

**Determining Efficacy of Single Agent Sclerotherapy in Two Sessions for Early Symptomatic Haemorrhoidal Disease: A Tertiary Centre Study**Pranoy Ghosh<sup>1</sup>, Subir Kumar Majumdar<sup>2</sup>, Kunal Sanyal<sup>3</sup>, Subhendu Bikas Saha<sup>4</sup><sup>1</sup>Junior Resident, Department of General Surgery, Midnapore Medical College, Midnapore, West Bengal, India.<sup>2,4</sup>Associate Professor, Department of General Surgery, Midnapore Medical College, Midnapore, West Bengal, India.<sup>3</sup>Assistant Professor, Department of General Surgery, Midnapore Medical College, Midnapore, West Bengal, India.

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**Abstract:****Background:** Hemorrhoids or piles are bundles of vascular structure composed of arterio-venous channels and connective tissue of anal canal. Usually these vascular piles work as venous cushions, which play an important role in continence. In symptomatic patients, non-response to conservative therapy can be managed by various procedures like sclerotherapy.**Objective:** Injection sclerotherapy, the oldest technique, still being used for the management of symptomatic haemorrhoids. Patients with grade I and II haemorrhoids were treated with 3% Polidocanol and their symptoms were compared pre and post-procedure to assess the efficacy as well as complications and long term outcome.**Material & Methods:** Total of 100 patients with symptomatic grade I and II haemorrhoids were randomly selected for this prospective observational study for one and half year. Sclerotherapy (ST) was performed on OPD basis on two separate sessions at an interval of one month sclerotherapy session 1 and 2 (ST1 and ST2) and patients were asked for four sessions of follow-up at three, six, twelve and eighteen months. Recurrence of symptoms was noted and analyzed using standard statistical tool.**Results:** Fifty five percent patients were female. Mean age was 50.13years (28-74; SD ± 9.85). Most patients belonged to upper middle socioeconomic status (45%). Improper dietary habit and obesity were common risk factors. No complications were noted during the procedure. Symptomatic relief was observed in 92.1% with bleeding and 96.1% with mucosal prolapse at the end of 18 months of follow-up. Multiple sclerotherapies in our study revealed excellent cure rate and low recurrence rate although it was not found so effective on symptoms like mucoid discharge and altered bowel habit.**Conclusion:** Sclerotherapy with 3% Polidocanol injection is safe, painless, patient-compliant and minimally invasive OPD based procedure with high cure rate though this procedure needs multiple therapies to combat recurrence and repeated follow-up.**Keywords:** Haemorrhoids, sclerotherapy, polidocanolThis is an Open Access article that uses a funding model which does not charge readers or their institutions for access and distributed under the terms of the Creative Commons Attribution License (<http://creativecommons.org/licenses/by/4.0>) and the Budapest Open Access Initiative (<http://www.budapestopenaccessinitiative.org/read>), which permit unrestricted use, distribution, and reproduction in any medium, provided original work is properly credited.**Introduction**

Hemorrhoids or piles are bundles of vascular structure composed of arterio-venous channels and connective tissue of anal canal. Usually, these vascular piles work as venous cushions, which play an important role in continence. Symptomatic hemorrhoids are classified either internal or external and graded as per Goligher's classification: into four grades.[1] Prominent risk factors commonly associated includes consumption of low fiber diet, chronic constipation, chronic diarrhea, chronic straining during defecation, pregnancy, sedentary lifestyle and obesity.[2]

Treatment guidelines of American college of Gastroenterology (ACG) recommend that patients with sympto-

matic first to third degree hemorrhoids initially be treated with simple lifestyle changes and medication. Non-response to conservative therapy can be managed by various procedures, including sclerotherapy, rubber banding, infrared coagulation and hemorrhoidal artery ligation. Patients with fourth degree or large third-degree hemorrhoids should be treated surgically by hemorrhoidectomy.[3]

In this study, patients clinically diagnosed as grade I and II haemorrhoids were treated using 3% Polidocanol and their symptoms were compared pre and post-procedure to assess the efficacy and recurrence rate.

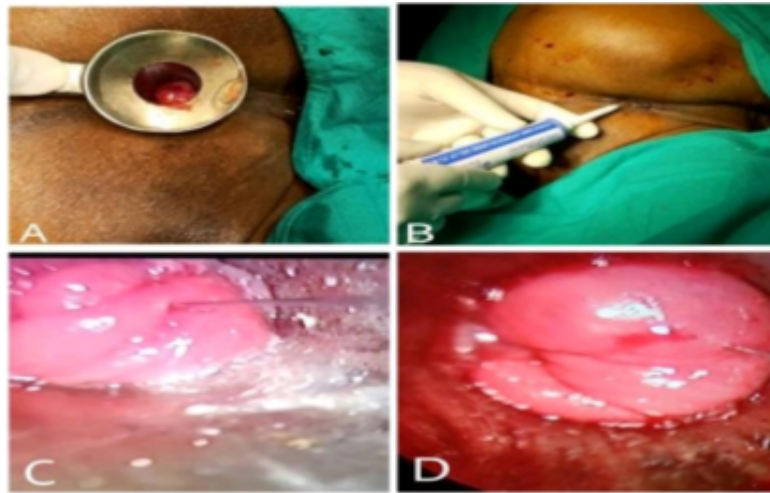
## Methods

This prospective observational study was conducted for a period of one and half year in Midnapore Medical College. A total of 100 patients, clinically confirmed as Grade I and Grade II haemorrhoid, who attended surgical outpatient department (OPD) of our Institute were randomly selected by simple randomization technique for sclerotherapy (ST) procedure with 3% polidocanol. Patients with known history of allergy to polidocanol, pregnancy, co-morbidities, anal fistula, anal fissure, anal ulcer, coagulation disorders or in any anti-coagulant therapy, portal hypertension, recurrent and grade III and grade IV haemorrhoids, malignancy were excluded.

Once the diagnosis was made, pre-procedural counselling regarding steps, expectations and probable complications were done to make them clearly understand and informed consent were taken

from all willing patients. Subsequently, they were informed to attend Minor OT where the procedure was carried out, usually a fixed day every week, to perform sclerotherapy.

Pre-procedure bowel clearance was ensured for clear visualization during the procedure. Procedure was carried out in Sims' position under local anaesthesia with a proctoscope, illuminated by an external light source. Position of haemorrhoids and dentate line were checked before the procedure. A Cusco's self-retaining speculum was then inserted and the haemorrhoid was placed between two blades. A 25G spinal needle was used to instill the sclerosant tangentially into the submucosal space at the base of haemorrhoid above the dentate line. The syringe was aspirated prior to sclerosant injection to avoid systemic entry. A dose of 1 ml (30mg/ml) of Polidocanol was injected submucosally at each of the primary haemorrhoidal sites (3, 7 and 11'O clocks) sufficient enough to raise a wheal. [Figure 1]



**Figure 1. Procedural photographs**

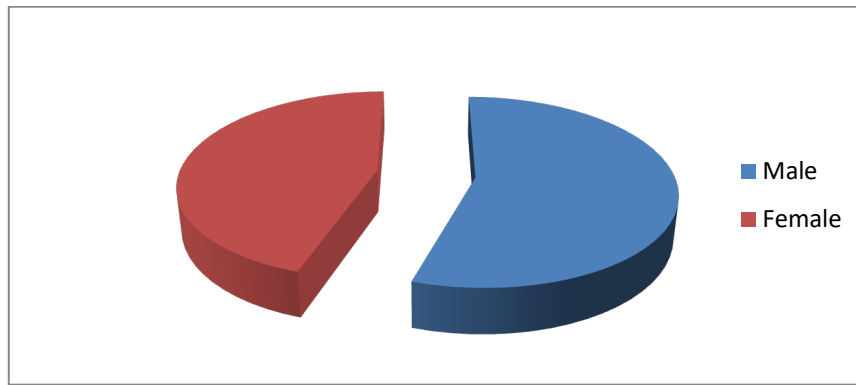
**A. Pre-procedural proctoscopy. B. 0.2% Lignocaine jelly for adequate analgesia. C. Sclerosant is injected tangentially at the base of hemorrhoid. D. Formation of sub-mucosal wheal**

The entire procedure of sclerotherapy in first [ST1] and second session [ST2] usually took 14 to 18 minutes (Mean time: 14.86 minutes, SD  $\pm$  1.52) and we kept the patients for observation for few hours. Some patients complained about bleeding and pain which were managed by local compression, tranexamic acid and acetaminophen tablets. All the patients were discharged on the same day safely after few hours of observation and were encouraged to avoid straining during bowel movements, and were instructed to use fibre supplement or stool bulking agent. All the patients were asked to come for the ST2 just one month after ST1. The same procedure was repeated during ST2. Unfortunately, out of 100 patients in ST1, only 5 patients were unwilling for

ST2 and they were excluded from our study. A follow-up [FU] schedule was informed to all participants at 3 [FU1], 6 [FU2], 12 [FU3] and 18 [FU4] months from the date of ST1. A visual analog score (VAS) was used for assessment of post-procedural pain at every follow ups.[4] Haemorrhoid Severity Score (HSS) questionnaire tool was also used for pre-procedural and follow up evaluation.[5] During each follow-up, patients were also routinely subjected to digital proctological and proctoscopic examination.

## Results

Among 100 participants, a male to female ratio of 9:11 was observed. [Figure 2].



**Figure 2: Gender distribution of the patients**

Mean age of patients was 50.13 years (28-74; SD ± 9.85). [Table 1]

**Table 1: Distribution of patients according to their Age**

| Age (Years) | Number of patients |
|-------------|--------------------|
| 26-35       | 11                 |
| 36-45       | 20                 |
| 46-55       | 34                 |
| 56-65       | 30                 |
| 66-75       | 5                  |

Most of the patients (45%) belonged to upper middle category of modified updated Kuppaswamy’s socioeconomic status. [6] Dietary problems (78%), Obesity (93%), constipation/diarrhea (43%) and straining during defecation (63%) were most noted in our study which may be considered as signification risk factors for haemorrhoids. [Table 2]

**Table 2: Distribution of patients according to Risk factors of hemorrhoids (n=100)**

| Risk Factors  | Number of patients | Percentage |
|---|--------------------|------------|
| Dietary problems (intake of low fibre diet, poor hydration, increased high spicy food intake) | 78                 | 78%        |
| Straining during defecation   | 33                 | 33%        |
| Constipation / Diarrhoea  | 43                 | 43%        |
| Pregnancy   | 10                 | 10%        |
| Occupation  | 10                 | 10%        |
| Sports  | 4                  | 4%         |
| Obesity (BMI > 23.0)  | 93                 | 93%        |

Out of total symptomatic patients (n=100), 46% were presented with Grade I and 54% were presented with Grade II haemorrhoids during ST1. Five patients were excluded from study at ST2 due to non-participation.

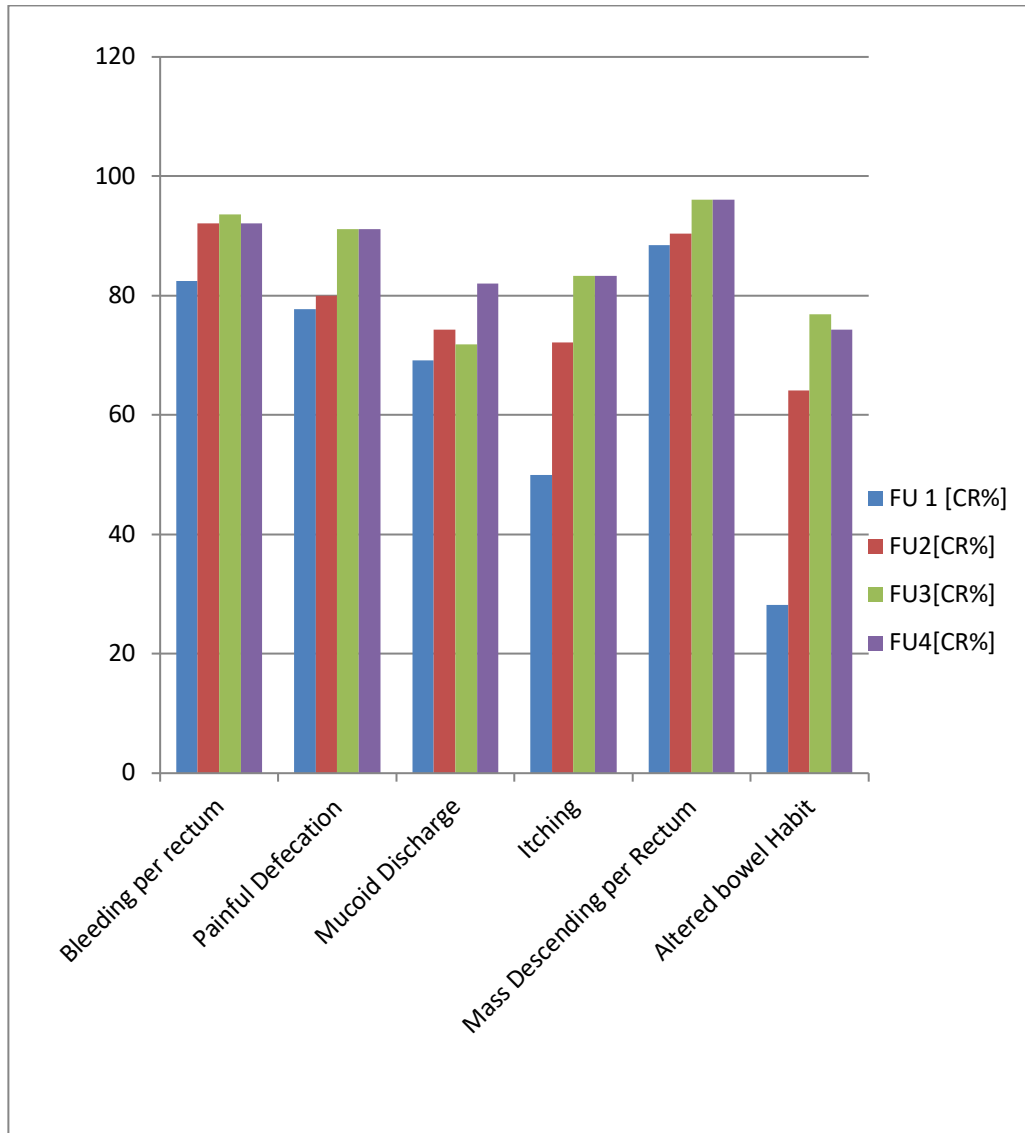
Among the study group patients, number of symptomatic bleeding per rectum cases steadily

declined from 17.5% at FU1 to 7.9% at FU4 which was statistically significant (p<.00001, f-ratio 44.20858 at p<0.05). Similarly number of symptomatic mass descending per rectum steadily declined from 11.5% at FU1 to 3.9% at FU4. Cure rates (CR) of all studied symptoms had been depicted in table

**Table 3: Distribution of patients according to their presenting symptoms and outcome in terms of cure rate of symptoms during follow-ups**

| Symptoms                   | Number of patients during ST1 (n=100) | Number of patients during ST2 (n=95) | No. of pts At 3month follow up and symptomatic cure rate [CR%] (n=95) | No. of pts at 6 month follow up and [CR%] (n=95) | No. of pts 12 month follow up and [CR%] (n=95) | No. of pts 18 month follow up and [CR%] (n=95) |
|----------------------------|---------------------------------------|--------------------------------------|---|--|--|--|
| Bleeding per rectum        | 67                                    | 63                                   | 11 [82.5]   | 5 [92.1]   | 4 [93.6]                                       | 5 [92.1]                                       |
| Painful Defecation         | 47                                    | 45                                   | 10 [77.7]   | 9 [80.0]   | 4 [91.1]                                       | 4 [91.1]                                       |
| Muroid Discharge           | 42                                    | 39                                   | 12 [69.2]   | 10 [74.3]  | 11 [71.8]                                      | 7 [82.0]                                       |
| Itching                    | 57                                    | 54                                   | 27 [50.0]   | 15 [72.2]  | 9 [83.3]                                       | 9 [83.3]                                       |
| Mass Descending per Rectum | 54                                    | 52                                   | 6 [88.5]  | 5 [90.4]   | 2 [96.1]                                       | 2 [96.1]                                       |
| Altered bowel Habit        | 40                                    | 39                                   | 28 [28.2]   | 14 [64.1]  | 9 [76.9]                                       | 10 [74.3]                                      |

A comparative analysis of cure rates of different symptoms at different follow-up schedules were shown in figure 3. Sclerotherapy was most efficient in controlling symptom of mass descending per rectum (CR 96.1%), followed by bleeding per rectum (CR 92.1%) at FU4. Such excellent result was not seen however with symptom of altered bowel habit (CR 74.3%) and mucoid discharge (CR 82.0%) at FU4 ( $p= 0.002287$ ,  $F$ -ratio 7,79095 at  $p<0.01$ ).[ Figure 3]



**Figure 3. Cure rate of symptoms at different follow up visits [Symptoms under study at four follow ups (FU). FU1=at 3 months, FU2= at 6 months, FU3=at 12 months and FU4=18 months. CR= Cure rate**

In this study of one hundred patients, only 5% patients complained of mild pain and 9% presented with occasional mild bleeding within few hours of procedure which were controlled satisfactorily with conservative management. No other adverse effect was found. At the end of 18 months follow-up recurrence of bleeding per rectum was 7.9% and symptom of prolapsing mass was 3.9% which values are not significant ( $p$ -value 0.361187 at  $p<0.05$  chi-square statistic 0.8338).

**Discussion**

Although haemorrhoids are recognized as a very common cause of bleeding per rectum and anal

discomfort, the true epidemiology of this disease is still unknown because patients always have a tendency to use self-medication rather than to seek proper medical attention.[7] Haemorrhoids affect about most of the population by the age of 45 to 65 years.[2, 8] In our study, most common age group affected with haemorrhoids was middle age group (46-55 years); mean age was 50.13 years (28-74; SD  $\pm 9.85$ ). The data is almost similar with studies of Kann BR et al and Johanson et al but contrary to that Ali SA et al and Rivadeneira DE et al claimed that the most common age group was below 40 years.[9, 10, 11, 12]

While calculating sex wise distribution of occurrence of hemorrhoids, slight female dominance [F: M = 1.22:1] was found in our study. In a study of risk factors and clinical features of hemorrhoids Ali SA and Shoeb MF noted 55% male predominance.[11] The rate was higher in studies of Rivadeneira DE et al (66.7%) and demographic study of Malviya et al (69%).[2, 12] They assumed that greater likelihood of men seeking treatment for their hemorrhoids and embarrassment felt by women to consult for ano-rectal problems. We should take a positive note that more women were consulting for their ano-rectal problems without any embarrassment.

Socio-economic status always has a significant impact on patients presenting with haemorrhoids. Our study showed that most of the patients with haemorrhoids belong to higher socio-economic status which is similar with most of studies.[2,7,8] It was found that higher socioeconomic status individuals were affected more frequently and particularly those with sedentary life style and low intake of dietary fibres.[7] Lack of taking proper high fiber diet seemed to be a major causative factor (78%) in our study. Obesity (93%) was found as significant risk factor in our study by Kann BR et al.[9] Prolong straining during defecation (33%) and constipation (43%) along with hard stool led to obstruction of venous return, resulting in engorgement of the vascular piles and development of hemorrhoids. Pregnancy and childbirth led to formation of hemorrhoids in 10% of patients. But Staroselsky A et al in their study on hemorrhoids in pregnancy, they estimated that 25% to 35% of pregnant women were affected by this condition. Most were resolved spontaneously soon after delivery.[13]

At ST1, most common symptom presented were bleeding (67%) followed by pruritus ani (57%). Other symptoms are mucoid discharge (42%), mass descending per rectum (54%), experiencing pain during defecation (47%) and altered bowel habit (40%). Like risk factors, symptoms are also overlapping in nature.

Punia et al had given higher complications percentage of 80% for pain and 7% for bleeding post-operatively.[14] Also Al-Ghaniem et al in their study revealed 31% of surgeons reported urological complications following injection sclerotherapy.[15] In our study complication rate was low (5 to 9%) due to attention to of proper technique like small size long needle, tangential submucosal application.

In our study 92.1% of patients with symptom of bleeding and 96.1% of patient with mass descending per rectum were found cured on FU4. Satisfactory cure rate at FU4 was also observed for other symptoms. [figure]. This high cure rate can be compared with other similar studies.[14, 15, 16]

Sclerotherapy was not found so effective on symptoms like mucoid discharge (CR 82.0%) and

altered bowel habit (CR 74.3%) on FU4. Most of them were treated with albendazole, laxatives and other modalities. However, perianal itching was improved noticeably at FU4 (p-value).

Although Mukhopadhyay M et al reported only 5.17% recurrence after 1 year of follow-up, Kanellos et al. found that after 3 years 42.4% for 1<sup>st</sup> degree hemorrhoids and 64.1% of second degree hemorrhoids recur which is quite high.[16, 17] Our study revealed recurrence rate of symptoms after 1 and half year were 7.9% for bleeding and 3.9% for prolapsing mass. We assumed that the patients didn't follow proper dietary, hygienic modifications and guidelines we have advised during discharge.

Injection sclerotherapy was noted with high cure rate in our study while treating early hemorrhoids, although superiority of rubber band ligation (RBL) is reported in several studies. [18,19] However a meta-analysis by Johanson and Rimm and a comparative study by Makanjuola A et al did not find any significant statistical difference regarding improvement of symptoms and also a higher and statistically significant post procedure pain score among RBL group.[20, 21] Bleeding after 10-14 days in almost every patient, probably due to the sloughing of the ligated hemorrhoids noted after RBL, which was absent in sclerotherapy.[18-21] Doppler guided hemorrhoidal artery ligation with or without mucopexy is also considered as an option to treat Grade II hemorrhoids but not accepted widely due to its technical complexity and high cost.[22]

In a recent study in 2019 by Ranconi M showed that multiple sclerotherapy sessions are very effective to solve bleeding problem of hemorrhoid, particularly in managing recurrences.[23]

### Conclusion

We can conclude that sclerotherapy is an effective mode of therapy for grade I and grade II hemorrhoids. It is cost effective, easy to perform as OPD procedure, relatively painless with high cure rate with low complications rate. It can be performed in peripheral health facilities among rural populations where very limited resources are available. Multiple ST has shown very effective in controlling symptoms and recurrences.

### Limitation

Our study was based on a single center and sample size was not large enough and no appropriate control arm was used. Moreover, sclerotherapy was given by multiple faculties with a chance of inter-personal variation. Follow-up study could have been longer for best evaluation of long term results.

### Declarations

**Funding:** No funding sources

**Ethical approval:** The study was duly approved by the Institutional Ethical Committee of Institute. Individual informed consent was taken and patient safety was maintained as per Helsinki declaration.

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