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Epidemiological Profile of Cleft Lip and Palate Patients Attending Tertiary Care Hospital and Medical Research Centre, Belgaum, Karnataka–A Hospital Based Study

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Abstract: *Cleft Lip and/or Palate (CL±P) is the most common congenital malformation of the face and its pattern varies with geography worldwide. Pattern and magnitude remains uncertain due to very few studies. This study has been conducted to study the epidemiological profile of CL±P patients attending a Tertiary Care Hospital & Medical Research Centre, Karnataka, India. This study includes 2453 CL±P Patients registered from 2007-2012 in the Department of Plastic and Reconstructive Surgery of this Hospital & Medical Research Centre. Data were collected from January to September 2013. Variables like age, sex, socioeconomic status, cleft pattern, birth order and consanguinity were noted. Associations of clefts with different variables were studied using Chi-square test. Among all cleft cases, 55.7% were males and 44.3% were females. Age of patients at presentation ranged from 1 day to 71 years with a median age of 2 years. Cleft Lip, Cleft Lip-Palate, Cleft Palate and rare clefts were noted in 21.7%, 61.1%, 16% and 1.1% cases, respectively. Family history was present in 1.3% cases. Consanguineous marriage was noted in 48.9% parents. 54.6% had income of less than Rs 5000 per month. 77% cases were first and second born child. Prevalence of CL±P was significantly higher in children of consanguineous parents (p<0.0001).*

Key Words: *Cleft Lip, Cleft Lip-Palate, Cleft Palate, Consanguineous marriage, Epidemiological Profile*

I. Introduction

Birth defects are one of the important leading causes of child disability and mortality worldwide. Cleft Lip and/or Palate(CL±P) is the most common facial birth defect which occur in all races, both sexes and all socioeconomic groups and their distribution vary from country to country [1]. Cleft Lip-Palate (CLP) is a gap which occurs when the Lip or roof of the mouth does not fuse completely during the first trimester of fetal development. The Lip and Palate develops separately and child may develop Cleft Lip (CL) or Cleft Palate (CP) or both. The cleft may possibly be single sided (unilateral) or both sided (bilateral). CP may be restricted to the soft palate or may extend to the hard Palate and Lip [2]. Incidence and prevalence of CL±P are 1 in 600 (1:600) and 9.92 per 10,000 worldwide respectively. The CL and CLP prevalence are 3.28 per 10,000 & 6.64 per 10,000 [3]. In India, the number of infants born with CL±P is 28,600 per year (i.e. 78 infant with deformities are born every day or 3 infants every hour). Since India is second highest populated country in the world, it may consist of highest number of cleft cases if no any further steps are taken to control its occurrence [4]. A family history of the CLP has increased risk for development of CLP; while in CP, the risk is the same as a general population [5] Organizations like the Smile Train is working for the welfare of the CL±P patients worldwide [6]. The problem that CL±P deformity poses in India is different from the developed countries because of poverty and illiteracy [3]. Understanding variation of prevalence, region, nutrition, socioeconomic strata and ethnicity wise distribution will help to plan future course of action to improve cleft care.

In this context, a Tertiary Care Hospital i.e. KLE'S Dr. Prabhakar Kore Hospital and Medical Research Centre (KLE's Dr. PKH & MRC), Belgaum; Karnataka, India where specialist services are available, it is possible to draw inferences of such patients due to service access .An attempt has been made to study the epidemiological profile of CL±P patients attending Tertiary Care Hospital and Medical Research Centre.\

Objective: To study the epidemiological profile of CL±P patients attending a Tertiary Care Hospital & Medical Research Centre, Karnataka, India.

II. Materials And Methodology

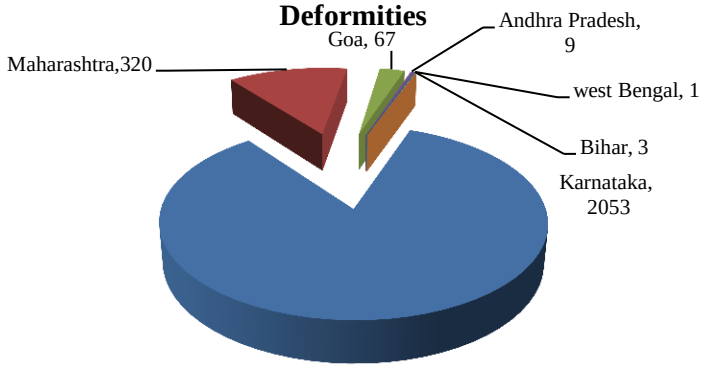
A hospital based descriptive study was conducted from January to September 2013 in which 2453 CL±P patients registered under the Smile Train Project during 2007 to 2012 in the Department of the Plastic and Reconstructive Surgery of KLE's Dr.PKH & MRC, Belgaum, Karnataka, India. This study included all the CL±P patients registered during this 6 years period and excluded syndromic cases & the cases of incomplete

information. Informed consent was taken from the patients/their parents before the surgery as per hospital policy. Ethical clearance was obtained from the Ethical Committee of Jawaharlal Nehru Medical College, Belgaum. All the data were collected through a structured questionnaire and entered into SPSS-20 version and analyzed in light with objective by keeping 95 % confidence interval. Results were presented in narrative, graph and tables form. Associations of cleft deformities with different variables were studied by using Chi-square test.

III. Results

The present study noted 2453 CL±P patients. The age of patients ranged from 1 day to 71 years with mean and median age of 6.77±8.74 and 2 years, respectively. 55.7% cases were males and 44.3% were females. Most of the cases 1484 (60.5%) were less than five years. Most of the cases 1339 (54.6%) had income of less than Rs. 5000 per month, 905 (36.9%) had income of Rs. 5000-10000 per month and 209 (8.5%) had income of more than Rs. 15000 per month. Parents of 1199 (48.9%) cases had consanguineous marriage. Only 31 (1.3%) patients had positive family history, whereas most of the cases 2422 (98.7%) of cleft deformities did not have any history of cleft deformities.

Figure 1: Geographical distribution of Cleft Deformities



In this study patients came from local area (i.e. Belgaum) Karnataka and also 2014 km farther from the service centre (i.e. KLE's Dr.PKH & MRC, Belgaum). Most of the cases 2053 (83.7%) had come from Karnataka followed by Maharashtra 320 (13%), Goa 67(2.7%), Andhra Pradesh 9 (0.37 %,), Bihar 3(0.1%), West Bengal 1(0.04%).

Table No. 1: Association of Cleft Deformities with Gender

Type of cleft	Sex					Total	
	Male		**Female**		**Ratio**		
	No.	Percent (%)	No.	Percent (%)		No.	**Percent (%)**
CL	**305**	22.31	**227**	20.9	1.34	532	**21.7**
CLP	**842**	61.6	**658**	60.6	1.28	1500	**61.1**
CP	**208**	15.22	**185**	17	1.12	393	**16.0**
Rare cleft	**12**	0.87	**16**	1.5	0.75	28	**1.1**
Total	**1367**	**100**	**1086**	**100**	**1.26**	**2453**	**100.0**

χ^2=3.784, df =3, p=0.28

Among all cases, 1500 (61.1%) had CLP, 532 (21.7%) had CL, and 393 (16%) had CP and only few 28 (1.1%) had rare clefts. 1367 (55.7%) were males and 1086 (44.3%) were females with the sex ratio of 1.26:1.Out of 1376 male cases, CLP was more common contributing 842 (61.6%) followed by CL 305 (22.31%), CP 208 (15.22%) and rare clefts 12(0.87%). In 1086 females cases, CLP was more frequent contributing 658 (60.6%) followed by CL 227 (20.9%), CP 185 (17%) and rare clefts 16 (1.5%).The sex ratio in CL, CLP, CP and rare cleft were 1.34:1,1.28:1,1.12:1 and 0.75:1 respectively. In both sex, CLP was more prevalent followed by CL, CP and rare clefts. There was no significant association between sex and cleft deformities were observed. (χ^2 =3.784, df =3, p=0.28).

Table No. 2: Association of Cleft Deformities with Consanguinity

Type of Cleft	Consanguineous Marriage				Total
	No		Yes		
	No. of patients	Percent (%)	No. of patients	Percent (%)	
CL	**208**	16.6	**324**	27	**532**
CLP	**739**	58.9	**761**	63.5	**1500**
CP	**294**	23.4	**99**	8.3	**393**
Rare cleft	**13**	1	**15**	1.3	**28**
Total	**1254**	**100**	**1199**	**100**	**2453**

χ^2 =121.342, df=3, p<0.0001

Of the 2453 cases, parents of 1199 (48.9%) cases had consanguineous marriage, whereas parents of 1254 (51.1%) cases did not have consanguineous marriage. In non consanguineous marriage, CLP was more frequent representing 739 (58.9%) followed by CP 294 (23.4%), CL 208 (16.6%) and rare clefts 13 (1%), whereas in consanguineous marriage, CLP was more common contributing 761 (63.5%) followed by CL 324 (27%), CP 99 (8.3%) and rare clefts 15 (1.3%). In both children of consanguineous as well as non consanguineous parents, CLP was more prevalent, whereas CL was more prevalent among children of consanguineous parents as compared to CP and rare clefts but CP was more frequent among children of non consanguineous parents as compared to CL and rare clefts. The significant association was observed between consanguineous marriage and cleft deformities. (χ^2 =121.342, df=3, p<0.0001).

IV. Discussion

In this study, the age of patients ranged from 1 day to 71 years. The mean age was 6.77 with SD of 8.74 and median age was 2 years. Clefts were more common (i.e. 60.5%) among 0-5 years. The age of patients ranged from 0.5 to 30 years with an average of 11.1 in a study of Saudi Arabia [7]. In a study conducted in Brazil, age ranged from 2 days to 87 years and mean age was 12.9 years; 13.5±5.6 years and median age was 9.9 years [8, 9]. A study in Kenya, age ranged between 1 week and 45 years with average age of 10 months.75% of the cleft cases were in between 0-5 years which was higher than our study [10]. In a study conducted in Mandya district of Karnataka, age of the patients ranged from 1 month to 18 years which was less than our study [11]. 55.7% cases were males and 44.30% were females with the sex ratio of 1.26:1. This study revealed that clefts were more frequent among male population. Our results were similar to the study done in Dehradun, Brazil, Kenya, Iran, Saudi Arabia, Japan and Gujarat [3,9,10,12-16]. Study conducted in BPKIHS Dhahran, Nepal presented that clefts were common among females (i.e. 56% Females and 44 % males) [21]. Sex ratios were recorded as 2:1, 1.62 &1.41:1 in the study conducted in Dehradun, Gujarat & Republic of Korea [3,16,17]. It was found that most of cleft cases 54.6% were having income of less than Rs. 5000 per month. A study in Dehradun, 82.38% cases was having family income below Rs. 3000 per month [3]. Parents of 1199 (48.9%) cases had consanguineous marriage in this study. The parents of 54.4%, 61.6%, 30.5% and 33.3% cases had consanguineous marriage in the study conducted in Saudi Arabia, Pakistan, Iran and Chennai, India [1,5,13,18]. The significant association was observed between consanguineous marriage and cleft deformities which was similar to the study conducted in Andhra Pradesh [4]. Frequency of CLP>CL>CP were found in our study which was similar with the study conducted in Brazil, Iran, Jordan [9,13,19]. The study conducted in Japan revealed that frequency of CLP>CP>CL, in Scotland CP>CLP>CL, in Republic CP>CL>CLP and in Andhra Pradesh CL>CLP>CP [15,17,20,21]. The sex ratio in CL, CLP, CP and rare clefts were 1.34:1, 1.28:1, 1.12:1 and 0.75:1 respectively but in a study of Republic of Korea the sex ratios were 2.1:1 in CL, 2.5:1 in CLP and 0.95:1 in CP [17].

V. Conclusion

The age of patients ranged from 1 day to 71 years. Majority of the cases were males with the sex ratio of 1.26:1. Majority of the cases came from Karnataka. Almost half of the parents of cases had consanguineous marriage. Only few patients had positive family history. It has been found that CLP were more common representing followed by CL, CP and rare cleft in both sexes. The significant association was observed between consanguineous marriage and cleft deformities. People should be advised to avoid consanguineous marriage. Government (Health sector) should develop strategies in health sector for awareness, identification and treatment of cleft deformities.

VI. Limitations

Population in the study is a variable factor as the patients registered under the smile train in the hospital and included in the study are from wide geographical area. Since this study was hospital based and dependent on available patient files, it seems that planning and performing a prospective study with an appropriate control group can provide more precise information.

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