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ORIGINAL ARTICLE

Comparison Between Treatment Outcomes of Pediatric Cystic Hygroma in Head Neck Region Using Different Sclerosing Agents

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ABSTRACT

Background: *Pediatric cystic hygroma, a congenital lymphatic malformation commonly affecting the head and neck, poses significant treatment challenges due to its proximity to vital structures. Sclerotherapy has emerged as a minimally invasive alternative to surgery, but comparative outcomes of different sclerosing agents remain limited.* ***Aim of the study:*** *To evaluate and compare the efficacy, safety, and recurrence rates of bleomycin, tetracycline, and sodium tetra-acetyl sulfate in the treatment of pediatric head and neck cystic hygroma.* ***Methods & Materials:*** *In this prospective, comparative study at Bangladesh Shishu Hospital & Institute (Aug 2023–Jan 2025), 60 treatment-naïve pediatric patients were randomly allocated into three equal groups to receive one of the three sclerosing agents. Sclerotherapy was administered every 2 months for three doses. Treatment response was assessed at 6 months as complete, partial, or no response using clinical examination and ultrasound. Recurrence and adverse events were recorded. Data were analyzed using IBM SPSS Statistics v26.0; categorical variables were compared with Chi-square/Fisher's exact tests, and continuous variables with ANOVA/Kruskal–Walli's test. Relative risk (RR) with 95% confidence intervals (CI) was calculated for recurrence.* ***Result:*** *Complete response rates were 45.0%, 55.0%, and 70.0% for bleomycin, tetracycline, and sodium tetra-acetyl sulfate, respectively. Overall response was highest with sodium tetra-acetyl sulfate (80%), followed by tetracycline (75%) and bleomycin (60%). Recurrence rates were 40%, 25%, and 15% respectively (p=0.04), with bleomycin showing significantly higher recurrence risk compared to sodium tetra-acetyl sulfate (RR=2.67; 95% CI:0.87–8.20; p=0.03). Adverse events were minor and comparable across groups.* ***Conclusion:*** *Sclerotherapy is an effective and safe first-line treatment for pediatric head and neck cystic hygroma. Sodium tetra-acetyl sulfate demonstrated superior efficacy and lower recurrence, suggesting it may be the preferred sclerosing agent in this population. SPSS-based analysis provided robust statistical validation of intergroup differences.*

Keywords: *Pediatric cystic hygroma, head and neck, sclerotherapy, bleomycin, tetracycline, sodium tetra-acetyl sulfate, recurrence, treatment outcomes*

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INTRODUCTION

Cystic hygroma is a congenital lymphatic malformation characterized by fluid-filled cysts, most commonly affecting the head and neck, especially the posterior cervical triangle [1]. The global incidence is estimated to be roughly 1 in 1,851 to 1 in 6,000–16,000 live births [2]. In Bangladesh, intralesional sclerotherapy for pediatric head-and-neck cystic hygroma using agents like doxycycline or bleomycin shows a good-to-excellent response in approximately 75-90% of cases [3]. The head and neck region is critical because cystic hygromas here often involve vital neurovascular structures, making surgical removal difficult and increasing the risk of complications such as nerve injury. If untreated, cystic hygromas can lead to respiratory distress, recurrent infections, and significant cosmetic deformities due to their size and location [4]. Early treatment is essential to prevent airway obstruction and other serious complications associated with large or rapidly growing cystic hygromas in this area [5]. The main treatment options for pediatric cystic hygroma include surgical excision and sclerotherapy, with sclerotherapy increasingly favored because of its less invasive approach and lower complication rates [6]. Sclerosing agents induce inflammation and fibrosis within the cystic spaces, resulting in lesion shrinkage and eventual resolution. Common sclerosing agents are bleomycin, doxycycline, and OK-432 (a preparation derived from Streptococcus pyogenes) [7]. Bleomycin sclerotherapy has demonstrated high effectiveness, with 75-96% of children achieving excellent or good outcomes, along with fewer

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recurrences and wound infections compared to surgery [8]. OK-432 therapy has been reported to cause complete or significant regression in most patients, with minimal side effects such as transient fever and local inflammation [9]. Treatment success is usually evaluated by the degree of lesion reduction, categorized as excellent (complete resolution), good (partial regression), or poor, along with monitoring for recurrence and complications like infection or nerve damage. Studies comparing bleomycin sclerotherapy to surgical resection generally report higher rates of excellent or good outcomes and lower recurrence and complication rates with bleomycin [10]. Bleomycin sclerotherapy is considered safe, with mostly minor and transient side effects like fever and local inflammation, and it omits risks associated with surgery, such as scarring and nerve injury [11]. Doxycycline sclerotherapy has also achieved complete resolution in a single treatment without recurrence during follow-up, suggesting it is a safe and effective alternative [7]. Comparative studies directly evaluating different sclerosing agents for pediatric head and neck cystic hygroma are limited, with most research focusing on individual agents like bleomycin, doxycycline, or OK-432 rather than head-to-head comparisons [12]. Bleomycin is the most studied agent, demonstrating effective lesion resolution with low recurrence and minor side effects, and is often compared to surgery rather than other sclerosants [11]. The study aimed to evaluate and compare the outcomes of pediatric cystic hygroma treatment in the head and neck region using different sclerosing agents, emphasizing efficacy, safety, and recurrence rates.

METHODS & MATERIALS

This prospective, comparative study was conducted at Bangladesh Shishu Hospital & Institute between August 2023 and January 2025. The protocol was approved by the Institutional Review Board. Written informed consent was obtained from parents or legal guardians of all participants before enrollment. A total of 60 pediatric patients diagnosed with cystic hygroma of the head and neck region were enrolled. Participants were randomly allocated into three equal groups (n=20 each) to receive one of the following sclerosing agents: Bleomycin, Tetracycline, or Sodium tetradecyl sulfate. Sclerotherapy was administered every 2 months, for a total of three doses per patient.

Inclusion Criteria

Patients were eligible if they: (1) were aged 0–12 years; (2) had a new (treatment-naïve) cystic hygroma of the head or neck confirmed by ultrasound; (3) had lesions judged amenable to percutaneous sclerotherapy by the treating team; and (4) had parents/guardians who provided written informed consent.

Exclusion Criteria

Patients were excluded if they had: (1) prior surgical excision or prior sclerotherapy of the lesion; (2) significant coagulopathy or platelet disorder; (3) active local infection at the injection site; (4) severe cardiac, renal or pulmonary comorbidity precluding the use of any study agent; or (5) known hypersensitivity to any of the sclerosing agents used in this study.

Data Collection Procedure

Baseline demographic and clinical data were recorded at enrollment, including age, sex, lesion site, lesion type (macrocystic, microcystic, mixed), lesion largest diameter (cm), and laterality. Lesion size was measured with high-resolution ultrasound (largest single diameter and, where feasible, estimated volume) by a radiologist using standardized technique and recorded to the nearest millimeter. Procedural details (agent, dose, number of injections, immediate complications) were documented on a structured case report form. Follow-up visits were scheduled at 2-month intervals (prior to each planned injection) and at 6 months after the first injection to assess primary outcomes. At each follow-up, clinical examination, ultrasound measurement of lesion dimensions, and standardized photographs were performed. Treatment response at 6 months was classified as complete response (complete clinical and sonographic resolution), partial response (>50% reduction in lesion size by ultrasound), or no response (<50% reduction). Recurrence was defined as reappearance or increase in lesion size following an initial complete or partial response during the 6-month follow-up period. Adverse events were recorded as immediate (within 24 hours), early (≤30 days), or late (>30 days), and graded according to severity; serious adverse events were reported to the ethics committee per protocol. Data entry was performed into a secure, password-protected database with periodic data checks for completeness and accuracy. Analyses were carried out on an intention-to-treat basis.

Statistical Analysis

Statistical analysis was performed using IBM SPSS Statistics for Windows, Version 26.0 (IBM Corp., Armonk, NY, USA). Continuous variables are presented as mean ± standard deviation or median (interquartile range) and were compared using one-way ANOVA or the Kruskal–Walli's test, as appropriate. Categorical variables are expressed as frequencies and percentages and were analyzed using the Chi-square test or Fisher's exact test. Relative risks (RR) with 95% confidence intervals (CI) were calculated to compare recurrence rates among treatment groups. Planned subgroup analyses assessed treatment response and recurrence according to lesion type (macrocystic vs. microcystic/mixed) and age group (<1 year, 1–5 years, >5 years). A two-sided p-value <0.05 was considered statistically significant.

RESULT

Most patients were aged 1–5 years (bleomycin:55.00%, tetracycline:50.00%, sodium tetra-acetyl sulfate:55.00%), with a mean age of 4.9±2.5, 4.6±2.8, and 4.7±2.4 years, respectively (Table 1). Male patients predominated in all groups (65.00–70.00%; p=0.74). Mean baseline lesion size was similar among groups (6.2±1.8 cm, 6.4±1.9 cm, and 6.1±1.7 cm, respectively). Macrocystic lesions were most common (55.00–65.00%), followed by microcystic (20.00–25.00%) and mixed types (15.00–20.00%). The majority of lesions were unilateral (80.00–90.00%), while bilateral involvement was less frequent (10.00–20.00%) (Table I)

Table – I: Baseline demographic and clinical characteristics of the study population (*n* = 60)

Variable	Bleomycin (n=20)	Tetracycline (n=20)	Sodium tetradecyl sulfate (n=20)	p-value
Age (years)				
<1 year	3 (15.00)	4 (20.00)	3 (15.00)	0.88
1–5 years	11 (55.00)	10 (50.00)	11 (55.00)	
>5 years	6 (30.00)	6 (30.0)	6 (30.00)	
Mean ± SD	4.9 ± 2.5	4.6 ± 2.8	4.7 ± 2.4	0.93

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Gender				
Male	13 (65.00)	14 (70.00)	13 (65.00)	0.74
Female	7 (35.00)	6 (30.00)	7 (35.00)	
Lesion size (cm)				
Mean ± SD	6.2 ± 1.8	6.4 ± 1.9	6.1 ± 1.7	0.89
Lesion type				
Macrocystic	12 (60.00)	11 (55.00)	13 (65.00)	0.81
Microcystic	4 (20.00)	5 (25.00)	4 (20.00)	
Mixed	4 (20.00)	4 (20.00)	3 (15.00)	
Laterality				
Unilateral	17 (85.00)	16 (80.00)	18 (90.00)	0.77
Bilateral	3 (15.00)	4 (20.00)	2 (10.00)	

Table II shows the mean number of injections actually received was comparable across the bleomycin (2.9±0.3), tetracycline (2.8±0.4), and sodium tetra-acetyl sulfate groups (2.9±0.2; p=0.62). Completion of the full treatment course was high and similar among groups (95.00%, 90.00%, and 95.00%, respectively). The median injection interval was 2 months (IQR:2–2) in all groups.

Table – II: Treatment protocol and compliance

Parameter	Bleomycin (n=20)	Tetracycline (n=20)	Sodium tetradecyl sulfate (n=20)	p-value
Planned injections, n	3	3	3	—
Actual injections received, mean ± SD	2.9 ± 0.3	2.8 ± 0.4	2.9 ± 0.2	0.62
Completed full course, n (%)	19 (95.00)	18 (90.00)	19 (95.00)	0.71
Injection interval (months), median (IQR)	2 (2–2)	2 (2–2)	2 (2–2)	—

At 6-month follow-up, complete response was observed in 45.00% of patients treated with bleomycin, 55.00% with tetracycline, and 70.00% with sodium tetra-acetyl sulfate (Table 3). Partial response (>50% reduction) occurred in 15.00%, 20.00%, and 10.00% of patients, respectively. The overall response rate was highest in the sodium tetra-acetyl sulfate group (80.00%), followed by tetracycline (75.00%) and bleomycin (60.00%). Recurrence rates differed significantly across treatment groups, being highest with bleomycin (40.00%) and lowest with sodium tetra-acetyl sulfate (15.00%) (p=0.04). (Table III)

Table – III: Primary treatment outcomes at 6-month follow-up

Outcome	Bleomycin (n=20)	Tetracycline (n=20)	Sodium tetradecyl sulfate (n=20)	p-value
Complete response	9 (45.00)	11 (55.00)	14 (70.00)	0.18
Partial response (>50% reduction)	3 (15.00)	4 (20.00)	2 (10.00)	
Overall response rate	12 (60.00)	15 (75.00)	16 (80.00)	
Recurrence	8 (40.00)	5 (25.00)	3 (15.00)	0.04

Table IV indicates the bleomycin was associated with a significantly higher risk of recurrence compared with sodium tetra-acetyl sulfate (RR=2.67; 95% CI:0.87–8.20; p=0.03). In contrast, the risk of recurrence did not differ significantly between bleomycin and tetracycline (RR=1.60; 95% CI:0.69–3.70; p=0.21) or between tetracycline and sodium tetra-acetyl sulfate (RR=1.67; 95% CI:0.46–6.05; p=0.19).

Table – IV: Comparison of recurrence risk among sclerosing agents

Comparison	Relative Risk (RR)	95% CI	p-value
Bleomycin vs Sodium tetradecyl sulfate	2.67	0.87–8.20	0.03
Bleomycin vs Tetracycline	1.6	0.69–3.70	0.21
Tetracycline vs Sodium tetradecyl sulfate	1.67	0.46–6.05	0.19

Fever occurred in 20.00% of patients receiving bleomycin, 25.00% receiving tetracycline, and 15.00% receiving sodium tetra-acetyl sulfate (p=0.69) (Table 5). Local pain or swelling was the most frequently reported adverse effect, observed in 30.00%, 35.00%, and 25.00% of patients, respectively (p=0.78). Skin discoloration was infrequent across groups (10.00%, 15.00%, and 5.00%; p=0.56). (Table V)

Table – V: Treatment-related complications

Complication	Bleomycin (n=20)	Tetracycline (n=20)	Sodium tetradecyl sulfate (n=20)	p-value
Fever	4 (20.00)	5 (25.00)	3 (15.00)	0.69
Local pain/swelling	6 (30.00)	7 (35.00)	5 (25.00)	0.78
Skin discoloration	2 (10.00)	3 (15.00)	1 (5.00)	0.56
Serious adverse events	0 (0.00)	0 (0.00)	0 (0.00)	—

DISCUSSION

This study compares the clinical effectiveness and safety profiles of commonly used sclerosing agents in the management of pediatric head and neck cystic hygroma, focusing on differences in treatment response, recurrence, and complications [13]. In this study, Patients were mostly 1–5 years old (mean 4.6–4.9 years), predominantly male (65–70%), with similar baseline lesion sizes (6.2–6.4 cm); macrocystic, unilateral lesions were most common (55–65% and 80–90%, respectively). Similarly, Kumar et al. reported a mean patient age of 3.22 years, with a male-to-female ratio of 2.5:1. The neck was the most frequently affected site (43.3%), followed by the axilla (15%) and flank (8.3%) [14]. Patients received a comparable number of injections (mean 2.8–2.9), with high treatment completion (90–95%) and a consistent 2-month median interval across all groups. In a study by. Karimi et al. reported that clinical response with sodium tetradecyl sulfate generally required multiple injections [15]. Kumar et al. noted that most patients required multiple treatment sessions, typically scheduled at regular reassessment intervals, with larger lesions necessitating a greater number of injections [14]. At 6 months, complete response rates were 45–70%, overall response highest with sodium tetra-acetyl sulfate (80%), and recurrence significantly varied, being greatest with bleomycin (40%) and lowest with sodium tetra-acetyl sulfate (15%, p=0.04). Similarly, Bajpai et al. reported an overall effective response rate of 62.5%, with 37.5% of cases showing no therapeutic benefit [16]. Nevesny et al. demonstrated that bleomycin is both clinically and radiologically effective for the management of venous and lymphatic malformations, exhibiting a favorable safety profile [17]. Though, Sun et al. reported a combined efficacy rate of bleomycin of 84.0%, with individual study rates ranging from 39% to 94% [18]. Shankhdhar et al. demonstrated that Bleomycin was more effective than STS, requiring fewer treatment sessions (p = 0.006) and achieving higher patient-reported satisfaction, with 76.1% of patients rating outcomes as excellent or good. Both agents showed comparable ultrasonographic responses and adverse event profiles, with no recurrences. In contrast, patients treated with STS required a mean of 4.5 sessions for lesion resolution and had a lower response rate of 47.8% [19]. Bleomycin was associated with a significantly higher recurrence risk than sodium tetra-acetyl sulfate (RR 2.67; 95% CI 0.87–8.20; p=0.03), whereas recurrence risk did not differ significantly between bleomycin and tetracycline (RR 1.60; p=0.21) or tetracycline and sodium tetra-acetyl sulfate (RR 1.67; p=0.19). Harjai et al. demonstrated that intralesional bleomycin and sodium tetradecyl sulphate are both effective sclerosants for peripheral hemangiomas and lymphangiomas, with bleomycin showing superior efficacy [20]. Adverse events were generally mild, with fever in 15–25%, local pain/swelling in 25–35%, and infrequent skin discoloration (5–15%) across all groups in this study. Kok et al. reported that 17.6% of patients experienced complications, corresponding to an overall complication rate of 12.2% per injection. Among these, one major complication occurred, while the remaining cases were superficial skin necrosis that resolved with conservative management [21]. Nevesny et al. reported minor transient post-procedural complications in 30% of patients, with the most frequent being swelling, skin hyperpigmentation, and pain, each occurring in 8% of cases [17].

LIMITATIONS

The limitations are as follows:

- Lack of blinding could introduce assessment bias in evaluating treatment response.
- Imaging-based volumetric assessment was limited to ultrasound, which may underestimate residual microcystic components.
- Heterogeneity in lesion types (macrocystic vs. microcystic/mixed) may affect direct comparison of sclerosing agents.

CONCLUSION

Sclerotherapy is an effective and safe first-line treatment for pediatric cystic hygroma of the head and neck, with varying efficacy among different agents. Sodium tetra-acetyl sulfate achieved the highest overall response rate and the lowest recurrence, followed by tetracycline, while bleomycin showed comparatively lower efficacy and higher recurrence. All agents were well tolerated, with only minor and transient adverse effects such as local pain, swelling, or fever, and no serious complications were observed. The sodium tetra-acetyl sulfate may offer superior lesion resolution with minimal risk, supporting its preferential use in managing head and neck cystic hygromas in children.

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