ADDIS ABABA UNIVERSITY

COLLEGE OF HEALTH SCIENCES

DEPARTMENT OF DERMATOVENEREOLOGY

Rate of Potassium Hydroxide Test Positivity Among Clinically Suspected Primary Onychomycosis Patients and Associated Factors at ALERT Addis Ababa, Ethiopia: A prospective study

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ADVISOR APPROVAL SHEET

This is to certify that the research thesis entitled "Rate of potassium hydroxide test positivity among clinically suspected primary onychomycosis patients, in ALERT hospital, Addis Ababa, Ethiopia**"** is submitted in partial fulfillment of the requirements for the certificate of specialty in Dermatovenereology" to the Graduate Program of the College of health sciences of Addis Ababa University and is carried out by Seada Nuru. Therefore, I recommend that the student has fulfilled the requirements and hence hereby can submit the thesis paper to the department.

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DECLARATION FORM OF PRINCIPAL INVESTIGATOR

I, the under Signed, hereby declare that this thesis is my original work and has not been presented for a degree in any other university and all sources of material used for this thesis have been duly acknowledged.

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This thesis has been submitted for examination with my approval as a university advisor:

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Abbreviations/Acronyms

AAU - Addis Ababa University

ALERT - All African Leprosy Rehabilitation Training Center

CW - Calcoflour white

DLSO – Distal lateral subungual onychomycosis

FMoH - Federal Ministry of Health

G.C. – Gregorian calendar

HIV – Human Immunodeficiency Virus

IRB – Institutional Review Board

KOH - Potassium hydroxide

OPD – Out Patient Department

PAS – Periodic Acid Schiff

PCR – Polymerase Chain Reaction

PSO – Proximal subungual onychomycosis

SPSS - Statistical Package for Social Science

SO – Superficial onychomycosis

TDO - Total dystrophic onychomycosis

USA – United States of America

Summary

Background:

Onychomycosis is a fungal infection of nails caused by dermatophytes, yeasts or nondermatophyte molds and one of the most common nail diseases seen in dermatology (1). Onychomycosis clinically presents with nail discoloration which could be yellow, white or, brown, detachment of the distal nail plate from the nail bed, easy fragility, nail plate thickening, and subungual hyperkeratosis (2). To arrive on accurate diagnosis of onychomycosis, mycological laboratory testing and confirmation is the optimal way and it is cost effective for the patient than treating the patient without confirming the diagnosis (3). Even though we usually use potassium hydroxide mount (KOH) as a diagnostic test for clinically suspected onychomycosis cases in our setting, the few studies done in Ethiopia gave emphasis on identification of the etiologic agents by culture.

Objectives:

The objective of this study was to determine the rate of KOH positivity among clinically suspected primary onychomycosis cases and the associated factors in patients visiting Dermatology unit of All African Leprosy Rehabilitation Training Center (ALERT) Hospital, Addis Ababa, Ethiopia, from March to August, 2023.

Methods:

A facility-based, prospective, cross-sectional study was conducted among patients with clinically suspected primary onychomycosis attending the dermatology clinic of ALERT Center in Addis Ababa, Ethiopia from March to August, 2023. A structured questionnaire was used to collect the data from patients. Data was analyzed by using Statistical package for social science version 26. Frequency distributions, percentages, tables and charts were used to show descriptive results. Chi square test was used to see the relation between dependent and independent variables.

Result:

100 patients with clinically suspected onychomycosis were included in the study. The mean age was 32.38 years, and the sex ratio (female/male) was 2.4:1. The rate of KOH positivity was 67%. The mean duration of nail abnormality was 3.57 years. Finger nails were commonly affected (50%) followed by toe nails (33%). Most patients had only 1 nail involvement (36%) followed by 2 nails (16%). Almost all had discoloration (98%) and 65% of them had subungual hyperkeratosis and nail plate thickening. DLSO was the most common type of onychomycosis identified (44%) followed by TDO (42%). Site of involvement and nail discoloration were associated with KOH positivity in bivariate analysis.

Conclusion:

According to our study the rate of KOH positivity in clinically suspected cases is relatively low. The finger nails are affected more by onychomycosis than the toe nails. Nail discoloration is the predominant presenting complaint of patients with onychomycosis. Site of involvement and nail discoloration are associated with KOH positivity.

1. Introduction

1.1. Background

One of the most prevalent nail conditions observed in dermatology is onychomycosis, a fungal nail infection brought on by dermatophytes, nondermatophyte molds, and yeast. The Greek words "onyxî, which means nail, and "mykesî, which means fungus, are the source of the phrase "onychomycosis." A nail infection caused by dermatophytes is referred to as tinea unguium (1). Nail deformation, thickness, and discoloration are symptoms of onychomycosis (4). The nail bed, nail plate, and matrix may all be affected by this persistent fungal invasion of the nail unit (5).

Onychomycosis is thought to account for up to half of nail abnormalities and roughly one-third of superficial fungal infections, according to numerous researches done worldwide (6). The prevalence of onychomycosis is approximately 5% worldwide (1).

Researches have shown that two dermatophytes account for almost 90% of onychomycoses: Trichophyton rubrum (71% of all infections) and Trichophyton mentagrophytes (20%) (7, 8).

The prevalence of onychomycosis is closely correlated with age and is more common in older adults. Humidity, tight-fitting shoes, trauma to the nails, a history of tinea pedis, obesity, cancer, genetic predisposition, and underlying comorbidities, such as diabetes, psoriasis, peripheral arterial disease, HIV infection, and other forms of immunocompromised conditions, are some of the predisposing factors.(2, 3, 9). According to a recent study, heavy smokers had an increased risk of onychomycosis (10). The increased incidence of onychomycosis has also been linked to long-distance running in sports and the regular usage of spas and public swimming pools (11).

The common types of onychomycosis are total dystrophic onychomycosis, endonyx onychomycosis, proximal subungual onychomycosis, superficial onychomycosis, and distal and lateral subungual onychomycosis (12). Distal lateral subungual onychomycosis and endonyx subungual onychomycosis are two subtypes of distal subungual onychomycosis. Primary and secondary total dystrophic onychomycosis are two other subtypes of total dystrophic onychomycosis (7).

Onychomycosis most often affects the toe nails, with the great toenail being most typically impacted. Clinical manifestations of onychomycosis include nail discoloration (yellow, white, or brown), fragility, nail plate thickening, separation of the distal nail plate from the nail bed and subungual hyperkeratosis. Extensive nail dystrophy with nail plate thickening, crumbling, ridging, and growth, as well as anonychia, may occur in chronic or severe cases (2, 3).

Pain and discomfort may exacerbate function loss in nails with dystrophies. Activities requiring manual dexterity or walking and standing may be hampered, making working and engaging in social activities difficult. It could also be challenging to properly manicure nails and wear shoes (4). Patients with onychomycosis also experience a lower quality of life due to social disengagement, embarrassment, low self-esteem, and anxiety about the way their nails look (13). Furthermore, in individuals with concurrent comorbidities including diabetes and HIV, the condition may increase the risk of soft tissue and bone infection (14).

Mycological laboratory testing and confirmation is the best method to arrive at an accurate diagnosis of onychomycosis, and it is more economical for the patient than treating the condition without verifying the diagnosis. The most often used diagnostic techniques include periodic acid-Schiff (PAS) staining on nail biopsies, culture, direct microscopy with KOH preparation, and, less frequently, immunohistochemistry, restriction fragment length polymorphisms, and polymerase chain reaction (PCR) tests. One of the quickest and least expensive ways to diagnose onychomycosis is using direct microscopy combined with KOH testing, which can be completed quickly at the point of care. It does, however, depend on the dermatologist's or the lab technician's experience. It is advisable to repeat the KOH investigation if the signs and symptoms correspond with onychomycosis before concluding that the results are negative. Keratin is dissolved in KOH, which also flattens the nail specimen and lessens reflection from cell boundaries. Light microscopy can be utilized to check the presence of fungal elements (2, 3, 9).

It is necessary to rule out nail conditions that could mimic fungal nail infections before beginning treatment for onychomycosis. Yellow-nail syndrome, nail lichen planus, bacterial infections, contact dermatitis, onychodystrophy after trauma, pachyonychia congenita, tumors of the nail bed, and idiopathic onycholysis are a few of these (1).

Treatment aims to eradicate the organism as shown by culture and microscopy. (8). Some of the available therapy options for onychomycosis include oral and topical antifungals (3). The two most often used systemic antifungals for the treatment of onychomycosis are azoles and allylamines. Both can be administered continuously or in a pulsed manner (9).

1.2. Statement of problem

Fungal infections account for around half of nail problems (15). Onychomycosis is estimated to afflict 10% of the general population, with older age groups being the most affected. About half of people over the age of 70 are affected, with a prevalence estimated to be around 20% among patients over 60. The physical changes associated with onychomycosis, such as pain, discomfort, trouble cutting thick nail plates, and difficulty walking, have a significant psychological influence on patients' lives (16).

Onychomycosis is only responsible for 50% of nail disorders, so making a clinical diagnosis based solely on the patient's symptoms and physical examination may not always be accurate. A correct diagnosis is necessary for successful treatment and involves identifying physical changes as well as positive laboratory analysis (17). Since onychomycosis necessitates long-term systemic therapy with antifungals, the diagnosis is crucial. Missing the diagnosis of onychomycosis will result in the patient's ongoing suffering and nail deformity. However, misdiagnosing other nail conditions as onychomycosis will result in an ineffective, costly, and long course of treatment (18). Onychomycosis can resemble a number of different nail unit-related disorders. Therefore, a precise diagnosis is essential for the continued management of onychomycosis as well as to prevent wrong diagnosis and treatment delay. Onychomycosis cannot be diagnosed solely based on a patient's history or physical examination. When onychomycosis is treated empirically for clinically suspected cases, diagnosis errors and reduced cure rates may result. A diagnosis based only on patients' sign and symptoms and physical examination can be misleading. Confirming the clinical suspicion by appropriate testing before the initiation of therapy is more cost effective than treating empirically (16).

Currently, KOH and culture are thought to be the standards for onychomycosis diagnosis. Because it is inexpensive, produces results quickly, and is a simple office procedure, direct microscopy is a useful diagnostic tool. Despite the potential for false-negative results, KOH is advised as the initial diagnostic test for onychomycosis. It has been estimated that over 53% of cutaneous mycosis cases would go undiagnosed if direct microscopy (KOH) is not utilized (19). The KOH test is a well-known method that is used as a first line test for confirmation of onychomycosis and with accuracy dependent on proper specimen collection, preparation, and

experience of the lab technician or the dermatologist. The test is cheap, the results are readily available, and it can be performed in a clinician's office (16).

Even though we usually use KOH as a diagnostic test for clinically suspected onychomycosis cases in our setting, the few studies done in Ethiopia gave emphasis on identification of the etiologic agents by using culture. It would be beneficial to conduct a study in our setting and compare the results with other literatures.

1.3. Significance of the study

The present study will assess the rate of KOH positivity in clinically suspected primary onychomycosis cases and associated factors. It compares the rate seen in this study with other African, western, and Asian studies.

As there are only few studies done to determine the rate of KOH positivity in clinically suspected onychomycosis cases in Ethiopia, this study will give an additional insight how much is the rate of positive outcomes when we use KOH as a diagnostic modality for confirming onychomycosis.

The present study can also encourage other researchers to carry out further studies in the field by utilizing it as a base and to compare it with other diagnostic modalities for onychomycosis.

2. Literature review

Because of its growing frequency and incidence, propensity to spread to healthy people, and potential consequences such superimposed bacterial bone and soft tissue infections, fungal nail infections have emerged as a major global public health concern. Onychomycosis has been more common, particularly in patients with underlying comorbidities including diabetes mellitus and HIV and in older age groups. Onychomycosis has effect on physical, functional, psychosocial, and emotional aspects of life (4). If one has suspected onychomycosis as a cause of the patients nail abnormality, then the clinical suspicion should be confirmed by mycology. The mycological examination is composed mainly by two parts: direct microscopic exam and culture (20). Most of the world literatures are based on the comparison of KOH with other diagnostic modalities that are utilized for the diagnosis of onychomycosis.

There was a study done by J.M Weinberg et.al in New York, United states of America (USA) to compare KOH preparation, culture, Biopsy/PAS stain, and calcofluor white (CW) stain in the diagnosis of onychomycosis and to determine their sensitivity and specificity. They evaluated 105 patients with suspected onychomycosis using 4 diagnostic methods: KOH preparation, culture, Biopsy/ PAS, and CW stain. The KOH preparations were made by placing samples on a glass slide with 20% KOH. The specimen was briefly heated, and then evaluated microscopically for the presence of fungal elements. From 105 samples which were evaluated, 63 had positive KOH result making the rate of KOH positivity 80% (21).

A repeated-measure, single blinded, cross-sectional evaluation of 7 diagnostic tests was conducted at the Minneapolis Veterans Affairs Medical Center in Minnesota, America between March and May 2003 to determine the Cost-effectiveness of diagnostic tests for toenail onychomycosis. Two hundred four participants were enrolled; their average age was 69.5 years. Inclusion criteria included at least one toenail with 25% or more clinical involvement, defined as subungual debris with onycholysis and/or onychauxis. Exclusion criteria included: age younger than 18 years, individuals with known psoriasis, lichen planus, or other nail dystrophies, treatment with oral antifungal medication for 2 months or longer within 12 months of enrollment, and use of topical ciclopirox nail lacquer within 6 weeks of enrollment. They used 20% KOH for microscopic examination. Out of 164 patients for whom KOH was performed 144 patients were KOH positive making the KOH positivity rate 87.8% (22).

A large, single-institute study was done by C.E Litz et.al in USA to determine the range of fungal species detected by the PCR technique and to compare this technique with KOH, PAS and culture on patient specimens. Five hundred and fifty nail specimens from 550 patients with suspected onychomycosis were split and tested concurrently with PCR, PAS, KOH and culture. For the KOH examination, scrapings from nails were mixed with a 10% solution of KOH in glycerol and were examined microscopically for the presence of hyphae and/or yeast cells. Out of 550 specimens which were subjected to all four tests (KOH, PCR, PAS and culture), KOH was positive in 222 specimens making the KOH positivity rate 40% (23).

A descriptive, transversal and comparative study was done at the Dermatology Services of General Hospital of Mexico and General Hospital "Dr. Manuel Gea Gonzalez" between October and December of 2011 to compare the percentage of positivity and the degree of correlation of KOH, cultures and CW for the diagnosis of onychomycosis. 33 patients with clinical characteristics of distal or lateral subungual onychomycosis or total dystrophic onychomycosis of the toenails were included in the study. Direct examination with KOH was performed and KOH was considered positive when hyphae and/or conidia were observed. Out of 33 samples examined 22 were positive up on KOH examination thus making the rate of KOH positivity 66.67% (24).

A latent class analysis was done in Turkey to determine diagnostic values of KOH examination, histological examination, and culture for onychomycosis. Direct microscopic examination, histological examination, and culture were performed on samples taken from 106 consecutive patients having changes clinically suggestive of onychomycosis, namely discoloration, dystrophy, thickening, subungual hyperkeratosis, and onycholysis in great toenails. Samples were taken only from one involved great toenail. If both great toenails were involved, the more severely involved one was chosen for sampling. Direct microscopic examination was done by wet mount preparation with 20% KOH. The KOH mount was designated as positive only if hyphae were seen. Out of 106 samples examined under microscopy KOH was positive on 78 patients making the KOH positivity rate 74% (25).

There was a study done in South Korea on onychomycosis and tricosporon beigelii, from July 1996 to December 1998. It was a retrospective study of the mycologic laboratory records of patients having clinically suspected onychomycosis and attending the Asian medical center

dermatology clinic. There were 2592 samples included in the study. Nail clippings and scrapings were taken from the patients who were suspected clinically to have onychomycosis. Each sample was taken for direct microscopic examination after 10% KOH treatment. Out of a total of 2591 nail samples examined, 1524 patients were KOH positive making the overall positive rate for the KOH mount examination 58.8% (26).

A study was done in South Korea to compare the sensitivities of direct microscopy with KOH, fungal culture and PAS-stained nail clippings, and to define an efficient, high-yield and cost-effective diagnostic strategy for the diagnosis of onychomycosis in the clinical setting. In total, 493 patients with dermatologist suspected onychomycosis were retrospectively evaluated. Samples from 400 patients (group A) were evaluated using fungal culture and PAS, while samples from 93 patients (group B) were evaluated using KOH, fungal culture and PAS. The nail samples were placed on a glass microscopy slide with 20% KOH. Out of 93 patients (group B) KOH was positive on 52 patients making the rate of KOH positivity 55.9% (27).

A study was done in India in 2007 for comparison of standard laboratory tests in the diagnosis of onychomycosis which include KOH mount and mycological culture, with histopathologic examination using PAS staining of the nail clippings. A total of 101 patients with clinically suspected onychomycosis were selected. Nail scrapings and clippings were subjected to KOH mount for direct microscopic examination, culture using Sabouraud's dextrose agar and histopathologic examination with PAS staining. For the KOH mount 20% KOH was used and slides were microscopically evaluated for the presence of hyphae or spores. Out of 101 samples evaluated with KOH, 54 were positive and made the KOH positivity rate 53% (28).

Comparative Cross-sectional study was carried out on 40 clinically suspected cases of onychomycosis in the Department of Microbiology, Rajarajeshwari Medical College and Hospital over a period of one year to isolate and identify causative dermatophytes and nondermatophytes in clinically suspected cases of onychomycosis and to compare the efficacy of direct microscopy and culture with histologic examination using PAS in the diagnosis of onychomycosis. All specimens were subjected to direct microscopy in 40% KOH solution and examined for the presence of fungal mycelia and spores. Out of 40 samples examined 14 were positive for KOH thus making the rate of KOH positivity 35% (29).

A cross sectional comparative study was carried out from September 2012 to August 2016, on 300 clinically diagnosed cases of onychomycosis in Department of Microbiology, Quaid-e-Azam Medical College Bahawalpur and Department of Histopathology King Edward medical University Lahore, Pakistan, for comparison of microscopy and culture with histopathologic examination by using PAS staining of nail clipping in the diagnosis of Onychomycosis. Non-probability convenience sampling technique was applied. Specimen was processed by 20% KOH and examined by direct microscopy. If either hyphae or spore was seen, the test was considered positive. Out of 300 samples examined 180 were positive for KOH thus making the rate of KOH positivity 60% (30).

A study was done in Iran for comparison of direct smear, culture and histology for the diagnosis of onychomycosis in 2007. A total of 96 adult patients with onychomycosis suspected clinically by a dermatologist were enrolled in the study. According to their nail changes, they were categorized in to three groups: superficial white onychomycosis, distal lateral subungual onychomycosis and full-thickness onychodystrophy. Patients with proximal subungual onychomycosis and patients who had other skin diseases with nail involvement (such as psoriasis, lichen planus) were excluded. None of the patients had used any topical or systemic antifungal treatment in the previous 3 months. The specimens were hydrolyzed with 10% KOH, and were subsequently evaluated under a microscope, and considered positive if branched or septate hyphae or spores were seen. Out of 96 of patients who were evaluated with KOH 36 had positive KOH result and made the KOH positivity rate 37.5 % (31).

A prospective and comparative study was done in Kuwait Farwaniya Hospital, to examine the relative prevalence of dermatophytic, yeast and non-dermatophytic mould onychomycosis among diabetic patients, and to compare it with nondiabetic patients. The study included 460 consecutive diabetic patients and the same number of nondiabetic age matched subjects attending dermatology clinics at Farwaniya Hospital, Kuwait, over a period of 4 years from January 2005 to December 2008. All patients were examined clinically and mycologically for any evidence of onychomycosis. The prevalence of clinical onychomycosis in the diabetic and control group was 18.7% (86 cases) and 5.7% (26 cases), respectively. The nail scrapings were incubated in 40% potassium hydroxide for 30 minutes and examined under microscope for the presence of fungal

elements. Of the 86 patients with clinical onychomycosis, KOH was positive on 62 patients thus making the rate of KOH positivity 72.1% (32).

There was a study done in Tunisia to determine the prevalence, the clinical and mycological characteristics of onychomycosis. It was a retrospective study performed over a 22-year period (1986–2007). 7151 patients with suspected fingernails and ⁄ or toenails onychomycosis were included in the study. During the study period, 7662 samples were collected from nails of 7151 patients. Each sample was submitted to a microscopic examination in 30% KOH solution. Direct examination was positive in 4870 samples thus making the rate of KOH positivity 63.6% (33).

A research was done in Nigeria for evaluation of Onychomycosis in Sokoto. A total of 30 samples were collected from patients attending Ammannawa General Hospital Sokoto. Direct microscopic examination was carried out on the specimens by dissolving a portion of each sample in freshly prepared 20% KOH for 60 minutes to be examined under high power objective for the presence of fungal elements such as hyphea, yeast cells, pseudohyphea, budding cells, spores and the blastoconidia. Out of 30 samples examined 14 samples were found to be KOH positive thus making the rate of KOH positivity 46.7% (34).

A prospective nonrandomized study on the prevalence of onychomycosis was carried out from September 2017 to April 2018 at ALERT, Addis Ababa, Ethiopia. A total of 303 nail scrapings were collected from clinically diagnosed patients with nail infections of fungal origin by dermatologists. Clinical samples were investigated microscopically for the presence of fungal elements after grinding nail scrapings with mortar and treating them with a drop of 20% potassium hydroxide. Out of 303 study subjects, fungi were detected by KOH in 65 patients thus making the rate of KOH positivity 21.4% (11).

A clinic-based, prospective, non-randomized cross-sectional study was carried out between October 2018 and June 2019 at Rank Higher Specialized Dermatology Clinic, Addis Ababa, Ethiopia. 200 subjects with clinically suspected onychomycosis were included in the study. Each nail scrapings from each patient was examined for the presence of fungal elements microscopically after digesting the specimen for 5–10 minutes with 20% KOH supplemented with 5% glycerol solution using 10 and 40 magnification power objective lenses. Out of 200 subjects, KOH was positive in 61 patients thus making the rate of KOH positivity 30.5% (14)

3. Objective of the study

- To determine the rate of KOH positivity and associated factors among clinically suspected primary onychomycosis patients

4. Methods and materials

4.1. Study area

The study was conducted at ALERT. ALERT is located in an area locally called Zenebework, Kolfe Keraniyo sub city of Addis Ababa. It was initially established as a treatment center for leprosy and it focuses on rehabilitation of leprosy patients, training programs for leprosy personnel from around the world and leprosy control. The hospital is the main dermatologic center in the country that functions as the referral dermatology institute in and around Addis Ababa, but also gives specialized services in the field of internal medicine, orthopedics, physiotherapy, reconstructive and plastic surgery and ophthalmology.

4.2. Study period

The study was conducted from March to August, 2023

4.3. Source population

All dermatology patients visiting ALERT Dermatology Unit

4.4. Study population

All patients with onychomycosis visiting Dermatology unit of ALERT Center during the study period

4.5. Study design

A facility-based, prospective, cross-sectional study was conducted among clinically suspected primary onychomycosis patients attending the dermatology clinic of ALERT Center in Addis Ababa, Ethiopia from March to August, 2023.

4.6. Eligibility criteria

4.6.1. Inclusion criteria

- All clinically suspected onychomycosis patients

4.6.2. Exclusion criteria

- Patients with other dermatologic condition with nail involvement
- Patients who took oral antifungal or who applied topical antifungal the previous 6 months
- Patients with history of trauma to the affected nail

4.7. Sample size determination and sampling technique

Convenience sampling technique was used and all patients with clinically suspected onychomycosis visiting ALERT dermatology OPD in the given time period was included in the study.

4.8. Study variables

4.8.1. Dependent variables

- KOH positivity as determined by utilizing 20% KOH and examining under light microscope

4.8.2. Independent variables

- Age and sex of the patients, risk factors for the development of onychomycosis, duration of nail abnormality, number of nails involved, site of nail involvement, clinical characteristics of the involved nail, and types of onychomycosis are independent variables.

4.9. Operational definitions

- **Onychomycosis** – a fungal nail infection presenting as nail discoloration, thickening, brittleness, separation of the nail plate from the nail bed and subungual debris
- **Primary onychomycosis** – onychomycosis which is not superimposed on traumatized nail or any underlying nail disorder
- **Positive KOH result** – when fungal filament, element, or spore is seen on microscopy
- **Negative KOH result** - when none of fungal element/filament/spore is seen on microscopy

4.10. Data collection tools and procedures

After obtaining ethical clearance, onychomycosis patients visiting ALERT center dermatology clinic was selected based on the inclusion and exclusion criteria. Diagnosis was made clinically by the treating physician at the outpatient department (OPD). Patients were assessed by a structured questionnaire that was filled by the data collectors. The data collection tool consists of two parts. The first part was filled before sending the patient to the laboratory and the second part was filled after the patient come up with the laboratory result.

4.11. Data processing and analysis

Data entering, coding, cleaning and statistical analysis was done using Statistical Package for Social science (SPSS) version 26. Frequency distributions, percentages, tables and charts are used to show descriptive results. Chi square test was used to see the relationship between dependent and independent variables. P-value of <0.05 was considered as statistically significant. Binary logistic regression was also used to see the association between both variables.

4.12. Data quality management

A structured questionnaire was used. Trained data collectors were involved in data collection. The principal investigator closely supervised and actively participated in the data collection process. Data was checked for completeness, clarity and consistency after being filled each day.

4.13. Ethical considerations

Prior to starting the research, Ethical Clearance was obtained from Institutional Review Board (IRB) of Addis Ababa University (AAU). The letter of cooperation was submitted to the clinical director of ALERT Hospital. Information from the patients will only be used for the purpose of this research and confidentiality will be kept for all patients.

4.14. Data dissemination and utilization

The findings of the study will be submitted to AAU, Department of Dermatovenereology and FMoH. It will also be submitted to scientific journals for possible publication.

5. Result

During the research period, 106 patients with clinically suspected onychomycosis were included in the study. Among these the KOH test was not done for 6 patients. So, they were excluded from the analysis. There were 71 (71%) female patients and 29 (29%) male patients. The age distribution of the patients revealed that most were in the age range 25-44 years (39%). The mean age was 32.38 years and the median age was 30 years. The age range was 3-78 years.

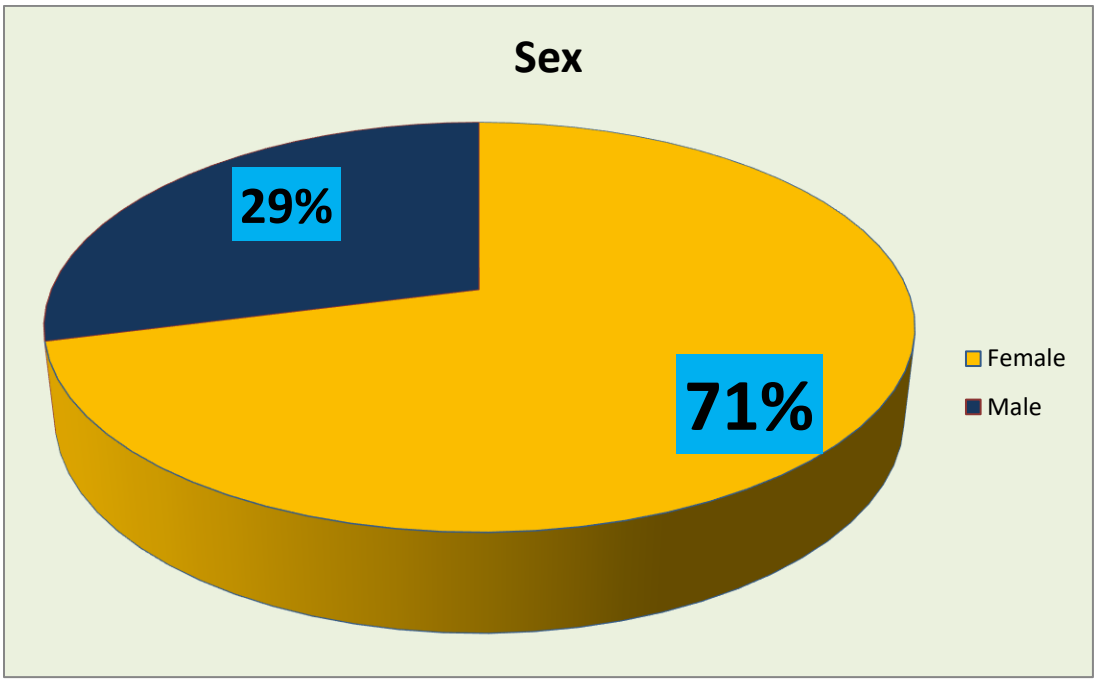

Figure 1 - pie chart showing sex distribution of the study participants

Table 1 – a table showing age distribution of study participants

Age range (in years)	Frequency	Percentage
1-14	14	14%
15-24	22	22%
25-44	39	39%
45-65	22	22%
>65	3	3%
Total	100	100%

44 (44%) patients had Dermatophytosis on other body site up on examination. Only 13 (13%) had previous history of onychomycosis out of 100 patients. 48(48%) patients use occlusive feet wear and 20 (20%) patients had history of use of communal bathing rooms.

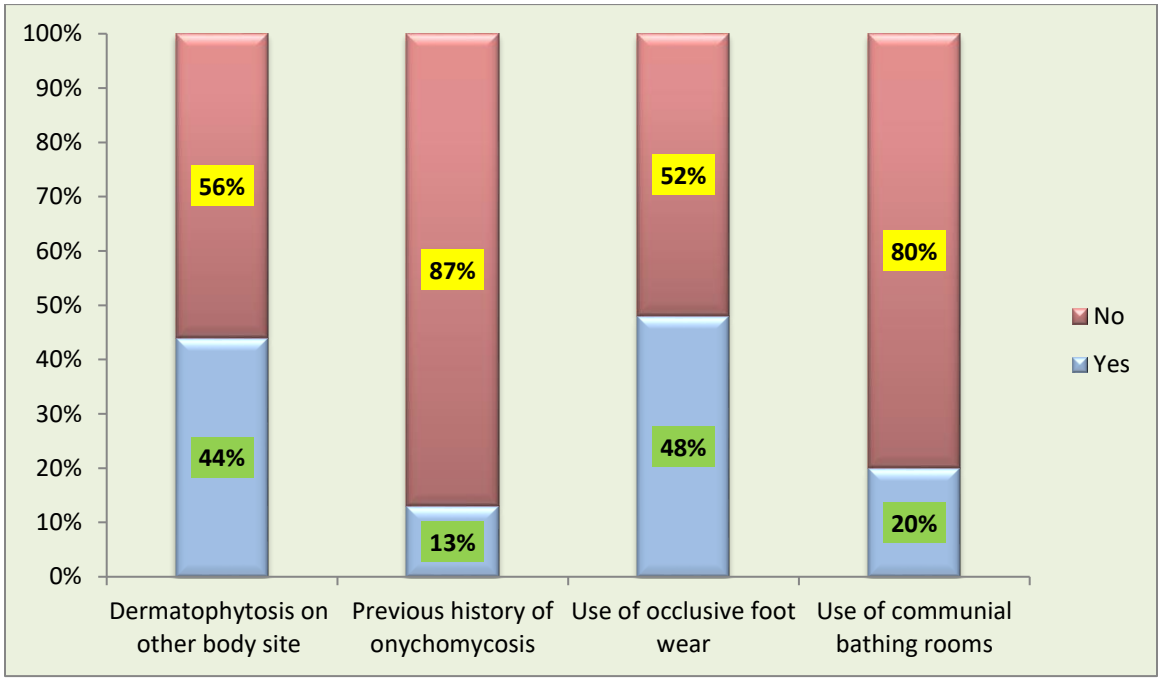

Figure 2 - risk factors for onychomycosis

The mean duration of nail abnormality was 3.57 years and the median duration was 1 year. The minimum time to presentation was 2 weeks and 25 years being the maximum. Most patients present within one year of nail involvement (55%) and from these 29% presented within 6 months.

Regarding site of nail involvement, finger nails were commonly affected (50%) followed by toe nails (33%) and both were affected in 17% of patients.

Table 2 - duration of nail abnormality

Duration of nail abnormality (in months)	Frequency	Percentage
0-6	29	29%
7-12	26	26%
13-24	9	9%
>24	36	36%
Total	100	100%

Most patients had only one nail involvement (36%) followed by 2 nails (16%). The maximum number of involved nails was 16.

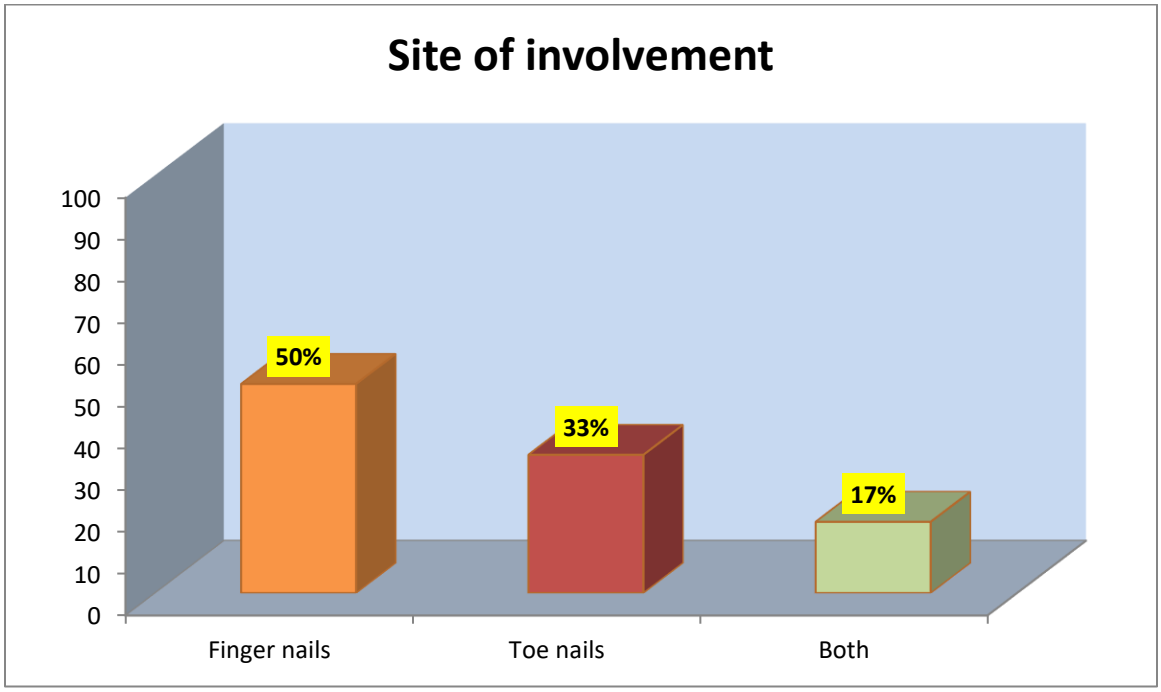

Figure 3 - site of nail involvement

Table 3 – number of involved nails

Number of nails involved	Frequency	Percentage
1 nail	36	36%
2 nails	16	16%
3-5 nails	25	25%
>5 nails	23	23%
Total	100	100%

Regarding the clinical characteristics of the nails involved almost all had discoloration (98%), 47 of patients had onycholysis, 65 of them had subungual hyperkeratosis and nail plate thickening.

DLSO was the most common type of onychomycosis identified (44%) followed by TDO (42%) and SO (10%). PSO was the least common type (4%).

Out of the 100 patients sent for KOH examination, fungal filament, element or spore was seen in 67 (67%).

Table 4 – clinical characteristics of the involved nails

Clinical characteristics of the involved nails	Frequency
Nail discoloration	98 nails
Onycholysis	47 nails
Subungual hyperkeratosis	65 nails
Nail plate thickening	65 nails

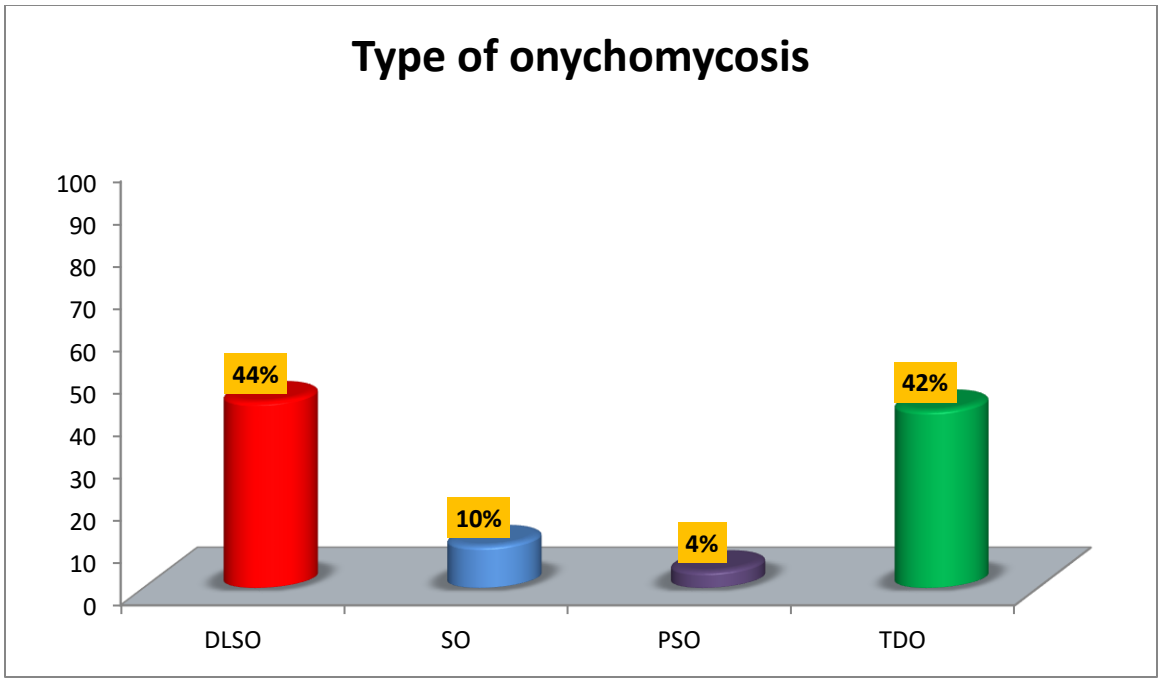

Figure 4 – patterns of onychomycosis

From those who present within 6 months of nail involvement (29) 17 samples were positive for KOH. From patients who presented after 2 years of nail involvement (36), KOH was positive in 27. Among patients who had only involvement of one nail (36), two nails involvement (16), 3-5 nails involvement (25), and greater than 5 nails involvement (23), 24, 10, 19, and 14 patients had positive KOH result respectively.

Among the involved finger nails (50) KOH was positive in 39. From toe nails (33) it was positive in 17. From patients with involvement of both finger and toe nails (17) KOH was positive in 11.

Among patients who were classified as having DLSO (44), 26 had positive KOH result. From TDO (42), 31 had positive KOH, from SO (10), 7 had positive KOH, and from PSO (4), 3 had positive KOH result.

Among patients who had nail discoloration (98) KOH was positive in 67 and from those patients who had subungual hyperkeratosis (65) 41 had positive KOH.

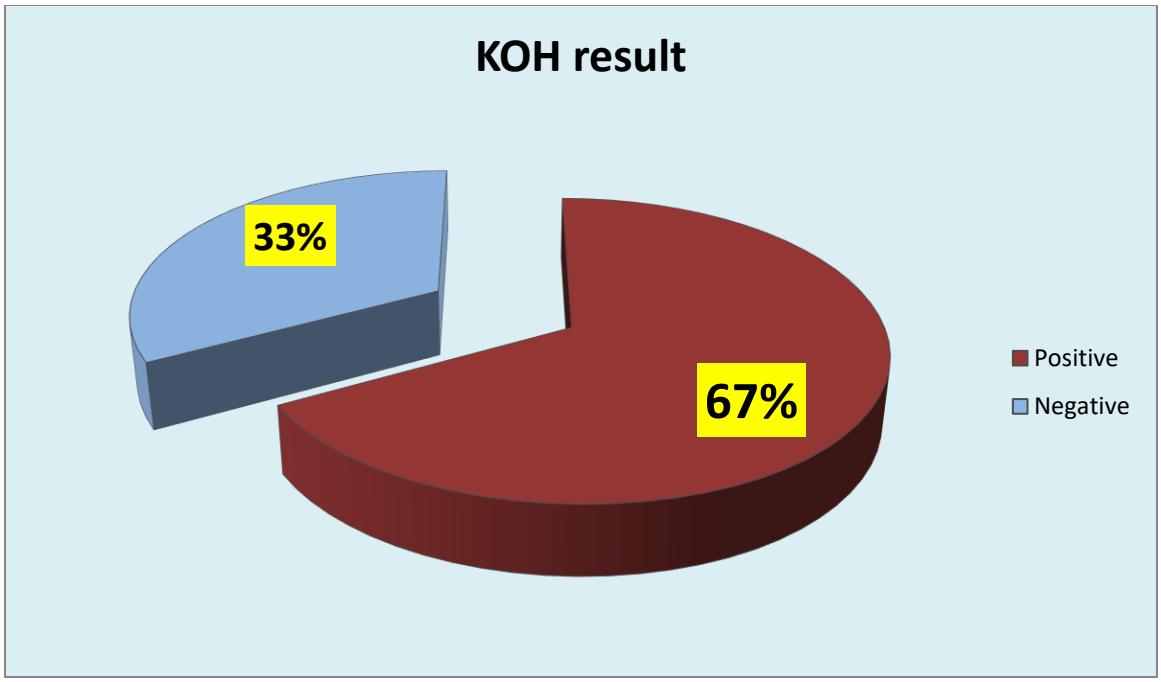

Figure 5 – KOH result

Table 5 - duration of nail involvement with KOH result

		KOH result		Total
		Positive	Negative	
Duration of nail involvement	0-6 months	17	12	29
	7-12 months	17	9	26
	13-24 months	6	3	9
	>24 months	27	9	36
	Total	67	33	100
Number of nails involved	1 nail	24	12	36
	2 nails	10	6	16
	3-5 nails	19	6	25
	>5 nails	14	9	25
	Total	67	33	100

Table 6 – site of involvement with KOH result

		KOH result		Total
		Positive	**Negative**	
Site of involvement	Finger nails	39	11	50
	Toe nails	17	16	33
	Both	11	6	17
	Total	67	33	100
Type of onychomycosis	DLSO	26	18	44
	SO	7	3	10
	PSO	3	1	4
	TDO	31	11	42
	Total	67	33	100

Table 7 - nail characteristics with KOH result

		KOH result		Total
		Positive	**Negative**	
Nail characteristics	Nail discoloration	67	31	98
	Onycholysis	29	18	47
	Subungual hyperkeratosis	41	24	65
	Nail plate thickening	42	23	65

The Pearson chi square test was employed in bivariate analysis to display the correlation between KOH positivity and the independent variables. The significance threshold was set at 5%. Site of involvement and nail discoloration were associated with KOH positivity in bivariate analysis (*p* value = 0.042 for both).

Table 8 – relationship between independent and dependent variables (chi square test)

Characteristics of patients and nails		**Total**	**KOH result**		***p*-value**
			Positive	**Negative**	
Duration of nail abnormality (in months)	0-6	29	17	12	0.574
	7-12	26	17	9	
	13-24	9	6	3	
	>24	36	27	9	
Site of involvement	Finger nails	50	39	11	**0.042**
	Toe nails	33	17	16	
	both	17	11	6	
Nail characteristics	Discoloration	98	67	31	**0.034**
	Onycholysis	47	29	18	0.289
	Subungual hyperkeratosis	65	41	24	0.256
	Nail plate thickening	65	42	23	0.489
Type of onychomycosis	DLSO	44	26	18	0.516
	SO	10	7	3	
	PSO	4	3	1	
	TDO	42	31	11	

Binary logistic regression was also used to see the association between the dependent and independent variables. None of the independent variables show association with KOH positivity.

Table 9 – association between dependent and independent variables (binary logistic regression)

Characteristics of patients and nails		**Total**	**KOH result**		***p*-value**
			Positive	**Negative**	
Duration of nail abnormality (in months)	0-6	29	17	12	0.627
	7-12	26	17	9	
	13-24	9	6	3	
	>24	36	27	9	
Site of involvement	Finger nails	50	39	11	0.179
	Toe nails	33	17	16	
	both	17	11	6	
Nail characteristics	Discoloration	98	67	31	0.999
	Onycholysis	47	29	18	0.668
	Subungual hyperkeratosis	65	41	24	0.280
	Nail plate thickening	65	42	23	0.346
Type of onychomycosis	DLSO	44	26	18	0.239
	SO	10	7	3	
	PSO	4	3	1	
	TDO	42	31	11	

6. Discussion

Clinical diagnosis of onychomycosis should be assisted by laboratory confirmation because there are many dermatoses that affect the nail and mimic onychomycosis. KOH is one of such confirmatory studies.

Our study showed that the rate of KOH positivity to be 67%. The positivity rates of KOH in literature are highly variable. Our study result is in par with bonifaz et al. and dhib et al. who reported positivity rates of 66.67 % and 63.6% respectively (24, 33). Comparatively less positivity rates of 35% and 46.7% in India and Nigeria have been reported by vishwajith et al. and Aliyu et al. respectively (11, 29). These could be due to the small number of patients (40 and 30 patients respectively) enrolled in the study. Two American studies report KOH positivity rates of 87.8% and 80% by kia et al. and Jeffery et al. respectively (21, 22). These can be explained by the variability in the expertise who asses the samples.

In our study females were most likely to present with a complaint which match with a clinical diagnosis of onychomycosis than males. Different studies worldwide showed that onychomycosis is more common in females (25, 31, 33). The same is true in studies done in our country (11, 14). The possible reason for this could be females are more concerned about the cosmetic appearance of their nails and in our country females are more engaged in wet work.

Regarding the age distribution of our study participants, onychomycosis was more diagnosed in the age range of 25- 44. This is the same as the studies done in our country by Bitew et al. (11, 14) and study done by gupta et al. (37). The explanation could be again the concern of young adults about the appearance of their nails. However studies from developed counties showed that it is more common on older adults (23, 25). This may be due to the increment of the aging population in these countries.

The current study showed that finger nails were more involved than toe nails which are in contrast to most other studies which reported more toe nail involvement (34, 32, 35). Given that female young adults were the predominant participants in our study as discussed above, finger nail involvement is common since females are more engaged in kitchen work in our set up.

In this study almost all study participants present with nail discoloration (98%) followed by subungual hyperkeratosis (65%). This was also the case in the studies done by Vasava et al. and Gupta et al. (36, 37). There reason behind could be dyschromic nails have unpleasant appearance and oblige the individual to seek medical care.

DLSO was the most common type of onychomycosis identified in our study followed by TDO. This is the same as the studies done by Attal et al., Jain et al., and Husain et al. (35, 38, 39). This could be due to the ability of the fungi to invade the hyponychium followed by the nail bed and the nail plate rather than directly invading the nail plate.

Among the assessed variables only nail discoloration and site of involvement had association with KOH positivity. The reason is a bit difficult to explain but it could be due to the relatively small sample size of the study.

7. Conclusion

According to our study the rate of KOH positivity in clinically suspected cases of onychomycosis is 67% which is relatively low. This shows around one third of suspected cases will be missed if KOH is used as the sole test to detect fungi. Young adult females more commonly present with onychomycosis. The finger nails are more prone to be affected by onychomycosis than the toe nails. Nail discoloration is the predominant presenting complaint of patients with onychomycosis. DLSO is the most common pattern of onychomycosis. KOH will be more yielding if nail discoloration is the predominant sign and if onychomycosis involves the finger nails.

8. Limitation

It would have been better if KOH was compared with culture and histopathology. They were not done due to financial issues.

9. Recommendations

1. KOH should be combined with other diagnostic tests in order not to miss false negative cases

2. Other studies should be done that compare KOH with culture and histopathology

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Annexes

Annex I

Informed Consent

You will be invited to participate in a study to assess the rate of KOH positivity and associated factors among clinically suspected primary onychomycosis patients visiting Dermatology unit of ALERT Center and I would like to ask few questions.

The information that will be obtained in this survey is only for scientific research without any commercial interests. Your name will not be written on this form and the information you give will never be shared to others. Your participation is voluntary and you are not obligated to answer any question you don't wish to answer**.**

I have read this form or it has been read to me in the language I comprehend and understand all conditions stated above

Are you willing to participate in this study?

1- No (say thank you)

2- Yes (continue interviewing)

I confirmed to participate in the study by my own signature----------

Name of interviewer_____ signature_____

Date of interview (Ethiopian calendar) _____/_____/____

Informed Assent (for less than 12years)

Your child will be invited to participate in a study to assess the rate of KOH positivity and associated factors among clinically suspected primary onychomycosis patients visiting Dermatology unit of ALERT Center and I would like to ask few questions.

The information that will be obtained in this survey is only for scientific research without any commercial interests. Yours and your child name will not be written on this form and the information you give will never be shared to others. Your participation is voluntary and you are not obligated to answer any question you don't wish to answer**.**

I have read this form or it has been read to me in the language I comprehend and understand all conditions stated above

Are you willing to participate in this study?

1- No (say thank you)

2- Yes (continue interviewing)

I confirmed to participate in the study by my own signature----------

Name of interviewer_____ signature_____

Date of interview (Ethiopian calendar) _____/_____/____

Informed Consent In Amharic

ሠላም፣ ዶ/ር ሠአዳ እባላለሁ KOH የተባለው ምርመራ የጥፍር ፈንገስ ኢንፌክሽን ያለባቸው ሰዎች ላይ ፈንገሡን የመለየት አቅሙ ምን ያህል ነው የሚል ጥናት እያካሄድኩ ነው እና አንዳንድ ጥያቄዎች እጠይቆታለሁ።

እርሶ የሚሰጡን መረጃ ሳይንሳዊ ምርምር እንጂ ለሌላ ለምንም ነገር አይውልም። የእርስዎ ስም ምርምሩ ላይ አይጠቀስም።

የእርስዎ ተሳትፎ ፈቃደኝነቶ ላይ የተመሰረተ ነው እንዲሁም መመለስ ያልፈለጉትን ጥያቄ አለመመለስ ይችላሉ።

ይህንን ፅሁፍ አንብቤዋለሁ ወይም ተነቦልኛል እንዲሁም ሀሳቡን ተረድቼዋሁ።

በጥናቱ ላይ ለመሣተፍ ፍቃደኛ ነዎት?

1. አይደለሁም ☐
2. ፍቃደኛ ነኝ ☐

ጥናቱ ላይ ለመሣተፍ ፍቃደኛነቴን በፊርማዬ አረጋግጣለሁ _____

የመጠይቅ አድራጊው ስም _____ ፊርማ _____

ቀን _____

Informed assent in Amharic (for <12 years)

ሠላም፣ ዶ/ር ሠአዳ እባላለሁ KOH የተባለው ምርመራ የጥፍር ፈንገስ ኢንፌክሽን ያለባቸው ሰዎች ላይ ፈንገሡን የመለየት አቅሙ ምን ያህል ነው የሚል ጥናት እያካሄድኩ ነው እና ልጅዎትን አንዳንድ ጥያቄዎች መጠየቅ እፈልጋለሁ።

እርሶ የሚሰጡን መረጃ ሳይንሳዊ ምርምር እንጂ ለሌላ ለምንም ነገር አይውልም። የእርስዎ ስም ምርምሩ ላይ አይጠቀስም።

የእርስዎ ተሳትፎ ፈቃደኝነቶ ላይ የተመሰረተ ነው እንዲሁም መመለስ ያልፈለጉትን ጥያቄ አለመመለስ ይችላሉ።

ይህንን ፅሁፍ አንብቤዋለሁ ወይም ተነቦልኛል እንዲሁም ሀሳቡን ተረድቼዋሁ።

በጥናቱ ላይ ለመሣተፍ ፍቃደኛ ነዎት?

1. አይደለሁም ☐
2. ፍቃደኛ ነኝ ☐

ጥናቱ ላይ ለመሣተፍ ፍቃደኛነቴን በፊርማዬ አረጋግጣለሁ _____

የመጠይቅ አድራጊው ስም _____ ፊርማ _____

ቀን _____

Annex II

Data collection format

I. Socio-demographic data

1. Age in years --------
2. Sex
   A. Male
   B. Female

II. Possible risk factors for development of onychomycosis

1. Dermatophytosis on other body site: □ Yes □ No
2. Previous history of onychomycosis: □ Yes □ No
3. Use of occlusive feet wear: □ Yes □ No
4. Use of communal bathing and swimming pools: □ Yes □ No

III. Nail associated characteristics

1. Duration of nail abnormality ……..
2. Site of involvement
   A. Finger nails
   B. Toe nails
   C. Both
3. Number of nails involved ……
4. Clinical characteristics of the involved nail
   A. Nail discoloration: □ Present □ Absent
   B. Onycholysis: □ Present □ Absent
   C. Subungual hyperkeratosis: □ Present □ Absent
   D. Nail plate thickening: □ Present □ Absent
5. Type of onychomycosis
   A. Distal lateral subungual onychomycosis
   B. Superficial onychomycosis
   C. Proximal subungual onychomycosis
   D. Total dystrophic onychomycosis

IV. Result of the investigation

1. KOH result

   A. Positive (fungal filament, element, or spore seen)

   B. Negative (none seen)