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International Journal of Pharmaceutical Research & Allied Sciences, 2016, 5(2):412-416

Research Article

ISSN : 2277-3657
CODEN(USA) : IJPRPM

Investigating the surgical outcomes of Nasoalveolar Molding (NAM) approach in cleft lip and palate repairing operations

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ABSTRACT

Cleft lip and palate is the most common congenital craniofacial malformation which leads to decreased nostril width and columella height, downward malposition of alar base and outward cavity of alar edge in addition to nose deformity. The best treatment is surgical repair which is preferred at the third month of life for infants with cleft lip. Main post-surgical complications include unpleasant suture line scar and unresolved nasal deformities. There is a direct relationship between increased size of cleft lip, increased tension and severity of scars. One of the helpful measures to take before surgery is Nasoalveolar Molding (NAM) which leads to better outcomes in terms of beauty and complications by decreasing the cleft size and tension and improved shape of nose. This study aimed at studying the effects of NAM on outcomes of cleft lip and palate repair surgery. The study sample size included all patients with cleft lip and palate operated by one same surgeon and the same technique (Millard) with presurgical NAM (PNAM) approach. The outcomes of this approach were compared with a control group with the same sample size and severity of disease operated by the same surgeon using a similar technique, Millard, but without PNAM. Complications based on medical records and beauty outcomes were classified into 5 main criteria by three skilled plastic surgeons including surgical scar, vermilion position, alar rim shape, nostril width and collumela height based on pre and post surgical photographies without knowing patient groups were classified from 5 to 50 scores. Data were analyzed using SPSS (version 21). Chi-square and Mann-Whitney U-test were used to compare the complications of both groups and the scores of beauty, respectively. To determine the correlation between beauty score and severity of the cleft and beginning age of NAM and surgery age, Pearson Correlation Coefficient was employed. Significance level was considered $P<0.05$. Out of 34 patients operated with PNAM (first group), 9 patients were excluded due to different reasons. Of the 25 patients, there were 16 unilateral and 9 bilateral clefts in each group. There were 17 and 16 male patients in first and second group, respectively. The first group had no second surgery in less than one year. While 12% of the second group had second surgery in less than one year but this difference was not significant. Except one case of oronasal fistula in the first group which improved without surgery, no other complications were observed. Mean and standard deviation of the total score of beauty in the first group equaled 40.76 ± 3.66 which was higher than the second group with 33.3 ± 3.23. In each of the beauty criteria, NAM group scores were higher than the second group which were statistically significant except in vermillion with $P=0.059$. Parents' consent was significantly higher in the first than the other group. Individual beauty scores of boys and girls were very similar in both groups. Total beauty score decreases as the beginning age of MNA increases, $R= -0.13$ (correlation coefficient) which is not significant. Also, with increased age at time of operation, the beauty score decreases, $R= - 0.15$ versus. $R=-0.09$. None of them were statistically significant. Considering few post-surgical complications and outcomes in terms of beauty in NAM users, it seems that PNAM especially in severe cases of cleft lip and palate is appropriate and sensible. The sooner the appliance of NAM, the better the outcomes would be. Cleft lip and palate, nose and alveolus molding before surgery, cleft lip and palate repair, surgery complications, beauty score.

INTRODUCTION

Cleft lip and palate are the most common congenital dissonance of craniofacial; its prevalence is about 0.37% - 0.11% in every hundred births. These dissonances highly depend on race and are more common in Asian nations. Isolated cleft of lip in boys and palate in girls is common (1). From its causes can mention the mother use from some medicines, infections during pregnancy, syndromic causes + genetic talent (1, 2). In early life may cause difficulty in eating plus aspiration of food and at older ages can create the problems of the beauty, speech and function. *Many* dental complications such as number reduction, size, shape and abnormal location plus buccal cross bite plus enamel hypoplasia may be with cleft, these patients post-surgery also is at risk for complications such as deformed scars of surgery, oronasal fistulas, bone and alveolar deficiencies, and nose deformity. One tool that helps to reduction of surgery complications and the number of next surgeries is Persurgical Infantorthopedic (PSIO) methods or NAM pre-surgery that causes the speech reinforcement, beauty and function post-surgery, and also complications reduction of surgery such as Fistulas and the need to next surgeries for complications repair or bone graft; after the infant Teethes these methods are known to orthodontic (1-5).

The effect mechanism of this instrument (NAM) is Reduction the severity and distance cleft lip – alveolar and palate, and also effect on nasal cartilage form so, and according to presence of estrogen in the first few weeks of life that through the placenta is reached to the child and Plasticity properties of cartilage, the sooner the better be the method used (3-5). In general, there is the nose deformity in the gap side in gap lip patients to the weakening of the LLC and lowing of its internal Cruz in area of columella – dome lower from normal side, smoothing external Cruz, rotating ala base outwards (flare), vestibule lining shortage, reduction of cartilage support in the skin of alar rim area, and its relocation and serve reduction of columella height. Several studies have shown the efficacy of this approach pre-surgery but still has not conducted the comprehensive review in Iran and meantime, few studies in the world is compared applied outcomes of the surgery of lip and palate cleft with and without NAM (6). So, the present study was done for this comparison in Iran that according to operating by an individual surgeon and the method of Millard surgery, it can be said is rare even on a global level. Possible complications NAM itself includes skin stimulation, pressure sore around gum, airway obstruction, and growth reduction challenge.

MATERIALS AND METHODS

The present study is a sectional comparative observational. Case population includes all referred babies with cleft lip (and palate) to Dr. Kalantar Hormuzi who with his recommendation were exposed under the application embed NAM (Pre-surgery nasoalveolar molding) and control group included the same number of babies who were repair of cleft lip (and palate) operated by him without NAM. This number was diagnosed based on study of full list of archive his patients that was the first case in 2011. In total, 34 patients were exposed under the NAM embed who 9 patients of them due to presence of syndromic disease (1 patient), lack of access to the photos post-surgery (1 patient), lack of photo of the preoperative (3 patients), and interval of less than 6 months from the final surgery of patient (4 patients) were existed from study. 25 patients were exposed in NAM+ group (first group) then for comparison of results from 25 patients who had been used from NAM pre-surgery as evidence group was used (second group). For comparison of surgery results of two groups was conducted to two aspects of surgery complications and results beauty. In part of early criteria complications was studied such as bleeding, hematoma, wound infection, wound Dehiscence and late criteria such as renewed surgery and appearance of oronasal fistula was considered. All patients exclusively by the Dr. Kalantar Hormuzi and one specific technique (Millard) were under repair surgery placed. The remaining 25 patients that were studied, 17 patients were boys and 8 patients, girl and 16 people unilateral cleft lip (and palate) (11 patients left and 5 right) and 9 patients had bilateral cleft lip (and palate). Then, the group that had not been used from NAM pre-surgery and had far more number, that number (25 patients) who had more similar in terms of sex and gap with the first group were chosen and compared with NAM user group. Meantime, all the patients were introduced by respective surgeon - Dr. Kalantar Hormuzi- to orthodontic in the first 2 weeks of birth. The average age of babies in time of NAM embed was 17 days and this work was done by orthodontist in the operating room of 15 Khordad. Then, infants once a week to set (adjust) NAM were visited by orthodontist. The duration mean of NAM brokerage was three months. In part of beauty results, first at least 12 photographs of each patient as 4 Photos (Face, right profile, left profile, basal view) were prepared in the three periods pre-surgery, 2 weeks and more than 6 months post-surgery and only were encoded by the number of patients' file in the sheets. Then, three professors from 15 Khordad Hospital based on the severity of the gap and comparison photos of pre-surgey and post-surgery and without patient notification from being in each group was scored them. For the convergence of scores and more accurate estimate of its quantitative, based on references and

journals, 5 known basic criteria and accepted by society of plastic surgeons including: surgery scar, nostril width, lip position (in millions), columella height, Alar rim shape were defined and referees were scored to each of these 5 patients from 1 to 10. So, each patient' score from each referee was between 3 to 5 and the overall score that was considered for each patient was acquired from scores mean of 3 referees. Then patients' scores generally and also partially were compared in each criterion together in two groups. After collection of information, data were entered into SPSS software version 21. To determination of complications rate from frequency and confidence interval 95% and to determination of beauty was used from beauty score mean. For comparison of two groups' complications was used from chi square test and for comparison of beauty scores mean was used from Mann-Whitney U- test. To study of correlation of beauty score with gap severity and also age of surgery fulfillment and age of NAM was used from Pearson correlation coefficient.

RESULTS

In first group, from 25 patients, 16 patients had unilateral cleft lip (and palate) (11 patients left, 5 right) and 9 patients had bilateral cleft lip (and palate) (10 patients left, 6 right). In first group, 17 patients (68%) boy and 8 patients (32%) were girl, and in second group 16 patients (64%) boy and 9 patients (36%) were girl that there was not a significant difference (P=0.76).

Table 1. The comparison of surgery and start of NAM age, gender and gap severity between the two groups

Type of NAM						
NAM -			NAM +			
P	Column N %	Count	Column N %	Count		
.0910	3.80± 1.1		4.30± 1.0		(Month) Age at surgery (Mean±SD	
.7650	64.0%	16	68.0%	17	Boy	Gender
	36.0%	9	32.0%	8	Girl	
	100.0%	25	100.0%	25	Total	
-	-		1.13± 0.80		(Month) NAM age of onset (Mean±SD	
.0001	8.0%	2	0.0%	0	Slight	Gap severity
	60.0%	15	8.0%	2	Medium	
	32.0%	8	92.0%	23	Sever	
	100.0%	25	100.0%	25	Total	

The mean age of patients at the time of the first surgery in first group was $4.3 \pm 1\ NAM^{+}$ months and in second group was $3.8 \pm 1.1 \quad NAM^{-}$ months and was not significant (P=0.091). The severity of the gap in the first group in 2 patients was medium and in others was severe but in second group, gap severity in 2 patients was slight and in 15 patients medium and 8 severe and was significant (P<0.05) (Table 1). To resolve the issue, referees were asked the beauty score be given based on comparison of photos pre-surgery and post-surgery not just based on observe the photographies of post-surgery.

The number of renewed surgery in under the one year was not observed while in second group, there were three cases of renewed surgery which despite the existent difference was not significant difference (P= 0.117). Oronasal fistula was seen in one patient of first group that was improved without surgery treatment and there was not any report from oronasal fistula post-surgery that was not significant difference in this survey (P=0.5). Other complications such as bleeding, hematoma, infection were not seen in none of the two groups (Table 2).

Table 2. The comparison of renewed surgery frequency, oronasal fistula, and other complications between the two groups

	NAM -		NAM +			
P	Column N %	Count	Column N %	Count		
0.117	12.0%	3	0.0%	0	Yes	The renewed surgry under one year
	88.0%	22	100.0%	25	No	
0.083	.12±0.33(0-1)		0±0(0-0)		The number of renewed surgeries (Mean±SD (Range)	
0.5	0.0%	0	4.0%	1	Yes	Oronasal fistula
	100.0%	25	96.0%	24	No	
-	0.0%	0	0.0%	0	Yes	Other complications
	100.0%	25	100.0%	25	No	

In first group, the average of total score was (40.76±3.66) that significantly was higher than second group (33.3±3.23) (P<0.01). Parent satisfaction from beauty results o f surgery in first group 4.16±0.75 from total score 5

and was significantly more than second group 3.32±0.8 (P<0.05). Basis of results is based on Independent t−test or Mann Whitney U test. There were not early complications such as infection, bleeding, and hematoma in none of the two groups NAM $^{+}$, and NAM $^{-}$. In beauty criteria in terms of vermelion position, the first group with mean and standard deviation of scores of 7.03±1.07 despite had more scores from second group with mean and standard deviation of 7.03±1.07, but the difference was not significant (P= 0.059). In term of nostril width, the first group by taking the average score of 8.12±0.76 had significantly more scores than second group with average of 6.48±0.59 (P<0.01) (Table 3).

Table 3. The comparison of beauty scores each of beauty criteria between the two groups

P*	Mean Rank	Std. Error Difference	Mean difference	Std. Deviation	Mean	N	Type of NAM	**Score**
.00001	33.16	.26	1.24	0.86	8.28	25	+	The beauty in term of wound scar
	17.84			0.96	7.04	25	-	
.00001	37.24	.21	2.09	0.91	8.59	25	+	The beauty in term of ALAR RIM shape
	13.76			0.55	6.51	25	-	
.00001	35.54	.26	1.65	1.00	7.81	25	+	The beauty in term of columella height
	15.46			.79	6.16	25	-	
.059	29.38	.30	.98	1.07	8.01	25	+	The beauty in term of vermilion (Lip line)
	21.62			1.07	7.03	25	-	
.00001	37.52	.19	1.64	.76	8.12	25	+	The beauty in term of nostril width
	13.48			.59	6.48	25	-	

The mean of beauty total score of boys in NAM+ was equal 40.43 ± 3.23 and girls score of same group was 41.46 ± 4.58 that with a slight difference, the girls sore are more. The total beauty score was reduced with increasing start age of NAM and for each month delay in the start NAM was reduced to 0.59 that was not significant with R= - 0.13 (P= 0.54).

DISCUSSION

In late complications, the number of renewed surgery was less in user group NAM (0% versus 12%) which is a privilege to do NAM and when it is significant to note that user patients of NAM has been intensified were more strongly; 23 from 25 people equal with (92%) from severe type versus 8 people (32%) from severe type in group without use of NAM, so it seems that NAM with reduction of TENSION and reduction of the risk of wound dehiscence is caused less actions and is reduced from psychological and financial burden. The beauty total score in this study significantly was in group with more NAM than group without NAM and also in all minor criteria more scores was belonged to NAM group which except in criterion of vermilion position (Lip line) was significant in other cases; in addition, disease severity was more in NAM group. Extreme close of boys and girls scores in each of the studied two groups clears which gender does not effect on beauty results that in addition predictability, implies on homogeneity of each group and, more importantly accuracy of referees' comment. The reduction of beauty results by increasing the start age of NAM is according to previous studies. Also, in this research with less age at surgery, the beauty results were better that with references are consistent that of course it was more significant in the group with NAM. Therefore, according to survey results, must in patients who need to NAM, embed of it be implemented as soon as possible. Also, parent satisfaction score were higher from the results of surgery in the NAM group. So it can be concluded that the use of PNAM of cleft lip and palate patients can improve the surgery results of lip cleft repair about the complications especially beauty and so the recommendation for fulfillment of PNAM in logical. Another promising point that supports the use of NAM is that certainly in time pass and with increase of experience and orthodontists skill of NAM improviser, and technological advances in materials and equipment, the benefits of using it increases. In theory of reduction of bone graft surgery along with use of NAM, according to that these surgeries is done about 7-10 years and fulfillment of NAM in Iran is novel, and the first patient of the study which has been placed under the NAM embed is related to 2011, so the difference on the issue in this study is not possible.

CONCLUSION

One of the limitations of this study was low sample size which according to the number of patients, candidate for NAM was inevitable. The next point was more severe disease in patients of NAM group. In this study for decreasing of the problem, were asked from 3 assessors to be scored based on comparison of photos pre-surgery and post-

surgery and not just based on photographs of postoperative. Perhaps this issue has been caused to create the paradox increase of scores in patients with more gap intensity and was caused the NAM group scores which had more percent from severe type of disease be more. To more precise determine this issue, the patients of severe type in two groups were compared separately and beauty results in both overall score and each of criteria was higher in the group NAM. The next point is photographs quality which older images may be due to poor technology and a lower resolution have been acquired fewer score and because group of non-NAM had older photos, they have received lower scores. Following this theory, last section photos –more than 6 months from surgery time- that in patients of NAM group had more interval with surgery time and perhaps the time difference through the appearance of hypertrophic scars, diss pigmentation, changes lips form,… have been caused the catch lower scores in this group. The other point is probably the patients who under the embed NAM had higher economic level and their parents in term of cultural and social had better position than second group that itself is caused better participation in treatment including follows up and more regular visits and more precise cares pre-surgery and post-surgery, and better operating results without regardless of NAM. In conclusion, the NAM approach can yield better results in the lip and palate repairing surgery.

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