

Role of sclerotherapy in management of symptomatic first and second degree internal haemorrhoids

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Abstract:

Background: Despite of various treatment modalities available, haemorrhoids are commonly encountered conditions at surgery departments with poor satisfaction, recurrence and low quality of life of the patients because of pain and discomfort associated with it.

Objective: To evaluate efficacy, safety and outcome of injection polidocanol (3%) as sclerosant in treatment of haemorrhoids

Methodology: Total 60 patients haemorrhoids meeting inclusion-exclusion criteria were divided into two groups of injection sclerotherapy (3% polidocanol) and conservative management. Demographic parameters, duration of symptoms, degree of haemorrhoids, patient outcome and adverse events were recorded and compared for both the groups.

Results: Out of 60 patients, 31 were treated with injection sclerotherapy and 29 were treated with conservative management. Mean age of patient 40 years with male preponderance 2:1. Total 33(55%) and 27(45%) patients had first and degree haemorrhoids respectively. Symptoms duration <6 months gives better outcome in both the treatment groups ($p < 0.05$). As duration of symptoms increases, satisfactory response decreases. Outcome is significantly better ($p < 0.05$) in sclerotherapy group as compare to conservative management. 83.87% patients showed satisfactory response with single injection of sclerotherapy. Most common complications after injection sclerotherapy were pain (11, 35.47%), bleeding from site (10, 33.33%) and haematuria (4, 13.33%). Recurrence occurred in 16.12% patients among sclerotherapy vs 58.62% in conservative management group ($p < 0.05$). Sclerotherapy found to be significantly better than conservative management in patients' perception ($p < 0.05$).

Conclusion: Sclerotherapy, though procedure is painful and invasive, is significantly more effective and safe with high level of satisfaction compared to conservative management for treating early haemorrhoids.

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I. Introduction:

Haemorrhoids are common anorectal disorder defined as venous dilatation and distal displacement of anal cushions commonly characterized by rectal bleeding, perineal irritation, anal itching or fecal soiling. (1). Pathological congestion of the vascular cushion is one of the most important pathogenic mechanisms of internal hemorrhoids with sliding anal canal lining due to deterioration of the supporting tissue of anal cushions. Internal hemorrhoids are located near the dentate line and are innervated by visceral nerves, so it is a painful condition affecting quality of life also (2,3).

Depending upon the severity of symptoms and clinical condition various therapeutic modalities are employed for management of haemorrhoids. Diet and lifestyle modifications are considered to be conservative medical management practice. High intake of fibrous foods helps in elimination of straining during defecation which leads to clinical improvement of hemorrhoids by reducing the persistent symptoms and bleeding by 50%. (4) However in case of aggravated symptoms where patients do not respond to conservative approach various non-surgical modalities like sclerotherapy have proved to be more promising and practiced to treat internal haemorrhoids since last many decades as an alternative to more invasive surgical hemorrhoidectomy. (5,6)

Sclerotherapy has always been the mainstay of non-surgical treatment for the management of grades 1 and 2 hemorrhoids by creating a fibrous reaction leading to fixation of mucosa. (6) Various sclerosant agents are available for the treatment of haemorrhoids but lack appropriate standardization. Use of 5% phenol in almond

oil is considered as conventional and primary sclerosing agent for management of haemorrhoids but it lacks effect in cases of prolapse. (7) Polidocanol, a detergent solution was developed as anesthetic agent in 1950's and was used in the treatment of spider veins as sclerosing agent a decade later. The use of sclerotherapy (ST) with polidocanol injection induces anti-inflammatory response with sclerosis of the submucosal tissue in addition to local adhesive thrombosis in the area of the damaged endothelium. (7) Selecting an appropriate safe concentration and dose of polidocanol needs exploration as an effective and reliable sclerosant. Therefore, objective of this study was to evaluate the efficacy, safety and recurrence of 3% Injection polidocanol as sclerosant in the treatment of Symptomatic first- and Second-degree haemorrhoids.

II. Methodology:

This was a prospective study conducted in a surgery department of a tertiary care teaching hospital. The study protocol was approved the institutional ethics committee and written informed consent was obtained from all patients.

Case selection was done with the criteria of history, clinical presentation, digital rectal examination and proctoscopy findings. In Patients above age of fifty years with bleeding per rectum, sigmoidoscopy was also done to rule out other causes like carcinoma colon or rectum. Inclusion criteria were patients of more than 18 years of age and of either gender having confirm diagnosis of grade 1 and grade 2 hemorrhoids by digital rectal examination and proctoscopy examination, newly diagnosed cases and patients not willing to undergo surgery, not fit for anesthesia and willing to undergo sclerotherapy after understanding different treatment options were included for the study. Pregnant females, patients with diabetes mellitus and complicated cases of hemorrhoids were excluded from the study.

All patients were given life style modifications like high fiber diet, training regarding defecation habits and regular exercise, cessation of smoking etc. Half of the patients were additionally given sclerotherapy with Polidocanol 3% solution.

Procedure: All the patients undergoing sclerotherapy were given pre-injection enema because if patient passes stools after therapy, that disperse the solution and decrease the effectiveness of the sclerosant. Pre-operative one dose of intravenous cefazoline 1gm was administered to all patients. Proper local anesthesia and lubrication was given to decrease the pain and relieve anxiety. Patients were given either left lateral position or lithotomy position and injection of the sclerosant should be given at the base of the hemorrhoid above dentate line. Tip of the needle was inserted 1 to 2 cm deep and parallel to the anal canal. Each core of haemorrhoids was injected slowly with 3 to 5 ml sclerosant. If patient felt pain while injecting, it was stopped immediately. The needle was withdrawn slowly after holding for at least 1 minute so that the needle track gets sealed.

All cases will be followed up till relief of the symptoms. First follow up after one month, second after six months and third after one year. At each visit patients were evaluated for recovery, recurrence and complications. Patients were also asked about their subjective perception regarding treatment outcome.

Statistical analysis:

Data were analyzed using Microsoft excel 2013. All the data were recorded as actual frequencies, percentage, mean, standard deviation as appropriate. Comparison of treatment modalities were carried out using chi-square test and p value less than 0.05 was considered significant.

III. Results:

Out of 60 patients suffering from haemorrhoids enrolled for the study, 31 patients were treated with injection sclerotherapy and 29 patients were treated with conservative management. Age and gender wise distribution of study patients is shown in table 1. Majority of the patients 58.06% and 55.17% were of 18-40 years in sclerotherapy and conservative groups respectively. Out of total 31 patients in injection sclerotherapy group, 24 (77.49%) were male and 7 (22.58%) were female while out of 29 patients treated with conservative management 16 (55.17%) patients were male and 13 (44.82%) were female. There was no statistical difference for age and gender distribution among both the groups ($p > 0.05$)

Table: 1 Age and gender wise distribution of study patients (n=60)

Parameter	No. of Patients N (%)		Total	P value
	Injection (Sclerotherapy)	Conservative Management		
Age in years				
≤ 40	18 (58.06)	16 (55.17)	34 (56.67)	0.4
41-50	5 (16.29)	3 (10.34)	8 (13.33)	
> 50	8 (25.80)	10 (34.48)	18 (30)	
Total	31	29	60	
Gender				0.08
Male	24 (77.49)	16 (55.17)	40 (66.67)	
Female	7 (22.58)	13 (44.82)	20 (33.33)	

Total	31	29	60
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Figure 1 shows type of haemorrhoids among study patients. Out of total 60 patients, 33 (55%) were having first degree haemorrhoids and 27 (45%) were having second degree haemorrhoids.

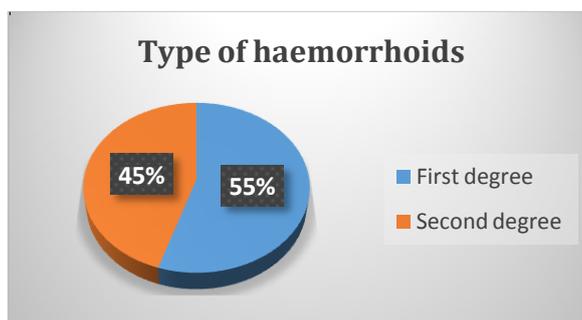


Figure 1: Type of Haemorrhoids in study patients

Table 2 shows duration of symptoms in both the study groups. 31 patients having symptoms for less than 6 months out of which 20 (64.51) were treated with Injection Sclerotherapy and 11 (37.93) were treated with conservative management. 15 patients were having symptoms for 6 months to 1 year in which 6 (19.35) were treated with injection sclerotherapy and 9 (31.03) were treated with conservative management and 14 patients were having symptoms for more than 1 year in which 5 (16.13) patients were treated with injection sclerotherapy and 9 (31.03) patients were treated with conservative management. Association of duration of symptoms and treatment modality used was analyzed. Symptoms duration less than 6 months gives better outcome in both the treatment groups ($p < 0.05$). As duration of symptoms increases, satisfactory response decreases. Outcome is significantly better ($p < 0.05$) in injection sclerotherapy group as compare to conservative management.

Table 2: Association of duration of Symptoms and treatment outcome in study patients

Duration of Symptoms	No. of patients				P value
	Injection Sclerotherapy (n)	Outcome of the patient (satisfactory response)	Conservative Management (n)	Outcome of the patients (satisfactory response)	
< 6 months	20	20	11	8	0.01
6 months – 1 Year	6	6	9	4	<0.05
> 1 Year	5	4	9	2	<0.05
Total	31	30	29	14	<0.05

Table 3 gives details about sclerotherapy injection required for satisfactory response. Out of 31 patients 26 (83.87%) patients were showing satisfactory response. The 5 patients which were showing unsatisfactory response were treated with second injection in which 2 (40%) patients were showing satisfactory response. The remaining 3 patients were treated with third injection in which 2 (66.67%) patients shows satisfactory response.

Table 3: Number of injections required for satisfactory response (n=31)

Number of sclerotherapy injections	Total Number of patients	Total patients showing Satisfactory response
First	31	26 (83.87)
Second	5	2 (40)
Third	3	2 (66.67)

Most common complication found post injection sclerotherapy were pain, bleeding and urinary trouble. Pain was scaled as mild, moderate and severe; 6 patients have mild and 5 have moderate pain and none of the patients developed severe pain. While bleeding was present in 10 (33.33%) patients and only 4 (13.33%) patients have faced urinary trouble (hematuria) as details shown in Table 4. In the group which is treated with injection sclerotherapy only 5 (16.12) patients had recurrence of haemorrhoids while the group treated with

conservative management 17 (58.62) patients had recurrence of haemorrhoids injection sclerotherapy has significantly less recurrence as compared to conservative management ($p < 0.05$).

Table 4: Post-operative complications and Failure of therapy

Complications		No. of Patients
Pain	Mild	6 (19.35)
	Moderate	5 (16.12)
	Total	11 (35.47)
Bleeding		10 (33.33)
Hematuria		4 (13.33)
Treatment		Recurrence
Injection Sclerotherapy		5 (16.12)
Conservative Management		17 (58.62)

Patient's perception of the treatment option is one of the important factors for deciding outcome of the study and shown in table 5. 22 (70.96) patients found injection sclerotherapy excellent while 4 (13.79) patients found with conservative management. 7 (22.58) patients treated with injection sclerotherapy was having moderate success while 19 (65.51) patients found conservative management a moderate success. 2 (6.45) patients and 6 (29.69) patients with injection sclerotherapy and conservative management respectively was having treatment as little help. Injection sclerotherapy was significantly better than conservative management in patients' perception ($p < 0.05$).

Table 5: Patient's perception of the Treatment

Patient's Perception	Injection Sclerotherapy	Conservative Management	P-value
Excellent	22 (70.96%)	4 (13.79%)	<0.05
Moderate Success	7 (22.58%)	19 (65.51%)	
Little Help	2 (6.45%)	6 (29.69%)	

IV. Discussion

Haemorrhoid is found to affect about one third of the population and is considered to be the fourth leading outpatient gastrointestinal diagnosis, accounting for 3.3 million ambulatory care visits in the United States. Population based surveys have reported a higher prevalence of haemorrhoid of more than 4% in USA, Spain and Japan. (8, 9) Few studies have reported higher incidence of haemorrhoidal disease in old age population. (10) However the Indian data is very less in this regard. The results of our study were found to be contrasting wherein patients with less than 40 years of age were found to be more affected with Haemorrhoids compared to old age population which was found to be consistent with previously reported study by Ravindranath GG at el wherein young age adults were found to be most affected with haemorrhoids contributed to western lifestyle, dietary habits and stressful living condition. (11)

Prevalence of hemorrhoids and gender wise distribution also varied in different studies. Few earlier studies have reported no significant difference among males and females in the prevalence of haemorrhoids (12, 13), while in another study by Riss et al higher prevalence of haemorrhoid was observed in females compared to males. (14) In this study, the females were more affected with hemorrhoids as compared to males. Genetic or environmental factors may play role in such distribution which needs further evaluation.

Majority of patients in present study belong to grade I and grade II category of haemorrhoids for whom conservative treatment was usually recommended including sclerotherapy or rubber band ligation however for patients with grade III and grade IV with lower prevalence haemorrhoids due to higher severity surgery was recommended. Reported literature also demonstrates higher prevalence of grade I and grade II haemorrhoids which was consistent to the results of our study. (15) Duration since the first appearance of symptoms significantly affects the outcome of the treatment. Majority of patients in the study experienced symptoms within less than 6 months of duration.

Injection sclerotherapy is a technique practiced for destruction of abnormal veins by injecting medications which destroys the vein endothelium, leading to occlusion and subsequent fibrosis of the target vessel. A UK National Health Service research study compared arterial ligation technique with non-surgical treatments for effective management of low grades of hemorrhoids and suggested that non-surgical treatments like injection sclerotherapy are best in terms of cost-effectiveness and serious adverse events for effective management of grade I and grade II hemorrhoids. (16, 17) Patients with hemorrhoids require multimodality

treatments to obtain complete relief of their symptoms. In majority of patients single sclerotherapy injection session was found to be adequate for effective management of hemorrhoids. Rare number of patients with ineffective and incomplete ligation required the procedure to be performed again.

Prolonged compression of the treated vein after injection sclerotherapy is necessary to help with the healing process keeping the treated walls apposed and preventing recanalization. (18) Bleeding pain and Hematuria were the most common post-procedural complications observed in majority of the patients in our study which is in accordance to results of previous studies also. Hematuria and urological complications have been suggested to result from an anteriorly misplaced injection. (19)

Therapeutic efficacy of injection sclerotherapy was determined on the basis of its clinical outcomes which depends on recurrence or re-bleeding which are compared with the outcomes of conventional treatments. Recurrence occurred in only 5(16.1%) patients in injection sclerotherapy group compared to 17 (58.62%) in conservative management group which may be attributed to lower dose of sclerosant agent. Bleeding was a common complication observed in 33.3% patients which was similarly experienced in previous studies which observed bleeding due to larger needles. (20,21) Cessation of bleeding occurs within 1 to 2 weeks with conservative medical management practice similar observations were made by other authors with an overall success rate of 78.8% after one single sclerotherapy session which raised to 86% after second session.

This study has highlighted role of sclerotherapy in management of internal hemorrhoids. Few limitation of the study are single center and long term effectiveness data could not be generated. However analysis of outcome with different dosage of sclerosant can be explored for other group of patients with severe symptoms and recurrence which can have an impact on determination of treatment regimen.

In conclusion, injection sclerotherapy proves to be an effective choice of treatment modality for grade I and II haemorrhoids due to low cost, minimum invasiveness minimum post procedural complications and reduced hospital stay with better functional improvement. Recurrence and complications are found to be rare with injection sclerotherapy as compared to conservative management with better patient compliance.

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Role of sclerotherapy in management of symptomatic first and second degree internal haemorrhoids

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