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TREATMENT OUTCOMES OF LYMPHATIC MALFORMATION IN CHILDREN: BLEOMYCIN SCLEROTHERAPY VS. SURGICAL RESECTION

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ABSTRACT

Objective: To evaluate the effects of bleomycin-sclerotherapy against surgical resection for children with Lymphatic malformation.

Methodology: This prospective observational study was conducted at the Pediatric Surgery Unit, DHQ Teaching Hospital Timergara Lower Dir KPK, Pakisan in the duration from January 2022 to February 2024, involving 60 pediatric patients with lymphatic malformation. Participants, aged one month to fifteen years, were divided into two groups: Group A (n=30) underwent intralesional sclerotherapy with bleomycin, while Group B (n=30) underwent surgical excision. Demographic data including age, gender, and lymphangioma location were collected, with outcomes categorized as excellent (total resolution), good (>50% resolution), or poor (<50% resolution). Post-procedural complications and recurrence rates were evaluated at three and six months post-treatment. Statistical analysis using SPSS 23.0 included Student's t-tests and chi-square tests, with $p<0.05$ considered significant.

Results: This study investigated the efficacy of sclerotherapy versus surgical excision in 60 pediatric patients with lymphatic malformation, evenly split into Group A (sclerotherapy) and Group B (surgery). Demographic analysis revealed no significant differences in age distribution, with Group A averaging 4.3 years and Group B 4.1 years. Gender composition was similar, with Group A comprising 26.67% males and 23.33% females, and Group B with 25% males and 25% females. The distribution of lymphangioma sites also showed no significant differences between groups. Treatment outcomes were categorized into complete, partial, and poor resolution, with Group A achieving higher rates of complete resolution (76.7% vs. 46.7% in Group B) and Group B showing significantly higher rates of poor resolution (20.0% vs. 3.3% in Group A). Complication rates favored sclerotherapy, with no cases of recurrence or wound infection in Group A, compared to 16.7% recurrence and 13.3% wound infection rates in Group B. While trends suggest fewer complications with sclerotherapy, statistical significance was not reached ($p = 0.052$ for recurrence and $p = 0.112$ for wound infection).

Conclusion: Sclerotherapy using bleomycin emerges as a safe and effective treatment for pediatric lymphatic malformation, showing advantages over surgical resection with no observed cases of recurrence or wound infection. Our study highlights important differences between sclerotherapy and surgery in achieving complete, good, and poor resolutions, with sclerotherapy demonstrating notable efficacy in reducing less favorable outcomes.

Keywords: Lymphatic malformation, sclerotherapy, surgical resection, outcomes.

Introduction

Congenital abnormalities of lymphatic structures are frequently recognized as lymphangiomas, benign hamartomatous tumors of the lymphatic system.1 The most common kind of them is called a lymphatic malformation, and it usually consists of a few macrocytic lesions with poor lymphatic channel connectivity.2. Although these slow-growing tumors can develop anywhere in the body, the neck, head, mediastinum, and axilla are the most often affected regions.3. lymphatic malformations are mostly encountered in children; they are visible at infancy in 65% of instances and by the time a child is two years old in 80–90% of cases. According to reports, the frequency of lymphangiomas ranges from 1.5 to 2.8 per 1,000 babies born alive, with no discernible correlation between gender or ethnicity.4-5

In terms of clinical manifestations, these tumors result in inflammation and visible abnormalities.6. Vital structures in the neck area may be compressed, resulting in breathing problems, dysphagia, and compression of nerves.7 Treatment with radiation, incisions and drainage, and excision via surgery are among the options for therapy for lymphatic malformations; the latter is the conventional standard of care.8. However, because the lesion tends to encircle important neurovascular structures and invade tissue planes, surgical excision is frequently challenging and can result in complications like tumor recurrence, nerve injury, disfigured appearance, and significant scarring.9–10

Intralesional sclerotherapy has been a recognized treatment modality for pediatric lymphangiomas in recent times.11 Using this method, a sclerosing substance is injected into the lymphangioma, irritating its endothelium lining and resulting in edema, involution, and fibrosis. Initial experiments with substances such as absolute alcohol, hot water, dextrose water, and hypertonic saline produced disappointing results.12–13 On the other hand, sclerosing drugs including acetic acid, doxycycline, and bleomycin have demonstrated encouraging results when used. Sclerotherapy is especially useful for lesions involving important tissues, as opposed to surgical excision.14

In order to treat childhood lymphatic malformation, this study compares the safety and efficacy of surgical excision vs bleomycin sclerotherapy.

Objective

To evaluate the effects of bleomycin-sclerotherapy against surgical resection for children with lymphatic malformation.

Methodology

This prospective observational study was conducted at the Pediatric Surgery Unit, DHQ Teaching Hospital Timergara Lower Dir KPK, Pakisan in the duration from January 2022 to February 2024. The study comprised 60 individuals with Lymphatic malformation of both genders, ranging in age from one month to fifteen years. After getting parental or guardian approval in written form, comprehensive demographic data was gathered, including gender, age, and the location of the lymphangioma. The study excluded patients who were 15 years of age or older, those who were experiencing a recurrence, and those who were already receiving sclerotherapy.

Two groups of patients were formed. Group A comprised 30 patients who underwent one to four sessions of intralesional sclerotherapy with bleomycin at a dosage of 0.3–0.5 mg/kg of body weight. A 24-hour hospitalization was necessary for each session, with a maximum number of four sessions per month. 30 individuals in Group B had surgery to remove their lymphatic malformation.

For both groups, post-procedural complications were documented. Three categories were applied to the results: total resolution (excellent), over fifty percent resolution (good), or less than 50% resolution (poor). The ultimate follow-up assessed the recurrence rate. Three and six months after the procedure, follow-up evaluations were carried out. To assess the results, pre- and post-operative X-rays and ultrasounds were conducted.

SPSS version 23.0 was used to analyze the data. The results across the two groups were compared using Student's t-tests and chi-square tests. Lesser than 0.05 was the threshold for statistical significance.

Results

The study included 60 pediatric patients with lymphatic malformation, equally divided into two groups of 30 patients each. Group A received sclerotherapy, and Group B underwent surgical excision. The average age was 4.3 years in Group A and 4.1 years in Group B, showing no significant age difference. In terms of age distribution, 30% of Group A and 33.33% of Group B were below 5 years old, while 20% of Group A and 16.67% of Group B were 5 years or older, with no significant difference (p-value = 0.789). Gender distribution was similar, with 26.67% males and 23.33% females in Group A, and 25% males and 25% females in Group B (p-value = 1.000). The site of lymphangioma was also comparable between the groups: neck (30% in Group A, 28.33% in Group B), axilla (11.67% in Group A, 13.33% in Group B), face (3.33% in Group A, 1.67% in Group B), and trunk (5% in Group A, 6.67% in Group B), with no significant differences (p-value = 0.903). Overall, the groups were well-matched in terms of demographic characteristics. [Table-1]

Table-1: Demographic Characteristics

Characteristics		**Group A (Sclerotherapy) N=30**	**Group B (Surgery) N=30**	**Total N= 60**	**p-value**
Mean Age (years)		4.3 ± 2.5	4.1 ± 2.6	-	-
Age Groups	**Below 5 years**	18 (30%)	20 (33.33%)	38 (63.33%)	0.789
	5 years & above	12 (20%)	10 (16.67%)	22 (36.67%)	
Gender	**Male**	16 (26.67%)	15 (25%)	31 (51.67%)	1.000
	Female	14 (23.33%)	15 (25%)	29 (48.33%)	
Site of Lymphangioma	**Neck**	18 (30%)	17 (28.33%)	35 (58.33%)	0.903
	Axilla	7 (11.67%)	8 (13.33%)	15 (25%)	
	Face	2 (3.33%)	1 (1.67%)	3 (5%)	
	Trunk	3 (5%)	4 (5%)	7 (11.67%)	

Our study's results show varying levels of effectiveness between Group A (Sclerotherapy) and Group B (Surgery) in treating the condition. In the category of "Excellent (Complete Resolution)," Group A demonstrated a higher percentage (76.7%) compared to Group B (46.7%), but this difference was not statistically significant (p = 0.162), indicating both treatments achieved similar rates of complete resolution. Similarly, in the "Good (>50% Resolution)" category, Group A had a lower percentage (20.0%) compared to Group B (33.3%), with no statistically significant difference observed (p = 0.207), suggesting comparable effectiveness in achieving partial resolution between the groups. However, in cases categorized as "Poor (<50% Resolution)," Group B had a significantly higher percentage (20.0%) compared to Group A (3.3%), with a statistically significant difference (p = 0.021). This suggests that while both treatments showed similar effectiveness in achieving excellent and good outcomes, Group B had a notably higher incidence of less favorable outcomes compared to Group A, illustrated in table-2.

Table-2: Post-treatment outcomes

Outcome	**Group A (Sclerotherapy) N=30**	**Group B (Surgery) N=30**	**p-value**
Excellent (Complete Resolution)	23 (76.7%)	14 (46.7%)	0.162
Good (>50% Resolution)	6 (20.0%)	10 (33.3%)	0.207
Poor (<50% Resolution)	1 (3.3%)	6 (20.0%)	0.021

Our study shows that there were no cases of recurrence or wound infection in Group A (sclerotherapy), while Group B (surgery) had 16.7% recurrence and 13.3% wound infection rates. Although these differences suggest a trend towards fewer complications with sclerotherapy, the p-values (0.052 for recurrence and 0.112 for wound infection) indicate that these differences are not statistically significant.

Table-3: Post-intervention complication rates

Complication	Group A (Sclerotherapy) N=30	Group B (Surgery) N=30	p-value
Recurrence	0	5 (16.7%)	0.052
Wound Infection	0	4 (13.3%)	0.112

Discussion

This study compared the outcomes of sclerotherapy versus surgical excision for Lymphatic malformationin 60 pediatric patients, evenly distributed into Group A (sclerotherapy) and Group B (surgical excision). The demographic characteristics, including age distribution (average 4.3 years in Group A and 4.1 years in Group B) and gender distribution (26.67% males in Group A, 25% in Group B), were similar between the groups, consistent with findings from Mustafa et al. and Fiaz et al.15-16 The distribution of lymphangioma sites (neck, axilla, face, trunk) also showed no significant differences, further enhancing the comparability of treatment cohorts.

In terms of treatment efficacy, sclerotherapy (Group A) demonstrated a higher percentage of Excellent (Complete Resolution) outcomes (76.7%) compared to surgical excision (Group B) at 46.7%. However, this difference did not reach statistical significance ($p = 0.162$), aligning with Mustafa et al.'s findings that both treatments can effectively achieve complete resolution.15 Notably, Group B had a significantly higher rate of Poor outcomes (20.0%) compared to Group A (3.3%), with a statistically significant difference ($p = 0.021$). This contrasts with previous studies, where resolution categories might not have been as detailed or statistically compared.

Complications such as recurrence and wound infections were absent in Group A but present in 16.7% and 13.3% of Group B, respectively. Although statistical significance was not achieved ($p = 0.052$ for recurrence, $p = 0.112$ for wound infection), these findings suggest a trend towards fewer complications with sclerotherapy, similar to trends observed by Fiaz et al. and others, despite differing methodologies in complication reporting.16

Our study contributes valuable insights by directly comparing treatment modalities with detailed outcome categories and complication rates. It builds upon previous research by highlighting both similarities and differences, particularly in the resolution of outcomes and complication rates. The findings support the notion that while both sclerotherapy and surgical excision are effective treatments for lymphatic malformation, sclerotherapy may offer advantages in achieving better resolution outcomes and potentially lower complication rates. Further research in larger, multicenter studies is warranted to confirm these findings and refine treatment guidelines for pediatric patients with lymphatic malformation.

Conclusion

Sclerotherapy using bleomycin emerges as a safe and effective treatment for pediatric lymphatic malformation, showing advantages over surgical resection with no observed cases of recurrence or wound infection. Our study highlights important differences between sclerotherapy and surgery in achieving complete, good, and poor resolutions, with sclerotherapy demonstrating notable efficacy in reducing less favorable outcomes. These findings emphasize sclerotherapy's potential as a preferred treatment option, emphasizing the need for further research to validate its benefits and refine treatment protocols.

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