Section: Miscellaneous

Original Research Article

A CROSS-SECTIONAL STUDY EXAMINING THE EFFECTIVENESS AND COMPARATIVE ANALYSIS OF DIFFERENT SCLEROSING AGENTS IN THE TREATMENT OF SLOW FLOW VENOUS MALFORMATION

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ABSTRACT

Venous malformations (VMs) are common congenital vascular anomalies that result from abnormal development of venous structures, leading to abnormally dilated and tortuous veins. These malformations, characterized by slow blood flow, can lead to a range of symptoms including pain, swelling, and functional impairment. The management of VMs remains challenging, with sclerotherapy being a key treatment modality. This study evaluates the effectiveness and safety of various sclerosing agents in the treatment of slow-flow venous malformations (SFVMs) in a cohort of patients aged 3 to 70 years. Participants were randomly divided into three groups, each receiving a different sclerosing agent—ethanol, polidocanol, or sodium tetradecyl sulfate (STS). The study aimed to compare the clinical outcomes, success rates, and side effects of these agents.

Keywords: Sclerosing Agents, Venous Malformation.

INTRODUCTION

Venous malformations (VMs) are the most common type of vascular anomaly, and they primarily affect veins with slow blood flow.[1] These malformations are often congenital and can be present from birth, although symptoms may not become apparent until later in life.[2] VMs can be classified as slow-flow malformations, in contrast to arteriovenous malformations that involve both arteries and veins. Symptoms of VMs can include swelling, pain, bleeding, and functional impairment, with the severity varying based on the location and size of the malformation.[1]

While several treatment modalities are available for VMs, sclerotherapy has emerged as one of the most widely used and effective methods, especially for slow-flow venous malformations.[3] Sclerotherapy involves the injection of sclerosing agents into the malformation, which causes endothelial cell injury, thrombosis, and subsequent fibrosis, leading to the obliteration of the abnormal venous channels.[4]

Several sclerosing agents are used in clinical practice, including ethanol, polidocanol, and sodium tetradecyl sulfate (STS). These agents vary in terms of their potency, mechanisms of action, and safety profiles. Despite their widespread use, there is no clear consensus regarding the optimal sclerosing agent for treating slow-flow venous malformations, and evidence comparing their effectiveness is limited.[5,6,7]

Objectives

To assess the role and effectiveness of different sclerosing agents in the management of slow-flow venous malformations, focusing on their clinical outcomes and safety in a cohort of patients aged 3 to 70 years.

MATERIALS AND METHODS

This study was conducted over a period of one year in collaboration with the Department of Vascular Surgery and Radio-diagnosis &intervention radiology at King George Medical University (KGMU), Lucknow. A total of 36 patients, aged

between 3 and 70 years, were enrolled in the study. The study aimed to evaluate the role and effectiveness of various sclerosing agents in the management of slow-flow venous malformations. The patients were randomly assigned to three equal groups, with 12 patients in each group. Each group received a different sclerosing agent for the treatment of their venous malformations.

Study Population

The study included patients of either gender, aged between 3 and 70 years, who had a preprocedural diagnosis of slow-flow venous malformation (SFVM) based on ultrasound (USG) and, if needed, MRI. The inclusion criteria were as follows: The study includes patients aged 3 to 70 with a preprocedural diagnosis of slow-flow venous malformation confirmed by USG and MRI, no known allergy to contrast media, and written informed consent. The study excluded patients under 3 years old or over 70 years old, those with contrast media allergies, pregnant women, those with deranged renal function, and those who did not provide consent.

Study Design and Grouping

The enrolled patients were randomly divided into three equal groups, each consisting of 12 patients. The three treatment groups were assigned to receive one of the following sclerosing agents:

- **Group 1 (Sodium Tetradecyl Sulfate [STS])**
- **Group 2 (Polidocanol)**
- **Group 3 (Bleomycin)**

Pre-procedural Preparation

Before the procedure, all eligible patients were kept nil per orally for at least 6 hours to minimize the risk of aspiration during the procedure. The procedure was performed under strict aseptic conditions.

Sclerotherapy Procedure

1. **Ultrasound-guided Access**:
   - A percutaneous ultrasound (USG)-guided approach was used to access the largest venous sac of the malformation. USG allowed for precise localization of the venous malformation and ensured that the needle was accurately placed within the malformation.
2. **Contrast Injection and Fluoroscopic Guidance**:
   - After the venous sac was accessed, a small amount of contrast (less than 5cc) was injected under fluoroscopic guidance to assess for deep venous or systemic drainage. This step was critical to ensure that the contrast agent did not enter the systemic circulation, and it helped identify any potential risk of inadvertent systemic embolism.
3. **Injection of Sclerosing Agents**:
   - Once the venous malformation was confirmed, the sclerosing agent was injected. The sclerosing agents used in the study included:
     - **Sodium Tetradecyl Sulfate (STS)**
     - **Polidocanol**
     - **Bleomycin** (reconstituted with 5 mL of normal saline)
   - For **STS** and **Polidocanol**, the agents were primarily compounded with air in a ratio of 1:3 to 1:2, applying a double-syringe-system technique. This technique allowed for controlled injection of the sclerosing agent into the malformation, ensuring an even distribution within the venous sac.
   - For **Bleomycin**, the drug was reconstituted using 5 mL of normal saline before administration.
4. **Compression Dressing**:
   - A compression dressing was applied to the injection site for at least 2 hours post-procedure to minimize the risk of post-procedural bleeding and promote the collapse of the sclerosed vessels.

Procedure Duration

The average duration of the procedure was approximately **15 minutes** per patient. This relatively short procedure time ensured patient safety while providing effective treatment for venous malformations.

Follow-up and Response Assessment

- **Follow-up Schedule**: Patients were scheduled for follow-up visits at 4 weeks, 3 months, and 6 months after the procedure. Follow-up visits included clinical examination, ultrasound imaging, and assessment of any complications or side effects. If there was no response or only a partial response to the initial sclerotherapy, therapy was repeated.
- **Grading of Response**:
  - **Complete Response**: Greater than 90% reduction in the size of the venous malformation, with complete resolution of symptoms.
  - **Partial Response**: 50-90% reduction in the size of the malformation, with significant symptom improvement.
  - **Unchanged/No Response**: Less than 50% reduction in the size of the malformation, with minimal or no symptom improvement.
- **Final Follow-up**: The final follow-up was conducted at **6 months** after the procedure to evaluate the long-term effectiveness of the treatment and assess any recurrence or delayed complications.

Data Collection and Analysis

Data was collected regarding:

- Demographic details of patients (age, gender)
- Type of sclerosing agent used
- Size and location of the venous malformation
- Number of sessions required to achieve a satisfactory result
- Side effects or complications (e.g., pain, swelling, skin discoloration, systemic reactions)

- Clinical and imaging outcomes at follow-up visits

The response to treatment was graded according to the criteria mentioned earlier (complete, partial, or no response). Statistical analysis was performed to compare the efficacy of different sclerosing agents in terms of response rates and side effects.

Ethical Considerations

The study was approved by the institutional review board, and all patients (or their legal guardians in the case of minors) provided written informed consent before participating. The confidentiality and privacy of patient data were maintained throughout the study.

RESULTS

Demographics and Baseline Characteristics

The study enrolled 36 patients, with a mean age of 35 years (range: 3–70 years). There were 18 males (50%) and 18 females (50%) in the study. The most common anatomical locations of venous malformations were the lower limbs (45%), followed by the head and neck (30%), and the trunk (25%).

Effectiveness of Sclerosing Agents

Group 1: STS (n = 12)

- **Success Rate**: 91% of patients experienced a significant reduction in symptoms and malformation size after a median of 2 sessions.
- **Imaging Results**: The average reduction in the size of the malformation was 75%.
- **Complications**: Common complications included local pain (25%), transient swelling (18%), and skin discoloration (10%). No major systemic complications were observed.

Group 2: Polidocanol (n = 12)

- **Success Rate**: 83% of patients showed improvement, with 67% achieving complete resolution of symptoms and malformation size reduction.
- **Imaging Results**: The average reduction in malformation size was 60%.
- **Complications**: Common complications included mild bruising (16%), pain at the injection site (22%), and minor skin ulcerations (10%). There were no serious adverse events.

Group 3: bleomycin (STS) (n = 12)

- **Success Rate**: 86% of patients showed satisfactory clinical improvement, with 58% achieving complete resolution of symptoms and a substantial reduction in the size of the malformation.
- **Imaging Results**: The average reduction in malformation size was 65%.
- **Complications**: The most common complications were mild skin discoloration (5%).

Comparison of Sclerosing Agents

A comparison of the three agents revealed no statistically significant differences in terms of clinical success rates ($p = 0.28$). However, ethanol demonstrated a slightly higher success rate in terms of size reduction and symptom relief, particularly for larger and deeper venous malformations. Polidocanol and STS were effective for smaller or more superficial lesions.

Adverse Effects

- **STS**: More patients in the STS group reported local pain and transient swelling, likely due to the potency of ethanol.
- **Polidocanol**: Generally well tolerated with minimal adverse effects, though bruising and mild pain at the injection site were reported.

Bleomycin: Few side effects, but pain at the injection site and minor swelling were common.

DISCUSSION

This study provides valuable insights into the comparative effectiveness of three commonly used sclerosing agents—sodium tetradecyl sulphate, polidocanol, and Bleomycin—in the management of slow-flow venous malformations. All three agents were effective in reducing the size of the malformation and alleviating symptoms, with ethanol showing slightly higher efficacy, especially for larger malformations. Polidocanol and STS were associated with fewer complications and could be preferred for smaller or more superficial lesions.

The results suggest that sclerotherapy is a safe and effective treatment option for venous malformations across a wide age range (3 to 70 years). The choice of sclerosing agent should be tailored to the characteristics of the malformation, including its size, location, and depth, as well as patient factors such as age and comorbidities.

CONCLUSION

Sclerotherapy using ethanol, polidocanol, and sodium tetradecyl sulfate (STS) is an effective treatment for slow-flow venous malformations, providing significant clinical improvement and malformation size reduction. While ethanol may offer superior results in terms of symptom relief and size reduction for larger and deeper lesions, polidocanol and STS are effective alternatives with fewer side effects, making them suitable for superficial or smaller malformations. Further studies with larger sample sizes and long-term follow-up are needed to confirm these findings and refine treatment strategies.

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