

Prospective randomised comparison of rubber band ligation (RBL) and combined hemorrhoidal radiocoagulation (CHR)

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Abstract. – Background: In this prospective randomized study we compared two groups of patients with grade II hemorrhoids treated with standard Rubber Band Ligation (RBL) and Combined Hemorrhoidal Radiocoagulation (CHR), respectively.

Methods: 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 the grade of pain felt immediately after the procedure and at the first evacuation (score from 1 to 10), bleeding, patient's satisfaction after 15 days and after 6 months from the treatment (score from 1 to 10), appearance of failures.

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

Conclusions: Satisfactory results were reported in both groups of patients after different treatments, which confirm the validity and efficacy of the two techniques used in this study. At least all patients reported positive results in terms of immediate and long-term comfort after both procedures. CHR showed better results than standard RBL, but further studies are required to evaluate the validity of these methods.

Key Words:

Hemorrhoids, Radiofrequency, Radioablation, Proctology.

Introduction

Almost all patients affected by hemorrhoid disease (grade I and II) can be treated with conservative therapies. The most common and efficacy methods used in ambulatory treatment are the Rubber Band Ligation (RBL), the Infrared Photocoagulation (IRC) and the Injecton Sclerotherapy (IS). All those different techniques present several advantages and/or disadvantages and controversial views are reported in literature¹⁻³.

From 15 years radio-bistoury scalpel is commonly used in proctology, replacing different techniques that had been used in the past for the treatment of common anal diseases (hemorrhoids, fissures, fistulas, stenosis)⁴⁻⁶.

In this prospective randomized study we compared the results obtained in patients with grade II hemorrhoids treated with standard RBL and combined hemorrhoidal radiocoagulation (CHR).

Patients and Methods

Patients were randomized following CONSORT criteria⁷. Ninety patients with grade II hemorrhoids were selected and studied at the Department of Surgical Sciences of the University of Rome Tor Vergata. Symptoms reported by patients are listed in Table I. Before enrolling into

Table 1. Preoperative symptoms.

Preoperative symptom	n.	%
Bleeding	42	46.7
Pain	46	51.1
Perianal irritation	31	34.4
Anal itching	23	25.5
Secretions	12	13.3

the study, all patients underwent through a proctological visit and to an accurate rettoscimoidoscopy to exclude other proctological diseases associated or previous. Pregnant women and individuals with other diseases that require medication, such as anticoagulants and painkillers, were excluded because it could influence final results.

The randomized study was performed with the method of sealed envelopes. Any special preparations or diet before the procedure was needed, but only a mild laxative (30 ml of lactose) was administrated the day before the treatment.

Technique

All patients were placed in left lateral position sec. Sims. Patients randomized in *group A* were treated in ambulatory with RBL using a disposable proctoscopy and an haemorrhoid suction with ligation. In *group B* RBL has been combined with radiofrequency coagulation of the hemorrhoidal nodule (CHR).

A 4MHz radiofrequency generator was used; it was equipped with an handle which can be mounted on various types of electrodes. In those procedures we indifferently used ball electrodes or large tip electrodes for the coagulation. The intensity of the output power of radiofrequency generator was adjusted as required to obtain coagulation, without causing charring. The gradual variation of the nodule's aspect to a grayish white color indicated a sufficient state of necrosis (Figure 1).

All selected patients had three internal hemorrhoidal nodules located in the usual positions. We proceeded to ligation of a single hemorrhoidal node every 15 days, so each patient underwent a total of 3 procedures.

The ligation was performed just above the dentate line, sufficiently distant from the skin edge to avoid the involvement of neural structures. Any kind of anesthetic was used, in fact the method resulted painless: patients reported only minor discomfort, however, tolerable.

**Figure 1.** Nodule's necrosis after CHR.

All patients were immediately discharged after the procedure. A high-fiber diet and administration of paraffin oil (3 spoons/day) were prescribed during following weeks in order to make stool softer and reduce traumatism in the anal canal. A careful hygiene and use of local emollient and disinfectant soap were recommended. All patients were clinically visited and underwent to anoscopy after 3 days, 15 days and 6 months from the procedure.

Statistical Analysis

In this study primary endpoints was to evaluate the efficacy of different treatments and related aspects, considering the grade of pain immediately after the procedure and at the first evacuation, bleedings, patient's satisfaction after 15 days and 6 months from the treatment, appearance of failures.

For pain's evaluation we used a score based on overall impressions reported by patients at the end of treatment: 1 was the minimum value (no pain) and 10 the maximum value (maximum pain reported). We also assessed the degree of patients' satisfaction at after 15 days and 6 months from the procedure using a score that goes from 1 (minimum) to 10 (maximum), that indicated the highest satisfaction in relation to expectations.

Data were processed using the Statistical Package for the Social Sciences, Windows version 13.0 (SPSS Inc, Chicago, IL, USA). The level of significance was determined using 95% confidence intervals and *p*-value. Variables were compared using Student's *t*-test.

Results

Between January 2008 and June 2010 we conducted a randomized study on 90 patients treated with RBL (*Group A*, 45 patients) and CHR (*group B*, 45 patients). Nine patients in *group A* and 6 patients in *group B* were lost during the follow-up. Altogether, we enrolled 75 patients with a total of 225 procedures. The study was completed in June 2010 with the last visit.

Group A consisted of 23 male and 13 females with a mean age of 37 years (range 21-49), while *group B* included 21 males and 18 females with a mean age of 41 years (range 23-56). At the first visit all patients reported symptoms occurred at least 6 months before.

The mean pain score reported at the end of procedures was 2.08 ± 1.1 (range 1-6) for *group A* and 2.13 ± 1.26 (range 1-7) for *group B*.

In both groups, the first evacuation generally occurred after 24-36 hours from the ligation. The mean pain score at the first evacuation was 2.69 ± 1.12 (range 1-6) for *group A* and 2.38 ± 1.18 (range 1-5) for *group B* (Figure 2).

Five patients in *group A* and 6 patients in *group B* required treatment with analgesics (Ketorolac 20-25 drops, when needed). No patient received benzodiazepines.

Bleedings occurred at the end of the procedures, after the first evacuation and in following days were irrelevant and didn't require any particular interventions and/or coagulants.

The mean satisfaction' score during the first 15 days was 6.61 ± 2.35 (range.3-10) for *group A*

and 6.72 ± 2.28 (range 3-10) for *group B*. Thus, the mean score on overall satisfaction at 6 months from the treatment was 7.11 ± 2.11 (range 3-10) and 7.31 ± 2.04 (range 4-10) for *group A* and *group B*, respectively (Figure 3).

At first visit, after 3 days from the procedure, an early lost of elastic ligatures were observed in 19 cases of 108 procedures in *group A* (17.6%) and in 22 cases of 117 ligatures in *group B* (18.8%). However, in this group after 15 days we observed eschars as results of CHR, while in *group A* failure of the procedure was reported.

During all the study no complications were observed. Readmission to work was straightforward in all cases, with no correlation with the type of work.

At 6 months of follow-up we observed the completely remission of symptoms in 25 patients from a total of 36 patients in *group A* (69.4%) and in 31 patients from a total of 39 patients in *group B* (79.5%).

Discussion

It's very difficult found the ideal technique identification for ambulatory treatment of patients affected of grade I or II hemorrhoids. Literature describes several different methods and the choice depends mostly from the personal experience of the proctologist and from his surgical school traditions.

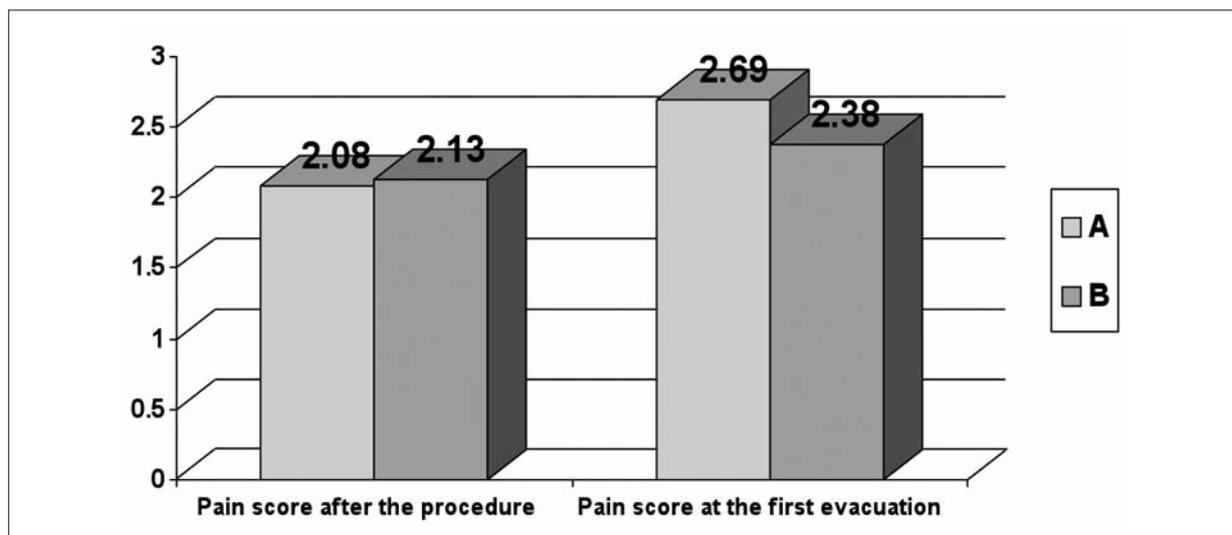


Figure 2. Mean pain scores after the procedure and at the first evacuation.

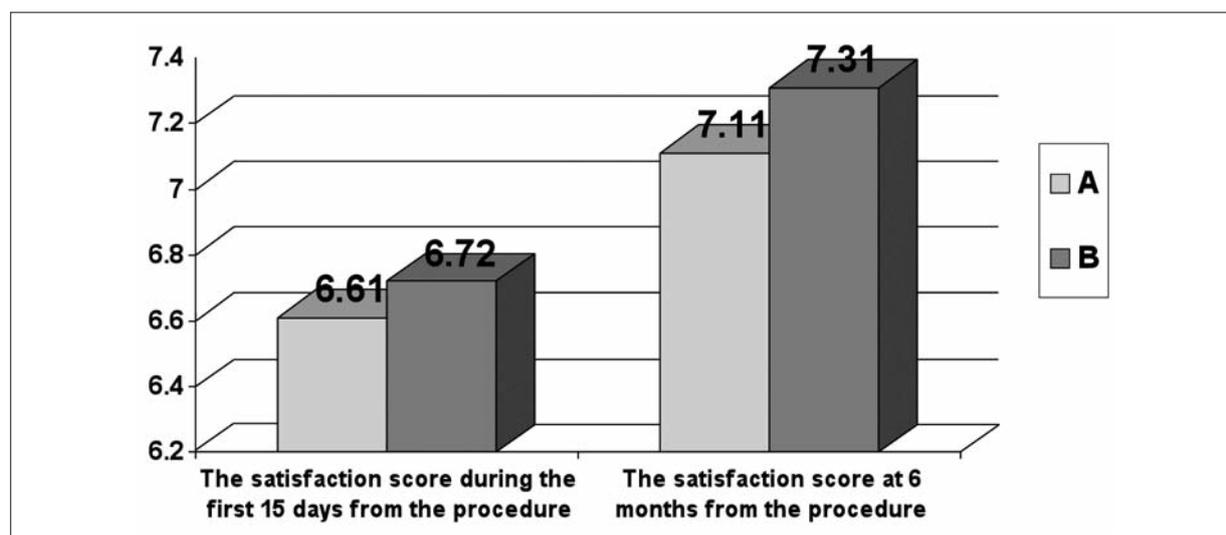


Figure 3. Mean satisfaction scores during the first 15 days and at 6 months from the procedure.

The ideal technique should determine a low frequency of immediate and remote complications and a faster return to normal work activities.

RBL was introduced by Barron in 1963 and initially spread especially in the US⁸. Later in time, Neiger and Nath devised the use of infrared photocoagulation for nonsurgical treatment of hemorrhoids^{9,10}. These techniques, together with the older IS¹¹, were often applied, more than the others, with good results, but their success rate and complications varied according to author's casuistry¹².

In our study, we compared traditional RBL with CHR in ambulatory treatment, to evaluate improves immediate and remote results.

“Radiosurgery” is a new application field for radiofrequency that facilitates, extends and improves many surgical techniques. It works with “HF Radioscalpel”, that cuts and coagulates tissues using heat generation from high frequency radio waves passage^{5,6}.

The main difference with traditional electric scalpel is increasing in frequency (4 MHz compared to 500 KHz traditional electrical scalpel) that allows using less power (60 W vs. more than 300 W) then developing lower temperatures (45-70°C vs. 300-600°C). Final result is the minimization of the traumatic effect related to heat burns^{13,14}.

Currently, HF Radioscalpel is applied in general surgery, plastic surgery, vascular surgery, dermatology, orthopedics, neurosurgery, ophthalmology. More recently, radiosurgery found appli-

cation in proctology. The finding that the HF Radioscalpel can further improve immediate and remote results of all proctologic interventions encouraged massive spreading of this instrument.

In previous studies for proctologic surgery, we already used HF Radioscalpel in hemorrhoids treatment according to Parks submucosal hemorrhoidectomy^{4,14}, in open hemorrhoidectomy according to Milligan-Morgan¹⁵, and in closed hemorrhoidectomy according to Ferguson¹⁶. We observed results obtained from modification of traditional technique in such a way, instead of the mere application of the classical method. We also examined surgical techniques for the remnants proctologic most common diseases (fissures, fistulas, etc.), and we constantly noted better results in patients treated with radio waves than those treated with traditional methods^{6,17-19}.

Literature reports numerous Authors describing their experience about radiofrequency in proctology. In particular Gupta describes a radioablation technique for ambulatory treatment of grade I or II hemorrhoids and declares a personal failure rate of 13%²⁰. The same Author previously led a randomized trial to compare the results obtained with radiocoagulation and band ligation, noting that the latter method, despite being effective in the same way, had a higher pain frequency²¹. Failure rate in our series is higher than results presented by Gupta. However it should be considered that we treated only patients with grade II hemorrhoids, while Gupta's casuistry included patients with both grade I or II hemorrhoids.

We never experienced major complications of any kind. Mean pain score reported at the end of each procedure and at the moment of first evacuation was not relevant and it is not statistically significant. Only 13.9% of patients in *group A* and 15.4% patients in *group B* required use of analgesics, and benzodiazepines were necessary in no case. Some Authors²²⁻²⁴ correlate pain with not correct positioning of the elastic. We never met this situation at third post operative day controls, nor we ever observed important proctitis arisen after each procedure. When we encountered the ligation, it was always correctly standing above the dentate line. We, therefore, believe that difference in pain tolerance of single patients represents the only variable in our study.

We considered persistence of bleeding, if already reported on patient's history, a failure of technique. Occasional bleeding after ligation was not considered, because not massive and rapidly regressed without use of anticoagulants.

According to literature we didn't observed radiocoagulation scarring. Undoubtedly the reason is due to specific characteristics of radiofrequency. Radio waves, unlike other methods, reduce traumatic action on tissues because of use of low temperatures. This fact is an important gain, considering that scar stenosis is one of the most common remote complication in proctology, independently of the intervention, and often, not easy to solve²⁵⁻²⁷.

Results look better in group of patients treated with high frequency Radioscalpel, although statistical significance of this observation is not entirely confirming it, probably because of persistence of eschar as result of radio coagulation. Therefore, early elastic loss does not undermine completely procedure in *group B*, while early fall of the same elastic is considered cause of failure in *group A* patients.

Mean score on satisfaction at 6 months after procedure, could not be considered completely reliable, because it is affected more by news of success/failure of the technique in patients' mind, than from real comfort experienced from the single.

Conclusions

These results confirm the validity of both the used techniques. No major complications were observed. Most of patients gave an overall favor-

able impression of immediate and remote comfort. However CHR seems to allow a reduction in the appearance of failures.

In the end evaluation of results together with the consideration that CHR is a low cost ambulatory treatment of easy application with no risk of major complications, allows us to express a very positive judgment about this technique and recommend it for the ambulatory treatment of patients affected by grade II hemorrhoids.

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