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AN EXPERIENCE OF OUTCOME FROM RUBBER BAND LIGATION OF HAEMORRHOIDS WITH SPECIAL EMPHASIS IN THIRD DEGREE HAEMORRHOIDS IN CMH MANGLA. A PROSPECTIVE STUDY

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ABSTRACT

Objective: To evaluate the efficacy and effectiveness of rubber band ligation in 2nd & 3rd degree haemorrhoids. **Methods:** Study was conducted at Surgical Unit, CMH MANGLA, during a period of 15 months from December 2014 to March 2016. Out of total 300 patients, 100 patients were with 3rd degree internal haemorrhoids and and 200 pateints with second degree haemorrhoids; all were treated with Rubber band ligation (RBL). Outcome data was recorded for success of treatment. The patients were asked to return to out-patient clinic for follow up at 2 weeks, 1 month,, 3 months,6 months. **Result:** Among 100 patients, 92 (92%) were symptom free. Symptoms of prolapse or bleeding per rectum fully recovered after second and third session of RBL 100%, 5 (5%) patient had complaint of pain for one month after completion of treatment and 85 patients had complaints of constipation before treatment and only 5 (2.8%) had it after the treatment, the recovery rate was 97.14%. **Conclusion:** RBL is an efficient, cost-effective and simple out-patient procedure for symptomatic third degree haemorrhoids with minimum complications. RBL is a reliable, safe procedure requiring no hospitalization and no use of any anaesthetic drugs (JPMA 60:952; 2010).

KEYWORDS: Hemorrhoids,, outpatient, rubber band ligation, treatment.

INTRODUCTION

Haemorrhoids are considered one of the most frequent diseases of the anal region with high prevalence (nearly 50% of proctological visits in a colorectal unit),[1,2] involving any age and

affecting both males and females equally.[3,4] They commonly occur in patients with chronic increased intra-abdominal pressure as well as in pregnancy.[5] Clinically, haemorrhoids usually present with bleeding, prolapse, pain (with thrombosis or ulceration), perianal mucous discharge, or pruritus. The complications of haemorrhoids are thrombosis, infection with inflammation, ulceration.

Internal haemorrhoids are classified into four grades, as follows:

- First degree - Veins of anal canal increase in number and size, and they bleed on daefecation
- Second degree - Haemorrhoids prolapsed outside anal canal but reduce spontaneously.
- Third degree - Haemorrhoids protrude outside anal canal and require manual reduction
- Fourth degree - Irreducible haemorrhoids that remain constantly prolapsed

Numerous modalities and techniques have been developed to treat symptomatic haemorrhoids ranging from simple dietary measures and bowel habit regulation, through a number of non-operative procedures, to different techniques of excision of diseased anal cushions. The vast amount of treatment options means none are close to perfection.[6] While many non-operative procedures are effective in controlling symptoms, at least from the patients' perspective, they all share the common problem of recurrence.[7] Although, surgical haemorrhoidectomy is more definitive in symptom control, it has a reputation for being a painful procedure for a relatively benign disorder.[8] First, second and third degree haemorrhoids can be treated by non- surgical methods in outpatient clinics while severe prolapsed or circumferential haemorrhoids can be treated using a variety of surgical techniques ,includes open or closed haemorrhoidectomy and stapled haemorrhoidopexy. e.g. Milligan Morgan, Longo and others.[9,10]

The initial treatment for symptomatic first- and second-degree haemorrhoids with a short history of bleeding, prolapse, or itching and pain is directed toward controlling constipation with dietary measures such as a high-fiber diet, sitz bath, stool softeners, laxatives, and various topical creams.[1,2]

When medical treatment fails, ambulatory treatment (non surgical) is advised. Ambulatory treatments for haemorrhoids include injection sclerotherapy, rubber band ligation, cryosurgery, infrared coagulation, and ultrasonic Doppler-guided transanal haemorrhoidal ligation.[7,8,9]

Haemorrhoid rubber band ligation is considered the most widely used outpatient procedure/treatments available for patients with first-degree, second-degree, and some cases of third-degree haemorrhoids when the patient complains of bleeding or prolapse of haemorrhoids.[6] Rubber Band ligation may also be considered for bleeding in severely anaemic patients with fourth-degree haemorrhoids who are unfit for surgery.

In this procedure, a rubber band is applied to the base of the haemorrhoid to hamper the blood supply to the haemorrhoidal mass. The haemorrhoids will then shrink and fall off within 2-7 days. Rubber band ligation can be performed in an ambulatory setting. The procedure causes less pain and has a shorter recovery period than surgical haemorrhoidectomy. Its success rate is between 60% and 80%.[1,2,3]

Nowadays, rubber band ligation (RBL) is the most widely used procedure and it offers the possibility to resolve haemorrhoids disease without the need for hospitalization or anaesthesia and with a lower incidence of complications when compared to conventional studies.[1] Not more than two haemorrhoids should be banded at each session and three weeks at least should elapse between each treatment. To avoid pain one of the major complications of banding, bands should be applied at least 1.5cm above the dilatation. Haemorrhoids are the clinical manifestation of the downward disruption of the normal, functional structures known as the anal cushions. The symptoms of bleeding from their exposed upper mucosal part, protrusion and sometimes pain, reflect this fact. Rubber bands are placed above the base of haemorrhoids i.e. above the insensate dentate line; the procedure should be painless. The strangulated haemorrhoid becomes necrotic and sloughs of resulting in fibrosis which leads to the fixation of the underlying tissue to the rectal wall.

The aim of the study was to evaluate the efficacy and effectiveness of RBL in symptomatic 2nd and third degree haemorrhoids with special emphysis in management of third degree haemorrhoids.

A prospective study was conducted at the CMH Mangla Pakistan, which covers the health care of patients coming from various areas of Punjab and nearby area of Azad Kashmir especially Mirpur and surrounding area. All successive patients referred from peripheral MI rooms, CWC and different out-patient departments of CMH Mangla and, suffering from haemorrhoidal disease between December 2014 till March 2016. For this study a total of 300 patients of haemorrhoids were registered (200 patients of 2nd degree and 100 patients of

haemorrhoids) but only 100 patients of third degree internal haemorrhoid were further evaluated for outcome of RBL. The mean age was 39.13 ± 14.75 years (ranging from 15 to 70 years old).

Following inclusion and exclusion criteria

Patients with, second or third degree internal piles were included.While, patients with previous ano-rectal surgery, associated ano-rectal pathology "fissure, fistula,, fourth degree haemorrhoids and complicated piles (infection, ulceration or strangulation) were excluded.

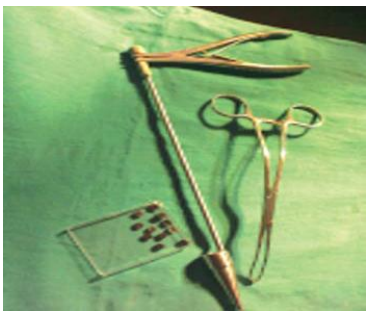
MATERIAL AND METHOD

In all our patients who fulfilled inclusion criteria were subjected to a detailed medical history taking including the following characteristics; age, sex, occupation and residence, presentation (bleeding, prolapse, anal pain, discharge, and pruritus).and local examination of anal region which was carried out by inspection, palpation, digital rectal examination, and proctoscopic examination.

RBL was carried out on all patients.Either manual or suction method can be used but in this study suction method was used because it is less time consuming and relatively easy.

Equipment for haemorrhoid ligation includes the following:

- Barron haemorrhoidal ligator with rubber rings/bands /loading core
- Haemorrhoid-grasping forceps
- Proctoscope / anoscope /lubricant
- Light source (torch/OT light)
- Surgical Gauze piece (for wiping/ cleaning)
- Negative pressure suction machine and Artery forceps



Before starting the procedure written informed consent was taken and the procedure explained to each patient.

Procedure was done with the help of an assistant, neither bowel preparation nor NPO status was required and male patients were examined in knee elbow position while female patients in the left lateral position.

The procedure was performed through the proctoscope, which was inserted and placed about 1-2 cm. above the dentate line using xylocaine gel as a lubricant. A suction haemorrhoid band ligator was used which draws the haemorrhoidal mass into the drum through suction. After the pile mass has been adequately drawn into the drum by means of suction,and patient experienced no pain; the trigger is released to apply the rings at the base of the haemorrhoid. Maximum of upto two band ligations were applied at a time.

After the procedure the patients were asked to stay in waiting area for 30 minutes for any acute complaint of pain and were given following advise:

A: Avoid straining at stools for at least 24 hours.

B: Stool softeners e.g. syrup cremaffin or Syrup paraffin 2 TSF three times a day.

C: Tab. Diclofenac sodium 50mg twice daily for 2-3 days then sos.

D: Isphagol huskh /High residual diet

E: Local anal hygiene

F: Information regarding early and late complications and

G: Follow-up visits at 2 weeks, 1 month, 3 month and 6 months.

Subsequent ligations were performed at 2 weeks and 1 month after the prior first one, if the patients still had symptoms. Results were classified as following;

a. Cure if the patient was asymptomatic after the end of treatment,
b. Improvement if the symptoms had been minimized, and as
c. Failure of the method if no improvement whatsoever occurred.

Post ligation complications include: pain, Vaso-vagal symptoms (dizziness or fainting), retention of urine, bleeding per rectum whether primary, secondary or reactionary and post ligation infection were recorded. Also, the patients were asked about continence and anal stricture during scheduled digital rectal examinations.

Complete data was documented and all adverse events were recorded.

Statistical analysis

The statistical analysis of data was done by using SPSS (Statistical Package for Social Science) version 10 under Microsoft Windows XP. The description of data was done in form of mean ± SD for quantitative data; while frequency and proportion for qualitative data. The analysis of data was done to test the statistical significant difference between groups. For quantitative data, to compare between 2 groups Student t-test was used and for qualitative data $\chi 2$ test was used. $P < 0.05$ was considered significant.

RESULTS

As far as the practicality of the method is concerned, it must sound easy, safe and Patient friendly.

Table 1: Total patients included in the study.

Total patients	2nd degree haemorrhoids	3rd degree haemorrhoids
300	200	100

In the present study which was conducted in the surgical department of CMH mangla during the period from December 2014 to March 2016. A total 300 patients were included; out of which 100 patients had third degree haemorrhoids and all patients were treated with RBL. Males were found more (61%) as compared to the females (39%) and majority of the patients were found in the age group between 46 to 60 years.

Table-2: Basic characteristics of the patients.

Characteristics	Total Frequency	3rd degree haemorrhoids	%
Male	183	61	61%
Female	117	39	39%
Age groups			
15 - 30	57	19	19%
31- 45	111	37	37%
46 - 60	88	26	26%
>60	54	18	18%
Symptoms			
Constipation	265	85	85%
Bleeding	300	100	100%
Prolapsing haemorrhoids	243	81	81%
Irritation	102	34	34%
Discharge	75	25	25%

The most common symptom found were bleeding per rectum(100%); constipation or straining during defecation (85%), manually reduceable prolapsing haemorrhoids(81.25%), irritation and discharge as 34% and 25% respectively.

No of band ligation sessions were more in third degree haemorrhoids.

In this study a maximum of two haemorrhoids were ligated per session, with the condition that there was not much mucosal swelling. In cases with too much mucosal swelling and prolapse only one haemorrhoid was ligated per session.

Number of third degree internal haemorrhoids at the time of presentation were distributed as, single haemorrhoid in 18(18%), 12 (66.67%) males and 6 (33.33%) females, two haemorrhoids were found in 34 (34%), 23 (67.64%) males and 11 (32.36%) females, three haemorrhoids in 48(48%) of which 32 (66.67%) were males and 16 (33.33%)females.

Table-3: Distribution of third degree haemorrhoids (total No =100).

NO of Haemorrhoids	Males	Females	Total	Percentage
1	12	6	18	18%
2	23	11	34	34%
3	32	16	48	48%

Among 48 (48%) patients with 3 internal, third degree haemorrhoids, 30 (62.5%) were done in three sessions and 18(37.5%) were done in two sessions ligating two haemorrhoids in first session and one in the next session. The 34(34%) patients with 2 internal third degree haemorrhoids, were done in two sessions, ligating single haemorrhoid per session. All 18(18%) patients with 1 third degree haemorrhoid, were ligated in a single session.

Table 4: NO of Sessions of RBL.

Number of Sessions	Number of Patients
Three Sessions	30 (30%)
Two Sessions	52 (52%)
One Session	18 (18%)

Symptoms of prolapse or bleeding per rectum fully recovered after second and third session of RBL 100%, 2 (2.5%) didnt turn up for second follow up, 1 (1.25%) patient had complaint of pain for one month after completion of treatment and 85 patients had complaints of constipation before treatment and only 5 (2.8%) had it after the treatment, the recovery rate was 97.14%.

Table 5: Symptyoms after RBL.

Symptoms before Rubber Band Ligation	Number of patients	Symptoms after Rubber Band Ligation	Symptoms free	Percentage
Bleeding Per rectum	100	Non	All	100%
Prolapse	100	Non	All	100%
Constipation	85	5	80	94.17%
Pain/irritation	34	2	32	94.17%

The relief of constipation could be the result of the advice given to the patient during the treatment and follow-up visits, as no control group was selected to compare the relief of constipation as a result of post procedure instructions or due to the end of haemorrhoidal disease.

Complications		
Intensive pain	15	15%
Transient Bleeding	9	9%
Tenesmus	2	2%
Dysuria / urinary retention	3	3%
Hospital stay		
30 Minutes	80	80%
Few hours	15	15%
1 day	05	05%
2 days	00	00%
Recurrences		
Re band ligation	12	12%
Outcome		
Poor	15	15%
Good	35	35%
Best	50	50%

DISCUSSION

The need to treat haemorrhoids is based primarily on the severity of symptoms, but the type of treatment is based on the traditional classification of haemorrhoids, which may have little to do with symptom severity.[15] The best treatment remains unanswered despite of the wide variety of treatment options in use. Nowadays, rubber-band ligation is the most widely used procedure, and it offers the possibility to resolve haemorrhoids disease without the need for hospitalization or anaesthesia, and with a lower incidence of complications when compared to conventional surgery.[15] RBL was introduced by Blaisdell 1958.Barron popularized the procedure and later on the procedure became known by his name. The only flaw of RBL is that it is not effective against the skin covered component of haemorrhoid or an associated skin tag.12

In the present study of hemorrhoidal band ligation male were found more as compare to the females, Syed Asad ali found male to female ratio in his study 9:1 16. According to the age group in this study majority of the patients was noted in the age group of 31 to 45 years of the age. However Malik showed age range "18 to 73" year with the mean age of (46 years),17 and Greenberg reported mean age 42 year18. Symptoms were found in the patients as constipation, bleeding, irritation and discharge as percentage 85%, 100%, 34% and 25% respectively. Corman ML et al, reported the high percentage 90% of the cases with bleeding, while 80% of cases with prolapsed haemorrhoids19. In another study 10% patients had burning, 55% of patients with itching while majority of the cases 85% of the patients with constipation16.

Sheikh AR and Ahmad I[8] reported good results and recommended it as a first line management and as an alternative to haemorrhoidectomy. Ahmad R[9] presented that RBL is an effective form of therapy that can control pain, itching, bleeding and discharge.

In our series a maximum of two bands were placed per session, The reason behind avoiding triple band ligation is because stretching the mucosa can lead to pain and sometimes stenosis. It was observed that the patients on whom single band was applied per session were more comfortable and pain free as compared to the group on whom two bands were applied, who had complaints of pain, straining Lee et al19 reported that patients with multiple haemorrhoidal banding in a single session compared with patients with single banding had greater discomfort and pain (29 vs 4.5%).at defecation and discomfort.

Komborozzos and associates13 described 43 (8.6%) patients presenting with pain, and in all cases pain appeared immediately or a few hours after ligation and lasted less then 2-3 days, pain occurred most frequently when the ligation was placed too low in the anal canal. In our series 7.5% (6/80) had complaints of pain before treatment and 83.33% (5/6)were relieved of their pain after RBL, only 16.66% (1/6) had pain which gradually settled in one month.

The cause of pain in rubber banding is banding below the dentate line.14 Gupta P J15 compared rubber band with infrared therapy. He reported more pain with RBL but less chances of recurrence. Mattana and associates16 reported severe pain in 7.5% of cases.

Wehrmann T and colleagues17 reported pain in 25% of patients with RBL. Arroyo A and associates18 concluded that open haemorrhoidectomy was associated with significant pain.

Poen at el,[20] have shown RBL to be as effective as haemorrhoidectomy. The study also confirms that RBL is an effective treatment for symptomatic haemorrhoids. Kumar et al[21] described a cure rate up to 70%, whereas in our study cure rate was 96.25%.

All our patients were kept under observation in the waiting area for 30 mins following which they were allowed to go home. Few of our patient was admitted after rubber band ligation. This is comparabe to other international studies.

According to the complications intense pain was noted in the 55% of the cases while other complications were seen in very few patients and many patients were seen without any complication.

Mehanna et al,[22] reported 4% of patients with RBL had a minor bleed, which required no active surgical management. In our study there were no patients who had episodes of bleeding after RBL which is compatible to Sheikh A R 8 who reported no bleeding after RBL. Iyer V S and associates,[23] reported bleeding in 28% of patients. They concluded that placement of four or more bands were associated with higher complications. Their success was 70.5%. Su M Y and associates[24] reported control of bleeding and prolapse in 93% and 91% of patients after RBL. In our study the control of bleeding and prolapse was 100%. O'Regan P J,[25] reported excellent results with no bleeding with a disposable RBL device. This study supports our series of patients in the control of bleeding by RBL.

Hospital stay of only one day was noted in the very few patients and mostly patients were discharged after few hours of the procedure. Ming Yao Su et al reported that minor complications occur as; anal bleeding and pain, and 5 cases underwent re -treatment21. 11

Fakuda A and associates,[26] reported excellent results in 89% of patients, good in 9% and poor in 2% of patients with RBL. Bursics A and associates,[27] reported that both nasal and squeeze pressure dropped after haemorrhoidectomy, whereas they remained unchanged in RBL. Vincent P and associates,[28] experienced excellent results with 6% complications. The most frequent complications were rectal tenesmus, dysuria and transient bleeding. Go Kalp,[29] and associates recommended local anaesthesia with RBL as it significantly reduces pain.

CONCLUSION

From the study it is concluded that RBL is a simple, safe and cost-effective method for treating symptomatic second and third degree hemorrhoids as an out patient procedure that requires no anaesthesia and no post-operative care and with significant improvement in quality of life. RBL is an ideal choice for pregnant females and old age patients who are not fit for general anesthesia.

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