



ROLE OF SCLEROSANT POLIDOCANOL IN BLEEDING EARLY HAEMORRHOIDS & COMPARE EFFICACY OF IT'S FOAM & LIQUID FORM

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ABSTRACT

Background: Sclerotherapy is the established treatment modality for bleeding Grade 1 & 2 haemorrhoids. Surgery conventional or stapled hemorrhoidectomy has many side effects but proctoscopic sclerotherapy is an ambulatory method of controlling bleeding early hemorrhoids. It is safe without major complications, low in cost, and very effective. Out of many sclerosants, inj polidocanol either as foam or liquid stop bleeding efficiently. The aim of this study was to assess the efficacy and safety of polidocanol & compare outcome of polidocanol in foam and liquid form. **Methods:** 100 patients with early haemorrhoids were randomised to foam or liquid sclerotherapy (polidocanol 3%) and blinded to treatment assignment in equal proportion. After first sclerotherapy, injection was stopped as bleeding stopped but 2nd session done if after 2 weeks bleeding continued. Follow up was done after 12 weeks of last sclerotherapy. **Results:** 90% Patients in foam group were treated successfully after 1st sclerotherapy session compared to the liquid group (80%; $p = 0.01$) in grade I haemorrhoid patients. More patients were satisfied with their treatment in the foam group than in the liquid group (99 vs. 84%; $p = 0.009$). Additionally, in the foam group, bleeding stopped after 2nd sessions but in liquid group 2% patient required 3rd session. ($p < 0.001$). In foam group, the total amount of injected polidocanol was reduced ($p < 0.001$). **Conclusions:** In the treatment of bleeding early haemorrhoids, polidocanol 3% is very effective and safe non surgical entity to control bleeding. The results of this study show that polidocanol 3 % foam, prepared by Tessari method from liquid form of polidocanol is more effective and safe compared to 3% liquid polidocanol.

Key Words: Bleeding, Haemorrhoids, Polidocanol, Sclerotherapy.

INTRODUCTION:

Hemorrhoids are one of the most common Ano Rectal diseases, presenting mostly with Fresh bleeding per rectum resulting in anaemia leading to other mild to severe diseases. Control of bleeding is essential even when haemorrhoids are early of Grade I & II type, not coming out of anal verge. Conservative treatment with bulk diet, laxative & soothing cream of lignocaine with, endothelium stabiliser, steroid & coagulants often relieves but definite therapy with rubber band ligation, thermal hot, cold, laser photo coagulation, sclerotherapy with 5% phenol, Castor oil, absolute Alcohol, Sodium Tetradecyl Sulphate, foam & liquid Polidocanol 3% is required for obliteration of haemorrhoidal vessels in 1 to 2 session. Surgery conventional or stapled haemorrhoidectomy is done for grade III & IV hemorrhoids and is a major intervention often with many complications. Rubber band ligation (RBL) provides higher efficacy and lower recurrence rate but high post-procedural bleeding rates (ranging from

3.5% to 50%), including late bleeding, have been reported. Sclerotherapy is associated with lower bleeding rates but is more recurrence-prone but polidocanol as foam or liquid show improved sclerosing capacity, superior efficacy, the need for fewer outdoor-based sessions and less complications, including bleeding and pain. Polidocanol sclerotherapy induces a local inflammatory reaction that leads to local sclerosis of submucosal tissue, fixation of the hemorrhoidal tissue and obliteration of the vascular bed with tissue fibrosis. This technique has been shown to be reproducible, cost effective, and associated with much patient satisfaction. Instead of fine needle injection of liquid Polidocanol, fine bubble foam prepared by Tessari Method from liquid provides better result and aim of this study is to evaluate Polidocanol efficacy & superiority of foam over liquid polidocanol.

MATERIAL & METHODS

100 patients attending emergency or OPD of NDMC Medical College & HR Hospital with bleeding per rectum due to grade I & II hemorrhoids were randomised to foam or liquid sclerotherapy (polidocanol 3%) and blinded to treatment assignment in equal proportion. Patient with bleeding disorder, cirrhosis of liver, pregnancy with malignancy, fistula, fissure, allergy to polidocanol excluded. In 50% patients, diluted 3% polidocanol 2ml with 8 ml of distilled water and in 50% micro bubble foam freshly prepared by 2ml of polidocanol with 8 ml of air taken in two syringes, connected by a 3 way connector using Tessari Method used. 9ml of sclerosant was injected in sub mucosal tissue

surrounding a Haemorrhoid pile as per *Blanchard's* technique using a transparent proctoscope in lithotomy position. Thus in each session about 0.9 ml of 3% polidocanol used. As foam spread widely and adheres to tissue firmly so less amount of Polidocanol is used and its chance of instillation in vessel is also less compared to liquid form. Session is repeated biweekly up to 03 sessions provided bleeding is persisting as judged by patient on 2nd and 3rd day after 1st injection. Patients are followed up every month for 12 weeks. During this period, beside bleeding, any adverse effect as pain, pruritus, discharge, infection, inflammation forming abscess and bowel habit is noticed.

RESULTS

Out of 100 patients, 80 patients have grade I hemorrhoid and 20 patients had grade II hemorrhoid, 70 patients were male and 30 patients were female. 90% Patients in foam group were treated successfully after 1st sclerotherapy session compared

to the liquid group (80%; $p=0.01$) in grade I hemorrhoid. Additionally, in the foam group, remaining 10% bleeding stopped after 2nd session in grade I hemorrhoid. Foam obliterated 50% of grade II hemorrhoid in first session 70% in 2nd

session and 80% in 3rd session but 02 Patients opted for surgery as refused for 4th session of sclerotherapy but in liquid group, 70% in first session but 90% in 2nd session and 100% in 3rd session of grade I haemorrhoid but 40% patients of grade II patients after 1st session, 60% after 2nd session and 70% patients after 3rd session in Grade II haemorrhoid patients. 03 patients (6%) required surgery as bleeding did not stop even after 3rd session, so opted for plication of Haemorrhoid surgery in one patient and Haemorrhoidectomy in another 02 patients. These were grade II haemorrhoid patients. Bleeding stopped after first session in grade I haemorrhoid patients by both liquid and foam polidocanol. In foam group, the

total amount of injected polidocanol was reduced ($p < 0.001$). Minimum amount injected 6ml of drug diluted with air (2ml drug + 8ml air) to maximum 12 ml in foam group but in liquid group, diluted with water (2ml drug + 8 ml water) minimum 8 ml to 20 ml drug used. More patients were satisfied with their treatment in the foam group than in the liquid group (99 vs. 84%; $p = 0.009$). Injection site pain and inflammation for 4 to 5 days was reported by foam receiving 20% patients while 10% patients presented with pain and inflammation for 2 to 3 days on liquid polidocanol. This pain and inflammation subsided with mild analgesic only.

DISCUSSION

Haemorrhoidal disease is most common ano rectal disease and its commonest manifestation is bleeding per rectum. Dietary habits of having high rich food with spices, less water and fibre intake, constipation, prolonged standing or being associated with bleeding disorder, cirrhosis of liver or malignancy, or idiopathic, in every bleeding Haemorrhoidal disease, arrest of bleeding is must. If bleeding is due to grade I and II haemorrhoid, Conservative treatment with bulk diet, laxative & soothing cream of lignocaine with, endothelium stabiliser, steroid & coagulants often relieves but definite therapy with rubber band ligation, thermal hot, cold, laser photo coagulation, sclerotherapy with 5% phenol, Castor oil, absolute Alcohol, Sodium Tetradecyl Sulphate, foam & liquid Polidocanol 3% is required for obliteration of haemorrhoidal vessels in 1 to 2 session. Surgery conventional or stapled haemorrhoidectomy is done for grade III & IV hemorrhoids and is a major intervention often with many complications. Rubber band ligation (RBL) provide higher efficacy and lower recurrence rate but high post-procedural bleeding rates (ranging from 3.5% to 50%), including late bleeding,

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STATISTICAL ANALYSIS

Table:1 Result of Patients treated with Foam Polidocanol 3%

Patient Category	Ist Sclerotherapy Session	2 nd Sclerotherapy Session	3 rd Sclerotherapy Session	Surgical Intervention
Grade One Haemorrhoid	90%(36 / 40)	100% (40 / 40)	Not Reqd	Not Reqd
Grade Two Haemorrhoid	50%(05 / 10)	70% (7 / 10)	80% (8 / 10)	06% (02 /10)
Total	82%(41 / 50)	94% (47 / 50)	96% (48 / 50)	100%(50 / 50)

Table:2 Result of Patients treated with Liquid Polidocanol 3%

Patient Category	Ist Sclerotherapy Session	2 nd Sclerotherapy Session	3 rd Sclerotherapy Session	Surgical Intervention
Grade One Haemorrhoid	80%(32 / 40)	90% (36 / 40)	100% (40/ 40)	Not Reqd
Grade Two Haemorrhoid	40%(04 / 10)	60% (06 / 10)	70% (07 / 10)	09% (03 /10)
Total	72%(36 / 50)	84% (42 / 50)	94% (47 / 50)	100%(50 / 50)

CONCLUSION

In the treatment of first and second grade bleeding haemorrhoids,Injectable Sclerosant Polidocanol 3% is very effective and safe to control bleeding,It is used in both liquid and foam form but instantly made foam from liquid provided better result than liquid form.It can be done in outdoor setting even when patient's general condition is compromised as in moderate to severe anaemia due to bleeding,The results of this study show that foam sclerotherapy is a new, innovative, effective and safe non-surgical treatment option for early bleeding haemorrhoidal disease.

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