

Original research article

Rubber band ligation for internal haemorrhoids: A safe and successful outpatient procedure

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Abstract

Background: Haemorrhoids are cushions of submucosal tissues containing venules, arterioles and smooth muscle fibres that are located in the anal canal. The incidence of haemorrhoids in the United States is 10 million per year, corresponding to 4.4% of the population. Both genders have peak prevalence in the age group 45 to 65 years. Notably, Caucasians are affected more frequently than African Americans, and higher socioeconomic status is associated with increased prevalence

Aims and Objectives: To evaluate the safety and effectiveness of rubber band ligation for internal hemorrhoids as outpatient treatment- a. To evaluate the success/failure of the rubber band ligation in grade-II hemorrhoids. b. To analyze complications due to rubber band ligation.

Material and Methods: The present prospective interventional study was conducted in the Department of General Surgery, Pt. B. D. Sharma Postgraduate Institute of Medical Sciences, Rohtak. In this study 80 patients of both sex who underwent rubber band ligation for hemorrhoids were included. The study was approved by the ethical committee of our hospital and informed consent was taken from the patients.

Results and Observations: Total 80 patients were taken into study out of which 69 (86.2%) were male and 11 (13.8%) were female. 69 (86.2%) were male and 11 (13.8%) were female Age patients in the age group of 18-30 and 61-70, each had 21.2% of patients while it was 18.8% in 41-50 age group, in age group 31-40 and 41-60 had 15% of patients, 81-90 age group had 6.2% of patients while least number of patients that is 2.5% in age group 71-80. The mean age was 49.04 ± 17.86 years. The variable Age (Years) was not normally distributed (Shapiro-Wilk Test: $p = 0.033$). The mean (SD) of Age (Years) was $49.04 (17.86)$. The median (IQR) of Age (Years) was 48.50 (35-64). The Age (Years) ranged from 19 – 87.

Conclusion: Haemorrhoidal disease patients are bread and butter of surgical outpatient department. This disease significantly compromises patients' quality of life and day to day work. There are various methods of treatment of this ailment is available in which Rubber band ligation is much safer. Rubber band ligation doesn't require hospitalization and much of the investigations. It is a cost-effective method and a better option of treatment as majority of patients were relieved of symptoms by the technique.

Keywords: Haemorrhoidal disease, Rubber band ligation, Outpatients, Haemorrhoids, Internal Haemorrhoids.

Introduction

Haemorrhoids are cushions of submucosal tissues containing venules, arterioles and smooth muscle fibres that are located in the anal canal ^[1]. The incidence of haemorrhoids in the United States is 10 million per year, corresponding to 4.4% of the population. Both genders have peak prevalence in the age group 45 to 65 years. Notably, Caucasians are affected more frequently than African Americans, and higher socioeconomic status is associated with increased prevalence. Contributing factors for increased incidence of symptomatic haemorrhoids include conditions that elevate intra-abdominal pressure such as straining, or those that weaken supporting tissue ^[2]. The anorectal vascular cushions along with the internal anal sphincter are essential in maintenance of continence by providing soft tissue support and keeping the anal canal closed tightly. Haemorrhoids are due to the downward displacement of suspensory (Titz) muscle ^[3, 4].

Haemorrhoids are classified as 'internal' or 'external' by where they are located in relationship to the

pectinate line, the dividing point between the upper 2/3 and lower 1/3 of the anus. The actual burden of the disease remains unknown. Internal haemorrhoids are located above the pectinate line and are covered with cells that are the same as those that line the rest of the intestines. External haemorrhoids arise below the line and are covered with cells that resemble skin. Haemorrhoids become an issue only when they begin to swell, causing itching, pain and/or bleeding. The actual cause of haemorrhoids remains unknown [5]. But it is proposed to be caused by temperament, body habits, customs, passions, sedentary life, tight-laced clothes, climate [6]. Patients with spinal cord injuries, constipation, chronic diarrhoea, poor bathroom habits, postponing bowel habits, and low-fibre diet are also considered to be contributing causes [7]. Other causes that have been attributed to this condition are genetic predisposition, increased intra-abdominal pressure from many causes, including prolonged forceful defecation, obstruction of venous outflow secondary to pregnancy and hard stools in the rectal ampulla [8].

The location of the haemorrhoidal cushions is of prime importance to the proctologic surgeon. In the lithotomy, position these are located in the left lateral, right anterior and right posterior positions which correspond to the 3, 7 and 11 o'clock positions respectively. Various approaches are available to manage haemorrhoidal disease, depending on the degree of disease, and involvement of tissue close to the dentate line where in somatic sensation exists. Grade I internal haemorrhoids can often be treated with lifestyle modifications but majority of Grade II needs some intervention like rubber band ligation. Anoscopy is necessary to visualise the anal column and to visualise the dentate line reliably to ensure it is avoided [9].

While no taxonomy of external haemorrhoids is used clinically, internal haemorrhoids are further stratified by the severity of prolapse. First-degree internal haemorrhoids do not prolapse out of the canal but are characterized by prominent vascularity. Second-degree haemorrhoids prolapse outside of the canal during bowel movements or straining but reduce spontaneously. Third-degree haemorrhoids prolapse out of the canal and require manual reduction. Fourth-degree haemorrhoids are irreducible even with manipulation [10].

There are various modalities of treatment for haemorrhoids like: medical management, instrumental techniques *viz* rubber band ligation, sclerotherapy, infrared photocoagulation, cryotherapy, doppler guided haemorrhoid artery ligation, laser therapy etc [11]. These methods are considered to be the primary option for grades I and II and selected cases of grade III haemorrhoids [12]. The indications for the surgical treatment include the presence of a significant external component, hypertrophied papillae, associated with anal fissure, extensive thrombosis or recurrence of symptoms after repeated Rubber band ligation. The various surgical techniques are Open (Whitehead's haemorrhoidectomy Milligan Morgan Technique), closed (The Parks or Ferguson Technique), Stapled Haemorrhoidectomy. Surgical haemorrhoidectomy with its described pitfalls and morbidity put great economic burden on any family and country. In modern treatment there has been a strong trend in favour of day care procedures like rubber band ligation for the treatment of haemorrhoids because of cost effectiveness, better patient compliance, less morbidity, early return to work, absence of unbearable pain and lesser risk of complications with the newer techniques [1].

In spite of so many treatment techniques available, there is still no ideal and gold standard technique available for treatment of haemorrhoids. Hence this study was conducted to evaluate the safety and effectiveness of rubber band ligation for internal haemorrhoids as outpatient treatment.

Material and Methods

Study Design

The present prospective interventional study was conducted in the Department of General Surgery, Pt. B. D. Sharma Postgraduate Institute of Medical Sciences, Rohtak. In this study 80 patients of both sex who underwent rubber band ligation for hemorrhoids were included. The study was approved by the ethical committee of our hospital and informed consent was taken from the patients.

Inclusion criteria

Patients with second-degree hemorrhoids.

Exclusion criteria

- Patients using anticoagulant
- Any septic process in the anorectal region
- First, Third and Fourth degree hemorrhoids

The demographic profile, clinical symptoms, no of patients in whom rubber band ligation was done. Follow-up was at day 7, 14 and One month after rubber band ligation. A descriptive analysis of data collected of these patients was done. All the patients who presented with symptomatic hemorrhoid disease were evaluated by routine investigations like complete blood picture, bleeding time, clotting time, blood urea and sugar.

Operative Procedure

Rubber Band Ligation

Rubber band ligation is the most commonly performed procedure for internal hemorrhoids as out patient approach. Patients were placed in jackknife or left lateral position and the procedure is performed through an anoscope. The McGivney forceps ligator was used. Small rubber band rings are deployed tightly around the base of the internal hemorrhoids. They were placed at least half a centimeter above dentate line to avoid placement into somatically innervated tissue. Patients were asked about presence of pain prior to release of rubber bands.

Statistical Analysis

Descriptive statistics was analyzed with SPSS version 25.0 software. Continuous variables were presented as mean \pm SD. Categorical variables were expressed as frequencies and percentages. The Pearson's chi-square test or the chi-square test of association were used to determine if there is a relationship between two categorical variables. For all statistical tests, a p value less than 0.05 was taken to indicate a significant difference.

Results and Observations: Patients were divided into age group and frequency was noted as follow

Table 1: Distribution of the Participants in Terms of Age (n = 80)

Age	Frequency	Percentage	95% CI
18-30 Years	17	21.2%	13.2% - 32.1%
31-40 Years	12	15.0%	8.3% - 25.1%
41-50 Years	15	18.8%	11.2% - 29.4%
51-60 Years	12	15.0%	8.3% - 25.1%
61-70 Years	17	21.2%	13.2% - 32.1%
71-80 Years	2	2.5%	0.4% - 9.6%
81-90 Years	5	6.2%	2.3% - 14.6%

As per table 1 and figure 2, 3 showing distribution of participants in terms of age patients in the age group of 18-30 and 61-70, each had 21.2% of patients while it was 18.8% in 41-50 age group, in age group 31-40 and 41-60 had 15% of patients, 81-90 age group had 6.2% of patients while least number of patients that is 2.5% in age group 71-80.

The mean age was 49.04 ± 17.86 years.

Table 3: Distribution of the Participants in Terms of Gender (n = 80)

Gender	Frequency	Percentage	95% CI
Male	69	86.2%	76.3% - 92.6%
Female	11	13.8%	7.4% - 23.7%

Total 80 patients were taken into study out of which 69 (86.2%) were male and 11 (13.8%) were female. As per table 3, figure 4 showing 69 (86.2%) were male and 11 (13.8%) were female.

Table 4: Distribution of Presentation

Presentation	Yes	No
Painless Bleeding PR	77 (96.2%)	3 (3.8%)
Mass Prolapse	16 (20.0%)	64 (80.0%)
Painful Defecation	12 (15.0%)	68 (85.0%)
Constipation	4 (5.0%)	76 (95.0%)
Purulent Discharge	3 (3.8%)	77 (96.2%)
Decreased Micturition	3 (3.8%)	77 (96.2%)

As per table 4 and figure 5 bar diagram showing percentage wise distribution of presentation 77 (96.2%) of the patients presented with painless bleeding per rectum.

Patients presented with mass prolapsed were 16(20%). Painful defecation was present in 12 (15%). 4(5%) of the patients had presentation as constipation. Three (3.8%) of the participants presented with purulent discharge and similar number of patients had presentation of decreased micturition.

As per table 6 and figure 7 showing distribution of patients in terms of ass prolapse as presentation only 16(20%) of patients presented with mass prolapse as primary complaint while rest of patient presented with other complaints.

Table 12: Distribution of the Participants in Terms of Duration of Symptoms (Days) (n = 80)

Duration of Symptoms (Days)	
Mean (SD)	3.91 (2.99)
Median (IQR)	3 (2-6)
Range	0.5 - 12

The variable Duration of Symptoms (Days) was not normally distributed (Shapiro-Wilk Test: p = <0.001).

The mean (SD) of Duration of Symptoms (Days) was 3.91 (2.99). The median (IQR) of Duration of Symptoms (Days) was 3.00 (2-6). The Duration of Symptoms (Days) ranged from 0.5 - 12.

As per table 12 and figure 13 bar diagram showing distribution of patients in terms of duration of symptoms.

Table 13: Distribution of the Participants in Terms of Disease Onset (n = 80)

Disease Onset	Frequency	Percentage	95% CI
Insidious	80	100.0%	94.3% - 100.0%

As per table 13 and figure 14, 100.0% of the participants had insidious onset of disease. The mean Duration of Symptoms (Days) was 3.91 ± 2.99. All of the participants had insidious onset of disease.

Table 14: Summary of Blood Investigations

Blood Investigations	Mean ± SD	Median (IQR)	Min - Max
Hemoglobin (g/dL)	9.43 ± 1.83	9.30 (8.00-10.90)	4.7 - 13.0
TLC (/mm ³)	5588.12 ± 1678.61	5000.00 (4300.00-6750.00)	3000.0 - 10500.0
S. Creatinine (mg/dL)	0.91 ± 0.14	0.90 (0.80-1.00)	0.7 - 1.2
S. Sodium (mEq/L)	140.19 ± 2.94	140.00 (138.00-142.00)	135.0 - 148.0
S. Potassium (mEq/L)	3.90 ± 0.30	3.90 (3.70-4.10)	3.2 - 4.7

As per table 14, the patients were investigated for blood investigations and Hemoglobin, Total leucocyte count (TLC), serum Creatinine, serum Sodium and serum Potassium were determined.

Hemoglobin of patients was present in range between 4.7-13.0 (g/dl) and mean hemoglobin was 9.43±1.83 (g/dl). The total leucocyte count was in range between 3000-10, 500 /mm³ and mean was 5588.12±1678/mm³. The mean serum creatinine of patients was 0.91±0.14mg/dl. Mean serum Sodium was 140.19 ± 2.94mEq/L. Mean serum Potassium was 3.90±0.30 mEq/L.

Mean (SD)	0.91 (0.14)
Median (IQR)	0.9 (0.8-1)
Range	0.7 - 1.2

As per table 17 and figure 17, the variable S. Creatinine (mg/dL) was not normally distributed (Shapiro-Wilk Test: p = <0.001).

The mean (SD) of S. Creatinine (mg/dL) was 0.91 (0.14). The median (IQR) of S. Creatinine (mg/dL) was 0.90 (0.8-1). The S. Creatinine (mg/dL) ranged from 0.7 - 1.2.

Table 20: Distribution of the Participants in Terms of Number of Ligations (Session 1) (n = 80)

Number of Ligations (Session 1)	Frequency	Percentage	95% CI
1 Ligation	47	58.8%	47.2% - 69.5%
2 Ligations	33	41.2%	30.5% - 52.8%

As per table 20 and figure 20, in all the patients, rubber band ligation was performed in two sessions and a maximum of two ligations per session and a minimum of one ligation per session were done.

In session one 47(58.8%) patients had a single ligation and rest 33(41.2%) had two ligations of hemorrhoids.

Table 23: Distribution of the Participants in Terms of Immediate Complications (n = 80)

Complications (Immediate)	Frequency	Percentage	95% CI
None	28	35.0%	24.9% - 46.6%
Pain + Bleeding	22	27.5%	18.4% - 38.8%
Pain	15	18.8%	11.2% - 29.4%
Bleeding	11	13.8%	7.4% - 23.7%
Pain + Dizziness	4	5.0%	1.6% - 13.0%

As per table 23 and figure 22, out of a total of 80 patients 28(35%) of the patients had no immediate complications after rubber band ligation. Pain and minor bleeding was present in 22(27.5%). In 15(18.8%) of the patients had immediate complications as pain. In 11 (13.8%) of the patients had minor bleeding and four (5.0%) of the patients experienced pain and dizziness after rubber band ligation.

Table 24: Distribution of the Participants in Terms of Complications on Day 7 (n = 80)

Complications (Day 7)	Frequency	Percentage	95% CI
None	40	50.0%	39.3% - 60.7%
Bleeding	18	22.5%	14.2% - 33.5%
Ulcer	16	20.0%	12.2% - 30.7%
Pain	5	6.2%	2.3% - 14.6%
Bleeding + Constipation	1	1.2%	0.1% - 7.7%

As per table 24 and figure 23, on day seven of rubber band ligation patients were followed up in outpatient department and complications were noted. In 40(50%) of the patients had no complications. Bleeding was present in 18(22.5%) of the patients. Ulcer at the banding site was present in 16(20%) patients. Five of the patients had pain as complication on day seven only one of the patient had complain of bleeding and constipation after ligation on day seven.

Table 25: Distribution of the Participants in Terms of Complications at 1 month (n = 80)

Complications (1 month)	Frequency	Percentage	95% CI
None	60	75.0%	63.8% - 83.7%
Bleeding	19	23.7%	15.2% - 34.8%
Bleeding + Mass Prolapse	1	1.2%	0.1% - 7.7%

As per table 25 and figure 24, after one month of follow up 60(75.0%) of patients were relieved of symptoms and had no complaint. In 19 (23.8%) of the patients still had complaint of bleeding. In only one (1.2%) patient bleeding and mass prolapse was still present.

Table 26: Distribution of the Participants in Terms of Outcome (n = 80)

Outcome	Frequency	Percentage	95% CI
Relieved	67	83.8%	73.4% - 90.7%
Symptomatic	13	16.2%	9.3% - 26.6%

As per table 26 and figure 25, 67(83.8%) of the participants were relieved of all symptoms. Thirteen (16.2%) of the participants remained symptomatic.

Discussion

Haemorrhoids are commonly encountered disease in outpatient department of general surgery. Rubber band ligation is commonly performed procedure with ease and associated with minor complication. Patients were followed up on day seven and one month and final outcome were measured in terms of safety and efficacy of rubber band ligation. Complications related to procedure were noted.

Patients of internal haemorrhoids presented to the outpatient department mainly with the complaints of bleeding per rectum, mass prolapse, pain during defecation and constipation.

After one month of follow up patients were asked about the presenting complaint whether it is still present or get relieved. Majority of the patients got relieved of primary complaints and were satisfied with the procedure.

In our study we performed rubber band ligation in outpatient procedure from May 2020 to December 2021 in the Department of General Surgery, PGIMS, Rohtak in 80 patients, the study was to evaluate the safety and effectiveness of rubber band ligation and results were discussed as follows:

Age

In internal haemorrhoids majority of patients were of middle age and usually presented late with higher grade and with other co-morbidities. In our study we included only grade II internal haemorrhoids

patients and age was not a bar, but majority of patients were of middle age.

Table 27: Age comparison of different studies

Sr. No	Study	Mean Age (years)
1	Nakeeb <i>et al.</i> , (2008) ^[37]	39.13±14.75
2	Giorgio <i>et al.</i> , (1997) ^[34]	46.6
3	Aram (2016) ^[39]	45±14.75
4	Vicente <i>et al.</i> , (2003) ^[41]	45.6
5	Present study	49.04±17.86

Nakeeb *et al.*,^[37] conducted a study on 750 patients and performed rubber band ligation, mean age of the patients was 39.13±14.75 (ranging from 15 to 90 years). Giorgio *et al.*,^[34] conducted study in 84 patients and mean age of male patients was 46.6 years and that of female patients was 42.6 years. Aram^[39] studied rubber band ligation in 890 patients with the mean age of 45±14.75 years (ranging from 16-86 years). Vicente *et al.*,^[41] performed a prospective study on 232 patients of rubber band ligation and mean age was 45.6 years.

In the present study majority of the patients, were in fourth and fifth decade of life i.e., 49.04±17.86 age range was 19 to 87 years. Hence the current study is as par comparable to the other peer studies.

Sex

Gender is an important criterion in determining the prevalence of internal haemorrhoids however most of patients were male compared to female. Gender of the patient however doesn't seem to influence the mode of management.

Table 28: Gender comparison of different studies

S. No.	Study	Male	Female
1	Nakeeb <i>et al.</i> , ^[37] (2008)	82.8%	17.2%
2	Aram ^[39] (2016)	85%	15%
3	Vicente <i>et al.</i> , ^[41] (2003)	64.4%	35.6%
4	Present study	86.2%	13.8%

In a study done by Nakeeb *et al.*,^[37] on 750 patients of internal haemorrhoids, majority of patients were males 82.8% and 17.2% were females. In another study done by Aram^[39] 85% were male and 15% were female. In a study done by Vicente *et al.*,^[41] on 232 patients, 64.4% were male and 35.6% were female. Study comparison of gender in internal haemorrhoids has been shown in the above table in the present study.

In the present study majority of patients were male i.e, 86.2% and 13.8% were female. In our study male to female ratio was 6.14:1. Male to female ratio was comparable to other peer studies.

Males are more commonly affected because of high incidence of chronic liver disease secondary to alcohol. As majority of the patients were from rural areas, where female literacy and awareness to haemorrhoidal disease is relatively lower. Hence this could be the reason for lesser involvement in the study by females. Hence the current study is relatable to other peer studies.

Clinical Presentation

There are various presentations in the internal haemorrhoidal disease, painless bleeding per rectum, mass prolapse, painful defecation, constipation, purulent discharge, and decreased micturition. Such presentation can give a clue towards the diagnosis of internal haemorrhoids.

As per our inclusion and exclusion criteria of our study patients were selected. Patients were selected were of second-degree internal haemorrhoids while first, third and fourth degree haemorrhoidal patients were excluded.

In the study done by Nakeeb *et al.*,^[37] in 2200 patients and rubber band ligation was performed in 750 cases. The clinical presentation as bleeding per rectum was in 612 (81.6%) patients, while prolapse was the main complaint in 496 (66.13%). 267(35.6%) patients presented with chief complaints of constipation, pruritus was presenting complaint in 64 (8.53%) patients while pain was least common among complaints which was in 30 (4%).

In another study done by Aram^[39] in 890 patients from 2007 to 2013 and rubber band ligation was performed in second- and third-degree haemorrhoids and the objective of the study was to analyse the safety, effectiveness, quality of life and results of treatment. The clinical presentation of patients in this study were as, painless bleeding was the chief complaint in 318 (36%) second most common presentation was prolapse which were present in 227 (26%) of the patients while constipation in 186 (21%) of the patients in 83 (9%) patient had chief complaints of pruritus while pain was least common among 76(8%)

of the patients.

Table 29: Showing comparison of different studies in terms of presentation

S. no	Study	Painless bleeding	Prolapse	Constipation	Pruritus	Pain	Decreased micturition
1	Nakeeb <i>et al.</i> , ^[37] [2008]	81.6%	66.13%	35.6%	8.53%	4%	-
2	Aram ^[39] [2016]	36%	26%	21%	9%	8%	-
3	Komborozos <i>et al.</i> , ^[38] [2000]	28.4%	6.6%	-	-	-	-
4	Present Study	96.2%	20%	5%	-	15%	3.8%

In a similar study done by Komborozos *et al.*,^[38] in 500 cases of internal haemorrhoids performing rubber band ligation in symptomatic second third- and fourth-degree haemorrhoids the patient presented with complaints of bleeding in 142(28.4%) cases while prolapse was present in 33(6.6%) and both bleeding and prolapse were present in 325 cases (65%) they also included patient with liver cirrhosis and portal hypertension.

In our study the chief complaint was painless bleeding PR in 77(96.2%) while mass prolapse was present in 16(20%). Constipation was chief complaint among 4(5%). Painful defecation was present in 12(15%) of patients while purulent discharge and decreased micturition was present in 3(3.8%) each.

The variation of presentation of different patients in current study can be attributed to the grade of haemorrhoid as we only included patients with grade II and did not include I, III, IV. Hence the current study is at par comparable to other peer studies.

Grade

Grade of internal haemorrhoid as described in the review of literature was assigned to the patients after history, digital per rectal examination and proctoscopy done at the outpatient department. In our study we included only grade II internal haemorrhoid patients which were 65 (81.2%) and some of the patients had findings in between grade II and grade III, those were 15(18.8%) and rubber band ligation was performed in them also.

In another study performed by Nakeeb *et al.*,^[37] patients with symptomatic haemorrhoidal disease were 77.6% of the grade II group and 22.4% of the grade III group. Aram³⁹ conducted another study and found that 75% patients lied in the grade II group and 25% patients were in the grade III group.

According to grade of haemorrhoid our study is at par comparable to the other peer studies.

Table 30: Showing comparison of different studies in terms of grade of haemorrhoids

S. No	Study	Grade-II	Grade III	Grade II/III
1	Nakeeb <i>et al.</i> , ^[37] [2008]	77.6%	22.4%	-
2	Aram ^[39] [2016]	75%	25%	-
3	Present study	81.2%	-	18.8%

Number of ligations

Rubber band ligation was performed in among all 80 patients in two sessions and maximum number of ligations performed in a session were two and minimum single ligation per patient was done as outpatient procedure. In session one single ligation was performed in 47 patients and double ligation was done in 33 patients. And patients were followed up after one week, patients who were symptomatic even after one week another session of ligation of rubber band was done. In 20 patients out of which 12 patients required single ligation and double ligation was done in eight patients. In other peer studies one-three bands were placed in multiple sessions and patients were followed up to two years. But in present study we followed up to one month. So comparable data is not available.

Complications

Complications after the procedure of rubber band ligation were noted as immediate, on day 7 and on one month of follow up, majority of complications were immediate and minor, no major complication occurred during the procedure or even after follow-up. Minor complication included pain, bleeding at banding site, dizziness as immediately after procedure and were managed conservatively with oral analgesia and neither of the patient required hospitalisation. On day 7 majority of complications were bleeding pain, ulcer at banding site, in majority of patients bleeding was because of primary disease and was not due to rubber band ligation procedure. On one month neither of the minor complications related to procedure were present but only bleeding which was because of primary disease.

In a study performed by Vincente *et al.*,^[41] for the effectiveness of rubber band ligation in 232 patients and were followed up to 32 months. Majority of complications were immediate and following few days after procedure which include rectal tenesmus in 11% mild anal pain in 7.4%, dysuria in 4.3% and transient anal bleeding in 3.7%.

In another study performed by Watson *et al.*,^[30] in 88 patients for pain and patient satisfaction as out-

patient rubber band ligation for internal haemorrhoids, pain immediately after the procedure was the commonest and occurred in almost 90% and at one week only 7% patients experiencing pain and rectal bleeding after RBL was the second most occurring in 65% patients mostly on the day after the procedure and at one week 24 percent were still experiencing bleeding. In 30% patients there were Vaso-vagal symptoms as dizziness or fainting and was rare after the day after the procedure. No major complication occurred during or after the procedure.

Aram *et al.*,^[39] performed rubber band ligation in 890 patients and noted post band complication as pain in 2.3% of patients. Bleeding in 0.9% patients and Vaso-vagal symptoms occurred in 0.6% patients.

Nakeeb *et al.*,^[37] conducted rubber band ligation in 750 cases and complications were noted as pain and bleeding in 4.13% of patients, Vaso-vagal symptoms in 1.33% of patients.

Ricci *et al.*,^[40] conducted a study in internal haemorrhoids for rubber band ligation and infra-red photocoagulation as outpatient procedure and noted complications as bleeding in 34.8% of patients and painful mucosal ulcer occur in 13% of patients and peri-anal dermatitis occurred in 2 patients only.

Table 31: Showing comparison of different studies in terms of complications

S. No	Study	Follow up	Pain	Pain+bleeding	Bleeding	Dizziness (vasovagal symptoms)	Ulcer	Dysuria
1	Vincente <i>et al.</i> , ^[41] [2003]	Immediate	7.4%	-	3.7%	-	-	4.3%
2	Watson <i>et al.</i> , ^[30] [2006]	Immediate	90%	65%	-	-	-	-
		One week	7%	24%	-	30%	-	-
3	Aram ^[39] [2016]	Immediate	2.3%	0.9%	-	5%	-	-
4	Nakeeb <i>et al.</i> , ^[37] [2008]	Immediate	4.13%	-	4.13%	1.33%	-	-
5	Ricci <i>et al.</i> , ^[40] [2008]	Immediate	-	-	34.8%	-	13%	-
6	Present study	Immediate	18.8%	27.5%	13.8%	5%	-	-
		One week	6.2%	-	22.5%	-	20%	-
		One month	23.8%	-	-	-	-	-

As we performed rubber band ligation with the McGowenligator, so bleeding and pain were more common complication during and after the procedure as compared to other peer studies where suction ligator was used. Rest other complications are as comparable to other peer studies. Hence the current study is at par comparable to other studies.

Outcome

Outcome of the rubber band ligation was measured as relieved or symptomatic of the primary complaint with which patients presented to us. Majority of patients were relieved and few experienced minor complications after the procedure.

Table 32: Showing comparison of different studies in terms of outcome

S. No	Study	Relieved	Symptomatic
1	Aram ^[39] [2016]	79-91.8%	8.2-21%
2	Nakeeb <i>et al.</i> , ^[37] [2008]	86.66%	13.34%
3	Komborozos <i>et al.</i> , ^[38] [2000]	88%	12%
4	Vincente <i>et al.</i> , ^[41] [2003]	97.4%	2.6%
5	Komporozos <i>et al.</i> , ^[36] [2021]	86.8%	13.2%
6	Alemdaroglu <i>et al.</i> , ^[32] [1993]	93.9%	6.1%
7	Present study	83.8%	16.2%

In a study conducted by Aram *et al.*,^[39] 79-91.8% were relieved of symptoms while 8.2-21% were symptomatic after rubber band ligation. In another study conducted by Nakeeb *et al.*,^[37] 86.66% of patients were relieved of symptoms and 13.34% of patients were still symptomatic. Komborozos *et al.*,^[38] conducted a study in which 88% were asymptomatic while 12% remained symptomatic even after treatment. Vincente *et al.*,^[41] conducted a study in rubber band ligation and found that 97.4% of patients were relieved while 2.6% were symptomatic. Komporozos *et al.*,^[36] found 86.8% patients were relieved and 13.2% patients were symptomatic. Alemdaroglu *et al.*,^[32] conducted a study on rubber band ligation and found that 93.9% patients were relieved and while 6.1% remained symptomatic even after treatment. In our study 83.8% of patients were relieved of symptoms while 16.2% patients remained symptomatic after rubber band ligation and follow up. Hence from the above results the current study is at par comparable to other peer studies.

Conclusion

Haemorrhoidal disease patients are bread and butter of surgical outpatient department. This disease significantly compromises patients' quality of life and day to day work. There are various methods of treatment of this ailment is available in which Rubber band ligation is much safer. Rubber band ligation doesn't require hospitalization and much of the investigations. It is a cost-effective method and a better option of treatment as majority of patients were relieved of symptoms by the technique. Our study also supported that rubber band ligation for grade II internal haemorrhoid disease is appears to ideal in large numbers of patients. These patients can be managed in outpatient department without the need for hospitalization and is a safe method with minimal complications. It was noted that majority of complications occurred after immediate post banding and majority of them were relieved by managing the patient at home without the need of hospitalization. Complications at day seven and one month were mainly because of primary disease not related to procedure; hence from our study we conclude that rubber band ligation is a safe and effective method for grade II haemorrhoidal disease.

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