Clinical outcome after Doppler-guided hemorrhoidal artery ligation and rubber-band ligation for the treatment of primary symptomatic hemorrhoids

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Objective
The aim of this study was to compare the efficacy and clinical outcome after rubber-band ligation (RBL) and Doppler-guided hemorrhoidal artery ligation (DG-HAL) for primary symptomatic (grades II and III) hemorrhoids.

Patients and methods
Fifty patients with symptomatic grade II and grade III uncomplicated internal hemorrhoids were randomly assigned to be treated with either RBL or DG-HAL. Patients were assessed clinically for postoperative complications and recurrence through 6 months after surgery.

Results
Preoperative characteristics were similar between the two groups. The main preoperative complaint was protrusion of piles followed by bleeding. The overall rate of complications was 16% after RBL (9.1% for grade II and 21.4% for grade III) and 4% after DG-HAL (6.7% for grade II and 0% for grade III) ($P = 0.07$). The overall rate of recurrence was 12% after RBL (9.1% for grade II and 14.3% for grade III) and 4% after DG-HAL (0% for grade II and 10% for grade III) ($P = 0.2$). All complications were conservatively controlled with no need for reintervention. At the end of 6 months of follow-up, the overall freedom from symptoms was 88% after RBL (90.9% for grade II and 85.7% for grade III) and 96% after DG-HAL (100% for grade II and 90% for grade III). With regard to grade of hemorrhoids (II or III), there were statistically insignificant differences between the two procedures in terms of recurrence and complications.

Conclusion
DG-HAL is safer and effective compared with RBL in the treatment of grade III hemorrhoids; however, in grade II patients, both procedures had nearly equal rate of complications despite no recurrence with DG-HAL.

Keywords:
Doppler, hemorrhoids, ligation, rubber

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Introduction

Hemorrhoids are normal collections of submucosal, fibrovascular, arteriovenous sinusoids that are a part of the normal anorectum [1]. Approximately 39% had visibly enlarged hemorrhoidal complexes, but only about half of the participants with anatomical abnormalities were symptomatic [2]. Potential causes of symptoms range from weakening of supportive tissues with prolapse of the cushions to abnormal dilatation of arteriovenous anastomoses and hemorrhoidal venous complexes [3].

Numerous modalities and techniques have been developed to treat symptomatic hemorrhoids, ranging from simple dietary measures and bowel habit regulation, through a number of nonoperative procedures, to different techniques of excision of diseased anal cushions [4].

Rubber-band ligation (RBL) is considered the most widely used nonoperative procedure, and it offers the possibility to resolve hemorrhoidal disease without the need for hospitalization or anesthesia, and with lower incidence of complications [5,6].

Doppler-guided hemorrhoidal artery ligation (DG-HAL) is a nonexcisional surgical technique for the treatment of hemorrhoidal disease, consisting of the ligation of the distal branches of the superior rectal artery, resulting in a reduction of blood flow and decongestion of hemorrhoidal plexus resulting in fibrosis. It has been considered as the treatment of choice for second-degree and third-degree hemorrhoids, with minimal postoperative pain and quick recovery [7].

Therefore, the aim of the present study was to compare the safety and clinical efficacy of DG-HAL and RBL in

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terms of intensity of postoperative pain, postoperative complications, and recurrence rate through 6 months after treatment of grade II and III hemorrhoids.

Patients and methods

Selection of patients

Fifty patients with symptomatic hemorrhoids of grade II (prolapsed with spontaneous reduction) and grade III (prolapsed during defecation but are manually reducible) were included in the study, conducted between January 2012 and December 2014, at the Department of General Surgery, Minia University Hospital, and in Alseef Hospital in Kuwait. The patients were selected for the study after exclusion of patients with acute thrombosed hemorrhoids, patients with grade IV hemorrhoids, patients with other concomitant anal diseases, patients with inflammatory bowel disease or hematological disorders, patients on anticoagulants, and patients with a previous history of anorectal surgery. Half of the patients who fulfilled the selection criteria were treated with RBL and the remaining half were treated with DG-HAL.

All patients were subjected to local examination, proctoscopy, sigmoidoscopy, routine baseline laboratory investigations, and ECG. In the RBL and DG-HAL groups, the patients received a short rectal washout 1–2 h before treatment to avoid bowel movements during the first 24 h. Before each procedure, informed consent was obtained from all patients.

Technique of rubber-band ligation

The principle of RBL is to produce submucosal fibrosis. The mucosa 1–2 cm above the dentate line was grasped and pulled into a rubber band applier (the Barron gun). Two black rubber bands were placed for each pile. Only one or two quadrants are banded per visit. No anesthesia was required.

Technique of Doppler-guided ligation

Spinal anesthesia was induced in all patients. The equipment includes a lighted anal retractor with Doppler, needles, and a needle driver. With the patient placed in the lithotomy position, the transanal hemorrhoidal dearterialization device was placed into the anal canal. The Doppler probe was used to identify pulsatile arterial segments. Arteries were suture ligated through the lateral window using absorbable sutures and a long needle-holder. The procedure was duplicated circumferentially until all signals were obliterated. Six to seven separate bites were frequently required. No pack or gauze was used. Stool softeners were used to ensure a more comfortable first bowel movement. Pain was alleviated with non-narcotic analgesics.

Postoperative evaluation and follow-up

The patients were examined with anoscope and evaluated for clinical outcome at 1 week, 1 month, 3 months, and 6 months after each procedure at outpatient clinic. The evaluated postoperative complications include the following: (a) complications including postoperative bleeding within the first 15 days, severe anal pain, urinary retention, poor wound healing (anal fissure or ulceration), abscess or fistula, incontinence or anal stenosis, and (b) recurrence at the end of 6 months of follow-up, which was defined by evidence of intermittent bleeding or prolapsing hemorrhoids.

Statistical analysis

Data were analyzed using SPSS statistical software package for Windows, version 16.0 (SPSS Inc., Chicago, Illinois, USA). Quantitative data were expressed as mean ± SD and were compared using Student's *t*-test, whereas qualitative data were expressed as number and percentage and were compared using the χ^2-test. Cumulative probability of symptom-free patients during the follow-up period was determined using the Kaplan–Meier analysis, and this probability was compared between the two procedures using the log-rank (Mantel–Cox) test. A *P*-value of less than 0.05 was considered to indicate significance.

Results

Preoperative characteristics were similar between the two groups (Table 1). Male sex was predominant in both groups, with a percentage of 60% in the RBL group and 72% in the DG-HAL group. The average

Table 1 Preoperative characteristics of the studied groups

Variables	RBL (*n* = 25)	DG-HAL (*n* = 25)	*P*-value
Age (years)	42.3 ± 13.3	45.4 ± 14.2	0.42
Sex (M/F)	15 (60%)/10 (40%)	18 (72%)/7 (28%)	0.37
Grade (II/III)	11 (44%)/14 (56%)	15 (60%)/10 (40%)	0.25
Duration of complaint (months)	14.2 ± 7.4	13.8 ± 8.5	0.84
Main complaint [*n* (%)]			
Protrusion of piles	25 (100)	25 (100)	1
Bleeding	15 (60)	13 (52)	0.56
Pain	7 (28)	8 (32)	0.75
Constipation	2 (8)	1 (4)	0.55
Itching	1 (4)	3 (12)	0.29

DHAL, Doppler-guided hemorrhoidal artery ligation; RBL, rubber-band ligation.

age was 42.3 ± 13.3 years in the RBL group and 45.4 ± 14.2 years in the DG-HAL group. In the RBL group, 11 (44%) patients had grade II hemorrhoids versus 15 (60%) patients in the DG-HAL group. Grade III was diagnosed in 14 (56%) patients of the RBL group and in 10 (40%) patients of the DG-HAL group. The main preoperative complaint was protrusion of piles in all patients, in addition to bleeding (60% of RBL group patients and 52% of DG-HAL group patients), pain (28% of RBL group patients and 32% of DG-HAL group patients), and constipation (8% of RBL group patients and 4% of DG-HAL group patients).

The overall rate of complications was 16% after RBL and 4% after DG-HAL, whereas the overall rate of recurrence was 12% after RBL and 4% after DG-HAL. There were no statistically significant differences between patients with grade II hemorrhoids regardless of whether they underwent RBL (n = 11) or DG-HAL (n = 15) in terms of postoperative complications and recurrence (Table 2). The overall rate of complications among patients with grade II hemorrhoids was 9.1% in patients who underwent RBL and 6.7% in patients who underwent DG-HAL. In patients with grade II disease who underwent RBL, the complications included severe pain in 9.1%, whereas it included minor bleeding in 6.7% of patients who underwent DG-HAL. The recurrence rate was 9.1% in patients who underwent RBL and 0% in patients underwent DG-HAL.

There were no statistically significant differences between patients with grade III hemorrhoids regardless of whether they underwent RBL (n = 14) or DG-HAL (n = 10) in terms of postoperative complications and recurrence (Table 3). The overall rate of complications among patients with grade III disease was 21.4% in patients who underwent RBL and no complication was seen in patients who underwent DG-HAL. In patients with grade III hemorrhoids who underwent RBL, the complications included bleeding in 7.1% and severe pain in 14.3%. The recurrence rate was 14.3% in patients who underwent RBL and 10% in patients who underwent DG-HAL. All complications after both procedures were mild, treated conservatively, and did not required further intervention.

The four patients with recurrent symptoms at the end 6 months of follow-up (Table 4) had an average age of 50 ± 6.8 years (range = 33–65 years) and most of them were male (three vs. one female). In addition to protrusion of piles, three of those patients had preoperative symptoms of bleeding and one patient had constipation as main complaint at admission. The average duration of complaint was 12.7 ± 2.5 months (range = 10–16 months). Most of the patients with recurrent symptoms had preoperative grade III piles (three of four; 75%) and most of them underwent RBL (three of four; 75%).

The overall percentage of symptom-free patients (Fig. 1) was 88% after RBL and 96% after DG-HAL at the end of 6 months of follow-up, with insignificant difference between the two procedures [Log-rank (Mantel–Cox) test, P = 0.62]. The average symptom-free time was 11.5 months for all patients, 5.1 months for RBL patients, and 5.8 months for DG-HAL patients.

After exclusion of patients with recurrence in the present study, the overall success rate was 88% after RBL and 96% after DG-HAL. RBL procedure had

Table 2 Postoperative complications and recurrence at 6 months in the studied groups with grade II hemorrhoids

Variables	Grade II		*P*-value
	RBL (n = 11) [n (%)]	DG-HAL (n = 15) [n (%)]	
Any complication	1 (9.1)	1 (6.7)	0.73
Minor bleeding	0 (0)	1 (6.7)	0.20
Severe pain	1 (9.1)	0 (0)	0.23
Recurrence	1 (9.1)	0 (0)	0.23

DG-HAL, Doppler-guided hemorrhoidal artery ligation; RBL, rubber-band ligation.

Table 3 Postoperative complications and recurrence at 6 months in the studied groups with grade III hemorrhoids

Variables	Grade III		*P*-value
	RBL (n = 14) [n (%)]	DG-HAL (n = 10) [n (%)]	
Any complication	3 (21.4)	0 (0)	0.11
Minor bleeding	1 (7.1)	0 (0)	0.39
Severe pain	2 (14.3)	0 (0)	0.21
Recurrence	2 (14.3)	1 (10)	0.75

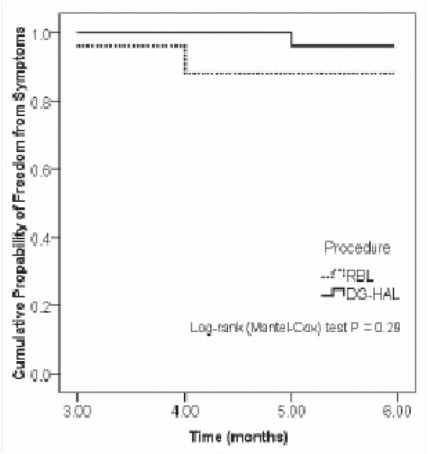
DG-HAL, Doppler-guided hemorrhoidal artery ligation; RBL, rubber-band ligation.

Table 4 Preoperative characteristics of four patients with postoperative recurrence

Number of patients	Procedure	Age (years)	Sex	Main complaint[a]	Duration of complaint (months)	Grade of piles
1	RBL	65	Male	Constipation	10	II
2	RBL	64	Female	Bleeding	13	III
3	RBL	33	Male	Bleeding	16	III
4	DG-HAL	38	Male	Bleeding	12	III

DG-HAL, Doppler-guided hemorrhoidal artery ligation; RBL, rubber-band ligation, [a]All patients had preoperative protrusion of pile.

Figure 1



Cumulative probability of symptom-free patients (no recurrence), as determined using Kaplan–Meier survival analysis, 6 months after rubber-band ligation (RBL) and Doppler-guided hemorrhoidal artery ligation (DG-HAL).

a success rate of 90.9% for grade II and 85.7% for grade III, whereas after DG-HAL the success rate was 100% for grade II and 90% for grade III.

Discussion

Hemorrhoids are a very common anorectal disorder defined as the symptomatic enlargement and abnormally downward displacement of anal cushions associated with degenerative change of supportive tissue within the anal cushions, vascular hyperplasia, and hyperperfusion of hemorrhoidal plexus [8]. When symptoms of hemorrhoidal disease do not respond to medical therapy, procedural intervention is recommended. The conventional surgical procedure includes excision of the external and internal components of the hemorrhoidal tissue, using various techniques, with or without closure of the anorectal mucosa or the anoderm [9].

RBL is the most widely used nonsurgical procedure, and it is reported to be a safe and effective treatment for symptomatic internal hemorrhoids of grades I and II and selective patients with grade III hemorrhoids, with a lower incidence of complications when compared with conventional surgery [5,10,11], and it has been recommended as the first-line treatment for those patients in whom there is contraindication for surgery or anesthesia [12].

In the present study, the postoperative complications after RBL occurred in 16% and included minor bleeding in 4% (1/25) who had grade III disease and severe pain in 12% (3/25) who had grade II (one patient) and grade III (two patients) disease. Although RBL procedure is supposed to be painless, some authors reported severe pain necessitating systemic analgesics, which is believed to be from ischemia induced by the procedure or from application of the bands below the dentate line [13]. Our incidence of postbanding pain is within the recently documented incidences in the literature between 1 and 51% [10,13–15].

Early postoperative bleeding is a significant complication after RBL, which most probably occurred as a result of the fall of the hemorrhoidal nodule and local inflammation [4]. In the present study, minor early postoperative bleeding occurred in 4%, and it was mild and treated conservatively in all cases without further hospitalization or intervention. Forlini *et al.* [10] reported that 2.4% of the patients who underwent RBL experienced rectal bleeding after a week. In the study by El Nakeeb *et al.* [4], complications after RBL were pain, rectal bleeding, and vasovagal symptoms (4.13, 4.13, and 1.33% of patients, respectively).

In the present study, RBL results in an overall freedom from hemorrhoidal symptoms in 88% of patients, which was 90.9% for grade II and 85.7% for grade III hemorrhoids. These findings are confirmed by other findings published in the literature as regards the efficacy of RBL. Recently, Gagloo *et al.* [12] reported freedom from symptoms in 77% of grade II patients and 50% of grade III patients, and concluded that RBL is not as effective as hemorrhoidectomy in grade III.

Early results of RBL in the study by El Nakeeb *et al.* [4] showed overall freedom from symptoms in 86.66% of patients, which was 89.7% in grade II and 76.19% in grade III patients. In the study by Forlini *et al.* [10], no residual symptoms were reported at 1-year follow-up in 90% of the patients with grade II and 75% of patients with grade III hemorrhoids. Bernal *et al.* [16] also reported freedom from rectal symptoms (bleeding and hemorrhoidal prolapse) not requiring further intervention in 86.1% of patients, 90.2% of patients with grade II and 74% of patients with grade III hemorrhoids. Other recent prospective studies reported that an overall freedom from symptoms ranged from 84 to 97.5% after RBL, for all grades of hemorrhoids [5,13,14].

DG-HAL of the terminal branches of the superior hemorrhoidal artery was introduced by Morinaga *et al.* in 1995 [17]. In the literature, DG-HAL has been shown to be associated with potential benefits for symptomatic hemorrhoids (grades II and III) particularly with regard to the perioperative parameters

and 1-year recurrence rate [18–20]. However, some authors have shown that DG-HAL is an effective procedure for treating low-grade hemorrhoid; despite low complication rates with DG-HAL, recurrences are more frequent with this procedure in case of grade III and IV hemorrhoids [21–23].

In the present study, the postoperative complications after DG-HAL occurred in one patient (4%), who had grade II hemorrhoids and suffered from postoperative minor bleeding. This finding relies within the spectrum of postoperative bleeding after DG-HAL reported in other studies, which ranged from 0 to 18.8% [19,23]. Other complications with variable rates were reported after DG-HAL by other authors, including postoperative pain (range = 0–28.6%) [22,23], thrombosis (range = 1.5–6.7%) [24], and anal fissure (range = 1.1–3%) [21,25].

In the present study, after DG-HAL procedure the overall freedom from hemorrhoid symptoms was 96%, which was 100% for grade II and 90% for grade III hemorrhoids. Similarly, the recent study by Yamoul *et al.* [26] reported that after DG-HAL freedom from symptoms was 97% over 1 year (residual rectal bleeding in 3%). Moreover, those authors concluded that DG-HAL is not only effective for stage III and IV hemorrhoids for which the effect is spectacular but also for stage I and II symptoms, which can expand its indications. In a recent systemic review of 28 studies including 2904 patients, the freedom from symptoms ranged from 40 to 97% with a recurrence range between 3 and 60% [25].

Yilmaz *et al.* [7] reported that DG-HAL can be the choice of treatment for grade II and III hemorrhoids with minimal postoperative pain and quick recovery, with complete freedom from symptoms in 88% of patients after 2 years of surgery. Spyridakis *et al.* [25] concluded that DG-HAL seems to be a safe and effective treatment option for all grades of hemorrhoidal disease, and freedom from symptoms was 93.4% with recurrences in six patients (6.6%), two patients with initial grade III and four with grade IV hemorrhoids. The study by Walega *et al.* [27] showed that 92.4% of patients with grade II and 84% of patients with grade III had very good results (patient was free of the disease) or good results (significant symptom relief).

The results by Pol and colleagues showed freedom from symptoms in 67% of patients after DG-HAL, which seems very effective in treating lower-grade hemorrhoids. However, in more advanced disease, recurrence occurs due to persisting mucosal prolapse [22]. Szmulowicz *et al.* [23] stated that recurrences after DG-HAL are more frequent during the learning curve, with freedom from symptoms in 79% of patients (residual hemorrhoids were evident in 21% of patients).

Testa and Torino [28] reported success of DG-HAL in 90% of patients affected by II or III degree hemorrhoids, which suggests the safety, efficacy, and low invasity of DG-HAL in the treatment of II and III degree hemorrhoids, and highlight its use in treating patients with unhealthy conditions, which are a contraindication to the usual surgical treatments. Moreover, those authors suppose the use of HAL Doppler in low-degree hemorrhoids as a therapeutic and also prophylactic rule of advanced degree. Moreover, Conaghan and Farouk [29] reported that DG-HAL reduces the need for conventional hemorrhoid surgery where RBL has been unsuccessful, with freedom from symptoms in 77% of patients (recurrence was 23%); 52 patients with recurrent symptoms after RBL, subsequently underwent DG-HAL.

In the present study, comparison of DG-HAL and RBL in terms of postoperative complications and recurrence revealed statistically insignificant differences; this is in agreement with the results of Pol and colleagues, who retrospectively compared the results of DG-HAL and RBL for the treatment of hemorrhoidal disease, through analysis of 239 DG-HAL patients and 47 RBL patients. Those authors reported an incidence of 67% in the DG-HAL group and 79% in the RBL group as regards improvement in symptoms after one treatment, with statistically insignificant difference [22].

In conclusion, when compared with RBL procedure, DG-HAL results in nearly equal rate of complications in patients with grade II hemorrhoids, but with no recurrence of hemorrhoid symptoms. In grade III patients, DG-HAL results in lower rates of complications and recurrence compared with RBL. All comparisons between the two procedures had statistically insignificant differences. Further comparative, large-scale, and long-term studies are recommended.

Conclusion

DG-HAL is safer and effective compared with RBL in the treatment of grade III hemorrhoids. However, in grade II patients, both procedures had nearly equal rate of complications despite no recurrence with DG-HAL.

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Conflicts of interest

There are no conflicts of interest.

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