Evaluation of Double-Layer Closure Of Anterior Palatal Fistula in Secondary Management Of Bilateral Cleft Lip And Palate

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Abstract

**Purpose:** To assess the clinical outcomes of a therapeutic protocol for anterior palatal fistula (APF) management by double-layer closure using premaxillary palatal flap (PPF) in BCLP patients who underwent primary premaxillary setback.

**Methods:** Using a prospective study design, the investigators enrolled 12 BCLP patients who underwent premaxilla setback procedure attended to repair their residual anterior palatal fistulas. Each fistula was closed surgically using premaxillary palatal flap (as a nasal layer) and cover it with lateral palatal flaps (as an oral layer). The primary study variable was the clinical outcome which classified as good: (complete fistula closure with no symptoms occurred) and bad: (residual or recurrent fistula with persistent symptoms). To measure the relationships between the clinical outcome and patient's sex or fistula's size, chi-square test was performed. (P value was set as 0.05).

**Results:** The sample was composed of 12 BCLP patients with APF. 11 patients showed successful fistula closure (91.7%) and 1 patient partially presented with recurrent fistula (8.3%). There was no statistically significant association between patient's sex or fistula's size and the clinical result.

**Conclusions:** The results of this study suggest that PPF provided a good barrier aiding in closure of APF in BCLP patients.

**Keywords:** Bilateral Cleft Lip And Palate; Anterior Palatal Fistula; Oronasal Fistula; Premaxilla Setback; Premaxillary Palatal Flap; Double-Layer Closure.

Introduction

Palatal fistula is one of the most common problems in cleft palate surgery. It describes an unrepaird cleft palateor a resultant of failure in primary closure [1]. A symptomatic palatal fistula affects patient's quality of life and present nasal regurgitation of air, food, and liquid [2]. As a result, patients can have difficulty with eating, drinking, and speech [3, 4]. Treatment options include non-surgical treatment by obturators and surgical repair techniques which vary from local flaps to regional flaps to using graft materials [5-9].

Local flaps techniques are dependent on utilizing mucosa surrounding the fistula itself. One of these approaches is to reflect the premaxillary palatal mucosa in order to achieve nasal layer closure and reflect the lateral palatal mucosa in order to achieve oral layer closure. Rahpeyma et al used the palatal premaxillary mucosa for reconstruct nasal floor in fistula region [10]. Double-layer closure is considered the gold standard in achieving successful fistula closure and providing maximum isolation between nasal and oral cavities [11].

In general, high failure rates after palatal fistula closures have been reported in the literature and range from 33% to 50% [6, 7, 12-14]. Many factors of failure have been reported including tension along the fistula repair, infection, hemorrhage, single-layer closure, and compromised vascularity of flaps [8, 15].

Persistent anterior palatal fistula is particularly challenging to repair [16-18]. It has the highest failure rate in bilateral cleft palate patients [6, 13]. Due to lack of adequate surrounding tissue [8], Vomerine ostectomy and premaxillary setback may be useful for surgical repair of these cases [19].

The purpose of this study was to assess the outcomes of a therapeutic protocol for the management of persistent anterior palatal fistula in secondary management of bilateral cleft lip and palate.
tal fistula after double-layer closure using the premaxillary palatal flap.

Materials and Methods

This study was conducted at oral and maxillofacial surgery department, Tishreen university hospital, Latakia, Syria from January 2017 to March 2020. It was approved by the Tishreen university IRB and all participants signed an informed consent agreement. Informed consents were taken from patients’ parents. Twelve patients with confirmed diagnosis of symptomatic anterior palatal fistula were included in the current study. Clinically significant fistula was identified by the presence of either hypernasality or fluid regurgitation from the nose. The exclusion criteria were: unilateral cleft lip and palate, syndromes or associated malformation. All operations were conducted by one surgeon.

The sample consisted of seven males (58%) and five females (42%). The age ranged from 3 to 8 years, with a mean age of 5.75 years. The size of each fistula was graded as small [<3mm] (17%), medium [3-5mm] (50%), and large [>5mm] (33%). Statistical analysis was performed using chi-square test to assess the effects of sex and fistula's size on the clinical result of fistula's closure.

The procedures were undertaken under general anesthesia. Incisions were made along the fistula margins, and the palatal mucosa were elevated from the premaxilla and turned over the fistula (nasal layer). The lateral palatal flaps were closed with sutures (oral layer). In all patients, a good watertight double-layered closure was achieved without any tension applied. An acrylic plate was used for a week after the surgical closure. Liquid/soft diet was instructed for patients for the first two weeks. Patients were followed up for six months and assessed with respect to infection, dehiscence, and persistent fistula.

The current study primary outcomes were: fistula closure, sufficient covering mucosa, and the clinical signs and symptoms (fluids leakage, foul smell, recurrent fistula, residual fistula opening and the need for additional surgical closure). The outcomes were classified as good: (complete fistula closure with no symptoms occurred) and bad: (residual or recurrent fistula with persistent symptoms).

Results

A total of twelve patients; seven males [58%] and five females [42%] (Fig:1), with symptomatic anterior palatal fistulae were included in the study. Two fistulas were classified as small [17%], six as medium [50%], and four as large [33%] (Fig:2). All patients had persistent symptoms like nasal regurgitation of fluids, halitosis, recurrent infection, or hypernasality.

Eleven patients showed successful fistula closure [91.7%] after the double-layer closure with sufficient mucosal thickness covering the fistula area (Fig: 3, 4, 5, 6). No signs or symptoms were observed. One patient partially presented with recurrent fistula. The rate of fistula recurrence was [8.3%].

Chi-square test was performed to measure the relationships between the clinical outcome and patient’s sex or fistula’s size. There was no statistically significant association between patient’s sex or fistula’s size and the clinical result (P value = 0.05).
Discussion

Anterior palatal fistula is one of the most difficult sequelae to treat due to limited availability of surrounding healthy mucosa for adequate flap mobilization and tension-free closure [20-23]. It leads to functional problems like nasal regurgitation of fluids and food particles, nasal twang, and malodor [8, 15]. The indications for fistula repair relate to the associated symptoms which related to the size and location of the fistula [12]. These symptoms have been extensively discussed elsewhere [5, 13].

Various methods have been advocated in order to facilitate the treatment and increase success rate. These include nonsurgical techniques utilizing palatal appliances [24] and surgical techniques involving mobilization of surrounding tissues, mucoperiosteal flaps with and without turn-over double layer flaps, revision of the primary palate repair with or without addition of a vomer flap, hinge flaps, vestibular mucosal flaps, tongue flaps, bone grafting, maxillary down fracturing, Le Fort I osteotomies with labial mucosal flaps, free radial forearm flaps for large or difficult fistulas, and tissue expansion [5, 6, 13, 14, 25-27]. Regardless of the method of fistula repair, recurrence rates have generally been disappointing, with Cohen et al reporting a rate of 37% [6]. However,
Emory et al has reported successful closure of fistulas in 91% of cases [20]. The success rate which is reported in the current study (91.7%) is higher than previous studies.

Any unnecessary palatal dissection can compromise the vascularization of sutured mucosa and, consequently, result in early dehiscence with possible flap detachment and the resulting defect would be much larger than the initial defect [28]. A very high failure rate has been associated with attempted palatal fistula repair, sometimes as high as 65% [25]. This failure rate seems to increase with increasing attempts at repair [25]. Limited tissue availability, scarred adjacent mucosa, poor blood supply and early wound contraction often lead to fistula recurrence [8]. Closure with one well-vascularized layer provides better results than that with two poorly vascularized layers, which was shown by Cohen et al [6]. A few authors had done a single-layer closure but it was not accepted by the most surgeons [29]. The closure of nasal layer has been judged as an essential step in repair of palatal fistula [21,23,30]. It inhibits recurrence of fistula in the case of necrosis or detachment of flaps [10]. Local turns down flaps are the most recommended way for fabricating nasal floor [31].

Freda et al [11] described a technical strategy for APF closure with local flaps. They used a combination of three flap designed, and they did not report any isolated success rate for the group of patients who treated with double-layer flap. The sample consisted of patients treated with single-layer closure which could decrease the overall success rate.

In a retrospective study conducted by Mahajan et al [32], the authors concluded that tongue flaps were better than local flaps for managing APF in the difficult and challenging situations. There was a high correlation between the reported complications and the size of the fistula. In the present pilot study, we divide the sample into three categories according to fistula size and there was no significant association between fistula recurrence and size of the APF.

Free tissue transfer had drawbacks of donor-site morbidity, increased surgical time, increased reliance on patient compliance in the postoperative period, increased discomfort to patients, and need for a second surgery for division and inset [7-9].

Sohail et al [33] compared the mean of surgical time between facial artery myomucosal flap (155±38 minutes) and tongue flap (242±10 minutes). The mean of surgical time in our technique was 30 minutes.

In authors’ experience, when a bilateral cleft lip and palate with protruded premaxilla, it might not be possible to achieve an anterior palatal fistula closure. However, early premaxilla setback in primary palatoplasty is helpful for providing adequate surrounding tissues to achieve nasal layer closure using premaxillary palatal flap (PPF) in these cases.

The approach to bilateral cleft palate treatment was discussed in this study. The treatment protocol entails premaxilla setback with simultaneous cleft lip repair at the first stage, and cleft palate repair with fistula closure at the second stage. The result is a considerable narrowed palatal cleft which requires less extensive procedure for closure at the second stage. This treatment proto-
col has played a significant role in minimizing the palatal fistula.

To our knowledge, previous reports of cleft palatal fistula do not include patients treated by a two-stage palatoplasty protocol similar to ours [1, 5, 6, 13, 24-26].

This study observed that PPF provided a good barrier aiding in closure of APF. A patient non-compliance and improper postoperative oral hygiene probably led to the closure failure.

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