Cleft Palate Demographics and Complications: A Single-Center Study in Baghdad, Iraq

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Received: 11/5/2026; Accepted: 29/6/2026; Published: 30/6/2026

Abstract

Background: Cleft palate, with or without cleft lip, is one of the most common congenital orofacial anomalies and is associated with functional, otologic, and surgical complications. Despite global literature on CP, data from Iraq particularly regarding demographics and postoperative complications remain limited. **Objective:** To evaluate the demographic characteristics and postoperative complications of cleft palate patients treated in one of Baghdad's hospitals, with particular focus on fistula formation, infection, and otitis media, and their relationship to age, gender, and timing of surgery. **Methods:** This study included 34 patients who underwent cleft palate repair at Al-Karkh General Hospital in Baghdad over approximately 10 months, from October 2024 to July 2025, with ongoing follow-up. Demographic data, age at surgery, and postoperative complications were recorded. Surgical techniques primarily included von Langenbeck bipedicled flaps and Bardach two-flap palatoplasty, with vomer flaps used for wide clefts. **Results**: The study population consisted of 55.9% males and 44.1% females, with most patients aged between 6 months and 6 years (mean age ≈ 39 months). Gender and age group distributions showed no significant deviation from randomness ($P>0.05$). In contrast, timing of surgery demonstrated a highly significant tendency toward early intervention, with 50% of cases operated on before 6 months of age ($P<0.01$). Postoperative complications were infrequent: fistula (15%), infection (6%), and otitis media (9%), all showing highly significant restricted distributions toward negative outcomes ($P<0.01$). Although no statistically significant associations were

identified between complications and demographic variables, clinically relevant trends suggested higher fistula rates in older children and increased otitis media in younger patients, particularly males. **Conclusion:** This study evaluated the demographic characteristics and postoperative complications of cleft palate repair, focusing on fistula formation, wound infection, and otitis media. Fistula occurrence appeared to increase with advancing age at repair, whereas otitis media was more common in younger patients, particularly those younger than 12 months. Male patients also demonstrated higher odds of developing fistula and otitis media compared with females.

Keywords*: cleft palate, fistula, otitis media, complications.*

1. Introduction

Cleft palate (CP) and cleft lip (CL) are among the most common congenital orofacial anomalies, arising from the failure of fusion of the frontonasal and maxillary prominences during embryologic development. These defects may present as isolated cleft palate, isolated cleft lip, or as a combined cleft lip and palate (CL + P). Although CL and CP originate from closely related developmental processes, combined CL + P is considered epidemiologically and etiologically distinct from isolated CP, with differences in incidence, risk factors, and clinical outcomes [1]. Globally, the incidence of CLP shows marked ethnic and geographic variation, ranging from approximately 0.3 per 1,000 live births among African American populations to as high as 2.1 per 1,000 among Japanese populations [2]. In contrast, isolated cleft palate demonstrates relatively uniform distribution across racial groups, with a reported incidence of about 0.5 per 1,000 live births [3]. Early cleft repair offers advantages in speech and hearing [1]. However, it is generally accepted that early and extensive mobilization of the mucoperiosteum is the chief factor to interfere with facial growth in the long term [2, 3]. Various modifying surgical flap techniques have been designed to decrease the hard palate area involved for avoiding the dilemma [4]. The one-stage palatoplasty (also known as the “hole-in-one” repair) has become an increasingly popular technique in recent years, particularly in resource-limited settings where repeated procedures are often not feasible. This technique advocates both hard and soft palate closure around 10 months of age with minimal disturbances in facial bone growth [13]. Beyond surgical concerns, children with cleft palate frequently experience systemic complications. Respiratory problems are common, often related to feeding difficulties and nasal regurgitation of milk and saliva, which predispose patients to recurrent chest infections. Moreover, cleft lips and palate may occur in association with

more than 400 recognized syndromes, including Pierre Robin sequence, 22q11.2 deletion syndrome, Van der Woude syndrome, Stickler syndrome, CHARGE syndrome, Goldenhar syndrome, Down syndrome, Treacher Collins syndrome, spina bifida, limb defects, and congenital heart diseases. In Down syndrome, cleft lip or palate occurs in approximately 1 in 200 cases, while in trisomy 13 (Patau syndrome) the prevalence may reach up to 70%, making it one of the syndromes most associated with CL + P [5].

In Iraq, and particularly in Baghdad, data regarding the demographics and complications of cleft palate remain limited. Understanding local patterns of presentation, associated anomalies, and perioperative complications is essential for improving surgical outcomes and healthcare planning. Therefore, this study aims to evaluate the demographics and complications of cleft palate patients treated in one of Baghdad's hospitals, providing institution-specific data that may contribute to the regional and international cleft palate literature.

2. Materials and methods

2.1 Patients sample

This prospective study included 34 cases who underwent management and repair of cleft palate at Al-Karkh General Hospital, Baghdad, Iraq, in the Department of Maxillofacial Surgery. The study period extended over approximately 10 months, from October 2024 to July 2025, with ongoing postoperative follow-up. No specific selection criteria were applied; the study included patients who underwent surgery by two specialists at this hospital during the study period.

2.2 Preoperative and postoperative evaluation

Each patient underwent general blood investigations, chest radiography, and echocardiography to exclude systemic diseases or deformities that may be associated with cleft palate. The analysis included documentation of each child's age at the time of repair, gender, and intraoperative and postoperative complications. Postoperative monitoring required hospitalization for only 24 hours.

2.3 Statistical Analysis

Statistical analysis was performed using the Statistical Package for the Social Sciences (SPSS), version 22.0. Descriptive statistics included observed frequencies, percentages, mean values,

standard deviations, and odds ratios. Data was presented graphically using pie charts and clustered bar charts.

2.3.1 Inferential data analysis

Inferential statistics were used to test the study hypotheses and included the one-sample chi-square test and the binomial test based on Z approximation.

3. Results

I. Demographic characteristics

Table (1): Demographic and clinical characteristics of the study sample (n=34).

	Groups	No.	Percentage	C.S. P-value
Gender	**Male**	**19**	**55.9%**	**P=0.607 (**)**
	Female	**15**	**44.1%**	
Age Groups (Per Months.)	**< 12 m.**	**8**	**23.5%**	**P=0.168 (**) Mean ± SD (23.41± 19.75)**
	12-24	**14**	**41.2%**	
	24-36	**6**	**17.6%**	
	≥ 36 m.	**6**	**17.6%**	
	Total	**34**	**100%**	
Date of Surgery Surgical age onset	**< 6 m.**	**17**	**50%**	**P=0.008 (*) Mean ± SD (14.71± 20.01)**
	6-12	**4**	**11.8%**	
	12-24	**6**	**17.6%**	
	≥ 24 m.	**7**	**20.6%**	
	Total	**34**	**100%**	

(*) HS: Highly Sig. at P<0.01, (**) Non Sig. at P>0.05; Testing based on One-Sample Chi-Square test, and Binomial

The elementary variables of the study patients showed no restricted distribution according to gender or age group, as no significant differences were observed between the observed and expected frequencies under the assumption of random distribution (P>0.05). However, surgical timing showed a highly significant difference (P<0.01), with a higher number of patients in the first group (<6 months). The mean surgical age was 14.71 months, with a standard deviation of 20.01 months.

II. Prevalence of postoperative complications

Table (2) Distribution of postoperative complications (n=34)

complication	Status	No.	Observed proportion	Test proportion	Asymp. Sig. (2-tailed)
Fistula	**absent**	**29**	**0.85**	**0.5**	**P=0.000 HS**
	present	**5**	**0.15**		

Infection	**absent**	**32**	**0.94**	**0.5**	**P=0.000 HS**
	present	**2**	**0.06**		
Otitis Media	**absent**	**31**	**0.91**	**0.5**	**P=0.000 HS**
	present	**3**	**0.09**		

(*) HS: Highly Sig. at P<0.01, Testing based on Z- Approximation.

Postoperative complications showed a restricted distribution, with highly significant differences between observed frequencies and expected outcomes (P<0.01). In this study, positive postoperative complications were limited to a small number of cases: fistula in 5 patients (15.0%), infection in 2 patients (6.0%), and otitis media in 3 patients (9.0%).

Part III: The relation between the complications and patients' elementary variables.

The relationships between postoperative complications and patients' elementary variables, including gender, age group, and surgical timing, were evaluated. Age groups and surgical timing were redistributed into two categories for analysis: patients younger than 12 months and those aged 12 months or older for age groups, and patients younger than 6 months and those aged 6 months or older for surgical timing. Table (3) presents the contingency coefficient relationships and their statistical significance.

Table (3): Relationship between postoperative complications and patient demographic characteristics and surgical timing (n=34)

complications		**No. & %**	**Gender**		**total**	**Comparison of significance. (*) P_{-value}**
			Male	**Female**		
Fistula	**absent**	**No.**	**16**	**13**	**29**	**CC=0.034 OR=1.218**
		%	**84.2%**	**86.7%**	**85.3%**	
	present	**No.**	**3**	**2**	**5**	
		%	**15.8%**	**13.3%**	**14.7%**	
Infection	**absent**	**No.**	**18**	**14**	**32**	**CC=0.030 OR=0.889**
		%	**94.7%**	**93.3%**	**94.1%**	
	present	**No.**	**1**	**1**	**2**	
		%	**5.3%**	**6.7%**	**5.9%**	
Otitis Media	**absent**	**No.**	**17**	**14**	**31**	**CC=0.067**
		%	**89.5%**	**93.3%**	**91.2%**	
	present	**No.**	**2**	**1**	**3**	**OR=1.647**
		%	**10.5%**	**6.7%**	**8.8%**	
Complications	**Status**	**No. & %**	**Age Groups**		**Total**	**C.S. (*) P_{-value}**
			< 12 m.	**≥ 12 m.**		
Fistula	**absent**	**No.**	**8**	**21**	**29**	**CC=0.224**
		%	**100%**	**80.8%**	**85.3%**	

	present	No.	0	5	5	
		%	0.00%	19.2%	14.7%	
Infection	absent	No.	8	24	32	CC=0.137
		%	100%	92.3%	94.1%	
	present	No.	0	2	2	
		%	0.00%	7.7%	5.9%	
Otitis Media	absent	No.	6	25	31	CC=0.302 OR=8.333
		%	75.0%	96.2%	91.2%	
	present	No.	2	1	3	
		%	25.0%	3.8%	8.8%	
Complications	**Status**	**No. & %**	**Time of Surgery (Age off set)**		**Total**	**Comparison of significance (*) P_{-value}**
			< 6 m.	**≥ 6 m.**		
Fistula	absent	No.	15	14	29	CC=0.083 P=0.628 (NS) OR=1.607
		%	88.2%	82.4%	85.3%	
	present	No.	2	3	5	
		%	11.8%	17.6%	14.7%	
Infection	absent	No.	16	16	32	CC=0.000 P=1.000 (NS) OR=1.000
		%	94.1%	94.1%	94.1%	
	present	No.	1	1	2	
		%	5.9%	5.9%	5.9%	
Otitis Media	absent	No.	14	17	31	CC=0.297 P=0.070 (NS) For Cohort < 6m. =0.452
		%	82.4%	100%	61.3%	
	present	No.	3	0	3	
		%	17.6%	0.00%	8.8%	

(*) NS: Non Sig. at P>0.05; Statistical hypothesis are based on a Contingency's Coefficients test.
OR: Odds Ratio.

4. Discussion

The present study aimed to evaluate patient demographics, the distribution of postoperative complications including fistula, infection, and otitis media, and their relationships with elementary variables such as gender, age group, and timing of surgery. A recently published and validated classification system divides orofacial cleft (OFC) subphenotypes into groups according to their underlying developmental mechanisms, with some subphenotypes showing female predominance (8). Males have a higher predisposition to cleft lip and palate, whereas isolated cleft palate is more common in females (9). In the present study, however, males outnumbered females, which may be related to the relatively small sample size. Regarding patient age groups and the optimal timing of cleft palate repair, most patients in this study were younger than 2 years, including 23.5% who were younger than 12 months and 41.2% who were 12–24 months old. Medically fit infants who underwent primary surgery for isolated cleft palate at 6 months of age in adequately resourced

settings were less likely to have velopharyngeal insufficiency at 5 years of age than those who underwent surgery at 12 months of age (10). Common complications associated with cleft palate surgery include airway obstruction, palatal fistula, flap necrosis, wound infection, wound dehiscence, bleeding, velopharyngeal insufficiency, and other complications (11). The present study focused on three major postoperative complications: fistula, wound infection, and otitis media.

Mahboubi et al. studied 10,450 cleft palate corrective surgeries performed between 1997 and 2011 across 107 hospitals in California (12). The most common complication was fistula, abscess, or infection, which occurred in 159 cases (1.5%). In the present study, we evaluated the relationship between postoperative complications and patients' gender and age groups. The results showed weak relationships between the studied complications and patients' elementary variables, with no statistically significant contingency coefficients ($P>0.05$). However, observed trends suggested that fistula was more likely to occur in patients older than 12 months, whereas otitis media was more likely to occur in patients younger than 12 months. Odds ratios also suggested that males were more likely than females to develop otitis media and fistula. These findings are consistent with the report by Annigeri et al., who found that postoperative fistula developed in 31% of patients with bilateral clefts, 17% of patients with left unilateral clefts, and 9% of patients with isolated cleft palate ($P<0.05$). They also reported that 8% of patients operated on before 2 years of age developed a fistula compared with 66.6% of those repaired after 2 years of age ($P<0.01$), indicating that bilateral cleft type and older age at repair are risk factors for fistula formation. Other studies, such as that by Ceremsak et al., have focused on the association between complications and cleft classification. Oronasal fistula rates are strongly associated with Veau classification, with reported rates of 2%, 7%, 9%, and 13% for Veau I through Veau IV defects, respectively (14). These findings indicate that postoperative complications may be influenced by multiple variables that can affect surgical outcomes after cleft palate repair. Despite the global literature on cleft palate, data from Iraq, particularly regarding demographics and postoperative complications, remain limited.

5. Conclusion

This study evaluated the demographic characteristics and postoperative complications of cleft palate repair, focusing on fistula formation, wound infection, and otitis media. Although no

statistically significant associations were identified between complications and patients' gender, age group, or timing of surgery (P>0.05), observed trends suggested that fistula occurrence increased with advancing age at repair, whereas otitis media was more common in younger patients, particularly those younger than 12 months. Male patients also demonstrated higher odds of developing fistula and otitis media compared with females. These findings are consistent with previous reports indicating that older age at repair may increase the risk of postoperative fistula formation. The results highlight the multifactorial nature of cleft palate surgery outcomes and emphasize the need to consider additional factors, including cleft severity and classification. Given the limited available data from Iraq, further multicenter studies with larger sample sizes are recommended to better define risk factors for postoperative complications and optimize patient outcomes.

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