

Efficacy and Safety of Ethanolamine Oleate as Sclerotherapy in Children with Cystic Hygroma

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ABSTRACT

Background: Cystic hygroma, a congenital lymphatic malformation, frequently occurs in the cervicofacial region and may cause airway obstruction, dysphagia, or cosmetic deformity. Traditional surgical excision carries risks of recurrence and morbidity, making minimally invasive approaches desirable. Ethanolamine oleate (EAO) has emerged as a promising sclerosing agent with favorable efficacy and safety profiles in pediatric populations. Aim of the study: To evaluate the efficacy and safety of ethanolamine oleate sclerotherapy in children with cystic hygroma. **Methods & Materials:** This prospective observational study enrolled 60 children aged 0-10 years with clinically and ultrasonographically confirmed cystic hygroma at Dhaka Shishu Hospital, Bangladesh, between January 2012 and June 2013. All patients underwent ultrasound-guided sclerotherapy with 5% EAO, with sessions repeated at 4-6-week intervals as required. Lesion size reduction, clinical response, and procedure-related complications were documented. Statistical analysis was performed using SPSS, with significance set at $p < 0.05$. **Result:** The mean patient age was 28.83 ± 29.59 months, with a male predominance (56.67%). Lesions were most commonly located in the neck (53.33%) and were predominantly macrocystic (63.33%). Patients received a mean of 1.8 ± 0.6 treatment sessions, with a mean injection volume of 2.6 ± 1.1 mL. Mean lesion size decreased significantly from 6.8 ± 2.7 cm to 0.9 ± 1.1 cm ($p < 0.001$), yielding a mean reduction of $87.5 \pm 12.3\%$. Complete response was achieved in 80% of patients, with an overall favorable outcome of 96.67%. Adverse events were minor and transient, including temporary swelling (10%), tenderness (6.67%), redness (3.33%), and

low-grade fever (6.67%). **Conclusion:** Ethanolamine oleate sclerotherapy is a highly effective, safe, and minimally invasive alternative to surgical management for pediatric cystic hygroma. Ultrasound-guided administration enables precise treatment, reduces recurrence risk, and minimizes procedural morbidity.

Keywords: Cystic hygroma, lymphatic malformation, ethanolamine oleate, sclerotherapy, pediatric surgery, minimally invasive treatment.

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INTRODUCTION

Cystic hygroma, also referred to as lymphatic malformation, is a congenital benign lesion arising from abnormal development of the lymphatic system, leading to the formation of single or multiloculated cystic cavities filled with lymphatic fluid [1]. Its estimated prevalence is about 1 in 6,000 to 16,000 live births and approximately 1 in 750 spontaneous abortions, making it a significant congenital anomaly encountered in pediatric surgical practice [2,3]. The majority of cystic hygromas about 75-90% occur in the cervicofacial region, followed by the axilla, mediastinum, and other less common sites. Nearly 60% are present at birth, and up to 90% are diagnosed before the age of two years. These lesions, though histologically benign, may enlarge over time and compress adjacent vital structures, leading to airway obstruction, dysphagia, or cosmetic deformity, which can severely impact the quality of life of affected children and their families [1,3]. Embryologically, cystic hygroma results from the failure of lymphatic sacs to establish proper connections with the venous system during development. It can present as an isolated anomaly or, in some cases, be associated with chromosomal abnormalities such as Turner's syndrome,

Down syndrome, or Noonan syndrome [4-6]. Clinically, the swelling is soft, fluctuant, and compressible, often transilluminant, and may increase in size during upper respiratory infections. Although the lesion is benign, spontaneous regression is rare, and without intervention, it can lead to progressive enlargement and potential complications depending on its site and size [7]. For decades, surgical excision was regarded as the gold standard of treatment. However, surgery for cystic hygroma presents significant challenges due to the infiltrative nature of the lesion and its close relationship with critical structures such as major blood vessels and nerves. Complete excision is often difficult, and incomplete removal carries a high recurrence risk ranging from 15% to 27% [8]. Postoperative complications such as infection, hemorrhage, seroma, nerve injury, or disfigurement are also common concerns. Moreover, in neonates and small children, repeated surgeries under general anesthesia pose additional anesthetic risks, making surgical treatment less desirable for extensive or deep-seated lesions [9-11]. To overcome these limitations, sclerotherapy has emerged as a less invasive, safe, and effective therapeutic alternative. The technique involves injecting a sclerosing agent into the cyst cavity, producing

endothelial injury, inflammation, and fibrosis. Several sclerosants have been utilized in clinical practice, including bleomycin, doxycycline, sodium tetradecyl sulfate, and ethanolamine oleate [12]. Each has demonstrated varying degrees of efficacy and safety. Among them, ethanolamine oleate has shown particular promise due to its strong sclerosing effect, favorable safety profile, and cost-effectiveness. It induces localized inflammation and subsequent fibrosis, causing the cystic lesion to shrink progressively with minimal systemic toxicity [13]. Evaluating its therapeutic efficacy and safety in this population is therefore essential to establish it as a reliable, minimally invasive, and cost-effective option for managing cystic hygroma. The present study was conducted to assess the efficacy and safety of ethanolamine oleate as a sclerotherapy agent in children with cystic hygroma, focusing on treatment response, recurrence rate, and procedure-related complications.

METHODS & MATERIALS

This prospective, observational study was conducted in the Department of Pediatric Surgery, Dhaka Shishu (Children's) Hospital, Bangladesh Institute of Child Health (BICH), Sher-e-Bangla Nagar,

Dhaka, between January 2012 and June 2013. Ethical approval was obtained from the Institutional Ethical Review Committee, and written informed consent was secured from the parents or legal guardians of all participants prior to enrollment. A total of 60 children diagnosed with cystic hygroma were enrolled consecutively. Diagnosis was based on detailed clinical assessment and ultrasonographic confirmation of cystic lesions compatible with lymphatic malformations. Patients were recruited according to the following criteria:

Inclusion criteria

- Children aged 0–10 years with clinically and ultrasonographically confirmed cystic hygroma
- Lesions suitable for percutaneous sclerotherapy
- No previous surgical or sclerotherapy treatment

Exclusion criteria

- Immediate life-threatening lesions requiring emergency intervention
- Cysts containing pus or blood on aspiration
- Intra-abdominal or mediastinal extension of the lesion
- Incomplete treatment schedule or loss to follow-up
- Refusal of consent by parents or guardians

Baseline Assessment and Data Collection

Demographic and clinical information was collected using a structured data sheet, including age, sex, lesion site, number, size, consistency, color, local temperature, tenderness, transillumination, and fixation to surrounding structures. History of onset, growth rate, prior infection, and previous treatments was recorded. Lesion size was measured in centimeters along the largest dimension using a flexible tape. Ultrasonography confirmed lesion type

(macrocytic, microcytic, or mixed) and guided procedural planning. Routine hematological and biochemical investigations were performed to ensure procedural fitness.

Sclerotherapy Procedure and Dose Determination

Prior to treatment, all patients underwent detailed ultrasound mapping with a high-frequency linear transducer (7.5–10 MHz) to delineate cyst morphology and plan needle entry. The dose of 5% ethanolamine oleate (EAO) was calculated according to patient body weight and lesion surface area, following established safety guidelines, with a maximum dose of 20 mg (0.4 mL/kg) or 0.4–1.0 mL/cm² of lesion surface area. All procedures were performed under strict aseptic conditions with real-time ultrasound guidance. Following aspiration of cystic fluid with a 22- or 23-gauge needle, EAO was slowly instilled into the cavity, limited to approximately one-third of the aspirated volume, not exceeding 5 mL per session. For multiloculated or large lesions, multiple punctures were made to ensure homogeneous sclerosant distribution. Gentle manual compression was applied for 5–10 minutes post-injection. Patients were observed for 2–4 hours to monitor for immediate adverse events, including pain, erythema, swelling, fever, or systemic reactions, before discharge.

Treatment Schedule and Follow-up

Patients were reviewed at 4–6-week intervals. Additional sclerotherapy sessions were performed if ultrasonography revealed residual or recurrent cystic components. Clinical and ultrasonographic assessments were repeated at each visit to document lesion regression. The total number of sessions, volume of sclerosant, and interval between sessions were recorded. Follow-up continued for a minimum of six months after the final treatment session to assess both efficacy and safety outcomes.

Outcome Assessment

Therapeutic efficacy was determined by comparing pre- and post-treatment lesion sizes. Responses were classified as complete response (CR; >90% reduction in lesion size), partial response (PR; 50–90% reduction), or no response/progression (NR; <50% reduction or increase). The overall response rate was defined as the proportion of patients achieving CR or PR. Safety assessment included documentation of all local and systemic adverse events during and after the procedure, including pain, redness, swelling, fever, vomiting, or transient lesion enlargement.

Statistical Analysis

Data were analyzed using IBM SPSS Statistics for Windows, Version 26.0 (IBM Corp., Armonk, NY, USA). Continuous variables were expressed as mean $\pm$ standard deviation (SD), and categorical variables were presented as frequencies and percentages. Paired *t*-tests were applied to compare lesion size before and after treatment. A two-tailed *p*-value <0.05 was considered statistically significant.

RESULT

The study population had a mean age of 28.83 ± 29.59 months. The majority of patients were aged between 12 and 30 months, representing 50% of the study. This was followed by infants aged 0–12 months, who accounted for 43.33%, and older children aged 30–120 months, comprising 6.67% of the population. Males comprised 56.67% of patients, while females accounted for 43.33%. Lesions most commonly involved the neck (53.33%), followed by the axilla (16.67%), trunk (13.33%), and forearm and cheek (8.33% each). The mean lesion size was 6.8 ± 2.7 cm. Macrocytic lesions predominated (63.33%), while microcytic and mixed types were observed in 20.00% and 16.67% of cases, respectively (*Table I*).

Table IBaseline demographic and clinical characteristics of the study population ($n=60$).

Variable	Frequency (n)	Percentage (%)
Age (months)		
0–12	26	43.33
12–30	30	50.00
30–120	4	6.67
Mean $\pm$ SD	28.83 $\pm$ 29.59	
Gender		
Male	34	56.67
Female	26	43.33
Lesion site		
Neck	32	53.33
Axilla	10	16.67
Trunk	8	13.33
Forearm	5	8.33
Cheek	5	8.33
Lesion size (cm)		
Mean $\pm$ SD	6.8 $\pm$ 2.7	
Cyst type		
Macrocystic	38	63.33
Microcystic	12	20.00
Mixed	10	16.67

Table II showed that all procedures were performed under ultrasound guidance (100%), with a mean of 1.8 ± 0.6 treatment

sessions per patient. The mean injection volume administered per session was 2.6 ± 1.1 mL, with an average interval of 6.2 ± 1.9

weeks between sessions. Patients were followed for a mean duration of 10.4 ± 3.6 months.

Table II

Treatment parameters of ethanolamine oleate sclerotherapy.

Parameter	Value
Mean number of sessions	1.8 ± 0.6
Mean injection volume (mL)	2.6 ± 1.1
Mean interval between sessions (weeks)	6.2 ± 1.9
Ultrasound-guided procedure, n (%)	60 (100.00)
Mean follow-up duration (months)	10.4 ± 3.6

The mean baseline lesion size was 6.8 ± 2.7 cm, which decreased to 0.9 ± 1.1 cm after treatment, representing a mean percentage

reduction of $87.5 \pm 12.3\%$ and this reduction was statistically significant ($P < 0.001$) (Table III).

Table III

Comparison of lesion size before and after ethanolamine oleate sclerotherapy.

Measurement	Mean $\pm$ SD	P-value*
Baseline lesion size (cm)	6.8 ± 2.7	<0.001
Post-treatment lesion size (cm)	0.9 ± 1.1	
Mean % reduction in lesion size	87.5 ± 12.3	

Table IV demonstrated that a complete response, defined as $>90\%$ reduction in lesion size, was achieved in 80.00% of patients. A partial response (50–90%

reduction) was observed in 16.67% of cases, while only 3.33% of patients showed no response or lesion progression ($<50\%$ reduction or increase). Overall, 96.67% of

patients demonstrated a favorable outcome, encompassing both complete and partial responses.

Table IV

Clinical response to ethanolamine oleate sclerotherapy in children with cystic hygroma.

Response Category	Frequency (n)	Percentage (%)
Complete response (CR) ($>90\%$ reduction)	48	80.00
Partial response (PR) (50–90% reduction)	10	16.67
No response/progression (NR) ($<50\%$ reduction or increase)	2	3.33
Overall response (CR + PR)	58	96.67

The most frequently observed adverse event was a temporary increase in lesion size,

occurring in 10.00% of patients. Tenderness and fever were each reported in 6.67% of

cases, while redness was observed in 3.33% of patients. No instances of vomiting were recorded in the study population (*Table V*).

Table V
Complications and adverse events observed during treatment among study population.

Complication	Frequency (n)	Percentage (%)
Redness	2	3.33
Tenderness	4	6.67
Vomiting	0	0.00
Fever	4	6.67
Temporary increase in size	6	10.00

DISCUSSION

Cystic hygroma, a common congenital lymphatic disorder in children, is known for its variable presentation and risk of recurrence [14]. In this study of 60 pediatric patients with cystic hygroma treated by ultrasound-guided ethanolamine oleate (EO) sclerotherapy, we demonstrated a high rate of clinical response, marked volumetric reduction, and a favorable safety profile. Our study had a mean age of 28.83 ± 29.59 months, with most patients (93.33%) being younger than 30 months. The male predominance (56.67%) and lesion distribution—with more than half located in the neck (53.33%) and a substantial proportion in the axilla (16.67%)—are consistent with the typical epidemiology of lymphatic malformations in children. Previous studies on pediatric lymphatic malformations, including cystic hygroma, similarly report that the neck is the most common site, and many lesions present in early childhood [15]. Importantly, in our sample, the majority of lesions (63.33%) were macrocystic, while 20.00% were microcystic and 16.67% mixed. This composition may influence response, because macrocystic lesions are well-known to respond more favorably to sclerotherapy. For instance, in earlier work using EO, purely macrocystic lymphatic malformations had better outcomes [16]. We used, on average, 1.8 ± 0.6 sessions of EO, with mean injected volume 2.6 ± 1.1 mL per session, and maintained an interval of 6.2 ± 1.9 weeks between sessions. All treatments were ultrasound-guided, ensuring precise delivery, and patients were followed for 10.4 ± 3.6 months on average. These parameters compare well with prior reports of EO use. In a single-center series for venous malformations, percutaneous EO sclerotherapy showed good safety, using similar per-session dilution and guided delivery [17]. Furthermore, a multicenter trial in difficult-to-resect venous malformations (including pediatric cystic-type lesions) used a maximum dose of 0.4 mL/kg per session of 5% EO [18]. Our lower number of sessions and modest injection volumes support that for lymphatic cystic lesions, EO can be effective even without very large cumulative dosing. The use of ultrasound guidance in all our cases also aligns with

standard practice; imaging guidance reduces the risk of extravasation, ensures contact between sclerosant and cyst wall, and helps minimize complications [19]. After treatment, the mean lesion size reduced dramatically from 6.8 ± 2.7 cm to 0.9 ± 1.1 cm, corresponding to a mean reduction of $87.5 \pm 12.3\%$. Clinically, 80.00% of patients achieved a “complete response” (>90% reduction) and another 16.67% had a partial response (50–90%), giving an overall response rate of 96.67%. These efficacy results are highly encouraging, particularly when compared to other sclerosants. For example, in a pediatric series from Stanford (2000–2014) using EO, OK-432, and doxycycline, the average volume reduction was 84.5%, with no significant differences in final outcome among agents. This suggests our response rate is consistent with, or perhaps even somewhat better than, previously reported work [20]. By contrast, intralesional aqueous bleomycin, another commonly used agent, has also shown good efficacy: in a cohort of 26 children, 88.4% had an “excellent” response (complete disappearance), and none had “poor” response after up to five monthly injections [21]. Bleomycin is well known for its effectiveness, but also carries long-term risks (e.g., pulmonary toxicity), especially when used systemically or at high cumulative doses [22]. Compared to these, our high proportion of complete responses and large mean size reduction underscore that EO is a highly effective sclerosant in pediatric cystic hygroma, especially in macrocystic lesions. In our study, complications were mild: redness in 3.33%, tenderness in 6.67%, transient fever in 6.67%, and temporary increase in size in 10%. No serious adverse events (e.g., systemic toxicity) were observed. These safety outcomes are comparable to earlier EO experiences. In percutaneous EO therapy for head-and-neck venous malformations, no major complications were reported [18]. Similarly, in a multicenter clinical trial of EO for difficult-to-resect venous malformations (including pediatric patients), while hemoglobinuria occurred in ~52% of cases, there were no serious or permanent adverse events; patients recovered with prompt haptoglobin therapy [18].

Nonetheless, prior literature warns of potential risk for hemoglobinuria (macroscopic hemoglobin in urine) after sclerotherapy with EO: in a retrospective analysis of 94 patients (130 procedures), macroscopic hemoglobinuria occurred in 27.7% of procedures, and one major risk factor was a dose ≥ 0.18 mL/kg of 5% EO [23]. In our study, perhaps due to lower per-session volumes, careful dosing, or hydration protocols, we did not observe this complication but this highlights the need for vigilance, especially in pediatric settings [24].

LIMITATIONS

Despite demonstrating high efficacy and safety, this study has several limitations. It was conducted at a single tertiary-care center with a relatively small sample size, which may limit generalizability. The follow-up period, averaging 10.4 months, may be insufficient to capture late recurrences or long-term complications. Additionally, the study lacked a comparative control group receiving alternative sclerosing agents or surgical treatment. Variability in lesion size, type, and anatomical location could have influenced treatment response, and operator experience may have affected procedural outcomes.

CONCLUSION

The findings of this study demonstrate that ethanolamine oleate is a highly effective and safe sclerotherapy agent for managing cystic hygroma in children. Treatment resulted in a substantial mean lesion size reduction of 87.5%, with complete response achieved in 80% of cases and an overall favorable outcome in 96.67% of patients. The procedure was well tolerated, with only minor, transient adverse events such as temporary lesion enlargement, tenderness, redness, or low-grade fever, and no serious systemic complications were observed. Ultrasound-guided administration facilitated precise delivery and optimized treatment efficacy. These results support ethanolamine oleate sclerotherapy as a minimally invasive, cost-effective, and reliable alternative to surgery, particularly for lesions in challenging anatomical locations, reducing the need for repeated

surgical interventions and associated morbidity in pediatric patients.

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CONFLICT OF INTEREST

None declared

ETHICAL APPROVAL

The study was approved by the Institutional Ethics Committee.

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