

## **Title- A comparative study to evaluate the effect of sclerotherapy in grade I and grade II internal haemorrhoids with Sodium tetradecyl sulphate (STD) and 50% Dextrose water.**

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### **ABSTRACT**

**Background-** Hemorrhoidectomy is the procedure of choice for treating hemorrhoids most effectively. Now a day's the emphasis is on conservative therapies and newer outpatient methods for treating hemorrhoids.

**Material and Methods:** In 2 non-consecutive series of 50 patients, sodium tetradecyl sulphate and 50% dextrose water were injected. Dextrose is used as a 50% concentration (not diluted), while sodium tetradecyl sulphate is diluted 1:2 with distil water before administration.

**Results:** Total 127 patient were recruited , Sodium Tetradecyl Sulphate(std) group 63 patients were selected and in dextrose 50% group 63 patients were selected. Mean age of std group was 38.75 years and d50% group was 39.5 years. Peak incidence of disease is between age group 20 to 50 years. Mean number of sessions required of STD – 1.61(±0.60), Mean number of sessions required of D50% - 2.40(±0.49) t =6.52 ; p <0.0001 The mean sessions of sclerotherapy required for D50% group was significantly higher.

**Conclusion:** STD performs better than D50%. Within 12 weeks, no sclerotherapy patients relapsed. Sclerotherapy has been well. Neither patient objected to therapy. No patient objected to a second or third injection. Sodium tetra decyl sulphate was more expensive than 50% dextrose sclerotherapy. Dextrose 50% requires multiple sessions. Our low-income patients mostly accepted government-funded care. Dextrose 50% may be preferable for sclerotherapy.

**Keywords: Sclerotherapy; Hemorrhoids; Bleeding; Prolapsed**

**Introduction** - The most frequent condition in the clinical practise of general surgery is haemorrhoids. The most frequent cause of rectal bleeding in adults is internal haemorrhoids. [1] The human anatomy of the anal canal includes haemorrhoids. When bloated or irritated, they develop pathologically or into piles. They serve as a cushion for the transit of stools in their physiological state since they are made of connective tissue and arteriovenous channels. Only clinical situations where these cushions are aberrant and present symptoms should be considered haemorrhoids. [2] According to the severity of the haemorrhage, the patient's preferences, the procedure's availability, and the procedure's level of expertise, the treatment of hemorrhoid disease must be customised. There are

non-operative and surgical therapy options for haemorrhoids. In general, non-operative treatment is used to treat grade I and II haemorrhoids. This non-operative treatment can take the form of dietary changes, injection sclerotherapy, rubber band ligation, endoscopic band ligation, electro coagulation (bipolar diathermy and direct current electrotherapy), or infrared coagulation. [1,3] For internal haemorrhoids of the first grade, injection sclerotherapy is ideal. Hemorrhoids in the early second grade can frequently be treated in this way. [3] One of the oldest, most widely used, and accessible non-surgical treatments is sclerotherapy. Due to cost effectiveness, improved patient satisfaction, and reduced risk of complications with the more recent treatments, there has been a considerable trend in the treatment of internal haemorrhoids toward day care and office operations. While the patient's compliance is linked to a quicker hospital stay, lower morbidity, an earlier return to work, and the lack of excruciating agony, which is typically related to hemorrhoidectomy. Sclerotherapy for piles is a quick procedure that is frequently performed as an outpatient day case. When treating piles, sclerotherapy produces far better short-term results than more invasive surgical techniques like cutting haemorrhoids off or cauterising with heat or lasers. Numerous sclerosing agents, including -N butyl cyanoacrylate, Ethanolamine oleate, 5% phenol in almond, Sodium tetradecyl sulphate, Sodium morrhuate, and more recently 50% Dextrose water, have been utilised for a long time. The sclerosant is injected into the hemorrhoid to destroy the vascularity, causing fibrosis and inflammation that fuses the haemorrhoids to the surrounding tissue and prevents prolapse. Sclerosants are frequently utilised, however they are quite expensive and not biological. The morbidity associated with sclerosants, such as anorectal abscess, hepatic abscess, necrotizing fasciitis, retroperitoneal sepsis, oleogranuloma (with oil-containing solutions), and pulmonary allergic reaction, has made this treatment unattractive. [4] The disease is widespread in our nation, and the majority of its victims come from lower socioeconomic groups. In this situation, surgical therapy, with all of its potential drawbacks and morbidities, placed a heavy financial strain on both the family and the nation. We prospectively evaluate 50% dextrose water, used as a non-allergenic sclerosant, in the treatment of bleeding internal haemorrhoids in order to take into account the aforementioned factor as well as the global changing trend in the treatment and to reduce the morbidity associated with non-physiological agents.

**Methodology-** Our study includes all OPD or casualty patients with hemorrhoidal complaints. Rectal and proctoscopy confirm illness. Proforma grades prolapsed hemorrhoidal mass. 100 patients (men and women) were studied. In 2 non-consecutive series of 50 patients, sodium tetradecyl sulphate and 50% dextrose water were injected. Dextrose is used as a 50% concentration (not diluted), while sodium tetradecyl sulphate is diluted 1:2 with distil water before administration. Using a 22-23-gauge spinal needle, 2–5 ml of sclerosant was injected into the submucosa of each hemorrhoidal bundle at the summit or 1 cm proximal to the dentate line. Aspiration was done before sclerosants to avoid vascular injection. The injection was deep enough to not blanch the mucosa but not the muscle. Before returning home, each patient was watched for 30 minutes. Immediate post-sclerotherapy symptoms develop within 30 minutes. Post-sclerotherapy complaints include intolerance, temporary warmth, mild-to-moderate pain, and modest discomfort. If the initial session of sclerotherapy did not achieve the desired result (cessation of bleeding for Ist grade hemorrhoid and cessation of bleeding and absence of prolapse for IInd grade hemorrhoid), patients underwent repeat sclerotherapy (up to 3 sessions) at 1 week intervals.

**Results-** Table 1 shows demographic and clinical characteristic of patients the age of patient was between 18 to 78 years. Mean age of std group was 38.75 years and d50% group was 39.5 years. Peak incidence of disease is between age group 20 to 50 years. In sodium tetradecyl sulphate(std) group total number of cases were 63 , out of them 53 were males and 10 were females; while in dextrose 50%(d50%) group there were total 64 cases 54 were males and 10 females . More number of males were there in both std and 50% dextrose 50% group. Among total 63 patient in STD group 44 were Ist

grade and 19 were IInd grade. In dextrose group out of total 64 patient 37 were Ist grade and 27 were IInd grade patients. So in both the group we were having more number of patients with Ist grade hemorrhoids.

**Table 1**  
**Demographic And Clinical Characteristic Of Patients**

		<b>Sodium Tetradecyl Sulphate</b>	<b>Dextrose 50%</b>
<b>Age</b>	Mean Age(in years)	38.75 years	39.5 years
<b>Sex</b>	Male	53(84.1%)	54(84.4%)
	Female	10(15.9%)	10(15.6%)
<b>Grade</b>	I	44	37
	II	19	27

Table 2 shows No. of sclerotherapy sessions required and immediate Post sclerotherapy complaints Total 44 patient of grade I administered STD, out of them 20 required single session sclerotherapy ,21 required 2 sessions and only 3 required 3 sessions of sclerotherapy for symptom control. In D50%-I group patients out of total 37, none of patient improved by single session of sclerotherapy , 22 patient required 2 sessions while 15 required 3 sessions for symptom control. Mean number of sessions required of STD – 1.61( $\pm$ 0.60), Mean number of sessions required of D50% - 2.40( $\pm$ 0.49)  $t=6.52$  ;  $p < 0.0001$  The mean sessions of sclerotherapy required for D50% group was significantly higher. Only 5 patient experience mild pain and 9 experience slight discomfort as immediate post sclerotherapy complaints out of total 44 patient of STD-I group. Similarly in D50%-I patient, 4 experience mild pain and 6 experience slight discomfort out of total 37 patient. Intolerance and transient warming was not observed in any of the cases in both the groups. In STD group pain reported in 11.4% cases while in D50% group it was 10.08% cases and no significance was observed ( $p > 0.05$ ). In STD group slight discomfort reported in 20.5% cases while in D50% group it was 16.2% cases and no significance was observed ( $p > 0.05$ )

**Table 2**

**No. Of Sclerotherapy Sessions Required And Immediate Post Sclerotherapy Complaints**

		<b>1st grade hemorrhoid</b>		<b>2nd grade hemorrhoid</b>	
		<b>STD</b>	<b>D 50%</b>	<b>STD-II</b>	<b>D 50%-II</b>
<b>No. of sessions of sclerotherapy required</b>	<b>Single (I)</b>	20	0	4	0
	<b>Double (II)</b>	21	22	4	9
	<b>Triple (III)</b>	3	15	11	18
<b>Immediate Post</b>	<b>Intolerance</b>	0	0	0	0

<b>sclerotherapy complaints</b>	<b>Transient warming</b>	0	0	0	0
	<b>Pain(mild-moderate)</b>	5(11.4%)	4(10.8%)	3(15.8%)	2(7.4%)
	<b>Slight discomfort</b>	9(20.5%)	6(16.2%)	8(42.1%)	7(25.9%)

Table 3 shows Grade I Post sclerotherapy outcome Bleeding symptom improved in all 20 patient with STD sclerotherapy at 1<sup>st</sup> week follow up and not required further sclerotherapy. None of patient improved with single session of D50% sclerotherapy. Bleed was observed improved in 100% cases in STD group. Since in D50% group no case showed relief in per rectal bleed, this resulted in application of the second session for the 50% group therefore at this stage the data were uncomparable for both the group.

**Table 3**  
**Grade I Post sclerotherapy outcome**

<b>Bleeding(Improved )</b>	<b>1st week</b>		<b>4th week</b>		<b>12th week</b>	
	<b>Std</b>	<b>D50%</b>	<b>Std</b>	<b>D50%</b>	<b>Std</b>	<b>D50%</b>
<b>Single session group</b>	20	0	0	0	0	0
<b>Double session group</b>	21	22	-	-	-	-
<b>Three session group</b>	3	15	0	0	0	0

Table 4 shows Grade II Post sclerotherapy outcome Only 3 patient experience mild pain and 8 experience slight discomfort as immediate post procedure complaints out of total 19 patient of STD-II group patient. Similarly in D50% II patient, 2 experience mild pain and 7 experience slight discomfort out of total 27 patient. Intolerance and transient warming was not observed in any of the cases in both the groups. In STD group pain reported in 15.8% cases while in D50% group it was 7.4% cases and no significance was observed ( $p>0.05$ ). In STD group slight discomfort reported in 42.1% cases while in D50% group it was 25.9% cases and no significance was observed ( $p>0.05$ ). Bleeding symptom improved in all 4 patient at 1<sup>st</sup> wk follow up and not require further sclerotherapy. While prolapse of hemorrhoid found to be excellent improved on 4<sup>th</sup> week follow up. None of patient improved with single session of D50% sclerotherapy. Per rectal bleed was observed improved in 100% cases in STD group at 1<sup>st</sup>, 4<sup>th</sup> and 12<sup>th</sup> week. For prolapse symptom 100% patient not improved at 1<sup>st</sup> week. At 4<sup>th</sup> week 100% observed to be excellent which is similar for 12<sup>th</sup> week. While none of cases relieved with single session of sclerotherapy in dextrose group. Since the D50% group was not having any case at this stage thus the result were uncomparable.

Table 4

## Grade II Post sclerotherapy outcome

Symptoms	1 <sup>st</sup> week		4 <sup>th</sup> week		12 <sup>th</sup> week	
	Std	D50%	Std	D50%	Std	D50%
<b>Single session group</b>						
<b>Bleeding (Improved)</b>	4 (100%)	0	0	0	0	0
<b>Bleeding (Unimproved)</b>	0	0	0	0	0	0
<b>Prolapse (Excellent)</b>	0	0	4 (100%)	0	4 (100%)	0
<b>Prolapse (Not improved)</b>	4 (100%)	0	0	0	0	0
<b>Double session group</b>						
<b>Bleeding (Improved)</b>	4 (100%)	9 (100%)	0	0	0	0
<b>Bleeding (Unimproved)</b>	-	0	0	0	0	0
<b>Prolapse (Excellent)</b>	0	4 (44.4%)	4 (100%)	8 (88.9%)	4 (100%)	9 (100%)
<b>Prolapse (Not improved)</b>	4 (100%)	5 (55.5%)	0	1 (11.1%)	0	0
<b>Three session group</b>						
<b>Bleeding (Improved)</b>	11 (100%)	18 (100%)	0	0	0	0
<b>Bleeding (Unimproved)</b>	0	0	0	0	0	0
<b>Prolapse (Excellent)</b>	0	2 (11.1%)	10 (90.9%)	13 (72.2%)	11 (100%)	18 (100%)
<b>Prolapse (Not improved)</b>	11 (100%)	16 (88.9%)	1 (9.1%)	5 (27.8%)	0	0

**DISCUSSION-** Most OPD patients in our system have haemorrhoids and are treated as day care patients. In "the diagnosis and current treatment of hemorrhoidal illness," Arullani A et al (1994) wrote, "quick and painless techniques that can be performed in the office without anaesthetic will be increasingly necessary." [15] Haemorrhoids can affect either sex, but they are more common in men (5:1) than in women (3:1). [16] 18-78-year-olds were patients. Haemorrhoids can affect either sex and are most common between 20 and 50. Our analysis found the highest prevalence between 20 and 50. Shackelford (1969) and Javed reported something similar (1992). [18] Injection sclerotherapy is a rapid and effective approach to cure bleeding haemorrhoids, according to numerous studies. Sclerotherapy is safe, well-tolerated, and connected to high patient satisfaction, few complications, and favourable long-term outcomes. Bhuiya MFA, Rahman S, and Ali A conducted the 10-month study at a military hospital. According to the study, sclerotherapy is beneficial for first- and early-second-grade haemorrhoids. [16] Our research found the same thing. Sclerosants aren't physiological. Also expensive. Sclerosants can cause anorectal abscess, hepatic abscess, necrotizing fasciitis, retroperitoneal sepsis, oleogranuloma (with oil-containing therapies), and pulmonary allergic reaction. Ponsky JL, Mellinger JD, and Simon IB used 23.4% saline during endoscopic retrograde hemorrhoidal sclerotherapy to reduce non-physiological agent morbidity. This study evaluates a flexible endoscopic treatment for internal haemorrhoids that uses 23.4% saline. [19] The operation is well-tolerated, with high patient satisfaction and low complication rates. The modality is appropriate for one-session investigation and therapy of lower GI haemorrhage. The findings concern haemorrhoids. [20] Alatisse OI and colleagues used 50% dextrose as a non-allergic sclerosant for bleeding haemorrhoids. 40 adults (median age 50; range 35-67; 22 women) with bleeding haemorrhoids received 50% dextrose water injection sclerotherapy over a 2-year period. We analysed response, tolerance, and problems. 3 to 15 months of symptoms preceded diagnosis. All bleeding stopped after the injection. Nobody needed another operation. The 2-to-12-month follow-up period saw no issues. Endoscopic hemorrhoidal sclerotherapy with 50% dextrose water is simple, safe, and effective, according to Alatisse OI and colleagues. [4] Dextrose was efficacious, safe, and complication-free, like Alatisse OI et al's study. No research has compared physiological and non-physiological sclerosants. A previous study tracked one sclerotherapy treatment. Up until symptom remission, sclerotherapy results are greater with more sessions, according to our study. Most sclerotherapy patients in the study were in first grade (2:1). In the D50% group, 1st grade patients needed more sclerotherapy treatments. Both sclerosants had comparable post-sclerotherapy results (i.e., cessation of per rectal haemorrhage and lack of prolapse). Both sclerosant groups had similar post-procedure complaints and problems. Average second-grade sclerotherapy treatments are unremarkable. Early and late post-sclerotherapy symptoms are similar for both sclerosants. Both D50% and STD are reliable sclerosants, but STD performs better. No sclerotherapy patients showed recurrence within 12 weeks. Patients liked sclerotherapy. The trial found that neither patient objected to therapy. No patient in this trial objected to a second or third injection. In this study, sodium tetradecyl sulphate was more expensive than 50% dextrose sclerotherapy. Dextrose 50% requires more than one sclerotherapy session. Most of our patients were low-income and only accepted government-funded care. Dextrose 50% may be preferred for sclerotherapy in our circumstance.

**Conclusion-** Both D50% and STD are trustworthy sclerosants, but STD performs better. Within 12 weeks, no patients who received sclerotherapy demonstrated recurrence. Sclerotherapy was popular with patients. The trial revealed that neither patient raised concerns about therapy. To a second or third injection, no subject in this trial complained. According to this study, 50% dextrose sclerotherapy was more expensive than sodium tetradecyl sulphate. Sclerotherapy sessions must be repeated for dextrose 50%. The majority of our patients were underprivileged and would only take government-funded care. For sclerotherapy in our case, dextrose 50% might be recommended.

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