

ORIGINAL ARTICLE

Prevalence of Palatal Fistula in Cleft Palate Repair

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ABSTRACT

Background: Cleft palate is a common birth defect. Its incidence is 0.33 in 1000 live births. There is a correlation of family history with cleft lip and palate; present in about 33% to 36% cases. Early complications of cleft palate repair include fistula formation, complete dehiscence, bleeding and palatal flap necrosis. The reported incidence rate of palatal fistula is 29.8%. The study aims to identify the prevalence of fistula formation in complete cleft palate repair.

Methodology: It was a prospective, cohort study aimed to see the occurrence of palatal fistula in cleft palate patients. The study was performed in the Plastic Surgery Department at Patel Hospital, Karachi. All patients fulfilling the inclusion criteria were included in the study. The two-flap palatoplasty was used (Bardach's technique) to repair the cleft palate. Patients were examined weekly and at 4 weeks postoperatively in the outpatient department to assess fistula formation.

Results: 116 patients with complete cleft palate were included and operated. Later, followed for occurrence of palatal fistula. The mean age was 23.6±20.4 months. During follow up 18 patients developed palatal fistula (15.5 %). The highest fistula rates were observed in older age groups (30.8%) in >36 months.

Conclusion: The frequency of palatal fistula in our study is 15.5 %; showing less fistulae occurrence before the age of 18 months as compared to that of after 18 months.

Keywords: Orofacial congenital anomaly, Cleft palate, Palatal fistula, Bardach technique, Pittsburgh classification

INTRODUCTION

Cleft lip or palate is the fourth most common congenital¹ orofacial defect². The incidence of isolated cleft palate is 0.33 in 1000 live births and the incidence of combined cleft lip and palate is 0.45 per 1000 live births³. The possibility of developing palatal fistula is quite common after cleft palate repair⁴⁻⁹. There is a paucity of data reported on the complications of cleft palate surgery in Pakistan. There is a lot variance between national and international statistics regarding the development of palatal fistula after surgery^{4,6-8}. According to Abdurrazzaq TO et al, the reported incidence rate of fistula is 29.8%⁴.

Several techniques have been available to repair cleft palate. The commonly practiced method of palatoplasty is two flaps palatoplasty (i.e. Bardach technique with intravelarveloplasty and Von Langenbeck's technique) and Furlow's double opposing Z plasty¹⁰. The other techniques may include local mucoperiosteal flaps, tongue flap¹¹ and plasma rich in growth factors¹².

Palatal fistula is an epithelialized communication between the nasal and oral cavities¹. The complications of repair other than palatal fistula include complete dehiscence, mucoperiosteal flap necrosis, bleeding, hematoma, damage to vascular pedicle or rarely airway compromise^{4, 13-17}. However, the fistula may result in fetor Oris, food regurgitation, speech problem, social stigma, hyper nasality, and psychological issues to the wellbeing of patients^{1, 11}. There are variable classifications available on palatal fistula location to reduce the ambiguity on documentation, most commonly used classification is Pittsburgh classification¹³⁻¹⁵.

The rationale of this study is to provide data; on prevalence of palatal fistula in local population as per age group between 9 months to 12 years in three strata. There is a wide variation available in the incidence of palatal fistula in international data i.e. 0% to 29.8%^{4, 16-46}. This study will supplement our national data. Hence, it will provide a benchmark in comparing the international statistics with the local statistics. This will highlight the knowledge on cleft palate repair and reinforce the need for optimal care. It will accentuate the necessity of early treatment to restore normal speech mechanism at an appropriate age.

The objective of this study is to determine the frequency of palatal fistula in different age groups; after cleft palate repair in complete bilateral cleft palate patients by using Bardach's technique.

MATERIALS & METHODS

This was a prospective case series performed in the department of Plastic Surgery from March 2019 to February 2023. The sampling technique was non-probability consecutive sampling.

We included all the patients undergoing primary cleft palate repair diagnosed clinically as non-syndromic having complete cleft palate. Both genders are included; aged 9 months to 12 years, admitted in Plastic Surgery Department, after evaluation by the consultant. We excluded syndromic, incomplete cleft palate cases, secondary surgeries, and patients above 12 years of age. Based on incidence of fistula in cleft palate 17.9%,⁷ confidence interval of 95% and 7% margin of error, the sample size was 116.

Informed consent was taken from each candidate. We performed two flap palatoplasty techniques to repair the cleft palate, Bardach's repair was done. The soft palate defect was closed in three layers with intravelarveloplasty and hard palate closed in two layers. We routinely did not perform primary Gingivoperiostoplasty. All the cases were operated by the consultant plastic surgeons with a minimum of 5 years' experience post fellowship. Postoperative elbow splints were applied as institutional protocol. Patients were discharged after 48 hours and kept on liquid diet for 3 weeks. Patient subsequently examined weekly in outpatient department for 4 weeks and fortnightly for 1 more month. Postoperatively, documentation of any palatal fistula done at 4 weeks.

Post-operative fistula would be suspected if patient complained of nasal regurgitation of food. It was confirmed clinically by visualizing the opening in the soft/hard palate across the suture lines. A Performa was developed by the study authors to document all demographics and occurrence of any palatal fistula and its site. The location of the fistula was classified using the Pittsburgh classification.

The data analyzed into Statistical Package for the Social Sciences (SPSS version 20). Mean and standard deviation used to describe numerical variables like age. Frequencies and percentages computed for categorical variables including gender, site of cleft palate and occurrence of fistula. Effect modifiers were controlled through stratification of data including age, gender, site and type of cleft palate; to see the effects of these variables on outcome. The chi-square test and fisher exact test were used for categorical variables assessment. The level of significance had taken as less than 5%.

RESULTS

During the study period 116 patients were admitted with primary cleft palate fulfilling inclusion criteria and inducted in study. Among them 73% (n = 85) were males and 27% (n = 31) females. The mean age was 23.6±20.4 months. The minimum age was 9 months and maximum age was 120 months. The median age was 18 months.

The overall frequency of palatal fistula was found to be 15.5% (n = 18) in our studied patients. We divided the patients in age groups 9 to 18 [n=67; 57%] months, 19 to 36 months [n=49; 42%] and > 36 months [n = 15; 17%]. The most common location of fistula formation is Pittsburgh type V i.e. at the junction of primary and secondary palate (77%, n =14), followed by type III (23%, n= 4) i.e. junction of hard and soft palate. (Table 1)

The occurrence of palatal fistula was significantly associated with gender, with all cases reported in males (21.2%, p = 0.0125) and none in females. Although higher fistula rates were observed in older age groups (30.8%) in >36 months and (22.5%) in 19–36 months compared to (7.9%) in 9–18 months, the association with age was not statistically significant (p = 0.0935). Similarly, bilateral cleft cases showed a higher fistula rate (22.9%) than unilateral cleft cases (12.3%), but the difference was not statistically significant (p = 0.2477). (Table 2)

Table 1: Patients Demographics and Clinical Characteristics

Characteristic	Categories	n (%)
Gender	Male	85 (73%)
	Female	31 (27%)
Age	9 – 18 months	67 (57%)
	19 – 36 months	49 (42%)
	> 36 months	17 (15%)
Type of Cleft	Unilateral	81 (70%)
	Bilateral	35 (30%)
Palatal fistula	Yes	18 (15.5%)
	No	98 (84.4%)
Location of Fistula (Pittsburgh Type)	Type V	14 (77%)
	Type III	4 (23%)

Table 2: Stratification of Palatal fistula

Variable	Category	Fistula (n, %)	No Fistula (n, %)	P value
Gender	Male	18 (21.2%)	67 (78.8%)	0.0125
	Female	0 (0.0%)	31 (100.0%)	
Age Group	9–18 months	5 (7.9%)	58 (92.1%)	0.0935
	19–36 months	9 (22.5%)	31 (77.5%)	
	>36 months	4 (30.8%)	9 (69.2%)	
Type of Cleft	Unilateral	10 (12.3%)	71 (87.7%)	0.2477
	Bilateral	8 (22.9%)	27 (77.1%)	

DISCUSSION

It is a prospective study, showing clinical outcomes in 116 patients after cleft palate repair by two flap palatoplasty. The study has observed the outcomes after four weeks of surgery. It is a single institution case series with primary cases of complete cleft palate. The purpose of the study is to identify the frequency of fistula formation after repair to aid in literature as per national demographics and to identify influential factors for causing fistula formation.

Our study has reported the frequency of palatal fistula as 15.5%. However, the other studies and metaanalyses have reported the incidence rate range from 0.71% to 23.7%^{7, 19-26} showing a wider variation in both national and international data. The study by Khan et al. has observed the fistula rate as 2%⁴⁴. However, the study of Geisman et al, presented the frequency as 27%⁴. Further literature search has shown the fistula rate as 25% in study of Ethiopia⁴⁶. However, in the middle of fistula occurrence, the study of Schmidt G et al. claimed the incidence as 0%¹⁸. These variations in statistics have clearly proved the existence of discrepancy and wide range of fistula occurrence worldwide.

The disparity in prevalence can be due to variable factors. These can be intrinsic and extrinsic factors^{29,32-36}. The intrinsic ones include gender, type of cleft, width of cleft, age at the time of repair, experience of surgeon and anesthetist. The extrinsic causes include tension on repair, poor surgical technique and radical dissection of levator veli palatini muscle²⁹.

The literature search has also emphasized the importance of technique adopted to repair cleft palate. The 25 years' experience of Park et al. has shown the fistula rate to be 3.1% and highlighted that the incidence is quite low in those cases where two flap palatoplasty used for repair (2%)³² same as our study using two flap palatoplasty technique. On the contrary, study by Dong et al. showed no difference in outcome; operated either by Furlow or two flap palatoplasty³⁶.

Our study has shown highest occurrence of fistula formation in the age group; greater than 36 months (30.8%) as compared to those operated between 9 - 18 months; which is supposed to be ideal age for palate repair. However, the study of Wang et al and others, showing fistula incidence is irrelevant to the patient age²⁹⁻³³. In spite of that, Eliason et al. has noticed the incidence rate is more if the surgery has done before 6 months³⁵. Hence, our study also supported the fact that repair should be done before the speech development between 12 to 18 months. This period is also having less chances of fistula occurrence as per our study. The timing of palatal closure is important to achieve good outcomes.

According to Hosseinabad et al, palatal fistula has no association of fistula to any gender or age²² in comparison to our study which has shown significant results in male gender. Following to his study; symptomatic hypernasality has observed in males. Hence, the study of Amaratunga et al. has showed the incidence rate is doubled in males as compare to females³⁷. Hence, the others have shown no statically significant association to gender²⁹.

Our study has shown more prevalence of fistula in unilateral type as compare to bilateral cleft palate. The reason may be the biased data as more unilateral cases have been included in study but this factor has not been verified as statistically significant. Regardless, there are studies available showing more incidence in bilateral type in comparison to unilateral type as 20.3% and 4.4% respectively⁴¹⁻⁴³. Further literature review has shown that actual cleft width is the most accurate assessment for the occurrence of fistula⁴³. However, our study has not utilized this parameter.

The Pittsburg classification is a well-recognized classification introduced by Smith in 2007¹³. In our study, Pittsburgh type V fistula prevails more than type III; which is consistent to the study of Park et al and other studies, showing more incidence of fistula on hard palate^{26, 32}. On the contrary the other studies have shown prevalence of fistula at junction of soft and hard palate³⁷⁻³⁸. Despite that, there is literature available showing equally distributed location either on hard palate, soft palate or junctional³⁹⁻⁴⁰.

We recommend that the repair should be performed with two flap palatoplasty in the age group between 9 to 12 months to reduce frequency of complications. There is need to accentuate the nursing care in conjunction with parents. This would result in achieving the best clinical outcome after cleft palate repair. Our results are comparable to other national and international studies. This study would provide a benchmark to further future studies which can bridge the international statistics to the local stats. There is a strong urge to identify other influential factors that can affect cleft palate repair.

The limitations of the study include a single center study, inclusion of limited number of patients and short follow up interval. This study has observed the association of few influential factors on fistula formation including gender, age and type of cleft. Future studies should investigate the other influential factors. There is a need to have a randomized controlled trial, multicenter study with a long duration of follow up.

CONCLUSION

The frequency of palatal fistula in our study is 15.5%; showing less fistulae occurrence before the age of 18 months. There are more chances of developing type V fistula in cases of complete cleft palate. We highly recommend the two-flap palatoplasty closure results in less chances of palatal fistula formation.

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