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Comparison of early and 1-year follow-up results of conventional hemorrhoidectomy and hemorrhoid artery ligation: a randomized study

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Introduction

The history of treating piles dates back to ancient times. In addition to the historical methods, there are well established operations (such as the Milligan-Morgan [1] Parks [2], and Ferguson [3] operations) developed in the past 75 years which are still considered to be the gold standards in treating hemorrhoidal disease. Meanwhile surgeons have continued to seek new solutions. This effort has resulted in outpatient treatments such as sclero-therapy [4], rubber band ligation [5], cryotherapy [6], and infrared photocoagulation [7]. This process was accelerated by the need for "minimally invasive" operations. Stapled hemorrhoid artery ligation (DG-HAL)

Abstract Background and aims: Doppler-guided hemorrhoid artery ligation is a new approach for treating hemorrhoids. Early and 1-year follow-up results of the procedure are presented and compared with those of closed scissors hemorrhoidectomy in a prospective randomized study. Patients and methods: Sixty consecutively recruited patients were randomized into two groups: group A (n=30) was treated with standardized closed scissors hemorrhoidectomy and group B (n=30) with Dopplerguided hemorrhoid artery ligation. The follow-up period was 11.7±4.6 months. Results: The average need for minor analgesics was 11.7±12.6 doses in group A and 2.9±7.7 in group B. Patients in group A spent 62.9 ± 29.0 hours in hospital postoperatively and those in group B

19.8±41.8 hours. Return to normal daily activities took 24.9±24.5 days in group A and 3.0±5.5 days in group B. Neither the disappearance (26 vs. 25 patients) nor the recurrence of preoperative symptoms (5 vs. 6 patients) differed significantly between the two groups. Conclusion: Both procedures were effective in treating hemorrhoids. The 1-year results of Doppler-guided hemorrhoid artery ligation do not differ from those of closed scissors hemorrhoidectomy. Doppler-guided hemorrhoid artery ligation seems to be ideal for 1-day surgery, and it fulfills the requirements of minimally invasive surgery.

Keywords Hemorrhoids · Ligation · Prospective studies · Ultrasonography, Doppler · Surgical procedures, minimally invasive

[9] are procedures which are in accordance with this concept. The essentials of the latter operation are the high, exact, and selective ligation of the arteries supplying blood to the piles. A specially developed anoscope can be used for this purpose which incorporates a sideviewing Doppler head. The submucosal arteries approaching the anal canal from above can be identified by the guidance of the arterial Doppler sound. They can be stitched and ligated through a window situated just above the Doppler head. The success of the stitch can be judged by the disappearance of the arterial Doppler sound. The arterial inflow to the pile suddenly drops after the ligation of the artery. While venous outflow is not compromised, the ratio of the inflow/outflow also drops. The piles collapse and both the bleeding and the pain

cease. The decreasing tension allows regeneration of the connective tissue within the pile which facilitates the shrinkage of the hemorrhoid and eventually leads to the definitive decrease in the prolapse. This present study compares the early and 1-year results of the traditional closed scissors hemorrhoidectomy with those of the DG-HAL operation.

Materials and methods

Patients

This prospective, longitudinal, randomized study examined 60 consecutive patients (27 men, 33 women; mean age 47.5 \pm 3.9 years). Patients were randomized based on the date of the first visit to our outpatient department to either group A, undergoing standardized closed scissors hemorrhoidectomy (9 men, 21 women; mean age 46.7 \pm 13.0 years), or group B, undergoing DG-HAL (18 men, 12 women; 47.4 \pm 15.0 years). The follow-up period was 11.8 \pm 6.0 months in group A and 11.5 \pm 3.1 months in group B. Patients were informed about the possible modalities of treating hemorrhoids and about possible complications, and each signed a standard informed consent form.

Clinical data were collected prospectively. Patients underwent careful history taking, clinical examination, rigid sigmoidoscopy, and anoscopy for the diagnosis and staging of the disease. If the hemorrhoidal cushion was found to be enlarged but without any protrusion into the anal canal, we staged the disease as stage I. If there was protrusion into the anal canal but no prolapse through the anal orifice, we staged it as stage II. When we saw prolapse which could be reduced, we classified the disease as stage III. At stage IV of the disease the prolapsed hemorrhoid could no longer be reduced. Other underlying pathologies were excluded by barium enema or colonoscopy where necessary.

The two groups were comparable in sex distribution, patient age, and length of follow-up. There was no statistically demonstrable difference between the two groups in the stages of the disease; group A consisted of 7 patients in stage II, 9 in stage III, and 14 in stage IV hemorrhoids, and group B 1 patient in stage I, 6 in stage II, 10 in stage III, and 13 in stage IV disease. Preoperative complaints were also similarly distributed; in group A there were 26 patients who complained of bleeding, 15 of pain, and 1 of mucus discharge, and in group B 23 who complained of bleeding, 11 of pain, 3 of prolapse, and 1 of discharge. (Some patients had more than one complaint.)

Methods

Conventional hemorrhoidectomy was performed under general anesthesia in all but three cases. During the operation we tied the arteries high in the three primary directions. After scissors hemorrhoidectomy the anoderm was reconstructed with running 3/0 absorbable sutures. We left a sponge soaked in lignocaine jelly in the anal canal after the procedure. We performed the first DG-HAL operations under general anesthesia. As we gathered the experience, we changed to local anesthesia. We used 100 mg pethidine, 50 mg promethazine, 0.25 mg atropine as intramuscular injection for premedication prior to the operation, and 1% procaine for local infiltration anesthesia can give satisfactory results, and therefore after the same premedication as described above we used 20 ml 2% lignocaine jelly rectally prior the operation.

The operation was performed in lithotomy position (similarly to the conventional hemorrhoidectomy). The Doppler anoscope was inserted to the rectum and the Doppler head was situated 1–2 cm above the dentate line. We looked for the arteries while rotating the device completely around the rectum. We put "figureeight" stitches above the Doppler head where we received arterial Doppler signs. We used 2/0 absorbable stitches with a strong 5/8 curved needle. When we completed the first round we withdrew the anoscope 0.5 cm and did a second round to check the accuracy of the procedure. If we received arterial sound, we put new stitches in but always took maximal care to ensure at least 1 cm distance from the dentate line. After finishing the second round we removed the Doppler anoscope and checked the position of the stitches by digital examination.

In group A the operation was carried out under general anesthesia in 27 patients, in 2 under local anesthesia, and in 1 under spinal anesthesia. In group B 10 patients underwent the operation under general anesthesia and 20 under local anesthesia. In the latter cases, 15 had infiltration local anesthesia and 5 surface anesthesia. In group B we used local anesthesia significantly more frequently (P<0.05).

In the postoperative period we used on-demand analgesics. The first injection of nonopioid analgesics was given intramuscularly (e.g., 75 mg diclofenac) if the patient required it. If this proved insufficient, we administered opioid (50–100 mg pethidine) intramuscularly. On the day after the operation and thereafter we used peroral pain killers (e.g., 50 mg tramadol three times daily, 75 mg diclofenac twice daily, or 250 mg niflunic acid three times daily). We discharged the patients when they felt fit enough to leave, provided that we did not recognize any negative reaction (e.g., fever, urinary retention, nausea) or complication (e.g., postoperative bleeding, perianal abscess). They were advised to use one of the pain killers above if needed.

In the postoperative period we recorded the type of anesthesia, length of postoperative inpatient care, negative reactions, complications, and the need for pain killers especially the need for opioids. We examined the patients in the 6th postoperative week and every 3 months thereafter. No patients were completely lost to follow-up, but three in group A and one in group B did not attend the examinations after 3 months. These patients were contacted by letter or by phone. At follow-up we performed rectal digital examination and asked the patients to strain to observe any prolapsing pile, but did not carry out rigid sigmoidoscopy unless the patient had complaints. On the first occasion we asked the patients if their preoperative symptoms had disappeared, for how long they had to stop their normal daily activity, and how much pain killer they took at home. The return to "normal daily activity" was defined as the point at which patients returned to their job or patients on pension needed no further help for taking care of themselves. On any further controls we asked specifically for any recurrent symptom and for any late complication (e.g., stricture, fistula, impaired defecation, incontinence).

Statistical analysis

Groups were compared by the χ^2 homogeneity test at 5% probability or by comparison of the 95% confidence interval (95% CI). Results showing normal distribution are given as mean with standard deviation. Statistical significance for these data were assessed with the two-tailed Student's *t* test for independent samples. Statistical significance of differences was accepted when the *P* value was less than 0.05.

Results

Early results

We would like to stress that, with the aid of the Doppler anoscope, we found and ligated an average of 6 ± 1.7 arteries.

In the postoperative period we did not experience any complications requiring surgical intervention in either group. In group A 9 patients had fever during the first postoperative week, and 1 had a temperature not exceeding 37.5° C. Two patients were put on antibiotics, and the others resolved without any specific treatment. Six patients had nausea and required postoperative parenteral fluid support. One patient had urinary retention demanding catheterization. In group B 2 patients had nausea and thus required parenteral fluid replacement in the postoperative hours. Overall 14 patients developed some negative reaction in group A and only 2 in group B (P<0.05).

Table 1 compares the two groups in terms of early results. In group A 9 patients needed opioid analgesics but none in group B; there were 23 patients in group B who did not require pain killer at all but only 2 in group A. Table 1 presents the mean length of postoperative hospitalization. Among group B patients this period was 47.6 ± 46.3 h in those undergoing general anesthesia (*n*=10) and 5.9 ± 4.4 h in those undergoing local anesthesia (*n*=20; *P*=0.07). The length of time needed to return to normal daily activity is also presented in Table 1.

One-year results

We encountered no stricture formation, incontinence, or evacuation problems in either group. In the 6th postoperative week we assessed the results by the disappearance of the preoperative symptoms and by the regression of prolapsing piles. We found no statistical difference between the two groups based on 95% CI. In group A the symptoms ceased in 26 patients, and 4 patients had further complaints. One of these later proved to have bleeding diverticulosis and became symptom-free on conservative therapy. One patient underwent three sessions of rubber band ligation and also became symptom free. Two patients did not undergo any further therapies although they claimed to keep at least some of the preoperative problems. One patient (otherwise free of problems) presented with a prolapsing secondary pile in one direction.

Table 1 Early results of treatment by standardized closedscissors hemorrhoidectomy(group A) and by Doppler-guided hemorrhoid arteryligation (group B)

	Group A (<i>n</i> =30)	Group B (<i>n</i> =30)	Р
Need for minor analgesics (doses)	11.7±12.6	2.9±7.7	<0.005
Length of hospital postoperative stay (h)	62.9±29.0	19.8±41.8	<0.0001
Return to normal daily activities (days)	24.9±24.5	3.0±5.5	<0.0005

 Table 2
 Summary of failures, recurrences and final outcome

Patient no.	Initial symptom	Failure	Recurrent symptom	Therapy	Final outcome
Group A					
1	Bleeding	Bleeding, diverticulosis on colonoscopy	_	High-fiber diet	Complaint free
2	Bleeding	Bleeding	-	Rubber band ligation	Complaint free
3	Bleeding, pain	Bleeding, pain	-	Suppositories	Bleeding, pain
4	Bleeding	Bleeding, pain	_	Suppositories	Bleeding, pain
5	Bleeding	_	Discharge, pain	Suppositories	Discharge, pain
6	Bleeding	_	Bleeding	Suppositories	Bleeding
7	Bleeding, pain	_	Pain	Suppositories	Pain
8	Pain	_	Prolapse	Suppositories	Prolapse
Group B					
1	Bleeding, pain	Discomfort	_	Suppositories	Discomfort
2	Bleeding, prolapse	Pain	_	Suppositories	Pain
3	Pain, bleeding	Pain	_	Suppositories	Complaint free
4	Bleeding	Pain, bleeding	_	Suppositories	Complaint free
5	Bleeding, pain, prolapse	Pain	-	Suppositories	Complaint free
6	Bleeding	_	Bleeding	DG-HAL	Complaint free
7	Pain	_	Anal fissure	Fissurectomy	Complaint free
8	Bleeding, pain	_	Anal fissure	Suppositories	Complaint free
9	Pain	_	Anal fissure	Subcutaneous lateral sphincterotomy	Complaint free

In group B 25 patients reported being symptom free 6 weeks after the operation and 5 patients still had problems. Three patients reported experiencing perianal fullness and/or pain. In these patients we observed prolapse on straining. Despite this they ceased to bleed and did not require further therapy. In fact, one of them became completely symptom free without any specific treatment. The remaining two patients (one who bled and one who complained of pain) was put on suppositories which solved their problems. These two patients did not have prolapse.

In group A five patients developed perianal complaints during the follow-up period (mean $11.8\pm$ 6.0 months). Two of these also had problems at the 6week follow-up as well. The other three patients developed new problems during the follow-up period. They complained of bleeding in three instances, pain in four, discharge in one, and prolapse in one. Their problems persisted during the entire follow-up period.

In group B 6 patients presented symptoms during the follow-up period (mean 11.5 ± 3.1 months). The frequency of recurrence did not differ from that of group A. Two of these had problems as early as the 6-week follow-up, and their perianal discomfort or pain persisted throughout the follow-up period. One patient reported recurrent bleeding which did not cease on conservative measures. He underwent a second DG-HAL operation which rendered him symptom free. Three patients presented with anal fissure. One of these healed after undergoing conservative therapy, and two had to be operated on (one fissurectomy and one subcutaneous lateral sphincterotomy were performed). Both patients healed by the end of

the follow-up period, which means that 1 year after the initial DG-HAL operation 28 patients were complaint free, whereas in group A the corresponding figure was 25 patients (n.s.). Failures and recurrences are presented in detail in Table 2.

Discussion

Patients after DG-HAL operations need significantly less pain killer, their hospital stay is shorter, and they return to their normal daily activity much more quickly. This is not surprising, given that there is no real wound left after the operation. The operative trauma is minimal. This operation can be performed under local (surface) anesthesia, and this further decreases the number of negative postoperative reactions and the length of the postoperative hospital stay [10, 11]. We observed comparable symptomatic recurrence rate in groups A and B. Both procedures had cured problems related to hemorrhoidal disease at an acceptable level at 1-year follow-up.

We saw a marked reduction in the prolapse in both groups. It was not surprising in group A, where the excess tissue was mechanically removed, but it was somewhat unexpected after the DG-HAL procedure. The pathophysiology can be that after successful ligation of the arteries the inflow to the piles drops. While the venous outflow remains intact, the tension within the anal cushions drops. The piles collapse and both the bleeding and the pain cease. The decreasing tension allows regeneration of the connective tissue within the piles which facilitates the shrinkage of the hemorrhoid and eventually leads to the

	Morinaga et al. [9] (<i>n</i> =116)	Sohn et al. [10] (<i>n</i> =60)	Arnold et al. [11] (<i>n</i> =105)
Stage	Not specified	II 33%, III 45%, IV 22%	II 17%, III 74%, IV 9%
Type of anesthesia	Surface 2% lignocaine jelly alone	Sedation with i.v. propofol and local anesthetic (0.5% bupivacaine)	Spinal anesthesia or local EMLA +5 mg midazolam i.v. +2% lignocaine jelly
Number of stitches in mean	Treatment completed in 2–3 sessions, no mention of the number of stitches	6	8
Analgesics after the op.	Not specified	Not specified	19% of patients per os diclofenac twice a day, all patient received flavonoid
Hospital stay	No, outpatient settings	No, outpatient settings	2 days on average
Complications	Posttreatment pain in 5%, blood in stool 1 week after treatment in 12%	Pain lasting more than 2 days 8%, anal fissure 2%, thrombosed external hemorrhoids 7%	Anal fissure 2%, fistula 1%, thrombosed external hemorrhoids 3%
Success rate	Bleeding stops in 96%, prolapse shrinks in 78%, pain ceases in 95%, recurrence 2.6%	97%	91%

Table 3 Comparison of studies carried out on DG-HAL procedure

definitive decrease in the prolapse. The whole process supports the "hypertensive cushion" theory [12, 13].

During the DG-HAL procedures we found more arteries than we had expected on the basis of the traditional anatomical concept [10, 11]. The anatomical picture drawn by Miles shows three descending arteries [14]. These are described as the end-branches of the superior rectal artery. The concept of either traditional hemorrhoidectomies (e.g., Parks, Milligan-Morgan, Ferguson) is based on this anatomical view. We found an average of six arteries during the DG-HAL procedure with the aid of the Doppler anoscope. These can be the subdivided endbranches of the superior rectal artery, although it is possible that some other vessels break through the wall of the distal rectum. Not all of these vessels are ligated during conventional hemorrhoidectomy. An intention to deal with all of these vessels (to perform hemorrhoidectomy on both the primary and the secondary piles at the same time) would sacrifice much anoderm and would risk both extensive scaring and sensory insufficiency. In fact we observed a similar situation after Whitehead operations [15, 16].

We experienced no early complications in either group which needed surgical intervention, although we saw a number of negative reactions in the postoperative period. A majority of these occurred in group A (14 vs. 2). As late complications we had three anal fissures in group B, but all of these patients healed on appropriate therapy. If we accept the ischemic origin of anal fissures, the appearance of fissures as a late complication indicates that the DG-HAL procedure effectively decreases the blood flow to the anal canal for months [17].

The comparable results of other publications dealing with DG-HAL procedure are summarized in Table 3. These results seem to be coherent and supportive of our main observations, namely: the DG-HAL procedure can be carried out under surface anesthesia, the postoperative need for analgesics is minimal, and hospital stay is short. Most of the above complications (fissure, thrombosed external hemorrhoids, prolonged pain) may be related to the altered blood circulation within the mucosa of the anal canal. Every author has tried to ligate all the audible arteries above the anal canal. Further studies are needed to determine whether fewer stitches would still effectively eliminate the hemorrhoidal symptoms without the danger of anal mucosal ischemia.

In conclusion, both the closed scissors hemorrhoidectomy and the DG-HAL procedure proved effective in treating hemorrhoids in both the short and the long term. The 1-year results of DG-HAL procedure do not differ from those of the closed scissors hemorrhoidectomy. The short hospital stay, the low complication rate, and the minimal postoperative pain make the DG-HAL procedure ideal for 1-day surgery and is in accordance with the requirements of minimally invasive surgery.

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