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Original article

Epidemiological Profile of Cleft Lip and Palate Cases in A Libyan Neonatal Unit at Al Wahda Teaching Hospital, Derna: A Comprehensive Analysis

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ABSTRACT

Aim. *This study aims to assess the prevalence and associated risk factors of Cleft lip and palate (CLP) among neonates in Derna, Libya, over a six-year period from 2016 to 2021.* ***Methods.*** *This retrospective observational study analysed data from the neonatal unit registry at Al Wahda teaching hospital in Derna, Libya. The study population comprised neonates admitted to the hospital from 2016 to 2021. Inclusion criteria specified Libyan neonates diagnosed with CLP, while exclusion criteria excluded stillbirths and non-Libyan neonates. Data analysis involved calculating incidence rates, descriptive statistics, and subgroup analyses to identify demographic characteristics and associated risk factors.* ***Results.*** *Out of 2,887 neonatal records reviewed, 10 cases of cleft lip ± palate (CL±P) were identified, yielding an overall incidence rate of 0.6 cases per 1000 live births. The majority of cases (50%) presented with both cleft lip and palate, followed by cleft palate only (40%) and cleft lip only (10%). Demographic analysis revealed a higher prevalence among females (60%), full-term neonates (80%), neonates from larger families of more than 6 children (50%), and those with birth weights between 2.5 and 4 kg (70%). Left-sided clefts were more common (90%) than right-sided clefts (10%). Potential risk factors included maternal history of abortion (20%), irregular pregnancy follow-up (90%), and gestational diabetes (10%).* ***Conclusion.*** *This study provides insights into the prevalence and associated risk factors of cleft lip ± palate (CL±P) among neonates in Derna, Libya. The findings underscore the importance of comprehensive prenatal care and public health interventions to address modifiable risk factors and reduce the incidence of cleft lip ± palate in affected populations. Further research is needed to explore additional factors contributing to cleft anomaly occurrence and outcomes.*

Keywords: Cleft Lip, Cleft Palate, Incidence, Risk Factors, Libya

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الأهداف. تهدف هذه الدراسة إلى تقييم مدى انتشار الشفة المشقوقة والحنك المشقوق وعوامل الخطر المرتبطة به بين حديثي الولادة في درنة، ليبيا، على مدى ست سنوات من 2016 إلى 2021. **طرق الدراسة**. قامت هذه الدراسة الرصدية الاسترجاعية بتحليل البيانات من سجل وحدة حديثي الولادة في مستشفى الوحدة التعليمي في درنة، ليبيا. تألف مجتمع الدراسة من حديثي الولادة الذين تم إدخالهم إلى المستشفى من عام 2016 إلى عام 2021. حددت معايير الشمول حديثي الولادة الليبيين الذين تم تشخيص إصابتهم بـــCLP ، في حين استبعدت معايير الاستبعاد حالات الإملاص والولدان غير الليبيين. وشمل تحليل البيانات حساب معدلات الإصابة، والإحصاءات الوصفية، وتحليلات المجموعات الفرعية لتحديد الخصائص الديموغرافية وعوامل الخطر المرتبطة بها. **النتائج**. من بين 2887 سجلاً لحديثي الولادة تمت مراجعتها، تم تحديد 10 حالات من الشفة المشقوقة(CL±P) ، مما أدى إلى معدل حدوث إجمالي قدره 0.6 حالة لكل 1000 ولادة حية. غالبية الحالات (50%) تعاني من الشفة المشقوقة والحنك المشقوق، يليها الحنك المشقوق فقط (40%) والشفة المشقوقة فقط (10%). كشف التحليل الديموغرافي عن ارتفاع معدل الانتشـــار بين الإناث (60%)، وحديثي الولادة مكتملي النمو (80%)، وحديثي الولادة من أسر أكبر تضـــم أكثر من 6 أطفال (50%)، وأولئك الذين تتراوح أوزانهم عند الولادة بين 2.5 و4 كجم (70%). كانت الشقوق في الجانب الأيسر أكثر شيوعًا (90٪) من الشقوق في الجانب الأيمن (10٪). وتشـــمل عوامل الخطر المحتملة تاريخ الأم للإجهاض (20٪)، ومتابعة الحمل غير المنتظمة (90٪)، وســـكري الحمل (10٪). **الخاتمة**. تقدم هذه الدراسة نظرة ثاقبة حول مدى انتشار وعوامل الخطر المرتبطة بالشفة المشقوقة والحنك المشقوق (CL±P) بين الولدان في درنة، ليبيا. تؤكد النتائج على أهمية الرعاية الشاملة قبل الولادة وتدخلات الصحة العامة لمعالجة عوامل الخطر القابلة للتعديل وتقليل حدوث الشفة المشقوقة والحنك المشقوق في السكان المتضررين. هناك حاجة إلى مزيد من البحث لاستكشاف العوامل الإضافية التي تساهم في حدوث الشذوذ المشقوق ونتائجه.

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INTRODUCTION

Cleft lip and palate are congenital conditions characterized by a separation or gap in the upper lip and/or roof of the mouth (palate) that occurs during foetal development. The laterality of cleft lip and palate can vary, ranging from unilateral, affecting one side, to bilateral, affecting both sides. These conditions result from the incomplete fusion of facial structures in the early weeks of pregnancy [1,2]. Cleft lip and palate are significant global concerns, impacting over 10 million individuals worldwide [3]. While the precise causes of cleft lip and palate are not always clear, a combination of genetic and environmental factors is believed to contribute. Non-modifiable risk factors include a family history of cleft defect, certain genetic syndromes, and maternal age [4]. Modifiable risk factors involve environmental influences, such as maternal smoking, inadequate prenatal nutrition, and exposure to certain medications during pregnancy.

Overall, orofacial clefts occur across all ethnicities, genders, and socioeconomic strata, exhibiting international variation. The affected child and their family often endure significant psychological challenges and socioeconomic burdens. Each case of cleft lip and/or palate necessitates multiple surgical interventions and intricate medical interventions [5,6].

Addressing modifiable risk factors through prenatal care and adopting healthy lifestyle choices may help mitigate the risk of cleft lip and palate, underlining the importance of comprehensive prenatal care in reducing the incidence of these congenital conditions. This study aims to evaluate the incidence rate cleft lip and palate (CLP) cases per 1000 live births among neonates born at the city hospital in Derna, Libya over the six-year study period (2016 to 2021), to identify demographic characteristics associated with neonates diagnosed with CLP, including age, gender, birth weight, geographic location, and birth order within the family, to explore potential risk factors contributing to the occurrence of CLP among neonates, including maternal history of abortion, irregular pregnancy follow-up, gestational diabetes, and family history of cleft lip and/or palate, to examine the distribution and types of cleft defects (cleft lip only, cleft palate only, or both) among the studied neonatal population and determine any patterns or variations. Thereby, contribute to the understanding of the epidemiology, etiology, and public health implications of CLP within the context of the study population in Derna, Libya.

METHODS

Study Design

This study utilizes a retrospective observational design, relying on data obtained from the neonatal unit's registry at the city hospital in Derna, Libya. The investigation aims to assess the prevalence of cleft lip and palate cases and identify associated risk factors within the timeframe of 2016 to 2021.

Data Source

The primary data source is the neonatal unit's registry, which comprehensively records information on neonates admitted to the hospital during the specified period.

Study Population

The study population comprises neonates admitted to the city hospital in Derna, Libya, from 2016 to 2021, with a specific focus on cases diagnosed with cleft lip and palate. The total number of admitted cases over this period is documented as 2871.

Inclusion and exclusion criteria

The study set specific criteria for inclusion: infants born from 2016 to 2021 with cleft lip and/or palate and born to Libyan parents. Exclusion criteria were also defined: infants born to non-Libyan parents, stillbirths and atypical oro-facial clefts such as transverse or oblique clefts.

Variables and Measures

The key variables include the prevalence of cleft lip and palate, demographic details (e.g., age, gender, birth weight, geographic location), and clinical characteristics (e.g., type of delivery). Risk factors, both modifiable (e.g., maternal smoking, nutrition, and medication use during pregnancy) and non-

modifiable (e.g., family history and genetic syndromes), were also assessed.

Data Analysis

The incidence of cleft lip ± palate (CL±P) babies per 1000 births was calculated. Descriptive statistics, such as frequencies and percentages, were employed to characterize the prevalence of cleft lip and palate cases.

Ethical Considerations

This study adheres to ethical guidelines, ensuring patient confidentiality and data privacy. Institutional review board approval has been obtained, and the research adheres to the principles of the Declaration of Helsinki.

RESULTS

The study reviewed a total of 2887 neonatal records over a period of 6 years. Among these records, 10 neonates were identified as having a cleft anomaly. The total living birth over a period of 6 years was 17464. This yields an overall incidence rate of 0.6 cases per 1000 live births. 4 (40%) of neonates had cleft palate alone, 1 (10%) had cleft lip alone, and 5 (50%) had both cleft lip and cleft palate.

Given the limited number of cases (10 neonates) and the nature of the data, **Table 1** provides a structured overview of each case, with regard to age, delivery method, sex, weight, residence, mother's illness, and the anomaly observed.

Table 1: Overview of neonatal cleft anomaly cases: Age, Delivery Method, Sex, Weight, Residence, Mother's Illness, and Anomaly Observed.

Age	Delivery	Sex	Weight	Residence	Mother's illness	Anomaly
Term	NVD	F	3.7kg	Derna	No	Cleft lip and palate
Term	NVD	F	2.9 kg	Derna	No	Cleft palate
Preterm	NVD	F	3.5 kg	Ras Alhelal	No	Cleft palate
Term	NVD	F	1.9 kg	Derna	No	Cleft palate
Term	C/S	F	2.1 kg	Derna	HTN, IDDM	Cleft palate
Preterm	NVD	M	3.2 kg	Derna	No	Cleft lip and palate
Term	NVD	M	3 kg	Derna	No	Cleft lip and palate
Term	C/S	M	2.6 kg	karsa	No	Cleft lip and palate
Term	NVD	F	2.3 kg	Derna	No	Cleft lip and palate
Term	NVD	M	3.1 kg	Ain mara	No	Cleft lip

The incidence rate compared the new cases to the total number of living birth each year is depicted in Table 2.

Table 2. Incidence rate of total cleft anomaly per year

Year	New Cases	Total living birth	Incidence Rate
2016	3	3548	0.8/1000
2017	2	3041	0.6/1000
2018	0	1977	0
2019	1	2665	0.4/1000
2020	2	3197	0.6/1000
2021	2	3036	0.6/1000

Table 3 provides an insight into the types and sides of cleft defects among neonates, indicating a predominant occurrence of both cleft lip and cleft palate and a higher prevalence of left-sided defects. 40% of neonates with cleft defects have cleft palate only, 10% have cleft lip only while the majority (50%) have both cleft lip and cleft palate. 90% of neonates with cleft defects have left-sided clefts. 10% have right-sided clefts. None of the neonates have bilateral clefts.

Table 3. Pattern of Cleft Lip (CL) and Cleft Palate (CP) among the studied neonatal population. Data shown are frequency; number (n) and percentage (%)

Characteristics		Number	%
Type	Cleft Palate only	4	40
	Cleft lip only	1	10
	Both cleft lip and cleft palate	5	50
Side	Right-sided	1	10
	Left-sided	9	90
	Bilateral	0	0

The relevant characteristics of the studied neonates with cleft lip and/or cleft palate are depicted in Table 4 provides an insight into various demographic factors associated with neonates with cleft defects,

including gender, birth order, birth weight, mode of delivery, delivery month, blood group distribution, and area of residence. 60% of neonates with cleft defects are female, while 40% are male. Most neonates with cleft defects come from families with more than six children (50%). 30% are from families with 4th - 5th children, and 20% are from families with 2nd-3rd children. The majority (70%) of neonates with cleft defects have a birth weight between 2.5 and 4 kg. 30% have a birth weight of less than 2.5 kg. 80% of neonates with cleft defects are delivered through normal vaginal delivery, while 20% are delivered via caesarean section. The majority (80%) of neonates with cleft defects are delivered in the 9th month of pregnancy. Blood group distribution among neonates with cleft defects varies, with each group representing between 10-20% of the total. A+ and B+ are the most common blood groups. 70% of neonates with cleft defects reside in urban areas, while 30% reside in rural areas.

Table 4. Demographic Analysis of Neonates with Cleft Defects. Data shown are frequency; number (n) and percentage (%)

Characteristics		n	%
Child gender	Male	4	40
	Female	6	60
Child order within the family	First	0	0
	2nd-3rd	2	20
	4th - 5th	3	30
	> 6th	5	50
Childbirth weight	<2.5 Kg	3	30
	2.5 - 4 Kg	7	70
	> 4kg	0	0
Mode of delivery	Normal vaginal delivery	8	80
	Caesarean section	2	20
Delivery month	7th	1	10
	8th	1	10
	9th	8	80
Child blood group	A+	2	20
	A-	1	10
	B+	2	20
	B-	0	0
	AB+	1	10
	AB-	1	10
	O+	1	10
	O-	2	20
Area of residence	Urban	7	70
	Rural	3	30

Table 5 highlights various potential risk factors associated with neonates with cleft defects, including a maternal history of abortion, irregular pregnancy follow-up, and gestational diabetes. It also indicates the absence of a family history of cleft lip and/or palate among the cases studied. 20% of mothers have a history of abortion during the pregnancy. The majority, 90%, of neonates with cleft defects were associated with irregular pregnancy follow-up. 10% of neonates with cleft defects were born to mothers with gestational diabetes. None of the neonates had a family history of cleft lip and/or palate. 40% of the neonates have other congenital anomalies specifically Pierre robin's sequence in 4 cases; Pierre Robin sequence (PRS) is characterized by the clinical trial of micrognathia (mandibular hypoplasia), glossopteris (downward displacement of the tongue), and upper airway obstruction.

Table 5. Potential risk factors for cleft lip and/or cleft palate among the studied neonatal population. Data shown are number (n) and percentage (%)

Risk factor	n	%
Maternal history of abortion	2	20
Irregular pregnancy follow-up	9	90
Gestational diabetes	1	10
Family history of cleft lip and/or palate	0	0
The child having other congenital anomalies	4	40

DISSCUSION

The findings of this study provide valuable insights into the incidence, characteristics, and potential risk factors associated with neonates diagnosed with cleft anomalies.

The overall incidence rate of cleft anomalies in this study population was found to be 0.6 cases per 1000 live births. While this rate may seem relatively low, the study findings are consistent with global trends, highlighting cleft lip (CL) and cleft palate (CP) as significant congenital anomalies, occurring at a rate of approximately one in every 700 to 1000 live births [7]. CL/CP ranks as the second most common birth defect after Down syndrome, with an incidence of 10.48 cases per 10,000 births [8]. Nonetheless, this study observed slight variations in the incidence rate over the six-year period, with rates fluctuating

between 0 and 0.8 per 1000 live births, suggesting some degree of variability in occurrence over time.

The demographic analysis of current study revealed several notable characteristics among neonates diagnosed with cleft anomalies. The majority of affected neonates were female (60%), and a significant proportion came from families with more than six children (50%). Most neonates had a birth weight between 2.5 and 4 kg (70%), and the majority were delivered vaginally (80%) during the 9th month of pregnancy (80%). Blood group distribution varied, with A+ and B+ being the most common groups. Additionally, a higher proportion of affected neonates resided in urban areas (70%).

However, several other studies highlight some contrasting observations. For instance, other study found that most children with cleft lip and/or palate were males [9] with a significant portion of neonates who were born underweight [10]. Additionally, our study noted that a significant proportion of affected neonates came from families with more than six children, whereas other study reported a higher incidence among male children born to consanguineous couples [11]. Furthermore, research conducted by Ghaib et al. [12] revealed that the AB blood group is the most common subtype associated with cleft lip and/or palate (CL/CP), whereas group O is the least commonly associated.

The analysis of cleft defect types revealed that the majority of neonates (50%) had both cleft lip and cleft palate, while half of them exhibited either type (40% had cleft palate only, 10% had cleft lip only. Furthermore, left-sided clefts were significantly more prevalent (90%) than right-sided clefts (10%). This observation aligns with the findings of Tettamanti et al. [13], who reported a predominance of unilateral combined cleft lip and palate (46%), followed by cleft palate only (33%).

Several potential risk factors for cleft anomalies were identified, inadequate follow up during pregnancy ranked first (90%), followed by a history of maternal abortion (20%) and gestational diabetes in a minority of cases (10%). Notably, no neonates had a family history of cleft lip and/or palate. Furthermore, 40% of affected neonates had other congenital anomalies, specifically Pierre Robin sequence. These observations contrasted the evidence in literature regarding reported risk factors of CL-CP that included strong genetic factors, and maternal-related risk such as associations between gestational diabetes and cleft anomalies [14,15]

These findings highlight the multifactorial nature of cleft anomalies and the importance of considering various maternal and foetal factors in their aetiology, albeit in different contexts.

One of the key strengths of this study lies in its pioneering nature, being the first to determine the incidence and characteristics of orofacial clefts in Derna city, Libya. Additionally, the study sheds light on some potential risk factors associated with these conditions, providing valuable insights into the epidemiology and etiology of orofacial clefts in this specific geographic location.

However, it's crucial to acknowledge the limitations of this study. The relatively small sample size of 10 neonates may limit the generalizability of the findings to broader populations. Additionally, the retrospective nature of the study and reliance on medical records may introduce bias or incomplete data with the potential underreporting in the registry. Furthermore, the study's focus on a specific geographical area may limit its applicability to other regions or populations with different demographic characteristics or healthcare systems. Moreover, the study acknowledges the absence of certain socio-demographic data, including information on parent consanguinity, maternal and paternal age, paternal tobacco smoking, as well as detailed maternal history during pregnancy. This includes factors such as passive smoking, folic acid intake, multivitamin deficiency, poor nutrition, use of medications, exposure to infection, radiation exposure, and maternal epilepsy. These additional variables could provide further insights into potential risk factors associated with orofacial clefts and enhance the comprehensiveness of the study's analysis.

CONCLUSION

In conclusion, this study provides valuable insights into the incidence, characteristics, and potential risk factors associated with neonates diagnosed with cleft anomalies. Despite its limitations, the findings

contribute to our understanding of the epidemiology and clinical presentation of cleft defects and underscore the importance of early detection, management, and preventive strategies in affected neonates. Further research with larger, more diverse populations is warranted to validate these findings and explore additional factors influencing cleft anomaly occurrence and outcomes.

Conflict of Interest

There are no financial, personal, or professional conflicts of interest to declare.

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