return to normal activities (no longer requiring help to care for themselves; from 3 to 25 days) in the 30 patients treated with haemorrhoidal artery ligation compared with the 30 patients treated by closed haemorrhoidectomy ($p < 0.005$ for both)[2].

The RCT of 45 patients reported that the 15 patients treated by arterial ligation and the 15 patients treated by stapled haemorrhoidectomy had a significantly better improvement in pain than the 15 patients treated by open haemorrhoidectomy during the first 24 hours after the procedure (measured on a 10-cm visual analogue scale [VAS] with 10 as worst pain; less than 3 in the first 2 groups and 8 in the open group; $p > 0.01$)[3].

The RCT of 41 patients reported lower postoperative pain in the 23 patients treated with haemorrhoidal ligation than the 19 patients treated with stapled haemorrhoidopexy at 3-week follow-up (3.1 versus 5.1 at 1 day and 1.6 to 3.2 at 7 days; a higher number referred to higher pain but the VAS scale was not described). This difference was no longer significant at 6-week follow-up[9].

Patient satisfaction

The case series of 616 patients reported a mean score of 8.2 (10-cm VAS from 1 to 10; 10 being most satisfied) among the 523 patients who were reported on at 1-year follow-up (reason for loss to follow-up not reported) [8].

Of the 507 patients in the case series, 69% (351) considered that they had ‘good’ results (good symptom relief) and 15% (75) had results they felt were acceptable (remaining 81 patients not reported). ‘Very good’ (free of disease) or ‘good’ results were reported in 92% (133/144) and 84% (272/324) of patients with grades II and III haemorrhoids respectively. Only 41% (18/44) of patients with grade IV haemorrhoids were satisfied with the operation[5].

Safety

The systematic review reported 3 cases of significant postoperative haemorrhaging requiring blood transfusion in 2 patients (the other patient developed coagulopathy and treatment was not further described)[1].

An RCT reported significantly more complications in the 30 patients treated with closed scissor haemorrhoidectomy than the 30 treated by arterial ligation ($p < 0.05$). In the closed scissor haemorrhoidectomy group fever, nausea and urinary retention requiring catheterisation were reported in 9, 6 and 1 patient respectively while only 2 patients developed nausea among those treated with arterial ligation (all patients with nausea required intravenous fluid replacement)[2].

The non-randomised trial of 70 patients reported significantly more complications in those in the control group (not clearly described) than in those treated with arterial ligation 8 days after treatment (74% [26/35] versus 11% [4/35]; $p < 0.01$;

complications not described)[4]. The difference in complications was no longer significant 25 days after the procedure (11% [4/35] versus 2.8% [1/35]).

The case series of 616 patients reported complications in 9% (56/616) of patients including perianal thrombosis (12), bleeding requiring readmission (4), pain requiring readmission (2), urinary retention (9), pruritus ani (or itchiness; 2), mucosal prolapse (6), skin tag (13), constipation (4) and tenesmus (or feeling of incomplete defaecation; 4) [8].

The case series of 507 patients reported haemorrhoidal thrombosis (very painful haemorrhoids which may require hospitalisation to manage the pain) (18), fistula (1) and fissure (11) which occurred postoperatively (time of occurrence not reported)[5].

The case series of 330 patients reported a 7% (23/330) complication rate (fissure 2, haemorrhoidal thrombosis 5, urinary retention requiring catheterisation 2, submucosal haematoma 4, haematuria 1, immediate bleeding 4 and delayed bleeding 3; time of occurrence not reported)[6].

The case series of 100 patients reported 6 early and 6 late complications.[7] The early complications included 3 cases of acute fissure at 9, 10 and 15 days postoperatively, 1 case of bleeding 11 days postoperatively, and 1 case of dyschezia (painful defaecation) lasting 6 days (not requiring treatment). Late complications included 1 case of anal pain, 2 cases of anal fissure at 8 and 11 months postoperatively, and 3 cases of thrombosis 4, 7 and 17 months postoperatively. The patients with thrombosis had grade III haemorrhoids and were treated with thrombectomy (2) or haemorrhoidectomy (1).

Validity and generalisability of the studies

- There were 3 randomised studies (one included in the systematic review). One compared the procedure with closed scissor haemorrhoidectomy, another compared the procedure with both stapled haemorrhoidopexy and open haemorrhoidectomy, and a third compared it with stapled haemorrhoidopexy [2,3,9]. A non-randomised trial compared the procedure with a control group but the control treatment was not well defined [4]. The remaining studies were case series.
- The longest follow-up reported in the studies was on 219 patients at 46 months[6]; another study reported on 100 patients at 36 months (3 years) [7].
- Most studies include patients with grade II to IV haemorrhoids. Very few patients with grade I haemorrhoids were included.

- There were a number of non-English publications on the use of this procedure which were identified in the literature but were not included; the conditions that would have required recourse to non-English literature as set out in the Programme's guides were not met.
- The notifier of the procedure (also the manufacturer) had stated that the procedure is used with general anaesthetic in the UK, but local anaesthetic or sedation is sometimes used for early grades of haemorrhoids in other countries. The variation in the use of anaesthetic in the evidence reflects this.
- Only 3 studies in this overview completed plication or mucopexy after arterial ligation[6, 8, 9]. This appears to be a newer addition to arterial ligation, but there is not much evidence on the use of this procedure that includes this element. A study in appendix A (Conaghan 2009) describes the use of Doppler-guided haemorrhoidal arterial ligation with rectoanal repair (RAR) which some of the literature suggests is a similar concept.

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

- Circular stapled haemorrhoidectomy. NICE interventional procedures guidance 34 (2003). Available from www.nice.org.uk/IPG34

Technology appraisals

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

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 does not represent the view of the society.

Mr Steve Brown, Mr Simon Middleton, Miss Karen Nugent, Mr Graham Williams (Association of Coloproctology of Great Britain and Ireland).

- Less than 10% of specialists are engaged in this area of work.
- Surgeons should be trained and mentored by an experienced surgeon. Training should include observation, and, if possible, practice on a bowel or anal model.
- Comparator procedures include mucosal banding, conventional haemorrhoidectomy or stapled anopexy.

Efficacy

- Key efficacy outcomes include reduction in postoperative pain compared with other treatments, resolution of haemorrhoids, and resolution of symptoms such as bleeding, prolapse, swelling, pain, soreness, itching in the short and long term.
- One Adviser states that while surgeons have been performing the procedure for up to 5 years, the efficacy is uncertain, particularly in the long term. There are no randomised trials that show that short-term results are maintained in the long term. The published evidence only includes lesser-grade piles and does not compare the procedure with alternatives which would be considered 'lesser means' (such as banding).

Safety

- It appears to be as safe as conventional surgery and potentially has fewer risks than banding or haemorrhoidectomy.
- Anal fissure, external anal thrombosis, pain and bleeding were reported as anecdotal adverse events.
- Theoretical adverse events include rectal perforation, pelvic abscess, stenosis, haemorrhage, infection, acute and chronic pain, urinary retention, faecal incontinence, and complications associated with general anaesthesia.

Patient Commentators' opinions

NICE's Patient and Public Involvement Programme was unable to obtain patient commentary for this procedure.

Issues for consideration by IPAC

- A publication on the use of stapled haemorrhoidopexy (the other minimally invasive technique for this condition) reported a broken condom in a homosexual patient. Since THD does not involve the use of staples, it may be of significant benefit and of less risk of a safety event than stapled haemorrhoidopexy.
- The terms 'transanal haemorrhoidal dearterialisation', and 'Doppler-guided haemorrhoidal arterialisation' refer to specific devices used for this procedure (both involve the use of Doppler guidance).

References

1. Giordano P, Overton J, Madeddu F et al. (2009) Transanal hemorrhoidal dearterialization: a systematic review. Diseases of the Colon and Rectum 52: 1665–71.

2. Bursics A, Morvay K, Kupcsulik P et al. (2004) Comparison of early and 1-year follow-up results of conventional hemorrhoidectomy and hemorrhoid artery ligation: a randomized study. International Journal of Colorectal Disease 19: 176–80.

3. Khafagy W, El NA, Fouda E et al. (2009) Conventional haemorrhoidectomy, stapled haemorrhoidectomy, Doppler guided haemorrhoidectomy artery ligation; post operative pain and anorectal manometric assessment. Hepato-Gastroenterology 56: 1010–15.

4. Hajdarevic B, Slaku J, Pandza H et al. (2009) Application of simple digital methods in the treatment of hemorrhoid disease. Studies in Health Technology and Informatics 150: 433–7.

5. Walega P, Scheyer M, Kenig J et al. (2008) Two-center experience in the treatment of hemorrhoidal disease using Doppler-guided hemorrhoidal artery ligation: functional results after 1-year follow-up. Surgical Endoscopy 22: 2379–83.

6. Dal Monte PP, Tagariello C, Giordano P et al. (2007) Transanal haemorrhoidal dearterialisation: nonexcisional surgery for the treatment of haemorrhoidal disease. Techniques in Coloproctology 11: 333–9.

7. Faucheron J-L, Gangner Y. (2008) Doppler-guided hemorrhoidal artery ligation for the treatment of symptomatic hemorrhoids: Early and three-year follow-up results in 100 consecutive patients. Diseases of the Colon and Rectum 51: 945–9.

8. Gupta PJ, Kalaskar S. (2008) Ligation and mucosopexy for prolapsing haemorrhoids – a ten year experience. Annals of Surgical Innovation and Research 2: 5. https://www.asir-journal.com/content/2/1/5.

9. Festen S, van Hoogstraten MJ, van Geloven AAW et al. (2009) Treatment of grade III and IV haemorrhoidal disease with PPH or THD. A randomised trial on postoperative complication and short-term results. International journal of colorectal disease 24: 1401–5.

Appendix A: Additional papers on haemorrhoidal arterial ligation

The following table outlines the studies that are considered potentially relevant to the 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
Abdeldaim Y, Mabadeje O, Muhammad KM et al. (2007) Doppler-guided haemorrhoidal arteries ligation: preliminary clinical experience. Irish Medical Journal 100: 535–7.	Case series n = 35 Follow-up = 18 months	91.5% (11/12) success in those with pain, 85% (28/33) in those with bleeding, 93% (14/15) in those with pruritis, 92% (12/13) in those with discharge and 81% (17/21) in those with prolapse.	Studies with more patients and longer follow-up in table 2.
Conaghan P, Farouk R. (2009) Doppler-guided hemorrhoid artery ligation reduces the need for conventional hemorrhoid surgery in patients who fail rubber band ligation treatment. Diseases of the Colon and Rectum 52: 127–30.	Case series n = 52 Follow-up = 18 months	12 had recurrence (6 with prolapsed and 6 with bleeding) and were subsequently treated with haemorrhoidectomy (1) or the same procedure with recto-anal repair (11).	Studies with more patients and longer follow-up in table 2.
Felice G, Privitera A, Ellul E et al. (2005) Doppler-guided hemorrhoidal artery ligation: an alternative to hemorrhoidectomy. Diseases of the Colon and Rectum 48: 2090–3.	Case series n = 68 Follow-up = 11 months	Resolution of bleeding in 91%, of pain in 73% and of prolapse in 94%.	Studies with more patients and longer follow-up in table 2.
Gehlen JMLG, van Gemert WG, de Haan MW et al. (2007) Severe anal bleeding in Proteus syndrome: A case report. Techniques in Coloproctology 11: 158–60.	Case report n = 1	Description of a patient with proteus syndrome treated with this procedure.	Studies with more patients and longer follow-up in table 2.
Greenberg R, Karin E, Avital S et al. (2006) First 100 cases with Doppler-guided hemorrhoidal artery ligation. Diseases of the Colon and Rectum 49: 485–9.	Case series n = 100 Follow-up = 12 months	Mean pain decreased from 2.1 postoperatively to 1.3 one day later. 94 patients remained asymptomatic at 6 months (4 required additional surgical excision and 2 required rubber band ligation).	Studies with more patients and longer follow-up in table 2.
Morinaga K, Hasuda K, Ikeda T. (1995) A novel therapy for internal hemorrhoids: ligation of the hemorrhoidal artery with a newly devised instrument (Moricorn) in conjunction with a Doppler flowmeter. American Journal of Gastroenterology 90: 610–13.	Case series n = 116 Follow-up = not stated (presumably postoperative)	78% (50/64) of patients with prolapse successfully treated (96% [50/52] and 96% [92/96] of patients with pain and bleeding were successfully treated).	Studies with more patients and longer follow-up in table 2.
Ramirez JM, Aguilella V, Elia M et al. (2005)	Case series	19 patients free from symptoms at 1 year and	Studies with more patients and longer

Doppler-guided hemorrhoidal artery ligation in the management of symptomatic hemorrhoids. Revista Espanola de Enfermedades Digestivas 97: 97–103.	n = 32 Follow-up = 1 year	6 with significant symptom relief (failed in patients with grades III or IV).	follow-up in table 2.
Scheyer M, Antonietti E, Rollinger G et al. (2006) Doppler-guided hemorrhoidal artery ligation. American Journal of Surgery 191: 89–93.	Case series n = 308 Follow-up = 18 months	Average of 6 ligatures placed; recurrence in 15.6 % (48/308) of patients: fissure in 1.3% (4), thrombosis in 2.9% (9), and fistula, proctitis and stool retention in 1 patient each (0.3%).	Same patients as reported in Walega (2008).
Sohn N, Aronoff JS, Cohen FS et al. (2001) Transanal hemorrhoidal dearterialization is an alternative to operative hemorrhoidectomy. American Journal of Surgery 182: 515–19.	Case series n = 60 Follow-up = 5 to 12 months	Resolution of bleeding in 88%, of protrusion in 92% and of pain in 71%. Unsuccessful in 2 (3%).	Studies with more patients and longer follow-up in table 2.
Wallis de Vries BM, van der Beek ES, de Wijkerslooth LR et al. (2007) Treatment of grade 2 and 3 hemorrhoids with Doppler-guided hemorrhoidal artery ligation. Digestive Surgery 24: 436–40.	Case series n = 110 Follow-up = 37 weeks	88% (97/110) had significant improvement at 6 weeks, 84.5% (93/110) were satisfied at 37 weeks.	Studies with more patients and longer follow-up in table 2.
Wilkerson PM, Strbac M, Reece-Smith H et al. (2009) Doppler-guided haemorrhoidal artery ligation: long-term outcome and patient satisfaction. Colorectal Disease 11: 394–400.	Case series n = 113 Follow-up = 30 months	90% (93/103) had complete or significant relief at 6 weeks and 86% (77/90) at 30 months.	Studies with more patients and longer follow-up in table 2.

Appendix B: Related NICE guidance for haemorrhoidal arterial ligation

Guidance	Recommendations
Interventional procedures	**Circular stapled haemorrhoidectomy. NICE interventional procedures 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: www.acpgbi.org.uk).
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.

Appendix C: Literature search for haemorrhoidal arterial ligation

Database	Date searched	Version/files
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	29/09/2009	Issue 3, 2009
Database of Abstracts of Reviews of Effects – DARE (CRD website)	30/09/2009	-
HTA database (CRD website)	30/09/2009	-
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	29/09/2009	Issue 3, 2009
MEDLINE (Ovid)	28/09/2009	1950 to September Week 3 2009
MEDLINE In-Process (Ovid)	28/09/2009	September 25, 2009
EMBASE (Ovid)	29/09/2009	1980 to 2009 Week 39
CINAHL (NLH Search 2.0/EBSCOhost)	29/09/2009	1981-present
BLIC (Dialog DataStar)	01/01/2009	-

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

1 exp Hemorrhoids/
2 Hemorrhoid*.tw.
3 Haemorrhoid*.tw.
4 ((Intern* or Extern* or prolaps*) adj3 (hemorrhoid* or haemorrhoid* or pile*)).tw.
5 pile*.tw.
6 or/1-5
7 Dearteriali?at*.tw.
8 THD.tw.
9 Transan* Haemorrhoid* dearterialis*.tw.
10 Transan* Hemorrhoid* dearterialis*.tw.
11 Transan* Hemorrhoid* dearterializ*.tw.
12 Transan* Haemorrhoid* dearterializ*.tw.
13 (THD adj3 Doppler*).tw.
14 (transanal* adj5 (hemmor* or haemorrhoid*)).tw.
15 (transan* adj3 doppler*).tw.
16 (Transan* adj3 doppler* Guid*).tw.
17 (Doppler*- Guid* adj3 Transan*).tw.
18 Ligation/
19 ligatio*.tw.
20 Ultrasonography, Doppler/
21 (Ultrasonograp* adj3 Doppler*).tw.

22 or/7-21
23 22 and 6
24 Animals/ not Humans/
25 23 not 24
26 from 25 keep 1-556