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Prevalence and characteristics of palate fistula post-palatoplasty in cleft palate patients at Hasan Sadikin Hospital (2018-2022)

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Abstract
Palatal fistula is a common complication following palatoplasty, characterized by an abnormal connection between the nasal and oral cavities through the palate. This study aimed to explore the prevalence and characteristics of post-palatoplasty fistula cases at the Oral and Maxillofacial Surgery Department, Dr. Hasan Sadikin General Hospital, Bandung, from 2018 to 2022. A descriptive retrospective study design was utilized, involving 25 patients who underwent fistula repair during this period. Data were collected from medical records, including patient demographics, fistula classification, cleft type, and surgical stages. Results showed that most fistula repairs were performed in children ≤5 years (56%), with a higher prevalence in females (52%) compared to males (48%). The most common fistula type was Pittsburgh Type V (34%), frequently associated with complete unilateral cleft palate (Veau Class III). One-stage palatoplasty was the predominant surgical technique used (92%). These findings highlight the need for optimizing surgical approaches to reduce fistula incidence and enhance postoperative outcomes. Further research is warranted to evaluate long-term impacts on patient functionality and quality of life.

Keywords: Palatal fistula, cleft palate, palatoplasty, prevalence, Veau

Introduction

Orofacial clefts are birth defects that occur when a baby's lips and/or mouth do not form properly during pregnancy. This condition is characterized by irregularities or hypoplasia of the tissue in the affected area [1]. Orofacial clefts can present as a cleft lip with or without a cleft palate, or as an isolated cleft palate, occurring in approximately 1 in 500 to 1,000 births [2]. Cleft lip and palate are the most common congenital abnormalities, involving disruptions in the embryologic tissue above the lip that may extend to the hard palate and/or soft palate. Cleft palate itself can vary, ranging from submucosal clefts to complete clefts of the soft and hard palate [2, 3].

The incidence of cleft lip and palate varies between 1:750 and 1:650 births, depending on the geographical region. The distribution of cleft types is as follows: cleft lip and palate (46%), cleft palate (33%), and cleft lip (21%). Asian populations have the highest prevalence of cleft lip and palate, while African populations have the lowest prevalence. In Indonesia, the incidence of cleft lip and palate reaches approximately 7,500 cases per year (Kemenkes, 2019) [3].

Cleft palate can cause various problems, such as difficulty eating, swallowing, and speaking, as well as aesthetic concerns. This condition can also lead to issues with jaw development, malnutrition, hearing problems, and psychosocial challenges related to communication barriers [3, 4]. To address cleft palate, surgery known as palatoplasty is performed. However, even when the surgery is done properly, some complications may arise, such as speech disorders, hearing issues, problems with the growth of the maxillary area, and palatal fistulas [5].

Palatal fistula is a common complication following palatoplasty, where there is an abnormal connection between the nose and mouth through the palate. The incidence of post-operative palatal fistula varies between 0-68%, with more than half of children who undergo palatoplasty reported to experience a palatal fistula [6]. Research on the prevalence and characteristics of palatal fistula cases in post-palatoplasty patients at Dr. Hasan Sadikin General Hospital, Bandung, has not been conducted, especially within the scope of the Oral and Maxillofacial Surgery Medical Staff Department. This study aims to further explore the prevalence and characteristics of palatal fistula in post-palatoplasty patients at Dr Hasan Sadikin General Hospital Bandung during the period of 2018-2022.

Materials and methods

1. Study design

This study is a descriptive research using medical record data of patients with palatal fistula post-palatoplasty. The research was conducted at the Oral and Maxillofacial Surgery Medical Staff Department of Dr. Hasan Sadikin General Hospital, Bandung, from January 2018 to December 2022. The aim of the study is to describe the characteristics of patients with palatal fistula post-palatoplasty based on relevant clinical variables.

2. Subjects and Sampling

The study population includes all patients with palatal fistula post-palatoplasty at Dr. Hasan Sadikin General Hospital, Bandung. Sampling was performed using the total sampling method, meaning all patients who met the inclusion criteria and were not excluded by the exclusion criteria were included. The inclusion criteria are patients who present with complaints of palatal fistula and have been diagnosed with palatoschisis, while patients with incomplete medical records were excluded from the study.

3. Data Collection
The study data were collected from patient medical records, including age at fistula repair, age at palatoplasty, gender, syndrome involvement, Pittsburgh classification of palate fistula type, Veau classification of cleft palate type, and previous surgical stages. Data also included photo documentation of palate fistula to support further analysis.

4. Variables
The research variables include the age when the repair is carried out, namely the patient's age when the fistula is repaired, and the age at the time of palatoplasty, which is the patient's age when undergoing palatoplasty. Other variables are the patient's gender, which is classified as male or female, as well as the involvement of the syndrome, which indicates whether the patient has a syndrome associated with the palatal cleft. The classification of palatal fistulas is carried out based on the involvement of anatomical structures according to Pittsburgh, while the previous types of palatal fissures were categorized based on the Veau classification. In addition, the study also considers the stages of palatoplasty surgery, which includes the type of single-stage or two-stage surgical procedure.

5. Data Processing and Analysis
The data that has been collected is processed through the process of editing, coding, entry, and cleaning. Numerical data is expressed as mean and standard deviation, while categorical data is expressed in proportion and percentage. Data processing was carried out using Microsoft Excel, and further analysis was carried out to describe the distribution of the variables studied.

6. Ethical Considerations
This research has received ethical approval from the Research Ethics Committee of Faculty of Medicine Padjadjaran University/ Dr Hasan Sadikin General Hospital. Medical record data is kept confidential, with the patient's name changed to initials and only known to the researcher. The data is used solely for research purposes, with the cost of patient follow-up, if required, borne by the researcher.

Results
This study involved 25 cases of palatal fistula patients who were treated at Dr. Hasan Sadikin Hospital Bandung in January 2018–December 2022. Data is collected from medical records to determine the characteristics of patients based on age, gender, classification of fistulas, association with syndrome, initial diagnosis, and type of surgery performed.

1. Demographic and Clinical Characteristics of Palatoplasty Patients

Table 1: Characteristics Based on Age at the Time of Palatoplasty Repair

Characteristic	Category	Frequency (n)	Proportion (%)
Age at the Time of Palatoplasty Repair	≤ 5 years	14	56%
	6-10 years	7	28%
	11-15 years	3	12%
	> 15 years	1	4%
Age at the Time of First Palatoplasty	≤ 18 months	9	41%
	> 18 months	16	59%
Gender	Male	12	48%
	Female	13	52%
Association with Other Syndromes	Present	2	10%
	Absent	23	90%

The table provides an overview of the demographic and clinical characteristics of patients undergoing palatoplasty. In terms of age at the time of palatoplasty repair, most patients were 5 years old or younger (56%), with decreasing proportions in older age groups: 6-10 years (28%), 11-15 years (12%), and above 15 years (4%). Regarding the timing of the first palatoplasty, 41% of patients underwent the procedure at or before 18 months of age, while the majority (59%) underwent it after 18 months. The gender distribution was relatively balanced, with 48% of patients being male and 52% female. Additionally, 90% of the patients were non-syndromic, while 10% presented with associated syndromes. These findings emphasize the predominance of early intervention in younger age groups, the nearly equal gender representation in treatment, and the predominance of non-syndromic cases in this population.

2. Distribution Based on Fistula Classification According to Pittsburgh

Table 2: Characteristics Based on Fistula Classification According to Pittsburgh

Characteristic	Frequency (n=…)	Proportion (%)
Pittsburgh		
Type I	4	12%
Type II	5	15%
Type III	2	6%
Type IV	6	18%
Type V	11	34%
Type VI	1	3%
Type VII	4	12%

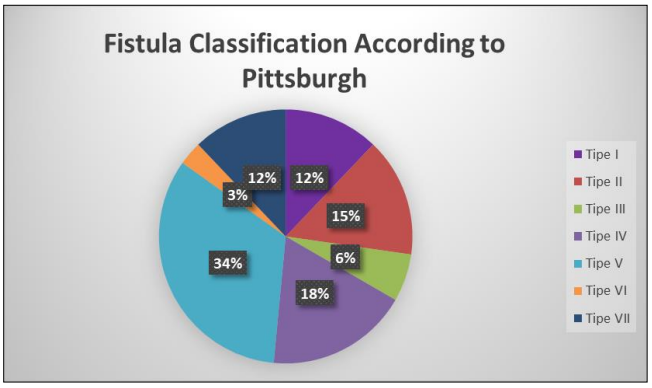

Fig 2: Diagram of Patient Characteristics Based on Fistula Classification According to Pittsburgh

Based on the results of the study through medical records according to the Pittsburgh classification, there were 4 patients (12%) with type I fistula, 5 patients (15%) with type II, 2 patients (6%) with type III, 6 patients (18%) with type IV, 11 patients (34%) with type V, 1 patient (3%) with type VI, and 4 patients (12%) with type VII fistula.

3. Distribution Based on Initial Cleft Palate Diagnosis

Table 3: Characteristics Based on Initial Cleft Palate Diagnosis

Characteristic	Frequency (n=…)	Proportion (%)
Initial Cleft Palate Diagnosis		
Veau Class I	2	8%
Veau Class II	4	16%
Veau Class III	12	48%
Veau Class IV	7	28%

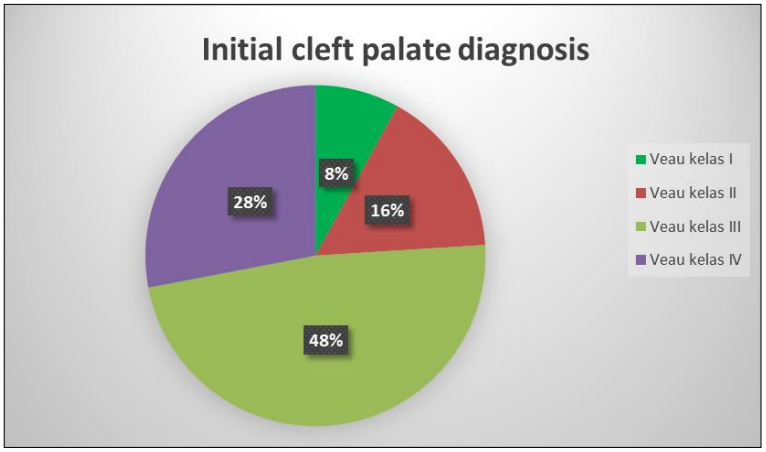

Fig 3: Diagram of Patient Characteristics Based on Initial Cleft Palate Diagnosis

Table 4: Correlation Between Initial Cleft Type and Fistula Location

	Veau class I	Veau class II	Veau class III	Veau class IV		
Characteristic	**Frequency (n=…)**				**Total**	**Proportion**
Type I		1	2	1	4	12%
Type II	1	1	2	1	5	15%
Type III	1			1	2	6%
Type IV		2	4		6	18%
Type V		1	5	5	11	34%
Type VI	1				1	3%
Type VII			1	3	4	12%

Based on the study through medical records according to the initial cleft palate diagnosis, 2 patients (8%) were diagnosed with Veau Class I, 4 patients (16%) with Veau Class II, 12 patients (48%) with Veau Class III, and 7 patients (28%) with Veau Class IV. The most commonly found fistula type was Type V (11 fistulas). This type came from patients with bilateral complete cleft palate (Veau Class IV) accounting for five individuals, unilateral complete cleft palate (Veau Class III) also accounting for five individuals, and soft and hard palate cleft (Veau Class II) in one individual. The results for other fistula types can be seen in Table 7.

4. Distribution Based on Types of Palatoplasty Surgical Stages

Table 5: Characteristics Based on Types of Palatoplasty Surgical Stages

Characteristic	Frequency (n=…)	Proportion (%)
Type of Palatoplasty Surgical Stages		
One stage	23	92%
Two stage	2	8%

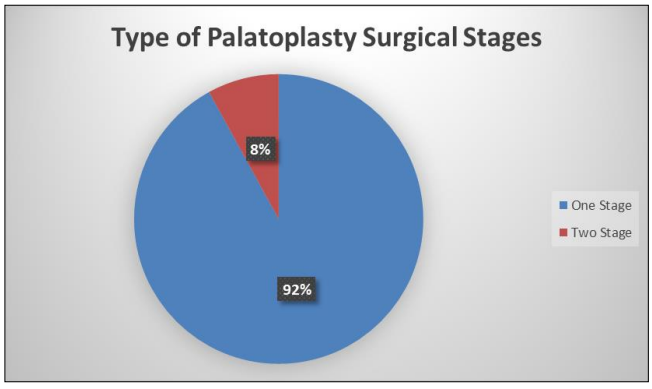

Fig 4: Diagram of Patient Characteristics Based on Types of Palatoplasty Surgical Stages

Based on the study through medical records regarding the types of palatoplasty surgical stages previously performed, 2 patients (8%) underwent a two-stage operation, and 23 patients (92%) underwent a one-stage operation.

Discussion

The study on the prevalence of palatal fistulas post-Palatoplasty at the Oral and Maxillofacial Surgery Department of Hasan Sadikin General Hospital from January 2018 to December 2022 recorded 28 patients, with 25 medical records meeting the inclusion criteria. The technique used was the two-flap pushback method. The incidence of palatal fistulas varied, with the main causes being infection and excessive pressure at the surgical site. Factors related to fistula formation include the patient's age at repair, age at the time of first Palatoplasty, gender, syndrome involvement, previous diagnosis of cleft palate, and the type of surgical approach [7].

Most patients who underwent surgery at ≤ 5 years of age were 14 patients (56%), which differs from Ravi *et al.* (2018), who found the most common age group to be 6-10 years. Patients who underwent Palatoplasty at ≤ 18 months were 9 patients (41%), while 16 patients (59%) had the procedure after 18 months. However, age did not significantly affect the incidence of fistula, consistent with Nurardhilah *et al*. (2013) [7].

The gender distribution was almost balanced, with 12 male patients (48%) and 13 female patients (52%). No significant relationship was found between gender and fistula formation, which aligns with the findings of Nurardhilah *et al*., Emory *et al*., and Muzaffar and Lu *et al* [7, 8, 9].

The relationship between syndrome involvement and cleft palate, and its effect on the incidence of fistulas post-Palatoplasty, remains controversial. Saothonglang *et al.* (2001) reported that syndromic clefts are a predictive factor for fistula formation, and Bresnick *et al.* (2001) found that

patients with Treacher Collins syndrome have a higher likelihood of fistulas compared to non-syndromic patients. In this study, 2 patients (10%) had syndromic involvement, one with Treacher Collins syndrome and the other with Down syndrome [10, 11]. No significant statistical relationship was found between palatal fistula occurrence and syndromic involvement.

The most common location of fistulas was found around the incisive foramen (34%), followed by the hard palate (18%) and the soft palate (15%), which is in line with the study by Nurardhilah *et al*. (2013), although some previous studies by Smith, Buller, and Park reported that fistulas are often found in the hard palate [10, 11, 12, 13, 14]. These differences could be attributed to the different techniques used, as only the two-flap pushback technique is employed at RS Hasan Sadikin, which prioritizes the movement of the soft palate for articulation function [13, 10].

The type of cleft palate prior to Palatoplasty also influences the incidence of fistulas. In this study, the highest incidence of fistulas was found in patients with unilateral complete cleft palates (Veau Class III). The most common type V fistulas (11 fistulas) were from patients with bilateral complete clefts (Veau Class IV) and unilateral complete clefts (Veau Class III), with five cases in each group [12, 14].

The majority of patients underwent one-stage Palatoplasty, with 23 patients (98%), compared to two-stage surgery, which only had 2 patients (2%). Previous studies have shown that fistulas are more frequent after two-stage surgeries(17,18). However, Rajgopald *et al*. found no significant difference between one-stage and two-stage operations in terms of fistula formation [19].

Regarding one-stage surgery, there is no clear evidence regarding the optimal strategy to prevent palatal fistulas. Most studies are limited to explaining only one surgical technique or comparing two techniques. For example, Amartunga *et al*. reported a higher fistula rate with the Langenbeck technique, while Cohen *et al*. showed better results with Langenbeck compared to the Wardill technique(14). Two-stage surgery is believed to allow tension-free closure of the hard palate, which minimizes the formation of fistulas, especially in wide clefts, which are a risk factor for fistula formation. However, the impact of two-stage surgery on articulation remains debatable, with studies like Funayama *et al*. showing higher incidences of malarticulation in patients who underwent soft palate repair at 18 months compared to those who had one-stage surgery [14, 20].

Conclusion

The study conducted at the Oral and Maxillofacial Surgery Department of Dr Hasan Sadikin General Hospital from January 2018 to December 2022 involved 25 patients who met the inclusion criteria. The average fistula closure was performed at an age of ≤ 5 years (56%). The majority of patients underwent their first palatoplasty at an age of > 18 months (59%). The gender distribution of patients was nearly balanced, with 48% male and 52% female. One patient with Treacher Collins syndrome was also found in this study. The most common location of the fistula was at the junction of the primary and secondary palates (Pittsburgh type V, 34%). Patients with unilateral complete cleft palates (Veau Class III) were the most numerous (48%). The majority of patients (92%) had previously undergone a one-stage palatoplasty surgery.

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