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COMPARISON OF FOAM POLIDOCANOL AND LIQUID POLIDOCANOL SCLEROTHERAPY IN TREATMENT OF GRADE II AND GRADE III HEMORRHOIDS IN A TERTIARY CARE HOSPITAL, SALEM

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Abstract

Introduction: Patients with hemorrhoids if not managed properly may have significant high morbidity. There is no literature available for comparing the outcomes of foam polidocanol with liquid polidocanol for treatment of grade 2 and 3 hemorrhoids and hence we are pursuing this study. **Aim :**To compare the efficacy of foam polidocanol to liquid Polidocanol sclerotherapy in treating symptomatic grade II and III hemorrhoidal disease. **Methodology:**68 patients volunteered for the study. Patient were randomized into liquid and foam group by using block randomization separately for grade 2 and 3 hemorrhoids. In Liquid group, 2ml of 3% polidocanol was injected at the base of hemorrhoids .In foam group 1ml of 3% polidocanol with 7 ml air was used to create foam immediately before injection .Sclerotherapy was done for both groups (maximum of 2 sittings) and patients were followed up at week1,2 and 4 and findings based on bleeding , pain , perianal itching and reduction in hemorrhoid size was noted at each follow up. **Results:** There is significant lesser amount of sclerosant used in foam with mean sclerosant injected in ml is 2.06 and 1.44 (p value - 0.002) in liquid and foam group respectively in grade 2 hemorrhoids and 2.88 and 1.50 (p value-0.001) in liquid and foam in grade 3 hemorrhoids respectively. Foam group had lesser incidence of peri-anal itching than liquid group at week 1 (p value-0.04) for grade 2 hemorrhoids but in further weeks it is not significant. **Conclusion :**Foam sclerotherapy and liquid sclerotherapy with 3% polidocanol have equal efficacy at week 4 of sclerotherapy.In Foam sclerotherapy significantly lesser sclerosant was needed to be injected there by subjecting the patients to lesser risk of local complications.

Keywords: Foam Polidocanol, Liquid Polidocanol, Haemorrhoids, Sclerotherapy, Pain

INTRODUCTION

Hemorrhoids is a common disease of the anal region and constitutes majority of colorectal investigations (1) Its incidence are often seen at any age and in both genders equally.(1)It is estimated that 50-85% of individuals round the world had haemorrhoids[1].·Hemorrhoids, generally has the peak prevalence at the age of 45 to 65 years and affects both the genders[2]. Main symptoms associated with hemorrhoids are bleeding, itching, soiling and pain[3].

Hemorrhoid disease has a high impact on quality of life and can be managed with a multitude of surgical and nonsurgical treatment[4]. Hemorrhoids are usually treated with a conservative approach using methods such as lifestyle modification, fiber supplement, suppository delivered anti-inflammatory drugs and administration of venotonic drugs. Non-operative approaches include sclerotherapy, rubber band ligation, laser therapy.Surgical approach is indicated when nonsurgical approaches have failed or complications have occurred[5]. The surgical approaches for treating hemorrhoids like hemorrhoidectomy and stapled hemorrhoidopexy have postoperative pain and morbidity such as anal stricture and incontinence[6].

We come across many cases of hemorrhoid in our OPD. Hemorrhoids often cause troublesome symptoms to the patients. Patients with hemorrhoids if not managed properly may have significant high morbidity. Earlier most of the patients with hemorrhoids were subjected to surgery. Since the introduction of non-surgical modalities for hemorrhoids ,sclerotherapy has become one of the leading modalities in treatment of grade 1 and grade 2 hemorrhoids .Sclerotherapy can be done on opd basis and as there is no requirement of anesthesia it can be done across all patients including those who are at high risk for anesthesia . It is significantly cost effective and patients can resume work on the same day. There are many sclerosants available in the market. It has been proved that 3% polidocanol is one of the best choice of sclerosants as it is easily available, cost effective and have good outcomes when compared to other sclerosants. Foam sclerotherapy has shown significant results when compared to liquid sclerotherapy in cases of grade 1 hemorrhoids. So far, there is no literature available for comparing the outcomes of foam polidocanol with liquid polidocanol for treatment of grade 2 and 3 hemorrhoids and hence we are pursuing this study.

AIMS AND OBJECTIVES

To compare the efficacy of foam polidocanol to liquid Polidocanol sclerotherapy in treating symptomatic grade II and III hemorrhoidal disease. To compare the two groups with reference to:

a) Number of sittings of sclerotherapy required to stop bleeding
b) Reduction of hemorrhoid size
c) Amount of sclerosant injected
d) Time period for stoppage of bleeding after sclerotherapy session
e) Complications

MATERIAL AND METHODS

This was a Comparative Study which was conducted at the Vinayaka Mission's Kirupananda Variyar Medical College and Hospital,Salem .This study was conducted from May2022 to May2023, patients above the age of 18 years participated in this study. Written informed consent was obtained from the patient to participate in the study.

Study Population: Patients having symptomatic Grade II and III haemorrhoids.

Sample size : A total of 68 patients fulfilled the eligibility criteria, with each group consisting of 34 patients. The distribution within the groups was as follows: 17 patients

in the Foam Group with Grade II Hemorrhoids, 17 patients in the Foam Group with Grade III Hemorrhoids, 17 patients in the Liquid Group with Grade II Hemorrhoids, and 17 patients in the Liquid Group with Grade III Hemorrhoids.

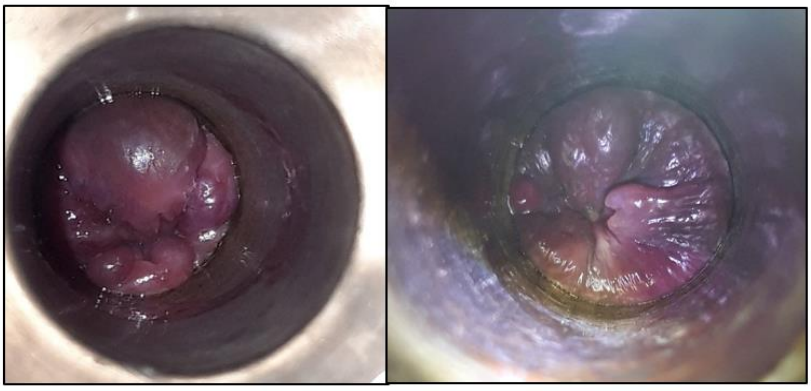
Sampling Method: Block Randomization separately for grade II and III haemorrhoids

The study's inclusion criteria encompassed individuals aged 18 years and above, who were experiencing symptoms related to Grade II and III hemorrhoids. On the other hand, certain conditions led to exclusion from the study, such as acute inflammation in the anal region, thrombosed hemorrhoids, co-existing anal fissures, bleeding diathesis (tendency to bleed), known cases of rectal or anal canal malignancy, pregnant women, and those who had received sclerotherapy within the past 12 months.

Procedure:

All patients undergoing study underwent Digital Rectal Examination followed by proctoscopy to diagnose hemorrhoids and to asses sphincter tone. No antibiotic was given before procedure. Sclerosant was injected using a proctoscope. According to Blanchard's technique , the sclerosant was injected in submucosa at the base of each hemorrhoid with help of 24G spinal needle. In the liquid group, the sclerosing agent 3%polidocanol was used for sclerotherapy. The doses per treatment session was 2 mL (60mg) of liquid 3 %polidocanol. In foam group the standardized foam was prepared by Tessari method with 1 mL (30 mg) liquid 3%polidocanol and 7mL air using a three-way connector and two syringes. It created a fine-bubbled, homogenous and stable micro foam. The polidocanol foam was made just before each session. Patients who required second session of sclerotherapy were given after 2 weeks (Maximum-2 sclerotherapy sessions/Patient). One patient was symptomatic after 2 sessions of sclerotherapy for which Open hemorrhoidectomy was done

Post -Procedure: Both groups will be treated with T. Paracetamol 500mg SOS and dietary Modifications (High fiber Diet, Plenty of oral fluids, emollients) for 1 month Follow up was done at week 1, week 2, week 4 after sclerotherapy session. Bleeding, pain, perianal itching and reduction in hemorrhoid size was seen at follow-up and findings were noted based on the scoring system.Scores were given at every follow-up with 12 being the best outcome and 4 being the worst outcome(figure-1).



Pre-sclerotherapy Post foam sclerotherapy at week 4

Fig 1: Comparision of hemorrhoids before and after sclerotherapy sessions

RESULTS

A Comparative study was done to compare the efficacy and complications of foam polidocanol to liquid polidocanol in treatment of grade 2 and grade 3 hemorrhoids who presented to general surgery OPD Vinayaka Mission's Kirupananda Variyar Medical College and Hospital,Salem.68 patients gave consent and enrolled for our study, out of which 1 patient was excluded as patient had adenocarcinoma of rectum and 2 patients dropped out of the study. Block randomization was done separately for grade 2 and grade 3 hemorrhoids. Group 1 was given liquid sclerotherapy and group 2 was given foam sclerotherapy. All patients were followed up at week 1,2,4 and both groups were assessed for bleeding, pain, reduction in hemorrhoids size, perianal itching according the scoring system along with total sclerosant injected and number of sessions of sclerotherapy. All data was entered into a Data Collection Proforma Sheet and were entered into Excel (MS Excel 2011) . Statistical analysis was carried out using SPSS version 19.0 (IBM SPSS, US) software with Regression Modules installed.

Bleeding:

In Group 1 with Grade 2 hemorrhoids, out of 17 patients, 35.3% (6 patients) had a score of 2, and 64.7% (11 patients) had a score of 3. In Group 2 with Grade 2 hemorrhoids, out of 16 patients, 25% (4 patients) had a score of 2, and 75% (12 patients) had a score of 3. The p-value was 0.52, indicating no significant difference.For Grade 3 hemorrhoids, in Group 1, out of 16 patients, 31.3% (5 patients) had a score of 2, and 68.8% (11 patients) had a score of 3. In Group 2, out of 16 patients, 25% (1 patient) had a score of 2, and 93.8% (15 patients) had a score of 3. The p-value was 0.07, suggesting that there is a notable closeness to significance.

Pain:

In Group 1 with Grade 2 hemorrhoids, among 17 patients, 17.6% (3 patients) had a score of 1, 5.9% (1 patient) had a score of 2, and 76.5% (13 patients) had a score of 3. In Group 2, out of 16 patients with Grade 2 hemorrhoids, none had a score of 1, 12.5% (2 patients) had a score of 2, and 87.5% (14 patients) had a score of 3. For Grade 3 hemorrhoids, in Group 1 with 16 patients, 12.5% (2 patients) had a score of 1, 25% (4 patients) had a score of 2, and 62.5% (10 patients) had a score of 3. In Group 2, out of 16 patients with Grade 3 hemorrhoids, none had a score of 1, 12.5% (2 patients) had a score of 2, and 87.5% (14 patients) had a score of 3. While Group 1 had more cases with score 1 pain compared to Group 2 at week 1, this difference was not statistically significant.At week 4 all patient across both the groups were pain free.

Peri anal itching:

Amongst the 17 patients in Group 1 Grade 2 hemorrhoids 4(23.5%) and 13(76.5%) patients got a score of 2 and 3 respectively and amongst the 16 patients in Group 2 grade 2 hemorrhoids 0(0%) and 16(100%) got a score of 2 and 3 respectively. None of the patients in group 2 had any perianal itching at week 1 is of significance with a p-value of 0.04. Amongst the 16 patients in Group 1 Grade 3 hemorrhoids 1(6.3%) and 15(93.8%) patients got a score of 2 and 3 respectively and amongst the 16 patients in Group 2 grade 3 hemorrhoids 4(25%) and 12(75%) got a score of 2 and 3 respectively. After week 4 none of the patients across both the groups had peri-anal itching.

Hemorrhoid Size:

Amongst the 17 patients in Group 1 Grade 2 hemorrhoids, 10(58.8%) and 7(41.2%) patients got a score of 2 and 3 respectively and amongst the 16 patients in Group 2 grade 2 hemorrhoids 9(56.3%) and 7(43.8%) got a score of 2 and 3 respectively. Amongst the 16 patients in Group 1 Grade 3 hemorrhoids, 4(25%),9(56.3%) and 3(18.8%) patients got a score of 1,2 and 3 respectively and amongst the 16 patients in Group 2 grade 3 hemorrhoids 0(0%),14(87.5%) and 2(12.5%) got a score of 1,2 and 3 respectively. Reduction in hemorrhoids is better for grade 2 than grade 3 across both the groups

Total Score

Table 1: Comparison of total score for Grade 2

	GRADE 2	Mean	Std. Deviation	P VALUE
GROUP1	Week 1 Total Score	9.41	1.372	0.001
	Week 2 Total Score	10.94	.966	
	week4 Total score	11.41	.507	
GROUP2	Week 1 Total Score	10.06	1.289	0.001
	Week 2 Total Score	11.25	.577	
	week4tot	11.63	.500	

There is significant improvement (p value - 0.001) in total score across both groups from week 1 to week 4 .

Table 2: Comparison of total score for Grade 3

	GRADE 3	Mean	Std. Deviation	P VALUE
GROUP1	Week 1 Total Score	9.41	1.372	0.001
	Week 2 Total Score	10.94	.966	
	week4 Total score	11.41	.507	
GROUP2	Week 1 Total Score	10.06	1.289	0.001
	Week 2 Total Score	11.25	.577	
	week4tot	11.63	.500	

There is significant improvement (p value - 0.001) in total score across both groups from week 1 to week 4 .

Amount Of Sclerosant Injected

Amount of sclerosant required in group 2 is significantly less than group 1 with a p value of 0.006 and 0.001 for grade 2 and 3 respectively.

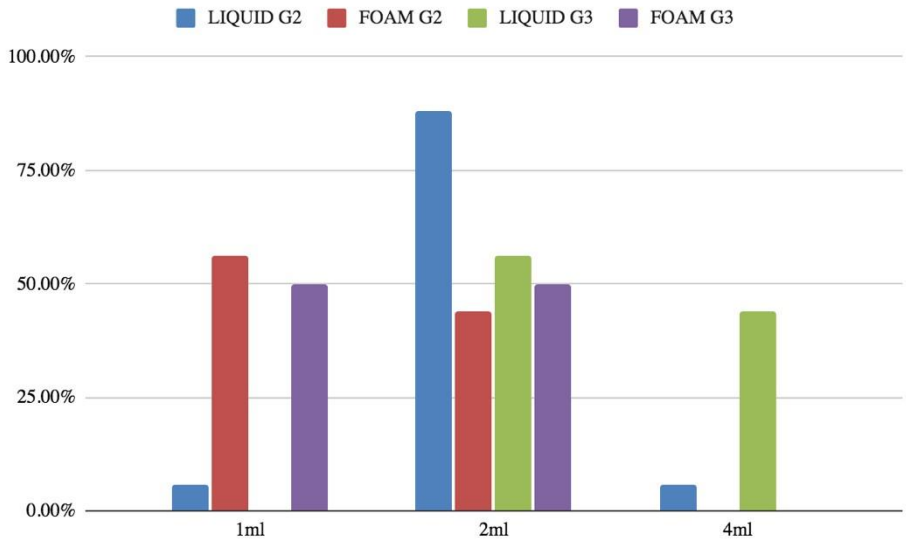


Fig 2: Comparison of amount of sclerosant injected in ml

As shown in figure -2 Mean sclerosant in injected in ml is 2.06 and 1.44 in group 1 and 2 respectively in grade 2 hemorrhoids with a significant p value of 0.002 .Mean sclerosant in injected in ml is 2.88 and 1.50 in group 1 and 2 respectively in grade 3 hemorrhoids with a significant p value of 0.001. Thus significantly lesser amount of sclerosant is required in foam group when compared with liquid group .Number of sittings required in both the groups in grade 2 and 3 is almost similar.

DISCUSSION

The result of this comparative study demonstrated that total amount of sclerosant required in ml is significantly less in foam group than liquid group in grade 2 and 3 hemorrhoids with p-value of 0.006 and 0.001 respectively (table 1). With this analogy we can say that foam 3% Polidocanol is superior to liquid 3%polidocanol as significantly lesser amount of foam causes the same effect as liquid 3% polidocanol.

The success rate of sclerotherapy in stopping bleeding in this study is above 95% in liquid group and 100 % in foam group. Ambrose et all in their study showed using high doses of phenol in oil, excellent and improved results could be demonstrated in 84 % of patients[7]. In a study done in South India in 2016 to 2017, the efficacy and safety of sclerotherapy with polidocanol 3 % was compared with phenol in oil in the treatment hemorrhoids showed that 60.6 % and 94.7% showed resolution in bleeding after first and second session of 3%polidocanol sclerotherapy respectively[8]. A study in Italy was done in 2007 in which foam sclerotherapy was done with STD in grade 2-4 hemorrhoids which showed bleeding and hemorrhoidal prolapse were resolved with two sclerotherapy sessions and pain disappeared after the first session[9]. Similarly, in our study bleeding was resolved in almost all cases after second sitting but full reduction of hemorrhoids was not achieved in both the groups (table 2) at the last follow up and 3 of our patients in liquid group had some tolerable pain even after 1st week. In a study done by Rathore, published in 2019, showed after giving 3 doses of polidocanol at the interval of three weeks 24 (96%) and 19 (72%) patients showed significant reduction in the size of hemorrhoids and the bleeding was reduced completely in grade 2 and 3 respectively[10-13]. From the remaining patients 4

patients achieved resolution of further 2 sittings of sclerotherapy and 3 patients were subjected to surgical treatment. With this we can conclude that more than 2 sittings of sclerotherapy can lead to satisfactory reduction in hemorrhoid size in grade2 as well as grade 3.

CONCLUSION

In this study we can conclude that foam sclerotherapy and liquid sclerotherapy with 3% polidocanol have equal efficacy at week 4 of sclerotherapy. Immediate local complications like perianal itching is significantly more in the liquid group initially but in the long term both the groups don't have any local complication.

Limitation:

limitation of this study is small sample size and the short follow up of the patients, need to do large group of study across the country.

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Conflict of interest: Nil

Author's contribution: Dr Arun Balaji M S - conceptualization, data curation, investigation, methodology, project administration, visualization, writing—original draft, writing—review and editing; **Dr A.P. Subburaaj** -conceptualization, methodology, writing—original draft, writing—review and editing; **Dr. J. Sridhar** - conceptualization, visualization, supervision, writing—original draft; **Dr Kumaran.K** and **Dr Subalakshmi.P** - methodology, writing—original draft, writing, review and editing. All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work. All authors have read and agreed to the published version of the manuscript.

Data Availability: All datasets generated or analysed during this study are included in the manuscript.

IEC Approval: Institutional Ethics Committee Approval from Vinayaka Mission's Kirupananda Variyar Medical College and Hospital, Salem, Tamil Nadu.Written informed consent was obtained from the participants before enrolling in the study.

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