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Randomized controlled study between suture ligation and radio wave ablation and suture ligation of grade III symptomatic hemorrhoidal disease  
Gupta · Heda · Kalaskar  

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Abstract

Purpose: Suture ligation is a simple method to curb the hemorrhoids. The present study was conducted to determine the usefulness of suture ligation in third-degree hemorrhoids and to compare it with author’s procedure of suture ligation and radio wave ablation and suture ligation of grade III symptomatic hemorrhoidal disease.
ligation coupled with hemorrhoidal ablation through radiowave.

**Materials and methods:** One hundred and twenty-four consecutive patients with grade III hemorrhoids requiring surgery were randomized into two groups. Half of them were treated by suture ligation, while the remaining patients underwent a radiowave ablation of hemorrhoids using an Ellman radiowave generator followed by suture ligation. A blinded observer evaluated postoperative pain scores, amount of analgesics consumed, and complications encountered. He also assessed recurrence of hemorrhoids after 1 year.

**Results:** The postoperative pain score was significantly higher in the suture ligation group (3.4 ± 0.2 vs. 2.2 ± 0.1, *p* < 0.005). The mean total analgesic dose and duration of pain control using analgesics were greater and longer for suture ligation group than radiowave group (29 ± 4 vs. 23 ± 3 tablets, and 15 ± 3 days vs. 12 ± 4 days, respectively; *p* < 0.001). Complications were seen more frequently in radiowave group (22% vs. 18%). At 1 year follow-up, the recurrence of hemorrhoids was more significant with the suture ligation group (five patients vs. one patient, *p* < 0.05).

**Conclusion:** Suture ligation of hemorrhoids is a simple, cost-effective, and a convenient modality in treating third-degree hemorrhoids. The efficacy and postoperative comfort is further enhanced if the hemorrhoids are ablated with radiowave prior to ligating them.

| Keywords separated by '-' | Hemorrhoids - Ligation - Radio wave - Suture - Pain |

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33  Foot note information
Randomized controlled study between suture ligation and radio wave ablation and suture ligation of grade III symptomatic hemorrhoidal disease

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Keywords Hemorrhoids · Ligation · Radio wave · Suture · Pain

Introduction

Hemorrhoids are the most common problem that the colorectal surgeon encounters. In the general hospital of our city, 27% of patients attending the colorectal outpatient department were diagnosed as patients of hemorrhoids, highest amongst the total number of patients. The hemorrhoids may cause different complaints such as bleeding, prolapse, pain, discharge, and itching.

Numerous modalities and techniques have been developed to treat symptomatic hemorrhoids. First- and second-degree hemorrhoids can be treated conveniently on an outpatient basis by means of sclerotherapy, photocoagulation, cryotherapy, and rubber band ligation, while third-degree or severely prolapsed or circumferential hemorrhoids can be treated using the Milligan–Morgan hemorrhoidectomy or stapled hemorrhoidectomy. In India, hemorrhoid surgery is carried out in a wide range of hospitals, mostly peripheral ones, where the sophisticated equipments and specific training to carry out hemorrhoid surgery with modern methods like the stapled hemorrhoidopexy and transanal hemorrhoidal dearterialization are not available. The cost of these procedures is another constrain.

A simpler technique for the reduction of the size of the hemorrhoids with control of bleeding and prolapse is the ligation of hemorrhoids under vision. This technique is based on the fact that the hemorrhoidal vessels have a...
grade III hemorrhoidal disease, which could be treated by a dusky white color (blanching) indicated satisfactory ablation. Care was taken to avoid charring of rectal mucosa.

**Materials and methods**

A total of 128 patients were randomized over a 15-month period at Fine Morning Hospital and Research Center, Nagpur. Inclusion began in July 2003 and ended in May 2005.

**Study design** Patients were randomized to undergo either the suture ligation technique (SL) or the radio wave ablation and suture ligation (RSL). Two groups were constituted: a SL group (64 patients) and a RSL group (64 patients). After patients had given their written consent, they were informed of the result of randomization. Two patients from each group rejected the result of the randomization. The protocol was approved by an ethics committee. The main inclusion criterion was symptomatic grade III hemorrhoidal disease, which could be treated by either surgical technique. Exclusion criteria were acute hemorrhoidal episodes with thrombosis, prior hemorrhoidectomy, and intercurrent anal pathology (i.e., fistula and/or fissure). The primary end point was a comparison of the two groups with respect to postoperative pain. Secondary end points included outcome after a minimum of 12 months.

**Surgical procedures** Under short-term general anesthesia or under a caudal block with the patient in a lithotomy position, the three skin tags corresponding to three principle sites of hemorrhoidal cushions, namely 3, 7, and 11 o’clock position were held with artery forceps and retracted out to visualize the hemorrhoids (Fig. 1).

The hemorrhoidal cushion was then sutured using a half-circle 45-mm round needle and absorbable 1–0 chromic catgut (no. 4246 Ethicon, UK). Firstly, a transfixing suture was applied at the hemorrhoidal pedicle. A new sutting began caudally in a continuous locking manner and included the mucosa, submucosal, and half the depth of the anal sphincter muscles to end just 5 mm below the dentate line (Fig. 2).

In the other group of the patients, prior to suture ligation, the hemorrhoids were ablated using radio waves. An Ellman dual-frequency 4-MHz radio wave generator (Ellman International, Oceanside, New York) was used for ablation of hemorrhoids. The unit is provided with a handle to which different electrodes could be attached to meet the requirements of the procedure. A ball electrode meant for coagulation was used in this procedure. Beginning at the pedicle, the complete hemorrhoidal mass was evenly coagulated by gradually rotating the ball electrode. The output power intensity of the radiofrequency generator was so adjusted as to produce shrinkage of the tissues without creating a char. The gradual change of hemorrhoidal mass to a dusky white color (blanching) indicated satisfactory ablation. Care was taken to avoid charring of rectal mucosa.

**Fig. 1** Hemorrhoids held with artery forceps showing hemorrhoids at 11 and 3 o’clock positions
or the anoderm by targeting the hemorrhoids alone (Fig. 3).

This was followed by suture ligation of the complete hemorrhoidal mass in the same manner as described above (Fig. 4).

All the hemorrhoids were dealt with in a similar fashion in one session. Any secondary hemorrhoids found were also treated on the same line as the primary hemorrhoids. A single surgeon (PJG) performed all the procedure. The patients were assessed after 6 h of the procedure and were discharged if they were found comfortable with regard to pain and reporting no difficulty in passing urine.

Postoperative analgesia Pain was assessed using a visual analog scale (VAS) in which 0 corresponds to “no pain” and 10 to “maximum pain.” All patients were prescribed with a combination of Tramadol hydrochloride and Paracetamol for post-procedure analgesia. They were instructed to take two tablets per day or more as required and to attend the casualty department whenever the pain was intolerable or any significant complications developed, especially spontaneous bleeding or perianal sepsis. An information sheet pertaining to the trial together with a VAS pain scoring assessment chart (0–10) were given to the patient for completion.

They were then given a day 30 clinic follow-up appointment. At follow-up, a single physician, blinded to the type of procedure performed, assessed pain and complications. The complications assessed were bleeding (after each defecation or needing admission for blood transfusion) and painful defecation at all times post-procedure until the follow-up date, tenesmus, urinary retention, perianal sepsis, and residual hemorrhoids. Pain assessments focused on the amount of pain experienced immediately, 24 h, 7, 14, and 30 days following the procedure. Patients were also required to disclose the total number of analgesic tablets consumed during the month after the procedures. Patient monitoring included a series of clinical examinations by the surgeon: prior to the operation, then after 4 weeks, and finally after a minimum of 12 months.

Statistical analysis

The two different groups were compared using a chi-squared test for qualitative variables and a parametric t test to compare means for quantitative variables. Performance and safety were evaluated using a chi-squared test. The software used was SPSS version 11.0 for Windows. Some of the results are expressed in the text as a mean standard deviation (minimum; maximum).

Results

A total of 124 patients (62 for each group) were included, randomized, and received treatment. There were no significant differences between the two groups with respect to sex, weight, history, or risk factors. The mean age in the SL group was higher than in the RSL group (52 versus...
47 years; \( p<0.003 \). The mean numbers of hemorrhoids treated were equally distributed at 3.02 in the SL group and 3.06 in the RSL group (\( p=0.435 \)).

Surgical time was shorter for group SL (8±0 min; range, 6–15 min) than for group RSL (12±1 min; range, 10–18 min, \( p<0.001 \)). The mean total analgesic dose and duration of pain control using analgesics were greater and longer for suture ligation group than radio wave group (29±4 vs. 23±3 tablets, and 15±3 days vs. 12±4 days, respectively; \( p<0.001 \)).

The total admission period was shorter for RSL group than for SL group patients (12±4 vs. 14±5 h; \( p<0.19 \)).

The demographics and clinical characteristics of the patients in pre- and postoperative periods are given in Table 1.

Mean grades of the visual analogue pain scale were greater in suture ligation group than in radio wave suture ligation group (3.4±0.2 vs. 2.2±0.1, \( p<0.005 \)).

Complications were divided into minor complications like constipation, urinary retention, pruritus, and anal skin tags and major complications like tenesmus, prolapse, and recurrence. Complications were identified in 13 (22%) RSL group patients and 11 (18%) SL group patients, but this difference was not statistically significant (Table 2).

The follow-up at 12 months postoperatively showed recurrence of hemorrhoids in five patients from suture ligation group and one patient from radio wave suture ligation group (\( p<0.05 \)).

Anatomic assessment at 1-year physical examination revealed fibrosis of the hemorrhoidal cushions in the RSL group, while the cushions were looking shrunken and segmented in the suture ligation group. The two techniques were effective against both skin tags and external hemorrhoids. This was normal in 92% of patients in SL group, the corresponding figures for the RSL group being 95%. At 1-year follow-up, no patients exhibited functional impairments, i.e., severe defecation difficulty or incontinence.

### Discussion

Hemorrhoids consist of degenerative connective tissue and vessels and are generally known as the outward manifestation of a downward displacement of the anal cushions [8].

A large number of treatments for symptomatic hemorrhoids have been proposed, and as the understanding of their etiology as well as technology improves, the numbers of treatment techniques are bound to increase. However, it is important to bear in mind that the hemorrhoidal syndrome is a benign disease and its management should be as minimally aggressive as possible.

Traditional treatment methods for hemorrhoids fall into two broad groups: less invasive techniques including rubber band ligation, which tend to produce minimal pain, and the more radical techniques like excisional hemorrhoidectomy, which are inherently more painful. Numerous studies have proven that rubber band ligation is best suited for grade I and grade II hemorrhoids [9, 10], while when used in grade III hemorrhoids, return of symptoms in the long term affects more than half of patients treated [11].

The procedure described by us can be termed as a minimally aggressive, as it does not involve any mucosal or anodermal excision and is very simple to perform as it follows a very basic surgical maneuver, i.e., suturing. Suture ligation has been previously performed as a single procedure and in combination with other surgical techniques for treating early and advanced grades of hemorrhoids [12–14].

Doppler-guided hemorrhoidal dearterialization is another technique, which is getting popular being less invasive as compared to conventional or stapled hemorrhoidectomy. However, as more cases of recurrence have been reported with this procedure in long term and especially in grade III hemorrhoids, the procedure is being modified by applying...
running suture with three to five stitches which is termed as ‘suture anopexy’ [15] ‘mucopexy’ [16], or ‘recto-anal repair’. This running suture application is almost identical to our procedure of suture ligation, which also needs an expensive Doppler-guided hemorrhoidal ligator.

The suture ligation of the hemorrhoidal pedicle and adjacent branches efficiently enable obliteration of profuse hemorrhoidal vessels [17]. The corpus cavernosum recti, constituting the hemorrhoidal pedicle, are located in the anorectal submucosa above the dentate line approximately 3–5 cm from the anal verge [18]. This suture ligation procedure includes underlying anal sphincter muscles, an advantage of which is the prevention of mucosal prolapse and remnant hemorrhoids originating from the aberrant corpus cavernosum recti piercing the rectal wall [19]. It has been suggested that the source of remnant or secondary hemorrhoids is from the unobliterated vessels, which are present on the posterolateral position of the rectal wall [20].

Suture ligation ably takes care of these vessels too. As suture ligation is confined to the protruding hemorrhoids only and as it does not attempt any excision, it preserves the sensitive anoderm and the rectal mucosa [21]. Apart from fixing the prolapsing hemorrhoids to the underlying structure to prevent prolapse, the treatment should also be aimed at removal of the dilated submucous anal venous plexus and induce fibrosis of the hemorrhoidal tissue which will attach and draw in the hemorrhoidal cushion, obliterating the submucous space and eventually preventing recurrence of bleeding and relapse of the hemorrhoids [22]. The procedure of radio wave ablation precisely serves this purpose [23–25].

In the present study, it was observed that the postoperative pain as well as the overall consumption of analgesics was significantly lower in the radio wave group, as ablation of hemorrhoids causes destruction of the sensory nerves within the hemorrhoidal cushion and thereby reduces pain during defecation [26]. The histological picture of the hemorrhoidal cushion after radio wave ablation shows few distinct features like thrombosis of the blood vessels, increase collagen deposits, and fibrosis in the inter-vascular stroma with increased lymphoplasmocystic infiltration, which results in firm tethering of the hemorrhoidal tissue to the underlying structures.

The recurrence rate was significantly higher in suture ligation group when compared with the radio wave ablation group, as hemorrhoidal ablation ensures firmer fixation of the hemorrhoidal tissue to the underlying structures due to fibrosis and cicatrisation, and this combined procedure leads to complete obliteration of the submucosal and transmural hemorrhoidal vessels [27].

The radio wave device has an ability to accurately deliver specific amounts of radiofrequency energy at relatively low temperatures (38–70°C) to the target tissue, so that the heat dissipation and damage to adjacent tissue structures are minimized. Limiting tissue desiccation spares surrounding mucosa and underlying muscle and blood vessels, thus reducing edema, pain, and risk of hemorrhage. Laser and electrocautery techniques, by contrast, deliver temperatures around 750°C to 900°C, which are far in excess of therapeutic needs, since tissue protein denatures at 47°C, thus extending collateral damage to surrounding structures [28–30].

### Conclusion

In conclusion, suture ligation of hemorrhoids is a simple, cost-effective, and convenient modality in treating third-degree hemorrhoids because it does not need any expensive instrumentation like the staplers or the Doppler-guided hemorrhoidal artery ligator. The efficacy and postoperative comfort is further enhanced if the hemorrhoids are ablated with radio wave prior to ligating them. Comparison between these two methods in our study has proven that radio wave ablation followed by suture ligation of hemorrhoids is superior to suture ligation alone for the treatment of third-degree hemorrhoids in terms of pain tolerance, amount of analgesics consumed, and in recurrence at the end of 1 year.

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