



COMPARATIVE EVALUATION OF INTRALESIONAL SCLEROTHERAPY WITH SODIUM TETRADECYL SULFATE VERSUS BLEOMYCIN FOR SLOW-FLOW VASCULAR MALFORMATIONS OF HEAD AND NECK

Plastic Surgery

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ABSTRACT

Background: Slow-flow vascular malformations (VMs) of the head and neck are congenital vascular anomalies that pose both aesthetic and functional challenges. Sclerotherapy has become the first-line treatment, but the best sclerosant remains debated. This study compared the efficacy and safety of intralesional Sodium Tetradecyl Sulfate (STS) versus Bleomycin in the management of slow-flow VMs of the head and neck, and also evaluated outcomes when sclerotherapy was used alone or as an adjunct to surgery. **Methods:** A prospective, comparative study was conducted in the Departments of Plastic Surgery and Radiodiagnosis, Jawaharlal Nehru Medical College, Aligarh Muslim University, from June 2022 to July 2024. Thirty-two patients with clinically and radiologically confirmed low-flow vascular malformations were enrolled. They were divided into three groups: sclerotherapy alone, sclerotherapy followed by surgery, and surgery alone. Within the sclerotherapy cohort, 11 patients received STS and 11 received Bleomycin. The following parameters were assessed including lesion size reduction, ease of operability, complication profile, and patient satisfaction. Statistical analysis was performed using SPSS version 25.0. **Results:** The mean age of patients in the study was 17.4 ± 11.6 years, with a slight female predominance (59%). Common lesion sites included lip (32%) and neck (27%). The mean lesion size was 6.8 ± 5.4 cm. Resolution rates were comparable between STS (48.1%) and Bleomycin (49.6%) groups ($p = 0.84$). Ease of operability was marginally higher in the STS group (64% vs. 45%), while satisfaction was greater with Bleomycin (55% vs. 27%). Complications were minimal, with pain (27%) and ulceration (14%) being the most frequent. There was one complicated case of necrosis and recurrence after resolution of lesion. **Conclusion:** Both these drugs, STS and Bleomycin are effective and safe agents for treating slow-flow vascular malformations of the head and neck. STS provides easier intra-operative handling, while Bleomycin offers higher patient satisfaction with fewer complications. Combining preoperative sclerotherapy with surgery optimizes operability and aesthetic outcomes.

KEYWORDS

Bleomycin, Sodium Tetradecyl Sulfate, Sclerotherapy, Vascular Malformations, Head and Neck, Plastic Surgery.

INTRODUCTION

Vascular malformations are congenital abnormalities affecting the blood vessels or lymphatic system. They occur due to abnormal development during embryogenesis. These abnormal dilated vessels grow proportionally to body size and do not usually show spontaneous regression. Venous malformations have an estimated incidence of 1/5000–1/10,000 births¹ and an estimated prevalence of 1%². The International Society for the Study of Vascular Anomalies (ISSVA) categorises the vascular anomalies into two main types: First is vascular tumors (such as the common infantile hemangioma) and second is vascular malformations.³ The 2018 International Society for the Study of Vascular Anomalies classification divides vascular malformations into groups: simple, combined of major vessels, and those associated with other anomalies⁴ Of these, simple venous malformations (VMs) are the most commonly encountered in clinical practice and account for the majority of referrals to a vascular anomaly clinic for symptom management.⁵

Traditionally, surgery was the mainstay of management; however, it carries a high risk of bleeding, scarring, and neurovascular injury. Sclerotherapy has emerged as a minimally invasive, first-line alternative that induces endothelial injury and fibrosis, leading to lesion regression. Several sclerosing agents are available — including ethanol, polidocanol, sodium tetradecyl sulfate (STS), and Bleomycin — yet no universal consensus exists on the ideal agent.

This study aimed to perform a comparative evaluation of STS and Bleomycin for treating slow-flow vascular malformations of the head and neck, focusing on lesion resolution, ease of operability, and safety profile. It also analyzed outcomes of sclerotherapy alone versus combined sclerotherapy with surgery to establish optimal management guidelines.

MATERIALS AND METHODS

Study Design and Setting

This prospective, comparative clinical study was conducted in the Departments of Plastic Surgery and Radiodiagnosis, Jawaharlal Nehru

Medical College and Hospital (JNMCH), Aligarh Muslim University, Aligarh, India. The study period spanned from June 2022 to July 2024. Ethical approval was obtained from the Institutional Ethics Committee (IEC), and the trial was registered under the Clinical Trials Registry of India (CTRI/2023/05/053122).

Study Population

Thirty-two patients diagnosed with slow-flow vascular malformations of the head and neck were included. Diagnosis was based on clinical examination and confirmed using Doppler ultrasonography or MRI.

Inclusion Criteria

- Patients of any age with venous or lymphatic malformations of the head and neck.
- Patients providing informed consent.
- Exclusion criteria:
- High-flow (arteriovenous) malformations.
- Known hypersensitivity to sclerosants or contrast media.
- Refusal to undergo the procedure.

Grouping and Treatment Protocol

Patients were divided into three treatment arms:

1. Sclerotherapy alone ($n = 10$)
2. Sclerotherapy followed by surgery ($n = 12$)
3. Surgery alone ($n = 10$)

Within the sclerotherapy cohort, patients were randomly allocated to:

- **Group A:** Sodium Tetradecyl Sulfate (STS) – 11 patients
- **Group B:** Bleomycin – 11 patients

Sclerotherapy was performed under sterile conditions.

- **STS Protocol:** 3% foam solution (30 mg/ml) injected in doses of 2–6 ml per session (not exceeding 0.5 ml/kg or 20 ml/session).
- **Bleomycin Protocol:** 15 units (15 mg) per session, not exceeding 15 units per sitting.

Post-injection, manual compression was applied for 5 minutes followed by a pressure dressing. Patients received oral analgesics for 3–5 days post-procedure.

Each patient was evaluated after 4–6 weeks and underwent up to 2–3 sessions as required. Surgical excision was performed under general anesthesia for lesions requiring debulking or showing incomplete response.

Assessment Parameters

- Primary outcomes: Reduction in lesion size and ease of operability.
- Secondary outcomes: Complications (pain, ulceration, necrosis, infection, recurrence) and patient satisfaction (graded as satisfied, partially satisfied, unsatisfied).
- Statistical Analysis: Data were analyzed using SPSS version 25.0 (IBM, Chicago, USA). Parametric data were expressed as mean $\pm$ SD; non-parametric data as median (IQR). Independent t-test, Fisher's exact test, and Mann-Whitney U test were applied. Significance level: $p < 0.05$.

RESULTS

Demographic Profile

The mean age of participants in the study was 17.4 ± 11.6 years (range 6 months–37 years). There was a slight female predominance (59%). Most lesions were located on the lip (31.8%), followed by neck (27.3%), cheek (18%), and face/scalp (9%).

Lesion Size and Sclerotherapy Sessions

The mean lesion size in the study was 6.8 ± 5.4 cm (range 1.5–20 cm). Majority of patients required 1–2 sclerotherapy sessions. There was no significant difference in mean lesion size or number of sessions between STS and Bleomycin groups ($p > 0.05$).

Clinical Outcomes

Both groups demonstrated a comparable mean resolution rate (STS 48.1% vs. Bleomycin 49.6%, $p = 0.84$).

Ease of operability was slightly greater in the STS group (63.6% vs. 45.5%), while the average operative time was 80 ± 23 minutes for combined procedures.

Complications

Complications were generally mild and transient:

- Pain: 27% (managed conservatively)
- Infection/Ulceration: 14%
- Edema: 9%
- Skin necrosis: 1 case
- Recurrence: 1 case (4.5%) after 1 year

No systemic complications, pulmonary fibrosis, or allergic reactions were observed.

Patient Satisfaction

Overall, 50% of patients were partially satisfied, 41% satisfied, and 9% unsatisfied. Satisfaction was higher in the Bleomycin group (55%) compared to STS (27%), though this difference was not statistically significant.

DISCUSSION

Vascular malformations of the head and neck represent a therapeutic challenge due to their variable presentation, functional significance, and aesthetic implications. Surgical excision alone, though definitive, is often limited by bleeding, incomplete removal, and scarring. Hence, sclerotherapy has emerged as a safe, reproducible, and cost-effective modality.

In our study, both STS and Bleomycin demonstrated similar efficacy in lesion reduction. Previous literature by Bajpai et al. and Bhandari et al. reported superior outcomes with Bleomycin, achieving $>70\%$ regression in most cases, while STS showed a slower but satisfactory response requiring multiple sessions. Our findings corroborate this, showing comparable but not statistically different outcomes between agents.

STS acts as a detergent sclerosant causing endothelial damage and subsequent fibrosis. It is inexpensive, easily available, and well-tolerated for small to moderate lesions. Bleomycin, on the other hand, exerts a cytotoxic effect through induction of endothelial apoptosis and fibrosis via the mTOR pathway. It offers minimal pain and lower risk of pigmentation or scarring, but repeated injections may be needed for large lesions.

In our study, ease of operability was marginally better in the STS

group, likely due to greater reduction in vascularity and induration, facilitating dissection. However, Bleomycin yielded higher patient satisfaction owing to less post-injection discomfort and fewer inflammatory reactions. Both drugs exhibited a low complication rate, with only minor local reactions. Importantly, no systemic toxicity was observed, confirming the safety of the doses used.

Combination therapy — sclerotherapy followed by surgery — achieved optimal cosmetic and functional outcomes, especially for extensive or deforming lesions. This aligns with global literature emphasizing a multidisciplinary approach integrating plastic surgery and interventional radiology for best results.

CONCLUSION

Sodium Tetradecyl Sulfate and Bleomycin both are safe and effective agents for sclerotherapy in slow-flow vascular malformations of the head and neck.

STS offers slightly easier operability for subsequent surgery, whereas Bleomycin provides superior patient comfort and satisfaction with minimal side effects. The mean percentage reduction in size was greater with bleomycin as compared to STS after intralesional sclerotherapy injections.

Preoperative sclerotherapy followed by surgical excision appears to yield the most favorable outcomes in terms of lesion reduction, operative ease, and aesthetic recovery.

Ethical Considerations

Ethical approval was obtained from the Institutional Ethics Committee, Jawaharlal Nehru Medical College, Aligarh Muslim University. Written informed consent was obtained from all participants or their guardians.

Conflict of Interest

None declared.

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