Comparison between Ultroid and Rubber Band Ligation in Treatment of Internal Hemorrhoids

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Abstract- Hemorrhoid is one of the most common surgical diseases and different methods are available for its treatment. This study is a comparison between two methods of treatment of internal hemorrhoid, Monopolar low voltage instrument (Ultroid) and Rubber Band Ligation. This method has been carried out prospectively in which 50 patients who were treated with rubber band ligation and 50 patients with Ultroid were compared according to the incidence of complications, post-operative pain and treatment response. According to this study complete success rate with Ultroid was 82% and partial success rate was 10% and no response to treatment was seen in 8%. In Rubber Band method the complete response rate was 94% (*P*=0.2). With Ultroid, 74% of patient reported no postoperative pain, 24% reported mild and moderate pain and 2% of patients complained of severe pain. With Rubber band ligation, 72% of patients reported no post-operative pain, 26% reported mild and moderate pain and 1% complained of severe pain (*P*=0.00). Rubber Band ligation and Ultroid are both considered as outpatient procedures for treatment of hemorrhoids. Both methods are mostly used for grade 1, 2 and sometime grade 3 hemorrhoids. In Ultroid method the operator is required to hold the probe for a period of time, and in most cases, the surgeon should spend between 20-25 minutes for the coagulation of three piles. Some surgeons do not have patience for this modality of internal hemorrhoid treatment. In this study we achieved acceptable results comparable with those of other techniques.

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Introduction

Hemorrhoid has been a cause of human discomfort for many years. Nowadays many people suffer from this disease, and according to the present knowledge more than 50 percent of people above age 50 have some problems associated with hemorrhoid (1). Many patients have scarce knowledge about anorectal diseases, which lead to significant errors in the estimation of the prevalence of these diseases. Patient with hemorrhoid complains of bleeding, itching, burning, mass sensation or pain in the region that may be due to other causes, such as benign and malignant anorectal tumors, most of these are identifiable with a simple digital rectal examination.

There are different medical and surgical therapeutic approaches to hemorrhoids that can be performed outpatient or inpatient. Our study compares two outpatient methods in the treatment of internal hemorrhoid, Rubber band ligation (RBL) and direct current monopolar low voltage coagulation (Ultroid).

Rubber band ligation is one of the outpatient treatments of hemorrhoid. It leads to ischemic necrosis and mucosal fixation of hemorrhoid. It will be better to use two rubber bands instead of one. However using two or three ligations in the first visit are feasible, time saving and also economically cost effective, but Barron has proposed that only one ligation should be taken each time, with an interval of three weeks between consecutive ligations (1).

These techniques have some complications that the most common ones are intra or post-operative pain.

In most cases the pain is mild and lasts only one or two hours, and relieves with Acetaminophen. Bleeding is another complication, which can be ceased with one or two minute of local compression.

In the study performed by Gupta postoperative pain during the first week was intense in the band ligation group (2-5 on a visual analogue scale). Post-defecation

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pain and rectal tenesmus were also more intense in this group of patients (2). Bleeding is other complications of these techniques that arises from tissue necrosis and avulsion of this necrotic tissue.

Sometimes rubber band ligation leads to pelvic cellulitis and clostridial infection that in the case of delayed diagnoses and treatment can lead to death (3,4).

Thrombosis, ulceration and slippage are another and less common complication may be seen in RBL (5).

Ultroid is another method of the patient treatment for hemorrhoids. It is minimally invasive and is based on using of monophasic, low voltage current on supplying vessels of hemorrhoids. This method is painless, safe, without any need to anesthesia and any bleeding or infectious complication. It is associated with high success rates in improving patients' quality of life and early return to their social activities.

The aim of this study is the comparison of these two methods in patients with hemorrhoids.

Patients and Methods

This study is an analytical cross-sectional study. The data collection was performed via observation and physical examination of the patients. Questionnaires were filled during the study. The study population was selected among the patients with hemorrhoids, referring to the colorectal clinic of Hazrat-e-Rasool Hospital, Iran University of Medical Sciences and a private clinic, during October 2003 to March 2005.

Patients with grade 4 prolapsed hemorrhoids were excluded for surgical management. Patients over 45 years of age underwent rectosigmoidoscopy and in the presence of pathology, were biopsied and excluded from the study. All patients who were inaccessible for any reason have also been excluded.

Our study samples were 100 cases (50 cases undergone RBL and 50 cases received treatment with Ultroid). One Bisacodyl suppository was prescribed in the day just before the day of procedure and one at 6 am of the operation day. The patients were informed about both RBL and Ultroid and then one of the methods was considered randomly for the treatment of each patient.

The patient could be placed in left lateral, knee chest or lithotomic position, but the most comfortable one was left lateral decubitus. Proctoscope is better to be held by an assistant, in order to let the surgeon's hands be free. Proctoscope was passed through the anal canal until the hemorrhoid was prolapsed into its lumen. Mucosa was grasped by a Forceps (McGivney hemorrhoid ligator) and the Rubber Band was placed around the base of hemorrhoid about 1.5 ~ 2 cm above the dentate line.

In Ultroid method (Hemoron® NHN electronics v.o.s, Czech Republic, 2002) after examination of the perianal area and the rectum, the electrodes were installed on the probe after switching the generator on. Then the anoscope was introduced into the anal canal and rotated until the hemorrhoid was prolapsed into it.

The electrodes were placed tangential to the base of the hemorrhoid, and pushed on the tissue in a perpendicular direction to the electrode axis. The probe was switched on, and the current intensity was gradually increased until the patient felt discomfort. At this point the intensity was decreased 1 degree, which was named "Preselected" current. Then the current was maintained constant until the tissue changes and mucosal necrosis around the electrodes, a crack sound and the foamy substance appeared. The application time of this process was determined based on the tissue appearance around the electrode, but it should not be less than 5 minutes. In sensitive patients, using of low current intensity and long durations is recommended.

After the treatment, Cefixime 400 mg (Suprax®, third generation cephalosporin), once daily was prescribed prophylactically for 3 days. The patients were recommended to refer if a major problem such as bleeding or severe pain occurred. The patients were visited one week and one month after receiving treatment and the remained symptoms or new problems were recorded if present.

Data analysis has been performed using SPSS Software 11.05, using descriptive statistics indices, Mann-Whitney U and Chi-Square tests. The Statistical significance was determined at the level of 0.05.

Results

Overall, 100 patients with hemorrhoid underwent treatment with Ultroid (Group A) and Rubber Band Ligation (Group B), were evaluated in one year follow up period. The patients ranged from 25-75 years of age with mean age of 44.5 (SD=13.2), and 43.6 (SD=13.6) for group A and B, respectively. Fifty nine cases out of 100 were male. In group A, 29 patients (58%) were male and in group B, there were 30 (60%). The Major referral symptoms of the patients were bleeding (94%). Hemorrhoid prolapse (24%), pain (24%), itching (5%) and constipation (3%) were in the next steps (Table 1).

Seven of 100 evaluated patients (7%) had graded one, 66% had grade two, 27% had grade three of the

disease. The mean number of treated piles was 2.6 (±0.5) in group A and 2.2 (±0.4) in group B (*P*=0.00).

In group A, 36 of 50 (72%) had no bleeding after operation. Three of 50 (6%) had bleeding in 1-24 hours, another 3 (6%) had bleeding in 24-48 hours and 8 cases (16%) had bleeding after 48 hours post-operatively. In group B, 32 patients (64%) had no bleeding, 11 cases (22%) had bleeding in 1-24 hours, 6 cases (12%) had bleeding 24-48 hours and only one patient (2%) had bleeding after 48 hours post-operatively.

Before beginning of the procedures, the patients were classified into four groups according to the severity of interoperative pain. The fist group consisted of the patients that their operations were painless. In the second group, the patients complained of feeling pressure and pain, but do not have any pain reflex in the area. Patients in the third group had painful procedure and retraction of perineal area during the operation, but the procedure is tolerable. In the fourth group, the pain was so severe which leaded to discontinuation of the procedure. According to this categorization, there were no patients in the first and forth group. In patients treated with Ultroid, 46 (92%) cases were in groups 2 and 4 (8%) in grade 3 respectively.

In patients treated with RBL, 31 (62%) cases and 19 (38%) cases were in groups 2 and 3, respectively.

Post-operative pain was classified as painless, mild, moderate and severe. Pains were considered as mild if relieved with acetaminophen and Sitz bath. Pain was considered as moderate if required a NSAID for relief, and severe form had take place when the pain needed hospitalization and narcotic use for relief. In group A, 37 cases (74%) had no pain, 12 patients (24%) had mild and moderate, and only one patient (2%) had severe post operative pain.

In group B, 36 cases (72%) had no pain, 13 cases (26%) had mild and moderate, and one patient (2%) had severe post operative pain (*P*=0.00).

The patients were classified into three groups according to their response to the treatment: Group 1 had no change in severity, duration, and interval of symptoms, and therefore had no response. Group 2 had relative response to treatment from the point of view of severity, duration and interval of symptoms. Group 3 had complete response to treatment and their symptoms were disappeared and no recurrence in the follow-up period was detected. Among patients treated with Ultroid, 4 cases (8%) had no response, but 5 (10%) and 41 (82%) patients had relative and complete response, respectively. Among patients treated with RBL, one patient showed relative response and 47 cases (94%) had complete response; however, two patients indicated no response.

The comparison of patients' condition in group A and B was shown in Table2.

In group A, the tolerated current intensity, and the duration of the procedure were different. The maximum tolerated current intensity was 16 milliamps and the mean duration of the procedure was 18.1 (±4.1) minutes.

In group B, 1-2 rings were used during the procedure and the duration of operation was 14.6(±1.9) minutes, which was significantly lower (*P*=0.00).

Table 1. Frequency of major chief complains in Ultroid and Rubber Band Ligation Groups

Major Referring Symptoms	Total (n=100)	Ultroid (n=50)	Rubber Band Ligation (n=50)
Bleeding	94	47(94%)	47(94%)
Prolapse	24	9(18%)	15(30%)
Pain	24	9(18%)	15(30%)
Itching	5	1(2%)	4(8%)
Constipation	3	0	3(6%)

Table 2. Comparison of patients' condition in Ultroid and Rubber Band Ligation Groups

	Ultroid (n=50)	Rubber Band Ligation (n=50)	P Value
Mild ~ Moderate Intraoperative Pain	46(92%)	31(62%)	0.00
Negative Post-Operative Bleeding	36(72%)	33(66%)	0.5
Negative Post-Operative Pain	35(70%)	27(54%)	0.00
Complete Treatment	41(82%)	47(94%)	0.2

Discussion

Nowadays non-invasive techniques are commonly used for treatment of hemorrhoids, and RBL is one of the most common alternatives to formal operative hemorrhoidectomy.

There is small number of articles in the literature on the Ultroid technique. Many studies have been performed to evaluate RBL, and this technique accepted as an excellent alternative to conventional surgical method (6). In one of these major researches, Bartizal et al (7) studied 670 patients with hemorrhoids undergone rubber band ligations in 1977 retrospectively. Severe pain in 0.6 % and mild to moderate pain in 4.5 % of these cases had been reported. In another study in 1980 by Mourie et al (8) 43 patients had been treated with rubber band and 31 cases (72%) were associated with complete response, 7 cases (16.2%) had moderate and 5 cases (11.6%) had no response. Khubchandani et al (9) in a research in 1983 on 100 patients randomly performed one, two or three ligations in one cession, and there was no significant difference in morbidity and complications rates between the groups.

In a few studies has been done to assess this modality of hemorrhoid treatment, the Ultroid direct current electro coagulation therapy and follow-up results revealed that Ultroid technique is good and that is associated with less discomfort and fewer complications.

In Ervin Rusek's study (unpublished), 411 patients with hemorrhoid (grade 1 to 4) had undergone treatment with Ultroid method, between years 2000 to 2002 (10). A success rate of 90% without postoperative complication has been reported. Sheldon S. Zinberg et al reported 95% improvement in 192 cases undergone Ultroid treatment in California (11). In another study, which was performed by Randall et al in California University in 1994, on 50 hemorrhoid cases, Ultroid was reported as an appropriate method of treatment for grade 1 to 3 hemorrhoids, with a recurrence rate of 8% after one-year follow-up(12). In the study of Norman D.A *et al*. in Nevada University on 120 cases of grade 1 ~ 4 hemorrhoids undergone treatment with Ultroid, there was no recurrence after 23 months follow-up and Ultroid was reported as a method with no major complications (3).

RBL (1, 5) and Ultroid are both considered as outpatient procedure for the treatments of hemorrhoids. Rubber Band method is mostly used for hemorrhoids with Grade 1, 2 and sometimes 3.

Ultroid method based on its manufacturer statement is mostly used for grade 1, 2, 3 and sometimes for grade 4 hemorrhoids. In this study, two patients with grade 4 hemorrhoids considered for treatment with Ultroid method, that one of them had complete response and the other had no response. Both of these cases excluded.

In Rubber Band method the complete response rate was 94% and in Ultroid method this rate was 82%, which was not significantly different. (P=0.2)

The success rate of Rubber Band method in our study is comparable with other studies like Murie et al (8) research on 44 cases (with success rate of 86.5%) and Corman (5) and his colleagues reported their long-term results with RBL, of 352 patients,266(76%) responded, the condition of 80% of the respondents was improved by the procedure.

In Ultroid group patients with grade 1 and 2 hemorrhoids consist 70% and with grade 3 consist 30% of cases. In Rubber Band group these are 76% and 24% respectively. There was no difference in the hemorrhoid Grade distribution between two groups.

Seventy-two percent of cases in Ultroid group had not any bleeding after treatment and this was 66% for Rubber Band group. Other patients had some degrees of bleeding for a few days after treatment and finally bleeding stopped in all of them. Although both methods had similar efficacy in stopping the most common symptoms of hemorrhoids, the RBL method seems to be more successful.

About intraoperative pain 92% and 62% of patients treated with Ultroid and Rubber Band, respectively were in group 2 (experiencing mild pain) and 6% and 38% of them, respectively were in group 3 (experiencing moderate pain). It seems that high severity of pain in patients treated with Ultroid is related to longer time of holding anoscope in the anus.

About post-operative pain, 74% and 72% of patients treated with Ultroid and Rubber Band respectively had no pain and there were no significant difference between two groups. In conclusion, we conclude that Ultroid and Rubber Band Ligation are both acceptable methods as an outpatient procedure, and both have high success rates, especially with Rubber Band Ligation. Success rate in lower grades of hemorrhoids is greater than higher grades.

Post-operative pain was significantly lower in patients, undergone Ultroid method.

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