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Ten Years Prevalence And Patterns of Palatal Fistula Following Primary Palate Repair at Yekatit 12 Hospital Medical College, Addis Ababa, Ethiopia

By

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A Research thesis Submitted to the Department of Surgery, School of Medicine, College of Health Sciences, Addis Ababa University in Partial Fulfillment of the Requirements for Subspecialty Training in Plastic and Reconstructive Surgery

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Declaration

I hereby declare that the thesis is my original work and has not been presented for a degree in any other university. All sources of material used in the document have been duly acknowledged and properly cited.

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The undersigned have examined the thesis report entitled “Ten Years Prevalence And Patterns of Palatal Fistula Following Primary Palate Repair at Yekatit 12 Hospital Medical College, Addis Ababa, Ethiopia.” presented by Dr. Firegenet Woldearegay with registration number GSR 2175/15, a candidate for fellowship certificate in Plastic & Reconstructive Surgery and hereby certify that it is worthy of acceptance.

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Above all, I give all glory and honor to Almighty God, whose divine guidance and unwavering presence have been the cornerstone of my life.

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Acronyms

AAU- Addis Ababa University

CHS- College of Health Sciences

SOM- School of Medicine

ALERT- All African Leprosy Tuberculosis Rehabilitation Training Center

ONF- Oro-Nasal Fistula

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Abstract

Background: Palatal fistula is a common complication following primary cleft palate repair, negatively impacting speech, swallowing, and quality of life. The incidence of palatal fistula varies significantly depending on surgical techniques, cleft severity, and perioperative care. However, there is limited data regarding the patterns and rates of palatal fistula in Ethiopia. This study aims to determine the rate of palatal fistula post-surgery at Yekatit 12 Hospital Medical College, and assess the risk factors associated with their development

Methods: A hospital based retrospective study was conducted by reviewing the medical records of all patients who underwent primary cleft palate repair at Yekatit 12 Hospital from 2014 to 2024. A structured data abstraction form was used to collect the information on patient demographics, cleft characteristics, surgical techniques, and postoperative outcomes. The data was analyzed using SPSS version 26, employing descriptive statistics to determine the palatal fistula rate.

Results: A total of 47 participants with documented fistula surgeries were included in the study. Of these, 51.1% were female, with a mean age of 12 years at the time of surgery. The majority (80.9%) presented with cleft lip and palate, and 55.3% underwent repair at Yekatit 12 Hospital. 53.2% of participants presented for fistula surgery within five years post-repair, with an average presentation of 6.6 years. Local flap techniques accounted for 59.6% of surgeries, while the Bardach palatoplasty was the most common surgical method performed for palate repair. Demographic factors, including age and sex, did not significantly correlate with fistula formation ($p=0.11$ and $p=0.54$, respectively).

Conclusion: This study highlights the need for ongoing evaluation and improved surgical techniques to reduce the incidence of palatal fistulas and enhance patient outcomes. Future research should focus on long-term follow-up and the effectiveness of various surgical interventions in mitigating complications associated with palatal repair.

Keywords: *Cleft palate, palatal fistula, primary palate repair, Ethiopia, Yekatit 12 Hospital*

1. Introduction

1.1. Background of the study

Cleft palate is one of the most prevalent congenital craniofacial anomalies, significantly impacting feeding, speech, hearing, and overall quality of life if not properly managed. Surgical repair is the standard treatment; however, postoperative complications such as palatal fistula formation remain a significant challenge, especially in resource-limited settings like Ethiopia. A palatal fistula results in persistent communication between the oral and nasal cavities, leading to unpleasant symptoms such as nasal spillage of feeds, hypernasal speech, and articulation problems, which undermine the success of palate repair (1).

Despite advances in surgical techniques, fistula rates vary widely, with higher rates reported in low-resource settings due to factors such as delayed presentation, limited surgical expertise, and inadequate postoperative care (2).

A postoperative palatal fistula is among the most serious long-term consequences. When the main surgical repair of the palate fails or breaks down, a palatal fistula develops, which causes nasal regurgitation of food and drink, hypernasal speech, and articulation problems (3).

Over the last decade, numerous studies have highlighted variations in fistula rates across different geographic regions and socio-economic contexts. Complete palate closure is typically achieved with palatoplasty in high-income nations, and fistula rates of 3–10% are typical, attributed to advanced surgical techniques and comprehensive postoperative care(4). The final incidence of persistent ONF was 24.3%, which is within the global range of 5% to 60% described in a Nigerian investigation. In a study conducted in Uganda, the overall frequency of palatal fistula was 35%(5). In an Ethiopian study, oral fistula was seen in 25% of patients(6,7). These disparities indicate a critical need for further investigation into the causes behind these elevated rates.

In Ethiopia, specialized cleft care is limited, with only a few hospitals, such as Yekatit 12 Hospital in Addis Ababa, offering regular cleft palate repair services. Yekatit 12 Hospital serves as a major referral center for cleft surgeries, receiving patients from across the country. However,

the changing patterns and rates of palatal fistula among patients undergoing primary palate repair at this institution over the timeframe from 2014 to 2024 remain unclear. Studies in other low-income countries have reported fistula rates ranging from 10% to 45%, influenced by factors such as cleft severity, surgical technique, and postoperative follow-up (5). Given the high patient volume at Yekatit 12 Hospital and the constraints in healthcare infrastructure, understanding the temporal trends and patterns of palatal fistula formation over this decade is critical for improving surgical outcomes.

Notably, there has been limited research examining how the patterns of palatal fistulas, as well as their rates, have evolved over specific timeframes. Our study aims to address this gap by analyzing cleft palate surgeries performed in Ethiopia from 2014 to 2024. By comparing historical and current data, we aim to identify any significant changes in fistula rates and the underlying factors influencing these trends.

Additionally, a separate but pertinent study conducted at Yekatit 12 Hospital Medical College in Addis Ababa, Ethiopia, reported an oronasal fistula incidence of 25% among 149 patients, with moderate to severe velopharyngeal insufficiency observed in 45.7% of cases(7). This study highlighted, that age at the time of surgery, sex, and type of surgery have no significant association with the presence of fistula. Combined, these findings emphasize a pressing need for improved surgical practices and patient care strategies, particularly in lower-resource settings.

Understanding whether improvements in surgical techniques, changes in patient management, or variations in local health conditions have impacted fistula occurrences during this decade is crucial. There is little and poor-quality data on the results of reconstructive surgery missions. Studies that specifically stated the length and rate of follow-up reported higher rates of complications(8) This analysis will provide valuable insights into the effectiveness of surgical practices in Ethiopia and inform future healthcare strategies aimed at enhancing surgical outcomes for patients with cleft lip and palate.

1.2. Statement of the problem

Despite the increasing number of primary cleft palate repairs performed in Ethiopia, there remains a significant gap in data regarding the frequency and patterns of postoperative palatal

fistulas. The scarcity of locally relevant studies hinders the assessment of surgical intervention effectiveness and the identification of potential areas for improvement in cleft care management.

Most existing literature on palatal fistula rates is derived from studies conducted in high-income countries with well-established cleft care programs that report rates as low as 2.6%(4). These findings may not be applicable to the Ethiopian context, where variations in patient demographics, nutritional status, and healthcare infrastructure could significantly affect surgical outcomes. Additionally, the limited availability of surgical expertise, postoperative follow-up and essential rehabilitation services—such as speech therapy—complicates the management of cleft-related complications, contributing to a changing landscape of fistula occurrence (7)

A retrospective analysis of cleft palate surgeries performed at Yekatit 12 Hospital Medical college using data of patients operated from January 2024 to December 2024 aims to provide essential insights into the burden of palatal fistulas in Ethiopia. Identifying trends in fistula occurrence, including anatomical location, severity, and associated risk factors, will be crucial for informing surgical best practices and improving patient outcomes. Moreover, understanding how variations in surgical techniques and changes in perioperative care impact fistula rates over this timeframe can guide efforts to optimize cleft palate repair strategies in resource-limited settings. This research is vital for promoting better long-term results and ensuring that the unique challenges faced by Ethiopian patients are adequately addressed in clinical practice.

1.3. Significance of the study

Understanding the changing patterns and rates of palatal fistula from 2014 to 2024 in this context is crucial for optimizing cleft care protocols and improving patient outcomes. Identifying the specific risk factors contributing to fistula formation over this period will help guide surgical training, patient selection, and postoperative management strategies to reduce complication rates. Additionally, data from this study will provide valuable insights for policymakers and healthcare providers aiming to enhance cleft care services in Ethiopia. By documenting the temporal trends and prevalence of palatal fistula at Yekatit 12 Hospital over this decade, this research will serve as a foundation for quality improvement initiatives, including the adoption of best surgical practices and the establishment of standardized follow-up programs.

This study aims to fill the existing knowledge gap by systematically analyzing the incidence, patterns, and rates of palatal fistula at Yekatit 12 Hospital over the timeframe from 2014 to 2024. The findings will not only contribute to the global literature on cleft surgery outcomes in low-resource settings but will also provide practical recommendations for improving cleft care in Ethiopia. By identifying the key factors associated with fistula formation and examining how these trends have evolved over the past decade, this research can help guide future surgical interventions, training programs, and policy decisions to ensure better outcomes for patients born with cleft palate

2. Literature review

2.1. Overview of cleft palate and surgical repair

Cleft palate is a common congenital craniofacial disorder characterized by a split or opening in the roof of the mouth that results from inadequate tissue fusion during fetal development. Due to the aberration that affects the separation of the nasal and oral cavities, this condition can have an impact on the feeding, breathing, and speaking of infants as well as children. Due to their increased effort, infants with cleft palates may tire fast during feeding and frequently struggle with nasal reflux and developing a secure latch (9). Interprofessional treatment usually includes long-term speech and hearing support as well as early intervention for eating difficulties(4).

Primary palate surgery (palatoplasty) aims to restore the velopharyngeal sphincter completely, reposition muscles, and reconstruct the oral and nasal cavities anatomically in order to promote speech development and provide sufficient velopharyngeal closure (10). Techniques for palatal closure have gradually changed over time, with a stronger focus on realigning the velar muscles to guarantee a low risk of complications and a functional velopharyngeal sphincter(10). Various surgical techniques have been developed over the years, each with distinct advantages and limitations. The Von Langenbeck technique, Bardach two-flap palatoplasty, and Furlow double-opposing Z-plasty are the most commonly used approaches(6). Among these, Furlow Z-plasty yielded excellent speech results in our patient population with minimal and acceptable rates of fistula formation, velopharyngeal insufficiency, and the need for additional corrective

surgery(11). However, despite advancements in surgical methods, postoperative complications remain a significant challenge, particularly in resource-limited settings(12)

A review of cleft surgeries performed in other African countries has highlighted common challenges such as late presentation, malnutrition, and limited access to multidisciplinary cleft care teams, all of which contribute to poor surgical outcomes(12). A study conducted in Kenya reported a fistula rate of 22% following primary cleft palate repair, with risk factors including wide cleft defects, tension at the surgical site, and surgeon experience(13). Similar trends have been observed in Uganda and Nigeria, where fistula rates exceed 25% in some centers(5,6). Despite these findings, there is a lack of published data on the prevalence, patterns, and risk factors associated with palatal fistula in Ethiopia, particularly at Yekatit 12 Hospital, over the specified timeframe.

2.2. Palatal fistula: incidence, classification, and clinical impact

Palatal fistula is a persistent communication between the oral and nasal cavities following primary cleft palate repair. Even in the best hands of skilled surgeons, palatal fistulae, or the patency between the oral and nasal cavities, are a common complication following cleft palate surgery, with a frequency of 4–45% and a high recurrence rate of 37–50%(14). In high-income countries, where cleft surgeries are performed under optimal conditions, the reported fistula rates are as low as 3–5%. However, in low-resource settings, such as Ethiopia, the incidence can be as high as 25% due to limited access to specialized surgical care and inadequate postoperative follow-up(7).

Palatal fistulas are classified based on their size, location, and clinical symptoms. In terms of size, it has been categorized as <2 mm (little), 2–5 mm (medium), and >5 mm (big). It has also been separated into anterior, middle, and posterior palatal fistulas, with anterior fistulas being more common in cases of wide clefts(15). The presence of a fistula can lead to significant morbidity, including hypernasality, nasal regurgitation of food and liquids, articulation difficulties, and increased risk of upper respiratory infections(15). These complications necessitate secondary surgical intervention, which may be challenging due to tissue scarring and limited local tissue availability(15).

2.3. Risk factors for palatal fistula formation

Several factors contribute to the development of palatal fistulas after primary repair:

Cleft Severity and Width: Larger and more severe clefts, such as complete bilateral clefts, are associated with a higher risk of fistula formation due to increased tissue tension at the repair site(6).

Surgical Technique: Studies have shown that the Von Langenbeck technique has a higher fistula rate compared to the Furlow palatoplasty, as the latter provides better muscular repositioning and tension-free closure(11,16).

Surgeon Experience: The proficiency of the operating surgeon plays a crucial role in determining surgical outcomes. High-volume cleft centers report lower fistula rates compared to centers where surgeries are performed by less experienced surgeons(5)

Postoperative Infections and Wound Dehiscence: Poor wound healing, secondary to infection or inadequate vascularization of the repaired tissue, significantly increases the likelihood of fistula formation(5,17).

Timing of Surgery: Studies indicate that early repair (before 12 months of age) is associated with better healing outcomes. Delayed repairs (after 18 months) tend to have a higher risk of wound breakdown and fistula formation(5).

2.4. Management strategies for palatal fistula

The management of palatal fistulas depends on their size, location, and associated symptoms. While small, asymptomatic fistulas may not require intervention, larger fistulas with significant functional impact necessitate surgical repair(18).

Several surgical techniques are employed to close palatal fistulas, including:

Local Flap Techniques: These involve using adjacent tissue to close the defect, such as the two-layered closure technique using mucoperiosteal flaps.

Buccal Mucosal Grafts: These are particularly useful for larger defects where local tissue is insufficient.

Tongue Flaps: Used for large, recurrent fistulas, especially in cases where previous repairs have failed.

Free Tissue Transfer: In extreme cases, microvascular free flaps may be used to reconstruct the defect(18).

Despite advancements in surgical techniques, the recurrence of palatal fistulas remains a challenge. Some recent studies have explored the use of biomaterials, tissue engineering, and growth factors to enhance wound healing and minimize recurrence rates(19).

2.5. Studies on palatal fistula in Africa and Ethiopia

Most studies on cleft palate complications originate from high-income countries, where cleft care is well established. However, research from African countries, including Ethiopia, highlights unique challenges such as delayed presentation, inadequate surgical expertise, and poor access to comprehensive cleft care services(7).

Palatal fistula, a common complication following primary cleft palate repair, remains a significant challenge in low-resource settings, with reported rates varying widely across studies and regions. For instance, a study at a Ugandan institution found a fistula rate of 35%, attributed to factors such as severe clefting (cleft width >12 mm, palatal index >0.4), malnutrition, two-stage repair, and postoperative infection, highlighting the complex interplay of anatomical, nutritional, and socioeconomic barriers in achieving optimal surgical outcomes[(5).

A study conducted at Yekatit 12 Hospital in Addis Ababa reported a palatal fistula rate of 25%, significantly higher than the global average. This study highlighted the influence of patient factors such as age and cleft type on surgical outcomes and found that advancements in surgical techniques and optimal timing have improved results, yet issues like delayed surgical intervention, malnutrition, and inadequate postoperative follow-up remain key contributing factors (7). Similarly, a study in Kenya found fistula rates of 22%, reinforcing the need for standardized surgical protocols and improved cleft care infrastructure in African settings(13).

These findings emphasize the importance of training specialized cleft surgeons, establishing multidisciplinary cleft care teams, and implementing postoperative follow-up programs to improve surgical outcomes in Ethiopia and other resource-limited settings.

3. Objectives

3.1. General objectives

To determine the pattern and risk factors of palatal fistula among patients who underwent primary cleft palate repair at Yekatit 12 Hospital, Addis Ababa, Ethiopia, over the past 10 years.

3.2. Specific objectives

- To analyze the trends in incidence of palatal fistulas from 2014 to 2024
- To evaluate the impact of surgical techniques and advancements on the development of palatal fistulas during the study period
- To asses demographic and clinical risk factors associated with the formation of palatal fistulas.

4. Material and methods

4.1. Study area

The study was conducted at Yekatit 12 Hospital, one of Ethiopia's leading referral and teaching hospitals located in Addis Ababa. The hospital provides specialized cleft lip and palate surgeries and receives a high volume of cleft patients from all over the country. It also serves as a training center for surgical residents and fellows specializing in plastic, maxillofacial, and reconstructive surgery. The hospital collaborates with international cleft care organizations such as Smile Train and Transforming Cleft, which support surgical care for children with cleft conditions.

Yekatit 12 Hospital has a dedicated cleft clinic where patients receive preoperative evaluations, surgical interventions, and postoperative follow-ups. The hospital's medical records department maintains detailed surgical records, which will be the primary data source for this study.

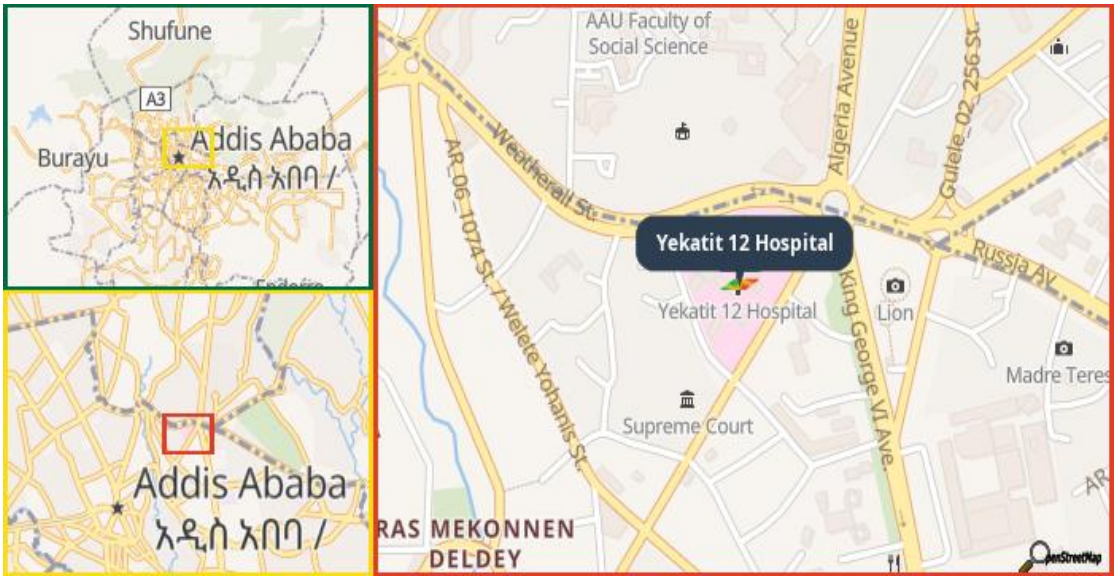


Figure 4.1: Map of Yekatit hospital, Arada sub city, Addis Ababa, Ethiopia

4.2. Study design and period

A hospital based retrospective study was used to analyze medical records of patients who underwent cleft palate repair surgeries between 2014 and 2024 to determine the patterns, and risk factors of palatal fistulas.

Data was collected from hospitals or surgical databases, focusing on demographic details (age, gender), clinical factors (cleft type, surgical techniques), fistula characteristics and postoperative outcomes.

4.3. Source and study population

4.3.1. Source population

All patients who developed palatal fistula after primary palate surgery who came to Yekatit 12 hospital between 2014 and 2024.

4.3.2. Study population

Patients with have complete medical records documenting preoperative assessment, surgical procedure, and postoperative follow-up were included in the study.

4.4. Inclusion and exclusion criteria

4.4.1. Inclusion Criteria

- Patients who underwent primary cleft palate repair at Yekatit 12 Hospital and other hospitals.
- Patients with complete medical records, including preoperative, intraoperative, and postoperative follow-up data.

4.4.2. Exclusion Criteria

- Patients who underwent secondary cleft palate repair or fistula closure surgeries.
- Incomplete or missing medical records, particularly those lacking postoperative follow-up data.

4.5. Study variables

4.5.1. Dependent variables

- Patterns of palatal fistula

4.5.2. Independent variables

- Socio demographic factors such as age and sex
- Clinical factors such as Type of cleft palate, surgical techniques, postoperative care

4.6. Data collection tools and procedures

Patient medical records and follow-up documentation were reviewed by the principal investigator. A structured data collection form was used to extract relevant patient, surgical, and postoperative information. Inconsistent or incomplete data were rejected from further analysis.

4.7. Data Processing and Analysis

Data entry and analysis were conducted using the Statistical Package for Social Sciences (SPSS) version 26. Descriptive statistics were calculated to summarize the data. Descriptive statistics were computed to summarize the data. Pearson's chi-square test was used to assess associations between dependent and independent variables. Associations were considered statistically significant if the p-value was less than 0.05.

4.8. Data quality assurance

The Data quality assurance in this study was achieved through rigorous adherence to standardized protocols, extensive training for data collectors, and thorough verification of data sources.

4.9. Ethical clearance

Ethical approval was obtained from the Institutional Review Board (IRB) of Yekatit 12 Hospital, and the Research Ethics Review Committee of the surgical department, the School of Medicine, College of Health Sciences, Addis Ababa University.

Patient identifiers were not collected, and all patient data were anonymized to maintain confidentiality. The collected information was stored on a password-protected computer to ensure its security.

Operational definitions

- **Palatal Fistula:** A persistent opening between the oral and nasal cavities after primary cleft palate repair, diagnosed clinically.
- **Primary Cleft Palate Repair:** The first surgical procedure performed to close the cleft in the palate.
- **Fistula Rate:** The percentage of patients who develop a palatal fistula following primary repair.
- **Early Follow-up:** Postoperative evaluation within 6 weeks of surgery.
- **Late Follow-up:** Postoperative evaluation after 6 months of surgery.

5. Results

5.1. Sociodemographic and clinical characteristics

We have reviewed more than 400 cleft palate patient's data from the last 10 years retrospectively from the department of Plastic surgery at Yekatit 12. Hospital. After reviewing the patient's data, we have identified 63 patients had undergone a fistula surgery. Out of these 63 patients, due to the incompleteness of the data, we have come up with 47 study participants and we have analyzed our study based on these patients.

Of the 47 study participants, 51.1% (n=24) were females and the rest were male patients. The age of the participants during the fistula surgery varied from 2 to 41 years, with a mean age of 12 ± 8.6 SD years. The age group less than 10 years of age had the highest number of study participants *n* = 24 (51.1%). Majority of the study participants (80.9 %) had a cleft lip and palate whereas the rest 19.1% of the study participants had cleft palate only. 80.9% (n=38) of the patients had a complete cleft type and the 19.1 % (n=9) had incomplete cleft type. Palate repair was performed at Yekatit hospital for the 55.3% (n=26) of the study participant. The overall sociodemographic and clinical characteristics of the study participants are provided in **Table 5.1**.

Table 5.1: Sociodemographic and clinical characteristics of the study participants

Characteristics	Number	Percent
Study participants (*n* = 47)		
Sex		
Male	23	51.1
Female	24	48.9
Age at palate repair		
<10	41	87.2
11-20	4	8.5
>20	2	4.3
Age at Fistula surgery		
<10	24	51.1
11–20	17	36.2
>20	6	12.8
Cleft type		

Cleft Lip and Palate	38	80.9
Cleft Palate	9	19.1
Cleft palate type		
Complete	38	80.9
Incomplete	9	19.1
Palate surgery hospitals		
Yekatit 12	26	55.3
Other hospital	21	44.7

5.2. Trend of the fistula surgery

Majority (53.2%) of the study participants presented for the fistula surgery within 5 years after they undergone a palate repair. However,46.2 % of the study participants were presented for fistula surgery after 5 years of palate repair. The average presentation for fistula surgery was 6.6 ± 5.6 SD years. The trend of fistula surgery for the previous ten years (2014-2024) showed the increment over the years **(Figure 5.1)**.

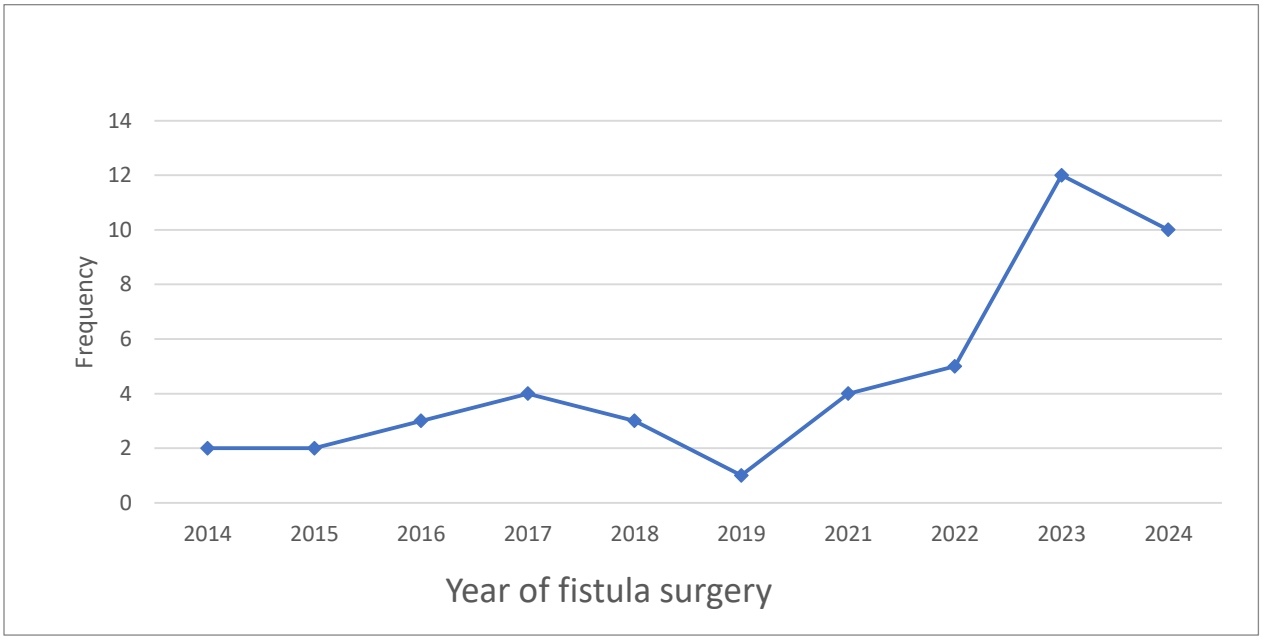


Figure 5.1: Trend of fistula surgery at Yekatit 12 hospital from 2014-2024, Addis Ababa, Ethiopia

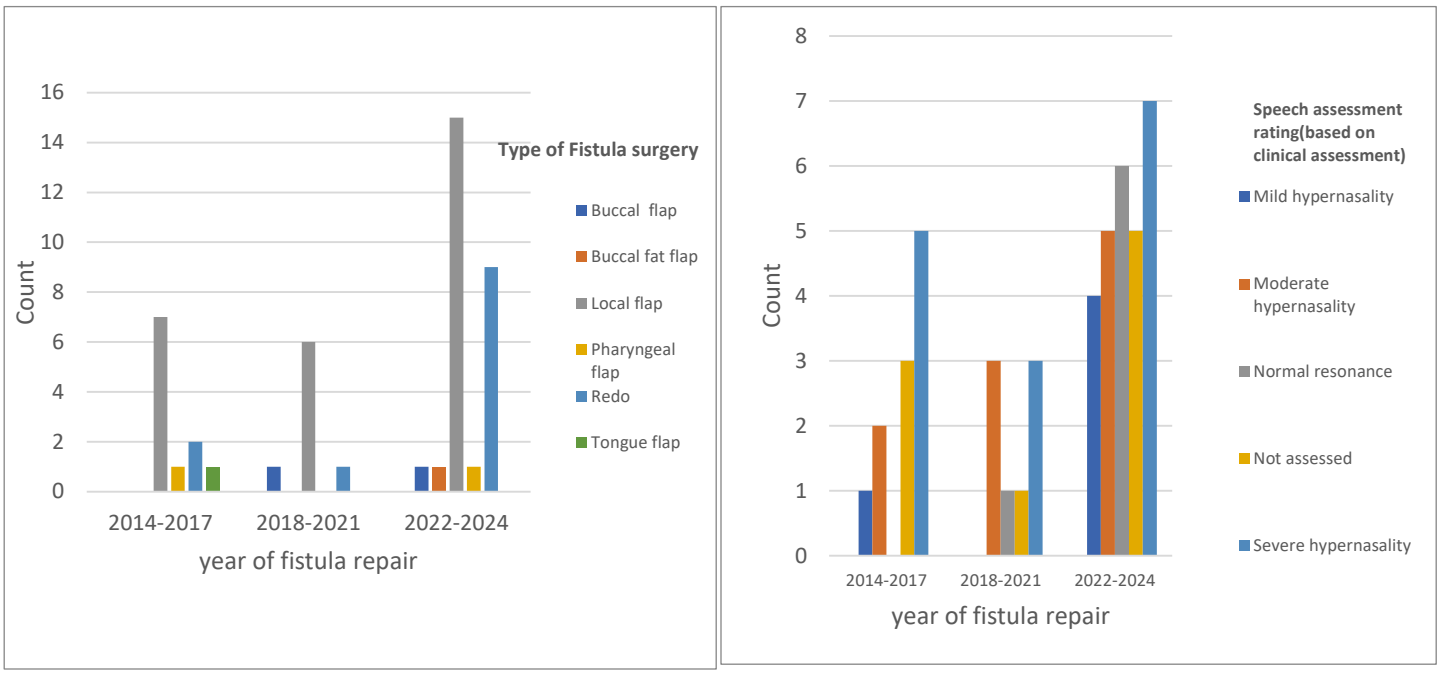
When we categorized into three groups, 58.7% (n=27) of fistula surgery was performed on the last three years (2021-2024). Wheras, 17.4% and 23.9 % of fistula surgery was performed within

the years of 2018-2020 and 2014-2017 respectively. The number of fistula surgery performed across age groups within the last 10 years is presented in **Table 5.2.**

Table 5.2: Trend of fistula surgery within age groups at Yekatit 12 hospital from 2014-2024, Addis Ababa, Ethiopia

			Age group fistula			Total
			<10	**11-20**	**>21**	
Year of fistula repair	**2014-2017**	Count	4	5	2	11
		% within year of fistula repair	36.4%	45.5%	18.2%	100.0 %
		% within Age group fistula	16.7%	29.4%	40.0%	23.9%
		% of Total	8.7%	10.9%	4.3%	23.9%
	2018-2021	Count	6	1	1	8
		% within year of fistula repair	75.0%	12.5%	12.5%	100.0 %
		% within Age group fistula	25.0%	5.9%	20.0%	17.4%
		% of Total	13.0%	2.2%	2.2%	17.4%
	2022-2024	Count	14	11	2	27
		% within year of fistula repair	51.9%	40.7%	7.4%	100.0 %
		% within Age group fistula	58.3%	64.7%	40.0%	58.7%
		% of Total	30.4%	23.9%	4.3%	58.7%

For the last 10 years, majority of the study participants had a local flap type of fistula surgery (59.6%, n= 28). Redo type of fistula surgery accounts 25.5% (n=12), buccal flap 4.3% (n=2) and pharyngeal flap 4.3% (n=2). Each of the buccal and tongue flap surgery accounts 2.1% (n=1) of the total surgery type performance. **Figure 5.2** and b shows the patterns of fistula repair in years with respect to surgery types and speech assessment.



(a) **(b)**

Figure 5.2: Patterns of fistula repair in years with respect to surgery types and speech assessment at Yekatit 12 hospital at Addis Ababa, Ethiopia from 2014-2024.

5.3. Impacts of surgical techniques vs development of palatal fistula

The type of palate surgery performed for the study participants were Bardach palatoplasty (48.9%), Furlow palaoplasty (4.3%), Intervelar veloplasty (4.3%). The rest 42.5% of the study participants had no information about their surgery types. The complications after undertaking the palatoplasty were also determined. Majority of the patients had Oronasal fistula (74.5%, n=35) followed by Oronasal fistula with Hypernasality (19.1%, n=9). The rest of the patients lied on the categories of Oronasal fistula, Hypernasality, Velopharyngeal insufficiency (VPI) (6.3%, n=3). We have not observed any significant associated with the type of surgery and the complications (p value = 0.98). The distribution of the palate surgery types and the complications are seen in the bar graph **(Figure 5.3)**.

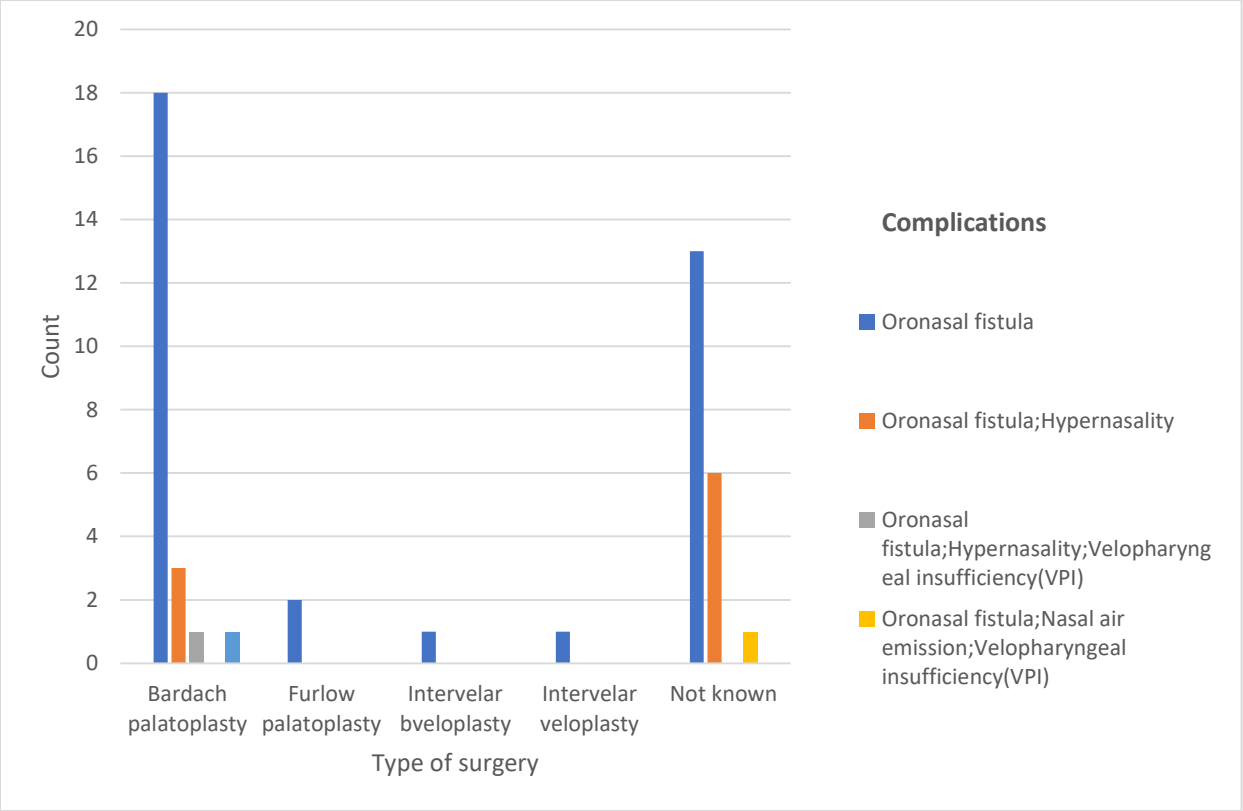
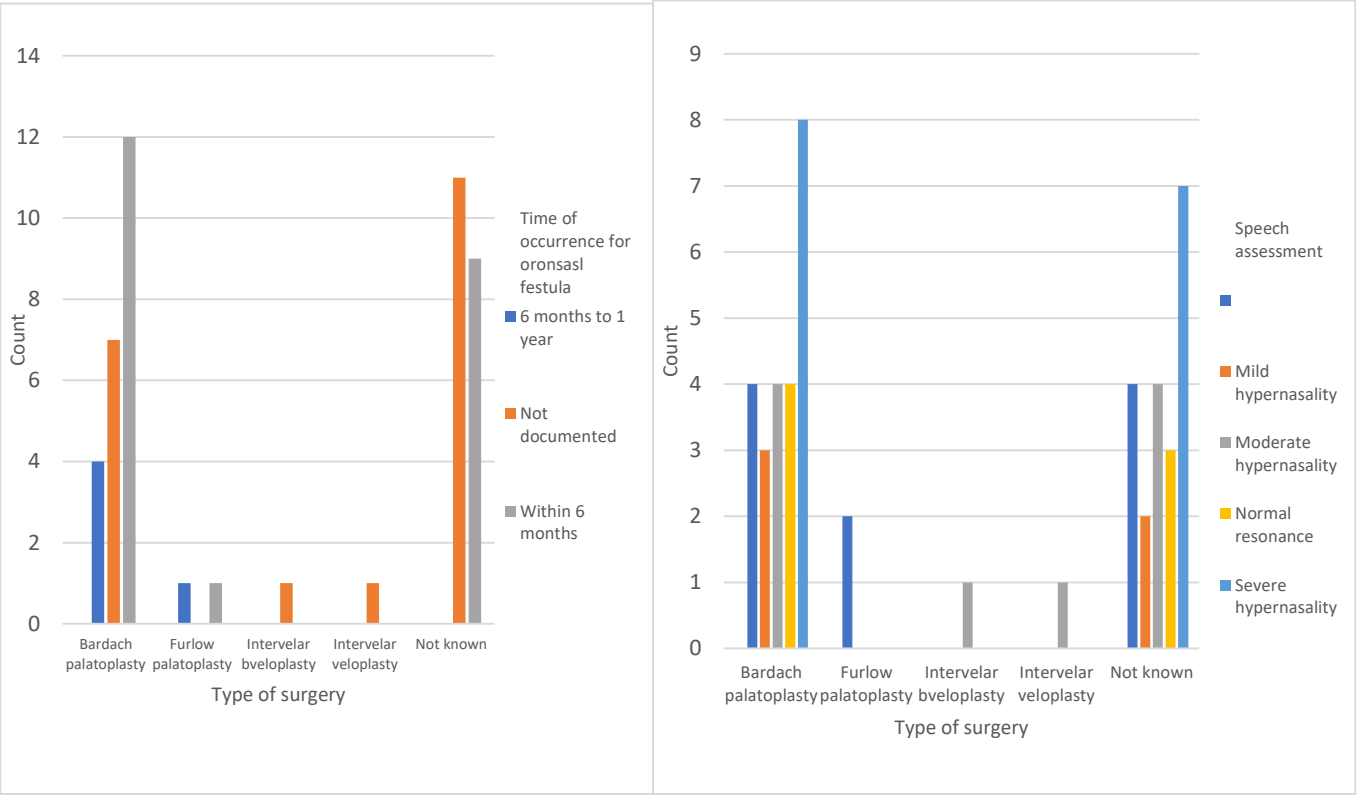


Figure 5.3: Techniques of palate surgery and complications of palatoplasty at Yekatit 12 hospital from 2014-2024, Addis Ababa, Ethiopia

We have also assessed the time frame for occurrence of oronasal fistula post-surgery and 46.8% of the patients came within 6 months of surgery. 10.6% of them had the oronasal fistula occurrence within 6-12 months of post-surgery. The rest 42.6 % of the patients had no data about the occurrence. There was no significant association between the palate surgical techniques and time frame for the occurrence of ONF (*p=0.19*) and based on the clinical assessment, the speech assessment of the study participants was categorized under sever hypernasality (31.9%), moderate hypernasality (21.3%), normal resonance (14.9%) and mild hypernasality (10.6%). 21.3% of the study participants hand no speech assessment was performed. No significant association was also observed between the surgical techniques and speech assessment (*p=0.49*) (**Figure 5.4**).



(a) **(b)**

Figure 5.4: Types of surgical techniques with time of occurrence of ONF and speech assessment at Yekatit 12 hospital, Addis Ababa, Ethiopia

5.4. Demographic and clinical factors with the formation of palatal Fistulas

We determined the sociodemographic factors such as age and sex of the study participants during palate surgery have an effect for the formation of palatal fistula. Of the 41 study participants aged under 10 years, formation of oronasal fistula was observed in 75.6% of the subjects. 75% and 50% of the study participants under the age of 10 had also oronasal fistula. There is no significant association within the age group during palate repair and formation of palatal fistula ($p=0.11$). In addition, sex was not also significantly associated with the formation of palatal fistula ($p=0.54$). Other clinical factors such as type of cleft, type of palate cleft, type of surgery performed was also determined **(Table: 5.3)**. The presence of associated syndrome after the repair was evaluated and all (100%) the study participants were non-syndromic.

Table: 5.3: Sociodemographic and clinical factors with the formation of palatal fistula at Yekatit 12 hospital, Addis Ababa, Ethiopia

Characteristics		Formation of palatal fistula						
Study participants (*n* = 47)		**Oronasal fistula**	**Oronasal fistula, Hypernasality**	**Oronasal fistula, Hypernasality, Velopharyngeal insufficiency (VPI)**	**Oronasal fistula, Nasal air emission, Velopharyngeal insufficiency (VPI)**	**Oronasal fistula, Velopharyngeal insufficiency (VPI)**	**Total**	**P-value**
Sex								***0.11***
Male	Number	17	5	1	0	1	24	
	Percent	70.8	20.8	4.2	0.0	4.2	100	
Female	Number	18	4	0	1	0	23	
	Percent	78.3	17.4	0	4.3	0	100	
Age at palate repair								***0.54***
<10	Number	31	8	1	0	1	41	
	Percent	75.6	19.5	2.4	0.0	2.4	100	
11-20	Number	3	0	0	1	0	4	
	Percent	75	0	0	25	0	100	
>20	Number	1	1	0	0	0	2	
	Percent	50	50	0	0	0	100	
Type of Cleft								***0.94***
Cleft Lip and Palate	Number	28	7	1	1	1	38	
	Percent	73.7	18.4	2.6	2.6	2.6	100	
Cleft palate	Number	7	2	0	0	0	9	
	Percent	77.8	22.2	0	0	0	100	
Type of cleft palate								***0.94***
Complete	Number	28	7	1	1	1	38	
	Percent	73.7	18.4	2.6	2.6	2.6	100	
Incomplete	Number	7	2	0	0	0	9	
	Percent	77.8	22.2	0	0	0	100	
Type of Surgery Performed								***0.89***
Bardach palatoplasty	Number	18	3	1	0	1	23	
	Percent	78.3	13	4.3	0	4.3	100	
Furlow Palatoplasty	Number	2	0	0	0	0	2	
	Percent	100	0	0	0	0	100	
Intervelar veloplasty	Number	2	0	0	0	0	2	

Percent	100	0	0	0	0	100	
Not known Number	13	6	0	1	0	20	
Percent	65	30	0	5	0	100	

6. Discussion

Palatal fistula is the most common complication following cleft palate surgery (20) Several factors contribute to this issue, including insufficient tissue mobilization, closure under tension, inadequate postoperative pain management, and hematoma formation (21)

Palatal fistula can be either symptomatic or asymptomatic. Symptomatic fistulas may lead to persistent regurgitation, hygiene challenges, frequent halitosis, and hypernasal speech. In contrast, asymptomatic fistulas typically do not require treatment. However, symptomatic fistulas pose significant surgical challenges due to the diverse clinical manifestations, the presence of previous scars complicating re-interventions, limited local tissue availability, and a lack of consensus on the optimal repair technique (3). The incidence rates of palatal fistulas reported in the literature vary widely, reflecting differences in surgical techniques, patient demographics, and study methodologies(23).

In our study, we investigated the prevalence and characteristics of palatal fistulas following primary palate repair at Yekatit 12 Hospital Medical College in Addis Ababa, Ethiopia, over a ten-year period (2014-2024). The findings from our retrospective study provides significant insights into the prevalence, demographic patterns, and surgical outcomes related to this complication. The trend of fistula surgery at Yekatit 12 Hospital showed an increase over the ten-year period, with the highest number of surgeries performed in the last three years (2021-2024). This increase could be attributed to various factors, such as improved awareness and access to care, changes in surgical techniques, or a higher number of complex cases being treated at the hospital (24).

The predominance of females (51.1%) in this cohort aligns with the study conducted by Yarhere KS et al. (53.4%)(6). However, no sex differences were found in the number of fistulas in other studies (25,26). In contrast, a study conducted in India by Mahajan RK et al. revealed that male

predominance was reported (27). This variation may be attributed to differences in the number of study participants, the age groups involved, and the characteristics of the hospitals where the palate surgeries were performed.

The study indicated that most patients (53.2%) presented for fistula surgery within 5 years after primary palate repair, while a substantial proportion (46.2%) presented after 5 years. The average presentation time for fistula surgery was 6.6 years. This suggests that while many fistulas manifest relatively soon after the initial repair, some may develop or become symptomatic later (28,29)

Managing a patient with a palate is a complex process. While several widely-used surgical techniques are available, there is no consensus on the most effective treatment strategy(30). Of the surgery types for the palate, Bardach palatoplasty was the most common primary palate surgery (48.9%), while Furlow palatoplasty and intervelar veloplasty were less common. On the other hand, a study conducted in Nigeria showed that Bardach surgery was the least surgery performed (24.4%) (6). However, information on the primary surgery type was unavailable for 42.5% of the study participants, which limits definitive conclusions about the impact of specific surgical techniques on fistula formation.

Cleft palate repair can lead to several complications, including the development of fistulas, velopharyngeal insufficiency, and negative impacts on the growth of the upper jaw (10,32). In our study, the most common complication post-palatoplasty was oronasal fistula (74.5%), sometimes accompanied by hypernasality (19.1%) which is also similar with many studies conducted in worldwide (7,33,34).

Various surgical techniques are employed for palatal fistula repair, including local flaps, regional flaps (such as buccal flaps and tongue flaps), and free flaps for larger defects (35). Among various techniques used for palatal fistula closure, local flap surgery (59.6%) was most commonly used in our study which is similar with another study conducted in India(36). The predominance of local flap surgeries aligns with current recommendations that advocate for this technique due to its effectiveness in maintaining palatal function (37)

Palatal fistulas can negatively impact speech, leading to hypernasality, nasal emission, and articulation disorders (38,39) The speech assessment outcomes in our study indicated that a concerning rate of hypernasality, with 31.9% of participants showing severe hypernasality. This is consistent with previous studies that have documented speech complications following palate repair(40). Another study at Yekatit 12 Hospital also found a moderate and severe hypernasality (45.7%) in patients who underwent palatoplasty(7).

The study assessed the impact of demographic and clinical factors on palatal fistula formation. But, no significant association was found between the risk factors and the incidence of palatal fistula. Similarly, a study conducted by Park MS et al. also revealed that the incidence of fistula was not significantly associated with sex, age at cleft palate repair, the presence of an associated syndrome, cleft lip, and the extent of the cleft (29). However, many factors, including the surgical technique, timing of surgery, extent of cleft, presence of cleft lip, surgeon's experience, and associated syndromes, are known to increase the risk of palatal fistula (41,42).

Limitations

Several limitations should be considered when interpreting the results of this study. The incompleteness of data for some patients especially regarding the primary surgery type and the time of the occurrence of ONF limited the ability to draw strong conclusions about the factors influencing fistula formation. The lack of standardized speech assessment data for all participants also makes it difficult to evaluate the impact of fistula on speech outcomes

7. Conclusion and recommendations

Our study contributes valuable data to the understanding of palatal fistula incidence and outcomes following palate repair in Ethiopia. The study provides valuable insights into the patterns and factors associated with palatal fistula following primary palate repair at Yekatit 12 Hospital Medical College. The findings highlight the necessity for proper documentation and continued monitoring as well as the importance of comprehensive postoperative care to mitigate the risk of complications.

We recommend that long-term follow-up to detect and manage fistulas that may develop years after the initial surgery. Further research is needed to identify the specific factors that contribute to fistula formation in this population and to evaluate the effectiveness of different surgical techniques for fistula repair. These future studies should include larger sample sizes, standardized data collection protocols, and detailed information on surgical techniques and patient-specific factors

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Annexes

Annexes 1: Questionnaire for the study

Title: Medical Record Review Format for Ten-Year Prevalence and Patterns of Palatal Fistula Following Primary Palate Repair at Yekatit 12 Hospital Medical College, Addis Ababa, Ethiopia

Instructions: please fill the following questions based on the information you find on the medical records of the patients

Demographic Information

1. Patient ID: ----------
2. Age at the time of fistula repair (in years): ----------
3. Sex: ----------
4. Type of cleft (select one)
    - Cleft lip
    - Cleft palate
    - Cleft lip and palate
5. Type of cleft palate
    - Complete
    - Incomplete
    - Not known
6. Presence of associated syndrome
    - Syndromic
    - Non-syndromic

Surgical Information

7. Year of palate surgery: ----------
8. Age at the time of palate repair: ----------
9. Where the surgery performed at yekatit 12 hospital
    - Yes
    - No
10. Type of surgery performed:
    - Bardach palatoplasty
    - Furlow palatoplasty
    - Other: ----------
    - Not known
11. Lead surgeons experience
    - Trainee
    - Large volume operator (more than 50 cleft surgeries per year)
    - Low volume operator

- Not known

Postoperative Outcome

12. Where there any of the following complications?
    - Oronasal fistula
    - Hypernasality
    - Velopharyngeal insufficiency (VPI)
    - Dehiscence
    - Other ----------
13. What was the time frame for occurrence of oronasal fistula post-surgery?
    - Within 6 months
    - 6 months to 1 year
    - 1 to 2 years
    - 2 to 5 years
    - More than 5 years
    - Not documented
14. What was the date of surgery for the oronasal fistula(mm/dd/yy)
    - ----------
15. What was the type of fistula surgery?
    - Local flap
    - Tongue flap
    - Buccal flap
    - Buccinator flap
    - Temporalis flap
    - Other----------
16. Speech assessment ratings (based on clinical assessment)
    - Normal resonance
    - Mild hypernasality
    - Moderate hypernasality
    - Severe hypernasality
    - Additional comments: ----------