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FREQUENCY OF ORO-NASAL FISTULA AFTER BARDACH REPAIR IN CLEFT PALATE PATIENTS

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ABSTRACT

Background: Cleft lip and palate are common craniofacial defects requiring complex surgical repair. Oro-nasal fistulae are a known complication of cleft palate surgery, particularly using the Bardach technique. This study aims to determine the incidence of these fistulae following cleft palate repair using this method.

Methods: A prospective study was conducted from August 2020 to February 2021 on 138 children undergoing primary cleft palate repair using the Bardach technique. Inclusion criteria included age between 6 and 24 months, while patients with previous cleft surgery or other craniofacial anomalies were excluded.

Results: The study included 138 patients aged 6-24 months undergoing cleft palate repair. Oro-nasal fistula developed in 11% of patients, with a higher incidence in males and those with complete cleft palate. No significant difference in fistula rate was found between age groups.

Conclusion: Oro-nasal fistula developed in 11% of cases, male patients with complete cleft palate showing higher incidence. Multilayer repairs were successfully provided by the two-flap palatoplasty (Bardach Technique).

Keywords: Bardach repair, Oro-nasal fistula, Cleft Palate.

Introduction:

The most prevalent congenital craniofacial defects that plastic surgeons treat are cleft lip and palate. Technical proficiency, a thorough understanding of the aberrant anatomy, and an awareness of the three-dimensional facial aesthetics are necessary for the successful treatment of these patients. In unilateral complete cleft palate there is a connection between the nasal and oral canals all the way to

the labial-gingival fold. The objectives of repair are to make a shelf between the two cavities and cover the fissure with a fused flap **(1).**

Although it is typically a single congenital anomaly, cleft palate can be linked to several other syndromes. The most common risk factor is consanguinity among parents. Cleft lip is more prevalent than cleft lip/palate, yet the two conditions are not the same; cleft lip is distinct from cleft lip and palate **(2)**. Cleft palates can be repaired using a variety of methods, such as double opposing Z-plasty, push back palatoplasty, and two flap palatoplasty (Bardach Technique). The ideal window of time for cleft palate repair is between six and eighteen months of age **(3)**. Following cleft palate repair, bleeding, airway obstruction, infection, dehiscence, and the development of Oro-nasal fistulae are common complications. Palatal fistulae may develop at any point along the cleft closure trajectory **(4).** It may result in symptoms including trouble speaking and fluid reflux from the nose. The size of the cleft palate, the patient's age at palatal closure, and the experience of the operating surgeon all influence the frequency of fistula formation **(5)**. The best defense against fistula formation is meticulous surgical technique to produce well-perfused flaps that are gently approximated without any tension. After cleft palate repair, about 5–20% of patients develop palatal and nasolabial fistulae, which are typically surgically repaired. Another recent study found that during the 3-week follow-up, the incidence of Oro-nasal fistula was 12.8%. A key factor in getting the best possible clinical outcome after palate repair in pediatric patients is the parents role in active monitoring of their infants (**4,5).**

Our study's goal is to ascertain how frequently Oro-nasal fistulas arise in cleft palate patients following palate surgery utilizing Bardach's approach.

Methods

This study was conducted from August 14, 2020, to February 13, 2021at the Department of Plastic & Reconstructive Surgery, PGMI/Hayatabad Medical Complex, Peshawar. Sample size included 138 patients, which was determined by the WHO formula with a 5% margin of error, a **(6)** 95% confidence range, and a 9.94% proportion of Oro-nasal fistula. Patients with sub-mucous cleft palate, alveolar clefts, previously repaired clefts , patients with oronasal fistulae and patients with co-morbid conditions were excluded from the study. The study included patients with cleft palate with or without cleft lip, those undergoing single stage Bardach's repair, patients aged between 6 months and 24 months, and patients of both gender.

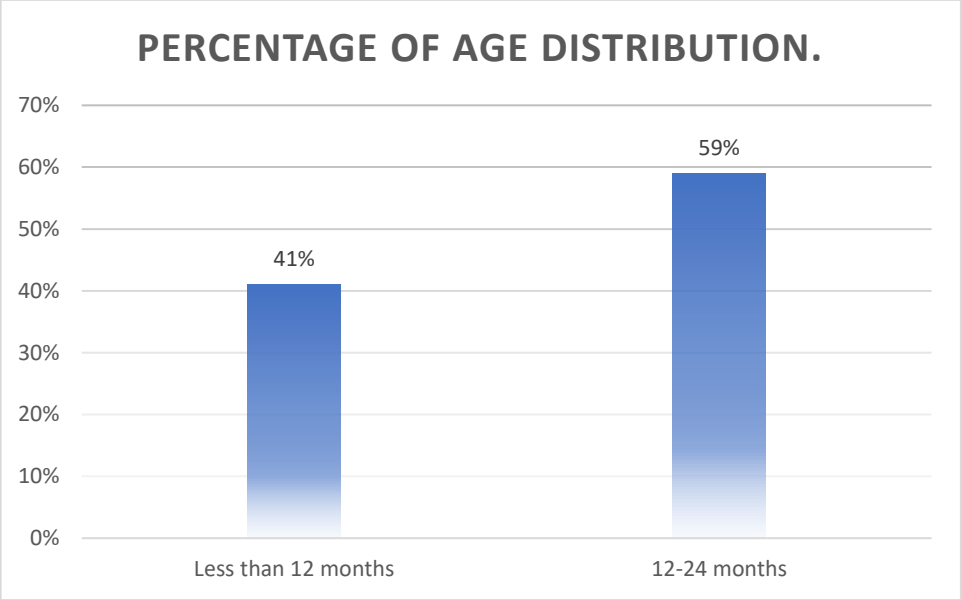
Patients who met the inclusion criteria and had a cleft palate deformity were recruited from the outpatient department after receiving approval from the Research Committee of the hospital. A thorough medical examination and history were obtained. The patients were admitted into plastic surgery ward. The parents of the patients were told about the procedure and the study protocols, and each parent provided signed informed consent. The day before the procedure, every necessary laboratory investigation was performed. A minimum of five hours were spent nil by mouth prior to surgery. Consultant Plastic Surgeon operated upon each patient. Under general anesthesia, a one stage, two-flap Palatoplasty utilizing Bardach repair was performed. All of the patients were prescribed oral antibiotics and analgesics after surgery. After that, patients were monitored for four weeks. Following four weeks, details including the patient's name, age, gender, weight at presentation, address, and procedure date were noted and documented. The predesigned pro forma was used to record the frequency of Oro-nasal fistulas.

SPSS version 25 was used to enter and evaluate the data. We computed descriptive statistics. For quantitative data such as age, mean and standard deviation were calculated; frequency distribution and percentages were used to show qualitative data, including sex, kind of cleft, and Oro-nasal fistula. To see the effect modifiers, Oro-nasal fistula was stratified by gender, age, and kind of cleft. Applying the post-stratification Chi square test, a significant P value of less than or equal to 0.05 was used. Tables and graphs were used to display the data.

Results

The age distribution of the 138 patients in this study was evaluated; 57 (41%) had ages under 12 months, and 81 (59%) had ages between 12 and 24 months. The mean age of repair was 14 months, with a standard deviation of ±5. **(Figure 01)**.

Figure 01 showing percentage of age distribution.



An analysis of the gender distribution of the 138 patients revealed that 37 (27%) of the patients were female and 101 (73%) of the patients were male **(Figure 02)**

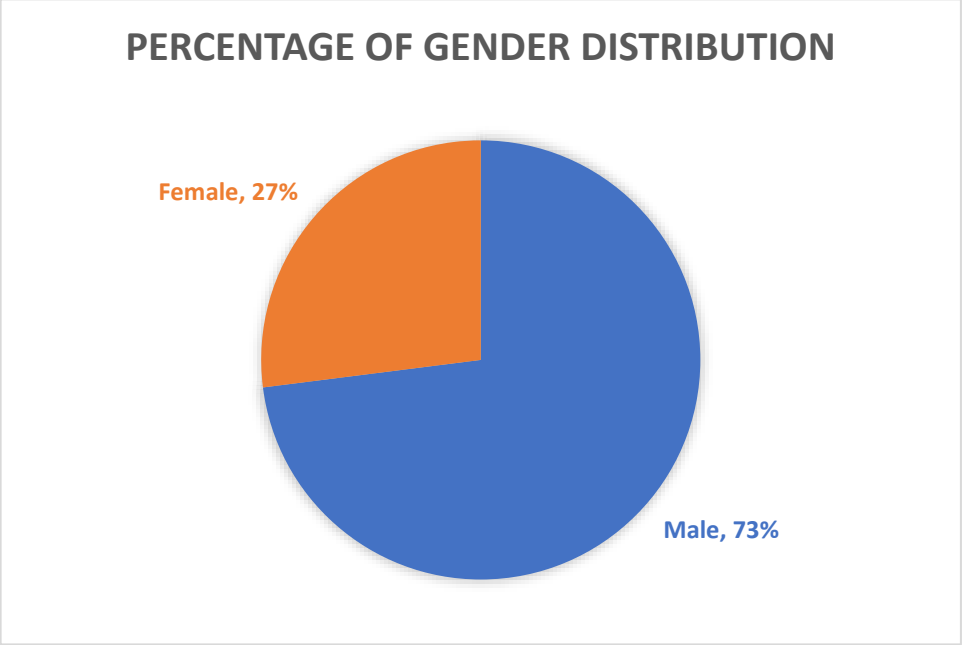


Figure 02 showing percentage of gender distribution.

Among the 138 patients, the type of cleft was examined; 54 (or 39%) had an incomplete cleft palate, and 84 (or 61%) had a complete cleft palate. **(Figure 03)**.

Figure 03 shows distribution of the type of cleft palate.

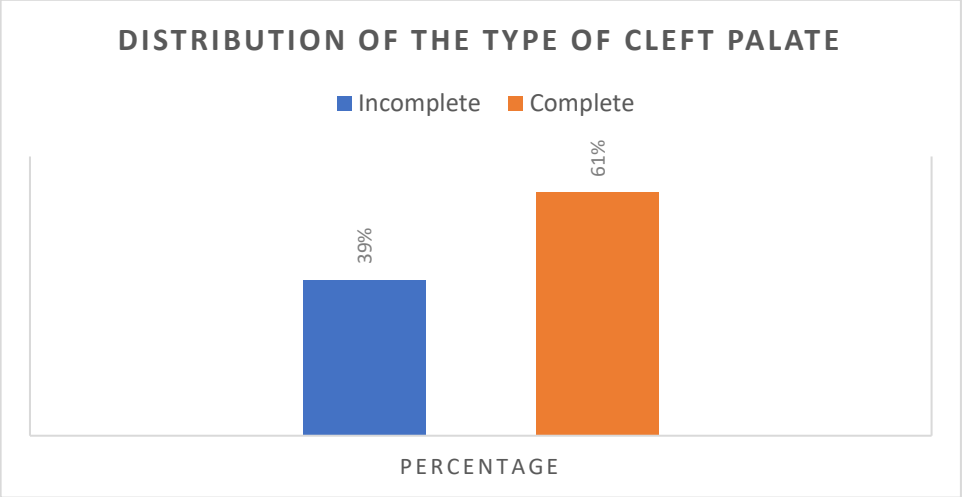


Figure 03 shows distribution of the type of cleft palate.

Analysis of 138 patients' Oro-nasal fistula revealed that 123 patients (89%) had no Oro-nasal fistula and 15 patients (11%) had post-operative Oro-nasal fistula. **(Figure 04)**

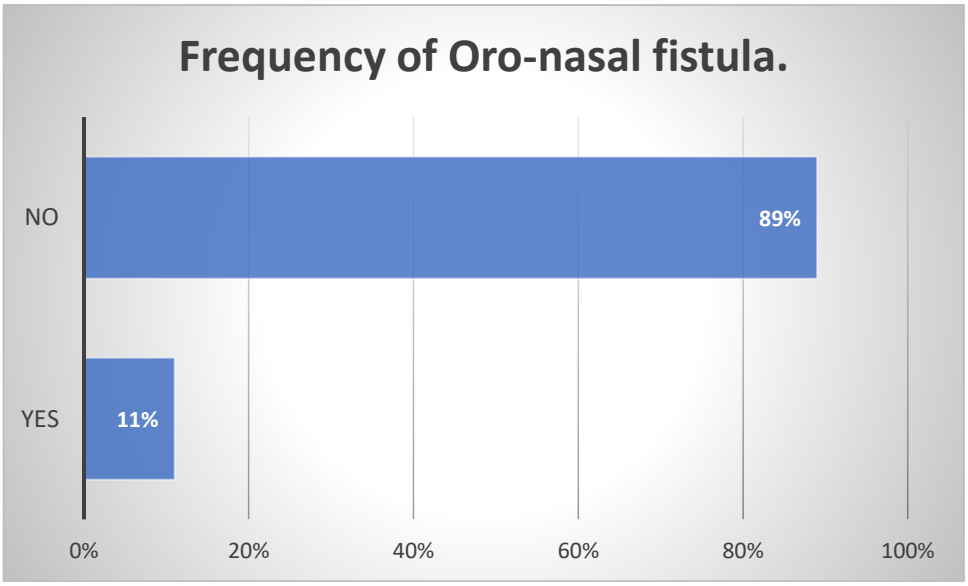


Figure 04 showing frequency of Oro-nasal fistula in percentages.

The age distribution of the stratification of post-operative Oro-nasal fistulas was investigated. Out of the 15 patients with post-operative Oro-nasal fistulas, 8 patients belonged to the age group of less than 12 months, and 7 patients to the age group of 12-24 months. **(Table 01)**.

Table 01 showing age with respect to post op Oro-nasal fistula.

Oro-nasal fistula	Less than 12 months	12-24 months	Total	P value
Yes	7	8	15	0.9684
No	50	73	123	
Total	57	81	138	

Twelve of the fifteen patients with Oro-nasal fistulas were male, and three were female. The stratification of post-operative Oro-nasal fistula with gender distribution was evaluated. **(Table 02).**

Table 02 showing gender with respect to post op Oro-nasal fistula.

Oro-nasal fistula	Male	Female	Total	p value
Yes	12	3	15	0.9466
No	89	34	123	
Total	101	37	138	

The analysis of post-operative stratification of Oro-nasal fistula with different types of clefts revealed that, out of 15 patients with Oro-nasal fistula, 6 had palate surgery for an incomplete cleft palate and 9 had palate repair for a complete cleft palate. **(Table 03)**

Table 03 showing type of cleft palate with respect to post op Oro-nasal fistula.

Oro-nasal fistula	Incomplete	Complete	Total	P value
Yes	8	9	15	0.9466
No	48	75	123	
Total	54	84	138	

Discussion

Currently, there is no conventional approach to treating cleft palate fistulae, and the results are frequently unsatisfactory **(7).** The main objectives of palatal repair are to minimize any negative effects on maxillofacial growth and to create a functional velopharyngeal system for the development of normal speech. Both of these goals are met by the two-flap palatoplasty (Bardach Technique), which emphasizes the following important ideas: minimizing the area of exposed hard palate bone to minimize any negative effects on maxillary growth, **(8)** closing the entire palatal cleft in a single operation, and extensive dissection of the abnormal velar muscle attachments, reorienting the muscles, and suturing them without tension are all necessary steps in the construction of an adequately functioning soft palatal muscular sling. Primary palatal repair remains unsuccessful due to palatal fistulas, even with advancements in cleft palate repair procedures. For cleft surgeons, the correction of cleft palates is a difficult scenario. Recurrence rates can reach 21 percent even with exacting skill.**(9)** A total of 138 patients were monitored in this study; 41% of the patients were between the ages of 12 and 24 months, and 59% of the patients were less than 12 months. The operation's mean age was 11 months, with a standard deviation of ±9.33. Of the patients, 27% were female and 73% were male. 61% of patients had a complete palate cleft, compared to more than 39% who had an incomplete cleft. 89% of patients did not have any postoperative fistulas, compared to 11% who had Oro-nasal fistulas following surgery. Patients who had two-flap palatoplasty surgery showed relatively low rates of velopharyngeal insufficiency and Oro-nasal fistula formation (5.7% and 8.6%, respectively) in a study by Black and Gampper **(10)**. 9.94% was the mean fistula rate following primary cleft palate repair in another study by Tache A et al. (**11)**. In terms of fistula formation, his study found no statistically significant differences between syndromic and non-syndromic patients, male and female patients, or between a single stage and two-stage palatoplasty. The time of the palatoplasty was not a significant predictor.

The hard and soft palates can be closed in two and three layers, respectively, using the two-flap palatoplasty (Bardach Technique). Bardach (1967) emphasized the need for early (before 12 months) tension-free closure of the whole palate **(12).** Furthermore, palatal lengthening was not necessary for speech; rather, the development of a muscular sling was. Early palate repair has been linked to improved speech development, according to several studies**. (9,13)** Additionally, 80% of kids who have a two-flap palatoplasty go on to have normal velopharyngeal function, according to Morris et al**.(12)** The level of comprehension and the intended postoperative care were not always met, which was one of the study's few weaknesses. This study did not note the effect of outcomes on the patient's speech. Three patients' follow-up visits were postponed because of travel concerns.

In an ideal world, a specialized cleft clinic would employ an interdisciplinary team of professionals to treat patients with clefts. In order to guarantee coordination and consistency in the delivery of care,

this team should adhere to the protocols established for similar groups. Assessments and treatments should be appropriately ordered based on the patient's medical and psychological requirements. The team has to include a craniofacial surgery qualified surgeon in order to reduce surgery-related complications, such as the establishment of an Oro-nasal fistula.

Conclusion

According to this study, 11% of patients who had two-flap Palatoplasty with Bardach repair developed Oro-nasal fistulas. Tension-free, multilayer repairs were successfully provided by the two-flap palatoplasty (Bardach Technique), which was used to repair a unilateral complete cleft palate by a single consultant surgeon.

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