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Factors associated with elevated alanine aminotransferase levels among HIV patients on HAART at Naguru Hospital in Kampala District. A cross-sectional study.

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ABSTRACT

Background:

The study aimed to establish the factors associated with elevated ALT levels among HIV patients on HAART at Naguru Hospital in Kampala District.

Methodology:

The study utilized a cross-sectional design involving participants attending HIV care clinics. Data were collected through patient records, interviews, and laboratory investigations, including liver function tests and metabolic assessments. The prevalence of liver diseases and treatment-related adverse effects was determined. Statistical analysis was conducted to explore relationships between variables. Ethical considerations were observed by obtaining approval from relevant authorities and informed consent from participants, ensuring confidentiality and voluntary participation throughout the research process.

Results:

A total of 88 participants were included. Regarding age, the largest proportion of respondents were aged 21–40 years, accounting for 46 (52.3%). This was followed by those aged 41–60 years with 18 (20.4%), and respondents aged below 20 years who constituted 11 (12.5%). The least represented age group was those aged above 61 years, with 13 (14.8%). Most respondents were single (58, 65.9%), while 20 (22.7%) were married. A smaller proportion were divorced (8, 9.1%), and 2 (2.3%) were widowed. Lifestyle was local 53.7% (22/41), intermediate 29.3% (12/41), and modernized 17.0% (7/41). Co-infection was present in 85.4% (35/41), and alcohol use in 92.7% (38/41). Age distribution among elevated ALT cases was 7.3%, 68.3%, 19.5%, and 4.9%.

Conclusion:

Many factors were found to be associated with elevated ALT levels among HIV patients, and these included, but were not limited to: residential areas, lifestyle, co-infection, alcohol consumption, and age group.

Recommendation:

The Government of Uganda, together with the health service provider, should devise means to come up with drugs that counteract the effects of HART drugs, such as liver damage.

Keywords: *Hepatotoxicity, Antiretroviral side effects, Co-infection impact, Alcohol-related liver injury, Urban health determinants, Liver enzyme abnormalities.*
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BACKGROUND OF THE STUDY

Liver enzyme abnormalities, particularly elevated alanine aminotransferase (ALT) levels, among HIV patients on HAART have been associated with multiple clinical and lifestyle factors across different settings. A study conducted in Poland involving 79 patients (40 males and 39 females) with a mean age of 14.0 ± 5.1 years and an average duration of combined antiretroviral therapy (cART) of 11.5 ± 4.7 years found that 10% were co-infected with hepatitis B virus (HBV) or hepatitis C virus (HCV), which was linked to higher ALT levels. Additionally, detectable HIV viral load

was significantly associated with elevated ALT (Marczyńska et al., 2020).

Drug-induced liver injury (DILI) has also been identified as a major contributor to elevated ALT levels, with incidence varying across populations and being more common among hospitalized patients. Increased medication exposure, particularly among older individuals and females, has been associated with a higher risk (Suzuki et al., 2024). In Uganda, factors such as male sex, early HIV disease stage, and detectable viral load at initiation of dolutegravir (DTG)-based regimens have been significantly associated with adverse drug effects, including elevated ALT levels (Namulindwa et al., 2022).

Furthermore, broader risk factors for liver disease, regardless of HIV status, include viral hepatitis B and C, which contribute up to 80% of the global liver disease burden. Emerging non-communicable disease risk factors such as harmful alcohol consumption, obesity, and metabolic disturbances are also increasingly implicated in elevated ALT levels (Wekesa et al., 2022). These findings highlight the multifactorial nature of elevated ALT among HIV patients on HAART.

The study aimed to establish the factors associated with elevated ALT levels among HIV patients on HAART at Naguru Hospital in Kampala District.

METHODOLOGY

Study design

A descriptive cross-sectional study design was used to evaluate the ALT levels in HIV patients on HAART at Naguru Hospital. This was the study design of choice because it allowed conclusions to be drawn about the general population after taking a sample of the population at a certain point in time.

Study area

The study was conducted at Naguru hospital located at Naguru Road, on Naguru Hill, Nakawa Division, Kampala District, in Kampala, the capital of Uganda, and the largest city in that country. This location lies approximately 4 kilometers (2 min), by road, east of the central business district of Kampala.

The hospital handles both inpatient and outpatient departments with contact of about 350 clients per day. This was the study area of choice because this facility mostly handles many patients, which helped to draw a conclusion from a large population pool.

Study population

All HIV patients on HAART at Naguru Hospital, Kampala District.

Study variables

Independent variable

HIV status

Dependent variable

ALT levels

Sample size determination

Sample size refers to the number of participants who were included in the study, which was determined by Kish and Leslie (2000) as follows;

$$n=\frac{Z2pq}{d\ 2}$$

Where;

n is the sample size.

Z = the standard normal deviation (1.96) at the 95% confidence level.

p=13.5% (0.135) (estimated prevalence of elevated ALT levels) (Spearman, C. W et al., 2021) q=1- p (1-0.135=0.865)

d= desired level of precision (0.1) Therefore;

$$n=\frac{(1.96)\ 2 \times 0.397 \times 0.603}{(0.1)\ 2}$$

The minimum sample size required = 88

Therefore, a total of 88 participants were selected and included in the study.

Sampling technique

A convenience sampling technique was used to select 88 HIV patients from the entire study population. This technique is of choice because it allows the sample size of the study to be obtained in a short period of time.

Selection criteria

Inclusion criteria

All HIV patients on HAART during the period of data collection have consented to participate in the research exercise.

Exclusion criteria

All non-HIV patients were not included in the research exercise.

All HIV patients who were not on HAART at the time of data collection.

Sampling procedure

All HIV patients who were available each day of data collection and who had come for medical services at Naguru Hospital were informed about the objectives of the study.

A consent form was given to each of those who are to participate in the study to sign and agree to be part of the study. This was done until the sample size was reached.

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Data collection method

Quantitative data, such as the ALT levels of participants, were obtained by the chemistry analyzer from the chemistry department, and other relevant information was obtained using a question-and- answer method.

Data collection tool

The data collection tool used was a data collection sheet and a questionnaire, onto which relevant information about this study was captured. The tool possessed the following information: the laboratory number of the patient, age, gender, and the ALT test results.

Data collection procedure

After a clear explanation and consent from participants, a questionnaire containing both open and closed-ended questions was issued, and a blood sample was collected in a serum-separating vacutainer (yellow-topped tube). From the questionnaire, information regarding factors associated with elevated ALT was obtained.

The blood sample from the participant was taken to the laboratory (chemistry department), where the ALT test was run, hence the prevalence of elevated ALT and its principle discussed below.

ALT test principle

Alanine aminotransferase (ALT/GPT) catalyzes the transfer of the amino group from alanine to oxoglutarate with the formation of glutamate and pyruvate. The latter is reduced to lactate by lactate dehydrogenase (LDH) in the presence of reduced nicotinamide adenine dinucleotide (NADH).

The reaction is monitored kinetically at 340 nm by the rate of decrease in absorbance resulting from the oxidation of NADH to NAD+, proportional to the activity of ALT present in the sample.

ALT/GPT

L-Alanine + 2-Oxoglutarate ⟶ L-Glutamate +Pyruvate

M-L-Glutamate + Pyruvate

LDH

Lactate + NAD+ ⟶

Procedure of the ALT test Sample

Serum, heparinized or EDTA plasma.

Reagent Composition

R1a. Buffer/Substrate

Tris buffer 100 mmol/l, pH 7.5

L-alanine 0.6 mol/l

R1b. Enzyme/Coenzyme / -oxoglutarate

-oxoglutarate 15 mmol/l

LD ≥1.2 U/ml

Procedure (for manual use)

Wavelength: 340 nm (Hg 334 nm or Hg 365 nm)

Cuvette: 1 cm light path

Temperature: 30/37

Measurement: against the air

Pipette into cuvette:

Sample 0.2 ml 0.1 ml

R1. Enzyme / Coenzyme / -oxoglutarate 2.0 ml 1.0 ml Mix, read initial absorbance after 1 min.

Read again after 1,2, and 3 min. Note if the absorbance Change per minute is between

0.11 and 0.16 at 340 nm/Hg 334 nm

0.06 and 0.08 at Hg 365 nm, use only the values for the first 2 minutes for the calculation.

Manual Calculation

To calculate the ALT activity, use the following formulae:

U/l = 1746 x A 340 nm/min U/l = 1780 xA Hg 334 nm/min U/l = 3235 x A Hg 365 nm/min

Results interpretation

0 – 364 days: Normal range 5 – 33 U/L

1 – 12 years: Normal range 9 – 25 U/L

13 – 18 years female: Normal range 8 – 22 U/L

13 – 18 years male: Normal range 9 – 24 U/L Adult: Normal range <5 – 55 U/L

Quality control

Validity of the results

To establish the validity of the data, the data collection tools were given to the research supervisor and the laboratory in charge of the chemistry department at Naguru Hospital to evaluate the relevance of the tool to the collected information. To establish reliability, the researcher first obtained prior knowledge about the study before data collection.

Data Analysis and Presentation

Quantitative data obtained were analyzed using descriptive statistics and presented using Microsoft Excel in the form of column graphs and tables.

Ethical consideration

An introductory letter was obtained from the school administration of Mildmay Laboratory School, which will be presented to the Naguru Hospital administration to seek permission to carry out my research, and once the permission is granted, I will proceed with the data collection.

Privacy and confidentiality of patients' data were highly observed, and accessibility of the research findings was only available to the researcher and other specified authorities.

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RESULTS

Social demographic data of Respondents

Table 1: Showing Demographic Characteristics of Respondents

Characteristics	Category	Frequency(n)	Percentage (%)
Gender	Male	32	36.4
	Female	56	63.6
	Total	**88**	**100.0**
Age group	<20 years	11	12.5
	21-40 years	46	52.3
	41-60 years	18	20.4
	61< years	13	14.8
	Total	**88**	**100.0**
Education level	Primary	10	11.4
	Secondary	42	47.7
	Tertiary	8	9.1
	University	16	18.2
	None	12	13.6
	Total	**88**	**100.0**
	Single	58	65.9
	Married	8	9.1
	Divorced	20	22.7
	Widow	2	2.3
	Total	**88**	**100.0**
	Rural	28	31.8
	Urban	60	68.2
	Total	**88**	**100.0**

As shown in Table 1, of the 88 participants, the majority were females, 56 (63.6%), and only 32 (36.4) were males. The majority of the participants had attended secondary level as their highest education level, 42 (47.7%), and the least number had attained primary level, 10 (11.4%). Most of the participants were single, 58 (65.9%), and the least were widows, 2 (2.3%). The majority were urban dwellers, 60 (68.2%), and the remaining 28 (31.8%) came from rural areas.

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Factors associated with elevated ALT levels among HIV patients on HAART

Table 2: Showing factors associated with elevated ALT levels among HIV patients on HAART

Factors	Category	Frequency (N)	Percentage (%)
Residential Areas	Rural area	5	12.2
	Urban area	36	87.8
	Total	**41**	**100.0**
Life style	Modernised	7	17.0
	Intermediate	12	29.3
	Local	22	53.7
	Total	**41**	**100.0**
Have a Co-infection	Yes	35	85.4
	No	6	14.6
	Total	**41**	**100.0**
Alcohol consumption	Yes	38	92.7
	No	3	7.3
	Total	**41**	**100.0**

Table 4: ***Showing age as a factor associated with elevated ALT levels among HIV patients on HAART***

Age group	< 20	3	7.3
	21-40	28	68.3
	41-60	8	19.5
	61<	2	4.9
	Total	**41**	**100.0%**

As shown in Tables 2 and 3, (88%) 36 of the people with elevated ALT resided in urban areas, while 5 (12%) resided in rural areas. Most of the HIV patients with elevated ALT lived a local (low budget) lifestyle, 22 (53.7%), while the least lived a modernized lifestyle, 7 (17.0%). The majority of the HIV patients with elevated ALT levels had and stayed with co-infections 35 (85.4%). The majority of the HIV patients with elevated ALT levels were found to be alcohol consumers 38 (92.7%). The age groups of 21-48years had the greatest number of HIV patients with elevated ALT level 28 (68.3%), and the least were those above 61years 2 (4.9%).

DISCUSSION

Among the factors associated with elevated ALT levels among HIV patients was the residential areas; the majority of the patients with elevated ALT levels were more urban dwellers, 36 (87.8%), than those who stayed in rural areas, 5 (12.2%). This is probably because, besides the drug toxicity, a lot of factors come along with urban life that may lead to liver damage, causing elevated ALT levels, such as poor diet, exposure to pollution, and stress.

Lifestyle was also another factor; those with a local lifestyle were found to suffer more from elevated ALT levels 22 (53.7%), probably because of a lack of awareness about how to prevent liver damage that leads to elevated ALT levels.

Having a co-infection was also revealed to be a major factor associated with elevated ALT levels, with 85.4% (35) of the patients found to have a co-infection. This was probably because these co-infections were also targeting liver cells, having Hepatitis B, the major co-infection, and thus elevated ALT levels.

Alcohol consumption was also a factor associated with elevated ALT levels, and the majority of the victim patients

were found to be alcohol consumers 38 (92.7%). This was probably because alcohol damages and also kills liver cells, and prolonged alcohol use may also reduce the ability of the liver to develop new cells, thereby increasing ALT levels.

The age group of 21- 40 years was found to have the highest number of victims of elevated ALT levels, 28 (68.3%), and this was probably because during the study, this age group had the greatest number of participants.

The study results are in agreement with those of Marczynska M, 2010, who in his study revealed that many patients were co-infected with either HBV or HCV, leading to high ALT levels.

However, the study results also contradict the study results of Suzuki A, 2024, who spotted prolonged stay in hospital as a factor of elevated ALT levels, which was not the case with the study at hand.

CONCLUSION

Many factors were found to be associated with elevated ALT levels among HIV patients, and these included, but were not limited to, residential areas, lifestyle, co-infection, alcohol consumption, and age group.

RECOMMENDATION

The Government of Uganda, together with the health service provider, should devise means to come up with drugs that counteract the effects of HART drugs, such as liver damage.

Acknowledgement

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A lot of thanks also go to my siblings and all my classmates.

List of abbreviations

ALT – Alanine Aminotransferase
HAART – Highly Active Antiretroviral Therapy
HIV – Human Immunodeficiency Virus
DILI – Drug-Induced Liver Injury
HBV – Hepatitis B Virus
HCV – Hepatitis C Virus
cART – Combined Antiretroviral Therapy
DTG – Dolutegravir
LDH – Lactate Dehydrogenase
NAD^+ – Nicotinamide Adenine Dinucleotide (Oxidized Form)

Source of funding

The study received no external funding.

Conflict of interest

The authors declare no conflict of interest

Author contributions

HK: collected the data.
AS: supervised the study.
HN: supervised the study.
FS: supervised the study.
JFN: supervised the study

Data availability

Data is available upon request from the author

Informed consent

Written informed consent was obtained from all participants prior to their inclusion in the study. Participants were informed about the purpose of the study, procedures involved, potential risks and benefits, and their right to withdraw at any time without penalty.

Author biography

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