

Original Research Article

Efficacy of foam sclerotherapy in treatment of grade I and grade II bleeding hemorrhoids at Nalanda Medical College and Hospital, Patna

Raj Shekhar*, V. K. Gupta

Department of General Surgery, Nalanda Medical College and Hospital, Patna, India

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*Correspondence:

Dr. Raj Shekhar,

E-mail: dr.rajshekhar@yahoo.in

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ABSTRACT

Background: Sclerotherapy is the treatment of choice for first and second grade haemorrhoidal disease. The aim of this study is to assess the efficacy and safety of polidocanol foam for haemorrhoidal disease.

Methods: A total of 50 patients were treated with foam sclerotherapy (polidocanol 3%). Patients who presented with complain of bleeding per anum and diagnosed with first and second grade hemorrhoidal disease were included. Patients without bleeding per anum were not included. The primary objective was the stopping of perianal bleeding after one sclerotherapy session. Sclerotherapy was repeated at 2-week intervals until patients were free of bleeding. The final follow-up was 12 weeks after the last sclerotherapy session.

Results: After one foam sclerotherapy session, 82% of patients (41 out of 50) were treated successfully. After second sclerotherapy, 98% of the patients (46 out of 50) were treated successfully. 2% of the patients received third sclerotherapy.

Conclusions: In the treatment of first and second grade haemorrhoidal disease, polidocanol 3% foam is very effective and safe. The results of this study show that foam sclerotherapy is a new, innovative, effective and safe non-surgical treatment option for haemorrhoidal disease.

Keywords: Haemorrhoids, Haemorrhoidal disease, Foam sclerotherapy, Polidocanol

INTRODUCTION

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 to 65 years in both genders.¹ Due to the recurrent and relapsing nature of clinical symptoms, feelings of embarrassment, social stigma, patients often opt for self-medication or local therapies many years before getting medical care. They often present to hospitals late when they are severely anaemic.

Depending on the severity of haemorrhoidal disease, dietary measures, sclerotherapy, rubber band ligation and

various surgical procedures are mainly used for treatment.²⁻⁴

According to the traditional classification, the disease is divided into four grades depending on the extent of the prolapse into the anal canal or outside the anus. In first-grade hemorrhoidal disease, the enlarged corpus cavernosum recti protrude into the lumen of the anal canal but does not prolapse outside the anal canal and can therefore only be diagnosed by proctoscopy. In grade II disease there is mild prolapse which reduces spontaneously. Perianal bleeding during defecation is the leading symptom and complaint in patients suffering from first-grade hemorrhoidal disease.

Conservative treatment is successful for most patients with symptomatic grade I or II internal hemorrhoids, including dietary and lifestyle modification to reduce constipation and straining at defecation, as well as topical or oral medications to relieve symptoms.⁵

For patients with symptomatic internal hemorrhoids refractory to conservative treatment, an outpatient department (OPD) based procedure such as rubber band ligation, sclerotherapy, rather than surgical hemorrhoidectomy, should be recommended as the initial intervention. Surgical treatment is associated with more pain and more complications such as bleeding, anal deformity, and in- continence, being usually reserved for patients with permanently prolapsed grade IV hemorrhoids, concurrent symptomatic external hemorrhoids, or failure of nonsurgical treatment.⁶ Although the preferred technique may depend on diverse factors such as local availability and expertise, sclerotherapy is one of the proven techniques for management of grade I and grade II hemorrhoids. This clinical study is aimed to study the efficacy and safety of polidocanol 3% foam in the treatment of patients with bleeding first and second grade hemorrhoidal disease.

METHODS

A prospective study of 50 patients who attended surgical OPD or emergency, in Nalanda Medical College and Hospital with complain of bleeding per anum and found to be suffering from grade I or II hemorrhoids was conducted during a period from November 2017 to January 2020.

Inclusion criteria was patients coming to hospital with bleeding per anum and diagnosed to be suffering from grade I or II hemorrhoids and willing for foam sclerotherapy. Patients without bleeding per anum were not included.

Exclusion criteria were previously operated patients, positive pregnancy test, known allergy to polidocanol, any acute inflammation in the anal region, faecal incontinence, perianal fistula, anal fissure, not willing for follow up.

The sclerosing agent 3% polidocanol was used for sclerotherapy. The standardized foam was prepared with 2 mL liquid polidocanol 3% and 8 ml air using two 10 ml syringes and a 3-way connector. The polidocanol foam was prepared just before each treatment.

Injections were given using an open-ended proctoscope, which provided a better overview during foam sclerotherapy. According to Blanchard's technique, the sclerosant was injected strictly submucosally at the base of each hemorrhoidal node into the surrounding tissue of the feeding vessels at the 3, 7 and 11 o'clock positions.⁷

The doses per treatment session were 9 mL of polidocanol foam. The 9 mL foam injected at each foam sclerotherapy

session was equivalent to a volume of 0.9 ml polidocanol 3%, corresponding to 27 mg polidocanol.

Sclerotherapy sessions were performed on a bi-weekly schedule, until patients were free of perianal bleeding. Four treatment sessions per patient were done depending on the treatment success. If bleeding persisted after the fourth sclerotherapy session, alternative treatment methods (e.g. rubber band ligation) were recommended by the study protocol. Patients were followed up on monthly basis for 3 months after the final session of sclerotherapy.

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 during the day, regardless of whether one or more times, was defined as bleeding for that given day.

At each follow-up visit, the patient diary was checked, and bleeding was defined as persistent if there were at least 3 days with bleeding after day 2 following sclerotherapy. 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" were used. In addition, the patients free of bleeding will be termed as "successfully treated".

Secondary study end points were the number of sclerotherapy sessions necessary and the total amount of injected sclerosant required for treatment success, as well as the stopping of perianal bleeding after the second and subsequent sclerotherapy sessions, the occurrence of anal pain during and after sclerotherapy and the occurrence of adverse drug reactions.

During the treatment and the follow-up period, any adverse events were recorded. All the results were evaluated using statistical software.

RESULTS

Between November 2017 and October 2019, 50 patients underwent foam sclerotherapy. There was a predominance of males (56%) in the study population. Out of 50 patients 40 (80%) had grade I hemorrhoids and 10 (20%) had grade II hemorrhoids.

After one foam sclerotherapy session, 82% of patients (41 out of 50) were treated successfully. It consisted of 36 patients with grade I hemorrhoids and 5 patients with grade II hemorrhoids. After second sclerotherapy, 94% of the patients (47 out of 50) were treated successfully. All the patients with grade I hemorrhoids were relieved of symptoms whereas 70% of grade II hemorrhoids were treated. 6% of the patients received a third sclerotherapy.

Due to persistent bleeding after three sclerotherapy sessions, two patients refused the fourth sclerotherapy and were treated conventionally with surgical

hemorrhoidectomy. Consequently, 4% of patients (2 out of 50) did not respond to foam sclerotherapy after three sessions. These patients had grade II hemorrhoids (Table

1). Temporary injection site mild pain and discomfort was the only complication found during treatment in few patients which subsided with analgesics.

Table 1: Result of patients treated after 1st, 2nd and 3rd session of sclerotherapy.

Patient category	First sclerotherapy session	Second sclerotherapy session	Third sclerotherapy session
First degree haemorrhoids	92% (36/40)	100% (40/40)	-
Second degree haemorrhoids	50% (5/10)	70% (7/10)	80% (8/10)
Total	82% (41/50)	94% (47/50)	96% (48/50)

DISCUSSION

The results of this study demonstrated that significant number of patients were treated successfully after one sclerotherapy session with polidocanol 3% foam thus establishing its effectiveness in the treatment of hemorrhoidal disease.

Foam sclerotherapy allows the number of treatment sessions to be reduced. Sclerotherapy effectiveness after just one session increases the patient's and surgeon's trust in the non-operative therapy of hemorrhoidal disease. In addition, the total amount of active substance necessary for treatment success was significantly reduced by nearly 50%.

The primary outcome criterion of this study covers the leading symptom of hemorrhoidal disease (bleeding during defecation) and thus the main complaint of patients who seek medical advice for treatment. The only side effect observed after sclerotherapy was local pain during injection, which patients in all age group tolerated well and managed with low dose of analgesics. Thus foam sclerotherapy showed a good safety profile. Most importantly, there were no serious adverse events at all.

With regard to safety, an important finding of the present study was that the total amount of active substance required for treatment success was reduced by 50% as compared to liquid sclerotherapy. A higher volume of the foamy polidocanol can be injected, and it may provide better adhesion to the endothelium and increased sclerosing capacity, with improved efficacy.⁸

To sum up, high overall safety of sclerotherapy with polidocanol could be demonstrated in this study. Comparing with a study conducted by Bhuiya et al in 2010, the efficacy and safety of sclerotherapy with polidocanol 3% in present study was compared with 5% phenol in oil in the treatment of first- and second-grade hemorrhoidal disease.⁹ After one sclerotherapy session, success rates of 60.4% with phenol in oil and 82% with polidocanol were seen. After two treatment sessions, a total of 76.18% of the patients were treated successfully in phenol group as compared to 94% in the present study, thus showing significant difference concerning efficacy, between the two groups (Table 2). Also, polidocanol showed fewer adverse drug reactions. After injection, temporary injection site pain were found significantly more frequently in the phenol group. In our study no incidence of anal stricture or ulceration was noted.

Table 2: Comparison of percentage of patients treated after 1st, 2nd and 3rd session of sclerotherapy (5% phenol versus polidocanol 3%).

S. no.	Study	Name of sclerosant	Number of sessions		
			1 st	2 nd	3 rd
01	Bhuiya et al ⁹	5% phenol	60.4%	76.18%	79.3%
02	Present study	Foam sclerotherapy (polidocanol 3%)	82%	94%	96%

CONCLUSION

In the therapy of first and second degree hemorrhoidal disease, the sclerosing agent polidocanol 3% is very effective when used as foam. It is also very useful in patients with severe anaemia where surgery cannot be performed immediately and foam sclerotherapy effectively controls bleeding. The results of this study demonstrate that foam sclerotherapy is a new, innovative, safe and highly effective method in the treatment of first and second grade hemorrhoidal disease. Foam sclerotherapy almost achieves 100% cure rate in grade I

hemorrhoidal disease although long term efficacy requires further study.

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REFERENCES

- Johanson JF, Sonnenberg A. The prevalence of haemorrhoids and chronic constipation. *Gastroenterol.* 1990;98:380-6.

2. Corman ML. Haemorrhoids. In: Corman ML (ed) Colon and rectal surgery, 5th edn. Williams & Wilkins, Philadelphia. 2005: 177-253.
3. Madoff RD, Fleshman JW. American Gastroenterological Association technical review on the diagnosis and treatment of haemorrhoids. *Gastroenterol.* 2004;126:1463-73.
4. Sim AJW, Murie JA, Mackenzie I. Comparison of rubber band ligation and sclerosant injection for first and second degree haemorrhoids: a prospective clinical trial. *Acta Chir Scand.* 1981;147:717-20.
5. Perera N, Liolitsa D, Iype S, Croxford A, Yas-sin M, Lang P, Ukaegbu O, van Issum C. Phle-botonics for haemorrhoids. *Cochrane Database Syst Rev.* 2012;15(8).
6. Shanmugam V, Thaha MA, Rabindranath KS, Campbell KL, Steele RJ, Loudon MA. Rubber band ligation versus excisional haemorrhoidectomy for haemorrhoids. *Cochrane Database Syst Rev.* 2005;20(3).
7. Blanchard CE. A textbook of ambulant proctology. Medical Success Press, Youngstown, Ohio. 1928; 192849.
8. Bruno Rosa. Polidocanol foam: a breath of fresh air for the treatment of internal hemorrhoids. *GE Port J Gastroenterol.* 2019;26:153-4.
9. Bhuiya MFA, Rahman S, Ali A. Effective of injection sclerotherapy on early haemorrhoids reported to surgical outpatient department. *JAFMC.* 2010;6(2):25-7.

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