Infrared coagulation versus rubber band ligation in early stage hemorrhoids

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Abstract

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The ideal therapy for early stages of hemorrhoids is always debated. Some are more effective but are more painful, others are less painful but their efficacy is also lower. Thus, comfort or efficacy is a major concern. In the present randomized study, a comparison is made between infrared coagulation and rubber band ligation in terms of effectiveness and discomfort. One hundred patients with second degree bleeding piles were randomized prospectively to either rubber band ligation (N = 54) or infrared coagulation (N = 46). Parameters measured included postoperative discomfort and pain, time to return to work, relief in incidence of bleeding, and recurrence rate. The mean age was 38 years (range 19-68 years). The mean duration of disease was 17.5 months (range 12 to 34 months). The number of male patients was double that of females. Postoperative pain during the first week was more intense in the band ligation group (2-5 *vs* 0-3 on a visual analogue scale). Post-defecation pain was more intense with band ligation and so was rectal tenesmus (P = 0.0059). The patients in the infrared coagulation group resumed their duties earlier (2 *vs* 4 days, P = 0.03), but also had a higher recurrence or failure rate (P = 0.03). Thus, we conclude that band ligation, although more effective in controlling symptoms and obliterating hemorrhoids, is associated with more pain and discomfort to the patient. As infrared coagulation can be conveniently repeated in case of recurrence, it could be considered to be a suitable alternative office procedure for the treatment of early stage hemorrhoids.

Introduction

Hemorrhoids or piles are a very common disease affecting in various forms almost 50% of people over the age of fifty (1). For early stage hemorrhoids, i.e., grades 1 and 2, many treatment options have been proposed and tried (2). The treatment procedures commonly adopted are injection of a sclerosant solution (sclerotherapy) and rubber band ligation (RBL). Other procedures include chemical destruction of pile mass with a direct current probe (Ultroid), or by thermal destruction with bipolar diathermy (Bicap), cryoablation, and infrared coagulation (IRC) (3).

In the climate of cost containment, malpractice suits and competition for patients, a definite trend is developing towards office treatment for hemorrhoids. The search is ever on for a procedure that is easily learned, is cost effective, gives satisfactory results,

and lacks complications. A method that could return the anal cushions to their normal size and positions would be naturally preferred to methods that destroy tissue and may interfere with the mechanism of continence. Infrared photocoagulation, a technique introduced in the late seventies by Nath (4), satisfies these requirements. In this procedure the tissue is coagulated by infrared photocoagulation using mechanical pressure (5).

The present study was conducted to assess post-procedure pain and effectiveness of the procedure following RBL and IRC of early stage bleeding hemorrhoids.

Patients and Methods

In the present study, IRC and RBL were compared in terms of postoperative pain, time taken to resume routine work and effectiveness of the procedures. In this prospective, blind study, 100 patients with second degree bleeding hemorrhoids were assigned randomly to IRC or RBL and identified by number.

Blinding was done by using a sealed envelope, which was opened by the operating room nurse.

The study was carried out at Fine Morning Hospital and Research Institute, Gupta Nursing Home, Nagpur, India, between July 2000 and June 2001. Both procedures were carried out by the author who had experience in more than 200 procedures using each of the two methods.

Second degree bleeding piles are defined as hemorrhoids which prolapse during defecation, cause bleeding through the rectum and are spontaneously reduced after the act.

Exclusion criteria

Patients with associated anal fissures, anal spasm or infective anal pathologies like cryptitis or proctitis, and patients who refused to sign an informed consent form were excluded from the study. The procedure was approved by the Indian Council of Medical Research Ethics Committee and was performed according to the guidelines of the Declaration of Helsinki.

No anesthesia was administered during the procedures. However, a 5% xylocaine ointment was generously applied to the anorectal region 10 min before the procedure to reduce the sensitivity of the area.

Infrared coagulation

In most cases, the lithotomy position was preferred because it permitted sufficient ease of maneuver. The left lateral position was chosen in cases in which the lithotomy position was not possible.

All the pile bases were coagulated one after the other. There was no special preference for the positions of the hemorrhoids to be dealt with first, although the largest pile was dealt with first and so on. The mean treatment duration was 3 min (range: 2 to 5 min). The IRC instrument used for the study was supplied by Lumatec (Munich, Germany). A 220-mm light guide with a tip diameter of 6 mm was used for coagulation. IRC was applied to all three principal positions of hemorrhoids, i.e., at 3, 7 and 11 o'clock.

Rubber band ligation

RBL was performed at the same sites as IRC, but by drawing in the pile mass into the ligator and placing the band over the pedicle. Care was taken to place the band exactly above the dentate line. Patients were sent home 1 h after the procedure. A regular dose of laxative was prescribed. A 5% xylocaine ointment was prescribed for local application to relieve the post-defecation discomfort and the possible burning sensation at the site. No analgesics were prescribed to the patients from either group. The patients were cautioned not to strain at stool and were warned that they should expect some bleed-

ing during the first week.

Pain was assessed using a visual analogue scale from 0 (no pain at all) to 10 (the worst pain the patient had ever experienced).

Statistical analysis

The unpaired Student *t*-test was used to measure postoperative parameters. Data were entered into a database and analyzed using the GraphPad Software (San Diego, CA, USA*).* The level of significance was set at $P < 0.05$.

Results

One hundred patients were randomized prospectively to the IRC (46 patients) and RBL (54 patients) groups and followed up for a period of 12 months from the date of the procedure.

Patient demographics

There was no significant demographic difference between the two groups (Table 1). The post-procedure results are described in Table 2.

Postoperative pain

The intensity and duration of postoperative pain in the first week were greater in the RBL than in the IRC group (2-5 *vs* 0-3 on a visual analogue scale). The duration of post-defecation pain during the first ten days was significantly shorter in the IRC group (7 min) than in the RBL group (19 min), although no difference was observed thereafter, with negligible pain in both groups.

Rectal tenesmus

Nine patients from the RBL group had rectal tenesmus when assessed after one week, as opposed to only two patients in the IRC group.

Time off work is defined as the total period taken to return to the usual activities of domestic and social life at the discretion of the patient. Patients from the IRC group were able to resume their routine activities comparatively earlier than patients from the RBL group.

Sepsis. None of the patients from the two groups had any sepsis in the form of local infection or systemic manifestation.

Complications. Two patients from the RBL group returned within a day of the procedure complaining of severe pain. The bands were removed to provide relief to these patients.

One of the patients from the RBL group reported urine retention and consequent discomfort. He was catheterized for relief and did not report a similar complaint thereafter. Seven of the patients from the IRC group complained of bleeding. Such complaints were reported mostly during the period from

Table 1. Patient demographic data.

	Infrared coagulation	Rubber band ligation
No. of patients	46	54
Mean (range) age (years)	37 (20-68)	39 (19-65)
Sex ratio (male:female)	32:14	36:18
Duration of disease (mean)	18 months	17 months
Number of hemorrhoids under treatment	153	133

Table 2. Comparison of infrared coagulation and rubber band ligation in early stage hemorrhoids.

Events observed	Infrared coagulation (N = 46)	Rubber band ligation (N = 54)
Intensity of postoperative pain (first week)[a]	2-5	0-3
Period of post-defecation pain	7 min	19 min*
Rectal tenesmus	2 patients	9 patients*
Time off work	2 days	4 days*
Obliteration of hemorrhoids	80%	92%*
Recurrence of bleeding	6	4*
Recurrence of prolapse	1	0

[a]Measured on a visual analogue scale.
*$P < 0.05$ compared to infrared coagulation (unpaired Student *t*-test).

day 5 to day 10 after the procedure. The bleeding was almost always associated with defecation. Experience confirmed that this condition was attributable to sloughing of the tissue at the base of the hemorrhoids and the resulting oozing from the raw area thus formed at the coagulation site.

Two of the patients from the RBL group reported bleeding between the 7th and 9th day, presumably due to detachment of the pile mass from the pedicle.

Follow-up examination one year after the procedures

At a follow-up examination one year after the procedures, six patients from the IRC group had recurrence of symptoms in the form of bleeding. Only one patient complained of recurrence of prolapse of piles. In an identical comparison, four of the patients from the RBL group had recurrence of bleeding. No patient from this group, however, complained of any prolapse.

The obliteration of the treated hemorrhoids, confirmed by anoscopy at the end of one year, was 80% in the IRC group and 92% in the RBL group.

Discussion

Numerous nonoperative treatments have been proposed and are being extensively used for the management of first and second degree hemorrhoids, but no single therapy has been shown to be consistently better (6).

The developing trend is to prefer an improved technique for the ablation of hemorrhoids rather than opting for their excision. Infrared radiation works by penetrating the tissues to a predetermined depth at the speed of light, being instantly converted into heat. This coagulation method has a number of significant advantages in the treatment of hemorrhoids. The tissue damage that does occur with IRC is very superficial and is comparable to that which occurs with lasers.

The mechanical pressure applied by the instrument reduces blood flow and brings the blood vessels closer to the surface where a minimal energy dose achieves the coagulation effect. The depth of coagulation can be precisely determined according to the duration of exposure (4). The duration of the radiation delivered is regulated by a timer built in the power unit of the instrument and can be preset from 0.5 to 3 s. Exposure for 1 s causes a necrosis of approximately 6 mm in diameter and 1 mm in depth of the pile mass. Usually 3 to 4 applications are enough to achieve coagulation of each hemorrhoid. It is important to point out here that the mucosa proximal to the hemorrhoid, and not the hemorrhoid proper, is exposed to radiation.

The result of IRC presumably is the immediate reduction of blood flow to the hemorrhoids followed by tethering of the mucosa to the underlying tissue as healing occurs in the process by cicatrization (5). A significant advantage of IRC is that the tissues treated with the instrument do not adhere to its tip as they do with electrocoagulation.

RBL is considered to be an effective treatment for symptomatic internal hemorrhoids (7). Since its introduction by Barron, many new useful modifications have been introduced in the procedure. Suction ligation (8), synchronous ligation (9) of all the hemorrhoids with a modified anoscope (10) and using a videoscopic anoscope (11) are a few of such innovations that have helped achieve still better results.

However, despite all of these modifications, one problem that persists and continues to bother proctologists is the post-ligation pain and discomfort associated with RBL. With the introduction of IRC, it is possible to eliminate this potential cause of concern while achieving results that almost match those obtained with RBL (12).

Both treatments (IRC and RBL) can be performed as office procedures. While the cost of each band is approximately US$ 0.50, the cost of coagulation is limited to the

acquisition of the coagulator, which requires no maintenance, except for the normal care involved in its sterilization and use. The running cost of the IRC instrument is negligible. In our study, only one new tungsten halogen bulb needed replacement during our use of the instrument in over 200 procedures. The cost of the bulb was US$ 100.00, corresponding to US$ 0.50 per procedure.

Although the RBL method demonstrated a greater and long-term efficacy, it was associated with a significantly higher incidence of post-treatment pain (13-15). In contrast, IRC has been reported to be a painless procedure (16).

No special training is required for a surgeon to carry out the coagulation, except scrupulously keeping the area of coagulation above the dentate line. On the other hand, application of a rubber band needs expertise in placing the band in the right place, with failure to do so possibly leading to complications like bleeding (17), pile strangulation (18), necrosis, or sepsis (19).

In view of the previous experience of discomfort with RBL, some observers have even tried injection of local anesthetics into the post-banded pile mass to relieve the pain occurring after the procedure (20,21). This indicates that the pain intensity after the procedure is truly as severe as generally described in the literature. The characteristics of post-ligation pain most often include mild anal discomfort (11), rectal tenesmus (22), painful priapism (19), urinary hesitancy (13,23), and anal urgency (6). The intensity of pain may at times lead to fainting (24) and vasovagal attacks (25).

While band ligation is marked by a large number of complications of an inflammatory character (26,27), no such incidence has been reported with IRC (28).

Life-threatening complications like tetanus, band-related abscess (29,30), pelvic cellulitis (31), rectovaginal fistula, and bacteremia (19) have been reported after RBL. The septic complications are manifested as a clinical triad of pain, fever and urine retention (32). In contrast, IRC is virtually safe and free from such dreaded complications (33). IRC is also well tolerated by younger patients with a hyperactive anal sphincter, in whom RBL reportedly causes considerable pain after therapy (34). A few other complications that follow RBL include thrombosis of external hemorrhoids (18), chronic longitudinal ulcer (35), severe hemorrhage (29), anal stenosis (9), nausea, and shaking (21).

Pain after RBL occurs more often than previously recognized (36). It is suggested that informed consent should be obtained before RBL and that patients should be given the opportunity to delay treatment if they so wish (14,24).

IRC is a therapy which fixes the hemorrhoidal cushions to the underlying muscle fibers (15). The anatomical results after IRC suggest that the progression of hemorrhoids and, in most cases, the need for surgery, most often are prevented (33).

The long-term effectiveness of RBL compared to IRC is probably related to the depth of tissue destruction involved in the two. The strangulating effect of the rubber band leads to necrosis of hemorrhoidal tissue. The resulting sloughing, which occurs after about one week, causes tissue destruction with scarring and a subsequent fixation of the submucosa. In contrast, IRC causes only a small burn that results in minimal tissue injury of a depth of about 2 to 3 mm. This decreased depth presumably causes less scarring and tissue fixation, thereby increasing the chances of incomplete destruction of offending tissue and the possibility of recurrence (37).

The difference in post-treatment pain between IRC and RBL may also be the result of a difference in the depth of tissue injury. The greater the tissue destruction, the greater the amount of post-procedural pain.

The results of the present study demonstrate that RBL is without doubt a more effective therapy in the management of early

stage hemorrhoids in that only a few patients require additional therapy for symptom recurrence. The most effective therapy, however, may not be the optimal one if the risks of potential complications outweigh the benefits of treatment (15). This apparent therapeutic advantage, however, should be examined in the light of the rate and severity of complications associated with RBL (38). While IRC is nearly as effective as RBL, it is significantly less painful and consequently more acceptable to the patient. The ultimate aim of all therapies is to provide optimum relief and satisfaction to the patient. Weighed on this scale, IRC certainly is destined to outweigh traditional procedures like RBL.

When the potential life-threatening complications associated with RBL are taken into consideration, IRC appears to be a logical choice because of its effectiveness, cost benefits and reduction in the rate of morbidity (39).

The present study shows that IRC is a safe and effective alternative to RBL since it is quick, hassle-free and safe. Except for the initial cost of the instrument, there are no expenses of a recurring nature. The application is easy and requires no special training and the procedure is better tolerated than band ligation. Thus, it can be considered as a suitable alternative office procedure for early hemorrhoids.

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