Management of oronasal fistula in patients with cleft palate by double-flap technique: short-term follow-up

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Background
Cleft lip and palate is the most common congenital anomaly affecting the orofacial region. Palatal fistula is a challenging complication following repair of cleft palate. The purpose of the study was to check the efficacy of the double-flap technique in closure of postcleft oronasal fistula.
Patients and methods
A total of 24 patients with postcleft palatoplasty oronasal fistula, aged from 6 to 15 years, were included in this study. They were subjected to the double-flap technique for fistula closure. Follow-up was up to 6 months postoperatively for each patient. Proper healing and functional aspects were evaluated. Approval of the ethical committee has been obtained for this study.
Results
A total of 15 females and nine males with cleft oronasal fistula were included. The maximum width of fistulae ranged from 4 to 12 mm. Successful closure was achieved in 80% of patients, 10% of patients had reduction of fistula size, and 10% of patients had recurrent fistula. Six patients had anterior palatal fistula closure by double-flap technique, 13 patients had simultaneous alveolar bone graft, and 10 patients had lip splitting for layered closure of vestibulonasal fistula.
Conclusion
The obtained results support the double-flap technique for closure of oronasal fistula. It has many advantages as it is a single-stage procedure that can be done simultaneously with alveolar bone graft, from the same surgical field, and with less discomfort to the patient.

Keywords:
cleft, fistula, flap, palate, palatoplasty

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Introduction

Repair of postcleft palate fistula remains a challenging procedure. Wide clefts of the primary palate are prone to repair under tension, making them more vulnerable to postoperative oronasal fistula formation [1].

Secondary fistulae of the palate are not uncommon sequelae after repair of cleft palate. Fistulae can occur at any site along the line of repair. The recurrence rate, following cleft palate repair, ranges between 10 and 30%, depending on the age at the time of repair and surgical method of palatal repair [2].

Oronasal fistulae form due to failed healing or breakdown after healing. Occurrence or recurrence of oronasal fistulae is attributed to many factors such as repair under tension, hemorrhage, infection, compromised vascularity due to fibrosis or pedicle injury, and lack of adequate closure of the primary palate [3,4].

Small palatal fistulae have no symptoms, but larger fistulae may lead to speech problems including nasal emission, nasal regurgitation of liquids, and inflammatory irritation. Some surgeons report that oronasal fistulae lead to detrimental effects on the function of the palate, leading to velopharyngeal incompetence and malodor due to impacted foods [5,6].

Treatment of postcleft palate oronasal fistulae could be conservative for minute nonsymptomatic fistulae, simple procedure, or a great challenge. If it is not feasible to close the fistula using adjacent tissues directly, then tissue will need to be displaced from a neighboring area, for example, vomer flaps, transposition flaps, double-palatal flaps, total palatal redo surgery, tongue flaps, combination of pharyngeal, tongue, temporal muscle flaps, and free tissue transfer as radial forearm free flap [7]. Moreover, attempts have been made to use

synthetic biomaterials that can help decrease incidence and recurrence of postoperative oronasal fistulae [8].

Patients and methods

This prospective study included patients with postcleft oronasal fistula, from May 2017 to May 2021, to Oral & Maxillofacial Department, King Fahd Specialist Hospital, Buryada, Qassim Province, Saudi Arabia. Cases with noncleft palatal fistulae, those with asymptomatic fistulae, and those whose parents refused to be included in research work were omitted from this study. Parents of all patients signed routine informed consent after explanation of the technique and its possible complications. Another consent was signed for the possible use of patient's data for research work.

A total of 24 patients with postcleft oronasal fistula were included in this study.

Full history was obtained. Detailed clinical and radiographic examination were done for all patients. Postoperative complications were recorded.

Surgical technique

All patients were operated under general anesthesia with oral endotracheal tube. Patients were prepared for intraoral surgery.

Draping, application of Dingman's retractor, and local infiltration by 1% lidocaine in 1 : 200 000 adrenaline were done. Injection facilitates mobility of the flaps, which will be mobilized to seal the fistula. Lateral relaxing incisions were extended along the gingival border to the posterior end of the fistula, followed by vertical incision along the fistula edges and raising of the mucoperiosteal flaps on both palatal fistula sides for wide exposure of the fistula.

Sharp division of the nasal and oral mucosa at the fistula in the plane of the palatal bone was done, and then the nasal layer was sutured as a separate layer, followed by tension-free closure of the palatal mucoperiosteal flaps with interrupted vicryl sutures.

In case of a large vestibulonasal fistula, lip splitting was done to seal the fistula using bilateral mucosal flaps with gingival extension. Patients having associated alveolar bone defect had iliac bone graft at the same session. Patients with bilateral cleft fistulae were operated starting with the wider side followed by the narrower one after 3 months. Perioperative broad-spectrum antibiotics and analgesics were continued for 1 week postoperatively. Patients were instructed to maintain soft diet for 1 month postoperatively. Postoperative follow-up was performed at 1 week, 1 month, 3 months, and 6 months after surgery. In case of fistula recurrence, additional follow-up was performed, and patients were shifted to other techniques as complete palatal redo procedure (Figs 1–4).

Results

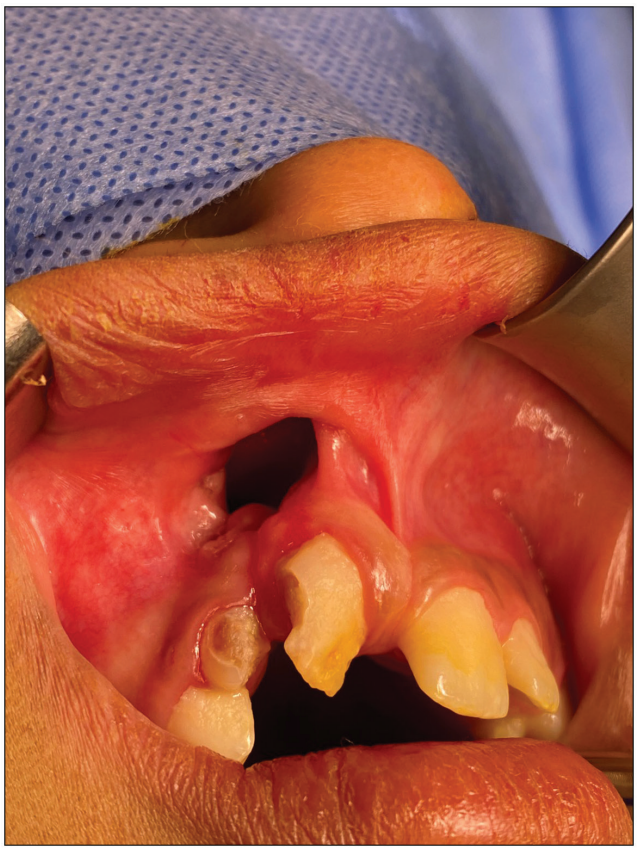
A total of 24 patients, comprising 15 females and nine males, with cleft oronasal fistula were included in this study. There were five bilateral and 19 unilateral (12 left sided, seven right sided), with a total number of 29 palatal fistulae (n=29).

Their age ranged from 6 to 15 years. The maximum fistula width ranged from 4 to 12 mm. All patients had their cleft palate repaired via von Langenbeck palatoplasty technique, which is the standard procedure in our hospital.

All included patients were free from systemic diseases.

Palatal fistulae were classified according to their sites into anterior palatal (6/29), alveolar (13/29), and vestibulonasal (10/29).

Figure 1

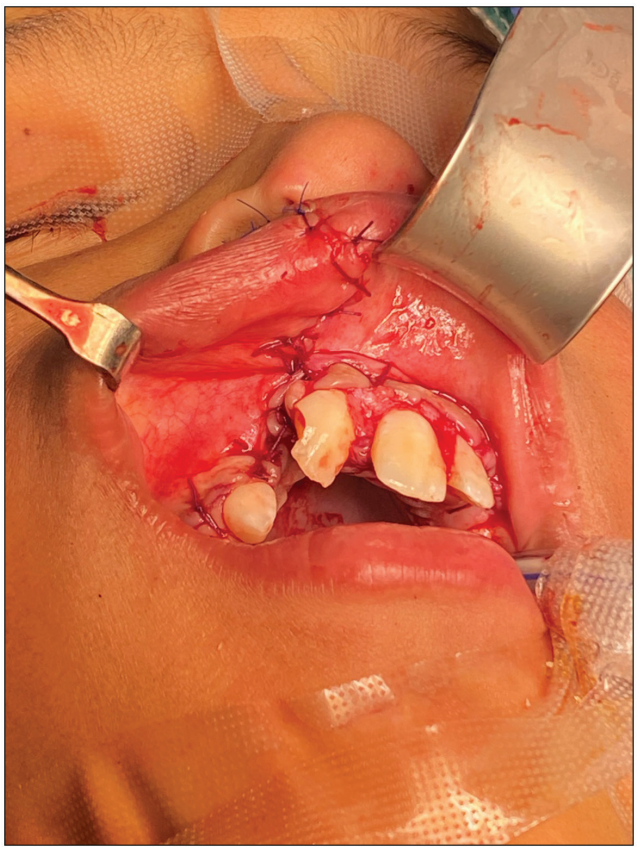


Preoperative postcleft vestibulonasal fistula.

Figure 2

Intraoperative flap design after lip splitting.

Figure 3



Intraoperative fistula closure.

Figure 4

Complete closure at 1 month postoperatively.

A total of 13 patients had alveolar bone graft at the same time for alveolar cleft, and 10 patients had lip splitting for closure of vestibulonasal fistula.

Overall, 23 patients had complete success (complete fistula closure), three patients had reduction of width but still recurrent fistula, and three patients had complete failure with recurrent fistula by the same width.

In this study, there were no reported cases of significant postoperative bleeding, infection, or flap necrosis.

Table 1 summarizes our patient's data and the statistics done.

The data were fed to the computer and analyzed using IBM SPSS software package, version 20.0. (IBM Corp., Armonk, New York, USA). Categorical data were represented as numbers and percentages. χ^2 test was applied to compare between different groups for categorical variables. Alternatively, Monte-Carlo correction test was applied when more than 20% of the cells have expected cell count less than 5. For continuous data, they were tested for normality by the Shapiro–Wilk test. Quantitative data were expressed as range (minimum and maximum), mean, SD, and median for

Table 1 Comparison between the different studied groups according to demographic data

	Total (*N*=29)	Failure (*N*=3)	Reduction (*N*=3)	Success (*N*=23)	Test of significance	*P*
Age (years)						
Mean±SD	9.7±2.6	13.3[a]±1.5	11.3[ab]±1.5	8.96[b]±2.3	*F*=6.303*	0.006*
Median (minimum–maximum)	9 (6–15)	13 (12–15)	11 (10–13)	9 (6–14)		
Significance between groups		P_1=0.510, P_2=0.008*, P_3=0.199				
Sex [*n* (%)]						
Male	12 (41.4)	3 (100)	1 (33.3)	8 (34.8)	χ^2=4.318	^{MC}P=0.144
Female	17 (58.6)	0	2 (66.7)	15 (65.2)		
Site [*n* (%)]						
Right	12 (41.4)	2 (66.7)	0	10 (43.5)	χ^2=2.624	^{MC}P=0.280
Left	17 (58.6)	1 (33.3)	3 (100)	13 (56.5)		
Type [*n* (%)]						
Alveolar	13 (44.8)	2 (66.7)	2 (66.7)	9 (39.1)	χ^2=2.009	^{MC}P=0.859
Anterior palatal	6 (20.7)	0	0	6 (26.1)		
Vestibulonasal	10 (34.5)	1 (33.3)	1 (33.3)	8 (34.8)		
Width (mm)						
Mean±SD	6.6±2	8.3[a]±2.1	7.7[a]±2.3	6.3[a]±1.9	*F*=1.924	0.166
Median (minimum–maximum)	6 (4–12)	9 (6–10)	9 (5–9)	6 (4–12)		

Means with common letters are not significant (i.e. means with different letters are significant). χ^2, χ^2 test; MC, Monte-Carlo. *F*: *F* for one-way analysis of variance test, pairwise comparison between each two groups was done using post-hoc test (Tukey). *P*: *P* value for comparing between the studied groups. P_1: *P* value for comparing between failure and reduction. P_2: *P* value for comparing between failure and success. P_3: *P* value for comparing between reduction and success. *Statistically significant at *P* value less than or equal to 0.05.

normally distributed quantitative variables. One-way analysis of variance test was used for comparing the three studied groups followed by post-hoc test (Tukey) for pairwise comparison. Significance of the obtained results was judged at the 5% level.

Statistical analysis revealed that a higher success rate is associated with younger patients.

Discussion

Up till now, surgical repair of cleft palate is considered a big challenge in reconstructive surgery. A successful palatal repair includes normal speech without increasing of maxillary growth disturbances. Occurrence of a fistula after surgery clearly compromises these goals [9].

Most common cause of cleft palate oronasal fistula is primary palatal repair under tension with incomplete mobilization of the mucoperiosteal flaps. Postoperative infection is another common cause. Other factors that may lead to development of oronasal fistula include inadequate hemostasis, excessive diathermy use, failure to get a two-layered closure, and poor handling of tissues [10].

The choice of repairing method for cleft palate oronasal fistula depends on site, size, and severity of the fistula. Other factors to be considered before planning treatment option include the previous surgical repair technique, presence of inflammation, amount of scarring, available local tissues, presence of velopharyngeal incompetence, and need for alveolar bone grafting [11,12].

In this study, the two-flap technique, which is considered a modification of the classic palatal island flap used for cleft palate closure, was used. For fistulae extending to the alveolar margin, we used alveolar extension of the flaps with interdental sutures, to seal the whole palatal raw area, which is the same procedure as described by Denny and Amm in their series [2].

Alveolar fistulae with anterior palatal extension required combined buccal and palatal flaps associated with iliac bone grafting, which is the same technique described by Jackson [13]. For the large vestibule-nasal fistulae, we did lip splitting which has the advantages of helping the creation of the nasal floor, helping layered fistula closure, facilitating nostril width adjustment, and revising the lip scar.

In this study, 23 (80%) patients had success with complete fistula closure; three (10%) patients had reduction of fistula size, where one patient had asymptomatic fistula and was managed conservatively and the other two patients were managed by redo technique; and three (10%) patients had failure with recurrent fistula, who were treated by revision surgery.

From the statistics, we found better results with younger age (significant *P* value for age), meaning that it is much better to close palatal fistulae early. From these results, we found that age of the patient and experience of the surgeon are important factors for successful fistula closure.In comparison with the tongue flap, the double-flap technique avoids many disadvantages of the tongue flap, such as being a two-staged procedure, difficulties of intubation and extubation, postoperative

tongue deformity, risk of premature flap separation due to tongue movement, and possible postoperative respiratory complications [14].

This study has a limited sample size. A large sample-sized prospective comparative study is still needed to get more accurate results about the best technique to be used to close anterior palatal fistulae.

Conclusion

Postcleft oronasal fistula is an indication for surgical interference. Double-flap procedure is successful for closure of medium-to-large size cleft palate oronasal fistulae (5–10 mm). Double-flap procedure is well tolerated by the patient, with early ambulation, and little reported complications.

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Conflicts of interest

There are no conflicts of interest.

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