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Designing a Protocol for Reconstruction of Cleft Lip in Neonatal Period

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Abstract

For many years the reconstructive surgeons were adherent to what's called the role of ten (10 pounds in weight, 10 grams for Hb %, 10 weeks for age), the early management was lip adhesion only. The optimal timing of surgery depends on several factors, including the surgeon's experience, how risky anesthesia is for the patient and other health problems they have. For most babies, surgeons recommend having cleft lip surgery between 10 and 12 weeks. To find a protocol that facilitates cleft lip repair in the neonatal Period. This is a prospective, interventional randomized study on Plastic and Pediatric surgery departments. We conducted this study on 10 cases fulfilling the inclusion criteria in neonatal period. Anticipated outcomes include insights into the impact of Millard technique on early cleft lip repair on facial aesthetics, feeding difficulties, as regard parents satisfaction were 80% of cases satisfied by early repair, 20% not satisfied due to problems with anesthesia as regard surgical satisfaction 1% of cases was fair result, 50% of cases were good result, 30% of cases were very good result, 1% of cases was excellent result. performing the Millard technique early in neonates with cleft lips has several advantages. Early intervention can help prevent feeding difficulties and speech problems; it can also help improve the child's overall quality of life by early returning to normal life and getting rid of family psychological problems due to presence of congenital anomalies.

Key words: Cleft lip and palate, Neonatal, Cleft Lip Repair.

1. Introduction

Cleft Lip Is one of the most Common Congenital facial malformations, incidence about 1: 700 births. The Most Common Risk factors are parent age more than 30 Years, Genetic Factor, and teratogenic drugs as phenytoin During 1st trimester of Pregnancy. A cleft lip may be Unilateral or bilateral, Complete or incomplete. Associated with cleft plate or not.

Embryological Defect Failure of fusion between Maxillary process, Naso medial Process, Naso lateral Process [1]. Care for children with CL and palate starts from birth and continues throughout their childhood and maybe until adulthood. The aim of early intervention is to improve both functional and aesthetic outcomes. This surgery is crucial for normal facial development, for them to speak well, and for proper dentition [2]. Cleft lip usually develops at the junction between the lateral and central segments of the upper lip. The cleft usually affects the upper lip and may extend into the maxilla and palate [3]. Early cleft lip repair provides additional advantages like better appearance of surgical scars, easily feeding and acceleration of weight gain and growth, and improving infant-maternal socialization [4].

2. Patients and Methods

This is a prospective interventional study, done in pediatric surgery unit and plastic surgery department at AL- Zahra university hospital, Cairo. We conducted this study on 10 cases fulfilling the inclusion criteria in neonatal period

2.1 Inclusion criteria

(I) Males &females in neonatal period. (II) All types of CL. (III) Weight > 10 Pound. (iv) Hb > 10 gm.

2.2 Exclusion Criteria:

(I) Neonate with other congenital abnormalities affecting life or interfere with anesthesia such as renal, cardiac, hydrocephalus, etc. (II) Neonate of diabetic mother. (III) Neonate admitted to neonatology units (IV) Neonate with uncooperative parents (refusing early intervention). (V) Neonate suffered from physiological jaundice.

2.3 Study Period and Follow-up:

This study started October 2022, Finished October 2023 and follow-up for 6 months post operative.

2.4 Surgical Techniques: *(CL Repair)*

- **Unilateral:** (Rotation-advancement flap developed by Millard)
- **2-Bilateral:** (Bilateral rotation advancement with attachment to premaxilla mucosa)

2.5 Post Operative Complication

- **Early:** I. Dehiscence, II. Infection
- **Late:** III. Thin White Roll, IV. Excess Tension.

3. Results

This study was conducted on ten cases with CL at the departments of pediatric surgery and plastic surgery at AL Zahraa University Hospital, located in Cairo, Egypt. As shown in Table 1, regarding demographic data, the average age of the participants in the study was 18.6 ± 7.9 days. Regarding the gender, 60% were male and 40% were female. The Mean ± SD of the body weight was 3.59 ± 0.4 Kg. As shown in table 2 according to the CL laterality, it was found that 70% of the study population were unilateral CL and 30% were Bilateral. We also found that 20% of study cases were in complete type and 80% of the study cases had complete CL and palate. As shown in table 3, regarding the preoperative lab findings of the study cases, it was found that the mean Hb level of the study cases was 12.6 g/dl, about WBCs it was 10.05 (× 109 /L), in addition platelet count was found 353.5 ±78.8 (× 10^3 /L). As shown in Table 4, as regards the associated congenital, it was found that 70% had no associated congenital anomalies, 20% of cases had PFO as well as 10% of patients had PDA. As shown in table 5, as regards

post operative complications, 60% of the study cases had no post operative complications, 20% of patients had post operative infections and 20% of cases had reported post operative atrophic changes. As show in table 6 as regards Parents satisfaction, there were 80% of the study parent's cases were satisfied and 20% not satisfied. As shown in Table 7, as regards the lip length, the post operative mean was significantly lower than the preoperative mean. Also, the post operative Commissure length was significantly lower than the preoperative length. Moreover, the nostril width and breadth were significantly lower than the preoperative values.

Classification depends on many items:

- Parents, surgeon satisfaction on follow up
- Get rid of psychological trauma to patient families due to presence of congenital anomalies.
- Improvement of feeding difficulties and weight gain
- Aesthetic outcome
- Post-operative complications

Table 1: Demographic data of participants

Variable	Study population
Age (days)	2-28 days
Mean ± SD	18.6 ± 7.9
Sex	
Males N (%)	6(60%)
Females N (%)	4(40%)
Weight	
Mean ± SD	3.59 ± 0.4

Table 2: Cleft lip and palate evaluation

Variables	
Cleft lip and palate	
Unilateral	7(70%)
Bilateral	3(30%)
Cleft Severity	
Incomplete	2(20%)
Complete	8(80) %

Table (3): Preoperative lab findings of the study cases

Variables	Study population (N =10)
Hb (g/dl)	
Mean ± SD	12.61±1.23
WBC (× 109 /L)	
Mean ± SD	10.05 ±1.42
Platelet count (× 103 /L)	
Mean ± SD	353.5 ±78.8

Table (4): Associated Congenital anomalies

Associated Congenital Anomalies	
None	7(70%)
PFO	2(20%)
PDA	1(10%)

Table (5): Post operative complications

Post operative complications	
None	6(60%)
Infection	2(20%)
Atrophic changes	2(20%)

Table (6): Parents satisfaction

Parents satisfaction	
Satisfied	8(80%)
Not satisfied	2(20%)

Table (7): Preoperative and Postoperative lip and nose parameters

	Preoperative	Postoperative	P value
Lip length			
Mean ± SD	0.41 ± 0.16	0.13 ± 0.11	<0.001
Commissure length			
Mean ± SD	0.63 ± 0.59	0.14 ± 0.12	<0.001
Nostril width			
Mean ± SD	1.17 ± 0.97	0.23 ± 0.27	<0.001
Nostril Breadth			
Mean ± SD	0.86 ± 0.79	0.16 ± 0.22	<0.001

Highly significant p<0.001

Table (8): Surgical satisfaction

Surgical satisfaction	Fair	Good	Very good	Excellent
Class A	1 (10%)			
Class B		5 (50%)		
Class C			3(30%)	
Class D				1(10%)

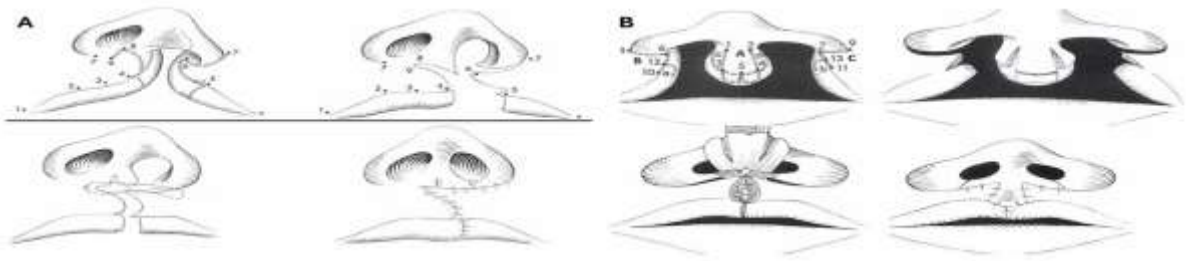

Figure (1): Surgical Techniques for Cleft Lip Repair. A: Unilateral: Rotation-advancement flap developed by Millard. B: Bilateral: (Bilateral rotation advancement with attachment to premaxilla mucosa).

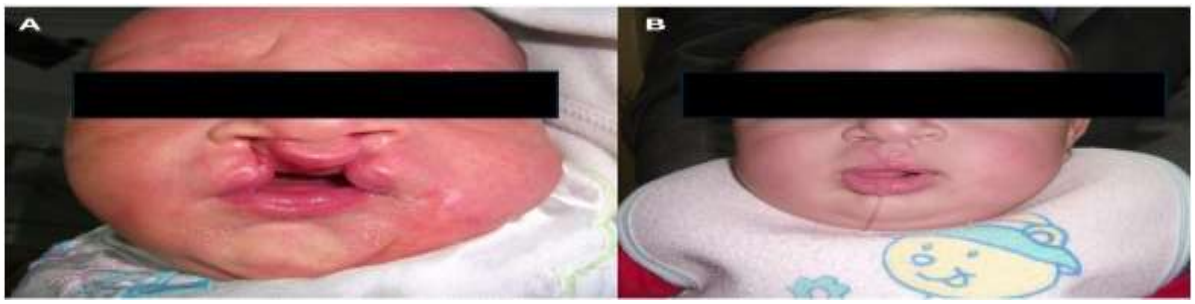

Figure (2): Photograph of Male patient with bilateral complete CL with cleft alveolus, A: 4 days old (Before), B: 6 months old (After)

Figure (3): Photograph of Female patient with complete unilateral CL. A: 2 days old (Before) B: 6 months old (After).

Figure (4): Photograph of Female patient with unilateral complete CL. A: 3 weeks old (Before). B: 3 months old (After) Fig. 1

4. Discussion

CL and palate are a very common birth defect, ranking first among craniofacial anomalies and fourth overall. How often it occurs can vary depending on location, family history, and environmental influences. It affects roughly one in every 650 to 750 babies born alive. Cleft palate is a common symptom found in over 300 well-defined groups of congenital malformations [5].

A study by Semb et al. [6]. evaluated the effectiveness of the Millard technique in repairing CL in early neonates and found that the technique was effective in achieving good functional and aesthetic outcomes.

A study conducted by Manlove and Linnerbur [7] found that early Millard repair was linked with better nasal symmetry and function compared to late repair. The study also found that early repair was associated with a lower incidence of secondary surgeries also we found that in our research.

Hodges, [8] in a larger number (106 patients) with CL aging from 6 weeks to 10 months he had a very encouraging results in early reconstruction lip regarding the surgical obstacles. Also Borsky [9] consider early (44 patients under the age of 1 week) combining lip surgery with nasal correction as the most effective approach. We propose to follow suit and implement this method while closely monitoring its effects on jaw and nasal growth in developing patients. Our study aligns with their recommendation for early intervention whenever possible.

Early repair of CL is essential for the improvement of the child's ability to eat, speak, and hear normally in case with cleft palate and to achieve a normal facial appearance. Most cases of CL are repaired within the first 3 - 6 months of age, while cleft palate repair is done at the age of 12 months or earlier if possible. The first surgical procedure for babies born with a complete CL is likely to be a lip adhesion, which is usually performed between 2 - 4 weeks of age. The surgery aims to convert a complete CL to an incomplete CL. The timing of the surgery is important because it can affect the development of the child's speech and language skills. Early repair of CL and palate can improve the child's speech and language development, as well as their social and emotional well-being [10]. We also agree with this study as early repair has a good impact on speech and language development.

Accurately evaluating aesthetics is challenging due to its inherent subjectivity and the lack of universally accepted criteria for beauty [11]. In our study we used visual analogue scale of parents and surgeons to assist with aesthetics outcome and of course it needs to be more realistic and controlled this will be in the future studies. In contrast to the typical approach of using photos and questionnaires, the study assessed facial aesthetics after CL surgery [6].

A study evaluated the aesthetic outcome of CL surgery and looked at how the public perceived the results of CL surgery using postoperative photographs. On average, people rated the overall look as 7.55, the mouth area as 7.40, and the nose as 7.23 [12].

Discrepancies between the scores of the study and earlier investigations may be due to methodological variations, specifically the limitations of the photographic technique in evaluating lip and nasal aesthetics [13]. For our study, because of the limited number of cases we did not concentrate on this point of view.

5. Conclusion

In conclusion, early intervention can improve feeding difficulties and speech problems. It can also help the child's overall quality of life by reducing the time needed to return to normal life and decreasing family psychological problems

due to presence of congenital anomalies. Studies have shown that early Millard repair is associated with better speech outcomes, better nasal symmetry and functions.

6. Our protocol for early repair of cleft lips needs multi-disciplinary team:

1. Gynecologist and Radiologist for proper antenatal care and detection of CL by 3 D sonar that can be used to diagnose these congenital anomalies and any associated congenital anomalies intra uterine.

2. Obstetrician and Pediatrician for primary surveys are just post-delivery and reconsult pediatric and plastic surgeons.

3. Role of pediatric and plastic surgeon (examination, investigation for the patient and anesthetic consultation) For evaluation of the ability to reconstruct the defect of the patient for early surgical intervention.

Conflict of interest

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