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Incidence of Palatal Fistula at Time of Secondary Alveolar Bone Grafting

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Abstract

Objective—We aim to establish consistent time points for evaluating palatal fistula incidence to standardize reporting practices and clarify prospective literature.

Design—An institutional retrospective chart review was conducted on 76 patients with unilateral or bilateral complete cleft lip and palate who underwent secondary alveolar bone grafting between 2006–2015.

Main Outcome Measures—Early fistula incidence rates were reported prior to maxillary expansion, and late fistula rates were reported at the time of alveolar bone grafting. Fistula recurrence rates after primary repair were also measured.

Results—We found an early fistula incidence rate of 20% (n=15) and a late fistula rate of 55% (n=42) at the time of secondary ABG. Fistulae recurred after initial repair in 43% of cases. Fistulae were classified using the Pittsburgh Classification System as type III (33%), type IV (60%), or type V (7%). The presence of a bilateral cleft ($p=0.01$) and history of early fistula repair ($p<0.01$) were associated with late fistula incidence in a univariate analysis. In a logistic regression model, only early fistula repair was associated with late fistula incidence (OR=17.17) and overall likelihood of recurrence (OR=70.89).

Conclusions—Early fistulae should be reported immediately prior to orthodontic expansion of the maxillary arch. Late fistulae should be reported at the time of ABG, following palatal expansion. Patients who develop an early fistula after palatoplasty are likely to experience recurrent fistula formation.

Keywords

Cleft lip and palate; cleft palate fistula; alveolar cleft reconstruction; alveolar bone grafting

Introduction

Cleft lip and palate are among the most common birth defects in the world, occurring in approximately 1 out of every 500–550 live births (Ahmed et al., 2015). Early repair of a palatal cleft promotes the normal development of speech, hearing, and swallowing in an affected child (Rohrich et al., 2000; Sousa et al., 2009). Palatal fistulae are a potential complication of primary cleft palate repair, resulting from impaired wound healing or tissue breakdown along the surgical site. The reported incidence of palatal fistulae ranges from 0–78%, with recurrence rates after repair varying between 10–65% (Muzaffar et al., 2001; Ahmed et al., 2015; Hardwicke et al., 2014). This variability is a reflection of broader ambiguity in the literature with regard to the definitions, classification schemes, and reporting time points for postoperative fistulae (Smith et al., 2007; Cohen et al., 1991; Schultz, 1986).

The development of a fistula is influenced by many factors, including the extent and diameter of the initial cleft, achievement of tensionless repair, and perioperative control of bleeding and infection (Eberlinc and Kozelj, 2012; Lithovius et al., 2014; Hardwicke et al., 2014). Other variables such as surgeon experience, type of palatal closure, and patient age at palatoplasty, have also been implicated in fistula formation (Rohrich and Gosman, 2004; Cohen et al., 1991; Schultz, 1986). Although small fistulae are often asymptomatic, larger defects can lead to hypernasal speech or oronasal regurgitation of food and liquid. Failure to repair these symptomatic fistulae can affect normal development, leading to maladaptive speech patterns or permanent hearing impairment (Hardwicke et al., 2014; Ahmed et al., 2015).

A lack of consensus in reporting practices and follow-up time for postoperative fistulae contributes to an underreporting of true incidence and limits the validity of the current literature (Smith et al., 2007). Our study aims to establish consistent time points for reporting fistula incidence in order to standardize the literature and clarify future studies. Our secondary objective is to identify predictors of fistula formation and recurrence.

Methods

A retrospective chart review was conducted on 81 consecutive patients with unilateral or bilateral complete cleft lip and palate who underwent secondary alveolar bone grafting (ABG) between 2006–2015. All patients in this series received care from two craniofacial surgeons at St. Louis Children's Hospital at Washington University in St. Louis. Although exact techniques of fistula repair differed between these surgeons, closure was generally achieved through re-elevation of palatal flaps. A total of 76 patients were included in the study; five patients were excluded due to incomplete medical records or insufficient follow-up. Insufficient follow-up was defined as fewer than two postoperative examinations after ABG.

A palatal fistula was defined as any residual opening between the oral and nasal cavities along the primary surgical repair site. In accordance with earlier studies, fistulae anterior to the incisive foramen were excluded from our analysis, as it was difficult to reliably

determine from medical records whether these defects were intentionally left unrepaired (Muzaffar et al., 2001). Early fistulae were defined as any symptomatic or asymptomatic palatal defects that appeared prior to palatal expansion, including immediate postoperative fistulae. Late fistulae were defined as any newly identified palatal defects or any recurrence of previously repaired fistulae at the time of ABG. All fistulae were categorized according to the Pittsburgh Fistula Classification System as types III, IV, or V.

Collected variables included age at operation, gender, syndromic status, cleft type, presence and type of palatal fistula, symptoms prior to fistula repair, fistula repair prior to ABG (early fistula repair), and fistula recurrence after initial repair. Discrete and continuous variables associated with fistula formation and recurrence were analyzed using Fisher's exact and Student's *t* tests, respectively. Univariate relationships with $p < 0.05$ were considered statistically significant. Two logistic regression models were constructed to evaluate predictors of fistula occurrence and recurrence. Variables entered in the logistic regression models met the dual criteria of clinical relevance and $p < 0.20$ in the univariate analysis.

This study was reviewed and approved by the Washington University Institutional Review Board. Data were collected using the electronic medical records systems at Washington University in St. Louis and analyzed with IBM SPSS Statistics (version 23.0 for Windows; IBM Corp).

Results

Fistula Incidence and Recurrence

Seventy-six patients with unilateral (67%) or bilateral (33%) complete cleft lip and palate were included in the study. Median age at the time of alveolar cleft repair was 10.6 years, and mean age was 12.0 years. The early palatal fistula rate prior to maxillary expansion was 20% ($n=15$), and the late fistula rate at the time of secondary ABG was 55% ($n=42$). All fistulae extended from the alveolar cleft, and were classified using the Pittsburgh Fistula Classification System as type III (33%), type IV (60%), or type V (7%). [Figure 1; Table 1] 51% of patients with unilateral clefts developed a late fistula, most commonly at the level of the hard palate (78%) or hard/soft palate junction (22%). In comparison, 76% of patients with bilateral clefts developed a late fistula, appearing at the hard/soft palate junction (47%), hard palate (37%), or primary/secondary palate junction (16%). 74% of fistulae were diagnosed in clinic, but 26% remained occult until examination in the operating room. The overall fistula recurrence rate at any time point after initial repair was 43% ($n=18$). Type V fistulae (67%) were more likely to recur than type III (57%) or type IV (32%).

Univariate Analysis

Patients with a complete bilateral cleft lip and palate were more likely to develop a fistula than those with a unilateral cleft ($p=0.01$). Children who experienced early fistula formation prior to palatal expansion were more likely to have a fistula during ABG compared to those without early fistula formation ($p < 0.01$). Late fistula occurrence was not associated with patient age at ABG ($p=0.05$), sex ($p=1.00$), or syndromic status ($p=0.50$). [Table 2] Patients with early fistula formation were more likely to experience recurrence than patients whose

first fistula was identified after maxillary expansion ($p<0.01$). Fistula recurrence was not associated with patient sex ($p=0.30$), syndromic status ($p=0.50$), operating surgeon ($p=0.15$), type of cleft ($p=0.35$), or type of fistula ($p=0.20$). [Table 3]

Logistic Regression Modeling

A forced-entry logistic regression model including age, cleft type, and history of early fistula formation and repair was constructed to predict late fistula occurrence at the time of ABG. [Figure 2A] Although cleft type was found to be associated with fistula occurrence in a univariate analysis, it did not achieve significance in the multivariate model (OR =3.20; 95% CI: 0.99–10.34). In this model, neither age at ABG (OR=1.13; 95% CI 0.96–1.33) nor cleft type (OR=3.20; 95% CI 0.99–10.34) were predictors of late fistula formation. Only a history of early fistula repair was a significant predictor, increasing the odds of a fistula at the time of ABG by 17.17 (95% CI 2.07–142.89). This model correctly predicted 74% of the observed fistulae in the sample, with a sensitivity of 71% and specificity of 77%.

A second logistic regression model was used to predict fistula recurrence after initial repair. This model included a history of early fistula formation and repair, operating surgeon, and fistula type as variables. [Figure 2B] Only a history of fistula repair prior to palatal expansion was shown to be a significant predictor of fistula occurrence at the time of ABG (OR=70.89; 95% CI 6.62–758.75). Type of fistula (OR=1.13; 95% CI 0.95–1.33) and operating surgeon (OR=1.34; 95% CI 0.14–12.84) were not significant. This model correctly predicted 88% fistula recurrences, with a sensitivity of 78% and specificity of 96%.

Discussion

Cohen and colleagues described a postoperative fistula as a failure of healing or breakdown of tissue at the original site of cleft repair. These authors were among the first to classify fistulae by anatomic location along the palate (Cohen et al., 1991). Subsequent studies from Muzaffar et al. (2001) and others built upon these definitions by excluding intentionally unrepaired naso-alveolar defects from measures of fistula incidence. In 2007, the Pittsburgh Fistula Classification System introduced a numerical grading system to standardize subjective, surgeon-specific fistula descriptions and facilitate cross-study comparisons (Folk et al., 1997; Muzaffar et al., 2001; Smith et al., 2007). These efforts helped form a consistent framework in the literature to classify and report fistulae. However, a lack of consensus in reporting end points for postoperative fistulae continues to limit meaningful comparisons of outcomes across treatment protocols or interventions.

Time Points for Fistula Reporting

Valid measures of fistula occurrence should include both early postoperative fistulae as well as late fistulae that are observed after upper arch expansion. In the literature, early fistulae have been reported as quickly as one week after primary palatoplasty, although more common reporting end points are at 1 month or 6 months (Hardwicke et al., 2014). While these relatively early time points would capture defects that arise as immediate postoperative complications, they may neglect fistulae that are identified years after primary palatoplasty. Late fistulae are not immediately visible or symptomatic after primary repair, and may only

appear after orthodontic expansion of the maxillary arch. Schultz and others noted that it was not uncommon to see completely healed, closed palates develop new fistulae after palatal expansion. In the absence of significant clinical symptoms, both Schultz (1986) and Rintala (1980) recommended deferring repair of these late fistulae until maxillary expansion was complete.

In contrast to Schultz, we do not believe that late-forming fistulae are created through orthodontic expansion—instead, we contend that these fistulae are small, previously existing defects that are made more visible through the expansion process. In order to accurately record both early and late fistulae, we propose the following reporting time points:

1. Early fistula rates should be reported immediately prior to palatal expansion. This measure of cumulative incidence should include immediate postoperative fistulae as well as any additional defects discovered prior to orthodontic expansion.
2. Late fistula rates should be reported after maxillary expansion, or at the time of secondary alveolar bone grafting (ABG) for Veau III and IV clefts. This measure should include both newly discovered fistulae and any recurrence of previously repaired fistulae.

We recommend investigating the palate for defects while the patient is under anesthesia. Superior lighting, patient positioning, and the use of a lacrimal probe to explore the palate in the operating room may improve the sensitivity and specificity of a visual search. In our experience, 26% of fistulae remained occult until intraoperative examination at the time of ABG. [Figure 3] Although intraoperative identification may not facilitate surgical planning, discovery of these fistulae after prepping and draping the patient may be of value in estimating the length of surgery. The surgeon should always be prepared for fistula repair during alveolar bone grafting, and plan appropriately for the potential increase in operative time.

Fistula Incidence and Recurrence

Rates of fistula formation after primary palatoplasty range from 0–78% in the literature, while rates of recurrence vary from 10–65% (Rohrich et al., 1996; Emory et al., 1997; Hardwicke et al., 2014; Muzaffar et al., 2001). For patients with complete clefts of the primary and secondary palate, we discovered an early postoperative fistula rate of 20% (n=15) prior to palatal expansion and a late fistula rate of 55% (n=42) at the time of secondary ABG. Fistulae recurred after repair in 43% of cases, in line with findings from Muzaffar et. al (33%) and Cohen et. al (37%) (Muzaffar et al., 2001; Cohen et al., 1991). As previously mentioned, we excluded all fistulae anterior to the incisive foramen in our analysis. Although discrepancies in reporting standards and inclusion criteria weaken cross-study comparisons, our fistula rate is greater than the mean incidence of 17.9% reported in a meta-analysis of studies since the year 2000 (Hardwicke et al., 2014). This may be partially attributed to the characteristics of our study population, which only included patients with complete unilateral or bilateral clefts. This subgroup is more susceptible to fistula formation at baseline—a regression study by Ahmed et al. previously found that each stepwise increase in Veau class increased the odds of fistula formation by 2.64 (Ahmed et al., 2015). We also

believe that our practice of methodically exploring the palate for defects during ABG improved our discovery of otherwise occult, asymptomatic fistulae.

Fistula Location

The most common locations for fistulae in this study were at the level of the hard palate (60%), soft/hard palate junction (33%), and primary/secondary palate junction (7%), respectively. The literature regarding the anatomic distributions of palatal fistulae is still evolving, and further complicated by the lack of standardization. Our results are similar to those of Smith et al. (2007), who reported that types IV and III fistulae were most common in their population. The higher incidence of type IV fistulae in our study may be related to the limitations of retrospectively reviewed medical records. The use of ambiguous terminology in operative notes occasionally blurred the distinctions between fistula categories, and may have led to an over-counting of fistulae at the level of the hard palate. Our series only contained three type V fistulae, each of which occurred in patients with a bilateral (Veau IV) cleft. Two of these three fistulae recurred, although meaningful conclusions about fistula recurrence cannot be drawn given our sample size. Losee and Smith (2011) observed that large type V defects in bilateral clefts were particularly problematic, and tended to recur despite the use of acellular dermal matrix during repair.

Predictors of Fistula Formation and Recurrence

A history of early fistula formation and repair significantly increased the odds of a persistent fistula at the time of ABG and beyond. Fistulae selected for early repair are typically large, clinically significant defects whose closure cannot be deferred until a later surgery. It is therefore unsurprising that early fistulae are more problematic for the surgeon. Repeated cycles of fistula repair and breakdown may contribute to scar formation, soft tissue contracture, and enlargement of the original defect (Ninkovic et al., 1997). In our sample, although cleft type and patient age at the time of ABG were associated with late fistula formation in a univariate analysis, these relationships were no longer significant after controlling for other variables in a logistic regression model. As we included only Veau III and IV clefts in our study, we suspect that Veau class still has an impact on fistula rates. This difference is likely easier to identify when comparing isolated clefts of the secondary palate (Veau I and II) to complete clefts of the primary and secondary palate (Veau III and IV).

Strategies to Minimize Fistula Formation

A two-layer, tension-free, and watertight closure is of utmost importance in minimizing fistula formation (Losee and Smith, 2011). In our practice, we stress the importance of releasing the tensor aponeurosis to adequately mobilize mucosal flaps and achieve closure during primary palatoplasty. Mendonca and colleagues have further described a series of surgical techniques to release fibrous attachments around the greater palatine foramen and posterior edge of the hard palate (Mendonca et al., 2014). Others, including Hopper et al. (2014), recommend an aggressive release of the nasal mucosa off the medial pterygoid plates to ensure closure of the nasal lining. These methods may reduce the high rate of fistula formation across the hard palate and hard/soft palate junction. In our sample, each fistula across the primary/secondary palate junction (Type V) occurred in patient with a bilateral cleft. At our institution, initial repair of the junction between the primary and

secondary palates was delayed in these patients due to a large pre-maxillary gap. We recommend the use of pre-surgical orthopedics to align the premaxilla and facilitate closure during palatoplasty, and feel this is the best method to reduce the incidence of type V fistulae. For patients with unilateral clefts, proper alignment of the arches may also improve closure of the palate and reduce fistula incidence.

Losee and Smith (2011) have reported excellent outcomes when using acellular dermal matrix (ADM) to supplement the repair of through-and-through fistulae. An alternative approach from Martin-Smith et al. (2013) demonstrated successful closure of 85% of difficult fistulae when employing iliac cancellous bone grafting and postoperative palatal splinting to protect the repair site. When necessary, we employ ADM or bone grafts during fistula repair when defects are large and there exists dead space between the nasal and oral closure. ADM may serve as an additional barrier between the two overlying suture lines of the nasal and oral closures, but we do not advocate its use as a replacement for nasal lining. Eight patients in our sample underwent fistula repair with ADM, of whom five experienced later recurrences. Of note, each of these patients had large, problematic defects that had failed multiple prior attempts at repair. As such, selection bias likely played a role in our relative lack of success using this material. It is now our institutional practice to use ADM in selected patients not only during fistula repair, but also during primary palatoplasty to augment the integrity of the closure. Given the recency of this repair protocol, patients in this study were too young to have received ADM during primary cleft palate repair.

Limitations

This study was limited by its retrospective design and relatively small sample size, which affected the power of statistical analyses. We were further constrained by the quality of patients' medical records, which at times used vague, subjective, or poorly defined terms to describe fistulae. Given that many patients underwent primary repair at outside institutions, we were unable to obtain information regarding specific techniques for primary palatoplasty. We could not assess the relationship between the presence of a fistula at the time of ABG and success of bone grafting, as a significant proportion of our patients received clinical rather than radiographic assessments of bone graft take. Although this study excluded patients with an isolated cleft of the secondary palate, fistula formation in these patients may still be classified into early and late categories based on orthodontic expansion.

Conclusions

True palatal fistula rates should be reported before maxillary expansion and again at the time of secondary alveolar bone grafting to capture both early and late postoperative fistulae. Patients who develop an early fistula after primary palatoplasty are more likely to have a persistent or recurrent fistula at the time of ABG and beyond.

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Figure 1. Pittsburgh Fistula Classification System

Fistulae were classified by anatomic location along the palate using the Pittsburgh Fistula Classification System. Figure reproduced from Losee et al (Losee JE, Smith DM, Afifi AM, et al. A successful algorithm for limiting postoperative fistulae following palatal procedures in the patient with orofacial clefting. *Plast Reconstr Surg.* 2008;122:544–554.)

Figure 2. Odds Ratio Plots: Fistula Occurrence and Recurrence

* $p < 0.05$

Logarithmic odds ratio plots are shown for risk factors associated with (A) late fistula occurrence at time of ABG and (B) fistula recurrence after initial repair. Point estimates are shown in parentheses and 95% confidence intervals are marked with solid lines.

Figure 3. Intraoperative Identification of Fistulae

Two type IV palatal fistulae (A, B) are identified intraoperatively with the use of a lacrimal probe.

Table 1

Late Fistula Incidence by Cleft Type

<i>Cleft Type</i>	<i>Fistula Type</i>		
	<i>III</i>	<i>IV</i>	<i>V</i>
Unilateral	5 (22%)	18 (78%)	0 (0%)
Bilateral	9 (47%)	7 (37%)	3 (16%)
Total	14 (33%)	25 (60%)	3 (7%)

Table 2

Univariate Analysis: Late Fistula Occurrence

<i>Variable</i>	<i>(n=42)</i>	<i>(n=34)</i>	<i>p value</i>
	<i>Fistula (%)</i>	<i>No fistula (%)</i>	
Sex			
Male	30 (71.4)	25 (73.5)	1.00
Female	12 (28.6)	9 (26.5)	
Cleft type			
Unilateral	23 (54.8)	28 (82.4)	0.01 *
Bilateral	19 (45.2)	6 (17.6)	
Syndromic status			
Syndromic	2 (4.8)	0 (0.0)	0.50
Non-syndromic	40 (95.2)	34 (100.0)	
Early fistula			
Present	14 (33.3)	1 (2.9)	<0.01 *
Not present	28 (66.6)	33 (97.1)	
Age at ABG (mean, SD)	12.8 (4.6)	11.0 (2.5)	0.05 *

* Variable included in logistic regression model

Percentages are calculated for each variable based on the presence or absence of a fistula. Fisher's exact test was conducted for each categorical variable and results with $p < 0.05$ were considered significant.

Table 3

Univariate Analysis: Fistula Recurrence after Repair

<i>Variable</i>	<i>(n=42)</i>	<i>(n=34)</i>	<i>p value</i>
	<i>Fistula (%)</i>	<i>No fistula (%)</i>	
Sex			
Male	30 (71.4)	25 (73.5)	1.00
Female	12 (28.6)	9 (26.5)	
Cleft type			
Unilateral	23 (54.8)	28 (82.4)	0.01 *
Bilateral	19 (45.2)	6 (17.6)	
Syndromic status			
Syndromic	2 (4.8)	0 (0.0)	0.50
Non-syndromic	40 (95.2)	34 (100.0)	
Prior fistula repair			
Prior repair	15 (35.7)	1 (2.9)	<0.01 *
No repair	27 (64.3)	33 (97.1)	
Age at ABG (mean, SD)	12.8 (4.6)	11.0 (2.5)	0.05 *

* Variable included in logistic regression model

Percentages are calculated for each variable based on fistula recurrence. Fisher's exact test was conducted for each categorical variable and results with $p < 0.05$ were considered significant.

Table 4

Univariate Analysis: Fistula Recurrence After Repair

	(n=18)	(n=24)	
<i>Variable</i>	<i>Recurrence (%)</i>	<i>No recurrence (%)</i>	<i>p value</i>
Sex			
Male	11 (61.1)	19 (79.2)	0.30
Female	7 (38.9)	5 (20.8)	
Cleft type			
Unilateral	8 (44.4)	15 (62.5)	0.35
Bilateral	10 (55.6)	9 (37.5)	
Syndromic status			
Syndromic	0 (0.0)	2 (8.3)	0.35
Non-syndromic	18 (100.0)	22 (91.7)	
Prior fistula repair			
Prior repair	14 (77.8)	1 (4.2)	<0.01*
No repair	4 (22.2)	23 (95.8)	
Fistula type			
III	8 (44.4)	6 (25.0)	0.20*
IV	8 (44.4)	17 (70.8)	
V	2 (11.1)	1 (4.2)	
Operating surgeon			
A	2 (11.1)	8 (33.3)	0.15*
B	16 (88.9)	16 (66.7)	
Age at ABG (mean, SD)	12.8 (5.1)	12.7 (4.3)	0.95