Transanal Doppler-guided Hemorrhoidal Artery Ligation and Recto Anal Repair vs Closed Hemorrhoidectomy for treatment of grade III-IV hemorrhoids. A randomized trial

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Abstract: Objective: HAL-RAR is a technique whereby Doppler-guided ligation of hemorrhoidal arteries is combined with a mucopexy of the mucosal prolapse, known as Rectal Anal Repair (RAR). HAL-RAR is presented here as an alternative to hemorrhoidectomy. Early and 1-year follow-up results of the procedure are presented and compared with those of closed-scissors hemorrhoidectomy (CH) in a prospective randomized study. Patients and methods: One hundred and thirty-five patients with grade III-IV hemorrhoids were randomized for HAL-RAR (n = 65) or CH (n = 70). All operations were done under general anesthesia and local block as day-case surgery. Results: Comparing the two groups, there was no significant difference between them in terms of the operating time (36.2±2.3 vs 35.5±3.1 p>0.05), or when the first postoperative bowel movement occurred. The median pain score was higher for the CH group during the first ten days (p<0.05). The average need for minor analgesics was 32.3±12.6 mg (ketorolac tromethamin) in the HAL-RAR group, and 46.1±7.7 mg in the CH group (p=0.001). Patients in the HAL-RAR group spent 18.3±3.5 hours in the hospital postoperatively, and those in the CH-group 62.0±12.4 hours. Patients in the HAL-RAR group returned to normal daily activities after 2.8±0.7 days, and those in the CH group after 21.1±2.7 days (p<0.001). Complications occurred in a total of five patients within 30 days of surgery: three patients from the CH group suffered from urinary retention, one patient from the CH group from bleeding, and one from the HAL-RAR group from a thrombosed hemorrhoid. The appearance of skin tags (HAL-RAR 9 vs. CH 1, p=0.047) significantly differed between the groups. Neither the reappearance of prolapse (HAL-RAR vs. 0 CH patients) nor the recurrence of the symptoms bleeding (HAL-RAR 2 vs. 1 CH patients) or pain (HAL-RAR 0 vs. 1 CH patients) differed significantly between the two groups. Conclusion: HAL-RAR appears to cause less postoperative pain and results in better patient-satisfaction in the early postoperative period than closed hemorrhoidectomy. Doppler-guided hemorrhoidal artery ligation fulfills the requirements of minimally invasive surgery and appears to be ideal for 1-day surgery.

Key words: Hemorrhoids; Doppler-guided hemorrhoidal artery ligation; Transanal rectal mucopexy; Prolapse; Rectal bleeding.

INTRODUCTION

Today, hemorrhoidal disease (HD) is considered to be a typical disease of civilization or lifestyle, and some 70% of the working population is faced with this problem at some stage. In most cases, the severity of ailments depends on how advanced the disease is.1 Therapeutic treatment of hemorrhoidal disease ranges from diet to medication. During the early stages of hemorrhoidal disease, good results can be achieved with infrared coagulation,2 sclerotherapy, and rubber-band ligation.3 Hemorrhoidectomy is the definitive treatment for grade III or IV hemorrhoids.4 Standard methods include the open (Milligan-Morgan)5 or closed (Ferguson)6 hemorrhoidectomy, which are considered the gold standard for treating grade III-IV hemorrhoidal disease. However, these are usually associated with significant postoperative pain and a prolonged hospital stay. The majority of randomized clinical trials have demonstrated that the classical hemorrhoidectomy, including the Milligan-Morgan and Ferguson methods and their modifications, is accompanied by numerous complications. The most common complications are sphincter dysfunction (in up to 25% of patients) and pain severe enough to prevent 75% of patients from returning to work for up to 3 weeks following surgery. Other complications include postoperative urinary retention (2%-36%), bleeding (5%-15% of patients), anal stenosis (0%-6%), infection (0.5%-5.5%), and incontinence (2%–12%). Furthermore, the risk of a recurrence of the disease can reach up to 30%.7,15

The majority of trials show that there is no difference in the duration of the rehabilitation process, irrespective of which technique is used for the hemorrhoidectomy. Much research over the last two decades has concentrated on reducing the pain after hemorrhoidectomy which results from the surgical incisions. Postoperative pain, slow convalescence and occasional long-term complications have encouraged the development of less invasive techniques.

At the end of the twentieth century, two technologies were developed as an alternative to standard hemorrhoidectomy. Stapled hemorrhoidopexy is a procedure first described by Longo in 1998,16 which has rapidly emerged as a potentially less-painful alternative for treating hemorrhoidal disease. In randomized trials, stapled hemorrhoidopexy has shown a greater reduction of postoperative pain, a greater reduction in the length of hospital stay, and an earlier return to normal activity than excisional hemorrhoidectomy, but it is ineffective as a definitive cure for prolapse. Complication rates after stapled hemorrhoidopexy vary between 6% and 31%, and include such serious surgical complications as rectal anastomotic leakages with pelvic sepsis, rectal obstruction, perforation, recto–vaginal fistula, sphincter damage, retroperitoneal hematoma, and Fournier gangrene.17-19 This technique requires the resection of rectal mucosa and therefore cannot be considered as minimally-invasive.

The HAL-RAR method is a new, minimally-invasive treatment option for high-grade hemorrhoids which combines in one procedure HAL (Hemorrhoidal Artery Ligation)20 and a “lifting” of the hemorrhoidal prolapses, known as a mucopexy, described by Hussein21 in 2001. This technique serves to treat the vascular factors with Doppler-guided suturing of the terminal branches of the hemorrhoidal arteries, and subsequently to treat the hemorrhoidal prolapses.

This present study compares the early and 1-year results of the traditional closed-scissors hemorrhoidectomy with those of the HAL-RAR operating technique.

PATIENTS AND METHODS

The present study is a randomized, clinical trial. The study was approved by the medical center’s ethics’ committee. Informed consent was obtained from every patient included in the trial. Neither sponsorship nor financial support of any kind was received for this study. The study in-
cludes adult patients only with symptomatic grade III or IV hemorrhoids. All patients were subjected to a detailed clinical examination prior to the procedure using rigid sigmoidoscopy and anoscopy for the diagnosis and staging of the disease. Any prolapse which could be reduced was classified as grade III hemorrhoidal disease. Permanently prolapsed anal cushion that prolapse immediately after replacement were classified as grade IV. Other underlying pathologies were excluded by barium enema or colonoscopy where necessary. Prior to surgery, a photograph was taken of the anal aspect of the patient. Exclusion criteria included concomitant anal disease (acute thrombosed hemorrhoids, fissure, abscess, fistula, incontinence, inflammatory bowel disease), previous anal surgery, ongoing treatment with oral anticoagulants, disease or hematological disorders. The patients were classified in category I-II of the ASA score (American Society of Anesthesiologists). Recruited patients were randomly allocated, by means of sealed envelopes, to one of the two study arms: (1) Doppler-guided Hemorrhoidal Artery Ligation and mucopexy (HAL-RAR) or (2) standardized closed-scissors hemorrhoidectomy (H). A single person performed all randomizations, which were done in blocks, so that the number of patients in the two groups was balanced over the course of the trial.

Preoperative preparation

Patients were prepared for surgery with an oral intake of fluids from midday before the procedure, and were given two “Microlax” enemas (Kabi Pharmacia AB) two hours before the procedure. One hour before the procedure, Emila ointment (Astra Zeneca, Sweden) was applied to the perianal region and intramuscular butorphanol (Stadol, Bristol-Myers Squibb) was applied. Prophylactic antibiotics were not routinely prescribed.

Operative technique

Closed hemorrhoidectomy or HAL-RAR was performed under general anesthesia as a day-case or short-stay procedure. General anesthesia was administered intravenously (1%-Propofol Fresenius, Kabi Deutschland GmbH) and the airway maintained using a laryngeal mask airway. To eliminate a surgeon-related bias, all procedures were performed by a single surgeon. All procedures were performed in the lithotomy position. After cleaning the perianal skin region and covering the patient with sterile draping around the perianal area, an anococcygeal ligament incision of 5 ml bupivacaine 0.5 percent (Astra Zeneca, Sweden) was administered. A surgical proctoscope (BeaK; SapiMed, Alessandria), was placed in the anal canal, and the hemorrhoidal tissue was elevated with an injection of 0.5 percent bupivacaine with 1:200,000 adrenaline. The closed hemorrhoidectomy was carried out according to the Ferguson technique. The vascular pedicle was ligated with 2/0 polyglactin braid-ended synthetic resorbable suture (A.M.I. HAL Suture, 2/0 polyglactin, tapered needle, 5/8 circumference, reinforced needle-thread connection). Obliteration of the vessels was confirmed by the absence of any Doppler sounds distal to the sutures. The transanal mucopexy was carried out using the RAR probe (see Figure 1) in combination with the special RAR metal sleeve, by applying longitudinal continuous running sutures in 3-4 quadrants.

Figure 1. – A.M.I. RAR Probe.

Postoperative management

Food was allowed in the immediate postoperative period. For pain relief, dolgesic was prescribed. Intramuscular Butorphanol tartrat (Stadol, Bristol-Myers-Squibb) 1 mg/kg body weight) or ketorolac trometamin (30-60 mg) injections were given on demand. For stool softening, patients received Macrogol 4000 (Forlax, Beaufour Ipsen International) 10 gram 1-2 times a day for 3-4 weeks. Additionally, we prescribed «Detralex» (micronized purified flavonoid fraction-Daflon 500) for all patients 1000 mg/day orally for a period of 3 weeks. For the first 10 days, patients were advised to take anti-inflammatory suppositories. Discharge from hospital was only authorised if the following strict criteria were met: (1) the patients were fully ambulatory; (2) «Butorphanol tartrat » injection was no longer required; and (3) the patients did not complain of bleeding or urinary retention. Patients were advised not to subject themselves to any physical strain for another 3 weeks.

Measured outcomes

Operative data and postoperative complications were recorded. Postoperative hemorrhage was defined as: (1) when the bleeding required surgical intervention, or (2) when hospital readmission was required. A 100-mm visual analog scale (VAS) - from 0 (no pain) to 100 (the worst pain imaginable) - was used to evaluate the intensity of pain postoperatively. The patient was instructed to score pain according to this. The first pain score was made three hours after the effect of the intravenous anesthesia had worn off. Thereafter, the pain score was made on a daily basis from the first to the seventh postoperative day, and a mean pain score was calculated. This score thus took into account the intensity and duration of pain. Because the time of maximal pain perceived by different patients might be quite different, a mean pain score is a better reflection of the pain experienced in the first postoperative week. The number of intramuscular «Butorphanol tartrat» and «ketorolac trometamin» injections given during hospitalization, and the total number of dolgesic tablets (Ketorolac) taken by the pa-
tient during and after hospital discharge, were recorded. Other information, including the first bowel movement after surgery and the time it took to return to work, was also recorded.

Results of long-term follow-up were evaluated by means of a standardized questionnaire before and then again one year after surgery. The following signs and symptoms were evaluated: prolapse, bleeding, itching, tenesmus, urgency, and continence. Tenesmus was defined as a sensation of incomplete evacuation of feces. Urgency was defined as the inability to control the defecatory reflex; that is, bowel movements cannot be prevented because of a strong desire to defecate. Prolapse was assessed by the physician according to his observation. Continence was scored on a scale of 0 to 20 according to the incontinence score system of Jorge and Wexner. All data were recorded by an independent physician. In the study, the following signs and symptoms were evaluated: prolapse, bleeding, itching, tenesmus, urgency, and continence. Tenesmus was defined as a sensation of incomplete evacuation of feces. Urgency was defined as the inability to control the defecatory reflex; that is, bowel movements cannot be prevented because of a strong desire to defecate. Prolapse was assessed by the physician according to his observation. Continence was scored on a scale of 0 to 20 according to the incontinence score system of Jorge and Wexner. All data were recorded by an independent physician.

Outpatient follow-up was made at 2 weeks, 1, 6, 8 and 12 months after the procedure.

Statistical analysis

Data is expressed as either mean and standard deviation, or median and range. Categoric variables were analyzed with the chi-squared or Fisher’s exact test, and numeric (continuous or parametric) variables were analyzed by use of Student’s t-test or Mann-Whitney U test, as appropriate. The statistical analysis was made with the program SPSS® (Windows version 11.0; SPSS Inc., Chicago, IL).

RESULTS

Between December 2006 and December 2007, we registered one hundred and thirty-five patients with grade III-IV hemorrhoids. The average period of supervision was 15 (6-24) months. No patient was lost to follow-up research. The two groups were comparable in terms of age and gender distribution. There was no significant difference between the groups in admission status, type of anesthesia or grade of hemorrhoids. There were no statistically significant distinctions between the duration or type of clinical symptoms. The characteristics of the patients included in the study are presented in Table 1.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>HAL-RAR</th>
<th>CH</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years), mean and range</td>
<td>43 (28-63)</td>
<td>45(27-67)</td>
<td>0.511c</td>
</tr>
<tr>
<td>Gender (M:F)</td>
<td>54/11</td>
<td>59/11</td>
<td>0.849b</td>
</tr>
<tr>
<td>Grade (III:IV)</td>
<td>41/24</td>
<td>39/31</td>
<td>0.383b</td>
</tr>
<tr>
<td>GA</td>
<td>65</td>
<td>70</td>
<td>NS</td>
</tr>
</tbody>
</table>

Symptoms of hemorrhoids

<table>
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<tr>
<th>Characteristic</th>
<th>CH</th>
<th>HAL-RAR</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prolapse</td>
<td>65</td>
<td>70</td>
<td>0.473</td>
</tr>
<tr>
<td>Bleeding</td>
<td>65</td>
<td>70</td>
<td>0.908</td>
</tr>
<tr>
<td>Pain</td>
<td>43</td>
<td>48</td>
<td>0.554</td>
</tr>
<tr>
<td>Itching</td>
<td>1</td>
<td>5</td>
<td>0.210</td>
</tr>
<tr>
<td>Tenesmus</td>
<td>0</td>
<td>0</td>
<td>NS</td>
</tr>
<tr>
<td>Incontinence</td>
<td>(0-3)</td>
<td>(0-4)</td>
<td>0.868c</td>
</tr>
</tbody>
</table>

HAL-RAR: Doppler-guided Hemorrhoidal Artery Ligation and Recto Anal Repair
CH: Closed Hemorrhoidectomy; GA: General Anesthesia
aMann-Whitney U test
bFisher’s exact test
cChi-squared test

Comparing the two groups, there was no significant difference observed between the operating times and no difference between the times of the first bowel movement after surgery (Table 2).

Table 2. – Clinical results after surgery.

<table>
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<th>CH</th>
<th>P Value</th>
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<tbody>
<tr>
<td>Operation time</td>
<td>36.18±2.3</td>
<td>35.5±3.1</td>
<td>0.512c</td>
</tr>
<tr>
<td>«Stadol» injection (n)</td>
<td>1 (0-1)</td>
<td>2 (0-4)</td>
<td>0.001</td>
</tr>
<tr>
<td>etorolac toremetamin injection (n)</td>
<td>2 (1-3)</td>
<td>4 (2-4)</td>
<td>0.001</td>
</tr>
<tr>
<td>First bowel movement (days after surgery)</td>
<td>2 (1-2)</td>
<td>2 (1-3)</td>
<td>0.015</td>
</tr>
<tr>
<td>Hospital stay (hours)</td>
<td>18.3±3.5</td>
<td>62.0±12.4</td>
<td>0.001c</td>
</tr>
<tr>
<td>Return to work (number of days after surgery)</td>
<td>2.8 (2-4)</td>
<td>21.1 (12-27)</td>
<td>0.001d</td>
</tr>
</tbody>
</table>

Values are mean (standard deviation); Values are median; Mann-Whitney U test; Student’s t-test

Preoperative pain experienced by the patients was similar for the two groups. Postoperative pain was significantly lower in the HAL-RAR group on all postoperative days (p < 0.001 Mann-Whitney U test) (Figure 2).

Figure 2. – Pain scores (visual analog score/VAS) before and after HAL-RAR and Closed Hemorrhoidectomy.

Preoperative pain was similar for the two groups. HAL-RAR patients experienced significantly less pain than closed hemorrhoidectomy on all postoperative days (p < 0.001 Mann-Whitney U test). The number of analgesics required was lower in the HAL-RAR group (p<0.001 Mann-Whitney U test) for days 1 - 6. From the seventh day onwards, none of the patients in the HAL-RAR group required analgesics (Figure 3).

In the CH group, all patients required analgesics during the 10 days following the operation. In the HAL-RAR group during the first two postoperative days, 63 (96.9%) and 62 (95.4%) patients respectively required analgesics. From the third postoperative day onwards, the number of patients requiring analgesics in this group decreased markedly, with 21 (33.8%) and 13 (20%) requiring analgesics on the third and fourth post-operative day respective-
Patients, who underwent the HAL-RAR procedure, also had a shorter hospital stay (p = 0.01) and resumed work on average sooner than patients in the CH group (2.8 vs. 21.1; p = 0.001).

Overall, a total of thirteen patients developed complications, with three of those patients belonging to the HAL-RAR group and 10 belonging to the CH group (Table 3).

In the CH group, three patients developed transient urinary retention. One patient developed postoperative hemorrhaging, stopped by anoscopy and the submucous injection of bupivacaine with adrenaline 1:200,000. One patient in the HAL-RAR group suffered from thrombosed hemorrhoids. This complication was resolved conservatively with local therapy. Three patients from the HAL-RAR group and six patients from the CH group suffered hyperthermia. The hyperthermia was probably connected to an operational trauma, and subsequently passed without requiring treatment with antibiotics.

Resolution of hemorrhoidal symptoms after 1 year

Incidental bleeding of no significance was reported for 2 of 65 patients in the HAL-RAR group (3.1 %) and for 1 patient of 70 (1.4 %) in the CH group (p = 0.472). During clinical inspection and anoscopy, minor prolapses were revealed in 3 of the 65 patients (4.6%) in the HAL-RAR group. These required two sessions of sclerotherapy for liquidation of symptoms. In the CH group, there were no prolapses evident (p = 0.109). Input from patients and the clinical survey showed that 6 (9.2%) patients in the HAL-RAR group and 1 (1.4%) in the CH group (p = 0.047) developed skin tags that were subsequently removed under local anesthesia. The periodic occurrence of pain after defecation was noted in 1 patient from the CH group (p=0.519), causing cryptitis and demanding local conservative therapy. There was no difference noted in the incontinence scores. None of our patients scored higher than 2 points (Jorge-Wexner) either before or after treatment. Patients evaluated the surgical result after the HAL-RAR procedure as excellent in 54 cases (83.1%) and good in 11 cases (16.9 percent) and excellent in 67 cases (95.7 percent) and good in 3 cases (4.9 percent) after closed hemorrhoidectomy.

DISCUSSION

Introduced into surgical practice in 1937 and theoretically substantiated, the Milligan and Morgan method for hemorrhoidal treatment remains the principal method of treatment for patients with hemorrhoids of grade III-IV, because minimally-invasive methods of treatment are considered to achieve inferior results. The majority of randomized prospective studies comparing open and closed hemorrhoidectomy shows no difference in pain, analgesic use, hospital stay or complications. Recently, the harmonic scalpel and bipolar diathermy LigaSure have been widely used in the surgical treatment of hemorrhoids. The majority of randomized research has shown that both the duration of surgery and the blood loss decrease when compared to electrocautery hemorrhoidectomy, but there is no effective reduction of pain. The key issue in all hemorrhoidectomy operations has always been postoperative pain, because pain is still the most common reason for patients to refuse surgery. The hemorrhoidectomy predisposes patients to pain relating to damaged perianal skin and sensitive anoderm, and some pa-
patient relatively low pain levels. The HAL-RAR procedure
not only reduces postoperative pain, but also from fewer complications. In addition,
patients have reported less pain, better bleeding, prolapse, skin tags, incontinence
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time. On the basis of that questionnaire and clinical exami-
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HAL-RAR group respectively.

Of this group 83.1% confirmed that they were no longer experienc-
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Another aim of this study was to assess the effectiveness
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osen to apply HAL-RAR, the method which does not lead to
potentially fatal complications.


