

# International Journal of Medical Science and Advanced Clinical Research (IJMACR)

Available Online at:www.ijmacr.com

Volume -7, Issue -2, March - 2024, Page No.: 181 - 194

# A comparative study of Injection sclerotherapy, Rubber band ligation and Calcium dobesilate in treatment of Grade 1 and Grade 2 Internal haemorrhoids

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**How to citation this article:** Dr. Parul Garg, Dr. Sajal Gupta, Prof. Dr. Atul Mahajan, Dr. M Sathish Chandra Tej, "A comparative study of Injection sclerotherapy, Rubber band ligation and Calcium dobesilate in treatment of Grade 1 and Grade 2 Internal haemorrhoids", IJMACR- March - 2024, Volume – 7, Issue - 2, P. No. 181 – 194.

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**Type of Publication:** Original Research Article

**Conflicts of Interest:** Nil

#### **Abstract**

**Introduction:** Hemorrhoids cause significant discomfort due to symptoms such as bleeding, prolapse and pruritus. The search for a simple, outpatient based, convenient and cost effective treatment of early stage haemorrhoids still continues. The present study was done to know the effectiveness of rubber band ligation, sclerotherapy and calcium dobesilate in the treatment of 1st and 2nd degree hemorrhoids.

Materials And Methods: This was a prospective controlled study conducted on 300 patients with uncomplicated first and second degree hemorrhoids on examination. The patients were divided into three treatment groups A, B & C with 100 patients in each group by computerized randomization method. Group-A were subjected to injection sclerotherapy (SCL), Group-B

patients elastic rubber band ligation (RBL) and in Group – C tablet calcium dobesilate was given. Patients were followed up for three months for improvement in symptoms and inta and post operative complications.

Results: In our study, treatment with rubber band ligation had lesser intra and post procedure complications, fastest bleeding arrest time, and almost equivalent overall success rate to sclerotherapy, with least recurrence rate and least cost. Although the overall success rate was highest with sclerotherapy, especially in Grade 1 hemorrhoids, the intra and post procedure complications are higher. Treatment with calcium dobesilate had least success rate and highest reoccurrence rate and cost.

**Conclusion:** Rubber band ligation can be recommended as an effective outpatient treatment for 1st and 2nd degree hemorrhoids. Sclerotherapy can be recommended for

treatment of grade 1 hemorrhoids, however, use of calcium dobesilate in treatment of hemorrhoids is questionable.

**Keywords:** Haemorrhoids, Injection Sclerotherapy, Rubber Band Ligation, Calcium Dobesilate.

#### Introduction

Hemorrhoidal disease is one of the commonest ailments that affects mankind and is currently believed to be caused by distal displacement and structural distortion of anal cushions, which are physiological structures. One of the most common anorectal disease, it give rise to distressing symptoms such as bleeding, prolapse, and pruritus, with bleeding as the most common presenting symptom.<sup>(1)</sup>

Treatment of haemorrhoids ranges from life style and dietary modification to surgery depending on the degree of hemorrhoid and the severity of the symptoms. The goals of treatment include reduction of hemorrhoid vascularity, fixation of haemorrhoid to the rectal wall and reduction of redundant tissue. (2)

Conventionally surgery was considered the gold standard treatment of haemorrhoids, because it achieves the lowest recurrence rate. Over the years, alternative minimally invasive techniques and non surgical techniques have gained popularity. These techniques are successful in 80%-99% of patients with hemorrhoids and surgery is now reserved for non responders. (3,4)

The non-surgical treatments for hemorrhoids include rubber band ligation (RBL), injection sclerotherapy (IS), infrared coagulation (IRC), anal stretch, cryosurgery, laser hemorroidectomy. These treatments have the advantage of being performed in outpatient clinics without anesthesia, so reducing the costs related to hospital stay, operation-theatre and anesthesia; moreover, these techniques are time-saving and allow

preserving patients' working days. In this study we aim to compare three such treatments namely injection sclerotherapy, rubber band ligation and calcium dobesilate in treatment of early grade haemorrhoids.

#### **Materials and Methods**

This prospective study was conducted in the Department of Surgery on outdoor patient basis, at MMIMSR, Mullana after getting clearance from institutional ethical committee.

#### **Inclusion Criteria**

All consecutive patients, diagnosed having 1st & 2nd degree hemorrhoids attending Surgery outpatient clinic and gave their consent to undergo this treatment were included in this study.

## **Exclusion Criteria**

Following patients were excluded:

- 1 Immuno-compromised patients
- 2 Patients with bleeding disorders
- 3 Pregnant patients
- 4 Hypertensive patients
- 5 Diabetic patients with uncontrolled sugar levels
- 6 Patients with cardio-vascular disease on antiplatelet drugs
- 7 Patients with deranged liver function tests
- 8 Patients with previous ano-rectal surgery or previous treatment of hemorrhoid disease with any method other than diet modification and/or topical agents for hemorrhoids
- Patients having proctitis, anal fissure, complicated hemorrhoids e.g. complete prolapsed, strangulated, thrombosed, ulcerated, gangrenous, fibrotic and with suppuration
- 10 Age < 18 years.
- 11 Patients having concurrent bleeding from hemorrhoids and other source proximal to them.

#### **Patient Evaluation**

Regardless of the age and sex, 300 patients attending the out patients department of surgical unit with uncomplicated first and second degree hemorrhoids on examination were enrolled in the trial after their informed consent. The patients were divided into three treatment groups A, B & C with 100 patients in each group by computerized randomization method.

Group-A were subjected to injection sclerotherapy (SCL) of the primary hemorrhoids with 2 ml of 5% Phenol in Almond oil, which was used as sclerosing agent injected at the site with Gabriel's Syringe. In Group-B patients elastic rubber band ligation (RBL) of the primary hemorrhoids with Hemorrhoidal Gun (Barron's Band applicator) was done. Group – C were given tablet calcium dobesilate 500mg twice a day for 4 weeks.

All were sent home with the advice to take stool softener to avoid constipation. Patients were advised to review in OPD on the day bleeding PR stops, with a rectal swab which was tested for occult blood. All patients were Table 1: Post operative pain in each group

reviewed after 4 weeks after treatment procedure and then at 3 months. At each visit patient was assessed for improvement in symptoms and any complication. The data was collected on a proforma.

Outcome of study was taken as improvement in symptoms in terms of arrest of bleeding and decrease in anal discharge. Complications during and following treatment like bleeding, pain, sphincter spasm, urinary retention were recorded and compared in the two groups. Patients were followed up after 4 weeks and after three months and incidence of rebleeds, residual disease and recurrence after 3 months was noted in the three groups.

## Results

#### **Post Operative Pain**

In this study post operative pain was assessed in each patient on visual analog score. Group A patients who were treated with Injection sclerotherapy revealed that 68 patients (68%) had no pain after the procedure as compared to 86% in rubber band ligation group. Group C (calcium dobesilate) patients had no pain as no intervention was done. (Table 1)

				Group	os	Total
			SC	RBL	CD	
	No Pain	Count (%)	68	86	100	254
Post Operative Pain	Vas 2	Count	14	8	0	22
During Procedure		(%)	14%	8%	0%	7.3%
	Vas 4	Count	12	4	0	16
		(%)	12%	4%	0%	5.3%
	Vas 5	Count	2	0	0	2
		(%)	2%	0%	0%	0.7%
	Vas 6	Count	4	2	0	6
		(%)	4%	2%	0%	2%
	Total	Count	100	100	100	300
		(%)	100%	100%	100%	100%

P=0.0001 (significant)

# Post Operative Discharge per Rectum

In our study post operative discharge per rectum was noticed in 26 patients (8.7%), of whom 22 patients had underwent sclerotherapy and 4 had undergone rubber band ligation. (Table 2.1)

Table 2.1: Post operative discharge per rectum

			Groups			Total
			SC	RBL	CD	
Post Operative	No	Count	78	96	100	274
Discharge Per Rectum		(%)	78%	96%	100%	91.3%
	Yes	Count	22	4	0	26
		(%)	22%	4%	0%	8.7%
	Total	Count	100	100	100	300
		(%)	100%	100%	100%	100%

P = 0.0001 (significant)

In grade 1 hemorrhoids discharge per rectum was present in only 1 patient who was treated with sclerotherapy. (Table 2.2)

Table 2.2: Comparison of post operative discharge after procedure in grade 1 hemorrhoids in various groups

Group	No Discharge	Discharge Present	
Sclerotherapy	32	2	
Rubber Band Ligation	40	0	
Calcium Dobiselate	56	0	
Total	128	2	

P=0.262 (insignificant)

In grade 2 hemorrhoids discharge per rectum was noticed in 20 patients who were treated with sclerotherapy and in 4 patients who had undergone rubber band ligation. (Table No. 2.3)

Table 2.3: Comparison of post operative discharge after procedure in grade 2 hemorrhoids in various groups

Group	No Discharge	Discharge Present
Sclerotherapy	46	20
Rubber Band Ligation	56	4
Calcium Dobiselate	44	0
Total	146	24

P=0.002 (significant)

## Post operative urinary retention

Post operative urinary retention was seen in 10 patients. 6 patients were from sclerotherapy group while rest 4 patients were from rubber band ligation group. No retention was seen in calcium dobesilate group. (Table No. 3.1)

Table 3.1: Post operative urinary retention

			Groups			Total
			SC	RBL	CD	
Post Operative Urinary Retention	No	Count	94	96	100	290
		(%)	94%	96%	100%	96.7%
	Yes	Count	6	4	0	10
		(%)	6%	4%	0%	3.3%
	Total	Count	100	100	100	300
		(%)	100%	100%	100%	100%

P=0.168 (insignificant)

In grade 1 hemorrhoids no patient had urinary retention after treatment. (Table 3.2)

Table 3.2: Comparison of post operative urinary retention after procedure in grade 1 hemorrhoids in various groups

Group	No Retention	Retention Present
Sclerotherapy	34	0
Rubber Band Ligation	40	0
Calcium Dobiselate	56	0
Total	130	0

P= 1.000 (insignificant)

In grade 2 hemorrhoids 10 patients had post operative urinary retention of which 6 were from sclerotherapy group and rest 4 were from rubber band ligation group. (Table 3.3).

Table 3.3: Comparison of post operative urinary retention after procedure in grade 2 hemorrhoids in various groups

Group	No Retention	Retention Present
Sclerotherapy	60	22
Rubber Band Ligation	56	8
Calcium Dobiselate	44	0
Total	160	10

P=0.434 (insignificant)

# Post operative sphincter spasm

In this study, post operative sphincter spasm was seen in 14 patients (4.7%). 12 patients were from sclerotherapy group while 2 patient was from rubber band ligation group. (Table 4.1)

Table 4.1: Post operative sphincter spasm

			Groups			Total
			SC	RBL	CD	
Post Operative Sphincter Spasm	No	Count	88	98	100	286
		(%)	88%	98%	100%	95.3%
	Yes	Count	12	2	0	14
		(%)	12%	2%	0%	4.7%
	Total	Count	100	100	100	300
		(%)	100%	100%	100%	100%

P=0.0037 (significant)

In grade 1 hemorrhoids only 2 patients had post operative sphincter spasm, which belonged to sclerotherapy group. (Table 4.2)

Table 4.2: Comparison of post operative sphincter spasm after procedure in grade 1 hemorrhoids in various groups.

Group	No Spasm	Spasm Present
Sclerotherapy	32	4
Rubber Band Ligation	40	0
Calcium Dobiselate	56	0
Total	128	2

P=0.264 (insignificant)

In grade 2 hemorrhoids post operative sphincter spasm was seen in 6 patients. In Sclerotherapy group 5 patients had sphincter spasm while in rubber band ligation group 1 patient had sphincter spasm. (Table 4.3)

Table 4.3: Comparison of post operative sphincter spasm after procedure in grade 2 hemorrhoids in various groups.

Group	No Spasm	Spasm Present
Sclerotherapy	56	10
Rubber Band Ligation	58	2
Calcium Dobiselate	44	0
Total	158	12

P=0.099 (insignificant)

## Average Time for Arrest of Bleeding Per RECTU

In our study the average time for arrest of bleeding per rectum after sclerotherapy was 5.68 days with range of 3 to 11 days. In rubber band ligation group the duration was 2.74 days with range of 2 to 8 days. Treatment with calcium dobesilate took longest duration for arrest of bleeding with average duration of 13.84 days and range of 9 to 23 days. (Table No.5)

Table 5: Average time for arrest of bleed after treatment in each group.

Group	Average time in days
Sclerotherapy	5.68
Rubber band ligation	2.74
Calcium dobesilate	13.84

P=0.0001(significant)

## **Rectal Swab after Arrest of Bleeding Per RECTUM**

In our study, rectal swab after arrest of bleed was positive in 17 patients (11.3%). Maximum number of patients with positive rectal swab was from calcium dobesilate group (15 patients). The other 2 patients belonged to sclerotherapy group. Rubber band ligation group patients had no positive swab. (Table 6.1).

Table 6.1: Rectal swab

			Groups			Total
			SC	RBL	CD	
Rectal Swab On Day	Negative	Count	96	100	70	266
Bleeding Stops		(%)	96%	100%	70%	88.7%
	Positive	Count	4	0	30	34
		(%)	4%	0%	30%	11.3%
	Total	Count	100	100	100	300
		(%)	100%	100%	100%	100%

P=0.0001 (significant)

In grade 1 hemorrhoids, out of 6 positive rectal swabs, 5 were from calcium Dobiselate group while 1 was from sclerotherapy group. (Table 6.2)

Table 6.2: Comparison of rectal swab after bleeding stopped in grade 1 hemorrhoids in various groups.

Group	Negative	Positive
Sclerotherapy	32	2
Rubber Band Ligation	40	0
Calcium Dobiselate	46	10
Total	118	12

P=0.087 (insignificant)

In grade 2 hemorrhoids 11 patients had positive rectal swab. Out of 12 patients of grade 2 hemorrhoids who were treated with calcium dobesilate 10 (83.3%) had positive rectal swab. (Table 6.3)

Table 6.3: Comparison of rectal swab after bleeding stopped in grade 2 hemorrhoids in various groups.

Group	Negative	Positive
Sclerotherapy	64	2
Rubber Band Ligation	60	0
Calcium Dobiselate	24	20
Total	148	22

P=0.0001 (significant)

## **Re- Bleed after Treatment**

In this study, re-bleeding after treatment occurred in 30 patients. These included 17 patients from calcium dobesilate group, 9 patients from rubber band ligation group and 4 patients from sclerotherapy group. (Table 7.1)

Table 7.1: Re-bleed after treatment in each group

			Groups			Total
			SC	RBL	CD	
	Negative	Count	92	82	66	240
		(%)	92%	82%	66%	80%
Re - Bleeding After	Positive	Count	8	18	34	60
Treatment		(%)	8%	18%	34%	20%
	Total	Count	100	100	100	300
		(%)	100%	100%	100%	100%

P=0.005 (significant)

In grade 1 hemorrhoids, re-bleeding occurred in 10 patients (18.2%). In Rubber band ligation group 5 patients (33.3%) had re-bleed after treatment. 5 patients (21.7%) with re-bleed were from calcium dodesilate group. No re-bleed occurred in sclerotherapy group in grade 1 hemorrhoids. (Table 7.2).

Table 7.2: Comparison of re-bleed after treatment in grade 1 hemorrhoids in various groups.

Group	Absent	Present
Sclerotherapy	34	0
Rubber Band Ligation	30	10
Calcium Dobiselate	46	10
Total	110	20

P= 0.085 (insignificant)

In grade 2 hemorrhoids, re-bleeding was seen in 20 patients (23.5%). Highest number of patients with re-bleeding was from calcium dobesilate group (12 patient's i.e.54.5%). Sclerotherapy group had 4 patients (12.1%) with re-bleed and rubber band ligation group had 4 patients (13.3%). (Table No.7.3)

Table 7.3: Comparison of re-bleed after treatment in grade 2 hemorrhoids in various groups.

Group	Absent	Present
Sclerotherapy	58	16
Rubber Band Ligation	52	8
Calcium Dobiselate	20	24
Total	130	40

P=0.001 (significant)

#### Residual disease at 4 weeks

In our study, 4 week follow-up after treatment reveled residual hemorrhoids in 32 patients (20%). Maximum patients with residual disease were from calcium dobesilate group (23 patients i.e. 46%). Minimum patients with residual disease

were seen in sclerotherapy group (4 patients i.e. 8%). Rubber band ligation group had residual hemorrhoids in 5 patients (10%). (Table 8.1)

Table 8.1: Residual after 4 weeks

		Groups			Total	
			SC	RBL	CD	
	Negative	Count (%)	92	90	54	80
	Positive	Count (%)	8	10	46	20
		Count (%)	100	100	100	300

P=0.0001 (significant)

In grade 1 hemorrhoids, 5 patients (7.7%) had residual disease. Maximum numbers of the patients were in rubber band ligation group (3 patient's i.e.15%). 2 patients (7.1%) with residual hemorrhoids after 4 weeks were from calcium dobesilate group. Sclerotherapy group had no residual hemorrhoids. (Table 8.2)

Group	No	Yes
Sclerotherapy	34	0
Rubber Band Ligation	34	6
Calcium Dobesilate	52	4
Total	120	10

P=0.310 (insignificant)

In grade 2 hemorrhoids, 27 patients (31.7%) had residual hemorrhoids. Out of these 27 patients, 21 patients (95.5%) were from calcium dobesilate group. Sclerotherapy group had residual disease in 4 patients (12.1%). In rubber band ligation group only 2 patients (6.7%) had residual hemorrhoids, which was least among all groups. (Table No.8.3)

Table 8.3: Comparison of residual after 4 weeks in grade 2 hemorrhoids in various groups.

Group	No	Yes
Sclerotherapy	58	8
Rubber Band Ligation	56	4
Calcium Dobesilate	2	42
Total	116	54

P=0.0001 (significant)

#### Change of treatment modality after 4 weeks

In this study, all patients with residual hemorrhoids at 4 weeks were subjected to change in treatment modality as per choice of patient. These patients were excluded from study for 3 month follow-up.

#### Follow-Up after 3 Months

In our study, follow-up after 3 months was done in 118 patients who had no residual hemorrhoids at 4 weeks. 93 patients (78.8%) showed no reoccurrence after 3 months while rest 25 patients (21.2%) had reoccurrence. Highest reoccurrence

was seen in calcium dobesilate group (18 patients i.e. 64.3%). Lowest reoccurrence was seen with rubber band ligation 4.5% (2 patients). (Table 10.1)

# **Change of Treatment Modality after 4 Weeks**

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Table 10.1: Recurrence of hemorrhoids after 3 months

			Groups			Total
			SC	RBL	CD	
	No	Count	82	84	20	186
		(%)	89.1%	95.5%	35.7%	78.8%
Recurrence of hemorrhoids	Yes	Count	10	8	36	50
after 3 Months	Total	Count	92	88	56	236
		(%)	100%	100%	100%	100%

P=0.0001 (significant)

In grade 1 hemorrhoid group, maximum reoccurrence was seen in calcium dobesilate group i.e. 17 patients (60.7%). Lowest reoccurrence was noticed in treatment of grade 1 hemorrhoids with rubber band ligation i.e. 1 patient (5.9%). (Table 10.2).

Table 10.2: Reoccurrence after 3 months in grade 1 hemorrhoid in each group.

Group	No	Yes
Sclerotherapy	28	6
Rubber Band Ligation	32	2
Calcium Dobesilate	18	34
Total	84	36

P=0.0001 (significant)

In grade 2 hemorrhoids, again the reoccurrence rate was minimum with rubber band ligation i.e. 1 patient (3.6%). In calcium Dobiselate group 1 patient (100%) had reoccurrence. (Table 10.3)

Table 10.3: Reoccurrence after 3 months in grade 2 hemorrhoids in each group

Group	No	Yes
Sclerotherapy	54	4

Rubber Band Ligation	54	2
Calcium Dobesilate	0	2
Total	128	8

P=0.069 (insignificant)

#### **Discussion**

In this study we compared rubber band ligation, injection sclerotherapy and calcium dobesilate for treatment of early grades of haemorrhoids. Age of our patients ranged from 18 to 70 years and mean age was 39.3 years. Incidence of hemorrhoids was higher in males as compared to females with male to female ratio of 2.19:1.

# **Rubber Band Ligation**

This procedure is performed as an outpatient approach and consists in positioning elastic bands above the dentate line to strangulate the piles leaving an area where inflammation fixes the mucosa to the sub-mucosa preventing subsequent development of new hemorrhoidal tissue.

RBL seems effective for bleeding and prolapse. Awad et al in an RCT reports overall subjective improvement from 73% to 84%<sup>(5)</sup>. The common complications are bleeding and pain. Post-operative pain ranges from 8% to 80 % in different RCTs (6-13). Post-operative bleeding is reported in up to 50% of patients in the RCT proposed by Ramzisham, however lower rates are presented in others RCTs (10) (Table 2). Recurrences of bleeding and prolapsed at follow-up occur respectively in 10%-18% and in 2.2% of patients (14); Kanellos reported higher percentages of minor complications (46% of recurrence for bleeding and 34% for prolapses in II degree hemorrhoids) (12). Compared to Milligan-Morgan haemorrhoidectomy, RBL appears safe and effective in II and III degree symptomatic haemorroids (21). Moreover, RBL is associated with low rates of postoperative pain and complications (22).

In our study, treatment with rubber band ligation had lesser intra and post procedure complications, fastest bleeding arrest time, and almost equivalent overall success rate to sclerotherapy, least recurrence rate and least cost. Hence rubber band ligation can be recommended as an effective outpatient treatment for 1st and 2nd degree hemorrhoids as compared to sclerotherapy and calcium dobesilate.

## **Injection Sclerotherapy**

Injection schlerotherapy, through the local infiltration with sclerosant agents, leads to the necrosis of hemorrhoidal tissue with scarring and subsequent fixation of mucosa to the submucosa<sup>16</sup>.

An RCT reported resolution of bleeding in 69% to 88% of I degree of hemorrhoids<sup>17</sup>; while 3 case series showed an improvement of bleeding in 100% of II and III degrees hemorrhoids<sup>17,18,20</sup>.

90%-100% of prolapses' resolution in II degree is reported in a RCT and two case series <sup>17,20,22</sup>. However, the RCTs presented in literature are poor of data. A subjective excellent improvement is reported by Yuksel in 51% of patients with I and II degrees of hemorrhoids and in 80% of patients with I degree by Moser <sup>16,19</sup>.

Patients submitted to IS have a relatively low occurrence of post-procedural pain: 36% in I degree is reported by Moser, 49% is reported by Takano<sup>15,19</sup>. Bleeding is a very rare harm. IS appears effective for treatment of II degree of hemorrhoids.

We observed that the overall success rate was highest with sclerotherapy, especially in grade 1 hemorrhoids. However, intraoperative complications like mild bleeding during procedure was seen in 94% patients and pain during the procedure was seen in 68% patients which is maximum in the three groups. All post procedure complications (pain, discharge, urinary retention and sphincter spasm) were common after treatment with sclerotherapy.

Hence it can be recommended for treatment of grade 1 hemorrhoids, but the intra and post procedure complications are higher as compared to rubber band ligation especially in grade 2 haemorrhoids.

#### **Calcium Dobesilate**

Calcium dobesilate (calcium 2,5 dihydroxybenzenesulfonate) is a drug with previously demonstrated efficacy in the treatment of diabetic retinopathy and chronic venous insufficiency<sup>26,27,29</sup>. It is venotonic agent which decreases permeability, platelet aggregation and blood viscosity and increases lymphatic transport. These properties are believed to contribute to improvement in the acute inflammatory attacks of hemorrhoidal disease<sup>28</sup>. Studies conducted by Mentes B B and Patel et al have reported a significant improvement in the inflammation of hemorrhoids<sup>23,24</sup> and resolution of symptoms in early grades of haemorrhoids by using Calcium dobesilate in conjunction with fiber supplement. Patel et al<sup>23</sup> showed that after six weeks of calcium dobesilate therapy, cessation of rectal bleeding plus lack of severe anitis occurred with calcium dobesilate, with a success rate of 81.35%. Sarabia et al<sup>25</sup> reported an efficacy of 76% with calcium dobesilate in hemorrhoidal disease. They stated that the drug was effective and well tolerated.

In our study treatment with calcium dobesilate, even though devoid of complications, had the longest time to arrest of bleed (13.84 days), the lowest success rate (54%) and highest cost and rate of recurrence (64.3%). Hence, medical management by calcium dobesilate,

though effective, is superceded by RBL and IS in terms of higher success rate and lower rates of recurrence.

#### Conclusion

Treatment with rubber band ligation had lesser intra and post procedure complications, fastest bleeding arrest time, and almost equivalent overall success rate to sclerotherapy, least recurrence rate and least cost. Hence rubber band ligation can be recommended as an effective outpatient treatment for 1<sup>st</sup> and 2nd degree hemorrhoids as compared to sclerotherapy and calcium dobesilate.

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