



## To Compare the Effectiveness of 20% Hypertonic Saline Versus 5% Phenol in Almond Oil as a Sclerosing Agent in Grade 1 and 2 Hemorrhoids

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### Abstract

**Background:** Hemorrhoidectomy is the procedure of choice for treating hemorrhoids most effectively. Now a day's the emphasis is on conservative therapies and newer outpatient methods for treating hemorrhoids.

**Objective:** To compare the effectiveness of 20% hypertonic saline vs. 5% phenol in almond oil as a sclerosing agent in grade 1 and 2 hemorrhoids.

**Material and Methods:** A total of 60 patients randomly distributed in two groups were included in the study. One group was for sclerotherapy with hypertonic saline 20% and other group for sclerotherapy with 5% phenol in almond oil.

**Results:** 21 (75%), 5 (71.4%) and 2 (100%) patients out of 28 patients were relieved of bleeding after 1<sup>st</sup>, 2<sup>nd</sup> and 3<sup>rd</sup> sitting of sclerotherapy with hypertonic saline, while 16 (57.14%), 8 (67.66%) and 1 (25%) patients were relieved of bleeding after 1<sup>st</sup>, 2<sup>nd</sup> and 3<sup>rd</sup> sitting of sclerotherapy with phenol in almond oil. Relief from prolapsed was present in 11 (45.83%) patients in hypertonic saline group while 13 (54.17%) experienced decrease in the prolapsing symptoms. In phenol in almond oil group about 11 (61.11%) patients experienced relieve in the prolapsing symptoms while 7 (38.9%) of population experienced decrease in the prolapsing symptoms.

**Conclusion:** Sclerotherapy is effective, safe, simple and economical in the treatment of symptomatic I and II degree internal hemorrhoids. 20% hypertonic saline is slightly better than 5% phenol in almond oil both in relieving prolapse as well as bleeding.

**Keywords:** Sclerotherapy; Hemorrhoids; Bleeding; Prolapsed

### Aims and Objectives

1. To assess the clinical outcome of injection sclerotherapy using hypertonic saline 20% and 5% phenol almond oil in grade 1 and grade 2 hemorrhoids.
2. To compare the efficacy of hypertonic saline 20% vs. 5% phenol almond oil as a sclerosant in grade 1 and grade 2 hemorrhoids.

### Introduction

Hemorrhoidal disease is a common problem that affects a large number of patients [1]. Treatment is directed solely based on the symptoms and not at the appearance of the hemorrhoids [2].

In the modern treatment there has been a strong trend in favor of day care procedures for the treatment of internal hemorrhoids because of cost effectiveness, better patient's satisfaction and lesser risk of complications with the newer 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 3<sup>rd</sup> and 4<sup>th</sup> degree hemorrhoids. For 1<sup>st</sup> and 2<sup>nd</sup> degree hemorrhoids, non operative treatment is effective [3,4]. These include sclerotherapy [5], rubber band ligation [6], heat coagulation [7] and cryotherapy [8].

In sclerotherapy, a sclerosing agent is injected into the base of the hemorrhoid causing inflammation and scarring, which holds the nearby tissues and veins in place and prevents them from bulging into the anal canal. This procedure is done as an outpatient procedure. Symptoms

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**Table 1:** Comparison of results of 1<sup>st</sup>, 2<sup>nd</sup> and 3<sup>rd</sup> sitting of hypertonic saline and phenol in almond oil groups.

Bleeding	1 <sup>st</sup> sitting		2 <sup>nd</sup> sitting		3 <sup>rd</sup> sitting	
	Hypertonic saline	Phenol in almond oil	Hypertonic saline	Phenol in almond oil	Hypertonic saline	Phenol in almond oil
	No. (%)	No. (%)	No. (%)	No. (%)	No. (%)	No. (%)
Relieved	21 (75)	16 (57.14)	5 (71.40%)	8 (66.67)	2 (100)	1 (25)
Not relieved	7 (25)	25 (42.86)	2 (28.60%)	4 (33.33)	0 (0)	3 (75)
Total	28 (100)	28 (100)	7 (100%)	12 (100)	2 (100)	4 (100)

of hemorrhoids may return after several years and requires further treatment.

Various sclerosants used are 5% phenol in almond oil [9,10], phenol in *Arachis* oil [11], Sodium tetradecyl sulphate, Polidocanol, Quinine and urethane, hypertonic saline [12], Ethanolamine oleate, Aetoxisclerol [13], Xiao zhi ling XZL (which consists of Chinese nutgalls and aluminum potassium sulphate) [14]. Despite of a large number of sclerosants used so far there is little literature comparing their efficacies [15,16].

Surgical procedures include hemorrhoidectomy, open and closed hemorrhoidectomy, Doppler-guided Hemorrhoidal Artery Ligation, Stapled hemorrhoidectomy [17-20].

## Methods and Materials

### Method

In our study all those patients who attended outpatient clinics or casualty having cardinal symptoms of the hemorrhoidal disease were picked up. Digital rectal examination and proctoscopic examination was performed to confirm the disease. The degree and position of hemorrhoids was recorded on the proforma and on outdoor patient's case. A total of patients 60 patients of both gender, were included in the study. Patients were randomly distributed into two groups, one group for injection with hypertonic saline 20% and other group for injection with 5% phenol in almond oil. Details of the procedure were discussed with the patient for proper understanding and consent was taken. Patient details were recorded in a proforma and the procedure was performed. The patients were advised to revisit for follow up as per schedule to assess the results of the procedure performed.

**Group A:** 30 patients with 1<sup>st</sup> and 2<sup>nd</sup> degree hemorrhoids were included who were to receive hypertonic saline 20% as sclerosant (HS group).

**Group B:** 30 patients having 1<sup>st</sup> and 2<sup>nd</sup> degree of hemorrhoidal disease selected for sclerotherapy with 5% phenol in almond oil (P group).

### Exclusion criteria (or contraindications)

Sclerotherapy was not performed if the patient had:

1. Previous history of intolerance to other sclerosants
2. Pregnancy
3. Severe cardiac disorders
4. History of recent thrombosis
5. Inflammatory and other ano-rectal conditions e.g. fissures and fistula, Crohn's disease and ulcerative colitis.
6. Acute prolapsed and thrombosed piles
7. Bleeding diathesis

8. Grade 3 and 4 hemorrhoids

### Materials required

1. Hypertonic saline (20%)
2. 5% Phenol in almond oil (Phenol 5% w. - v)
3. 2% Lignocaine solution for hypertonic saline
4. Spinal needle 18G for 5% phenol in almond oil and 23G for hypertonic saline
5. 5cc syringe for hypertonic saline and 10CC syringe for phenol group.
6. Proctoscope with source of illumination (e.g. torch)
7. Lignocaine jelly
8. Gloves
9. Gauze piece
10. Oral Antibiotic

### Preparation of sclerosant

Hypertonic saline solution- 4:1 dilution of hypertonic saline with in Lignocaine to constitute 3 cc for a single sitting, 1cc for each hemorrhoid.

5% phenol in almond oil- 3cc for each hemorrhoid.

### Procedure

Preparation: Patient should have passed stools so that the rectum should not be loaded with faecal matter. The anal canal was properly lubricated and local Anesthetic gel was applied.

**Position:** The patient was usually laid down on his or her left side in the left lateral (Sims) position, with the buttocks projecting over the edge of the table.

**Injection:** Per rectal examination was done first and then a proctoscope with a wide-bore was inserted into the anal canal whereby under adequate illumination one looks for the number, position and degree of hemorrhoids. After due identification, sub mucosal injection (around pedicle) of pre defined amount sclerosant (1cc each in case of hypertonic saline and 3cc in a case of 5% phenol in almond )was injected raising a bleb (Blanchard's method) which turns pale in contrast to surround mucosa which was pinkish red in colour. Injection should be given, above the dentate line, where no or little pain should be felt. This is because the dentate line separates the insensitive columnar epithelium from the sensitive squamous epithelium below. If excessive pain is felt at the injection site, it is likely that injection site is incorrect. Same procedure was repeated for second and third hemorrhoidal mass.

### Post-procedure

After sclerotherapy injection is complete, the needle should not be

**Table 2:** Comparison of results of bleeding post sclerotherapy in hypertonic saline and phenol in almond oil groups.

Bleeding	Hypertonic Saline		Phenol in almond oil	
	Number	Percentage	Number	Percentage
Yes	0	0	3	10.71
No	28	100	25	89.29
Total	28	100	28	100

**Table 3:** Comparison of relief of prolapse after sclerotherapy in hypertonic saline and phenol in almond oil groups.

Prolapse	Hypertonic Saline		Phenol in almond oil	
	Number	Percentage	Number	Percentage
Decreased	13	54.17	7	38.9
Relieved	11	45.83	11	61.11
Total	24	100	18	100

withdrawn immediately, since this may lead to bleeding and leaking of the sclerotherapy solution. The leakage of sclerosant on withdrawal of the needle signifies too rapid injection. Instead, the needle should be held in place for a few seconds and then slowly withdrawn to facilitate the sealing of the tract. When proper technique is employed the patient should not experience more than mild ache or discomfort. Slight bleeding after injection can be controlled by the topical application of a 1:10,000 adrenaline solution and a gauze piece can be left in place for a while.

The patient was allowed to rest in supine position for a few minutes & observed for any adverse effect. The goal was to keep patient stools soft by giving a high bulk diet and plenty of fluids. Non-steroidal anti-inflammatory drugs will usually control any discomfort. Sitz's bath may help in rare cases where needed. Suppositories were rarely necessary. Non-steroidal anti-inflammatory drugs were given if there is dull pain or discomfort. Sclerotherapy was given every 3 weeks for a maximum of three sessions if required. Patient will be called for follow up at one week, three weeks and six weeks. Proctoscopy is done to evaluate hemorrhoids.

Antibiotic prophylaxis is indicated for patients with predisposing valvular heart disease or immunodeficiency because of possibility of bacteremia after sclerotherapy.

### Follow-up

After the first sitting, the patient was asked to follow-up as per the following schedule.

- After one week, if bleeding or any complication occurs (not for sclerotherapy session), if uneventful.
- Then, after three weeks and
- Then, after six weeks.

The patient is counseled to seek advice in between follow-ups if there is bleeding or any other complication arises.

In most patients, a maximum of three separate injections to the base of the hemorrhoids were given.

### Investigations

Hemoglobin % - is made a routine part of management.

Other specific ones included are:

1. Bleeding time, clotting time, prothrombin time: to rule out

**Table 4:** Comparison of pain during sclerotherapy with hypertonic saline and phenol in almond oil groups.

Pain	Hypertonic Saline		Phenol in almond oil	
	Number	Percentage	Number	Percentage
Yes	3	10.71	10	35.71
No	25	89.29	18	64.29
Total	28	100	28	100

bleeding diathesis, HIV, HBsAg, HCV.

2. Barium enema. Sigmoidoscopy & Colonoscopy wherever indicated to rule out aetiologies like ulcerative colitis, Crohn's disease, colorectal malignancy etc. At the end of the study, the data was collected and analysed by using Student t-test and Chi-square test.

### Observations

A total of 60 patients were included in this study to compare the effectiveness of 20% hypertonic saline versus 5% phenol in almond oil as a sclerosing agent in grade 1 and grade 2 hemorrhoids. Each group had 30 patients each. At the end of follow up the following were the observations of the present study.

#### Age distribution

In both the groups' maximum number of patients were in the age group of 31-45.

#### Sex distribution

In hypertonic saline group of 30 patients, 25 patients (83%) were males and 5 (17%) were females; while in 5% phenol in almond oil group males were 22 (73%) and females were 8 (27%).

### Pretreatment Symptoms

In hypertonic saline group and phenol in almond oil group all pts (60) had bleeding. While 24 (80%) patients in 20% hypertonic saline group and 20 (67%) in phenol in almond oil group had symptoms of prolapse. Constipation was present in 27% of patients in hypertonic saline group and 24% of patients in phenol in almond oil group.

#### Bleeding after 1<sup>st</sup> sitting of sclerosing agents

The results were as shown in the table 1. On comparison of first session of sclerotherapy it was found to be statistically insignificant ( $p > 0.05$ ).

Two patients in each group were lost in the follow up.

#### Bleeding after 2<sup>nd</sup> sitting of sclerosing agents

All re-bleeding patients after first session of sclerotherapy were subjected to the second session of sclerotherapy. The results were as shown in the table 1. On comparison there was found no statistical difference between two groups ( $p > 0.05$ ).

All those patients who were still bleeding were subjected to the third session of sclerotherapy.

#### Bleeding after 3<sup>rd</sup> sitting of sclerosing agent

All those patients who failed second session of sclerotherapy and continued to bleed were subjected to the third session of sclerotherapy. The results were as shown in the Table 1. These patients were subjected to other surgical treatment modalities.

#### Bleeding post sclerotherapy

No statistical significance was found on the comparison between

**Table 5:** Comparison of percentage of patients requiring 1<sup>st</sup>, 2<sup>nd</sup> and 3<sup>rd</sup> session of sclerotherapy.

S.no	Study	Name of sclerosant	Number of sessions			Total (%)
			1 <sup>st</sup>	2 <sup>nd</sup>	3 <sup>rd</sup>	
1	Bhuiya et al. [22]	5% phenol	60.40%	15.78%	3.12%	79.31%
2	Present study	5% phenol	57%	28.60%	3.60%	89.30%
		Hypertonic saline 20%	75%	17.90%	7.10%	100%

**Table 6:** Comparison of effectiveness of 20% hypertonic saline versus 5% phenol in almond oil in present study.

Name of sclerosant	Bleeding (n)	Relieved of bleeding (%)	Prolapse (n)	Relieved of prolapsed (%)	Decrease in prolapsed (%)
Hypertonic saline 20%	28	100	24	45.8	54.1
5% phenol in almond oil	28	25 (89.3%)	18	61.1	38.89

two groups in view of bleeding (p value>.05) after three sessions of sclerotherapy (Table 2).

## Relief of Prolapse

Prolapse accounts to one of major symptom besides bleeding in grade 2 hemorrhoids. On comparison prolapse got relieved in 11 (45.83%) patients in hypertonic saline group while 13 (54.17%) experienced decrease in the prolapsing symptoms. In phenol in almond oil group about 11 (61.11%) patients experienced relieve in the prolapsing symptoms while 7 (38.9%) of population experienced decrease in the prolapsing symptoms (Table 3).

## Pain during Procedure

Pain while injecting hypertonic saline as sclerosing agent was experienced by 3 (10.71%) patients as compared to 5% phenol in almond oil in which 10 (35.71%) patients experienced pain. On comparison statistical significance was found (p<0.05) (Table 4).

## Other complications

During three sessions of sclerotherapy in both groups no major complication was encountered. Vasovagal attack occurred in one patient of 5% phenol in almond oil group. No such complication was seen in the hypertonic saline group.

Thus from above studies sclerotherapy can be considered as one of the safer option of treatment in grade I and grade II hemorrhoids.

## Discussion

The mean age of presentation in our study was 39 which was comparable to studies by Khan, Malik [21] and Bhuiya et al. [22] and was lower than as compared to western studies like Santos et al. [19]. The reason may be difference in diet, demographic and social factors and small number of patients in our study. The male to female ratio was 3.6:1 and was comparable to studies by Khan N, Malik [21] and Bhuiya et al. [22]. The male female ratio was nearly equal in western studies like Santos et al. [19]. The low incidence in female patients in present study as compared to western studies may be because of social factors, as many females do not report the disease accounting for small number of female patients.

The presenting symptoms of bleeding and prolapse in patients in present study are comparable to the other studies [9,21,22]. There is difference in symptom of constipation which can be explained by difference in dietary habits in various parts of the world and high fiber diet especially in north India. It shows the role of dietary modifications in management of hemorrhoids.

A study reported by Ponsky et al. [12] showed that 23.4%

hypertonic saline was used as a non allergic sclerosant in symptomatic internal hemorrhoids. Bleeding was relieved in 86% of cases and prolapse reduced in 6% of cases. The technique has proven to be well tolerated and associated with high patient satisfaction and low complication rates with no serious complication noted thus showing effectiveness of using hypertonic saline as a sclerosing agent in hemorrhoids [12].

In our study too, excellent results were obtained in 20% hypertonic saline group where 85.7% were relieved of bleeding and 45.8% of cases got relief of prolapse and 54.17% cases experienced decrease in prolapsing symptoms. The difference in relieve of prolapse can be explained by small number of patients involved in study conducted by Ponsky et al. [12]. There is not much literature regarding use of hypertonic saline as a sclerosant in hemorrhoids but there is literature showing its role as a sclerosant in esophageal varices, varicose veins, leg telangiectasia and reticular veins etc.

For effectiveness of 5% phenol as a sclerosing agent, study conducted by Ambrose et al. [3] showed that at 12 months follow up 50% patients were asymptomatic while study by Gartell et al. [4] showed that at 2.75 years follow up 70% patients were asymptomatic. Study conducted by Khan, Malik [21] showed that at 8<sup>th</sup> week 67.3% patients were asymptomatic while study by Bhuiya et al. [22] showed that at 6 months 79.31% patients were asymptomatic. In our study it was 89.25% at the end of 6 weeks follow up. The difference in effectiveness can be explained by duration of follow up in different studies and number of patients. It is clear from various studies that there is a definitive role of 5% phenol as a sclerosing agent in hemorrhoids. The Table 5 shows comparison of requirement of first, second and third session of sclerotherapy for relieving symptoms of hemorrhoids. It is comparable in both the studies.

There is no study available in literature comparing effectiveness of 20% hypertonic saline and 5% phenol in almond oil as sclerosing agent in hemorrhoids although individual study exists. In our study on comparison between hypertonic saline group and 5% phenol in almond oil it was found that hypertonic saline is better than 5% phenol in almond oil both in relieving pain and prolapse as well (Table 6).

As hypertonic saline can be easily administered with fine 18 gauge spinal needles so post sclerotherapy pain and discomfort was less in hypertonic saline group. Procedural bleeding was also less due to use of fine needle. The number of patients who continued to bleed even after three sessions was nil in this group in our study. There was no other serious complication on follow up in this group.

Out of 60 patients 4 (6.67%) were lost in the follow up. Few

patients were found reluctant at their first visit because of fear of the needle or their anticipation of needle being painful. But after due explanation of the procedure they were convinced and subsequently they were cooperative till their further follow up.

Sclerotherapy may be accompanied by certain difficulties particularly for the beginners. One may face difficulty in proper displaying of the hemorrhoids and may inject into the summit of hemorrhoidal tissue. Rather than injecting at their pedicle near the anorectal ring. No serious complication is usually encountered during the procedure except a minor degree of discomfort, pain and post procedure spotting.

## Conclusion

Sclerotherapy is cost effective form of treatment with good results and least complications for grade I and II hemorrhoids especially with minimal prolapse in which the patient can go to his work right after the procedure and there is no need to take off from the work.

Among 20% hypertonic saline and 5% phenol in almond oil as a sclerosing agent in hemorrhoids, 20% hypertonic saline is slightly better than 5% phenol in almond oil both in relieving prolapsed as well as bleeding.

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