

Frequency of Oronasal Fistulae in Complete Cleft Palate Repair

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ABSTRACT

Objective: To determine the frequency of oro-nasal fistula in patients undergoing complete cleft palate repair by two flap-palatoplasty.

Study Design: Case series.

Place and Duration of Study: Department of Plastic Surgery, Services Hospital, Lahore, from January to December 2013.

Methodology: Patients admitted to the study place for repair of cleft palate after informed consent obtained were included. Cleft palate was repaired by two-flap palatoplasty, using Bardach technique. Patients were discharged on the second post-operative day and followed-up at third week postoperatively. During follow-up visits, fistulae formation and their sites were recorded on pre-designed proforma.

Results: Among the total 90 patients, 40 patients (44.4%) were male and 50 patients (55.6%) were female. The mean age was 6.4 ± 5.7 years ranging from 9 months to 20 years. At third week follow-up, 5 patients (5.6%) had fistulae formation. Four patients (80%) had anterior fistulae and one patient (20%) had posterior fistula.

Conclusion: With two-flap palatoplasty Bardach procedure for repair of cleft palate, the complication of fistula formation was uncommon at 5.6%, provided the repair was tension free and multi-layered.

Key Words: Cleft palate. Two-flap repair. Oro-nasal fistula. Unilateral complete palatoplasty.

INTRODUCTION

Cleft lip and palate are the most common congenital craniofacial abnormalities treated by Plastic Surgeons. Successful treatment of these patients requires technical skills, in-depth knowledge of the abnormal anatomy, and appreciation of the three dimensional facial aesthetics. Unilateral complete cleft palate has communication between oral and nasal cavities upto labio-gingival fold on one side. To create shelve between the two cavities and to cover the cleft by fused flap are the goals of repair.¹

Cleft palate is generally an isolated congenital abnormality but can be associated with multiple syndromes. Among the risk factors cousin marriages is a most frequent risk factor. Cleft lip is more common than cleft lip/palate and cleft lip alone is a different entity than cleft lip and palate combined.² Multiple techniques are available for the repair of cleft palate which include push back palatoplasty, two flap palatoplasty (Bardach Technique) and double opposing Z-plasty. The timing of cleft palate repair should be between 6 - 18 months of age.³

Common complication of cleft palate repair includes bleeding, respiratory obstruction, infection, dehiscence and oro-nasal fistulae formation. Palatal fistulae can occur at any site along the line of cleft closure.⁴ It may

cause symptoms such as speech problems, nasal regurgitation of fluids or difficulty with oral hygiene. The frequency of fistula formation is related to the severity of the cleft palate, age at palatal closure and also to the operating surgeon's experience.⁵ Meticulous surgical techniques to create well perfused flaps that are carefully approximated without tension is the best pre-requisite against fistula formation. Palatal and nasolabial fistulae occur in 5 - 20% patients after palatal surgery and is usually corrected by surgery.⁶ The incidence of oro-nasal fistula of 12.8% at 3 weeks follow-up has been reported in another recent study.⁷ Close monitoring of babies by the parents' participation plays very important role in achieving the best possible clinical outcome from palate repair in paediatric patients.^{4,5}

The "Two Flap Palatoplasty, Bardach Technique" is used in our setup for cleft palate repair. The purpose of this study is to calculate frequency of oro-nasal fistulae with this technique. This will prove to be extremely beneficial for the medical field and patients because by using this technique postoperative complication of fistula formation can be minimized.

METHODOLOGY

Study was conducted in the Department of Plastic Surgery, Services Hospital, Lahore, from January to September 2013. A total 90 patients were included in the study with 95% confidence level, 7% margin of error and taking expected percentage of oro-nasal fistula i.e 12.8% after 3 weeks of surgery in patient of cleft lip and palate. Study design is descriptive case series with non-probability purposive sampling technique. Patients with primary unilateral complete cleft palate on clinical

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assessment of either gender from 9 months to 20 years with Hb %age > 9 gm/dl, were included in the study, while those with unilateral incomplete, bilateral, soft palate and secondary clefts were excluded.

Patients were admitted in Plastic Surgery Department of Services Hospital, Lahore, for repair of cleft palate who fulfilled the inclusion criteria and informed consent was obtained. Cleft palate was repaired by two flap palatoplasty, Bardach technique. Patients were discharged on 2nd postoperative day and were followed-up at 3rd week postoperatively. At follow-up visits fistulae formation and its site were seen and all these information were recorded on pre-designed proforma.

The quantitative variables including age were presented as mean and standard deviation. The qualitative variables including gender and fistulae formation were presented as frequency and percentages and site of fistulae formation were also presented by frequency and percentage.

RESULTS

In this study, 90 patients were included. Regarding the age distribution, 40 patients (44.4%) were between 9 months to 1 year, 15 (16.7%) were between 1 to 5 years, 20 (22.2%) were between 6 - 10 years and 15 (16.7%) were between 11 - 20 years. The mean age was 6.4 ± 5.7 years. Regarding gender, 50 patients (55.6%) were female and 40 patients (44.4%) were male. Post-operative fistula formation was noted in 5 patients (5.6%) and the remaining 85 patients (94.4%) were not having palatal fistula. The fistula was located anteriorly in 4 patients (80%) and posteriorly in one patient (20%).

DISCUSSION

The treatment of cleft palate fistulae is currently unstandardized, and the outcome is often unsuccessful.⁸ The primary goals of palatal repair are to provide a functional velopharyngeal mechanism for the development of normal speech and to minimize any detrimental effects on maxillofacial growth. The two-flap palatoplasty (Bardach Technique) addresses both these objectives by emphasizing the following key points:⁹ construction of an adequately functioning soft palatal muscular sling is essential, by extensive dissection of the abnormal attachments of the velar muscles, reorienting the muscles, and suturing them without tension; minimization of the area of exposed bone of the hard palate to reduce any adverse effects on maxillary growth,¹⁰ and complete closure of the entire palatal cleft in a single operation.

The relative importance of speech development versus optimization of maxillary growth continues to be debated. Proponents of delayed or staged palatoplasty believe that cleft palate repair itself is detrimental to growth.¹¹

The raw bony surface that remains after palatoplasty may cause alveolar collapse,¹² but good orthodontic care addresses this problem, and orthodontics is an important integral part of our multidisciplinary approach to the management of the cleft patient. Raising of mucoperiosteal flaps during palatoplasty, if done with good surgical technique and avoiding dissection in the space of Ernst, has minimal effect on sagittal growth of the maxilla.¹³

It appears that there may be the potential normal maxillary growth in unilateral cleft lip and palate patients, and early surgical repair of the cleft palate may affect sagittal maxillary growth pattern in patients with cleft lip and palate.¹⁴ The functional closure according to the technique by Delaire narrows the transverse dimensions of the maxilla, while simultaneously preserving initial sagittal growth.¹⁵ The vertical and transverse dimensions of the facial growth as well as incisor inclination were not affected significantly by Gingivoperiosteoplasty.¹⁶

Therefore, the primary goal of palatoplasty is to enable good speech development. The timing of palatal closure is critical, and the best time to achieve this is before the development of palate-related sounds, or the phonemic stage of development. It should be done as a single-stage procedure to obtain full closure of the entire palate to optimize speech outcome.

Children whose palates were repaired prior to the onset of speech production demonstrated significantly better speech than those whose palates were repaired between 12 and 27 months of age. The supposition that earlier palatal repair results in more normal speech development was, in fact, demonstrated in these cases.¹⁷ The delayed cleft palate repair led to worse speech outcomes; thus, the authors' center abandoned this technique in favor of single-stage repair. In addition, their data showed that the delayed cleft palate repair led to deleterious maxillary growth.¹⁸ That radical intravelar veloplasty may enhance the functional results of the two-flap palatoplasty (Bardach Technique) without increasing postoperative morbidity.¹⁹

Palatal fistulas are epithelialized openings within the repair between the mouth and nasal cavity, have significant functional consequences. Complication by a palatal fistula represents a technical failure resulting from poor wound healing, tension, or absent multilayer repair. Fistulae leak fluid and air; leaking air can cause a speech impediment because of nasal air escaping. Leakage of fluids from the nose can be embarrassing. Food particles that become lodged in these fistulas produce fetor oris. Avoidance of palatal fistulas in the treatment of cleft palates is critical because nearly 50% of children with fistulas require re-operation. Furthermore, the treatment of palatal fistulas has proved challenging; conventional methods of surgical closure

have reported success in only 35% of cases. Palatal fistulae occur in 5 - 20% patients after palatal surgery and oro-nasal fistula of 12.8% at 3 weeks follow-up.^{6,7} The low fistula rate of 4.5% with the two-flap palatoplasty technique discussed in this article is, therefore, noteworthy.

Two-flap palatoplasty remains a highly successful technique for closure of a variety of palatal clefts, with low fistula incidence. Surgical technique and experience are factors associated with low fistula incidence.²⁰ Emory *et al.* suggested age at repair as a factor in fistula formation, with a rate of 19.5% at 12 - 25 months of age compared with 7.7% at younger than 12 months. No significant difference was found between genders in terms of development of a CP fistula.

Emory *et al.* also found no association between CP severity and fistula formation. However, Cohen *et al.* reported that patients who developed CP fistulas had significantly more severe clefting, as assessed by the Veau classification, compared with patients without fistulae. Muzaffar *et al.* reinforced this finding in 2001, showing a statistically significant correlation between cleft fistula formation and severity of the cleft. Musgrave and Bremner found in a series of 780 procedures that if the CLP was bilateral, the chance of fistula formation (20%) was increased compared with unilateral CLP (7.7%) and CP (4.6%).²¹ Patient's age, experience of surgeon, and duration of surgery had no influence on the early outcome. High leucocyte count had a tendency for and reduced weight had a significant influence on fistula occurrence.²² Tension-free closure, lower risk of fistula, good restoration of velopharyngeal functions, ability to be performed on all types of cleft palate, ability to provide a good intraoperative exposure, and being a single stage seem to be the most important advantages of this technique.²³ In general, the recurrence rate of ONF is around 25%. With better technique and skill, the incidence and recurrence rate of ONF can both be minimized.²⁴

The two-flap palatoplasty (Bardach Technique) provides a two layer and three-layer closure of the hard and soft palates, respectively. In 1967, Bardach stressed the goal of tension-free closure of the entire palate at an early age (before 12 months).²⁵ Moreover, the creation of a muscle sling was essential to speech, not palatal lengthening. Several studies demonstrated improved speech development with early palatal repair.^{26,27} Furthermore, Morris *et al.* reported that 80% of children who undergo a two-flap palatoplasty develop normal velopharyngeal function.²⁵

In this study, Vicryl 5/0 was used for nasal layer, Vicryl 4/0 for muscle sling formation and Vicryl 4/0 for the oral layer closure, which theoretically resists untying and we used round body needles, which were less likely to lacerate, shred, and pull through the delicate mucosa in

these cleft-palate repairs. Mucoperiosteal flaps were mobilized by the adequate pedicle lengthening to avoid tension in the midline repair. Moreover, if closure of the lateral gutters seemed to produce tension in the midline of the repair or tenting of the flaps, they were left open. So we recommend that two-flap palatoplasty (Bardach Technique) is a best technique for the repair of cleft palate.

CONCLUSION

The experience of the two-flap palatoplasty (Bardach Technique) for the repair of unilateral complete cleft palate by single consultant surgeon was successful in providing tension-free, multilayer repairs.

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