

**EPIDEMIOLOGIC PROFILING OF CLIENTS AT USOFA AND FACTORS
INFLUENCING STATUS OF REHABILITATION SERVICES: A
RETROSPECTIVE STUDY**

YASHASWINI K

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Speech Language Pathology

University Of Mysore



**ALL INDIA INSTITUTE OF SPEECH AND HEARING, NAIMISHAM
CAMPUS, MANASAGANGOTHRI, MYSURU-570006**

June 2026

CERTIFICATE

This is to certify that this dissertation entitled "**Epidemiologic Profiling of Clients at USOFA and Factors Influencing Status of Rehabilitation Services: A Retrospective Study**" is a bonafide work submitted as part of fulfilment of the degree of Master of Science (Speech Language Pathology) of the student with Registration Number P01II24S123043. This has been carried out under the guidance of a faculty of this institute and has not been submitted earlier to any other university for the award of any other Diploma or Degree.

Mysuru
8th June, 2026


Dr. M. Pushpavathi

Director
All India Institute of Speech and Hearing
Manasagangothri, Mysuru-570 006

CERTIFICATE

This is to certify that this dissertation entitled "EPIDEMIOLOGIC PROFILING OF CLIENTS AT USOFA AND FACTORS INFLUENCING STATUS OF REHABILITATION SERVICES: A RETROSPECTIVE STUDY " has been prepared under my supervision and guidance. It is also being certified that this dissertation has not been submitted earlier to any other university for the award of any other Diploma or Degree.

Mysuru

June 2026

Manasa A.S
6/6/26

Guide

Mrs. Manasa A S
Assistant Professor in Speech Pathology
All India Institute of Speech and
Hearing
Manasagangothri
Mysuru-570 006

V. S. Lakshmi 5/6/2026

Co - Guide

Dr. Vasantha Lakshmi M S
Associate Professor in
Biostatistics
All India Institute of Speech and
Hearing
Manasagangothri
Mysuru-570 006

DECLARATION

This is to certify that this dissertation entitled " **Epidemiologic profiling of clients at USOFA and factors influencing status of rehabilitation services : a retrospective study** " " is the result of my own study under the guidance of Mrs. Manasa A S., Assistant Professor of Speech pathology, Dr. Vasantha Lakshmi M S , Associate Professor in Bio-Statistics All India Institute of Speech and Hearing, Mysuru and has not been submitted earlier to any other university for the award of any other Diploma or Degree.

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LIST OF FREQUENTLY USED ABBREVIATIONS

CLP: Cleft Lip and Palate

RCLP: Repaired Cleft Lip and Palate

SLP: Speech-language Pathologist

Abstract

Background: Cleft lip and palate is among the most common congenital craniofacial anomalies and is associated with communication, hearing, feeding, and psychosocial challenges. Understanding the epidemiological profile of individuals with CLP and factors influencing rehabilitation service utilization is essential for improving care delivery and outcomes.

Aim: To examine the epidemiological profile of clients attending the Unit for Structural Orofacial Anomalies (USOFA), AIISH, Mysuru, and identify factors influencing rehabilitation service utilization, follow-up status, and continuation or discontinuation of services.

Methods: A retrospective descriptive study was conducted using clinical records of 457 individuals registered at USOFA between April 2021 and April 2025. A content-validated semi-structured checklist was used for telephonic follow-up, and successful contact was established with 163 participants or caregivers. Data on demographic characteristics, cleft profile, feeding difficulties, surgical history, rehabilitation services, therapy outcomes, and factors affecting service utilization were analyzed using descriptive statistics.

Results: Most participants were pediatric clients (82.2%) and males (58.9%). Unilateral cleft lip and palate was the most common cleft type. Speech and language disorder was the predominant communication diagnosis, and feeding difficulties were reported by 77.3% of participants. The majority had undergone at least one surgical procedure, while 71.8% received rehabilitation services, primarily through face-to-face

intervention. Positive outcomes were reported in 93.3% of cases. However, loss to follow-up remained substantial.

Conclusion: Multidisciplinary rehabilitation services contributed to improved communication outcomes among individuals with CLP. Expanding family-centered care, telepractice, and hybrid rehabilitation models may enhance service utilization, continuity of care, and long-term outcomes.

Chapter 1

Introduction

Cleft lip and/or palate (CLP) are among the most common congenital craniofacial anomalies worldwide. These anomalies result from incomplete fusion of facial structures during embryo genesis and are associated with multifaceted challenges, including feeding difficulties, recurrent otitis media, hearing loss, speech and resonance disorders, dental malocclusion, and psychosocial difficulties (Kummer, 2020). The burden of CLP extends beyond medical implications to encompass social stigma, communication barriers, and reduced quality of life for affected individuals and their families. Early identification, timely surgical repair, and sustained multidisciplinary intervention are critical for optimal outcomes.

Based on research, the incidence of CLP in India ranges between 0.7 and 1.0 per 1000 live births which means that CLP is a major cause of the world incidence of the disease (Reddy et al., 2018; Mossey & Modell, 2012). It is a public health threat with regard to the size of the country's population. System issues such as late identification, ignorance, variability in service with geography, socio-economic constraints, and interruptions in long-term follow up are common challenges faced by those managing CLP in India (Sivakumar & Sundaresan, 2020). Surgeons, orthodontists, audiologists, psychologists, and speech-language pathologists (SLPs) all play a part in the care. Of all of these, speech therapy is critical because articulation and resonance often persist following surgery (Sell, 2015).

The All India Institute of Speech and Hearing (AIISH), Mysuru, is a institute dedicated to research, training, and clinical services in communication disorders. Its Unit for Structural and Orofacial Anomalies (USOFA) has emerged as a specialized center for the assessment and management of individuals with cleft lip and palate.

The unit for Structural and Orofacial Anomalies is a specialized clinical and research unit at AIISH, Mysure. It aims on the assessment and long-term management of patients with CL/P and other craniofacial anomalies. It was established as a part of AIISH's commitment to provide comprehensive treatment for communication disorders. It also provide multidisciplinary services focus on improving the functional, communicative and pyschosocial outcomes for affected individuals(AIISH2021).

USOFA follows multidisciplinary team approach which brings professionals together from other disciplines such as SLP, plastic surgery, audiology, orthodontics, psychology, prosthodontics. Within these professionals, SLP plays a main role in assessing, managing speech and resonance disorders by providing counselling to

parents and caregivers, and monitoring the clients and their progress via regular follow-up sessions (Sell 2015). This unit also places strong emphasis on early intervention and active parental participation, recognizing their importance for better outcomes and minimizing complications associated with CL/P (Rao, 2018).

Global healthcare services were interrupted by the COVID-19 pandemic in 2020, resulting in the postponement or suspension of therapy sessions and elective procedures (Ramanathan et al., 2021). In this setting, teleassessment and telepractice quickly became accepted as competitive substitutes for providing clinical services in person. In 2020, the Indian government's Ministry of Health and Family Welfare officially approved telemedicine and established moral and legal standards for its application in the provision of healthcare (MoHFW, 2020; Dinakaran et al., 2021). Despite limitations on in-person sessions, telepractice allowed for ongoing therapy, parent counseling, and follow-up monitoring for speech-language pathology services. Using remote technologies, teleassessment for CLP enabled doctors to analyze speech characteristics such as compensatory articulations, nasal emission, hypernasality, and overall intelligibility (Pamplona et al., 2020).

Even while telepractice has proven to be viable and acceptable, concerns about its long-term efficacy and sustainability still exist, particularly in low- and middle-income nation environments like India. Numerous factors, such as socioeconomic background, parental engagement, technology availability, internet stability, cultural perspectives, and the perceived value of therapy, can impact adherence to therapy and follow-up through telepractice (Baigorri et al., 2021; De Taeye et al., 2023). Treatment outcomes are compromised by considerable loss to follow-up in cleft services, according to prior research conducted in both developed and developing nations (Van

Swol et al., 2022). These issues could be made worse in the Indian context by disparities in caregiver literacy, language diversity, and digital divides (Rao, 2018).

Therefore, a systematic investigation into the epidemiological profile, therapy follow-up, and determinants of continuation or discontinuation of cleft services via teleassessment is necessary. Such an inquiry will provide evidence regarding who is accessing teleassessment services at USOFA, how regularly families engage with therapy sessions. This information is vital for tailoring telehealth interventions to maximize adherence, equity, and treatment outcomes in cleft care.

The current dissertation aims to close this gap by concentrating on the epidemiological profile, therapeutic follow-up, and factors influencing the continuation or discontinuation of cleft services via assessment at the USOFA Cleft Unit, AIISH, Mysuru (2020–2024). In addition to analyzing therapy attendance and follow-up patterns and documenting the clinical and demographic features of the clients served over this time, it will investigate the contextual facilitators and barriers that affect the use of telehealth-based cleft therapies. The results are anticipated to inform institutional procedures at AIISH, reinforce hybrid (in-person + tele) models of cleft treatment in India, and expand the small but increasing amount of knowledge on teleassessment in cleft management

1.1 Need of the study

The most common congenital craniofacial abnormality, cleft lip and palate (CLP), causes complicated functional, communication, and psychosocial challenges. Children with CLP frequently experience difficulties with speech, language development, nutrition, hearing, and appearance, all of which have an impact on their academic success, social integration, and psychological health. Therefore,

rehabilitation services necessitate a multidisciplinary, long-term strategy comprising speech-language pathologists, audiologists, psychologists, orthodontists, and surgeons rather than only surgical treatment.

There is still a large difference in awareness, access, and continuity of rehabilitation programs in India, a country with a high prevalence of CLP. Even though organizations like the Unit for Structural Oro-Facial Anomalies (USOFA) at AIISH, Mysuru, offer comprehensive cleft care, many patients miss follow-up appointments or stop therapy because of financial limitations, cultural beliefs, travel distance, and ignorance of the significance of ongoing intervention. In addition, the COVID-19 epidemic significantly impacted in-person services, necessitating the immediate adaptation and strengthening of teleassessment and tele-rehabilitation models.

The AIISH Annual Report (2023–2024) states that 155 people came to the USOFA at AIISH, Mysuru. They showed a fairly balanced gender distribution, with 75 males and 80 women. 77 children who had their CL/P corrected received 270 speech-language therapy sessions throughout that time. These figures demonstrate the active utilization of services, but they also raise serious questions regarding the larger population in need, their follow-up schedules, and potential obstacles to continuing therapy.

Particularly in the setting of a multidisciplinary cleft care unit like USOFA, there is currently a lack of thorough epidemiological data on the characteristics of people using cleft services, their therapy follow-up status, and the factors influencing the use of rehabilitation services. Planning for fair and long-term care, adjusting interventions to local requirements, and enhancing service delivery all depend on an understanding of these trends. This emphasizes the critical need for an epidemiological study to determine who

is using these services, how regularly they are attending therapy, and what barriers they could come across. The results can direct policy-level planning as well as clinical choices to guarantee equity, continuity, and accessibility in cleft care.

This research on the epidemiological profiling of USOFA clients provides important information about the demographics, clinical requirements, and distribution of cleft types in this community. Understanding obstacles in the provision of services also depends on determining the variables that affect the continuation or discontinuation of rehabilitation treatment. It is challenging to create individualized interventions that guarantee prompt, accessible, and long lasting rehabilitation for every client in the absence of such comprehensive data.

1.2 Aim and objectives: To develop an epidemiological profile of individuals with CL/P evaluate therapy follow-up patterns, and identify factors influencing the status of rehabilitation services delivered at the USOFA Cleft Unit, AIISH, Mysuru, during the period April 2021–April 2025.

Primary Objective: To develop the epidemiological profile of cleft lip and/or palate cases who visited the USOFA Cleft Unit at AIISH from April 2021–April 2025.

Secondary Objectives: To study the factors influencing the status of rehabilitation services of individuals with cleft lip and/or palate who visited the USOFA Cleft Unit at AIISH from April 2021–April 2025

Chapter 2

Review of Literature

India, one of the world's most heavily populated countries, substantially adds to the worldwide burden of (CLP) India shows us how biological, social, and health system factors interact in the epidemiology of CLP in India Datta and Singh (2025) conducted a large hospital-based cross-sectional study, as part of the Rashtriya Bal Swasthya Karyakram (RBSK) program in Bihar, and provided new insights into the distribution of cleft forms and associated factors .The study found that cleft palate alone accounted for 46% of cases, followed by cleft lip with palate (30%) and isolated cleft lip (16%). Bilateral clefts were present in 42% of cases, with a male-to-female ratio of 3:2. Maternal health characteristics had a substantial impact on outcomes. Over half of the women did not receive adequate prenatal care, 54% of them had anemia throughout pregnancy, and 57% did not take iron and folic acid supplements.

These results are consistent with larger public health issues in India, where access to healthcare and maternal nutrition continue to be important factors influencing neonatal outcomes. Another important factor was sociocultural beliefs, with 94% of households linking clefts to myths like exposure to solar or lunar eclipses. Twenty-two percent of cases had a family history of clefts, and syndromic correlations (such Apert syndrome) were also noted.

The Study persistent barriers in maintaining the therapy follow-up and long - term rehabilitation, despite improved access to surgical interventions via RBSK program. These results shows that surgery alone is not sufficient to provide better intervention

outcomes . Barriers like financial constraints, travel difficulties, and limited access to specialized services continue to impact therapy attendance and continuity of care.

Innovative approaches like tele assessment and tele rehabilitation may help to address the problems by reducing geographical and economic barriers while supporting ongoing therapy services . Similar findings have been reported in India, where adherence to long term rehabilitation stays a major concern despite increased availability of surgical treatment (Datta & Singh 2025)

Vaibhav et al. (2020) investigated environmental and genetic risk factors associated with cleft lip and palate among 48 patients attending a government hospital in Patna, Bihar. The study found that combined cleft lip and palate was the most prevalent presentation (64.58%), followed by cleft lip alone (25%) and cleft palate alone (10.42%). A slightly higher occurrence was observed among males, and first-born children appeared to be more frequently affected. Maternal risk factors were identified as stress during pregnancy (81%), previous miscarriages (29%) and low folic acid supplementation (17%). Paternal lifestyle factors were identified as most fathers admitted to drinking alcohol and/or smoking. In addition, 25% of mothers had a positive family history of clefts and consanguineous marriages. were reported in 37.5% of cases, highlighting the contribution of both genetic and environmental influences in the development of cleft lip and palate, highlighting the potential contribution of genetic factors to the occurrence of cleft conditions.

The findings corroborate the complex nature of cleft aetiology, where risk is impacted by both environmental and genetic predispositions. Despite its limitations due to its small sample size retrospective design, the study provides helpful baseline data

and demonstrates the importance of maternal health interventions and preventive knowledge in minimizing the prevalence of clefts in the area (Vaibhav et al., 2020). The frequency of cleft lip and palate in 84 patients treated during five free outreach surgical camps in Kenya was investigated by Mukami, Angela, and Wanjala (2021). The majority of cases (58.3%) involved children under the age of two, while males were more frequently afflicted (61.9%).

The most common deformity was cleft lip alone (46.4%), followed by cleft lip with palate (34.6%) and cleft palate alone (15.5%). Unilateral left-sided clefts were most common. The majority of patients had to travel more than 50 kilometers from under served and rural locations in order to receive surgical care, emphasizing the lack of access to specialized cleft services. The overall post-surgery complication rate was extremely low (<3%), and familial and syndromic correlations were uncommon. In order to meet the unfilled surgical needs of cleft patients in sub-Saharan Africa, the results highlight the significance of outreach programs in addressing healthcare disparities and point to the necessity of frequent, regionally distributed activities (Mukami, Angela, & Wanjala, 2021).

In order to create baseline epidemiological clinical data, Diwana et al. (2019) analyzed 926 cleft patients over a ten-year period at a tertiary care facility in Himachal Pradesh, India. The most prevalent kind was cleft lip palate (52.5%), followed by cleft palate (26.2%) and cleft lip alone (21.3%), with a small male predominance (male-to-female ratio of 1.2:1). Left-sided clefts were more common than right-sided ones, and unilateral clefts were more common than bilateral cases.

According to the study, only 24.9% of patients had surgery during infancy, with lip repair occurring at 2.8 years of age and palatoplasty occurring six years later than

advised. The most common related malformations were craniofacial abnormalities, and isolated cleft palate was more common in female patients.

The results highlight the need for better healthcare access and early surgical intervention by showing notable treatment delays, ignorance, and infrastructure constraints in cleft care, particularly in rural and hilly areas (Diwana et al., 2019). The diverse nature of CL/P has been highlighted by other research from various Asian nations that have similarly recorded the burden of CL/P and found a variety of contributory factors. Mirafazeli et al. (2012) calculated an incidence of 1.05 per 1,000 live births in Northern Iran based on a hospital-based study in Gorgan. Turkman children had a significantly higher risk (relative risk = 2.56) than Native Fars, according to the study, which also found significant ethnic differences and higher rates among boys.

In addition to genetic susceptibility, other risk factors were parental consanguinity, maternal smoking, nutritional deprivations and socio-economic status. Of importance, 20 – 30% of the children had other congenital anomalies and thus needed not only difficult medical care but also prolonged multi directional care and special speech therapy procedures. New data from Bhutan providing important epidemiological data in South Asia.

Tobgyal et al. (2024) Orofacial clefts accounted for 8.7% of all congenital anomalies registered in Bhutan. Period prevalence was 1.37/1000 live births as calculated from 8 years of data from the national birth defect surveillance system. Male to female ratio was 59%. The year of highest prevalence was 2019 (1.96/1000 live births). Most occurrences included term infants and CL/P was most commonly associated with mothers aged 25-29 years.

The most common sub types were unilateral clefts, specifically unilateral cleft lip and cleft palate with cleft lip. Increased availability to diagnostic services and improved maternal-child health monitoring were linked to an increasing trend in incidence. This emphasizes how crucial it is to set up reliable registries and monitoring systems throughout South Asia in order to precisely monitor prevalence and direct public health activities.

Gonzalez et al. (2008) examined 835 instances over a five-year period in Mexico and discovered that 70% of cases were CL/P, 21% were cleft palate, and 8% were cleft lip. Once more, a 1.5:1 male-to-female ratio suggested a male majority. Correlations between maternal and paternal traits, including parity, advanced parental age, and abortion history, were discovered in the study. Environmental risks were also connected, particularly maternal agricultural activities and pesticide exposure.

Significantly, the study indicated that children from low-income and rural families rarely finished multi-stage treatment, revealing geographical and socioeconomic limitations equal to those in India.

According to Teles et al. (2023), who studied 102 pediatric cases in Portugal, the most common intraoperative incident (21.6%) was respiratory problems, especially in children less than one year. Desaturation, laryngospasm, and difficult intubation were prevalent. 16.7% of patients had postoperative complications, such as fever, respiratory infections, and one death from hemorrhagic shock. Cleft lip and palate was the most common sub type (58.8%), with a slight male prevalence (52%) and syndromic connections including Pierre Robin and Stickler syndromes in 13.7% of patients, according to a follow-up study conducted by the same center between 2016 and 2021. The major perioperative risks and the requirement for specialist facilities with

standardized treatment protocols are highlighted by the nearly 39% of cases that had intraoperative problems (Teles et al., 2023).

A retrospective descriptive epidemiological study was carried out in Northern Finland by Lithovius et al. (2014) to investigate the cleft lip and palate pattern among 214 patients who received treatment at the Oulu Cleft Lip and Palate Center between 1998 and 2011. The examination concentrated on laterality, sex distribution, cleft type, and family history. In contrast to many other European groups, isolated cleft palate was the most prevalent phenotype, while cleft lip and palate and cleft lip alone were less common.

Additionally, sex-specific variations in presentation were found in the study. Males were more likely to have cleft lip with or without cleft palate, but females were more likely to have isolated cleft palate. Left-sided participation was more common in unilateral situations. A significant genetic component in this population is suggested by the fact that about one-fifth of the patients indicated a positive family history. The scientists came to the conclusion that, despite the retrospective design's limitations in assessing environmental and prenatal risk variables, the high percentage of cleft palates and the total incidence in Northern Finland may represent population-specific genetic influences.

Kianifar et al. A very large 30 year study in Mashhad, North-Eastern Iran by (2015); has been done to detect the prevalence and possible causes of CL/P among new born. They accessed records of births registered from 28,519 fullterm Iranian babies born in three major referral hospitals (Ghaem, Imam Reza and Ommolbani health centers), then they made sure that data were reflecting a wide urban population yet the study sample was homogeneously ethnically. The data of each infant such as sex, birth weight, date of birth type side cleft mother age number pregnancies abortion history

other congenital malformations present were recorded meticulously, which they explained enabled them to develop a straightforward image of how often CL/P occurred and what its normal presentation looked like. CL/P occurred at a rate of 1.9 per 1000 live births, greater than some earlier reports from other regions of Iran but similar to The East and South Asian countries suggest either the mean or ethnicity plays significant role in CL/P occurrence (10-20). (CLP) was the most common cleft type, reported for approximately half of all cases followed by isolated cleft lip and then isolated cleft palate respectively,

The majority of these clefts were bilateral, suggesting that more severe types were more prevalent in this area. Males significantly outnumbered females (male:female ratio = 2.3:1), which is consistent with other reports and provides some support for the possibility that boys are somehow less susceptible to acquiring CL/P. The researchers also found that 37% of the infants with CL/P had other congenital abnormalities, showing that babies with clefts are not a separate category of infant but often have more general congenital malformation. The overall rates of cleft lip alone and isolated cleft palate remained relatively constant over the course of the three decades, according to the researchers' analysis of changes over time. However, there was a notable increase in cases of cleft lip with palate between 2002 and 2011, which may be due to changes in risk factors or improved detection and reporting. Although they looked at a number of maternal and birth-related factors, they found no significant associations between CL/P and maternal age, season of birth, number of pregnancies, or history of abortion. Additionally, although babies with isolated cleft palate tended to have slightly lower birth weights, the difference was not statistically significant.

Even though the authors observed that their study lacked information on variables that are known or suspected to affect orofacial cleft risk, such as parental

consanguinity, maternal health issues, socioeconomic status, or environmental exposures, their work provides useful long-term regional data and emphasizes the need for future research that integrates genetic, environmental, and social data to better understand the causes of CL/P and to direct prevention and public health planning.

One of the most prevalent significant congenital defects, CL/P develops when the union of the facial processes is disturbed in the early stages of embryonic development. The structural separation of the lip, alveolus, and/or palate caused by this failure of normal fusion can result in long-term problems in speech, hearing, dentofacial growth, appearance, and psychosocial functioning, as well as feeding issues during infancy. As a result, affected individuals, families, and healthcare systems bear a significant emotional and financial cost as a result of CL/P.

Children with CL/P encounter a number of problems from the beginning of their lives, such as feeding problems which affect growth and weight, recurrent ear infections which may affect hearing, speech and language impairments, dental defects, and psychosocial problems, such as low self-esteem and avoidance behavior towards other people. Because the demands are both functional and psychosocial, the management of these children requires a multidisciplinary approach involving surgeons, dentists, audiologists, psychologists, social workers, and speech-language pathologists.

Research is to determine how genetic predisposition plays with environment exposure which includes that of folate related genes, poor maternal diet, and smoking.

Also we need more study which looks at the role of paternal age and lifestyle factors, regional differences in cleft palate laterality and severity, and the long term results of CL/P on cognitive growth, academic performance, mental health, and quality of life. We especially need longitudinal studies which follow up affected

individuals from childhood through to adulthood in which to compare different care models. Overall there is support from the evidence for the development of better surveillance systems and the incorporation of cleft prevention into maternal and child health programs. Key measures put forth are preconception counseling, folic acid supplementation, smoking cessation support, and reduction of environmental exposures in high risk groups. Also it is noted that which advances in prenatal diagnosis be combined with equal access to specialized multi disciplinary care which in turn will help to avoid family decision of termination or delayed treatment due to lack of services or finance mainly in resource poor settings.

Studies out of many parts of the world report that Asian populations do in fact have higher rates of a number of these issues as compared to Caucasian or African groups which in turn we see is a mix of heredity and also environmental issues like poor nutrition, chemical exposure, or illness which play at a critical stage of the fetus' development of the face. In Pakistan which is a large scale issue already due to high birth rate and also factors like poverty and limited health care which in the past were not well recorded for this issue mostly from hospital based reports rather than a full scale community look so the problem was reported to be of a smaller scale than what it presented to be. Also recent epidemiology out of South Asia and the bordering areas has done to present the very complex nature of CL/P. The in depth study we did also reported on what we found to be key risk factors. Consanguinity was a factor in almost one third of cases which we take to mean that genetics play a large role in this which in our population we see still has very much a place. Also we saw that advanced parental age, low folic acid intake, irregular pre natal care, maternal health issues during pregnancy, prematurity, and low birth weight were associated with CL/P. Moreover, we found that 20% of the affected newborns had chromosomal abnormalities or what

one can call related anomalies, for example, Pierre Robin sequence, which underscores the importance of a neonatal work-up and a team approach to therapy. Secondly, our results demonstrate the epidemiology of CL/P and the acute need for preventative measures, i.e., genetic counseling, better prenatal care, maternal nutrition, and birth defect surveillance that are so desperately needed in public health practice.

In a similar way a Gujarati study that examined potential etiological factors involved 166 children and teenagers with cleft lip and palate who received orthodontic treatment. Unilateral cleft lip and palate, particularly on the left side, was the most prevalent look in the cohort, which was predominately male. The research was found to be substantially correlated with parental consanguinity, positive family history, previous maternal miscarriages, maternal medication use during pregnancy, and large parental age disparities. Parental tobacco use was common in this group, although it was not statistically significant.

On the whole, the results support the notion of a diverse etiology for cleft problems with both environmental and genetic components. We requested the authors to conclude by emphasizing early identification, folic acid supplementation, community awareness and better preventive and rehabilitation programs.

Taken together, these studies have demonstrated that genetic vulnerability, maternal health and reproductive variables, and environmental exposures combine to affect occurrence of CL/P. They also underscore the need for an integrated public health approach encompassing long-term multidisciplinary care, early diagnosis and prevention.

Chapter 3

Methods

3.1 Research Design: This study adopt retrospective, observational, and descriptive design to analyze the epidemiological profile, therapy follow-up, and factors influencing rehabilitation services delivered at the Unit for Structural Orofacial Anomalies (USOFA), All India Institute of Speech and Hearing (AIISH), Mysuru between April 2021–April 2025.

3.2 Population:

The participants includes all individuals who registered and availed services at the USOFA unit, AIISH, Mysuru, between April 2021 and April 2025.

A total of 457 participants were identified from the clinical records and included in the study. Of these, successful telephonic contact was established with 163 participants or their caregivers, who completed the follow-up interview. The remaining 294 participants could not be reached despite repeated contact attempts and were therefore classified as non-respondents. While telephonic follow-up data were available only for the 163 respondents, record-based data from all 457 participants were included in the epidemiological analysis.

Inclusion criteria

Records of individuals who registered and consulted at the USOFA unit, AIISH, between April 2021 and April 2025.

- Availability of complete demographic details and valid contact information.

Exclusion criteria

- Records with incomplete or missing demographic or clinical data.
- Clients who could not be contacted despite three separate attempts made on different days.

Ethical Considerations: The study was adhere to the guidelines provided by AIISH Ethical Committee. Informed verbal consent was obtained prior to telephonic interviews. Participant confidentiality and data privacy was maintained throughout the study.

Materials/ Instruments: The following materials was used for data collection and data analysis:

1. Client registration and clinical records maintained by USOFA (covering April 2021–April 2025), including intake forms, assessment reports, therapy attendance registers, and multidisciplinary case notes.
2. Data sheet developed in Microsoft Excel and exported to SPSS for analysis.
3. Telecommunication devices (institutional mobile phones, laptops) for making calls and data entry.
4. Digital audio-recording devices applications for consented interviews

Procedure: The study was conducted in three phases

Phase I: Data identification and extraction

After obtaining the necessary permissions from USOFA and approval from the Institutional Ethics Committee, the research team will review registration records,

clinical files, therapy attendance records, and assessment reports from April 2021 to April 2025.

Phase II: To prepare and validate checklist for telephonic interview

A semi-structured checklist was developed to obtain information regarding therapy follow-up status, mode of service delivery, duration of therapy, reasons for discontinuation of services, barriers and facilitators influencing access to rehabilitation services, and overall client satisfaction. To establish content validity, the draft checklist was circulated among 11 experienced speech-language pathologists specializing in cleft care. The experts evaluated each item for relevance, clarity, and comprehensiveness and provided qualitative suggestions for improvement. Based on their feedback, the checklist was revised to enhance item wording, reduce ambiguity, and incorporate additional domains considered important for understanding therapy adherence and service utilization. These domains included transportation-related challenges, caregiver availability, financial burden, perceived benefits of therapy, and access to teletherapy resources and technology. The details of the checklist are mentioned in Appendix-2

The content validation was done by using the adapted version of the Feedback Rating Questionnaire prepared for Field Testing of Manual for Adult Fluent Aphasia Therapy in Kannada (Goswami et al., 2011). Relevant questions for the present checklist were chosen and given for content validation. The Content Validation Index (CVI) was calculated for each parameter to quantitatively evaluate the content validation. CVI is a widely accepted method to assess the degree to which individual items are relevant. In the present study, SLPs rated each section of the manual based on selected parameters using a 5-point rating scale. CVI values were calculated using the formula given below.

$$\text{Content Validation Index (CVI)} = \frac{\text{No. of SLPs rated either good/excellent}}{\text{Total number of SLPs}}$$

Table 3.1

Parameters and ratings used for content validation

Parameter	Very Poor (1)	Poor (2)	Fair (3)	Good (4)	Excellent (5)
Simplicity					
Familiarity					
Relevance					
Presentation					
Volume					
Trainability					
Categorical					
relevance					
Feasibility					
Stimulability					
Generalization					

According to Polit et al. (2007), an item-level CVI (I-CVI) value of 1.00 is considered excellent and 0.78 or higher indicates good content validity, when rated by 11 experts. These values provided a quantitative measure of the checklist content and these along with qualitative feedback were used to guide necessary revisions before finalization.

Phase III : Telephonic Follow-up and Identification of Influencing Factors

Data entered in the study data set were blinded and included a unique de-identified study ID for each participant, demographic information (age at first registration, sex, place of residence, socioeconomic indicators and caregiver relationship), clinical characteristics [type of cleft condition, syndromic or non-syndromic classification and associated medical conditions] and service utilization details. Clinical records was analyzed for details such as names of professionals consulted, services/service types received, date of commencement care (which begins when a clinician first introduces therapy), frequency and mode of service delivery (in person, teletherapy or hybrid service) and treatment recommendations. The documentation will also include the funding status of therapy continuation, discharge or discontinuation.

For the follow-up component, eligible clients or their caregivers was contacted telephonically. Up to three contact attempts was be made on different days and at different times, including evening and weekend calls whenever feasible, before classifying an individual as a non-respondents. All contact attempted and outcomes was systematically recorded. At the beginning of each call, the interviewer was introduce themselves, explain the purpose of the study, and obtain verbal informed consent for participation and audio recording. The consent process was be documented in the call records and audio recordings. The semi-structured interview was include both closed-ended and open-ended questions designed to explore factors related to therapy continuation or discontinuation, logistical and financial barriers to accessing services, perceived benefits of therapy, caregiver support, and suggestions for improving rehabilitation services.

Participant confidentiality was maintained throughout the study. Unique study codes were used instead of names during data collection and transcription. Personal information was stored separately in a secure, password-protected file accessible only to the research team. With verbal consent, telephonic interviews were audio-recorded, and each recording was begun with the participant's study code, date, and time of the interview. If an interview is only partially completed, the available information was included in the analysis, and missing responses were noted. Participants who do not respond after three contact attempts were considered non-respondents. They were excluded from telephonic interview analyses but may still be included in analyses based on clinical records.

Phase IV: Compilation and Data Entry

Extracted data was entered into the Excel template and imported into SPSS (or similar statistical software). Telephonic interview responses were entered into the same database using the participant's unique ID.

CHAPTER 4

RESULTS

This chapter presents the findings of the retrospective study conducted to examine the epidemiological profile of clients attending USOFA and to identify factors influencing the utilization and status of rehabilitation services. The results included 163 client records, and descriptive statistics were used to summarize demographic, socioeconomic, clinical, surgical, and rehabilitation-related variables. Frequencies and percentages were calculated for categorical variables, while mean, standard deviation, median, minimum, and maximum were reported for selected continuous variables.

4.1 Content Validation of the Semi-Structured Checklist

The content validity of the semi-structured checklist was evaluated by 11 experienced speech-language pathologists who involved in cleft care services. Generally, the experts considered the checklist items to be relevant, clear, and comprehensive for assessing therapy follow-up status and utilization of rehabilitation services among children with CLP. Based on expert feedback, a few modifications were done to improve the checklist. Revisions included clarification of item wording to enhance clarity, reduce the ambiguity in selected questions, and expansion of the checklist to cover other factors influencing therapy and service utilization. New field incorporated into the final version included transportation-related challenges, caregiver availability, financial burden associated with accessing services, receiving benefits of speech-language therapy, and availability of teletherapy.

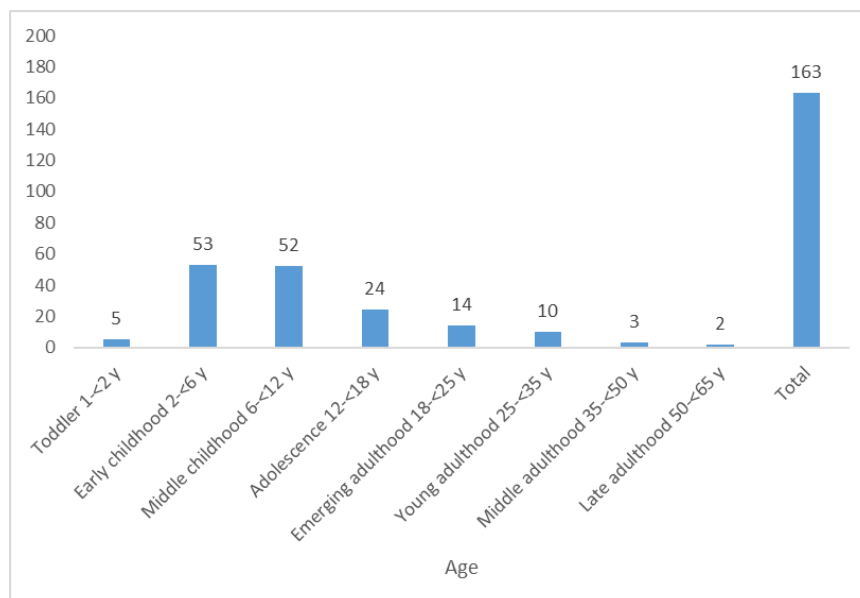
The approved checklist comprised items addressing therapy follow-up status, mode of service delivery, duration of therapy, reasons for discontinuation of services, barriers and facilitators affecting access to rehabilitation services, and entirely client satisfaction. Based on CVI calculation all the parameters value came greater than 0.75, that considered for the acceptance of the questionnaire.

4.2 Demographic Characteristics of the Participants

A total of 163 client records were included in the study. The age distribution showed that early childhood (2–<6 years) founded the largest proportion , accounting for 53 participants (32.5%), followed by middle childhood (6–<12 years), which included 52 participants (31.9%). Adolescents aged 12–<18 years reflected 24 participants (14.7%). Emerging adulthood (18–<25 years) accounted for 14 participants (8.6%), while young adulthood (25–<35 years) founded 10 participants (6.1%). Toddlers (1–<2 years), middle adulthood (35–<50 years), and late adulthood (50–<65 years) formed only small proportions.

Fig 4.1

Age distribution



When broadly categorized, pediatric clients were 134 participants (82.2%) ,whereas were 29 participants (17.8%). This shows that rehabilitation services

at USOFA were mainly utilized by children and adolescents. In terms of gender, males founded 96 participants (58.9%), while females founded 67 participants (41.1%). This shows a male user have utilized service more compare to female

Fig.4.2 (a)

Age group

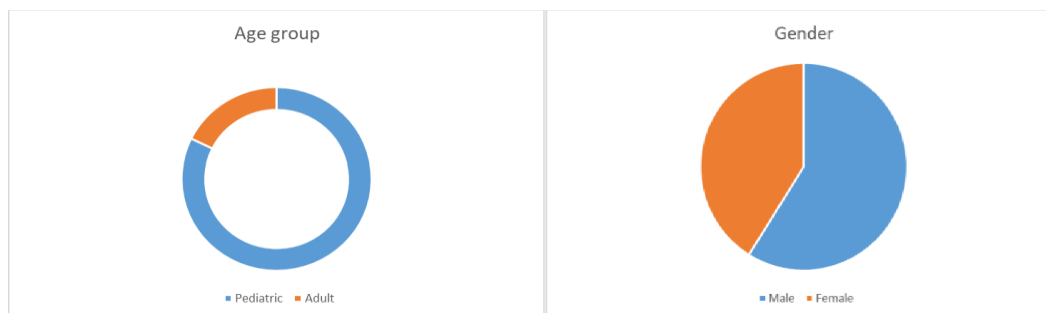
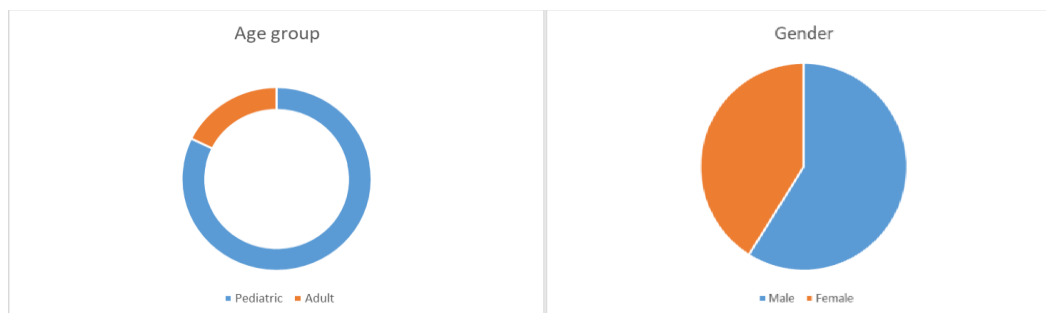


Fig.4.2 (b)

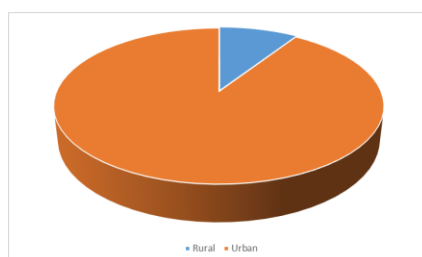
Gender



In place of residence, most participants were from urban areas, consists of 148 participants (90.8%), whereas only 15 participants (9.2%) were from rural areas. This shows that rehabilitation services were utilized maily by urban residing clients

Fig. 4.3

Residence of population



4.3 Socioeconomic Characteristics

The educational status of caregivers showed large diversities. More than one-third of caregivers were either had less than primary-level education (n = 61, 37.4%). Caregivers with SSLC/PUC education founded 57 participants (35.0%), while graduates and above founded 45 participants (27.6%). These shows that clients attending USOFA came from families with mixed educational backgrounds.

Family income showed a wide dispersion. A monthly income of less than ₹10,000 was founded 61 families (37.4%), and monthly income ₹10,000 and ₹25,000 founded 57 families (35.0%), whereas 45 families (27.6%) found a monthly income o greater than ₹25,000. In the same way caregiver occupation revealed that mixed socioeconomic profile. Unskilled or daily-wage occupations were founded 61 caregivers (37.4%), 57 caregivers (35.0%) were business and professional , and 45 caregivers (27.6%) were government or private skilled .

Table 4.1

Family income and caregiver education

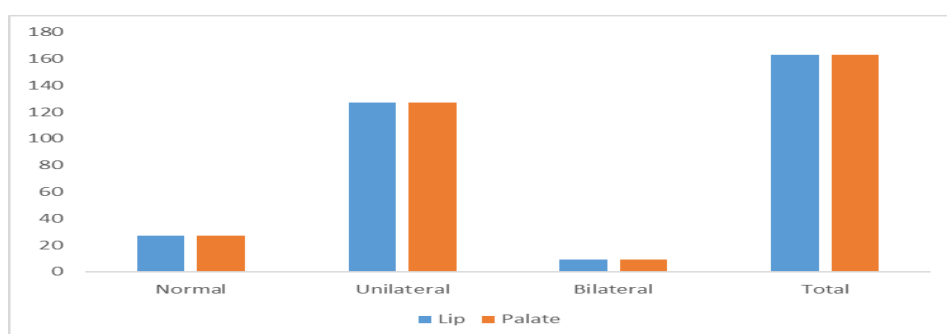
Family income	Frequency	Caregiver education	Frequency
<10000	61	Government/ private skilled	45
10000 - <25000	57	Business/ Professional	57
25000 - above	45	Unskilled/ daily wages	61
Total	163	Total	163

4.4 Clinical Characteristics and cleft profile

Clinical examination illustrated that unilateral cleft was the most common pattern in the population . Unilateral lip and palate cleft was seen in 127 participants (77.9%), while bilateral cleft lip was found in nine participants only (5.5%). Normal lip structure was founded in 27 participants (16.6%).

Fig. 4.4

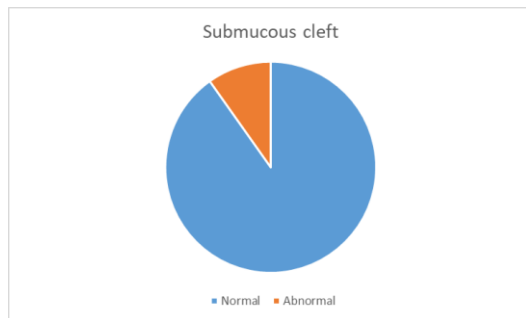
Type of cleft



Submucous cleft palate was detected in 16 participants (9.8%), while 147 participants (90.2%) had normal findings. Within communication disorders, speech and language disorder was the most frequently reported diagnosis, accounting for 146 participants (89.6%) of the total sample. Hearing loss was observed in seven participants (4.3%), developmental speech sound disorder with hearing impairment in five participants (3.1%), hearing impairment in three participants (1.8%), and developmental speech sound disorder alone in two participants (1.2%). These findings indicate that speech and language delay constituted the primary clinical concern among clients attending USOFA.

Fig. 4.5

Type of submucous cleft



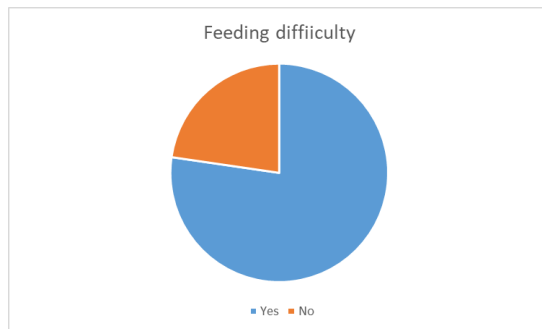
Within communication disorders, Speech and Language Disorder (SLD) was the most commonly found diagnosis, accounting for 89.6% (n = 146) of all participants. Hearing loss was observed in 4.3% (n = 7), Developmental Speech Sound Disorder (DSSD) with hearing impairment in 3.1% (n = 5), hearing impairment in 1.8% (n = 3), and DSSD alone in 1.2% (n = 2). These results show that speech and language disorders indicate the main clinical concern within clients attending USOFA.

4.5 Feeding Difficulties

Feeding difficulties were identified in 126 participants (77.3%), while 37 participants (22.7%) did not have any feeding-related problems. The feeding difficulties stress the early functional burden with cleft-related disorders in this population.

Fig. 4.6

Feeding difficulties



4.6 Surgical Characteristics

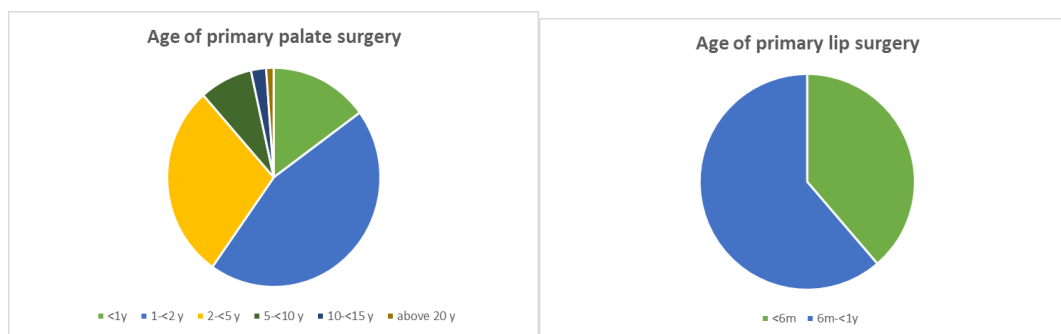
Lip surgery had been performed in 31 participants. Among these, the most common age of surgery was between six months and one year, founded in 19 participants (11.7%), followed by surgery before 6 months of age in 12 participants (7.4%). Palatal surgery was most commonly performed between one and two years of age, forming 39 participants (23.9%), followed by two to five years of age, which forming 25 participants (15.3%). Less population undergone surgery before one year or after five years of age.

Fig. 7(a)

Age of primary palate surgery

Fig. 7(b)

Age of primary lip surgery



The number of surgeries ranged from zero to nine, with a mean of 1.37 (SD = 1.39). One surgery was the most frequently reported category, accounting for 55 participants (33.7%), followed by no surgery in 47 participants (28.8%) and two surgeries in 34 participants (20.9%). These shows that surgical intervention differ among participants, but most of them had one or two surgeries.

4.7 Associated Conditions and Comorbidities

Evaluation of co-morbid conditions showed that repaired cleft palate was the most commonly found condition, forming 59 participants (36.2%). Submucous cleft palate was found 56 participants (34.4%), whereas repaired cleft lip and palate found 14 participants (8.6%). Other associated conditions, such as microtia, hearing loss, tongue tie, and unilateral cleft palate, were recorded less.

With respect to secondary comorbidity, 148 participants (90.8%) did not have any additional associated condition. five participants (3.1%) had reported hearing loss whereas intellectual disability, microtia, and fistula were found very few. This shows that majority of clients had a only primary condition without multiple associated anomalies.

Table 4.2

Associated Conditions and Comorbidities

Comorbidity 1	Frequency	Comorbid 2	Frequency2
Nil	2	Nil	148
Anotia	1	atresia	1
Bilateral Microtia	1	fistula	2
Bilateral RCP	1	HI	2
HL	6	HL	5
Microtia	4	ID	2
None	6	Microtia	2
RCL	5	SMC	1
RCLP	59		
RCP	56		
SMC	14		
SMCP	2		
Tongue tie	3		
UCP	1		
Unoperated soft palate	2		
Total	163	Total	163

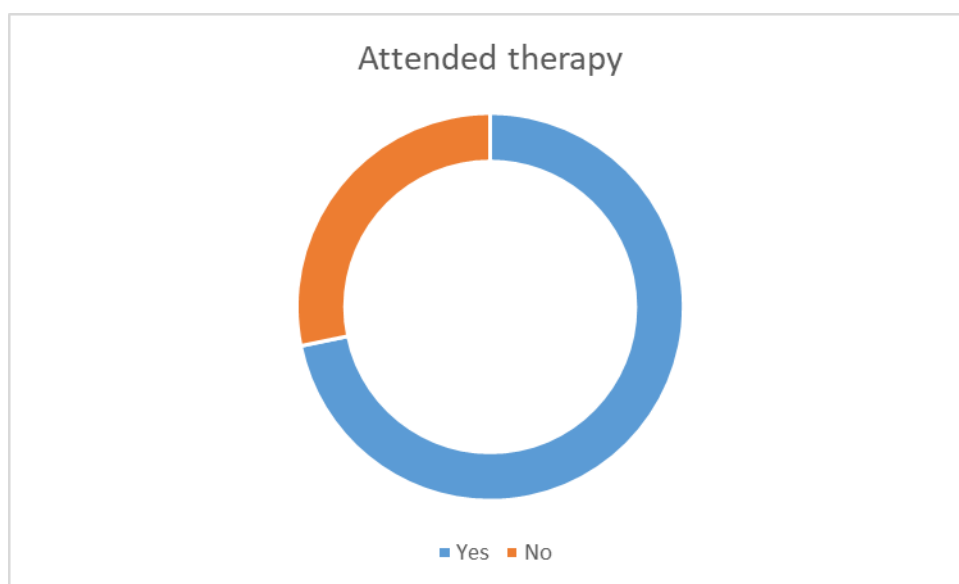
4.8 Rehabilitation Service Utilization

Within the 163 participants, 117 (71.8%) were attended therapy , whereas 46 (28.2%) were not attended therapy. With respect to duration of therapy, the largest

proportion of participants had attended therapy for more than six months ($n = 76$, 46.6%). Approximately one-third of participants ($n = 49$, 30.1%) had not attended therapy at all. Therapy for less than three months and six months each accounted for 19 participants (11.7%).

Fig. 4.8

Rehabilitation Service Utilization



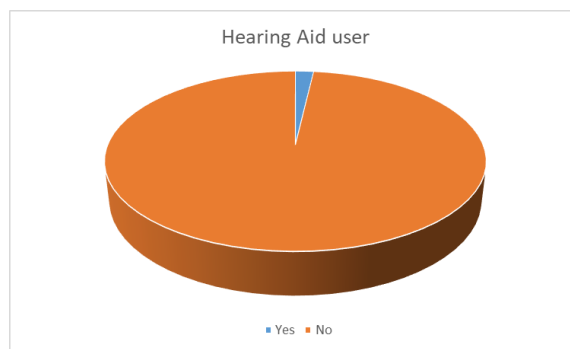
Offline rehabilitation services were the predominant mode of service delivery, used by 113 participants (69.3%). Only four participants (2.5%) received online therapy. The frequency of therapy sessions showed that 70 participants (42.9%) attended therapy three times per week, while 47 participants (28.8%) attended twice weekly.

4.9 Hearing Assessment and Amplification

All participants underwent hearing assessment as part of their clinical evaluation. However, only three participants (1.8%) required hearing aids, while 160 participants (98.2%) were not recommended to use amplification devices. This finding suggests that hearing amplification was required in only a small proportion of the clients studied.

Fig.4.9

Hearing Aid user



4.10 Reasons for Discontinuation of Services

Speech improvement was the most commonly reported reason for discontinuation of therapy services, was educational issues(children joined schooling) which accounting for 56 cases (34.4%). Preference for local rehabilitation services was the second most common reason, reported in 41 cases (25.2%). Educational commitments contributed to discontinuation in 23 cases (14.1%), while distance and travel-related difficulties accounted for 19 cases (11.7%). Personal reasons were reported in 14 cases (8.6%). Less frequent reasons included lack of benefit, medical comorbidities, COVID-related concerns, and lack of cooperation from the child.

Table 4.3*Reasons for Discontinuation of Services*

Reasons for Discontinuation of Services	Frequency	Percent
Distance/ travel	19	11.7
Lack of benefit	6	3.7
Medical comorbidity	1	0.6
COVID	1	0.6
Local services preference	41	25.2
Personal	14	8.6
Speech improved	23	34.4
Educational issues	56	14.1
No cooperation from child	2	1.2
Total	163	100

4.10 Rehabilitation Outcomes

The majority of participants demonstrated positive progress following rehabilitation intervention. Overall rehabilitation progress was reported in 155 participants (95.1%), while eight participants (4.9%) were categorized as not attending therapy services. Outcome assessment showed that 152 participants (93.3%) improved, whereas only one participant (0.6%) showed no improvement. An additional 10 participants (6.1%) were categorized as having no current issues requiring intervention. These findings indicate favorable rehabilitation outcomes among clients receiving services at USOFA.

Fig. 4.10

Current status of therapy

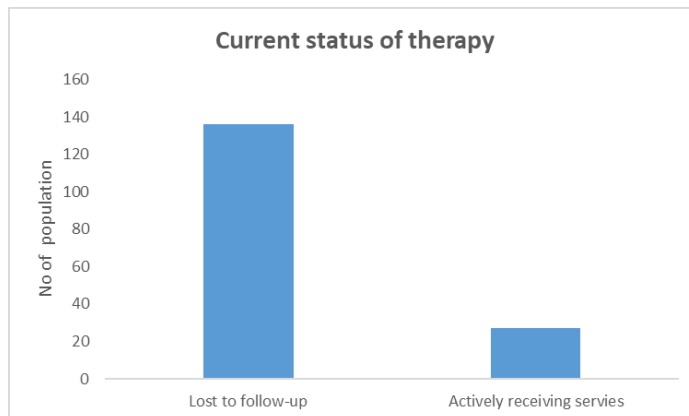
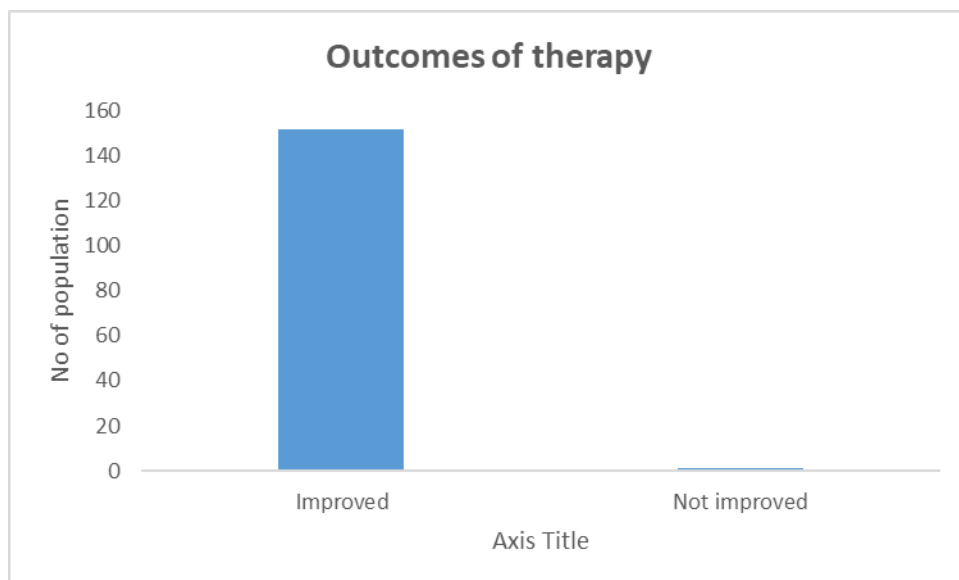


Fig. 4.11

Outcomes of the therapy



This investigation shows that , 136 participants were lost to follow-up, while only 27 participants were still attending therapy when data collection was happening . This shows that consistency in intervention is still a primary concern in rehabilitation service delivery.

4.12 Educational Status and Academic Performance

Within school-going participants, 160 participants going to regular schools, whereas only three participants going to special schools. Academic performance was good in 143 participants , average in 16 participants and poor in four participants. These results shows that most participants were able to participate in mainstream education and maintain satisfactory academic functioning.

Table 4.4

Educational Status and Academic Performance

School	Frequency	Percent	Academic		
			performance	Frequency	Percent
Regular	160	98.2	Good	143	87.7
Special	3	1.8	Average	16	9.8
			Poor	4	2.5
Total	163	100	Total	163	100

Chapter 5

DISCUSSION

5.1 Demographic Characteristics of the Study Population

This study examined the epidemiological profile of clients receiving services at USOFA and factors influencing rehabilitation service utilization. The findings revealed that the majority of participants belonged to the pediatric age group (82.2%), with the highest concentration observed in early and middle childhood. This finding is consistent with the developmental nature of communication disorders, where speech, language, and hearing concerns are typically identified during the early years of life when developmental milestones become more apparent.

Mukami et al. (2021) found similar results, noting that 58.3% of cleft patients attending outreach surgery camps in Kenya were under two years old. According to Diwana et al. (2019), children made up the majority of patients who visited a tertiary cleft clinic in Himachal Pradesh, underscoring the significance of early intervention services. Increased parental awareness and referral of children for communication-related issues at crucial stages of speech and language development is reflected in the study's preponderance of pediatric clients. There was a male predominance in the sample, with 58.9% of individuals being male. This result is in line with several epidemiological investigations carried out over the world. According to Datta and Singh (2025), children with cleft disorders in Bihar have a male-to-female ratio of roughly 3:2.

In the same way, Tobgyel et al. (2024) noted a male predominance of 59% in Bhutan, but Mukami et al. (2021) reported that 61.9% of their participants were men. Kianifar et al. (2015) in Iran and Peña-Soto et al. (2021) in Peru reported similar results.

5.2 Residential and Socioeconomic Characteristics

Urban areas accounted for 90.8% of the study's participants. This result probably indicates that metropolitan inhabitants have better access to specialist rehabilitation treatments, transit options, and awareness. Previous research looking at healthcare usage patterns have reported similar findings. However, issues with accessibility and equity in service delivery are brought up by the under representation of rural participants. Geographical constraints to specialized care were highlighted by Mukami et al. (2021), who noted that many patients traveled more than 50 kilometers to receive cleft services.

Similarly, Gonzalez et al. (2008) found that children from rural and low-income families were less likely to complete long-term treatment programs. The findings of the present study suggest that despite advances in cleft care and rehabilitation services, geographical accessibility continues to influence service utilization.

The socioeconomic profile showed that a most proportion of families belonged to lower-income categories and had limited educational background. These results align with Datta and Singh (2025), who found inadequate maternal healthcare utilization, poor nutritional supplementation, and limited awareness .Lower socioeconomic status may impact access to healthcare, continuity of therapy, transportation, and caregiver participation in rehabilitation services .

5.3 Clinical Characteristics

Speech-Language Disorder (SLD) was the most common diagnosis, formed nearly 90% of all cases. This results shows that the major problem of communication disorders within children needs rehabilitation services. Even though many epidemiological studies have aimed primarily on cleft classification instead of speech-language diagnoses, the outcomes verify the well-established association between structural anomalies and communication difficulties. Previous studies by Peña-Soto et al. (2021), Diwana et al. (2019), and Lithovius et al. (2014) reported that cleft-related conditions frequently require long-term speech-language intervention following surgical management.

The high prevalence of speech and language disorders in the present study underscores the importance of integrating speech-language pathology services within multidisciplinary cleft care programs. Effective management extends beyond surgical correction and requires continuous rehabilitation to address articulation, resonance, language, and communication outcomes.

5.4 Structural Characteristics and Cleft Patterns

This study reveals that unilateral lip and palate involvement was substantially more common than bilateral involvement. This results is consistent with the majority of international epidemiological studies.

Diwana et al. (2019) found that unilateral clefts were Significantly more than bilateral clefts within Indian patients. In the same way, Tobgyel et al. (2024) observed that unilateral clefts comprise the main sub type in Bhutan. Lithovius et al. (2014) found a significantly higher incidence of unilateral left-sided clefts in Finland, while Mukami

et al. (2021) also identified unilateral clefts as the most common in Kenya. A somewhat regular pattern of craniofacial development and embryological disturbance can be seen in the unilateral clefts seen in various populations. Genetic predisposition and environmental factors probably contribute to these developmental variances, even though the precise processes are still unknown.

5.5 Feeding Difficulties

In this study, more than 74% of participants said they had difficulty feeding themselves. This outcome is expected given the structural abnormalities associated with cleft diseases, which hinder effective sucking, swallowing, and oral motor function.

The findings are consistent with past studies that found feeding problems to be among children with cleft lip and palate's initial challenges. Studies by Peña-Soto et al. (2021) and Teles et al. (2023) emphasized the importance of interdisciplinary care beginning in infancy to address feeding difficulties and maximize nutritional status. The high frequency of eating problems in the current study highlights the significance of early feeding assessment and counseling as an essential component of cleft care.

5.6 Surgical Management

The majority of participants had undergone at least one surgical procedure. Lip repair was generally completed during infancy, while palate repair was commonly performed between one and five years of age.

These results show that availability to surgical intervention is better than in previous publications. Diwana et al. (2019) reported average ages of 2.8 years for lip repair and 6 years for palatoplasty, indicating significant delays in surgical care. On the other hand, the timing found in this study more closely resembles globally advised protocols. Improved feeding, speech development, psychosocial adjustment, and quality

of life have all been linked to early surgical intervention. Consequently, the results indicate that access to surgical cleft care treatments has improved.

5.7 Rehabilitation Service Utilization

Significant use of speech and hearing rehabilitation programs is indicated by the fact that about 72% of participants attended rehabilitation services. Additionally, most participants reported obtaining early intervention services, indicating better access to speech-language rehabilitation during the crucial developmental stage and heightened awareness among caregivers. For children with cleft lip and palate, early intervention is thought to be crucial for maximizing speech, language, and communication outcomes since prompt rehabilitation can lessen the severity of speech-related issues and promote general developmental advancement.

The majority of patients showed consistent involvement with intervention services by receiving therapy for longer than six months. Nevertheless, a sizable percentage of patients subsequently lost follow-up despite positive therapy participation. This outcome is consistent with observations made by Datta and Singh (2025), who noted that long-term rehabilitation still poses challenges despite improvements in surgical access through national healthcare initiatives.

A number of challenges that have been often noted in the literature as affecting continuity of care include travel distance, financial constraints, competing educational obligations, delayed referral for intervention, and the lack of local rehabilitation options. Similarly, Gonzalez et al. (2008) discovered that households residing in underserved areas had lower treatment completion rates due to socioeconomic constraints. Even while early intervention improves rehabilitation outcomes, sustaining

long-term therapy adherence is still very difficult, especially for families with socioeconomic and geographic disadvantages.

5.8 Rehabilitation Outcomes

In this study we report that which saw the high rate of improvement post rehabilitation services in fact over 90% of our participants did very well. These results support the value of structured speech and hearing rehabilitation programs. Also we see in the multidisciplinary cleft care literature that long term speech language intervention improves articulation, resonance, communication performance and psych social function. We note that in our study we saw very positive results which also put forward the value of early referral, regular in office visits, parent's role in therapy and a team approach. Also the results we report add to the body of evidence that which says rehabilitation services are a key element in total cleft care.

5.9 Factors Influencing Rehabilitation Status

The research determined that therapy duration and method of service delivery are key factors in rehabilitation. We saw that which groups had therapy for longer had better results than those which had less treatment which is in line with what is reported in the SLP literature which puts forth the value of repeat intervention and practice. Long term therapy also allows for progressive skill acquisition and consolidation of communication skills. While we did not have large representation of online therapy in our study we did find that method of service delivery played an important role. Datta and Singh (2025) report on the role of teleassessment and tele-rehabilitation in to break down barriers to follow up for families in remote areas.

Chapter 6

SUMMARY AND CONCLUSION

The study's findings shows that the results broadly align with national and international research on cleft lip palate and the related communication difficulties. Moreover, the significant evidence could indicate that the majority of the study population was children, which appears to support previous epidemiological research and highlights that early discovery and treatment remain critical given the congenital origin of cleft lip palate. Furthermore, the findings might indicate that male participants were more prevalent, which could demonstrate consistency with several studies showing that males are more likely than females to present with cleft lip with or without cleft palate. Given that the evidence demonstrates this pattern, the results may suggest that the distribution of cleft involvement aligns with previous research, with unilateral cleft lip and palate appearing as the most prevalent kind. Study shows unilateral clefts outnumber bilateral cases.

However, the significant findings could indicate that this outcome supports studies that suggest unilateral clefts make up the bulk of cases seeking multi modal cleft therapy. Additionally, the key results may suggest that an infant's ability to swallow, suck, and eat could be hampered by structural impairments due to cleft lip and palate. In light of the findings, the evidence might demonstrate that the high incidence of feeding problems reported by caregivers appears to support that structural impairments critically affect early feeding outcomes. Notwithstanding these results, the data could indicate that the important findings align with established evidence on the functional consequences of cleft lip and palate. Evidence links structural impairment to feeding difficulty.

Early-stage feeding issues are well recognized as a major worry for families and may need for expert counseling and assistance. The importance of early intervention programs is further emphasized by the study's findings. A significant number of participants had received early childhood rehabilitation services, suggesting that caregivers are more aware of the advantages of early speech-language intervention. Improved speech, language, and communication as well as improved social and academic engagement have all been linked to early intervention. The current study's high level of involvement with rehabilitation programs is indicative of the growing focus on comprehensive cleft treatment that includes long-term communication therapy in addition to surgical management. Significant use of speech and hearing intervention programs is indicated by the 72% of participants who reported receiving rehabilitation services.

The majority of patients remained to participate in the treatment process, as evidenced by their longer than six-month therapy sessions. Additionally, after the intervention, caregivers generally reported good outcomes, suggesting that speech-language rehabilitation significantly improved communication skills and general functioning. These results corroborate earlier studies that demonstrated the efficacy of structured rehabilitation programs in lowering speech-related challenges and enhancing quality of life for people with cleft lip and palate.

Service utilization and rehabilitation outcomes were promising, but a large percentage of participants were lost to follow-up. This finding is in line with previous studies that have found long-term adherence to rehabilitation to be an ongoing challenge. Cessation of therapy may be associated with travel distance, financial

burden, availability of a caregiver, competing educational responsibilities, and availability of local rehabilitation services. Similar issues have been documented in both industrialized and developing nations, highlighting the necessity of approaches that enhance care continuity.

The findings highlight the significance of improving conveniently accessible and family-centered rehabilitation services. Innovative approaches including telepractice, decentralized service delivery models, community-based rehabilitation programs, and improved caregiver counseling may help improve follow-up problems and increase long-term treatment adherence. To maximize communicative results and provide comprehensive care for people with cleft lip and palate, ongoing programs that promote early intervention, frequent monitoring, and interdisciplinary teamwork are crucial.

Implications for Clinical Practice

- The present study reports on what we found to be very important in terms of clinical practice. We note first that early detection and intervention is of top priority especially in pediatric populations.
- Also, it is recommended that we see that rehabilitation services are included in a team based approach to care for issues of communication, feeding, and psychos that go along with cleft care.
- Also very important are to put in place strategies that better support follow up and long term engagement.
- Telehealth, community outreach programs and the use of decentralized service models may do much to reduce the barriers related to travel and also to financial issues.

- Also we see that there is a need to do more in terms of education and counseling of caregivers to see that they in turn support the therapy and which in the end will lead to better long term rehabilitation results.

Reference

- AIISH. (2021). *Annual report*. All India Institute of Speech and Hearing, Mysuru.
- Baigorri, M., Jackson, C., & Schaefer, B. (2021). Current state of telepractice use across speech-language pathology service domains. *American Journal of Speech-Language Pathology*, 30(1), 231–246.
https://doi.org/10.1044/2020_AJSLP-20-00263
- Datta, P., & Singh, R. (2025). Epidemiological profile of cleft lip and palate in a tertiary center of Bihar under RBSK scheme. *International Journal of Oral and Maxillofacial Surgery*, 54(3), 410–418.
<https://doi.org/10.1016/j.ijom.2024.09.015>
- De Taeye, L., T'Sjoen, G., Vermeersch, H., & Van Lierde, K. (2023). Parents' and speech therapists' experiences with telepractice in cleft palate care: A mixed-methods study. *Journal of Communication Disorders*, 101, 106310.
<https://doi.org/10.1016/j.jcomdis.2023.106310>
- Dinakaran, D., Manjunatha, N., Naveen Kumar, C., & Math, S. B. (2021). Telemedicine practice guidelines of India, 2020: Implications and challenges. *Indian Journal of Psychological Medicine*, 43(1), 97–103.
<https://doi.org/10.1177/0253717620972585>
- Diwana, V. K., Gupta, G., Chauhan, R., Mahajan, K., Mahajan, A., Gupta, R., & Mahajan, K. (2019). Clinical and epidemiological profile of patients with cleft Himalayan state of Himachal Pradesh in Northern India. *Journal of Natural*

Science, Biology and Medicine, 10(1), 82–86.

https://doi.org/10.4103/jnsbm.JNSBM_220_17

Elahi, M. M., Jackson, I. T., Elahi, O., Khan, A. H., Mubarak, F., Tariq, G. B., & Mitra, A. (2004). Epidemiology of cleft lip and cleft palate in Pakistan. *Plastic and Reconstructive Surgery*, 113(6), 1548–1555.

<https://doi.org/10.1097/01.PRS.0000117184.77459.2B>

Gonzalez, B. S., López, M. R., Bustamante, R. A., & García, C. L. (2008). Cleft lip and palate: Retrospective study of prevalence and predisposal factors in the state of Mexico. *Medicina Oral, Patología Oral y Cirugía Bucal*, 13(7), E432–E438.

Kummer, A. W. (2020). *Cleft palate and craniofacial conditions: A comprehensive guide to clinical management* (4th ed.). Jones & Bartlett Learning.

Lithovius, R. H., Ylikontiola, L. P., Harila, V., & Sándor, G. K. (2014). A descriptive epidemiology study of cleft lip and palate in Northern Finland. *Acta Odontologica Scandinavica*, 72(5), 372–375.

<https://doi.org/10.3109/00016357.2013.840737>

Mirafzali, Z., Aryaie, M., & Mohammadi, M. (2012). Epidemiologic study of cleft lip and palate in Gorgan, Northern Iran: 2004–2010. *Journal of Gorgan University of Medical Sciences*, 14(4), 81–86.

Ministry of Health and Family Welfare. (2020). *Telemedicine practice guidelines: Enabling registered medical practitioners to provide healthcare using*

telemedicine. Government of India.

<https://www.mohfw.gov.in/pdf/Telemedicine.pdf>

Mossey, P. A., Little, J., Munger, R. G., Dixon, M. J., & Shaw, W. C. (2009). Cleft lip and palate. *The Lancet*, 374(9703), 1773–1785.

[https://doi.org/10.1016/S0140-6736\(09\)60695-4](https://doi.org/10.1016/S0140-6736(09)60695-4)

Mossey, P. A., & Modell, B. (2012). *Epidemiology of oral clefts 2012: An international perspective*. World Health Organization.

Mukami, G., Angela, M., & Wanjala, F. N. (2021). Epidemiological patterns of patients managed for cleft lip and palate during free outreach camps at a peripheral hospital in Kenya. *Journal of Cleft Lip Palate and Craniofacial Anomalies*, 8(1), 26–29. https://doi.org/10.4103/jclpca.jclpca_8_20

Pamplona, M. C., Ysunza, A., & Morales, S. (2020). Feasibility of telepractice for assessing speech in children with cleft palate in developing countries. *Cleft Palate-Craniofacial Journal*, 57(6), 664–670.

<https://doi.org/10.1177/1055665619890176>

Peña-Soto, C., Arriola-Guillén, L.-E., Díaz-Suyo, A., & Flores-Fraile, J. (2021). Clinical and epidemiological profile of cleft lip and palate patients in Peru, 2006– 2019. *Journal of Clinical and Experimental Dentistry*, 13(11), e1118–e1123. <https://doi.org/10.4317/jced.58976>

Ramanathan, R., Maben, A. V., & Thomas, J. (2021). Impact of COVID-19 on cleft services in India: Lessons learned and future directions. *Indian Journal of Plastic Surgery*, 54(2), 123–130. <https://doi.org/10.1055/s-0041-1735504>

- Rao, P. (2018). Barriers to continued care in cleft lip and palate: An Indian perspective. *Journal of Cleft Lip Palate and Craniofacial Anomalies*, 5(2), 73–79. https://doi.org/10.4103/jclpca.jclpca_21_18
- Reddy, S. G., Reddy, R. R., Bronkhorst, E. M., Prasad, R., Ettema, A. M., Sailer, H. F., & Bergé, S. J. (2018). Incidence of cleft lip and palate in the state of Andhra Pradesh, South India. *Indian Journal of Plastic Surgery*, 51(3), 336–342. https://doi.org/10.4103/ijps.IJPS_174_18
- Sell, D. (2015). Issues in perceptual speech analysis in cleft palate and related disorders: A review. *International Journal of Language & Communication Disorders*, 50(6), 708–715. <https://doi.org/10.1111/1460-6984.12172>
- Sivakumar, T., & Sundaresan, V. (2020). Challenges in cleft lip and palate management in India. *Indian Journal of Plastic Surgery*, 53(3), 285–292. <https://doi.org/10.1055/s-0040-1716784>
- Teles, D., Rodrigues, D., Barros, M., Silva, A., Maia, J., & Ferreira, A. (2023). Retrospective survey and analysis of anaesthesia and outcomes in paediatric cleft lip or palate surgery in a tertiary care center, Portugal. *Cureus*, 15(2), e34711. <https://doi.org/10.7759/cureus.34711>
- Tobgyel, T., Dendup, T., Dorji, P., Dorji, T., & Wangdi, K. (2024). Epidemiology of orofacial clefts in Bhutan: Insights from the National Birth Defects Surveillance, 2012–2019. *BMC Pediatrics*, 24(1), 55. <https://doi.org/10.1186/s12887-024-04289-7>

- Vaibhav, V., Kumar, K., Raj, R., Kedia, N. B., Singh, A. K., & Singh, R. (2020). A retrospective hospital-based study on factors influencing the incidence of cleft lip and palate cases in Bihar region. *IP Annals of Prosthodontics and Restorative Dentistry*, 6(1), 11–13.
<https://doi.org/10.18231/j.aprd.2020.004>
- Van Swol, R. L., Bardach, N. S., & Guglielmi, M. (2022). Loss to follow-up in cleft lip and palate care: A systematic review. *Cleft Palate-Craniofacial Journal*, 59(7), 829–840. <https://doi.org/10.1177/10556656211051186>
- World Health Organization. (2022). *Global strategies to reduce the health-care burden of craniofacial anomalies*. WHO Press.
- Zhou, X., Jiang, Y., Fang, J., Wang, H., Xie, D., Kuang, H., Li, T., Liu, Q., & He, J. (2023). Incidence of cleft lip and palate, and epidemiology of perinatal deaths related to cleft lip and palate in Hunan Province, China, 2016–2020. *Scientific Reports*, 13(1), 10304. <https://doi.org/10.1038/s41598-023-37436-y>

APPENDIX - 1

Ethical Clearance from AIISH-IRB



All India Institute of Speech and Hearing

(An autonomous Institute under the
Ministry of Health and Family Welfare, Govt. of India)
Center of Excellence - Assessed & Accredited by NAAC with 'A' Grade
ISO 9001:2015 Implemented Institute
Manasagangothri, Mysuru-570006

ಆಖಿಲ ಭಾರತೀಯ ವಾಕ್ ಶ್ರವಣ ಸಂಸ್ಥಾನ
ಮನಸಗಂಗೋತ್ರಿ, ಮೈಸೂರು-570006

अखिल भारतीय वाक् श्रवण संस्थान
मानसगंगोत्री, मैसूर - 570 006

INSTITUTE REVIEW BOARD (IRB) APPROVAL FOR BIO-BEHAVIOURAL RESEARCH PROPOSAL INVOLVING HUMAN SUBJECTS AT AIISH

AIISH Institute Review Board (IRB)

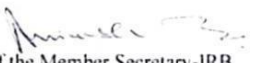
Ref: SH/IRB/M.5/SLP.41/2025-26

Date: 11.03.2026

Title of the Dissertation	: Epidemiologic profiling of clients at USOFA and factors influencing status of rehabilitation services: A retrospective study
Name of the Student	: Ms. Yashaswini K
Guide	: Mrs. Manasa A S
Co-Guide (if any)	: Dr. Vasantha Lakshmi M S
Proposed Duration of the Project	: 06 months
Source of funding	: Non-funded Master's dissertation
Estimated budget	: Nil
Reference Number of the Project	: Nil
Date on which the IRB meeting was held	: 05.03.2026

A clear statement of the decision reached IRB meeting
(In the event of the proposal is not APPROVED,
a statement of reasons for the same must be indicated) : APPROVED

Advice & suggestions (if any) : Nil


Signature & Name of the Member Secretary-IRB
Dr. Animesh Barman
Professor of Audiology
All India Institute of Speech and Hearing, Mysore-570006

ಮೈಸೂರು
ಆಖಿಲ ಭಾರತೀಯ ವಾಕ್ ಶ್ರವಣ ಸಂಸ್ಥಾನ
ಮನಸಗಂಗೋತ್ರಿ, ಮೈಸೂರು-570006

Phone : 0821-2502000 / 2502100 Toll Free No. 18004255218 Fax : 0821-2510515
e-mail : director@aiishmysore.in / @aiishmysuruofficial. @aiishmysuru
website : www.aiishmysore.in

APPENDIX - 2**QUESTIONNAIRE USED IN DATA COLLECTION****Part A****A. Study identifiers & consent**

1. Client name : _____
2. Record/Caregiver contact (if applicable): _____
3. Consent obtained for interview / additional info? (from caregiver/patient)
 - Yes
 - No

Part B**B. Demographic information**

4. Patient age at time of last contact (DOB): _____yrs _____months
5. Sex:
 - Male
 - Female
 - Other
6. Place of residence (village/town/city, District, State):

7. Distance from USOFA , AIISH (approx. km): _____km
8. Education level of caregiver (highest completed): _____
 - Illiterate/ primary schooling
 - SSLC/PUC
 - Graduate or above

9. Family monthly income (approx.):

- < 10,000
- 10,000–25,000
- 25,001 and above

10. Occupation of caregiver:

- Government /private job
- Bussiness/ professional
- Unskilled/ daily wages.

Part C

C. Clinical & cleft profile

11. Type of cleft (tick all applicable):

- Cleft lip only (unilatera/bilateral)
- Cleft palate only
- Cleft lip & palate (unilatera/bilateral)
- Any other

12. Associated craniofacial syndromes or other congenital anomalies?

- Yes — specify: _____
- No

13. Birth weight (kg): _____

14. Any history of feeding difficulties in infancy?

- Yes
- No

15. Age at primary cleft surgery (lip repair) (months/years): _____

16. Age at primary palate surgery (months/years): _____

17. Number of surgical procedures related to cleft to date: _____

Part D

D. Rehabilitation services received (speech-language therapy / audiology / prosthetics / counselling)

18. Has the patient received speech-language therapy at USOFA, AIISH?

- Yes
- No

19. Modality of service received (tick all that apply):

- Face-to-face / in-person
- Teleassessment (phone/video)
- Group therapy
- Home-based program (visits by therapist)
- Community outreach camp

20. Average frequency of sessions (when active):

- 2 session/week
- 3 session/week
- Demonstration therapy

21. Duration of therapy taken (total months/years): _____

22. Status of last therapy :

- Progress
- No progress
- Fair

23. Were hearing assessments performed?

- Yes
- No

24. If hearing impaired, was amplification (hearing aid) provided?

- Yes
- No

Part E

E. Follow-up , current status and barriers & enabling factors

25. Current rehabilitation status (based on last documented contact):

- Actively receiving services
- Previously received but discontinued
- Referred to another centre
- Lost to follow-up
- Completed planned treatment

26. If discontinued, primary reason for discontinuation :

- Distance / travel difficulty
- Financial constraints
- Perceived lack of benefit
- Child's medical comorbidity
- COVID-19 / pandemic-related disruption
- Preference for local services
- Cultural or family reasons
- Transportation or time conflicts

- Communication/appointment scheduling issues
- Any other

Part F

G. Clinical outcomes / caregiver-reported outcomes

27. Caregiver perception of speech outcome compared with before therapy:

- Much improved
- Improved
- No change
- Worsened

28. Current feeding status (if applicable):

- Normal feeding without assistance
- Requires modified feeds
- Nasal regurgitation present
- NPO / tube fed

29. School attendance / educational participation:

- Regular school attendance
- Irregular
- Not enrolled

30. Academic performance of child :

- Good
- Better
- average
- Worsened