A NEW INSTRUMENTAL PROCEDURE FOR NON-PROLAPSING HEMORRHOIDAL DISEASE

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SUMMARY: Radiofrequency ablation (RFA) is a new approach for treating Grades I and II hemorrhoids. In this procedure, the hemorrhoidal tissue is exposed to high frequency radio wave to produce coagulative necrosis and fixation of the vascular components of the hemorrhoids. This study reports the author's experience with this technique. The aim of this study was to determine the efficacy of RFA in the treatment of Grades I and II hemorrhoidal disease. The present retrospective study reviews the early and long-term effects of radiofrequency ablation. A separate prospective and randomized study compared the results of radiofrequency ablation and rubber band ligation (RBL) in 60 patients with Grade II hemorrhoids in terms of their effectiveness and patient comfort. Two hundred and forty patients with Grades I and II bleeding hemorrhoids were studied. Ellman radiofrequency generator was used for this procedure. Fisher's test was carried out for the statistical analysis of the outcome of the prospective study.

Twenty three patients reported recurrence of bleeding, and 29 complained of pain or discomfort. The comparative study showed that though rubber band ligation was a more effective procedure ($p<0.001$), the rate and severity of pain was higher ($p<0.001$) than the radiofrequency coagulation. It is therefore concluded that radiofrequency ablation of hemorrhoids is easy to perform, is less painful, and has low rate of complications. It is better tolerated than RBL and can safely be repeated in case of recurrence of symptoms. It is however less efficacious.

Key Words: Hemorrhoids, Radiofrequency ablation, Complications.

INTRODUCTION

Hemorrhoids are the most frequently observed anorectal disorders encountered in the primary care sitting. They are the most common cause of bleeding per rectum and are responsible for considerable patient suffering and disability (1).

A variety of treatment options for early grades of hemorrhoids i.e. Grade I (non prolapsing) and Grade II (prolapsing but spontaneously reducing) are available. The treatment procedures commonly adopted are injection of sclerosant solution (sclerotherapy), infrared coagulation (2), and rubber band ligation. Few other procedures practiced in some parts of the world include use of direct current probe, bipolar diathermy, and cryoablation. However, none of these methods could establish their superiority over the others.

In the present era, a fast and painless procedure that could be carried out in the office practice will always be preferred (3). Radiofrequency ablation is one such technique that results in immediate reduction of blood flow to the hemorrhoids followed by tethering of the mucosa to

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Table 1: Comparative evaluation of results after radiofrequency coagulation and rubber band ligation in Grade II bleeding hemorrhoids.

Treatment method	Rectal tenesmus	Anal pain	Bleeding	Vagal reaction	Recurrence	Satisfaction grading (mean)
Radiofrequency coagulation (n=28)	1	2	6	None	4	9.1
Rubber band ligation (n=32)	6	16	4	1	2	8.2
p*	< 0.05	< 0.05	< 0.05	< 0.05	< 0.05	< 0.05

* Fisher's exact test, 95% confidence interval, Degree of freedom 1

the underlying tissue, which subsequently induces healing by way of cicatrization (4).

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 this high frequency wave is released from the generator, it is focused at the affected tissue through an electrode. The tissue resistance in the path of these high frequency waves produces heat that makes the intracellular water boil, thereby increasing the cell inner pressure to the point of breaking it from inside to outside. This phenomenon is called as cellular volatilization. This in turn, produces coagulation and shrinkage of the tissues (5).

Radiofrequency, while ablating the vascular components of the hemorrhoidal tissue, does not cause any lateral thermal damage (6). Being a controlled procedure, it is a more effective and safe method for elimination of hemorrhoids (7, 8).

A radiofrequency generator Ellman dual frequency 4 MHz (Ellman International Inc, New York) was used. The output power intensity to be delivered can be set to range between 1 and 100. A ball electrode having length of 11 cm, supplied with the unit was used.

The motto behind this study was to assess the effectiveness of radiofrequency ablation of hemorrhoids and if it has any advantage over rubber band ligation of hemorrhoids, which by far, is the most preferred procedure.

MATERIAL AND METHODS

Two separate studies were conducted. The first one was a retrospective study, in which the effect of radiofrequency ablation on 240 patients with Grades I and II bleeding hemorrhoids was observed over a period ranging from 15 to 23 months. This included 126 males and 114 females. The mean age of the patients was 34 years (range between 19 and 69 years).

The second was a prospective and randomized study. In this, 60 patients of Grade II bleeding hemorrhoids were randomly chosen to undergo either radiofrequency ablation (RFA) or rubber band ligation (RBL).

In the first study, out of the 240 patients, 117 were having Grade I hemorrhoids and the remaining had Grade II hemorrhoids. One hundred and ninety seven of these patients had a treatment failure with medical treatment namely, use of laxatives and hemorrhoid creams. Patients having associated anal fissure or infective anal pathologies like cryptitis or proctitis were excluded from the study.

An informed consent was obtained from all the patients. The procedure was approved by the local ethical committee and was performed according to the declaration of Helsinki.

Procedure of radiofrequency ablation

No anesthesia or sedation was required during the procedure. However, 5% xylocain ointment was infused in the anus about 10 minutes before the actual procedure to reduce the sensitivity of the area.

The procedure was carried out keeping the patient in a lithotomy posture. Left lateral position was preferred in cases where lithotomy position was not possible.

A well-lubricated large size anoscope was gently inserted in the anal canal to visualize the hemorrhoids. Starting at the base of the pedicle, the whole hemorrhoid mass was ablated by gradual rotating the ball electrode over the hemorrhoid. Shrinkage and gradual change of hemorrhoids to dusky white color (blanching) indicated a satisfactory coagulation necrosis.

Hemorrhoids at all the three principal 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 time required for coagulation of each hemorrhoid was 20 to 40 seconds depending on its size. Care was taken to keep the coagulation above the dentate line to avoid pain.

Patients were assessed after an hour of the procedure and were sent home when they presented no complaint. They were asked to take 10 grams of psyllium husk (Fybogel) at bedtime for a month. They were cautioned not to strain at stool and that they should expect little bleeding in the first week of the procedure.

An independent observer, who was not from the operating team 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 postoperative day. Next follow-up was made after 1 month and then after 15 months or more of the procedure.

Statistical analysis

Data were analyzed using Fisher's exact test. They were entered in to a database and analyzed using statistical software (Graph pad Quick Calcs, San Diego, CA). A value of $p < 0.05$ was considered statistically significant.

RESULTS

Twenty three patients (10%) complained of bleeding in first 2 weeks. This most frequently occurred between day 5 and day 10 of the procedure. The bleeding was associated with defecation.

Four patients returned with heavy bleeding in the first week of the procedure. This bleeding was spontaneous, unassociated with defecation. They were admitted in the hospital. Three of these patients responded to conservative therapy with local compression and haemostatic medication. However, one patient needed examination under general anesthesia. The active bleeding source was located and duly secured. All of them had an uneventful recovery thereafter.

Twenty nine patients complained of pain in the anal region. The intensity of pain was 1 to 2 on visual analogue scale. They were prescribed appropriate analgesics. Rest of the patients did not complain of any pain.

Four patients complained of a brownish, foul smelling discharge from the anus soiling the clothes. This was noticed at the end of the first week of the procedure. No specific treatment was advocated. The discharge ceased of its own by the end of second week of the procedure.

Nine patients complained of itching in and around the anal canal. The itching was controlled using antihistaminic medication.

None of the patients developed any infective complications like suppuration in the operated area or perianal tissues.

Follow up findings

This was carried at a mean period of 18 months (range 15-23 months). Twelve patients were lost to follow up.

Between this period, 33 patients had recurrence of bleeding. They were re-examined. All of them had presence of hemorrhoid. They were asked for repeat radiofrequency ablation. While 27 patients agreed, remaining 6 patients refused to undergo the procedure again. Three patients continued to have bleeding even after repetition of the procedure while no bleeding was reported in the remaining.

Comparative study between radiofrequency ablation and rubber band ligation

Randomization of the patients was done by sealed envelope, which was opened by the hospital nurse. The post procedure assessment was carried out by an independent observer who was not from the operating team. The parameters measured included post procedure pain, rectal tenesmus, recurrence of bleeding and satisfaction grading (Defined as overall satisfaction with the surgical outcome using a visual analogue scale, 0 = dissatisfied, 10 = completely satisfied).

None of the patients from either group was prescribed any analgesics.

Of the 60 patients, RFA was carried out on 28 patients while 32 patients were assigned to undergo RBL. The groups were similar in terms of age, gender, hemorrhoidal degree, and indication for operation.

It was found that though rubber band ligation was more effective than radiofrequency coagulation, it was necessarily associated with more pain and discomfort to the patients. The patients expressed grater satisfaction with radiofrequency coagulation. The comparative findings are given in Table 1.

DISCUSSION

Despite availability of numerous non-operative therapies, none is considered totally safe and efficacious for the management of early grades of hemorrhoids (9).

Radiofrequency ablation is widely used in the field of ophthalmology, plastic surgery and for ablation of hepatic tumors (10). The system of radio wave surgery involves release of high frequency radio waves at 4.0 MHz, which vaporizes the tissue fluid. This vaporization of tissue fluid results in significant hemostasis without actually burning the tissue (11). This property of the radiofrequency wave has suggested to use them for coagulation of hemorrhoids.

Rubber band ligation is a common office procedure for hemorrhoids. While having a greater long-term efficacy, it is associated with a significantly higher incidence of post treatment pain (12). The most efficacious therapy, however, may not be the optimal one if the risks of potential complications outweigh the benefits of the treatment (13).

Radiofrequency ablation, on the other hand, is associated with fewer and less severe complications. The anatomical results following radiofrequency ablation suggest that the progression of hemorrhoids and probably, the need for surgery are prevented (14).

Band ligation is marked by a great number of complications of an inflammatory character (15, 16). Various life-threatening complications have been reported after bandage of hemorrhoids (17). These include tetanus (18), liver abscess (19), pelvic cellulitis (20), rectovaginal fistula, and bacteremia. The septic complications are manifested with a clinical triad of pain, fever and retention of urine (21). None of such complications has been encountered with radiofrequency ablation.

Radiofrequency ablation was well tolerated by the younger patients with hyperactive anal sphincter, where rubber band ligation had reportedly caused conceivable pain after therapy (22). It is suggested that patients should be given the opportunity to delay treatment if they so wish (23).

Radiofrequency ablation is a relatively new introduction in the treatment of hemorrhoids, though its applications in other fields of surgery are well accepted. Preliminary results of this study show that it is an effective method in controlling hemorrhoidal symptoms. The procedure is painless, quick, and easy to use by the operator without assistants. The equipment is portable, long lasting, and needs no maintenance. However, it is necessary to use multiple sessions to obtain good results. While rubber band ligation was found to be more effective in controlling the hemorrhoidal symptoms, the rate and severity of pain was higher when compared with radiofrequency ablation.

It is admitted that being a new technique, further observations with a longer follow-up, on a larger series of patients and comparisons with other conventional treatments are called for to prove its efficacy and long term benefits.

CONCLUSION

The study shows that radiofrequency ablation could be adopted as an alternative treatment for early grades of symptomatic hemorrhoids.

Save the initial cost of the instrument, there are no expenses of a recurring nature. The application is easy and requires no special training. In comparison, it is better tolerated than the hemorrhoidal band ligation.

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