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Original Article

Comparison of Doppler-guided haemorrhoidal artery ligation without mucopexy and rubber band ligation for haemorrhoids

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ABSTRACT

Background and study aims: Recurrences after Doppler-guided haemorrhoidal artery ligation (DG-HAL) tend to occur in patients with concurrent mucosal prolapse. We retrospectively compared the results of DG-HAL and rubber band ligation (RBL) for the treatment of haemorrhoidal disease.
Patients and methods: From 2005 to 2009, all patients who underwent either a DG-HAL procedure or RBL were selected. Follow-up was done by telephone using a standardised questionnaire survey to assess patient satisfaction and complaints. When recurrent disease was suspected, patients revisited the clinic for further examination and treatment.
Results: A total of 239 DG-HAL patients and 47 RBL patients were analysed. Sixty-seven percent in the DG-HAL group and 79% in the RBL group had an improvement in symptoms after one treatment ($p = 0.22$). Forty-six DG-HAL patients (19%) needed a second procedure versus three patients (6%) in the RBL group ($p < 0.05$). Cox regression analysis showed a significant difference in disease recurrence in favour of RBL (hazard ratio (HR) 3.71, 95% confidence interval (CI) 1.13–12.2). Patients in the DG-HAL group with recurrent haemorrhoids had a higher incidence of mucosal prolapse.
Conclusion: DG-HAL seems very effective in treating lower-grade haemorrhoids. In more advanced disease, recurrence occurs due to persisting mucosal prolapse. RBL seems much more effective in reducing the prolapse and the chance of recurrence.

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Introduction

With an estimated incidence of 4%, haemorrhoidal disease is a common problem in the Western world [1]. Because the aetiology is uncertain, the traditional treatment modalities focus mainly on symptoms, by either topical application of an anti-haemorrhoidal ointment to treat itching or pain or surgical therapy with excision of haemorrhoidal tissue. Disease recurrence is the main problem after conservative treatment, as is severe postoperative pain after surgical therapy. Even with less invasive techniques, such as stapled haemorrhoidopexy, postoperative pain and the potential risk for severe complications (bleeding, bowel obstruction or fistulas) still occur with some regularity. With Doppler-guided haemorrhoidal artery ligation (DG-HAL), it seems possible to selectively ligate the vessels in the haemorrhoidal plexus. This procedure can be performed in day care under epidural anaesthesia and has a suc-cess rate as high as 85.7% after short- or medium-term follow-up [2,3]. However, we observed in our DG-HAL population a tendency for persistent symptoms, and the need for a second procedure, in patients with concurrent mucosal prolapse [4]. This suggests that a resection or ligation procedure, such as rubber band ligation (RBL), would be more effective. RBL has already proven to be very effective, with long-term success rates of 70.5% and with cumulative success rates as high as 80.2% [5]. In this retrospective cohort study, we compared the results of DG-HAL and RBL for the treatment of haemorrhoidal disease, with respect to recurrent disease and redo procedures, and searched for prognostic parameters that could reduce the risk of recurrences.

Patients and methods

From 2005 to 2009, all patients who underwent a DG-HAL procedure or RBL were selected. The Goligher classification was used to describe the degree of haemorrhoidal disease. All patients underwent a complete medical history, with emphasis on haemorrhoidal symptoms and previous treatments, and a full proctologic examination. Prior to proctoscopy, a digital rectal examination

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was performed. Proctoscopy was conducted on a proctoscopy table, in a knee–elbow position. A lubricated, disposable, rigid and slotted rectoscope with a light source and a removable obturator was used. The anus and rectal cavity were inspected by obtaining a 360° view. Patients with grade 4 haemorrhoids were excluded from the analysis because of the anticipated high risk of recurrence and the low incidence in which it occurs. Grade 1 patients were only treated after conservative treatment with a fibre supplement and/or a topical haemorrhoidal ointment was unsuccessful. Patients from the age of 45 years on underwent a total colonoscopy procedure to exclude colorectal pathology as the bleeding source. The choice of either DG-HAL or RBL was decided by the surgeon after proctologic examination.

The procedure for DG-HAL has been described in previous publications by our group [3,4]. In short, DG-HAL is performed in day care under epidural anaesthesia in the lithotomy position. A phosphate enema is administered to all patients 3 h prior to surgery. After insertion of the proctoscope, which is connected to the Doppler device (DG-HAL system from AMI®), all arterial signals are detected and ligated with a figure-of-eight stitch (AMI HAL suture, 2// 0 vicryl, tapered needle, 5/8 circumference, reinforced needle-thread connection) and tied using a 20-cm knot-pusher. The absence of an arterial signal is verified using the Doppler transducer. Three full circles with the proctoscope are performed in the rectal canal. Extra ligators are placed, at the surgeon's discretion, when extra haemorrhoidal tissue is evidently visible.

In our hospital, RBL is performed under epidural anaesthesia and in the lithotomy position. Consistent with the DG-HAL procedure, all patients received a phosphate enema prior to surgery. A suction-assisted haemorrhoid ligator (Kilroid®, Astra Tech Healthcare, Benelux B.V.) was used. The distance from the dentate line was no restriction because of the postoperative epidural analgesia with continuous infusion (bupivacaine 0.125% with 1 cc morphine, first 2–3 days infused at a rate of 6–10 ml h^{-1}). After discontinuing the epidural, the patient started with a high dose of acetaminophen (1000 mg every 6 h) and an anti-inflammatory drug (Naproxen® 500 mg) twice daily.

All patients started with a bulk fibre supplement (Movicolon®, Norgin B.V., Amsterdam, The Netherlands) and were evaluated 6 weeks postoperatively with a proctologic examination. Grade, complaints and possible recurrence were assessed and recorded. Further follow-up was done by telephone using a standardised questionnaire survey to assess the final outcome, with regard to patient satisfaction and complaints. When patients were dissatisfied and/or recurrent disease was suspected, patients revisited the clinic for further proctologic examination and treatment. When a second procedure was necessary after a DG-HAL, this was done by redo DG-HAL or RBL. The decision to perform each treatment was made either at the surgeons' discretion or at the seriousness of symptoms or complaints. Patient who initially underwent a RBL were treated by redo RBL. Proctologic examination was repeated 6 weeks after each redo procedure and with outpatient control at regular intervals, when necessary. Because postoperative anorectal manometry is not standard in our clinic to objectively assess incontinence, this was done during outpatient follow-up and interview.

Statistical analysis

Analysis was performed with the Statistical Package for Social Sciences (SPSS) 17.0 package (SPSS Inc., Chicago IL, USA) for Windows and Excel (Microsoft, Redmond, WA, USA). Comparison of pre-and postoperative variables was performed using the Wilcoxon rank sum test on matched pairs.

Differences between the two groups were determined by the Pearson chi-square test.

Results were described as hazard ratio (HR) and 95% confidence intervals (CIs). Univariate and multivariate Cox proportional-hazards regression analysis was performed on all known symptoms associated with haemorrhoidal disease. Multivariate analysis was performed with both enter and backward selection. Follow-up data were analysed using Kaplan–Meier survival curves and differences between the curves were analysed with the log-rank test. Values of p less than 0.05 were considered statistically significant.

Results

A total of 239 consecutive DG-HAL patients were analysed versus 47 RBL patients. The groups were comparable with respect to sex, haemorrhoidal grade (Table 1) and complaints (Fig. 1).

The mean age was 49 years (range 26–81 years) for the DG-HAL group and 57 years (range 22–85 years) for the RBL group. The median time of follow-up was 24.8 months (range 1.4–37.3 months) for DG-HAL and 19.9 months (range 3.4–29 months) for the RBL group. The median number of ligations in the DG-HAL group was 6 (range 3–11). The median number of bandings in the RBL group was 4 (range 1–7).

After one treatment, 67% of the DG-HAL patients had an improvement in grading or symptoms, compared with 79% in the RBL group (Wilcoxon rank sum test $p = 0.22$) (Table 1). During follow-up, 46 patients (19%) in the DG-HAL group needed a second procedure compared with three patients (6%) in the RBL group because of recurrence or persistence. In univariate analysis, there was a significant difference in disease recurrence in favour of RBL (HR 5.95, 95% CI 1.68–21.08) (Table 2). With multivariate Cox regres-

Table 1
Baseline characteristics and outcome after the first treatment.

	DG-HAL[a]	RBL[b]	Sign[c]
Number of patients	239	47	
Sex			NS
Men	149 (62%)	24 (51%)	
Women	90 (38%)	23 (49%)	
Grade			NS
1	28 (11.7%)	7 (14.9%)	
2	116 (48.5%)	19 (40.4%)	
3	95 (39.7%)	21 (44.7%)	
Successful outcome[d]	167 (67%)	37 (79%)	$p = 0.22$

[a] Doppler-guided haemorrhoidal artery ligation.
[b] Rubber band ligation.
[c] Calculated with the Pearson chi-square test (NS = not significant, $p > 0.05$).
[d] Outcome was based on a comparison between pre- and postoperative grading without any further treatment being necessary.
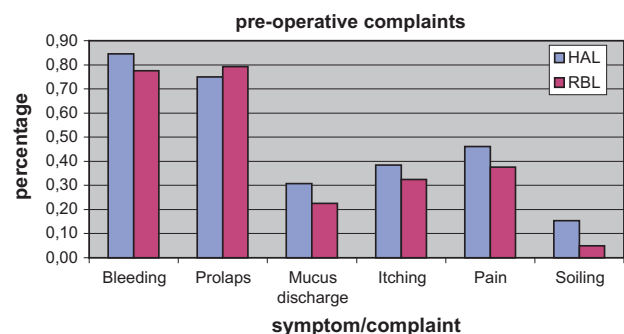

Fig. 1. Presenting symptoms of haemorrhoids in patients treated with DG-HAL or rubber band ligation (RBL). Symptoms are comparable in both groups with no statistical difference.

Table 2

Results of univariate Cox proportional-hazards regression analysis of haemorrhoidal symptoms for the prediction of treatment failure between DG-HAL and RBL[a].

Variables	Hazard ratio	95% confidence interval	
		Lower	Upper
Type of procedure[a]	5.95	1.68	21.08
Sex	1.58	0.88	2.78
Age	1.01	0.99	1.04
Bleeding	1.40	0.66	2.97
Prolapse	1.67	0.86	3.25
Itching	0.68	0.40	1.17
Soiling	1.02	0.40	2.45
Pain	0.86	0.51	1.48
Mucus discharge	0.94	0.51	1.48

[a] Doppler-guided haemorrhoidal artery ligation (DG-HAL) compared with rubber band ligation (RBL).

Table 3

Results of multivariate Cox proportional-hazards regression analysis of haemorrhoidal symptoms for the prediction of treatment failure between DG-HAL and RBL[a].

Variables	Hazard ratio	95% confidence interval	
		Lower	Upper
Type of procedure[a]	3.71	1.13	12.2
Sex	1.51	0.84	2.73
Age	1.01	0.997	1.04
Bleeding	0.92	0.43	1.99
Prolapse	1.78	0.89	3.54
Itching	0.92	0.53	1.58
Soiling	0.77	0.30	2.03
Pain	0.99	0.56	1.77
Mucus discharge	1.04	0.55	1.99

[a] Doppler-guided haemorrhoidal artery ligation (DG-HAL) compared with rubber band ligation (RBL).

sion analysis, this significant difference persisted (HR 3.71, 95% CI 1.13–12.2) (Table 3). Furthermore, patients in the DG-HAL group with recurrent or persistent haemorrhoids had a significant higher incidence of mucosal prolapse (HR 2.38 95% CI 1.10–5.15) (Fig. 3). For further verification, a Cox regression analysis was performed with backward selection. The type of procedure remained a significant factor for disease recurrence (HR 3.43, 95% CI 1.08–11.0). Although not statistically significant, prolapse was included in the final model (HR 1.81, 95% CI 0.94–3.51) (Table 4). Kaplan–Meier curves for recurrent haemorrhoidal disease and the need for a second procedure, comparing DG-HAL with RBL, confirmed the significant difference in the need for a second intervention in favour of RBL (HR 0.25, 95% CI 0.07–0.83, p = 0.02) (Fig. 2).

Complications were only minor in both groups and comparable with regard to number and statistical difference. In the RBL group, one patient (2%) developed urinary retention after removal of the Foley urinary catheter, one patient (2%) developed a urinary tract infection, which was treated with antibiotics without prolongation of hospital stay and one patient (2%) with persistent pain was re-

Table 4

Results of multivariate Cox regression analysis with backward selection for the prediction of treatment failure between DG-HAL[a] and RBL[b].

Variables	Hazard ratio	95% confidence interval	
		Lower	Upper
Type of procedure[c]	3.44	1.08	11.0
Prolapse	1.81	0.94	3.5

[a] Doppler-guided haemorrhoidal artery ligation.
[b] Rubber band ligation.
[c] Doppler-guided haemorrhoidal artery ligation (DG-HAL) compared with rubber band ligation (RBL).
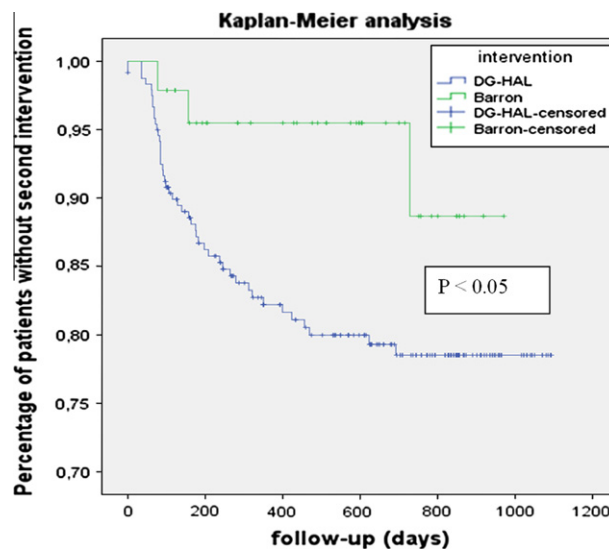

Fig. 2. Kaplan–Meier curves for recurrent haemorrhoidal disease and the need for a second procedure, comparing Doppler-guided haemorrhoidal ligation (DG-HAL) to rubber band ligation (RBL). There is a significant difference in the need for a second intervention in favour of RBL (p = 0.02).
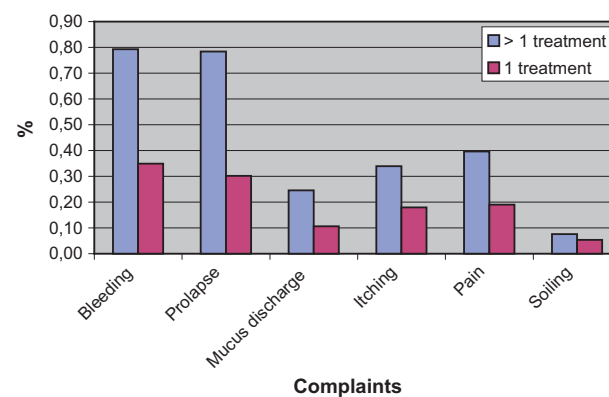

Fig. 3. Presenting symptoms of haemorrhoids after one or more treatments in patients treated with DG-HAL. Evidently, there is a significant higher prevalence of preoperative bleeding and prolapse in the recurrence group.

admitted for pain control with oral analgesics. In the DG-HAL group, three patients (1%) experienced rectal bleeding after the procedure, of whom two patients needed hospitalisation. Neither surgical intervention nor blood transfusions were necessary. Faecal incontinence was not observed as a postoperative complication in our study.

Discussion

This is the first study that compares DG-HAL with RBL. We found that DG-HAL has a much higher recurrence rate compared with RBL. Although the first results of DG-HAL were very promising, the long-term effects remain uncertain.[2–4,6,7] Whereas DG-HAL decreases arterial inflow, leading to regression of the vascular cushions, it does not lead to tissue retraction. This study has thus shown that mucosal prolapse in the DG-HAL group was an important factor for predicting disease recurrence and the need for a second procedure. This untreated factor after DG-HAL in haemorrhoidal disease could be one of the reasons for late recur-

rences. Various studies support this idea by also identifying a lower recurrence rate after more aggressive and invasive treatments [2]. Following this are the good results by Infantino et al., who obtained a high success rate of 87.5% after 15 months of follow-up by their approach of combining haemorrhoidal ligation with anopexy. The same accounts for the excellent results by Theodoropoulos et al., who describe a success rate of 96% in advanced (grades 3 and 4) haemorrhoids [8]. Their excellent results however are achieved by adding mucopexy or muco-cutaneous excision to the DG-HAL procedure. The before-mentioned results do affirm the limitations of DG-HAL in its current form and suggest that a form of mucopexy should be added to the current procedure of artery ligation.

RBL is a good alternative for treating haemorrhoids, both with and without concurrent mucosal prolapse [9,10]. It causes obliteration of haemorrhoidal tissue due to necrosis, scarring and formation of connective tissue, leading to mucosal fixity and seems to contribute to treating the concurrent prolapse. RBL has already been compared with new techniques, such as infrared coagulation, bipolar electro-coagulation and stapled haemorrhoidopexy, and also to more conventional therapies, such as injection sclerotherapy or open excisional (Milligan–Morgan) haemorrhoidectomy. Further, with the exception of open or stapled haemorrhoidectomy, RBL seems to be equal to or even more effective with regard to the number of treatments necessary, recurrent bleeding and overall efficacy [9–13]. Although it is often done as an outpatient procedure, the main drawbacks of RBL are its immediate adverse effects, such as severe post-banding pain and urination difficulties. These findings are still frequently reported in the literature [14,15]. We therefore opted for a clinical treatment with epidural anaesthesia for post-procedural pain alleviation. This allowed for multiple ligations being placed and additionally avoiding the restrictions of ligating lower haemorrhoids in somatically innervated tissue. To our knowledge and experience, this also leads to higher patient satisfaction and reduces the number of treatments necessary. This cumulative effect with the number of ligations placed has been reported before and leads to a success of 24% after one banding to 70.5% after more than four bandings [5]. In our series, we were able to place a median number of four bandings per session with an improvement rate of 79%. Although one could comment on the potential risk and complications accompanying epidural anaesthesia, fortunately we had no such events. In a Cochrane review, with the main objective being comparing epidural analgesia with systemic analgesia for postoperative pain after hip or knee replacement, no statistical significance was obtained as regards serious life-threatening complications, making it a safe alternative [16]. In our series, no rare complications, such as epidural haematoma or abscesses, were observed and the overall complication rate was very low in both groups. Albeit the number of bandings has been associated with the potential risk of stenosis, this was not observed in our study [8]. We applied a maximum of seven bandings in two patients (both grade 3) and neither stenosis nor other complication occurred.

There are, however, several drawbacks to this study that need to be addressed. First, this concerns a retrospective cohort study and no randomisation was performed. This has led to an unequal distribution of patients between the two treatment groups. The choice to each treatment was made at the surgeons' discretion and therefore a selection bias could be suspected. We have extensive experience with RBL in our hospital and with the introduction of DG-HAL we performed RBL to a lesser extent. However, the same criteria for intervention were applied and therefore no differences in haemorrhoidal grade of the treated patients occurred between the two groups (Table 1) (Fig. 1). Although we have no substantiated parameter to explain this difference, the degree of mucosal prolapse could have played a part in the decision making. This may unwittingly have led to an unequal distribution. The Goligher classification used in this study unfortunately does not discrimi-

nate between the presence and the absence of mucosal prolapse. Despite its limitations, we used this classification because of its international recognition and comparability. Second, we are aware of the somewhat controversial and non-customary choice for epidural anaesthesia during RBL. This decision has been made well before the start of this study and resulted in the protocol followed in this study. We realise that comparison with other studies, using the office-based/ambulatory procedure of RBL, is therefore difficult. However, the basis of this study was to compare the effect of both modalities and we believe the pathophysiological effect of the procedure was not affected by the use of epidural anaesthesia. One could say however that, with the ability to place more bands per procedure, we have achieved a higher success rate. One other finding worth mentioning during follow-up was the apparent discrepancy between patient's complaints and haemorrhoidal grading, which became obvious after the telephone interview. Most patients reported unremitting haemorrhoidal complaints, despite the obtained reduction in grade after redo proctologic examination. This phenomenon has been previously reported in the literature and is a potential problem for indicating the need for treatment [17]. Due to this poor correlation, we believe that concentrating on the symptoms present, instead of haemorrhoidal grade, for further treatment is preferred.

In conclusion, although DG-HAL has a very low morbidity and high patient satisfaction, it must be reserved for simple, low-grade, haemorrhoids that are unresponsive to conservative treatments. Its current role lies somewhere between the office-based procedures, such as injection sclerotherapy or infrared coagulation, and more invasive procedures, such as stapled or open haemorrhoidectomy. In our experience, RBL should be the treatment of choice when any suspicion of mucosal prolapse is present. Whether to do this in a clinical setting with epidural anaesthesia remains a personal preference. We believe that RBL performed in this setting is both an effective and patient-friendly manner of treating patients with grades 2 and 3 haemorrhoids with synchronous mucosal prolapse. A reduction in the number of treatments can be achieved and at very acceptable morbidity. To our knowledge, no other study or randomised controlled trail (RCT) is available to make a proper comparison between DG-HAL and RBL. Further studies, preferably RCTs, are needed to support our results.

Conflicts of interest

The authors declared that there was no conflict of interest.

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