# Role of Sclerosing Agents in the Management of Early Haemorrhoids

AKRAM Y., TARAR K.D., CHAUDRY Z.A. ILYAS M.Y., AYYAZ M., CHEEMA M.A.

Correspondence: Yasir Akram, 271 New Hostel Link McLeod Road KEMU, Lahore, Pakistan. Tel: 92-345-4330782

E-mail: myasir216@gmail.com, dryasir216@hotmail.com

**Background:** Hemorrhoids are common surgical problem all over the world. Various modalities for the treatment of haemorrhoids are available. However, efforts are being made to treat the haemorrhoids as outpatient procedure. Injection Sclerotherapy has been the orthodox treatment for early haemorrhoids. Various sclerosing agents have been used. 5% phenol in almond oil was more commonly used as, sclerosant. We carried out a prospective comparative study comprising the results of Sodium Tetra Decyl Sulphate (STD 3%) and phenol, as sclerosing agents.

**Methods:** Fifty patients having cardinal symptoms of haemorrhoids, 1<sup>st</sup> and early 2<sup>nd</sup> degrees were included in the study; divided into two equal groups. The purpose of study was to assess the role of STD 3% (Sodium Tetra-Decyl Sulphate) as sclerosing agent in the treatment of 1<sup>st</sup> and early 2<sup>nd</sup> degree haemorrhoids. All the patients were having bleeding symptoms in their presenting complaints. Prolapse was present in 52% patients of "STD group" and in 44% patients of "Phenol Group". A final review by questionnaire was under taken one to six months later.

**Results:** Our results showed an overall success rate of 70% in STD group and 80% in phenol group regarding the control of bleeding and prolapse, which were the cardinal symptoms, in our patients.

**Conclusion:** We concluded that the results of both sclerosing agent were comparable. Both were painless, effective, complication free and can be safely used in outpatient as sclerosant.

Key words: Haemorrhoids, Sclerosant, Sodium Tetra Decyl Sulphate (STD).

Haemorrhoids are one of the most common ailments of the anorectal region. Although the frequency of haemorrhoids in general population is unknown, but workers have reported the incidence in their studies. Kang found in a consecutive series of 115 patients that seventy nine percent (79%) of bleeding per rectum cases were due to haemorrhoids. In the age group of 50 years and over, 29% had asymptomatic haemorrhoids. Males however, had a significantly greater incidence of asymptomatic haemorrhoids than females .Various techniques for the treatment of haemorrhoids are haemorrhoidectomy, rubber band ligation. Lord's procedure, cryosurgery, phototherapy, sclerotherapy and Laser techniques. The aim of a perfect technique is its simplicity and cost effectiveness with an uneventful and uncomplicated recovery in a short period of time.

Operative treatment has been the method of choice for 2<sup>nd</sup> and 3<sup>rd</sup> degree haemorrhoids but in the recent past there has been a tendency to avoid haemorrhoidectomy in favour of day case procedures.

In the modern treatment there has been a strong trend in favour of day case and office procedures for the treatment of internal haemorrhoids because of cost effectiveness, better patient's satisfaction and lesser risk of complications with the newer techniques. While patient's compliance is related to shorter hospitalization, less morbidity, early return to work and absence of unbearable pain, which is usually associated with haemorrhoidectomy.

In our country, the disease is also prevalent and most of the sufferers belong to lower socio-economic class. In this set up, the haemorrhoidectomy with its described pitfalls and morbidity puts a great economic burden on the family as well as on the country.

Keeping in view the above mentioned factors and the world-wide changing trends in the treatment of haemorrhoids, a prospective study was planned in Department of General Surgery, Mayo Hospital, Lahore, Pakistan, to evaluate the role of Sodium Tetradecyl Sulphate 3% (STD 3%) and 5% phenol in almond oil in the management of 1<sup>st</sup> and early 2<sup>nd</sup> degree haemorrhoids.

## **Methods**

In our study all those patients who were referred to visiting surgeons, as well as those who were referred from G.Ps or presented themselves in Outpatient clinics or casualty, having cardinal symptoms of the haemorrhoidal disease, were picked up. Per Rectal (P/R) and Proctoscopic examination was performed to confirm the disease. The degree and size of prolapsed haemorrhoidal mass was recorded on the proforma and on outdoor patients slip with the help of diagram. A total of 50 patients, of both gender, were included in the study. It was a non-consecutive series and the patients were equally distributed into two groups (25 to each) on random basis, one group for injection STD and other group for Injection phenol in almond oil. Details of the procedure were discussed with the patient for proper understanding and a written informed consent was taken. A proforma was filled including the name, age, sex, profession, address with phone number, date of procedure, detailed history thorough examination and procedure performed. The patients were advised to revisit for follow up after one month, 2 months and 6 months to assess the results of the procedure performed.

**Group A**: Twenty five patients having 1<sup>st</sup> and early 2<sup>nd</sup> degree haemorrhoids selected after proper evaluation for sclerotherapy with STD as Sclerosant (**STD Group**).

**Group B**: Twenty five patients having same degree of haemorrhoidal disease selected for sclerotherapy with Phenol in almond oil (**Phenol group**).

In procedure no anesthesia was given in any patient. Position of the patients was knee-elbow in most of the cases; and this was the convenient and preferable position to inject the piles. Usually 2ml of the sclerosant was injected for each haemorrhoidal mass. During injection, particular consideration was made for the procedure to be painless. After injection needle was left in place for about ten seconds to avoid any reflux of the sclerosant and to minimise bleeding from the puncture site. A sterilized gauze was left in, to prevent submucosal haematoma etc.

After the procedure the patient was advised and stressed to take high fibre diet including fair amount of salad as well as three table spoonful Ispaghula husks in the evening with plenty of water daily. Patient was made to understand that constipation and straining at defecation must be avoided and keep the stools soft.

### **Results**

In STD group 22 patients were male and 3 were females; while in Phenol group there were 21 males and 4 female patients. Age of the patients was varied from 18 years to 65 years, with a mean age of 41 years.

On follow up all patients were assessed both subjectively as well as objectively. Main emphasis was laid on subjective assessment while compiling results because the object of treatment was to abolish the symptoms. On subjective assessment queries were made regarding simplicity, acceptability, efficacy, economy and any post treatment symptoms. The results were declared as excellent, improved and failure, based on this data.

### **STD Group**

On subjective assessment of symptoms bleeding was the presenting symptom in all the patients of the group. At the end of six months, 19 (76%) patients were free from bleeding. Two of the remaining patients had occasional bleeding during or after defecation. However, in 4 there was no effect and the bleeding was there as it was in the pre-treatment period. Prolapse was presenting symptoms in 13 (52%) out of 25 patients and all these patients had associated symptom of bleeding also. At the end of six months 9 out of 13 patients gain excellent result, 2 others observed improvement i.e. size of pile reduced and occasional prolapse on straining only; however, in two patients prolapse remained as such.

On objective assessment Pile size was reduced in 11 out of 13 patients; 70% patients obtained excellent result, 15% were improved regarding the size of pile while 15% were in the failure group so overall success rate was about 85%. Intolerance manifestations in the form of vertigo, mild nausea and slight faintness were noted in 3 Six patients felt warming sensations for a few minutes at the end of injection, which were of transient nature. Three patients felt mild to moderate pain for 1-3 hours. Fifteen felt mild discomfort for less than 24 hours. Neither of the patients in this group had post procedural bleeding problem. Other complications such as submucosal abscess, ulceration, prostatitis, hematuria etc. were also not found.

# **Phenol Group**

On subjective assessment After six months 20 (80%) patients were free from bleeding. Two of the remaining patients had occasional bleeding during or after defecation. However in 3 patients, there was no improvement and the overall success rate was 88% while the failure was 12%. Prolapse was present in 11 (44%) patients of this group and all these patients had associated symptom of bleeding also. 9 patients showed excellent result. One patient observed some improvement i.e. size of the pile was a bit reduced with occasional prolapse on straining only. However, in one patient prolapse remained as such.

On objective assessmentpile size was reduced in 10 patients. No prolapse was seen in the lumen of the proctoscope on straining. 81% patients obtained excellent result, 9% were improved regarding the size of the pile. The remaining 10% were in the failure group. So overall success rate was about 90% vertigo and slight faintness was noted in patients. Seven patients felt warming sensations for a few minutes at the end of injection which were of transient nature. Four patients felt mild to moderate pain for a few hours after injection. Fifteen felt mild discomfort which persisted for less than 24 hours and then relieved without medication.

Neither of the patients in this group faced post procedural bleeding problem. Other complications such as submucosal abscess, ulceration, prostatitis, hematuria etc., were also not found.

**Table 1:** *Pre treatment symptoms.* 

Complaints	Group A (n = 25)	Group B (n = 25)
Bleeding	25	25
Prolapse during defecation	13	11
Constipation	11	14
Itching	7	5

Symptoms	<b>Patients Opinion</b>	At 1 month (n)	At 2 months (n)	At 6 months (n)	Overall success rate or failure rate
Bleeding	Excellent	13	16	19	76%
	Improved	7	5	2	8%

**Table 2:** Symptomatic assessment/patients opinion of the efficacy of procedure of "STD Group".

Symptoms	Patients Opinion	(n)	(n)	(n)	or failure rate
Bleeding	Excellent	13	16	19	76%
	Improved	7	5	2	8%
	Not improved	5	4	4	16%
	Total	25	25	25	
Prolapse	Excellent	8	10	9	70%
	Improved	2	1	2	15%
	Not improved	3	2	2	15%
	Total	13	13	13	

**Table 3:** Symptomatic assessment/patients opinion for the efficacy of the procedure of "Phenol Group".

Symptoms	Patients Opinion	At 1 month (n)	At 2 months (n)	At 6 months (n)	Overall success rate or failure rate
Bleeding	Excellent	14	17	20	80
	Improved	6	5	2	8
	Not improved	5	3	3	12
	Total	25	25	25	
Prolapse	Excellent	7	9	9	81
	Improved	3	1	1	9
	Not improved	1	1	1	10
	Total	11	11	11	

Table 4 Post procedure complications rate

Complications	STD Group (n)	Phenol Group (n)
Intolerance manifestation vertigo, slight faintness	3	4
Transient warming sensations	6	7
Mild to moderate pain (Oral analgesic needed)	3	4
Slight discomfort (No analgesic needed)	15	15

#### **Discussion**

Haemorrhoids are known as disease entity since centuries. The incidence in both sexes is considerably high, though exact statistics are not known. Majority of the cases of piles are symptomatic. Hughes (1983) very rightly recommended definitive treatment only for symptomatic patients. Arullani A et al (1994), discussing "the diagnosis and current treatment of haemorrhoidal disease" stated that "in the modern treatment, fast and painless procedures that can be carried out in the office practice, without anesthesia will be more and more indicated".

In our study we have concluded that Injection Sclerotherapy is a simple and easy method which can be practiced as an office procedure. It is painless and no fancy equipment is required. No anaesthesia is needed. It can be performed even in those remote areas of Pakistan where electricity is not supplied and a torch light is sufficient. Clark et al 1967 reported that injection treatment is generally painless and well tolerated. Major symptoms of bleeding often dramatically relieved by injection therapy. Greca et al (1981) claimed that injection Sclerotherapy is a treatment of choice for first and nearly 2<sup>nd</sup> degree internal haemorrhoids.

The age of patients in this study was between 18-65 years. The highest incidence was between 24 to 48 years. This was approximately same as reported by Shckleford (1969) and Javed (1992). In our patients duration of symptoms varied from 2 months to 8 years. It was noted that patients whose duration of symptoms was relatively shorter had better control of bleeding and prolapse. Sclerotherapy may be accompanied by certain complications, particularly by the beginners. One may face difficulty in proper displaying of the haemorrhoids and may inject into summit of the haemorrhoidal tissue. Haemorrhoids must be injected at their pedicle near the anorectal ring. Bruhl W (1993) had nicely discussed it and stated that "in the case of enlarged, symptomatic haemorrhoids, an attempt should not be made primarily to reduce their size; rather the caudally displaced haemorrhoidal tissue should be fixed again above the dentate line. This is achieved by injecting the sclerosant not into the centre of the haemorrhoid convolute but into the base. Sclerotherapy of the haemorrhoids should not be aimed at shrinking, but fixing them".

Similarly inexperience person may go deep into the muscle or may remain superficial during injection. "Care should be observed, not to inject into the prostate anteriorly otherwise prostatitis would be crippling" (Bailey & Loves Short Practice of Surgery 1995). In our study, during injection, after recognising the pedicle, mucosa was steadied with the help of proctoscope and injected rightly into the submucosal tissue. No serious complication was encountered during the procedure, except a minor degree of discomfort and heaviness. The intensity of the post procedure pain was evaluated, because it is one of the important factors for acceptance or rejection of treatment. Roe et al (1987) suggested that patients usually conceal the rectal bleeding because of dread of pain of operation. In STD group, 3 patients and in Phenol group, 4 patients felt moderate pain for 1-3 hours. Two out of these patients of each group had to take oral analgesic while others got relief without medication.

Varma-JS et al 1991 made comparative study between current coagulation and injection sclerotherapy and stated "Sclerotherapy was found significantly less tedious than coagulation. Three patients in the coagulation but none in the injection group refused to be treated by the same method again due to discomfort".

Bleeding was the most common symptom in both groups of patients. Excellent results were obtained in 70% of STD group and in 80% patients of Phenol group. Similar observation was made by Varma- JS et al (1991), and stated that "Early cure rates for bleeding were 84% for sclerotherapy and 64% for current coagulation".

In the present study we found that the procedure was more cost effective with phenol in almond oil as compared to STD 3%. Maximum cost for phenol Injection was PK Rs.100/- while for STD was PK Rs.350/-, for one injection session. In our study 48% required one injection session, in 16% two injection sessions, and in 36% three injection sessions were required by the patient of STD group. On the other hand, in Phenol group, 56% were needed only single injection session, 8% two injection sessions, and in 36% three injection sessions were required. By considering all the factors it was calculated that 5% phenol in almond oil was about 3.5 times cheaper than STD as sclerosing agent.

An important observation made during the study was that neither of our patients had refused to accept the therapy. Few patients were found reluctant at their first visit because of the financial constraints; they were included in the "phenol group". Subsequently they remained happy till the end of treatment and none of patients, in this study, refused for 2<sup>nd</sup> or 3<sup>rd</sup> injection session. Similar observation was made by Varma-JS et al (1991) in their study.

In Pakistan most of the patients are those who are on daily wages. The patient can go to his work right from the out patient department and there is no need for time off from job. So his daily wages are not disturbed.

Another observation which was made during the study was that sclerotherapy was more effective in 1<sup>st</sup> degree and early 2<sup>nd</sup> degree of haemorrhoids where prolapse was minimal. More over the first injection session showed better and superior results than 2<sup>nd</sup> and 3<sup>rd</sup> injection session. In the study, achievement was 52% in STD group with 1<sup>st</sup> injection session while 48% achievement in phenol group. Similar observations had been noted in the past. Alexander et al (1975) found satisfactory results in patients with first degree haemorrhoids.

However, inspite of all these benefits, it has been observed that sclerotherapy is not practiced freely even at larger institutions.

#### Conclusion

Injection Sclerotherapy is effective, safe, simple, acceptable and economical in the treatment of symptomatic 1<sup>st</sup> and early 2<sup>nd</sup> degree internal haemorrhoids.

# Suggestions and recommendations

- (1) Sclerotherapy must be considered as procedure of choice for symptomatic 1<sup>st</sup> degree and early 2<sup>nd</sup> degree internal haemorrhoids with minimal prolapse and phenol in almond oil should be the preferred sclerosing agent.
- (2) To avoid the complications, correct procedure for injection is necessary for which training at graduate and post graduate level must be encouraged.
- (3) Awareness of public about the safety and efficacy of the procedure through print and electronic media is recommended.
- (4) Patients need to be educated that haemorrhoids can be treated without operation, without anaesthesia and without pain as a day case Surgery at low cost.
- (5) Therefore a combined effort is required at Government level and at institution level to promote that safe, quick, effective; pain free and economic treatment in the form "injection sclerotherapy" is available for 1<sup>st</sup> degree and early 2<sup>nd</sup> degree haemorrhoids.

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