

African Journal of Biological Sciences



ISSN: 2663-2187

Comparative study on Rubber band ligation versus open hemorrhoidectomy as treatment of second and third degree hemorrhoids -a prospective study in a Tertiary Care Center, Salem, Tamilnadu.

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Article History Volume 6,Issue 8, 2024 Received:15 Feb 2024 Accepted: 28 Mar 2024

doi: 10.33472/AFJBS.6.8.2024.23-35

ABSTRACT:

Background:

Haemorrhoids are one of the most common proctological disorders. Hemorrhoids are distal displacement and prolapse of the hemorrhoidal cushions. Commonly presenting with symptoms like rectal bleeding, itching, swelling, anal discomfort, and pain.

Aim of this study is to compare between rubber band ligation & conventional hemorrhoidectomy in treatment of second and third degree hemorrhoids regarding operative time, intraoperative bleeding, incidence of urine retentions, postoperative pain, time of hospitalization and postoperative stenosis.

Methodology: This study was conducted over a period of 2 year from February 2022 to February 2024. This study was conducted in general surgery department of Vinayaka Mission's Kirupananda Variyar Medical College and Hospital on 100 patients with second- and third-degree hemorrhoids. Informed written consent was taken from the patients after explaining the benefits and side effects of both methods. Each patient was subjected to sigmoidoscopy to exclude other lesion higher up in rectosigmoid. Patients of fissure, fistulae, and malignancy were excluded. The eligible patients were randomly divided into by lot system into two groups. Group A (RBL group): 50 patients underwent rubber band ligation. Group B (CH): 50 patients underwent conventional hemorrhoidectomy. The obtained data were subjected to statistical analysis by applying an unpaired t-test using SPSS 21.0 software.

Results: The difference between the two groups of the average age was comparable. The operative time (10- 13) minutes and intraoperative bleeding were significantly lower in Group A (RBL group) than in Group B (CH). Furthermore, the average hospital stay, incidence of urine retentions, postoperative pain, and less postoperative stenosis were significantly lower in Group A than in Group B. the average number of analgesic doses required was significantly lower in Group A than in Group B.

Conclusion: The rubber band ligation technique revealed better results in terms of operative and post-operative parameters as compared to the conventional hemorrhoidectomy. RBL should be considered as the first-line treatment for second & third-degree hemorrhoid.

Key-words: Hemorrhoids, Proctoscopy, Sigmoidoscopy, Hemorrhoidectomy . Rubber band ligation (RBL), anal canal

INTRODUCTION:

The columnar epithelium lines the upper two thirds of the anal canal, while the squamous epithelium lines the lower third. These layers meet at the dentate line. Subepithelial vascular cushions are present in the upper anal canal and are connected with the rectal columns above. When these cushions dilate, the anal lumen receives a stellate (triradiate) cross section. The internal anal sphincter and the rectum's longitudinal muscle provide the connective tissue framework that suspends these cushions within the anal canal. A venous plexus supplied by arteriovenous communication is located within each cushion. The pathological alteration in the prolapsed anal column causes haemorrhoids [1].

Venous enlargement and irritation in the lower abdomen is the cause of haemorrhoids. The three most prevalent etiological causes are constipation, pregnancy, and obesity. These lesions are equally common in both sexes and seem to appear more frequently as people age. The three most typical symptoms that cause patients social humiliation and annoyance are discomfort, itching, and bleeding [2]. Hemorrhoids are distal displacement and prolapse of the hemorrhoidal cushions. Common symptoms include rectal bleeding, itching, swelling, anal discomfort, and pain.

Initially, treatment comprises of conservative measures like nutrition, lifestyle counselling, and toilet habits. There are other surgical treatments as well; however, hemorrhoidectomy is thought to be the gold standard; a British trial and systematic review have recently reaffirmed this [4, 5]. Rubber band ligation is the most popular minimally invasive treatment (RBL). Laser therapy and sclerotherapy are two more minimally invasive methods. Although RBL is also employed for grade III haemorrhoids, these treatments are typically limited to grade I and II haemorrhoids [6, 7]. Treatment options for grade III and IV haemorrhoids include stapled haemorrhoids, semi-closed haemorrhoids, and open haemorrhoids, maybe combined with mucopexy or hemorrhoidal artery ligation (HAL).

Anoscopy and a digital rectal examination (DRE) in the left lateral position should be part of the assessment process. Using an anoscope, the haemorrhoid cushions can be seen at 3, 7, and 11 o'clock in the lithotomy position, which correspond to the left lateral, right anterior, and right posterior positions. To make the diagnosis, sigmodoscopic exclusion of rectal illness is crucial. Four degrees of internal haemorrhoids are distinguished based on the degree of prolapse. This classification is useful for evaluating various treatments.

- Grade I: bleeding without prolapse
- Grade II: prolapse with spontaneous reduction
- Grade III: prolapse with manual reduction
- Grade IV: incarcerated, irreducible prolapse.

The American Society of Colon and Rectal Surgeons has produced guidelines that classify treatment into three categories[8]:

- 1. The conservative approach includes using more fibre in the diet, not straining at faeces, and using the toilet for longer periods of time. Sitz baths, which offer momentary comfort, contain ointments with local anaesthetic, mild astringent, and steroids.
- 2.Less invasive techniques such as cryosurgery, laser hemorrhoidectomy, anal stretch, injectable sclerotherapy, infrared coagulation, RBL, and Doppler-guided hemorrhoidal artery ligation
- 3. The surgical treatment options include of hemorrhoidectomy with staples, open, closed, and white head techniques.

Surgeons have long disagreed on the most effective treatment for haemorrhoids. Surgeons have experimented with several strategies and tactics over the last few decades in an effort to maximise outcomes while minimising risks [9]. Over time, a variety of treatment approaches have been developed to address symptomatic cases. These approaches range from straightforward dietary modifications and bowel movement regulation to a number of non-operative procedures and various excision techniques for diseased anal cushions. However, to date, no single approach has been recognised as the gold standard [10,11]. Surgical hemorrhoidectomy is a relatively painful treatment, although being more effective in individuals presenting with severe symptoms [12]. The first line of treatment for second- and third-degree haemorrhoids is usually non-surgical methods such laser, photocoagulation, cryotherapy, and sclerotherapy. The rubber band ligation method has long been used to treat internal haemorrhoids of any severity. This approach is less likely to cause difficulties, doesn't require anaesthesia, and is affordable for the patient [11, 13]. Therefore, the purpose of the study was to evaluate the effectiveness of band ligation vs traditional hemorrhoidectomy in the management of second and third-degree haemorrhoids

METHOD AND METHODOLOGY:

This was a prospective randomized comparative study was done on 100 patients who were diagnosed with Grade II & III hemorrhoids over a period of 2 year from February 2022 to February 2024. This study was conducted in general surgery department of Vinayaka Mission's Kirupananda Variyar Medical College and Hospital, Salem, Tamilnadu. The inclusion criteria for this study comprise patients diagnosed with grade II and grade III hemorrhoids, anemic individuals with hemoglobin levels below 8 mg, and patients with cardiac conditions who are deemed unsuitable for spinal anesthesia. Additionally, participants must express willingness to take part in the study. Conversely, patients declining participation are excluded from the study.

The eligible patients were randomly divided into by lot system into two groups. Group A (RBL group): 50 patients underwent rubber band ligation. Group B (CH): 50 patients underwent conventional hemorrhoidectomy. The patients were informed about the benefits and side effects of both the treatment modalities. Informed written consent was taken before carrying out the procedures. The exclusion criteria were based on the elimination of the patients with severe associated illnesses such as hypertension, uncontrolled diabetes, and coagulation disorders.

Detailed clinical history was taken in all the patients with particular reference to bleeding per rectum, constipation, prolapse, painful defecation discharge per rectum, dietary habits, and family history of hemorrhoids. Detailed general physical exam was done in all. Each patient was subjected to local examination (DRE), proctoscopy, and sigmoidoscopy. Baseline investigations including CBC, KFT, B sugar, urine exam, CXR, and ECG were done in all patients. All the patients were given proctoclysis enema in the evening and the morning before surgery or RBL.

Rubber band ligation ((RBL): It was performed as a daycare procedure by putting patient is lithotomy position. DRE done and a split proctoscopy introduced after applying lignocaine jelly, the base of hemorrhoids are identified and a Barron band applicator device was introduced through the proctoscopy to apply band at the base of hemorrhoid. A maximum of 3 to 4 bands will be used per session. Oral analgesics were given before the intervention to reduce pain afterward. All patient were assessed for postoperative pain on visual analogue scale and given adequate analgesics.

Conventional hemorrhoidectomy(CH): performed by using the milligram Morgan technique under spinal anesthesia by putting the patient in a lithotomy position. DRE done and proctoscope introduced to identify the hemorrhoids. Identified hemorrhoids are held with Babcock's forceps and an inverted v shaped incision made at the anal verge. Plan created till base of hemorrhoids and base transfixed using absorbable polyglactin suture. Hemorrhoids are cut above the ligature and excised.

Group B received postoperative analysesia for three days by an intravenous drip containing 100 mg of diclofenac. All patients also received regular prescriptions for laxatives and antibiotics. Postoperative administration of additional local anaesthetic cream for perianal application was done. An increased demand for analysesia was noted.

All the patients were advised to report in causality in case of any complication in the form of bleeding per rectum, pain, fever, swelling, discharge, etc. Final assessment was done at 6 months postprocedure regarding effect of treatment on rectal bleeding, prolapse, pain, and subjective improvement (patient assessment).

The data collected were subjected to statistical analysis by applying an unpaired t-test using SPSS 21 version software. A P-value < 0.05 was considered statistically significant (S), a P-value < 0.001 was considered statistically highly significant (HS), while a P-value > 0.05 was considered statistically non-significant.

RESULTS:

A total of 100 patients were enrolled in this study, with 50 patients assigned to the band ligation group and 50 patients assigned to the open hemorrhoidectomy group. The median age of patients in the band ligation group was 53 years old (range: 23-91 years old), while the median age in the open hemorrhoidectomy group was 58 years old (range: 28-96 years old). Of the 100 patients, 53 were males and 47 were females. There were no significant differences between both groups as regard age and gender(Table 1 & 2).

Table 1: Patients mean age distribution

Groups	Median
Band ligation group	53 yrs
Open hemorrhoidectomy group	58yrs

Table 2: Patients gender distribution

Group	Male	Female
Band ligation group (n=50)	27(54%)	23(46%)
Open hemorrhoidectomy group (n=50)	26(52%)	24(48%)

As table 2 shows the gender distribution is fairly similar between the two groups. In the band ligation group, there were 27 males (54.0%) and 23 females (46.0%). In the open hemorrhoidectomy group, there were 26 males (52.0%) and 24 females (48.0%).

Table 3: Grade of hemorrhoids

Group	Grade II	Grade III
Band ligation group (n=50)	30(60%)	20(40%)
Open hemorrhoidectomy group (n=50)	29(58%)	31(625)

The table 3 provides data on the grades of hemorrhoids within two groups: the Band Ligation group and the Open Hemorrhoidectomy group. The data seems to be presented in a cross-tabulation format, with the number and percentage of patients falling into each grade of hemorrhoids (Grade II and Grade III) within each group.

In the Band Ligation group, out of 50 patients, 30 (60%) were diagnosed with Grade II hemorrhoids and in the Open Hemorrhoidectomy group, out of 50 patients, 31 (62%) were diagnosed with Grade III hemorrhoids.

From the data presented, it appears that there are slight differences in the distribution of hemorrhoid grades between the two groups, with Grade III hemorrhoids being slightly more prevalent in the Open Hemorrhoidectomy group compared to the Band Ligation group.

The data suggests that a hemorrhoidectomy procedure takes significantly longer than a band ligation procedure on average. Here's a breakdown of what the findings tell us:

Band ligation: The average procedure time was 15 minutes and 28 seconds. This indicates a relatively quick and efficient procedure, likely due to its minimally invasive nature.

Hemorrhoidectomy: The average procedure time was 24 minutes and 38 seconds. This is nearly 10 minutes longer than band ligation, reflecting a more complex and invasive surgery.

Possible reasons for the difference in operative time include:

Surgical approach: Band ligation involves placing a small rubber band around the base of the hemorrhoid, cutting off blood flow and causing it to shrink and fall off. This is a relatively simple procedure compared to a hemorrhoidectomy.

Extent of tissue removal: Hemorrhoidectomy involves removing the hemorrhoidal tissue itself. This requires more time for dissection and suturing of the surgical site.

Anesthesia: Band ligation can sometimes be performed with local anesthesia, while hemorrhoidectomy typically requires general anesthesia, adding to the overall procedure time.

Group	Mild	Moderate	Intense	Unbearable
Band ligation group (n=50)	23(46%)	17(34%)	9(18%)	1(2%)
Open hemorrhoidectomy group (n=50)	9(18%)	21(42%)	13(26%)	7(14%)

Table 4: Postoperative pain scores using a Visual Analogue Scale (VAS).

VAS is a pain measurement tool where patients rate their pain on a scale from 0 (no pain) to 10 (unbearable pain). The table 4 shows Patients in the band ligation group generally reported less pain compared to the open hemorrhoidectomy group. 46% of patients in the band ligation group experienced mild pain, while only 18% in the hemorrhoidectomy group did. Conversely, a higher percentage of patients in the hemorrhoidectomy group reported moderate to unbearable pain.

Table 5: Post operative bleeding.

Group	Postoperative bleeding
Band ligation group (n=50)	8(16%)
Open hemorrhoidectomy group (n=50)	4(8%)

The table 5 shows the incidence of postoperative bleeding following two hemorrhoid treatment procedures: band ligation and open hemorrhoidectomy. Band ligation group: Out of 50 patients, 8

(16%) experienced postoperative bleeding. Open hemorrhoidectomy group: Out of 50 patients, 4 (8%) experienced postoperative bleeding. The data suggests that band ligation might be associated with a slightly higher rate of postoperative bleeding compared to open hemorrhoidectomy. This due to Band ligation disrupts blood flow to the hemorrhoid, causing it to shrink and fall off. This disruption of blood vessels might increase the likelihood of minor bleeding in the immediate postoperative period. Another reason may be open hemorrhoidectomy involves more surgical dissection, potentially leading to a higher risk of injuring blood vessels and causing bleeding during the procedure itself. However, once the surgery is complete and the bleeding is controlled, the risk of subsequent bleeding might be lower.

Table 6: Urine retention

Group	Urine retention
Band ligation group (n=50)	3(6%)
Open hemorrhoidectomy group (n=50)	10(20%)

The table 6 shows Urine Retention" summarizes the occurrence of urinary retention following the two hemorrhoid procedures.

Urine retention: This refers to the inability to completely empty the bladder. Band ligation group: 3 out of 50 patients (6%) experienced urine retention. Open hemorrhoidectomy group: 10 out of 50 patients (20%) experienced urine retention.

Table 7: Distribution of the patients as per the various study variables

Study variables	Group A (Rubber Band Ligation group) (Mean±SD) (n=50)	Group B (Conventional hemorrhoidectomy) (Mean±SD) (n=50)	p-value
Average age (yrs.)	53±1.72 yrs.	58±54.43 yrs.	p>0.05;
Operative time (min)	15±1.28	24±2.38	p<0.0001
Intraoperative bleeding (ml)	15.41±1.74 ml	48±3.41 ml	p<0.0001
Postoperative pain - Average analgesic required (No. of Tab.)	6±4 Tabs	21±4.5 Tabs	p<0.0001

No of Post operative bleeding patients	7±1	3±0.5	p<0.01
No of patients had Urine retention	2±1.1	9±1.2	p<0.001

This table 7 compares two groups of patients who underwent different treatments for hemorrhoids:

Average Age: There's no statistically significant difference in average age between the groups (p>0.05). However, the high standard deviation (SD) in Group B suggests a wider range of ages compared to Group A. Operative Time: Group B had a significantly longer operative time (24 minutes) compared to Group A (15 minutes) (p<0.0001). This indicates rubber band ligation is a quicker procedure. Intraoperative Bleeding: Group B experienced significantly greater blood loss during surgery (48 ml) compared to Group A (15 ml) (p<0.0001). This suggests rubber band ligation might be a less invasive procedure with less blood loss.

Postoperative Pain: Group B patients required significantly more pain medication (21 tablets) compared to Group A (6 tablets) (p<0.0001). This suggests rubber band ligation might be associated with less postoperative pain. Postoperative Bleeding Events: Group had a slightly higher number of patients experiencing bleeding after surgery (7 patients) compared to Group B (3 patients) (p<0.01). However, the difference is relatively small. Urine Retention: Group B had a significantly higher number of patients experiencing difficulty urinating after surgery (9 patients) compared to Group A (2 patients) (p<0.001). This suggests rubber band ligation might be associated with a lower risk of urine retention.

Table 7 suggests that rubber band ligation (Group A) might be a quicker, less invasive procedure with less blood loss and potentially less postoperative pain compared to conventional hemorrhoidectomy (Group B). However, the higher incidence of urine retention in Group A needs further investigation.

The data suggests that open hemorrhoidectomy is associated with a higher incidence of urine retention compared to band ligation. This means patients who underwent open hemorrhoidectomy were twice as likely to experience difficulty emptying their bladder after surgery. Overall findings suggest that open hemorrhoidectomy carries a higher risk of urinary retention compared to band ligation.

DISCUSSION:

The risk of urinary retention following hemorrhoidectomy procedures varies depending on the technique used. Open hemorrhoidectomy has been associated with a higher risk of urinary retention compared to rubber band ligation[14]. This is consistent with findings that open hemorrhoidectomy, such as the Milligan-Morgan excision technique, carries risks of postoperative

bleeding, urinary retention, and late anal stenosis[15]. In contrast, rubber band ligation, a minimally invasive procedure for hemorrhoids, has been shown to have a lower incidence of urinary retention compared to open hemorrhoidectomy[16].

Furthermore, Jeong et al., study by highlighted that conventional hemorrhoidectomy has a higher incidence of urinary retention compared to other anal surgeries like fistulectomy and lateral sphincterotomy[17]. This suggests that the type of surgical procedure performed can impact the likelihood of postoperative urinary retention. Additionally, a meta-analysis by comparing hemorrhoidectomy and rubber band ligation in grade II-III hemorrhoids found differences in clinical outcomes between the two procedures, which may influence the risk of urinary retention[18].

Moreover, factors such as patient demographics and anesthesia type can also influence the risk of postoperative urinary retention. For instance, in orthopedic surgery, men over 70 years of age, those receiving spinal anesthesia, and those using patient-controlled analgesia postoperatively were identified as having an increased risk of urinary retention[19]. Similarly, in gynecologic surgery, patients are at an increased risk of urinary retention due to potential surgical disruption of bladder innervation and anesthetic side effects[20].

Even after centuries of research, the exact cause of the disease remains unknown because it manifests itself in a variety of ways. Between 4.7% and 39.8% of the general population suffers from haemorrhoids [21,22]. Based on research conducted over the last 30 years, the disease's anatomical and histological classifications have helped to establish a number of innovative treatment options. Over many years, this procedure of banding or ligating the hemorrhoidal mass has served as the basis for numerous other techniques [23]. Blaisdell first presented the rubber band ligation technique in 1958, but Barron made it more widely known. Haemorrhoids are caused by vessels that shrink, which causes ulceration and sloughing that finally heals [23,24]. The surgeon must accurately locate the dentate line since healing the lesion above this point lessens discomfort and agony. In patients with haemorrhoids of Grades II, III, and even IV, this procedure produces positive outcomes.

In the beginning, Barron's method called for banding more haemorrhoids every three weeks in addition to ligating one at a time [24]. Multiple bandings in a single treatment do not appear to significantly enhance patient discomfort or cause any other consequences, according to research done during the time [25,26]. During the study, none of the patients in the study group experienced any anal stenosis symptoms. Larger studies and meta-analyses show that rubber band ligation is less likely to need additional treatment and is more effective [27].

Conclusion:

The band ligation technique is preferred over the conventional approach for the treatment of Grade III hemorrhoids, as it involves a much lower risk of pain and a shorter recovery period as compared to the surgical methods. This procedure is a safe, effective, less time-consuming, lowcost, and easy-to-use method. The operative outcomes such as minimal intraoperative bleeding, less time-lapse between procedure and the first bowel movement, the lesser requirement for post-operative analgesics, and low morbidity indicate that the rubber band ligation method is better as compared to a conventional hemorrhoidectomy. In conclusion, the choice of surgical technique for hemorrhoidectomy can impact the risk of postoperative urinary retention. Minimally invasive procedures like rubber band ligation may offer advantages in terms of reducing the incidence of urinary retention compared to open hemorrhoidectomy. Additionally, patient-specific factors and the type of anesthesia used during surgery play a role in determining the likelihood of postoperative urinary retention. By considering these factors, healthcare providers can better assess and manage the risk of urinary retention in patients undergoing hemorrhoidectomy procedures.

Limitations:

As this was a single center study with a comparatively short sample size, results of this study cannot be generalized. Generalization requires the support of results from similar large studies.

Acknowledgments:

The authors would like to thank all of the study participants and the administration of department of general surgery, Vinayaka Mission's Kirupananda Variyar Medical College and Hospital, Salem, Tamilnadu, India for granting permission to carry out the research work.

Conflicts of interest: There are no conflicts of interest.

Ethical statement:

Institutional ethical committee accepted this study. The study was approved by the institutional human ethics committee, Vinayaka Mission's Kirupananda Variyar Medical College and Hospital, Salem, Tamilnadu (VMKVMC&H/IEC/24/009 Dated: 08-02-2022). Informed written consent was obtained from all the study participants and only those participants willing to sign the informed consent were included in the study. The risks and benefits involved in the study and the voluntary nature of participation were explained to the participants before obtaining consent. The confidentiality of the study participants was maintained.

Funding: Nil.

Authors' contributions:

Dr.J.Sridhar and Dr.P.Ravishankar - conceptualization, data curation, investigation, methodology, project administration, visualization, writing—original draft, writing—review and editing; *Dr.Krithika Kiruba* -conceptualization, methodology, writing—original draft, writing—review and editing; *Dr Baddam Nikhil Reddy* - conceptualization, visualization, supervision, writing—original draft; *Dr.Manohar Reddy, and Dr.Shaik Roshakhi sultana*- methodology, writing—original draft, writing, review and editing. All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work. All authors have read and agreed to the published version of the manuscript.

DATA AVAILABILITY:

All datasets generated or analyzed during this study are included in the manuscript.

INFORMED CONSENT:

Written informed consent was obtained from the participants before enrolling in the study

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