Predicting Success with Nasoalveolar Molding Therapy

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Abstract

Purpose: The central objectives of this retrospective chart review and voluntary questionnaire are: 1) to identify barriers to completing nasoalveolar molding (NAM) therapy, 2) to determine predictive factors that lead to NAM therapy success and failure and 3) to assess caregiver experience and satisfaction with NAM therapy at Children's Healthcare of Atlanta (Children's) Center for Cleft and Craniofacial Disorders.

Methods: The study consists of a retrospective chart review and a voluntary questionnaire completed by a primary caregiver of NAM therapy patients treated at Children's Center for Cleft and Craniofacial Disorders between January 1, 2021 and December 31, 2023. Information was obtained from Epic™ and Dentrix™, Children's electronic medical and dental record systems. The caregiver survey was administered, and data was analyzed using the Research Electronic Data Capture (REDCap) system.

Results: Caregivers that became comfortable with inserting and taping the NAM appliance over time were more likely to complete therapy (p=0.008). Additionally, those that felt that the NAM appliance improved the esthetic surgical outcome were more likely to complete NAM therapy (p= 0.012 for lip and p= 0.041 for nose). Preterm births were a negative predictor for NAM therapy completion (p=0.016).

Conclusion: Preterm infants face more barriers to successfully completing NAM therapy. Compliance may improve when caregivers are motivated by esthetic surgical outcomes and comfort level with appliance is increased.

Objectives

- Identify barriers to completing nasoalveolar molding (NAM) therapy
- Determine predictive factors that lead to NAM therapy success and failure
- Assess caregiver experience and satisfaction with NAM therapy at Children's Healthcare of Atlanta (Children's) Center for Cleft and Craniofacial Disorders

Background

Cleft lip and/or palate (CL/P) is the most common craniofacial disorder. In the United States, the prevalence of cleft lip with and without cleft palate is 1 in 1032 live births and the prevalence of cleft palate alone is 1 in 1583 live births.[1] The worldwide prevalence of CL/P is 1 in 700 live births.[2]

Nasoalveolar molding (NAM) therapy is a pre-surgical orthopedic treatment for infants with CL/P, consisting of an acrylic alveolar plate and nasal stent that is secured to the face with tape. The goal of this appliance is to improve the relationship of alveolar and lip segments by reducing the width of the cleft, improving the anatomy and symmetry of the nasal cartilage, lengthening the columella and retracting the premaxilla prior to the primary lip repair surgery. [3, 4, 5, 6]

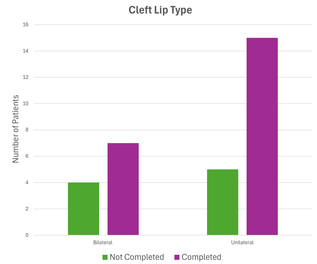
It is well documented in the literature that NAM therapy imposes a substantial burden on patient caregivers and compliance with the NAM protocol can be an issue. [6,7] NAM therapy has been demonstrated to improve surgical outcomes for the lip and nose.[3,4] NAM therapy may also reduce the need for subsequent surgical revisions and alveolar bone grafting.[5]

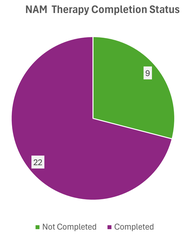
Methods

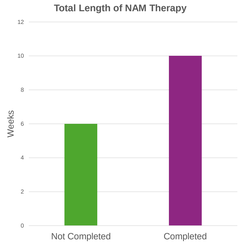
The study consisted of a retrospective chart review and an electronic questionnaire completed by a primary caregiver of NAM therapy patients treated at Children's Center for Cleft and Craniofacial Disorders between January 1, 2021 and December 31, 2023. Patient information for the chart review was captured from Epic™ and Dentrix™, Children's electronic medical and dental record systems. The Research Electronic Data Capture (REDCap) system was used for the questionnaire. All non-English speaking caregivers were surveyed with the assistance of a live interpreter.

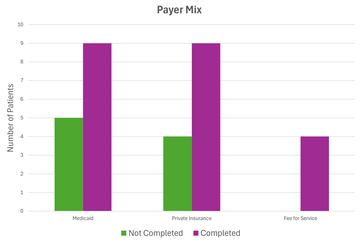
Statistical analysis of the data was completed using R version 4.4.1 software. Descriptive statistics were computed for patient characteristics, with continuous variables summarized by median and interquartile range (IQR), and categorical variables reported as counts and percentages. Fisher's exact test was applied to assess the association between categorical variables and the outcome (NAM completion), while the Wilcoxon rank-sum test was used for continuous variables. A p-value of less than 0.05 was used for statistical significance.

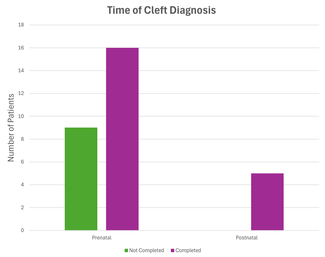
Results











Best Predictors for Completion of NAM Therapy
Fee for service payer type
Postnatal diagnosis
Strong support system
Felt NAM therapy esthetically improved the surgical outcome
Comfort level inserting the NAM appliance improved over time

The questionnaire response rate was 39.7% (31 out of 78 patient caregivers surveyed). In the sample group, there were 11 (35.5%) patients with bilateral cleft lip and 20 (64.5%) patients with unilateral cleft lip. 71.0% (22) of patients completed NAM therapy, while NAM therapy was discontinued early in 29.0% (9) patients. 6 patients were born at moderate to late preterm (32-37 weeks of gestation), 8 were born at early term (37-39 weeks of gestation) and 16 were born at full term (39-41 weeks of gestation). Patients born at early term were the most likely to complete while the preterm patients were the least likely to complete NAM therapy (p= 0.016). 83.3% (25) of patients had a prenatal diagnosis of cleft, while 16.7% (5) patients had a postnatal diagnosis. Patients with a postnatal diagnosis were more likely to complete NAM therapy and had a completion rate of 100% (p=0.286). The average length of NAM therapy was 10 weeks among patients that completed therapy and 6 weeks in patients that did not complete therapy (p=0.004). The payer mix was distributed with 45.2% (14) having Medicaid, 41.9% (13) having private insurance, and 12.9% (4) patients were fee for service. Fee for service payers were the most likely to complete NAM therapy and had a completion rate of 100% (p=0.489).

Caregivers with strong support systems were more likely to complete NAM therapy (p= 0.531). Additionally, caregivers that became more comfortable over time with inserting and taping the NAM appliance were more likely to complete therapy (p=0.008). 87.1% of caregivers felt that NAM therapy improved the esthetic surgical outcome of the lip. 74.2% of caregivers felt that NAM therapy improved the esthetic surgical outcome of the nose. Caregivers that felt that NAM therapy improved the esthetic surgical outcome were more likely to complete NAM therapy (p= 0.012 for lip and p= 0.041 for nose). The majority of caregivers under the age of 20 did not complete NAM therapy (3 out of 5). The highest level of education that the caregiver received did not have any consistent outcome.

Conclusion

Preterm infants face more barriers to successfully completing NAM therapy. Increased caregiver comfort with inserting and taping the NAM appliance and belief that the NAM appliance improved the esthetic surgical outcome of the lip and nose are predictive of NAM therapy completion. Data trends support that fee for service payer type, postnatal diagnosis of cleft lip and strong support systems are predictors for NAM therapy completion, although statistical significance was not achieved. The results of this study are limited by a small sample size and by the risk of participation bias.

References

1. Stallings EB, Isenburg JL, Rutkowski RE, Kirby RS, Nembhard WN, Sandidge T, Villavicencio S, Nguyen HH, McMahon DM, Nestoridi E, Pabst LJ; National Birth Defects Prevention Network. National population-based estimates for major birth defects, 2016-2020. Birth Defects Res. 2024 Jan;116(1):e2301. doi: 10.1002/bdr2.2301. PMID: 38277408; PMCID: PMC10898112.
2. Saikia A, Muthu MS, Orenuga OO, Mossey P, Ousehal L, Yan S, Campodonico M, England R, Taylor S, Sheeran P. Systematic Review of Clinical Practice Guidelines for Oral Health in Children With Cleft Lip and Palate. Cleft Palate Craniofac J. 2022 Jun;59(6):800-814. doi: 10.1177/10556656211025189. Epub 2021 Jun 23. PMID: 34159833; PMCID: PMC9121521.
3. Park JJ, Alfonso AR, Kalra A, Staffenberg DA, Flores RL, Shetye PR. Defining the Treatment Gap in Nasoalveolar Molding: Factors Affecting the Utilization of NAM in an Urban Cleft Center. The Cleft Palate Craniofacial Journal. 2024;61(1):131-137. doi:10.1177/10556656221148030.
4. Dean RA, Wainwright DJ, Doringo IL, Teichgraeber JF, Greives MR. Assessing Burden of Care in the Patient With Cleft Lip and Palate: Factors Influencing Completion and Noncompletion of Nasoalveolar Molding. Cleft Palate Craniofac J. 2019 Jul;56(6):759-765. doi: 10.1177/1055665618811526. Epub 2018 Nov 19. PMID: 30453775.
5. Grayson BH, Garfinkle JS. Early cleft management: the case for nasoalveolar molding. Am J Orthod Dentofacial Orthop. 2014 Feb;145(2):134-42.doi: 10.1016/j.ajodo.2013.11.011. PMID: 24485726.
6. Levy-Bercowski D, Abreu A, DeLeon E, Looney S, Stockstill J, Weiler M, Santiago PE. Complications and solutions in presurgical nasoalveolar molding therapy. Cleft Palate Craniofac J. 2009 Sep;46(5):521-8. doi: 10.1597/07-236.1. Epub 2008 Dec 24. PMID: 19929090.
7. Esmonde NO, Garfinkle JS, Chen Y, Lambert WE, Kuang AA. Factors Associated With Adherence to Nasoalveolar Molding (NAM) by Caregivers of Infants Born With Cleft Lip and Palate. Cleft Palate Craniofac J. 2018 Feb;55(2):252-258. doi: 10.1177/1055665617718550. Epub 2017 Dec 14. PMID: 29351029.