Original Article

Effectivness of Pre Surgical Naso-Alveolar Molding In Cleft Lip and Palate Infants At Prosthodontic Department of Rehman College of Dentistry Peshawar- A Cohort Study

Sidra Bashir*, Sajid Ali, Sana Murtaza, Shafqat Hussain, Uzma Khalil, Jodat Askari

Prosthodontics Department, Rehman College of Dentistry, Peshawar- Pakistan

Article Info

Corresponding Author
*Sidra Bashir
Prosthodontics Department,
Rehman College of Dentistry,
Peshawar- Pakistan
Email:sidrabashir1010@gmail.com

Date Received:
11th September, 2025
Date Revised:
01st December, 2025
Date Accepted:
06th December, 2025

Abstract

Objective: To assess the effectiveness of pre-surgical nasoalveolar molding (PNAM) in infants with unilateral cleft lip and palate.

Methodology: This Quasi experimental study included 30 infants with unilateral cleft lip and palate having cleft gaps greater than 10 mm, aged below 3 months. Bilateral clefts, syndromic cases, and systemically ill or malnourished infants were excluded. PNAM appliances were fabricated using dental impressions and adjusted weekly over a 3 to 4-month period. Measurements of the inter-alveolar gap, maxillary alveolar cleft length, and palatal gap were taken before and after treatment using Care Stream 3600 intra-oral scanning and Microsoft 3D Viewer software. Paired t-tests were used to compare pre- and post-treatment measurements.

Results: Of the 30 infants, 46.7% were below 1 month, 33.3% below 2 months, and 20.0% below 3 months; 66.7% were male. Significant reductions were observed post-treatment: inter-alveolar gap decreased from 12.58 ± 1.40 mm to 2.31 ± 0.92 mm, maxillary alveolar cleft length from 6.17 ± 1.21 mm to 3.52 ± 2.74 mm, and palatal gap from 13.99 ± 2.03 mm to 7.99 ± 2.03 mm (all $p < 0.001$).

Conclusion: This study shows that PNAM is associated with a reduction in cleft size in infants with unilateral cleft lip and palate. The greatest improvements were seen in infants who began treatment before one month of age.

Keywords: Cleft lip and palate, effectiveness, naso-alveolar molding

This article may be cited as:
Bashir S, Ali S, Murtaza S, Hussain S, Khalil U, Askari J. Effectivness of pre surgical naso-alveolar molding in cleft lip and palate infants at prosthodontic department of rehman college of dentistry peshawar- a cohort study. J Postgrad Med Inst. 2025;39(4):230-5. http://doi.org/10.54079/jpmi.39.4.3833

Introduction

Cleft lip and palate is the most common congenital anomaly affecting the head and neck region worldwide.[1] The cleft may involve the lip or the palate alone, or it may simultaneously affect the lip, alveolus, and palate.[2] It can present as either unilateral or bilateral. Literature suggests that cleft lip and palate occurs in approximately 1 in 500 to 2,500 live births globally.[3] In Pakistan, the estimated incidence is 1 in every 523 births.[4]

Pre-surgical nasoalveolar molding (PNAM) is a non-surgical intervention designed to align the alveolar segments and reshape the deformed nasal cartilage, aiming to reduce the size of the cleft.[5] The PNAM device has been shown to significantly improve surgical outcomes in the primary repair of cleft anomalies. Therefore, this therapy is recommended before surgical correction.[6] This technique is considered effective in improving nasal asymmetry, correcting a deficient nasal tip, and reducing a protruded premaxillary segment.[6] The PNAM appliance offers several advantages, including facilitating cleft closure, minimizing surgical scars, correcting nasal deformity, and being cost-effective. The success of PNAM depends on the moldability and plasticity of the cartilage; thus, it should be initiated early in infancy for optimal results.[7] PNAM has been reported to enhance aesthetic outcomes and has become a new standard of care in the management of cleft lip and palate.[7]

Babies born with cleft lip and palate are treated using a multidisciplinary approach involving an Oral and Maxillofacial Surgeon, Speech Therapist, Obstetrician, Orthodontist, and Prosthodontist. The obstetrician, gynecologist, and sonologist play a vital role in the early detection of cleft lip and palate.[8] They can guide parents by providing reassurance and referring them to a prosthodontist. Awareness and early referral significantly affect the outcome of PNAM therapy, as the plasticity of the tissues manipulated during this therapy decreases with the infant's age.[9] This tissue plasticity is attributed to the high levels of hyaluronic acid, which are related to elevated estrogen levels immediately after birth. One key recommendation includes the time and commitment invested by the parents and their compliance throughout the treatment process. The preferred age to initiate this therapy is around the 26th day of life, with an optimal treatment duration of 3 to 4 months.[10]

A significant reduction in the size of alveolar and palatal cleft gaps was observed over a period of 3–4 months with the use of the PNAM appliance. In unilateral cleft palate cases, the alveolar cleft size was reduced by up to 7.85 mm, while in bilateral cleft palate cases, reductions of 4.25 mm and 3.81 mm were noted on the right and left alveolar cleft sides, respectively. The palatal clefts in unilateral cases were reduced by 4.63 mm in the medial region and 3.72 mm in the posterior region. In bilateral cleft cases, the reductions were 3.00 mm in the medial and 2.88 mm in the posterior palatal cleft distances.[11]

Strong evidence exists regarding the effectiveness of PNAM appliance in cleft lip and palate patients. A few studies has been conducted in Pakistan regarding PNAM appliance and its success , while there are hardly any studies in KPK province. This study is for the best interest of population and to create awareness regarding the effectiveness of PNAM appliance.

The objective of this study was to assess the effectiveness of pre-surgical naso-alveolar molding in cleft lip and plate infants.

Methodology

This Quasi experimental study was conducted from February 22, 2025, to June 20, 2025, using a non-probability, consecutive sampling technique. The sample size was calculated as 30 infants using OpenEpi (version 3), based on the pre- and post-treatment means and standard deviations of 11.9 ± 4.3 and 4.3 ± 3.4, respectively.

The inclusion criteria for the study were: all unilateral cleft lip and palate cases with a cleft gap greater than 10 mm(to detect real change of intervention), infants below 3 months of age, and both genders. The exclusion criteria included all bilateral cleft lip and palate cases, as well as syndromic, malnourished, and systemically ill babies.

After obtaining approval from the hospital's ethical committee (IRB No: RCD-10-23-157) and informed consent was taken from the parents of the infants. Subjects were enrolled from the Prosthodontics Department of Rehman College of Dentistry, Peshawar. A detailed history was recorded, followed by a clinical examination. Impressions were made using silicone putty (Siloxil–Lascod) loaded in a pre-fabricated acrylic tray. Once the dental cast hardened, an acrylic molding plate was fabricated on it. This plate was lined with a thin layer of soft lining material, i.e., tissue conditioner, and placed in the oral cavity of the baby. The PNAM appliance was stabilized intraorally using surgical tapes applied extraorally and bilaterally, which were changed daily. The appliance was not removed from the infant's oral cavity except for cleaning purposes. The duration of treatment was 3 to 4 months. Parents or primary caregivers were instructed on proper appliance care, including guidance and commitment to weekly adjustments. These weekly adjustments involved relining the appliance with a soft tissue liner. Caregivers were also thoroughly advised on maintaining hygiene and proper handling of the appliance. Each patient was examined weekly over the 4-month treatment period.

At the end of the treatment, dental casts were assessed using the Care Stream 3600 intraoral scanner. Several reference points were identified on the casts following the method described by Zuhab et al.12 and measure-

ments were taken using Microsoft 3D Viewer software. A reference point P was marked as the most anterior point of the non-cleft maxilla on the gingival ridge of the cleft, while point P′ represented the most anterior point of the cleft maxilla on the same ridge. Point T was located on the maxillary tuberosity of the greater segment, and point T′ on the tuberosity of the lesser segment. Distances between these points were then calculated. The inter-alveolar gap (A) was measured as the distance between points P and P′. The length of the maxillary alveolar cleft (B) was calculated as the distance from point P to line TT′ minus the distance from point P′ to line TT′. The palatal gap (C) was defined as the distance between the widest points of the hard palate cleft. Measurements taken at baseline and at the end of treatment were compared to evaluate changes in cleft size

Presurgical nasoalveolar molding (PNAM) was a non-surgical technique used to reshape the gums, lips, and nostrils prior to cleft lip and palate surgery, thereby reducing the severity of the cleft. Its effectiveness was determined by the extent of cleft size reduction achieved through PNAM, which was assessed by comparing measurements taken at baseline and after four months of appliance use. In most cases, a reduction of up to 5 mm in cleft size was observed over the four-month period before surgical intervention.

The data were analyzed using the Statistical Package for Social Sciences (SPSS) version 20. Mean and standard deviation were calculated for numerical variables such as age, inter-alveolar gap, alveolar cleft, and palatal gap, while frequencies and percentages were computed for categorical variables such as gender. Pre- and post-treatment cleft sizes were compared using the paired t-test. Effect modifiers such as age, gender, and baseline cleft size were addressed through stratification. Post-stratification, the paired t-test was applied. The significance level was set at $P \leq 0.05$, with a 95% confidence interval.

Results

Among the 30 cases of cleft lip and palate, 46.7% were below 1 month of age, 33.3% were below 2 months, and 20.0% were below 3 months. The majority of the cases were male (66.7%), while females accounted for 33.3%. (Table 1)

Significant reductions were observed in all measured parameters following PNAM treatment. The mean inter-alveolar gap decreased from 12.58 ± 1.40 mm to 2.31 ± 0.92 mm ($p < 0.001$), the length of the maxillary alveolar cleft reduced from 6.17 ± 1.21 mm to 3.52 ± 2.74 mm ($p < 0.001$), and the palatal gap decreased from 13.99 ± 2.03 mm to 7.99 ± 2.03 mm ($p < 0.001$). (Table 2 & Fig 1)

A significant reduction was found in inter-alveolar gap in both females and males ($p<0.001$). The palatal gap also decreased significantly in both groups ($p<0.001$). A significant reduction in the length of the maxillary alveolar cleft was observed in males ($p<0.001$), but not in females ($p=0.10$). (Table 3)

Similarly, a significant reduction in inter-alveolar gap across all age groups (<1 month, 1–2 months, and 2.1–3 months; $p<0.001$). The palatal gap also decreased significantly in all groups ($p<0.001$). A significant reduction in the length of the maxillary alveolar cleft was observed in the <1 month ($p<0.001$) and 2.1–3 month ($p=0.043$) groups, while the reduction in the 1–2 month group was not statistically significant ($p=0.12$). (Table 4)

Reduction in inter-alveolar gap was significant in both cleft size groups (<12 mm and >12 mm; $p<0.001$). The palatal gap also decreased significantly in both groups ($p<0.001$). A significant reduction in the length of the maxillary alveolar cleft was observed in both groups, with $p<0.001$ for <12 mm and $p=0.007$ for >12 mm. (Table 5).

Discussion

The observed mean ~10 mm reduction in inter-alveolar gap and ~6 mm reduction in palatal gap are among the most pronounced reported. A recent study by Magyar et al.13, which focused on bilateral cleft lip and palate (BCLP), demonstrated that NAM therapy significantly reduced left ($p = 0.047$) and right ($p = 0.019$) alveolar clefts and expanded premaxilla width ($p = 0.037$) in a sample of 18 newborns. Their digital cast analysis also noted a significant increase in the anterior basal an-

Table 1. Distribution of demographics of the cleft lip and palate cases

Characteristic	N = 30
Age	
Below 1 month	14 (46.67)
1-2 month	10 (33.33)
2-3 month	6 (20.00)
Gender	
Female	10 (33.33)
Male	20 (66.67)

J Postgrad Med Inst 2025;39(4):230-5.
http://doi.org/10.54079/jpmi.39.4.3833

Table 2. Comparison of alveolar gap, length of maxillary alveolar cleft and palatal gap before and after treatment with PNAM

Characteristic	start, N = 30	end, N = 30	p-value*
Inter Alveolar gap (mm)	12.58 ± 1.40	2.31 ± 0.92	<0.001
Length of maxillary Alveolar Cleft (mm)	6.17 ± 1.21	3.52 ± 2.74	<0.001
Palatal gap(mm)	13.99 ± 2.03	7.99 ± 2.03	<0.001

Mean ± SD, Paired t test

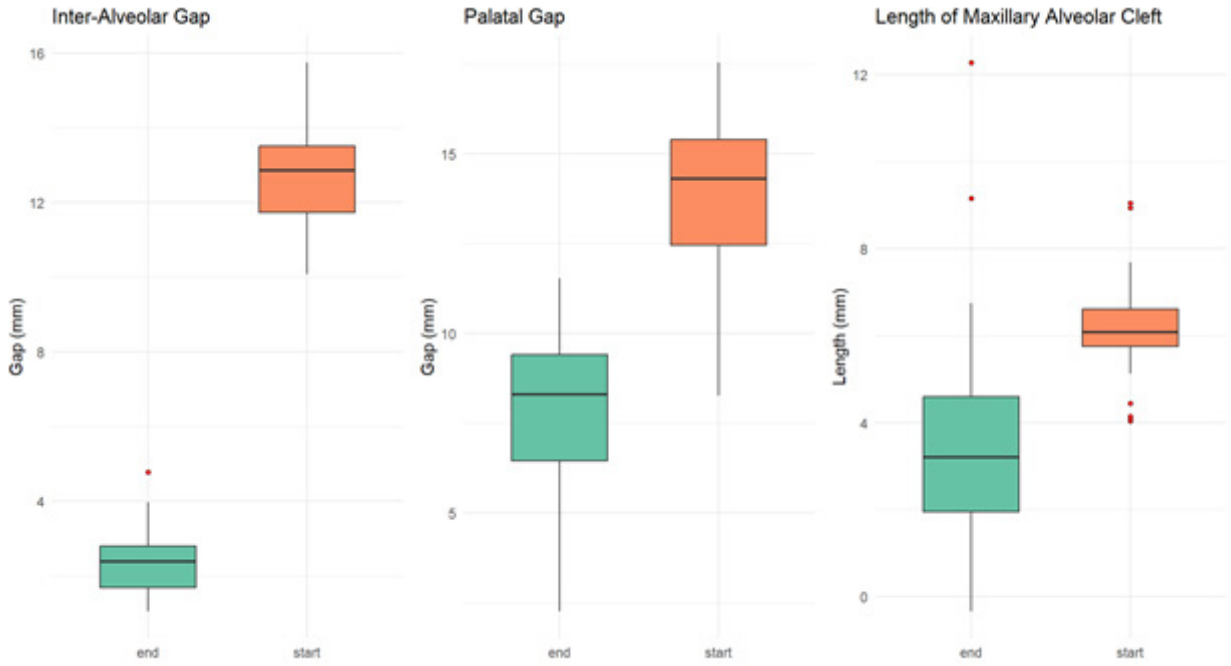

Figure 1: Alveolar gap, length of maxillary alveolar cleft and palatal gap before and after treatment with PNAM

Table 3. Comparison of alveolar gap, length of maxillary alveolar cleft and palatal gap before and after treatment with PNAM stratified by gender

Characteristic	Female(n=10)			Male (n=20)		
	Start, N = 10	End, N = 10	p-value	Start, N = 20	End, N = 20	p-value
Inter Alveolar gap(mm)	12.61 ± 1.73	1.94 ± 0.63	<0.001	12.56 ± 1.26	2.50 ± 1.00	<0.001
Length of maxllary Alveolar Cleft (mm)	5.93 ± 1.09	4.34 ± 2.57	0.10	6.29 ± 1.27	3.12 ± 2.79	<0.001
Palatal gap(mm)	13.78 ± 2.29	7.78 ± 2.29	<0.001	14.09 ± 1.95	8.09 ± 1.95	<0.001

Mean ± SD, paired t-test

gle, suggesting improvement in premaxillary orientation without adversely affecting transverse maxillary growth. These findings align with our observed reductions in cleft widths, particularly in patients with larger baseline gaps, and support the idea that NAM does not inhibit but rather complements maxillary arch development. Additionally, Zheng et al.[14] in as case report introduced a digital split-plate PNAM showing comparable gap decreases alongside nasal form improvements.

We found reductions of ~2.5–3 mm overall, with p values highly significant except in the 1–2 month subgroup. Abd El-Ghafour et al. in a randomized trial with

Table 4. Comparison of alveolar gap, length of maxillary alveolar cleft and palatal gap before and after treatment with PNAM stratified by age

Characteristic	Below 1 month			1-2 month			2.1-3 month		
	start, N = 14	end, N = 14	p-value	start, N = 10	end, N = 10	p-value	start, N = 6	end, N = 6	p-value
Inter Alveolar gap(mm)	12.66 ± 1.19	2.16 ± 0.74	<0.001	12.20 ± 1.71	2.21 ± 0.72	<0.001	13.00 ± 1.38	2.83 ± 1.48	<0.001
Length of maxllary Alveolar Cleft (mm)	6.44 ± 1.47	3.25 ± 2.40	<0.001	6.03 ± 0.95	4.04 ± 3.54	0.12	5.79 ± 0.88	3.32 ± 2.25	0.043
Palatal gap(mm)	14.17 ± 1.76	8.17 ± 1.76	<0.001	13.79 ± 2.50	7.79 ± 2.50	<0.001	13.89 ± 2.13	7.89 ± 2.13	<0.001

Mean ± SD, paired t-test

Table 5. Comparison of alveolar gap, length of maxillary alveolar cleft and palatal gap before and after treatment with PNAM stratified by baseline cleft size

Characteristic	<12mm			>12mm		
	start, N = 9	end, N = 9	p-value	start, N = 21	end, N = 21	p-value
Inter Alveolar gap(mm)	10.89 ± 0.68	2.04 ± 1.02	<0.001	13.30 ± 0.91	2.43 ± 0.88	<0.001
Length of maxllary Alveolar Cleft (mm)	6.71 ± 1.04	2.87 ± 1.52	<0.001	5.94 ± 1.22	3.80 ± 3.11	0.007
Palatal gap(mm)	14.52 ± 2.31	8.52 ± 2.31	<0.001	13.76 ± 1.92	7.76 ± 1.92	<0.001

3D-printed D-NAM appliances also demonstrated significant improvements in maxillary arch dimensions before lip repair, matching our device-augmented results.[15]

The infants treated very early (<1 month) in our cohort showed the largest reductions, consistent with Liang et al.'s findings on early PNAM yielding long-term arch stability.[16] This can be due to high level of hyaluronic acid. Several studies have explored the concentration of hyaluronic acid (HA) in the blood of infants, particularly in relation to liver health and age. In a large study involving 397 healthy infants and children, it was observed that serum HA levels were highest in the youngest age groups—approximately 93 µg/L in infants aged 1 to 3 months—and gradually declined with age, reaching around 20 µg/L by the age of 2 to 3 years.[17]

A prospective trial in Delhi involving newborns up to six months of age (average PNAM duration ~4 months) reported an average intraoral cleft gap reduction of 4.16 mm and an extraoral decrease of 4.42 mm, with greater columella height increase in infants treated before six weeks.[18] In Vietnam, 95 cast pairs from PNAM-treated infants revealed statistically significant decreases in cleft width and midline deviation alongside improved nostril height and width post-treatment.[19]

Within the limitations of the study, it can be concluded that presurgical nasoalveolar molding (PNAM) is an effective intervention for infants with cleft lip and palate, showing significant reductions in interalveolar gap, palatal gap, and alveolar cleft length, especially in those treated before one month of age. Although limited by a small sample size, single center design, and lack of long term follow up, the study has strengths such as a standardized protocol and inclusion of diverse subgroups, which support the clinical value of PNAM in improving cleft morphology before surgery.

Conclusion

Within the limits of this study, our findings show that PNAM is associated with a reduction in the inter-alveolar gap, palatal gap, and the length of the maxillary alveolar cleft in infants with cleft lip and palate. These improvements were seen across different age groups, genders, and cleft sizes. Infants who started treatment before one month of age showed the greatest association with better outcomes.

References

1. Preidl RH, Kesting M, Rau A. Perioperative management in patients with cleft lip and palate. J Craniofac Surg 2020;31(1):95-101.
2. Fitzsimons K, Hamilton M, van der Meulen J, Medina J, Wahedally M, Park M, et al. Range and frequency of congenital malformations among children with cleft lip and/or palate. Cleft Palate Craniofac J 2023;60(8):917-27.

3. Salari N, Darvishi N, Heydari M, Bokaee S, Darvishi F, Mohammadi M. Global prevalence of cleft palate, cleft lip and cleft palate and lip: a comprehensive systematic review and meta-analysis. J Stomatol Oral Maxillofac Surg 2022;123(2):110-20.
4. Sharif F, Mahmood F, Azhar MJ, Asif A, Zahid M, Muhammad N, et al. Incidence and management of cleft lip and palate in Pakistan. J Pak Med Assoc 2019;69(5):632-9.
5. Al-Lami HA, Al-Rudainy D, Mohammed-Salih HS, Salman SM. Presurgical management trends and nasoalveolar molding usage for infants with cleft lip and palate in the capital of a developing country. J Orthod Sci 2024;13(1):4-12.
6. Trivosa V, Halim M, Yongyan G. The impacts and outcomes of presurgical nasoalveolar molding (PNAM) in newborn sequential therapeutic implementation. J Dent Oral Sci 2021;3:1-10.
7. Dunworth K, Porras Fimbres D, Trotta R, Hollins A, Shammas R, Allori AC, et al. Systematic review and critical appraisal of the evidence base for nasoalveolar molding (NAM). Cleft Palate Craniofac J 2024;61(4):654-77.
8. Demirsoy KK, Çalış S, Büyük SK. Obstetrician–gynecologists' knowledge and awareness on nasoalveolar molding in newborns with cleft lip and palate. Turk J Orthod 2022;35(1):16.
9. Ferreira AN, Eswaramurthy P, Aras MA, Chitre V, Mascarenhas K. Rehabilitation of an orofacial cleft through presurgical nasoalveolar molding with a 1-year follow-up. Int J Clin Pediatr Dent 2023;16(1):162-5.
10. Kinouchi N, Horiuchi S, Yasue A, Kuroda Y, Kawai N, Watanabe K, et al. Effectiveness of presurgical nasoalveolar molding therapy on unilateral cleft lip nasal deformity. Saudi Med J 2018;39(2):169.
11. Aslan BI, Gülşen A, Findikçioğlu K, Uzuner D, Üçüncü N. Effects of nasoalveolar molding therapy on alveolar and palatal cleft deformities in unilateral and bilateral cleft lip and palate. J Craniofac Surg 2018;29(2):e179-84.
12. Zuhaib M, Bonanthaya K, Parmar R, Shetty PN, Sharma P. Presurgical nasoalveolar moulding in unilateral cleft lip and palate. Indian J Plast Surg 2016;49(1):42-52.
13. Magyar D, Pálvölgyi L, Swennen G, Shujaat S, Nagy K. Alteration in maxillary arch dimensions following preoperative nasoalveolar moulding therapy in bilateral cleft lip and palate patients. Clin Investig Orthod 2024;83(3):112-8.
14. Zheng J, He H, Kuang W, Yuan W. Presurgical nasoalveolar molding with 3D printing for a patient with unilateral cleft lip, alveolus, and palate. Am J Orthod Dentofacial Orthop 2019;156(3):412-9.
15. Abd El-Ghafour M, Aboulhassan MA, Fayed MMS, El-Beialy AR, Eid FHK, Hegab SE-D, et al. Effectiveness of a novel 3D-printed nasoalveolar molding appliance (D-NAM) on improving the maxillary arch dimensions in unilateral cleft lip and palate infants: a randomized controlled trial. Cleft Palate Craniofac J 2020;57(12):1370-81.
16. Likitkulthanaporn A, Boonpratham S, Honglertnapakul Y, Saengfai NN, Chaweewannakorn C, Peanchitlertkajorn S. Long-term effect of nasoalveolar molding on skeletal and dental development in patients with oral clefts: a systematic review and meta-analysis. Mahidol Dent J 2023;43(1):9-20.
17. Trivedi P, Cheeseman P, Mowat AP. Serum hyaluronic acid in healthy infants and children and its value as a marker of progressive hepatobiliary disease starting in infancy. Clin Chim Acta 1993;215(1):29-39.
18. Bhutiani N, Tripathi T, Verma M, Bhandari PS, Rai P. Assessment of treatment outcome of presurgical nasoalveolar molding in patients with cleft lip and palate and its postsurgical stability. Cleft Palate Craniofac J 2020;57(6):700-6.
19. Dinh TTN, Van Nguyen D, Dien VHA, Dong TK. Effectiveness of presurgical nasoalveolar molding appliance in infants with complete unilateral cleft lip and palate. Cleft Palate Craniofac J 2022;59(8):995-1000.

Authors' Contribution Statement

SB contributed to the design, acquisition, analysis, interpretation of data, drafting of the manuscript, and critical review of the manuscript. SA contributed to the conception, design, acquisition, drafting of the manuscript, final approval of the version to be published, and interpretation of data. SM contributed to the design, acquisition, interpretation of data, drafting of the manuscript, and final approval of the version to be published. SH contributed to the acquisition, analysis, interpretation of data, and drafting of the manuscript. UK contributed to the acquisition, analysis, interpretation of data, and drafting of the manuscript. JA contributed to the acquisition, analysis, interpretation of data, and drafting of the manuscript. All authors are accountable for their work and ensure the accuracy and integrity of the study.

Conflict of Interest

Authors declared no conflict on interest

Grant Suppport and Financial Disclosure

None

Data Sharing Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.