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ORIGINAL ARTICLE**Comparison between Primary Rhinoplasty and Simple Cheiloplasty in Unilateral Complete Cleft Lip**

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ABSTRACT

Background: Orofacial clefts involve several congenital deformities most often presented as cleft lip and palate. The best management of a child with cleft lip requires a coordinated effort including the fields of otolaryngology, maxillofacial surgery, plastic surgery, speech therapy, pediatrics, orthodontics, nursing, psychology, audiology, genetic counseling, and social work. Aim and objectives: To compare the results of primary rhinoplasty and primary simple cheiloplasty in infants with unilateral complete cleft lip nose according to symmetry and parents' satisfaction.

Methods: This is an intervention study, carried out in the plastic surgery department, Zagazig University Hospital in the period from December 2017 to June 2019. The study included 26 patients who had unilateral complete cleft lip nose divided into two groups (A & B), group A included 13 patients who had primary rhinoplasty, while group B included 13 patients who had simple cheiloplasty. All patients were subjected to complete history taking, full clinical examination, laboratory investigations including complete blood count, liver function tests, renal function, and coagulation profile tests. Patients were admitted to the hospital and the operations were done with general anesthesia.

Results: Operation time was significantly higher in group A. There was no significant difference between both groups regarding complication frequency. There was a significant difference between both groups regarding bilateral nasal symmetry in favor of group A.

Conclusions: The use of primary Rhinoplasty in all cases of cleft lip-nose has yielded cosmetic results and balanced nasal development.

Keywords: Rhinoplasty, Cleft lip, Plastic, Surgery.

**INTRODUCTION**

Orofacial clefts involve several congenital deformities most often presented as cleft lip with or without cleft palate (CLP) or isolated cleft palate (CP). Cleft lip palate is the second most popular congenital developmental disorder in the United States due to Down syndrome[1]. About 7,000 infants are born with orofacial clefts every year in the United States. In addition to the physical impact on the patient, Cleft lip palate also has important socio-economic and psychological influences on either the patients and family members, involving psychological disturbances and diminished quality of life (QOL) [2]. It is associated with high mortality due to several factors, like suicide, and significant cost of healthcare. Cleft lips could be unilateral or bilateral and could even include an alveolus or palate. Affected persons may have other chromosomal defects and could be part of a hereditary disease[3]. Efforts are required to discover the epidemiology

and underlying causes of this disease. The WHO-supported multinational integrative research study on craniofacial abnormalities represents an enormous network to create a comprehensive database and organize research approaches. The best management of a child with cleft lip requires a coordinated effort including the fields of otolaryngology, maxillofacial surgery, plastic surgery, speech therapy, pediatrics, orthodontics, nursing, psychology, audiology, genetic counseling, and social work[4]. The objectives are to optimize nutrition, facial development, speech, and language development. Another of the main tasks of plastic surgeons is to reestablish natural eating, speech, and presentation. effective reconstruction of the cleft lip is both satisfying and demanding [5]. Aim and objectives: To compare the results of primary rhinoplasty and primary simple cheiloplasty in infants with unilateral complete cleft lip nose according to symmetry and parents' satisfaction.

METHODS

An intervention study, carried out in the plastic surgery department, Zagazig University Hospital in the period from December 2017 to June 2019. The study included 26 patients who had unilateral complete cleft lip nose divided into two groups (A & B), group A included 13 patients who had primary rhinoplasty at the same time with cheiloplasty, while group B included 13 patients who had simple cheiloplasty. Inclusion criteria included patients with unilateral complete cleft lip nose at the age of three months till two years old of both genders. On the other side, exclusion criteria included children who were more than 2 years old with previous cheiloplasty, incomplete cleft lip and bilateral complete cleft lip. Detailed full history was taken from patient's parents including personal history as name, age, and sex. Present history was declared via analysis of parent's complaint (cosmetic & functional or both). Past History included asking about parents' consanguinity, if there was similar condition in the family and maternal history for very young patient. Full clinical examination was done with special stress on the state of nutrition, associated anomalies, presence of other diseases such as cardiac, respiratory, renal, or hepatic diseases and excluding syndromes. Local examination of the cleft lip nose defect was done. Routine investigations were done as complete blood count, liver function tests, renal function, and coagulation profile tests. The study was limited to vital stable infants who had not any other disease. Patients were admitted to the hospital before operation, fasting for four hours from milk and two hours from water or clear fluid prior to operation. The operations were done with general anesthesia with orally centrally located endotracheal intubation with iv line. All operations were done at Plastic Surgery Department at Zagazig University beside all operations were done by consultants of Plastic surgery at Zagazig University. The post operative follow up was done at day one post operative, after one week, after one month and lastly after six months in addition all these appointments were arranged with the parents by direct phone calls. All patients were photographed preoperatively & post operatively from frontal and basal views and the all parents were done questionnaire about their satisfaction and the intention for other operation.

Written informed consent was obtained from all participants and the study was approved by the research ethical committee of Faculty of Medicine, Zagazig University (Institutional Research Board IRB). The work has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

STATISTICAL ANALYSIS

The collected data were computerized and statistically analyzed using SPSS program (Statistical Package for Social Science) version 16.0 (SPSS Inc., 2007). For the statistical calculations data coding was done. Qualitative data were represented as frequencies and percentages, Chi- Square test (χ^2) and fisher exact test were carried out for testing the association between the qualitative data frequencies. Quantitative data were represented as mean, standard deviation (SD) and median, student's t-test was used to detect difference between groups which were normally distributed. The test results were considered significant when p-value ≤ 0.05 , highly significant when p-value ≤ 0.001 .

RESULTS

Table (1) shows the age distribution of the studied groups in months. There was no significant difference between groups regarding age. Table (2) shows the sex distribution of the studied groups. There was no significant difference between groups regard sex. Table (3) shows the operation time and hospital stay distribution of studied groups. Operation time was significantly higher in group A. However, there was no significant difference between both groups regarding hospital stay. Table (4) shows the frequency of complications in the studied groups. There was no significant difference between both groups regarding complication frequency. Table (5) shows the satisfaction distribution of the studied groups. There was a significant difference between both groups regarding parents' satisfaction in favor of group A. Table (6) shows the intention for further operation of both groups. Group B patients show the intention of parents for further operation is significantly high in comparison to group A patient. Table (7) shows the bilateral symmetry among studied groups. There was a significant difference between both groups regarding bilateral nasal symmetry in favor of group A.

Table (1): Age distribution of studied groups in months:

	Group A	Group B	t	P
Mean of age in months	4.15±1.14	4.0±1.0	0.365	0.718

T test was used. P value was set at <0.05 for significant results & <0.001 for high significant result. There was no significant difference between groups regarding age.

Table (2): Sex distribution of studied groups

			Group		Total	X ²	P
			Group A	Group B			
Sex	Male	N	10	9	19	0.19	0.65
		%	76.9%	69.3%	73.1%		
	Female	N	3	4	7		
		%	23.1%	30.7%	26.9%		
Total		N	13	13	26		
		%	100.0%	100.0%	100.0%		

Chi square test (X²) was used. P value was set at <0.05 for significant results & <0.001 for high significant result. There was no significant difference between groups regard sex.

Table (3): Operation time and hospital stay distribution of studied groups:

		Group A	Group B	t	P
Operation time in minutes	mean	59.61±10.5	38.46±13.2	4.503	0.00**
	Range	50-120	30-70		
Hospital Stay in days	mean	4.82±0.98	4.92±1.12	0.098	0.99
	Range	3-5	3-6		

T test was used. P value was set at <0.05 for significant results & <0.001 for high significant result. Operation time was significantly higher in group A. However, there was no significant difference between both groups regarding hospital stay.

Table (4): The frequency of Complications in the studied groups

			Group		Total	X ²	P			
			Group A	Group B						
Complication	No	N	3	3	6	1.33	0.72			
		%	23.07%	23.07%	23.07%					
	Wound dehiscence	N	1	1	2					
		%	0.076%	0.076%	0.076% %					
	Edema	N	3	3	6					
		%	23.07%	23.07%	23.07%					
	Fever	N	2	2	4					
		%	15.3%	15.3%	15.3%					
	Vermilion Notching	N	2	2	4					
		%	15.3%	15.3%	15.3%					
	Infection	N	2	2	4					
		%	15.3%	15.3%	15.3%					
	Total		N	13	13			26		
			%	100.0%	100.0%			100.0%		

Chi square test (X²) was used. P value was set at <0.05 for significant results & <0.001 for high significant result. There was no significant difference between both groups regarding complication frequency.

Table (5): Satisfaction distribution of the studied groups

			Group		Total	X ²	P
			Group A	Group B			
Satisfaction	Not	N	0	4	4	10.5	0.005*
		%	0.0%	30.8%	15.4%		
	Satisfied	N	2	6	8		
		%	15.4%	46.2%	30.8%		
	Very satisfied	N	11	3	14		
		%	84.6%	23.1%	53.8%		
Total		N	13	13	26		
		%	100.0%	100.0%	100.0%		

Chi square test (X²) was used. P value was set at <0.05 for significant results & <0.001 for high significant result. There was a significant difference between both groups regarding parents' satisfaction in favor of group A.

Table (6): Intention for further operation of both groups

			Group		Total	X ²	P
		N	Group A	Group B			
Intension for further operation	No	N	11	2	13	12.46	0.00**
		%	84.6%	15.4%	50.0%		
	Yes	N	2	11	13		
		%	15.4%	84.6%	50.0%		
Total	N	13	13	26			
	%	100.0%	100.0%	100.0%			

Chi square test (X²) was used. P value was set at <0.05 for significant results & <0.001 for high significant result. Group B patients show the intention of parents for further operation is significantly high in comparison to group A patient.

Table (7): Bilateral symmetry among studied groups

Parents opinion about symmetry	Group A		Group B	Total
Non symmetric	N	0	11	11
	%	0%	84.6%	42.3%
Fair symmetry	N	2	2	4
	%	15.04%	15.04%	15.04%
Excellent symmetry	N	11	0	11
	%	84.6%	0%	42.3%
Total	N	13	13	26
	%	100%	100%	100%

Qualitative data was represented as number and percentage. There was a significant difference between both groups regarding bilateral nasal symmetry in favor of group A

DISCUSSION

Nasal deformity in the unilateral lip is a problem and a liability to the patient and a concern to the surgeon. Lately, there's been a concern in fixing this issue especially in this time of lip repair and use a closed or open method rhinoplasty at the same time with cheiloplasty[6]. The Cleft lip Nose is so well identified. However, for a long period, cleft surgeons believed that fixing the Cleft lip Nose at time of primary repair may induce a growth disruption, particularly in the nose. Consequently, the facial deformity wasn't even repaired unilaterally [7]. Recent literature suggests that nasal reconstruction at the time of primary lip repair helps to improve the instantaneous look of the nose and also has a beneficial impact on long-term development, as the pattern of excessive nasal development is changed and the nose curvature is even less severe in teenage years[8]. This has been proved by other surgeons like Haddock in 2012. He assumed that primary nasal repair is effective and decreases the extent of secondary surgery in adolescents. However, there is still debate about the ideal corrective method, the right exposure and repair methods, and, most notably, the timing of the intervention[8]. The aim of this study is to compare the results of rhinoplasty & simple cheiloplasty in repairing of the unilateral complete cleft lip nose according to symmetry and parent's satisfaction. This prospective study was conducted on 26 patients, that were divided into two equal groups

(A & B). The demographic characteristics of group (A) patients showed male to female ratio of 10:3 while in group (B) 9:4. The gender incidences are like the figures of the general population reported by others[9]. Here, both groups (A & B), lip repair was done using Millard rotation advancement repair all patients. This technique provided minimal or no discarded tissue; the technique is flexible and adaptable; it allows creation of a normal-looking Cupid's bow[10]. In group (A) patients, nasal repair was done by using McComb's technique in which, nasal skin was freed from the nasal bone and cartilage via the incision in the upper buccal sulcus. The scissors were also passed up through the columella to free the skin from the medial crus and dome of the alar cartilage. The extent of the nasal dissection was from the alar rim over the nasal tip and up to the nasion on the cleft-side hemi-nose. A point of debate has been to retain the achieved location of the alar cartilage. Although most surgeons rely only on their suspension sutures [11]. Regarding the time of operations, it was higher in group (A) about 59 minutes while in group (B) was only 39 minutes. Regarding to the hospital stay there was no significant difference between both groups (A & B). The methods that used to evaluate the results of both techniques for repairing complete unilateral cleft lip nose are either subjective, objective, Objective assessment was done by asking parents whether they are satisfied, fairly satisfied, or not

satisfied. In this study, there was a significant difference between two groups. In the group (A), parent's satisfaction was excellent in 11 patients (84.6%) while only 2 cases (15.04%) are fairly satisfied. In the other group (B), only 3 parents (23.1%) were highly satisfied, 6 parents (46.2%) fairly satisfied and 4 parents (30.8%) completely unsatisfied. Only 15.4% of group (A) parents showed intention to do further operation while in group (B) 84.6 % were intent to do more operation [12]. Horswell and Pospisil in their study compared the results of Cheilorhinoplasty and Millard's cheiloplasty. They studied 33 children, 16 underwent Cheilorhinoplasty procedure and 17 underwent Millard's procedure. Using photos, they analyzed the nasal symmetry in the two groups and found that the cheiloplasty group appeared to have much more asymmetrical noses and greater tip variance, close to our findings [13]. Delaire's theory that muscular action around the perinasal region is essential for development sounds to be supported with these findings [14]. The extent of more correction in individuals who had primary cheilorhinoplasty is restricted to touch ups and fine tuning with excellent outcomes. Simple cheiloplasty and keeping the nose unchanged, on the other hand, may lead to a long-standing complicated nasal disfigurement, resistant to molding and reconstructing, with matured cartilage [15]. Regarding post-operative complications of studied groups as it has been showed in (table 4), there was no significant difference between both groups regarding rate of complication. 10 patients (76.13%) of each group had complications. At the first, post-operative, week, 3 patients of each group showed expected complications of edema, while 2 patients in both groups (A & B) had a severe infection, fever. Only one patient of each group had wound dehiscence. During follow up, after complete healing, the parents had notes about the shape of the scar, besides 2 patients of both groups (A & B) has developed vermilion notch.

CONCLUSIONS

The idea of primary nasal deformity repair at the time of lip repair is appealing. With pliable cartilage that can be formed without difficulty, it offers the chance to achieve symmetry. In this kind of surgery, the ideal alar left remains the cornerstone, followed by the nasal floor closure. Based on the finding of this study we recommend the use of primary rhinoplasty in all cases of cleft lip-nose for the better aesthetic results and balanced nasal growth that it yields. However, because of the limited number of patients and short period of follow-up our results should be taken cautiously. Further studies of the same design but

with larger number of patients and longer period of follow-up are also recommended.

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