IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)
e-ISSN: 2279-0853, p-ISSN: 2279-0861.Volume 19, Issue 11 Ser.4 (November. 2020), PP 45-53
www.iosrjournals.org

Demographic Analysis of Cleft Lip andPalate: A Single Institutional Study

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Abstract:
Objective:*The aim of the study was to analyse the demography of cleft lip and palate among other congenital anomalies foundin infantsdelivered in a single institutioninDharmapuri district, which is one of the most backward districts of Tamil Nadu, South India.*
Method:*This five-yearretrospective study was based on dataanalysisfor orofacial clefts. The data includesthe number of deliveries, the number of anomalies, and the sex of the babies, collected from the labour ward, NICU, and DEIC records during the year 2015 to 2019 in Government Dharmapuri Medical College, Tamil Nadu, India, after getting approvalfrom the institutional ethical committee.Other details, like consanguineous marriage andthe age of the parents, were collected by contacting through telephone.*
Result:*Our study showed 681 congenital anomalies among the total deliveries, that is 1.7 percent of total deliveries and 92 clefts, that is about 0.2 percent of total deliveries and 13.5 percent of congenital anomalies. Demographic details of 72 patients were collected. Our study showed male predominance in all three categories of Orofacial clefts as per our classification. Father and mother age group predominantlyfalls in 25to35years of age, andconsanguinity in marriage was found in 47percent.*
Conclusion:*Improvement of birth defect surveillance and research is required to identify and improve the quality of care for new-born babies and determine the genetic and environmental etiologyof clefts in India.*
Keywords: *Congenital defects, Orofacial clefts, Cleft lip, Cleft palate, institutional deliveries.*

Date of Submission: 31-10-2020 Date of Acceptance: 12-11-2020

I. Introduction

Orofacial clefts (OFC) are a range of abnormalities which manifests in the new-born and is a major health problem worldwide. (1) It includes structures around the oral cavity.OFCis considered the second leading cause of birth defects, especially in Asia. (2) It includes cleft lip and palate. The severity of OFCranges from traces of notching of the upper lip to complete non-fusion of thelip,with or without primary palate, secondary palate, and it could be life-threatening if associated with syndromes. Affected children have a range of functional as well as aesthetic problems. (3)

Global surveys have shown that the frequency of cleft lip and palate varies greatly from country to country. (4, 5)The prevalence of OFC varies from 0.15 to 2.5 per 1000 births.The incidence in the Asian population is reported to be 2.0 per 1000 live births. Cleft lip and palate are more common in Asians and Native Americans. (6) American Indians had the highest rate of lethal birth defects followed by Asians, Hispanics, and Africans.In the Indian subcontinent prevalence of clefts is somewhere between 27,000 and 33,000 per year.WHO has recognized that non-communicable diseases, including birth defects,causes significant infant mortality and childhood morbidity and have included cleft lip and palate in their global burden of disease initiative. This will fuel the interest of India in birth defects registration. (7)

A child is born with a cleft somewhere in the world approximately every 2 minutes. (11) Cleft lip and palate are some of the most common visible congenital abnormalities of the face. Clefts may be unilateral or bilateral and involves the lip, the palate, or both. It is often found in epidemiological studies that cleft lip/cleft palate are considered underneath syndromic or non-syndromic conditions.The etiology of non-syndromic cases of cleft lip and palate is lesser-known compared to those identified with a syndrome. Development of head and face represents one of the most intricate events during embryonic development, synchronized by a network of transcription factors. (5)

The facial region develops from the facial primordia, which consists of lateral and medial nasal prominences arising from the first brachial arches. Disturbance in fusion of this closely controlled cascade can result in a facial cleft where facial primordia ultimately fail to meet and fuse to form the proper structures.(13).

Cleft lip and palate can occur isolated, may present as part of a syndrome or other associated abnormalities. OFC are associated features in 400 recognized syndromes (14). The potential problem of the condition includes social handicaps such as impaired suckling, speech impairment, deafness, facial deformities, and psychological problems, along with dental problems like microdontia, ectopic eruption, delayed tooth maturation, and malocclusion.(7,10)

Clefting syndromes in which the mutated gene has been identified, such as T box transcription factor 22(TBX22),poliovirus receptor like-1(PVRL1), and interferon regulatory factor6(IRF6), are responsible for causing X linked cleft palate (5,11,13). In contrast, non-syndromic cleft lip and palate is complex and multifactorial in origin. Both genetic and environmental risk factors have been shown to influence the probability of occurrence. Further factors such as alcohol, chemical exposure, stress during pregnancy, and smoking, in particular, increases the risk. (1, 7, 10)

Deficient maternal folate intake has long been implicated in the risk of Orofacial clefts; retinoic acid also plays an important role during development. Exposure to teratogenic agents between the fourth and ninth week after conception is implicated as a risk factor for OFC since lip and palate are developed during these weeks after conception. (12)

Maternal drug usage plays only a small role in the origin of Orofacial clefts, but studies show that the use of NSAIDs, Corticosteroids, Benzodiazepines, and Folate antagonists such as Valproic acid andCarbamazepine are associated with a marked increase of cleft lip and palate. Babies born to non-gestational diabetic mothers have a high risk of OFC. (8, 2)

Recognition of syndrome is essential for assessing the risk faced by the child, providing the necessary treatment, and counselling the parents, leads to better care for the individual. (13)

II. Material and method

The present study isa cross-sectional study, which includes retrospective demographic data for congenital anomaly and cleft lip with or without cleft palate. The study also includesthe number of deliveries conducted in government Dharmapuri Medical college hospital, TamilNadu, India, for five years from the financial year 2015 to 2019. Dharmapuri district is one of the most backward districts in Tamil Nadu in South India(15).Ethical committee approval has been taken for the study.The data includes the number of deliveries, the number of congenitalanomalies, sex of the babies, consanguineous marriage and age of the parents, and any other sibling who also had the same problem. In our study, we classified the oral clefts into three categories: a) cleft lip,b) cleft palate, and c) cleft lip with cleft palate.The patient's parents were contacted telephonically for collecting demographic details.

III. Result

This study includes the total number of deliveries in five years conducted in Government Dharmapuri Medical College Hospital. The total numbers of deliveries were 39114 from 2015 to 2019. (Figure:1) Our study shows that the total numbers of congenital anomalies in these five years were 681,which is 1.7percent of the total institutional deliveries. (Figure: 2,2a) Totalnumbers of clefts found were 92(Figure :3) among the total deliveries, this is about 0.2 percent, and among congenital anomalies, this is about 13.5 percent (Figure:4). (Table:1)

Table no 1: Number of deliveries and congenital defects along with orofacial clefts for five years 2015-2019.

Financial year	Deliveries	Defects	Normal	% Defects	Cleft cases	% Clefts (Defects)	% Clefts (Deliveries)
2015	7643	137	7506	1.8%	18	13.1%	0.2%
2016	8363	113	8250	1.4%	16	14.2%	0.2%
2017	7219	103	7116	1.4%	12	11.7%	0.2%
2018	6473	122	6351	1.9%	20	16.4%	0.3%
2019	9416	206	9210	2.2%	26	12.6%	0.3%
Total	39114	681	38433		92		
	Weighted average	**140**		**1.7%**	**19**	**13.5%**	**0.2%**

Figure 1: Bar diagram showing number of deliveries for the financial year 2015-2019

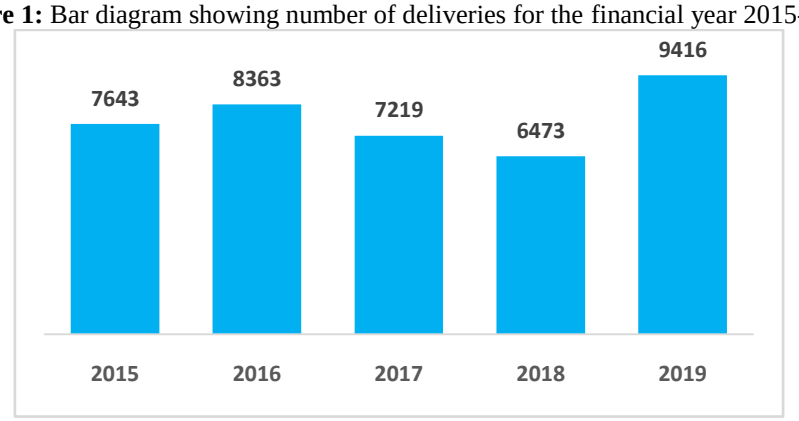


Figure2: Bar diagram showing number of congenital defects out of total deliveries

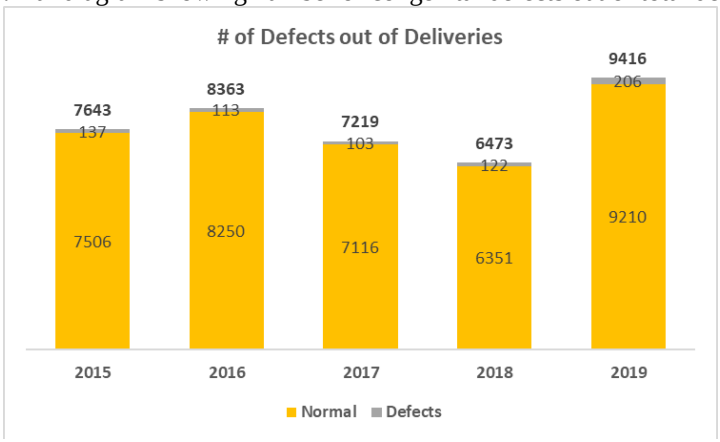


Figure 2a: Bar diagram, showing percentage of congenital defects found in the financial year 2015-2019

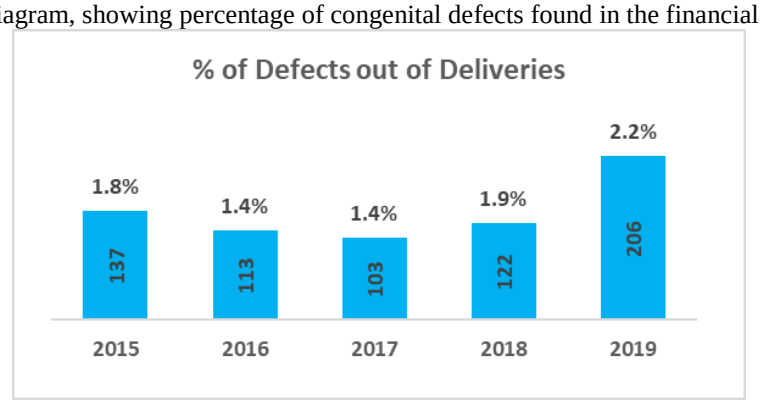


Figure3: Bar diagram showing number and percentage of Orofacial clefts out of congenital defects found in 2015-2019 financial year

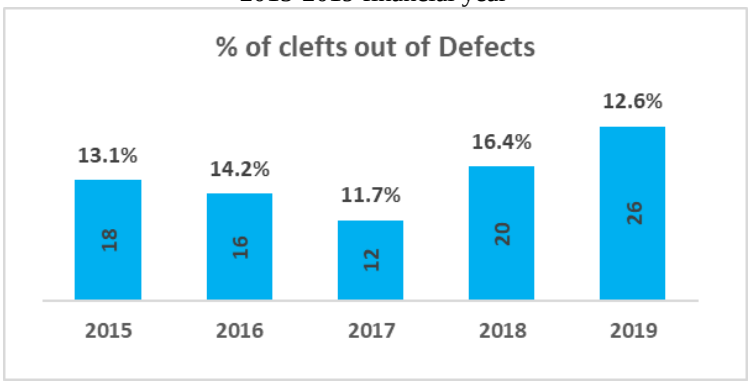
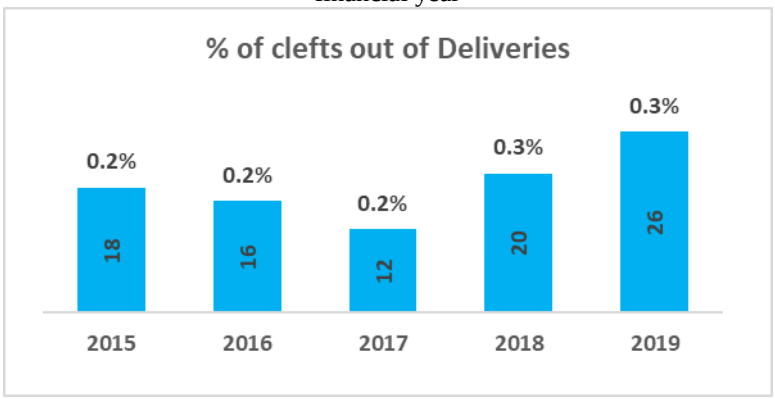


Figure4: Bar diagram showing the percentage of OFC out of the number of deliveries found in 2015- 2019 financial year



In the year 2015,the total deliveries conducted were 7643. In this, 137 cases had some congenital anomalies thatare1.8 percent of total deliveries.18 cases had clefts that are0.2 percent of total deliveries and 13.1 percent of congenital anomalies.2 children had oral clefts with other congenital anomalies, whichis 11.1percent of oral cleft found in the year 2015.

In the year 2016, the total deliveries conducted were 8363. In these deliveries, congenital defects were 113 cases,which is 1.4 percent of total deliveries.16 cases of clefts were found, which is 0.2 percent of total deliveries and 14.2 percent of congenital anomalies. 2 children had cleft along with other congenitalanomalies, which is 12.5 percent of oral clefts found in the year.

Intheyear 2017, the total deliveries conducted were7219.In this, 103 cases had some type of congenital anomalies. That is 1.4 percent of total deliveries. 12 children had some type of clefts that is 0.2 percent of total deliveries and 11.7 percent of congenital anomalies. 2 children had other congenital anomalies with clefts, which is 16.7 percent of oral clefts found in the year.

In the year 2018,the total number of deliveries conducted in the institution was 6473. In this, 122 cases had some type of congenital anomalies, which is 1.9 percent of total institutional deliveries. 20 children had some form of oral clefts, which is 0.3 percent of total institutional deliveries, and 16.4 percent of congenital anomalies. 8 children had clefts with other anomalies, whichis 40.0 percent of oral clefts found in the year.

In the year 2019, the total number of deliveries conducted was 9416. In this, 206 congenital defects were found, which is 2.2 percent of total institutional deliveries. 26 children had some type of oral defects that is 0.3 percent of total deliveries and 12.6 percent of congenital anomalies. 10 children had clefts with other congenital anomalies, which is38.5 percent of oral clefts found in the year.

IV. Discussion

The total number of oral clefts found in these five years data were 92 (Table:2, Figure:5). In these 92 cases, cleft lip alone cases were28,which is4.1 percent of total congenital anomalies and 30.4percent of oral clefts.Cleft palate alone cases were 18, which is 2.6percent of total anomaliesand19.6 percent of totalclefts. Another 46 patients had a combined cleft lip and palate type oforal cleft that is 6.75 percent of total congenital anomalies, and 50 percent of oral clefts.4 children had bilateral cleft lips,which is4.34 percent of oral cleft found in these five years.A total of about 24 children had oral clefts along with some other congenital anomalies, which is 0.061percent of total deliveries and 3.52 percent of total anomalies found, and 26.08 percent of total oral cleftsfound in the five-year period. Bilateral cleft lip was found in 4 patients that is 12 percent of total cleft lip cases. (Figure: 6)

Table 2: Orofacial clefts found from 2015-2019 financial year

Financial Year	Orofacial Cleft	Male	Female	Total
2015	Lip	1	3	4
	Palate	3	2	5
	Lip & Palate	5	4	9
2016	Lip	3	1	4
	Palate	2	2	4
	Lip & Palate	6	2	8
2017	Lip	3	1	4

	Palate	1	1	2
	Lip & Palate	5	1	6
2018	Lip	5	2	7
	Palate	3	0	3
	Lip & Palate	6	4	10
2019	Lip	6	3	9
	Palate	2	2	4
	Lip & Palate	8	5	13

Figure 5: Bar diagram showing number of OFC cases reported

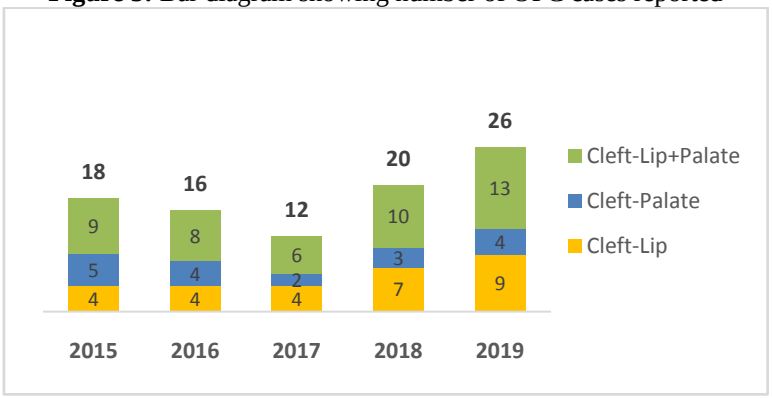


Figure5a: Bar diagram, showing details of number of OFC cases by sex found in 2015-2019.

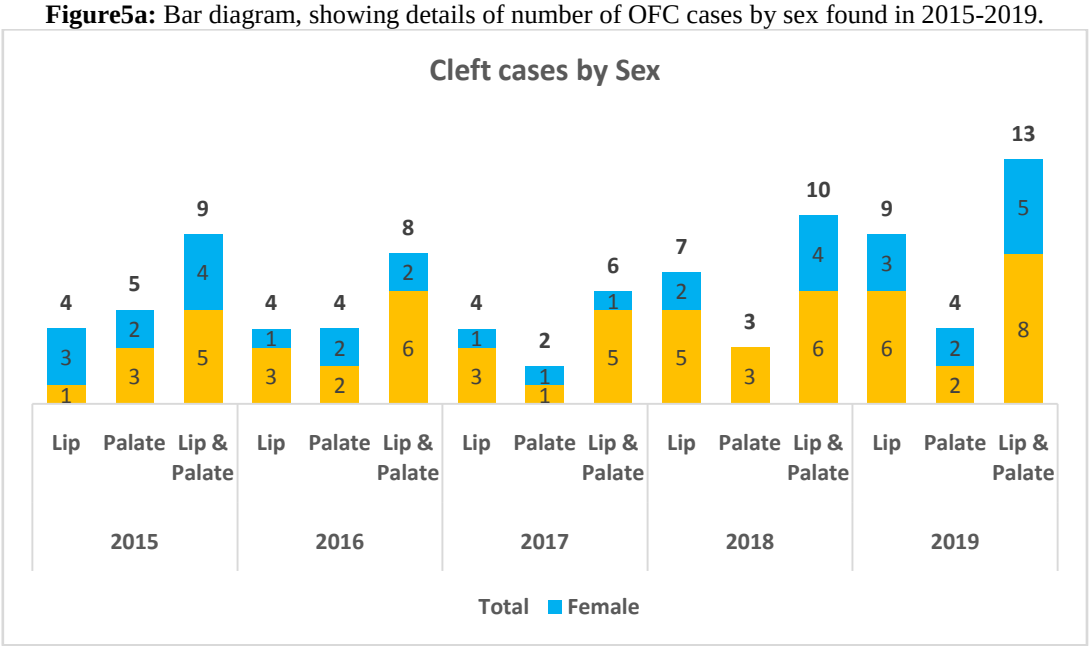
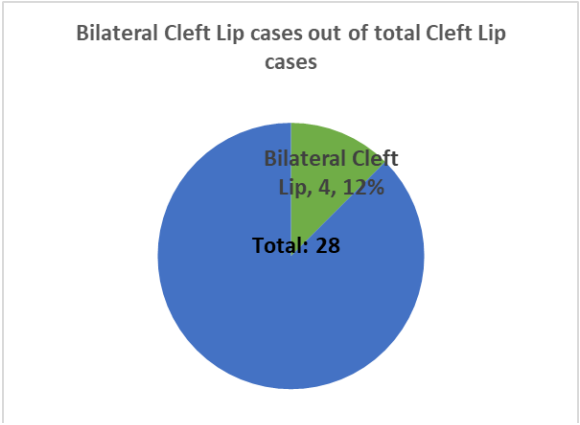
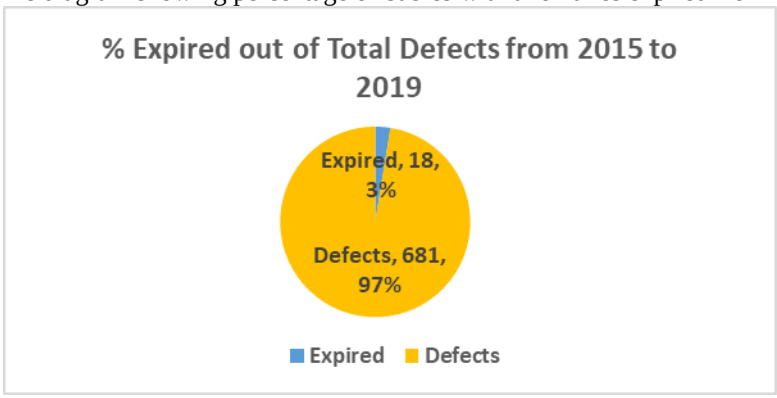


Figure 6: Pie diagram showing percentage of bilateral cleft lip cases out of total cleft lip found in five-year duration.



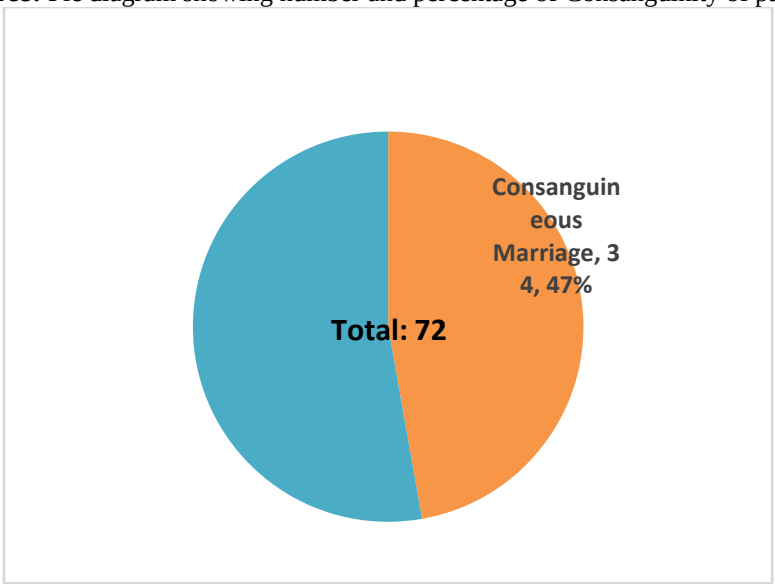
Data shows 18anomalybabies expired due to various reasons,which is about 2.64 percent of total anomaliesand 19.56 percent of oral cleft babies in thisperiod. (Figure: 7)

Figure 7: Pie diagram showing percentage of babies with anomalies expired from 2015-2019



About 47 percent of the patients showed consanguinity of their parents'marriage (Figure: 8), this result matchesthe Indian average consanguineous marriage statistics in the southern region (12).

Figure8: Pie diagram showing number and percentage of Consanguinity of parents



As shown in many of the studies, our study also found male predominance with 64%. (16) OFC was more commonly found in males in all three categories of our oral cleft classification (Table: 3).The male-female ratio in our study was 1.8:1.

Table 3: Showing number of male and female patients with OFC

Financial Year	Male	Female
2015	9	9
2016	11	5
2017	9	3
2018	14	6
2019	16	10
Total	59	33

Most of the fathers, which are about 50 percent, were in the age group of 26-35 years. (Figure 9) While most of the mothers,which are about 52.72 percent, were in the age group of 18-25 years (Figure 10).

Table 4: Age of the parents for OFC babies

Age in Years	Father	Mother
18-25	12	52
26-35	49	19
36-45	10	1
46-55	1	0

Figure 9: Fathers age group

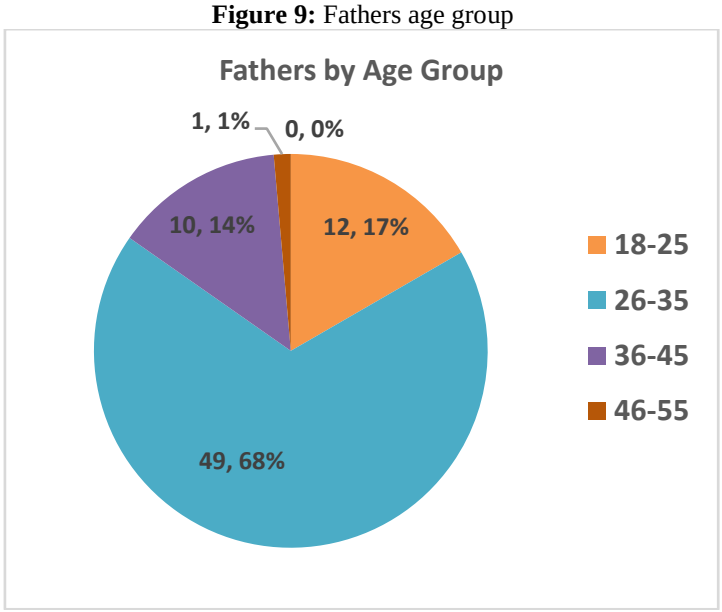
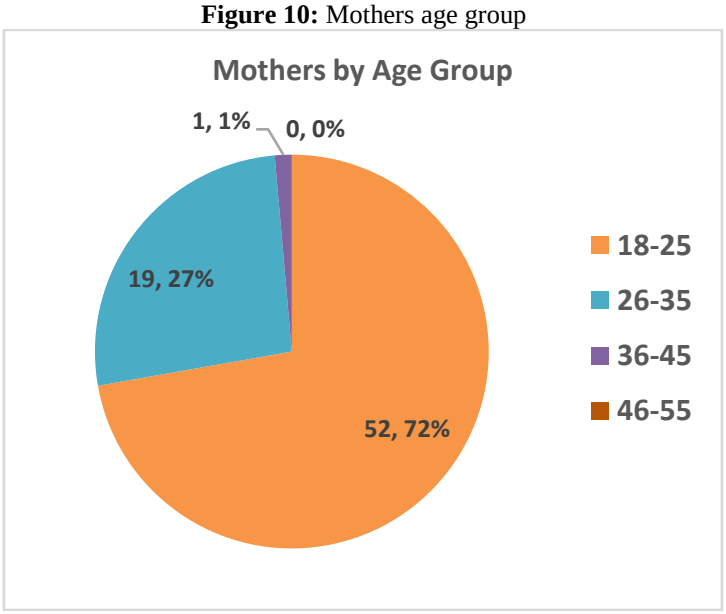


Figure 10: Mothers age group



The overall incidence of cleft lip and palate is approximately 1 in 600 to 800 live births (1.42 in 1000), and isolated cleft palate occurs approximately in 1 in 2000 live births.(2) Our study found a little higher percentage of the worldwide incidence of cleft lip and palate that is 2.35 OFC per 1000 deliveries.The worldwide incidence of OFC is approximately 1 per 700 live birth and matches our research. (8) Ourstudy shows2 per 1000 deliveries. **(**17**)**

Combined OFC, including both cleft lip and cleft palate, are more predominant with about 50 percent, which matches a study done by Young Greg (19). In the remaining 50 percent, cleft lip cases were 30%, and cleft palate caseswere 20% out of 92 OFCcases. Fewer bilateral cleft lip cases were found, which wasabout 12% out of 28 cases of cleft lip. 24 cases were found along with other congenital anomaliesout of a total of 92 OFC,which is 26% of OFC cases.In three cases out of 72 cases, OFC was also present in siblings.

Demographic profiles help to analyse and plan further courses of action to reduce the incidence of cleft cases. A multicentre control study to investigate environmental causes and genes operating in the etiology of OFC should be carried out.

V. Conclusion

Significant efforts must be made to strengthen health care services.Cleft lip and palate are typically identified before birth by ultrasonography.Periodic ultrasonography should be insisted in rural areas during pregnancy, as early detection allows time for parental education.

Improvement of birth defect surveillance and research is required to identify and improve the quality of care and determine the genetic and environmental etiology of clefts in India.

The long-term objectives are to initiate a national registry for the patient with congenital birth defects of the face and jaws and also to establish prevention and treatment of this deformity and improve the quality of life of affected children since India is thesecond-most populous country with around 27 million births every year. (14)

This study will give a baseline demographic profile of this region for future reference to cleft related studies and treatment planning.

LIMITATIONOFSTUDY

Our study was conducted in a single institution, and to acquire more demographic details associated with OFC,prospective long-term research should be done for live childbirth in collaboration with multiple hospitals.Data were collected with a limited number of samples, and out of 92 cleft patients, we were able to collect data like the age of the parents and consanguineous marriage details by telephone of only 72 patients due to non-availability of contact numbers. Therefore, the result cannot be generalized as further research with a large number of samples is required to determine the extensive nature of these defects.

Acknowledgement

Our sincere thanks of gratitudeto thepediatric department and obstetrics and gynecology departments HODs and staffs who gave us the necessary data to do the research on this topic.

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R.Thillaikarasi, et. al. "Demographic Analysis of Cleft Lip andPalate: A Single Institutional Study." *IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)*, 19(11), 2020, pp. 45-53.