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Patterns of Cleft Lip and Palate in Patients Seen at Four Selected Referral Hospitals in Kenya

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Abstract

Background: Cleft lip (CL) and cleft palate (CP) are among the most common congenital malformations of the craniofacial region, with an incidence of 1 in every 700 newborns worldwide. This global incidence varies across populations due to genetic, environmental, geographic and socioeconomic reasons. These malformations are a result of the failure of fusion of facial processes during embryogenesis and require long-term care from different specialties. However, data on their patterns in Kenya and the region are limited and variable, making the development of national policy guidelines for the management of these clefts more challenging. This study aimed to describe the patterns of cleft lip and cleft palate and the clinical characteristics of affected patients at four selected referral hospitals in Kenya. **Methods**: This was a hospital-based descriptive cross-sectional study conducted at four selected referral hospitals in Kenya. All patients who met the inclusion criteria and provided consent during the study period were recruited. Variables collected included gender of the patient, age of the patient and parent, type of cleft lip and cleft palate deformities, and associated malocclusion. Data were analyzed using SPSS 26th Version. **Results**: A total of 306 participants were recruited into the study. 175 (57.2%) of the participants were male, while 131 (42.8%) were female giving a male-to-female ratio of 1.3:1. Regarding family history, 55 (18.0%) had family history of similar condition. A combination of cleft lip and cleft palate was observed in 153 (50.0%) of the patients, cleft lip alone in 131 (42.8%), while only 22 (7.2%) had isolated cleft palate. On location of the clefts, 131 (46.1%) of the cases were on the left, 81 (28.5%) were on the right, 64 (22.5%) were bilateral while 8 (2.8%) were median. A majority, 149 (84.7%), of the type of CLP and CP were complete, and 27 (15.3%) were incomplete. The prevalence of dental malocclusion was 79.2% in a subset of 24 cases of the

study population. Syndromic clefts accounted for 12 (3.9%) of the total number of cleft cases. **Conclusion**: Combined cleft lip and palate were the most common types of clefts in this study. A male predominance was observed, and left-sided clefts were the most common, consistent with findings reported from other populations. There was a high burden of malocclusions, underscoring the need for changes in policy to address them. Isolated cleft palate cases appeared to present late to the health centers. These findings highlight the urgent need for early detection programs, improved referral systems and policy-driven, multidisciplinary cleft care in Kenya. Additionally, these findings provide important baseline data for the development of a national registry.

Keywords

Cleft Lip, Cleft Palate, Craniofacial Anomalies, Malocclusions, Epidemiology

1. Introduction

A cleft lip (CL) and cleft palate (CP) are the most common oral-facial congenital deformities. They are characterized by failure of fusion of the lip and/or palate during development. The incidence of cleft lip and palate worldwide is estimated to be 1 in 700 births, but this varies widely in different population groups due to factors such as ethnicity, socioeconomic conditions, geographic location, and environmental factors [1] [2].

The prevalence of cleft lip and palate differs among ethnic groups, with the least observed in the African population at 1/2500. Europeans have a prevalence of 1/1000, and Asians have the highest at 1/500 [3]. In most countries in Africa, there is no active surveillance of these deformities, and the reported prevalence is based on hospital-based data. Reported prevalence in African countries varies widely, with Nigeria having a low of 0.3/1000, while Kenya has 1.65/1000. The reported prevalence in Nigeria is comparable to findings in black Americans [4].

The aetiology of cleft lip and palate is a complex interaction between the genetic makeup and the environmental exposures. Several studies have demonstrated hereditary components in the causation of cleft lip and palate. The failure of the processes to fuse is postulated to cause irregularities in the tightly controlled pathways in the extracellular matrix. Environmental causes have also been implicated [5]-[7]. Nutritional deficiencies like iron and folate have been investigated. Exposure to environmental contaminants, drugs and alcohol has been associated with cleft lip and palate occurrence [8] [9]. Early antenatal care has demonstrated improved outcomes, yet Kenya still experiences challenges in this aspect [10]. Cleft lip and Palate are associated with a myriad of challenges, including stigma, feeding challenges, ear infections and hearing problems, speech difficulties and aesthetic problems, and this creates the need for early intervention [11] [12]. Cleft care must be undertaken in a well-equipped facility with a multidisciplinary skilled

workforce. The difficulties of managing cleft conditions have been elucidated in local and international studies [13]-[15]. There are disparities in access to antenatal care and essential comprehensive cleft care services in Kenya [4] [16] [17].

Despite the significant clinical needs of children with cleft lip and /or palate, there is a paucity of multicenter comprehensive data on epidemiological and clinical factors [4]. Previous studies in Kenya have been largely limited to single centers or outreach programs resulting in gaps. Notable gaps include limited knowledge on regional variation, associated anomalies and clinical characteristics such as malocclusions within the Kenyan population. Furthermore, the data available so far is likely biased due to disparities in access to healthcare. The absence of a national registry limits the ability to estimate the burden of the problem [2] [4] [16] [18]. Policy makers need accurate data estimates to plan for evidence-based curative and preventive cleft care services. This study aimed to describe the patterns of cleft lip and cleft palate and the clinical characteristics of affected patients at four selected referral hospitals in Kenya.

2. Methodology

This was a descriptive hospital-based study that was conducted between May 2023 and May 2024. In order to increase the population catchment area for this study, four CL and CP treatment Centers were selected. These were Kenyatta National Teaching and Referral Hospital, a public hospital in Nairobi; Gertrude's Children Hospital, a private hospital in Nairobi; Nyeri Level Five Hospital, a public Hospital in Central Kenya and Beralisu Medical Center, a non-governmental organization. These centers were major referral centers with high patient volumes making them suitable in capturing diverse patient characteristics. All eligible patients presenting with cleft lip and/or palate were recruited. Those with a previous history of treatment or those who withheld consent were excluded from the study.

Data were collected through structured interviews and clinical examination using a standardized data collection form. Variables examined included age and gender of the patient, age of mother at conception, timing of first antenatal visit, type, pattern and family history of CL and CP, associated syndromes, anomalies and malocclusion. Data were analyzed using SPSS 26th Version. Associations were tested using Fisher's exact test and the chi-square test. A p-value of less than 0.05 was considered statistically significant.

3. Results

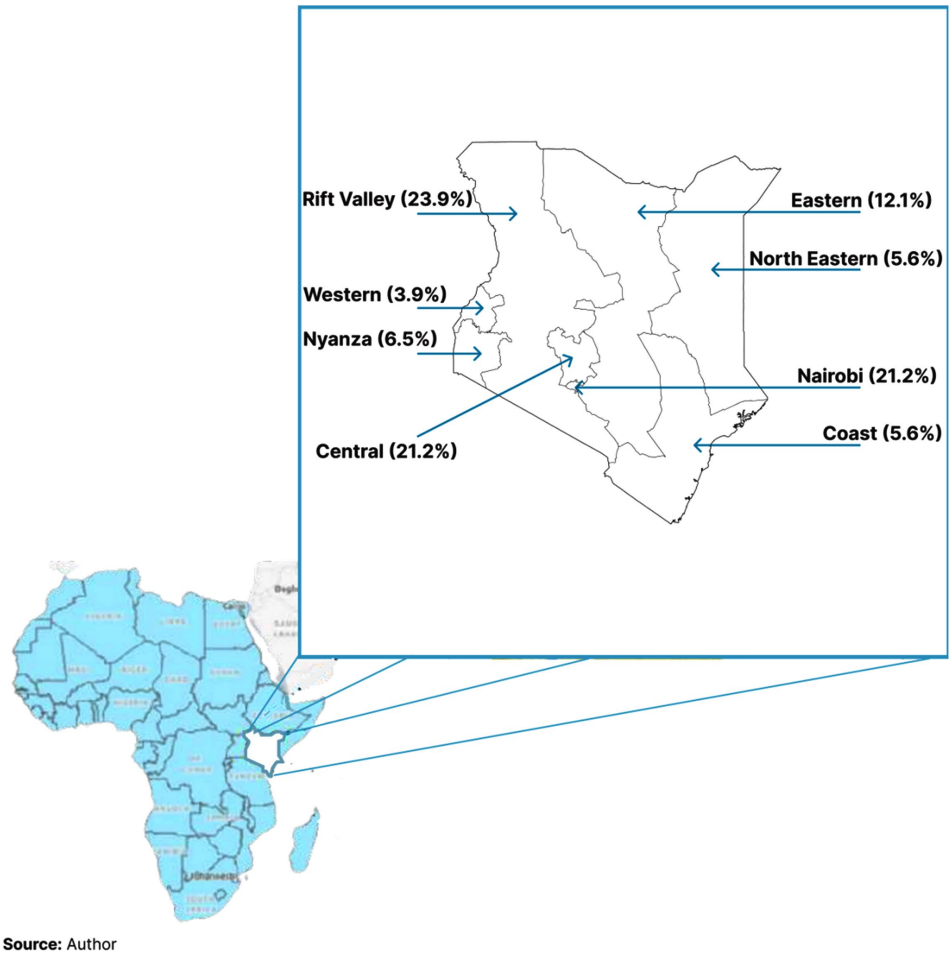
3.1. Demographic Characteristics

A total of 306 participants were included in the study. The study site with the highest cases was Belarisu Medical Center with 117 (38.2%). Kenyatta National Hospital with 99 (32.4%), Gertrude's Children Hospital with 62 (20.2%), and Nyeri level 5 Hospital with 28 (9.2%) cases.

Regarding gender distribution, 175 (57.2%) were male while 131 (42.8%) were female. The participants' ages ranged from 1 month to 56.0 years, with a mean age

of 2.3 ± 6.2 years and a median age of 0.5 years. The large difference between mean (2.3 years) and median (0.5 years) indicates a highly right-skewed age distribution due to few older patients. The isolated cleft palate had a significant late presentation, with only 7 (31.8%) cases out of 22 showing up in the first year after birth.

There was male predominance across most cleft types, except for isolated cleft palate, which occurred more in females. Regional disparities were observed. The Rift Valley region had the highest number of cases. In contrast, the Western region accounted for the lowest number of cases. Figure 1 shows the geographic distribution across the country.



Source: Author

Figure 1. Distribution of Participants by Region.

3.2. Age, Gender and Cleft Types

For isolated CL and the combination of CL and CP, the Modal age group of the participants was 1 yr and below, followed by 2 - 5 yrs. For isolated cleft palate, the modal age group was 2 - 5 years, followed by 1 yr and below (Table 1).

A Fisher's exact test showed a statistically significant difference in the distribution of cleft types by the patient's age groups (*Fisher's exact test statistic* = 29.441, $p < 0.001$).

Table 1. Distribution of participants by cleft type and age (n = 306).

Age (years)	n (%)	Cleft Lip n (%)	cleft Lip and Palate n (%)	Isolated Cleft Palate n (%)	Fisher's Exact Test	p-value
0 - 1	243 (79.4)	108 (35.3)	127 (41.5)	7 (2.3)	29.441	<0.001*
2 - 5	40 (13.1)	13 (4.2)	19 (6.2)	8 (2.6)		
6 - 12	9 (2.9)	4 (1.3)	3 (1.0)	2 (0.7)		
>12	15 (4.9)	6 (2.0)	4 (1.3)	5 (1.6)		
Total	306 (100)	131 (42.8)	153 (50.0)	22 (7.2)		

Notes: Data are presented as frequency (percentage) using the total sample size of 306. Fisher's exact test was used to assess the association between age and cleft type. *p < 0.05 indicates statistical significance.

Regarding gender, most cleft types had a male preponderance except isolated cleft palate that had a female predominance (Table 2).

A comparison of patients' cleft type by gender showed a statistically significant association between the patients' cleft type and gender ($\chi^2 = 6.361$, p = 0.042).

Table 2. Comparison of patients' cleft types by gender (n = 306).

Cleft Type	Total n (%)	Male n (%)	Female n (%)	χ^2	p-value
CL	131 (42.8)	76 (24.8)	55 (18.0)	6.361	0.042*
CLP	153 (50.0)	92 (30.1)	61 (19.9)		
CP	22 (7.2)	7 (2.3)	15 (4.9)		
Total	306 (100)	175 (57.2)	131 (42.8)		

Note: CL = Cleft Lip; CLP = cleft Lip and Palate; CP = Cleft Palate. χ^2 = Chi-square test. p < 0.05 indicates statistical significance.

3.3. First Time of Antenatal Care and Family History of Clefts

The time of antenatal visits ranged from 1 to 9.0 months, with a mean period of 3.8 months and a median period of 4.0 months indicating skewed distribution. The antenatal period with the modal visits was between 3 and 6 months. The mothers who visited health centers after 3 months were deemed late; beyond the critical period. Only 23% of mothers attended antenatal care at or before 3 months of gestation, while 72.5% attended between 3 and 6 months, and 4.5% after 6 months. On family history, 234 (76.5%), of the participants did not have a family history of cleft disorders. Fifty-five cases accounting for 18.0% had a family history of occurrence of clefts, and 17 (5.5%) had unknown family history of cleft disorders.

3.4. Patterns of the Cleft Lip and Palate

Cleft disorders analysis showed that half, 153 (50.0%), of the participants had cleft lip and palate. In contrast, 131 (42.8%), had cleft lip alone, and 22 (7.2%) had isolated CP as shown in Figure 2.

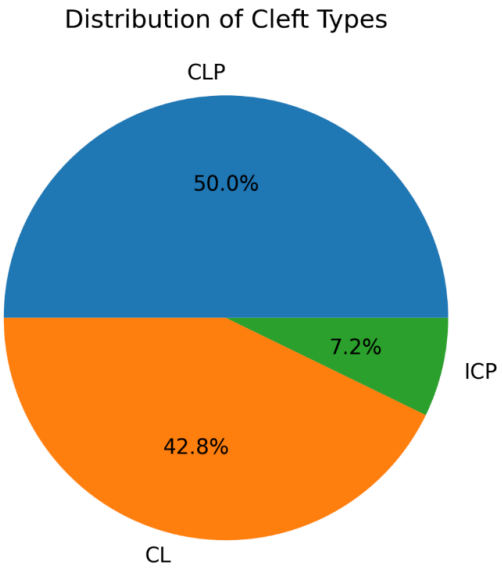


Figure 2. Distribution of participants by cleft types.

3.5. Clinical Features of Patients Presenting with Cleft Lip and/or Palate

Using the Extended Y classification system, the data captured were put into broad groups: cleft lip, isolated cleft palate, and a combination of the two. The cleft lips were classified as complete, incomplete, and involved in the cleft alveolus. An evaluation of clinical of CL and CLP showed that 185 (64.9%) of cleft lip were complete, 82 (28.8%) were incomplete, while 18 (6.3%) were associated with cleft alveolus. An observation of the laterality in 284 cases of the cleft disorders showed that 131 (46.1%) of the cases were on the left, while 81 (28.5%) were on the right, 64 (22.5%) were bilateral, and 8 (2.8%) were median. The majority, 149 (84.7%) of CP observed in the study were complete, and 27 (15.3%) were incomplete. Male predominance was observed cumulatively at 175 (57.2%) and 131 (42.8%) for females among the cleft lips and palates. Female predominance was only noted in isolated cleft palate, with 15 cases, while males were 7.

A comparison of patients' laterality by gender did not show a statistically significant association between the patients' cleft site and gender among the cases 284 that had a cleft lip component as demonstrated in Table 3 (*Fisher's exact test statistic* = 4.21, p = 0.25).

Table 3. Comparison of patients' laterality by gender (n = 284).

Laterality	Total n (%)	Male n (%)	Female n (%)
Right	81 (28.5)	41 (14.4)	40 (14.1)
Left	131 (46.1)	81 (28.5)	50 (17.6)
Median	8 (2.8)	4 (1.4)	4 (1.4)
Bilateral	64 (22.5)	42 (14.8)	22 (7.7)
Total	284 (100)	168 (59.2)	116 (40.8)

Fisher's Exact Test = 4.21, p = 0.25.

Associated Dental Malocclusions

Dental malocclusions were studied in selected cleft lip and palate patients. Malocclusion assessment was only conducted in those with erupted permanent first molars. This was to allow for a reliable assessment, thus 24 cases that met inclusion criteria were assessed. The patients' ages in whom the malocclusions were studied ranged from 6 to 56 years. The occurrence of malocclusion was 79.2% among of the subset of the study population. The commonest malocclusions were rotations of the anterior upper incisors, forwardly placed premaxilla, crowding and anterior crossbite. Table 4 shows the distribution of malocclusion among the 24 cleft cases studied.

Table 4. Clefts and associated malocclusions (n = 24).

Type of Malocclusion	Frequency
Normal	6 (25.0%)
Forward Premaxilla	4 (16.7%)
Class III	3 (12.5%)
Anterior Crossbite	3 (12.5%)
Rotations	4 (16.7%)
Crowding	4 (16.7%)

3.6. Distribution of Syndromic Clefts

Only 12 (3.9%) of the cases had syndromes, while 294 (96.1%) cases were non-syndromic. The 12 syndromic clefts were equally exhibited in both male and female genders. At the same time, all 12 (100%) cases had late antenatal visits. Six (50.0%) of the cases didn't have a family history of cleft, while 4 (33.3%) had a family history of similar conditions. Two cases, accounting for 16.7%, had an unknown family history of similar conditions.

4. Discussion

4.1. Demographics

This multi-center study provides important epidemiological data in Kenya. The data illustrated regional variation; Rift Valley had the most cases, similar to other previous studies, while Western Kenya had the fewest cases. This could be attributed to the several counties being close to the survey and the study sites [2] [4]. Maternal factors, such as the influence of antenatal care, were also evaluated. Most mothers went for antenatal care after the optimal time for folate supplementation. Benefit has been demonstrated in multiple studies of preconception advice and optimal antenatal care in the reduction of the occurrence of CLP [8] [9] [15].

The high age of presentation could point to failures in healthcare and the referral system, especially primary healthcare, and low awareness [2] [4] [16] [18]. Stigma remains a significant factor in our society for those living with congenital

anomalies, especially CLP, which plays a vital role in self-awareness and acceptance in society. These findings correlate with others local, that reported on stigma necessitating children with CLP to be hidden from the general public [2] [4] [11] [12]. The late presentation has also been observed in many developing countries, average age of presentation at 2 years and lower age of 10 months, in two local studies respectively [16] [18]. Another study reported a contrasting mean age of presentation of 4.01 years [2]. The differences may be attributed to the different health-seeking behaviors among the different cleft types, owing to the perceived severity, where combined clefts tend to present earlier than isolated cleft lip or incomplete cleft palate. Factors associated with delayed presentation include difficulty in accessing prompt healthcare and referral, stigma, low socioeconomic status, and inadequate public education [2] [4].

Various studies have demonstrated some noticeable benefits of folate supplementation in reducing the incidence of neural tube and orofacial defects with mixed results [8] [9]. The supplementation is offered during antenatal clinics in Kenyan hospitals. Late presentation to antenatal care has been associated with a higher incidence of CLP [10]. The best effect has been seen when the supplements are taken before and after conception. An 84% reduction in CLP clefts with multivitamins and 10 mg of folic acid before and after conception in mothers with predisposing factors for bearing children with clefts [8] [9]. The cleft lip occurs in the 4th to 8th week, while the cleft palate occurs in the 8^{th} to 12^{th} week during intrauterine development [4] [18]. Most mothers visited health centers for antenatal care after three months at a time after embryogenesis had occurred.

4.2. Clinical Characteristics of the Cleft Lip and Palate

Concerning various distributions of the CLP, the highest component had combined cleft lip and palate. Complete cleft palate was the most common; another study found contrasting patterns [2]. These findings on the predominance of the combination of CLP closely mirror those studies where CLP combination constituted the most significant percentage, underscoring the complex processes in the development of the face [4] [18]. The outcome contrasts with other local in which cleft lip alone predominated [2] [16]. A survey in South Africa found an interesting pattern where cleft palate alone accounted for 35.3%, closely followed by cleft lip and palate at 34.6% and cleft lip alone at 19.0% [1]. In Nigeria, a study showed cleft lip alone accounted for 49%, followed by CLP at 32 %, while CP alone contributed 19% [4]. The report in South Africa completely reverses the previously seen patterns in most African and Caucasian populations, where cleft lip and palate have been dominant at 50%, followed by cleft lip alone at 25% and cleft palate alone at 25% [1]. Genetic and environmental differences play a significant role in the observed distributions of the cleft types. The observed differences could also result from racial and geographical variation in addition to the health-seeking behaviors among the different populations, where children born at home fail to be reported when anomalies occur, thus influencing the observed variations [4] [10].

Delayed presentation was seen in patients with isolated cleft palate. This could be due to the hidden nature of the deformity. This was an important finding that requires attention from policymakers to increase awareness among caregivers.

4.3. Laterality of the Cleft Lip and Palate

Left-sided predominance was also observed in this study. This resembles many other studies locally and internationally. This worldwide trend is yet to be fully understood. Several theories have been put forth, including genetic influence, differential growth of the brain and its influence on facial development, and the differential growth of the facial artery on the right and left. Slower growth of the facial artery on the right has been implicated as a possible cause of the phenomenon [2] [4].

4.4. Malocclusions and CLP

Cleft lips and palates are categorized into several phenotypes and sub-phenotypes. Dental features are significant inclusions in the presentation of the cleft conditions. The occurrence of clefts and dental anomalies is closely associated and poses a serious challenge in the rehabilitation of patients with cleft lip and palate [19] [20]-[22]. This study described malocclusions in clefts albeit in a limited subset of the participants, which other local studies have not fully explored. A high prevalence of malocclusions of 82.1% has been reported in the literature, and more severe forms have been demonstrated for cleft patients [23]. The prevalence of malocclusion was similarly high in this study, despite the small case numbers. The most common malocclusions in literature are rotations of the anterior upper incisors, forwardly placed premaxilla, crowding, anterior crossbite, and class III molar malocclusion [23]. Other local studies have not fully explored the orthodontic needs of cleft patients [2] [4] [16] [18]. The high prevalence emphasizes the need for a multidisciplinary team and early intervention in the provision of holistic care.

4.5. Hereditary Characteristics

A significant number of CLPs had family associations. A study in Nigeria reported a 14% association between the occurrence of CLP and familial history, while in Kuwait, a higher number of 31.4%. The high number raises speculation on the influence of consanguinity [4]. Non-syndromic clefts have been recognized to have multifactorial pathogenesis. Genetic and environmental interaction as a causation of clefts has been extensively studied in this regard. The recurrence patterns in first-degree cleft lip and/or palate relatives are compatible with multifactorial threshold traits or generalized single major locus traits. Additional studies are ongoing to detect linkage loci that confer susceptibility [2]. The postulated genetic aberrations include IFR6, MSX1, and FGFR [2] [4]. This information was essential in laying the background of genetic studies before conception.

4.6. Syndromic Clefts

Syndromic clefts accounted for a number of cases in this study. A previous local study reported that syndromic clefts accounted for 16 (3.6%) [4]. Another local study did not report any syndromic cases [18]. The Kenyan studies showed fewer cases compared to a Nigerian study that found a 14% association and more diverse results with a survey in Kuwait that showed a 19.8% association of other anomalies. Patients with associated anomalies have an added psychological burden, more complex disorders that need more resource allocation, and an extended challenging management protocol [4] [24]-[26].

This study had several limitations. As a hospital-based, the findings may have limited generalizability. Population-based studies provide data that is less biased. Exclusion of previously treated patients' under-estimates the burden of the condition and the clinical characteristics.

5. Conclusion

Combined cleft lip and palate were the most common types of clefts in this study. A male predominance was observed, and left-sided clefts were the most common, consistent with findings reported from other populations. There was a high burden of malocclusions, underscoring the need for changes in policy to address them. Isolated cleft palate cases appeared to present late to the health centers. These findings highlight the urgent need for early detection programs, improved referral systems, and policy-driven, multidisciplinary cleft care in Kenya. Additionally, these findings provide important baseline data for the development of a national registry.

Ethical Approval and Consent

Ethical Clearance to conduct this study was obtained from the University of Nairobi—Kenyatta National Hospital Ethics, Research, and Standards Committee [P542/06/2023]. Another approval was sought from Gertrude's Children's Hospital ethical review committee, GCH539/2023. Permissions to conduct the study were obtained from the management of all the hospitals. Informed consent was granted by the participants; for minors, consent was obtained from parents or guardians.

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Conflicts of Interest

The authors declare that they have no competing interests.

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