OFFICE BASE MANAGEMENT OF NON-PROLAPSED INTERNAL HEMORRHOIDS: SINGLE VERSUS DOUBLE BAND LIGATION

Tahir Iqbal Mirza, Muhammad Ali Khan*, Waqas Ahmed*, Adee Hussain*

Combined Military Hospital Abbottabad/National University of Medical Sciences (NUMS) Pakistan, *Combined Military Hospital/National University of Medical Sciences (NUMS) Rawalpindi Pakistan

ABSTRACT

Objective: To compare single versus double band ligation in the office based management of non-prolapsed internal hemorrhoids.

Study Design: Randomized controlled trial.

Place and Duration of Study: Outpatient department of Surgery, CMH Rawalpindi, from Jan 2015 to Dec 2016.

Material and Methods: All patients (216 patients, 108 in each group) presenting with bleeding, non-prolapsed internal hemorrhoids were included in the study after approval from hospital ethical committee. Patients with bleeding disorders and other ano-rectal conditions causing bleeding per rectum were excluded. Lignocaine gel (2%), disposable proctoscope, Barron's ligator with grasper & black silicon bands (Germany) of 2mm diameter were used. The follow up regimen inclusive of Polycarbophil (Fibercon) sachet, Micro Purified Flavonoid Fraction (MPFF) (Daflon 500mg) and warm water sitz bath was same for both the groups of our study.

Results: A total of 216 patients meeting the inclusion and exclusion criteria were selected and divided into two equal groups. In group A of double band ligation, mean age was 39.3 ± 1.7 years and mean time for fall of band was 6.6 ± 1.3 days (p=0.000). While in group B of single band ligation, mean age was 41.2 ± 2.1 years & mean time for fall of band was 7.2 ± 1.5 days (p=0.03) while the mean time of fall between the two groups was insignificant (p=0.251).

Conclusion: Double band ligation for non-prolapsed bleeding hemorrhoids was found more simple, accessible, cost effective and more reliable than the single band ligation. Frequent visits of the patient can be minimized. The complications in both groups are same. It has reasonable early recovery, but equivocal recurrence.

Keywords: Hemorrhoids, Ligation and recovery, Office based management.

INTRODUCTION

Hemorrhoids have emerged as a common illness in the present era. As per available international data, 5-35% of the population exhibits symptomatology of this disease, out of whom more than half are above 50 years of age[1]. Though preponderance in both sexes is equal, yet the prevalence is high in the upper socioeconomic class. Low fiber diet has been speculated as a major predisposing factor. Delay in treatment and associated complications can lead to severe morbidity[2].

Hemorrhoidal ligation was first done by Hippocrates in 460 BC with a thread. Blaisdell introduced rubber band ligation in 1958 which was further refined in 1963 by Barron. Barron introduced the ligator named after him which is a mechanical, metal device used in outpatient or office settings for treatment of internal hemorrhoids[3].

Office based procedures are being preferred by the patients in lieu of financial constraints and non-anesthesia procedures. Dietary controls, Sclerotherapy and band ligation alone or with combination of high fiber diet and Micro Purified Flavonoid Fraction (MPFF) is in practice worldwide[3,4]. There are several different devices. A physician may perform the procedure with the traditional metal devices, endoscopic banding, and the CRH O'Regan System[5].

Rubber bands are popular devices to be used by physicians because their source is inorganic,

Correspondence: Dr Muhammad Ali Khan, Classified Surgeon & Laproscopic, CMH Rawalpindi Pakistan
Email: surgeon.alikhan@gmail.com
Received: 29 Apr 2018; revised received: 11 Jul 2018; accepted: 08 Aug 2018

not allowing bacteria to invade. In this method a small band is applied at the base of the hemorrhoid, stopping the blood supply to the main hemorrhoidal mass. The hemorrhoid will shrink and die within a few days with shriveled hemorrhoidal tissue. The band will fall off during normal bowel movements which may or may not be noticed by the patient. There may be a discomfort after application that can be addressed with analgesics. In practice in vogue a single rubber band is applied on a single unit of hemorrhoids but in our study we used two rubber bands on a single unit of hemorrhoids.

MATERIAL AND METHODS

We conducted a randomized controlled trial from Jan 2015 to Dec 2016 on patients reporting to the OPD of department of Surgery, Combined Military Hospital Rawalpindi with complaints of bleeding per rectum and diagnosed as a case of bleeding non-prolapsed hemorrhoids fulfilling the sample selection criteria. They were included in the study after approval from ethical review committee of Combined Military Hospital, Rawalpindi. A written informed consent was taken from every patient included in the study. The sample size was calculated by using the WHO sample size calculator with 90% confidence level, absolute precision of 0.07, anticipated population 1=96.7% and anticipated population 2=79.2%. The sample size was calculated as 108+108=216 patients[6]. The sampling technique was non-probability consecutive sampling.

A total of 216 patients (108 patients in each group) were included in the study and were randomized either to the double band ligation group (group A) or the Single band ligation group (group B) based on table of random numbers. All the patients were treated in general surgery outpatient department as office based procedures. Patients reporting with the complaint of per rectal bleeding were examined after thorough history. Digital rectal examination was performed in all cases. The exact assessment of hemorrhoids was made during proctoscopy. Patients of both gender, between ages of 20-70 years with first and second degree hemorrhoids were included in the study. Patients with bleeding disorders, prolapsed or thrombosed hemorrhoids and other anorectal conditions presenting with bleeding per rectum were excluded from the sample. Patients were given Kleen enema before starting the procedure.

All patients were explained and counselled in detail about the procedure. Band ligation was performed in the Left lateral position (fetal position). Traditional Barron's ligator with curved forceps was used to apply the bands. A disposable proctoscope was inserted into the anal opening. The pain sensitivity was tested to know the site of the pectinate line. The hemorrhoids were identified and grasped by forceps and were maneuvered into the cylindrical opening of the ligator. The ligator was then pushed up against the base of the hemorrhoid, and black silicon bands (Germany) of 2mm diameter were applied. Patients in group A were applied two bands while in group B single band was applied respectively.

Patients were advised to take Polycarbophil (Fibercon) sachet at night, MPFF (Daflon 500mg)

Table: Demographic data.

		Group A (n=108)	Group B (n=108)	*p*-value
Gender (M:F)		69 (63.89%) : 39 (36.11%)	75 (69.44%) : 33 (30.56%)	0.471
Age (years)		39.3 ± 1.9	41.2 ± 2.1	0.920
Socioeconomic status				
1	Upper middle class	40 (37.04%)	38 (35.19%)	0.77
2	Lower middle class	68 (62.96%)	70 (64.81%)	
Previous intervention				
1	Band ligation	11 (10.19%)	9 (8.33%)	0.466
2	Previous Surgery	5 (4.63%)	2 (1.85%)	

two times and acetaminophen 500 mg SOS. Patients were also advised to avoid strenuous exercise or heavy work and take warm water sitz baths twice daily. They were advised to look for any bleeding and visible fallen band. All patients

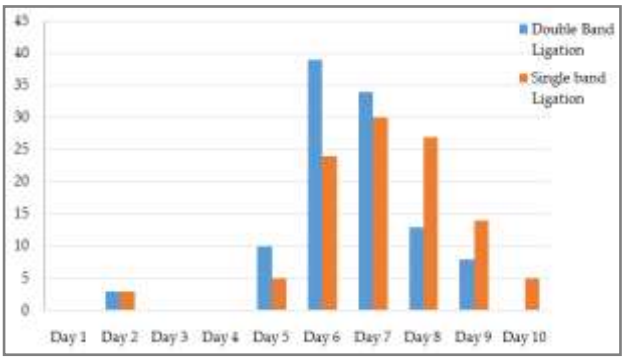

Figure-1: Duration of fall of bands in days.

were followed up after 02 weeks in outpatient department. Procedure of all patients were performed by the consultants, and data of the all patients enrolled in study were recorded. Follow up was ensured by taking contacts of patients.

Figure-2: Procedure.

Data was analyzed using SPSS version 23.0. Mean and SD was calculated for quantitative variables like age etc. Qualitative variables were recorded in terms of frequency percentage. Chi square test was applied for qualitative variables. Independent sample t-test was applied for quantitative variables. A *p*-value of ≤0.05 was considered as significant.

RESULTS

A total of 216 patients were included in the study and were divided into two groups of 108 patients each. The patients included 144 males (66.67%) and 72 females (33.33%). Male to female ratio was 3:1. Mean age group was 39.3 ± 1.9 years for double band ligation and 41.2 ± 2.1 years for single band ligation. Twenty seven patients had already undergone surgical intervention and band ligation procedures (table). In group A, 70 patients noticed blood staining of the stools and 32 patients noticed fallen band (23 collected the bands and brought on subsequent visit). The fall of bands was reported at interval of 5 to 8 days (mean 6.6 ± 1.3 days).

In group B, 82 patients with single band noticed blood staining of the stools and 40 patients noticed fallen band (29 collected the bands and brought on subsequent visit). The fall of band was reported at interval of 6 to 10 days (mean 7.2 ± 1.5 days). Three patients in group A and three patients in group B noticed fall of

band the very next day of application. While 80 patients showed full satisfaction and relief of symptoms in group A, 49 patients showed complete relief from symptoms in group B. The mean time of fall of bands between the two groups was statistically insignificant, 6.6 ± 1.3 days in double band ligationvs 7.2 ± 1.5 days in single band ligation respectively (p=0.251).

After six months, 10 patients (9.26%) reported with recurrence in cases of double band ligation while 15 (13.89%) patients reported recurrence in cases of single band ligation. In group A, 26 (24.07%) patients complained of mild to moderate pain while 32 (29.63%) patients reported mild to moderate pain in group B. Three patients (2.78%) of each group developed acute urinary retention which was relieved after a short trial of catheterization. One patient (0.93%) in group A & 3 patients (2.78%) in group B were hospitalized for evacuation of perianal hematoma. The complications in both the groups are expressed in the bar chart (fig-3). Thus, double band ligation was found to be more effective treatment option with less number of complications. The p-value with regards to complications between the two groups (p=0.001) was statistically significant.

DISCUSSION

Office based procedures are now the mainstay of the management of internal non-prolapsed bleeding hemorrhoids. Besides high fiber diet, MPFF, sclerotherapy and banding is one of the effective ways to get relief from symptomatic hemorrhoids. In our randomized controlled trial, the female contribution was one third of total patients. (36 patients in each group). The mean age was 39.1 ± 1.9 years and 41.2 ± 2.1 years for double band ligation and single band ligation respectively. In a similar study by Chew *et al* in 2003 found that the mean age was >55 years while a study by Gaj *et al* in 2015 from Italy found the mean age to be 47.6 years in patients presenting with internal non-prolapsed bleeding hemorrhoids[4,7].

A total of 27 patients had already undergone a previous surgical procedure for the management of their symptomatic hemorrhoids (table). The position of choice for the procedure was jack knife or left lateral position and the procedure is performed through an anoscope as recommended by Sun *et al* in 2016, a position soothing and acceptable to patients[8]. The disease was found to be more prevalent in patients (138 out of 216 patients) falling in lower middle class families in

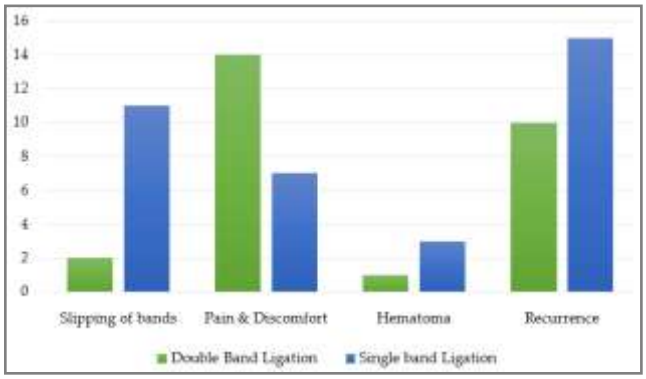

Figure-3: Complications.

our study and most patients (89 out of 216) were office workers who reported taking casual hoteling meals. Contrary to this,studies by Yik *et al* in 2000 and Chew *et al* in 2003 found that the disease was more prevalent in low fiber diet taking upper socioeconomic class[4,5]. Lohsiriwat advised increasing the intake of dietary fiber and oral fluids, regular exercise, refraining from straining on the toilet, and avoiding drugs causing constipation or diarrhea[9].

Double band ligation resulted in comparative fewer mean times as compared to single band application. The time of fall for group B was mean 8.6 ± 1.6 days. The recorded studies also bear almost same time duration[10,11]. The most common complication of the procedure was mild to moderate discomfort[12]. Mild bleeding, pain, vaso-vagal symptoms, slippage of bands, difficulty in urination, and anal fissures are the minor complications whereas massive bleeding, thrombosed hemorrhoids, severe pain, urinary retention, pelvic sepsis, fistula and death are major

complications that have been less commonly reported[13,14].

Recurrence for both groups was not significantly different at 5 to 6 months interval. For single band therapy Chew & Yki observed six month recurrence but their number of patients were more as compared to our study[4,5]. Eighty patients showed complete relief of symptoms in group A, and 49 patients showed complete relief from symptoms in group B. A study by Chaleoykitti *et al* found that 96.7 per cent of patients in the multiple band ligation group had cessation of bleeding within one week as compared to 79 per cent patients in the single band ligation group (p=0.004)[6].

A study by Ali *et al* in 2012 compared the outcomes of rubber band ligation with Morgan Milligan hemorrhoidectomy and found that rubber band ligation was an effective treatment option for symptomatic second and third degree hemorrhoids. In the study, patients treated with rubber band ligation had a lower incidence of intense pain, urinary retention, bleeding, and had a shorter hospital stay duration with early return to work as compared to open hemorrhoidectomy. However, recurrence rate was higher in RBL group as compare to operative hemorrhoidectomy group (p 0.001)[15].

Different innovations in usage of rubber band for anorectal surgery are being introduced. Mattana *et al* in 2013 treated prolapsed rectal mucosa with the application of rubber bands[16]. Serious complications following band ligation are very uncommon. It is pertinent to know the detailed medical history along with any comorbidities and use of medication before the procedure. After the procedure, patient education is mandatory, including analgesia, softening of the stools to prevent constipation, warm sitz baths and counselling regarding early and late complications. If complications do occur, early recognition and immediate treatment are fundamental for a successful outcome[7,16].

CONCLUSION

Double band ligation for non-prolapsed bleeding hemorrhoids was found more simple, accessible, cost effective and more reliable than the single band ligation. Frequent visits of the patient can be minimized. The complications in both groups are same. It has reasonable early recovery, but equivocal recurrence.

CONFLICT OF INTEREST

This study has no conflict of interest to be declared by any author.

REFERENCES

1. Van Tol RR, Melenhorst J, Dirksen CD, Stassen LPS, Breukink SO. Protocol for the development of a Core Outcome Set (COS) for hemorrhoidal disease: An international Delphi study. Int J Colorectal Dis 2017; 32(7): 1091-94.
2. Wrobleski DE. Rubber band ligation of hemorrhoids. RI Med 1995; 78(6): 172-3.
3. Nagy A, Willner P, Jankovich M, Törös P. Eight year experience in treatment of hemorrhoidal disease. Acta Chir Hung 1998; 37(2): 71-6.
4. Chew SS, Marshall L, Kalish L, Tham J, Grieve DA, Douglas PR et al. Short-term and long-term results of combined sclerotherapy and rubber band ligation of hemorrhoids and mucosal prolapse. Dis Colon Rectum 2003; 46(9): 1232-7.
5. Yik-Hong H, Margart T. Micronized purified flovonidic fraction vs rubber band in management of bleeding hemorrhoid. Dis colon rectum 2000: 45(5): 62-8.
6. Chaleoykitti B. Comparative study between multiple and multiple rubber band ligation in one session for bleeding internal hemorrhoids: a prospective study. J Med Assoc Thai 2002; 85(3): 345-50.
7. Gaj F, Biviano I, Sportelli G, Candeloro L. Rubber band ligation in treatment of hemorrhoids: Our experience. Clin Ter 2015; 166: 162-7.
8. Sun Z, Migaly J. Review of hemorrhoid disease: Presentation and management. Clin Colon Rectal Surg 2016; 29(1): 22-9.
9. Lohsiriwat V. Treatment of hemorrhoids: A coloproctologist's view. World J Gastroenterol 2015; 21(31): 9245-52.
10. Brown SR. Haemorrhoids: an update on management. Ther Adv Chronic Dis 2017; 8(10): 141-47.
11. Madoff RD, Fleshman JW, Clinical Practice Committee, American Gastroenterological Association. American gastro-enterological association technical review on the diagnosis and treatment of hemorrhoids. Gastroenterology 2004; 126(5): 1463-73.
12. Gélinas C, Fillion L, Puntillo KA, Viens C. Validation of the critical-care pain observation tool in adult patients. AJCC 2006; 15(4): 420-7.
13. Kleinubing H, Pinho MS, Ferreira LC. Longitudinal multiple band ligation: An alternate Mucosal prolapsed of the anterior rectal wall. Dis Colon Rectum 2006; 49(6): 876-8.
14. Albuquerque A. Rubber band ligation of hemorrhoids: A guide for complications. World J Gastrointest Surg 2016; 8(9): 614-20.
15. Ali SA, Mohammad AT, Jarwar M, Imran J, Siddique AJ, Dalwani AG. Outcome of the rubber band ligation with Milligan Morgan haemorrhoidectomy. J Ayub Med Coll Abbottabad 2010; 22(4): 56-60.
16. Mattana C, Maria G, Pescatori M. Rubber band ligation of hemorrhoids and rectal mucosal prolapse in constipated patients. Dis Colon Rectum 2013; 32(5): 372-5.
17. Jalihal U, BS SP, Avinash B. Colonoscopic band ligtation for internal hemorrhoids. A tertiary care experience. J Dig Endosc 2013; 4: 6-9.