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Foam Sclerotherapy VS Conventional Sclerotherapy in the Treatment of Multiple Haemorrhoids with 3% Polidocanol: A Comparative Study

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ABSTRACT

The haemorrhoidal disease is of enormous epidemiological and economic relevance, as it represents a common disease worldwide with a peak of prevalence at the age of 45-65 years in both genders. Hemorrhoidal disease is one of the most common benign disorders of the lower gastrointestinal tract. Hemorrhoids per se are vascular cushions forming a gas-tight seal at the anorectal junction and contribute to the physiological continence mechanism. Enlargement of these hemorrhoidal cushions and subsequent sliding into the anal canal or through the anus cause clinical symptoms such as bleeding, mucosal discharge, or pruritus and are the most common complaints defining hemorrhoidal disease. This clinical study is aimed to compare the efficacy and safety of foam sclerotherapy and conventional sclerotherapy in the treatment of multiple haemorrhoids with 3% polidocanol. A single center, comparative study using randomized controlled trial of patients both male and female with symptomatic grade I, II and few III haemorrhoids, divided randomly in to two groups where group A patients were given conventional (liquid) sclerotherapy with 3 % polidocanol and group B patients were given foam sclerotherapy with 3 % polidocanol. This study was conducted at Basaveshwara medical college and hospital, Chitradurga, Karnataka from October 2022 to march 2023. In Group A : Bleeding stopped in 60% of patients with conventional sclerotherapy after 1st session, whereas bleeding was stopped in 92 % of patients in Group B who received foam sclerotherapy. Pain was relieved in 64 % of patients in group A and 80% in group B during 1st sclerotherapy session and in between 1st and 2nd visits, 96% of patients in both groups were relieved of pain 40% of patients in group A were relieved of pruritus during 1st session, whereas 56% were relieved of pruritus in group B .Overall 64% of patients were satisfied in group A and 96% of patients were satisfied in group B. Foam sclerotherapy is a more safer, efficacious, cost-effective, reliable, therapeutic procedure in the treatment of hemorrhoidal disease, when compared with conventional sclerotherapy. Foam sclerotherapy may not help in regression of grade-III haemorrhoids, but can help regress symptoms of grade-I and II haemorrhoids With foam sclerotherapy, injections can be given in ≥ 3 locations , whereas with conventional sclerotherapy, injections were restricted to ≤ 3 places.

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Key Words

Hemorrhoids/hemorrhoidal disease, polidocanol , sclerotherapy, foam therapy, conventional/liquid therapy

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INTRODUCTION

There are few diseases more chronicled in human history than symptomatic hemorrhoidal disease[1,2]. References occur in ancient texts dating back to Babylonian, Egyptian, Greek and Hebrew cultures[1,2]. Included in many of these writings are multiple recommended treatment regimens, including anal dilation, topical ointments and the intimidating red hot poker[3,4]. The hemorrhoidal disease is of enormous epidemiological and economic relevance, as it represents a common disease worldwide with a peak of prevalence at the age of 45-65 years in both genders[5].

Etiology and Pathogenesis: The pathogenesis of hemorrhoidal disease is multifactorial and controversial[6].

- The hyperplasia theory describes disturbance of the drainage of the corpus cavernosum recti (CCR) as a result of increased sphincter resting tone, on the one hand and prolapse of the anal transition zone (ATZ) into the anal canal, on the other.
- The varicose vein theory has been abandoned because patients with portal hypertension do not show an increased incidence of hemorrhoidal disease.
- The anal sliding lining theory is associated with the first theory: increased intraabdominal pressure (during pregnancy or upon straining during dfaecation, especially by constipated patients) results in distension and rupture of submucosal smooth muscle fibers and subsequent prolapse of the ATZ[6].

Clinical Features: The most common complaints of patients with hemorrhodial disease are bleeding upon defecation, pruritus, anal seepage or soiling, anal pain and mucoanal prolapse. For symptomatic assessment, the individual burden of suffering is essential, since asymptomatic piles or skin tags are not an indication for treatment of hemorrhoids.

Classification: The traditional Goligher classification is applied for grading hemorrhoidal disease:

Grade 1: Hemorrhoids do not prolapse at examination and are only visible through a proctoscope.

Grade 2: Hemorrhoids prolapse during defecation but reduce spontaneously.

Grade 3: Hemorrhoids prolapse and need manual repositioning.

Grade 4: Hemorrhoids prolapse but cannot be reduced digitally into the anal canal by the patient.

From a clinical point of view, the Goligher classification is rather rigid, since other symptoms such as mucosal prolapse, fecal incontinence and segmental or circular prolapse of the hemorrhoidal tissue are not included. The classification according to MüellerLobeck[7] also differentiates between acute thrombosed (grade 4a) and chronic fibrosing (grade 4b) haemorrhoids.

Diagnosis: History taking is the most important step toward a diagnosis of hemorrhoidal disease and should include a question about pretreatment for hemorrhoidal complaints. Individual complaints and burden of disease should be taken into account. Questions about pain and discomfort upon defaecation, pruritus, bleeding, soiling, mucosal discharge and any kind of preexisting fecal incontinence, as well as the extent of prolapsing tissue, are mandatory. The position of the patient during examination and surgical intervention depends on the investigator's preference and does not matter from a clinical point of view (either the left lateral, lithotomy, or jack-knife position). Inspection of the perianal region should determine the presence of anal fissures, fistula openings and erythema. A digital rectal examination using the examinor's index finger should exclude tumor masses, polypoid structures, rectoceles and internal fistula openings and should assess the anal resting and squeeze pressures. The Valsalva maneuver can induce any kind of prolapse and facilitates the differentiation bewteen hemorrhoidal and rectal prolapse. Rigid proctoscopy and rectosocopy visualizing at least 15cm of the rectum is a standard requirement before treatment. Colonoscopy is recommended whenever the history suggests anything more than hemorrhoidal symptoms (e.g., colorectal cancer).

Treatment:

Conservative Treatment: Preventive treatment for hemorrhoidal disease should be considered as concomitant therapy (e.g., stool softeners, a fiber-rich diet, sufficient fluid intake and avoiding excessive straining during defecation), independent of the hemorrhoidal grade. Drugs (e.g., suppositories, ointments, creams, flavonoids) can reduce hemorrhoidal symptoms. The effect is characterized by the anti-inflammatory, analgesic and local anaesthetic properties of the drugs. Topical steroids should be applied only for short periods to avoid atrophy of the perianal skin and anoderm. A series of prospective randomized trials highlighted the healing effect of diosmin (flavonoid) regarding the end points of pain, bleeding and pruritus in terms of hemorrhodial disease[8].

Surgical Treatment: The leading indication for invasive techniques is the individual burden of hemorrhoidal disease, rather than grade of hemorrhoidal prolapse, since it is assumed that the associated symptoms are partly independent of the anatomic derangement (Table 1). Non-resecting minimally invasive techniques can be performed on an outpatient basis, with low morbidity. The major target is an induced inflammatory stimulus (e.g., sclerosing injection or rubber band ligation), resulting in "controlled" scarring and thereby fixation of the ATZ and the prolapsed mucosa to the rectal wall.

Table 1: Surgical Treatment of Hemorrhoidal Disease

Nonresection techniques
Sclerosing injection
Rubber band ligation
Infrared coagulation
Laser Hemorrhoidoplasty
Ligation-based techniques
Hemorrhoidal artery ligation without mucopexy
Resection Techniques
Stapled hemorrhoidectoxy
Conventional hemorrhoidectomy
Miligan-morgan
Parks
Ferguson
Fansler-arnold

Recently Minimal Invasive Procedure for Haemorrhoids (MIPH) has evolved as an alternative to these Surgical procedures. Depending on the severity of haemorrhoidal disease, dietary measures, sclerotherapy, rubber band ligation and various surgical procedures (Milligan-Morgan haemorrhoidectomy or Ferguson haemorrhoidectomy) are mainly used for treatment[9,10,11]. Sclerotherapy is defined as the targeted elimination of small vessels, varicose veins and vascular anomalies by the injection of a sclerosant. Polidocanol is the most widely used sclerosant in Sclerotherapy in western countries. Chemical Sclerotherapy has been performed for over 75 years[12]. The direct intravascular injection of liquid or foamed agent stimulates[13,14] endothelial cells damage of target vessels and then stimulates transmural vessel walls. The sclerotherapy damages the vessel wall and transforms it into fibrous tissue[15,16]. This procedure causes minimal discomfort to the patient, negligible blood loss, is less cumbersome, minimal surgical expertise is required and above all is economical. There is no requirement for local anaesthesia or postoperative dressings or any specific care[15-19]. Summarizing all surgical techniques, a tailored approach to hemorrhoidectomy should be applied on an individual basis since the traditional Goligher classification does not discriminate between segmental and complete circular hemorrhodial prolapse. Thus partial hemorrhoidectomies are justified regarding avoidance of overtreatment in patients where additional mucosal prolapse or bleeding hemorrhoids can best be treated by ligation-based techniques. A treatment algorithm is presented in (Fig.1). Hemorrhoidal surgery can be performed on an outpatient basis, especially when using minimally invasive techniques such as rubber band ligation, sclerotherapy and laser hemorrhoidoplasty for grade 1 and 2 hemorrhoids. However, patients must be sufficiently instructed to be readmitted in the case of an emergency.

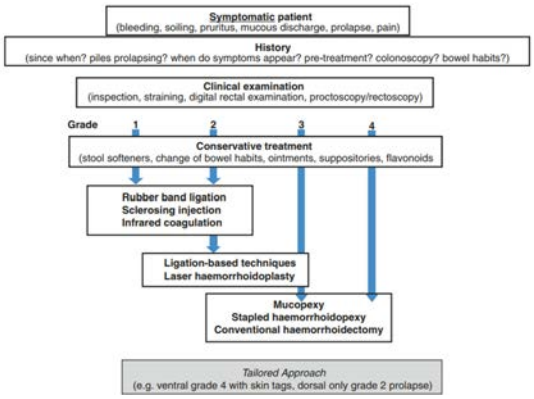

Fig. 1 Treatment Algorithm for Hemorrhoidal Disease.

Source of Data: This study was conducted comprising 50 patients with symptomatic grade 1, 2 and few selected grade 3 hemorrhoids, both male and female patients between age group 18-75 yrs attending the General Surgery outpatient department at Basaveshwara Medical college hospital and research centre, Chitradurga in the period of October 2022 to March 2023.

Inclusion Criteria: Patients both male and female, in the age group of 18-75 years, diagnosed with grade 1, 2 and few selected grade-3 hemorrhoids.

Exclusion Criteria: They were

- (1) Pregnancy.
- (2) anal fissure
- (3) anal infection/suppuration.
- (4) anal pain other than caused by hemorrhoids.
- (5) contraindication to polidocanol use: known allergy (anaphylaxis) to polidocanol.
- (6) Per-rectal bleeding other than anal lesions (ie. Colorectal carcinoma).

Method of Data Collection: All 50 patients, who matched the inclusion criteria , were admitted as a day

care procedure , Patients were encouraged to defecate before the procedure but did not under go any bowel preparation, including cleaning enemas. No prophylactic antibiotics were given. All large and symptomatic hemorrhoids were aimed to be treated at the same session, although a second session might be needed. No sedation was given during procedure. The 50 patients who presented to OPD were randomly equally divided in to two groups Group A(n=25) (conventional sclerotherapy with 2ml of 3% polidocanol) and Group B (n=25) (foam sclerotherapy, with a mixture of 2ml of 3% of polidocanol and 8 ml of air), irrespective of age/gender.

In the first group (Group A), patients received conventional sclerotherapy with 2ml of 3% of polidocanol (sclerosant) into the haemorrhoids. In the second group (Group B), patients received a form of foam sclerotherapy (a mixture of 2 ml 3% polidocanol mixed with 8 ml of air in the ratio of 1:4. Then patients followed up in OPD for progress later and results were tallied accordingly.

Study Medication and Treatment in Our Study: In group A, the sclerosing agent 3 % polidocanol was used for sclerotherapy, considered as conventional sclerotherapy. In Group B, a modified form of sclerotherapy known as foam sclerotherapy (Tessari's technique), known as foam sclerotherapy, where a foam was prepared by mixing 2 ml of 3 % polidocanol and 8ml of air in the ratio of 1:4 alternately by using a 3 way stop-cock and two syringes to generate a fine-bubbled, homogenous and stable microfoam (as depicted in the diagram below, (fig. 2).

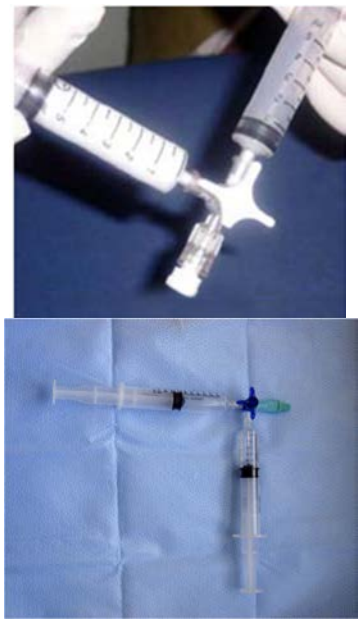

Fig. 2: Showing Preparation of Foam Sclerotherapy

According to Blanchard's technique[17-26], the sclerosant was injected strictly submucosally at the base of each haemorrhoidal node into the surrounding tissue of the feeding vessels at the 3, 7 and 11 o'clock positions. Sclerotherapy sessions were performed on a bi-weekly schedule, until patients were free of perianal bleeding. Four treatment sessions per patient were allowed depending on the treatment success.

Outcome Measures: The primary outcome was the stopping of perianal bleeding after the first sclerotherapy session. Patients were asked to record each bleeding during or directly after defecation in a patient diary. Any visible blood on stool or toilet paper during the day, regardless of whether one or more times, was defined as bleeding for this given day. At each follow-up visit, the patient diary was checked by the investigators and bleeding was defined as persistent if there were at least 2 days with bleeding after day 2 following sclerotherapy, or if there was 1 day with bleeding within the last 3 days before the follow-up visit. Bleeding on the first day after sclerotherapy was judged to be caused by the treatment itself. Based on this definition, the terms "persistent bleeding" and "free of bleeding" are used. In addition, the rate of patients free of bleeding will be described as "success rate" or "successfully treated". Secondary study endpoints were stopping of perianal bleeding after the second and subsequent sclerotherapy sessions, the occurrence of anal pain during and after sclerotherapy, the occurrence of pruritus ani, the satisfaction of patients. At each visit, the patients were asked to report on pain experienced during or directly after sclerotherapy. Pain was recorded directly after sclerotherapy using a three-point scale ("no pain", "little pain" and "severe pain") and during the visits using a three-point scale ("no pain" "during defaecation and "permanent pain"). Similar to the assessment of pain, patients were also asked about pruritus ani using a three-point scale for this variable ("no pruritus", "occasional pruritus" and "permanent pruritus"). Patient satisfaction was evaluated by using a four-point scale ("very satisfied", "satisfied", "less satisfied" and "not satisfied at all"). The study was conducted at a single center as a randomized single blind trial. As liquid polidocanol and foam polidocanol can be distinguished by appearance, it was not possible to blind the investigators. Therefore, blinding was only possible for the patients, who were responsible for the evaluation of the study outcome.

RESULTS AND DISCUSSIONS

Statistical Analysis: Data was entered into Microsoft excel data sheet and was analysed using SPSS ver. 22 software. Categorical data was represented in the form of bar diagrams and pie charts. Chi square test (X^2), (for 2x2 tables only) was used as test of significance for qualitative data.

Table 2: Showing Demographic Data

		Total (n)	Group A	Group B
		50	25	25
Age Group	**18-25 yrs**	7	4	3
	26-35 yrs	11	5	6
	36-45 yrs	6	3	3
	46-60 yrs	20	10	10
	61-75 yrs	6	3	3
Mean Age		43.86 yrs	43.36 yrs	44.36 yrs
Sex ratio	**M/F (%)**	30/20 (60/40%)	17/8 (68/32%)	13/12 (52/48%)

Table 3: Showing Efficacy Outcome

Efficacy Outcome	Group A	Group B	P-value[a] 1st
Cessation of bleeding after sclerotherapy	15 out of 25 (60%)	23 out of 25 % (92 %)	≤ 0.01, significant

a Fisher's exact test

Table 4: Showing Progression of Symptoms

Pain during and after sclerotherapy		Group A (n=25)	Group B (n=25)	p value
Pain during 1st sclerotherapy	No pain	16 (64%)	20 (80%)	Not significant[a]
	Little pain	7 (28 %)	5 (20%)	
	Severe pain	2 (8 %)	0	
Pain in interval between visits 1 and 2	No pain	24 (96%)	24 (96%)	Not significant[a]
	During defecation	1 (4%)	1 (4%)	
	Permanent pain	0	0	
Pruritus during 1st sclerotherapy	No pruritus	10 (40%)	14 (56%)	Not significant[a]
	Occasional Pruritus	14 (56%)	11 (44%)	
	Permanent Pruritus	1 (4%)	0	
Pruritus between visit 1 and 2	No pruritus	18 (72%)	20 (80%)	Not significant[a]
	Occasional Pruritus	7 (28%)	5 (20%)	
	Permanent Pruritus	0	0	

Data are counts (and percentages), a χ2 with test for trend

Table 5: Showing Satisfaction of the Patients Towards the Therapy

	Group A	Group B	P value[a]
Patient satisfaction			≤0.01 , significant
Very satisfied	12 (48%)	21 (84%)	
Satisfied	4 (16%)	3(12%)	
Less satisfied	6 (24%)	1 (4%)	
Not satisfied at all	3 (12%)	0	

Data are counts (and percentages)., a-χ2 with test for trend

Table 6: The Comparison of Outcomes of that Study and Our Study is Depicted

Demographics	Moser et al		P-value	Our study		P-value
	Group A (n=64)	Group B (n=66)		Group A (n=25)	Group B (n=25)	
Males	41	41		17	13	
Females	23	25		8	12	
Efficacy outcome	**%**	**%**	≤0.01 significant	**%**	**%**	**≤ 0.01, significant**
Cessation of bleeding	68.8%	87.9%		60	92	
Pain during first sclerotherapy	**%**	**%**	**Not significant**	**%**	**%**	**Not significant**
No pain	64.1 %	75.8 %		64%	80%	
Little/severe pain	35.8 %	24.2 %		36%	20%	
Pain in interval between visits 1 and 2	**%**	**%**	**Not significant**	**%**	**%**	**Not significant**
No pain	96.9%	97%		96%	96%	
Pain during defecation	3.1%	3%		4%	4%	
Pruritus before sclerotherapy	**%**	**%**	**Not significant**	**%**	**%**	**Not significant**
No pruritus	45.3%	60.6%		40%	56%	
Occasional pruritus	48.4%	33.3%		56%	44%	
Permanent pruritus	6.3%	6.1%		4%	0	
Pruritus between visit 1 and 2	**%**	**%**	**Not significant**	**%**	**%**	**Not significant**
No pruritus	78.1%	77.3%		72%	80%	
Occasional pruritus	21.9%	16.7%		28%%	20%	
Permanent pruritus	0	6%		0	0	
Patient satisfaction	**%**	**%**	**≤0.01, significant**	**%**	**%**	**≤0.01, significant**
Very satisfied	65.6%	80.3%		48%	84%	
Satisfied	18.8%	18.2%		16%	12%	
Less satisfied	14.1%	1.5 %		24%	4%	
Not satisfied at all	1.6%	0		12%	0	

Stastical Software: MS Excel, SPSS ver.22, was used to analysed data. EPI info (CDC Atlanta), Open epi, med calc. and Mendeley's desktop were used to estimate sample size, odds ratio and reference management in the study.

Age Distribution: Age distribution of 50 cases, of which the age of the youngest patient was 18 years and the age of the eldest patient was 74 years. The highest number of cases were found in the age group of 46-60 years of age (20). The average age of presentation of

patient is 43.86 years. These 50 were randomly divided into 2 groups equally of 25 patients each into Group A who received conventional sclerotherapy and Group B who received foam sclerotherapy with 3% polidocanol In Group A, youngest patient was 18 years old, whereas in Group B, the youngest patient was 20 years old. The highest number of cases were in the age-group of 46-60 years of age in both groups with 10 each in that age group. The mean age of presentation in Group A was 43.36 years and it was 44.36 years in Group B.

Sex Distribution: Of the total number (n=50) of participants, 30 were males (60 %), 20 were females (40 %) and male : female ratio was 3:2. All the patients were randomly divided in to Group A and Group B where there were 17 males (68 %)and 8 females (32%) in Group A and 13 males (52 %) and 12 females (48 %) in Group B. The demographic data has been represented in (table-2).

Efficacy: After one sclerotherapy session with conventional sclerotherapy, 60% of patients (15 of 25) were treated successfully in the 1st session. In the foam group, a single sclerotherapy session stopped perianal bleeding in 92% of the patients (23 of 25). Overall, success rates (i.e. rates of bleeding-free patients) and the treatment success of foam versus conventional sclerotherapy were very similar in the two participating trial sites. After a second sclerotherapy, 84 % of patients (21 of 25 patients) in the conventional group (Group A) and 96% of the patients (24 of 25 patients) the foam group(Group B) were treated successfully. In the conventional group, 16% of patients (4 of 25 patients) required a third sclerotherapy, whereas in the foam group, 4% of the patients (received a third sclerotherapy (1 of 25 patients). Refer t(o table 3).

Pain During Sclerotherapy and Other Symptoms of Hemorrhoidal Disease: Transient injection site pain during or directly after injection is well-known and occurs in connection with sclerotherapy of hemorrhoidal disease with liquid polidocanol. In rare cases, this pain may last for some hours. The aim of this data was to evaluate if foam sclerotherapy might be more or less comfortable for the patient. During the first sclerotherapy session, 64% (16 out of 25) of the patients treated with conventional sclerotherapy (Group A) were free of pain compared to 80% (20 out of 25) in the foam group. In Group A (conventional sclerotherapy), 28% (7 out of 25) suffered “little” pain and 8% of patients (2 out of 25) described their pain during sclerotherapy as severe; whereas in Group B (foam group), only 50% (5 out of 25) suffered “little” pain. However pain during sclerotherapy was dull and of short duration (less than 10 min) in all cases. Pain during the second sclerotherapy was observed in a similar proportion of patients. Generally, there was a tendency towards less pain in the foam group., however, there was no significant difference between the two treatment groups. It was also observed, that foam sclerotherapy did not help in regression of symptoms in Grade-III haemorrhoids but symptoms were regressed in Grade I and II haemorrhoids. The majority of patients (96%), independent of the therapy, were pain-free in the time period between the first sclerotherapy session and the second visit. Only 1 patient in each group reported pain during defecation in the time intervals between the visits. All other patients were free of pain. Post procedure symptoms are formulated in the table below. No patient reported permanent or severe pain. Regarding pruritus ani, 48% of the patients (24 out of 50) were free of pruritus, whereas 40% (20 out of 50) complained of occasional pruritus and 4% (2 out of 50) of permanent pruritus before the first sclerotherapy After the first sclerotherapy, around 76% of patients were free of pruritus ani independent of the treatment they had received. This indicates that after sclerotherapy be it conventional form and foam therapy, the incidence of pruritus ani was reduced, but there was no difference between the two treatment groups. It was also noted that conventional sclerotherapy could not be given in more than 3 locations whereas foam could be given in more than 3 locations with minimal post procedural symptoms (bleeding, pain and pruritus ani). Refer to (table 4).

Satisfaction of the Patients Towards the Therapy: There was high patient satisfaction in both treatment groups. After sclerotherapy, 64 % of the patients (16 out of 25) were satisfied or very satisfied with their treatment in group A compared to 96 % (24 out of 25) in group B. Independent of treatment success, a significantly higher degree of satisfaction was found amongst patients treated with polidocanol foam in comparison to the conventional therapy (p=0). Refer to (table 5).

Hemorrhoidal disease is one of the most common benign disorders of the lower gastrointestinal tract. Hemorrhoids per se are vascular cushions forming a gas-tight seal at the anorectal junction and contribute to the physiological continence mechanism. Enlargement of these hemorrhoidal cushions and subsequent sliding into the anal canal or through the anus cause clinical symptoms such as bleeding, mucosal discharge, or pruritus and are the most common complaints defining hemorrhoidal disease.

Anatomy: The vascular plexus within the subepithelial space of the anal transitional zone (ATZ) has been described as “corpus cavernosum recti” (CCR) and claimed to provide mechanical rather than nutritional

functions, resembling the morphological features of erectile tissues. Several anatomic investigations have demonstrated the existence of arteriovenous communications between the terminal branches of the superior rectal artery (SRA) and the CCR[20,21]. This sub epithelial vascular plexus is known to be a complex system of thin-walled tortuous venous structures supported by smooth muscle and fibre elastic tissue scaffolding[22]. These vascular structures, surrounded by fibre muscular tissue, have been described as so-called anal glomerula, corresponding to the anal cushions[23]. Anatomic investigations suggest the existence of a specialized functional vascular network at the anorectal region, similar to that of the penile corpora cavernosum. Others hypothesized the presence of some kind of regulating veins in the CCR[24]. Anatomic studies provide clear morphological and functional evidence for distinct vascular glomerula equipped with sphincter-like constrictions., these are most likely responsible for regulating the filling and drainage of the CCR[23,24]. Data suggest that the CCR possesses an intrinsic active contractile mechanism that is able to ensure effective blood transport through the CCR[23]. Disruption of this intrinsic blood flow regulation and concomitant replacement of smooth muscle tissue with connective tissue seem to be key factors in the pathogenesis of hemorrhoidal disease.

Management Through Sclerotherapy: Sclerotherapy remains one of the mainstay therapies of hemorrhoidal disease. Sclerotherapy is widely used for symptomatic grade 1, 2 and 3 hemorrhoids and consists of submucosal injection of a tissue-irritating agents such as 3% polidocanol, 5% phenol in almon oil, sodium morrhuate etc. The technique is to inset a long spinal needle into the hemorrhoidal pedicle via proctoscopy. and 2-3mL are injected at each site, depending on the agent and its concentration. It is important not to inject directly into the corpus cavernosum recti (CCR), the muscularis recti, or the internal sphincter muscle. Depending on the agent and its concentration, up to three injection sites are possible during one session. The injection procedure can be repeated at monthly intervals until symptoms (e.g., bleeding) have ceased[7]. The results of this randomized, single center, clinical trial demonstrated that significantly more patients were treated successfully after one sclerotherapy session when polidocanol 3% foam was injected instead of liquid polidocanol (92% and 60% respectively). Seen from the patient's point of view, these results can be considered as clinically relevant and therapeutically important, because foam sclerotherapy allows the number of treatment sessions to be reduced, thus being a first step towards developing a one-stop therapy. After the second session, 84% of patients in group A and 96% of the patients in the foam group were treated successfully. The primary outcome criterion of this study covers the leading symptom of haemorrhoidal disease (bleeding during defaecation) and thus the main complaint of patients who seek medical advice for treatment. After the 1st session , in group A, bleeding was stopped in 60% of patients and in Group A and 92 % of patients were relieved off bleeding in group B. Other secondary outcomes include pain during and after treatment. It could be possible that local pain during injection is dependent on the volume of sclerosing agent injected. More volume was injected per session in the foam sclerotherapy group than in the liquid group. The interesting result was that pain was not significantly different between the two treatment groups. Regarding the symptom pruritus ani, there was no difference between the two treatment groups. however, the data before and after therapy indicate that pruritus ani is reduced after sclerotherapy with both liquid and foamed polidocanol. The number of patients who were free of pruritus increased from 48% before therapy to 76% after one sclerotherapy. When patients were asked about their satisfaction, those who had received foam sclerotherapy were significantly more satisfied than those who had been treated with conventional sclerotherapy. In total, there was high patient satisfaction in both treatment groups (64% in group A and 96 % in group B). In detail, the foam injections should always be performed in such a way as to minimize the risk that the view in the proctoscope is obstructed by foam oozing out from the site from the previous injection. To avoid this, the first injection should, therefore, always be placed at 11 o'clock, with the patient in the lithotomy position. To sum up, high overall safety of sclerotherapy with polidocanol could be demonstrated in this study and there was no difference in safety between the foam and the liquid group. The success rates of sclerotherapy observed in this study fall into the range of previous studies, which were mainly performed in the mid 90s and 21st century. In a randomised clinical trial published in 1995, the efficacy and safety of sclerotherapy with polidocanol 3% was compared with 5% phenol in oil in the treatment of first-and second-grade haemorrhoidal disease[26]. After one sclerotherapy session, success rates of 91% with phenol in oil and 88% with polidocanol were seen. After two treatment sessions, a total of 97% of the patients were treated successfully in both groups. Concerning efficacy, there was no significant difference between the two groups. However, polidocanol showed fewer adverse drug reactions. After injection, temporary injection site pain and ulcers were found significantly more frequently in the phenol group. A study done by Yuksel[27] concluded that sclerotherapy with polidocanol was more effective as it had high cure

rate and lower recurrence rate when compared with venotonic flavonoid micronized purified flavonoid fraction (VF-MPFF). In 2018, a study done by Fernandes[28] showed that treatment of internal hemorrhoids with polidocanol foam injected in high doses is very effective and safe for the control of blood loss and prolapse, even for patients on anticoagulation /anti platelet treatment. Lobascio[29], conducted a study in 2020, concluded that treatment of grade-II and III with 3% polidocanol foam sclerotherapy is a safer, cost-effective and repeatable conservative therapeutic option. Salgueiro *et al*. in 2022, through their studies concluded that foam sclerotherapy better than rubber band ligation in treating Grade II and III haemorrhoids[32]. Studies done by Gallo *et al.* in 2022, 2023, concluded that treatment of hemorrhoidal disease with 3% polidocanol is a cost effective, safe, promising, painless, repeatable procedure with a 1 year success rate at 95.6%[30,31]. But to our knowledge there is one study done by Moser[33] which compared the efficacy of liquid/conventional with that of foam sclerotherapy with 3% polidocanol , which is similar to that of this study. It also concluded that Foam sclerotherapy with 3% polidocanol is a better option than liquid sclerotherapy in treating haemorrhoids. The comparison of outcomes of that study and our study is depicted in the (table 6). The difference between both studies is that the former one was treated for symptomatic grade I haemorrhoids but our study was on patients with symptomatic grade I, II and few grade III patients. On comparing both studies , we can see similarities of efficacy in group B with foam sclerotherapy which suggests that foam sclerotherapy is a better therapeutic option than conventional sclerotherapy. Pain during sclerotherapy was significantly less in both studies in group B. Patient satisfaction was also noted to be high In Group B in both studies, which suggests that foam sclerotherapy is very effective in alleviating symptoms related to hemorrhoidal disease. As liquid sclerotherapy is also frequently used to treat second-grade haemorrhoidal disease[33] , another important research question would be to determine how effective foam sclerotherapy may be in this subgroup of patients. In Italy, first experiences and results in the treatment of second- and third-grade haemorrhoidal disease with foam sclerotherapy were very promising[35].

CONCLUSION

Foam sclerotherapy is a more safer, efficacious, cost-effective, reliable, therapeutic procedure in the treatment of hemorrhoidal disease, when compared with conventional sclerotherapy. Foam sclerotherapy may not help in regression of grade-III haemorrhoids, but can help regress symptoms of grade-I and II haemorrhoids. With foam sclerotherapy, injections can be given in ≥ 3 locations, whereas with conventional sclerotherapy, injections were restricted to ≤ 3 places.

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Conflict of Interest: Nil

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