

ORIGINAL ARTICLE

Frequency of fistula in patients operated for primary cleft palate repair in a tertiary care center.

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ABSTRACT... Objective: To determine the frequency of fistula in patients undergoing primary cleft palate repair. **Study Design:** Descriptive Case Series study. **Setting:** Burns and Plastic Surgery Center, HMC, Peshawar. **Period:** February 2023 to December 2023. **Methods:** Patient of both genders males and females undergoing primary cleft palate repair were included in the study with age ranging from 9 to 18 months age excluding patients with comorbid and syndromic patients. Non-probability consecutive sampling was adopted. The data was acquired from patients and hospital record and analyzed with statistical package for social sciences (SPSS). **Results:** Our study shows that among 169 patients, mean age was 10 months with SD \pm 5.11. 100(59%) patients were male and 69(41%) patients were female. More over 3(2%) patients had fistula while 166(98%) patients didn't had fistula. **Conclusion:** In this study we observed an internationally acceptable frequency of post-palatal repair fistula for primary cleft palate in our study population.

Key words: Fistula, Interrupted Sutures, Primary Cleft Palate Repair.

INTRODUCTION

In Asian population the frequency of cleft lip with or without palate is higher.¹ Among the congenital abnormalities, cleft palate is one of the most frequently seen congenital anomaly (Figur-1). Without any racial differences, an overall incidence rate of 0.45 per 1000 live births is recorded for isolated cleft palate. Among the Asian population the incidence rate of cleft lip is recorded higher 2.1 per 1000 live births. The incident rate of cleft palate among the white people population is 1 per 1000 live births and in the black population the incidence rate become lesser 0.41 per 1000.² The common defects associated with palatal cleft are speech and hearing problems, difficulty in feeding and abnormal dentures. The suitable age of repairing cleft palate is between the age ranges 6 -12 months.³

The repairing of the cleft palate is done to achieve the separation of the nasal and oral cavity from each other. Creating levator muscle sling helps in facial growth and formation of the velopharyngeal

mechanism.⁴ The type surgical approach for repair of cleft palate is adopted depending upon the type of cleft palate meaning whether it is complete or incomplete.



Figure-1. Patient with left unilateral complete cleft palate

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Several effective repairing techniques for cleft palate are used worldwide. Bardach's 2-flap palatoplasty (Figure-2) is adopted for complete cleft palate worldwide while for incomplete cleft palate Furlow's double-opposing Z-plasty and von Langenbeck are practiced frequently. The main difference in these techniques are with respect of incision site, technique for dissection, elevation of mucosa, myomucosal and mucoperiosteal flaps. However the nasal and oral layers closure is accomplished with a standard practice of simple interrupted absorbable sutures.⁵

The complications which are associated with surgical procedures done for cleft palate are fistula formation, scar contracture, wound infection and dehiscence. Other complications include lip and nasal defects not fixed during the primary repair, involves notched vermillion, abnormality in nostril size, white roll malalignment, length discrepancy of the lip (short or enhanced), discontinuity of the orbicularis oris muscle, and alar base mal position.⁶

Fistula is possibly the most frequently observed complication related to surgery of cleft palate. The two major problems related to fistula formation are nasal regurgitation and speech difficulties like hypernasality. Fistula is usually formed due to under tension repair, but in adults it is commonly formed due to postoperative infection.⁷

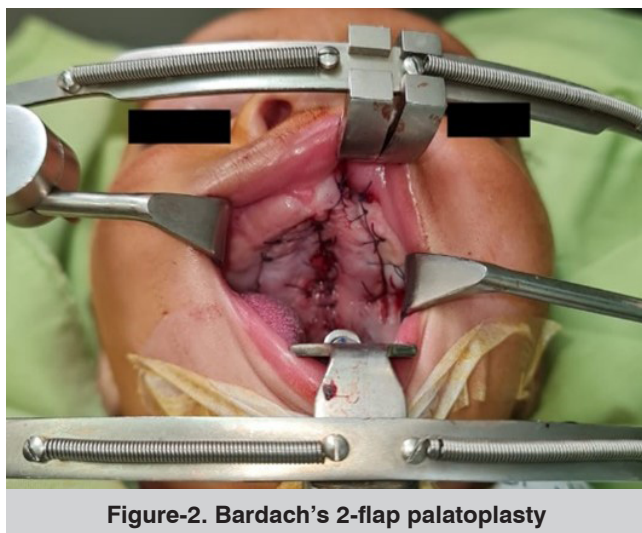


Figure-2. Bardach's 2-flap palatoplasty

In one of the study rate of development of fistula is 2.38% in repairs using interrupted sutures

for closure of primary cleft palate repair.⁸ Cleft palate is repaired surgically usually with applying interrupted suture by achieving the goal of closure of both nasal and oral layers. As a consequence sometimes a complication known as fistula (Figure-3) occurs. The outcome of this study will be shared with other medical colleagues in order to adopt a strategy for countering this complication and minimizing the risks associated with it. This study is aimed to determine the demographics, and frequency of complication in term of fistula formation in patients undergoing primary cleft palate repair at our hospital.

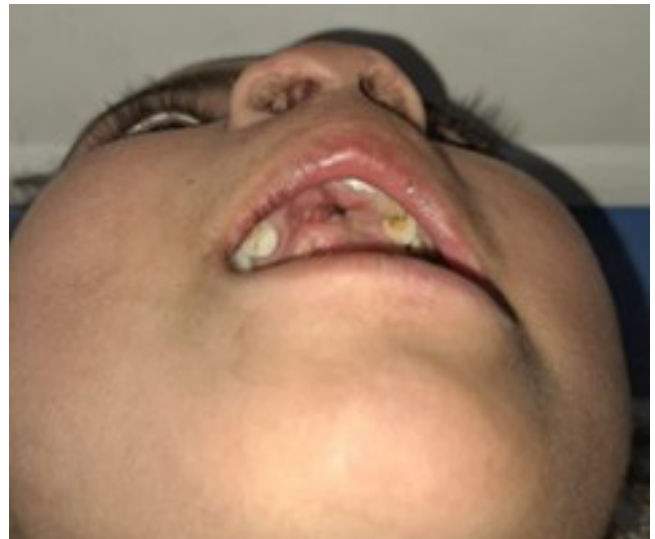


Figure-3. Post-operative anterior palatal fistula formation

METHODS

This Descriptive case series study was performed in Burns and Plastic Surgery Center, Hayatabad Medical Complex, Peshawar from February 2023 to December 2023, including all patients undergoing primary palate repair with age 6 months to 18 months, irrespective of the gender of patients who did not consent the study protocols, patients with comorbid and syndromic patients were excluded from this study. Non-probability consecutive sampling technique was adopted. Research work was carried out after obtaining approval from hospital ethical committee (06/REB/B%PSC/23-20-23). Patients fulfilling the inclusion criteria were enrolled in this research. The aim, advantages, and risks of the study had verbally explained to patients/ attendants before obtaining the written consent form.

The demographic detail like age, gender, and address were noted. Thorough physical examination was conducted and medical history was recorded. The diagnosis of the condition was performed through examination and then surgical repair was planned. Patients were subjected for careful tissue and muscle repositioning near the cleft and reconstruct the mouth roof. On either side of the cleft, incisions were made by adopting specialized two flap approach (Bardach 2-flap palatoplasty) for the repositioning of the soft and hard palate tissues, for repositioning of the muscle of soft palate interrupted suturers were applied by a plastic surgeon having minimum 2 years postgraduate fellowship experience.

Complication such as formation of the fistula was assessed during post-operative stay, and patient was followed for three months at follow up visits. All patients' information was recorded on a pre-defined Performa.

All collected data was analyzed using SPSS version 20. Mean and SDs was calculated for the numerical variables like age. Frequencies and percentages were calculated for categorical variables like gender, fistula, socioeconomic background, and residence. Fistula was stratified among age, gender, socioeconomic background, and residence. Post stratification chi-square test/ Fisher's exact test was used by keeping value $P < 0.05$ as significant. All the obtained results were presented in the form of tables, and graphs.

RESULTS

In this study age distribution among 169 patients was analyzed as 96(57%) patients were 9-12 months and 73(43%) patients were in age 13-18 months. Mean age was 10 months with $SD \pm 5.11$. (Table-I)

Gender distribution among 169 children was analyzed as 100(59%) patients were male and 69(41%) patients were female. (Table-II)

Socio economic status among 169 patients was analyzed as 79(47%) patients were poor, 69(41%) patients were middle class and 21(12%) patients

were rich. (Table-III)

Status of residence among 169 patients was analyzed as 64(38%) patients were from rural areas, 105(62%) patients were from urban areas. (Table-IV)

Fistula formation among 169 patients was analyzed as 3(2%) patients had fistula while 166(98%) patients didn't had fistula. (Table-V)

Stratification of fistula with respect to age, gender, socioeconomic status and residence is give in Table-VI,VII,VIII.

Total	Frequency (%)
9-12 months	96 (57%)
13-18 months	73 (43%)
Total	169 (100%)

Table-I. Age distribution (n=169)
Mean age was 10 months with $SD \pm 5.11$

Gender	Frequency (%)
Male	100 (59%)
Female	69 (41%)
Total	169 (100%)

Table-II. Gender distribution (n=169)

SES	Frequency (%)
Poor	79 (47%)
Middle Class	69 (41%)
Rich	21 (12%)
Total	169 (100%)

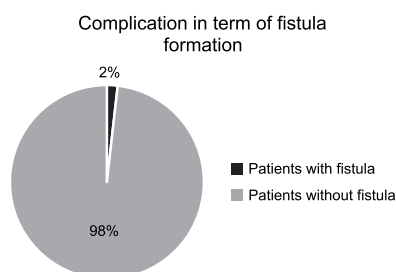
Table-III. Socioeconomic status (n=169)

Residence	Frequency (%)
Rural	64 (38%)
Urban	105 (62%)
Total	169 (100%)

Table-IV. Residence (n=169)

Fistula	Frequency (%)
Yes	3 (2%)
No	166 (98%)
Total	169 (100%)

Table-V. Fistula formation (n=169)



Fistula	9-12 Months	12-18 Months	Total
Yes	2(2%)	1(1%)	3(2%)
No	94(98%)	72(99%)	166(98%)
Total	96(100%)	73(100%)	169(100%)

Table-VI. Stratification of fistula formation with respect to age distribution (n=169)

Chi square test was applied in which P value was 0.728

Fisher's exact test was applied in which P value was 1.000

Fistula	Male	Female	Total
Yes	2(2%)	1(1%)	3(2%)
No	98(98%)	68(99%)	166(98%)
Total	100(100%)	69(100%)	169(100%)

Table-VII. Stratification of fistula formation with respect to gender distribution (n=169)

Chi square test was applied in which P value was 0.789

Fisher's exact test was applied in which P value was 1.000

Fistula	Poor	Middle Class	Rich	Total
Yes	2(3%)	1(1%)	0(0%)	3(2%)
No	77(97%)	68(99%)	21(100%)	166(98%)
Total	79(100%)	69(100%)	21(100%)	169(100%)

Table-VIII. Stratification of fistula formation with respect to socioeconomic status (n=169)

Chi square test was applied in which P value was 0.712

Fisher's exact test was applied in which P value was 1.000

DISCUSSION

The incidence of cleft lip and palate is reported higher in Asian population.¹ With no significant racial differences, an incidence rate of 0.45/1000 births recorded for isolated cleft palate. In Asian population the incidence rate for cleft lip is reported higher 2.1/1000 while in white people population the incident rate is 1/1000, and in black population the incidence rate become lesser 0.41/1000.² The recommended age for repairing of cleft palate deformity is between the age ranges 6-12 months, to enhance chances for the development of speech in a child.³

According to our study, among the total 169

cases, mean age of patients was 10 months with SD \pm 5.11. 100(59%) patients were male and 69(41%) patients were female. 79(47%) patients were poor, 69(41%) patients were middle class and 21(12%) patients were rich. 64(38%) patients were from rural areas while 105(62%) patients were belonging to urban areas. More over 3(2%) patients had fistula while 166(98%) patients didn't had fistula.

Similar to our study findings were observed in a study done by Fayyaz GQ et al.²² In this study 152 patients were enrolled out of these 152 patients 84 were repaired with continues suturing and rest were repaired with application of interrupted sutures. In group A closure time was 7.08 min for the closure of nasal layer of mouth roof, while in the group B was 11.50 min. According to this study there was no difference in term of outcome in both groups. Describing the outcome in this study it is stated that total 4 patients developed fistulae making 2.63% of the total patients, there were 2 postoperative fistulas formation in each group, making 2.38% in group A while 2.94 % in group B.

In another study done by Park MS et al²³ occurrence of fistulas formation was recorded in 20 of the total 636 cases; making frequency of fistula formation in this study population 3.1%. According to this study hard palate was the most common site for fistula formation (9/20 cases, 45% of total fistulas), second common site was at junction of the hard and soft palate (6/20 cases, 30% of the total fistulas) and the 3rd common site for fistula formation was soft palate (5/20 cases, 25% of total fistulas). In this study Fistula incidence was calculated against the technique adopted for repair. fistula formation was most common in the Furlow double-opposing Z-plasty technique (12.1% of the total cases). In the Busan modification it was 3.0% and in patients who undergone two-flap technique fistula formation was 2.0% of the total cases.

CONCLUSION

In this study we observed an internationally acceptable frequency of post-palatal repair fistula for primary cleft palate in our study population.

The techniques incorporating interrupted sutures for closure of palatal defects are equally effective in our population as they are in other groups of population.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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AUTHORSHIP AND CONTRIBUTION DECLARATION

No.	Author(s) Full Name	Contribution to the paper	Author(s) Signature
1	Nasir Hayat Khan	Idea, Conception co-ordinator, Methodology, Data collection, Correspondence.	
2	Abida Binte Wali	Data collection, Compiled results.	
3	Maria Fayyaz	Data analysis & review.	
4	Qazi Amjad Ali	Did procedure & provided data.	