Original article

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Doppler-guided haemorrhoidal artery ligation: long-term outcome and patient satisfaction

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Abstract

Objective Conventional Milligan–Morgan haemorrhoidectomy is associated with significant pain and potentially hazardous complications. Doppler-Guided Haemorrhoidal Artery Ligation (DGHAL) may offer a lower risk, pain-free alternative. We present our early and long-term outcome experience with DGHAL, combined with patient views and satisfaction with the procedure.

Method One hundred and thirteen DGHALs were performed over a 13 month period by two surgeons in a single centre. Patients graded the severity of postoperative pain on visual-analogue scales. Clinical follow-up was at 6 weeks ($n = 103$), with long-term follow-up ($n = 90$) by postal questionnaire at median of 30 months.

Results Seven out of one hundred and three (6%) patients reported postoperative discomfort requiring analgesia. Ninety-three out of one hundred and three (90%) patients reported complete relief or significant improvement in their symptoms at 6 weeks, dropping to 77/90 (86%) at 30 months. Anal fissures developed in 2/103 (2%) patients, both treated with Diltiazem ointment. Further surgery was required in 8/90 (9%) patients. Eighty-two out of ninety (91%) patients said they would undergo DGHAL again.

Conclusion DGHAL is a relatively painless, safe, and effective procedure for symptomatic stage I–III haemorrhoids, for which we have demonstrated long-term durability and acceptability. Its role lies between office based procedures and more invasive operative interventions.

Keywords Haemorrhoidal artery ligation, Doppler-guided, patient satisfaction

Introduction

Haemorrhoids affect 4–35% of the population [1]. Management traditionally depends on the grade of prolapse and the severity of symptoms. Treatments range from dietary manipulation through procedures such as rubber-band, ligation, and injection sclerotherapy to surgical haemorrhoidectomy, usually a Milligan–Morgan haemorrhoidectomy or one of its variants [2]. Haemorrhoidectomy is associated with significant postoperative pain, and carries potentially serious risks including sepsis, anal stenosis, bleeding, sphincter damage, and incontinence; Studies by Felt-Bersma *et al.* [3] and Ho *et al.* [4] still demonstrate the risk of unsuspected anal sphincter damage following haemorrhoidectomy. Recently Longo described the stapled haemorrhoidopexy or Procedure for Prolapsing Haemorrhoids (PPH) [5]. Randomized controlled trials (RCTs) have demonstrated reduced postoperative pain, reduced operating time and better patient satisfaction [6–9]. However, there has been some concern regarding the potential risk, in inexperienced hands, of bleeding, large bowel obstruction, retroperitoneal sepsis, rectovaginal fistulae and rectal perforation [10]. Moreover, there is a gulf in the degree of invasiveness of intervention between outpatient-based procedures such as injection sclerotherapy, and operative interventions such as PPH and haemorrhoidectomy.

In the last 10 years, Doppler-Guided Haemorroidal Artery Ligation (DGHAL) has gained popularity as an alternative treatment. While the procedure has been shown to be safe and effective [11–15], the durability of DGHAL has been questioned. There have been 12 month follow-up results published that suggest the early benefit is maintained [11,14,15]. We have not

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found any reports of longer follow-up after DGHAL. Only one RCT has been reported, and compares DGHAL with haemorrhoidectomy [16]; this demonstrated reduced postoperative analgesic requirement, reduced hospital stay, and quicker return to normal activities in the group undergoing DGHAL. However, their sample size was small, and comparing DGHAL directly to haemorrhoidectomy may not be valid. We present the results of our early outcome after DGHAL, together with long-term follow-up to over $2^1/_2$ years. We also report on patient satisfaction with the procedure and outcome.

Method

Preoperative assessment and patient selection

Patients with symptomatic haemorrhoids were assessed and examined by rigid sigmoidoscopy and proctoscopy in outpatient clinics. Colonoscopy, flexible sigmoidoscopy or barium enema was carried out appropriately to exclude other pathologies. Haemorrhoids were staged using the Goligher classification [17]; patients with stage I or small stage II disease were initially offered conservatively treatment by either rubber band ligation or oily Phenol injection. The indications for surgical intervention included patient choice (i.e. those who declined conservative treatments), failed conservative treatment, large stage II disease, up to stage IV disease. Failed conservative treatment was defined as the persistence of symptoms at 6- to 8-week follow-up after three treatments with oily Phenol injection or rubber band ligation. Those patients suitable for surgical intervention were offered an informed choice of PPH, open haemorrhoidectomy or DGHAL. Patients with stage IV disease were not deemed to be suitable for DGHAL, and other operative techniques were recommended.

Operative technique

Operations were scheduled as daycase procedures, and the rectum was prepared by either glycerine suppositories or phosphate enema. Patients were positioned in lithotomy. No analgesia was given with anaesthesia. Using a HAL Doppler Ultrasound Proctoscope (CJ Medical, Bucks, UK, Fig. 1), the signals from distal branches of the superior rectal artery were sought. The size and shape of the probe leads to a position 3–4 cm above the dentate line. Each vessel identified in this way was ligated with a 2/0 Vicryl suture on a 5/8 curved tapered needle (AMI HALSuture, order no. AHAL75), in a 'figure-of-eight' fashion. The second pass with the needle was made just proximal to the first, by advancing the proctoscope slightly. Only one circumferential pass was made with the Doppler probe, and once these vessels were ligated, no other signals were sought. A median of 6 (4–9) sutures were placed in this way. Prior to discharge, patients were asked to record the presence, duration, and severity of postoperative discomfort or pain on the visual analogue scale on the data collection form.

Follow-up

Clinical follow-up of patients was at 6–8 weeks, and included physical examination and completion of a data collection form. Digital examination was performed and patients asked to strain in order to assess prolapse. Patients were asked to record a pain score for the period of time since discharge again on a visual analogue scale. Any analgesic requirement was recorded. The incidence, duration and severity of bleeding and prolapse postoperatively were also recorded. Patients with residual symptoms were asked how these symptoms compared to preoperative levels. For the purposes of this study, 'improvement' in symptoms was only recorded if this change was significant

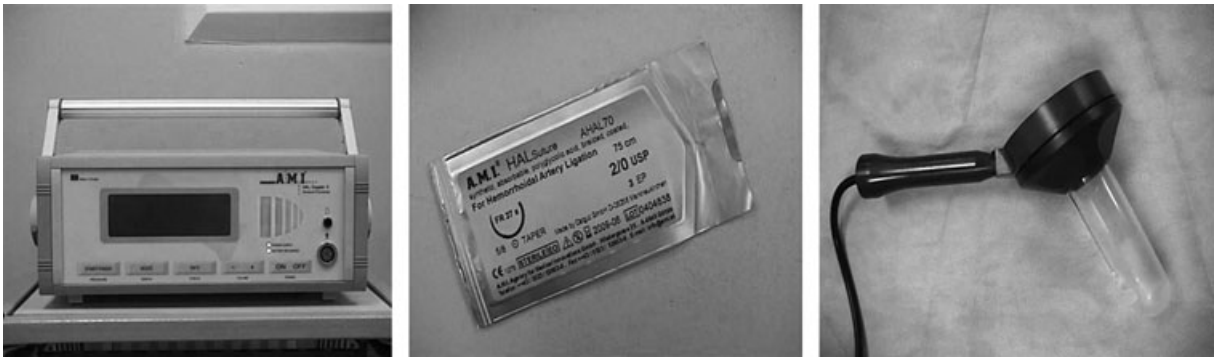

Figure 1 AMI-HAL proctoscope, doppler probe and HAL suture.

Table 1 Patient satisfaction scoring system.

1	Completely satisfied – asymptomatic
2	Highly satisfied but with residual symptoms or new symptoms not interfering with quality of life
3	Not satisfied – new symptoms interfering with quality of life
4	Not satisfied – no change compared to preoperatively
5	Completely unsatisfied – worse than preoperatively

in the patient's opinion. Those patients who reported persistence of these symptoms were offered conservative treatment in our outpatient clinics (Phenol injection or rubber band ligation) and reviewed in a further 6–8 weeks. Patient satisfaction was recorded on a 5 point scale as shown in Table 1. This has not been validated, but aims to assess patients' views of the success of the treatment they had received at this stage, independently of technical success. Patients were also asked about the speed of return to normal activities and work.

Long-term follow-up was performed using a standardized postal questionnaire. This involved a 10 point tick-box form assessing the effect of DGHAL on symptoms from the time of operation to the time the form was completed. Patients were also asked whether they would have the procedure again if their symptoms returned and if they would recommend it to a friend. Non-responders were contacted by telephone.

Results

Patient demographics

One hundred and thirteen patients underwent DGHAL in one centre between January 2004 and February 2005. Data were collected prospectively on data collection forms that were kept in each patient record throughout their preoperative assessment, surgery and postoperative follow-up. Ten patients were excluded from this study, as they did not attend follow-up appointments. All patients were recruited consecutively and the remaining 103 patients are presented. The sex distribution was 60 males and 43 females, with a median age of 55 years (20–82). Ninety-eight patients were classified as ASA I or II (95%), the remaining five being ASA III. Table 2 shows the previous treatments patients had received prior to DGHAL, and Fig. 2 shows the symptoms leading to surgical intervention. These were recorded as primary symptoms (which the patient presented with) and secondary symptoms (which were elucidated on direct questioning and examination). Following decision to treat, no differentiation was made between stage II or III prolapse for the purposes of this study. General anaesthesia was used in ninety-three patients (90%). Of the remainder, seven patients (7%) were given intravenous sedation and three patients (3%) underwent spinal anaesthesia. A further thirteen patients did not complete long-term follow-up (one death from unrelated causes, three declined, nine un-contactable).

Table 2 Previous treatments prior to DGHAL.

	Number of patients (% age)
Banding/injection	54 (52)
PPH	1 (1)
Haemorrhoidectomy	1 (1)
None	47 (46)

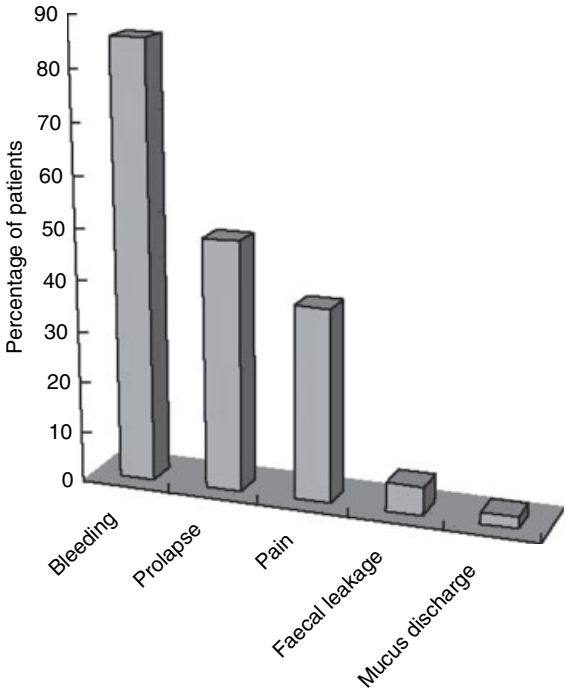

Figure 2 Presenting symptoms of patients undergoing DGHAL.

Postoperative discomfort or pain

Analgesia was only given when requested by patients. Figure 3 shows the proportions of patients experiencing pain or discomfort postoperatively, and whether they required analgesia or not. Of 113 patients undergoing the procedure, 94 patients (83%) reported no pain or discomfort, 12 patients (11%) reported mild discomfort requiring no analgesia, and 7 (6%) reported discomfort requiring Paracetamol in recovery. The median duration of the discomfort was 2 days (0–30), which included three patients reporting continuing mild discomfort for 10, 21,

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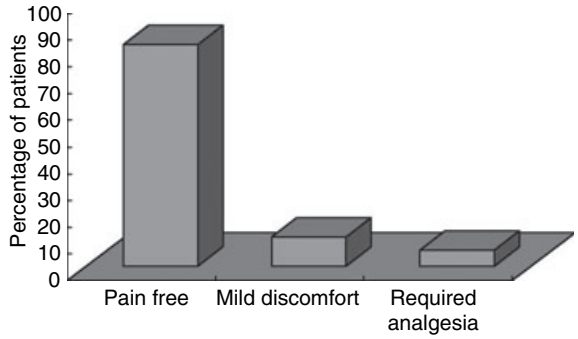

Figure 3 Immediate postoperative pain following DGHAL.

and 30 days postoperatively. These patients reported a pain severity of 5–10 out of 100 on a visual analogue scale. The median severity on the same scale for the whole group was 5% (4–50%); the patient reporting a severity of 50% was found to have an anal fissure at follow-up. This was treated with topical 2% Diltiazem cream for 6 weeks, with complete resolution of symptoms.

Overall outcome

Figure 4 shows the overall outcomes for all symptoms at 6 weeks, 18 months and 30 months. The outcome at 30 months refers to patients' symptoms at the end of their follow-up, 30 months being the median follow-up period. The figures for 18 month follow-up are extrapolated from the long-term data. At 6 weeks, 90% (93/103) patients were asymptomatic or had significant improvement in all their symptoms. This only dropped to 86% (77/90) patients by a median of 30 months postoperatively. The asymptomatic rate rose from 61% to 74% from 6 weeks to 18 months, before falling to 40% by 30 months. During this period the improvement rate fell from 29% at 6 weeks to 12% at 18 months before rising to 46% at 30 months. There was little change in the percentage of patients having no change in symptoms (10–14%).

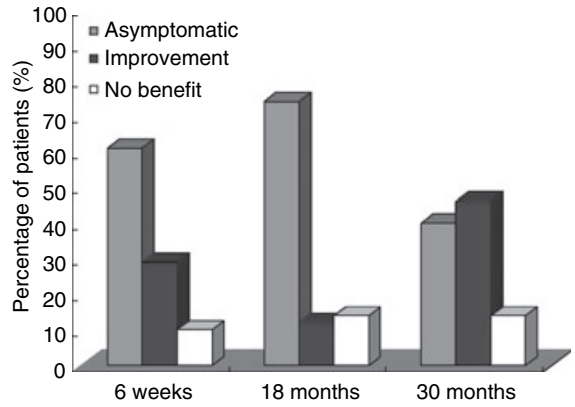

Figure 4 Overall outcome following DGHAL.

Outcome by symptoms

The outcomes for different symptoms varied, and Figs 5 and 6 show the outcomes across the follow-up period for bleeding and prolapse separately. For bleeding, the asymptomatic rate falls from 90% (87/97 patients) at 6 weeks to 61% (46/77 patients) at 30 months, while for prolapse the corresponding fall is from 69% (38/55 patients) at 6 weeks to 49% (18/44 patients) at 30 months. Three patients (3%) had no change in their bleeding across the follow-up period, while the proportion of patients with no change in their prolapse rose from 6 weeks (6/55 patients, 11%) to 30 months (8/44 patients, 18%). If the group of patients presenting with prolapse as one of their symptoms are analysed as a separate group, the outcomes are nearly identical to those shown in Fig. 4; this is due to the fact that when patients had a combination of symptoms it was invariably the prolapse which was still present at follow-up.

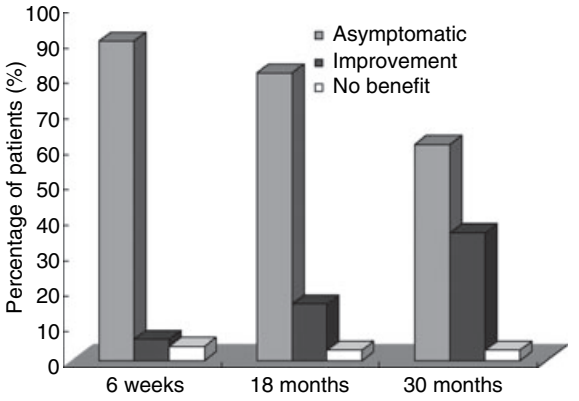

Figure 5 Outcome for bleeding following DGHAL.

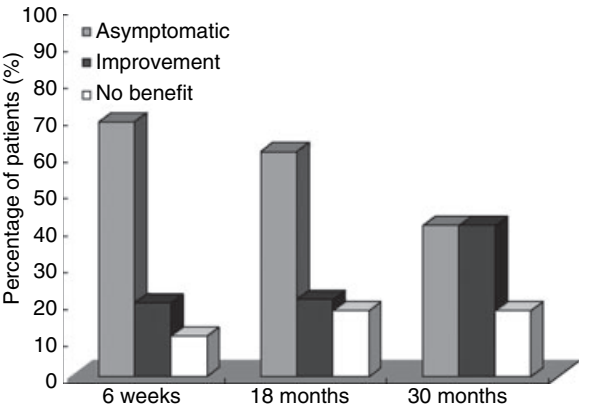

Figure 6 Outcome for prolapse following DGHAL.

Complications

There were no intra-operative complications. Two patients (2%) were found to have anal fissures at follow-up. These patients were treated with 2% Diltiazem cream, which resulted in healing in both cases. There were no septic complications.

Further treatment

Of the 90 patients followed-up to a median of 30 months, 16 patients had further interventions because of residual or recurrent symptoms, all within the first 4 months. Eight patients had one further treatment by injection sclerotherapy, while eight had further surgery (two haemorrhoidectomies, four PPH, and two DGHAL); i.e. the operative re-intervention rate was 9%.

Patient satisfaction

Using the 5 point scale, at 6-week follow-up, 57% (59/103) patients reported being completely satisfied and were asymptomatic. A further 33% (34/103) patients reported being highly satisfied with their treatment despite residual symptoms or new symptoms that did not interfere with their quality of life. These symptoms included spotting of blood on defecation (13 patients [13%]), prolapse (11 patients [11%]), pruritis (7 patients [7%]), and mucus discharge (3 patients [3%]). Patients with persistent pruritis were treated with analgesia and hydrocortisone cream with good effect. This group was primarily composed of patients whose primary and secondary symptoms of bleeding or prolapse were improved by their treatment, though not abolished. Some of these patients requested further treatment in the form of injection sclerotherapy or rubber-band ligation. Only 10% (10/103) patients reported dissatisfaction with DGHAL; 6% (6/103) patients reported no improvement in their symptoms, while 4% (4/103) patients reported worsening of their symptoms following DGHAL. All four patients reporting worsening of their symptoms complained of worsened prolapse, though at postoperative assessment, none of the patients had objectively larger haemorrhoids, nor had any progressed from one stage of disease to another. Taking this into account, the median time to return to normal activities was 2 days (0–14, with four patients taking more than 12 days skewing the results), and the median time taken to return to work was also 2 days (0–14, with 28 patients being retired).

At long-term follow-up, patients were asked to indicate their views of the procedure by answering two simple questions. Ninety-one per cent (82/90) of patients said if their symptoms returned they would be willing to undergo DGHAL again if it was offered. Ninety-three per cent (84/90) of patients said they would recommend the procedure to a friend or family member with the same symptoms.

Discussion

DGHAL is a safe, relatively painless, and effective treatment for stage I–III haemorrhoids, which meets the criteria for ambulatory therapy and is tailored to the disease. In our study 90% of patients reported resolution or significant improvement in their symptoms, with no major complications. We have also shown that this outcome is durable with an 86% resolution or significant improvement rate at a median of 30 months postoperatively. However, the outcomes for prolapse seem to be less favourable than those for bleeding, when symptoms were assessed separately. More than 95% of patients required no analgesia. The authors do not feel that the learning curve for this procedure was particularly steep, and felt that adequate proficiency was gained after 10 procedures.

Though haemorrhoids are extremely common, they are a benign and rarely life threatening condition. The most commonly used staging system is the Goligher classification [17]. However, patients' symptoms and objectively assessed pathology do not always match, and classifications do not take into account patient wishes and expectations of treatment. When deciding on the correct treatment for a patient, the efficacy and risk carried by the technique should be weighed against the potential benefit to the patient. Simple outpatient-based procedures still have complications, including urinary retention, prostatitis, pain, and haemorrhage. While haemorrhoidectomy, and its myriad modifications (open, closed [18], diathermy, Ligasure [19], and Harmonic scalpel [20]), is regarded as the gold standard in terms of efficacy, it carries significant morbidity. The most important and frequent of these from a patient's perspective is pain; despite various methods to reduce this (local anaesthetic, GTN, Diltiazem, botulinum toxin, and antibiotics), it continues to be a major cause of morbidity after haemorrhoidectomy. Other complications include sepsis, and impaired continence. Five per cent of patients have a transient bacteraemia postoperatively, and there have been reports of rates of impaired continence of up to 33% [21]. More recently, stapled haemorrhoidopexy (PPH) has gained favour as a technique which has been shown to be as effective as haemorrhoidectomy, but with less pain and quicker return to normal activity [6–9]. There may be significantly fewer septic complications, and with the

restoration of normal anatomy that comes with the procedure, continence is rarely impaired. There have, however, been reports of bleeding, rectal perforation, rectovaginal fistulae and large bowel obstruction [10]. While these complications are rare [22], they highlight the risk taken in treating this benign condition, and help emphasize the need to tailor the treatment to the condition.

DGHAL was first introduced in 1995 by Morinaga *et al.* [11]. Since then, there have been a number of reports of small series demonstrating the early efficacy of the procedure [12–15]. Sample sizes were in the range of 30–133 patients. The success rates reported vary from 80% to 92%. Some authors have reported success in treating various symptoms of haemorrhoids; Morinaga *et al.* had better resolution of bleeding (96%) than prolapse (78%) as our series also shows, while Sohn *et al.* reported better results for prolapse (92%) than bleeding (88%). A number of studies report anal fissures in 1–2% of patients undergoing DGHAL [12,13,16]. In order to justify the use of DGHAL, a direct comparison to the gold standard of haemorrhoidectomy was inevitable, though not necessarily relevant. Bursics *et al.* showed that the two procedures had an equal efficacy at 1 year follow-up, though the sample size was small (n = 30 each group) [16]. Despite this, there is a growing body of evidence to suggest that DGHAL has an adequate efficacy. There are no long-term data on recurrence rates following DGHAL.

In interpreting the data in other series, how success is measured is important. It is all too easy to concentrate on restoring anatomical normality, but the authors would advocate a policy of treating symptoms to a degree that is satisfactory to the patient. In our series, 69% of patients with prolapsing haemorrhoids had total resolution of their prolapse at 6 weeks. However, this did not correlate with patient satisfaction, which more closely resembled an asymptomatic or improved rate of 89% for prolapse. We did not differentiate between stage II and III disease in follow-up as this could not be assessed at long-term follow-up done by postal questionnaire, and so a subgroup analysis to determine if the stage of disease impacted on successful outcome was not possible. Our asymptomatic or improved rate for bleeding was 96%, and this reflected the results of Morinaga *et al.* in that outcome was better in the treatment of bleeding rather than prolapse.

In critically appraising this study, there are a number of points worthy of note. Despite using an un-validated scoring system to assess patient satisfaction, we feel we have been able to demonstrate patients' perception of DGHAL treatment, and its acceptability. We also did not record the grade of prolapse on the data collection sheet, as it would not have been possible to assess the stage by postal questionnaire during follow-up. With the variable success seen in treating prolapse with this procedure, perhaps the stage of disease is more important in selecting patients than first suspected, and comparisons to other authors' series would have been easier. Furthermore, a high proportion of the patients undergoing DGHAL in this series appeared to have early stage haemorrhoids (Fig. 2) or not have had any previous treatment (Table 2), and one could question the use of DGHAL in this setting. However, it should be noted that as we were relying on patients reporting these symptoms, there are a small number of patients with early grade prolapse that have not appeared in the data as they were not reported at the time the data collection forms were completed. This in part ties in with the idea that we should be treating patients' symptoms rather than anatomy, but can be misleading. We presented all treatment options to patients and allowed them to make informed decisions about whether to opt for surgical or non-operative intervention. Also, patients in this study were in no way randomized to receiving DGHAL, nor was there a control group for comparison; the authors accept this as a weakness of the study design, but in view of the gulf in morbidity between DGHAL and other surgical interventions, we wonder as to the validity of comparing DGHAL head to head with PPH or haemorrhoidectomy in terms of efficacy. Perhaps a comparison to office based procedures may be more relevant. This study was designed to assess the efficacy and durability of a procedure that is still in its infancy, with a secondary aim of trying to find its place in the pantheon of treatments for haemorrhoids. Many centres are now offering DGHAL under sedation routinely and even as an office based procedure. Given the low complication rates and therefore the low risk, it may well be reasonable to offer DGHAL as a first line treatment.

In conclusion, DGHAL is a safe, relatively painless, and effective day-case treatment for stage I to III haemorrhoids. Patient satisfaction is high. The authors feel that it's place lies somewhere between clinic-based procedures and PPH in the treatment cascade for haemorrhoids, which should be aimed at treating patients' symptoms rather than restoring normal anatomy. In the future, it is likely this will be performed routinely under sedation with topical anaesthesia, and patients may find it so acceptable that they will opt for this procedure on multiple occasions rather than undergoing a more invasive operation such as PPH and haemorrhoidectomy. With the advent of HAL-RAR (Recto-Anal Repair), outcomes for prolapse may improve and the place of PPH may also be questioned.

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