

Radiofrequency coagulation versus rubber band ligation in early hemorrhoids: pain versus gain

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Key words: hemorrhoids, radiofrequency coagulation, pain, rubber band ligation.

Summary. *Objective.* Band ligation of internal hemorrhoids is a well-established and accepted office procedure. However, there are several reports focusing on problems associated with this technique, which is perceived by many to be risk-free. This randomized study is aimed to compare radiofrequency coagulation and rubber band ligation of hemorrhoids on the parameters of effectiveness and comfort.

Material and methods. Eighty patients of 2nd degree bleeding piles were randomized prospectively for band ligation (44 patients) or radiofrequency coagulation (36 patients) technique. Parameters measured included postoperative discomfort and pain, time taken to return to work, complications accompanying the procedure and recurrence rate.

Results. The post defecation pain was more severe with band ligation ($p=0.01$) and so was rectal tenesmus ($p=0.01$). The patients from radiofrequency coagulation group resumed their duties early (2 versus 5 days, $p=0.05$). Recurrence rate was higher in radiofrequency coagulation group.

Conclusion. Rubber band ligation is associated with significantly higher post treatment pain and discomfort. As against this, radiofrequency coagulation results in significantly less pain and post defecation discomfort. However, chances of recurrence of bleeding and prolapse of hemorrhoids are comparatively higher using radiofrequency coagulation of hemorrhoids.

Introduction

Hemorrhoids are one of the most frequent anorectal disorders encountered in the primary care settings. They are the most common cause of bleeding *per rectum* and are responsible for considerable patient suffering and disability. With the newer techniques of diagnosis and office-based interventions, most of the symptoms can be effectively controlled.

A variety of treatment options for early degree of hemorrhoids i. e. 1st and 2nd grade are available. The treatment procedures commonly adopted are injection of sclerosant solution (sclerotherapy) and rubber band ligation. The other procedures in practice include chemical destruction of pile mass by direct current probe (Ultroid), or by thermal destruction with bipolar diathermy (Bicap), cryoablation, hemorrhoidal artery ligation and by infra red coagulation (1). Yet, despite presence of numerous non-surgical therapies for hemorrhoids, none of these has established its superiority over the rest.

While rubber band ligation is considered an easy and safe outpatient treatment of internal hemorrhoids, it is nevertheless associated with sizable number of

adversities (2). Ideally, a method that could return the anal cushions to their normal size and positions would be a natural preference to the one that destroys tissue and may interfere with the mechanism of continence. Radiofrequency coagulation is found to meet the preference (3). In radiofrequency coagulation, the tissues are coagulated by radiofrequency waves.

Aim of the study

This study was conducted to assess the amount of post procedure pain and effectiveness of the procedures following the band ligation technique and the radiofrequency coagulation technique while treating early grades of bleeding hemorrhoids.

Material and methods

This study compares radiofrequency coagulation (RFC) and rubber band ligation (RBL) performed in patients with 2nd grade bleeding hemorrhoids. The parameters measured were postoperative pain, time taken to resume routine work and effectiveness of the procedures. In this randomized, prospective study, 80 patients of 2nd degree bleeding hemorrhoids were randomly chosen to undergo the RFC or RBL procedures.

Randomization was done by sealed envelope, which was opened by the hospital nurse. The study was carried out at Fine Morning Hospital and Research Center, Gupta Nursing Home, Nagpur, between January 2001 and March 2002. Both procedures were conducted by the author himself who had to his credit more than 160 procedures by each of the two methods. Second-degree bleeding piles were defined as hemorrhoids, which prolapse during defecation, cause bleeding *per rectum* and get reduced spontaneously after defecation. Patients having associated fissure *in ano*, anal spasm or infective anal pathologies like cryptitis or proctitis were excluded from the study. An informed consent was obtained. The procedure was approved by the local ethical committee (Indian Council of Medical Research) and was performed according to the declaration of Helsinki. All the procedures were performed as office procedures. A 5% Xylocaine ointment was instilled per rectally via the nozzle of the tube 10 minutes before the procedure to produce surface anesthesia.

Principle of radiofrequency coagulation. Radio frequency unit generates a very high frequency radio wave of 4 MHz. The unit includes a plastic covered ground plate or antenna, and a "patient electrode" attached to a handle over it, which is held by the operating surgeon. No electrical contact needs to be made between the patient and the ground plate, unlike operating theatre diathermy equipment. When high frequency wave energy passes between the ground plate and patient electrode, it is concentrated at the electrode end resulting in the release of energy, which produces steam within the cells thereby vaporizing the fluid within and coagulating the tissues. This occurs because of the heat produced by tissue resistance to the passage of high frequency wave. The heat makes the intracellular water to boil, and thereby increasing the cell inner pressure to the point of breaking it from inside to outside. This phenomenon is described as cellular volatilization.

Procedure of radiofrequency coagulation. The radiofrequency generator used for this study was Ellman Dual frequency 4 MHz (Ellman International Inc. Hewlett NY, USA). The amount of energy to be delivered by this unit can be preset in the range between 1 and 100. A ball electrode having length of 11 cm, supplied with the unit proved handy and was exclusively used for this procedure. In most of the cases, lithotomy posture was preferred as it gave the surgeon enough ease of maneuver. Left lateral position was opted in cases where lithotomy was not possible. A well-lubricated anoscope was gently inserted in the

anal canal to visualize the hemorrhoids. Starting at the base of the pedicle, the whole pile mass was coagulated by gradually rotating the ball electrode of the radiofrequency probe over the hemorrhoid. Shrinkage and gradual change of hemorrhoids to dusky white color (blanching) indicated a satisfactory coagulation necrosis. Hemorrhoids at all three principle positions, i. e. at 3, 7 and 11 o'clock, were coagulated one after the other. There was no special preference for the positions of hemorrhoids to begin with; though the largest pile was dealt with first and so on. The mean treatment duration was 3 minutes, having ranged between 2 to 5 minutes.

Procedure of rubber band ligation. RBL was done at similar places by in drawing the pile mass in the ligator and placing the band over the pedicle. Care was taken that the band was meticulously placed above the dentate line. Patients were sent home 1 hour after the procedure. A regular dose of laxative (Fybogel) was prescribed. The patients were asked to apply Xylocaine 5% ointment locally just before and after defecation to relieve the pre and post defecation discomfort as also the possible burning sensation at the site. None of the patients from either group were prescribed any analgesics. They were cautioned not to strain at stool and that they should expect little bleeding in the first week.

An independent observer blinded to the type of procedure carried out the assessment of the postoperative findings. Pain was assessed using a visual analogue scale from 0 (no pain at all) to 10 (the worst pain the patient had ever experienced). The first follow up was made on the 7th post-procedure day. Subsequent follow-ups were made after 1 month and then after 1 year of the procedure.

Statistical analysis. An unpaired student's t-test was used to measure postoperative parameters. Data were entered in to a database and analyzed using statistical software (Graph pad Software, San Diego, CA). The level of statistical significance between groups was set at 5%.

Results

Eighty patients were randomized prospectively in two groups undergoing either radiofrequency coagulation (36 patients) or band ligation (44 patients) procedure. The follow up was carried out for a period of 12 months from the date of the procedure. There was no significant demographic difference between the two groups (Table 1).

Postoperative pain. The intensity and duration of postoperative pain in the first week was more in RBL

Table 1. Patient demographic data

Demographic data	Radiofrequency coagulation	Rubber band ligation
No. of patients	36	44
Mean (range) age (years)	29 (18–62)	31 (19–65)
Sex ratio (M:F)	24:12	28:16
Duration of disease (mean)	15 months	17 months
Number of hemorrhoids under treatment	116	123

than in RFC group (2-4 versus 0-2 on visual analogue scale). The duration of post defecation pain in the first seven days was significantly less in RFC group when compared with the RBL group, which lasted for about 6 minutes in the RFC group and 13 minutes in RBL group. But thereafter, no significant difference was recorded, as the pain was negligible in both groups.

Rectal tenesmus. Seven patients from RBL group had rectal tenesmus at a follow up after one week, while only 2 patients in the RFC group had this finding.

Time off work was defined as total period taken to return to the usual activity of domestic and social life at the discretion of the patient. Patients from RFC group resumed their routine comparatively earlier than their counter parts in the control group (2 days to 5 days).

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

Complications (Table 2). Two patients from RBL group returned back within a day of the procedure complaining about severe pain. The bands were removed to provide them relief. One patient from RBL group reported retention of urine and the consequential discomfort. He was catheterized to relieve him of the problem and did not face a similar complaint thereafter. Seven patients from RFC group complained of bleeding. Such complaints were reported mostly during the period spanning between 5th and 10th day af-

Table 2. Complication score after RFC and RBL of hemorrhoids

Complications	Radiofrequency coagulation	Rubber band ligation
Severe pain	None	2
Retention of urine	None	1
Post procedure bleeding	7	2

ter procedure. Bleeding almost always was associated with defecation. Two patients from RBL group reported with bleeding between 7th and 9th day.

Follow up after one year. At a follow up after 1 year of the procedures, 5 patients from the RFC group had recurrence of symptoms in the form of bleeding, while one patient complained of recurrence of prolapse of piles. In an identical comparison, 3 of the patients from RBL group had recurrence of bleeding. None from this group, however, complained of any prolapse. The obliteration of the treated hemorrhoids, confirmed by anoscopy at the end of the first year, was 82% in RFC group, while it was 93% in RBL group (Table 3).

Discussion

Numerous non-operative treatments have been proposed and are being extensively used for the management of the 1st and 2nd degree hemorrhoids. However, despite availability of such therapies, none is considered totally safe and efficacious. The developing trend is to prefer an improved technique for the ablation of hemorrhoids rather than opting for their excision. The system of radio wave surgery involves using high frequency radio waves at 4.0 MHz, which deliver low temperature through RF micro-fiber electrodes and is akin to the frequency of marine band radios. The tissue under treatment itself resists the path of the waves and gets heated, thereby leaving the RF micro-fiber electrode in a cool state. The intracellular tissue water-resisting the waves vaporizes. This vaporization of tissue fluid results in significant hemostasis without actually burning the tissue. This coagulation method has a number of significant advantages in the treatment of hemorrhoids. The tissue damage that does occur with RFC is very superficial and is comparable to that which occurs with lasers (3).

The result of radiofrequency coagulation presumably is notable in the immediate reduction of blood flow to the hemorrhoids followed by tethering of the mucosa to the underlying tissue as healing occurs in

Table 3. Comparative results between rubber band ligation and radiofrequency coagulation of hemorrhoids

Events observed	Radiofrequency coagulation	Rubber band ligation	P
Period of post defecation pain	6 minutes	13 minutes	0.010
Rectal tenesmus	2 patients	7 patients	0.019
Time off work	2 days	5 days	0.051
Obliteration of hemorrhoids	82%	93%	0.004
Recurrence of bleeding	5	3	0.105
Recurrence of prolapse	1	0	0.005

the process by cicatrization.

Rubber band ligation is being used as an efficacious treatment for symptomatic internal hemorrhoids. Since its introduction by Barron, a lot new useful modifications have been introduced in the procedure. Nevertheless, one problem that persists and continues to bother the proctologist is the post ligation pain and discomfort that is associated with RBL. With the introduction of RFC, it is possible to eliminate this potential cause of concern, while achieving results that almost match with those obtained with the rubber band ligation (4). Although, the RBL method demonstrated a greater and long-term efficacy, it was found to be associated with a significantly higher incidence of post treatment pain (5–7). In contrast, radiofrequency coagulation is reported to be a painless procedure (8).

No special training is required for a surgeon to carry out the coagulation. On the other hand, application of a rubber band needs expertise in placing the band at the right place, in opposite case, it could lead to complications like bleeding (9), strangulation of pile (10), necrosis, or sepsis (11).

With the previous experience of discomfort with RBL, some researchers have even tried injection of local anesthetics on the post-banded pile mass to relieve the pain occurring after the procedure (12). This indicates that the pain intensity after the procedure is tormenting than that is generally described in the literature. The variables of post-ligation pain most often include mild anal discomfort, rectal tenesmus (13), painful priapism (11), urinary hesitancy (14, 15) and anal urgency. The intensity of pain at times, might lead to fainting (16) and vasovagal attacks (17). While band ligation is marked by a great number of complications of an inflammatory character (18), no such incidence has been reported with RFC (19). Life threatening complications like tetanus, band related abscess (20, 21), pelvic cellulitis (22), rectovaginal fistula, and bacteremia (11) have been reported after RBL. The

septic complications are manifested with a clinical triad of pain, fever and retention of urine (23). RFC in contrast, is virtually safe and free from such dreaded complications (24).

Both treatments (RFC and RBL) can be performed as office procedures. While the cost of each band is approximately 50 US cents, the cost of coagulation is limited to the acquisition of the radiofrequency generator (US\$ 1600 for the basic unit), which does not require any maintenance, except the normal care during its sterilization and use. The running cost of RFC instrument is insignificant.

RFC is also well tolerated by the younger patients with hyperactive anal sphincter, where rubber band ligation had reportedly caused considerable pain after therapy in such patients (25).

Few other complications that follow RBL include thrombosis of external hemorrhoids (10), chronic longitudinal ulcer (26), severe hemorrhage (20), anal stenosis, nausea and shaking.

The post radiofrequency coagulation bleeding is attributable to sloughing of the tissue at the base of hemorrhoids and the resultant oozing from the raw area thus formed at the coagulation site. The reason of bleeding after a week of band ligation presumably is due to detachment of the pile mass from the pedicle.

Pain after RBL occurs more often than previously recognized (27). It is suggested that informed consent should be obtained before RBL and that patients should be given the opportunity to delay treatment if they wish so (6, 16).

RFC is a therapy, which fixes the hemorrhoidal cushions to the underlying muscular fibers (8). The long-term effectiveness of RBL over RFC probably relates to the amount of depth of tissue destruction involved in the two. The strangulating effect of the rubber band leads to a necrosis of the hemorrhoidal tissue. The resultant sloughing, which occurs after about a week causes tissue destruction with scarring

and a subsequent fixation of the submucosa. In contrast, RFC causes only a small burn that results in minimal tissue injury of a depth of about 2 to 3 mm (8). This decreased depth presumably causes less scarring and tissue fixation thereby increasing the chances of incomplete destruction of offending tissue and possibility of recurrence.

Results of this study demonstrate that RBL is without a doubt the most efficacious therapy in the management of early degree hemorrhoids and only a few patients require additional therapy for symptom recurrence (28). The most efficacious therapy, however, may not be the optimal one if the risks of potential complications outweigh the benefits of the treatment (7). This apparent therapeutic advantage however, is required to be examined in light of the rate and severity of complications associated with RBL. While RFC is nearly as efficacious as RBL, it is significantly less painful and consequently is more acceptable to the patient (8). In addition, when the potential life threatening complications associated with RBL are taken into consideration, RFC appears to be a logical choice

for its effectiveness, cost benefits and reduction in the rate of morbidity (29).

The difference in post treatment pain between RFC and RBL may also be the result of difference in the depth of tissue injury. The greater the tissue destruction, the greater is the amount of post-procedural pain. The cause of pain after banding is either due to constriction of the pile mass, or due to an inflammatory response in the form of local edema because of lymphatic permeability. Radiofrequency has been found successful in sealing the sensory nerve endings and the leaking lymphatics, and thereby reducing pain (30).

Conclusion

The study shows that radiofrequency coagulation could be adopted as a safe alternative to rubber band ligation, as it is a hassle free and safe procedure. Saving the initial cost of the instrument, it involves no expenses of a recurring nature. The application is easy and requires no special training. Being better tolerated than band ligation, it can be considered as an alternative office procedure for early hemorrhoids.

Hemoroidų perrišimas ar radiodažninė koaguliacija: kuris metodas taikytinas esant mažo laipsnio hemorojui

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Raktažodžiai: hemoroidai, radiodažninė koaguliacija, skausmas, perrišimas, kraujavimas.

Santrauka. Vidinių hemoroidų perrišimas – dažnai taikomas gydymo metodas. Paprastai šis metodas traktuojamas kaip nekeliantis jokios rizikos, vis dėlto esama problemų, susijusių su šio metodo taikymu. Siekiant palyginti, kuris gydymo metodas – radiodažninė koaguliacija ar hemoroidų perrišimas yra veiksmingesnis ir dėl kurio iš jų pacientui tektų patirti mažesnę diskomfortą, atliktas tyrimas.

Tirtųjų kontingentas ir tyrimo metodai. Atsitiktinės atrankos metodu atrinkta 80 pacientų, kuriems rasta antrojo laipsnio kraujuojančių hemoroidų. Šie pacientai suskirstyti į dvi grupes: vienos grupės ligoniniai gydyti perrišant hemoroidus, kitos – taikant radiodažninę koaguliaciją. Po gydymo vienu iš minėtų metodų įvertinti šie kriterijai: pooperacinis diskomfortas, skausmas, laikotarpis, po kurio pacientas jautėsi pakankamai gerai, kad galėtų grįžti į darbą; komplikacijos, susijusios su gydymo procedūra; hemoroidų atsinaujinimas.

Rezultatai. Pacientai, kuriems taikytas hemoroidų perrišimas, po gydymo juto didesnę skausmą tuštinantis ($p=0,01$) bei stanginantis ($p=0,01$). Pacientai, kuriems taikytas radiodažninės koaguliacijos gydymo metodas, buvo pajėgūs anksčiau grįžti į darbą (2–5 dienomis anksčiau, $p=0,05$). Hemoroidai dažniau vėl susiformuodavo tiems pacientams, kurie gydyti radiodažninės koaguliacijos metodu.

Išvada. Hemoroidų perrišimo metodas pacientams sukėlė didesnę skausmą ir diskomfortą pooperaciniu laikotarpiu. Po gydymo radiodažnine koaguliacija skausmas buvo ne toks intensyvus, o tuštinimasis kėlė mažesnę diskomfortą. Tačiau kraujavimo ir hemoroidų atsinaujinimo atvejų daugiau nustatyta pacientams, kuriems taikytas radiodažninės koaguliacijos gydymo metodas.

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