This is an electronic version of an accepted article which appeared in Colorectal Disease 2010;12(6)579-586. The definitive version is available at www.interscience.wiley.com

Randomised Controlled Trial Comparing Rubber Band Ligation With Stapled Haemorrhoidopexy for Grade II Circumferential Haemorrhoids

Long Term Results

V Shanmugam[1] MS, FRCS (Glasg.) - Specialist Registrar

G Muthukumarasamy[5] MB, MRCS (Edin), MRCS (London), Research Fellow

JA Cook[2], BSc, PhD - Statistician

L Vale[2,3], MA, MSc, PhD - Professor

AJM Watson[4] FRCS (Edin.), FRCS (General Surgery) - Consultant Surgeon

MA Loudon[5] MD, FRCS (Edin.), FRCS (General Surgery) - Consultant Surgeon

Departments of Surgery, Queens Medical Centre[1], Aberdeen Royal Infirmary [5] & Manchester Royal Infirmary[4], Health Services Research Unit[2] and Health Economic Research Unit[2,3], University of Aberdeen, Scotland

Corresponding author:

Mr V Shanmugam
Specialist Registrar
Department of Surgery
King's Mill Hospital
Mansfield Road
Sutton In Ashfield
Nottinghamshire
NG17 4JL
Venki411@yahoo.co.uk

Key words: Haemorrhoids, stapled haemorrhoidopexy, rubber band ligation, randomised controlled trial

Word Count:

Abstract - 226

Text -

Tables and figures:

Total number of tables = 3

Total number of figures = 2

Abstract

Aim: An improved understanding of pathophysiology of haemorrhoids has resulted in the introduction of new surgical techniques including stapled haemorrhoidopexy (SH). This randomised controlled trial compared the effectiveness of SH with rubber band ligation (RBL) in the treatment of grade II circumferential symptomatic haemorrhoids in the long-term.

Patients and Methods: A consecutive cohort of patients were randomly allocated to either SH or RBL. Data on haemorrhoidal symptoms, Cleveland continence scores, sphincter assessment, SF-36, EQ-5D, HAD score and prior treatment history were assessed at enrollment and reassessed by long-term postal questionnaire. The details were analysed using SPSS™ 12.0 from Microsoft™ Access®.

Results: Sixty patients were allocated by computer block randomisation. Both groups were balanced for age, sex and symptoms. Recurrence was significant, favoring SH [3 vs 11; OR 0.18, 95% CI (0.03 to 0.86), p=0.028] at one year and, at a mean of 40.67 (31-47) months [4 vs. 12; OR 0.23, 95% CI (0.05, 0.95); p=0.039]. SH patients experienced prolonged pain [Median (IQR) = 7 (5,7) vs. 3 (1,7), P=0.008] and took longer time to return to work [6 (3,7) vs. 3 (1,6) days, P=0.018]. No significant difference in quality of life.

Conclusion: SH achieved better disease control at one year without any major complication. This was sustained in the long-term. Further studies with greater number of patients are needed to confirm this small study.

Introduction

There is a plethora of treatments available for haemorrhoids but no single conventional modality combines immediate efficacy, sustained benefit, patient acceptability and a low complication rate. Rubber band ligation (RBL) is a commonly used, simple and out patient procedure. It is easily repeatable with better results compared to other non-operative treatments including injection sclerotherapy, cryotherapy, and infrared coagulation[1]. In spite of its simple nature RBL may be associated with a variety of complications including vaso-vagal syncope, severe pain, urinary retention, bleeding and more rarely with perineal and retroperitoneal sepsis, as well as recurrence of symptoms.[2-5]

If outpatient measures fail, the most commonly performed operative procedure is excisional haemorrhoidectomy[6]. This removes the haemorrhoidal tissue, unlike RBL, which aims to reduce prolapse with retention of the anal cushion by producing sub mucosal fibrosis at its apex. We recently undertook a systematic review comparing these two treatments which demonstrated that EH was a more effective method of successfully treating grade III haemorrhoids[7]. This was appeared to be achieved at the expense of an increased risk of procedure-related potential complications.. No evidence of a statistically significant difference was seen in grade II haemorrhoids.

Improved understanding of the pathogenesis of haemorrhoids[8], increasing belief in the importance of preserving the anal cushions and greater awareness of the complications associated with excisional haemorrhoidectomy lead to the invention of newer surgical procedures including stapled haemorrhoidopexy (SH). SH acts by relocating the haemorrhoidal cushions cranially into their original position by excising a strip of lower rectal mucosa (pain insensitive mucosa) and by interrupting the blood supply to the haemorrhoids[9].

A variety of studies have proved the efficacy and safety of SH compared with other treatment modalities (RBL, Excisional Haemorrhoidectomy)[10-15]. Most published comparative trials of SH have evaluated the new procedure against excisional haemorrhoidectomy. The fundamental difference in the mechanisms of action of these two procedures limits the validity of such a comparison. Since the introduction of SH there has been only one published randomised controlled trial comparing this procedure with RBL in the treatment of grade III and IV haemorrhoids.[10] In view of the relatively high recurrence rate for symptoms following RBL[16,17] (frequently adopted for grade II haemorrhoids) and the lack of comparative studies against SH, we conducted a pilot study to compare these two techniques in a randomised controlled setting.

Aims

The aim of the study was to evaluate the effectiveness of SH against conventional therapy (RBL) in the treatment of circumferential grade II haemorrhoids. All the patients included in the trial were symptomatic and keen for an intervention to allay the symptoms.

Patients and methods

This was a single centre, prospective, pragmatic, open, randomised controlled trial with parallel group design, comparing RBL with SH in symptomatic, circumferential (haemorrhoids in all the three primary positions with or without additional secondary haemorrhoids), prolapsing haemorrhoids that reduce spontaneously (grade II) or requiring only occasional manual reduction. The primary outcome addressed in this study was disease recurrence at one year and the cumulative costs to the NHS. Both subjective and objective evidence of disease recurrence were considered before making a conclusion that any particular patient had recurrent disease needing further treatment. This study was conducted as a pilot study and hence no power calculation performed. Additional outcome measures included quality of life [assessed by Short Form-36 (SF-36)[18], EuroQuol -5D (EQ-5D[19]) and Hospital Anxiety and Depression scale (HAD score)], Quality Adjusted Life Years (QUALY), symptom score[20], time to no pain, time to normal activity, patient satisfaction, effect on ano-rectal physiology and complication rates between the two procedures. A visual analogue scale (VAS) [21] was used to assess the severity of pain before and for seven days after the procedure. The Grampian local research ethics committee approved the conduct of the study (Ethics committee approval code – GREC 01/0297). Further long-term follow-up was obtained by a postal questionnaire and case notes review (where the questionnaire was not returned).

***Inclusion criteria*:** The study included a consecutive group of patients with symptomatic grade II haemorrhoids recruited between October 2002 and March 2004 without regard for age, sex or duration of symptoms. This cohort included symptomatic patients who had previously undergone non-operative treatment for haemorrhoids with at least 6 months elapsing prior to recruitment.

Exclusion criteria: Patients with peri-anal sepsis and malignant disease of the large bowel were excluded from the trial. Similarly, those with pre-existing evidence of sphincter injury were also excluded after appropriate investigations.

***Pre-treatment* assessment:** All trial participants underwent a standardised pre-operative evaluation of anal sphincter function by an endo-anal ultrasound and anal manometry. This assessment was performed prior to randomisation in order to facilitate the exclusion of patients with anatomical or functional defects of the sphincters. Then, the participants were randomised to one or other of the two interventions.

***Randomisation*:** A computerised block randomisation technique was utilised in this study. The Health Science Research Unit (HSRU), University of Aberdeen, created a computer program to generate a sequence of treatment allocations by block randomisation using a random number generator. Investigators were blinded to the block size to avoid selection bias. Allocation to treatment was performed on the day of the procedure using HSRUs secure automated telephone randomisation service.

RBL was performed using the standard suction banding technique. All three haemorrhoidal components were treated at one sitting. This was performed in the operating theatre but with out anaesthesia. SH was performed using the Procedure for Prolapse and Haemorrhoids 01 (PPH^{TM}, Ethicon Endo-Surgery® plc, Europe) kit. The patients were placed in prone jack-knife position as this was the routine practice of the surgeon. The procedural details are published elsewhere[12,14].

***Post-procedure evaluation*:** Time to no pain and time to return to normal activity were recorded for all participants. All the pre-operative data were collected after each procedure at 6-weeks, 6-months and 1-year after each procedure Proctoscopic examination was carried out at each stage of follow-up to identify recurrent disease. Patients who remained symptomatic after intervention could be re-treated within the trial protocol. RBL could be attempted four further times, 6-weeks apart, and SH patients could undergo two further stapling procedure before being classified into a complete treatment failure group.

An independent consultant colorectal surgeon, who was blinded to the intervention, performed the final follow-up assessment at 52 weeks. The disease was considered recurrent if there were both subjective and objective evidence of recurrent disease.

Statistical Analysis

Each comparison was analysed by intention to treat. The outcomes were analysed only after the completion of data collection from the final patient at the end of one year. Statistical significance for all outcomes was based on the two-sided t-test with $p \leq 0.05$. Recurrence was compared using a two-sided Fisher's exact test. The distribution of the numbers of days to no pain and return to normal activities were skewed and thus analysed using a Mann-Whitney U test. For health-related quality of life measures and all other outcomes, the mean difference between intervention groups adjusting for baseline values, was estimated using a linear regression model. For the long-term follow-up, Mann-Whitney U test for the Cleveland and symptom score were performed. All analyses were carried out using SPSS® 12.0 for Windows™ and STATA version 9.0.

Results

Of the sixty-nine patients identified with grade II symptomatic circumferential haemorrhoids, between October 2002 and March 2004, sixty patients were recruited into the study **(Fig. 1)**. There were forty-four male patients. The median age was 44 (range 22 to 71) years. The commonest symptom at presentation was bleeding (n=56). Details of other haemorrhoidal symptoms were also obtained **(Table 1)**. Reasonable balance was observed at baseline between the two treatment groups **(Table 2)**.

All 60 participants received the treatment to which they were allocated. Data for three patients in each group was missing at the one-year follow-up for a variety of reasons (one patient in the RBL group withdrew before the 3-week follow-up; another patient in the stapled group developed Crohn's disease of the small bowel and withdrew after the 6-week follow-up; an additional two patients in each group moved out of the area after the 6-month follow-up).

At the 3-week follow-up there was evidence of a lower SF-36 physical component score [mean (SD) 47 (7) versus 52 (9); mean difference: -3.5, 95% CI (-7.1 to 0.1); p=0.054], for SH. This was not observed for the mental component score [mean (SD) 47 (10) versus 49 (10); mean difference: 0.3, 95% CI (-3.6 to 4.2); p=0.883]. Similarly, no statistically significant difference was seen with the EQ-5D [mean (SD), 0.7 (0.3) versus 0.8 (0.2); mean difference: 0.0, 95% CI (-0.1 to 0.1); p=0.665] at 3-weeks.

One patient in the stapled group and 10 in the RBL group had recurrence of haemorrhoidal disease at 6-weeks. At one year, there was evidence of a lower rate of recurrence of haemorrhoidal disease in the SH group compared to RBL [3 vs. 11; OR 0.18 95% CI (0.03 to 0.86); p=0.028]. One patient in the stapled group

received a single re-treatment during the trial period whereas 10 patients in the RBL group had one or more (19 in total) further band ligations. There was a trend towards better overall symptom scores in the stapled group at the end of the follow-up period **(Table 3)**. Nevertheless, this did not achieve statistical difference between the two interventions.

A total of 46 out of 60 (77%) questionnaires (24 in SH and 22 in RBL group) were returned. Six patients had dropped out of the trial within the first year, for the reasons mentioned above. The case notes and hospital attendance record (electronic hospital database) were reviewed for the remaining 8 patients to assess if any further treatments had been performed after the one-year follow-up. The mean (SD) length of follow-up was 40.67 (±6.26) months. There was a statistically significant difference in the disease recurrence favouring SH, 4 vs. 12; OR 0.22 95% CI (0.04, 0.92); p=0.035. However, the Cleveland score (mean (SD), 3 (4) versus 3 (4); mean difference: 0.4, 95% CI (-1.8 to 2.7); p=0.686) and the symptom score (mean (SD), 6 (5) versus 7 (5); mean difference: -1.0, 95% CI (-3.8 to 1.7); p=0.456) did not reveal any significant difference between the two procedures.

Two participants developed postoperative retention of urine following SH. One patient each had faecal impaction and a fissure-in-ano following SH. Both patients were managed appropriately without further consequences. One other patient in the stapled group suffered mild symptomatic anal stenosis, which was managed conservatively and did not require surgical intervention. Three more patients were found to have residual staples at one year. There was no further bleeding in these patients once the staples were removed. Among the patients treated with RBL, one patient developed a severe post-procedure anal fissure. This did not resolve with medical treatment and required examination under anaesthesia and internal

sphincterotomy. The Cleveland continence score did not reveal a significant difference in continence between the procedures over either at 6-weeks [mean difference: 0.8 95% CI (-1.6 to 3.5), p=0.166)] or at 52-weeks [mean difference: 0.8 95% CI (-1.6 to 3.5), p=0.156)]. Moreover no statistically significant differences were observed for any of the quality of life measures at one year **(Table 3)**. One patient in the stapled group showed ultrasound evidence of minor damage to the internal sphincter (this was not reflected on anal pressures or continence). There was no other evidence of anatomical or functional damage to the internal or external anal sphincters on endo-anal ultrasound or manometry in either cohort.

Pain on the day of the procedure was similar for both groups, 5 (4, 8) vs. 6 (4, 8). However, patients took longer to become pain free after the SH procedure [median (IQR) - 7 (5,7) (n=30) vs. 3 (1,7) days (n=28); p=0.008] and to return to normal activity compared with RBL [6 (3,7) vs. 3 (1,6) days; p=0.018] **(Fig.2)**.

The mean cost per patient treated using stapled haemorrhoidopexy was significantly higher than that for RBL (£1620 compared to £252). Much of this difference can be attributed to the initial procedure cost. Based on the recurrence at 1-year, an incremental cost per recurrence avoided from stapling haemorrhoidopexy was £4560. It was unlikely that stapled haemorrhoidopexy would be considered cost-effective at threshold values for society's willingness to pay for a QALY based upon the 12 month data. However, given the finding of increased recurrences in the rubber band ligation arm it would be expected that the difference in cost would fall over a longer time horizon and that the quality of life associated with the rubber band ligation arm would be reduced. The cost effective analysis of this comparative study will be presented in a separate paper.

.

Discussion:

Excisional haemorrhoidectomy is considered the 'gold standard' for the surgical treatment of prolapsing and symptomatic haemorrhoids. This procedure is widely perceived as painful with potential complications[22]. Such considerations may alter treatment-seeking attitude amongst patients, and in particular, may result in under-reporting of recurrent or residual symptoms [23].

The outcome from a variety of studies has shown SH to be equally effective compared to excisional haemorrhoidectomy (EH) in the long term[24]. Initial comparative trials involving excision versus stapled procedures have demonstrated consistently reduced pain scores in favour of the stapled procedure[25-27]. It can be argued that, as the surgical mechanisms involved in the two procedures are so widely different, such comparisons have limited validity.

The intent and mechanism of SH is similar to that of RBL. The patient population was selected in an attempt to get a clinically meaningful group in whom most colorectal surgeons would consider RBL rather than immediate surgery. This group was also felt most likely to answer the question regarding the place, if any, of an earlier definitive treatment (albeit at greater initial expense) in modifying the natural history of the disease. If, however, sustained efficacy can be demonstrated, the reduced future costs of re-treatment may make this justifiable, even if intervention is carried out at an earlier pathological stage. Nevertheless, there was greater post-procedure pain and a prolongation of time away from normal activity in patients treated with SH. However both groups showed early return to normal activity (within one week) and compare favourably with historical trials of excisional haemorrhoidectomy.

There are some early and delayed complications reported in the literature for SH[28-30]. No such major complications were observed in our study in either group. Moreover, continued rectal bleeding experienced by some of the patients was actually due to residual staples rather than true recurrence of the disease. These patients were reassured and followed up after 6-weeks to identify any objective evidence of haemorrhoids. Hence, both independent consultant assessment and symptoms from patients were considered before any patients were declared to have recurrent disease needing further treatment.

A further concern with regard to SH has been the involvement of internal anal sphincter in the rectal doughnut specimen. However this does not appear to influence continence or anal symptoms in the long term.[20,31] By evaluating sphincter anatomy and physiology, this study has again shown no adverse effect of either treatment modality. The power of the study was reflected in the confidence intervals for the comparison. We cannot exclude the possibility of a difference of up to 3.5 in the symptom score at 52 wk and 3.8 at long-term follow up. The retrospective power calculation was not performed because it was not considered good practice as they merely reflect the result (http://www.cs.uiowa.edu/~rlenth/Power/).

Conclusion

The findings from previous studies of the effectiveness of SH in have been confirmed in our study. SH had less recurrence at 1 year than RBL although it was associated with a longer post-operative recovery. The clinical benefit of SH is maintained in the long-term. However, there is insufficient evidence about the cost-effectiveness of stapled haemorrhoidopexy for grade II haemorrhoids to recommend its use in place of rubber band ligation. Additionally, in view of the non-significant difference in the symptom score and because of the benign nature of the disease, it would be reasonable to perform RBL prior to considering the SH. A properly selected cohort of patients would benefit from the treatment with SH. The patients should be allowed to make an informed choice considering the severity and duration of symptoms. Further studies with greater number of patients need to be performed to substantiate the significant difference.

References:

1. MacRae HM, Temple LKF, McLeod RS. A meta-analysis of haemorrhoidal treatments. Seminars in Colon & Rectal Surgery 2002;**13 (1):**77-83
2. Shemesh EI, Kodner IJ, Fry RD, Newfield DM. Ligation of internal haemorrhoids. Dis Colon Rectum 1987;**30:**199-200
3. O'Hara V. Fatal clostridial infection following haemorrhoidal banding. Dis Colon Rectum 1980;**23:**570-71
4. Russel TR, Donohue JH. Haemorrhoidal banding: a warning. Dis Colon Rectum 1985;**28:**291-93
5. Savioz D, Roche B, Glauser T, Dobrinov A, Ludwig C, Marti MC. Rubber band ligation of haemorrhoids: relapse as a function of time. Int J Colorect Dis 1998;**13:**154-56
6. Beattie GC, Wilson RG, Loudon MA. The contemporary management of haemorrhoids. Colorect Dis 2002;**4(6):**450-54
7. Shanmugam V, Thaha MA, Rabindranath KS, Campbell KL, Steele RJC, Loudon MA. Systematic review of randomized trials comparing rubber band ligation with excisional haemorrhoidectomy. Br J Surg 2005; **92:** 1481-1487
8. Thomson WHF. The nature of haemorrhoids. Br J Surg 1975;**62:**542
9. Longo A. Treatment of haemorrhoid disease by reduction in mucosal and haemorrhoidal products with a circular stapling device – New procedure. Proceedings of the 6th World Congress of Endoscopic Surgery, Rome, Italy 3-6 June 1998
10. Peng BC, Jayne DG, Ho Y-H. Randomized trial of Rubber Band Ligation vs. Stapled Haemorrhoidectomy for Prolapsed Piles. Dis Colon Rectum 2003; **46(3):** 291-295
11. Roswell M, Bello M, Hemingway DM. Circumferential Mucosectomy (stapled haemorrhoidectomy) versus Conventional Haemorrhoidectomy: A Randomised Controlled trial. Lancet 2000; **355(9206):**782-785

12. Ho Y-H, Chong WK, Tsang C, Ho EUKW, Tsang CL, Seow-Cheon F. Stapled haemorrhoidal cost and effectiveness Randomised Controlled Trial including Incontinence scoring, Ano-rectal Manometry and Endoanal ultrasound Assessments up to Three months. Dis Colon Rectum 2000; **34:** 1666-1675
13. Mehigan BJ, Monson JRT, Hartley JE. Stapling procedure for haemorrhoids versus Milligan Morgan Haemorrhoidectomy: A randomised controlled trial. Lancet 2000;**355(9206):**782-785
14. Boccasanta P, Capretti PG, Cioffi U, De Simione M, Salamina G, Contessini-Avesani E, Peracchia A. Randomised controlled trial between stapled circumferential mucosectomy and conventional circular haemorrhoidectomy in advanced hemorrhoids with external mucosal prolapse. Am J Surg 2001; **182:** 64-68
15. Shao WJ, LI GCH, Zhang ZHK, Yang BL, Sun GD, Chen YQ. Systematic review and meta-analysis of randomized controlled trials comparing stapled haemorrhoidopexy with conventional haemorrhoidectomy. Br J Surg. 2008;**95:**147-60
16. Komborozos VA, Skrekas GJ, Pissiotis CA. Rubber band ligation of symptomatic internal hemorrhoids: results of 500 cases. Dig Surg 2000; **17(1):** 71-76
17. Konings M, Debets JM, Baeten CG. Rubber band ligation of haemorrhoids: symptoms almost gone after 6-weeks, bur many patients need re treatment in the long run. Ned Tijdscdr Geneeskd 1999; **143(24):** 1265-8 (Abstract)
18. Ware JE, Gandek B. Overview of the SF-36 Health Survey and the International Quality of Life Assessment (IQOLA) Project. J Clin Epidemilo 1998; **51(11):** 903-912
19. The EuroQoL- a new facility for the measurement of health-related quality of life. Health Policy 1990;**16(3):**199-208

20. Shanmugam V, Watson AJM, Binnie NR, Chapman AD, Loudon MA. Pathological audit of stapled haemorrhoidopexy. Colorect Dis 2005;**7(2):**172-75
21. Jensen MP, Chen C, Brugger AM. Post operative pain outcome assessment. Pain 2002; **99 (1-2):** 101-09
22. Marc-Olivier Guenin , Rachel Rosenthal, Beatrice Kern, Ralph Peterli, Markus von Flüe and Christoph Ackermann M. Ferguson haemorrhoidectomy: long-term results and patient satisfaction after Ferguson's haemorrhoidectomy. Dis Colon Rectum 2005;**48(8):**1523-27
23. Winter A, Sharp CM, Wright DM, Sunderland GT. Long-term outcome following day-case haemorrhoidectomy. Colorectal Dis;**2(Suppl. 1):**19
24. Smyth EF, BR, Wilken BJ Hartley JE, White TJ, Monson JR. Stapled versus excision haemorrhoidectomy: long-term follow-up of a randomised controlled trial. Lancet 2003;**361(9367):**1437-38
25. Shalaby R, Desoky A. Randomized clinical trial of stapled versus Milligan-Morgan haemorrhoidectomy. Br J Surg 2001;**88:**1049-53
26. Pavlidis T, Papaziogas B, Souparis A, Patsas A, Koutelidakis I, Papaziogas T. Modern stapled Longo procedure Vs conventional Milligan-Morgan haemorrhoidectomy: a randomised controlled trial. Int J Colorect Dis 2002; **17:** 50-53
27. Monson JRT, Mortensen NJ, Hartley J. Procedure for prolapsing haemorrhoids (PPH) or stapled anopexy. In: Consensus document for Association of Coloproctology of Great Britain and Ireland May 2002
28. Hidalgo Grau LA, Heredia Budó A, Fantova MJ, Suñol Sala X. Perirectal haematoma and hypovolemic shock after stapled mucosectomy for haemorrhoids. Int J Colorect Dis 2005; **20:** 471-72

29. Cheetham MJ, Mortensen NJ, Nystrom PO, Kamm MA, Phillips RK. Persistent pain and faecal urgency after stapled haemorrhoidectomy. Lancet 2000; **356:** 730-33
30. Mlakar B, Kosorok P. Complications and results after stapled haemorrhoidopexy as a day case procedure. Tech Coloproctol 2003;**7:**164-68
31. Kam MH, Mathur P, Peng XH, Seow-Choen F, Chew IW, Kumarasinghe MP. Correlation of histology with anorectal functions following stapled haemorrhoidectomy. Dis Colon Recum 2005;**48(7):**1437-41

Contribution: The authors designed the study, interpreted the data, wrote this manuscript and approved the final version. Malcolm Loudon is the guarantor.

Funding/Support: we are very grateful to Ethicon Endo-surgery, a Johnson & Johnson Company for funding this trial and economic evaluation. The Health Services Research Unit and the Health Economics Research Unit receives core funding from the Chief Scientists Office of the Scottish Government's Health Directorates. The views expressed in this paper are those of the authors.

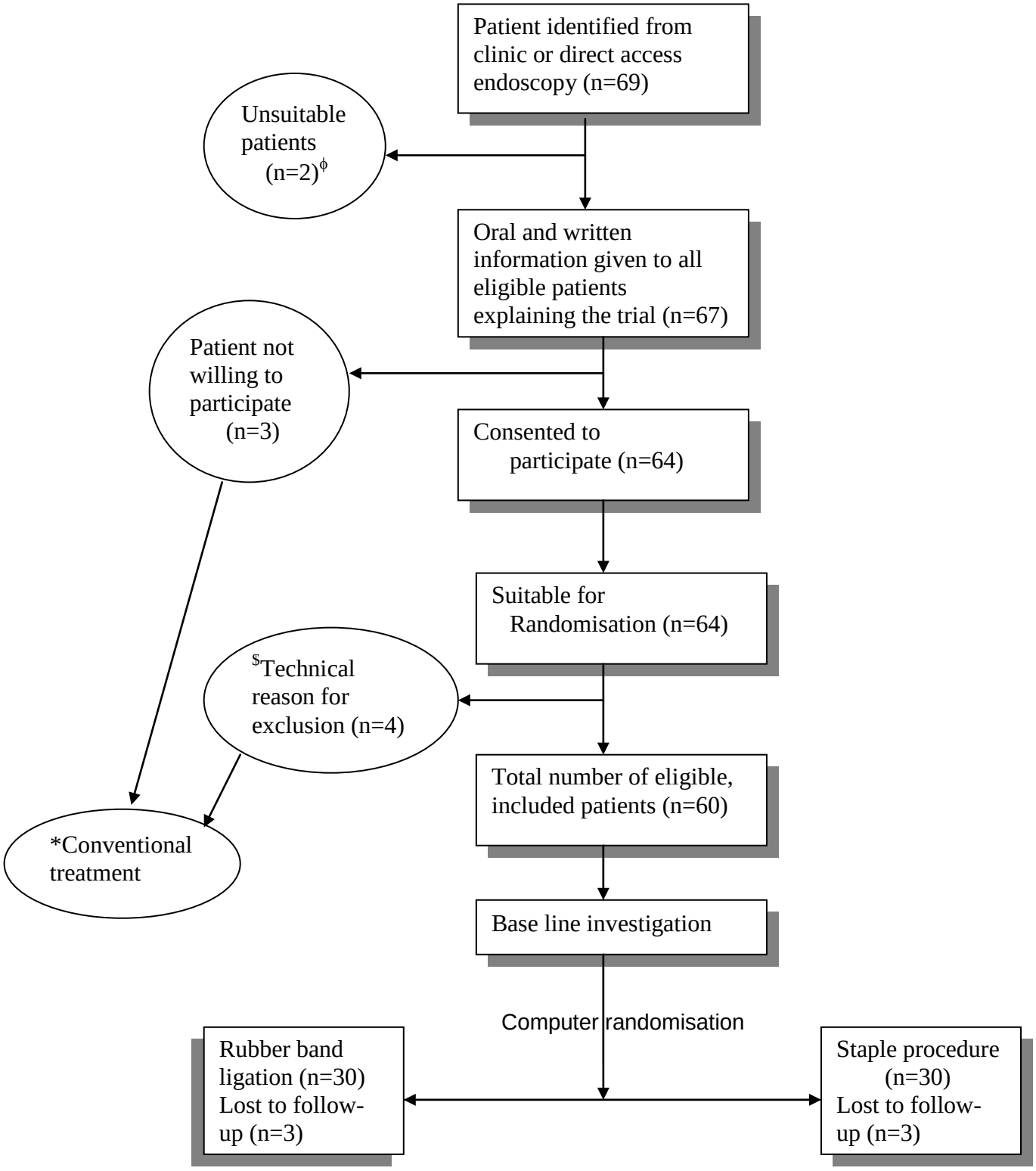
Statement of the independence of researchers from funder: the study funder had no role in the study design; collection, analysis, and interpretation of data; writing of the report; and in the decision to submit the paper for publication.

Acknowledgements: We are thankful to Gladys McPherson, computer programmer for her help with randomisation and all the consultants who contributed their patients for this study. We are grateful to Mr NR Binnie, Consultant Colorectal Surgeon, Aberdeen Royal Infirmary, for assessing all the patients at 52 weeks for recurrence of haemorrhoidal disease.

Ethical approval: ethical approval was obtained from the Grampian Research Ethics Committee (Ethics committee code – GREC 01/0297).

ISRCTN registration number - 23585705

Figure 1 Flow diagram showing the details of trial recruitment

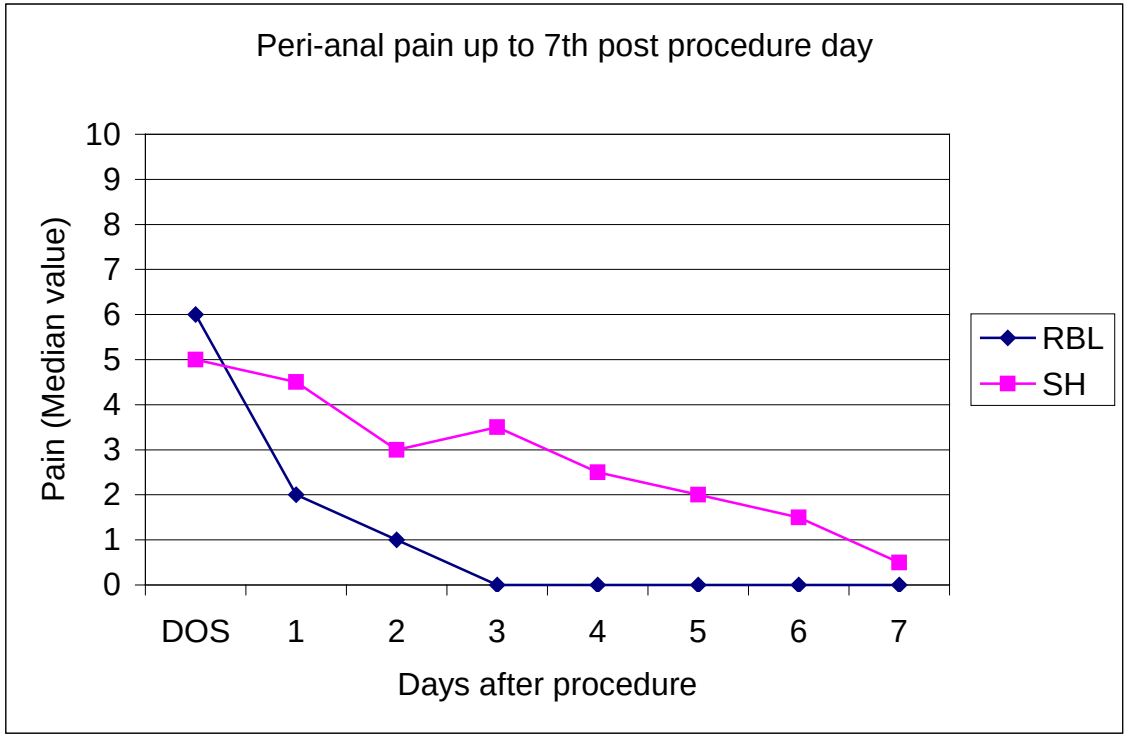


ϕ One patient underwent recent RBL (Within one 6 weeks) and another one was unfit for general anaesthesia.

$ Could not perform pre-op investigation (n=3) and not able to attend hospital on three occasions (n=1)

* Conventional treatment = RBL

Figure 2 Comparison of post procedure pain between the intervention groups



∗ DOS - Day of Surgery

Table 1 Symptoms [21] at initial presentation (Number of patients in each group)

I. Bleeding per rectum

	None (0)	Spotting (1)	Dripping into pan (2)	Without stool (3)	Staining underwear (4)
Staple (N)	3	14	10	1	2
RBL (N)	1	11	11	1	6

II. Pain

	None (0)	Only with stool (1)	Constant throbbing (2)
Staple (N)	7	18	5
RBL (N)	16	10	4

III. Other relevant symptoms

Symptom	Never (0)		Rarely (1)		Sometimes (2)		Often (3)		Always (4)	
	Staple	RBL	Staple	RBL	Staple	RBL	Staple	RBL	Staple	RBL
Itching	7	10	6	5	6	10	10	4	1	1
Mucous discharge	19	24	3	3	3	2	2	0	3	1
Urgency	10	14	9	7	8	5	2	3	1	1
Frequency	14	14	3	4	5	8	5	3	3	1
Prolapse	7	11	3	6	11	5	4	4	5	4

Table 2 Details of the baseline values between the two groups studied

Variable		Stapled haemorrhoidopexy (n=30)	Rubber band ligation (n=30)
Age (Years) – Median (Range)		49.5 (22 to 70)	40 (30 to 65)
Sex (M/ F)		23/7	21/9
ASA grade - Median		2	1
Previous treatment - Number of patients		5 (1 EH, 1 ST, 3 RBL)*	4 (1EH, 1 ST, 2 RBL)*
Maximum resting anal Pressure - Median (IQR)		93 (54,106)	80 (50,103)
Cough pressure – Median (IQR)		147 (105,184)	150 (50,194)
Squeeze pressure – Median (IQR)		180 (138,232)	184 (150,247)
Symptom score – Mean (SD)		9 (4)	8 (4)
Cleveland clinic continence score - Mean (SD)		3 (3)	2 (3)
SF–36 score	**Physical – Mean (SD)**	51 (7)	53 (9)
	Mental – Mean (SD)	47 (11)	49 (10)
EQ-5D – Mean (SD)		0.7 (0.2)	0.8 (0.2)
HAD	**Anxiety – Mean (SD)**	6 (4)	6 (4)
	Depression – Mean (SD)	3 (3)	3 (3)

***** EH – Excisional haemorrhoidectomy, ST – Sclerotherapy and RBL – Rubber Band Ligation

Table 3 Comparison of the results of the two interventions at different time points

	6-Week		26-Week		52-Week		
	SH	**RBL**	**SH**	**RBL**	**SH**	**RBL**	**MD (95% CI) p-value**
Anal manometry - Median, (IQR)							
MRP	90 (60,101)	75 (50,106)	100 (89,118)	100 (65,120)	99 (89,115)	100 (76,108)	--
Cough	136 (121,148)	129 (103,187)	160 (134, 190)	160 (127,188)	147 (132, 184)	160 (131, 219)	--
Squeeze	172 (136,228)	171 (111,231)	207 (139, 251)	195 (147,246)	212 (158, 297)	215 (182, 306)	--
Symptom score Mean (SD)	6 (4)	6 (4)	5 (4)	5 (4)	5 (4)	6 (4)	-1.6 (-3.5,0.3), 0.092
Cleveland score Mean (SD)	2 (3)	1 (2)	2 (2)	1 (2)	2 (2)	1 (2)	0.8 (-0.3,1.8), 0.156
SF-36 - Mean (SD)							
Physical	49 (7)	53 (8)	52 (7)	55 (8)	52(7)	54 (8)	-1.2 (-4.7, 2.3), 0.486
Mental	50 (9)	52 (9)	51 (8)	52 (7)	50(9)	51 (9)	-0.8 (-5.4, 3.8), 0.742
EQ-5D – Mean (SD)	0.7 (0.2)	0.8 (0.2)	0.8 (0.2)	0.9 (0.2)	0.9(0.2)	0.9 (0.1)	0.0 (-0.1,0.1), 0.758
HAD score – Mean (SD)							
Anxiety	6 (4)	5 (4)	5 (4)	5 (4)	6 (4)	5 (4)	0.9 (-0.8,2.5), 0.295
Depression	3 (3)	2 (3)	3 (3)	2 (3)	2 (2)	2 (2)	0.5 (-0.6,1.6), 0.356

MRP - Maximum Resting Anal Pressure, IQR – Interquartile Range, SD – Standard Deviation, MD – Mean Difference, CI – Confidence Interval

CONSORT **Checklist of items**

PAPER SECTION And topic	Item	Description	Reported on Page #
TITLE & ABSTRACT	1	How participants were allocated to interventions (*e.g.*, "random allocation", "randomized", or "randomly assigned").	1,2
INTRODUCTION Background	2	Scientific background and explanation of rationale.	3,4,5
METHODS Participants	3	Eligibility criteria for participants and the settings and locations where the data were collected.	6,7
Interventions	4	Precise details of the interventions intended for each group and how and when they were actually administered.	8
Objectives	5	Specific objectives and hypotheses.	5,6
Outcomes	6	Clearly defined primary and secondary outcome measures and, when applicable, any methods used to enhance the quality of measurements (*e.g.*, multiple observations, training of assessors).	6
Sample size	7	How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules.	6
Randomization -- Sequence generation	8	Method used to generate the random allocation sequence, including details of any restrictions (*e.g.*, blocking, stratification)	8
Randomization -- Allocation concealment	9	Method used to implement the random allocation sequence (*e.g.*, numbered containers or central telephone), clarifying whether the sequence was concealed until interventions were assigned.	8
Randomization -- Implementation	10	Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups.	8
Blinding (masking)	11	Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment. When relevant, how the success of blinding was evaluated.	9
Statistical methods	12	Statistical methods used to compare groups for primary outcome(s); Methods for additional analyses, such as subgroup analyses and adjusted analyses.	10
RESULTS Participant flow	13	Flow of participants through each stage (a diagram is strongly recommended). Specifically, for each group report the numbers of participants randomly assigned, receiving intended treatment, completing	11,12,13

		the study protocol, and analyzed for the primary outcome. Describe protocol deviations from study as planned, together with reasons.	
Recruitment	14	Dates defining the periods of recruitment and follow-up.	11
Baseline data	15	Baseline demographic and clinical characteristics of each group.	11,25
Numbers analyzed	16	Number of participants (denominator) in each group included in each analysis and whether the analysis was by "intention-to-treat". State the results in absolute numbers when feasible (*e.g.*, 10/20, not 50%).	12
Outcomes and estimation	17	For each primary and secondary outcome, a summary of results for each group, and the estimated effect size and its precision (*e.g.*, 95% confidence interval).	12,13,27
Ancillary analyses	18	Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating those pre-specified and those exploratory.	-
Adverse events	19	All important adverse events or side effects in each intervention group.	12,13
DISCUSSION Interpretation	20	Interpretation of the results, taking into account study hypotheses, sources of potential bias or imprecision and the dangers associated with multiplicity of analyses and outcomes.	14,15,16
Generalisability	21	Generalisability (external validity) of the trial findings.	15,16
Overall evidence	22	General interpretation of the results in the context of current evidence.	17