

# Comparison of Frequency of Successful Treatment after Sclerotherapy with 5% Phenol in Almond Oil (PAO) with Aluminum Potassium Sulfate and Tannic Acid (ALTA) for Grade-III Haemorrhoids

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## ABSTRACT

**Aim:** To compare the frequency of successful treatment after sclerotherapy with 5% phenol in almond oil (PAO) and aluminum potassium sulfate and tannic acid (ALTA) for grade-III haemorrhoids.

**Design:** The present study was an RCT (randomized controlled trial).

**Study Settings:** This study was carried at Surgical Unit-I of Sir Ganga Ram Hospital, Lahore over 6 months from August 2017 to January 2018.

**Methods:** The present study included 32 patients of either gender with age in the range of 18-60 years presenting with grade-III haemorrhoids which were randomly alienated into two treatment groups. Patients in Group-A received sclerotherapy with PAO while those in Group-B received sclerotherapy with ALTA. Outcome variable was frequency of successful treatment which was labeled on absence of bleeding ( $\geq 2$  weeks) and lack of prolapse on straining 4 weeks after the treatment. Frequency of successful treatment was compared between the groups.

**Results:-** The mean age of the patients was  $49.6 \pm 5.9$  years. There was a male predominance with a male to female ratio of 1.7:1. Both the groups were similar in terms of mean age (p-value=0.84) and age (p-value=0.48) and gender (p-value=0.47) groups distribution. The frequency of successful treatment was significantly higher in patients receiving ALTA (81.3% vs. 25.0%; p-value=0.001) as compared to PAO. Similar significant difference in the frequency of successful treatment was observed between the groups across various subgroups based on patient's age and gender.

**Conclusion:** Sclerotherapy with aluminum potassium sulphate and tannic acid (ALTA) was found superior to conventional practice of phenol in almond oil (PAO) in terms of significantly higher frequency of successful treatment in patients with grade-III haemorrhoids which advocate its preferred use among such patients in future practice.

**Keywords:** Haemorrhoids, Injection Sclerotherapy, Phenol in Almond Oil, Aluminum Potassium Sulphate with Tannic Acid

## INTRODUCTION

Haemorrhoids have attracted the interest of man since the beginning of history, as evidenced by numerous references to this affliction in the Bible and in the earliest recorded literature<sup>1-3</sup>. The reasons for the interest of the general public are the accessibility of the discomfort-producing area and the widespread incidence of the condition<sup>1</sup>. The exact frequency is not known but about 5% of the total population suffers haemorrhoids once in its lifetimes<sup>1,2</sup> and about 10 to 20% of symptomatic patients with haemorrhoids require surgery<sup>3</sup>. There are three main classes of hemorrhoids: external, internal and mixed<sup>2</sup>. External hemorrhoids appear in the perianal tissues, are covered by squamous epithelium, and are due to dilatation of veins connected with the systemic venous system<sup>3</sup>. Internal hemorrhoids, on the other hand, are due to dilatation of veins draining into the portal venous system. The latter have their origin superior to the anal canal and are covered by columnar epithelium<sup>3</sup>. Internal hemorrhoids are described as follows: Degree I—confined to rectum; Degree II—prolapse on straining; Degree III—continuously prolapsed; Degree IV—thrombosed and prolapsed<sup>1-3</sup>.

Surgical treatments comprise the conventional haemorrhoidectomy and the transanal haemorrhoidal dearterialization (THD)<sup>4</sup>. Conventional surgical hemorrhoidectomy is one of the most effective therapies for the bleeding hemorrhoid<sup>1,4</sup>. However, a few days' hospitalization is usually required and the complaint of postoperative pain is often encountered. Conventional sclerotherapy for the bleeding hemorrhoid is an effective and

less-invasive treatment for low-grade hemorrhoids available on an outpatient basis<sup>5</sup>.

In many hospitals, 5% phenol in almond oil (PAO) is used as a sclerosing agent in sclerotherapy for haemorrhoids<sup>4</sup>. The agent injected into the haemorrhoid causes an inflammatory reaction and as the blood flow into the haemorrhoid is disturbed, secondary fibrosis is expedited thus attenuating the haemorrhoid<sup>4</sup>. The results of sclerotherapy are rewarding to the patient because prolapse and bleeding usually stop immediately after the procedure. However, the surgeon may often be perplexed by the lack of any obvious change in the look of the piles at consequent anoscopy, notwithstanding improvement of patient's symptoms<sup>6</sup>.

Aluminum potassium sulfate and tannic acid (ALTA) has been recently developed in Japan as an injecting sclerosing agent for treating haemorrhoids<sup>7</sup>. It results in sclerosis and atrophy of the haemorrhoidal plexus, thereby treating prolapse and bleeding problems<sup>7</sup>. Yano et al.<sup>8</sup> (2015) in a recent randomized controlled trial reported that the frequency of successful treatment after sclerotherapy was significantly higher with ALTA (75% vs. 25.0%; p<0.01) as compared to PAO in patients with grade-III haemorrhoids. In the light of results of the study by Yano et al.<sup>8</sup> sclerotherapy with ALTA can be useful and can bring a hope for non-operative treatment of patients with Grade-III haemorrhoids. However, the evidence was currently limited to a single randomized controlled trial and there was no such local published material. The current practice in our setup was sclerotherapy with PAO or surgery when sclerotherapy fails in patients with Grade-III haemorrhoids. Therefore it was hoped that if the results of the present study confirm the supremacy of ALTA, it would bring a change in current practice and improve the non-operative management of such cases in future practice.

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## MATERIAL AND METHODS

It was an RCT (randomized controlled trial) conducted at Surgical Unit-I of Sir Ganga Ram Hospital Lahore over 6 months from August 2017 to January 2018. Sample size of 32 cases (16 in each group) was estimated with 95% significance level and 80% power of test while considering anticipated frequency of successful treatment after sclerotherapy to be 20% with PAO and 75% with ALTA in patients with Grade-III haemorrhoids<sup>8</sup>. Patients of both genders with ages in the range of 18-60 years presenting with Grade-III haemorrhoids were included in this study. Haemorrhoids were suspected in patients presenting with bleeding per rectum during defecation and something hanging out of anus for  $\geq 8$  weeks. The diagnosis was established clinically by the specialist surgeon on DRE (digital rectal examination; feeling of a soft lump with blood on finger after examination) along with proctoscope (direct visualization of mucosal mass of haemorrhoids). Only the 3<sup>rd</sup> degree haemorrhoids (prolapse outside of anus on straining) were included. Patients with history of abdominal malignancy (ultrasound evidence of abdominal mass), long-standing constipation (frequency of stools  $\leq 1$  in 24 hours for  $\geq 1$  months) and persistent cough ( $\geq 1$  month) and those with recurrent haemorrhoids or failed previous surgical treatment were excluded from study. Study participants were separated randomly into two groups using lottery method. At the night before surgery, these patients were given two bisacodyl suppositories and an enema of normal saline. Patients were advised liquid diet and NPO (nil per oral) 8 hours preceding the surgery. The treatment was conducted in the left lateral decubitus position after attaching an electrocardiograph and oxygen monitor, and no anesthesia was applied around the anus. An anoscope (endoscope) was introduced and retroflexed in the rectum. After observations, the 1<sup>st</sup> step injection was injected to the upper pole of the haemorrhoids. The 1<sup>st</sup> step injection was injected to 2-3 sites (3 mL/injection) while keeping the endoscope retroflexed. The retroflexed scope was then reverted to the normal position, and the 2<sup>nd</sup>-4<sup>th</sup> step injections (2-3 mL/injection) were injected under direct vision while confirming that the sclerosing agent was injected into the submucosa on the monitor. Injections were immediately discontinued if the patient complained of pain. The scope was removed after the injections. The region was then massaged with the index finger to diffuse the sclerosing agent throughout the region in order to avoid retention at the injection site. Patients were discharged home with oral analgesic in the form of Tab. Paracetamol 2 Tab x 8hr for a day and were called for follow-up in OPD after 4 weeks of treatment when treatment success (absence of bleeding  $\geq 2$  weeks and lack of prolapse on straining) was evaluated. All the sclerotherapy sessions were performed by a single consultant surgeon ( $\geq 5$  years' experience) and all the pre and post-operative care as well as evaluation of patients was done by a single resident under supervision of supervisor to eliminate bias. Confounding variables were controlled by strict exclusion criteria and stratification. Mean $\pm$ sd has been calculated for numerical variables like age while frequency and percentage has been calculated for categorical variables like gender and successful treatment. Chi-square test has been used to compare the frequency of successful treatment considering  $p \leq 0.05$  as significant. Frequency of successful treatment has been stratified across age and gender to address affect modifiers and chi-square test has been used considering  $p \leq 0.05$  as significant.

## RESULTS

Patient's age ranged from 37 years to 60 years with a mean age of  $49.6 \pm 5.9$  years. There were 20 (62.5%) male and 12 (37.5%) female patients with a male to female ratio of 1.7:1 as presented in Table 1. Both the groups were similar in terms of mean age ( $p$ -value=0.84) and age ( $p$ -value=0.48) and gender ( $p$ -value=0.47) groups distribution (Table 2). The frequency of successful treatment was significantly higher in patients receiving ALTA (81.3% vs. 25.0%;  $p$ -value=0.001) as compared to PAO as presented in Table 3. Similar significant difference in the frequency of successful treatment was observed between the two groups across various subgroups based on patient's age and gender (Table 4).

Table 1: Demographic characteristics of study participants

Characteristics	Participants
37-49 years	18 (56.3%)
50-60 years	14 (44.7%)
<b>Gender</b>	
Male	20 (62.5%)
Female	12 (37.5%)

Table 2: Demographic characteristics of study groups (n=32)

Characteristics	Phenol in Almond oil (PAO)	Aluminum Potassium Sulphate+Tannic Acid (ALTA)	P value
Age (years)	$49.8 \pm 5.8$	$49.4 \pm 6.1$	0.84
37-49 years	8 (50.0%)	10 (62.5%)	0.48
50-60 years	8 (50.0%)	6 (37.5%)	
<b>Gender</b>			
Male	11 (68.8%)	9 (56.2%)	0.47
Female	5 (31.2%)	7 (43.8%)	

Independent sample t-test and chi-square test, observed difference was statistically insignificant

Table 3: Frequency of successful treatment between study groups (n=32)

Successful treatment	Phenol in Almond Oil (PAO) (n=16)	Aluminum Potassium Sulphate+Tannic Acid (ALTA)
Yes	4 (25.0%)	13 (81.2%)
No	12 (75.0%)	3 (18.8%)

P value 0.001\*

\* observed difference was statistically significant (Chi-square test)

Table 4: Stratification of successful treatment between the study groups (n=32)

Characteristics	Phenol in Almond Oil (PAO) (n=16)	Aluminum Potassium Sulphate+ Tannic Acid (ALTA)	P value
<b>Age in years</b>			
37-49	2/8 (25.0%)	8/10 (80.0%)	0.020*
50-60	2/8 (25.0%)	5/6 (83.3%)	0.031*
<b>Gender</b>			
Male	3/11 (27.3%)	7/9 (77.8%)	0.025*
Female	1/5 (20.0%)	6/7 (85.7%)	0.023*

\*observed difference was statistically significant (Chi-square test)

## DISCUSSION

Anorectal discomfort, bleeding and prolapse are the outstanding symptoms of internal hemorrhoids. Discomfort is manifested by perianal itching, persistent moisture due to mucous secretion and the problem created by a difficulty in maintaining anal hygiene<sup>1</sup>. Symptomatic haemorrhoids are the commonest reason for attendance at the out-patient

department<sup>1-3</sup>. The logistics of a surgical operation to alleviate the symptoms includes the creation of a waiting list for admission which is unacceptable to both patient and surgeon<sup>2,3</sup>. There are financial benefits to both the patients and society by treating symptomatic haemorrhoids in the out-patient department and avoiding inpatient surgery<sup>3</sup>. Non-surgical methods of treatment for haemorrhoids have a tremendous patient appeal not only from the economic point of view but, more important, because they avoid postoperative distress and the relatively prolonged period of perineal discomfort that follows surgical removal<sup>3</sup>. The introduction of out-patient, non-surgical methods of treatment has enormous advantages but cannot in itself be justified unless the morbidity associated with such treatment & the outcome is acceptable<sup>1</sup>.

In the present study, the mean age of the patients was 49.6±5.9 years. Jeong et al<sup>9</sup>. in 2011 and Cho et al.<sup>10</sup> in 2010 reported similar mean age of 51.7±13.2 years and 50.2±15 years in Korean patients undergoing surgical management of haemorrhoids. A comparatively lower mean age of 42.3±11.8 years has been reported by Rotta et al<sup>11</sup> in Brazilian such pts.

We observed that there were 20 (62.5%) male and 12 (37.5%) female patients with a male to female ratio of 1.7:1. Faucheron et al.<sup>12</sup> in 2011 (1.7:1) in France and Walega et al.<sup>13</sup> in 2012 (1.5:1) in Poland described similar male predominance in patients presenting with Grade-III hemorrhoids. Yamoul et al<sup>14</sup> (2.8:1) in Morocco, Rotta et al.<sup>11</sup> (2.2:1) in Brazil, and Athar et al<sup>15</sup> (3.5:1) and Ahmad et al<sup>16</sup> (5:1) in Pakistan reported a much higher male predominance. However, Jeong et al<sup>9</sup> reported a female predominance (1:1.7) in Korean such pts.

We observed that the frequency of successful treatment was significantly higher in patients receiving ALTA (81.3% vs. 25.0%; p-value=0.001) as compared to PAO. Similar significant difference in the frequency of successful treatment was observed between the two groups across various subgroups based on patient's age and gender. The results of the present study are in line with the already published research by Yano et al.<sup>8</sup> (2015) who in a similar randomized controlled trial reported that the frequency of successful treatment after sclerotherapy was significantly higher with ALTA (75% vs. 25.0%; p<0.01) as compared to PAO in patients with grade-III haemorrhoids.

The present study is first randomized controlled trial comparing ALTA and PAO in local population and adds to the limited international research evidence on the topic. The results of the present study confirm the supremacy of ALTA over PAO in terms of significantly higher frequency of successful treatment after sclerotherapy in patients with grade-III haemorrhoids. It can be therefore advocated that in future practice aluminum potassium sulphate and tannic acid should be preferred over conventional practice of PAO for injection sclerotherapy.

A very strong inadequacy of this study was that it didn't compare these two agents in terms of side effects which are also very important and need to be determined before accepting it in routine surgical practice. Such a study is highly recommended in future research.

## CONCLUSION

Sclerotherapy with aluminum potassium sulphate and tannic acid (ALTA) was found superior to conventional practice of phenol in almond oil in terms of significantly higher frequency of successful treatment in patients with grade-III haemorrhoids which advocate its preferred use among such patients in future

**Disclosure of conflict of interest:** None

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