ADDIS ABABA UNIVERSITY

COLLEGE OF HEALTH SCIENCES

DEPARTMENT OF DERMATOVENEREOLOGY

Prevalence of HIV Seroreactivity in Anogenital wart Patients at ALERT, Addis Ababa, Ethiopia: A prospective study

By: Dr. Petros Habtamu (MD, Dermatovenerology Resident)

Advisors: Dr. Selamawit Girma (MD, MPH, Dermatovenerologist, Assistant Professor)

: Dr. Bethlehem Mehari (MD, MPH, Dermatovenerologist, Assistant Professor)

Addis Ababa, Ethiopia

Dec 2024 GC

ADVISOR APPROVAL SHEET

This is to certify that the research thesis entitled “Prevalence of HIV Seroreactivity in Anogenital wart Patients at ALERT, Addis Ababa, Ethiopia” is submitted in partial fulfillment of the requirements for the certificate of specialty in Dermatovenerology to the Graduate Program of the College of health sciences of Addis Ababa University and is carried out by Petros Habtamu. Therefore, I recommend that the student has fulfilled the requirements and hence hereby can submit the thesis paper to the department.

Name of Advisor	Signature	Date
Dr. Selamawit Girma		

Name of Advisor	Signature	Date
Dr. Bethlehem Mehari		

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.

Name: Petros Habtamu

Signature: _____

Place: Addis Ababa University College of Health Sciences, Tikur Anbesa Specialized Hospital, Department of Dermatovenerology

Date of submission: _____

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

Confirmed by: - Dr. Selamawit Girma (MD, MPH), Assistant professor of Dermatovenerology at Addis Ababa University College of Health Sciences, Tikur Anbesa Specialized Hospital, AA, Ethiopia.

Signature: _____

Date: _____

Confirmed by: - Dr. Bethlehem Mehari (MD, MPH), Assistant professor of Dermatovenerology at Addis Ababa University College of Health Sciences, Tikur Anbesa Specialized Hospital, AA, Ethiopia.

Signature: _____

Date: _____

Contents

List of Tables

List of Figures

Acknowledgement

I'm extremely grateful to the Department of Dermatovenerology at Addis Ababa University for granting me permission to conduct this research, which will help me in my future career endeavors. In addition, I would like to express my gratitude to Dr Selamawit Girma and Dr Bethlehem Mehari, who served as my advisors and helped me greatly throughout the development of this research proposal. Lastly, I would want to express my gratitude to the residents who provided suggestions for this plan's development and had enormous contribution during data collection.

Abbreviations and Acronyms

AAU – Addis Ababa University

AGW – Anogenital wart

AIDS – Acquired Immunodeficiency Syndrome

AIN – Anal intraepithelial neoplasia

ALERT – All African Leprosy Rehabilitation and Training Center

CDC – Centre for Disease Control

CA – Condyloma acuminata

DNA – Deoxyribonucleic acid

DRE – Digital Rectal Examination

ELISA – Enzyme linked immunosorbent assay

FMoH – Federal Ministry of Health

G.C – Gregorian calendar

HAART - Highly active antiretroviral therapy

HIV – Human Immunodeficiency Virus

HPV – Human papilloma virus

HR – High risk

IRB – Institutional Review Board

LW – Low risk

MSM – Men having Sex with Men

OPD – Out Patient Department

PICT – Provider Initiated Counselling and Testing

SPSS - Statistical Package for Social Science

STI – Sexually transmitted infection

TCA – Trichloroacetic acid

TPHA – Treponema pallidum Haemagglutination assay

VDRL – Venereal disease research laboratory

Abstract

Background:

Anogenital warts (AGWs) are visible warts seen in the body's perigenital and perianal regions(1). They are benign lesions caused by HPV types 6 or 11 which are low risk (LR) types, with the remaining 10% caused by a co-infection with high risk (HR) types(1–3).

In addition to epidemiological evidence, biological findings confirm the mechanisms for sexually transmitted infections (STIs) increasing Human Immunodeficiency Virus (HIV) acquisition and transmission via direct mucosal disruption, recruitment of HIV target cells to the genital tract, and increased HIV load in plasma and genital secretions(8).

Immunosuppression, on the other hand, is a key risk factor for chronic human papilloma virus (HPV) infections and, as a result, the development of HPV-induced lesions. The frequency and prevalence of benign and malignant HPV-induced anogenital lesions are much higher in HIV-infected patients(9).

Objectives:

The goal of this study was to assess the rate of HIV positivity among Anogenital Wart patients who visit the Dermatology unit of All African Leprosy Rehabilitation Training Center (ALERT) Hospital in Addis Ababa, Ethiopia, between March and August 2024.

Methods:

A facility-based, prospective, cross-sectional study was conducted among patients with Anogenital warts attending the dermatology clinic of ALERT Center in Addis Ababa, Ethiopia from March to August, 2024. Data was gathered from patients using a structured questionnaire. Version 26 of the Statistical Package for Social Science was used to analyse the data. Descriptive results were displayed using tables, charts, percentages, and frequency distributions. The relationship between the dependent and independent variables was examined using the chi square test, and the strength of the relationships was measured using binary logistic regression.

Result:

A total of 58 patients were included in the study (75.9% females and 24.1% males). The median age was 29.5. The rate of HIV positivity was determined to be 39.7%. AGWs were most commonly located over the genitalia. The median duration of anogenital warts was 6.5 months with interquartile range of 21 months. The median size of warts was 1.5cms with interquartile range of 2.4cms.The median for the number of warts was 6 with interquartile range of 9 and most study participants (65.5%) had at least 5 warts.

Site of warts and wart size were significantly associated with HIV positivity. Individuals with both anal and genital warts had a higher chance of being HIV positive than those with only genital warts (AOR = 5.424,95% CI = 1.198,24.547, p value = 0.028). Those with wart diameters greater than 2 cm had an 8.6-fold higher chance of being HIV positive than those with wart sizes less than 1 cm (AOR = 8.569, 95% CI = 1.863, 39.410, p value = 0.006).

Conclusion:

The prevalence of HIV in AGW patients, as seen in our study, is quite common. The study has demonstrated the connection between HIV serostatus and demographic features and the clinical presentation of AGWs.

1. Introduction

1.1 Background

AGWs are visible warts seen in the perigenital and perianal regions of the body(1). They are benign lesions caused by HPV types 6 or 11 (LR types), with the remaining 10% caused by a co-infection with high risk (HR) types(1–3).
Papillomaviruses are small, non-enveloped, icosahedral double-stranded deoxyribonucleic acid (DNA) viruses(4).
The majority of clinically visible AGWs are produced by HPV genotypes 6 or 11 and are only infrequently related with HPV kinds with a high risk. Warts can spread if left untreated, regress spontaneously, endure in unchanging form, or continue to expand in size(3).

The epidemiology of HPV genital infection is yet unknown. According to literatures, anogenital HPV infection affects approximately 40% of the general population. In industrialized countries, the annual incidence of genital warts is estimated to be around 0.15% of the adult population. Females aged 16-24 years and guys aged 20-24 years have the highest rate of warts. The projected number of instances of genital warts has been steadily growing in recent years across Western countries, most likely due to early age at first intercourse, a rise in lifetime sexual partners, and a lack of condom use(2).

Because the HPV virus cannot be cultivated in culture, information on its behaviour and transmission comes from clinical observations and animal trials. AGWs are primarily transmitted through sexual contact. They are highly contagious, with a transmission rate of approximately 65% within sexual partnerships from an infected to a vulnerable sexual partner, and an incubation time ranging from 3 weeks to 8 months, with the majority acquiring warts at around 2-3 months. In children, genital lesions caused by transmission of infection from hand warts have been reported, but not in adults. There is no conclusive proof of fomite transmission. Autoinoculation from a genital location to an extragenital site has been observed, however it is extremely unusual(2,5).

Solitary lesions of AGW are uncommon. The dimensions range from a few millimeters to several centimetres(2).
Individual cases are never identical since lesions are multifocal, multicentric, and multiform. Anogenital warts are classified as condylomata acuminata, flat warts, papular warts, and hyperkeratotic warts. Individual patients frequently exhibit more than one form of lesion. Warts frequently consolidate into plaques, especially in immunocompromised persons. The most prevalent type of anogenital wart is a 5 mm diameter papular lesion. They can grow on the anogenital skin or the mucosal surface. Lesions can occur anywhere in the anogenital

region. Genital warts can be found in the shaft of the penis, base of the penis, scrotum, pubic region, under the prepuce, glans and coronal sulcus, and rectal area in men, and in the moist parts of the labia minora and vaginal entrance in women. Anal lesions are prevalent in both sexes and are enhanced by, but not always connected to, anal sex. The same HPVs can cause extragenital lesions in the oral cavity, throat, conjunctiva, and nasal cavity. AGWs are nearly typically asymptomatic; if symptoms exist, they are mainly caused by irritation, hemorrhage, or secondary infection and manifest as itching or burning sensations(2,3,6).

The only suggested test for regular diagnosis is visual inspection, which can be helped by a magnifying lens. HPV typing has no place in ordinary clinical practice. Biopsy may be required to confirm the diagnosis in some cases, notably in immunocompromised patients, lesions of questionable diagnosis, lesions that do not respond to normal therapy and lesions that progress during therapy. The acetic acid test, which involves immersing the skin under examination in 5% acetic acid and looking for "acetowhite" lesions, is occasionally justified for lesions that may or may not be warts, or for targeted biopsy(7).
In the presence of perianal warts and/or symptoms such as discomfort, bleeding, or discharge, an examination of the anal canal via digital rectal examination (DRE) and/or anoscopy is indicated to identify probable internal warts(2).

AGWs do not normally cause considerable morbidity or mortality, but they do cause significant psychological morbidity and very high healthcare expenditures. AGWs can persist for lengthy periods of time, and in rare cases, such lesions might proceed to cancer(5).

Most patients seek therapy because warts cause discomfort, worry, distress, or social unacceptability. The ultimate goals of treatment are the elimination of visible clinical lesions, symptom alleviation, and relapse prevention. Ablative treatments (chemicals or physical procedures) are typically administered by doctors, while immunomodulatory treatments are mostly administered by patients. Physician-applied treatments include cryotherapy, TCA, laser and surgery while podophyllotoxin, Imiquimod and sinecatechin can be patient applied(2).

Following treatment, recurrence is common and is often recognized within 3 months in 25% of cases, while rates of up to 67% have been seen. In clinical practice, recurrences are frequently seen in sites of earlier lesions(5).

Immunocompromised patients typically have a decreased response and increased relapse rates. Anoscopy is recommended even if perianal warts are not evident since they have a greater risk of HPV-related neoplasia, most commonly in the anal canal. If CD4 >500 cells/mm3 in HIV patients, no extra therapy change is required; however, if CD4<200 cells/mm3, surgical/physical treatments are favored(2).

There is a substantial link between sexually transmitted diseases and HIV infection acquisition and transmission. This was originally shown in case series and retrospective investigations that found a link between prior STI and HIV. There are numerous such evidences but they have proven challenging to evaluate due to confounding due to similar risk variables, particularly sexual behavior, and challenges in defining temporal correlations. Biological results support the mechanisms for STI enhancing HIV acquisition and transmission through direct mucosal disruption, recruitment of HIV target cells to the genital tract, and increased HIV load in plasma and genital secretions, in addition to epidemiological evidence(8).

Conversely, Immunosuppression is a major risk factor for chronic HPV infections and, as a result, the development of HPV-induced lesions. In HIV-infected people, the incidence and prevalence of benign and malignant HPV-induced anogenital lesions are significantly higher(9).

Anal warts may also raise the risk of HIV infection by damaging the mucosa of the rectal cavity and increasing blood exposure, similar to the way genital ulcers in Africa are linked to HIV transmission. Anal and genital warts are more common in immunocompromised individuals. Therefore, the immunological deficit associated with HIV infection may potentially raise the incidence of warts. Thus, warts linked to the human immunodeficiency virus may be seen because they either help spread HIV or serve as a sign of HIV-induced immunosuppression(10).

Within the last eight years, more than 25% of HIV-infected females and more than 50% of HIV-infected males had genital warts. The prevalence of genital warts has been observed to be more than tenfold higher in HIV-positive women than in HIV-negative women(11).

1.2 Statement of the problem

Genital HPV infection is the most common sexually transmitted disease(12). Since the mid-1960s, the prevalence of genital warts has dramatically increased. Infection with the causative agent, HPV, may be latent or subclinical and may be a risk factor for cervical and genital malignancies(13).

Reported annual incidence of any AGWs (including new and recurrent) ranges from 160 to 289 per 100,000, with a median of 194.5 per 100,000(14). They are a major source of negative psychosexual reactions and an important reason for consultation in primary care, dermatology, gynaecology, and urology care settings, as well as a significant burden on the health-care system because patients frequently need to visit health-care providers for management(15).

Despite the likelihood of spontaneous reversion, patients frequently desire early therapy in order to avoid the psychosocial and psychosexual difficulties associated with a delayed regression process. Early research in the field suggested that women with genital warts experienced frustration, anxiety, anger, fear of rejection, isolation, guilt, embarrassment, shame, and feelings of being dirty or contaminated, and that these negative psychological effects may be more significant than the disease's medical effects(16).

At the molecular level, HPV and HIV each have interactions that favor the other infection. HPV infection promotes HIV acquisition in both men and women, and patients with suppressed cell mediated immunity, including those with HIV infection, may respond less favorably to genital wart treatment, experience more relapses, and be more susceptible to dysplasia(17).

Cancer-associated HPV varieties are more typically found in genital warts removed from immunocompromised people than in those removed from otherwise healthy people.
It has been shown that patients with anal warts and HIV have a higher likelihood of developing anal intraepithelial neoplasia (AIN)(18,19). In addition, extensive infiltrations and a significant rate of recurrence have been documented in HIV patients. Highly Active Retoviral Therapy (HAART) that causes an increase in CD4+ circulating cells while decreasing viral load may have an indirect effect on the clinical outcome of genital warts(20).

Even though it is commonly accepted that HIV and AGWs are linked and that the presence of HIV impacts AGW therapy and prognosis, only a few studies have been conducted around the world to determine the prevalence of HIV infection in AGW patients. This research attempts to fill that knowledge gap and provide insight into the situation in our country.

1.3 Significance of the study

The present study will assess the rate of HIV positivity in Anogenital wart patients. It compares the rate seen in this study with those done in other parts of the world.

As there are no studies done to determine the prevalence of HIV positive status in Anogenital wart patients in Ethiopia, this study will give an insight into how commonly Anogenital wart patients are coinfected with HIV.

The present study can also encourage other researchers to carry out further studies in the field by utilizing it as a base and assess associated risk factors.

2. Literature review

Genital warts, which are benign tumours that can affect a patient's quality of life and have an economic impact on society, can be caused by HPV infection. Geographic, regional, racial, and cultural differences may affect demographic data on genital warts as a sexually transmitted disease (STD) and sexual habits and risk factors(21).

HPV infections are related to other sexually transmitted infections such as the Human Immunodeficiency Virus (HIV)/Acquired Immunodeficiency syndrome (AIDS)(22). HIV and genital HPV are both STIs, and they may interact, but the specifics of any such interaction are unknown(23).

Strong evidence suggests that both ulcerative and non-ulcerative STDs, including anogenital warts, increase HIV infectiousness and susceptibility via a number of biological processes, hence promoting HIV transmission. Most directly, STIs can create a biological environment that strengthens HIV transmission in individuals who are already infected, as well as increase susceptibility in individuals who have a STI when exposed to HIV. Numerous risk factors and markers are associated with both types of infections, including individual risk factors for HIV, the prevention of infections in sex networks, and social and health care-related inequities. The risk estimates from multiple prospective studies from four continents, which range from 2.0 to 23.5, with the majority grouping between 2 and 5, reflect these impacts(24).

It seems complicated how important ulcerative and non-ulcerative STDs are in relation to one another. Non-ulcerative STDs may be more likely to transmit HIV than genital ulcers since they are more prevalent in many populations. However, the evidence that non-ulcerative STDs may increase risk exclusively for the receptive partner (rather than bidirectionally) and the limited reciprocal impact of HIV infection on non-ulcerative STDs may alter the impact of these diseases(24).

Rectal bleeding is prevalent among guys reporting intercourse with men. It is an independent risk factor for HIV infection and should be considered in attempts to prevent acquired immunodeficiency syndrome. Rectal hemorrhage caused by anal wart rupture may be a very powerful HIV transmission channel(25).

In a cross sectional study conducted in Iran by Soori et.al to evaluate demographic information and some sexual behaviours and risk factors among Iranian patients with genital wart, a total of 250 patients with anogenital warts were examined from March 2011 to April 2012. The questionnaires contained demographic and general information on the patients with genital warts, such as gender, age groups, marital and educational status, age of marriage, alcohol and cigarette smoking, pattern of sexual behavior and risk factors, and

other STDs. Among these, 7 patients were found to be HIV positive making the proportion of HIV reactive genital wart patients 2.8%(21).

In another study carried out retrospectively aiming to determine profile of condyloma acuminata using data from Dermatovenerology patient clinical records at Sanglah General Hospital in Denpasar, Bali, Indonesia, from 2015 to 2017, 260 condyloma accuminata (CA) cases were seen from a total visit of 4743 (5.48%). 59 out of 260 (22.31%) patients were HIV infected(26).

Coplan et al. conducted a prospective study in Mexico City to evaluate the frequency and determinants of rectal bleeding, as well as the association between rectal bleeding and the risk of human immunodeficiency virus (HIV) infection among homo-sexual/bisexual men. Men who visited a center in Mexico City (the CONASIDA-Flora testing center) to obtain an anonymous, free test for HIV infection between June 1991 and December 1992 were eligible to participate. Informed agreement was obtained for HIV testing and study participation, and the males were then requested to complete a standardized questionnaire before being tested. All consenting, eligible clients were interviewed by trained professionals about demographic variables, sexual conduct, psychological states, and HIV serostatus. Rectal bleeding was associated with older age, higher education, more receptive anal intercourse than insertive intercourse, receptive digital-anal contact, anal warts, and genital ulcers. In multivariate analysis, men who reported both rectal bleeding and anal warts were 3.5 times (95 percent CI 2.1-5.8) more likely to be HIV-infected than men who reported neither risk factor(25).

Another study conducted by Jiamton et.al reported HIV seroprevalence of 14.9% among male anogenital wart patients. They did a retrospective chart analysis of male patients diagnosed with anogenital warts at an STD clinic in Bangkok, Thailand, between January 2007 and December 2011. Demographic information, clinical symptoms, and therapies were gathered. VDRL (Veneral Disease Research Laboratory) titer, TPHA (Treponema Pallidum Haemagglutination Assay) titer, HIV antibody test, CD4 cell counts, and ELISA (Enzyme Linked Immunosorbent Assay) detection of hepatitis B surface antigen and hepatitis C antibodies were all performed. Clinical examination was used to determine the presence of genital warts (CDC, 2010). They also compared STD patients with anogenital warts to those without. The study comprised a total of 181 patients. The average age of the patients was 31.1 years, with 22.7% being MSM (Men having sex with men) and 14.9% infected with the human immunodeficiency virus (HIV). Anogenital warts were seen in 22.6% of MSM and 15.1% of HIV-infected patients(27).

A study was done in India between 13 May 1993 and 15 July 1994 on patients attending two clinics for sexually transmitted diseases to investigate the risk factors for HIV infection in patients attending clinics for sexually transmitted diseases in India (Rodrigues et al.). Of the 2800 patients evaluated for HIV-1 and HIV-2, 655 (23.4%) were positive for HIV antibodies, with 609 (93%) testing positive for HIV-1. Only 12 (0.4%) of 2800 were HIV-2 positive,

with 34 (1.2%) being dually reactive. A total of 153 genital wart patients were screened and 24.8% of them were HIV positive compared to 23% in those without genital warts(28).

In a retrospective study on the clinical characteristics and treatment options of condylomata acuminata conducted in Germany, data from 1124 patients with a confirmed diagnosis of CA who presented for outpatient consultation at Munich University Hospital between 2011 and 2015 were evaluated, and the efficacy of various types of treatments was addressed. 625 of 1124 patients (55.6%) responded to the questions about other infectious disorders. HIV infected 3.4% of the 625 patients(29).

Between 2016 and 2020, a descriptive-analytic study with a cohort retrospective design analyzed risk variables for HIV-positive status in condyloma acuminata. All CA patients who visited the polyclinic STI Dr. Mohammad Hoesin, General Hospital, Palembang, Indonesia, between 2016 and 2020 were included in the study. The study comprised 115 CA patients ranging in age from 14 to 71 years old. Out of 115 CA patients, 31 (26.8%) tested positive for HIV(30).

Another study was conducted in India to assess the incidence of various STDs as well as the frequency of HIV seropositivity among other STDs. It was carried out between January 1993 and December 1997 in the STD clinic of the department of dermatology and STD, JIP-MER, Pondicherry, south India. The study group included all new consecutive STD cases with high risk behavior and/or a current or previous history of STDs, regardless of age or gender. The necessary laboratory tests were used to form the diagnosis of various STDs among them. These patients were counseled about HIV testing and provided written consent. There were 168 HIV-positive patients among the 1110 patients, yielding a prevalence rate of 15.14 percent. 218 of the patients had CA, and 24 (11.01%) were HIV positive(31).

Over a 10-year period from 1990 to 1999, a clinical survey was conducted at the STD center in Brescia, Italy, to assess relapses after treatment of EGWs (External Genital Warts) between HIV positive and HIV negative patients. During this decade, there were 1336 cases of EGW, 241 (18%) of which were new cases involving HIV patients (196 males and 45 females, aged 20 to 60 years)(32).

A study in India analyzed the HIV status of 981 patients (824 men, 157 females) who visited an STD clinic in Chandigarh (north India) between January 1993 and July 1999. ELISA was used to screen for HIV. Those who tested positive were tested again with another blood sample and were termed HIV seropositive only if both samples proved positive. The STDs were identified using suitable laboratory techniques. 184 CA patients were checked for HIV among these STD clinic attendance, and 13 (7%) of them tested positive(33).

Devi et al. performed a retrospective record analysis of customers attending the STI clinic at JIPMER in Puducherry from June 2004 to June 2006. There were 866 people who attended the STI clinic, with 435 (50.2%) having proved STI. Herpes genitalis (107 patients, 32.8%)

was the most common ulcerative STI, while genital wart (56 patients, 17.1%) was the most prevalent nonulcerative STI. HIV was found in 11 of 56 (7.28%) genital wart patients(34).

A prospective open label non-randomized comparative study done at AERT Hospital, Ethiopia by Hailu SG et al. evaluated patients with anogenital wart to compare the efficacy and side effect profile of 10% potassium hydroxide solution and 80% TCA (trichloroacetic acid) in the treatment of genital warts over 15 months period. The study excluded individuals with giant genital warts, women who were pregnant, and those who were younger than three years old. The study comprised ninety patients with anogenital warts, ages four to fifty-two. Of these, eighty-two finished it, and sixteen patients (19.5%) tested positive for HIV(35).

3. Objective of the study

3.1 General objective

To determine the magnitude of HIV Seroreactivity in Anogenital wart patients visiting Alert Hospital, Dermatology OPD

3.2 Specific objective

To study the relation between the type of AGW and HIV seropositivity

To study the relation between size, size and number of AGWs and HIV seropositivity

4. Methods and Materials

4.1 Study area

The research was carried out at ALERT. A neighborhood in Addis Ababa's Kolfe Keraniyo Subcity known as Zenebework is where ALERT is situated. It was initially founded as a leprosy treatment facility and now focuses on leprosy patient rehabilitation, leprosy personnel training programs, and leprosy control. The hospital offers specialized services in internal medicine, orthopedics, physiotherapy, reconstructive and plastic surgery, and ophthalmology in addition to being the country's primary dermatologic center and serving as the referral dermatology institute in and around Addis Ababa.

4.2 Study period

The study was conducted from March to August, 2024

4.3 Source population

All dermatology patients visiting ALERT Dermatology Unit

4.4 Study population

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

4.5 Study design

A facility-based, prospective, cross-sectional study was conducted among Anogenital wart patients attending the dermatology clinic of ALERT Center in Addis Ababa, Ethiopia from March to August, 2024.

4.6 Eligibility criteria

4.6.1 Inclusion criteria

All AGW patients visiting ALERT dermatology OPD in the mentioned time period.

4.6.2 Exclusion criteria

All patients who are unwilling to disclose their HIV serostatus or undergo an HIV test

4.7 Sample size determination and sampling technique

Convenience sampling technique was used and all patients with AGWs visiting ALERT dermatology OPD in the given time period were included in the study

4.8 Study variables

4.8.1 Dependent variable

- HIV serostatus

4.8.2 Independent variables

- Age
- Sex
- Anogenital wart
- Duration of AGW
- Type, number and size of AGWs
- Presence of other STIs

4.9 Operational definitions

AGWs – visible warts that occur in the genital area, (e.g., penis, scrotum, perineum, vulva, perianal area, pubic area, upper thighs, and crural folds) as determined by clinical examination and/or biopsy

HIV positive – a patient with known HIV positive status or newly determined HIV Seroreactivity as determined by routine rapid test

4.10 Data collection tools and procedures

Following ethical approval from Institutional Review Board (IRB) of AAU (Addis Ababa University), AGW patients visiting the ALERT center dermatological clinic were chosen based on inclusion and exclusion criteria. The treating physician(s) made a clinical diagnosis in the OPD. After taking informed consent, patients were evaluated using a structured data collection checklist that data collectors filled out. The data collection tool consisted of two

components. The first part was be completed before sending the patient for PICT (Provider Initiated Counseling and Testing), and the second following the PICT result.

4.11 Data processing and analysis

Statistical Package for Social Science (SPSS) version 26 was used for data entry, coding, and cleaning and statistical analysis. To demonstrate descriptive results, frequency distributions, percentages, tables, and charts were used. The chi square test and binary logistic regression were used to see the association between independent and dependent variables.

4.12 Data quality management

A checklist for data gathering was employed. Data collectors were briefly instructed before beginning data collection. The investigator closely supervised the data collection process. Each day, data was reviewed for completeness, clarity, and consistency.

4.13 Ethical considerations

Prior to beginning the research, the Institutional Review Board (IRB) of AAU provided Ethical Clearance. The letter of collaboration was delivered to ALERT Hospital's clinical director. Written informed consent was obtained from each study participant before involvement in the study. The information from the chart and patients will only be utilized for this research. The patients' personal information was not collected. Because it was shared solely amongst the investigators specified in this protocol, the data gathered remained private and secret.

4.14 Data dissemination and utilization

The findings of the study will be submitted to AAU, Department of Dermatovenerology and FMoH (Federal Ministry of Health). It will also be submitted to scientific journals for possible publication.

5. Results

5.1 Sociodemographic characteristics

During the study period, a total of 58 anogenital wart patients were included in the study. There were 44(75.9%) females and 14(24.1%) males. The age distribution showed that 30(51.7%) were in the age range of 25-44 and the median age was 29.5 with interquartile range of 15.

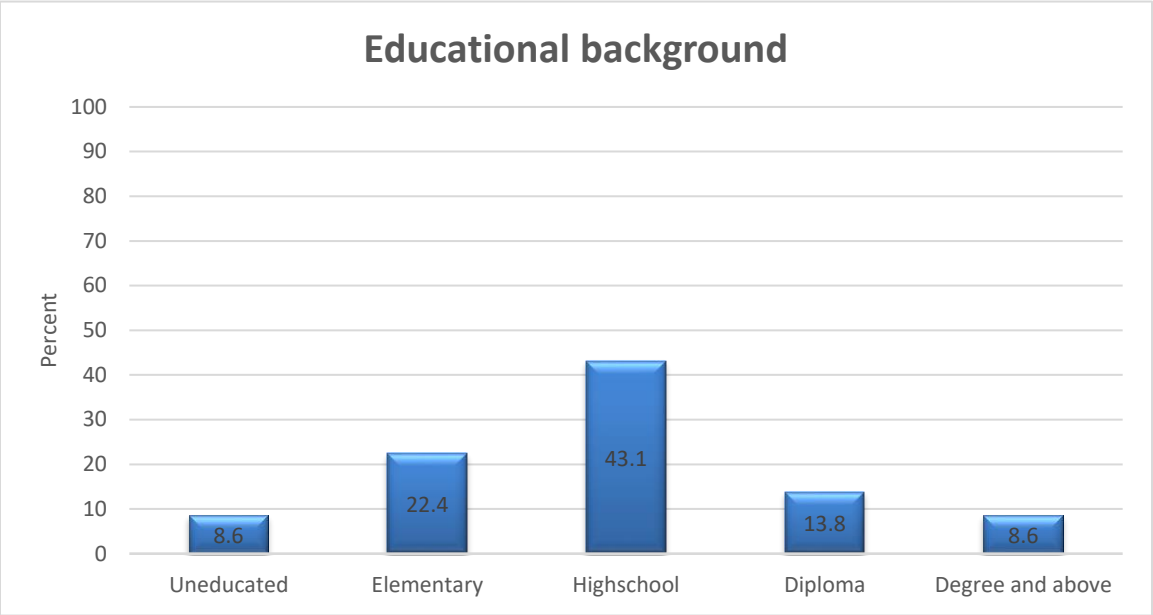
Regarding the area of residence, 40(69%) were from Addis Ababa followed by Oromia 14(24.1%). Of the 58 patients 25(43.1%) have educational background of high school.

Interms of marital status, 25(43.1%) were married, 24(41.4%) were single, 8(13.8%) were divorced) and 1 (1.7%) was widowed.

Table 1 – Age distribution of study participants

Age category	Frequency	Percentage
14 and less	4	6.9
15-24	14	24.1
25-44	30	51.7
45-64	8	13.8
65 and above	2	3.4
Total	58	100

Figure 1– Educational background of the study participants



5.2 Clinical data

From the total of 58 patients, 36(62.1%) had genital warts, 6(10.3%) had anal warts and 16(27.6%) had both anal and genital warts. Recurrent warts were present in 9(15.5%) of the cases and the rest presented with a new episode. The median duration of anogenital warts was 6.5 months with interquartile range of 21 months. The total duration ranged from 1 to 96 months and the duration in most patients was in the range of 2-6 months (37.9%)

Figure 2 – Site of warts

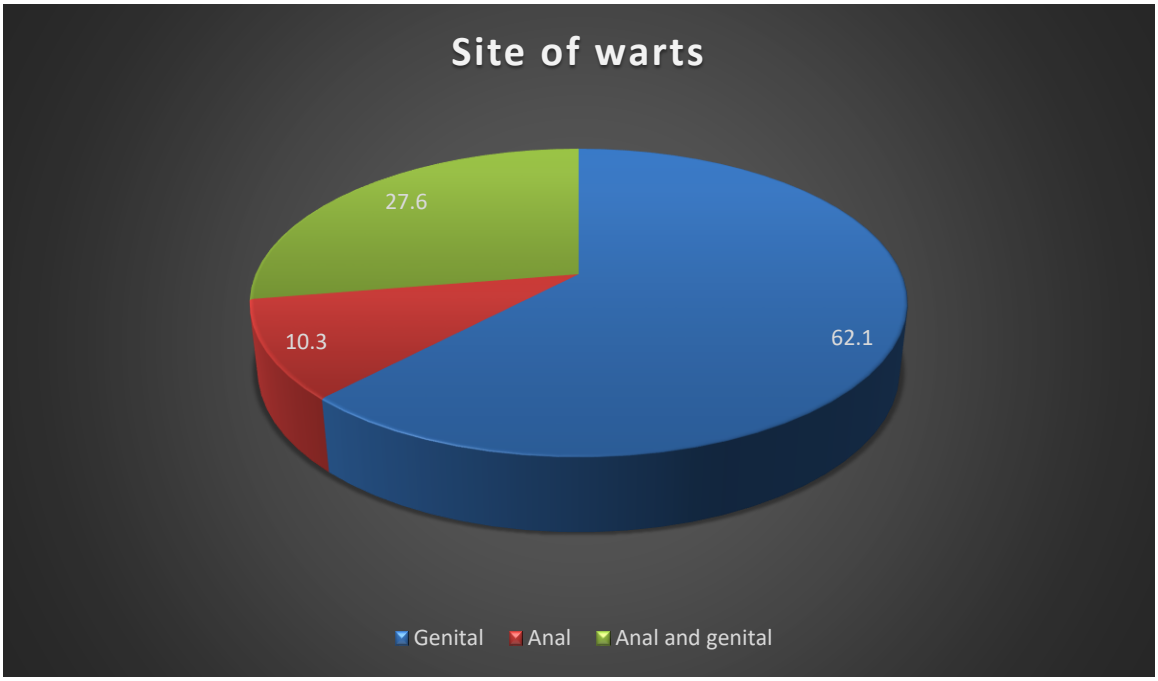


Table 2 – Duration of warts

Duration (months)	Frequency	Percentage
<2	7	12.1
2-6	22	37.9
7-12	13	22.4
>12	16	27.6
Total	58	100

Regarding the clinical subtype, condyloma accuminata was the most common subtype identified (39.7%) followed by popular warts (27.6%).

The average size of warts was 2.5 ± 2.64 cms and the median size was 1.5cms with interquartile range of 2.4cms.

The median for the number of warts was 6 with interquartile range of 9 and most study participants (65.5%) had at least 5 warts.

Of the 58 patients studied, 25(43.1%) had history of an STI and 17.2% had an underlying Chronic medical illness. 5(8.6%) reported having warts at other body sites in addition to AGWs and 53(91.4%) had warts only on anogenital skin.

Figure 3 – Clinical subtype of AGWs

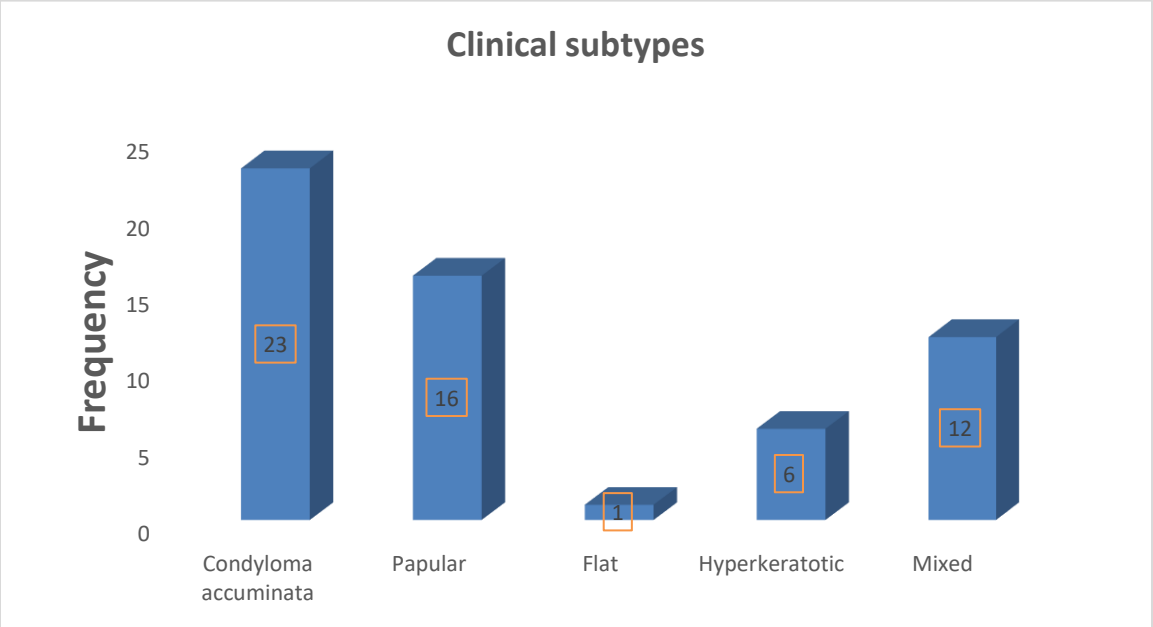


Table 3 – Size of warts

Size (cms)	Frequency	Percentage
<1	26	44.8
1-2	12	20.7
>2	20	34.5
Total	58	100

Table 4 – Number of warts

Number	Frequency	Percentage
1	12	20.7
2-4	8	13.8
At least 5	38	65.5
Total	58	100

Table 5 – Descriptive statistics for duration, size and number of warts

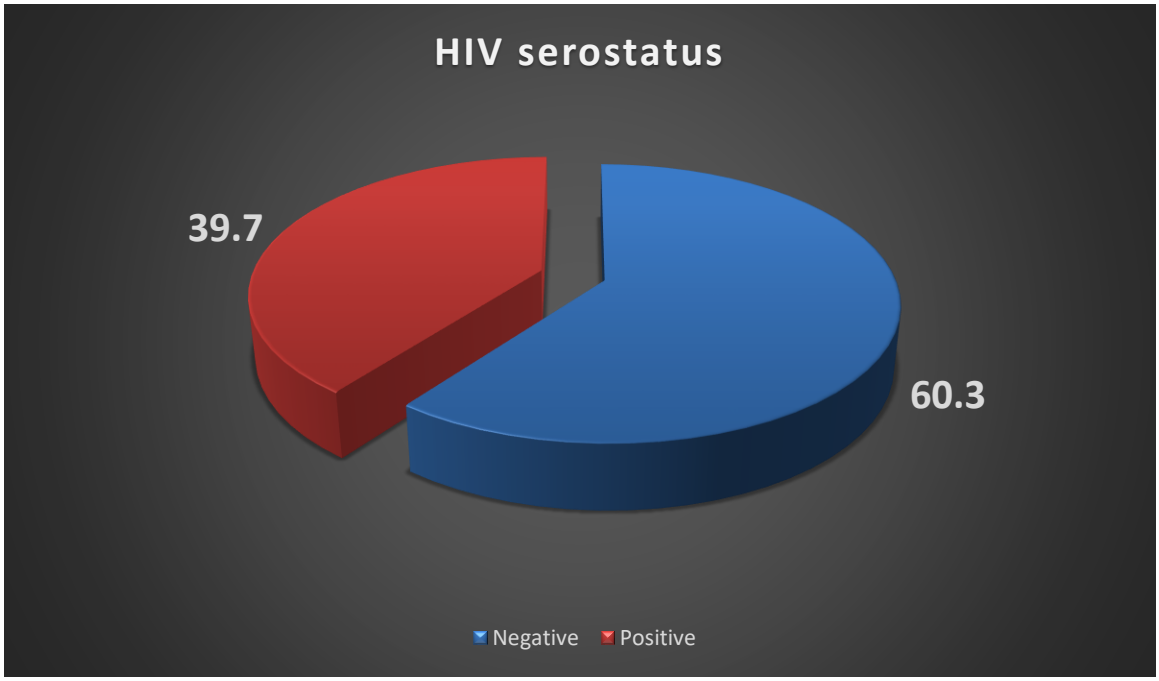
Descriptive statistics		Duration of warts	Size of warts	Number of warts
Mean		15.71	2.5	8.45
Median		6.5	1.5	6
Std, Deviation		22.126	2.64	7.74
Minimum		1	0.3	1
Maximum		96	15	40
Interquartile range		21	2.4	9
Percentiles	25	2	0.9	3
	50	6.5	1.5	6
	75	22.5	3.25	12

5.3 HIV Serostatus

From the total of 58 studied samples, 23 (39.7%) were found to be HIV Positive.from these 4(17.4%) were newly diagnosed and the rest (82.6%) had known HIV. All of the newly diagnosed cases were females. Two of the newly diagnosed cases were in the age group of 15-24 and the other 2 were in the age group of 25-44.

The mean duration of HIV was 6.4 ± 7.93 years with a range of 24 years. All of the HIV positive study participants were on HAART.

Figure 4 – HIV serostatus

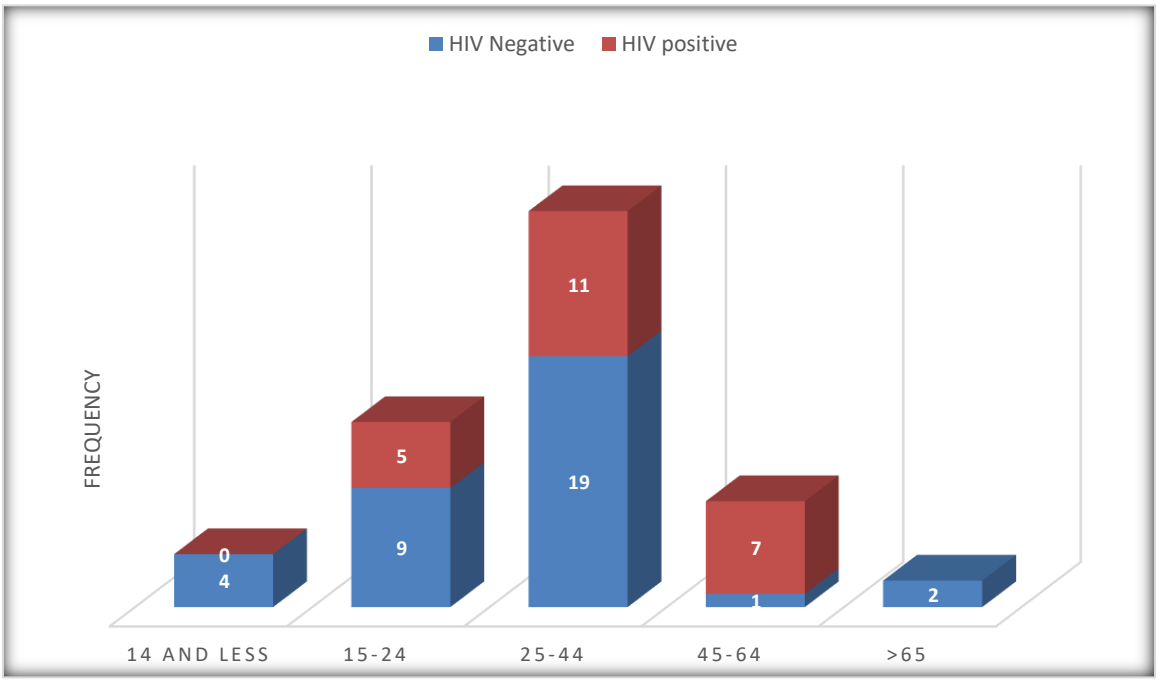


5.3.1 Relation between demographic factors and HIV serostatus

Among the HIV positive study participants, 19 (82.6%) were females and 4 (17.4%) were males. In our study it was found that 11 (47.8%) of HIV positive AGW patients were single and 6 (26.1%), 5 (21.7%) and 1 (4.3%) were married, divorced and widowed respectively.

Regarding the age distribution of HIV positive study participants, most (47.8%) were in the age group of 25-44 years followed by age group of 45-64 years (30.4%).

Figure 5 – Age groups with HIV serostatus



The Pearson chi square test and Fisher exact tests were performed to see the relation between different demographic factors and HIV serostatus. P values of <0.05% were taken as significant. Only Age was significantly associated with HIV serostatus (P=0.016). Accordingly, A significantly higher proportion of individuals in the age group of 25-44 years had HIV (47.8%) compared to age groups of 45-64 (30.4%), 15-24 (21.7), >65 (0%) and 14 and less (0%). New diagnosis of HIV was not associated with any of the demographic factors.

Table 6 – HIV serostatus and demographic characteristics

Demographic characteristics		Total N (%)	HIV serostatus N=58		*p*-value*
			Negative N (%)	Positive N (%)	
Marital status	Single	24(41.4)	13(37.1)	11(47.8)	0.072
	Married	25(43.1)	19(54.3)	6(26.1)	
	Divorced	8(13.8)	3(8.6)	5(21.7)	
	Widowed	1(1.7)	0(0)	1(4)	
Age	14 and less	4(6.9)	4(11.4)	0(0)	.016*
	15-24	14(24.1)	9(25.7)	5(21.7)	
	25-44	30(51.7)	19(54.3)	11(47.8)	
	45-64	8(13.8)	1(2.9)	7(30.4)	
	>65	2(3.4)	2(5.7)	0	
Educational Background	Uneducated	5(8.9)	2(6.1)	3(13)	0.174
	Elementary	13(23.2)	8(24.2)	5(21.7)	
	Highschool	25(44.6)	12(36.4)	13(56.5)	
	Diploma	8(14.3)	6(18.2)	2(8.7)	
	Degree and above	5(8.9)	5(15.2)	0(0)	
Gender	Male	14	10(28.6)	4(17.4)	0.330
	Female	44	25(71.4)	19(82.6)	

5.3.2 HIV serostatus and wart characteristics

From a total of 23 HIV positive AGW patients, 9(39.1%) had genital warts, 6(10.3%) had anal warts and 12 (52.2%) had warts on both genital and anal areas compared to HIV negative study participants in whom 27(77.1%), 4(11.4%) and 4(11.4%) had genital, anal and anogenital warts respectively.

Recurrent warts were seen in 5 (21.7%) of HIV positive individuals and 4(11.4%) of HIV negative individuals.

The proportion of patients with condyloma accuminata, papular, flat, hyperkeratotic and mixed warts with positive HIV serostatus was 52.2%, 13%, 0%, 4.3% and 30.4% respectively.

9(39.1%) of HIV positive study participants had wart duration of more than 12 months compared to those who are HIV negative (7(20%)).

Regarding the largest size of anogenital warts, 4(17.1%) of HIV positive individuals had largest wart size less than 1 cm, 5(21.7%) had size of 1-2cms and 14(60.9%) had size of more than 2 cms. In HIV negative study participants, those with largest wart size of less than 1cm accounted for 62.9%(4) of the cases and 17.1%(6) had largest wart size of more than 2cms.

From the total of 38 individuals who had warts more than 5 in number, (19)50% were HIV negative and (19) 50% were HIV positive.

The study also showed that out of the 5 patients with history of warts at other body sites, 4(80%) were HIV positive and 1 was HIV negative. Out of the 53 individuals who answered 'NO' to the presence of extragenital warts, 19(35.8%) were HIV positive and 34(64.2%) were HIV negative.

Regarding STI history, 12(48%) with history of STI had HIV compared to those with no history of STI (11(33.3%)).

The Pearson Chi square test (when applicable) and Fisher exact tests were employed to display the association between prevalence of HIV Seroreactivity and the various wart characteristics. The site of wart (Genital, anal or anogenital) and wart size showed significant association with HIV serostatus with P values of **0.002** and **0.001** respectively. In addition, new diagnosis of HIV was significantly associated with wart size with P value of **0.014.**

Table 7 – Cross tabulation of HIV serostatus and wart characteristics

Wart characteristics		Total N (%)	HIV serostatus N=58		*p*-value*
			Negative N (%)	Positive N (%)	
Site of warts	Genital	36(62.1)	27(77.1)	9(39.1)	0.002*
	Anal	6(10.3)	4(11.4)	2(8.7)	
	Anal and genital	16(27.6)	4(11.4)	12(52.2)	
Type of wart	New	49(84.5)	31(88.6)	18(78.3)	0.46
	Recurrent	9(15.5)	4(11.4)	5(21.7)	
Clinical subtype	CA	23(39.7)	11(31.4)	12(52.2)	0.071
	Papular	16(27.6)	13(37.1)	3(13)	
	Flat	1(1.7)	1(2.9)	0(0)	
	Hyperkeratotic	6(10.3)	5(14.3)	1(4.3)	
	Mixed	12(20.7)	5(14.3)	7(30.4)	
Duration of warts (months)	<2	7(12.1)	6(17.1)	1(4.3)	0.233
	2-6	22(37.9)	15(42.9)	7(30.4)	
	7-12	13(22.4)	7(20)	6(26.1)	
	>12	16(27.6)	7(20)	9(39.1)	
Size of warts (cms)	<1	26(44.8)	22(62.9)	4(17.4)	0.001*
	1-2	12(20.7)	7(20)	5(21.7)	
	>2	20(34.5)	6(17.1)	14(60.9)	
Number of warts	1	12(20.7)	10(28.6)	2(8.7)	0.09
	2-4	8(13.8)	6(17.1)	2(8.7)	
	5 or more	38(65.5)	19(54.3)	19(82.6)	

The binary logistic regression model was used to see the strength of association between the independent and dependent variables. Consequently, wart location and size were found to be substantially correlated with HIV serostatus using univariate analysis at the 25% level of significance. The final multivariable regression model then incorporated these variables. Accordingly, the size and location of warts were found to be substantially correlated with HIV serostatus using a multivariate binary logistic regression model. As a result, individuals with both anal and genital warts had a higher chance of being HIV positive after controlling for other variables (AOR = 5.424,95% CI = 1.198,24.547, p value = 0.028) than those with only genital warts.

Those with wart diameters greater than 2 cm had an 8.6-fold higher chance of being HIV positive than those with wart sizes less than 1 cm (AOR = 8.569, 95% CI = 1.863, 39.410, p value = 0.006).

There was no significant difference in wart characteristics in newly diagnosed versus known HIV patients.

Table 8 – Association between dependent and independent variables (binary logistic regression)

Variable		**COR (95% CI)**	**AOR (95% CI)**	**P- value**
Site of warts	Genital	1	1	
	Anal	1.500 (0.234, 9.611)	0.93 (0.111, 7.807)	0.947
	Anal and genital	9.000 (2.31, 35.066)	5.424 (1.198, 24.547)	0.028*
Size of warts	<1cm	1	1	
	1-2cm	3.928 (0.821, 18.806)	2.253 (0.400, 12.679)	0.357
	>2cm	12.833 (3.066, 53.715)	8.569 (1.863, 39.410)	0.006*

6. Discussion

HIV infection and sexually transmitted diseases are closely related. HPV is the cause of AGW, an STD(36).

Our study revealed that the rate of HIV seropositivity is 39.7%. This is slightly higher than the rate reported by other researchers such as Hailu SG et al. (19.5%), Puspawati et al. (22.31%) and Rodrigues et al (23.4%). This could have resulted from the relatively smaller sample size in our study and the exclusion of patients with giant warts in some of the other studies which may underestimate the overall HIV prevalence(26,28,35). In addition, our study area (ALERT hospital) is one of the ART centres in the city and this may have resulted in overestimation of HIV prevalence in our study population.

Regarding the sex distribution of Anogenital wart patients in our study, females were more likely to present with anogenital warts compared to males (75.9 Vs 24.1%) which is in par with a study done in Ethiopia by Hailu SG et al. where the percentage of females was 57.3%(35). This can be explained by the overall higher prevalence of STIs in females and heightened awareness of self-care in women. However, other literatures have reported both equal prevalence(21) and male predominance(29,30).

In this study, AGWs were more commonly diagnosed in young adults or age group of 25-44 years (51.7%) which is comparable to what has been reported by the likes of IH Purwoko et al (39.1% in early adulthood), Soori et al (47.3% in age groups of 21-30 and 24.7% in age groups of 31-40)(21,30). This can be explained by the fact that individuals in this age group are more likely to be sexually active.

According to our study, the most common location for AGWs was the genital skin (62%) which is similar to the findings in an Indonesian study by Purwoko, Izazi Hari, et al. where 57.4% of AGWs were located over the genital skin(30). In addition, our study showed that, a significantly higher number of patients with anogenital skin involvement had HIV compared to those with genital and anal skin involvement alone (52.2% Vs 39.1% Vs 8.7%). Opposing results were reported by Purwoko, Izazi Hari, et al. in which the rate of HIV positivity was similar in patient with anogenital and genital warts (2.6%) and higher in patients with anal warts (20.9%)(30). It may be difficult to attribute this difference to a single factor but it can be hypothesized that the presence of warts in anal area in our patients could be due extension of warts from the genital skin rather than resulting from anal intercourse which is an important risk factor for HIV acquisition.

50% of individuals in our study presented with wart duration of more than 6 months. This is in contrast to a study done in Kuwait by Al-Awadhi et al. who reported that only 27.6% had a duration of more than 6 months(37). The lesser health seeking behavior and accessibility of health facilities may have contributed for this discrepancy. The mean duration of warts in our

study is 15.71 ± 22.12 months which is more or less comparable to what has been reported by Hailu SG which is 10.4 ± 14.8 months(35).

Regarding the number of warts, 65.5% of individuals in our study had at least 5 warts and the mean number of warts was 8.45 ± 7.4. Similar findings were reported by SG Hailu et l. and Al-Awadhi et al(35,37). In this study, it was revealed that the number of individuals who present with largest wart size of more than 2cms was 34.5% which is a significantly higher percentage in comparison to the study by Al-Awadhi et al(37). Similarly, this can be due to the delayed presentation seen in our case. However, the mean size in our study (2.5 ± 2.64cms) is similar to findings by SG Hailu et al. where the mean size was found to be 2.6 ± 1.2cms

According to our study, the size of warts is significantly associated with HIV serostatus with patients having warts sizes of more than 2cm 8.6 times more likely to be HIV positive compared to patients with wart sizes of <1cm.

7. Conclusion

According to our findings, HIV is quite prevalent in anogenital wart patients. Young adults in the age group of 25-44 years with AGWs are more likely to be HIV positive. AGWs are more common in females and the most common location is the genital skin.

Our study also showed that AGW patients in our set up tend to have longer duration at presentation with higher number and larger size of warts.

Our study demonstrated that patients with larger size and anogenital location of warts are more likely to be HIV positive.

8. Limitations

We are unable to safely extrapolate the study's results to the broader population due to its limited sample size. Furthermore, to determine the relationships, a comparative study design involving patients with and without anogenital warts would have been more appropriate but time constraints prevented us from doing so in our circumstance.

9. Recommendations

1. All patients who come with anogenital warts should undergo HIV screening
2. Due to their propensity to grow larger and to involve the perianal skin, anogenital warts in HIV patients should be managed promptly.

10. References

1. Wiley DJ, Douglas J, Beutner K, Cox T, Fife K, Moscicki AB, et al. External genital warts: diagnosis, treatment, and prevention. Clin Infect Dis Off Publ Infect Dis Soc Am. 2002 Oct 15;35(Suppl 2):S210-224.

2. Delmonte S, Benardon S, Cariti C, Ribero S, Ramoni S, Cusini M. Anogenital warts treatment options: a practical approach. G Ital Dermatol E Venereol Organo Uff Soc Ital Dermatol E Sifilogr. 2020 Jun;155(3):261–8.

3. Ljubojevic S, Skerlev M. HPV-associated diseases. Clin Dermatol. 2014;32(2):227–34.

4. Chelimo C, Wouldes TA, Cameron LD, Elwood JM. Risk factors for and prevention of human papillomaviruses (HPV), genital warts and cervical cancer. J Infect. 2013 Mar;66(3):207–17.

5. Lacey CJN, Lowndes CM, Shah KV. Chapter 4: Burden and management of non-cancerous HPV-related conditions: HPV-6/11 disease. Vaccine. 2006 Aug;24:S35–41.

6. von Krogh G, Gross G. Anogenital warts. Clin Dermatol. 1997;15(3):355–68.

7. Maw R, HPV Special Interest Group of BASHH. Anogenital warts. Sex Transm Infect. 2006 Dec;82 Suppl 4(Suppl 4):iv40-41.

8. Ward H, Rönn M. Contribution of sexually transmitted infections to the sexual transmission of HIV: Curr Opin HIV AIDS. 2010 Jul;5(4):305–10.

9. Wieland U, Kreuter A, Pfister H. Human Papillomavirus and Immunosuppression. In: Ramírez-Fort MK, Khan F, Rady PL, Tyring SK, editors. Current Problems in Dermatology [Internet]. S. Karger AG; 2014 [cited 2023 Sep 27]. p. 154–65. Available from: https://www.karger.com/Article/FullText/357907

10. Kent C. The Role of Anal/Genital Warts in HIV Infection. JAMA J Am Med Assoc. 1987 Dec 18;258(23):3385.

11. Dolev JC, Maurer T, Springer G, Glesby MJ, Minkoff H, Connell C, et al. Incidence and risk factors for verrucae in women. AIDS Lond Engl. 2008 Jun 19;22(10):1213–9.

12. Scheinfeld N. Genital warts. Dermatol Online J [Internet]. 2006 [cited 2023 Sep 29];12(3). Available from: https://escholarship.org/uc/item/7v57p744

13. Beutner KarlR, Friedman-Kien AlvinE, Artman NitzaN, Conant MarcusA, Illeman M, Thisted RonaldA, et al. PATIENT-APPLIED PODOFILOX FOR TREATMENT OF GENITAL WARTS. The Lancet. 1989 Apr;333(8642):831–4.

14. Patel H, Wagner M, Singhal P, Kothari S. Systematic review of the incidence and prevalence of genital warts. BMC Infect Dis. 2013 Jan 25;13:39.

15. Steben M, Garland SM. Genital warts. Best Pract Res Clin Obstet Gynaecol. 2014 Oct;28(7):1063–73.

16. Scarbrough Lefebvre CD, Van Kriekinge G, Gonçalves MA, De Sanjose S. Appraisal of the burden of genital warts from a healthcare and individual patient perspective. Public Health. 2011 Jul;125(7):464–75.

17. Konopnicki D, De Wit S, Clumeck N. HPV and HIV coinfection: a complex interaction resulting in epidemiological, clinical and therapeutic implications. Future Virol. 2013 Sep;8(9):903–15.

18. Bryan JT, Stoler MH, Tyring SK, McClowry T, Fife KH, Brown DR. High-grade dysplasia in genital warts from two patients infected with the human immunodeficiency virus. J Med Virol. 1998 Jan;54(1):69–73.

19. Carter PS, de Ruiter A, Whatrup C, Katz DR, Ewings P, Mindel A, et al. Human immunodeficiency virus infection and genital warts as risk factors for anal intraepithelial neoplasia in homosexual men. Br J Surg. 1995 Apr;82(4):473–4.

20. Orlando G, Fasolo MM, Signori R, Schiavini M, Casella A, Cargnel A. Impact of highly active antiretroviral therapy on clinical evolution of genital warts in HIV-infected patients. AIDS Lond Engl. 1999 Feb 4;13(2):291–3.

21. Soori T, Hallaji Z, Noroozi-Nejad E. Genital warts in 250 Iranian patients and their high-risk sexual behaviors. Arch Iran Med. 2013 Sep;16(9):518–20.

22. Jayadharma IBG, Wiraguna AAGP. Gambaran karakteristik pasien kondiloma akuminata dengan infeksi HIV/AIDS di RSUP Sanglah, Denpasar, Indonesia tahun 2011-2015. Intisari Sains Medis. 2020 Dec 1;11(3):1308–12.

23. Mayaud P. The interrelation of HIV, cervical human papillomavirus, and neoplasia among antenatal clinic attenders in Tanzania. Sex Transm Infect. 2001 Aug 1;77(4):248–54.

24. Fleming DT, Wasserheit JN. From epidemiological synergy to public health policy and practice: the contribution of other sexually transmitted diseases to sexual transmission of HIV infection. Sex Transm Infect. 1999 Feb;75(1):3–17.

25. Coplan PM, Gortmaker S, Hemandez-Avila M, Spiegelman D, Uribe-Zuuiga P, Mueller NE. Human Immunodeficiency Virus Infection in Mexico City: Rectal Bleeding and Anal Warts as Risk Factors among Men Reporting Sex with Men. Am J Epidemiol. 1996 Nov 1;144(9):817–27.

26. Puspawati NMD, Sissy S, Gotama D. A Retrospective Study of Condyloma Acuminata Profile in Outpatient Clinic of Dermato-Venereology Sanglah General Hospital Denpasar, Bali-Indonesia Period 2015-2017. Bali Dermatol Venereol J [Internet]. 2018 May 11 [cited 2023 Sep 21];1(1). Available from: https://balidv.org/index.php/bdv/article/view/1

27. Jiamton S, Leeyaphan C, Maneeprasopchoke P, Omcharoen V. PREVALENCE AND CLINICAL MANIFESTATIONS OF MALE PATIENTS WITH ANOGENITAL WARTS ATTENDING A SEXUALLY TRANSMITTED DISEASE CLINIC PRIOR HPV VACCINE RECOMMENDATION. Southeast Asian J Trop Med Public Health. 2014 Nov;45(6):1337–43.

28. Rodrigues JJ, Mehendale SM, Shepherd ME, Divekar AD, Gangakhedkar RR, Quinn TC, et al. Risk factors for HIV infection in people attending clinics for sexually transmitted diseases in India. BMJ. 1995 Jul 29;311(7000):283–6.

29. Clanner-Engelshofen BM, Marsela E, Engelsberger N, Guertler A, Schauber J, French LE, et al. Condylomata acuminata: A retrospective analysis on clinical characteristics and treatment options. Heliyon. 2020 Mar;6(3):e03547.

30. Risk Factors for HIV-positive Status In Condyloma Acuminata. J Gen - Proced Dermatol Venereol Indones [Internet]. 2022 Dec 31 [cited 2023 Sep 21];6(2). Available from: https://scholarhub.ui.ac.id/jdvi/vol6/iss2/5/

31. Thappa DM, Singh S, Singh A. HIV infection and sexually transmitted diseases in a referral STD centre in south India. Sex Transm Infect. 1999 Jun;75(3):191.

32. De Panfilis G, Melzani G, Mori G, Ghidini A, Graifemberghi S. Relapses after treatment of external genital warts are more frequent in HIV-positive patients than in HIV-negative controls. Sex Transm Dis. 2002 Mar;29(3):121–5.

33. Kumar B. Rising HIV prevalence in STD clinic attenders at Chandigarh (north India)-- a relatively low prevalence area. Sex Transm Infect. 2000 Feb 1;76(1):59–59.

34. Devi SA, Vetrichevvel TP, Pise GA, Thappa DM. Pattern of sexually transmitted infections in a tertiary care centre at Puducherry. Indian J Dermatol. 2009;54(4):347–9.

35. EVALUATION OF TOPICAL 10% POTASSIUM HYDROXIDE SOLUTION VERSUS 80% TRICHLOROACETIC ACID IN THE TREATMENT OF GENITAL WART.

36. Dhumale SB, Sharma S, Gulbake A. Ano-Genital Warts and HIV Status- A Clinical Study. J Clin Diagn Res JCDR. 2017 Jan;11(1):WC01–4.

37. Al-Awadhi R, Al-Mutairi N, Albatineh AN, Chehadeh W. Association of HPV genotypes with external anogenital warts: a cross sectional study. BMC Infect Dis. 2019 May 2;19(1):375.

Annexes

Annex I

Informed Consent

You will be invited to participate in a study to analyze the rate of HIV positivity among Anogenital Wart patients visiting the ALERT Center's Dermatology unit, and I will ask you a few questions.

The information gathered in this survey will be used solely for scientific study and will not be used for commercial purposes. This form will not include your name, and the information you provide will never be shared with anyone else. A little amount of blood will be drawn for HIV test. There are no health risks associated with participating in the study, and no benefits are provided for participation. Your participation is entirely voluntary, and you are not required to answer any questions that you do not choose to answer.

I have read this form or had it read to me in the language I understand all of the requirements listed 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 analyze the rate of HIV positivity among Anogenital Wart patients visiting the ALERT Center's Dermatology unit, and I will ask you a few questions.

The information gathered in this survey will be used solely for scientific study and will not be used for commercial purposes. This form will not include your name, and the information you provide will never be shared with anyone else. A little amount of blood will be drawn for HIV test. There are no health risks associated with participating in the study and no benefits

are provided for participation. Your participation is entirely voluntary, and you are not required to answer any questions that you do not choose to answer.

I have read this form or had it read to me in the language I understand all of the requirements listed 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 ጴጥሮስ እባላለሁ የHIV ቫይረስ በምን ያኽሉ የመራቢያ አካል አካባቢ ኪንታሮት ታማሚያን ዉስጥ ይገኛል የሚል ጥናት እያካሄድኩ ነው እና አንዳንድ ጥያቄዎች እጠይቆታለሁ።

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

የHIV ምርመራ ለማድረግ ጥቂት ደም ከጣትዎ ጫፍ የሚወሰድ ይሆናል።

በጥናቱ ላይ መሳተፍዎ በጤና ላይ የሚያመጣው ምንም አይነት እክል የለም እንዲሁም ለተሳትፎ የሚሰጥ ምንም አይነት ጥቅማ ጥቅም የለም።

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 ጴጥሮስ እባላለሁ የHIV ቫይረስ በምን ያኽሉ የመራቢያ አካል አካባቢ ኪንታሮት ታማሚያን ዉስጥ ይገኛል የሚል ጥናት እያካሄድኩ ነው እና ልጅዎትን አንዳንድ ጥያቄዎች መጠየቅ እፈልጋለሁ።

እርሶ የሚሰጡን መረጃ ሳይንሳዊ ምርምር እንጂ ለሌላ ለምንም ነገር አይውልም። የእርስዎም ሆነ የልጅዎ ስም ምርምሩ ላይ አይጠቀስም።

የHIV ምርመራ ለማድረግ ጥቂት ደም ከልጅዎ ጣት ጫፍ የሚወሰድ ይሆናል።

በጥናቱ ላይ መሳተፍዎ በጤና ላይ የሚያመጣው ምንም አይነት እክል የለም እንዲሁም ለተሳትፎ የሚሰጥ ምንም አይነት ጥቅማ ጥቅም የለም።

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

Medical record number = ____

1. Age in years --------
2. Sex
   A. Male
   B. Female
3. Marital status
   a) Single c) Divorced
   b) Married d) Widowed
4. Educational background a) Uneducated b) High school c) Elementary d) Diploma e) Degree and above
5. Occupation
6. Area of residence or region

a. Addis Ababa

b. Afar Region

c. Amhara Region

d. Tigray Region

e. Benishangul-Gumuz Region

f. Central Ethiopia Regional State

g. Dire Dawa (city)

h. Gambela Region

i. Harari Region

j. Oromia Region

k. Sidama Region

l. Somali Region

m. South Ethiopia Regional State

n. South West Ethiopia Peoples' Region

II. Disease associated characteristics

1. Duration of warts in months ------

2. Site

a. Genital b. Anal c. Anal and Genital

3. Type of wart

b. New b. Recurrence

4. Clinical subtype

a. Condylomata acuminata c. Flat warts

c. Papular warts d. Hyperkeratotic warts

e. Mixed (specify) _____

5. Largest wart size in cm ------

6. Number of warts ------

7. Warts in other body sites: □ Yes □ No

8. History of and/or concurrent STI

a) Urethral discharge

b) Vaginal discharge

c) Genital ulcer

d) Lower abdominal pain (in women)

e) Scrotal swelling

f) Inguinal Bubo

9. Duration of HIV (if known HIV) --------

10. HAART initiated (if Known HIV) □ Yes □ No

11. Any Known comorbidity □ Yes □ No

III. PICT result

A. Positive B. Negative