ORIGINAL ARTICLE

Doppler-guided hemorrhoidal artery ligation does not offer any advantage over suture ligation of grade 3 symptomatic hemorrhoids

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Abstract

Background Doppler-guided ligation of hemorrhoidal vessels is being proposed as a treatment of grade 2 and 3 hemorrhoids. Many researchers are coupling this procedure with mucopexy or lifting of hemorrhoids to control the prolapse more effectively. The present study was conducted in patients with 3rd-degree hemorrhoids to determine the usefulness of Doppler-guided hemorrhoidal artery ligation compared to mucopexy of prolapsing hemorrhoids and to compare it with mere mucopexy of the hemorrhoids. Materials and methods A double-blind, randomized controlled study was conducted on 48 consecutive patients with grade III hemorrhoids requiring surgery. The patients were randomized into two groups. Half of them were treated with ligation and mucopexy [SL], while the remaining patients underwent a Doppler-guided hemorrhoidal artery ligation followed by ligation and mucopexy [DSL]. The patients were examined by a blinded independent observer at 2, 4, and 6 weeks and at the end of 1 year after the operation to evaluate postoperative pain scores, amount of analgesics consumed, and complications encountered. The observer also assessed recurrence of hemorrhoids after 1 year.

Results Operative time was significantly longer in the DSL group (31 min vs. 9 min P < 0.003). The postoperative pain score was significantly higher in the Doppler group [4.4 vs. 2.2, P < 0.002 (visual analogue scale)]. The mean total analgesic dose and duration of pain control using analgesics were greater and longer for the Doppler group than for the SL group (17 vs. 11 tablets, and 13 days

vs. 9 days, respectively; P < 0.01). Complications were similar in both the groups. At 1-year follow-up, the recurrence of hemorrhoids was not statistically significant in either group (4 patients in SL group and 3 patients in DSL group; P < 0.93).

Conclusions Suture ligation of hemorrhoids is a simple, cost-effective, and convenient modality for treating grade 3 hemorrhoids. Doppler assistance in ligating the hemorrhoidal vessels prior to hemorrhoidal mucopexy offers no advantage and is a time-consuming procedure.

Keywords Hemorrhoids · Ligation · Doppler · Suture · Pain

Introduction

Symptoms related to hemorrhoidal disease are frequently bothersome and difficult to treat. Nevertheless, patients are usually reluctant to undergo painful treatments for benign conditions such as hemorrhoidal disease. Over the last decade, several novel treatment options have been developed for high-grade hemorrhoids with the intention of minimizing the drawbacks of what is considered today to be the "gold-standard," that is, conventional hemorrhoidectomy. The aim of these new treatments is to preserve hemorrhoidal tissue that is important for anal sensation and continence and to reduce postoperative morbidity.

One of the new methods that accomplishes this is Doppler-guided hemorrhoidal artery ligation (DGHAL) [1]. This technique has been shown to be associated with potential benefits for symptomatic hemorrhoids, particularly with regard to the perioperative parameters and though only partially, with respect to long-term results too. However, DGHAL alone has proven less effective in the

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case of grades III and IV hemorrhoids [2]. Several studies have mentioned the poor ability of the HAL technique to control prolapse [3, 4].

To overcome the shortcomings of the HAL procedure, various additions have been made, which address the hemorrhoidal prolapse by fixing it within the anal canal. These procedures include "recto anal repair (RAR)" [5], "transanal hemorrhoid mucopexy" [6], "anal lifting" [7], or "hemorrhoidal fixation technique."

The HAL method requires the use of a proctoscope with a Doppler transducer attached. This Doppler transducer is used to detect the location and depth of arterial structures lying approximately 5-6 cm proximal to the anus. The essentials of the operation are the precise and selective ligation of the branches of superior hemorrhoidal arteries. The RAR method is an extension of the HAL method and is a two-step procedure. The first step is artery ligation (HAL) as described above, and the second step is mucopexy. The mucopexy secures the hemorrhoidal prolapse in the anal canal. Technically, the mucopexy begins with the placement of a running suture that starts proximally and ends distally. The distal part of the hemorrhoid is then pushed back into the anal canal, and it is secured in place by knotting the two ends of the absorbable suture. This second step of the RAR procedure is therefore also known as anal lifting. The procedure is carried out with a modified proctoscope and a special device for lifting and fixing the protruding hemorrhoids.

In our hospital, we use a similar but simpler technique to tackle prolapsing hemorrhoids, which controls both the bleeding and prolapse. This is called "ligation and mucopexy of the hemorrhoids under vision" [8]. The technique is based on the fact that most of the hemorrhoidal vessels have a constant anatomical location. Usually, they penetrate the hemorrhoid pile at the base. A stitch that transfixes the base of the prolapsing hemorrhoid is able to diminish the blood flow to the hemorrhoidal plexus significantly. And if this is followed by plication of the entire prolapsing hemorrhoid, the prolapse is controlled as well.

This technique addresses two parallel concepts that explain the development of symptomatic hemorrhoids: (A) increased arterial blood supply to the corpus cavernosum recti and (B) increased laxity of the rectal mucosa. Regardless of the reason for the hemorrhoidal disease, our procedure deals with both the above in an easy-to-learn, minimally invasive approach.

The present randomized controlled trial was designed to evaluate whether ligation of branches of superior hemorrhoidal artery using Doppler assistance prior to mucopexy of hemorrhoids offers any advantage over mucopexy of hemorrhoids alone with regard to duration of operation and postoperative morbidity, resolution of hemorrhoidal symptoms, and medium-term recurrence.

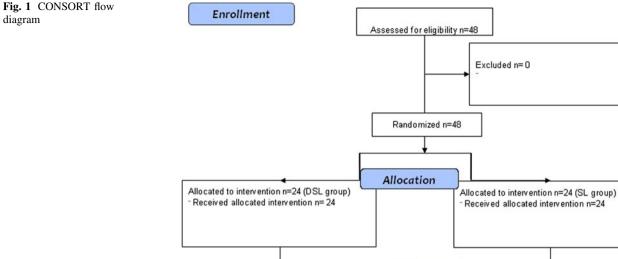
Materials and methods

The present study is a randomized, clinical trial. The study was approved by the hospital ethics committee. Informed consent was obtained from every patient included in the trial. Neither sponsorship nor financial support of any kind was received for the study. All consecutive patients with symptomatic grade III hemorrhoids, that is, piles that prolapse during defecation but are manually reducible, were enrolled. The following patients were excluded: (1) patients with acute thrombosed hemorrhoids; (2) patients with external hemorrhoids or other concomitant anal diseases (such as fissure, fistula, or abscess); (3) patients with inflammatory bowel disease or hematological disorders; (4) patients on anticoagulants; and (5) patients with a previous history of anorectal surgery, including previous hemorrhoidectomy or fistula surgery. Recruited patients were randomly allocated, by means of sealed envelopes, to one of the two study arms: (1) ligation and mucopexy [SL group] or (2) DGHAL plus ligation and mucopexy [DSL group]. A single person performed all randomizations, which were done in blocks so that the number of patients in the two groups was balanced over the course of the trial.

Patients were admitted on the day of operation. Prophylactic antibiotics were not routinely prescribed. Over a 5-month period, 48 patients were enrolled (Fig. 1). The characteristics of these patients are listed in Table 1. The two groups were matched for age and gender. There was no significant difference between the numbers of mucopexies performed in the groups. Twenty-two patients from the Doppler group and 3 patients from the suture ligation group were operated on under spinal anesthesia, while remaining patients from both groups were operated on under general anesthesia.

Operative technique

To eliminate surgeon bias, all operations were performed by a single surgeon (ST) who had experience performing more than 120 DGHAL procedures. The operation was performed under general or spinal anesthesia, with the patient in the lithotomy position. The DGHAL device consists of a specifically designed proctoscope equipped with a Doppler probe (placed on the lateral profile of the device) and a light source. Continuous Doppler technology is provided, with a double crystal allowing specific focusing of the ultrasound waves and capture of large-diameter arteries located in the superficial layers of the rectal wall. The Doppler probe is oriented toward the operative window, so that the artery identified by the Doppler signal lies within the operative window and can be selectively ligated. After lubricating the anal canal with electroconductive gel, a special proctoscope KM-25 (VaiDan Medical Corporation, St. Petersburg, FL)



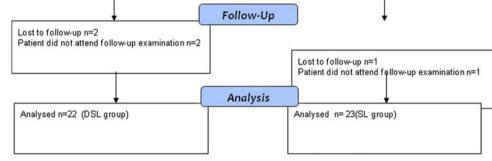


Table 1 Demographic, perioperative, and follow-up data

	DSL	SL	P value
Age (years)*	44 (11.2)	47.4 (10.4)	0.34
Gender (M:F)	13:11	12:12	0.45
Operation time (min)*	31 (5.4)	9 (6.3)	0.003 [§]
Pain VAS score [#] (0-10)	4.4 (2.9–6.3)	2.2 (1.7-5.9)	0.002 [¶]
Analgesic tablets (n) [#]	17 (8–18)	11 (4–13)	0.01 [§]
Days analgesic consumed (n) [#]	13 (9–12)	9 (4–9)	$0.02^{\$}$
Patients with postoperative complications (n)	4	4	0.51
Patients with recurrence at 12-month follow-up (n)	4	3	0.93

DSL DGHAL plus ligation and mucopexy under vision; SL ligation and mucopexy under vision; VAS Visual Analog (pain) Scale

* Values are mean (SD)

[#] Values are median (range)

¶ Mann–Whitney U test

[§] Student's *t*-test

was introduced through the anal canal reaching the lower rectum, about 6–7 cm from the anal verge. Tilting the proctoscope, the best Doppler signals were sought corresponding to the main trunks of the hemorrhoidal arteries. The rectal mucosa and submucosal layer of the rectal wall were then transfixed with a "Z" suture (stitch of 2–0 absorbable polyglycolic acid with a 5/8-inch needle) to ligate the artery. The depth of the transfixed stitches was easily and safely calibrated by the use of pivot hole

provided in the center of the proctoscope lumen. The tip of the needle holder was introduced into the pivot hole and rotated, so that the needle penetrated the rectal wall at a maximum depth of 6 mm, avoiding perforation of the entire rectal wall and involving primarily only the mucosa and submucosa. Pulling the suture back abolished or significantly reduced the Doppler signal, thus confirming the hold of the artery. Each suture was tied and dearterialization completed. The ligated vessels ranged between 6 and 11.

After performing HAL, the instrument was withdrawn and with the patient kept in the same lithotomy position, the 3 skin tags corresponding to 3 principle sites of hemorrhoidal cushions, namely right anterior, right posterior, and left lateral position, were caught with a vascular forceps and retracted out to visualize the hemorrhoids. An absorbable 0 chromic catgut (No. 4246 Ethicon UK) on a half-circle 45 mm round needle was used for the entire procedure. Firstly, a transfixing suture was applied at the hemorrhoidal pedicle. This was followed by another suture line next to the transfixing suture descending caudally in a continuous locking manner to include only the mucosa and submucosa of the visible hemorrhoids and was completed just 5 mm before the dentate line (Fig. 2). The procedure was performed for all the hemorrhoids seen, usually 3 in number. No anal packing was done after the procedure.

Postoperative management and follow-up

Oral alimentation was allowed in the immediate postoperative period. For pain relief, Tramadol Hydrochloride 50 mg was prescribed orally. Patients were instructed to take these tablets as and when required and to come to the emergency room whenever the pain was intolerable or any significant complications developed, especially spontaneous bleeding or anal sepsis. Home treatment also included a high-residue diet, stool softeners, and warm sitz baths. An independent assessor, who was unaware of the surgical technique performed, was assigned to obtain data like pain score and amount of analgesic consumed by the patients. Hospital discharge was governed by the followed strict criteria: (1) the patient was fully ambulatory and (2) the patient did not complain of bleeding or urinary retention. Patients were then assessed at 2, 4, and 6 weeks and then at 1 year after surgery. Anoscopic examinations were performed at the end of 4 and 6 weeks and then at follow-up after 1 year. Complaints of intermittent bleeding or prolapsing hemorrhoids at the last follow-up were considered as recurrence.

Measured outcomes and statistical analysis

Operative data and postoperative complications were recorded. Patients were instructed to assess postoperative pain using a 10-cm linear visual analog scale (VAS) in which 0 corresponds to "no pain" and 10 to "maximum pain" and to record the use of analgesics everyday for the first 14 days. Because the time of maximal pain perceived by different patients might be quite different, the VAS pain score on each day for the first 14 days was summated and presented as one value.

Power calculation suggested that at least 22 patients were needed in each group to detect differences of 1 standard deviation (SD) in the mean pain score with an 80% power at a 5% significance level.

All data were prospectively collected and entered into SPSS_ software (Windows version 10.0; SPSS Inc., Chicago, IL). Categoric variables were analyzed with the Chi-square or Fisher's exact test, and numeric (continuous or parametric) variables were analyzed by the use of Student's *t*-test or the Mann–Whitney U test, as appropriate. Data were expressed as either mean and standard deviation or median and range.

Results

The duration of surgery was significantly higher in the Doppler group (31 min vs. 9 min, P < 0.003). The postoperative pain score was significantly higher in the DSL group [4.4 vs. 2.2, P < 0.002 (VAS)]. The mean total analgesic dose and duration of pain control using analgesics were greater and longer for the Doppler group than for the SL group (17 vs. 11 tablets, and 13 days vs. 9 days, respectively; P < 0.01).

Eight patients developed complications. In the DSL group, 3 patients developed transient urinary retention, and another patient developed postoperative hemorrhage but was managed conservatively. In the SL group, one patient developed urinary retention, whereas 3 patients had

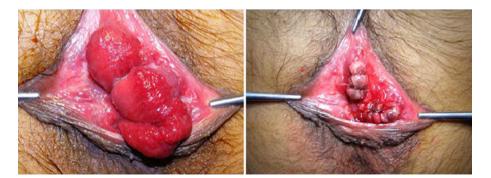


Fig. 2 Procedure of ligation and mucopexy

perianal thrombosis that resolved over a period of time. No septic complications occurred in the trial. Overall, there was no difference in complication rate between the 2 groups.

After 1 year, 2 patients from the DSL group and one patient from the SL group were lost to follow up. Although 4 patients in the SL group and 3 patients in the DSL group had recurrence, it was not statistically significant (P < 0.93) (Table 1).

Discussion

The present randomized study was conducted to assess the usefulness of doppler assisted ligation of hemorrhoidal vessels prior to mucopexy of the hemorrhoids (DSL) in comparison with mere mucopexy (SL). At 1-year follow-up, the recurrence rates in both groups were not statistically different, indicating that in addition to mucopexy, Doppler-assisted ligation of the branches of the superior hemorrhoidal artery has no extra benefit. It was also noted that operative time was significantly longer in DSL than in suture ligation and mucopexy. Postoperative pain had a greater intensity and longer duration in the DSL group than in the SL group, and a larger amount of analgesics was required in the DSL group.

The new pathogenetic explanation of hemorrhoidal diseases is that the enlarged plexus hemorrhoidalis and the increased mobility caused by insufficient supportive structures lead to prolapse and bleeding from the hemorrhoids [9]. The mucopexy procedure aims specifically at interrupting the arterial flow to the hemorrhoids, thought to be a main factor in the etiology.

The mucopexy procedure can be called minimally invasive as it does not involve any mucosal or anodermal excision and is very simple to perform as it involves a basic surgical maneuver, that is, suturing. As the arteries carrying the blood inflow are ligated, the internal pressure of the plexus hemorrhoidalis decreases and the typical symptoms of hemorrhoids disappear. During follow-up, the hemorrhoids treated with our technique initially look shrunken and segmented and on long-term follow-up were found to be replaced by segmented fibrotic scar tissue that firmly adhered to the underlying structures.

Mucopexy preserves the well-innervated hemorrhoidal tissue, and no costly instruments are necessary. The anus does not have to be dilated as much as in the DGHAL procedure. No retractor is used to stretch the anal sphincters that prevents a hidden "Lord Procedure effect" that causes inadvertent injury to the sphincters that negatively affects anal continence. Another advantage of our procedure is that it can be tailored to best treat each individual case, depending on the number of hemorrhoids identified. Nonetheless, as far as the learning curve for mucopexy is concerned, plication should be performed well above the dentate line to avoid postoperative pain and perianal thrombosis.

Suture ligation of hemorrhoids by different approaches has a long history and includes "pile suture" [10], "obliterative suture technique" [11], "ligation and anopexy" [12], "suture ligation" [13], and "modified pile suture" [14]. These procedures are quite similar to the mucopexy procedure performed in this study.

Several studies on HAL in patients with grade 3–4 hemorrhoids have shown that although a reduction in the blood supply to the hemorrhoidal plexus reduces the size of the hemorrhoids, the prolapse does not always fully disappear. With DGHAL, symptoms such as bleeding may improve shortly after surgery, but the reduction of prolapse is difficult.

Aigner et al. [15] studied the possibility of hemorrhoidal pile shrinkage with DGHAL alone, an anatomical study of 38 cases. Their anatomical study of 38 cases showed that ligation of the main trunk of the superior rectal artery was possible with the DGHAL technique, which can ligate a vessel 3 cm above the dentate line, but interruption of the additional branch of the superior rectal artery that supplies the corpus cavernosum recti by piercing the muscular layer of the rectal wall was difficult. For this reason, the authors explained that hemorrhoids may persist after DGHAL. Schuurman and his colleague also noted similar findings on cadavers [16].

Many researchers consider that Doppler-assisted ligation of branches of superior hemorrhoidal artery creates multiple areas of scar tissue above the hemorrhoids, which pull them up, much like what is achieved after rubber band ligation, infrared coagulation, or other thermal ablation methods [17]. Few studies have reported laser ablation of branches of hemorrhoidal artery located with Doppler ultrasound [18]. About 8–12 branches of the superior hemorrhoidal artery identified by Doppler ultrasound were laser ablated to produce shrinkage and obliteration of the vessels similar to what is achieved with ligation of these vessels, which raised doubts about the need for ligation of the branches of the artery [19].

Doppler-guided hemorrhoidal artery ligation interrupts the blood supply to the hemorrhoids. However, long-term results have shown that it is associated with a high recurrence and re-prolapse rate [20]. It should be noted, however, that this study refers to both third and fourth degree piles. This indicates that mere ligation of branches of the hemorrhoidal artery has no significant effect in curbing hemorrhoidal disease.

Many researches have obtained good results with procedures similar ours and have questioned the validity of Doppler-guided ligation of hemorrhoidal vessels. Bronstein et al. described a method called "ligation under vision of hemorrhoidal cushion" [21]. Pakravan achieved satisfactory outcomes in patients who had prolapsing hemorrhoids by using "transanal open hemorrhoidopexy" without the need of any costly instruments like the Doppler transducer [22]. Tagariello, who initially performed the DGHAL procedure for 7 years, has switched over to "manual hemorrhoidopexy" and achieved similar results with greater simplicity and shorter duration of surgery [23].

Thus, the present study calls into question the value of Doppler-assisted localization of vessels in hemorrhoid operations and implies that hemorrhoids can be managed with equal efficacy without the need of the costly Doppler instruments, with less operative time, and with reduced postoperative pain.

The limitations of this study are that both the surgical procedures were performed by a single surgeon and that it shows results of medium-term follow-up. It would be interesting to know the percentage of patients at long-term follow-up who need treatment for symptom recurrence. It would also be interesting to compare ligation and mucopexy of hemorrhoids to the recto anal repair procedure described in the literature. Multicentric randomized controlled trials would allow comparative analysis of the study groups to confirm the findings of this study.

Conclusions

The present study suggested that the technique of combining ligation and mucopexy of hemorrhoids offers a simple, cost-effective, and convenient modality for treating grade 3 hemorrhoids. Doppler-assisted ligation of the hemorrhoidal vessels offers no advantage, and it is a timeconsuming procedure.

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Conflict of interest No conflict of interest.

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