NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of circular stapled haemorrhoidectomy

Introduction

This overview has been prepared to assist members of IPAC advise on the safety and efficacy of an interventional procedure previously reviewed by SERNIP. It is based on a rapid survey of published literature, review of the procedure by specialist advisors and review of the content of the SERNIP file. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared by ASERNIP-S in November 2002

Updated by NICE in October 2003

Procedure name

Circular stapled haemorrhoidectomy; also known as circular stapled rectal mucosectomy.

Specialty society

Association of Coloproctology of Great Britain and Ireland (ACPGBI)

Executive summary

Due to small sample size, short follow-up times and lack of comparability between outcome measures no conclusions about efficacy or safety could be made from the studies included in the systematic review. However there was a statistically significant reduction in bleeding two weeks after stapled haemorrhoidectomy compared with conventional haemorrhoidectomy. Detailed results can be found in the full systematic review, a copy of which has been provided.

The four other included studies had similar methodological limitations as above. However results showed that stapled haemorrhoidectomy may be associated with decreased operative time, postoperative pain, and possibly incontinence than conventional haemorrhoidectomy. The procedure may also offer a quicker return to normal activities. One study suggested an increase in the removal of the internal anal sphincter muscle after stapled haemorrhoidectomy.[1] The included studies suggested a lower overall postoperative complication rate for stapled haemorrhoidectomy.

Indication(s)

Internal haemorrhoids develop when cushions of vascular tissue in the anus undergo pathological change. These cushions have an important role in maintaining continence as they function, along with the internal anal sphincter, to allow the complete closure of the anal canal.[2] Haemorrhoids may prolapse and may cause bleeding, faecal soiling, itching, and occasionally pain.[2,3] The prevalence of haemorrhoids is estimated at between 4% and 34%.[4]

Summary of procedure

Circular stapled rectal haemorrhoidectomy reduces the size of internal haemorrhoids by interrupting their blood supply, reducing the available rectal mucosa for the potential of prolapse. Whereas conventional surgical haemorrhoidectomy involves excision of haemorrhoidal tissue, anoderm and perianal skin, stapled haemorrhoidectomy simply excises an annulus of rectal mucosa above the haemorrhoids.

After dilatation of the anal canal, a purse string suture is placed four centimetres above the dentate line.[5] Subsequently, a circular stapler is introduced transanally. The anvil of the device is positioned proximal to the purse-string and the suture is tied down on to the anvil. Retraction of the suture pulls the attached rectal mucosa into the stapler. Closure of the anvil and firing of the stapler simultaneously excises a ring of mucosa proximal to the haemorrhoid(s), thus interrupting the blood supply,[6] but maintaining continuity of the rectal mucosa.[7]

Literature review

A systematic search of MEDLINE, PREMEDLINE, EMBASE, Current Contents, PubMed, Cochrane Library and Science Citation Index using Boolean search terms was conducted, from the inception of the databases until November 2002. The York Centre for Reviews and Dissemination, Clinicaltrials.gov, National Research Register, SIGLE, Grey Literature Reports, relevant online journals and the Internet were also searched in November 2002. Searches were conducted without language restriction.

Articles were obtained on the basis of the abstract containing safety and efficacy data on circular stapled haemorrhoidectomy in the form of systematic reviews or randomised controlled trials (RCTs). If there were more than five studies only the most important of these were reported. Foreign language papers in abstract form were included if they contained safety and efficacy data and were considered to add substantively to the English language evidence base. In the case of duplicate publications, only the latest, most complete study was included. Included studies are highlighted in bold in the reference list. Studies for which data were not tabulated are listed in the annex following the reference list.

One systematic review contains all of the published RCTs up to June 2001 (seven RCTs).[8] Another systematic review of haemorrhoidal RCTs (MacRae *et al*, 2002; see annex) incorporated the findings of three RCTs which were covered by the first review. In addition, six RCTs assessing circular stapled haemorrhoidectomy had been published since the completion of the systematic review.[8] Four[1,9-11] were included in this overview. One was excluded because it involved patients that were allocated to stapled haemorrhoidectomy with or without the use of an anal dilator (Ho *et al*, 2002; see annex). The other RCT was excluded as it fell outside of the search period for inclusion in the overview (Wilson *et al*, 2002; see annex).

List of studies found

Total number of studies: 8

- Systematic Reviews - 2
- RCTs - 6

Summary of key efficacy and safety findings

See following tables

Abbreviations

ACPGBI,	Association of Coloproctology of Great Britain and Ireland
CI	confidence interval
CNV	conventional haemorrhoidectomy
ns	not significant
RCT	randomised controlled trial
RR	relative risk
St	stapled haemorrhoidectomy
[]	standard deviation

Authors, date, location, number of patients, length of follow-up, selection criteria	Key efficacy findings	Key safety findings	Appraisal/Comments
Systematic literature review			
Sutherland *et al.*[8] 2001, AUSTRALIA Circular stapled haemorrhoidectomy and conventional haemorrhoidectomy 7 RCTs n=591 *Study period:* 1995 to 2001 *Follow-up range:* 4 weeks to 1 year postoperative	Circular stapled haemorrhoidectomy tended to result in: • possibly earlier resumption of usual activities and return to normal bowel function • possibly lower rates of early postoperative pain and, wound discharge, anal discharge, pruritus, and tenderness to per rectal examination • possibly lower analgesia requirement • possibly shorter operating time and hospital stay • no detectable difference in incontinence	Circular stapled haemorrhoidectomy tended to result in: • statistically significant reduction in the risk of bleeding at two weeks postoperative (45%, CI, 18-63%, p=0.003) • no detectable difference in early haemorrhage • possibly less frequent occurrence of faecal impaction, anal stricture, and stenosis • possibly more frequent occurrence of urinary retention and requirement for haemostatic sutures	• small sample sizes • short follow-up periods • variation in patient characteristics • incomplete reporting of important outcomes
SUMMARY:	• No conclusions about efficacy could be reached	• No conclusions about safety could be reached	• evidence limited by small sample size, short follow-up times, lack of comparability between outcome measures

Authors, date, location, number of patients, length of follow-up, selection criteria	Key efficacy findings	Key safety findings	Appraisal/Comments
Randomised Controlled Trials			
Hetzer *et al.*[9] 2002, SWITZERLAND n = 40 (20 stapled, 20 conventional - closed excision haemorrhoidectomy, Ferguson) *Follow-up:* up to 1 year postoperative *Selection criteria:* patients with second or third degree haemorrhoids between January 1999 to July 2000	Overall operating time (min) St 30 (range 15-45); CNV 43 (range 25-60) (p<0.001) Average amount of pain significantly lower in stapled group (p≤0.001) Mean length of hospital stay not significantly different (p=0.17) Mean return to work (days) St 6.7 (range 2-14); CNV 20.7 (range 7-45) (p=0.001) No difference in recurrence of haemorrhoidal disease (5% in both treatment groups) (1 year postoperative, % of patient at follow-up not stated) No incontinence in either treatment group in follow-up period (3 and 12 weeks, 100% of patients) Impaired wound healing St 0/20 (0%); 4/20 (20%) CNV (3 and 12 weeks follow up, 100% of patients, CVN impairment due to suture dehiscence)	<u>Complications within first postoperative week:</u> Total St 3/20 (15%); CNV 5/20 (25%) (p=0.60) Haemorrhage (bleeding) St 2/20 (10% - both required subsequent reoperation); CNV 0/20 (0%) Thrombosis St 1/20 (5%); CNV 0/20 (0%) Urinary retention St 0/20 (0%); CNV 1/20 (5%) Suture dehiscence St 0/20 (0%); CNV 4/20 (20%) Mortality 0% in both treatment groups <u>Complications at 1 year postoperative:</u> No stenosis, perirectal fistula or perirectal pain (% of patients at follow-up not stated)	*Outcome measures and their validity:* Visual analogue pain score (1-10) Williams incontinence score *Study details:* Patients randomised by drawing lots Patients blinded All procedures performed by one surgeon (previously performed > 30 stapled procedures) 10 patients had prior rubber band ligation and 2 that had refused rubber band ligation Follow-up data recorded by an independent surgeon.

Authors, date, location, number of patients, length of follow-up, selection criteria	Key efficacy findings	Key safety findings	Appraisal/Comments
Randomised Controlled Trials			
Correa-Rovelo *et al.*[10] 2002, MEXICO n = 84 (42 stapled, 42 conventional - closed excision haemorrhoidectomy, Ferguson) *Follow-up:* 6 to 14 months (n=41 stapled, n=41 conventional) *Selection criteria:* Patients with non-thrombosed third or fourth degree haemorrhoids were included while patients with anorectal comorbidity, previous anal surgery, or immunosuppression were excluded over the 10 month study period.	Mean operating time (min) St 11.9 [3.1]; CNV 46.4 [10.4] (p<0.001) Mean and maximal pain significantly less in stapled group (p<0.001) (first 24 h postoperatively)(Mean St 2.8 [1.4]; CNV 5.5 [1.4]: Maximal St 4.6 [1.2]; CNV 7.2 [1.7]) Less analgesia in stapled group (p<0.001) Mean time to first bowel movement (hr) St 26.3 [7.2]; CNV 34.3 [14.2] (p<0.002) Mean return to work (days) St 6.1 [3.5]; CNV 15.2 [4.8] (p<0.001) Symptomatic anal pruritus at 2 weeks St 10/42 (24%); CNV 16/42 (38%) (p=0.15) Symptomatic bleeding at 2 weeks St 33%; CNV 55% patients (p=0.048) Mean symptomatic pain at 2 weeks (visual analogue scale, 0-10) St 1.1 [1.4]; CNV 3.7 [1.5] (p<0.001) Incontinence (up to 3 weeks postoperative) St 0/42 (0%); CNV 1/42 (2%) (p=1.0) Pruritus (up to 3 weeks postoperative) St 1/42 (2%); CNV 2/42 (5%) (p=1.0) <u>Long-term follow-up (6 to 14 months):</u> Wounds healed in all patients Recurrence of haemorrhoidal disease St 2.4%; CNV 0% (p=1.0)	<u>Early complications (within first postoperative week):</u> Total St 3/42 (7%); CNV 9/42 (21%) (p=0.06) Urinary retention St 1/42 (2%); CNV 3 (7%) (p=0.62) Bleeding requiring revision St 1/42 (2%); CNV 0/42 (0%) (p=1.0) Submucosal haematoma St 1/42 (2%); CNV 0/42 (0%) (p=1.0) Wound dehiscence St 0/42 (0%); CNV 4/42 (10%) (p=0.12) Faecal impaction St 0/42 (0%); CNV 2/42 (5%) (p=0.49) <u>Late complications (up to 3 weeks postoperative):</u> Total St 3/42 (7%); CNV 4/42 (10%) (p=1.0) Anal stricture St 1/42 (2%); CNV 1/42 (2%) (p=1.0) Dyspareunia St 1/42 (2%); CNV 0/42 (0%) (p=1.0)	*Potential for bias:* Not mentioned whether patients were blinded *Outcome measures and their validity:* Visual analogue pain score (1-10) Incontinence score *Study details:* Patients randomised using random number tables Treating surgeons had performed stapled haemorrhoidectomy on 12 patients prior to commencement of the trial Follow-up data recorded by an independent surgeon

Continued

Authors, date, location, number of patients, length of follow-up, selection criteria	Key efficacy findings	Key safety findings	Appraisal/Comments
Randomised Controlled Trials			
Correa-Rovelo *et al*.[10] 2002, MEXICO	Long-term follow-up continued: Asymptomatic patients St 32/41 (78%); CNV 35/41 (85%) (p=0.39) Bleeding St 8/31 (20%); CNV 2/41 (5%) (p=0.043) Discomfort or anal pain St 2/41 (5%); CNV 3/41 (7%) (p=1.0) Pruritus St 2/41 (5%); CNV 4/41 (10%) (p=0.67) Prolapse St 1/41 (3%); CNV 0/42 (0%) (p=1.0) Incontinence St 0/41 (0%); CNV 2/41 (5%) (p=0.49) Skin tags St 5/41 (12%); CNV 2/41 (5%) (p=0.43)		

Authors, date, location, number of patients, length of follow-up, selection criteria	Key efficacy findings	Key safety findings	Appraisal/Comments
Randomised Controlled Trials			
Ortiz *et al.*[11] 2002, SPAIN n = 55 (27 stapled, 28 conventional - open diathermy haemorrhoidectomy) *Mean follow-up:* stapled 15.9 months, conventional 15.2 months (100% of patients) *Selection criteria:* patients with third or fourth degree haemorrhoids were included while patients with concomitant anal disease, previous surgery, or receiving treatment with oral anticoagulants were excluded between November 1999 to December 2000	Mean operating time (min) St 19.0 (range 14-35); CNV 33.5 (range 15-90) (p=0.001) Mean pain St 1.19 (range 0-2.29); CNV 3.46 (range 1.09-6.22) (p=0.007) (first 14 days postoperatively) Requirement for haemostatic suture St 19/27 (70%); CNV not stated Removal of internal anal sphincter muscle St 7/27 26% patients; CNV 0% patients Intramuscular analgesia of first postoperative day St 3/27 (11%); CNV 5/28 (18%) patients (p=ns) Mean time to first bowel movement (days) St 2.9 (range 0-5); CNV 3.2 (range 1-6) Return to work activities (weeks) St 3.3 (range 0-14); CNV 3.8 (range 0-16) (p=ns) Immediate prolapse (mucosal or haemorrhoidal) 0% of patients Thrombosed residual external haemorrhoid (2 days postoperative) St 1/27 (4%); CNV 0/28 (0%) Persistent pain (over 14 weeks postoperative) St 1/27 (4%); CNV 0/28 (0%) <u>Long-term follow-up (mean stapled 15.9 months, conventional 15.2 months):</u> Prolapse St 7/27 (26%); CNV 0/28 (0%) (p=0.004; 4th postoperative month onwards) (according to degree of haemorrhoids, 3rd degree St 2/17 (12%); CNV 0/12 (0%) (p=0.49, RR 0.08, 95%CI 0.27 to 1.05); 4th degree St 5/10 (50%); CNV 0/16 (0%) (p=0.003, RR 0.50, 95%CI 0.27 to 0.93)	<u>Postoperative complication:</u> Total St 10/27 (27%); CNV 12/28 (42%) (p=ns) Urinary retention St 6/27 (22%);CNV 10/28 (28%) Suture dehiscence St 1/27 (4%); CNV 0/28 (0%) Secondary haemorrhage St 0/27 (0%); CNV 1/28 (4%) Faeca1 impaction (4 days postoperative) St 1/27 (4%); CNV 0/28 (0%) Bleeding requiring suture ligation (7 days postoperative) St 0/27 (0%); CNV 1/28 (4%) Subcutaneous fistula (6 weeks postoperative) St 0/27 (0%); CNV 1/28 (4%) Septic complications St 1/27 (4%); CNV 1/28 (4%) <u>Complications at long-term follo-up (mean stapled 15.9 months, conventional 15.2 months):</u> Haemorrhage (persistence of bleeding) St 2/27 (8%); CNV 1/28 (4%) (p=ns) Stenosis St 0/27 (0%); CNV 0/28 (0%)	*Potential for bias:* Not mentioned whether patients were blinded *Outcome measures and their validity:* Visual analogue pain score (1-10) Incontinence score *Study details:* Consecutive patients randomised by a computer-generated table of random numbers All procedures performed by one surgeon (25 prior stapled procedures) Follow-up data were collected by an independent observer

Continued

Authors, date, location, number of patients, length of follow-up, selection criteria	Key efficacy findings	Key safety findings	Appraisal/Comments
Randomised Controlled Trials			
Ortiz *et al.*[11] 2002, SPAIN	Long-term follow-up (mean stapled 15.9 months, conventional 15.2 months): Pruritus St 3/27% (11%); CNV 2/28 (7%) (p=ns) Pain St 1/27 (4%); CNV 0/28 (0%) (p=ns) Faecal urgency St 2/27 (7%); CNV 4/28 (14%) (p=ns) Skin tags St 7/27 (26%); CNV 7/28 (25%) (p=ns) Incontinence St 0/27 (0%); CNV 0/28 (0%)		

Authors, date, location, number of patients, length of follow-up, selection criteria	Key efficacy findings	Key safety findings	Appraisal/Comments
Randomised Controlled Trials			
Pavlidis *et al.*[1] 2002, GREECE n = 80 (40 stapled, 40 conventional - Milligan Morgan) *Follow-up:* not stated *Selection criteria:* patients with second to fourth degree haemorrhoids were included, while those patients with fourth degree haemorrhoids that were thrombosed or strangulated were excluded between January 1999 to December 2000	Mean operating time (min) St 23 [5]; CNV 35 [10] ($p<0.05$) Mean epidural morphine requirement (mg) St 40 [15]; CNV 250 [17] ($p<0.01$) Mean hospital stay (days) St1.7 [0.05]; CNV 3.2 [0.3] ($p<0.05$) Postoperative pain at 3h St 2.5 [0.3]; CNV 3.4 [0.5] ($p<0.05$) Postoperative pain at 6h St 2.9 [0.5]; CNV 3.9 [0.7] ($p<0.05$) Postoperative pain at 12h St 2.3 [0.6]; CNV 3.6 [0.4] ($p<0.05$) Postoperative pain at 24h St 0.7 [0.2]; CNV 2.4 [0.5] ($p<0.01$) <u>Follow-up (1 to 3 months):</u> Recurrence of haemorrhoidal disease St 0/40 (0%); CNV 0/40 (0%) Mild incontinence St 1/40 (3%); CNV 2/40 (5%) <u>Follow-up (1 year or more telephone interview St 82% available; CNV 90% available):</u> Recurrence of haemorrhoidal disease St 0/40 (0%); CNV 0/40 (0%) Mild incontinence St 1/40 (3%); CNV 1/40 (3%) (Note: mild incontinence in the CNV cases were found to be associated with the removal of fibres of the internal anal sphincter)	Postoperative bleeding St 3/40 (8%) ; CNV 2/40 (5%) (p=ns) <u>Follow-up (1 year or more telephone interview St 82% available; CNV 90% available):</u> Stenosis St 0/40 (0%); CNV 0/40 (0%)	*Potential for bias:* Not mentioned as to whether the patients were blinded *Outcome measures and their validity:* The validity of the visual analogue pain score (1-10) was not specifically stated. The validation of the incontinence score was not specifically stated *Study details:* Method of randomisation not stated All procedures performed by one of three experienced surgeons Follow-up data recorded by an independent surgeon Loss to follow-up (stapled 7/40 (18%); conventional 4/40 (10%)

Specialist advisor's opinion / advisor's opinions

Specialist advice was sought from Association of Coloproctology of Great Britain and Ireland (ACPGBI)

The specialist advisors stated that the procedure of circular stapled haemorrhoidectomy had been in place for a number of years and that an increasing number of surgeons were using this approach for the treatment of haemorrhoids. They suggest that most of the safety concerns are theoretical and that many of these concerns are not supported by the trials that have been published. In terms of efficacy, there is limited long-term data available and in particular residual skin tags are more common after stapled haemorrhoidectomy than conventional excision haemorrhoidectomy. There is a requirement for training and they suggest a learning curve of 10-12 cases. The specialty surgeons state that the ACPGBI have just completed a review of this procedure and have developed a consensus position statement based on the published evidence.

Issues for consideration by IPAC

No further issues noted.

References

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APPENDIX A: Studies that met the inclusion criteria but which were not tabulated.

MacRae HM, Temple LKF, McLeod RS. A meta-analysis of hemorrhoidal treatments. *Seminars in Colon & Rectal Surgery* 2002; **3**(1):77-83.

Ho Y-H, Seow-Choen F, Tsang C, Eu K-W. Randomised trial assessing anal sphincter injuries after stapled haemorrhoidectomy. *British Journal of Surgery* 2002; **88**(11):1449-1455.

Wilson MS, Pope V, Doran HE, Fearn SJ, Brough WA. Objective comparison of stapled anopexy and open haemorrhoidectomy: a randomised controlled trial. *Diseases of the Colon & Rectum* 2002; **45**(11):1437-1444.

APPENDIX B: Studies that have been published since the production of the overview

Study details	Patient/ Follow-up	Comments
Maw, A., Concepcion, R., Eu, K.W., Seow-Choen, F., Heah, S.M., Tang, C.L., Tan, A.L. Prospective randomised study of bacteraemia in diathermy and stapled haemorrhoidectomy, British Journal of Surgery, 2003, 90(2) 222-6	205	
Ortiz, H., Marzo, J., Armedariz, P. Randomised clinical trial of stapled haemorrhoidopexy versus conventional diathermy haemorrhoidectomy. British Journal of Surgery, 2002, 89 (11) 1376-81.	55	
Stapled versus excision haemorrhoidectomy: long-term follow-up of a randomied controlled trial, Lancet, 2002, 361 (9367), 1437-1438.	36	Long-term follow-up of original study
Goulimaris, I., Kanellos, I., Christoforidis, E., Mantzoros, I., Odissesos, C., Betsis, D. Stapled haemorrdoidectomy compared with Milligan-Morgan excision for the treatment of prolapsing haemorrhoids: a prospective study. European Journal of Surgery, 2002, 168 (11), 621-625	85	

Note: this is not an exhaustive list