ORIGINAL ARTICLE

Safety and efficacy of single session 5% phenol almond oil injection sclerotherapy in second degree haemorrhoids

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Abstract:
Objective: To determine safety and efficacy of single session 5% phenol almond oil sclerotherapy in second degree haemorroids.
Study design: Cross sectional
Study duration: Study duration was 6 months (January 2019-June 2019).
Study settings: Study was conducted at Hayatabad Medical Complex (HMC), Peshawar.
Material and Methods: A sample size of 150-patients was calculated using WHO calculator. Patients were selected with non probability consecutive sampling. Patients were given 5% phenol almond oil injection and followed after 4 weeks for safety and efficacy measurement. SPSS version 24 was utilized for data collection. Chi-square and fissure exact test was applied. P value ≤0.05 was considered significant.
Results: Total 150 patients were included in study. There were 100(66.7%) males and 50(33.3%) females. Mean age of patients was 40.8±8.8SD. Degree of resolution was ≤90% in 64(42.7%) and >90% in 86(57.3%) patients. Treatment satisfaction was seen in 66.7% and acceptability in 73.3% patients. Anal bleeding was seen in 13(8.7%), anal protrusion in 12(8%), anal discharge in 13(8.7%) and pruritus ani in 10(6.7%) patients. A significant association between degree of resolution and number of haemorrhoidal tissue (p=0.000), satisfaction (p=0.02), however, insignificant association with acceptability (p=0.06) was found.
Conclusion: Injection sclerotherapy 5% phenol almond oil is safe, effective and acceptable treatment for second stage of haemorrhoids with limited complications.

Keywords: 2nd degree Haemorrohoids, injection sclerotheapy, 5% phenol almond oil

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Introduction:
Haemorrhoids are defined as pathological changes associated with anal cushions. These changes include connective tissue rupture within cushions leading towards vascular plexus enlargement.[1] Haemorrhoids pathogenesis showed symptoms of swelling, bleeding, seepage and prolapse as a result of peri-natal skin irritation and disruption of fine tuning continence. An estimated prevalence of haemorrhoids ranges 50-85%, globally.[2] However, prevalence of haemorrhoids is 75% in developing countries.[3] Haemorrhoids are very common (1 in 4 of population) and leads to significant community and hospital burden. Evidence exist that 20,000 haemorrhoidal procedures occur each year in United Kingdom (UK).[4]

Golighar classification system is used to classify haemorrhoids into four grades or degrees. In 1st grade hemorrohoids do not prolapse, however, they bleed. In 2nd degree of haemorrhoids bleeding and prolapse both occurred (both phenomenon decrease with spontaneous defeacation). In third grade, bleeding and prolapsed need to be reduced manually while in 4th degree permanent prolapsed occur at anal verge that cannot be reduced.[5]

Management of haemorrhoids varies depending upon the options available. Conservative management of haemorrhoids includes diet and lifestyle management. Fibre is used as traditional treatment for prevention of haemorrhoidal symptoms. Excessive use of oral fluids, avoid

straining, constipation inducing medication and regular exercise can be helpful in haemorrhoidal management. Drug therapy includes use of antiseptics, combination of steroids, barrier creams and anaesthetics are effective in temporary relief for acute symptoms. However, counter remedies are venotonic therapies and oral flavonoid drugs. These remedies control acute bleeding by reducing venous capacity, increasing vascular tone, anti inflammatory effects and lymphatic drainage facilitation.[6]

Outpatient interventions include rubber band ligation, injection sclerotherapy and infrared coagulation. Other therapies include bipolar, direct current and radiofrequency ablation therapy, combination therapy (RBL with injection sclerotherapy or infrared coagulation). Surgical therapy includes haemorrhoidectomy and haemorrhoidal artery ligation.[7]

Injection sclerotherapy with 5% phenol in almond oil is very common and associated with lower mucosal necrosis risk. The modality is indicated in patients with bleeding as major symptoms and where conservative therapy did not respond.[8] Literature reported that patients with advance cirrhosis, immunocompromized patients and patients with secondary haemorrhages (using anticoagulants) are suitable for injection slecrotherapy with 5% phenol in almond oil.[9] A similar study reported that bleeding was chief symptom with 92.3% resolution in 5% phenol almond oil group. Anal protrusion was resolved in 89.1% while overall complication rate was 3.6% (anal mucosal ulceration was only complication).[10]

Limited data is available on understanding safety and efficacy of sclerotherapy with 5% phenol in almond oil. Present study aims to determine safety and efficacy of single session 5% phenol almond oil sclerotherapy in second degree haemorroids.

Material and Methods:

A cross sectional study was conducted at department of surgery, Hayatabad Medical Complex (HMC), Peshawar. Study duration was 6-months (January 2019-June 2019). A sample size of 150-patients was calculated with 5% significance level, 95% confidence interval and 89%[11] bleeding resolution through WHO calculator. Non probability consecutive sampling was used for patients selection. Ethical permission was taken from ethical committee of hospital. Consent forms were taken from all willing participants. Patients with age ≥18 years, both genders and were diagnosed with 2nd degree of haemorrhoids, patients with no significant co morbidity (that can interfere with responding and communication of patients) were included in study. Exclusion criterion was based upon patients hypersensitivity to phenol, patients with retroviral diseases, malignancies, using anticoagulants, patients with inflammatory bowel diseases, faecal incontinence, patients with ano-rectal lesions (fistula-in-ano, anorectal neoplasia, fissure-in-ano, skin tags, perianal dermatoses), patients underwent anorectal surgery previously. Clinical assessment includes protoscopy of all patients followed by urine analysis and packed cell volume. Patients age > 50 were undergone colonoscopy for exclusion of other bleeding sources. Pre-operative antibiotics were administered before procedure initiation (intramascular gentamicin 80 mg). Procedure was initiated with administration of 2% topical ano-rectal lignocaine hydrochloride gel. Rectal examination was used for identification of haemorrhoidal swellings. 5% phenol almond oil (1-2ml) was injected using 23 guage needle in each haemorrhoidal swelling base at submucosal plan (1cm above dentate line). Post-operative oral analgesics were administered (50mg tramadol hydrochloride). Patients were followed after 4 weeks. Follow up measurements were taken for efficacy (Number of haemorrhoidal tissue, duration of first symptom, degree of bleeding resolution, patients satisfaction and acceptability), safety (pain, anal bleeding, anal protrusion, anal discharge and pruritus ani. Data was cleaned and analyzed in SPSS version 24. Frequency and percentages were calculated for qualitative data while mean and standard deviation were determined for descriptive data. Chi-square test was applied. P value ≤0.05 was considered significant.

Table 1*: Association between degree of resolution and other independent variables*

	Degree of resolution			
Age	**≤90%**	**>90%**	**Total**	**P value**
18-40 years	52(34.7%)	31(20.7%)	83(55.3%)	0.000
40-60 years	12(8%)	55(36.7%)	67(44.7%)	
Gender				
Male	44(29.3%)	56(37.3%)	100(66.7%)	0.72
Female	20(13.3%)	30(20%)	50(33.3%)	
No of haemorrhoidal tissue				
One	28(18.7%)	3(8.7%)	41(27.3%)	0.000
Two	18(12%)	48(32%)	66(44%)	
Three	18(12%)	25(16.7%)	43(28.7%)	
Satisfaction				
No	28(18.7%)	22(14.7%)	50(33.3%)	0.02
Yes	36(24%)	64(42.7%)	100(66.7%)	
Acceptability				
No	12(8%)	28(18.7%)	40(26.7%)	0.06
Yes	52(34.7%)	58(38.7%)	110(73.3%)	
Total	64(42.7%)	86(57.3%)	150(100%)	

Table 2*: Association between degree of resolution and safety*

	Degree of resolution			
Pain	**≤90%**	**>90%**	**Total**	**P value**
Mild	46(30.7%)	20(13.3%)	66(44%)	0.000
Moderate	13(8.7%)	43(28.7%)	56(37.3%)	
Severe	5(3.3%)	23(15.3%)	28(18.7%)	
Anal bleeding				
No	61(40.7%)	76(50.7%)	137(91.3%)	0.15
Yes	3(2%)	10(6.7%)	13(8.7%)	
Anal protrusion				
No	62(41.3%)	76(50.7%)	138(92%)	0.07
Yes	2(1.3%)	10(6.7%)	12(8%)	
Anal discharge				
No	56(37.3%)	81(54%)	137(91.3%)	0.24
Yes	8(5.3%)	5(3.3%)	13(8.7%)	
Pruritus ani				
No	62(41.3%)	78(52%)	140(93.3%)	0.19
Yes	2(1.3%)	8(5.3%)	10(6.7%)	
Total	64(42.7%)	86(57.3%)	150(100%)	

Results:

Total 150-patients were included in study. There were 100(66.7%) males and 50(33.3%) female. Mean age of patients was 40.8±8.8SD. There were 83(55.3%) patients in age group 18-40 years and 67(44.7%) patients in age group 40-60 years of age group. Mean duration of 1st symptom was 5.3 months ±1.6SD. Number of haemorrhoidal tissue was 1 in 41(27.3%) patients, 2 in 66(44%) patients and 3 in 43(28.7%) patients. Among all the patients 150(100%), 100(66.7%) were satisfied while 50(33.3%) were not satisfied. Out of all patients, acceptability was seen in 110(73.3%) while 40(26.7%) did not show acceptability. Pain was found to be mild in 66(44%) patients, moderate in 56(37.3%) and severe in 28(18.7%) patients. Degree of resolution was ≤90% in 64(42.7%) and >90% in 86(57.3%) patients. Anal bleeding was seen in 13(8.7%), anal protrusion in 12(8%), anal discharge in 13(8.7%) and pruritus ani in 10(6.7%) patients as shown in figure 1.

Majority of patients in age group 40-60 years had resolution degree >90% as compared to patients in age group 18-40 years (36.7% vs 20.7%, p=0.000). Majority of males had degree of resolution >90% as compared to females (37.3% vs 20%, p=0.72). A significant association between degree of resolution and number of haemorrhoidal tissue (p=0.000), satisfaction (p=0.02), however, insignificant association with acceptability (p=0.06) as shown in table 1.

Among all the patients who had ≤90% degree of resolution, 46(30.7%) has mild pain, 13(8.7%) had moderate and 5(3.3%) had severe pain. Among all the patients who had degree of resolution >90%, 20(13.3%) had mild pain, 43(28.7%) had moderate and severe in 23(15.3%) patients (p=0.000). There was an insignificant association between degree of resolution and anal bleeding (p=0.15), anal protrusion (p=0.07), anal discharge (p=0.24 and pruritus ani (p=0.19) as shown in table 2.

Patient satisfaction is significantly associated with Pain (p=0.00), anal protrusion (p=0.009), anal discharge (p=0.03) while insignificantly associated with Anal bleeding (p=1.00) and pruritus ani (p=0.497). Acceptence is significantly associated with pain (p=0.000), anal bleeding (p=0.000), anal protrusion (p=0.01), anal discharge (p=0.02) while insignificantly associated with pruritus ani (p=1.00).

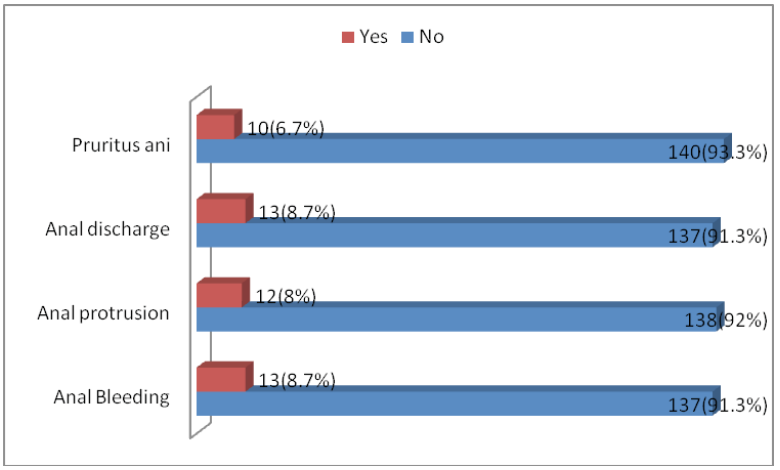

Figure 1: Safety of Treatment

Discussion:

Since centuries, haemorrhoids are defined as diseases entity. Injection sclerotherapy is reported as primary treatment for haemorrhoids. In present study, majority of males were diagnosed with haemorrhoids as compared to female (66.7% vs 33.3%). However, similar study reported an equal prevalence of haemorrhoids in both sexed while exact statistics are found to be conflicting.[12]

Literature reported that current treatment of haemorrhoidal diseases need to be fast, painless and effective to be carried out in clinical practice without anesthesia.[13] In present stud, 5% phenol in almond oil sclerotherapy is used for 2nd degree haemorrhoids. Johanson et al reported that injection sclerotherapy is easy method that can be simply practiced without fancy equipments and anesthesia.[14] Gazet et al reported that phenol almond oil injection sclerotherapy can be done in remote areas of developing countries where electricity is not available and majority of population using torch lights.[15]

In present study, degree of resolution was >90% in 57.3% patients. Johanson et al reported that degree of resolution in 3rd grade haemorrhoids with 5% phenol almond oil injection sclerotherapy was 88.7% from baseline.[16] Pigot et al reported that degree of bleeding resolution in 1st and 2nd grade of haemorrhoids is 91% with injection sclerotherapy of 5% phenol almond oil.[17] In present study treatment satisfaction was seen in 66.7% and acceptability in 73.3% patients. Similar study reported that majority of patients treated with injection sclerotherapy were satisfied with treatment (59.4%) while acceptability of treatment was moderately high (75%).[18]

In present study, Anal bleeding was seen in 13(8.7%), anal protrusion in 12(8%), anal discharge in 13(8.7%) and pruritus ani in 10(6.7%) patients. Lunniss et al reported that anal bleeding and prolapse was seen in 6% patients treated with injection sclerotherapy of 5% phenol almond oil.[19] Another similar study reported that anal bleeding and discharge after 3 months of injection sclerothery was 4% in patients of 1-2nd degree haemorrhoids.[20]

In present study majority of patients had mild to moderate pain 44%-37.3%. Acheson et al reported that injection sclerothery treatment with 5% phenol almond oil is painless and better tolerated as compared to other treatments.[21] Evidence exist that only 4% patients reported with severe pain after sclerotherapy treatment.[22]

Limitation: Small sample size and conduction of study at single center limits generlisability of study.

Conclusion:

Injection sclerotherapy 5% phenol almond oil is safe, effective and acceptable treatment for second stage of haemorrhoids with limited complications. There is need to conduct further randomized controlled trial at international level to understand details efficacy and cost of treatment.

Conflict of interest: None

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Role and contribution of authors:

Dr. Saeed Khan, collected the data of this study and also collected references and did the initial writeup

Dr. Bakhtiar Ullah, colelcted the data and helped in introduction writing.

Dr. M Mussadiq Jafri, helped in collecting the data, review the article and made useful changes.

Dr. Siddique Ahmad, critically review the article and made the final chages.

Dr. Amir Zeb, helped in collecting the data, references and helped in interpretation of data

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