

# Randomized Study to Evaluate the Effectiveness of the Injection Sclerotherapy for Bleeding Grade I Hemorrhoids on Outpatient Basis

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Objective : Polidocanol 3% is a novel agent used in sclerotherapy for hemorrhoids, and used for treatment of internal haemorrhoids without surgery. In our study we checked for the safety and postsclerotherapy results of polidocanol 3% using proctoscope.

Materials and Methods : Subjects comprised 90 internal hemorrhoid patients (67 males and 23 females). An anoscope was inserted injection was applied to submucosally to the hemorrhoids. The outcome post injection anooscopicsclero therapy were decided by examination of hemorrhoids after detailed questionnaire to the patient 1 month after the treatment.

Results : A complete resolution, some improvement, and no improvement were observed in 72,9 and 9 patients, treated with Polidocanol 3%. We found complications in 9 patients (pain in 9 in 3 and blood in urine in 6). 9 patients came with recurrence.

Conclusions : Our study concluded that Polidocanol 3% is a very useful and out patient minimally invasive procedure.

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### Key words : Polidocanol, Sclerotherapy.

Hemorrhoids are a very common proctological disease and it is classified as internal haemorrhoids when above dentate line and external when below the dentate line. Bleeding per rectum and prolapse piles are most common presentation of internal haemorrhoids.

Conservative therapies like stool softners, local ointments, lifestyle modifications and increase liquid intake (to avoid constipation) are primarily helpful in resolving Internal hemorroids; though sometimes active bleeding per rectum, pain which may interfere daily routine, subsequent therapies may needed. Non-surgical therapies are desirable as haemorrhoids are benign condition<sup>1,2</sup>.

When conservation therapies don't change symptoms other modalities which are useful are Injection sclerotherapy and Rubber Band Ligation for hemorroids, which are non-surgical methods and used by clinicians since many decades. Some researchers did an analysis of

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#### Editor's Comment :

- Bleeding haemorrhoids are most commonly ignored by common people
- Injection sclerotherapy is an OPD procedure which is easy and handy procedure
- Postsclerotherapy patient compliance is also good
- If surgeons want to plan for surgery then by releasing patient from bleeding, it will give window period for improving haemoglobin.

some studies and compared various treatment therapies for hemorrhoids which mentioned that rubber band ligation was more useful sclerotherapy and also that patients who underwent ligation needed further modality. Injection sclerotherapy is a simpler and safer treatment for bleeding hemorrhoids where 5% phenol in almond oil was commonest sclerosing agent used in the past mostly for haemorrhage but for prolapse its effects are not proven.

Patients with hemorrhoidal disease experience varying degrees of the following symptoms, bleeding, anal swelling, pain, discomfort, discharge, hygiene problems and pruritis. Usually, but not invariably, the larger the cushions and the more they prolapse the more troublesome are the symptoms<sup>2,3</sup>.

In this study all the cases of Hemorrhoids in OPD under Surgery Department has been studied and diagnosed, graded and treated with Injection Sclerotherapy to assess

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its effectiveness.

Polidocanol 3% (Sclerosing agent) is successfully used in the treatment for the bleeding oesophageal varices, since years. Here we have used the same agent in cases of bleeding Internal Hemorrhoids to check its efficacy in the patients on OPD bases.

Polidocanol 3% has very less complications and it stops hemorrhage after defecation and has many pros over surgery, and it is out patient period so hospitalization is avoided. So, Polidocanol 3% has become a striking sclerosing agent as a new hemorrhoid treatment method without surgery.

#### MATERIALS AND METHODS

Subjects comprised of 90 patients (67 males and 23 females) who required treatment for hemorrhage between June 2018 to June 2019 and were not satisfied with conservative supportive treatment methods.

Polidocanol 3% Sclerotherapy is indicated for only bleeding internal hemorrhoids so external piles and thrombosed piles were excluded.

With the proctoscope with attached light source, internal haemorrhoids are visualised and prepared polidocanol 3% is injected into the submucosal layer, appx 3-4 ml/injection and 2-3 injections.

#### **RESULTS AND DISCUSSION**

In our study out of 90 patients 51 were of age less than 40 years, 13 patients were of age group 41-50 and 26 were of age group above 50 years. Mean age was found of 42.24  $\pm$  17.65 years (Table 1).

In our study out of our 90 patients we checked for the complications and post procedural interview of the patient for the symptomatic relief after 1 month and 3 months. Where we found 72 patients with complete symptomatic relief while 9 patients had rebleeding and 9 patients found some complication like hematuria and pain (Table 2).

Hematuria was found in 6 and 8-9 Patients have post procedural pain reported.

Table 1 — Age Incidence					
Age	No of Patients	Percentage	$\chi^2$ -value		
≤40 Years	51	56.67%	24.86		
41-50 years	13	14.44%	Significant		
> 50 Years	26	28.89%	-		
Total	90	100%			
Mean ± SD	42	.24 ± 17.65 yea	ars		

Table 2 — Agent and Effects					
Sclerosant	Total Patients	Symptomatic Relief	Recurrence	Complications	
Ask 3% $\chi^2$ -value p-value	90	72	9	9	
$\chi^2$ -value		7	.53		
p-value		0.11, N	S, p>0.05		

Table 3 — Postoperative Sequel						
Complication	s	Injection sclerotherapy				
		Ask 3%				
Hemeturia	6					
Pain		9				
Anal Stenosis	8	0				
$\chi^2$ -value		1.41				
p-value		0.49, NS, p>0.05				
Table 4 — Effect of Treatment <sup>4,5,6,7</sup>						
	Table 4 — Effect of	f Treatment <sup>4,5,0</sup>	5,7			
Study	Table 4 — <i>Effect o</i> Asymptomatic	f Treatment <sup>4,5,0</sup> No relief	Complications			
Study Present series						
	Asymptomatic	No relief	Complications			
Present series	Asymptomatic 95%	No relief 5%	Complications 6%			
Present series Gartell <i>et al</i>	Asymptomatic 95% 35%	No relief 5% 45%	Complications 6% 20%			
Present series Gartell <i>et al</i> Sim <i>et al</i>	Asymptomatic 95% 35% 50%	No relief 5% 45% 30%	Complications 6% 20%			

None of the patients have anal stenosis or stricture in our series (Tables 3&4).

Hemorrhoids are the most commonly found disease of anal region. For internal hemorroids resection of hemorroids - Hemorroidectomy is most common performed method. but pain, longer duration of morbidity and complications such as bleeding and stricture formation are some associated fears. Therefore, Minimallyinvasive methods are required for the treatment of Hemorroids without surgery. Suturing hemorroids by the Farag method has traditionally been employed as a nonsurgical method for haemorrhoids. Now a days MIPH and transanal-hemorrhoidal dearterialization, are method of choice for haemorrhoids due to lesser pain and lesser stay. Rubber band ligation and injection sclerotherapy are found to be effective treatments and have been the mainstay of nonsurgical treatments many decades. Though Previous studies mentioned less effectiveness and higher recurrence rate with injection sclerotherapy to rubber band ligation. But our findings for Injection Sclerotherapy are different<sup>8-10</sup>.

Polidocanol 3% induces aseptic acute inflammation followed by Fibrosis followed by haemorrhoid scleroses and recesses. Immidietly after injection, vascular constriction occurs. By which blood flow is reduced and stops bleeding<sup>10,11</sup>.

#### CONCLUSION

For Large or prolapsed haemorrhoids or failed conservative supportive methods, only surgical therapies are recommended.Our study suggested that the post sclerotherapy effects of Polidocanol 3% were successful for bleeding hemorroids on OPD basis and also that it has the potential to become a mainstay treatment method for bleeding internal hemorrhoids without surgery. Therefore, Polidocanol has the potential to become a minimally invasive and useful approach for sclerotherapy.

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