# **Original Research Article**

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# Clinical and epidemiological profile of cleft lip/ palate deformities in Tamil Nadu, India

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#### **ABSTRACT**

**Background:** Cleft lip and palate deformities are commonly detected at the time of birth in most of the developing countries like India. The surgical management of cleft lip/ palate deformities involve multi-disciplinary approach with corrective measures from dental surgeon, plastic surgeon, speech pathologist and audiologist. The role of pediatricians in clinical management of cleft lip is often missed. This study was done to evaluate the clinical profile of cleft lip and palate deformities.

**Methods:** This cross sectional study was carried out among 1077 patients diagnosed with cleft lip or cleft palate deformity for a period of 5 years between 2014 and 2019. A structured patient information schedule was prepared and data regarding the age, gender, antenatal details and parental history were recorded. A detailed clinical examination was carried out to evaluate the presence of complete and incomplete deformity in the lip, alveolus, hard palate and soft palate.

**Results:** Complete cleft lip was present in 47.8% of the participants on the left side while on the right, complete cleft lip was present in 29.4% of the participants. Complete deformity of the alveolus on the left side was present in 45.4% of the participants while complete deformity on the right side of alveolus was present in 27.4% of the participants.

**Conclusions:** It is important the pediatricians sensitize the parents regarding the clinical and supportive management and also initiate the surgical correction of this deformity with help of a multidisciplinary team.

Keywords: Cleft lip, Cleft palate, Craniofacial deformity, Congenital anomaly, Embryology, Multidisciplinary team

# INTRODUCTION

Congenital maxillo facial deformities are common among the neonates and pediatric age group. Among the various such deformities, cleft lip and palate are heterogeneous group of deformities affecting the structure of the face and oral cavity.<sup>1</sup>

The problems associated with these deformities involve phonation, hearing, mastication, deglutition and ventilation issues. Globally, the incidence of cleft lip and palate deformities range from 0.8 to 1.6 per 1000 live births.<sup>2</sup> It is important to identify and provide aesthetic treatment for these anomalies as it involves various structural and psychosocial complications. The surgical management of cleft lip/ palate deformities involve multidisciplinary approach with corrective measures from dental surgeon, plastic surgeon, speech pathologist and audiologist. However, the success of the surgery depends on various factors including the time of presentation, type of repair, patient compliance and effect of physiotherapy.

There is a greater need for screening and early detection of these anomalies in order to plan for effective surgical management. In developed countries, there is ample scope for screening and early detection of these anomalies during the antenatal period, and also effective counseling and rehabilitative measures present for these patients to cope up with such deformities. However, in developing country like India, the delay in presentation of such cases are largely related to the prevailing socio economic status, illiteracy and lack of awareness.<sup>3</sup> Moreover, the corrective procedures for these deformities are also fairly successful and affordable.

Therefore, it is the onus of the primary care pediatrician to create awareness on these congenital deformities and also coordinate with the multidisciplinary specialists in ensuring a successful surgical management of these deformities. There is meagre data on the magnitude and intensity of these craniofacial deformities in India. This warrants the need for a complete scrutiny of the clinical presentation and epidemiological profile of such deformities in order to sensitize the primary care pediatricians on the impact of awareness and screening and also facilitate health education for parents and provide counseling so as to ensure successful surgical management of the problem.

The objective of this study was carried out to evaluate the epidemiology and clinical profile of cleft lip and cleft palate deformities among pediatric population in Tamil Nadu.

## **METHODS**

## Study setting and participants

This cross sectional study was carried out in a tertiary teaching hospital among patients diagnosed with cleft lip or cleft palate deformity for a period of 5 years between 2014 and 2019. All the participants who were diagnosed or referred to this center for surgical management where taken up for the study.

#### Ethical approval and informed consent

Approval from institutional ethics committee was obtained prior to the commencement of the study. Each parent was explained in detail about the study and informed consent was obtained from the parents prior to the commencement of data collection.

#### Data collection

A structured patient information schedule was prepared and data regarding the age, gender, antenatal details and parental history were recorded. A detailed clinical examination was carried out to evaluate the presence of complete and incomplete deformity in the lip, alveolus, hard palate and soft palate.

The weight of the child was recorded using standardize weighing scale. The type of surgery which was performed for correcting the deformity was also recorded. History of complications and adverse events during the procedure and hospital stay were also documented.

## Data analysis

Data was entered and analysed using SPSS version 20. The prevalence of type of deformity was expressed in percentages. The association with the type of deformity and background characteristics were evaluated using chisquare test. A p value <0.05 was considered as statistically significant.

## RESULTS

This study was carried out among 1077 participants who were diagnosed with complete or incomplete cleft lip/palate in this tertiary care institutions. Majority of the participants were < 15 years of age (62.1%) and were males (59.1%). None of the participants had premature delivery or any pregnancy related or birth complication. Moreover, none of the participant's parents were smokers or alcoholics or had history of any allergies or deformities (Table 1).

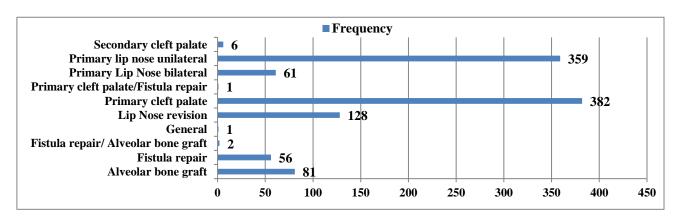


Figure 1: Type of operation.

Complete cleft lip was present in 47.8% of the participants on the left side while on the right, complete cleft lip was present in 29.4% of the participants. Complete deformity of the alveolus on the left side was present in 45.4% of the participants while complete deformity on the right side of alveolus was present in 27.4% of the participants (Table 2).

Regarding the hard palate deformity, complete deformity was present on left side in 47.8% of the participants while on the right side, it was present in 31.5% of the participants. Similarly, complete deformity of the soft palate was present in 73.5% of the participants. Additional craniofacial deformity was present in 0.2% of the study participants (Table 2).

**Table 1: Background characteristics.** 

Characteristics	Frequency N(1077)	Percentage (%)						
Age (in years)								
<15	669	62.1						
>15	408	37.9						
Gender								
Male	637	59.1						
Female	440	40.9						
Length of pregna	ancy(in months)							
9 months	869	80.7						
Don't know	208	19.3						
Pregnancy complication								
Yes	0	0.0						
No	1077	100.0						
Birth complicati	on							
Yes	0	0.0						
No	1077	100.0						
Smoking								
Yes	0	0.0						
No	1077	100.0						
Alcohol								
Don't know	1	0.1						
No	1076	99.9						
Allergies								
Yes	0	0.0						
No	1077	100.0						
Med allergy								
Yes	0	0.0						
No	1077	100.0						
Weight (in Kgs)	Weight (in Kgs)							
<17	658	61.1						
>17	419	38.9						

Majority of the participants underwent primary correction of cleft palate followed by primary unilateral lip nose correction (Figure 1). As far as the type of repair is concerned, majority of the participants underwent pushback variant followed by triangular variant (Figure 2).

Authors analyzed the association between the type of congenital deformity and background characteristics. Authors observed that age <15 years were increasingly associated with complete deformity (85%) compare to age < 15 years (77.9%). The observed difference was statistically significant (p value < 0.005) (Table 3).

Table 2: Particular regarding the deformities.

Characteristics	Frequency N(1077)	Percentage (%)						
Fam H/O left palate								
Yes	0	0.0						
No	1077	100.0						
Previous surgery	7							
Yes	1076	99.9						
No	1	0.1						
Lip left								
Complete	515	47.8						
Incomplete	168	15.7						
Not cleft	394	36.5						
Lip right								
Complete	317	29.4						
Incomplete	104	9.7						
Not cleft	656	60.9						
Alveolus								
Complete	489	45.4						
Incomplete	46	4.3						
Not cleft	542	50.3						
Alveolus-R								
Complete	295	27.4						
Incomplete	17	1.6						
Not cleft	765	71.0						
Hard palate-L								
Complete	515	47.8						
Incomplete	60	5.6						
Not cleft	501	46.5						
Submucous	1	0.1						
Hard palate- R								
Complete	339	31.5						
Incomplete	55	5.1						
Not cleft	683	63.4						
Soft palate								
Complete	792	73.5						
Incomplete	6	0.6						
Not cleft	276	25.6						
Sub mucous	3	0.3						
Additional crani	ofacial deformity							
Don't know	1	0.1						
Yes	2	0.2						
No	1074	99.7						

#### **DISCUSSION**

Cleft lip and cleft palate deformities are fairly common in Asian countries and in India. They appear either as a single deformity or as group of deformities as a syndromic presentation. It is essential to understand the embryology of facial development in order to comprehend the types of deformities. Embryologically, the face appears to develop at the end of the fourth week and is completed by the eighth week. However, the palate is formed by the end of tenth week.

Table 3: Association between disease and various risk factor.

Parameters	Deformity	Deformity				Chi sa	n voluo
	Complete	(%)	Incomplete	(%)	N (1077)	CIII Sq	p value
Age (in years)							
<15	521	(77.9)	148	(22.1)	669	8.334	0.004*
>15	347	(85.0)	61	(14.9)	408		

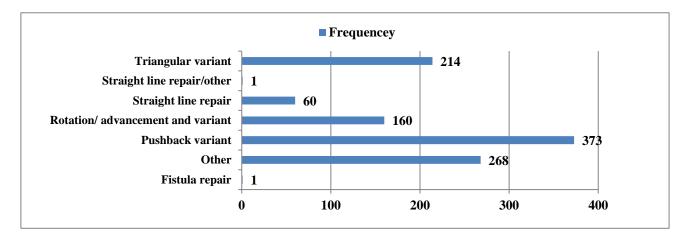


Figure 2: Type of repair.

At around fourth week, a series of swellings appear around the stomodeum namely frontonasal process, bilateral maxillary process and mandibular process. Further to that, developing nasal placodes arise as thickening on the either side of frontonasal process. At the fifth week, nasal placodes is surrounded by horseshoe shaped ridge consisting of lateral and medial nasal processes with nasal bit in the middle. These nasal bits deepen and rupture forming communication between the nasal and oral cavities called as primary choanae. At around seventh week, maxillary processes medially underneath the lateral nasal swellings and fuse with medial nasal swellings. This complex arising from the fused swellings form the primary palate and it is complete by the end of seventh week. The fusion of paired maxillary prominences with paired medial nasal prominences forms the complete upper lip. The lateral and nasal prominences form the bilateral nasal ala.4 The primary palate is formed by the fusion of medial nasal prominences and it consist of maxillary alveolar arch with four incisors and the hard palate anterior to the incisive foramen. During the sixth week, secondary palate is formed as shelf like outgrowths from the bilateral maxillary processes which grow vertically down on both sides of the tongue. During the seventh week the tongue moves inferiorly, and the palatal shelves migrate to a horizontal position above the tongue. Palatal fusion occurs in an anterior to posterior direction and completes with uvular fusion.4

The failure of fusion of these maxillary medial nasal prominences unilaterally or bilaterally result in unilateral and bilateral cleft lip with or without primary palate. Failure of the fusion of the palatal shelves result in clefts of the secondary palate. The cleft lip/palate could be unilateral or bilateral, complete or incomplete based on the level of the failure of the fusions. According to Davis and Ritchie classification, they are classified as group 1 and group 2 were group 1 is clefts anterior to the alveolus and group 2 which are post alveolar clefts. The other classification is Veau classification where the clefts are classified as class I which is incomplete cleft involving only the soft palate are class II where the cleft involves both the hard and soft palate and class III which is complete unilateral cleft involving the lip and palate and class IV which is the complete bilateral cleft. This study showed that majority of the deformities were of complete type and predominantly on the left side (47.8%). Similarly, complete deformity of the alveolus was seen in most of the patients (45.4%) while complete deformity of the hard palate was seen in 47.8% of the participants. Complete deformity of the soft palate was also present in 73.5% of this participant. In a study done by Uppal et al, majority of the study participants had findings similar to this study with complete cleft lip on the left side being predominant followed by complete alveolus deformity and bilateral deformity of hard and soft palate.<sup>3</sup>

In another study done by Diwana VK et al, cleft lip and palate were predominantly seen on the left side, which is similar to this study. Moreover, unilateral clefts were

more common than bilateral clefts and presence of both cleft lip and palate was seen in 52.5% of the participants, similar to this study.<sup>5</sup> In addition the male:female ratios showed that majority of the affected individuals were males similar to several studies.<sup>3</sup>

In this study majority of the participants underwent pushback variant of repair followed by triangular variant of repair. The disadvantage of using the pushback technique (Veau-Wardall-Kilner palatoplasty) involves increasing the length of the soft palate, thereby lengthening the large raw area of the nasal surface which is left open. The raw area heals by secondary intention and causes shortening of the palate.<sup>6</sup> There are several techniques available to repair the cleft palate. Some of the techniques commonly used include Langenbeck, alveolar extension palatoplasty, Vomer flap, Raw area free palatoplasty, etc. Ideal palatoplasty is the one which restores perfect speech without affecting the maxillofacial growth and hearing. Although there are various techniques available for palatoplasty, the basic steps involve correction of repair by correcting the mucoperiosteal flaps and soft palates which enable fusion of the processes into a straight line.7 The surgical management of cleft lip and palate involves teamwork with a dedicated team of specialist committed for the care and management. The craniofacial team involves variety of professionals including nursing, dentist, orthodontist, oral surgeons, otorhinolaryngologist, prosthodontists, speech therapist, radiologist, psychologist and plastic surgeons. The successes of the surgery depend on the coordination of the team and depends on various factors including the coordination of the team, type of deformity, type of surgery and also the timing of surgery.

As primary care paediatrician, it is important to be sensitised towards the need for the multidisciplinary team approach and it is the role of these paediatricians to coordinate with the team and ensure that the patients receive holistic management and care. The coordinated teamwork may be exemplified by the presence of social worker who helps communicate in the language which is comfortable for the patients and also for the team members. As paediatricians it may be important to create awareness among the parents of the children with cleft lip and palate deformities on reasoning out the causes of deformity and also the procedural course of action from time to time. Studies have shown that antenatal and prenatal screening may identify the presence of deformities in atleast 20-30% of the patients. Nevertheless, in developing countries like India such identification is often missed. especially underdeveloped regions and rural areas. Therefore, the post-partum visit of the pediatrician helps build liason with patient and the multidisciplinary team to coordinate and ensure that the patient care is kept at priority.8

#### **CONCLUSION**

Cleft lip and palate deformities are fairly common in Asian and developing country like India. They are effectively managed when detected early through screening in the antenatal period or early during the post-partum period. Among the various types of cleft lip and palate deformities complete unilateral left lip/palate deformities are more common than the other types of deformities. Cleft lip and palate can be easily detected by primary care pediatricians during the clinical evaluation of the newborn. It is important the pediatricians sensitize the parents regarding the clinical and supportive management and also initiate the surgical correction of this deformity with help of a multidisciplinary team.

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Ethical approval: The study was approved by the

Institutional Ethics Committee

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