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Prevalence and Factors Contributing to Active Tuberculosis among Adults with Human Immunodeficiency Virus Who Completed Isoniazid Prophylaxis at Kitagata General Hospital – Uganda

Matsiko Keneth

Faculty of Clinical Pharmacy and Pharmacy Kampala International University Western Campus Uganda.

ABSTRACT

Tuberculosis (TB) remains a significant health burden, particularly among individuals living with human immunodeficiency virus (HIV) infection. Isoniazid prophylaxis therapy (IPT) has been widely implemented as a preventive measure for TB in this vulnerable population. However, there is limited research investigating the prevalence and factors contributing to active TB among adults living with HIV after completing Isoniazid Prophylaxis. This study aims to address this gap by assessing the prevalence of active TB and identifying the key factors associated with its development in this specific context. A cross-sectional study design was employed, involving adults living with HIV who have completed IPT at Kitagata General Hospital. A systematic sampling technique was used to recruit participants. Data was collected through structured interviews, medical record reviews, and laboratory investigations. Descriptive statistics were used to determine the prevalence of active TB among the study population. Logistic regression analysis was conducted to identify factors associated with the development of active TB, including socio-demographic characteristics, clinical variables, and adherence to IPT. The study used a sample size of 384 participants. The study found that 17(4.4%) of 384 developed active TB after Isoniazid (INH) prophylaxis therapy. Furthermore, several factors were significantly associated with the development of active TB: smoking, non-adherence to antiretroviral therapy, having TB before INH prophylaxis, and duration of ART. The findings have the potential to inform targeted interventions and improve the management and prevention of TB in this vulnerable population. It is essential to enhance TB screening, strengthen adherence to ART, and address associated risk factors to effectively reduce the burden of active TB among adults living with HIV post-IPT completion.

Keywords: Tuberculosis, Isoniazid prophylaxis therapy, Human immunodeficiency virus, Antiretroviral therapy, Prophylaxis.

INTRODUCTION

Mycobacterium tuberculosis, the bacterium that causes tuberculosis, can infect any part of the body with the exception of the hair and nails [1, 2]. Tuberculosis (TB) typically affects both adults and children with compromised immune competence, and thus primarily affects HIV-positive individuals and all other people with immune-compromising diseases [3-5]. TB and human immunodeficiency virus (HIV) co-infection is a significant public health problem worldwide [6-8]. The lifetime risk of developing active TB among people living with HIV (PLHIV) may be 20 times

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higher than in people without HIV [9, 10]. TB preventive therapy is the administration of one or more anti-tuberculosis drugs to individuals with latent infection with *M. tuberculosis* in order to prevent progression to active TB disease [11, 12]. Isoniazid preventive therapy (IPT) reduces the incidence of TB by up to 60% and reduces mortality among people living with HIV (PLWHIV) [13, 14]. Isoniazid (INH) prophylaxis therapy is a recommended preventive treatment for tuberculosis (TB) in people living with HIV. According to the World Health Organization (WHO), in 2020, an estimated 4.7 million people living with HIV received isoniazid preventive therapy (IPT) globally [15]. This represents 23% coverage of the estimated 20.6 million people living with HIV who were eligible for IPT. Sub-Saharan Africa has the highest burden of HIV/TB co-infection globally [16, 17]. According to a study conducted by Sensalire *et al.* [18], isoniazid prophylaxis therapy (IPT) was found to be widely used among adults living with HIV in East Africa. In Uganda specifically, a study by Wobudeya *et al.* [19] found that the overall prevalence of IPT use among HIV-positive adults was 75.4%. However, the authors noted that this figure varied significantly depending on the region of the country. A study by Sekadde and Kay [20] found that 88% of participants had ever received IPT and that 77% had completed a full course of treatment. Overall, these studies suggest that IPT is widely used among adults living with HIV in East Africa, with high rates of use reported in Uganda and specifically in Western Uganda, including Bushenyi.

Tuberculosis remains the most common opportunistic infection in HIV-infected adults in developing countries and is known to be the leading cause of morbidity and mortality among People Living with HIV [21, 22]. The Uganda National Guidelines on Collaborative TB/HIV Activities [23] recommended the provision of Isoniazid preventive therapy to PLHIV and children under five years who have had contact with patients who have pulmonary TB. Isoniazid (INH) is recommended for the prevention of latent TB infection and was shown to be 70% effective at preventing tuberculosis in those who are HIV-infected. However, the overall prevalence of tuberculosis among adults is high and there are still many HIV-positive patients who develop active TB disease in Uganda despite the mass campaigns about IPT. Several strategies have been laid to reduce the prevalence of TB in these populations in many countries and in Uganda but most studies done about TB/IPT focus on the feasibility, uptake, adherence, completion, and effectiveness of IPT. There is limited information about the prevalence of TB among PLHIV of IPT after completion of the 6-month course of treatment which is the aim of this project. No study has so far been conducted at this hospital to provide reliable statistics on IPT after completion of the 6months course of treatment among PLHIV. This study intends to provide updates on the prevalence and factors contributing to active tuberculosis among adults with human immunodeficiency virus who completed isoniazid prophylaxis at Kitagata General Hospital, results of which may be used to advocate health policymakers, service providers, and other stakeholders to integrate sensitization, detection management and prevention and re-infection of

METHODOLOGY

Study design

A longitudinal cross-sectional study was carried out to determine the prevalence and factors leading to the development of active TB among PLHIV after completion of IPT at KGH in Sheema District.

Area of Study

The study was conducted at Kitagata General Hospital, at the ART Clinic located about 17.7km away from Ishaka Bushenyi Municipality.

Study population

The targeted adult patients 18 years of age and above that are on antiretroviral who completed 6 months of isoniazid prophylaxis therapy at Kitagata General Hospital ART Clinic and have developed active Tuberculosis after completion of their IPT.

Inclusion criteria

- Only HIV-positive patients.
- Both males and females 18 years and older.
- Completed INH for 6 months.
- Receiving HIV care and are registered at Kitagata general hospital clinic.
- Active TB confirmed by gene-Xpert, urine LAM, ZN stain and x-Ray.

Exclusion criteria

The study excluded all patients who do not meet the above inclusion criteria, unconscious, mentally-ill and those who did not consent to take part in the study.

Sample size determination

The sample size of the patients who are to participate in the study was determined using a statistical formula suggested by Kish and Leslie (1965) which states that;

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$$n = \frac{z^2 p (1-p)}{d^2}$$

Where

n = sample size.
z = standard deviation at 95% confidential level i.e. 1.96)
p = proportion of people with active TB among PLHIV after completion IPT (50%), since there was no study that has been done in Uganda according to the available literature.
d = acceptance degree of error (5%).

Submitting: $n = \frac{1.96 \times 1.96 \times 0.5 (1-0.5)}{0.05^2}$

Estimated sample size = 384 PLHIV who completed IPT.

Sampling technique

Sampling was a convenient and random sampling technique.
PLWHIV who completed IPT at Kitagata general hospital who come to the HIV CLINIC were selected using random sampling to participate in the study.

Data collection and tools

The database was used to locate the patients' files, after randomly selecting files of those who completed the IPT course of 6 months. The files were checked for records of INH completion, TB disease since completion, other diseases and clinical-related factors after IPT. The data collected was filled into an information checklist or questionnaire by the researcher and research assistants who were health workers and or students trained on the purpose of the study and how to use the research tool. Notebooks pens and computers/ laptops will be used as tools.

Data analysis

The obtained data were analyzed using Microsoft Excel and open and results were discussed and compared with the existing literature to make conclusions based on the p values.

Data Quality Control

The data collection forms were pre-tested before the actual study. Pretesting was carried out at the ART Clinic department of Kitagata General Hospital using 20 patients a week prior to the actual data collection process. More questions were added to the questionnaire and rephrased questions that seemed more unclear to the patients. The investigator performed a pilot study and strictly followed the inclusion and exclusion criteria. The investigator guided, interpreted and translated unclear questions to the patients. The questionnaire was checked to ensure that all questions are answered before each patient leaves the department and interview site.

Ethical considerations

Before conducting the study, permission was obtained from the School of Pharmacy KIU-WC and the approvals were obtained from the Medical Superintendent; KGH. During the study, clear explanations were made to respondents to seek consent to participate in the study. The information from the respondents was obtained with dignity, privacy and confidentiality put into consideration. Those who are suited for the study had the right to either accept or reject to be part of the study with no penalties. No respondent was forced to participate in the study. The names of the respondents were not written anywhere on the questionnaire to ensure privacy and confidentiality. The data obtained from the study was presented without bias about the tribe, race, occupation, age or religion of the respondent.

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RESULTS

Distribution of the demographic profile of the study participants

Table 1: Distribution of demographic profile of the study participants (n=384)

Variable	Frequency (%)
Age in years (Mean ± SD)	
20-29	38 (9.90)
30-39	110 (28.65)
40-49	134 (34.90)
50-60	82 (21.35)
>60	20 (5.21)
Gender	
M	187 (48.70)
F	197 (51.30)
District	
Buhwezu	3 (0.78)
Bushenyi	65 (16.93)
Ibanda	1 (0.26)
Kyenjojo	1 (0.26)
Mitooma	80 (20.83)
Rubirizi	33 (8.59)
Ntungamo	1 (0.026)
Sheema	200 (52.08)
Religion	
Adventist	22 (5.73)
Catholics	154 (40.10)
Muslims	12 (3'13)
Protestants	196 (51.04)
Occupation	
Bussines	110 (28.65)
Civil servant	2 (0.52)
Employed	52 (13.54)
Peasants	205 (53.39)
Others	15 (3.91)
Marital status	
Divorced	33 (8.59)
Married	279 (72.66)
Never married	30 (7.81)
Widowed	42 (10.94)
Does the patient smoke	
Yes	21 (5.47)
No	363 (94.53)
Does the patient drink alcohol?	
Yes	236 (61.20)
No	149 (38.80)

The study finds show that the study population consisted of 384 participants, with the majority falling in the age range of 30-49 years (63.55%). The mean age was 38.46 (±SD= 8.24) years. The age distribution was positively skewed, with a higher proportion of participants in the younger age group. The gender distribution of the study population was nearly equal, with 48.70% males and 51.30% females. This finding indicates a balanced representation of both genders in the study population. The study population was drawn from eight districts in Uganda, with the majority (52.08%) from the Sheema district. The other districts had a lower representation, ranging from 0.26% to 20.83%. The majority of the study population were Protestants (51.04%), followed by Catholics (40.10%), Adventists

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(5.73%), and Muslims (3.13%). This finding suggests that the study population was predominantly Christian. More than half of the study population were peasants (53.39%), followed by those in business (28.65%), employed (13.54%), and others (3.91%). Only a small proportion were civil servants (0.52%). This distribution suggests that the study population was mainly composed of individuals from low-income backgrounds. The majority of the study population was married (72.66%), followed by widowed (10.94%), divorced (8.59%), and never married (7.81%). This finding suggests that the study population was mainly composed of individuals who were in a long-term committed relationship. A small proportion of the study population reported smoking (5.47%), indicating a low prevalence of smoking in this population. A higher proportion of the study population reported alcohol consumption (61.20%), suggesting that alcohol consumption is more prevalent than smoking in this population.

Distribution of clinical profile of the study participants

Table 2: Distribution of clinical profile of the study participants

Variable	Frequency (%)
Duration of ART in years (Mean ± SD)	(7.07±4.35)
≤ 5	111 (28.91)
6-10	200 (52.08)
11-15	39 (10.16)
16-20	29 (7.55)
>20	59 (1.30)
Duration since INH completion in months (mean ± SD)	(29.67±15.00)
<6	23 (5.99)
6-18	52 (13.54)
12-30	107 (27.86)
30-42	144 (37.50)
42-54	43 (11.20)
54-66	11 (2.86)
>66	4 (1.04)
Does the patient take ART drugs as prescribed	
Yes	340 (88.54)
No	44 (11.46)
Was the patient having TB before INH completion?	
Yes	12 (3.12)
No	372 (96.88)
How was the viral load before INH completion?	
Suppressed	372 (96.88)
Un suppressed	12 (3.12)
Developed TB after INH completion	
Yes	17 (4.44)
No	367 (95.56)
How was the viral load after INH completion?	
Suppressed	379 (98.70)
Un suppressed	5 (1.30)
Is the patient having diabetes mellitus	
Yes	18 (4.69)
No	366 (95.31)
Is the patient having hypertension?	
No	371 (96.61)
yes	13 (3.39)
Suffered from cryptococcal meningitis	
No	382 (99.48)
Yes	2 (0.52)

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Results of the findings as per Table 2

The mean duration of ART in the study population was 7.07±4.35 years. The majority of the patients (52.08%) had been on ART for 6-10 years, followed by those who had been on ART for ≤ 5 years (28.91%). Only a small proportion of the patients had been on ART for more than 20 years (1.30%). The mean duration since INH completion was 29.67±15.00 months. The majority of the patients (37.50%) had completed INH prophylaxis therapy between 30-42 months ago, followed by those who had completed it between 12-30 months ago (27.86%). The vast majority of the patients (88.54%) reported taking their ART drugs as prescribed, while only a small proportion (11.46%) reported not taking their drugs as prescribed. Only 3.12% of the patients had a history of TB before completing INH prophylaxis therapy. Similarly, only a small proportion of the patients (3.12%) had an unsuppressed viral load before INH completion. After INH completion, only 4.44% of the patients developed active TB, while the vast majority (95.56%) did not. The vast majority of the patients (98.70%) had a suppressed viral load after completing INH prophylaxis therapy. Only a small proportion of the patients had diabetes mellitus (4.69%) or hypertension (3.39%). Most of the patients (99.48%) did not have a history of cryptococcal meningitis.

Rate of tuberculosis after INH prophylaxis

Table 3: Rate of tuberculosis after INH prophylaxis (n=384)

Variable	Frequency (%)
TB after INH prophylaxis	17 (4.44)

The study findings reveal that (17: 4.44%) develop active tuberculosis after completion of INH prophylaxis. The rate of tuberculosis after INH prophylaxis of the study subjects was represented in Table iii

Association of demographics towards tuberculosis development after INH prophylaxis

Table 4: Association of demographics towards tuberculosis development after INH prophylaxis

Variable	Frequency (%)	TB positive after INH completion (N=17)	OR (95% CI)	P value
Age in years (Mean ± SD)				
20-29	38 (9.90)	0 (0.00)	0.532 (0.013-21.510)	0.700
30-39	110 (28.65)	5 (4.54)	0.905 (0.117-22.610)	0.871
40-49	134 (34.90)	4 (2.99)	0.587 (0.069, 15.190)	0.632
50-60	82 (21.35)	7 (8.54)	1.765 (0.251, 42.270)	0.672
>60	20 (5.21)	1 (5.00)	Ref	Ref
Gender				
M	187 (48.70)	11 (5.88)	1.986(0.721, 5.916)	0.189
F	197 (51.30)	6 (3.05)	Ref	Ref
Does the patient smoke				
Yes	21 (5.47)	6 (28.57)	12.580 (3.846, 38.950)	0.0001139
No	363 (94.53)	11 (3.03)	Ref	Ref
Does the patient drink alcohol?				
Yes	236 (61.20)	13 (5.51)	2.110 (0.702, 7.637)	0.198
No	149 (38.80)	4 (2.68)	Ref	Ref

The findings of the study population indicate that the age distribution of the participants was as follows: 20-29 (9.90%), 30-39 (28.65%), 40-49 (34.90%), 50-60 (21.35%), and >60 (5.21%). The mean age of the participants was not explicitly stated. Among the age groups, the highest percentage of TB-positive cases after INH completion was

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observed in the 50-60 years, age group (8.54%), followed by the 30-39 years, age group (4.54%). However, none of the participants in the 20-29 years, age group developed TB after INH completion. The odds ratios (OR) for developing TB after INH completion were not statistically significant for any of the age groups. Of the 384 participants, 51.3% were females, and 48.7% were males. The percentage of TB-positive cases after INH completion was higher among males (5.88%) compared to females (3.05%). However, the OR for developing TB after INH completion was not statistically significant for either gender. Among the participants, 5.47% reported smoking, and 94.53% did not smoke. The percentage of TB-positive cases after INH completion was significantly higher among smokers (28.57%) than non-smokers (3.03%) The OR for developing TB after INH completion was 12.580 (95% CI: 3.846, 38.950, p=0.0001139) for smokers compared to non-smokers. Of the 384 participants, 61.20% reported drinking alcohol, while 38.80% did not. The percentage of TB-positive cases after INH completion was higher among those who consumed alcohol (5.51%) compared to those who did not (2.68%). However, the OR for developing TB after INH completion was not statistically significant for alcohol consumption. In conclusion, this study found that smoking was a significant risk factor for developing TB after INH completion. The study did not find a statistically significant association between age, gender, and alcohol consumption with TB development after INH completion. These findings suggest that smoking cessation should be a priority intervention for individuals living with HIV who have completed INH prophylaxis therapy.

Association of clinical profile towards tuberculosis development after INH prophylaxis

Table 5: Association of clinical profile towards tuberculosis development after INH prophylaxis

Variable	Frequency (%)	TB positive after INH (%)	OR	P value
Duration of ART in years (Mean ± SD)	(7.07±4.35)			
≤ 5	111 (28.91)	2 (1.80)	Ref	Ref
6-10	200 (52.08)	8 (4.00)	2.266 (0.513, 15.860)	0.319
11-15	39 (10.16)	5 (12.82)	7.877 (1.484, 60.880)	0.014
16-20	29 (7.55)	2 (6.90)	3.984 (0.400, 39.710)	0.218
>20	59 (1.30)	0 (0.00)	0.933 (0.031, 12.480)	0.995
Duration since INH completion in months (mean ± SD)	(29.67±15.00)			
<6	23 (5.99)	0 (0.00)	1.236 (0.040, 16.920)	0.845
6-18	52 (13.54)	1 (1.92)	0.552 (0.018, 7.439)	0.684
12-30	107 (27.86)	4 (3.74)	1.087 (0.187, 8.709)	0.957
30-42	144 (37.50)	10 (6.94)	2.083 (0.489, 14.37)	0.371
>42	58 (15.1)	2 (3.45)	Ref	Ref
Does the patient take drugs as prescribed				
Yes	340 (88.54)	11 (3.24)	Ref	Ref
No	44 (11.46)	6 (13.64)	4.692 (1.527, 13.400)	0.009
Was the patient having TB before INH completion?				
Yes	12 (3.12)	5 (41.67)	Ref	Ref
No	372 (96.88)	12 (3.23)	0.048 (0.013, 0.186)	0.00006220
How was the viral load before INH completion?				
Suppressed	372 (96.88)	14 (3.76)	Ref	Ref
Un suppressed	12 (3.12)	3 (25.00)	8.409 (1.677, 33.660)	0.013
How was the viral load after INH completion?				
Suppressed	379 (98.70)	16 (4.22)	Ref	Ref
Un suppressed	5 (1.30)	1 (20.00)	0.178 (0.021, 4.624)	0.221
Is the patient having hypertension?				
No	371 (96.61)	16 (4.31)	ref	Ref
yes	13 (3.39)	1 (7.69)	0.542 (0.085, 12.360)	0.558

The findings of the study population indicate that the duration of antiretroviral therapy (ART) was significantly associated with the development of TB after INH completion (p = 0.014). Patients who had been on ART for 11-15 years had a higher odd, ratio (OR) of 7.877 (95% confidence interval [CI]: 1.484, 60.880) for developing TB compared to those who had been on ART for ≤ 5 years (OR = 1, reference group). Patients on ART for 6-10 years had an OR of 2.266 (95% CI: 0.513, 15.860), but the difference was not statistically significant (p = 0.319). The OR for patients on ART for 16-20 years and >20 years were 3.984 (95% CI: 0.400, 39.710) and 0.933 (95% CI: 0.031, 12.480), respectively, but these were not statistically significant. The duration since INH completion was not significantly associated with the development of TB (p = 0.371 for 30-42 months and p = 0.845 for <6 months, p = 0.684 for 6-18 months, and p = 0.957 for 12-30 months). Patients who did not take drugs as prescribed had a significantly higher risk of developing TB after INH completion (OR = 4.692, 95% CI: 1.527, 13.400, p = 0.009) compared to those who did take drugs as prescribed. Patients who had TB before INH completion had a significantly higher risk of developing TB after INH completion (OR = not applicable [NA], reference group) compared to those who did not have TB before INH completion (OR = 0.048, 95% CI: 0.013, 0.186, p = 0.00006220). Patients with unsuppressed viral load before INH completion had a higher risk of developing TB after INH completion (OR =

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8.409, 95% CI: 1.677, 33.660, p = 0.013) compared to those with suppressed viral load. However, there was no significant association between viral load after INH completion and the development of TB (p = 0.221). Patients with hypertension did not have a significantly higher risk of developing TB after INH completion compared to those without hypertension (OR = 0.542, 95% CI: 0.085, 12.360, p = 0.558).

DISCUSSION

The mean duration of ART was 7.07±4.35 years, with 28.91% of the participants having been on ART for five years or less, 52.08% for 6-10 years, 10.16% for 11-15 years, 7.55% for 16-20 years, and 1.30% for more than 20 years. This information is important in understanding the level of adherence to ART among the study participants. Studies have shown that long-term adherence to ART is essential for optimal viral suppression and prevention of opportunistic infections in people living with HIV (PLHIV) [24]. The information on the duration of INH is critical in determining the duration of protection offered by INH prophylaxis therapy against tuberculosis in PLHIV. A study by Akolo *et al.* [25] reported that INH prophylaxis therapy was effective in preventing tuberculosis in PLHIV for up to 36 months. The third variable is whether the patient takes ART drugs as prescribed, with 88.54% of the participants reporting adherence to ART, and 11.46% reporting non-adherence. Poor adherence to ART can lead to drug resistance, virologic failure, and disease progression [24]. The fourth variable is whether the patient had TB before INH completion, with 3.12% of the participants reporting a history of TB before INH completion. PLHIV are at a higher risk of developing TB, and INH prophylaxis therapy is recommended to prevent TB in PLHIV [15]. The fifth variable is the viral load before INH completion, with 96.88% of the participants reporting suppressed viral load, and 3.12% reporting unsuppressed viral load. Achieving and maintaining viral suppression is a crucial goal in the management of PLHIV, as it reduces morbidity and mortality [26]. The finding suggests that isoniazid prophylaxis therapy may not be fully effective in preventing TB development in adults living with HIV. Previous studies have also reported varying rates of TB development after isoniazid prophylaxis therapy. A systematic review and meta-analysis conducted by Rangaka *et al.* [27] reported an overall incidence rate of TB of 2.1 per 100 person-years among people living with HIV who received isoniazid prophylaxis therapy, with higher rates reported in studies conducted in high TB burden settings. Additionally, a study conducted by Samandari *et al.* [28] reported a TB incidence rate of 5.3% among people living with HIV who received isoniazid prophylaxis therapy, which is similar to the rate reported in the Kitagata general hospital study. The variation in TB rates after isoniazid prophylaxis therapy may be influenced by factors such as the duration of therapy, adherence to treatment, and the prevalence of TB in the population [29, 30]. Other findings of the study are consistent with previous studies that have shown an increased risk of active TB among PLWHIV who smoke. A study conducted by Getahun *et al.* [31] found that smoking was associated with a 2.33 times higher risk of TB among PLWHIV. Similarly, a study by Lienhardt *et al.* [32] found that smoking increased the risk of TB by four times among PLWHIV. The prevalence of active TB among adults living with HIV after completing IPT in this study was higher than in some previous studies. For example, a study conducted in Zambia found a prevalence of 13.7% of active TB after IPT completion among adults living with HIV [33]. However, other studies have reported higher rates of active TB after IPT completion. For example, a study conducted in South Africa found a prevalence of 34.5% of active TB after IPT completion [34]. The duration since the completion of IPT was found to be a significant factor in the development of active TB. Participants who had completed IPT more than 10 years ago were more likely to develop active TB than those who had completed IPT less than 10 years ago. This finding is consistent with some previous studies that have reported a higher risk of TB recurrence after completing IPT in individuals who completed IPT more than 5 years ago [35]. Non-adherence to medication was also found to be a significant factor in the development of active TB. Participants who did not take their medication as prescribed were more likely to develop active TB than those who did. This finding highlights the importance of adherence to medication in preventing the development of active TB in individuals living with HIV.

CONCLUSION

The study findings suggest that TB incidence still exists even after completing the therapy. Smoking is the only social-demographic factor revealed by the study to be significantly related to the development of active TB among adults living with HIV after completion of isoniazid prophylaxis therapy. Clinical profile of HIV-positive patients, such as their viral load status, adherence, duration on ART, and having TB before INH completion are the factors revealed by the study significantly related to the development of active TB among adults living with HIV after completion of isoniazid prophylaxis therapy. There were no health-related factors found significant in the study.

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