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Pol, Robert; van der Zwet, Wil C.; Kaijser, Mirjam; Eeftinck Schattenkerk, Marinus; Eddes, EH

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Original Paper



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Results of 244 Consecutive Patients with Hemorrhoids Treated with Doppler-Guided Hemorrhoidal Artery Ligation

Robert A. Pol^a Wil C. van der Zwet^b Daniel Hoornenborg^a Babbeth Makkinga^a Miriam Kaijser^a M. Eeftinck Schattenkerk^a Eric-Hans Eddes^a

Departments of ^aSurgery and ^bEpidemiology, Deventer Hospital, Deventer, The Netherlands

Key Words

Hemorrhoids • Rubber band ligation • Doppler-guided hemorrhoidal artery ligation

Abstract

Aim: This study was designed to determine the effect of treating hemorrhoids with the Doppler-guided hemorrhoidal artery ligation (DG-HAL) procedure. *Methods:* From June 2005 to March 2008, 244 consecutive hemorrhoidal patients underwent hemorroidal artery ligation performed with the DG-HAL system from AMI®. All patients were evaluated postoperatively with a proctologic examination and interview. Further follow-up was performed by telephone with a standardized questionnaire. When indicated, patients revisited the clinic for further examination and treatment. Results: 244 patients were treated with DG-HAL. The mean follow-up time was 18.4 months (range 1.4–37.2). Sixty-seven percent of the patients had an improvement of symptoms after one treatment. Fifty-three patients (22%) underwent a second procedure because of persisting symptoms. Thirteen patients (25%) underwent a second DG-HAL and 40 (75%) underwent rubber band ligation. In total, 69% of the patients had a good response using the DG-HAL technique. Multivariate logistic regression analysis revealed prolapse to be an independent risk factor for persistent symptoms (OR = 2.38, 95% CI 1.10-5.15). Patients with grades 3 and 4 hemorrhoids

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Accessible online at: www.karger.com/dsu had a higher risk of developing recurrent disease (OR = 4.94, 95% CI 0.67–36.42). **Conclusion:** DG-HAL seems to be an effective procedure for treating low-grade hemorrhoids. A resection procedure should be the treatment for patients with recurrent disease. Copyright © 2010 S. Karger AG, Basel

Introduction

Hemorrhoidal disease is a common problem in the western world and affects about 4% of the population [1]. It arises from the hemorrhoidal plexus, which is located in the submucosal layer of the rectum. The pathogenesis of hemorrhoids is unclear, but a decrease in connective tissue, an increase in tone of the internal anal sphincter or a disfunction of local arteriovenous shunts are plausible hypotheses [2]. Most patients present with symptoms of bleeding, anal pruritus, prolapse and/or pain. Different modalities are available for the treatment of symptomatic hemorrhoids, varying from a conservative approach with a fiber-enriched diet and minimally invasive procedures, such as laser coagulation and rubber band ligation (RBL), to surgical therapy. Disease recurrence (mostly after conservative treatment) and postoperative pain (after the conventional surgical therapies) are the main concerns with these treatments [3].

Robert A. Pol Department of Surgery, Deventer Hospital Nico Bolkesteinlaan 75 NL-7416 SE Deventer (The Netherlands) Tel. +31 570 646 666, E-Mail r.pol@dz.nl In 1995, a new technique was described by Morinaga et al. [4]. By combining proctoscopy with a Doppler transducer, it is possible to selectively ligate the vessels in the hemorrhoidal plexus. Multiple studies have shown that Doppler-guided hemorrhoidal artery ligation (DG-HAL) is a safe and easy-to-learn technique with low recurrence rates, and possibly a good alternative to conventional treatments [5–9]. Nevertheless, the rates of effectiveness and patient satisfaction after long-term follow-up are still unknown and, currently, no large, prospective, randomized, controlled trial has been published. We previously published our first experiences and results with DG-HAL [10]. In this article, we describe the long-term follow-up results of this procedure.

Methods

From June 2005 to March 2008, 244 consecutive patients underwent DG-HAL. We initially intended to randomize all patients and conduct a prospective randomized controlled trial. Unfortunately, due to much attention in the local media, most patients refused participation and randomization and preferred the new technique.

The Goligher classification was used for grading the hemorrhoids [11]. All patients had symptomatic grade 1–3 hemorrhoids. When we started with DG-HAL, all gradings were included, which led to 5 patients being included with particularly advanced hemorrhoids. Eventually, grade 4 hemorrhoids were excluded and primarily underwent a two-stage procedure in which a DG-HAL was done to control the bleeding and reduce hemorrhoidal tissue, followed by a resection procedure or RBL. However, we decided to include these 5 patients in our analysis to fully understand the pathophysiology of hemorrhoids and the effect of DG-HAL. Grade 1 patients were only treated surgically after unsuccessful conservative treatment with a fiber supplement and/or a topical hemorrhoidal ointment.

Bleeding and prolapse were the main preoperative complaints. All patients from the age of 45 on underwent a total colonoscopy before the initial proctoscopy to exclude other colorectal pathologies as bleeding sources. The procedure was performed in day care under spinal anesthesia and in the lithotomy position. A phosphate enema was administered to all patients 3 h prior to surgery. We used the DG-HAL system from AMI®. After insertion of the proctoscope, which is connected to the Doppler device, all arterial signals were detected, ligated with a figure-of-eight stitch and tied using a 20-cm knot pusher. Care was taken to reach an adequate suture depth for ligation of the submucosal arterial branches. The absence of an arterial signal was confirmed using the Doppler transducer. Three full circles with the proctoscope were performed in the rectal canal and every arterial signal was ligated. Extra ligations were performed, at the surgeon's discretion, when extra-hemorrhoidal tissue was evidently visible. For the ligations, a vicryl stitch (AMI HAL suture, 2/0 vicryl, tapered needle, 5/8 circumference, reinforced needle-thread connection) was used. All patients started with a bulk fiber supplement (Movicol®, Norgine B.V., Amsterdam) and were standardly evaluated 6 weeks postoperatively by a proctologic examination. During the outpatient examinations and interviews, data on postoperative grade, recurrence, prolapse, pain, bleeding, soiling and itching were collected and recorded prospectively. Further follow-up was done by telephone in which a standardized questionnaire was used to asses the final outcome with regard to patient satisfaction and complaints. All symptoms mentioned were compared to the recorded preoperative levels. When disease recurrence was suspected, patients revisited the clinic for further examination and treatment. When we decided to perform a second procedure, this was done by either a repetition of DG-HAL or RBL. The decision of which treatment to use was made at the surgeon's discretion or depending on the seriousness of the symptoms or complaints. After a second procedure, patients were once again evaluated 6 weeks postoperatively by a proctologic examination and outpatient control at regular intervals when necessary.

Statistical Analysis

Analyses were performed using SPSS 16.0 (SPSS Inc., Chicago, Ill., USA) and Excel (Microsoft, Redmond, Wash., USA). A comparison of pre- and postoperative variables was made using the Wilcoxon rank-sum test on matched pairs. A multivariate logistic regression analysis was performed on all known symptoms associated with hemorrhoidal disease and the recorded hemorrhoidal grading. p < 0.05 was considered significant.

Results

From June 2005 to March 2008, 244 consecutive patients underwent a DG-HAL procedure for symptomatic hemorrhoids. Patients' mean age was 49 years (range 26– 81). The median of follow-up was 18.4 months (range 1.4– 37.2). On average, 6–8 ligations were necessary.

Prior to initial treatment, 28 patients (11%) had grade 1, 116 (48%) had grade 2, 95 (39%) had grade 3 and 5 patients (2%) had grade 4 hemorrhoids.

After the first treatment, 67% of the patients (164/244) had a satisfactory improvement of their hemorrhoidal gradation and complaints, when compared to the preoperative condition. Twenty-seven percent had no significant improvement in symptoms or gradation and 6% even had a worsening of gradation and/or symptoms (table 1; fig. 1).

Fifty-three patients (22%) underwent a second procedure because of persisting hemorrhoidal symptoms. Thirteen patients (25%) underwent a second DG-HAL and 40 (75%) underwent RBL. The median number of bandings placed in the RBL group was 3 (range 1–6) and all bandings were placed in one session. This procedure is done as an inpatient treatment in our clinic under epidural anesthesia.

Six patients (46%) in the DG-HAL group and 35 patients (88%) in the RBL group had a satisfactory improve-

Postoperative	Preoperative				Total
	1	2	3	4	1
0	17	55	18	1	91
1	7	26	24	0	57
2	2	30	21	1	54
3	2	<u>5</u>	27	1	35
4	0	0	5	2	7
Total	28	116	95	5	244

Table 1. Gradation of hemorrhoids before and after the first DG-HAL procedure

Numbers in bold represent patients with improvement (164/244, 67%). Numbers in italics represent patients without improvement (66/244, 27%). Underlined numbers represent patients with worsening symptoms (14/244, 6%).

Table 2. Gradation of recurrent hemorrhoids before and after the second DG-HAL procedure

Postoperative	Preo	Total			
	1	2	3	4	_
0	0	2	3	0	5
1	1	0	0	0	1
2	<u>0</u>	0	0	0	0
3	<u>0</u>	<u>1</u>	4	1	6
4	<u>0</u>	<u>0</u>	<u>1</u>	0	1
Total	1	3	8	1	13

Numbers in bold represent patients with improvement (6/13, 46%). Numbers in italics represent patients without improvement (5/13, 38%). Underlined numbers represent patients with worsening symptoms (2/13, 15%).

Table 3. Gradation of recurrent hemorrhoids before and after thesecond procedure using RBL

Postoperative	Preoperative				Total
	1	2	3	4	
0	4	10	7	2	23
1	1	2	4	0	7
2	<u>0</u>	3	2	2	7
3	<u>0</u>	<u>0</u>	1	2	3
4	<u>0</u>	<u>0</u>	<u>0</u>	0	0
Total	5	15	14	6	40

Numbers in bold represent patients with improvement (35/40, 88%). Numbers in italics represent patients without improvement (5/40 patients, 13%). Underlined numbers represent patients with worsening symptoms (0/40, 0%).



Fig. 1. Distribution of postoperative hemorrhoidal symptoms related to the postoperative hemorrhoid classification after the first DG-HAL treatment. There is a discrepancy between postoperative grading and complaints despite the obtained decrease in hemorrhoidal grading.

ment after the second procedure. This difference was significant (OR = 8.17,95% CI 1.94-34.4). Five patients (38%) in the DG-HAL group remained without improvement compared to 5 (13%) in the RBL group. Two patients (15%) in the DG-HAL group had a deterioration of symptoms and/or gradation vs. none in the RBL group (tables 2, 3).

In total, after 18.4 months of follow-up, 170 patients (69%) who underwent one or two DG-HAL procedures had a good response to the treatment with a reduction of grading and complaints. This leads to an evident decrease in the success rate compared to 85% after 9 months of follow-up. Besides this decline of the initial success rate, we noticed a discrepancy between patients' complaints and hemorrhoidal gradation, making a reliable and objective estimation of the severity of the disease difficult. After contacting the patients by telephone using the standardized questionnaire and repeating the proctologic examination, most of them still had hemorrhoidal complaints, despite the obtained reduction in gradation (fig. 1). Furthermore, all patients who required a second procedure scored higher on all symptoms in accordance with hemorrhoidal disease compared to patients who were treated just once (fig. 2, 3). Also, more patients (22/53, 42%) with grade 3 hemorrhoids underwent a second treatment compared to the initial treatment group (96/244, 39%) A multivariate logistic regression analysis was performed on all known symptoms associated with hemorrhoidal disease and the recorded Goligher classification for grading the hemorrhoids. Prolapse (OR = 2.38,

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Fig. 2. Presenting symptoms of recurrent hemorrhoids in patients treated with redo-DG-HAL or RBL. There is no difference in symptoms, in case of recurrent disease, in the DG-HAL group compared to the RBL group.

95% CI 1.10–5.15) was an independent risk factor for persistent symptoms and the need for a second procedure (table 4). As expected, patients with grade 3 and 4 hemorrhoids had a higher risk of developing recurrent disease and needing a second operation, although this did not reach statistical significance (OR = 4.94, 95% CI 0.67– 36.42).

Discussion

Various prospective and retrospective studies have shown that DG-HAL is a safe and easy method for treating hemorrhoids. With early success rates of up to 97% [12] and reportedly low complication rates, it seems to be an ideal treatment. Initially, we reported equally good results with a success rate of 85% after an average follow-up of 9 months [10]. Nevertheless, very little is known about its long-term effects and, until now, just 4 studies have shown their results after long-term (>1 year) follow-up [2, 5, 8, 13]. Although they report an estimated success rate of 84-92.5%, which is significantly higher than our results (69%), a decline in the final success rate and an increase in recurrences is noticed. This observation has also been reported by Wilkerson et al. [12], who observed a drop in the patients' asymptomatic rate from 74 to 40% after 30 months of follow-up.

We found the same discrepancy between patients' complaints and hemorrhoidal gradation in our population. This became apparent mainly after the telephone questionnaire on which most reported unremitting hem-



Fig. 3. Hemorrhoidal symptoms in patients treated with DG-HAL. A comparison between one or more treatments is made. A higher incidence in bleeding and mucosal prolapse is noticeable in the recurrence group.

Table 4. Multivariate logistic regression analysis on all symptomsassociated with hemorrhoidal disease

Patient characteristics and	OR	95% CI 1	95% CI for OR	
hemorrhoidal complaints		lower	upper	
Age	1.01	0.98	1.04	
Bleeding	0.96	0.40	2.32	
Prolapse	2.38	1.10	5.15	
Mucus/fecal discharge	1.26	0.59	2.67	
Pruritus	0.83	0.44	1.56	
Pain	0.92	0.48	1.80	

orrhoidal complaints despite the obtained reduction in gradation (fig. 1). This phenomenon was also found by Scheyer et al. [2], in whose study 46% of patients reported recurrent hemorrhoidal complaints which could not be validated after proctologic examination. Due to this poor correlation, we decided to concentrate on the presenting symptoms and no longer on gradation for further treatment. Although hemorrhoidal symptoms can be related to other anal diseases (bleeding, for example, can be due to anal fissure, rectal tears or solitary rectal ulcers), this was just a rare finding during follow-up examination. Therefore, this does not seem to play an important role or affect the outcome. One quite remarkable finding was the early worsening of symptoms. Although DG-HAL would never create prolapse or persistent hemorrhage, this is probably due to excessive swelling of the mucosal tissue or an underestimation of the preoperative gradation.

We found prolapse (grade 3 and higher) to be an independent risk factor for recurrent disease and the possible need for a second procedure. Although successes have been reported in treating grade 3 and 4 hemorrhoids using DG-HAL [5, 8, 14], most studies only dealt with grade 2 and 3 hemorrhoids. Dal Monte et al. [8] included a running suture (anopexy) in treating grade 3 and 4 hemorrhoids and found a reduction in prolapsed hemorrhoids compared to treatment with ligation alone. It does seem likely that persistent prolapse could be improved with some form of anopexy. Although this difference was not statistically significant, they do suggest that this modification is beneficial for grade 3 and 4 hemorrhoids. Similarly, Faucheron et al. [5] also found a higher recurrence rate in grade 3 and 4 hemorrhoids. Theodoropoulos et al. [15] conducted a multicenter prospective study on treating advanced hemorrhoids using DG-HAL with the selective addition of suture hemorrhoidopexy or mucopexy by recto-anal repair. They obtained a patient satisfaction rate of 95% after 15 months of follow-up in this difficult, often therapy-resistant group. Due to these results, we opt for a two-stage procedure. Patients undergo a DG-HAL first, in order to control bleeding and reduce hemorrhoidal tissue, followed by a resection procedure or RBL.

Different studies have shown that patients with recurrent disease and/or symptoms are suitable candidates for a second DG-HAL [2, 5, 9]. We initially performed 16 re-DG-HAL procedures. However, after finding high grading and prolapse to be independent risk factors, we eventually changed to a resection procedure, this being our treatment of choice for recurrent disease in these patients. Due to the known high morbidity and complication rates, no open (Milligan-Morgan) hemorrhoidectomies were performed. Because of personal preference and experience, we choose RBL for the treatment of patients with recurrent disease. This technique has already proven to be highly successful after short- and long-term follow-up. A recent publication by Forlini et al. [16] reported very good results after 1-year follow-up for grade 2 and 3 hemorrhoids, with success rates of 90 and 75%, respectively. After long-term follow-up, these result were sustained as 69% of patients remained asymptomatic. This result is comparable to our medium-term results after the DG-HAL. After stopping DG-HAL procedures for recurrent disease, we performed 40 RBLs as a second procedure. Following this, we saw a significant difference in improvement of symptoms between the 2 groups treated either by re-DG-HAL or RBL (OR 8.17, 95% CI 1.94–34.4). This confirms our assumption that recurrent hemorrhoids, especially when prolapse is present, seem unfit for a second DG-HAL procedure. Because of the known risk of severe postoperative pain when placing RBLs near or below the dentate line, this procedure is done as an inpatient treatment in our clinic under epidural anaesthesia. This leads to higher patient satisfaction, fewer outpatient controls and avoids the restrictions of ligating lower hemorrhoids in the somatically innervated tissue. Ligations placed near the dentate line lead to efficient treatment of all afferent arteries, reducing the known risk of recurrence. Furthermore, more and multiple ligations can be performed compared to the outpatient situation, reducing the number of treatments and increasing patient comfort.

In conclusion, our results show that the DG-HAL procedure seems effective for treatment of low-grade (1 or 2) hemorrhoids. After long-term follow-up, patient satisfaction and success rate decrease, mainly due to persistent prolapse. Although DG-HAL has proven its effectiveness, compared to more invasive treatments [17], it should be reserved for grade 1 and 2 hemorrhoids that are unresponsive to conventional conservative treatments. When treating grade 3 or 4 hemorrhoids using DG-HAL, patients should be adequately informed about the risk of recurrent or residual disease and the potential need for a second procedure. Although a second DG-HAL procedure can be performed when residual disease or symptoms come to light, a resection procedure aimed at treating the prolapse should be the treatment of choice. We found RBL, performed in a clinical setting under epidural anesthesia, to be an effective treatment modality for these patients. Nevertheless, more studies are needed to further support these results.

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