



## Original Report

# Treatment of Rectal Mucosal Prolapse with Radiofrequency Ablation and Plication - A New Surgical Technique

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## ABSTRACT

**Background:** *This study was designed to assess the outcome of using a new technique of mucosal ablation using a radiofrequency device followed by its plication for rectal mucosal prolapse and to compare its results with the conventional ligature and excision procedure.*

**Materials and Methods:** *The procedure of radiofrequency ablation and mucosal plication (RAMP) is described. A Ellman radiofrequency generator was used for the procedure. Out of the 46 patients with rectal mucosal prolapse, 24 patients were randomized to undergo ligature and excision procedure (LEP) and 22 were operated with RAMP. The operating time, amount of pain (VAS scale), postoperative analgesic requirement, time to return to work, wound healing period and postoperative complications were documented.*

**Results:** *Radiofrequency ablation and mucosal plication procedure on average resulted in short operation time (9 vs. 32 minutes,  $p < 0.05$ ), shorter hospitalization (16 vs. 42 hours,  $p < 0.05$ ) significantly less postoperative pain, fewer cumulative requests for analgesia by the patients (21 vs. 54 tablets,  $p < 0.05$ ), earlier return to work (7 vs. 18 days,  $p < 0.05$ ) and faster wound healing (14 vs. 35 days,  $p < 0.05$ ). The complication rate was 9% with RAMP group and 29% with LEP group.*

**Conclusion:** *The procedure of radiofrequency ablation and plication of mucosa shows promising results in patients with rectal mucosal prolapse. Being safe, effective, and a swift technique, it can be proposed as an improved alternative to conventional surgical procedure.*

**Keywords:** *Rectal mucosal prolapse, plication, radiofrequency ablation, ligature and excision, pain.*

## Introduction

External rectal mucosal prolapse (intermucosal prolapse) is defined as a circumferential descent of ano-rectal mucosa through the anus. It differs from the complete rectal prolapse in the sense that in complete rectal prolapse, the entire thickness of the rectal wall is extruded and there is gross disruption of the anal sphincters. It also differs from the third or fourth degree hemorrhoids where there is a segmental prolapse of the hemorrhoidal tissues namely at 3, 7 and 11 o'clock positions.

Contrary to traditional teachings, rectal mucosal prolapse is not a disease of young children alone, but it occurs at other ages of adult life quite frequently<sup>1</sup>.

The symptoms produced by partial rectal mucosal prolapse are quite identical to the symptoms of advanced hemorrhoidal disease including pain, bleeding, mucus discharge, and pruritus. The diagnosis can be confirmed by ano-rectal examination, where a ring of mucosa is seen projecting 2-4 cms beyond the skin of the perianal

region, especially when seen immediately after defecation. If the index finger is inserted in to the anal lumen and the protruding ring palpated between finger and thumb, two layers of mucosa could be easily made out. Palpation of anal canal usually reveals a normal sphincter function.

In children, the pathology is usually self-limiting, which responds well to appropriate toilet training, use of laxatives and in exceptional cases with submucosal injection of sclerosant solution<sup>2</sup>. However, in adults, it needs a more definitive treatment to contain the prolapse and its sequel. This includes the traditional extended hemorrhoidectomy by ligature and excision of the prolapsing mucosa<sup>3</sup>. More recently, the stapled transanal excision of the prolapse using the Longo's technique has been used with encouraging results<sup>4</sup>.

While conventional ligature and excision technique carry risks of postoperative bleeding, urinary retention, and late anal stenosis, the convalescence is significantly long and painful after the operation<sup>5</sup>. Stapled mucosectomy is definitely a less painful procedure, but it does not lead to a significant earlier return to work and is fraught with risks of fatal complications and development of new symptoms like persistent pain and fecal urgency in long term.<sup>6,7</sup>

We innovated a procedure combining radiofrequency ablation followed by a circumferential plication of the prolapsing mucosa<sup>8-9</sup> and found it to be a quicker, convenient, less painful and an equally effective procedure for patients with rectal mucosal prolapse. This paper describes the technique of radiofrequency ablation and plication and presents the results of a randomized controlled trial that compared our technique with conventional ligature and excision procedure in patients with rectal mucosal prolapse.

#### **Radiofrequency ablation-**

Radiofrequency is a method of coagulating the tissues using alternate electric current with the same frequency as of the radio waves. In this technique, the tissue is heated by electric resistive heating. During contact with the waves, water in the tissue gets vaporized while resisting the path

of radio waves. The tissue under application of radiofrequency gets coagulated during the process. As the temperature is kept under 1000 C, it causes little charring and carbonization. The vaporization phenomena also result in significant hemostasis.

A radiofrequency generator Ellman Dual Frequency 4 MHz [Ellman International, Oceanside, New York] was used for ablation of the hemorrhoids. The unit is provided with a handle to which different electrodes could be attached. A ball electrode, which is meant for ablation of the tissue, was used in this procedure.

#### **The procedure-**

Patients are operated either under a short-term general anesthesia or under caudal block based on the decision of the anesthetist. The procedure is performed with the patient in a lithotomy position. Holding the anal verge around 3,9 and 12'O clock with the help of straight artery forceps, the ano-rectal mucosa is exposed. To begin with, the complete mucosa projecting at the anal verge is ablated by evenly rotating the ball electrode over it. The gradual change of mucosal mass to dusky white color (blanching) indicates satisfactory ablation. The output power intensity of the radiofrequency generator is adjusted in such a way as to produce shrinkage of the mucosa without creating any char. Care is taken to restrict the ablation process proximal to the dentate line, which helps in minimizing postoperative pain.

Following this maneuver, the complete mucosal mass is over sewn with 1-0 chromic catgut on 45mm atraumatic needle [No. 4246 Ethicon UK]. The needle is inserted deep enough to fix the mucosa and the submucosa to the underlying internal sphincter. The prolapsing mucosa is divided into 4 quadrants. The first quadrant includes the mucosa extending from 3 to 6'O clock, next 6 to 9'O clock and so on. The suturing begins from the left lateral side (3'O clock), which is carried forwards towards 6'O clock in a continuous locking fashion. While reaching at the end of the quadrant, a knot is tied to secure the end.

The complete circumference of the mucosa is plicated in this fashion. The whole procedure takes about 7-10 minutes to perform. [Illustrations 1 to 6]

### **Materials and Methods**

This study was carried out at Procto Clinic Sai Suman Hospital, Solapur, Maharashtra, India from march 2010 to December 2011. In order to assess the advantage, if any, offered by this procedure of radiofrequency ablation and circumferential mucosal plication over the standard ligature and excision of mucosa, a prospective, blinded, and randomized study was performed. Eligible patients had rectal mucosal prolapse that were selected from the outpatient department of surgery or were referred from other centers. Patients were selected with a standard questionnaire for symptom evaluation, complete proctologic physical examination, and sigmoidoscopy. The diagnosis of rectal mucosal prolapse was reconfirmed by examining the patients immediately after an attempt at defecation produced by a glycerine suppository. We excluded patients having associated rectocele, hemorrhoids, sphincter laxity, perineal decent, those who had been operated previously for any anal pathology, and those who scored III or IV on the ASA score of the American Society of Anesthesiologists. Anal manometry was performed before and at 12 months postoperative follow-up.

Randomization was carried out using sealed envelope at the time of admission in the hospital. Patients and researchers were blinded to the treatment strategy. An informed consent was obtained from the patients explaining them the details about the procedure. The study was approved by the national ethical committee. Both the procedures were performed by the author who is having an experience of conducting more than 120 operations of such type.

Preoperative preparation consisted of a fleet enema given in the morning of the surgery. 1 gram of Ceftriaxone sodium was given intravenously at the induction of anesthesia as prophylaxis.

Patients randomized to radiofrequency ablation and mucosal plication [RAMP group] underwent the procedure as described above.

In the other group, ligature and excision procedure [LEP group] was carried out as described by Goligher<sup>1</sup>. The circular prolapse of the mucosa was caught by artery forceps placed in the right anterior, right posterior and left lateral positions respectively. By scissor cuts, the prolapse was then divided into three main portions like primary hemorrhoids with a narrow skin-mucosa bridges intervening between them. Each of these parts were then ligated and excised as in hemorrhoidectomy.

### **Postoperative care-**

Patients were asked to take 20ml of lactulose [Syp Duphalac] at bedtime from the day of operation. Pain was controlled with tablets containing 37.5 mg of tramadol hydrochloride and 325 mg of acetaminophen [Tab Esgipyrin T] two-times daily on demand but never more than 3 per day. Patients were discharged home after the first evacuation and when they found comfortable with bodily movements and pain.

An independent observer, who was not from the operating team, recorded all the data, which included postoperative events and follow-up findings. Patients were controlled with follow-up questionnaire and with clinical examination at 1,2,4, 12 and 54 weeks after operation. Each patient was provided with a diary and he was asked to enter the amount of pain he felt immediately after defecation and then after 6 hours [pain at rest] every day. The pain assessment was to be made using a visual analogue scale from 0 (no pain at all) to 10 (the worst pain ever experienced). Patients were asked to bring this diary on every visit during the first three follow-ups.

Wound healing was observed by parting the buttocks and confirmed with the use of a pediatric anoscope. Epithellization of the wound with no raw area was considered as a completely healed wound. Patients in whom the wounds were not healed at 4- week follow-up were asked to report

every week until a satisfactory wound healing was noticed.

**Statistical analysis-** The data was entered using a database and analyzed using statistical software (Graph pad Software, San Diego, CA). Fisher's exact test was used. A p value of <0.05 was considered statistically significant.

### Results

46 patients of rectal mucosal prolapse were randomized to undergo either the ligature and excision or the radiofrequency ablation and plication procedure. Of these 46 patients, 22 were randomized to radiofrequency ablation with mucosal plication [RAMP] procedure and 24 were assigned to ligature and excision procedure [LEP]. The follow-up protocol was identical in both the groups. Both the groups were homologous for age, gender, and presentation symptoms.

[Table 1]

The hospital stay was significantly less in patients operated by RAMP method than that of the LEP group (16 vs. 42 hours .p<0.05). Patients who had undergone RAMP had the first bowel movement much earlier in comparison to the patients operated by LEP (14 vs. 38 hours<0.05).

The pain during and immediately after defecation was significantly lower in the RAMP group and ranged between 2 and 5 on visual analogue scale, while the patients from LEP group experienced a pain score between 3 and 8 on the similar scale in the first week. The pain score at rest in patients from RAMP group was between 0 and 3 while it was between 2 and 5 in the LEP group in the first week after the procedure. (Figure 1)

The post defecation pain score was between 1 and 2 in the RAMP group, while it was between 2 and

5 in the LEP group at the 2-week follow-up. The pain score at rest was between 0 and 1 in the RAMP group, it was between 1 and 4 in the LEP group. (Figure 2)

While all the patients from the LEP group had pain ranging between 1 and 2, patients from RAMP group were pain free at the 4-week follow-up.

Because of these differences in the post procedure pain, the analgesic requirement was significantly higher in patients from LEP group (A mean of 54 vs. 21 tablets of analgesics, p<0.05).

Return to normal daily activity was quicker for patients in the RAMP group (7 vs. 18 days in LEP group, p<0.05). The wounds healed considerably faster in patients operated by RAMP technique when compared with the wounds after ligature and excision (14 vs. 35 days, p<0.05).

Complications like secondary hemorrhage and wound sepsis were not observed in any of the group. 2 patients from the ligature and excision procedure had incontinence for flatus in the first two weeks. Urinary retention was more frequent in LEP group (3 patients vs. 1 patient in RAMP group). Perianal thrombosis occurred in 1 patient from RAMP group while none had such complication from the LEP group.

At the 12-month follow-up, 2 patients from the LEP group developed narrowing of the anal canal; none of the patient from RAMP group had this complication. No recurrence was reported in either of the groups. Postoperative manometry did not show significant changes compared with preoperative findings.

The comparative data of this study is given in Table 2.

**Table 1-** Patient demographics

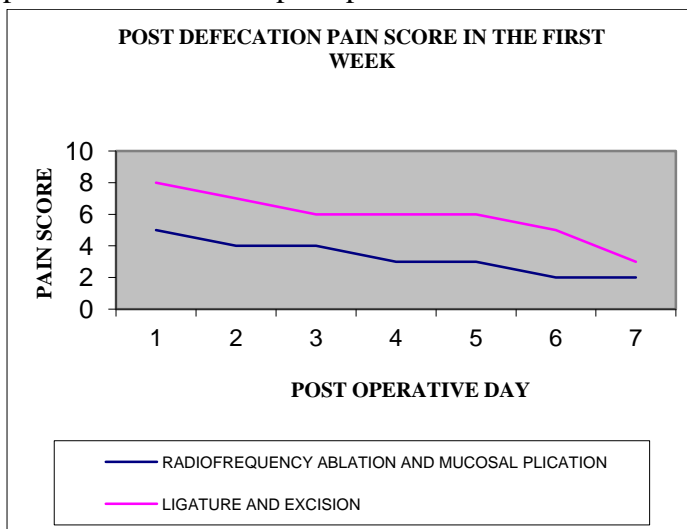
	Ligation and excision group (n=24)	Radiofrequency ablation and mucosal plication group (n=22)
Male: Female	14: 10	13: 9
Mean age (range)	39 years (25-55)	43 years (28-62)
Bleeding (%)	16 (67)	15 (63)
Pain (%)	7(29)	6(27)
Perianal irritation (%)	6(25)	8(36)
Anal pruritus (%)	5(21)	3(14)
Mucus discharge (%)	5(21)	4(18)

**Table 2-** Comparative outcome after ligature and excision procedure [LEP] and radiofrequency ablation & mucosal plication [RAMP] procedure.

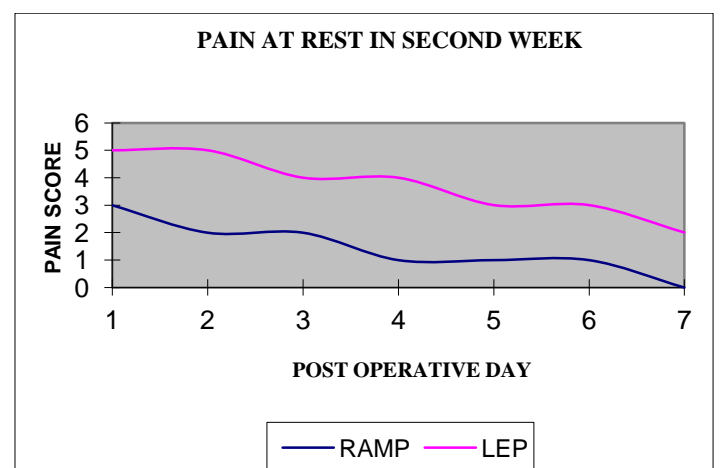
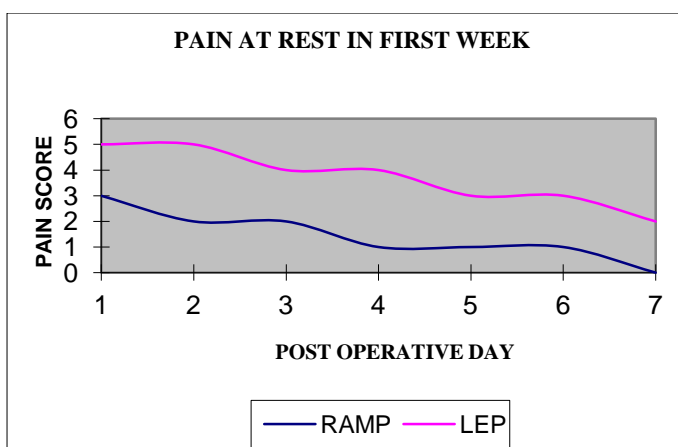
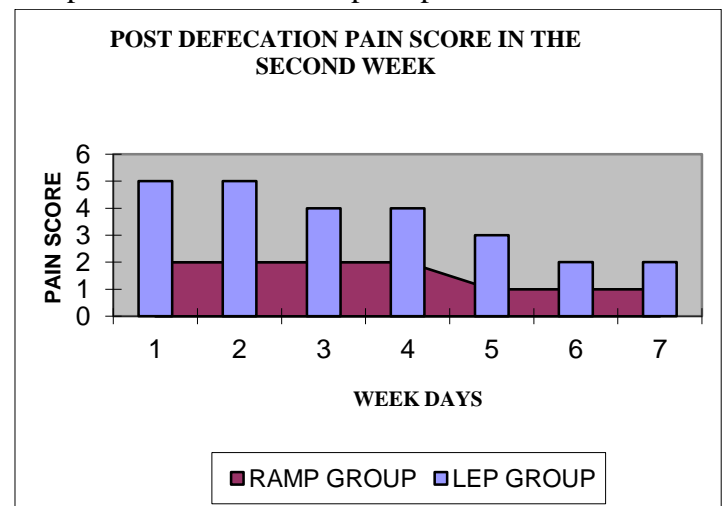
Observations	LEP group	RAMP group	p
Mean operation time (minutes)	32 (5)	9 (3)	<0.05
Hospital stay [Hours] *	42 (7)	16(3)	<0.05
Time to return to work [Days] *	18(5)	7(3)	<0.05
Analgesic requirement [Number of tablets] *	54(4)	21(2)	<0.05
First bowel movement [Hours] *	38(2)	14(3)	<0.05
Wound healing time [Days] *	35	14	<0.05
Urinary retention	3	1	NS
Incontinence for flatus	2	0	NS
Perianal thrombosis	0	1	NS
Anal stenosis	2	0	NS

\*Values are mean (SD) NS- Not significant

**Figure 1-** Comparative pain scores of the two procedures in the 1st postoperative week



**Figure 2-** Comparative pain scores between the two procedures in the 2nd postoperative week.



**Illustration 1-** The classical rectal mucosal prolapse



**Illustration 4-** Mucosal plication with absorbable suture



**Illustration 2-** Radiofrequency ablation of the mucosa



**Illustration 5-** After completion of plication of one quadrant of mucosa



**Illustration 3-** Circumferential mucosal ablation with radiofrequency



**Illustration 6-** After completion of plication of the total circumference of mucosa



**Discussion**

The conventional surgical techniques for rectal mucosal prolapse involve some or other form of excisional maneuver, with their accompanying complications. Radiofrequency ablation and

circumferential mucosal plication is a method that would fix the prolapsing mucosa to its normal position while abolishing its vascular components without resection, thereby minimizing the complications related with excisional procedures<sup>8</sup>. Radiofrequency ablation causes immediate reduction of vascular components of the mucosa followed by its tethering to the underlying tissue with subsequent healing by fibrosis<sup>10</sup>. This is possible because of the cellular molecular dissolution of the tissue cells, which are exposed to the radiofrequency waves<sup>11</sup>. The sensory nerve endings in the treated area are destroyed with radio ablation, minimizing postoperative pain.<sup>12,13</sup> Plication or suturing of the anal cushions is being practiced since long as an alternative treatment of hemorrhoids. Farag<sup>14</sup> had described a 'pile suture' method. He used three interrupted sutures to obliterate the hemorrhoidal mass. Awojobi<sup>15</sup>, while using the Farag's technique; operated twenty-five patients of prolapsing hemorrhoids on outpatient basis to achieve 96% success. Reefing of the prolapsing mucosa by multiple vertical purse-string sutures was found to be quite effective in the patients with partial rectal prolapse<sup>16</sup>. A cauterization-plication operation has been described by El-Sibai with a good outcome<sup>17</sup>. Gaj<sup>18</sup> has described a method using transfixing stitches for correction of prolapsing hemorrhoids. A simultaneous binding and sclerosis with electro coagulation was used by Marquez for the treatment of prolapsing hemorrhoidal mass.<sup>19</sup> Hussain<sup>20</sup> used absorbable sutures to fix the mucosa and submucosa to the underlying sphincter as a part of 'ligation and anopexy' for the treatment of advanced hemorrhoidal disease. A technique of plication of rectal mucosa has been described by Appel.<sup>21</sup> Mucosal plication with anal encircling is a procedure used for rectal prolapse in some parts of the world<sup>22</sup>. On comparison, the benefits of plication of prolapsing mucosa after radiofrequency ablation over the standard ligature and excision techniques are quite encouraging. Our technique requires a significantly less time to

perform in comparison to the ligature and excision.

The ablation and plication achieves two major goals, which are needed to tackle rectal mucosal prolapse; 1) it helps fixation of the redundant mucosa to the underlying internal sphincter, and thus arrests its prolapse,<sup>20,23</sup> 2) it minimizes the blood flow by eliminating the submucosal vascular components.<sup>24</sup>

The control of post surgical pain has always been the cause of concern for the surgeon, and in the procedure of ligature and excision, trauma to the pain sensitive perianal skin and the anal epithelium after excision of the mucosa is quite extensive to cause severe postoperative pain<sup>25</sup>. While in the radiofrequency ablation and plication procedure, the tissue under treatment lies well below the dentate line, thereby reducing the pain quotient significantly. The absence of external wound is another factor, which minimizes the pain.

In recommending this combination technique, a question maybe asked as to whether radiofrequency ablation is the key component of the procedure or is it the suture plication that does the work. Even the need for performing the radiofrequency ablation may be called in question. In our opinion, the combination is complimentary to each other. Though radio ablation takes care of the vascular components of the prolapsing mucosa by way of coagulation and cicatrisation,<sup>26,27</sup> it cannot effectively fix the redundant mucosa back to their positions, but the same is ably anchored by the plication procedure<sup>19,21</sup>. The hybrid procedure ensures a complete control of the mucosal prolapse and its sequel like bleeding and mucus discharge.<sup>28</sup>

Although, very promising results have been described with stapled circumferential mucosectomy<sup>29,30</sup>, the high cost of the procedure and the reported risk of formidable complications have deterred us from using this surgical approach for rectal mucosal prolapse<sup>31</sup>.

### Conclusion

This study shows that both the operations are safe, easy to perform and effective in the treatment of rectal mucosal prolapse. However, the combination of radiofrequency ablation and plication of prolapsing ano-rectal mucosa seems to be preferable as it produces better results over the conventional ligature and excision procedure in terms of postoperative pain; time to return to work, wound healing time and complications. A longer follow-up is required to confirm the true efficacy of this surgical method.

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