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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	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 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.

33	Keywords separated by ' - '	Hemorrhoids - Ligation - Radio wave - Suture - Pain
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34	Foot note information	
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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-
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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 cicatrization [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
 hemorrhoidal episodes with thrombosis, prior hemorrhoi-
 dectomy, 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. Second-
 ary 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 suturing
 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 Inter-
 national, 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 require-
 ments 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

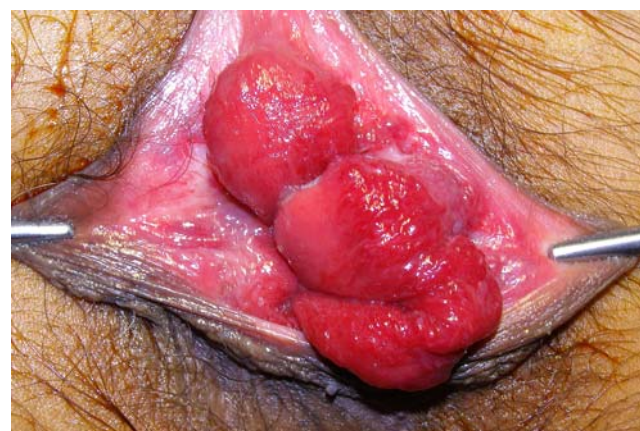


Fig. 1 Hemorrhoids held with artery forceps showing hemorrhoids at 11 and 3 o’clock positions



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 ± 0 min; range, 6–
 215 15 min) than for group RSL (12 ± 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 ± 4 vs. 23 ± 3
 219 tablets, and 15 ± 3 days vs. 12 ± 4 days, respectively; $p < 0.001$).
 220 The total admission period was shorter for RSL group than
 221 for SL group patients (12 ± 4 vs. 14 ± 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 ± 0.2 vs. 2.2 ± 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 ments, i.e., severe defecation difficulty or incontinence. 245

Discussion 246

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

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

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

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

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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