

A retrospective, single-centre analysis on Haemorrhoidal Artery Ligation (HAL) and Recto-Anal Repair (RAR) after ten years

M. De Vos, V. Maertens, L. Maes, K. Fierens, O. Van Kerschaver, M. Kint, L. Van Outryve, T. Onghena

Abstract

Introduction: Haemorrhoidal Artery Ligation (HAL) +/- Recto-Anal Repair (RAR) is a minimally invasive surgical technique for all grades of hemorrhoidal disease. This paper reports on the results after ten years of follow-up.

Methods: This retrospective study analyzed the outcomes of 274 consecutive HAL or HALRAR procedures between January 2004 and August 2014, at Sint-Lucas General Hospital in Ghent, Belgium. Data was collected through a questionnaire and the patient records. All data was analyzed with SPSS 24.0.

Results: The initial symptomatology was discomfort in daily life, anal blood loss, anal pain and hemorrhoidal prolapse. Before seeking medical treatment, 61.1% were symptomatic for years. Patients were treated by HAL or HALRAR. During a HAL procedure, a mean

of 5 sutures were placed. For RAR, a mean of 2 mucopexies were performed. The majority (74.8%) was treated on a day-clinic basis. Mean Visual Analog Scale (VAS) for postoperative pain is 5.28. The postoperative complication rate was 11.3%, most frequently anal pain (3.6%), hemorrhoidal thrombosis (3.3%) and urinary retention (2.6%). Symptoms of hemorrhoidal disease decreased significantly after HAL or HALRAR, but 44.4% of patients needed further treatment. Satisfaction after HAL or HALRAR was 84.4%.

Conclusion: These long-term results after HALRAR show a significant decrease in symptomatology and a high patient satisfaction but confirmed concerns about high recurrence rates. More prospective randomized trials are needed to evaluate long term results compared to other surgical techniques.

Keywords: Haemorrhoidal Artery Ligation, Recto-Anal Repair, Follow up.

Authors' addresses: Department of Surgery, Sint-Lucas General Hospital, Ghent, Belgium.

Corresponding Author: Marie De Vos (ORCID : 0000-0001-6114-6538) E-mail: medvos1@gmail.com

Introduction

Haemorrhoidal disease is the most common disease of the rectum. Usually, patients do not seek early treatment given the nature of the disease but the prevalence is estimated to range between 4.4% and 36.4% [1]. Approximately 10-20% of patients will require surgery [2].

Haemorrhoids are a physiological plexus of veins located between the lamina muscularis mucosa and sphincter muscle structures and consists of a superior (inner) and inferior (external) part divided by the dentate line. Because of arterial shunts and an extension of veins, this plexus becomes enlarged and plays an important role in "fine continence" of the anal canal [1,2].

Today, haemorrhoidal disease is considered as a typical "civilization" disease, and nutrition, hygiene, and constitution, plays an important role in its development. The main pathogenetic cause for haemorrhoidal disease is increased intraluminal blood pressure of the distal rectum. This results in an imbalance between arterial inflow and venous return. Reasons for the increase in intraluminal blood pressure are multifactorial and most probably individually different [3]. Fibre-free food, high tonus rates of the sphincter apparatus, stress and anatomic, physiologic and hereditary factors are currently considered possible causes.

Enlargement and displacement of haemorrhoids typically presents with symptoms such as bleeding, pruritus, prolapse, sensation of incomplete evacuation, soiling, recurrent thrombosis of piles, etc. (which are bothersome and difficult to attenuate) [4, 1]. However, the grade of prolapse and haemorrhoidal symptoms are often poorly correlated [5]

The current well-accepted grading of haemorrhoids, also known as the Goligher's classification [6], is based on the morphology of the

piles: grade I = enlarged haemorrhoidal plexus, without prolapse, but with bleeding; grade II = prolapsing piles with spontaneous repositioning of piles; grade III = manual repositioning of piles possible and required; grade IVa = prolapsing piles with acute incarceration and thrombosis; and grade IVb = repositioning of piles impossible, fibrotic prolapse occurs.

Initial treatment for grade 1, 2 (and 3) haemorrhoids is conservative management, meaning dietary and lifestyle modifications for example fibre rich diet and better defecation discipline [7], followed by medical treatment with local application of ointments or oral medication or minimally invasive treatment like sclerotherapy, photocoagulation and cryotherapy.

An outpatient treatment that seems to be more effective for both bleeding and prolapse is rubber banding. A meta-analysis [8] has shown that rubber banding is more effective in both the short and long term compared to photocoagulation. Overall, it appears that between 60-80% of patients who have undergone banding are satisfied with the outcome [8-11].

The disadvantages of all these methods include necessity of several sessions for successful results, a relatively high recurrence rate, impaired sense of well-being caused by foreign-body sensation or pain (10% in the case of rubber-band ligation), occurrence of necrosis, or allergic reactions to the sclerosant [1].

If symptoms prevail, there is a wide range of surgical treatment modalities.

A variety of surgical procedures are now available but no single technique has been universally accepted as superior. This is because the indication for treatment is not only based on the gradation of the haemorrhoids but mainly on the subjective severity of symptoms among patients and quality of life. While the choice of treatment

is based on the gradation of the haemorrhoids, local experience, surgeon's preference and availability of specialized equipment [7,12,13].

Conventional surgical haemorrhoidectomy according to Milligan and Morgan [14], the one modified by Parks [15] or according to Ferguson [16] represent the most effective treatments of persistent grade III and IV haemorrhoidal disease. These surgical interventions usually require several days of inpatient treatment and may lead to severe postoperative pain, severe enough to eliminate 75% of patients from professional life and normal daily activities for a considerable time [17,18]. Other complications are sphincter dysfunction (in up to 25% of patients), postoperative bleeding (in 5-15% of patients) and the risk of a recurrence of the disease, which reaches 30%. Also, an operative haemorrhoidectomy may be contraindicated for some patients (e.g., those suffering from incontinence) [17].

As patients are often reluctant to undergo painful treatments for benign conditions, management of haemorrhoidal disease has evolved to develop effective but less invasive treatment with the aim of reducing the risk of anatomical alterations and dysfunction of the anal canal, minimizing postoperative pain and providing relief of symptoms [12].

Implementing any type of surgical technique, it must be remembered that the plexus haemorrhoidalis (corpus cavernosum recti) plays an important role within the anal sphincter apparatus and that there is a fine line between successful treatment and the risk of damaging the anal sphincter.

Longo's [19] technique (stapled haemorrhoidopexy) is a less invasive surgical technique that consists of the resection of the mucosal prolapse with the use of a circular stapler. Possible severe complications are rectal anastomotic leakages with pelvic sepsis, rectal obstruction, perforation, recto-vaginal fistula, sphincter damage, retroperitoneal hematoma and Fournier gangrene. Complication rates vary between 6 – 31% [20,21].

The last two decades haemorrhoidal artery ligation (HAL), first described by Morinaga in 1995 [22], has become universally accepted for the treatment of haemorrhoids. The rationale for this procedure is based on the assumption that arterial blood flow is mainly responsible for the enlargement of the haemorrhoidal plexus due to the absence of capillary interposition between the arterial and venous systems within the anal canal. The intraluminal arteries, terminal branches of the superior rectal arteries, are located 2 cm proximal to the dentate line and ligated by means of a special proctoscope, which contains an integrated Doppler transducer and a lateral ligation window. The Doppler transducer is located distal to the lateral ligation window. With the applied frequency of 8.2Mhz and an introduction angle of approximately 60°, a screening depth of approximately 7mm is provided. Because the arteries carrying the blood inflow are ligated, the internal pressure of the plexus haemorrhoidalis has decreased, and the typical symptoms of haemorrhoids disappear.

Several studies have reported that (Doppler Guided) Haemorrhoidal Artery Ligation (HAL) is an effective and safe alternative to operative haemorrhoidectomy with the advantages of a short learning curve, no risk of postoperative faecal incontinence, less postoperative pain and a short recovery period [1,23-30]. The success rate observed 1 year postoperatively is 89%, and 73% 5 years postoperatively and recurrence seems to be the greatest during the first year after HAL [1,31-33]. It seems especially effective in grade 2 and 3 haemorrhoids [1,30,33,34]. It might be a good alternative to conventional haemorrhoidectomy but 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 [1,17,28].

Clinical experience has revealed that it can be difficult to silence all Doppler signals during the procedure, even after application of multiple ligations [1]. Nevertheless patients may experience relief of their complaints. In literature, it is assumed that on average 6 to 8 ligations would suffice to achieve complaint reduction, while in a recent anatomical study it was shown that the distal rectum is provided by more than 6 twisting arteries [1,9,35,36]. This discrepancy between peroperative experiences and clinical outcome and the insight into the anatomical configuration of the distal rectum raises the question in what way the proctoscope and Doppler transducer is intervening in the anatomical configuration and whether there might be another mechanism that could explain the beneficial effect of the HALRAR procedure. The findings of Jaap-Peter Schuurman [36] confirm that the haemorrhoidal artery ligation procedure reduces signs and symptoms of haemorrhoidal disease. But also claims that the Doppler transducer does not contribute to this beneficial effect and could be omitted during the ligation procedure. This topic remains contradictory [37]. HAL alone has proven being less effective in the case of grade III and IV haemorrhoids [30,35,38].

Several studies have mentioned the poor ability of the HAL technique to control prolapse [39,40]. To address this shortcoming, the technique was modified at the end of 2005 [40]. A new proctoscope was designed to allow a combination of classical HAL with a transanal rectal mucopexy that serves to lift and secure the protruding haemorrhoids [41-43]. The term Recto-Anal Repair (RAR) has been used to designate either the combined procedure [44,45], or as in the present report and others, the mucopexy alone [44-46].

In this study we analyzed long-term results after HAL or HALRAR procedures through information gathered from a questionnaire and from the patient records.

Methods

This study evaluates all patients who underwent Haemorrhoidal Artery Ligation (HAL) with or without Recto-Anal Repair (RAR) between January 2004 and August 2014 at Sint-Lucas General Hospital in Ghent, Belgium. The study was approved by the local Ethical Committee. Initially 365 patients were selected. After careful analysis of all the individual cases, 274 patients were included in the study. Inclusion criteria were grade I – grade IV haemorrhoidal disease and age between 18 and 75 yrs. Exclusion criteria were co-existent anal pathologies, such as anal fistula, anal fissure and perineal abscess; Inflammatory Bowel Disease (IBD), a history of colorectal tumors; portal hypertension; neurologic diseases that affect the colonic motility and/or the anal sphincter and pregnancy (Figure 1) (near here). In our protocol, patients previously treated for haemorrhoidal disease were not excluded from the study as this would reduce the patient population greatly and the possibility to perform the procedure after previous treatments is considered an advantage.

Patients characteristics, preoperative, peroperative and postoperative information (Table 1) was gathered through patient records and by a questionnaire that was drafted and sent (by post or by e-mail) to the patients after obtaining informed consent by phone. The questionnaire was created after thorough literature research for previously reported outcomes after Haemorrhoidal Artery Ligation (HAL) and Recto-Anal Repair (RAR).

Operative technique

All procedures were performed by one surgeon, Dr T. Onghena at the department of surgery in Sint-Lucas general hospital in Ghent, Belgium. Preoperatively, no bowel preparation and no antibiotic

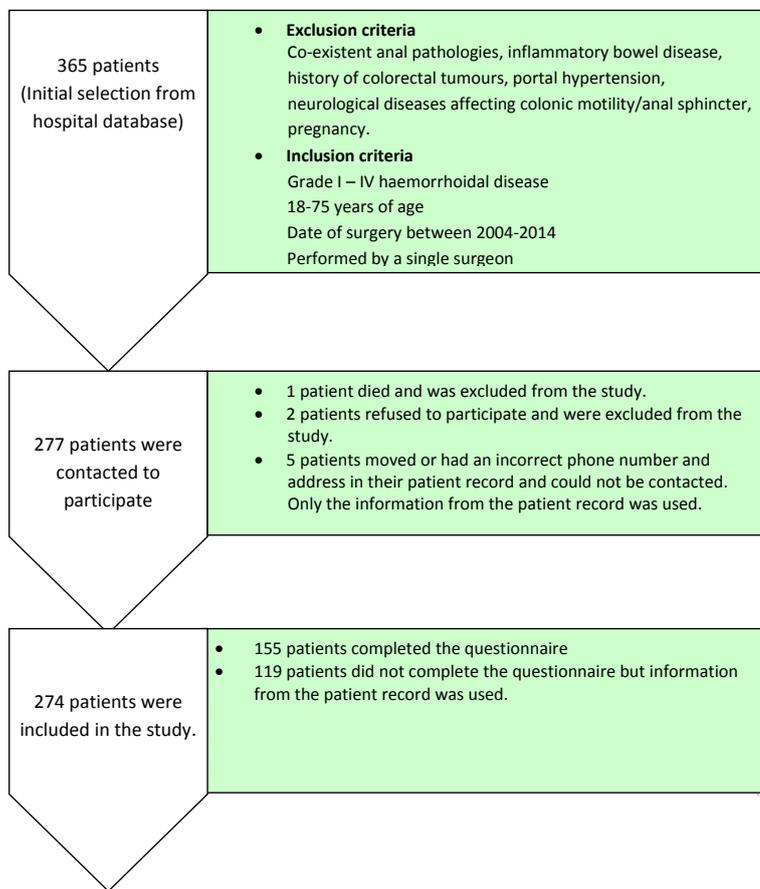


Figure 1 Flowchart of patient enrolment in the study.

prophylaxis was given. The procedure was performed with local, spinal or general anesthesia according to the preference of the patient and anaesthesiologist. The patient was positioned in the lithotomy position. The perineal skin region was cleaned and the patient was covered with sterile draping. The Haemorrhoidal Artery Ligation (HAL) and Recto-Anal Repair (RAR) was performed with HAL-Doppler II System (A.M.I. - Agency for Medical Innovations, Austria) and the accompanying HAL needle holder, knot pusher and suture (which is a 5/8 circle needle with synthetic, absorbable, 2/0 suture filament). The anal canal was gently dilated to a width of two fingers. Before the anoscope is inserted, defaecation was mimicked by inserting two surgical gauzes into the anus and pulling them back out, thereby visualizing prolapse of the haemorrhoidal piles. The anoscope was lubricated and inserted through the anal canal to a depth of 6-7cm from the anal margin and 2-3cm above the dentate line. The doppler was set at 6'o clock in the lithotomy position and proceeded clockwise. The Doppler system was activated and the anoscope was slowly rotated and tilted to search for all the haemorrhoidal arteries (branches of the superior rectal artery). After each quadrant the anoscope was pulled out and reinserted to prevent further rotation of the anal mucosa. A figure-of-eight suture was conducted at the sites where the doppler sound is most prominent and the accuracy of the ligation is confirmed by the loss of the Doppler signal afterwards. The procedure was repeated twice to make sure no arteries were left untied. After finishing the Haemorrhoidal Artery Ligation (HAL) procedure, 'the defaecation mimicking test' was repeated with special attention to previous sites of haemorrhoidal prolapse. Where residual prolapse was present, Recto-Anal Repair (RAR) was performed. The anoscope was again inserted and a longitudinal running plication suture was placed (0.5cm between each step) through the enlarging slot in the anoscope. This was executed from proximal to distal under direct vision. When the margo analis was visualized the anoscope was retracted and the suture was tied. The mucopexy could be felt while tying the suture. This procedure was then repeated for every prolapsing haemorrhoidal pile. Haemostasis was controlled and if

necessary a Spongostan Anal 8cmx3cm (Ethicon, Germany) was used. All patients received a pudendal block at the end of the procedure using 20ml of 0.75% Ropivacaine.

Statistical analysis

All data was analyzed using the statistical software SPSS 24.0. The categorical (ordinal) data was analyzed using the Wilcoxon matched pairs signed ranks test for two dependent samples, the Mann-Whitney U test for two independent samples and the Chi-square test for categorical data. These are non-parametric test as data was not normally distributed. The confidence level used is 95% (significance level $p < 0.05$).

Results

All the patients included in the study ($n=274$) were contacted by phone. After gaining informed consent, the questionnaire was sent by post or e-mail. One hundred and fifty-five patients completed the questionnaire, this resulted in a response rate of 56.6%. From those patients, who could not be contacted, information from the patient record was used.

Patient characteristics

The patients' mean age was 51 yrs (25-74 yrs).

There were 159 male participants (58%) and 115 females (42%), which resulted in a male:female ratio of 1.38.

Patient history

The grade of haemorrhoidal disease was gathered from the patient records. Most participants suffered from grade II haemorrhoidal disease (45.3%), followed by grade III (27.4%), grade I (22.6%) and grade IV (4.0%).

The patients who participated in the study were asked to describe their initial complaints.

Table 1 Patients characteristics, preoperative, perioperative and postoperative variables.

Patient characteristics	Descriptor
Date of birth	DD.MM.YYYY
Age	18 – 70 yrs
Gender	M/F
Preoperative variables	
Grade of hemorrhoidal disease	Goligher's classification, grade I – IV [6]
Initial symptoms	
Discomfort in daily life	Never
Anal blood loss	Seldom
Anal pain	Sometimes
Anal itching	Often
Anal discharge	Daily
Hemorrhoidal prolapse	
Unpleasant odour	
Constipation	
Fecal incontinence	
Tenesmus	
Hemorrhoidal thrombosis	
Duration of complaints	
Previous treatments	
Conservative (high fiber diet, hygiene, etc.)	Y/N
Medical (ointment, laxatives, venotropic drug, etc.)	Y/N
Minimally invasive treatment	
Rubber band ligation	Y/N
Photocoagulation	Y/N
Sclerotherapy	Y/N
Surgery	
Haemorrhoidectomy	Y/N
Perioperative variables	
Date of surgery	DD.MM.YYYY
Type of surgery	HAL, HALRAR, RAR
Anaesthesia	Local, Spinal, General
Duration of surgery	Minutes
Peroperative blood loss	mL
Hemorroidal Artery Ligation – Sutures	Total amount and according to the position of the suture
Recto-Anal Repair – Mucopexies	Total amount and according to the position of the suture
(Perioperative complications)	(None were recorded)
Postoperative variables	
Hospital days	Days
Pain after Surgery	VAS scale (0-10)

Early postoperative complications	
Anal pain	Y/N
Anal blood loss	Y/N
Hemorrhoidal thrombosis	Y/N
Proctitis	Y/N
Anal fissure	Y/N
Anal fistula	Y/N
Fecal incontinence	Y/N
Urinary tract infection	Y/N
Urinary retention	Y/N
Follow-up after one month	
Discomfort in daily life	Never, seldom, sometimes, often, daily
Anal blood loss	
Anal pain	
Anal itching	
Anal discharge	
Hemorrhoidal prolapse	
Unpleasant odour	
Constipation	
Fecal incontinence	
Tenesmus	
Hemorrhoidal thrombosis	
Residual perianal tags	
Additional treatment	
Conservative (high fiber diet, hygiene, etc.)	Y/N
Medical (ointment, laxatives, venotropic drug, etc.)	Y/N
Minimally invasive	
Rubber band ligation	Y/N
Photocoagulation	Y/N
Sclerotherapy	Y/N
Surgery	
Hemorrhoidal Artery Ligation (HAL) / Recto-Anal Repair (RAR)	Y/N
Hemorrhoidectomy	Y/N
Satisfaction after surgery	Not satisfied, Displeased, Neutral, Satisfied, Very satisfied
If necessary, would you choose the HALRAR surgery again?	Y/N

Never

Seldom = 1-3 times a month

Sometimes = once a week

Often = more than once a week

Daily

The majority of patients had discomfort in daily life, anal blood loss, anal pain and haemorrhoidal prolapse. These four seem to be the cardinal symptoms of haemorrhoidal disease in this group of patients and was present on 'a weekly basis' or 'often'. Anal itching was a more variable symptom, but is still apparent 'more than once a week' in 23.9% of all cases. Anal discharge, unpleasant odour, constipation, fecal incontinence and tenesmus were less frequent symptoms, only seldomly present in a minority of patients. The questionnaire also showed that 61.1% of all patients had one or multiple episodes of haemorrhoidal thrombosis.

When asked about the duration of their complaints, it seemed most patients faced years of symptomatic haemorrhoidal disease before seeking medical treatment. In this study 86/170 patients or 50.6%. Very few people were treated instantly, 9/170 or 5.3%. The majority of patients, 127/172 or 73.8%, already received some sort of treatment of their haemorrhoids. Mostly medical treatment, 87/159 or 54.7%, which means application of ointments, the use of laxatives, etc. This was followed by minimally invasive sclerotherapy, 45/166 or 27.1%, conservative therapy (high-fiber diet, hygiene, etc), 31/159 or 20.1%, minimally invasive rubber band ligation, 27/160 or 16.9%, surgical haemorrhoidectomy, 23/161 or 14.3% and minimally invasive photocoagulation, 20/162 or 12.3%.

Surgery

The patients included in this study either had Haemorrhoidal Artery Ligation (HAL) alone, either in combination with Recto-Anal Repair (RAR). 130 out of 274 patients were treated by HAL, this is 46.4%. The other 143 patients or 52.2% (1 missing, 0.4%) got both (HALRAR) because of haemorrhoidal prolapse. In the majority of patients, 77.0%, the procedure was performed under general anesthesia, 2.6% got spinal anesthesia and 5.5% received only local anesthesia. In 40 cases the type of anesthesia was not mentioned in the patient record.

In 195 cases the duration of the surgery was listed. The mean operating time was 44.5 minutes (20-80 minutes). Perioperative blood loss was estimated in 195 cases and can be considered negligible.

HAL

Of all the patients included (N=274), the total amount of HAL sutures was recorded in 259 cases and further details about the location of the sutures was found in 231 cases. A minimum of 2 sutures and a maximum of 8 were placed. The mean amount of sutures was 5. In Figure 2 the distribution of the sutures is visualized.

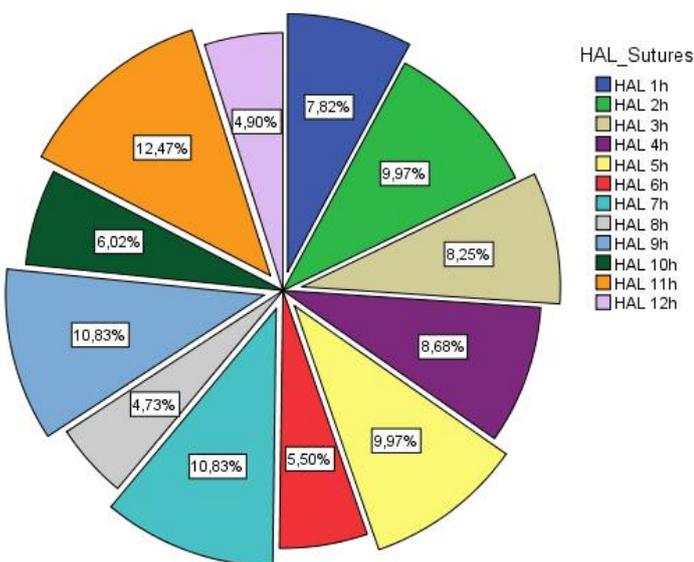


Figure 2 Total of HAL sutures placed per hour.

RAR

One hundred forty-eight patients needed an additional RAR. The total amount of mucopexies was recorded in 142 cases and further details about the location of the sutures was found in 132 cases. A minimum of 1 RAR mucopexy and a maximum of 3 were placed, with a mean of 2 mucopexies. In Figure 3 the distribution of the mucopexies is visualized.

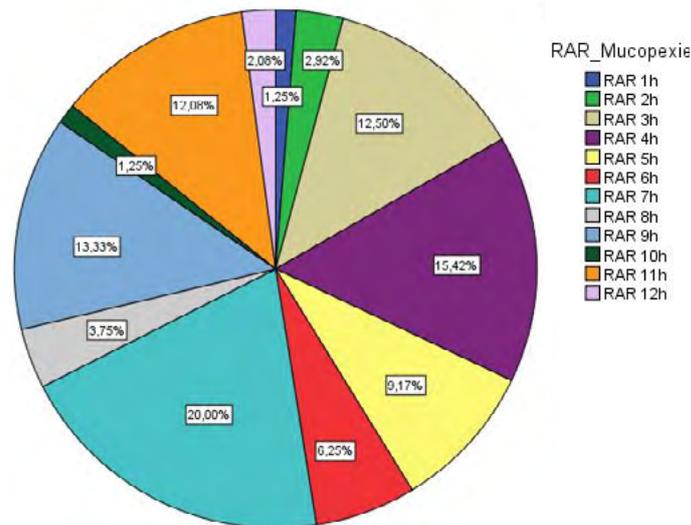


Figure 3 Total of RAR mucopexies placed per hour.

Postoperative care

Patients stayed in the hospital during minimum one day and maximum 4 days. The 4-day hospitalization was needed for only one patient, who suffered from postoperative haemorrhoidal thrombosis. The mean hospital stay was 1.30 days. Most patients, 205/274 or 74.82%, were treated on a day-clinic basis.

Postoperative pain was evaluated by the Visual Analogue Scale (VAS) pain score and ranges between 0 and 10. Zero equals no pain and 10 unbearable pain. Analysis showed a wide distribution of pain perception among patients postoperatively, with a mean VAS pain score of 5.28 (Figure 4). Statistical analysis with the use of the Mann-Whitney U test was performed to determine if there is a statistical difference between pain after HAL and pain after HALRAR. The result was statistically significant, with a higher pain score for HALRAR ($p < 0.05$) (Figure 5). The mean VAS pain score after HAL is 4.17 and the mean VAS pain score for HALRAR is 6.06.

Patients were asked if they had any postoperative complications in the first month after surgery. 93/274 or 33.9%

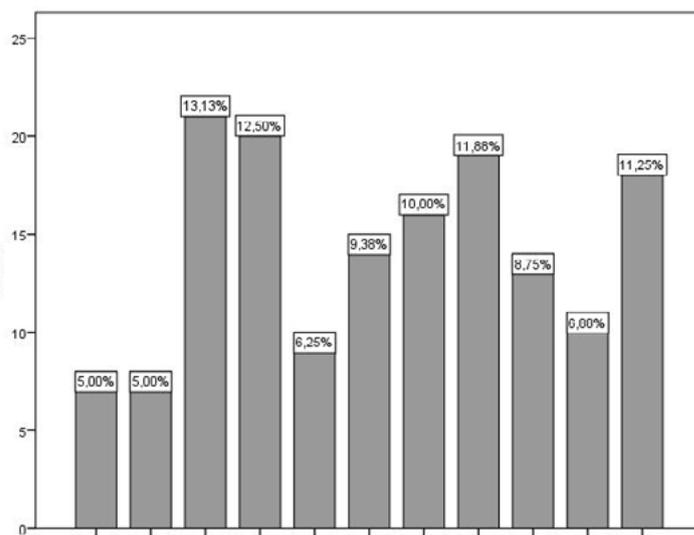


Figure 4 Postoperative pain by Visual Analog Scale (VAS-score).

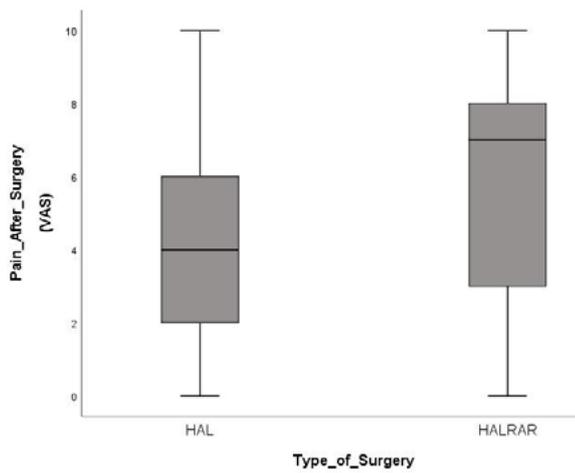


Figure 5 Difference in pain (measured by Visual Analog Scale (VAS) score) between HAL and HALRAR.

answered 'yes'. They were asked to specify their postoperative complication. Those with the highest prevalence were anal pain, 54/274 or 19.7%, followed by anal blood loss, 39/274 or 14.2%, and haemorrhoidal thrombosis, 20/274 or 7.3%. These three complications already accounted for 41.2% of all early postoperative complications according to the patients. Less frequently, patients experienced an anal fissure, 12/274 or 4.4%, urinary retention, 11/274 or 4.0%, proctitis, 9/274 or 3.3%, fecal incontinence, 8/274 or 2.9%, anal fistula, 5/274 or 1.8% and urinary tract infection, 5/274 or 1.8%.

Because the questionnaires gave us an exceptionally high number of postoperative complications and it seemed that the answers in the questionnaire did not match the postoperative information in the patient record, we compared them.

Based on the patient record alone, only 31/274 patients, or 11.3%, suffered a postoperative complication. The most abundant postoperative complications was anal pain, 10/274 or 3.6%, followed by haemorrhoidal thrombosis, 10/274 or 3.3%, urinary retention, 4/274 or 2.6%, anal fissure, 4/274 or 1.5%, anal blood loss, 2/274 or 0.7%, urinary tract infection, 1/274 or 0.4%, and proctitis, 1/274 or 0.4%. There was no report of postoperative fecal incontinence or anal fistula.

These results show a much lower postoperative complication rate but also a different ranking order.

We analyzed the data by using the Wilcoxon signed rank test ($p < 0.05$). Overall there is a significant reduction in postoperative complications between the answers from the questionnaire and the patient record ($p < 0.05$). After analyzing the different possible postoperative complications, there is a significant difference for anal pain, anal blood loss, haemorrhoidal thrombosis, proctitis and fecal incontinence. But not for urinary retention, urinary tract infection, anal fistula and anal fissure. An overview can be seen in Figure 6.

Of all patients treated, 235/274 or 85.8%, were questioned after one month. At this point they were asked to formulate their residual complaints. In all the categories the majority of patients never complained about discomfort in daily life, 70/154 or 45.5%, anal blood loss, 90/147 or 61.2%, anal itching, 93/148 or 62.8%, anal pain, 87/150 or 58.0%, anal discharge, 107/146 or 73.3%, haemorrhoidal prolapsed 79/151 or 52.3%, unpleasant odour, 129/154 or 83.8%, constipation, 91/155 or 58.7%, faecal incontinence, 135/153 or 88.2%, tenesmus, 115/156 or 73.7% and haemorrhoidal thrombosis, 113/161 or 70.2%, after surgery. Still 31/160 or 19.4% experienced one or multiple haemorrhoidal thromboses after HAL or HALRAR. An additional category was

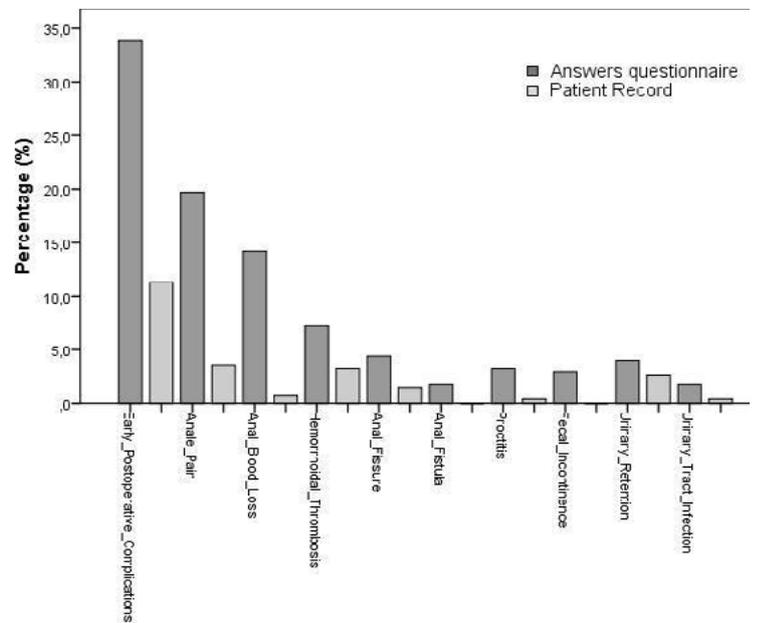


Figure 6 Early Postoperative Complications – answers from the questionnaire compared to patient record.

added named 'residual perianal tags'. Ninety-six out of 152 or 63.2% never complained about residual perianal tags, on the other hand 24/152 or 15.8% did on a daily basis.

We analyzed the difference between initial and postoperative symptoms by using the Wilcoxon signed rank test ($p < 0.05$). Symptoms are all significantly less apparent after HAL or HALRAR surgery except for fecal incontinence ($p = 0.505$), which has a similar prevalence pre- and postoperatively (Figure 7).

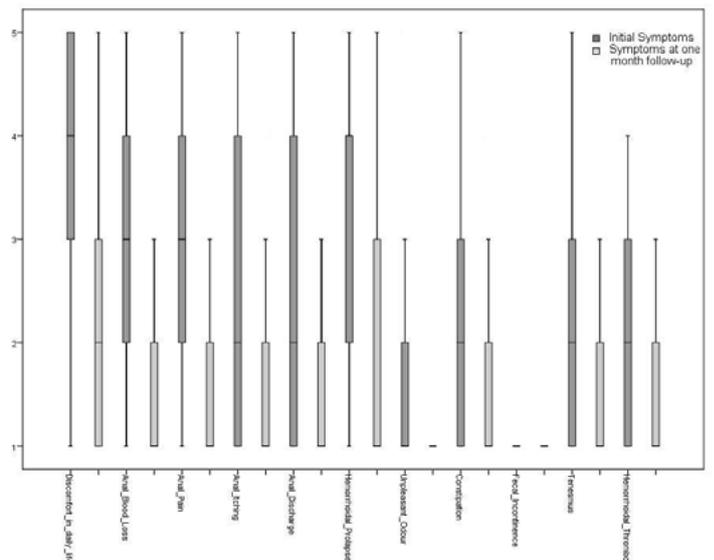


Figure 7 Comparison between initial symptomatology and symptoms one month after surgery.

We also analyzed the data grouped by grade of haemorrhoidal disease. As reported earlier, grade II haemorrhoidal disease was most and grade IV haemorrhoidal disease least abundant. The Wilcoxon signed rank test shows a significant difference in almost all symptoms ($p < 0.05$) in grade I to grade III. Grade IV haemorrhoidal disease could not show any significant difference in symptomatology pre- and postoperatively. There are only 11 patients who presented with grade IV haemorrhoidal disease. There is no significant difference in 'unpleasant odour' and 'haemorrhoidal thrombosis' in grade III haemorrhoidal disease. There is no significant difference in 'tenesmus' in grade I haemorrhoidal disease.

After their initial HAL or HALRAR surgery, 71/161 or 44.1%, needed additional treatment for their haemorrhoidal disease. Most of them medical treatment, 36/153 or 23.5%, followed by redo HAL or HALRAR surgery, 22/153 or 14.4%, conservative treatment, 15/153 or 9.8%, haemorrhoidectomy, 14/153 or 9.2%, photocoagulation, 8/153 or 5.2%, rubber band ligation, 7/153 or 4.6%, or sclerotherapy, 4/153 or 2.6%. There was no significant difference in the need for additional treatment after HAL or HALRAR surgery ($p < 0.05$), using the Mann-Whitney U test for two independent samples.

Satisfaction after HAL or HALRAR was also evaluated. The majority of patients, 102/161 or 84.4%, are neutral, satisfied or very satisfied with the results after surgery. 25/161 or 15.5% are displeased or not satisfied.

When asked if they would consider the same surgery when necessary, the majority said yes, 118/160 or 73.8%. Twenty-eight out of 160 or 17.5%, 'don't know' if they would choose the same surgery and 14/160 or 8.8% would not consider it. There is no significant difference in satisfaction after surgery or redo surgery between HAL or HALRAR. This was evaluated by using the Chi-square test ($p < 0.05$) (Figures 8 & 9).

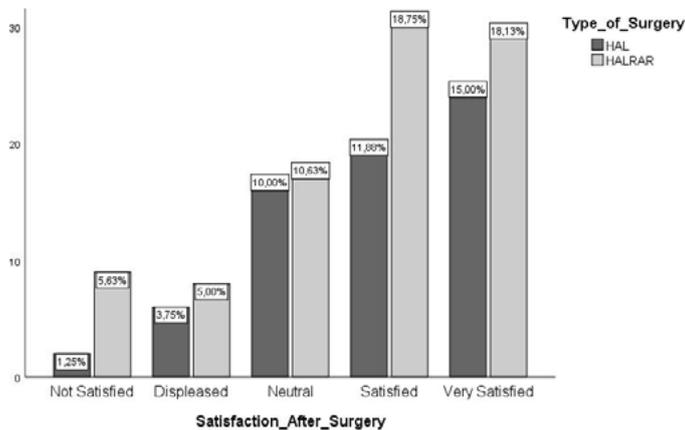


Figure 8 Satisfaction after surgery results compared between HAL and HALRAR.

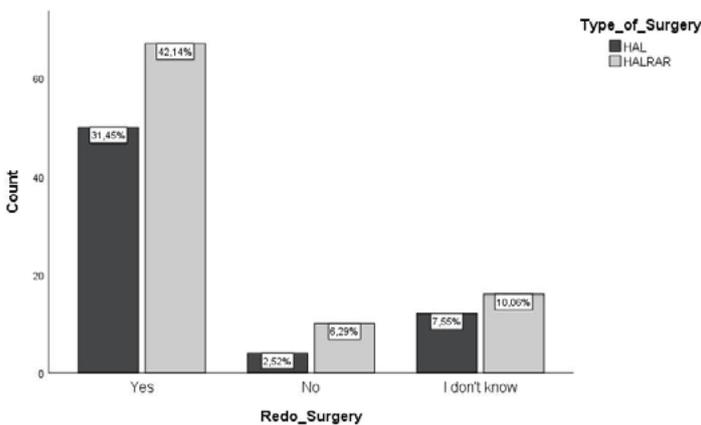


Figure 9 Answers to the question: If necessary, would you choose the HALRAR surgery again? Comparison between HAL and HALRAR.

Discussion

Since the introduction of Haemorrhoidal Artery Ligation by Morinaga et al. [22] and Recto-Anal Repair by Dal Monte et al. [27], many papers have been published to evaluate and compare this procedure to surgical haemorrhoidectomy [24, 47-49], stapled haemorrhoidopexy [50] and rubber band ligation [51]. Until today none of the above are considered superior although the surgical haemorrhoidectomy

was considered the golden standard and the results of the HALRAR procedure are based on short/medium term follow-up only.

In literature, the advantages of the HALRAR procedure are absence of anal wounds with decreased postoperative pain compared to conventional haemorrhoidectomy and stapled haemorrhoidopexy [24, 47-50], but not compared to rubber band ligation [51]. There is a faster return to work/daily activities, and the possibility to organize it as a day case procedure. The anal anatomy and physiology is preserved, resulting in near absent risk of fecal incontinence. There are no reports of serious complications and the procedure can be considered safe. Finally it can be performed under general, spinal or even local anesthesia, which makes it appealing when general anesthesia is contra-indicated.

However, reported disadvantages are recurrent prolapse after HAL, compared to surgical haemorrhoidectomy [24, 47-49] and stapled haemorrhoidopexy [50]. The recurrence ameliorated after the introduction of RAR but remains high. Additionally, Lehur et al. [52] published an economic evaluation regarding cost-effectiveness, comparing HALRAR and stapled haemorrhoidopexy. HALRAR is more expensive compared to surgical haemorrhoidectomy and stapled haemorrhoidopexy, which is only partially compensated by the shorter 'sick leave' of patients. Their conclusion states that HALRAR can be cost-effective when performed in under 35 minutes, with outpatients. This statement makes our mean operating time, 44.5 minutes, almost 10 minutes too long.

This study was performed to address the need for long term results after HAL and HALRAR and presents outcomes after 10-year follow-up. The decision to perform the HALRAR procedure was mainly based on the patients' symptoms and clinical findings because symptomatology is often poorly correlated to the grade of haemorrhoidal disease [5], and literature states that haemorrhoidal artery ligation can be successfully performed in all stages of haemorrhoidal disease [30]. Most of the patients had haemorrhoidal disease grade II, but patients with grade I-IV haemorrhoidal disease were treated.

During the 10-year period, the applied sutures and mucopexies were well kept in the operative report, as is visualized in the pie chart (Figure 2 & 3). The odd-numbered clock positions are highlighted and account for 60.17% of all sutures. The remaining 39.83% are applied in even-numbered clock positions with the highest frequency at 2 and 4 o'clock. Although determining the position of the sutures is subjective, over 1/3rd of the terminal branches would be missed if it were not for the Doppler-assistance, conform the literature [31]. So we consider the Doppler-assistance as a necessary tool to correctly localize all the terminal branches of the superior rectal artery. On the other hand, we had some trouble to silence the Doppler signal after ligation, which has been reported in literature as well. This could be explained by the statements of Aigner et al. [53] and Schuurman et al. [36], that the Doppler equipment operate at 7-8 MHz, where they can detect deeper rather than superficial arteries that may not directly contribute to the blood supply of the haemorrhoidal piles. These deeper arteries cannot be ligated by suture. Future clinical research in this field should investigate the role of the Doppler-assistance in Haemorrhoidal Artery Ligation.

As for the Recto-Anal Repair, the pie chart also shows a total of 68.33% sutures placed in the odd-numbered positions and the remaining 31.67% in the even-numbered positions. These results are comparable to the distribution of the HAL sutures. This seems logical as the haemorrhoidal piles grow where there is excessive blood flow in a terminal branch of the superior rectal artery.

Postoperative data showed that 74.82% of the procedures could be performed in day clinic. Which is important to attribute to the cost-

effectiveness of the procedure as mentioned above [52].

Postoperative pain was evaluated by the Visual Analog Scale (VAS) pain score and resulted in a wide range of pain perception among patients. Statistical analysis reveals that the level of postoperative pain significantly increased when RAR was added to the HAL procedure (Figure 5). Still a mean VAS score of 5 is rather high as other papers report mean VAS scores of 2.1-3.1 post-procedure [54, 55]. Although, comparing our results to those of Schuurman JP et al. [56], a VAS score between 5-6 is normal on the first postoperative day. The Visual Analog Scale was one of the subjects in the questionnaire, which, for some patients, must be difficult to report correctly ten years after surgery, without a medically trained supervisor present. Another explanation could be that the RAR procedure is continued beneath the dentate line, where pain receptors are present.

Regarding postoperative complications, a striking 33.9% of patients reported they experienced some postoperative complication(s). Most reported are anal pain, anal blood loss and haemorrhoidal thrombosis. Because this number is exceptionally high and the answers from the questionnaire did not match the postoperative information reported in the patient record, this was further investigated. When the results are based solely on the patient record, there were postoperative complications in 11.3% (in literature 6-17% [22-24, 51]). Anal pain remains the most abundant, followed by haemorrhoidal thrombosis and urinary retention (Figure 6).

We believe that the liberal documentation of postoperative complications by the patients are biased because of a response rate of 56.6%, a non-validated questionnaire and the lack of medical supervision while filling out the questionnaire. Furthermore, some patients were treated more than five years ago, which could make it difficult to correctly remember the postoperative phase. The results from patients records alone are more comparable to previously reported postoperative complications. We presume that, to report a correct postoperative complication rate, a randomized study with long-term follow-up is necessary where postoperative complications are reported by a member of the medical staff.

The majority of patients (85.8%) were seen one month after surgery. In the questionnaire they were asked to formulate their residual complaints after one month. The results are shown in Figure 8. Statistical analysis showed a significant reduction in symptomatology for every symptom, except for fecal incontinence, which had the same prevalence pre- and postoperatively.

As for the recurrence rate, 44.4% of patients reported the need for additional treatment regarding haemorrhoidal disease. 33.3% still needed conservative or medical measures to minimize symptoms. 12.4% got an additional minimally invasive (non-surgical) procedure, i.e. photocoagulation, rubber band ligation, sclerotherapy. In 14.4% redo HAL or HALRAR surgery was performed and in 9.2% a surgical haemorrhoidectomy was necessary. These results are confirming the previously reported concerns about recurrence of the disease, which seems to gradually increase in time [12, 31, 35]. As reported earlier, there was no significant difference in the need for additional treatment after HAL or HALRAR.

When we looked at the satisfaction after surgery, 84.4% of patients were satisfied (very satisfied, satisfied and neutral) after surgery and 73.8% would consider the same surgery if needed. The satisfaction rate is comparable to other studies (82-92%) [9,25,31,32,55]. Only 8.8% would not consider the HALRAR procedure again. Wilkerson et al. [25] reports a similar 10%.

This study had several limitations. It is a single centre, single surgeon, open, non - randomized study, consisting of a non validated

questionnaire, filled out by patients without medical support and no clinical re-evaluation. This leads to considerable bias and confounding factors. It was performed to analyze the first ten years of performing HALRAR in our centre, to evaluate the results and compare them to other published papers regarding this subject and search for ways to improve.

Conclusion

This paper is the first to report long-term results after HALRAR procedures. Our study shows a significant decrease in symptomatology and good patient satisfaction, however it also confirms recently published concerns about high recurrence rates and need for re-interventions. Prospective randomized trials are needed to evaluate long term results compared to other surgical techniques.

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