



## Randomized controlled study: radiofrequency coagulation and plication versus ligation and excision technique for rectal mucosal prolapse

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### Abstract

**Background:** A novel technique of radiofrequency ablation and plication of the rectal mucosa (RAMP) as a treatment for rectal mucosal prolapse is reported. The results of this technique are compared with the conventional ligation and excision procedure (LEP).

**Methods:** Radiofrequency ablation was performed using an Ellman radiofrequency generator. Patients with rectal mucosal prolapse were randomized to undergo either LEP or RAMP. The intra- and postoperative outcomes and complications were recorded.

**Results:** RAMP on average resulted in reduced operation time, shorter hospitalization, and significantly less postoperative pain. Return to work was earlier and wound healing times were shorter than that of patients in the control group. The complication rates also were significantly shorter (9% in the RAMP group and 29% in the conventional LEP group).

**Conclusion:** The procedure of radiofrequency ablation and plication of rectal mucosa is safe, effective, and swift. It can be proposed as an effective alternative to conventional surgical procedures. © 2006 Excerpta Medica Inc. All rights reserved.

*Keywords:* Rectal mucosal prolapse; Plication; Radiofrequency ablation; Ligation and excision; Pain

Partial rectal mucosal prolapse is defined as a circumferential descent of anorectal mucosa through the anus [1]. The symptoms produced by partial rectal mucosal prolapse are quite identical to the symptoms of advanced hemorrhoidal disease, which include pain, bleeding, mucus discharge, and pruritus. However, it differs from prolapsing hemorrhoids, where there is a segmental prolapse of the hemorrhoidal tissues, namely, at the 3, 7, and 11 o'clock positions [2].

The diagnosis can be confirmed by proctologic examination, where a ring of mucosa is seen projecting 2 to 4 cm beyond the skin of the perianal region, particularly immediately after defecation. Palpation of the anal canal usually reveals normal sphincter function [3].

The conventional approach towards this pathology is extended hemorrhoidectomy by ligation and excision (LEP) of the prolapsing mucosa [4]. Recently, stapled transanal excision of the prolapse using Longo's technique has been used with encouraging results [5].

The conventional LEP technique carries risks of postoperative bleeding, urinary retention, and late anal stenosis, and convalescence is often long and painful [6]. Stapled

mucosectomy is a less painful procedure, but it does not lead to significantly earlier return to work and is fraught with risks of fatal complications and development of new symptoms such as persistent pain and fecal urgency in the long term [7,8].

We innovated a procedure combining radiofrequency ablation followed by circumferential plication of the prolapsing rectal mucosa (RAMP) [9,10]. The current report describes the RAMP technique and presents the results of a randomized controlled trial that compared our technique with conventional LEP in patients with rectal mucosal prolapse.

### Subjects and Methods

A prospective, blinded, and randomized study was performed. The diagnosis of rectal mucosal prolapse was confirmed by examining patients immediately after an attempt at defecation produced by a glycerine suppository. We excluded patients who had associated rectocele, hemorrhoids, sphincter laxity, and perineal decent, as well as those who had been operated on previously for any anal pathology and those who had an ASA score of III or IV according to the American Society of Anesthesiologists. Anal manometry

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Fig. 1. The classical rectal mucosal prolapse.



Fig. 3. Circumferential mucosal ablation with radiofrequency.

was performed before surgery and at 12 months postoperative follow-up.

Randomization was performed using a sealed envelope at the time of admission to the hospital. Patients and researchers were blinded to the treatment strategy. Informed consent explaining the details of the procedure was obtained from the patients. The study was approved by the national ethical committee.

Patients were admitted to the hospital on the day of the operation and received a fleet enema before the procedure. One 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 below.

#### *Radiofrequency ablation*

Radiofrequency is a method of coagulating the tissues using alternate electric current with the same frequency as of the radio waves. As the temperature with the device can be kept under 100C, it causes little charring and carbonization as with diathermy. The vaporization phenomena also result in significant hemostasis.

A radiofrequency generator, an Ellman Dual Frequency 4 MHz (Ellman International, Oceanside, NY), was used for

ablation of the mucosa. A ball electrode, which is meant for coagulation of the tissue, was used in this procedure.

#### *The procedure*

Patients were operated on either under short-term general anesthesia or under caudal block based on the decision of the anesthetist. The procedure was performed with the patient in a lithotomy position. Holding the anal verge around the left lateral, right lateral, and anterior midline positions with the help of straight artery forceps, the anorectal mucosa was exposed. First, the complete mucosa projecting at the anal verge was 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 was adjusted in such a way as to produce shrinkage of the mucosa without creating any char. Care was taken to restrict the ablation process proximal to the dentate line, which helped in minimizing postoperative pain.

Following this maneuver, the complete mucosal mass was oversewn with 1-0 chromic catgut on a 45-mm atraumatic needle (No. 4246, Ethicon, Livingston, UK). The needle was inserted deep enough to fix the mucosa and the submucosa to the underlying internal sphincter. The pro-



Fig. 2. Radiofrequency ablation of the mucosa.



Fig. 4. Mucosal plication with absorbable suture.



Fig. 5. After completion of plication of one quadrant of mucosa.

lapsing mucosa was divided into 4 quadrants. The first quadrant included the mucosa extending from the left lateral to posterior midline position, next from the posterior midline to right lateral position, and so on. The suturing beginning from the left lateral side was carried forward towards the posterior midline in a continuous locking fashion. On reaching at the end of the quadrant, a knot was tied to secure the end. The complete circumference of the mucosa was plicated in this fashion (Figs. 1 through 6).

In the other group, the ligature and excision procedure (LEP group) was performed as described by Goligher et al [11]. Each of the 4 quadrants of mucosal circumference was ligated and excised as in hemorrhoidectomy.

#### Postoperative care

Patients were asked to take 20 mL of lactulose (Syp Duphalac; Solvay Pharma, Mumbai, India) 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 Ultraset; Janssen-Cilag, Mumbai, India) 2 times daily on demand but never more than 3 times per day.

An independent observer, who was not from the operat-



Fig. 6. After completion of plication of the total circumference of mucosa.

ing team, recorded all of the data, which included postoperative events and follow-up findings, including continence score. Patients were monitored by follow-up questionnaire and clinical examination at 1, 2, 4, 12, and 54 weeks after operation. Each patient was provided with a diary and asked to enter the amount of pain felt immediately after defecation and then after 6 hours (pain at rest) every day. The pain assessment was made using a 10-cm linear analogue pain scale [12] from 0 (no pain at all) to 10 (the worst pain ever experienced).

Wound healing was observed by parting the buttocks and confirmed by using a pediatric anoscope. Epithelization of the wound without any raw area was considered as a completely healed wound.

One year after the procedure, the patients were examined personally in the office. A rectal digital examination was performed to observe any anal narrowing, and while viewing through an anoscope, the patient was asked to strain to look for any prolapse.

#### Statistical analysis

Power calculations estimated that 20 patients would be needed in each group to detect a difference of 1 SD in mean analgesic requirement with 80% power at the 5% significance level. To prevent losses during follow-up, at least 22 patients were included. Results were expressed as means and ranges. Groups were compared by 95% confidence intervals. Data were entered into a database and analyzed using statistical software (Graphpad Software, San Diego, CA). Continuous variables were compared using the Mann-Whitney *U* test and categorical variables using the chi-square test or Fisher exact test. A *P* value less than .05 was considered statistically significant.

#### Results

Forty-six patients with rectal mucosal prolapse were randomized to undergo either LEP or RAMP. Of these 46 patients, 22 were randomized to the RAMP group and 24 were assigned to the LEP group. The follow-up protocol was identical in both groups. Both groups were homologous for age, gender, and presentation symptoms (Table 1).

Table 1  
Patient demographics

	LEP group (n = 24)	RAMP group (n = 22)
Male:female	14:10	13:9
Mean age (range)	39 y (25–55)	43 y (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)

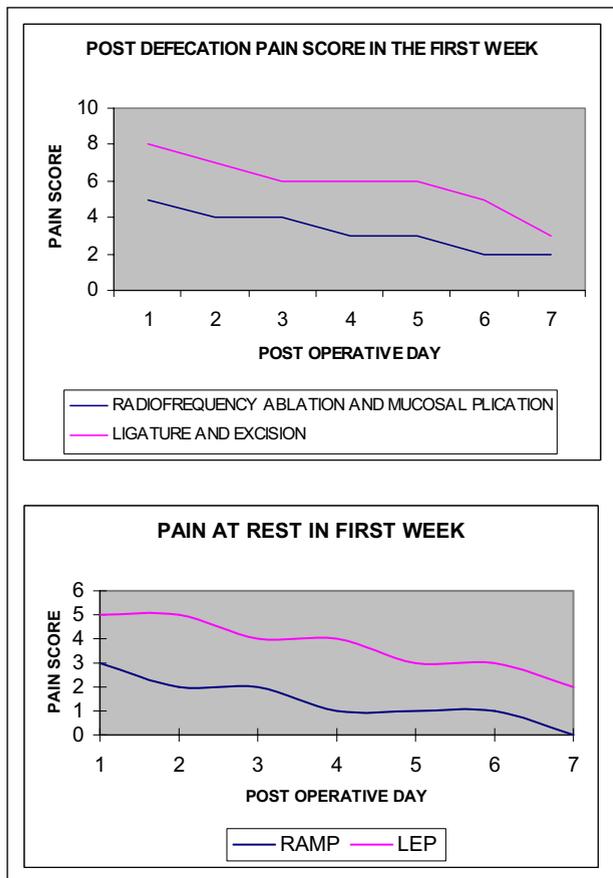


Fig. 7. Comparative pain scores of the 2 procedures in the first postoperative week.

The hospital stay was significantly shorter in patients operated using the RAMP method than those undergoing the LEP (16 vs 42 hours,  $P < .0001$ ). Patients who had undergone RAMP had the first bowel movement much earlier in comparison to the patients operated by LEP (14 vs 38 hours,  $P < .0001$ ).

Pain during and immediately after defecation was significantly lower in the RAMP group and ranged between 2 and 5 on the visual analogue scale, while 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 the 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 (Fig. 7).

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, and between 1 and 4 in the LEP group (Fig. 8).

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

Because of these differences in post-procedure pain, the analgesic requirement was significantly higher in patients

from the LEP group (mean of 54 vs 21 tablets of analgesics,  $P < .0001$ ).

Return to normal daily activity was quicker for patients in the RAMP group (7 vs 18 days in the LEP group,  $P < .0001$ ). The wounds healed considerably faster in patients operated on by the RAMP technique when compared with the wounds after LEP (14 vs 35 days,  $P < .0001$ ).

Complications like secondary hemorrhage and wound sepsis were not observed in either group. No significant difference was observed between the continence scores of the 2 groups either before surgery or at 3 months post-procedure. Two patients from the LEP group had incontinence for flatus in the first 2 weeks. Urinary retention was more frequent in LEP group (3 patients vs 1 patient in RAMP group) and was observed in patients operated on under caudal block. Perianal thrombosis occurred in 1 patient from the RAMP group and in none of the patients in the LEP group.

At the 12-month follow-up, 2 patients from the LEP group and 1 patient from the RAMP group were lost to follow-up. Two patients from the LEP group developed mild anal stenosis and were treated by outpatient digital dilatation. None of the patients from the RAMP group had this complication. No recurrence was reported in either of the groups. No significant difference was observed in ano-rectal manometry between the 2 groups.

The comparative data of this study are listed in Table 2.

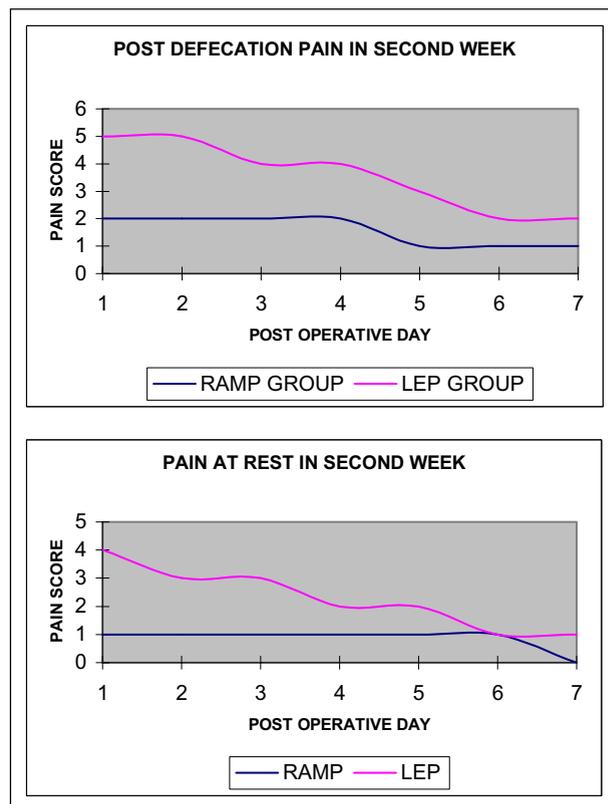


Fig. 8. Comparative pain scores between the 2 procedures in the second postoperative week.

Table 2  
Comparative outcome after LEP and RAMP procedures

Observations	LEP group (n = 24)	RAMP group (n = 22)	P
Mean operation time (min)*	32 (5)	9 (3)	<.0001‡
Hospital stay (h)*	42 (7)	16 (3)	<.0001‡
Time to return to work (d)*	18 (5)	7 (3)	<.0001‡
Analgesic requirement (no. of tablets)*	54 (4)	21 (2)	<.0001‡
First bowel movement (h)*	38 (2)	14 (3)	<.0001§
Wound healing time (d)*	35	14	<.0001§
Urinary retention†	3 (12.5%)	1 (4.5%)	NS¶
Incontinence for flatus†	2 (8.3%)	0	NS¶
Perianal thrombosis†	0	1 (4.5%)	NS¶
Anal stenosis†	2 (8.3%)	0	NS¶

NS = not significant.

\* Values are mean (SD).

† Number of patients.

‡ Mann-Whitney *U* test.

§ Chi-square test.

¶ Fisher exact test.

## Comments

RAMP is a method of fixing the prolapsing mucosa to its normal position while abolishing its vascular components without their resection, which results in minimizing the complications attendant with excisional procedures [6]. Radiofrequency ablation causes immediate reduction of vascular components of the mucosa followed by its tethering to the underlying tissue with subsequent healing by fibrosis [9]. This is possible because of the cellular molecular dissolution of the tissue cells, which are exposed to the radiofrequency waves [10,13]. The sensory nerve endings in the treated area are destroyed with radioablation, minimizing postoperative pain [14,15].

Plication or suturing of the anal cushions has long been in practice as an alternative treatment of hemorrhoids. Farag [15] described a “pile suture” method. He used 3 interrupted sutures to obliterate the hemorrhoidal mass. Awojobi [16], while using Farag’s technique, operated on 25 patients with prolapsing hemorrhoids on an outpatient basis and achieved a 96% success rate. Reefing of the prolapsing mucosa by multiple vertical purse-string sutures was found to be effective in patients with partial rectal prolapse [17]. A cauterization-plication operation was described by El-Sibai and Shafik with a good outcome [18]. Gaj et al [19] described a method using transfixing stitches for correction of prolapsing hemorrhoids. A simultaneous binding and sclerosis with electrocoagulation was used by Marquez et al for the treatment of prolapsing hemorrhoidal masses [20]. Hussein [21] 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 [22].

Mucosal plication with anal encircling is a procedure

used for rectal prolapse in some parts of the world [23]. The radiofrequency ablation and plication achieves 2 major goals needed to address rectal mucosal prolapse: (1) it helps fixation of the redundant mucosa to the underlying internal sphincter, and thus arrests its prolapse [21,24] and (2) it minimizes blood flow by eliminating the submucosal vascular components [25].

The control of postsurgical pain has always been a cause of concern for surgeons, 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 and causes severe postoperative pain [26]. Using RAMP, the tissue under treatment lies well below the dentate line, thereby reducing the pain quotient significantly. The absence of an external wound is another factor that minimizes pain.

While radiofrequency ablation addresses the vascular components of the prolapsing mucosa by way of coagulation and cicatrization [27,28], it is not possible to fix the redundant mucosa back to their positions effectively with mere ablation, which is ably anchored by the plication procedure [20,22,29].

Although promising results have been described with stapled circumferential mucosectomy [30,31] 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 [32].

## Conclusion

This study shows that both procedures are safe, easy to perform, and effective in the treatment of rectal mucosal prolapse. However, the combination of radiofrequency ablation and plication of prolapsing anorectal mucosa seems to be preferable, as it produces better results over conventional LEP. A longer follow-up is required to confirm the true efficacy of this surgical method.

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