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Research Article

AN EVALUATION OF THE EFFECTIVENESS OF RUBBER BANDLIGATION AS A MODALITY OF TREATMENT OF SECOND DEGREE HAEMORRHOIDS

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A R T I C L E I N F O

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Rubber Band Ligation, Sepsis, Vasovagal reflex, Bleeding, Prolapse, Irritation, Discharge

A B S T R A C T

Background: Rubber band ligation, an outpatient's procedure for treatment of 2nd degree hemorrhoidsisa effective mode of management.
Objectives: To evaluate the effectiveness of Rubber band ligation in the treatment of 2nd degree hemorrhoids.
Methods : This is a prospective study of 50 cases who underwent rubber band ligation as an outpatient procedure for 2nd degree hemorrhoids. Binomial probability pre-post test were used for statistical analysis, p value less than 0.05 was taken as significant.
Results: 50 patients underwent rubber band ligation as a outpatient procedure for 2nd degree hemorrhoids. No major post procedure complications as sepsis, vasovagal reflex were observed. Only 30 patients had discomfort following procedure, which lasted for 1-2 days and 41 patients did not need pain relief, 40 patients returned to work just after procedure and 26 cases spent just Rupees 100-150 post procedure. As of symptom improvement post procedure compared to at presentation only 6 patients had bleeding post procedure out of 45 patients who had bleeding at presentation p value of which was significant as p value=0.00025, 2 patients had pain post procedure out of 12 patients who had pain at presentation p value-0.00314 was found significant. Only 1 patient after procedure had prolapse out of 28 patients who had prolapse on presentation (p value = 0.00250). No patient had irritation or discharge post procedure (p value) = 0.0025.41 patients assessed Rubber band ligation as excellent and 9 patients as of moderate help.
Interpretation and conclusion: Rubber band ligation for 2nd degree hemorrhoids is a effective modality of treatment which is convenient, simple, cost efficient has high patient acceptance with limitations as post procedure discomfort, pain.

INTRODUCTION

For centuries the human race has been plagued by a very common condition called haemorrhoids. Yet the whole subject is still clouded by misconception and folklore. It is almost impossible to calculate its prevalence for many patients with haemorrhoids never have symptoms so whether such persons should be considered as diseased is still a question. So only symptomatic patients with haemorrhoids should be taken into consideration.

Haemorrhoids the word is derived from Greek, haima meaning blood and rhoos meaning flowing, the common man's term piles is derived from Latin word pila meaning a ball. Haemorrhoids have been defined differently over the years from oversimplified definition of varicosities of haemorrhoidal plexus to the more recent study describing them as specialized highly vascular "cushions" of discrete masses of thick submucosa, containing blood vessels, smooth muscles, elastic and connective tissue which may slide down due to breakage of collagen and anchoring supporting connective tissue causing symptoms like prolapse, bleeding, pain etc. The cause of which is still hypothesized as erect posture, constipation, straining during defecation, sedentary work and diet low on fibre, heredity, high resting anal pressures.

Aims and Objectives

The present description is a prospective study of 50 cases of haemorrhoids in Krishna Institute of Medical Sciences, Karad treated with rubber band ligation.

- To know the effectiveness of Rubber Band Ligation in the treatment of second degree haemorrhoids.
- To know the complications associated with Rubber Band Ligation.
- To know the limitations of Rubber Band Ligation.
- To know the cost effectiveness, and time off work of patients treated by Rubber Band Ligation.

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METHODS

Source of Data

The present study is a prospective study from 1st June 2017 to 31st June 2018. The data for which was drawn from patients visiting Krishna Institute of Medical Sciences, Karad a total of 50 cases.

MATERIALS AND METHODS

In the present study 50 cases of 2nd degree haemorrhoids were chosen with complaints of bleeding per rectum, pain during defecation, mass per rectum, discharge and irritation.

A detailed history of each patient was taken with personal history, family history, diet history with systemic examination of respiratory, cardiovascular, per abdominal examination to know any associated disease and to rule out any cause predisposing to haemorrhoids and local examination including proctoscopy was done as per proforma made for the study and the data entered in the proforma.

The patients were explained in detail about their disease and the various modalities of treatment as Rubber band ligation, cryotherapy, sclerotherapy with the advantages and disadvantages of each.

Willing patients were selected and examined and investigated as per proforma. Analysis was made on basis of percentages, mean, standard deviation, binomial
probability tests.

Inclusion Criteria

- Patients with complaints of bleeding per rectum, mass per rectum, pain, irritation, discharge per rectum
- Patients with 2nd degree hemorrhoids
- Both male and female aged 20 years to 55 years
- Patients demanding non-surgical treatment

Exclusion Criteria

- Immunocompromised patients
- Patients with bleeding disorders
- Hypertensive patients.
- Patients with deranged liver function tests
- Pregnant patients

Procedure

Rubber band ligation was done in minor operation theatre for this study.

Preparation

Soap water enema or neotomicenemawas given to evacuate the rectum on the night before and themorning of the planned day of procedure.

Position

Patient was put in left lateral (SIMS) position while the procedure was performed.

Principle

Rubber bands applied to the pedicle of mucosa of internal hemorrhoids causes ischaemia, necrosis and scarring preventing further bleeding or prolapsed of the respective hemorrhoids and gradually cuts off through the tissues and within a period of seven to ten days these hemorrhoids slough off.

Instruments required

- Proctoscope
- Light source
- Barron Band applicator
- Alligator forceps
- Rubber bands (Barron Bands)

Proctoscope

Proctoscope with obturator was used in our study.

Light Source

The needed illumination was provided by a over head lamp tilted to the needed angle.

Barron Band Applicator

The Barron band applicator consists of a pair of ligating drums at one end which has a conical rubber band loader which can be screwed into the inner ligating drum with help of threading on the distal end. The diameter of the ligating drum is 11 mm. The ligating drum communicates with the handle through a shaft, the handles are interchangeable which fixes to the trigger which has spring action which bring it back to its original position after the bands on the drum are fired around the pedicle of the haemorrhoid.

Alligator Forceps

Alligator forceps have smooth atraumatic tooth at one end to firmly grasp the hemorrhoids and prevent bleeding on traction. The distal end has a shaft and a handle, which helps the tooth to open or close.

Rubber Bands (Barron Bands)

Black rubber bands with inside diameter of 1/16th of an inch are slid into the inner cylinder of the ligating drum were used.

Technique

The proctoscope is well lubricated with local anaesthetic jelly and gently introduced into the rectum first in the direction of umbilicus till anal canal is passed and later directed posteriorly to enter the rectum. Now the obturator is withdrawn to examine the interior as the proctoscope is withdrawn slowly the hemorrhoids protrude into the lumen of the proctoscope, the whole of the internal cushion is made to prolapse into the lumen so that the base of the cushion is easy to recognize. The hemorrhoids can be grasped with the alligator forceps and pulled into the cylinder of the ligating drum without causing discomfort. Then with gentle downward traction with alligator forceps and upward pressure with ligating drum the inner cylinder fills with hemorrhoid and underlying vascular tissue forming the pedicle. Now the trigger is pressed so that the rubber bands on the inner cylinder of ligating drum strangulate about 1 cm diameter of tissue. The procedure was repeated with another hemorrhoid.

Post-Procedure Advice and Follows up

Post-procedure pain was relieved by oral analgesia if necessary. Warm sitz bath was also advised in case of pain. Patient was advised to take up liquids and semisolids for one day, following the procedure so that attempts at defecation are minimal. Oral intake of bulk forming agents for 6-8 weeks was

advised to the patients. The patient was watched for post procedure pain, discomfort, bleeding, urinary retention, sepsis, need for analgesia, cost of treatment and days off work were evaluated.

Patient was followed up regularly at intervals of one, three and six months for symptoms as pain, bleeding, prolapse, irritation, mucous discharge and to look out for anal stenosis or incontinence and were enquired whether pre-procedure symptoms had mostly resolved or residual symptoms were present. Patients were requested to assess the form of treatment as excellent, moderately successful or of little help based on their results post-procedure.

Fig 1 Equipments required for Rubber Band Ligation

Fig 2 Loading of Rubber Band on the conical loader of Barron Band Applicator

Fig 3 Rolling down of the Rubber Band on the conical loader of Barron Band Applicator and Positioning of Alligator forceps inside the ligaitng drums of Barron Band Applicator

Fig 4 Proctoscopic view of second-degree haemorrhoids andProcess of Barron Band Ligation

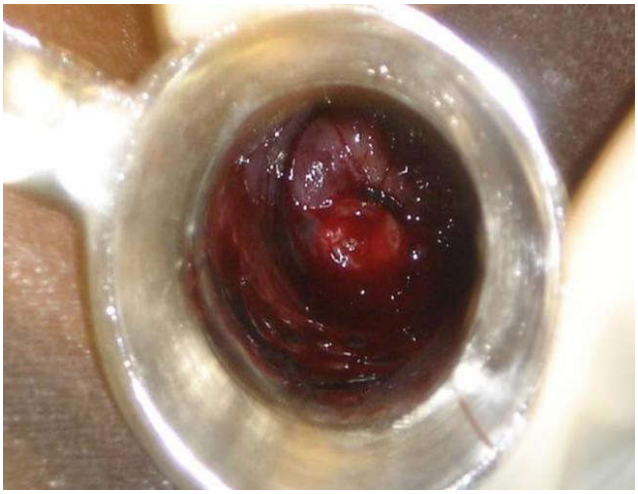


Fig 5 Second Degree Haemorrhoids after Rubber Band Ligation

RESULTS

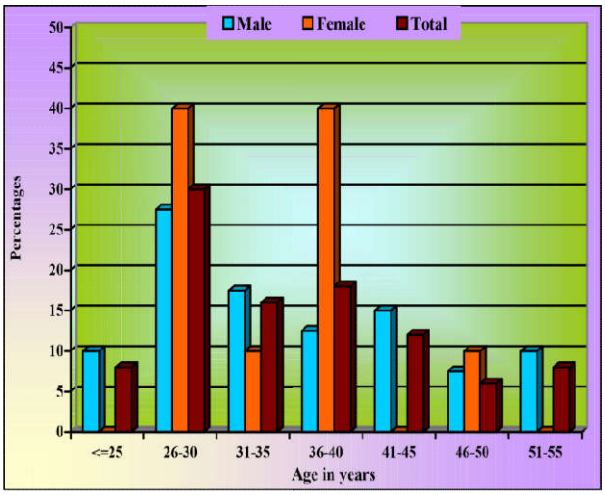
In the present prospective study the following data for clinical studies was obtained from patientsvisiting Krishna Institute of Medical Sciences, Karad. 50 cases of symptomatic second-degree hemorrhoids who wanted to be treated by Rubber Band Ligation were chosen during the period from 1st June 2017 to 31st June2018.

Age distribution with sex

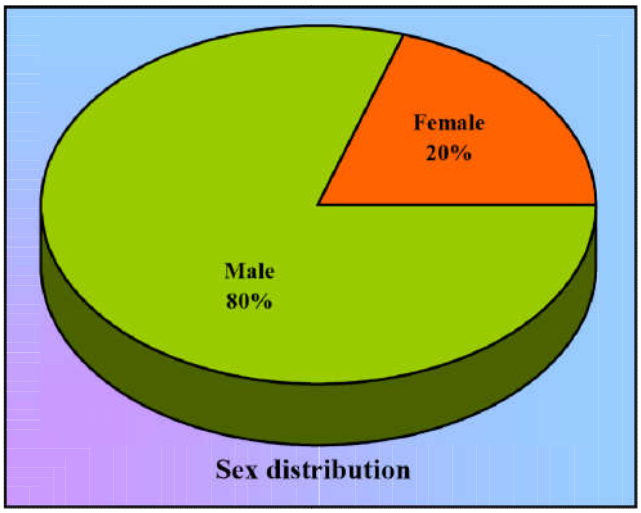
The age and sex distribution of the cases who underwent rubber band ligation is as follows:

Table 1 Age distribution with sex

Age in years	Male		Female		Total	
	No	%	No	%	No	%
≤ 25	4	10	-	-	4	8
26-30	11	27.5	4	40	15	30
31-35	7	17.5	1	10	8	16
36-40	5	12.5	4	40	9	18
41-45	6	15	-	-	6	12
46-50	3	7.5	1	10	3	6
51-55	4	10	-	-	4	8
Total	40	100	10	100	50	100
Mean ± SD	36.45±9.65		34.90±6.77		36.14±9.04	



Graph 1a



Graph 1b

In the present study the minimum age recorded is 20 years and the maximum age recorded is 55 years. The male female ratio of patients is 4:1 respectively. In both males and females second-degree hemorrhoids were more common in the age group 26-30 years showing 27.5% males and 40% females. Whereas in the female patients in 36-40 years range also there were 40% cases.

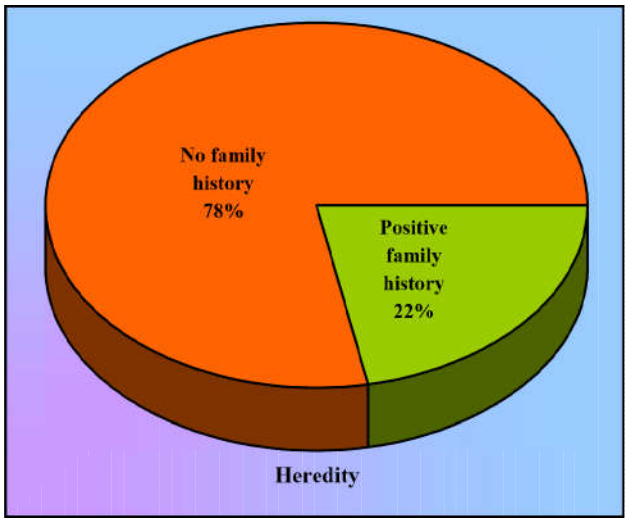
In the present study the mean age for males was 36.45 years with a standard deviation of 9.65. Whereas in females the mean age was 34.90 years with a standard deviation of 6.77. The overall mean age was 36.14 years with a standard deviation of 9.04.

Heredity

In the present series the incidence of hemorrhoids in parents (Either father or mother) is as follows

Table 2 Heredity

Heredity	No of cases	Percentage
Either father or mother affected with hemorrhoids	11	22
Parents not affected	39	78



Graph 2

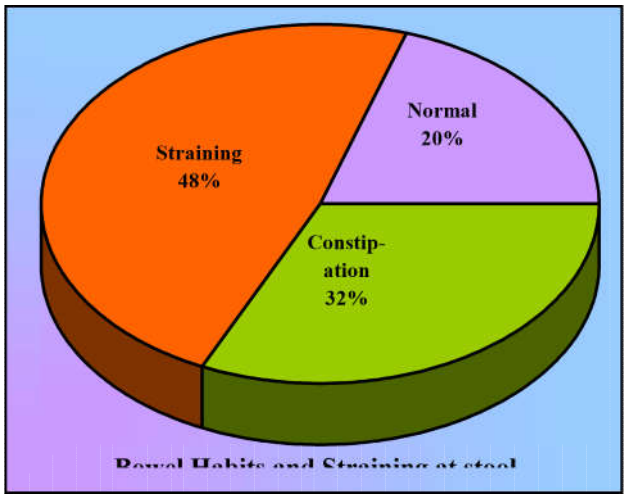
In the present study 22% of patients had significant family history of either father or mother affected by hemorrhoids.

Bowel Habits and Straining at Stool

The bowel habits of the present study were grouped under normal or with history of constipation or straining at stool.

Table 3 Bowel Habits and Straining at stool

Bowel Habits and Staining at stool	Number (n=50)	%
Constipation	16	32.0
Straining	24	48.0
Normal	10	20.0



Graph 3

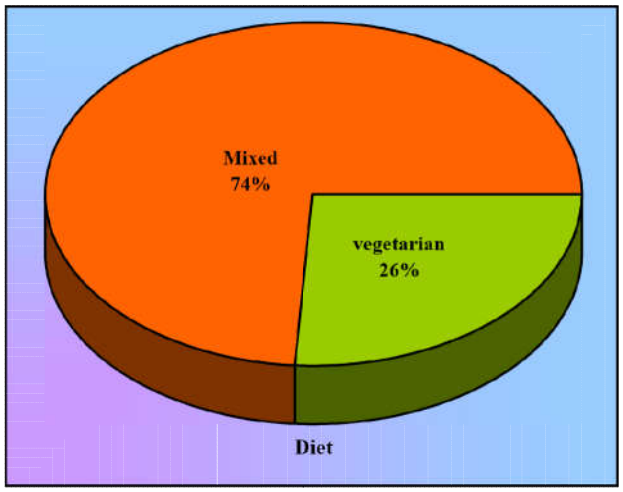
It was observed that 32% of cases were constipated whereas 48% cases had history of straining at stools. Normal bowel habits were seen in only 20% cases. Maximum percentage i.e., 48% had history of straining at stools.

Diet

The dietary habits of the patients of the study is as follows

Table 4 Dietary habits of the study group

Diet	Number (n=50)	%
Vegetarian	13	26.0
Mixed	37	74.0



Graph 4

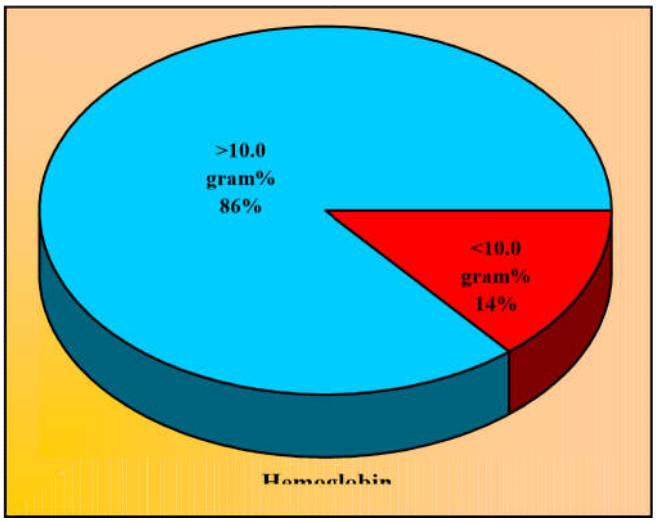
Most patients i.e., about 74% of the subjects were on mixed diet consuming low fibre mostly non-vegetarian diet.

Haemoglobin

The cases were allotted to groups as < 10gm%, signifying anemia and > 10 gm% as normal. The observations were as follows:

Table 5 Hemoglobin

Hemoglobin gram%	Number (N=50)	%
<10.0 gram %	7	14.0
>10.0 gram%	43	86.0



Graph 5

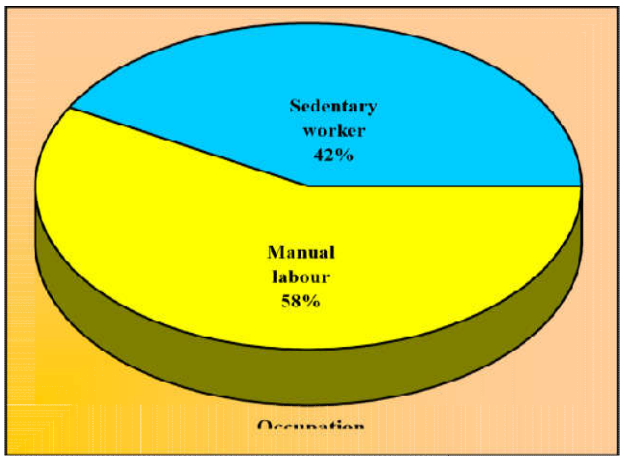
Only 14% of the observed cases who underwent rubber band ligation were seen to be anemic.

Occupation

Based on whether the occupation of patients needed them to do manual labourer cases were allotted in manual labourer group or sedentary worker group. And the observations were:

Table 6 Occupation

Occupation	Number(n=50)	%
Manual Labourer	29	58.0
Sedentary worker	21	42.0



Graph 6

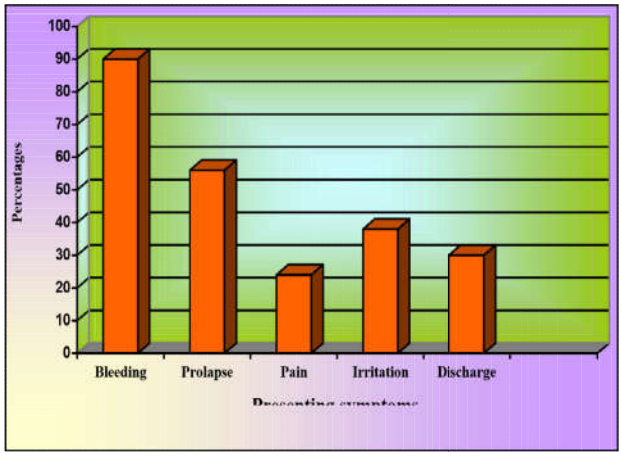
About 58% of patients who underwent rubber band ligation were manual labourers whereas 42% were sedentary workers.

Presenting symptoms

The presenting symptoms of the 50 cases who underwent rubber band ligation is as follows:

Table 7 Presenting symptoms of the study group

Presenting symptoms	Number	%
Bleeding	45	90.0
Prolapse	28	56.0
Pain	12	24.0
Irritation	19	38.0
Discharge	15	30.0



Graph 7

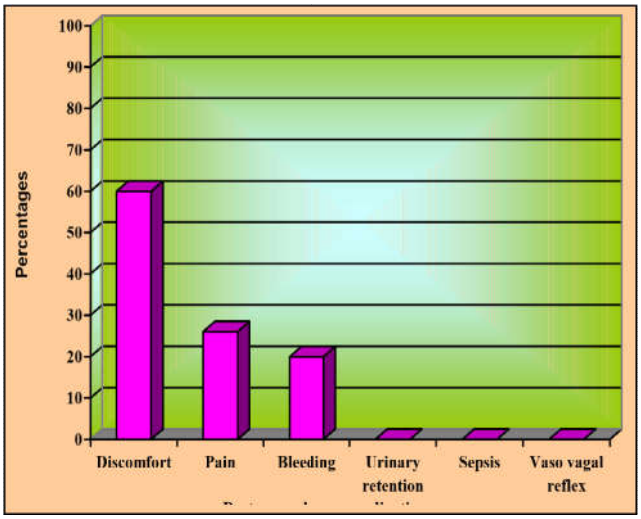
Majority of cases i.e., 90% had bleeding as the predominant symptom, followed by haemorrhoidal prolapse is 56%, pain in 24% cases, irritation in 38% cases and discharge in 30% cases.

Immediate post procedure complications

Following rubber band ligation of the 50 cases the following post procedure complications were observed in the respective number:

Table 8 Post-procedure complications

Post-procedure complications	Number (n=50)	%
Discomfort	30	60
Pain	13	26
Bleeding	10	20
Urinary retention	-	-
Sepsis	-	-
Vasovagal Reflex	-	-



Graph 8

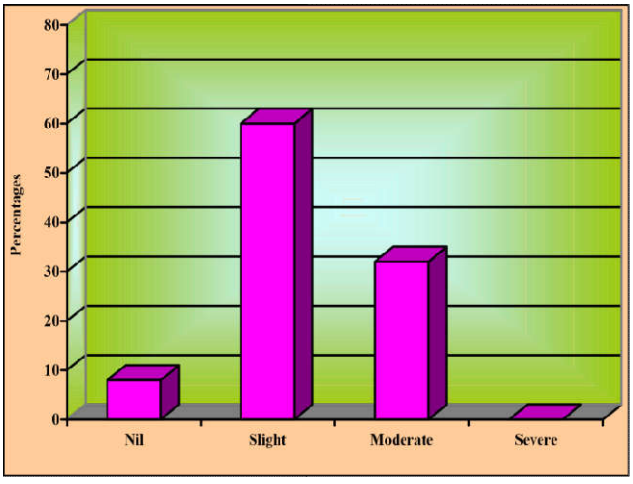
Maximum number of cases about 60% had discomfort, bleeding was seen in least number of cases around 20% and pain in about 26% cases. Complications such as urinary retention, sepsis, vasovagal reflex were not seen in the study.

Post ligation discomfort

Depending on the number of days discomfort was experienced the cases were categorized as slight discomfort lasting about one to two days. Moderate discomfort which was experienced for more than or equal to three days and severe discomfort.

Table 9 Post-ligation discomfort

Post-ligation discomfort	Number (n=50)	%
No	4	8.0
Slight (1-2 days)	30	60.0
Moderate (≥3 days)	16	32.0
Severe	0	0.0



Graph 9

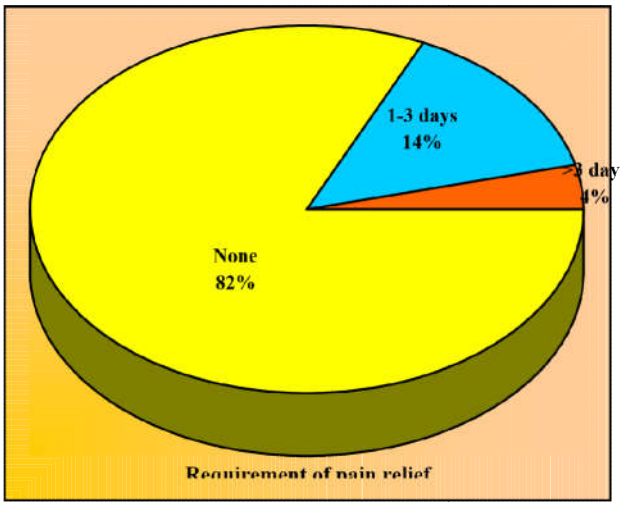
None of the cases had severe discomfort whereas maximum patients about 60% had slight discomfort.

Requirement of pain relief

Regarding the patients requirement of analgesics for pain relief post procedure cases were divided as requiring relief for one to 3 days, more than 3 days or no requirement.

Table 10 Requirement of pain relief

Requirement of pain relief	Number (n=50)	%
None	41	82.0
1-3 days	7	14.0
More than 3 days	2	4.0



Graph 10

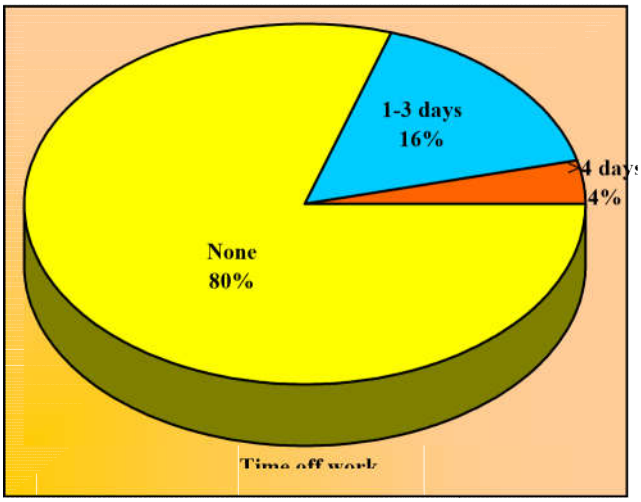
82% cases did not require pain relief, whereas 14% cases required it for 1-3 days and 4% for more than 3 days.

Time off work

Post rubber band ligation the patients were assessed for time spent without going for work as no time off work, 1 to 3 days off work or > 4 days off work.

Table 11 Time off work

Time off work	Number (n=50)	%
None	40	80.0
1-3 days	8	16.0
>4 days	2	4.0



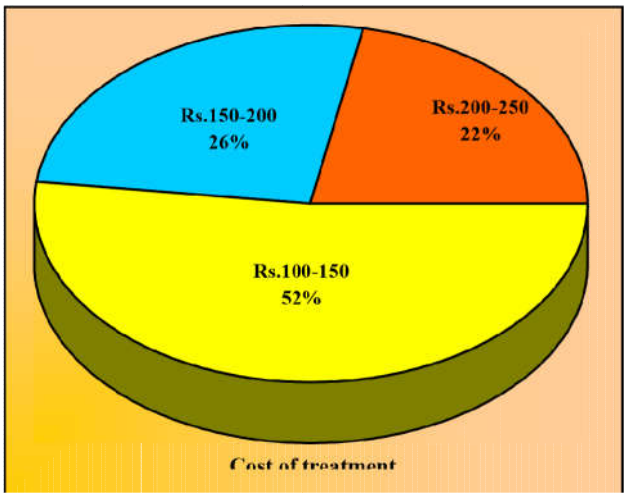
Graph 11

Maximum number of case 80% returned to work the next day, only 4% cases took off work for more than 4 days, whereas 16% were off work for 1 to 3 days.

Cost of Treatment

Table 12 Cost of treatment

Cost of treatment In rupees	Number (N=50)	%
100-150	26	52.0
150-200	13	26.0
200-250	11	22.0



Graph 12

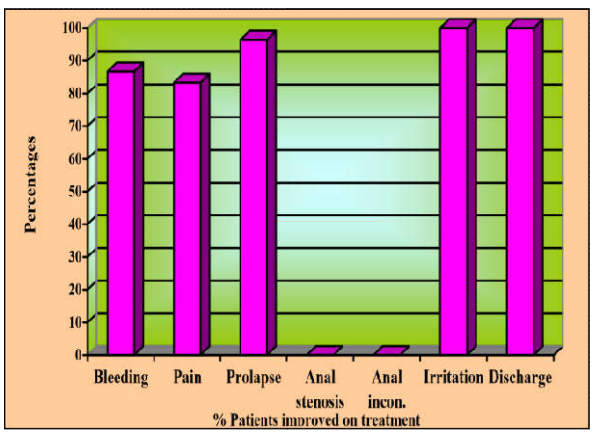
The amount of money spent post procedure for pain relief and to manage complications with hospital visits was arbitrarily divided into groups who spent Rs.100-150, Rs.150-200 rupees and Rs.200-250.Maximum number of cases about 52% spent 100-150 Rupees following rubber band ligation.

Symptoms at follow up

The effect of rubber band ligation on symptom improvement was assessed using parameters as bleeding, pain, prolapse, pruritis, mucous discharge, anal stenosis, and Anal incontinence.

Table 13 Effect of Rubber band treatment on symptom improvement

Symptoms	At presentation	At 1 month	At 3 months	At 6 months
Bleeding	45 (90.0%)	12 (24.0%)	10 (20.0%)	6 (12.0%)
Pain	12 (24.0%)	7 (14.0%)	3 (6%)	2 (4.0%)
Prolapse	28 (56.0%)	4 (8.0%)	2 (4%)	1 (2.0%)
Anal stenosis	-	-	-	-
Anal incontinence	-	-	-	-
Irritation	19 (38.0%)	-	-	-
Discharge	15 (30.0%)	-	-	-



Graph 13

At one-month post rubber band ligation, bleeding seen in 90% cases at presentation decreased to 24%, which further decreased to 10% at 3 months. Pain seen in 24% cases at presentation decreased to 14% at one month and 6% at 3 months. Prolapse observed in 56% cases at presentation decreased to 8% at one month and 4% at 3 months.

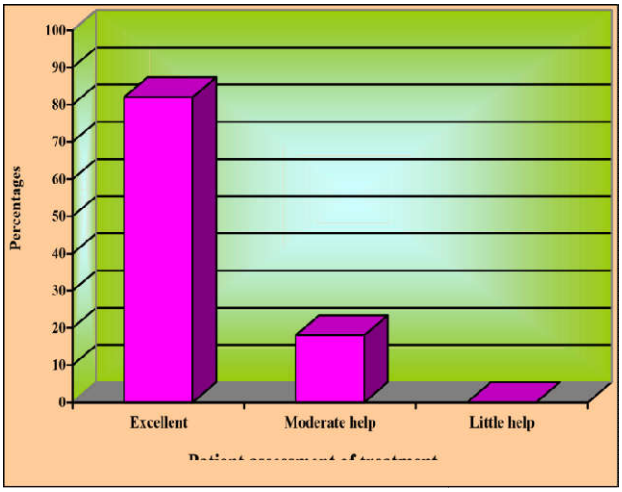
At 6 months 12% cases still had bleeding, 4% had pain and 2% has prolapse.

Patient assessment of treatment

After follow up patients were asked to assess treatment as excellent of moderate help or of little help, depending on patient's satisfaction with the treatment.

Table 14 Patient assessment of treatment

Patient assessment of treatment	Number (n=50)	%
Excellent	41	82.0
Moderate help	9	18.0
Little help	-	-



Graph 14

82% cases assessed treatment as excellent and 18% with some residual symptoms assessed the treatment as of moderate help. Nil assessed treatment as of little help.

DISCUSSION

Rubber band ligation proved to be a simple technique to acquire did not need expertise or too much skill. Rather no anaesthesia, no pre-procedure elaborate work up. No expensive equipment and no need for bed rest. Patients were made ambulatory and treated as day cases.

Age distribution

Age distribution of the present study group is as follows: Comparing with other studies. Though the number of cases were higher in other groups as Khubchandaniwith 100 cases and Lee *et al* with 177 cases, the lower age limit of all study groups were around 20 to 25 years whereas the upper age limit was higher in all studies ranging form 70-85 years.

Table 15 Age Distribution

Studies	No	Range
Present Study	50	20-55
Ruffinhood	24	25-71
KhubChandani	100	25-85
Lee	177	19-85

Sex distribution

In the present study the sex distribution of cases of haemorrhoids were compared to other studies as follows:

The present study is comparable with that of Khubchandani's who had a male:female ratio of 70:30 and Ruffinhood'swho showed a 75:25 male:female ratio respectively. Lee performed rubber band ligation for higher number of female cases with a ratio of 52:48 i.e., male:female respectively.

Table 16 Sex Distribution in %

Studies	Male	Female
Present Study	80	20
Ruffin hood	75	25
KhubChandani	70	30
Lee	52	48

Etiology

As the etiology is not exactly defined some etiological factors were taken into consideration as occupation, diet, family history, history of constipation, straining at stool.

Taking the type of occupation into consideration cases were divided as manual labourers and sedentary workers. There was hemorrhoids preponderance in manual labourers with 58% cases. This observation is supported by Willian, LJ and Turell who noted that occupational strain and stress played important role in precipitating prolapse of existing internal hemorrhoids.

In the present study 22% cases had family history of haemorrhoids, which is supported by Greham Stewart's theory of familial tendency due to, generalized weakness of venous walls due to hereditary predisposition.

Taking into consideration diet, bowel habits and straining at stool. 74% cases were on mixed diet, low on fibre, which was mostly non-vegetarian. Similar to studies, which showed, the close relationship of hemorrhoids with Western type of diet which is more refined and low in fibre.

This low fibre diet inturn increases bowel transit time and forms hard stools, which causes constipation and straining of stools. Constipation was seen in 32% cases and straining was seen in 48% cases. Nivatongs has noted constipation and raised abdominal pressure due to straining as predisposing and associated factors of haemorrhoids.

Symptoms and signs

The presenting symptoms of the 50 cases who underwent rubber band ligation is as follows in comparison with other studies.

The principal presenting symptom in most studies was bleeding per rectum seen in 97% of Murie *et al*, 88% of Arabi *et al*,62% of David Marshman's studyand 91% of David Steinberg, prolapse was seen in 56% of the present study. 36% of Murie, 55% of Arabi, 20% of David Marshmans study and 64% of David Steinbergs. Pain in the present study was 24% comparable with 15% in David Marshmans. Murie and Steinberg had 46% and 43% respectively. Arabi *et al* had a maximum about 62% pain. Irritation in present study was comparable to Arabi *et al* and Steinberywhereas Murie *et al* had very high of 56% and Marshman had a very low of 3%. The percentage of patients with discharges was comparable to Arabi *et al* with 29% and Steinberg with 23% whereas Murie had a maximum of 58%.

Table 17 Presenting Symptoms

Presenting symptoms	Present Study	%	Murie *et al*		Arabi *Et al*		David Marshman		David M Steinberg	
	Number		Number		Number		Number		Number	
	n=50		n=39	%	n=51	%	n=241	%	n=125	%
1.Bleeding	45	90	38	97	45	88	149	62	114	91
2.Prolapse	28	56	14	36	28	55	48	20	80	64
3.Pain	12	24	18	46	32	62	36	15	54	43
4.Irritation	19	38	22	56	19	37	7	3	48	38
5.Discharge	15	30	23	58	15	29	-	-	29	23

Treatment

All fifty cases underwent rubber band ligation as a outpatient procedure with no anaesthesia. Multiple hemorrhoids were banded in a single session as it was earlier tried by Lee *et al*, Khubchandani.

Immediate post procedure complication

The cases were watched for immediate complications and compared with studies of Paulvannan and Kumar and Lee *et al*.

Maximum patients about 60% in present study were comparable with Paulvannan and Kumars[31] study had just 21% discomfort, pain was noted in 26% in the present study and 29% in Paulvannan and Kumar. 20% of the cases of present study had bleeding comparable to 11% of Lee's whereas only 1% of Paulvannan and Kumars had bleeding.

No cases of urinary retention, sepsis or vaso-vagal reflex was seen in the present study.

Table 18 Post-procedure complications

	Present Study		Paulvannan, Kumar		Lee	
Complications	Number n=50	%	Number n=98	%	Number n=155	%
Discomfort	30	60	21	21	-	-
Pain	13	26	29	29	-	-
Bleeding	10	20	1	1	18	11
Urinary retention	-	-	8	8	19	12
Sepsis	-	-	-	-	-	-
Vasovagal Reflex	-	-	15	15	8	5

Post-ligation discomfort

Post rubber band ligation vague discomfort was experienced by most patients, which lasted for about three days. This discomfort was categorized as no discomfort, slight discomfort lasting about one to two days. Moderate discomfort, which lasted upto3 days, was compared with other studies. Maximum patients 60% in present study and 62% in both Ruffinhoods and Anthony R Groves study had slight discomfort lasing for 1-2 days were comparable. Moderate discomfort in present study was seen in 32% cases comparable to 33% in Ruffinhoods and 40% in Poons.No discomfort was seen in a minimum of 8% in present study comparable to 4% in Ruffinhoods and 12% of Groves study. None had severe discomfort in the present study.

Table 19 Post-ligation discomfort

Post-ligation discomfort	Present Study		Ruffin hood		Poon		Anthony Groves	
	Number n=50	%	Number n=24	%	Number n=97	%	Number n=149	%
No	4	8	1	4	23	23	18	12
Slight (1-2 days)	30	60	15	62	32	33	92	62
Moderate (³3 days)	16	32	8	33	39	40	39	26
Severe	0	0	0	0	3	3	0	0

Time off work

Post rubber band ligation number of days taken off without going to work was estimated and arbitrarily divided into groups when no days were lost, 1-3 days lost and > 4 days lost. 80% of the present study group lost no days off work, comparable with 68% of Anthony R Groves.16% had 1-3 days off work comparable to 12% of Arabi *et al* and a least of only 4% cases in present study had > 4 days of work comparable to 5.8% in Arabi *et al* and 6% in Anthony Groves study.

Table 20 Time off work

Time off work	Present Study		Arabi *et al*		Anthony Groves	
	Number n=50	%	Number n=51	%	Number n=149	%
None	40	80	26	51	103	68
1-3 days	8	16	6	12	38	26
>4 days	2	4	3	5.8	8	6

Symptoms at follow up

The effect of rubber band ligation on symptom improvement was assessed using parameters as bleeding, pain, prolapse, pruritis, mucous discharge, stenosis, and incontinence

Table 21 Effect of Rubber band treatment on symptoms improvement

Symptoms	At presentation	At 1 month	At 3 months	At 6 months	% of improvement	p value
Bleeding	45 (90.0%)	12 (24.0%)	10 (20.0%)	6 (12.0%)	86.7%	0.00025
Pain	12 (24.0%)	7 (14.0%)	3 (6%)	2 (4.0%)	83.3%	0.00314
Prolapse	28 (56.0%)	4 (8.0%)	2 (4%)	1 (2.0%)	96.4%	0.00250
Anal stenosis	-	-	-	-	-	-
Anal incontinence	-	-	-	-	-	-
Irritation	19(38.0%)	-	-	-	100.0%	0.00025
Discharge	15(30.0%)	-	-	-	100.0%	0.00026

At one-month post rubber band ligation, bleeding seen in 90% cases at presentation decreased to 24% which further decreased to 10% at 3 months. Pain seen in 24% cases at presentation decreased to 14% at one month and 6% at 3 months. Prolapse observed in 56% cases at presentation decreased to 8% at one month and 4% at 3 months.

Maximum percentage of symptom improvement was seen in irritation, discharge with 100% improvement with p value of 0.00025 and 0.00026 which were significant as <0.05 respectively. Followed by 96.4% improvement for prolapse with p value 0.00250 whereas for bleeding it was 86.7% with p value of 0.00025 and pain with 83.3% improvement with p value 0.00314. 82% of patients had remarkable symptoms improvement at the end of six months. Whereas 18% of cases i.e, 9 patients still had residual symptoms in terms of bleeding in 12% (6 cases), pain in 4% (2 cases), prolapse in 2% (1 case).

Patient assessment of treatment

Depending on the responses to the questionnaire put forward to patients on follow up regarding their satisfaction with treatment by rubber band ligation. Patients categorized treatment as either excellent, of moderate help, or of little help and compared with other studies. 82% of present study cases remarked as excellent comparable to 72% in Murie *et al*, 18% assessed treatment as of moderate help similar to 16.% in Murie *et al*. None of the cases assessed it as of no help. This self-assessment by patients has been important in knowing

patient acceptance, which was high as 82% cases assessed the treatment as excellent.

Table 22 Patient assessment of treatment

Patient assessment of treatment	Present Study Number (n=0)	%	Ruffinhood Number n=24	%	Murie Number n=43	%	Anthony Groves Number n=149	%
Excellent	41	82	14	58	31	72	98	66
Moderate help	9	18	10	42	7	16	37	25
Little help	-	-	0	0	5	11	14	9

Cost of treatment

The patient's expenditure for treatment and during follow up was questioned and the expenses were arbitrarily divided into groups spending 100-150 rupees, 150-200 rupees, 200-250 rupees.

52% cases reported as saying they spent 100-150 rupees, 26% as 150-200 rupees and 22% as 200-250 rupees. This being an outpatient procedure is much less expenditure other forms of treatment as assessed by Barzital who found office procedure of Rubber band ligation $1/10^{th}$ the cost of surgery Poon *et al*and Lee at el have also acknowledged the cost effectiveness of Rubber band ligation.

Serious complications

None of the cases in the present prospective study had any serious complications as acute perianal sepsis or any deaths. But there have been studies by Thomas R. Russell and Eli Shemesh showing clostridial sepsis four days following treatment.

O' Hara noted a death following seven days post treatment. It was also highlighted by Thomas R. Russell about deaths following rubber band ligation but he remarked not to abandon Rubber band ligation but to carefully watch out for the symptoms as severe pain, fever, urinary retention which preceded sepsis and should prompt immediate evaluation under anesthesia. Treatment of Perianal sepsis include debridement of necrotic tissue, drainage of associated abscess and administration of triple antibiotics. It is for fear of this fatal complication that this procedure is not performed in immunocompromised patient.

Long-term results

Though the present study followed up patients only for six months. There have been studies evaluating the long term results of rubber band ligation as David M. Steinberg, who followed up the cases for 4.8 years and reported 89% as cured or satisfied with results of treatment and Murie *et al*who followed up for 42 months post procedure and found favourable results.

CONCLUSION

This prospective study of 50 cases who underwent rubber band ligation was done to evaluate the effectiveness in treatment of symptoms of second degree hemorrhoids with reference to post procedure complications, post ligation discomfort, time off work, cost effectiveness and to know its limitations. Though some residual hemorrhoidal tissue was seen on follow up – in the cases in the study it has to be appreciated that that treatment was carried out to obtain symptomatic relief rather than with the aim of removing all hemorrhoidal tissue.

From the above done prospective study the following conclusions were derived.

- Rubber band ligation is a simple out patient treatment not needing much expertise to perform.
- Rubber band ligation does not necessitate the need for expensive equipment can be done with minimal infrastructure without need for major operation theatre.
- Rubber band ligation is a beneficial procedure in operation apprehensive patient.
- Youngest patient in the study was 20 years and eldest 55 years so wide range of patient acceptance for procedure was noted.
- No anaesthesia is required for the procedure.
- Careful patient selection was important with second degree hemorrhoids.
- Procedure consumed very less time about 5-10 minutes.
- Banding site to be selected above dentate line to reduce discomfort and pain.
- Multiples hemorrhoidal bandings can be done at single session without fear or severe discomfort, pain or bleeding.
- After rubber band ligation no severe complications were noted which required hospitalization.
- Antibiotic administration was not found necessary.
- No case of sepsis or infection or death occurred in the study.
- Rubber band ligation was found effective based on significant symptom improvement with 82% symptom free at follow up, assessing the treatment as excellent with 82% requiring no pain relief post procedure and 60% showing slight discomfort post procedure lasting 1-2 days.
- Post rubber band ligation complications like vague discomfort was seen in 60% cases. Pain in 26% and bleeding in 20% cases with 32% patients having moderate discomfort for upto 3 days. And 4% cases required pain relief, for more than 3 days.
- Rubber band ligation is limited to only healthy patients with second degree hemorrhoids not to be tried in immunocompromised or patients with bleeding disorder.
- Rubber band ligation was found cost effective with 52% cases spending 100-150 rupees.
- 80% of patients took no time off work after rubber band ligation.
- Saves time for patient, doctor, staff. Saves bed rest, Patient is ambulatory following treatment can carry on routine work.

Based on these conclusions, rubber band ligation can be recommended as a effective outpatient treatment for second degree hemorrhoids.

Summary

Hemorrhoids is one of the oldest diseases suffered by mankind, though most of the times not life threatening still it causes significant discomfort. Though different modalities of treatment are recommended for second-degree hemorrhoids like rubber band ligation, cryotherapy, bi-polar and direct current therapy. Sclerotherapy, infrared photocoagulation and surgical procedures like Lords anal dilatation, lateral

sphincterotomy, haemorrhoidectomy. The search for a simple, outpatient based, convenient cost effective treatment still continues.

The present study was done to know the effectiveness of rubber band ligation in the treatment of 2nd degree hemorrhoids. In the present study bleeding was the principle presenting symptoms seen in 90% cases, followed by prolapse seen in 56% and irritation in 38% cases. In the etiology straining at stools was seen in 48%, 74% cases were on mixed diet and 58% were manual labourers.

There was no serious complications post procedure, vague discomfort was noted in 60% case with bleeding in only 20% cases. The study revealed slight post ligation discomfort in 60% cases, which lasted for 1-2 days. Post procedure pain was not significant with 82% cases not needing pain relief and 80% cases taking no time off work post procedure. 52% patients spent just 100-150 rupees following treatment.

The study at follow up of 1, 3 and 6 months revealed the following findings. Bleeding seen in 90% cases at presentation decreased to 12% at 6 months post procedure. Prolapse seen in 56% cases at presentation had decreased to 2% at 6 months. No patients had irritation and mucous discharge at follow up.

The present study reveals the following assessment of treatment by patients with 82% cases assessing it as excellent and 18% cases who has some residual symptoms had assessed the treatment as of moderate help.

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