ORIGINAL ARTICLE

Compare the Effectiveness of 5% Phenol Almond Oil Versus Polidocanol Sclerotherapy in Patients with Second Degree Hemorrhoids

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ABSTRACT
Objective: The aim of this is to determine the effectiveness of 5% phenol almond oil versus polidocanol sclerotherapy in patients with second degree hemorrhoids.
Study Design: Randomizedcontrol trial
Place and Duration: Study was conducted at department of Surgery Bakhtawar Amin Medical & Dental College, Multanfor duration of one year i.e from January 2020 to December 2020.
Methods: Total 120 patients of both genders were presented in this study. Patients detailed demographics age, sex and body mass index were recorded after taking informed written consent. Patients were equally divided into groups, I and II. All the patients of 2nd degree hemorrhoids were included. Group Ihad 60 patients and received 3% polidocanol sclerotherapy and group II received 5% phenol almond oil. Satisfaction, bleeding, and pain were measured among both groups in follow up of 4 months. Complete data was analyzed by SPSS 24.0 version.
Results: Total 80 (66.7%) patients were males (40 in each group) and 40 (33.33%) were females. (20 in each group) Mean age of the patients in group I was 50.4 ± 18.4 years with mean BMI 25.4 ± 17.8 kg/m^2 and in group II mean age was 51.4 ± 12.4 years with mean BMI 25.9 ± 21.2 kg/m^2. Rectal bleeding was stopped at first sclerotherapy session and its frequency in group I was 63.33% and in group II was 41.7%. And after 2nd session of sclerotherapy, frequency of stopped bleeding in group I was 95% and in group II was 80%. Treatment sessions was greater in almond phenol group II was 2.26±0.22 as compared to group I 1.88±1.94. Volume of sclerotherapy was lower in group I 4.15±1.69 mL and in group II was 5.30±0.78mL. Satisfaction rate was higher in group I 54 (90%) patients as compared to group II 45 (75%) patients.
Conclusion: We concluded in this study that used of injected (sclerotherapy session) 3% polidocanol in the treatment of internal hemorrhoids was effective, safe and reliable method as compared to 5% phenol almond oil.
Keywords: Phenol, Hemorrhoids, Polidocanol, Sclerotherapy

INTRODUCTION
Two agents are mainly used in injection therapy for hemorrhoids. Five percent almond oil phenol (PAO) has been used worldwide for many decades as a well known agent [1, 2]. The latest introduction in Japan and Korea has included an additional agent, potassium sulfate aluminum and tannic acid (ALTA; Zion, Mitsubishi Pharma Corp., Osaka, Japan). In terms of the effectiveness of grade 3 treatment injection sclerotherapy (IS), the inefficiency of PAO was reported[1], while ALTA had a very successful outcome [3]. IS is not widely used with ALTA in the world, however.

Hemorrhoids are very common anal diseases and are known as hemorrhoids both inside and outside when they are produced on the upper and lower sides of the dentate line. The most common anal condition are internal hemorrhoids, with hemorrhages and prolapse symptoms.

In addition to lifestyle modification and avoidance of pressure on defecation, conservative treatments with suppositories and salt are partial to resolve internal hemorrhoids; however, more treatments may be needed when symptoms worsen and interfere with day-to-day live activities. This condition should be treated without resection, as internal hemorrhoids tend to be benign.

For patients who do not respond to conservative medical care, multiple treatment options are available[4-7]. For a period of more than a century rubber band ligation and sclerotherapy for injection have been the basis of the non-operational treatment and are considered adequately for treating hemorrhoids. A meta-analysis of 18 randomized trials comparing different hemorrhoid therapy approaches concluded that ligation of rubber band was more efficient than sclerotherapy, and that subsequent therapies were less often needed in patients with ligation[8]. Yet sclerotherapy by injection represents an easy and effective palliative treatment for hemorrhoids. The most common sclerosing agent used is phenol almond oil, most productive for hemorrhage, but it has an insufficient effect on prolapse [8].

A new sclerosing agent (ALTA: Zione; Mitsubishi Pharma Corporation, Osaka, Japan) is useful not only for bleeding from, but also for the prolapse of, and can replace, internal bloody fluids[9-11]. ALTA hemorrhoid injection sclerotherapy is now conducted in Japan, with a confirmed effectiveness. ALTA resolves prolapse and hemorrhage after defecation and offers many surgical benefits, as it is linked to less complications such as pain and hemorrhage following treatment and shortens the treatment time. As a novel method of hemorrhoid treatment without resection, ALTA has thus attracted interest.

On the other hand tissue damage was identified for ALTA and for the injection misplaced complications, including the rectal ulcer and rectal stenosis[12]. At workshops ALTA injections were thus recommended following adequate knowledge of anal diseases and a thorough understanding of the technique. ALTA injections were thus recommended. An ALTA-sclerotherapy injection is performed through the so-called '4-step injections' method that varies from that of traditional injection sclerotherapy in that the agent is injected into 4 hemorrhoid regions (top, bottom, middle and bottom sections), using an ALTA-exclusive injection needle. Since ALTA is injected primarily into the submucosa, endoscópic injections using a colonoscope is considered to be relevant to submucosal injections[13]. As the needle for injection for ALTA is too long for use in submucosal layer injections, it can also help avoid misplacement of an endoscopic injection needle[14].

MATERIAL AND METHODS

This randomized control trial study was conducted at department of Surgery Bakhtawar Amin Medical & Dental College, Multan for duration of oneyeari.e from January 2020 to December 2020and it was comprised of 120 patients. Patients detailed demographics were recorded after taking written consent. Patients with previous history of anal surgery, bleeding disorders, pregnant patients and had previous session of sclerotherapy were excluded from this study.

Patients were aged between 20-80 years presented with history of per rectal bleeding and grade 1 and 2 of internal hemorrhoids. Patients were equally divided into groups, I and II. All the patients of 2nd degree hemorrhoids were included. Group I had 60 patients and received 3% polidocanol sclerotherapy and group II received 5% phenol almond oil. Satisfaction, bleeding, and pain were measured among both groups in follow up of 4 months. Chi square and t test was used to analyzed the data. Complete data was analyzed by SPSS 24.0 version.

RESULTS

Total 80 (66.7%) patients were males (40 in each group) and 40 (33.33%) were females. (20 in each group) Mean age of the patients in group I was 50.4 ± 18.4 years with mean BMI 25.4 ± 17.8 kg/m^2 and in group II mean age was 51.4 ± 12.4 years with mean BMI 25.9 ± 21.2 kg/m^2. (Table 1)

Table 1: Baseline detailed demographics of enrolled cases

Variables	Group I (n=60)	Group II (n=60)
Sex		
Male	40 (66.7%)	40 (66.7%)
Female	20 (33.3%)	20 (33.3%)
Mean age	50.4 ± 18.4	51.4 ± 12.4
Mean BMI	25.4 ± 17.8	25.9 ± 21.2

Rectal bleeding was stopped at first sclerotherapy session and its frequency in group I was 63.33% and in group II was 41.7%. And after 2nd session of sclerotherapy, frequency of stopped bleeding in group I was 95% and in group II was 80%. Treatment sessions was greater in almond phenol group II was 2.26±0.22 as compared to group I 1.88±1.94. Volume of sclerotherapy was lower in group I 4.15±1.69 mL and in group II was 5.30±0.78mL. (Table 2)

Table 2: Comparison of efficacy outcomes among both groups

Variables	Group I	Group II
Blockage of bleeding		
At First sclerotherapy session	38 (63.3%)	25 (41.7%)
At 2nd sclerotherapy session	57 (95%)	48 (80%)
Mean sclerotherapy sessions	1.88±1.94	2.26±0.22
Volume of sclerosabnt (mL)	4.15±1.69	5.30±0.78

Satisfaction rate was higher in group I 54 (90%) patients as compared to group II 45 (75%) patients. At first sclerotherapy frequency of no pain in group I was 45 (75%) and in group II was 36 (60%) and after 2nd session no pain observed in group I was 54 (90%) and in group II was 48 (80%). (table 3)

Table 3: Comparison of satisfaction and pain after sclerotherapy between both groups

Variables	Group I	Group II
Satisfaction		
Yes	54 (90%)	45 (75%)
No	6 (10%)	15 (25%)
At first session of sclerotherapy		
Pain	15 (25%)	24 (40%)
No pain	45 (75%)	36 (60%)
At 2nd session of sclerotherapy		
Pain	6 (10%)	12 (20%)
No pain	54 (90%)	48 (80%).

DISCUSSION

The most common cause of painless rectal bleeding in the adult population is internal hemorrhoids. They are also visible in the extreme age, but rare. Inner hemorrhoid treatment varies depending on hemorrhoid grade. Nonoperative techniques are applied to hemorrhoids of grade 1 and 2. Sclerotherapy for injection is a simple, secure and workable non-chirurgical solution. There is a lack of comparative analysis of polidocanol and phenol as injection sclerotherapy in several studies compared with other types of therapy for hemorrhoids.

In present study 120 patients of both genders with ages 20-80 years were presented. Mostly were males 66.7%. Patients were divided into two groups I (3% Polidocanol) and II(5%phenol almond oil). Mean age of the patients in group I was 50.4 ± 18.4 years with mean BMI 25.4 ± 17.8 kg/m^2 and in group II mean age was 51.4 ± 12.4 years with mean BMI 25.9 ± 21.2 kg/m^2.2-sclerotherapy sessions were implemented on patients of internal hemorrhoids. Rectal bleeding was stopped at first sclerotherapy session and its frequency in group I was 63.33% and in group II was 41.7%. And after 2nd session of sclerotherapy, frequency of stopped bleeding in group I was 95% and in group II was 80%. These results were comparable to the many previous studies.[15,16]

Treatment sessions was greater in almond phenol group II was 2.26±0.22 as compared to group I 1.88±1.94. Volume of sclerotherapy was lower in group I 4.15±1.69 mL and in group II was 5.30±0.78mL.In internal hemorrhoids, individual studies confirm the efficacy of phenol in oil and polidocanol sclerotherapy [17,18]. Similar studies comparing the two are missing, however. Nijhawan et al. [20] conducted 1.5 percent polidocanol video-endoscopic injection sclerotherapy and showed the median therapy success sessions to 1.2. In a German analysis, 1.42±0.64 was found to be essential to successfully use polidocanol for sclerotherapy. [21]

In present study satisfaction rate was higher in group I 54 (90%) patients as compared to group II 45 (75%) patients. At first sclerotherapy frequency of no pain in group I was 45 (75%) and in group II was 36 (60%) and after 2nd session no pain observed in group I was 54 (90%) and in group II was 48 (80%). Madhumita et al. [17] announced that 89.66% of the patients had satisfactory results after three doses of injection polidocanol. 39 of 58 (67.24%) patients had good outcomes following the initial injection dose. The second injection dose of the remaining 19 patients was given, of which 11 (57.89%) were effective. Just in two (25 percent) cases the third injection dose offered to the other eight patients was satisfactory. Six cases (10.34%) did not show any reaction after three doses of injection. It is noted in Kuleshrestha that 78.86% (265/336) of patients were cured with polidocanol sclerotherapy, 17.86% (60/336) improved, 1.986% [19] of the patients were uncured. Of 336 patients, 15 (4.4%) were repeated and 17 (5.05%) were subsequently ill.[18]

Patients receiving polidocanol were even more pleased than patients receiving phenol with respect to patient satisfaction. Other individual studies using phenol in oil and polidocanol have shown similar results. The higher level of patient satisfaction is due to the relatively small amount of sclerosant needed for polidocanol community sclerotherapy. The smaller number of sclerotherapy sessions needed to achieve the result can also be linked. To conclude, polidocanol was found to be more effective than phenol when utilized for injection sclerotherapy in the treatment of internal hemorrhoids in the first and second degrees. After the second session, polidocanol was highly successful in the treatment of internal hemorrhoids of the first and second grade. The two groups had similar problems and patient satisfaction.

CONCLUSION

We concluded in this study that used of injected (sclerotherapy session) 3% polidocanol in the treatment of internal hemorrhoids was effective, safe and reliable method as compared to 5% phenol almond oil.

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