



# A Randomized Clinical Study to Compare the Outcome of Hemorrhoidal Artery Ligation (HAL) Procedure with and without Doppler Guidance in Grades I–III Hemorrhoidal Disease

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## Abstract

Hemorrhoidal artery ligation (HAL) procedure aims specifically at reducing the arterial flow to the hemorrhoids. The Doppler probe allows an accurate localization of the branches of superior rectal artery which are individually ligated. However, the vessels can also be ligated by digital palpation of vessels without the help of Doppler probe. In this study, we have compared the results of hemorrhoidal artery ligation procedure with and without Doppler guidance in symptomatic grades I–III hemorrhoids. The study was a single-blinded randomized clinical study. Patients were randomly allocated into two groups, the non-Doppler group (HAL group) and the Doppler group (DGHAL group). The outcome was assessed by using HDSS questionnaire as proposed by Nyström et al. Patients were followed at 6 weeks, 6 months, and 1 year following the procedure. In this study, the overall control of bleeding was 86.9% (86.0% in HAL group and 87.9% in DGHAL group) after 1 year of follow-up. The overall recurrence of prolapse in patients with grade II hemorrhoids after 1 year of follow-up was 16.9% (17.9% patients in HAL group and 16.0% in DGHAL group). The overall recurrence of prolapse in patients with grade III hemorrhoid after 1 year follow-up was 58.6% (60% patients in HAL group and 57.1% in DGHAL group). However, there was no significant difference between both groups. No significant difference was found in both groups in the secondary outcome measures (pain, soiling, and itching). Our study indicates that the hemorrhoidal artery ligation procedure can be performed effectively without the use of Doppler transducer. The study also suggests that HAL procedure is more effective in early grade hemorrhoids (grades I and II).

**Keywords** Hemorrhoids · Hal · DGHAL

## Introduction

Hemorrhoids are one of the most common clinical conditions to affect humans with prevalence of 4.4%. [1–3] Hemorrhoids are vascular cushions within the anal canal, usually found in three main locations, left lateral, right anterior, and right posterior position. They lie beneath the epithelial lining of the anal canal and consist of direct arteriovenous communications, mainly between the terminal branches of the superior rectal, middle, and inferior hemorrhoidal arteries. It has been suggested that their presence is essential for continence; they contribute approximately 15 to 20% of the resting anal pressure. The theory of sliding cushions is widely accepted and hemorrhoids become symptomatic when the vascular cushions erode or descend. [4–8]

Treatment of hemorrhoid ranges from dietary and lifestyle modification to excision of hemorrhoid, depending on degree and severity of symptoms [9, 10]. Medical management

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includes micronized purified flavonoid fraction (MPFF), consisting of 90% diosmin and 10% hesperidin. [11] Office procedures used in hemorrhoid treatment are sclerotherapy, rubber band ligation, and infrared coagulation (IRC) with variable results. [12–16] Excisional hemorrhoidectomy is the most effective treatment for hemorrhoids with the lowest rate of recurrence compared with other modalities. In clinical practice, the third-degree or fourth-degree internal hemorrhoids are the main indication for hemorrhoidectomy. A major drawback of hemorrhoidectomy is postoperative pain. [17]

A new technique based on Doppler-guided ligation of the terminal branches of the superior hemorrhoidal artery (DGHAL) was introduced in 1995 as an alternative to hemorrhoidectomy. [18] The rationale of this treatment was later supported by the findings from studies which demonstrated that patients with hemorrhoid had increased caliber and arterial blood flow of the terminal branches of the superior rectal arteries. DGHAL technique aims specifically at interrupting the arterial flow to the hemorrhoids, thought to be a main factor in the etiology. The Doppler probe allows an accurate localization of all the branches of superior rectal artery which reduces the inflow. The connective tissue in the collapsed hemorrhoid slowly regenerates with resolution of the prolapse. Postoperative pain is minimal compared with hemorrhoidectomy. None of the severe complications (sepsis, perforation, fistulas) associated with other techniques has been seen. There is no anal wound left to heal. There is no risk of incontinence or strictures. The technique is simple and very easy to master. Patients can be discharged safely on the day of operation, thus reducing hospital costs. [19–21] Success rate is well beyond that of other methods of treatment such as rubber band ligation that usually requires multiple banding procedures. In a multicenter, open-label randomized controlled trial comparing hemorrhoidal artery ligation versus rubber band ligation, at 1 year post-procedure, 87 (49%) of 176 patients in the RBL group and 48 (30%) of 161 patients in the HAL group had hemorrhoid recurrence (adjusted odds ratio [aOR] 2.23, 95% CI 1.42–3.51;  $p = 0.0005$ ). [22]

The three main branches of superior rectal artery are usually consistent in position. The vessels are usually found in the area of visible hemorrhoidal tissue and sometimes the vessels can be identified by digital examination by fingertip. Some recent studies have shown that the Doppler transducer does not contribute to the beneficial effect of HAL procedure and can be omitted during the ligation procedure in the treatment of hemorrhoidal disease. [23] Thus, we hypothesize that the HAL procedure can be performed by finger palpation of hemorrhoidal vessels (FPHAL) or ligation of vessels at the anatomical position at the site of visible pathological hemorrhoidal tissue.

The aim of this study is to compare the outcome of the hemorrhoidal artery ligation (HAL) procedure in grades I–III symptomatic hemorrhoids with and without the use of the Doppler transducer.

## Material and Methods

The single-blinded randomized clinical study was conducted at the Department of Surgery, King George's Medical University, Lucknow, UP, India. Patients with symptomatic grades I–III hemorrhoids who did not respond to medical treatment were included in the study. Patients who are pregnant, with Crohn's disease, and those with abscesses, colorectal carcinoma, or portal hypertension were excluded from the study. Patients with predominant external hemorrhoids and grade IV hemorrhoids were not included in the study. Patients with concomitant anal fissure were also excluded from the study. A written informed consent was obtained from the patients after describing the procedures involved, perceived benefits, and possible side effects/complications of each of the two treatment modalities and informing the right of patient not to participate and to withdraw from the study at their will without affecting the quality of their care. Ethical approval was obtained from the Institutional Ethics Committee.

Sample size assessment was done keeping in consideration a targeted mean pain score difference of 0.40 and a pooled standard deviation of 0.8 between two groups at 80% power (beta error 20%) and 95% confidence (alpha error 5%). The calculated sample size was 53 for each group. After making contingency provisions, the sample size was kept as 60 in each group. Selection bias was removed through randomization. Randomization was done using computer-generated tables and patients were distributed into two groups, the Doppler group (DGHAL group) and the non-Doppler group (HAL group). Allocation bias/confounder effect was analyzed statistically by matching the two groups demographically and for baseline characteristics. Treatment bias could not be controlled as blinding was not possible. Analytical bias was removed by coding the group names instead of naming them.

All patients were operated in spinal anesthesia in lithotomy position. The ligations were performed with an absorbable, synthetic, braided suture (2/0 Vicryl, 5/8 circumference). Patients in non-Doppler group received the artery ligation procedure without the help of Doppler transducer, and the ligations were placed after digitally palpating the artery about 2–3 cm above the pectinate line. In approximately one-third of cases, the arterial pulsations were not felt and the sutures were placed in the area of visible pathologic hemorrhoidal tissue. In patients of the Doppler group, the standard artery ligations were performed with the help of Doppler transducer using A.M.I. HAL/RAR system. In both groups, a figure of eight

ligations was applied with a maximum of 6 ligations. In both groups, no additional procedures were performed. All procedures were performed by surgeons and residents under the supervision of the same surgeon.

Patients were followed at 6 weeks, 6 months, and 1 year after surgery. Symptoms were assessed using frequency of the 5 symptoms including bleeding, prolapse, pain, soiling, itching, as proposed by Nystrom et al. [24] A questionnaire was filled at the outpatient department and also telephonically for patients who did not present themselves at the outpatient department. The symptoms were categorized as mild (once a week), moderate (one to six per week), and severe (every day) based on their frequency.

Categorical variables were presented in number and percentage and continuous variables were presented as mean and SD. Qualitative variables were compared using chi-square test/Fisher’s exact test as appropriate. A *p* value of <0.05 was considered statistically significant. The data was entered in MS Excel spreadsheet and analysis was done using Statistical Package for Social Sciences (SPSS) version 17.0.

### Results

There were 120 patients included in the study. The DGHAL procedure was performed in 60 patients and HAL procedure (without Doppler) was performed in 60 patients. Out of 120 patients, 38 patients had grade I, 53 patients had grade II, and 29 patients had grade III hemorrhoids. The distribution of age, gender, and grade of hemorrhoidal disease was found to be comparable in both groups. At 1 year follow-up, five patients were lost to follow-up. The five different symptoms in both groups were analyzed.

In patients who had undergone HAL procedure, at 1 year follow-up, no bleeding was found in 86% of patients, mild bleeding was found in 12.3% of patients, and moderate bleeding was found in 1.8% of patients. In patients who had undergone DGHAL procedure, at 1 year follow-up, no bleeding was found in 87.9% of patients, and mild bleeding was found in 12.1% of patients. There was no statistically significant difference between the two groups (Table 1).

In patients with grade II hemorrhoids who had undergone HAL procedure, at 1 year follow-up, no prolapse was found in 82.1% of patients, and mild prolapse was found in 17.9% patients. For patients who had undergone DGHAL procedure, at 1 year follow-up, no prolapse was found in 84% of patients, and mild prolapse was found in 16% patients. However, the results were comparable and there was no statistically significant difference between the two groups.

In patients with grade III hemorrhoids who had undergone HAL procedure, at 1 year follow-up, no prolapse was found in 40% of patients, mild prolapse was found in 40% patients, moderate prolapsed was found in 13.3%, and severe prolapsed was found in 6.7% of patients. For patients who had undergone DGHAL procedure, at 1 year follow-up, no prolapse was found in 42.9% of patients, mild prolapse was found in 35.7% of patients, and moderate prolapse was found in 21.4% of patients; however, the results were comparable between the two groups (Table 2).

There was no significant difference in the other outcome measures (pain, soiling, and itching) in both groups.

### Discussion

In our study, the overall control of bleeding was 86.9% after 1 year of follow-up. The results were comparable in the non-Doppler (86.0%) and Doppler group (87.9%). Mild bleeding was present in 12.3% patients of HAL group and 12.1% patients of DGHAL group. None of the patients in either group reported severe bleeding at 1 year follow-up. In a randomized clinical trial to compare the outcome of hemorrhoidal artery ligation procedure with and without Doppler transducer in grades II–III hemorrhoidal disease, at 6 months follow-up, no bleeding was reported in 87.0% patients, mild bleeding was present in 13.0% patients and none of the patients reported severe bleeding in the non-Doppler group. In Doppler group at 6 months follow-up, no bleeding was present in 62.5% of patients, mild bleeding was seen in 33.3% patients, and severe bleeding was found in 4.2% patients. The result of both groups was comparable and statistically non-significant (*p* = 0.221). [23]

**Table 1** No statistically significant difference between HAL and DGHAL groups

	6 weeks			6 months			1 year		
	HAL	DGHAL	<i>p</i> value	HAL	DGHAL	<i>P</i> value	HAL	DGHAL	<i>p</i> value
No bleeding	49 (81.7%)	50 (83.3%)	0.559	51 (85.0%)	50 (83.3%)	0.540	49 (86.0%)	51 (87.9%)	0.597
Mild	9 (15.0%)	10 (16.7%)		8 (13.3%)	10 (16.7%)		7 (12.3%)	7 (12.1%)	
Moderate	1 (1.7%)	0 (0%)		0 (0%)	0 (0%)		1 (1.8%)	0 (0%)	
Severe	1 (1.7%)	0 (0%)		1 (1.7%)	0 (0%)		0 (0%)	0 (0%)	

**Table 2** Results between HAL and DGHAL groups in grades II and III were comparable

Grade		At 6 weeks		<i>p</i> value	At 6 months		<i>p</i> value	At 1 year		<i>p</i> value
		HAL <i>N</i> (%)	DGHAL <i>N</i> (%)		HAL <i>N</i> (%)	DGHAL <i>N</i> (%)		HAL <i>N</i> (%)	DGHAL <i>N</i> (%)	
II	No	20 (71.4)	17 (68.0)	0.786	22 (78.6)	20 (80)	0.898	23 (82.1)	21 (84)	0.857
	Mild	8 (28.6)	8 (32.0)		6 (21.4)	5 (20.0)		5 (17.9)	4 (16.0)	
	Moderate	0 (0)	0 (0)		0 (0)	0 (0)		0 (0)	0 (0)	
	Severe	0 (0)	0 (0)		0 (0)	0 (0)		0 (0)	0 (0)	
	Total	28	25		28	25		28	25	
III	No	10 (66.7)	9 (64.3)	0.999	7 (46.7)	8 (57.1)	0.766	6 (40)	6 (42.9)	0.739
	Mild	3 (20)	3 (21.4)		5 (33.3)	4 (28.6)		6 (40)	5 (35.7)	
	Moderate	1 (6.7)	1 (7.1)		2 (13.3)	2 (14.3)		2 (13.3)	3 (21.4)	
	Severe	1 (6.7)	1 (7.1)		1 (6.7)	0 (0)		1 (6.7)	0 (0)	
	Total	15	14		15	14		15	14	

A prospective study on suture ligation of internal hemorrhoids without Doppler guidance concluded that 82.81% of patients can be satisfactorily managed by HAL procedure without Doppler transducer, at the end of 1 year. [25]

In our study, out of 53 patients with grade II hemorrhoids, 16.98% of patients had persistent prolapse after 1 year. Out of 29 patients with grade III hemorrhoids, 58.62% of patients had persistent prolapse after 1 year. Therefore, correction of prolapse was better in patients with grade II hemorrhoids as compared with grade III hemorrhoids. However, there was no significant difference between the two groups in grade II (*p* value = 0.857) and grade III hemorrhoids (*p* value = 0.739).

A systematic review of 5-year follow-up of Doppler-guided hemorrhoidal artery ligation study (17 studies, comprising 1996 patients) reported an overall recurrence rate at 1 year or more of 10.8% for prolapse and 9.7% for bleeding, while the recurrence rate for grade IV hemorrhoids was higher than for grades II and III. In this study, they report a decreasing success rate of the DGHAL procedure during the 5-year post-operative period, with a trend toward a higher recurrence rate for grade III hemorrhoids compared with grade II. [26]

Another systematic review of twenty-eight studies including 2904 patients found that recurrence varied from 3 to 60%, at 6 weeks to 5 years. The pooled total recurrence rate was 17.5% with the highest rates for grade IV hemorrhoids. [27]

In a multicenter trial, a total of 803 patients affected by symptomatic hemorrhoids, who failed a conservative approach, were treated primarily with the Doppler procedure. Recurrence of hemorrhoidal prolapse, bleeding, and both prolapse and bleeding requiring a medical or surgical therapy was seen in 26 (8.7%), 10 (3.4%), and 3 patients (1.0%), respectively. [28]

The other outcome measures (pain, soiling, and itching) were comparable in both groups. None of the patients reported any serious problem in the postoperative period. The study

indicates that the results of hemorrhoidal artery ligation procedure are similar with and without the use of the Doppler transducer.

## Conclusion

This study indicates that the hemorrhoidal artery ligation procedure can be performed effectively without the use of Doppler transducer. The finger-palpated HAL is a learned procedure and one may get the premonition after having done a score of DGHAL. However, the training of the new surgeons for finger-palpated HAL (FPHAL) can start from the beginning. The study also suggests that HAL procedure is more effective in early grade hemorrhoids (grades I and II) as compared with grade III hemorrhoids.

**Author Contributions** All authors contributed in the study.

**Compliance with Ethical Standards** Ethical approval was obtained from the Institutional Ethics Committee.

**Conflict of Interest** The authors declare that they have no conflict of interest.

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