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Original Research Article

A Prospective Study to Assess the Efficacy and Safety of Sclerotherapy with Sodium Tetradecyl Sulphate in the Treatment of Pyogenic Granuloma

Dr. Namrata C. Manjunath[1*], Dr. Meghana Kempanna[2]
[1*]Associate Professor, Department of Dermatology, Kempegowda Institute of Medical Sciences, Bangalore, Karnataka, India.
[2]Senior resident, Department of Dermatology, Kempegowda Institute of Medical Sciences, Bangalore, Karnataka, India.

Corresponding Author: Dr. Namrata C. Manjunath
Associate Professor, Department of Dermatology, Kempegowda Institute of Medical Sciences, Bangalore, Karnataka, India.

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ABSTACT
Background: Pyogenic granuloma (PG) is a benign vascular tumor. It is a misnomer as it is neither pyogenic nor a granuloma. It commonly occurs after minor injury, with a higher prevalence in children and young adults. Angiogenesis and rapid growth are linked to nitric oxide synthase mechanisms. Treatment options include surgical excision, electrocautery, and sclerotherapy with sodium tetradecyl sulfate (STS), which facilitates chemical ablation through cell lysis and thrombosis.
Methods: A prospective interventional study was conducted with 30 patients at the Kempegowda Institute of Medical Sciences, Bangalore, India, over 12 months. Patients above 18 years of age, who gave consent were included in the study. Patients with lesions on lips/genitals, immunocompromised individuals, and pregnant/lactating women were excluded. STS (1-1.5%) was injected until blanching occurred, with follow-ups every week for up to four weeks.
Results: Among 30 patients, 40% were under 30 years; 53.3% were male. Lesions primarily affected hands (36.6%) and the face (26.6%). Complete cure was achieved in 96.7% after a maximum of four injections. Immediate adverse events included burning sensations in 93.3% of patients.
Conclusion: Sclerotherapy with STS demonstrates high efficacy and safety in PG treatment, offering a non-surgical option with minimal scarring and lower recurrence rates, making it suitable for challenging lesions.

Keywords: Pyogenic Granuloma; Sclerotherapy; Sodium Tetradecyl Sulphate.

INTRODUCTION

Pyogenic granuloma (PG) is a benign vascular tumor.[1] The word Pyogenic granuloma is a misnomer, it's neither pyogenic nor granuloma.[2] It occurs following minor penetrating skin injury, prolonged frictional trauma to the toe nail, immobilization in a cast, drugs such as retinoid, cyclosporine, cancer chemotherapy and antiretroviral drugs and pregnancy.[3] A nitric oxide synthase dependent mechanism is thought to contribute to angiogenesis and rapid growth of PGs.[4]

PGs occur in children and young adults with a peak incidence in the second decade. There is a slight male preponderance. In adults, they are more common in females because it has higher incidence in pregnancy.[3] It begins as a red papule and grows rapidly. They usually present as solitary, well-circumscribed, dome-shaped, 1–10 mm in diameter, sessile or pedunculated, bright or dusky red-colored, smooth, firm nodules. A collarette at the base, tenderness and tendency to bleed are characteristics of this lesion.[2] Uncommon variants include PG with satellitosis, subcutaneous, and intravenous PG.[5] Histopathology reveals lobular patterns separated by fibrous septae. Each lobule comprises capillaries and venules lined by plump endothelial cells. They are embedded in an edematous gelatinous stroma. The overlying epidermis is hyperplastic and forms a collarette, partially embracing the lesion.[2,3] Treatment includes shave removal, surgical excision, curettage, chemical or electrocautery, cryotherapy, sclerotherapy and pulsed dye laser.[5,6]

Sclerotherapy is targeted chemical ablation. Sodium tetradecyl sulphate is a detergent sclerosant. It is a long chain fatty acid, which forms an amphiphilic bilayer called micelles. Micelles extract the cell surface proteins from endothelial cells by the process of protein theft denaturation resulting in irreversible cellular change and cell death without hemolysis.[7,8] 1-3% STS can be injected into the lesion depending on the size, till the point of blanching. The procedure is repeated after 1- 2 weeks, if there is remnant tissue.[9] Advantages of sclerotherapy are reduced recurrences, non-surgical procedure, painless, no risk of bleeding and no scarring.[8,10]

MATERIALS AND METHODS

The aim of the study is to assess the efficacy and safety of sodium tetradecyl sulphate in the treatment of pyogenic granuloma. Purposive sampling is done among the patients attending OPD of department of Dermatology, Venereology and Leprosy at Kempegowda Institute of Medical Sciences, Bangalore, Karnataka, India and the study includes 30 patients. It is a prospective, interventional study and the duration of the study is 12 months.

The study includes subjects aged over 18 years and who consent for being included in the study as well as for the treatment. Subjects excluded are those with lesion on the lips and genitals, immunocompromised subjects, pregnant and lactating subjects.

30 patients attending the OPD and satisfying the above-mentioned inclusion and exclusion criteria are enrolled in the study. The study procedure is explained and written informed consent is taken from all these patients. After inclusion in the study, the patient's demographic details and detailed history of disease are recorded by a pre-structured proforma and clinical photographs are taken. 3% STS was diluted using distilled water to obtain 1% and 1.5% STS. After following aseptic precautions, 1-1.5% of Sodium tetradecyl sulphate is injected using insulin syringe into the lesion till blanching of the lesion is noticed. It was followed by compression for 1 minute. The patient is observed for one hour in the procedure room for any adverse events. The patient is reviewed every week in the OPD, up to 4 weeks maximum, to see the results and note any adverse events. The procedure is repeated depending on the need in the following visits.

Statistical analysis was carried out using statistical packages for IBM SPSS vs 22 for Windows. Continuous and categorical variables were expressed as mean ± SD and percentages, respectively. Descriptive statistics was done for distribution of age, gender, characteristics of lesion, number of session. Chi –square test/Fischers exact test was used to compare efficacy of sclerotherapy in different age group and gender. Two sided p values was considered as statistically significant at $p<0.05$.

RESULTS

A total of 30 patients were recruited for the study, after satisfying the inclusion and exclusion criteria and written informed consent. The diagnosis of pyogenic granuloma was made by clinical examination.

Among the 30 people included in the study, 40% were under 30 years of age and the rest were more than 30 years of age. 46.7% of the patients were females and 53.3% of the patients were males. (Table 1)

36.6% of the lesions were present over the hand/fingers, followed by face in 26.6% of the patients. 13.3% of the patients had the lesion on the scalp and 10% had over foot/toe. The average duration of lesion was 5.6±12.8 months, with 86.7% of the patients had the lesion for less than 1 year and 13.3% of the patients had the lesion for more than a year. 93.3% of the patients had not taken any treatment previously, one patient had got it excised and another patient had been treated with radiofrequency. (Table 2)

Out of the 30 patients, 33.3% of the patients received 1% STS and 66.7% of the patients received 1.5% STS. 96.7% of the patients achieved complete cure at the end of 4 weeks of assessment and 3.3% of the patients did not attain complete cure. Immediate adverse event in the form of burning sensation and burning sensation with erythema was noted in 93.3 and 6.7% of the patients respectively. (Table 2)

Complete resolution of the lesion was achieved with single dose of injection in 2.7% of the patients, two doses of injection in 30% of the patients, three injections in 36.7% and four injections in 3.3% of the patients. (Table 3)

Figure 1 shows pyogenic granuloma on lower lip and Figure 2 shows complete resolution after three injections

Variables	Numbers	Percentage
Age		
<30 years	12	40.0
>30 years	18	60.0
Gender		
Male	14	46.7
Female	16	53.3

Table 1: Demographic Characteristics of Study Population

Variables	Numbers	Percentage
Location		
Face	8	26.6
Foot/Toe	3	10
Hand/Finger	11	36.6
Scalp	4	13.3
Others	4	13.3
Duration of lesion		
Less than 1 month	13	43.3
1 month -1year	13	43.3
>1year	4	13.3
Mean $\pm$ SD	5.6$\pm$12.8 months	
Previous treatment		
Excised and sutured	1	3.3
Radio-frequency	1	3.3
No Treatment	28	93.3
Percentage of Sodium tetradecyl sulphate		
1%	10	33.3
1.50%	20	66.7
Resolution		
Complete	29	96.7
Partial	1	3.3
Immediate Adverse event		
Burning sensation	28	93.3
Burning sensation and mild erythema	2	6.7

Table 2: Characteristics of lesion

Number of sessions of injection	Numbers	Percentage
One	8	26.7
Two	9	30.0
Three	11	36.7
Four	1	3.3
Eight	1	3.3

Table 3: Frequency of Number of Sessions of Injection for Complete Resolution of Lesion

Resolution	Age		Total
	<30 yrs	>30 yrs	
Complete	11 (91.7%)	18 (100%)	29 (96.7%)
Partial	1 (8.3%)	0	1 (3.3%)
Total	12 (100%)	18 (100%)	30 (100%)

Table 4: Comparison of Efficacy of Sclerotherapy in Different Age Groups. (N=30)Chi-square value=1.55, p value =0.40 (not significant)

Resolution	Gender		Total
	Male	Female	
Complete	14 (100%)	15 (93.8%)	29 (96.7%)
Partial	1 (6.3%)	0	1 (3.3%)
Total	16 (6.3%)	14 (100%)	30 (100%)

Table 5: Comparison of Efficacy of Sclerotherapy in Both the Genders. (N=30)

Chi-square value=0.905, p value =1.00 (not significant)

Figure 1 (Pre Treatment)

Figure 2 (Post Treatment)

DISCUSSION

Pyogenic granuloma is a benign, acquired vascular tumor, commonly seen on digits or face.[11] It can arise following injury; as a complication of pulse dye laser;[12] drugs like retinoids, anti-CD20 monoclonal antibody (rituximab), taxanes (paclitaxel), epidermal growth factor-receptor inhibitors (cetiximab and panitumab), epidermal growth factor-receptor tyrosine kinase inhibitors (geftinib, erlotinib, icotinib, afatinib and osimertinib), tyrosine kinase inhibitors (imatinib), Mitogen-activated protein kinase inhibitors and ERK inhibitors (trametinib and selumetinib), BRAF inhibitors and VEGF inhibitors[13].It is a common condition encountered in the Dermatology OPDs and is diagnosed by the patient's history and clinical examination. Surgical excision, electrocautery, laser photocoagulation, shave excision, chemical cautery (silver nitrate), etc. are various modalities available to treat pyogenic granuloma.[14,15] The treatment of the lesion is challenging due to its high vascularity, location of the lesion and the risk of recurrence. Sclerotherapy is injection of sclerosant into lumen of vessels for targeted elimination of small vessels, varicose veins and vascular anomalies.[16] Commonly used sclerosants are

sodium tetradecyl sulphate, polidocanol, sodium morrhuate, sodium psylliate, ethanolamine oleate, and ethanol, pingyangmycin, OK-432.[17] Sodium tetradecyl sulphate, anionic sclerosant disturbs the phospholipid membrane of cells. It induces coagulation by creating negative charge over the cell membrane of endothelial cells at lower concentration and membrane solubalisation and cell lysis at higher concentratiom.[18] The therapeutic effect is obtained by endothelial cell damage, thrombus formation, obliteration of vessel wall and non-specific necrotic changes.[18,19]

Surgical modality of treatment might not be suitable, if the lesion is large or is situated in a surgically difficult area. Surgical excision of the lesion can leave a cosmetically undesirable scar.[20] Thicker lesions do not respond well to treatment with laser and requirement of machines, training of the staff and cost stands as a drawback.[21] Surgical excision and laser requires administration of local anesthetic agents. Sclerotherapy is suitable for surgically challenging and larger lesion of pyogenic granuloma. It is a better technique due to its simplicity, low cost, availability and fewer adverse evets.

Dr. Moon, et al., in their study diluted 3% STS using distilled water to 0.5% STS and injected it using a 30G needle to the base on the lesion until blanching was observed. They noticed that 14 out of 15 patients had complete resolution. Pain and swelling were the common side effects noted.[22] Similarly, in our study 3% STS was diluted using distilled water to obtain 1% and 1.5% STS. In a case report published by Abhishek Govind Soni, 3% STS is used as the sclerosant in oral pyogenic granuloma.[23] Dr. Rutaba Kiran, et al., in their study injected 0.1 ml of 3% STS till blanching was noticed. It was followed by compression for 2 mins and patients were asked to follow- up every two-weekly. They found that 30 (85.7%) patients had complete clearance of the lesion.[24] Tanya Khaitan, et al., in their study used 0.2- 0.5 ml of 3% STS. They noted 100% clearance of lesions. Local discomfort and mild bleeding was documented in two cases.[25] Samantha et al. reported a case series on oral pyogenic granulomas, in which four cases resolved completely, while one became fibrotic following treatment with a sclerosing agent.[26] Rahman et al. effectively treated a case of scalp pyogenic granuloma, with no recurrence noted.[27] Similarly, in our study complete cure was obtained 96.7% of the patients included in the study at the end of assessment and all the patients experienced burning sensation following injection of the sclerosant.

Limitations

- The sample size is small to generalize the results to the population.
- Assessment of the lesion is subjective.
- Assessment of long term recurrence is not done.

CONCLUSION

The findings of this study suggests that sclerotherapy using the sclerosant, Sodium tetradecyl sulphate is an effective treatment modality in the treatment of pyogenic granuloma. The advantage of this modality of treatment is that it is minimally invasive compared to most other treatment options available, complete cure of the lesion and no recurrence after sclerotherapy according to our study. However, the disadvantage of this modality is that it has to be done by a trained personnel, requiring hospital visit and the burning sensation experienced by the patient during the administration of the drug.

For clinicians, the choice of treatment depends on patient factors such as pain tolerability or tolerance to local irritation, ability to visit the medical facility and the size and site of the lesion.

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