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Early results of the treatment of internal hemorrhoid disease by infrared coagulation and elastic banding: a prospective randomized cross-over trial

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Abstract Background Rubber band ligation (RBL) is probably the most commonly performed nonsurgical therapy for hemorrhoidal disease. Infrared coagulation (IRC) is one of the most recent advances based on the use of “heat”. Recent studies have demonstrated similar efficacy for both modalities. This prospective randomized cross-over trial compared IRC and RBL for pain, complications, effectiveness, and patient satisfaction and preference in the treatment of internal hemorrhoids (IH). **Methods** Patients were randomized to receive either RBL (Group A) or IRC (Group B) for treatment of the first hemorrhoid; in a second procedure two weeks later, patients underwent the other procedure on the second hemorrhoid, thereby serving as their own control. The procedure preferred by the patient was employed two weeks later for the third hemorrhoid. Post-treatment pain was evaluated on a visual analog scale and on the basis of the percentage of patients requiring analgesics. Bleeding and early outcome of treatment were also recorded, together with the patient’s satisfaction. **Results** A total of 94 patients were included in this study (47 patients in each group). At 30 minutes and 6 hours after treatment, pain scores were significantly higher in patients treated with RBL than in those treated with IRC ($p<0.01$). There was no significant

difference in pain scores between the two procedures immediately and 24 hours after the procedures ($p<0.05$). After 72 hours and one week, the pain scores for RBL and IRC were similar. The percentage of patients using analgesics was significantly higher in RBL group than in IRC group at 6 hours (29.6% vs. 19.2%, respectively; $p<0.05$) and 24 hours (22.5% vs. 13.5%, respectively; $p<0.05$) after treatment. However, significant differences were not noted at 72 hours (12.7% vs. 6.4%; $p<0.05$) and one week (5.6% vs. 7.1%; $p>0.05$) after the procedures. There were significantly higher incidences of bleeding immediately, 6 hours, and 24 hours after RBL compared to IRC (immediate: 32.4% vs. 4.3%; 6 hours: 13.4% vs. 3.6%, 24 hours: 26.8% vs. 10.2%, respectively; $p<0.01$). However, there were no significant differences noted regarding the incidence of bleeding between the two groups at 72 hours. Complications were more likely after RBL than IRC, however this difference was not significant ($p>0.05$). Overall, 91 patients (96.8%) were successfully treated and 93 patients (99%) were very satisfied with the treatment. In the third treatment session, 50% of patients selected RBL and 50% chose IRC. **Conclusions** Both RBL and IRC were well-accepted and highly efficacious methods for the treatment of IH; in addition, both procedures were associated with relatively minor complications. However, RBL was associated with more pain than IRC in the 24-hour postoperative period.

Key words Hemorrhoids • Adverse effects • Collateral effects • Infrared coagulation • Rubber band ligation • Prospective trial

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Introduction

Hemorrhoids are normal components of human anatomy. The disintegration of support tissue promotes loss of the

anatomic relationship with the sphincter, resulting in vascular malformations such as varicoses or varicoceles [1–4].

Hemorrhoidal disease occurs in one out of 25–30 individuals in developing countries, and in 58% of the population over 40 years of age in the United States [5, 6]. The treatment of hemorrhoids may be associated with considerable pain, therefore only one-third of these individuals consults a physician [6]. Delay in the precise diagnosis of hemorrhoidal disease is one of the major problems related to this pathology, as these symptoms can often be mistaken for malignant colorectal neoplasia.

Appropriate non-operative treatment modalities are highly effective with less morbidity and pain than surgical management. Conservative (non-operative) treatment is recommended for first- and second-degree and, in some cases, third-degree internal hemorrhoids (IH) [2]. Conservative treatments currently used include alteration of dietary habits [7], sclerotherapy [8], cryotherapy [9], rubber band ligation (RBL), [10, 11] and infrared coagulation (IRC) [12]. Comparative studies between IRC and RBL have favored both treatment modalities [13–16]. Therefore, the aim of this prospective randomized cross-over trial was to compare these two non-operative methods for the treatment of IH.

Materials and methods

Between March 1999 and August 2000, the study prospectively enrolled consecutive patients with three first- and second-degree IH, confirmed by anoscopy. Colonoscopy was performed to exclude other sources of bleeding, when necessary. Exclusion criteria included concomitant anal diseases (e.g. anal fissure, perianal fistula, and neoplasia), immunosuppression or oral anti-coagulant therapy, and any other colorectal pathology.

Patients were randomized by the use of sealed envelopes into one of two groups. Randomization was undertaken by one of the study investigators on the day of the procedure. In Group A, the initial treatment (week 1) consisted of RBL of one hemorrhoid, followed by IRC (2 weeks later) of the second hemorrhoid. In Group B, the initial treatment (week 1) consisted of IRC of one hemorrhoid, followed by RBL (2 weeks later) of the second hemorrhoid. If no complications occurred with either of the two treatments, the patient was then asked to choose between one of the two methods for treatment of the third hemorrhoid (2 weeks later). In all cases, the hemorrhoids were treated in order of size, the largest first, in order to avoid selection bias.

All patients were evaluated after each session for pain, immediate and late complications, efficacy of the procedure, and satisfaction and preference of each procedure. All patients served as their own control.

This study was approved by the Ethics Committee of the University of São Paulo and performed according to the Declaration of Helsinki. All patients were asked to provide written informed consent prior to enrollment, after explanation of the associated risks and benefits and description of the study protocol.

Treatment of hemorrhoidal disease

The Infrared Coagulator (Redfield, NJ, USA) was utilized with the patient placed in the left lateral position. After a digital examination, anoscopy was used to select the hemorrhoid to be treated. The tip of the coagulator, lined with Teflon, was directed toward the base of the hemorrhoid and slight pressure was applied to the rectal tissue. Four light impulses, each lasting 1.5 seconds, were applied to the base of each hemorrhoid.

Rubber band ligation (RBL) was performed as modified by Nivatvongs and Goldberg [18], in which the band is placed at the base of the hemorrhoid and not at the hemorrhoid itself, as originally described by Barron [19].

Pain assessment

Pain was assessed immediately following each procedure, after 30 min, 6 h and 24 h (while the patient was still hospitalized), after 72 hours (first return postoperative visit), and after one week (second postoperative visit). Pain was assessed on the visual analog scale (VAS) and on the basis of the percentage of patients who required analgesics. Patients were instructed to take 500 mg dipyrone for pain relief, if necessary, every 6 h. For persistent pain, patients were instructed to take 30 mg codeine every 8 h. No other analgesics or anti-inflammatory drugs were permitted.

Assessment of complications

Complications were assessed at the same time intervals as pain. Patients were questioned regarding tenesmus, symptomatic hypotension, profuse perspiration, a feeling of heaviness in the anorectal area, headache, nausea and vomiting, interruption of routine activities, urinary retention, frequency and volume of bleeding with and without associated bowel movement, and fever. Patients were instructed to notify the study investigator in cases of persistent severe pain, fever, urinary retention, or massive and uncontrollable bleeding.

Assessment of efficacy

Patients were clinically assessed relative to the efficacy of the procedure one month after the third treatment session. If symptoms persisted, the technique of the last session was re-attempted. If the symptoms worsened or treatment was unsuccessful, the patient was offered a hemorrhoidectomy and the non-surgical treatment was deemed ineffective.

Assessment of patient satisfaction and preference

Patients were asked to rate their satisfaction with their procedure, classed as very satisfactory, satisfactory and unsatisfactory, according to a visual decimal scale similar to the VAS for pain (unsatis-

factory, 1–6; satisfactory, 7–8; very satisfactory, 9–10) [17]. Patient preference for one of the two treatment methods was determined from their choice of a specific method for the final session.

Statistical analysis

Numeric data were expressed as mean and standard deviation or median and range if data were not normally distributed. Categorical data were presented as percentages. Statistical analysis was completed using the ANOVA, t, Wilcoxon, and chi-square tests, as appropriate with a statistical software package (SPSS 12.01). Statistical significance was defined as $p < 0.05$.

Results

A total of 94 patients were enrolled into this study and completed the treatment protocol (Fig. 1). Group A consisted of 47 patients (24 men) of mean age 46 years (SD=13 years). Group B had 47 patients (26 men) of mean age 50 years (SD=14 years). There were no significant differences relative to age or gender between the two groups. The ratio of patients who selected RBL or IRC as their third treatment was 1 to 1. During all three sessions of treatment, 282 procedures were performed, 141 of each.

Eighty patients experienced postoperative pain within 24 hours after each procedure, but pain scores decreased over time. Only 9 patients complained of persistent but slight pain more than 24 hours after the procedures. The crossover data for the first two treatment sessions are listed in Table 1. After 30 minutes and 6 hours, the pain scores were significantly higher in patients treated with RBL compared to those treated with IRC ($p < 0.01$), Chi square test. There was no significant difference in pain scores

between the two procedures immediately and 24 hours after the procedures ($p > 0.05$), Chi square test. At 72 hours and one week after treatment, the pain scores for RBL and IRC were also similar (data not shown). After the third treatment session, the pain scores were higher in patients treated by RBL than in those treated with IRC, immediately and after 30 minutes, 6 hours, and 24 hours (Table 2). However, this finding was not statistically significant.

The percentage of patients who required analgesics was significantly higher in the RBL group compared to the IRC group 6 hours (29.6% vs. 19.2%, respectively; $p < 0.05$, Chi square test) and 24 hours (22.6% vs. 13.5%, respectively; $p < 0.05$, Chi square test) after treatment. However, significant differences were not noted at 72 hours (12.7% vs. 6.4%, respectively; $p > 0.05$) and one week (5.6% vs. 7.1%, respectively; $p > 0.05$).

Postoperative complications and symptoms included bleeding, urinary retention, tenesmus, and abnormal rectal sensation. There were significantly higher incidences of bleeding immediately, 6 hours, and 24 hours after RBL compared to IRC (immediate: 32.4% vs. 4.3%, 6 hours: 13.4% vs. 3.6%, 24 hours: 26.8% vs. 10.2%, respectively; $p < 0.01$, Chi square test). However, there were no differences noted regarding the incidence of bleeding between the two groups at 72 hours (16.2% vs. 11.4%, respectively) and one week (16.9% vs. 17.0%, respectively) after treatment ($p > 0.05$). The incidence of complications was more likely after RBL than after IRC (Table 3), however this difference was not statistically significant ($p > 0.05$).

Overall, 91 patients (96.8%) were successfully treated. The remaining 3 patients (3.1%; 2 in RBL group and 1 in IRC group) required further treatment; one RBL patient required hemorrhoidectomy. Moreover, 93 patients (99%) were very satisfied with their treatment. One patient (1%) indicated less than 7 on the satisfaction scale and subsequently underwent hemorrhoidectomy.

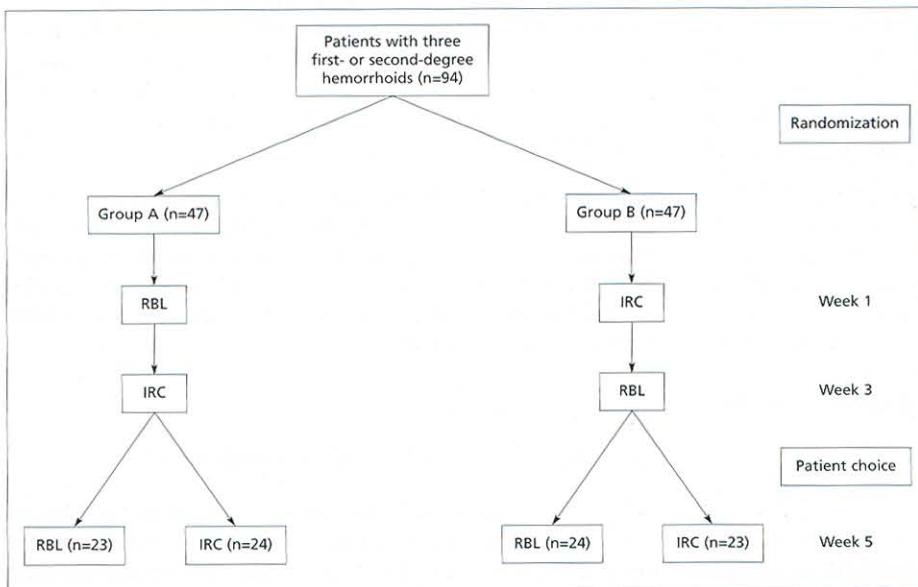


Fig. 1 Flow of patients through the clinical protocol

Table 1 Pain scores after first and second treatment sessions, by study group. Values are median range. Statistic analysis: Wilcoxon test

	Immediate	30 minutes	6 hours	24 hours
Group A-RBL	2.43 (2.30)	2.00 (2.21)	0.77 (1.06)	0.21 (0.78)
Group A-IRC	2.45 (2.04)	1.02 (1.26)	0.23 (1.16)	0.12 (0.64)
Group B-RBL	2.57 (2.19)	2.13 (2.22)	2.11 (3.14)	0.68 (1.88)
Group B-IRC	3.17 (2.39)	1.49 (1.88)	0.64 (1.45)	0.45 (1.40)
<i>p</i> value	0.15	<0.01	<0.01	0.26

RBL, rubber band ligation; IRC, infrared coagulation

Table 2 Pain scores after the third treatment session. Values are median range. Statistic analysis: Wilcoxon test

Time after surgery	RBL	IRC
Immediate	2.52 (2.26)	1.85 (1.95)
30 minutes	1.66 (1.95)	1.41 (1.50)
6 hours	1.23 (2.40)	0.98 (2.43)
24 hours	0.68 (1.93)	0.26 (1.06)
72 hours	0.15 (0.79)	0.17 (0.73)
One week	0	0.02±0.15

RBL, rubber band ligation; IRC, infrared coagulation

Table 3 Incidence of postoperative complications and symptoms, by treatment group. Values are percentage of patients

	6 hours	24 hours	72 hours	One week
Urinary retention				
RBL	2.8	4.2	2.8	1.4
IRC	0	0.7	0.71	0
Tenesmus				
RBL	7.8	9.2	7.04	3.5
IRC	6.4	7.1	2.13	2.1
Abnormal sensation				
RBL	14.8	17.6	12.0	9.9
IRC	12.8	12.1	9.9	5.0

RBL, rubber band ligation; IRC, infrared coagulation

Since equal numbers of patients chose RBL or IRC for the third treatment sessions, no significant difference was found between the treatment groups regarding patient preference for a specific method.

Discussion

Hemorrhoidal disease is one of the most common, dating back to antiquity. Fear has always been a prevailing factor in hemorrhoidal disease due to the associated pain. Among the various non-surgical procedures, IRC and RBL have earned a high reputation as they are associated with the least pain, are safe, effective, and preferred by patients.

In a comparative prospective study by Ambrose et al. [13] between IRC and RBL, no difference was noted in the recurrence of symptoms at one month or one year of follow-up. In our study, the follow-up period was selected in order to facilitate assessment of pain and other parameters, and thus better clarify which procedure is the least painful, associated with the least complications, and most satisfactory.

The measurement of pain is subjective and responses vary depending on physiological circumstances that are influenced by culture and behavior. Additionally, anxiety resulting from an unknown treatment may also affect the results. In our study, patients served as their own control for all three sessions. The use of two methods of treatment in the same patient avoided comparison of pain and complications among different individuals. Although a drawback of cross-over studies is the potential for a lingering effect from the previous treatment, we feel that an adequate time interval was employed between the three treatment sessions, thereby avoiding this possibility.

The majority of comparative trials reported in the literature did not employ standardized treatment protocols, making comparison of the two techniques difficult [13–16, 20, 21]. In our trial, a uniform method was used with each treatment including location of infrared radiation and rubber bands, number of hemorrhoids treated at each session, time of exposure of tissue to IRC, and pre- and post-treatment analgesia. Similarly, the literature reports the measurement of pain when comparing IRC with RBL using various methods and time periods [13–16, 20, 21]. Our study employed two methods for measuring pain, which should make the assessment of pain more precise. This association of the two methods has not been previously reported for comparison of post-treatment pain after RBL and IRC. Furthermore, the time intervals at which pain was assessed coincided with important time points in the study.

Pain scores of less than two were obtained for all sessions, regardless of the treatment employed. This coincides with mild pain and is in keeping with the results reported by Weinstein et al. [22]. In fact, pain did not exceed moderate levels in any individual, which may have been due to the strict treatment protocol employed in this study. However, pain scores were significantly higher in patients treated with RBL than with IRC 30 minutes and 6 hours after treatment, indicating patients treated with IRC

suffer less postoperative pain. These results are in agreement with those of other authors [20] who have also observed more persistent pain after RBL than IRC. Our study showed that the consumption of analgesics was generally greater 24 hours after RBL than IRC; however, there was no significant difference after 24 postoperative hours. This is contrary to another series that reported IRC as the more painful method [21]. The use of dipyron was higher after each treatment session with RBL. The higher prevalence of analgesic use is in agreement with other studies that report more pain after RBL [13–16, 20].

The percentage of patients with bleeding was generally higher after RBL and may be explained by greater inflammation and depth of necrosis associated with this method. A higher bleeding rate has also been reported by other authors [13–16, 20, 21]. Urinary retention occurred more frequently after RBL, although this was not statistically significant. This finding seems contrary to the study by Poen et al. [14] who reported significantly similar rates of urinary retention after both RBL and IRC. This may have been a consequence of greater inflammation of rectal tissue, more pain, and more difficulty urinating associated with RBL.

Contrary to some reports in the literature, septic complications [23–26], severe hemorrhage [27], and death [23, 27] did not occur in any patients in our study, which indicates that both these procedures are safe. Furthermore, the low morbidity in this series emphasizes the necessity for close post-procedural monitoring especially after RBL, as was done in our study.

Various studies in the literature have evaluated efficacy in different ways, although efficacy is usually related to the recurrence of symptoms or the necessity for retreatment and hemorrhoidectomy. The 3.1% retreatment rate in our study is quite low compared to other studies in which rates ranged between 10% and 12% for RBL between 5% and 25.5% for IRC [13–16, 20, 21]. Similarly, the low rate of hemorrhoidectomy (1%) cannot be attributed to a specific treatment, but was considerably lower compared with other trials in which rates ranged between 5% and 35% for RBL and 1.2% and 40% for IRC [13–16, 20, 21]. However, these good results may be attributed to the shorter follow-up period of our study, compared to periods of up to four years in the literature and to the fact that only one hemorrhoid was treated in each session.

In conclusion, this study found that both RBL and IRC are well-accepted and highly efficacious treatments for IH. In addition, they are associated with relatively minor complications. RBL, however, was associated with more pain than IRC in the 24-hour postoperative period.

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