

Ambulatory therapy with combined hemorrhoidal radiocoagulation

V. FILINGERI, R. ANGELICO, M.I. BELLINI, M. MANUELLI, D. SFORZA

Department of Surgical Sciences, School of Medicine, University of Rome "Tor Vergata", Rome, Italy

Abstract. – BACKGROUND: This is a prospective randomized study to analyze results obtained in two groups of patients affected of grade II hemorrhoids and treated with Radiofrequency Coagulation (RFC) or Combined Hemorrhoidal Radiocoagulation (CHR).

PATIENTS AND METHODS: The study comprehended 30 patients of which 27 had at least 6 months of follow-up. Two groups of patients were considered: group A, represented by 12 individuals treated with RFC, and group B, consisting of 15 patients treated with CHR.

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

RESULTS: Mean pain score reported immediately after procedure was 2.08 ± 0.9 for group A and 2.40 ± 1.5 for group B ($p = \text{NS}$). At first evacuation, mean pain score for group A and for group B was 2.16 ± 1.1 vs 2.33 ± 1.17 , respectively ($p = \text{NS}$). Satisfaction score during first 15 days was 6.75 ± 2.76 for patients treated with RFC and 6.08 ± 2.20 for patients who received CHR ($p = \text{NS}$), while mean score of overall satisfaction after 6 months was 6.33 ± 1.96 (group A) vs 7.83 ± 2.05 (group B) ($p < 0.05$). At 6 months of follow-up, we observed 8 patients free from pain in group A (66.7%) and 13 patients in group B (86.7%).

CONCLUSIONS: Results reported in both groups of patients confirm validity and efficacy of the two techniques used in this study, even if later in time CHR showed better results than RFC.

Key Words:

Hemorrhoids, Radiofrequency, Proctology.

Introduction

Despite several surgical techniques are available for ambulatory treatment of hemorrhoids, i.e. sclerotherapy, band ligation, cryotherapy and infrared photocoagulation, there is still a current controversy regarding risks and benefits of each one, so that no evidence of an ideal technique exists¹⁻³.

Many alternative methods have been developed with radiofrequencies using "radioscalpel", a new device able to simultaneously cut and co-

agulate tissues with no traumatic effect, conversely to electric scalpel⁴⁻⁶.

The purpose of this study was to compare results obtained in two groups of patients affected of grade II hemorrhoids treated with Radiofrequency Coagulation (RFC)^{7,8} or Combined Hemorrhoidal Radiocoagulation (CHR)⁹.

Patients and Methods

Between June 2009 and June 2010 thirty patients affected of grade II hemorrhoids were selected and studied at the Department of Surgical Sciences of "Rome Tor Vergata University". All patients underwent a thorough proctological visit and an accurate rettosigmoidoscopy to exclude other associated or previous proctological diseases. Pregnant women and individuals presenting other diseases requiring anticoagulants and painkillers therapies were excluded. Symptoms referred from patients are listed in Table I.

No special preparation or diet before procedure was necessary, only a mild laxative (30 ml of lactose) was administrated the day before surgery.

Patients were randomized following CONSORT criteria¹⁰.

Our intention was to determine pain grade immediately after procedure and at first evacuation, bleeding, patient's satisfaction 15 days and 6 months after treatment and failure rate.

In the regard of pain evaluation, we used a score based on overall impression 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 15 days and 6 months after procedure using a scale range from 1 to 10 to indicate the highest satisfaction in relation to expectations.

Statistical Analysis

All data were processed with Statistical Package for Social Sciences, Windows version 13.0 (SPSS Inc, Chicago, IL, USA). Level of signifi-

Table I. Preoperative symptoms.

Preoperative symptoms	n.	%
Bleeding	16	53.3
Pain	19	63.3
Perianal irritation	11	33.7
Anal itching	10	33.3
Secretions	10	33.3

cance was determined using 95% confidence intervals and *p*-value. Variables were compared using Student's *t*-test.

Technique

Patients undergone an ambulatory treatment in left lateral position sec. Sims. Two groups were considered: group A, treated with RFC and group B treated with CHR. In this latter case we use a disposable proctoscopy for nodule ligation and suction together with radiofrequencies.

We used 4MHz radiofrequency generator; there was a mountable handle 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 for a sufficient state of necrosis.

All selected patients had three internal hemorrhoidal nodules located in usual positions. Nodules were treated singularly per time, so each patient underwent three sessions, with an interval of about 15 days between two consecutive sessions. Ligation was performed just above dentate line, distantly enough from skin edge to avoid neural structures involvement. No anesthetic of any kind was required; therefore, we deduced that this method is painless.

After procedure a high-fiber diet and administration of paraffin oil (3 spoons/day) were prescribed 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 3 days, 15 days and 6 months after procedure.

Results

We conducted a randomized study on 30 patients treated with RFC (group A, 15 patients) or

CHR (group B, 15 patients). Three patients in group A were lost during the follow-up; therefore, we enrolled 27 patients for a total of 81 procedures. The study was completed in December 2010 with the last visit of follow-up.

Group A consisted of 6 male and 9 females with mean age of 33 years (range 21-43), group B included 10 males and 5 females with mean age of 43 years (range 23-49). In all patients symptoms appeared at least 6 months before surgery.

Mean pain score reported at the end of procedures was 2.08 ± 0.9 (range 1-4) for group A and 2.40 ± 1.5 (range 1-7) for group B (*p* = NS).

In both groups, first evacuation generally occurred 24-36 hours after treatment. Mean pain score at first evacuation was 2.16 ± 1.1 (range 1-4) for group A and 2.33 ± 1.17 (range 1-5) for group B (*p* = NS).

Mean satisfaction score during first 15 days was 6.75 ± 2.76 (range 2-10) in group A and 6.08 ± 2.20 (range 3-9) in group B (*p* = NS). Thus, mean score and overall satisfaction at 6 months visit of follow up was 6.33 ± 1.96 (range 3-10) in group A and 7.83 ± 2.05 (range 4-10) in group B (*p* < 0.05).

At first visit, 3 days after procedure, an early loss of elastic ligature was observed in 10/45 treatments in group B (22.2%); besides in this group we noted eschars as a consequence of radiofrequencies approximately 15 days after surgery.

One patient in group A and 3 patients in group B required analgesics (Ketorolac 20-25 drops, sporadically). No patient assumed benzodiazepines.

No bleeding was present at the end of procedure, after first evacuation and in the following days, then no intervention and/or coagulant therapy was necessary.

Postoperative course was regular, in lack of complications. Readmission to work was uneventful in all cases, independently to patient's kind of job.

At 6 months of follow-up complete remission of symptoms was achieved in 8/12 patients in group A (66.7%) and 13/15 patients in group B (86.7%).

Discussion

In this study, we used a new instrument, "HF radioscalpel", able to cut and coagulate 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 results in using less power (60 W versus more than 300 W) and developing lower temperatures (45-70°C vs. 300-600°C). Final result is minimization of traumatic effect related to heat damage^{11,12}.

Currently HF radioscalpel is applied in General Surgery, Plastic Surgery, Vascular Surgery, Dermatology, Orthopedics, Neurosurgery and Ophthalmology. More recently, radiosurgery found application 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 our previous experiences we already used HF radioscalpel in proctology and our personal convincement was that it led to better final results^{4,12-14} in comparison to traditional techniques.

Literature reports numerous Authors describing their experience about radio frequency in proctology. In particular Gupta describes a radio-coagulation technique for ambulatory treatment of grade I or II hemorrhoids and affirms his personal failure rate of 13%²⁰. The same Author previously conducted a randomized trial to compare results obtained with radiocoagulation and band ligation²¹, noting that this latter method, despite being effective in the same way, had a higher pain incidence⁷⁻⁸. In a precedent article, we compared traditional RFC vs CHR in ambulatory treatment, to evaluate immediate efficacy and optimize long-term results⁹.

In this randomized prospective study our intention was to analyze results obtained in two groups of patients affected by grade II hemorrhoids and treated with RFC or CHR to determine pain grade felt immediately after procedure and at first evacuation, bleeding, patient's satisfaction 15 days and 6 months after treatment and frequency of failures. We observed satisfactory results in both groups. Patients treated with RFC showed better results after surgery, even if it was not statistically significant. Results obtained at 6 months rather showed greater satisfaction in patients treated with CHR, with statistical significance at this time. However, 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.

Failure rate in our series is higher than results presented by Gupta in patients treated with radio-coagulation, but we treated only patients with grade II hemorrhoids, while Gupta's series included patients with either grade I or II hemorrhoids.

We considered persistence of bleeding, if already reported on patient's history, a failure of technique. Occasional bleeding after any procedure was not considered, because it was not massive and rapidly regressed with no use of drugs.

No major complications of any kind was observed. According to literature, also in our experience no scarring stenosis occurred. 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 stenosis is one of the most common remote complication in proctology, independently of the intervention, and often, not easy to solve¹⁵⁻¹⁷.

Conclusions

Our results allow to give a positive opinion on both techniques used in this study. Major complications were not observed. Most patients gave an overall favorable impression regarding immediate comfort after treatments. However the main acquisition of our study is that satisfaction score reported at final 6 months visit of follow up is statistically significant in favor of subjects treated with CHR with an associated reduction in failure incidence.

For a complete evaluation of results, it should be also considered that CHR is a low cost a ambulatory treatment, easy to apply in lack of relevant complications.

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