Original article

Evaluation of awareness, attitudes, and satisfaction levels of families of children with unilateral complete cleft lip and palate treated with nasal alveolar molding appliances

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Received: 18/03/2025; **Accepted:** 06/04/2026; **Published:** 30/04/2026
DOI: 10.34071/jmp.2026.2.1091

Abstract

Background: Cleft lip and palate (CLP) significantly impacts aesthetics, function, and the psychological well-being of both the child and their family. Presurgical orthopedics, particularly the Nasoalveolar Molding (NAM) appliance, it reduces the width of the lip cleft, improves nasal symmetry, and enhances feeding function for the child. This study aims to evaluate the awareness, attitudes, and satisfaction levels of families of children with unilateral complete CLP treated with NAM appliances, providing insight into the psychosocial benefits of this therapy.

Materials and methods: A descriptive cross-sectional study was conducted on 31 parents or caregivers of children diagnosed with unilateral complete CLP. Participants were recruited from Hue University of Medicine and Pharmacy Hospital and Nghe An Obstetrics and Pediatrics Hospital between February 2022 and September 2024. Data on demographics, awareness, attitudes, and satisfaction were collected using a structured questionnaire administered through direct interviews after the completion of NAM therapy.

Results: Among the 31 infants, none were able to breastfeed at birth. After the first day of NAM appliance placement, 30 infants (96.8%) were able to bottle-feed successfully. All parents believed that NAM improved their child's appearance and considered the orthodontist a key member of the CLP care team. Majority (96.8%) recognized that NAM improved feeding. However, 67.7% of families reported that their quality of life was affected by having a child with CLP. Regarding attitudes, 77.4% of families felt the infant experienced discomfort during the impression-taking process, yet 96.8% found the treatment useful for the child and 19.4% found frequent follow–up appointments to be time–consuming or inconvenient. Nonetheless, all were willing to encourage other parents to use NAM before surgery. The overall satisfaction rate was high, with 74.2% of families reporting being "completely satisfied" with the treatment results.

Conclusion: These findings underscore the importance of incorporating NAM into CLP care protocols and providing comprehensive support to families throughout the treatment process.

Keywords: *Nasoalveolar Molding (NAM); Presurgical Orthopedics; Unilateral Complete Cleft Lip and Palate; Parental Satisfaction; Quality of Life.*

1. INTRODUCTION

Cleft lip and palate (CLP) is one of the most prevalent congenital deformities in the craniofacial region, with an incidence of approximately one in 500 to one in 2,500 live births, varying by country and influenced by socioeconomic status, genetics, and ethnicity [1]. In Vietnam, the incidence was notably high, at approximately 1.4-1.6 per 1,000 live births (about one in 600-700 births) [2]. According to the Ministry of health of Viet Nam, with a population of 97.582 million and a crude birth rate of 16.3 per 1,000 (2020 statistics), it was estimated 2.244-3.000 new cases each year based on 2020 national statistics [3]. Children with CLP face significant challenges, including facial deformities affecting the nose, lip, and maxilla, which impair aesthetics, function, and the psychological well-being of both the child and their family. Families often experience feelings of disappointment, helplessness, anxiety, and fear [4]. Consequently, the management of CLP requires a lifelong, multidisciplinary approach [5].

The introduction of the Nasoalveolar Molding (NAM) appliance, first described by Grayson in 1993, marked a significant advancement in CLP treatment [6]. NAM appliance offers numerous advantages, such as reducing the width of the lip and alveolar

clefts, improving nasal cartilage symmetry, and increasing columella length [7]. These improvements create more favorable conditions for primary surgical repair and may reduce the number of required surgical interventions compared to other presurgical techniques.

While several studies in Vietnam have focused on the clinical efficacy of NAM, the psychosocial impact on families has been underexplored . Therefore, the aims of this study is to evaluate the awareness, attitudes, and satisfaction levels of families of children with unilateral complete cleft lip and palate who have undergone treatment with a NAM appliance.

2. MATERIALS AND METHODS

2.1. Study design and participants

A descriptive cross-sectional study was conducted involving 31 parents or caregivers of children diagnosed with unilateral complete CLP treated with NAM appliances. The study was carried out at the Hue University of Medicine and Pharmacy Hospital and Nghe An Obstetrics and Pediatrics Hospital from February 2022 to September 2024. A non-probability convenience sampling method was used.

Inclusion criteria: (1) All children were diagnosed with unilateral complete CLP, (2) with an alveolar cleft width > 5 mm, and (3) all children were treated with NAM appliance between 0 and 4 months of age. Exclusion criteria were: (1) Chlidren with CLP associated with other congenital craniofacial syndromes, (2) children with respiratory problems, (3) family declined to participate this study, or (4) family was non-cooperation during the study period.

2.2. Data collection

Data were collected through direct interviews with parents or caregivers using a pre-designed structured questionnaire. The interviews were conducted by trained medical staff after the child had completed the presurgical NAM treatment. The questionnaire included sections on:

- **Demographics:** Parent's age at the child's birth (under 35 years-old and 35 years old or older), education level, and occupation.

- **Infant Care Characteristics:** Ability to breastfeed after birth and time required to bottle-feed after NAM placement.

- **Awareness, Attitudes, and Satisfaction [8]:** A series of questions assessed perceptions and attitudes toward the NAM treatment process. Satisfaction was measured using a 5-point Likert scale (completely satisfied, quite satisfied, neutral/ no opinion, not satisfied, very unsatisfied).

2.3. Data analysis

Data were entered into Microsoft Excel 365 and analyzed using SPSS version 27.042. Descriptive statistics were used to present the data. Categorical variables were described using frequencies (n) and percentages (%).

2.4. Ethical considerations

This study was approved by the Biomedical Research Ethics Committee of Hue University of Medicine and Pharmacy (Approval No. H2022/256). Approval was also obtained from the Departments of Odonto-Stomatology at both participating hospitals. Informed consent was obtained from all participating families after a clear explanation of the study's objectives. All patient and family's information was kept confidential and used solely for research purposes.

3. RESUTLS

3.1. Demographic characteristics of parents

Table 1. Demographic characteristics of parents (N=31)

Characteristic		Father		Mother	
		Number of children (n)	(%)	Number of children (n)	(%)
Age at Child's Birth	< 35	20	64.5	24	77.4
	≥ 35	11	35.5	7	22.6
	Mean ± Deviation Min - Max	33.55 ± 5.71 23 – 46		30.32 ± 5.41 20 – 43	
Education Level	Middle School	7	22.6	5	16.1
	High School	13	41.9	16	51.6
	University	11	35.5	10	32.3

Occupation	Farmer	5	16.1	5	16.1
	Factory Worker	3	9.7	2	6.5
	Office Staff	4	12.9	5	16.1
	Self-employed	12	38.7	10	32.3
	Other	7	22.6	9	29

The mean age of fathers was 33.55 ± 5.71 years, while the mean age of mothers was 30.32 ± 5.41 years. All parents had completed at least a middle school education, with 35.5% of fathers and 32.3% of mothers holding a university degree. Occupations were diverse, including farming, factory work, office administration, and self-employment (Table 1).

3.2. Infant feeding characteristics

Table 2. Infant feeding characteristics during NAM treatment (N=31)

Characteristic		Number of children (n)	(%)
Able to breastfeed after birth	Yes	0	0
	No	31	100,0
Time to achieve bottle-feeding with NAM	First day	30	96.8
	Third day	1	3.2

As seen on table 2, none of the 31 infants in the study were able to breastfeed after birth. Following the placement of the NAM appliance, 30 infants (96.8%) were able to bottle-feed within the first day. One infant (3.2%) adapted to bottle-feeding on the third day.

3.3. Awareness and attitudes of caregivers

Table 3. Awareness and attitudes of caregivers regarding NAM treatment (N=31)

Statement	Number of caregivers (n)	Percentage (%)
Awareness		
Noticed any signs of injury after impression-taking	0	0
Impression-taking process is invasive	10	32.3
Difficulty following instructions for appliance insertion/taping	15	48.4
Believe all CLP infants need NAM treatment	29	93.5
NAM improves the infant's feeding	30	96.8
NAM improves the infant's facial aesthetics	31	100,0
Presurgical treatment with NAM appliance allows scheduling an earlier corrective surgery	4	12.9
The orthodontist is an important member of the CLP team	31	100.0
Having a child with CLP affects family life	21	67.7
Attitude		
Felt anxious after the impression-taking procedure was explained	15	48.4
Felt the child endured discomfort during impression-taking	24	77.4
Presurgical orthopedic treatment is helpful for the child	30	96.8
Felt embarrassed when the child wore the NAM appliance	3	9.7
Found frequent appointments time-consuming and/or inconvenient	6	19.4
Willing to recommend NAM treatment to other parents	31	100.0

- Awareness: No caregiver reported any physical injury to their child during or after the impression-taking procedure. All caregivers (100%) believed that NAM improved their child's facial appearance and agreed that the orthodontist is an essential member of the CLP care team. A significant majority (96.8%) felt the appliance improved feeding. However, 67.7% of families reported that having a child with CLP negatively

affected their family life.

- Attitudes: In terms of attitude, 77.4% felt their child endured discomfort during the impression-taking process, and 48.4% felt anxious after the procedure was explained to them[61]. Despite these concerns, 96.8% found the presurgical orthopedic treatment helpful. A small percentage found the frequent appointments time-consuming (19.4%) or felt embarrassed by the appliance (9.7%). Importantly, all caregivers (100%) stated they would recommend NAM treatment to other parents.

3.4. Satisfaction with treatment outcomes

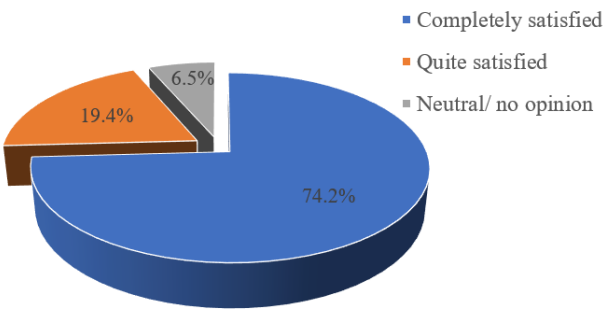

Figure 1. Satisfaction with NAM treatment outcomes (n = 31)

The overall satisfaction with the results of NAM treatment was high. A majority of caregivers (74.2%) were "completely satisfied", 19.4% were "quite satisfied", and 6.5% were "neutral/no opinion". None of caregivers reported being dissatisfied. Following treatment with the NAM appliance, parents or caregivers reported no instances of 'dissatisfied' or 'very dissatisfied' levels.

4. DISCUSSION

The management of CLP extends beyond surgical repair to address functional and psychosocial challenges faced by children and their families. These CLP children often face heath problems such as slow weight gain, malnutrition, and increase susceptiblity to respiratory illnesses. Additionally, families with CLP children often expericence high level of psychological stress such as feelings of disappointment, helpness, anxiety, and fear [9, 10]. In a study in the northern provinces of Vietnam, most parents felts shocked, anxious, and painfull when their family has a child with CLP [11]. Providing presurgical support and comprehensive nursing care are effective strategies in reducing parents' social anxiety and stigma, and preventing depression [12]. NAM therapy serves as a foundational step, aligning the alveolar segments and molding nasal cartilages to optimize surgical outcomes. The success of this therapy is heavily dependent on caregiver cooperation, as they are responsible for the daily management of the appliance. This study provides critical insight into the family's perspective, which is essential for treatment success.

A major initial challenge for infants with CLP is feeding [13]. The cleft prevents the creation of negative intraoral pressure necessary for effective sucking. Our finding that 96.8% of infants could bottle-feed on the first day of NAM placement highlights a significant functional benefit. The appliance's palatal plate acts as an obturator, separating the oral and nasal cavities. This facilitates efficient feeding, reduces nasal regurgitation, and decreases feeding time, which is consistent with findings from other studies that report improved weight gain and nutritional status in infants treated with NAM [14]. In a study by Maria et al. (2022), maternal perception of breastfeeding in children with unilateral cleft lip and palate were explored. All interviewed mothers reported that NAM was beneficial, as it facilitated closure of the palatal cleft, thereby it significantly improving the infants' ability to feed effectively with a bottle [15].

The treatment process, particularly the initial impression-taking, can be a source of significant anxiety for parents. Therefore, collecting their opinions and attitudes regarding this process is crucial for promoting cooperation and ensuring psychological reassurance in the innitial stage of treatment. In our study, a high proportion of caregivers reported that they felt anxious after receiving an explanation of the impression-taking

procedure (48.8%). Futhermore, 77.4% of caregivers felt their child endured discomfort, and nearly 33% were anxious about the procedure. This aligns with research indicating that parenting a child with a chronic or complex medical condition is associated with elevated stress. However, our finding that no infants sustained injuries demonstrates that the procedure can be performed safely. This emphasizes the need for clinicians to provide thorough explanations and emotional support to alleviate parental anxiety, which can, in turn, improve cooperation and treatment adherence.

Despite the challenges, including the difficulty that nearly half of the caregivers (48.4%) initially faced with appliance management and the burden of frequent appointments (19.4%), the overwhelming majority perceived the treatment as beneficial. The technique of removing and inserting the NAM appliance represents a considerably challenging procedure that demands a high degree of dexterity; particularly when performed by caregivers who lack prior experience and the patients are infants. As showed in table 3, the majority of caregivers considered NAM to be necessary for infants with cleft lip and palate, perceived NAM therapy as beneficial for the child, and reported that it improved feeding. All participants (100%) recognized the aesthetic improvements and were willing to recommend NAM to others, and regarded the orthodontist as an essential member of the CLP treatment team. Additionally, nearly 13% of caregivers reported that NAM facilitated an earlier scheduling of surgical repair. This positive response suggested that caregivers believe the benefits of NAM outweigh the burdens. The active involvement in their child's care, coupled with visible improvements, can empower parents and increase their sense of self-efficacy, transforming initial anxiety into positive engagement. Therefore, these findings highlight the critical importance of delivering thorough pre-treatment explanations and detailed guidance throughout the course of NAM therapy.

The study by Sischo et al. (2015) reported that most caregivers experienced initial anxiety and stress asociated with NAM therapy (such as tape repositioning and applicance cleaning) in the first appointment [16]. However, caregivers exhibited more positive attitudes toward the treatment process in subsequent appoitments. Although caregivers acknowledged the burden associated with lip taping, mucoal ulceration caused by the appliance, and the requirement for weekly follow-up visits; they accepted these challenges when they recognized the clinical benefits provided by NAM [16]. In our study, 9.7% of caregivers reported that they felt embarrassed when using the NAM appliance, and 19.4% of caregivers felt that the frequent appointment were time-consuming and/or inconvenient. Furthermore, nearly 68% caregivers felt that CLP affected their family's daily life. Caring for a child with CLP can impact not only their caregivers but also the entire family in various ways. Parents often have to devote more time and effort to organizing daily activities and providing specialized their child requires. The impact can be influenced by the type of cleft, family characteristics such as the number of children or household income, the level of social support, as well as culture factors. The cooperation of caregivers during the treatment process is a crucial factor for the achieving success with NAM therapy. Most families of children with CLP in our study lived far from the treatment facility. As a result, they often felt exhausted and worried about subjecting their young child to such lengthy journeys. Missing scheduled appointments or attending irregularly also reduced the effectiveness of the treatment.

The above research data indicated a relatively high level of awareness and positive attitudes among caregivers toward the care of children with unilateral cleft lip and palate undergoing presurgical NAM therapy. According to the data in Table 1, most parents had a relatively high educational level with over 80% of parents having completed at least high school. Additionally, the majority of parents were under 35 years of age when their child was born. Consequently, they were easily understand medical guidance, diligently follow treatment protocols, and proactively seek additional information about cleft lip and palate as well as the NAM appliance; all of which contributed to favorable treatment outcomes.

In healthcare, the level of satisfaction among patients and their families is a critical indicator frequently used to assess the quality of treatment [17]. Although NAM can achieve sucessful outcomes in both aesthetic and functional dimensions of cleft lip and palate manegement, it remains a technically demanding intervention that is time-intensive, resource-consuming. The findings decated that caregivers of children expressed satisfaction and felt better when their chidren treated with NAM appliance (74.2% were completely satisfied, and 19.4% were quite satisfied). This satisfaction likely stems from the tangible improvements in aesthetics

and feeding, which directly address the primary concerns of most parents. Therefore, personalizing the NAM treatment is very important to overcome challenges in treatment process [18].

Furthermore, the high education level and relatively young age of the parents (under 35 years old) in our cohort may have contributed to their ability to process information, adhere to complex instructions, and appreciate the long-term benefits of the therapy. Addressing logistical barriers, such as travel distance and financial strain, is crucial for ensuring equitable access to care and maintaining family engagement, especially for those in remote or underserved areas.

The above results underscore that the level of family satisfaction carries clinical significance as an indicator of treatment efficacy. Clinicians should evaluate the factors influencing treatment quality, identify both facilitating elements and obstacles; then select a proper treatment protocol that balances the child's clinical needs with the family's practice capacities. Thereby, treatment plan ensured feasibility, safety, and sustained parental trust and satisfaction.

5. CONCLUSION

Nasoalveolar Molding is an effective presurgical treatment for infants with unilateral complete CLP, offering significant improvements in facial aesthetics and feeding function. The therapy has a profound positive psychological effect on families, leading to high levels of satisfaction despite the inherent challenges of the treatment process. Clinicians should acknowledge and address the anxieties and burdens experienced by caregivers to foster a collaborative partnership, which is essential for achieving optimal treatment outcomes.

ACKNOWLEDGMENT

This research is funded by Hue University under grant number DHH2023-04-187.

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