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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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32	Abstract	<b>Purpose:</b> 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 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 ( $3.4 \pm 0.2$  vs.  $2.2 \pm 0.1$ ,  $p < 0.005$ ). The mean total analgesic dose and duration of pain control using analgesics were greater and longer for suture ligation group than radiowave group ( $29 \pm 4$  vs.  $23 \pm 3$  tablets, and  $15 \pm 3$  days vs.  $12 \pm 4$  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.

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33	Keywords separated by ' - '	Hemorrhoids - Ligation - Radio wave - Suture - Pain
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4 **Randomized controlled study between suture ligation**  
5 **and radio wave ablation and suture ligation of grade III**  
6 **symptomatic hemorrhoidal disease**

7 **P. J. Gupta · P. S. Heda · S. Kalaskar**

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12 **Abstract**

13 *Purpose* Suture ligation is a simple method to curb the  
14 hemorrhoids. The present study was conducted to deter-  
15 mine the usefulness of suture ligation in third-degree  
16 hemorrhoids and to compare it with author’s procedure of  
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fort is further enhanced if the hemorrhoids are ablated with 42  
radiowave prior to ligating them. 43

**Keywords** Hemorrhoids · Ligation · Radio wave · Suture · 44  
Pain 45

**Introduction** 46

Hemorrhoids are the most common problem that the 47  
colorectal surgeon encounters. In the general hospital of 48  
our city, 27% of patients attending the colorectal outpatient 49  
department were diagnosed as patients of hemorrhoids, 50  
highest amongst the total number of patients. The hemor- 51  
rhoids may cause different complaints such as bleeding, 52  
prolapse, pain, discharge, and itching. 53

Numerous modalities and techniques have been devel- 54  
oped to treat symptomatic hemorrhoids. First- and second- 55  
degree hemorrhoids can be treated conveniently on an 56  
outpatient basis by means of sclerotherapy, photocoagula- 57  
tion, cryotherapy, and rubber band ligation, while third- 58  
degree or severely prolapsed or circumferential hemorrhoids 59  
can be treated using the Milligan–Morgan hemorrhoidec- 60  
tomy or stapled hemorrhoidectomy. 61

In India, hemorrhoid surgery is carried out in a wide 62  
range of hospitals, mostly peripheral ones, where the 63  
sophisticated equipments and specific training to carry out 64  
hemorrhoid surgery with modern methods like the stapled 65  
hemorrhoidopexy and transanal hemorrhoidal dearterializa- 66  
tion are not available. The cost of these procedures is 67  
another constrain. 68

A simpler technique for the reduction of the size of the 69  
hemorrhoids with control of bleeding and prolapse is the 70  
ligation of hemorrhoids under vision. This technique is 71  
based on the fact that the hemorrhoidal vessels have a 72

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73 constant anatomical location [1]. Usually, they penetrate the  
 74 hemorrhoid pile in the base. A stitch that is put on the base  
 75 of the hemorrhoid cushion is able to diminish significantly  
 76 the blood flow to the hemorrhoidal plexus. Thus, the  
 77 consecutive ligation in this manner of all the visual  
 78 hemorrhoidal cushions will arrest the bleeding and control  
 79 prolapse as well. This procedure of ligation of hemorrhoidal  
 80 cushion has a long history and is termed with various  
 81 nomenclatures like ‘pile suture’ [2], ‘obliterative suture  
 82 technique’ [3], ‘ligation and anopexy’ [4], and ‘suture  
 83 ligation’ [5], etc.

84 We further modified this technique by exposing the  
 85 hemorrhoids to radio waves before their suture ligation.  
 86 Radio wave ablation is a technique that results in immediate  
 87 reduction of blood flow of the tissue under focus of these  
 88 waves and induces healing by way of cicatrisation [6].  
 89 These waves ablate the tissue by converting radio waves  
 90 into heat. The alternating current passes down from an un-  
 91 insulated electrode tip to the targeted tissues and generates  
 92 changes in the direction of ions within the tissue fluid. This  
 93 creates ionic agitation and frictional heating. This process  
 94 drives out the extra and intracellular water from the tissue  
 95 and ultimately destroys the tissue by coagulative necrosis.  
 96 The result of this ablation is fibrosis and fixation of the  
 97 ablated tissues [7].

98 The purpose of this study was to evaluate the adequacy  
 99 of resolution of hemorrhoidal prolapse with these two  
 100 methods and also to examine the influence of radio wave on  
 101 hemorrhoidal cushions before their suture ligation and  
 102 comparing the results with patients undergoing the conven-  
 103 tional suture ligation of hemorrhoids in terms of postoper-  
 104 ative pain, postoperative complications, effectiveness in  
 105 symptom control, and recurrence rate through a blinded,  
 106 prospective, controlled, and randomized trial.

107 **Materials and methods**

108 A total of 128 patients were randomized over a 15-month  
 109 period at Fine Morning Hospital and Research Center,  
 110 Nagpur. Inclusion began in July 2003 and ended in May  
 111 2005.

112 *Study design* Patients were randomized to undergo either  
 113 the suture ligation technique (SL) or the radio wave  
 114 ablation and suture ligation (RSL). Two groups were  
 115 constituted: a SL group (64 patients) and a RSL group  
 116 (64 patients). After patients had given their written consent,  
 117 they were informed of the result of randomization. Two  
 118 patients from each group rejected the result of the  
 119 randomization. The protocol was approved by an ethics  
 120 committee. The main inclusion criterion was symptomatic  
 121 grade III hemorrhoidal disease, which could be treated by

either surgical technique. Exclusion criteria were acute 122  
 hemorrhoidal episodes with thrombosis, prior hemorrhoi- 123  
 dectomy, and intercurrent anal pathology (i.e., fistula and/ 124  
 or fissure). The primary end point was a comparison of 125  
 the two groups with respect to postoperative pain. Second- 126  
 ary end points included outcome after a minimum of 127  
 12 months. 128

*Surgical procedures* Under short-term general anesthesia or 129  
 under a caudal block with the patient in a lithotomy 130  
 position, the three skin tags corresponding to three principle 131  
 sites of hemorrhoidal cushions, namely 3, 7, and 11 o'clock 132  
 position were held with artery forceps and retracted out to 133  
 visualize the hemorrhoids (Fig. 1). 134

The hemorrhoidal cushion was then sutured using a half- 135  
 circle 45-mm round needle and absorbable 1–0 chromic 136  
 catgut (no. 4246 Ethicon, UK). Firstly, a transfixing suture 137  
 was applied at the hemorrhoidal pedicle. A new suturing 138  
 began caudally in a continuous locking manner and 139  
 included the mucosa, submucosal, and half the depth of 140  
 the anal sphincter muscles to end just 5 mm below the 141  
 dentate line (Fig. 2). 142

In the other group of the patients, prior to suture ligation, 143  
 the hemorrhoids were ablated using radio waves. An Ellman 144  
 dual-frequency 4-MHz radio wave generator (Ellman Inter- 145  
 national, Oceanside, New York) was used for ablation of 146  
 hemorrhoids. The unit is provided with a handle to which 147  
 different electrodes could be attached to meet the require- 148  
 ments of the procedure. A ball electrode meant for 149  
 coagulation was used in this procedure. Beginning at the 150  
 pedicle, the complete hemorrhoidal mass was evenly 151  
 coagulated by gradually rotating the ball electrode. The 152  
 output power intensity of the radiofrequency generator was 153  
 so adjusted as to produce shrinkage of the tissues without 154  
 creating a char. The gradual change of hemorrhoidal mass to 155  
 a dusky white color (blanching) indicated satisfactory 156  
 ablation. Care was taken to avoid charring of rectal mucosa 157



Fig. 1 Hemorrhoids held with artery forceps showing hemorrhoids at 11 and 3 o'clock positions



**Fig. 2** Hemorrhoids after suture ligation



**Fig. 4** Hemorrhoids after radio wave ablation and suture ligation

158 or the anoderm by targeting the hemorrhoids alone (Fig. 3).  
 159 This was followed by suture ligation of the complete  
 160 hemorrhoidal mass in the same manner as described above  
 161 (Fig. 4).

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

169 *Postoperative analgesia* Pain was assessed using a visual  
 170 analog scale (VAS) in which 0 corresponds to “no pain”  
 171 and 10 to “maximum pain.” All patients were prescribed  
 172 with a combination of Tramadol hydrochloride and Para-  
 173 cetamol for post-procedure analgesia. They were instructed  
 174 to take two tablets per day or more as required and to attend  
 175 the casualty department whenever the pain was intolerable  
 176 or any significant complications developed, especially  
 177 spontaneous bleeding or perianal sepsis. An information  
 178 sheet pertaining to the trial together with a VAS pain



**Fig. 3** Hemorrhoids after radio wave ablation

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

211 47 years;  $p < 0.003$ ). The mean numbers of hemorrhoids  
 212 treated were equally distributed at 3.02 in the SL group and  
 213 3.06 in the RSL group ( $p = 0.435$ ).

214 Surgical time was shorter for group SL ( $8 \pm 0$  min; range, 6–  
 215 15 min) than for group RSL ( $12 \pm 1$  min; range, 10–18 min,  
 216  $p < 0.001$ ). The mean total analgesic dose and duration of  
 217 pain control using analgesics were greater and longer for  
 218 suture ligation group than radio wave group ( $29 \pm 4$  vs.  $23 \pm 3$   
 219 tablets, and  $15 \pm 3$  days vs.  $12 \pm 4$  days, respectively;  $p < 0.001$ ).  
 220 The total admission period was shorter for RSL group than  
 221 for SL group patients ( $12 \pm 4$  vs.  $14 \pm 5$  h;  $p < 0.19$ ).

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

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

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

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

237 Anatomic assessment at 1-year physical examination  
 238 revealed fibrosis of the hemorrhoidal cushions in the RSL  
 239 group, while the cushions were looking shrunken and  
 240 segmented in the suture ligation group. The two techniques  
 241 were effective against both skin tags and external hemor-  
 242 rhoids. This was normal in 92% of patients in SL group, the  
 243 corresponding figures for the RSL group being 95%. At

t1.1 **Table 1** Demographics and clinical characteristics of the patients

t1.2		Suture ligation group	Radio wave ablation and suture ligation group	P value
t1.3	No. of patients	62	62	
t1.4	Male /female ratio	38:24	36:26	0.231
t1.5	Preoperative symptoms			
t1.6	Bleeding	48	51	0.674
t1.7	Pain	32	29	0.153
t1.8	Pruritus	11	14	0.461
t1.9	Constipation	27	24	0.743
t1.10	Tenesmus	18	16	0.153
t1.11	Continence disturbances	9	8	0.679
t1.12	Postoperative symptoms after 4 weeks			
t1.13	Bleeding	4	2	0.398
t1.14	Pain	3	3	0.192
t1.15	Pruritus	2	5	0.743
t1.16	Constipation	11	13	0.246
t1.17	Tenesmus	4	1	0.113
t1.18	Continence disturbances	4	3	0.582

**Table 2** Postoperative complications

Minor complications	Suture ligation group	Radio wave ablation group	
Perianal thrombosis	2	1	t2.3
Constipation	0	2	t2.4
Urinary retention	1	4	t2.5
Pruritus ani	1	3	t2.6
Skin tags	2	1	t2.7
Tenesmus	2	1	t2.8
Mucosal prolapse	30	1	t2.9
Recurrence after 1 year	5	1	t2.10
Continence disturbances	3	2	t2.11

1-year follow-up, no patients exhibited functional impair- 244  
 245 ments, i.e., severe defecation difficulty or incontinence.

**Discussion** 246

Hemorrhoids consist of degenerative connective tissue and 247  
 248 vessels and are generally known as the outward manifes-  
 249 tation of a downward displacement of the anal cushions [8].  
 250 A large number of treatments for symptomatic hemorrhoids  
 251 have been proposed, and as the understanding of their  
 252 etiology as well as technology improves, the numbers of  
 253 treatment techniques are bound to increase. However, it is  
 254 important to bear in mind that the hemorrhoidal syndrome  
 255 is a benign disease and its management should be as  
 256 minimally aggressive as possible.

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

266 The procedure described by us can be termed as a  
 267 minimally aggressive, as it does not involve any mucosal or  
 268 anodermal excision and is very simple to perform as it  
 269 follows a very basic surgical maneuver, i.e., suturing.  
 270 Suture ligation has been previously performed as a single  
 271 procedure and in combination with other surgical techni-  
 272 ques for treating early and advanced grades of hemorrhoids  
 273 [12–14].

274 Doppler-guided hemorrhoidal dearterialization is another  
 275 technique, which is getting popular being less invasive as  
 276 compared to conventional or stapled hemorrhoidectomy.  
 277 However, as more cases of recurrence have been reported  
 278 with this procedure in long term and especially in grade III  
 279 hemorrhoids, the procedure is being modified by applying a

280 running suture with three to five stitches which is termed as  
 281 'suture anopexy' [15] 'mucopexy' [16], or 'recto-anal  
 282 repair'. This running suture application is almost identical  
 283 to our procedure of suture ligation, but which also needs an  
 284 expensive Doppler-guided hemorrhoidal ligator.

285 The suture ligation of the hemorrhoidal pedicle and  
 286 adjacent branches efficiently enable obliteration of profuse  
 287 hemorrhoidal vessels [17]. The corpus cavernosum recti,  
 288 constituting the hemorrhoidal pedicle, are located in the  
 289 anorectal submucosa above the dentate line approximately  
 290 3–5 cm from the anal verge [18]. This suture ligation  
 291 procedure includes underlying anal sphincter muscles, an  
 292 advantage of which is the prevention of mucosal prolapse  
 293 and remnant hemorrhoids originating from the aberrant  
 294 corpus cavernosum recti piercing the rectal wall [19]. It has  
 295 been suggested that the source of remnant or secondary  
 296 hemorrhoids is from the unobliterated vessels, which are  
 297 present on the posterolateral position of the rectal wall [20].  
 298 Suture ligation ably takes care of these vessels too. As  
 299 suture ligation is confined to the protruding hemorrhoids  
 300 only and as it does not attempt any excision, it preserves the  
 301 sensitive anoderm and the rectal mucosa [21].

302 Apart from fixing the prolapsing hemorrhoids to the  
 303 underlying structure to prevent prolapse, the treatment  
 304 should also be aimed at removal of the dilated submucosa  
 305 anal venous plexus and induce fibrosis of the hemorrhoidal  
 306 tissue which will attach and draw in the hemorrhoidal  
 307 cushion, obliterating the submucosa space and eventually  
 308 preventing recurrence of bleeding and relapse of the  
 309 hemorrhoids [22]. The procedure of radio wave ablation  
 310 precisely serves this purpose [23–25].

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

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

330 The radio wave device has an ability to accurately  
 331 deliver specific amounts of radiofrequency energy at  
 332 relatively low temperatures (38–70°C) to the target tissue,

so that the heat dissipation and damage to adjacent tissue 333  
 structures are minimized. Limiting tissue desiccation spares 334  
 surrounding mucosa and underlying muscle and blood 335  
 vessels, thus reducing edema, pain, and risk of hemorrhage. 336  
 Laser and electrocautery techniques, by contrast, deliver 337  
 temperatures around 750°C to 900°C, which are far in 338  
 excess of therapeutic needs, since tissue protein denatures 339  
 at 47°C, thus extending collateral damage to surrounding 340  
 structures [28–30]. 341

**Conclusion** 342

In conclusion, suture ligation of hemorrhoids is a simple, 343  
 cost-effective, and convenient modality in treating third- 344  
 degree hemorrhoids because it does not need any expensive 345  
 instrumentation like the staplers or the Doppler-guided 346  
 hemorrhoidal artery ligator. The efficacy and postoperative 347  
 comfort is further enhanced if the hemorrhoids are ablated 348  
 with radio wave prior to ligating them. Comparison 349  
 between these two methods in our study has proven that 350  
 radio wave ablation followed by suture ligation of 351  
 hemorrhoids is superior to suture ligation alone for the 352  
 treatment of third-degree hemorrhoids in terms of pain 353  
 tolerance, amount of analgesia consumed, and in recurrence 354  
 at the end of 1 year. 355

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