

# The role of radiofrequency surgery in the treatment of hemorrhoidal disease

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**Abstract. – Background:** In this article we reported results obtained in our previous studies concerning application of Radiofrequency (RF) in proctology and in particular for hemorrhoids treatment.

**Methods:** We compared Radiofrequency Submucosal Hemorrhoidectomy (RSH) and Conventional Parks' Hemorrhoidectomy (CPH) (group 1), Radiofrequency Open Hemorrhoidectomy (ROH) and Milligan-Morgan Hemorrhoidectomy (MMH) (group 2), Radiofrequency Closed Hemorrhoidectomy (RCH) and Ferguson Hemorrhoidectomy (FH) (group 3), Combined Hemorrhoidal Radiocoagulation (CHR) and Rubber Band Ligation (RBL) (group 4).

In this work primary endpoints were determined as evaluation of the grade of pain felt immediately after the procedure and at the first evacuation, bleeding, operation time, readmission to work, incidence of failures and patient's satisfaction.

**Results:** *Group 1* – In comparison to Parks' technique, use of radiofrequency scalpel reduced mean operation time (61.2 min, range 50-75, vs. 37.4 min, range 30-51;  $p < 0.05$ ), first postoperative day pain score (5.9, range 3-10, vs. 4.0, range 1-10;  $p < 0.05$ ), pain score at first evacuation (5.7, range 2-10, vs 4.2, range 1-8;  $p < 0.05$ ) and pain score on postoperative days (3.6, range 1-9, vs. 2.8, range 1-8;  $p < 0.05$ ). *Group 2* – Results show a substantial similarity between these techniques, however the procedure lasted 7 minutes less with RF scalpel (18.6 min, range 16-21, vs. 25.55 min, range 20-30;  $p < 0.05$ ). *Group 3* – Patients treated with RF showed significant reduction in surgical time (23 min, range 21-31, vs. 33 min, range 24-35;  $p < 0.01$ ), in pain at 1st post-operative day (VAS score  $3.4 \pm 1.3$  vs.  $4.8 \pm 1.0$ ;  $p < 0.05$ ) and at the first evacuation ( $3.4 \pm 1.0$  vs.  $5.0 \pm 0.8$ ;  $p < 0.05$ ). *Group 4* – The study confirmed validity of both the used techniques, however CHR seems to allow a reduction in incidence of failures.

**Conclusions:** Results obtained from radiofrequency surgery compared with those achieved with classic surgery for hemorrhoidal disease show in the majority of cases that radiosurgery facilitates, accelerates and improves surgical procedures.

*Key Words:*

Hemorrhoids, Radiofrequency, Proctology.

## Introduction

Hemorrhoids are considered the most frequent proctologic disease requiring surgery for definite cure. Surgical techniques for hemorrhoids treatment are numerous and still now object of controversial. In order to reduce postoperative complications and discomfort, new techniques have been introduced by modifying standard techniques.

In the recent past we experienced a new instrument, radiofrequency (RF) scalpel, which cuts and coagulates using radio waves. Besides we modified original techniques<sup>1-2</sup>. By now, different proctologic operations have been performed working with RF: RF coagulation, RF ablation, RF open, submucosal and closed hemorrhoidectomy. Results obtained with RF operations were compared to their classic counterparts and the analysis showed that addition of RF facilitates and accelerates surgical procedures with final better results.

In this paper we reported results obtained in our previous studies concerning application of RF in proctology and in particular for hemorrhoids treatment. We compared Radiofrequency Submucosal Hemorrhoidectomy (RSH) and Conventional Parks' Hemorrhoidectomy (CPH) (*group 1*), Radiofrequency Open Hemorrhoidectomy (ROH) and Milligan-Morgan Hemorrhoidectomy (MMH) (*group 2*), Radiofrequency Closed Hemorrhoidectomy (RCH) and Ferguson Hemorrhoidectomy (FH) (*group 3*), Combined Hemorrhoidal Radiocoagulation (CHR) and Rubber Band Ligation (RBL) (*group 4*).

## Patients and Methods

Patients were randomized following the CONSORT criteria<sup>3</sup>.

Before enrollment, all patients underwent a thorough proctologic visit with an accurate retosigmoidoscopy to exclude associated or previous proctological diseases. Pregnant women and people in therapy with anticoagulants and painkillers were excluded to not influence final results.

Patients of *group 1-3* affected by grade IV hemorrhoids who presented to Department of Surgical Sciences of Tor Vergata University of Rome were included in the study. Pre-operative medication consisted in enemas applied four to five hours before the procedure. Metronidazole (400 mg I.V.) and Ceftriaxone (2 g I.V.) were used for antibiotic prophylaxis.

Patients of *group 4* with grade II hemorrhoids were selected and studied.

No special preparation or diet before procedure was required, only mild laxative (30 ml of lactose) was administered the previous day.

Randomization occurred using sealed envelopes.

**Group 1.** This randomized study compared results obtained using RSH vs. CPH. In RSH nodules were grasped with Ellis clamp, then initial incision with RF scalpel was performed in the mucocutaneous junction. The opposed "V" incision of anal canal mucosa described by Parks<sup>4</sup> was modified in an inverted "T" incision. Underlying planes were separated in layers up to the margin of internal sphincter and then hemorrhoidal tissue was freed. Vascular pedicle was then tied at its base with a transfixed stitch of absorbable suture (Vicryl 2/0) and removed. The edges were then anchored to the muscular plane and a part of the cutaneous margin was not sutured at the external portion of the wound<sup>5</sup>. Patients in the control group were subjected to CPH<sup>4</sup>.

**Group 2.** We compared the results of patients undergoing ROH and MMH. In both groups after exteriorization of hemorrhoidal nodule through Kocher forceps, a open "V" incision towards anal orifice was performed and nodule was detached from internal sphincter until vascular pedicle. Then ligation through transfixed stitch in Vicryl 2/0 and dissection upstream ligation were executed. At the end of surgery you could see 3 elliptic areas, with a

radial disposition, interrupted by large mucocutaneous bridges. These bridges should be carefully preserved large enough to avoid post-operative stenosis. The substantial difference with the above-described technique<sup>6-7</sup> is that it could be possible to isolate and dissect vascular pedicle by RF scalpel.

**Group 3.** The aim of the study was to compare results obtained with RCH vs. FH. A Parks' divaricator was applied to achieve adequate exposure of anal canal. Vertical elliptic incision was performed by RF scalpel from anal margin up to dentate line until origin of vascular pedicle was reached. Dissection of mucosal edges was reached up to internal sphincter. Vascular pedicle was then removed tying its base with a transfixed stitch of absorbable suture (Vicryl 2/0). Wound was closed with continuous suture from internal to external margin. The most external portion on the skin margin was left open to drain eventual serosanguinous oozing<sup>8</sup>.

Patients in the control group underwent the FH<sup>9</sup>.

**Group 4.** The first group of patients was treated in ambulatory with RBL using a disposable proctoscopy and an hemorrhoid suction with ligation. In the other group RBL has been combined with radiofrequency coagulation of the hemorrhoidal nodule (CHR). Ligation was performed just above dentate line, distantly enough from skin edge to avoid neural structures involvement. We used 4MHz radiofrequency generator; there was an handle mountable on various electrode types. In those procedures we indifferently used ball electrodes or large tip electrodes for coagulation. Intensity of radiofrequency generator output power was regulated according to obtain coagulation without charring. Gradual variation of the nodule's aspect to a grayish-white color was our indicator a sufficient state of necrosis<sup>10-11</sup>.

## Statistical Analysis

Descriptive statistics for qualitative variables were performed with occurrences and described with relative frequencies. Comparison was performed with the Student's t test for parametric continuous variables, the Mann-Whitney test for non-parametric variables and the Fisher's exact test for categorical variables in which the occurrence of observations within cells was inferior to 5. All *p* values were considered significant if less than 0.05.

## Results

### Group 1

A total of 102 patients were randomized to undergo RSH (51 patients, *group A*) or CPH (51 patients, *group B*); loss of some patients at follow-up resulted in 49 and 45 patients available for analysis, respectively. Operation time, amount of pain (VAS score from 1 to 10), postoperative analgesic requirement, intra and postoperative complications were documented. In comparison to Parks' technique, use of radiofrequency scalpel reduced mean operation time (61.2 min, range 50-75, vs. 37.4 min, range 30-51;  $p < 0.05$ ), first postoperative day pain score (5.9, range 3-10, vs. 4.0, range 1-10;  $p < 0.05$ ), pain score at first evacuation (5.7, range 2-10, vs 4.2, range 1-8;  $p < 0.05$ ) and pain score on postoperative days (3.6, range 1-9, vs. 2.8, range 1-8;  $p < 0.05$ ). Fecal incontinence was never observed. Incontinence to flatus with spontaneous resolution within 2-3 weeks was reported by 4 subjects for each group. Urinary retention requiring catheterization occurred in 21 patients in *group A* and 18 patients in *group B*. No complication was referred at 6-month follow-up in each group.

### Group 2

Two homogeneous groups, each of 20 patients, were investigated. Both of them were affected by fourth grade hemorrhoidary prolapse. They were homogenous for age, sex and initial symptoms reported. We treated one group with ROH (*group A*) and the other with MMH (*group B*). Every subject underwent a follow-up protocol based on outpatient visits at 15, 30, 45 postoperative days and 3, 6 and 12 months. Results show a substantial similarity between these techniques. However, RF scalpel further improved technical simplicity and postoperative adverse effects. In particular, procedure was shorter 7 minutes less than RF scalpel (18.6 min, range 16-21, vs. 25.55 min, range 20-30;  $p < 0.05$ ). Patients treated with ROH had their first postoperative evacuation 24 hours before standard technique. Incidence of postoperative pain was reduced in patients treated with RF scalpel and follow-up controls in both groups did not show any complication as stenosis or incontinence.

### Group 3

It consisted in a prospective randomized study of twenty-eight patients affected by grade IV hemorrhoids, randomized to receive either

RCH (*group A*) or FH (*group B*). Operation time, intra- and post-operative bleeding, post-operative pain and overall patient satisfaction were recorded. Six patients (three for each group) did not attend follow-up controls. *Group A* showed significant reduction in surgical time (23 min, range 21-31, vs. 33 min, range 24-35;  $p < 0.01$ ), pain at 1<sup>st</sup> post-operative day (VAS score  $3.4 \pm 1.3$  vs.  $4.8 \pm 1.0$ ;  $p < 0.05$ ) and at the first evacuation ( $3.4 \pm 1.0$  vs.  $5.0 \pm 0.8$ ;  $p < 0.05$ ). No significant differences were observed for pain score at the 7<sup>th</sup> post-operative day, or overall satisfaction scores at the 7<sup>th</sup> post-operative day and six months post-operatively ( $p = NS$ ). No severe complications were recorded. Two patients in *group A* (18.2%) and four patients in *group B* (36.4%) reported transitory gas incontinence that spontaneously resolved within one month ( $p = NS$ ). Three patients in *group A* (27.3%) and four patients in *group B* (36.4%) required post-operative catheterization due to urinary retention ( $p = NS$ ).

### Group 4

Out of 90 patients initially randomized, a total of 75 patients regularly returned to visit controls at least for 6 months of follow-up. Consequently, two groups of patients were considered: *group A*, represented by 36 individuals treated with RBL, and *group B*, consisting of 39 patients treated with CHR.

In this study primary endpoints were determined as evaluation of grade of pain felt immediately after procedure and at first evacuation (score from 1 to 10), bleeding, patient's satisfaction after 15 days and after 6 months from treatment (score from 1 to 10), incidence of failures.

Comparing these two techniques, mean pain score reported immediately after procedure was  $2.08 \pm 1.1$  for *group A* and  $2.13 \pm 1.26$  for *group B* ( $p = NS$ ). At first evacuation, mean pain score for *group A* and *group B* was  $2.69 \pm 1.12$  vs  $2.38 \pm 1.18$ , respectively ( $p = NS$ ). Satisfaction score during first 15 days from procedure was  $6.61 \pm 2.35$  for patients treated with RBL and  $6.72 \pm 2.28$  for patients who received CHR ( $p = NS$ ), while mean score on overall satisfaction after 6 months was  $7.11 \pm 2.11$  (*group A*) vs  $7.31 \pm 2.04$  (*group B*) ( $p = NS$ ). At 6 months follow-up, we observed remission of symptoms in 25 patients in *group A* (69.4%) and 31 patients in *group B* (79.5%).

## Discussion

Radiosurgery is a recent technique utilizing a new instrument, RF scalpel, able to simultaneously cut and coagulate tissue by a thin electrode. The main difference between this device and traditional scalpel consists in higher frequency in generation of waves (4MHz vs. 500KHz), so that it is possible the use of lower powers (60-100 vs 300 W) developing decreased temperatures (45°-70°C vs. 300°-600°C). Final result is a significant reduction in tissue burning compared to traditional electric scalpel<sup>1,12-13</sup>. RF works differently than diathermy: it adds energy to electrons inducing vibration of cellular ions. This vibration, called "molecular resonance", affects low energy molecular bindings with heat generation. Passage of radiowaves disintegrates cells and fuses tissues on their trajectory; it let then the surgeon incise tissue without bleeding. Furthermore, atraumatic nature of RF in addition of contemporary cutting-coagulating ability, helps eliminating unfavorable postoperative sequelae, mainly represented by pain, excessive blood loss and oedema. RF scalpel eliminates diffuse bleeding by coagulating all vessels up to 1.5-2.0 mm in diameter. Hemostasis is controlled without difficulty with a correct, easy and bloodless exposure of the operative field. Small heating spreading to surrounding tissues limits damage to section line. Histological analysis of hemorrhoidal specimens removed with RF demonstrated that heat damage spawned for 0.75 mm instead with diathermy it was 1.78 mm. For this reasons, healing times are shorter compared to traditional techniques and subsequent risk of cheloid formation or scars is virtually zero<sup>2</sup>.

After the initial clinical applications in anti-cancer treatment (hypertermia) and in invasive cardiology (catheter ablation of the arrhythmogenic myocardium), RF have recently been introduced into surgery. So far RF scalpel has been used in different fields of general, plastic and vascular surgery, in dermatology, orthopedics, neurosurgery and minimally invasive surgery. Among them, proctology last arrived to take advantage from potential benefits of this technique, primarily because proctologist surgeons were, and sometimes they are even now, satisfied with the current techniques.

Hemorrhoids are the proctologic disease that most frequently requires surgery for cure. Surgical techniques used are several and they have

been developed to eliminate the most troublesome adverse effect of surgery: the post-operative pain.

Use of RF in hemorrhoids treatment has been very useful and many techniques have been developed with. These are RF caogulation<sup>10,14</sup>, RF ablation with plication<sup>15</sup>, RF Parks<sup>5,16,17</sup>, RF Milligan-Morgan<sup>6,18</sup> and RF Ferguson hemorrhoidectomy<sup>8,19</sup>.

Literature results are in accordance with our studies. Use of RF simplifies and improves all procedures because it makes use of lower temperatures than those of classic diathermy, with less burns and post-operative pain. RF gives an almost bloodless operating field and shortens coagulation time. Surgery becomes briefer and easier and postoperative stay is limited to day surgery or at maximum to the first postoperative day. For all this reasons RF is considered a revolutionary method in hemorrhoids treatment.

There are no literature data comparing RF with other techniques for hemorrhoids surgery as Stapler hemorrhoidopexy, cryotherapy or laser therapy.

Stapler hemorrhoidopexy, since its introduction in 1998, received and still receives favourable opinion with great emphasis<sup>20</sup>. Randomized trials compare this procedure vs. open or Milligan-Morgan hemorrhoidectomy<sup>21</sup>, closed hemorrhoidectomy<sup>22</sup>, sealing vessel generator hemorrhoidectomy<sup>23</sup>. All above mentioned studies report less postoperative pain, shorter recoveries, faster return to normal activities and more satisfaction rates for Stapler hemorrhoidopexy, but sometimes this technique is associated with major incidence of stenosis and/or incontinence in the long term.

Rare but potentially fatal complications have been described too, such as retroperitoneal hematomas, Fournier gangrene, retroperitoneal perforations up to the subcutaneous emphysema and sepsis, rectovaginal fistulas<sup>24-28</sup>. These complications are related to depth of applied metal stitches. In addition, a biggest quantity of tissue is excised that results in lower strength of rectum wall to counter fecal pressure. Furthermore, Stapler hemorrhoidopexy induces appearance of tenesmus, severe anal pain, severe post-operative bleeding, formation of anal fissure and persistency of prolapsing piles. For all these reasons, we think that Stapler hemorrhoidopexy is not as simple and safe as certain surgeons describe. Other Authors believe in fact that it can be a dangerous

procedure in the hands of the less experienced surgeons<sup>29</sup>. Anyway, no randomized trial compared Stapler hemorrhoidopexy with RF.

Cryotherapy has been forbidden for external hemorrhoids treatment by the American Colon Rectal Surgeons Society, because it is associated with risk of anal stenosis.

Few controlled studies have compared laser with conventional hemorrhoidectomy<sup>30</sup>. In some studies there was no difference between laser and conventional hemorrhoidectomy with regard to quality and timing of wound healing<sup>31</sup>. In one prospective and randomized study comparing laser vs. cold scalpel conventional hemorrhoidectomy, it was stated that the only significant difference was a greater degree of wound inflammation in the early postoperative period, and the higher average cost per case in the laser group<sup>32</sup>.

## Conclusions

In conclusion, RF scalpel is a valuable new surgical tool that recently has been introduced even in proctology. The most important different feature than the other devices is its cutting-coagulating ability deriving from radiowaves. Tissue temperature obtained does not exceed 70°C, so it is named as a “cold” scalpel. It is an important advantage when you operate in a delicate tissue such as anal canal mucosa, because atraumatic nature of the cut allows a dramatic reduction of tissue oedema and post-operative pain. Moreover, healing processes are optimal and faster than normal with fewer long term complications. Last but not least, RF scalpel facilitates execution of every proctologic technique, and in the future it will have a greater diffusion.

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