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Assessment of the Epidemiological Factors and Their Relationship with Non Syndromic Cleft Lip and Cleft Palate Patients of 0-24 Months Old, Attending a Tertiary Care Hospital in Bangalore: A Cross Sectional Study

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Abstract

Background: Cleft lip or palate is a congenital opening or fissure occurring in the lip or palate. Many environmental factors have been examined in epidemiologic studies of risk factors for oral clefts. For many of these factors, no conclusive trend in cleft incidence has been demonstrated across populations because there are several sources of bias and it is not easy to prove their roles in the cleft formation.

Objectives: To assess the epidemiological factors associated with non-syndromic cleft lip and cleft palate patients of 0-24 months old and to find the relationship of epidemiological factors with non-syndromic cleft lip and cleft palate.

Methods: A cross-sectional study was conducted on 352 non syndromic cleft lip and cleft palate patients of 0-24 months old, attending Bhagwan Mahavir Jain Hospital Bangalore, a tertiary care hospital where smile train organization work. A total of 352 cleft lip and cleft palate patients were selected according to the inclusion criteria after sample size determination. The information was recorded by self – administered questionnaire. The structured Performa was used, consisted of three parts 1) epidemiologic profile, 2) questions about factors effecting oral clefts, oral health behavior, feeding habits 3) examination part of oral clefts. Descriptive and inferential analyses were done.

Results: The study group consisted of 145 female subjects comprising 41% and 207 male subjects comprising 59% of the total population. Among 352 participants 146 subjects i.e. 42% were having cleft lip, 58 subjects i.e. 16% were having cleft palate, and 148 subjects i.e., 42% were having cleft lip and palate. Out of 352 oral clefts patients 306 i.e. 86.93% had presence of given epidemiologic factors. 46 i.e. 13.06% didn't had any of these epidemiologic factors.

Conclusion: It can be concluded that the parental consanguinity, family history of oral clefts, maternal smoking and alcoholism, teratogenic drugs , less uptake of folic acid and socio-economic factors could play an important role for these conditions.

Keywords: Cleft lip and palate, consanguinity, family history.

Introduction

Oral health is an essential part of optimal health for all – and is much more than healthy teeth. Oral refers to the whole mouth – the teeth, gums, hard and soft palate, linings of the mouth and throat, tongue, lips, salivary glands, chewing muscles, and upper and lower jaws. Oral health means being free of cavities and gum disease, but it also means being free of chronic oral pain conditions, oral

cancers, birth defects such as cleft lip and palate, and other conditions that affect the mouth and throat.

Cleft lip or palate is **"**A congenital opening or fissure occurring in the lip or palate".[1] Orofacial cleft is one of the most common congenital abnormalities affecting people worldwide with high prevalence especially in Asians, native American population and Caucasians; prevalence in the African population is however recorded as low. Cleft Lip and Palate (CLP) is the most prevalent congenital birth anomaly in live births with an incidence of cleft lip with or without palate 1 in 600 live births.[2] Indian statistics Acc. To Tata institute of social studies in the year of 2000 in India, birthrate is roughly 25 million/year. Among this incidence cleft palate is 1:800 live birth. So total 30,000 children are born with cleft palate per year. Among that only 25 % of children get any form of treatment.[3] The incidence of cleft lip and palate vary widely across geographical area.[4] The incidence of cleft lip and palate is 1 in 500 in Japanese and Indian.[5] Cleft lip and palate are currently the most prevalent oral congenital anomalies today.[5] Cleft lip (CL), cleft lip with or without cleft palate (CL/P) and isolated cleft palate (CP), collectively termed oral clefts, Approximately 75% of CL/P and 50% of CP cases are isolated defects and no other deformities are found in those children. Those Oral Clefts are therefore called nonsyndromic.[6] Phenotypically, this complexity is manifested by a range of cleft conditions, from relatively superficial unilateral clefts of the lip to complete bilateral cleft affecting both the lip and secondary palate. In addition, the left side is affected more often than the right side for unilateral cases and cleft lip with or without cleft palate (CL/P) is more prevalent in male than female subjects.[7] The study of the development of the face, lip, and palate, in uterus after conception is important to enhance the understanding of the timing, complexity, and factors that may influence the occurrence the oral clefts. Facial development largely occurs between the fourth and eighth weeks of pregnancy, and the face has a clearly human appearance by 10 weeks.[8] CL can be the result of the deficient development of nasal prominences and their subsequent failure to converge. It also can be caused by partial or complete lack of fusion of the maxillary prominence with the medial nasal prominence on one or both sides. CP results from the failure of the palatine shelves to meet in the midline, owing to the decreased size of the shelves, failure of the shelves to elevate, inhibition of the fusion process itself or failure of the tongue to drop from between the shelves due to micrognathia. Although they are the subject of a great deal of investigation, genetic and other etiologic factors contributing to orofacial congenital anomalies in humans remain largely unknown.[9] It can be concluded that oral clefts result from failure of migration or fusion of the facial prominences between the 4th and 8th weeks after conception, during the period of time when the embryo is most susceptible to environmental factors predisposing to clefts.[8] Cleft lip and palate is a polygenic and multi-factorial involving both genetic and environmental influences.[10]In recent years, scientists have identified candidate genes (a gene, located in a chromosomal region suspected of being involved in the expression of a trait) that seem to contribute to oral clefts.[8] Developmental instabilities are thought to result in a reduced capacity to buffer against perturbations during an organism's normal development, possibly resulting in size discrepancies for both bilateral traits and dysmorphologies.[7]Many environmental factors have been examined in epidemiologic studies of risk factors for oral clefts. Some implicate risk factors include exposure to medications during pregnancy, maternal alcohol consumption, maternal smoking, dietary and vitamin deficiencies, maternal metabolic factors like diabetes, exposure to environmental toxins, altitude, birth order, socioeconomic status, and parental age consanguinity and hereditary. For

many of these factors, no conclusive trend in cleft incidence has been demonstrated across populations because there are several sources of bias and it is not easy to prove their roles in the cleft formation. The best evidence to date is for maternal alcohol consumption, smoking, folic acid deficiency and certain medications during pregnancy.[8]The relatively high birth prevalence of orofacial cleft anomalies in a developing country like India with its rigid religious, social and dietary customs, coupled with large family size provide an opportunity for studying various etiologic factors like dietary influence, birth rank of cleft subjects and other factors underlying the relatively high incidence of cleft lip and palate.[11] Child with this anomaly not only suffers for poor dental development but also deprived from breast feeding due to improper oral seal, swallowing and nasal regurgitation, other associated problems are hearing difficulties due to abnormalities in the palatal musculature, and speech difficulties due to nasal escape and articulation problems. Untreated clefts of the lip and palate is consider as significant health care problem in India leading to aesthetic loss as well as psychological trauma in early childhood to adulthood.[12] Patients who have clefts of the lip and palate often need complex and extensive treatment, usually provided by an interdisciplinary team of orthodontists, plastic surgeons, pediatric dentists, maxillofacial surgeons, speech therapists, and others. Following surgical repair of the cleft, the long-term oral health management of patients centers around dental caries, malocclusions, hypoplasias, and gingivitis. In some cases, the prevalence of these conditions is greater in children with clefts as compared with their peers.[13] Though oro-facial cleft defects can be surgically repaired in early childhood, but post-surgical residual deformity is due to scarring and abnormal facial growth and development results in continuing functional and psychosocial problems. India have diversity and varied population which provide huge diverse population in terms of genetics, social-demography as well as cultural difference but lack in proper reporting of cleft lip and palate registry and thus many children with this defect is not treated in their early childhood. Thus, clefts have a prolonged, adverse influence on the health and social integration of affected individuals.[12]There are paucity of studies carried out in relationship with epidemiological factors and cleft lip and palate in India. Hence the present study will add more value to the literature and a conscious effort in the health research to assess the relationship of epidemiological factors with the same.

AIM

- To assess the epidemiological factors associated with non-syndromic cleft lip and cleft palate patients of 0-24 months old.

Objectives of the Study

- To find the relationship of epidemiological factors with non-syndromic cleft lip and cleft palate.

Methodology

A cross-sectional study was conducted to assess the epidemiological factors and their relationship with non syndromic cleft lip and cleft palate patients of 0-24 months old, attending a tertiary care hospital in Bangalore.

Brief profile of the study area

A tertiary care hospital where international voluntary organization “smile train” is functioning in Bangalore, was selected for study setting as enough number of samples can be achieved. The smile train is currently working in Bhagwan Mahavir Jain hospital, Bangalore since 2007 and has corrected around 7000 cleft lip/palate defects with free of cost.

Obtaining approval from authorities

Before the starting of the study, an ethical clearance was obtained from the ethical committee of Vydehi Institute of Dental Sciences and Research Centre, Bangalore. For the

cleft lip/palate patients an official permission was obtained from the respective authority of Bhagwan Mahavir Jain Hospital, Bangalore.

Schedule of the survey

The study was conducted over a period of four months (March 2016 to June 2016). Self – administered questionnaire was distributed to the either of the parent of available subjects each day followed by their examination for cleft lip/palate.

Sample size & design

A pilot study was conducted and the sample size was determined by using standard statistical procedure. The formula being,

$$n = \frac{z^2 pq}{L^2}$$

Where,

n = sample size

z = standard normal distribution= 1.96

p = 0.35

q = 1- p = 0.65

L = 0.05

$$n = \frac{(1.96)^2 \times 0.35 \times 0.65}{(0.05)^2}$$

= 349.58

A total of 352 cleft lip and cleft palate patients would be selected according to the inclusion criteria from a tertiary care hospital in Bangalore.

Study population

Cleft lip and cleft palate patients aged 0 month to 24 months old, attending tertiary care hospital, Bangalore, were selected as per inclusion and exclusion criteria.

Inclusion Criteria

- Patients with non syndromic cleft lip and cleft palate.
- Within the age group of 0-24 months.
- Parents who were willing to participate.

Exclusion Criteria

- Parents who do not give consent.
- Subjects with any systemic diseases and syndrome were excluded.
- Children under the care of persons other than their parents.

The study design

A cross sectional study was conducted among 0 month to 24 months old cleft lip and palate patients attending a tertiary care hospital, Bangalore, who sufficed the inclusion criteria. Before the start of the study the examiner was standardized and calibrated in the Department of Oral and maxillofacial surgery, Bhagwan Mahavir Jain Hospital, Bangalore, under the guidance of the oral maxillofacial surgeon, first by practicing the examination on a group of 10 subjects and then applying the diagnostic criteria on a group of 20 subjects with a time interval of at least 30 minutes between examinations. This was done to ensure uniform interpretations, understanding, and application of the criteria for the cleft lip/palate to be observed and recorded.

Method of collection of data

The data was collected from either of the parent who fulfilled the inclusion criteria after obtaining necessary permissions from hospital authorities. Written informed consent was taken from either of the parent after explaining the nature and purpose of the study.

The information was recorded by self – administered questionnaire. A specially designed, close ended proforma was used for collection of data in this study. The structured proforma used consisted of three parts, the first part consisted of consent and questions that included demographic information of subjects and parents. The demographic variables considered were name, age, gender birth place and permanent address of subjects, education and occupation and socioeconomic status of parents. The 2nd part consisted of questionnaire which contained 19

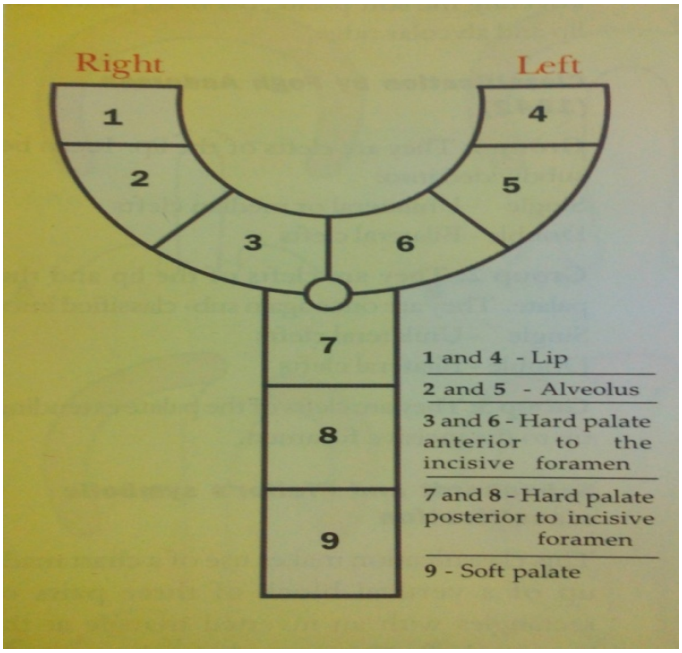
questions regarding family history of clefts, consanguinity, history of smoking, history of drinking, history of drug, prenatal care, oral health care behaviour and feeding behaviour and the 3rd part was about oral examination, the oral examination was carried out on cleft lip and cleft palate patients by using kernahan's striped y classification 1971. The questionnaire was translated from English to local language (Kannada) by Registered Institute of Translational Study, Bangalore. Assistance was provided by the examiner to fill questionnaire. For illiterate and single parent, examiner had filled the questionnaire by asking and explaining the questions.

Clinical examination

Status of cleft

It was examined using kernahan's striped y classification (1971).

Classification of the cleft has evolved over a century. Many descriptive, diagrammatic, and coding systems have been proposed to be used. However, there are only few which have stood the test of time. Kernahan proposed "Y" classification in nine boxes with nasopalatine foramen as the central point. Kernahan's "Y" classification represents the cleft deformity exactly as it exists and is very versatile. This has unquestionable utility for the clinicians. This classification is a diagrammatic or symbolic representation of the cleft deformity and used for documentation or charting very effectively. The other benefit, it was most accepted principle for cleft classification as shown in picture 1.[14]



(Picture1. Kernahan's striped y classification,1971)

Recording clerk

An examiner himself was trained and calibrated to record the study proforma.

Organizing clerk

An organizing clerk at the examination site maintained a constant flow of patients to the examiner. Usually the organizing clerks were the nurses from the Bhagwan Mahavir Jain Hospital. Sufficient sets of instruments were taken during the study to avoid the need to interrupt examination.

Examination procedure, examination area and lighting

Type IV (screening) oral examination was conducted on cleft lip and cleft palate patients, as there was less of cooperation from the mentioned age group subjects. The examination was carried out on dental chair or in the lap of mother with sufficient light and illumination. For the patients with poor visibilities for examination, mouth mirrors and gloves were used. A kidney tray with required instruments and supplies was placed within easy reach of examiner. The organizing clerk was allowed to sit close enough to the examiner so that instructions and codes could be easily heard and the examiner could see that findings were being recorded correctly.

Pilot study

Pilot study was done among 40 subjects to check the internal consistency of the questionnaire. Cronbach's alpha value for the questionnaire obtained was 0.861 which showed good internal consistency. Validity of questionnaire was assessed. Face validity was checked by asking experts to scrutinize the questions, while content validity was checked by ensuring that the questions covered all the areas of knowledge mapped out by initial objectives. The translated questionnaire was also pilot tested.

Organization of data

All the data were entered into the proforma. The data was then arranged systematically and the information from the collected forms was transferred to the computer for analysis using SPSS (statistical package for social sciences) version 15.

Statistical analysis

The Statistical software namely SAS 9.2, SPSS 15.0 were used for the analysis of the data and Microsoft word and Excel have been used to generate graphs, tables etc. Descriptive and inferential analysis were done for the data. The results were statistically analyzed using chi-square test.

Results

A sample of 352 cleft lip and palate patients who met the inclusion criteria was included in the study. The subjects were in the age group of 0-24 months. The study group consisted of 145 female subjects comprising 41% and 207 male subjects comprising 59% of the total population .

Among 352 participants 146 subjects i.e. 42% were having cleft lip, 58 subjects i.e. 16% were having cleft palate, and 148 subjects i.e, 42% were having cleft lip and palate. (table 1) Out of 207 male subjects 77 i.e. 37% and out of 145 female subjects 70 i.e. 48% were having only cleft lip, which was significantly associated (p= 0.038*). Out of 207 male subjects 42 i.e. 20% and out of 145 female subjects 16 i.e. 11% were having only cleft palate, which was significantly associated (p= 0.021*). Out of 207 male subjects 89 i.e.43% and out of 145 female subjects 59 i.e. 41% were having both cleft lip and palate, which was not statistically significant (p= 0.666). (table 2) Comparison between three groups: cleft lip, cleft palate and cleft lip and palate was done. Out of 146 cleft lip subjects, 9 i.e. 6% belonged to upper class, 80 i.e. 54% belonged to upper middle class, 37 i.e. 25% belonged to lower middle class, and 21 i.e. 14% belonged to upper lower class with the statistical value of p=0.513 which was not significant. Out of 58 cleft palate subjects, 3 i.e. 5% belonged to upper class, 34 i.e. 59% belonged to upper middle class, 12 i.e. 21% belonged to lower middle class, and 9 i.e. 16% belonged to upper lower class with the statistical value of p=0.746 which was not significant. Out of 148 cleft lip and palate subjects, 18 i.e. 12% belonged to upper class, 69 i.e. 47% belonged to upper middle class, 35 i.e. 24% belonged to lower middle class, and 25 i.e. 17% belonged to upper lower class and 1 i.e.1 % belonged to lower class with the statistical value of p=0.135 which was not significant.(table 3) It was found that out of 146 cleft lip patients 32 i.e.21.9% were having history of cleft lip and palate. Among 58 cleft palate patients 10 were having history of cleft lip and palate. Among 148 cleft lip and palate patients 25 were having history of cleft lip and palate. This values were not statistically significant (p=0.509). It was found that out of 146 cleft lip patients 34 i.e.23.3% were having history of familial marriage/consanguinity. Among 58 cleft palate patients 14 i.e. 24.1% were having history of familial marriage/consanguinity. Among 148 cleft lip and palate patients 40 i.e. 27% were having history of familial marriage/consanguinity. This values were not statistically significant (p=0.750). Out of 146 cleft lip patients 6 i.e. 4.1% mothers were having history of smoking. Among 58 cleft palate patients 1 i.e. 1.7% mothers were having

history of smoking. Among 148 cleft lip and palate patients 10 i.e. 6.8% mothers were having history of smoking. This values were not statistically significant (p=0.276). Among of 146 cleft lip patients 61 i.e. 41.8% mothers were having history of passive smoking. Among 58 cleft palate patients 25 i.e. 43.1% mothers were having history of passive smoking. Among 148 cleft lip and palate patients 69 i.e. 46.6% mothers were having history of passive smoking. This values were not statistically significant (p=0.697). Out of 146 cleft lip patients 13 i.e. 8.9% mothers were having history of alcohol. Among 58 cleft palate patients 3 i.e. 5.2% mothers were having history of alcohol. Among 148 cleft lip and palate patients 17 i.e. 11.5% mothers were having history of alcohol. This values were not statistically significant (p=0.364). It was found that out of 146 cleft lip patients 9 i.e. 6.2% were having teratogenic drug/medicine. Among 58 cleft palate patients 3 i.e. 5.2% were having teratogenic drug/medicine. Among 148 cleft lip and palate patients 6 i.e. 4.1% were having teratogenic drug/medicine. This values were not statistically significant (p=0.714). Among 146 cleft lip patients 81 i.e. 55.5% were not having prenatal care/vitamin intake during pregnancy. Among 58 cleft palate patients 30 i.e. 51.7% were not having prenatal care/vitamin intake during pregnancy. Among 148 cleft lip and palate patients 73 i.e. 49.3% were not having prenatal care/vitamin intake during pregnancy . This values were not statistically significant (p=0.570).(table 4) When gender wise comparison was done between group of male and female patients, it was found that; 38 i.e.18% parents of male participants and 29 i.e. 20% parents of female participants were having history of oral clefts, which was not significant (p=0.699) statistically. It was found that 52 i.e. 25% parents of male participants and 36 i.e.25% parents of female participants were having familial marriage/consanguinity, which was not significant (p=0.950) statistically.8 i.e.4% mothers of male participants and 9 i.e. 6% mothers of female participants were having history of smoking, which was insignificant (p=0.313) statistically. Around 92 i.e. 44% mothers of male patients and 63 i.e. 43% mothers of female patients were having history of passive smoking, which was not significant (p= 0.853) statistically. The study revealed that 18 i.e. 9% mothers of male patients and 15 i.e. 10% mothers of female patients were having history of alcoholism, which was not significant (p=0.601) statistically. Very few, 11 i.e. 5% mothers of male patients and 7 i.e. 5% mothers of female patients were having history of drug/medicine that can cause clefts, which was not significant (p=0.838) statistically. It was also found that 108 i.e. 52% mothers of male patients and 76 i.e. 52% mothers of female patients didn't have prenatal care/vitamin intake during pregnancy, which was not significant (p=0.965) statistically.(table 5) The final result for the study was: out of 352 oral clefts patients 306 i.e. 86.93% had presence of given epidemiologic factors. 46 i.e. 13.06% didn't had any of these epidemiologic factors.(table 6)

Table 1: Distribution of Oral Clefts.

Parameter	Present		Absent		Total
	N	%	N	%	
Cleft Lip	146	42%	206	58%	352
Cleft Palate	58	16%	294	84%	352
CLP	148	42%	204	58%	352

Table 2: Distribution of Gender among Oral Clefts Patients.

Oral clefts		Male	Female	χ^2	P value
Cleft lip	Present	77(37%)	70(48%)	4.302	0.038*
	Absent	130(63%)	75(52%)		
Cleft palate	Present	42(20%)	16(11%)	5.308	0.021*
	Absent	165(80%)	129(89%)		
Cleft lip and palate	Present	89(43%)	59(41%)	0.186	0.666
	Absent	118(57%)	86(59%)		

Table 3: Distribution of Socioeconomic Status

Oral clefts		Socio economic status					Total	χ^2	P - value
		1 (upper)	2 (upper – middle)	3 (lower – middle)	4 (upper-lower)	5 (lower-lower)			
Cleft lip	Present	9(6%)	79(54%)	37(25%)	21(14%)	0	146	3.271	0.513
	Absent	21(10%)	103(50%)	46(22%)	34(17%)	1(0%)	205		
Cleft palate	Present	3(5%)	34(59%)	12(21%)	9(16%)	0	58	1.946	0.746
	Absent	27(9%)	149(51%)	71(24%)	46(16%)	1(0%)	294		
Cleft lip and palate	Present	18(12%)	69(47%)	35(24%)	25(17%)	1(1%)	148	7.025	0.135
	Absent	12(6%)	114(56%)	48(24%)	30(15%)	0	204		

Table 4: Distribution of Epidemiologic Factors in Oral Clefts

Epidemiologic factors		Types of oral clefts				X^2 value	P value
		Cleft lip (n=146)	Cleft palate (n=58)	Cleft lip and palate (n=148)	Total		
History of oral clefts	Yes	32(21.9%)	10(17.2%)	25(16.9%)	67(19%)	1.349	0.509
	No	114(78.1%)	48(82.8%)	123(83.1%)	285(81%)		
History of Familial marriage/consanguinity	Yes	34(23,3%)	14(24.1%)	40(27%)	88(25%)	2.576	0.750
	No	112(76.7%)	44(75.9%)	108(73%)	264(75%)		
History of smoking	Yes	06(4.1%)	1(1.7%)	10(6.8%)	17(4.8%)	2.578.	0.276
	No	140(95.9%)	57(98.3%)	138(93.2%)	335(95.2%)		
History of passive smoking	Yes	61(41.8%)	25(43.1%)	69(46.6%)	155(44%)	0.723	0.697
	No	85(58.2%)	33(56.9%)	79(53.4%)	197(56%)		
History of alcoholism	Yes	13(8.9%)	3(5.2%)	17(11.5%)	33(9.4%)	2.020	0.364
	No	133(91.1%)	55(94.8%)	131(88.5%)	319(90.6%)		

History teratogenic medicine	Yes	9(6.2%)	3(5.2%)	6(4.1%)	18(5.1%)	0.675	0714
	No	137(93.8%)	55(94.8%)	142(95.9%)	334(94.9%)		
History of prenatal care/ vitamin intake	Yes	65(44.5%)	28(48.3%)	75(50.7%)	168(47.7%)	1.124	0.570
		81(55.5%)	30(51.7%)	73(49.3%)	184(52.3%)		

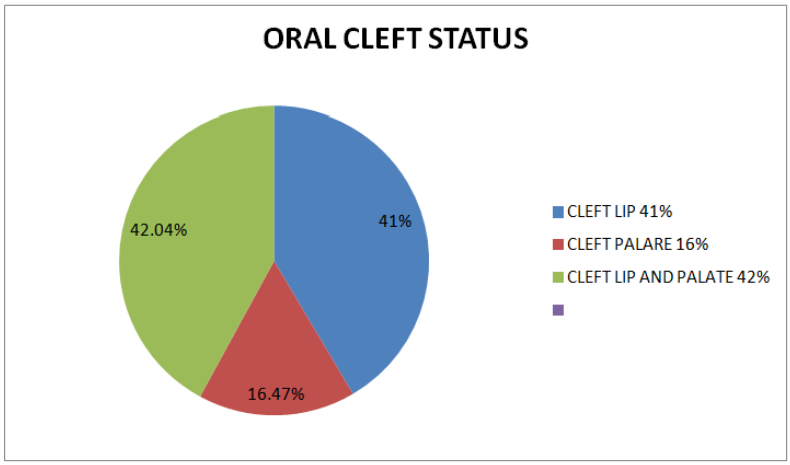
Table 5: Distribution of Responses Based On Gender

Question	Response	Male		Female		χ^2	P-Value
		N	%	n	%		
Family History of Cleft Lip/Palate	Yes	38	18%	29	20%	0.149	0.699
	No	169	82%	116	80%		
	Total	207	100%	145	100%		
Familial Marriage/Consanguinity	Yes	52	25%	36	25%	0.004	0.950
	No	155	75%	109	75%		
	Total	207	100%	145	100%		
History of smoking (Mother)	Yes	8	4%	9	6%	1.018	0.313
	No	199	96%	136	94%		
	Total	207	100%	145	100%		
Passive smoking (Mother)	Yes	92	44%	63	43%	0.034	0.853
	No	115	56%	82	57%		
	Total	207	100%	145	100%		
History of alcoholism (Mother)	Yes	18	9%	15	10%	0.273	0.601
	No	189	91%	130	90%		
	Total	207	100%	145	100%		
History of drug/medicine (Mother)	Yes	11	5%	7	5%	0.042	0.838
	No	196	95%	138	95%		
	Total	207	100%	145	100%		
Prenatal Care/Vitamin intake during pregnancy	Yes	99	48%	69	48%	0.002	0.965
	No	108	52%	76	52%		
	Total	207	100%	145	100%		

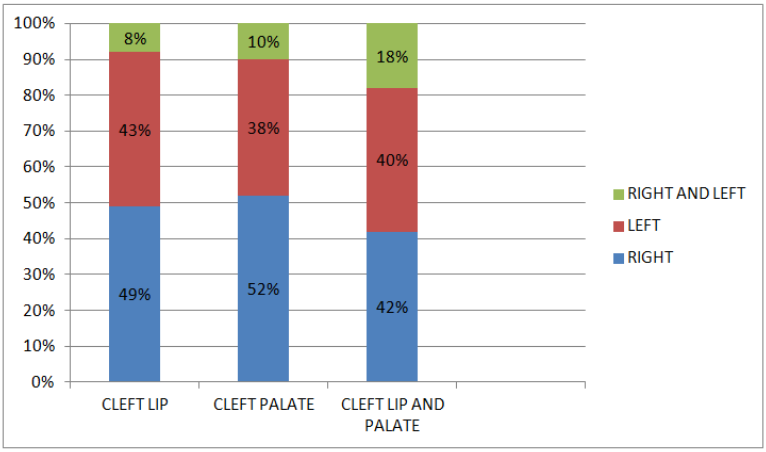
Table 6: Distribution of Frequency Of Epidemiologic Factors In Oral Clefts

Total no. Oral clefts patients	Presence of epidemiologic factors in oral clefts patients	Frequency of presence of epidemiologic factors in oral clefts patients	Absence of epidemiologic factors in oral clefts patients	Frequency of absence of epidemiologic factors in oral clefts patients
352	306	86.93%	46	13.06%

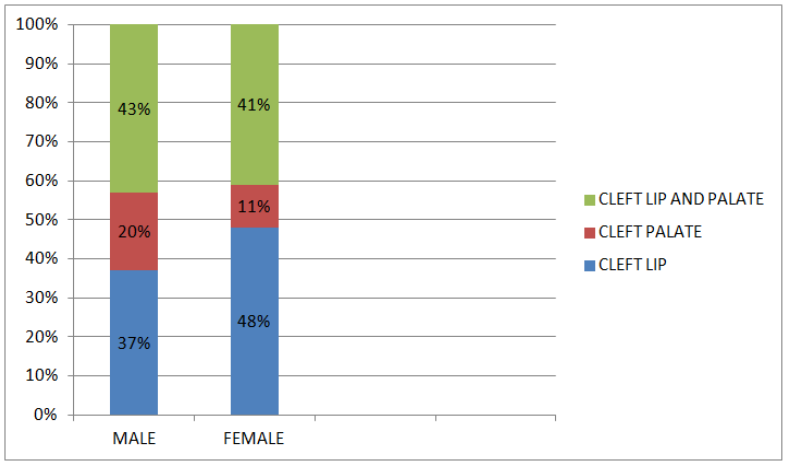
Graph 1: Distribution of Oral Clefts.



Graph 2: Distribution of Oral Cleft Based On the Site



Graph 3: Gender Wise Distribution of Cleft Lip and Palate.



Discussion

Cleft lip (CL), cleft lip with or without cleft palate (CL/P) and isolated cleft palate (CP), collectively termed oral clefts (OC), are the second most common birth defects among newborn. These defects arise in about 1 in 700 live born babies, with ethnic and geographic variation.[6] Oral clefts are a heterogeneous group (cleft lip, cleft palate; unilateral, bilateral; complete, incomplete) of birth defects

known to be multifactorial in origin, in that both genes and environmental factors contribute to their etiology. The genetic contribution to the causation of clefts is 20% to 50% and the remainder is attributable to environmental factors or gene-environment interactions.[8]Although Oral Clefts is usually not a life-threatening condition, many functions such as feeding, digestion, speech, middle-ear ventilation, and hearing, respiration, facial and dental development can be disturbed because of the structures involved. These problems can also cause emotional, psychosocial and educational difficulties. Affected children need multidisciplinary care from birth until adulthood. Orofacial clefts pose a burden to the individual, the family, and society, with substantial expenditure, and rehabilitation is possible with good quality care. Care for children born with these defects generally includes many disciplines-nursing, facial plastic surgery, maxillofacial surgery, otolaryngology, speech therapy, audiology, counseling, psychology, genetics, orthodontics, and dentistry. Fortunately, early and good quality rehabilitation of children with Oral Cleft usually gives satisfactory outcomes.[6]There will always be a need for surgical missions (local and international) to deal with the backlog and increasing number of patients with cleft lip and palate around the world. This amount of accumulated cases is huge because most patients need an average of three surgical procedures and highly specialized multidisciplinary treatment. Meanwhile, the incidence of oral clefts is increasing every day. If we want to win the battle against clefting we need to better understand the causative factors of clefts, in order to develop strategies to reduce incidence. It is necessary to focus more attention on genetic and environmental research.[8] Identification of etiological factors for OC is the first step towards primary prevention.[6]

The present cross sectional study was conducted to evaluate epidemiological factors and their relationship with non syndromic cleft lip and cleft palate patients of 0-24 months old, attending a tertiary care hospital in Bangalore. There were 145 female subjects comprising 41% and 207 male subjects comprising 59% of the total population. The subjects and their parents were questioned for the study.In the present study, 147 subjects i.e. 42% were having cleft lip, 58 subjects i.e. 16% were having cleft palate, and 148 subjects i.e, 42% were having cleft lip and palate. The results showed higher prevalence cleft lip and palate followed by cleft lip and cleft palate which was in accordance with the study done by Shah R and Powar R in Belgaum, Karnataka.[15] The study done by N. Farhadian and Z. Shahrokhi in Hamdan,Iran and Nouri M.A, Hameed SA and Rasheed NE in Erbil city showed same finding about their prevalence rate.[16,17]

The present study shows right side (46.59%) of oral cleft were more prevalent than left(40.62%) followed by right and left combined clefts (12.78%) which was in accordance with the study done in North-East Iran done by Kianifar H et al and study done in south east Ghana by Agbenorku P et al.[18,19]In the present study most of the patients i.e. 76% were from middle socioeconomic status. This was not in accordance with the study done by Taghavi N which showed that most of participants belong to low socioeconomic status. The reason behind this may be the different methods used to record the socioeconomic status and state/country's economy. The study also found 28% of the parents were educated below highschool level, which was in accordance with the study done by N.Taghavi et al, in Tehran. It has been speculated that low socioeconomic status as a risk factor should be considered because it can be a marker of parental health and life style. Individuals with low education tend to smoke more and have less healthy diets and

nutrients. The life style factors, either alone or combination with occupational activities and genetic background, play a role in the etiology of orofacial cleft.[20]Parents of 67 subjects i.e. 19% reveled about positive family history of oral clefts. This finding was in accordance with the study done in Gujarat by Parihar A et al and study done in N. Farhadian and Z. Shahrokhi in Hamdan,Iran.[5,12] A study done by Stevrtsen A in Norway found that the stronger family recurrence of cleft palate only suggests a larger genetic component for cleft palate only than for any cleft lip.[15] Around 88 participants' parents i.e. 25% were having familial marriage/consanguinity. This was in accordance with the study done in South India by Murthy J. In their study they found Parents of 30.47% cases had the consanguineous marriage.[21] The study done by Shah R and Powar R in Belgaum, Karnataka found that Consanguineous marriage in 48.9% parents. Prevalence of CL±P was significantly higher in children of consanguineous parents ($p<0.000$).[22] However the value were not significant for the present study.($p=0.950$). Orofacial morphogenesis is controlled by multiple genes. This underlines the role that parental consanguinity and family history may play in the pathogenesis. Animal experimental trials have also proven a multi-factorial threshold model of inheritance for oral clefts. The recurrence risk seems to increase with degree relation and extent of anatomical severity in the affected relation.[23] In the autosomal recessive inheritance pattern the gene is expressed phenotypically when both alleles on a chromosome pair are present. The child receives a mutated allele from each parent. Both parents must have the mutated gene. A consanguineous relationship (descending from a common ancestor) can increase the likelihood of occurrence of a recessive disorder.[8] Cleft lip and palate incidence in India is that a large proportion of it arises from consanguineous relationships.[24]

Among 352 participants 5% mothers had habit of smoking. Which was in accordance with the study done by P.A. Romitti et al in Iowa.[25] Moreover, 44% admitted to history of passive smoking in the present study, which was in accordance with the study conducted by Little et al in U.K.[26] The assumption is that maternal hypoxia induces malformations in the fetus. In murine models, this oxygen deficit has been attributed to carbon monoxide interference with hemoglobin function, disruption of the electron transport chain through substitution of an analogue of the nicotinamide in NADH dehydrogenase, or the effects of nicotine. Occurrence of CLP that resulted from maternal hypoxia was also discovered in genetically susceptible CL/Fr mice, suggesting the potential interaction between an antecedent genetic predisposition and this environmental teratogen.[25]The small increased risk for cleft lip with or without cleft palate in the offspring of women who smoke during pregnancy observed in this study is in line with previous evidence. In contrast to some previous studies, an increased risk was also apparent for cleft palate. In these data, there was evidence of an effect of maternal smoking for both types of cleft. The data were compatible with a modest effect of maternal passive smoking, but the study lacked statistical power to detect or exclude such an effect with confidence. It may be useful to incorporate information on the effects of maternal smoking on oral clefts into public health campaigns on the consequences of maternal smoking.[26]Tobacco use and alcohol consumption during pregnancy have been associated with unfavorable pregnancy outcomes, but their teratogenic effects in

humans are still debated. In the present study 9% of mothers reported with history of alcoholism. This was in accordance with study conducted by Lorente C. in Europe.[27] This study provides further evidence of the possible role of prevalent environmental exposures such as tobacco and alcohol in the etiology of oral clefts. 5 % of mothers had taken antibiotics, and steroids for infections and allergies and had history of anti-epileptic drugs usage. The study was in accordance with study done by Olufunmilayo O F, Niyi M O in Nigeria.[28] One of the major finding was, 52% mothers of the participants did not had any prenatal care or vit B12 supplement. Drugs are known to have a teratogenic effect on facial development from exogenic factors and include valporate acid, an anticonvulsant, retinoic acid derivates, thalidomide and phenytoin . Dietary factors such as deficiency of vitamins and folic acid, and intrauterine irritation have all been implicated. Folic acid is recommended as a supplement for women of childbearing age not only to prevent neural tube and abdominal wall defects, but also to help prevent CL/P.[29] A study done by Kelly D et al shows that the Odds Ratio for cleft lip palate for infants of such mothers was 4.36-fold higher than for mothers who had taken folic acid in early pregnancy. Current recommendations state that women planning pregnancy should use a folic acid supplement of 400 µg per day fromat least 4 weeks before, until 12 weeks after, conception. The consumption of folic acid was suboptimal in 36.3%of this sample.[30] In the present study, it was found that there was 86.93% of the participants were having presence at least one of the above mentioned epidemiologic factors. Moreover many of them were having 2 or more than 2 epidemiologic factors present. Though there were no significant results for many of the factors, the percentage of their presence were very high among the participants.

Recommendations

As we gain more knowledge it is very important that every person committed to cleft care, including patients, parents and health professionals have a basic understanding of the current theories about the causation of clefts. Families may want an explanation of why the cleft occurred and what the risk of recurrence is. Families and patients should have a good understanding of the problems faced by researchers looking for a cause and the potential implications (benefits-risks) of participating in research studies. Health care professionals and administrative personal could then use the information collected to develop and advocate for public health programs and health policies promoting the prevention of oral clefts and other congenital malformations. There is a need for more studies to be carried out, especially in the field of cleft genetics. Support education efforts for use of folic acid prior to and during pregnancy to reduce neural clefts (including cleft lip and/or cleft palate). Educating the general public, in particular pregnant women who access antenatal care in health facilities may reduce ill effects associated with the anomaly. There is the need for public health education programmes and advocacy activities on the identified risk factors from this study for the development of cleft lip with or without cleft palate and preventive measures to obviate the occurrence amongst the populace. Genetic studies of the anomaly should also be encouraged to help decrease the incidence. Because parents often lack confidence about performing oral hygiene care for their child because they do not have enough information about their child's dental growth and development, training opportunities should be provided for parents and caregivers to educate on dental conditions, management of such conditions and provision of daily dental home care (brushing and flossing) Dental care for children and adolescents with more severe disabilities is often done by dental pediatric specialists. Assess the

number of children and adolescents with special health care needs in India, their oral health needs, and issues affecting dental access.

Conclusion

The Indian sub-continent remains one of the most populous areas of the world with an estimated population of 1.1 billion in India alone. This yields an estimated 24.5 million births per year and the birth prevalence of clefts is somewhere between 27,000 and 33,000 clefts per year. The cause of clefts is multi factorial with both genetic and environmental input and intensive research efforts have yielded significant advances in recent years facilitated by molecular technologies in the genetic field. India has tremendous potential to contribute by virtue of improving research expertise and a population that has genetic, cultural and socio-economic diversity. In 2008, the World Health Organisation (WHO) has recognised that non-communicable diseases, including birth defects cause significant infant mortality and childhood morbidity and have included cleft lip and palate in their Global Burden of Disease (GBD) initiative. This will fuel the interest of India in birth defects registration and international efforts aimed at improving quality of care and ultimately prevention of non-syndromic clefts of the lip and palate.[31] Understanding the factors that are more common among babies with a birth defect will help us learn more about the causes. The present study has tried to find out relation of some of the known factors with oral clefts. The current study revealed that, oral clefts in male neonates was slightly higher than females. The right side of oral clefts were more common than left side. Among the oral clefts, cleft lip was more prevalent followed by cleft lip and palate and cleft palate. It was found that that the parental consanguinity, family history of oral clefts, maternal smoking and alcoholism ,teratogenic drugs , less uptake of folic acid and socio-economic factors played an important role for these conditions. The findings of this study can be used as a model for other studies of the outcomes associated with medical/dental intervention or to educate/council the parents provided by visiting health care workers.

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