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Socio-Demographic and Clinical Patterns of Cleft Lip and Palate Patients

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ABSTRACT

Introduction: Cleft lip and palate (CLP) is among the most common congenital craniofacial anomalies worldwide, with multifactorial aetiology influenced by genetic, environmental, and socioeconomic factors. Despite its significant public health burden in India, region-specific epidemiological data from tertiary care centres remain limited.

Materials and Methods: A cross-sectional, prospective observational study was conducted over one year at the Cleft Outpatient Department of PGIMS Rohtak, Haryana. All consenting patients diagnosed with cleft lip, cleft palate, or cleft lip and palate were included. Demographic details, parental characteristics, socioeconomic background, habits, family history, cleft type, laterality, and diagnostic grouping based on the Nagpur classification were recorded using a standardized proforma. Descriptive statistics were applied, and associations between diagnostic groups and selected variables were analysed using the Chi-square test at a 5% significance level.

Results: A total of 48 patients were evaluated, with equal gender distribution (50% males, 50% females). The mean paternal and maternal ages were 33.4 and 28.2 years, respectively. Most fathers were labourers or unemployed, while 91.7% of mothers were homemakers, reflecting a predominantly low socioeconomic background. Deleterious parental habits were present in 18.8% of cases, and a positive family history was observed in 8.1%. Left-sided cleft involvement was most common (64.3%). Chi-square analysis revealed no statistically significant association between diagnostic group and sex ($p = 0.801$), deleterious habits ($p = 0.604$), or family history ($p = 0.576$).

Conclusion: This study defines the local epidemiological and clinical profile of CLP patients at PGIMS Rohtak, demonstrating equal sex distribution, socioeconomic vulnerability, and predominance of left-sided clefts, with diagnostic patterns independent of major demographic and behavioural confounders.

Keywords: Cleft lip; Cleft palate; Congenital abnormalities; Cross-sectional studies; Epidemiology.

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Introduction

Congenital anomalies are commonly referred to as birth defects. These abnormalities can encompass structural, morphological, metabolic, psychological, behavioral, and functional issues. Such defects can result in physical or mental disabilities, or even death. Furthermore, these anomalies negatively impact quality of life and life expectancy, while imposing substantial economic costs on affected households [1,2]. Cleft lip and/or palate (CLP) stand out as the most common facial birth defect that affects people across all races, sexes, and socioeconomic backgrounds, though its distribution varies worldwide [3]. It is typically multifactorial, and its development is influenced by both genetic makeup and external (exogenous) factors. These external contributors include malnutrition, hormonal imbalances, exposure to certain medications or toxins, and biological factors [4].

Based on a meta-analysis of multiple studies, the estimated worldwide prevalence per 1,000 live births is 0.33 for cleft palate, 0.30 for cleft lip, and 0.45 for cleft lip and palate combined [5]. In India, Cleft Lip and Palate (CLP) occurs at a rate of 1 in every 1,000 live births. Given the country's estimated 24.5 million annual births, this incidence translates to approximately 27,000 to 33,000 babies being born each year with a cleft of the lip, the palate, or both [6]. Parental age has been suggested as a potential risk factor contributing to the development of orofacial clefts [7,8]. Research findings on parental age and orofacial clefts are mixed, with one study showing that an increase in maternal age decreases the risk of birthing a child with the defect, while another study suggested the risk increases for mothers aged 35 and older, though both studies found no association with paternal age [9,10]. Parental educational attainment is also viewed as a modifiable risk factor for cleft lip and palate [11].

Socioeconomic status also plays an important role in the occurrence of cleft lip and palate. The situation regarding Cleft Lip and Palate (CLP) is exacerbated in tropical nations like India, primarily because of poverty and low literacy rates. This lack of awareness often results in affected patients either remaining untreated or receiving inappropriate care from unqualified practitioners [12]. Given that PGIMS Rohtak is the sole government hospital in the state frequently managing a high volume of Cleft Lip and Palate (CLP) patients in its OPD, this study is vital as no previous research has focused on the epidemiology of CLP patients specifically within this tertiary care center. The aim of this study was to examine the epidemiology and characteristic features of cleft lip and palate in a span of a year in the tertiary care center of PGIMS, Rohtak.

Materials and Methods

The study conducted was a cross-sectional, prospective, and observational investigation designed to determine the epidemiology and characteristic features of Cleft Lip and Palate (CLP) and predict the total burden of CLP in one year at the tertiary care centre, PGIMS Rohtak. The study was carried out over a one-year period.

Study Population and Setting

The study included all cases that reported to the Cleft OPD (Outpatient Department) of PGIMS Rohtak during the defined one-year period.

- **Participants:** The study enrolled patients of all age groups diagnosed with cleft lip, cleft palate, or cleft lip and palate. The final total sample size was 48 participants.

- **Inclusion Criterion:** Participants were included if they gave consent to participate in the study.

- **Exclusion Criterion:** Patients who did not give consent were excluded from the study.

Ethical Approval

This study was rigorously reviewed and approved by the necessary ethics committees:

- The study received approval from the RPAC committee in 2024.

- It also received approval from the BHRC committee in 2025.

Data collection

Data collection was standardized and maintained high accuracy through the use of a specialized Performa (Appendix 1), which was custom-designed by the subject matter experts within the Department of Orthodontics and Dentofacial Orthopedics at the institution. A comprehensive and detailed patient history was rigorously collected from both the affected individual and their parents. This collection included several key categories of information:

- Patient Characteristics: Data specific to the patient's presentation were recorded, including the patient's age, sex, height, and weight. Critically, the cleft classification and the side involvement of the cleft (e.g., uni-

lateral, bilateral, left-sided, right-sided) were carefully documented.

• **Parental Demographic Data:** Information about the parents was essential for epidemiological profiling, encompassing the fathers' and mothers' ages and their respective professions.

• **Risk Factor Assessment:** The history included specific inquiries regarding the parents' health and lifestyle, specifically the presence of any deleterious habits.

• **Medical Background:** A detailed family history was obtained to identify any recurrence patterns, as well as a thorough drug history to note any potential exposures during pregnancy.

Data analysis

The statistical analysis involved using descriptive statistics such as mean, standard deviation (SD), and percentages/proportions. For assessing the association between various qualitative variables, the one-way Chi-square test was applied at a 5% (P = 0.05) level of significance. The software utilized for analysing the data included MICROSOFT EXCEL version 2010 and SPSS version 16 (SPSS for Windows, Version 16.0).

Conflict of interest disclosure

All institutional or corporeal affixations of mine and all funding sources for the study are acknowledged. I certify that I have no commercial association that might represent a conflict of interest in connection with the submitted manuscript.

Results

A total of 48 participants were assessed in a span of a year in the cleft OPD of PGIMS, Rohtak having cleft lip, cleft palate or cleft lip and palate.

Demographic Characteristics

• The total sample size had a balanced distribution of gender representation: 50% males and 50% females. Table 1 and Figure 1 illustrate the distribution of gender of the participants.

• The mean ages were 33.4 years for the fathers and 28.2 years for the mothers which fall within the typical reproductive age and may thus indicate a stable and socially representative population [Table 2].

Distribution of Diagnostic Groups and laterality

• The diagnosis was done based on the Nagpur classification, with Groups 2 and 3 being the most abundant among the study sample (37.5% and 29.2%, respectively) [Table 3] [Figure 2].

• Laterality assessment showed:

• Right side involvement of cleft: 46.4% [Table 4].

• Left side involvement of cleft: 64.3% [Table 4].

• This strong representation provides a strong base for meaningful statistical comparisons across the diagnostic categories.

Socioeconomic Characteristics

Occupational data from both parents showed a varied socio-economic background, the professions ranging from: fathers being laborers 30.6%, farmers 11.1%, drivers 11.1%, etc.; mothers were mostly homemakers 91.7%, which denotes family stability and a culturally typical pattern and enhances the generalizability of findings. Tables 5 and 6 represent the occupation of the fathers and mothers of the affected patients.

Habits and family history

An exceptionally high percentage of participants' parents did not have deleterious habits 81.3%, and most of the patients did not have any family history of the condition under study, 91.9%. Tables 7 and 8 represent the same. Figures 3 and 4 show the pie chart of the percentages of parents with deleterious habits and a family history. This favorable distribution reduces confounding factors and ensures that clinical findings are primarily representative of the groups' characteristics, rather than external influences.

X^2 Tests – Independence of Variables

Chi-square tests showed no significant associations between Group and: [Table 9]

• Sex: p = 0.801.

• Presence of deleterious habits: p = 0.604.

• Family history: p = 0.576.

This independence shows that demographic or behavioral confounders do not affect the diagnostic grouping, which increases internal validity. It suggests that the differences observed among the groups are due more to real clinical variation than to demographic features.

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Table 1. Frequencies of sex distribution of the patients.

Sex	Counts	% of total
Male	24	50
Famale	24	50

Table 2. Mean, Median & SD of patient's age, father's age & mother's age.

Age	Mean	Median	SD	Minimum	Maximum
Patient (in months)	46.7	13	74	0.03	312
Father (in years)	33.4	30	9.41	20	65
Mother (in years)	28.2	25.5	6.95	20	55

Table 3. Distribution of diagnosis.

Diagnosis	Counts	% of total	Cumulative %
Group 1AL	1	2.10	2.10
Group 1L	2	4.20	6.30
Group 1L+Group 3	1	2.10	8.30
Group 1R+	1	2.10	10.40
Group 2	18	37.50	47.90
Group 2S	2	4.20	52.10
Group 3L	14	29.20	81.30
Group 3R	7	14.60	95.80
Group 3R+L	2	4.20	100

Table 4. Occurrence of cleft on sides.

Sides	% of total
Left	64.30
Right	46.40

Table 5. Distribution of occupation of father.

Occupation of Father	Counts	% of total	Cumulative %
Driver	4	11.10	11.10
Farmer	4	11.10	22.20
Lab Technician	1	2.80	25
Laborer	11	30.6	55.60
Tailor	2	5.60	61.10
Teacher	1	2.80	63.90
Transportation	2	5.60	69.40
Job	11	30.6	100

Table 6. Frequencies of occupation of mother.

Occupation of mother	*Counts*	*% of total*	*Cumulative %*
Housewife	*33*	*91.70*	*91.70*
Labourer	*1*	*2.80*	*94.40*
Tailor	*1*	*2.80*	*97.20*
Job	*1*	*2.80*	*100*

Table 7. Frequencies of Deleterious Habits.

Deleterious Habit	*Counts*	*% of total*	*Cumulative %*
No	*39*	*81.30*	*81.30*
Yes	*9*	*18.80*	*100*

Table 8. Frequencies of Family History.

Family History	*Counts*	*% of total*	*Cumulative %*
No	*34*	*91.90*	*91.90*
Yes	*3*	*8.10*	*100*

Table 9. Association of diagnostic groups with sex, deleterious habits and family history.

Variable	*Group 1 (n = 5)*	*Group 2 (n = 20)*	*Group 3 (n = 23)*	*Total*	*Chi-Square Value*	*P value*
		Sex			*0.443*	*0.801*
Male	*2 (8.3%)*	*11 (45.8%)*	*11 (45.8%)*	*24*		
Famle	*3 (12.5%)*	*9 (37.5%)*	*12 (50.0%)*	*24*		
		Deleterious Habit			*1.01*	*0.604*
No	*4 (10.3%)*	*15 (38.5%)*	*20 (51.3%)*	*39*		
Yes	*1 (11.1%)*	*5 (55.6%)*	*3 (33.3%)*	*9*		
					1.1	*0.576*
No	*4 (11.8%)*	*14 (41.2%)*	*16 (47.1%)*	*34*		
Yes	*1 (33.3%)*	*1(33.3%)*	*1(33.3%)*	*3*		

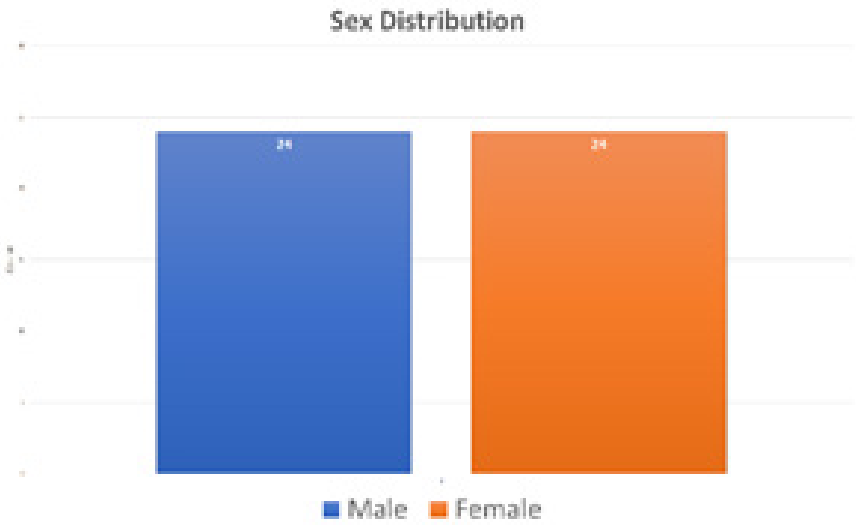

Figure 1. Bar diagram showing the sex distribution of the affected patients.

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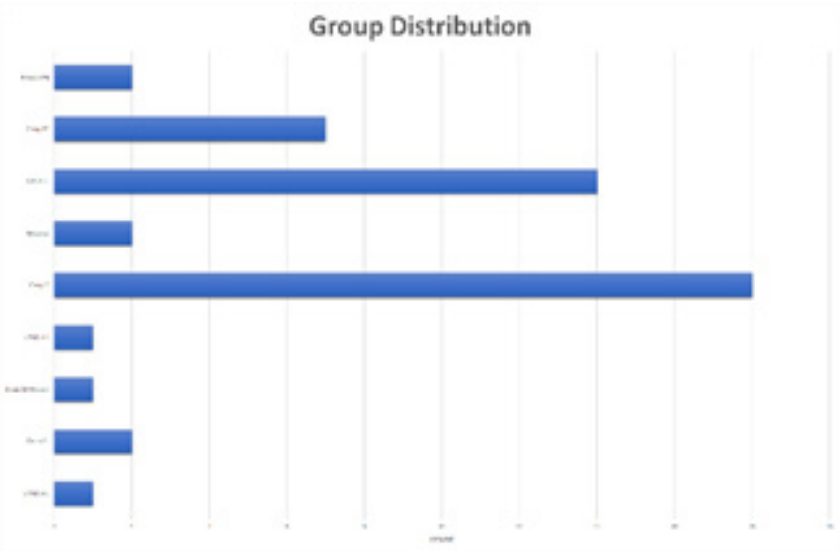

Figure 2. Histogram representing the group distribution of the patients according to Nagpur classification of cleft lip and palate.

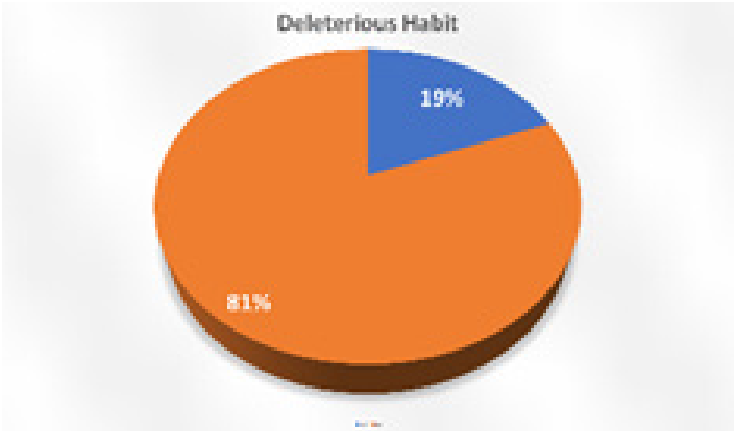

Figure 3. Pie diagram illustrating parents having deleterious habit.

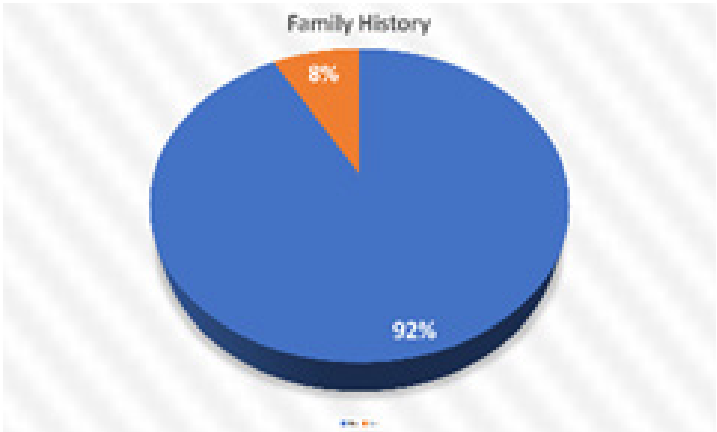

Figure 4. Pie diagram representing family history.

Discussion

Cleft lip and palate represent the most common facial deformity, which can affect the lip alone, the palate alone, or both structures, and its occurrence in infants is primarily attributed to a combination of environmental factors (like smoking, poor nutrition, or alcohol consumption) and genetic factors (such as familial history and chromosomal issues) [13]. In the study by DRB Martelli et al, a higher prevalence of cleft was associated with that of males [14]. Similar finding was seen in the article by Y Shapira et al., where males had higher incidence of cleft rates than that of females [15]. Study by Parikh and Rao [16] demonstrates a higher prevalence of cleft in females with that of a similar finding by I Dutta et al [17] in their cross-sectional study at a tertiary care hospital in Manipur. In our study, we have found an equal gender distribution on the prevalence of the cleft lip and palate with the affected being 50% males and 50% females and this finding coincides with the one by WA AlHayyan [18] where equal gender prevalence was observed among the children born with cleft lip or palate.

Parental age has been suggested as one of the factors that might influence the risk of orofacial clefts. Camilla et al [19] found that the risk of clefts increases as both the mother's age (20 to 40 years) and the father's age (20 to 50 years) increase. James et al [7] found the opposite, the highest risk was for mothers aged 25 years or less. Mothers older than 25 had a significantly lower risk (reduced odds) of having a child with a cleft. They also found that as the father's age increases, the risk significantly decreases. Study by Karina et al. [10] suggested the risk increases for mothers aged 35 years or more. In our study, the mean age of mother is 28.2 years and that of father is 33.4 years which is also consistent with a study done by Jamilian et al. [20] who concluded a significantly higher incidence of CL/P in mothers aged between 21 and 34 years. In our current study, a majority of the cases exhibited left-sided involvement of the cleft. This finding aligns with the left-side dominance observed in several other published reports. For instance, similar findings were reported by Nagalo et al [21], where of cases were left-sided, and by I Dutta et al. [17], where left-side dominance also prevailed. Furthermore, the results of the study conducted by A Sundoro et al [22] also showed patterns consistent with our findings. Parental educational attainment is regarded as a modifiable risk factor for orofacial clefts. A systematic review by Inchingolo et al [23] indicated that a low paternal educational level contributes to the occurrence of non-syndromic orofacial clefts. Another study by Figuireido et al [24] noted a possible correlation between lower educational levels in both parents and the incidence of orofacial cleft. However, a recent study by da Silva et al [25] offered a contrasting finding, showing that the maternal education level of children with an orofacial cleft was found to be average. In our study, most of the parents belong to the low strata of socioeconomic background which is a similar finding to the one by Giap H Vu et al [26], where the authors investigated the association between socioeconomic status and the occurrence of cleft in the United States after controlling for demographic and environmental risk factors. Studies by H Kurita et al. [27] and X Yin et al. [28] showed no significant association between alcohol consumption and occurrence of clefts which was a similar finding in our study where only 18.8% of the parents had deleterious habit associated with cleft. Only 8.1% of patients had a positive family history in our study which is also identified in a study by K Philipp et al [29] and PK Neela et al [30], where only 10.9% and 3.5% of the patients had a positive family history, respectively. This study also reveals that there's no statistically significant association between sex (M/F), family history and presence of deleterious habits with group categories (group 1,2,3).

Conclusion

This cross-sectional study successfully characterized the epidemiological profile of Cleft Lip and Palate (CLP) patients at PGIMS Rohtak, identifying a cohort with equal sex distribution (50% male, 50% female) and a significant socioeconomic disparity, highlighted by low parental occupational levels. Clinically, a left-sided involvement predominance (64.3%) was observed across cases. Crucially, the dataset demonstrated robust internal validity, confirmed by Chi-square analysis which found no significant association between diagnostic groupings and key confounders (sex, habits, or family history, $p > 0.5$). These results confirm that the observed clinical variations reflect true underlying patterns independent of these demographic biases, providing essential, evidence-based data for targeted public health and clinical resource allocation in the Haryana region.

Conflict of Interest

There is no conflict of interest to declare.

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