Volume-4, Issue-7, July-2015	• ISSN No 2277 - 8160
------------------------------	-----------------------

SUAL FOR RESEARCE	Research Paper	Medical Science			
International	Comparison of Post-Operative Complications of Rubber Band Ligation & Sclerotherapy In The Management of Second Degree Hemorrhoid				
Khedkar Indira         Assistant Professor Dept of Surgery , Surat Municipal Institute           Medical Education And Research         Medical Education					
Gurnani Jenil C	4th Year Resident Dept of Surgery, Surat Municip Education And Research	oal Institute Of Medical			
Jyoti Rekha Desai	Prof & HOD Dept of Surgery, Surat Municipal Ins Education And Research	titute Of Medical			
ABSTRACT Intro	ABSTRACT Introduction: Hemorrhoids are one of the most common reasons that patients seek consultation from a colon and rectal surgeon. Sclerotherapy had been used in the office setting prior to ligations for internal hemorrhoid bleeding.				

Rubber band ligation is perhaps the most common outdoor procedure performed as it can be accomplished quickly without anesthesia or a bowel preparation The present study was conducted to find post operative complications of rubber band ligation & sclerotherapy in the management of second degree hemorrhoid. Aims & objectives : To find post operative complication of rubber band ligation & sclerotherapy in the management of second degree hemorrhoid. Material & Methods: History of Retention of Urine, Post-Operative Pain, Immediate Bleeding in the subjects in both types of surgeries, Causes of post-operative bleeding, Follow up at 7 days , at 3weeks, at 6 months. Result: We found statistically significant difference indicating that retention of urine is more in Sclerotherapy group.post operative bleeding in more in Sclerotherapy group. Among the RBL cases, 4 patients of had bleeding PR,2 had post operative pain and none had sphincter spasm. Out of the 5 patients having complaint of post operative bleeding in RBL group, 4 patients had band slippage (80%) and in one patient it was due to faulty technique (20%)& recurrence rate is less in RBL compared to Sclerotherapy.

**Conclusion:** Although Sclerotherapy is cost effective and a simple method which can be done single handedly and not requiring specialized instruments while RBL requires specialized instruments and an assistant. RBL is a better and more efficient method than Sclerotherapy in treatment of second degree hemorrhoids in terms of lesser postoperative complications and recurrence rate.

## **KEYWORDS**:

## Introduction:

Hemorrhoids are one of the most common reasons that patients seek consultation from a colon and rectal surgeon. The contributing factors include situations that increase intra-abdominal pressure such as pregnancy, constipation, or prolonged straining, as well as weakening of supporting tissue as a result of aging or genetics. It is thought that clinical disease develops as a result of dilation and distension of the veins along with weakening of the supporting connective tissue.<sup>1</sup>

Hemorrhoids are highly vascular submucosal cushions that generally lie along the anal canal in three columns—the left lateral, right anterior, and right posterior positions. These vascular cushions are made up of elastic connective tissue and smooth muscle, but because some do not contain muscular walls, these cushions may be considered sinusoids instead of arteries or veins. Clinically evident bleeding arises from the peri-sinusoidal arterioles and are therefore arterial in nature.<sup>2</sup> Hemorrhoids play a significant physiologic role in protecting the anal sphincter muscles and augment closure of the anal canal during moments of increased abdominal pressure (e.g., coughing, sneezing) to prevent incontinence and contribute 15 to 20% of the resting anal canal pressure.<sup>3</sup> Increases in abdominal pressure increases the pressure in the inferior vena cava that cause these vascular cushions to engorge and prevent leakage. This tissue is also thought to help differentiate stool, liquid, and gas in the anal canal.<sup>4</sup>

Treatment is often divided between non-operative management, office procedures, and surgical management utilizing an operating room. Sclerotherapy is being used in the office setting prior to ligations for internal hemorrhoid bleeding. <sup>5</sup> Injection of a caustic agent into the submucosa of the hemorrhoid results in diminished vascularity, intravascular thrombosis, and fibrosis. The fibrosis is also believed to result in mucosa fixation and diminish prolapse as well. In grade 1, 2, and 3 hemorrhoids, it is 75 to 89% effective, <sup>5</sup> but recurrence is seen in 30% of patients at 4 years.<sup>6</sup>

Rubber band ligation is perhaps the most common outdoor procedure performed as it can be accomplished quickly without anesthesia or a bowel preparation. It is most effective on first- and second-degree internal hemorrhoids and many third-degree hemorrhoids. It is successful in roughly 60% to 80% of patients, but may recur with<sup>7</sup>Recurrent symptoms often resolve with repeated banding and only 10% will go on to surgical excision.<sup>8</sup>The advantage of ligations is that it can be performed in an office setting with patients resuming normal activities after treatment.

This is a cost-effective treatment because operating room resources are not needed and patients are able to resume work afterward. Depending upon patient tolerance, multiple hemorrhoids may be treated simultaneously, but the least amount of discomfort is achieved when hemorrhoids are treated individually.

The present study was conducted to find comparison of post-operative complications of rubber band ligation & sclerotherapy in the management of second degree hemorrhoid.

## Aims & Objectives:

To find post operative complications of rubber band ligation & sclerotherapy in the management of second degree hemorrhoid

- (b) To know the type of complications occurring to the cases
- c )To know the proportion of recurrences in both the groups during follow up period after intervention

## Methodology:

The study was the cohort study conducted on the patients admitted in the surgical wards of all units with clinically diagnosed second degree hemorrhoid.

Owing to ethical considerations, strict confidentiality of data has been maintained and permission has been obtained from Institutional Ethical Committee (IEC) of SMIMER before conducting the study. Informed written consent would be taken after persuading the participants about the possible benefits/risks and implications of the study.

The duration of study was spread over two and half years. All the patients who were diagnosed with second degree hemorrhoid from July 2012 up to March 2014 were enrolled in the study. The cases were then followed for a period of 6 months from the date of commencement of surgical procedure for the management of second degree hemorrhoid. The last date for the follow-up of case was 30<sup>th</sup> September 2014 i.e., exactly six months after the last day of period of enrolment of the last case. The data entry was done simultaneously with the enrolment of the cases in the study. The data cleaning and the retrieval of the missing data were done over a period of one month after collection of data. The collected data was analyzed over a one month period in October 2014 and the report writing was completed by end of November 2014.

We have selected a total of 100 patients who were diagnosed with second degree hemorrhoid and in whom the surgical intervention was warranted. The cases were then randomly divided into 2 groups, Group A: Sclerotherapy and Group B: Rubber band ligation. These patients were enrolled in the study after taking written informed voluntary consent after persuading patients with possible benefits/risks of study.

Patients coming to the institute with second degree hemorrhoid and in whom surgical intervention was needed. The inclusion criteria were: Second degree hemorrhoid, No underlying pathology like infection, immunosuppression, anemia, age group above 18 years.

As the study tries to compare whether the surgical procedure sclerotherapy is better than rubber band ligation in treatment of second degree hemorrhoid, known disease or pre-existing disease which can alter the results of the study are excluded from the study. First degree hemorrhoid ,Third degree hemorrhoid, Piles situated at all 3 sites <sup>7</sup> Other causes of bleeding per rectum like fissures, Prolapsed piles, External thrombosed piles, Anemia due to other causes, Patients with age below 18 years.

The study was conducted by pretested semi-structured questionnaire. Information regarding socio-demographic profile like age, gender, date of admission were obtained.

Most of the patients of hemorrhoids presented with bleeding per rectum with diagnosed first and second degree piles on proctoscopy. Third degree prolapsed and thrombosed and external piles were excluded. Among these, the cases that were above 18 years of age were selected in the study. The intra-operative and immediate post operative complication after the surgery was also noted on the data collection sheet. The first follow-up was done at the end of 3 months from date of surgery to know the status of the cases and any complications. At 6 months again the patient was followed to know the any complications like bleeding, sphincter spasm, and fever, retention of urine etc. or reoccurrence status. History of Retention of Urine, Immediate Bleeding in the subjects in both types of surgeries, causes of post-operative bleeding were noted, Follow up at 7 days , at 3 weeks, at 6 months were noted. All patients were subjected to postoperative follow up with three consultations after surgery. After taking the written informed voluntary consent for the procedure, intra-operative finding of type of hemorrhoids and site is recorded.

Sclerotherapy is currently recommended as a treatment option for first- and second-degree hemorrhoids. 8 The rationale of injecting chemical agents is to create a fixation of mucosa to the underlying muscle by fibrosis. Rubber band ligation (RBL) is a simple, quick, and effective means of treating second-degree hemorrhoids and selected patients with third-degree hemorrhoids. 9Ligation of the hemorrhoidal tissue with a rubber band applied using a Barron's banding gun causes ischemic necrosis and scarring, leading to fixation of the connective tissue to the rectal wall. Placement of rubber band too close to the dentate line may cause severe pain due to the presence of somatic nerve afferents and requires immediate removal. RBL is safely performed in one or more than one place in a single session with one of several commercially available instruments, including hemorrhoid ligator rectoscope and endoscopic ligator which use suction to draw the redundant tissue in to the applicator to make the procedure a one-person effort. 10

#### Data analysis:

Data management and analysis was done using Microsoft excel and Epi-info software. Double data entry procedure was adopted and

digitized data were checked for completeness and consistency. The categorical variables were assessed using Pearson chi-square. Mantel Hanzel Odds Ratio (OR) and corresponding 95% Confidence Interval (CI) were calculated for dichotomous variables. Statistical significance will be measured at 95% confidence interval.

#### Result &Observations: Table 1: Retention of Urine in the subjects in both types of surgeries

Type of procedure					Tatal	0/	Dualua
Retention of urine	RBL (n=50)	%	Sclerotherapy (N=50)	%	(n=100)	%	Pvalue
Yes	4	8.0	11	22.0	15	15.0	0.049
No	46	92.0	39	78.0	85	85.0	
Total	50	100.0	50	100.0	100	100.0	

In RBL group retention of urine was found in 4 patients while in Sclerotherapy group it was there in 11 patients. This difference was statistically significant indicating that retension of urine is more in Sclerotherapy group.

 Table 2 :Immediate Bleeding in the subjects in both types of surgeries

	Type of procedure				Total	04	Duoluo
Bleeding	RBL (n=50)	%	Sclerotherapy (N=50)	%	(n=100)	70	r value
Yes	5	10.0%	13	26.0%	15	15.0%	0.037
No	45	90.0%	37	74.0%	85	85.0%	
Total	50	100.0%	50	100.0%	100	100.0%	

In RBL group post op bleeding was present in 5 patients while in Sclerotherapy group it was there in 20 patients. This difference was statistically significant indicating that post operative bleeding in more in Sclerotherapy group.

Table 3: Mean Pain Score in the subjects in both types of surgeries

Type of procedure	Subjects	Mean Pain score	Std. Deviation	P value
RBL	50	3.36	1.638	0.001
Sclerotherapy	50	5.00	2.030	

Mean post operative pain score of the patients in RBL group was 3.36 while it was 5 in Sclerotherapy group. This difference was statistically significant which indicate that pain was significantly less after RBL compare to Sclerotherapy.

None of the patients in both the groups had fever or pain in abdomen in post operative period All patients who did not have complications in immediate post operative period were discharged on the same day of the surgery and called for follow up at regular interval. At the end of 7 days all patients were reviewed. Among the RBL cases, 4 patients of had bleeding PR, 2 had post operative pain and none had sphincter spasm

In Sclerotherapy 7 patient had post operative bleeding 5 patients had post operative pain and 4 patients had pain with bleeding and 2 pt had sphincter spasm. This shows the incidence of post operative bleeding and pain is more in SCL group. Out of the 5 patients having complaint of post operative bleeding in RBL group, 4 patients had band slippage (80%) and in one patient it was due to faulty technique (20%).At follow up at 3 weeks, 1 patient had bleeding and none had pain and in SCL group 5 had bleeding and 2 had pain which is significant (p=0.046).

In RBL group recurrence was in 7 patients while in SCL group it was present in 17 patients. This difference was statistically significant indicating recurrence rate is less in RBL compared to Sclerotherapy.

#### Discussion:

Meta-analysis confirmed that fibre supplements moderately improve overall symptoms and bleeding and should be recommended at an early stage. Other lifestyle modifications such as improving anal hygiene, taking sitz baths, increasing fluid intake, relieving constipation, and avoiding straining are used in primary care and may help in the treatment and prevention of hemorrhoids, although the evidence for this is lacking. Most large trials and a meta-analysis in 1995 suggest that rubber band ligation is the most effective outpatient treatment for hemorrhoids, with some authors suggesting that up to 80% of patients are satisfied with the short term outcomeoutcome.<sup>51/11</sup>

An Injection sclerotherapy into first or second degree hemorrhoids is an alternative to banding. It has no benefit in large prolapsing hemorrhoids or those with a large external component. It is cheap and easy to perform, but it is less widely used than banding because of the high failure rate. Conservative treatment with fibre supplementation may be as effective as injection Sclerotherapy. Complications with sclerosant are rare but include local infections, prostatitis, portal pyaemia, and erectile dysfunction.52/12

The following immediate Complications after Surgery were noted

Retention of urine: In the present study, the proportion of retention of urine cases in the RBL group was 8% while in the Sclerotherapy group the proportion of retention of urine cases were 22%. In the present study, retention of urine was significantly different in both the groups. In Sclerotherapy retention of urine is usually seen due to injection in a deeper plane

Complications	Our study		Brahadeeswaran.S M. et al <sup>55</sup>	
	RBL SCL I		RBL	SCL
Retention of urine	8%	22%	17.4%	24.2%
Immediate Bleeding	10%	26%	6.7%	33.3%

In the present study, complaint of immediate post procedural bleeding was significantly different in both the groups.Urological complications are likely to result from an anteriorly misplaced injection into the substance of the prostate, urethra or the peri-prostatic venous plexus. Immediate post procedure bleeding in sclerotherapy occurs due to intra mucosal injection or puncturing of vessels. Misplacement of injection occurs despite the design of the shaft of the needle, which incorporates a beveled buffer at a distance of 1-2 cm from the tip of the needle. This distance is too long to prevent injection deeper to the submucosa.

Follow up at 7 days was done .In present study the proportion of bleeding post op in RBL group is 8% and in SCL it is 14%. Bleeding at 7 days occurs in RBL group due to sloughing of pile mass and in sclerotherapy occurs due to injection of extra amount of sclerosant which gets absorbed and causes delayed bleeding .Pain in RBL was present in 4% of the patients which occurs to ring being placed below dentate line or mispositiong of ring due to fibrosis of pile mass. The proportion of pain in SCL is 10% which occurs due to injection of sclerosant below dentate line. In the present study, the proportion of sphincter spasm cases in the RBL group was zero while in the Sclerotherapy group the proportion of sphincter spasm cases were 04%. In the present study, sphincter spasm was significantly different in both the groups. The sphincter spasm which is usually seen in Sclerotherapy cases are due to wrong technique of injection or injection in the internal sphincter.

In the present study, the proportion of follow-up recurrence cases after 6 month of surgery in the RBL group was 14% while in the Sclerotherapy group the proportion of follow-up recurrence cases after 6 month of surgery were 34%. In the present study, follow-up recurrence cases after 6 month of surgery was significantly higher in Sclerotherapy group.

Injection Sclerotherapy is relatively cheap and requires one clinician to administer it but it is shown to be less effective than RBL in controlling symptoms and long-term outcome.63/13 A meta-analysis of published randomized controlled trials by MacRae HM, McLeodetal. has not shown a significant difference in the incidence of complications following RBL and Sclerotherapy (including hemorrhage).<sup>64/14</sup> The number of patients in this analysis was less than 400, which is not enough to account for the less frequent, but often serious, complications. For grades 2 hemorrhoids, RBL appears to be the treatment of choice. Patients who undergo RBL showed a significantly better response to therapy than did those treated with sclerotherapy and a significantly decreased need for further therapy than patients having sclerotherapy.

Although Sclerotherapy is cost effective and a simple method which can be done single handedly and not requiring specialized instruments while RBL requires specialized instruments and assistant. RBL is a better and more efficient method than Sclerotherapy in treatment of second degree hemorrhoids in terms of lesser postoperative complications and recurrence rate.

# **REFERENCES**

1. Chen, Herbert (2010). Illustrative Handbook of General Surgery. Berlin: Springer. p. 217. | 2. Schubert, MC; Sridhar, S; Schade, RR; Wexner, SD (July 2009). "What every gastroenterologist needs to know about common anorectal disorders". World J Gastroenterol15 (26): 3201–9. | 3. Lorenzo-Rivero, S (August 2009). "Hemorrhoids: diagnosis and current management".AmSurg75 (8): 635–42. | 4. Beck, David (2011). (2nd ed. ed.). New York: Springer. pp. 174–177. | 5. Kaidar-Person, O; Person, B; Wexner, SD (January 2007). Journal of the American College of Surgeons204 (1): 102–17. | 6. Davies, RJ (June 2006). Clinical evidence (15): 711-24. | 7. Dayton, senior editor, Peter F. Lawrence; editors, Richard Bell, Merril T. (2006). (4th ed. ed.). Philadelphia ;Baltimore: Williams & Wilkins. p. 329. | 8. Azimuddin, edited by IndruKhubchandani, Nina Paonessa, Khawaja (2009). (2nd ed. ed.). New York: Springer. p. 21. | 9. Reese, GE; von Roon, AC; Tekkis, PP (Jan 29, 2009). Clinical evidence2009. | 10. National Digestive Diseases Information Clearinghouse (November 2004). "Hemorrhoids". National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK),. Retrieved 18 March 2010. | 11. O'Callaghan JD, Matheson TS, Hall R. Inpatient treatment of prolapsing piles: Cryosurgery versus Milligan –Morgan haemorrhoidectomy. Br J Surg. 1982;69:157-9. | 12. Konsten J, Baeten CG. Hemorrhoidectomy Vs Lord's method: 17-year follow-up of a prospective randomized trial. Dis Colon Rectum. 2000;43:503–6. | 13. Milligan ET, Morgan CN, Jones LE, Officer R. Surgical anatomy of the anal canal and operative treatment of haemorrhoids. Lancet. 1937;11:1119–94. 14. Adotey JM, Jebbin NJ. Anorectal disorders requiring surgical treatment in the University Teaching Hospital, PortHarcourt. Niger J Med. 2004;13:350-4.