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Evaluation of Serological Assays for the Diagnosis of HIV1 and HIV2 among Patients in Wad Medani, Gezira State, Sudan

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Research Article

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Abstract

Background: Infections HIV-2 and HIV-1 cause acquired immunodeficiency syndrome (AIDS). Serological investigation of the HIV in the community enables early guidance of antiviral treatment for carriers of the disease. There are no confirmed statistics on the sero-positivity of HIV in Sudan.

Methods: Socio-demographic data and blood samples were collected from 288 HIV Patients dually seropositive at Anti-retrovirus Treatment Centre (ART) center in Wad Madni at Gazeria state in Sudan.

Results: The results obtained revealed that the RDT showed 287 of them had HIV-1 positive while 1 sample were negative.288 had positive by ELISA test. Majority of participant were males, most of individuals in age group 39-49 years and most of them were single and had basic study status (p. value 0.001).

Conclusions: This study of HIV-1 and HIV-2 infection suggests that routine clinical care is less than optimal and that management and treatment of HIV-2 could be further informed by ongoing studies and randomized clinical trials in this population.

Keywords: HIV-1; HIV-2; ELISA; RDT; Sudan

Abbreviations: HIV: Human Immunodeficiency Virus; AIDS: Acquired Immunodeficiency Syndrome; EIA: Enzyme Immunoassay; WHO: World Health Organization; PLHIV: People Living with HIV; CCR5: Cysteine-Cysteine Chemokine Receptor Type 5; ELISA: Enzyme Linked Immune Sorbent Assay; ICT: Immune-Chromatography Test; SPSS: Statistical Package for the Social Sciences; RDTs: Rapid Direct tests.

Introduction

Human immunodeficiency virus (HIV) is retrovirus that causes Acquired Immunodeficiency Syndrome (AIDS), a condition in human in which immune system begins to fail, leading to life-threading opportunistic infection and cancer to attack the body [1]. Infection of HIV occurs by transfer

of contaminated blood, semen, vaginal fluid, pre-ejaculate, or breast milk [2]. Within these body fluids, HIV present as both free virus particles and virus with in infected immune cell [3]. The four major routes of transmission are unsafe sex, contaminated needles, breast milk, and transmission from an infected mother to her baby at birth (vertical transmission) [4]. Early analysis and linkage to precaution are necessary [5]. Serological investigations based on the enzyme immunoassay (EIA) have generally been the primary method for HIV diagnosis and currently stay the gold standard method for analyzing HIV infection in adults and children (older than 18 months) [6]. The assessment of HIV assay technology has resulted in faster, cheap and developed test precision [7]. Scientific improvement in HIV assay technology, clinicians are still faced in a minority of patient cases by false-positive and false-negative HIV results [8].

According to the facts of the World Health Organization (WHO), human immunodeficiency virus (HIV) and AIDS is the most important threat to global health despite this fact, the number of people living with HIV (PLHIV) is increasing rapidly [9]. The prevalence of HIV in Sudan increased in 1998 to reach 2% and remained at this level until 2020, as documented by the World Bank; this level keeps Sudan in the ranks of countries with a low prevalence rate, although its geographical surroundings with several highly affected countries. In 2016 estimated and reported number of PLHIV in Sudan was 56,000 and 21,471 respectively, while prevalence among sex workers increases to1.3 %. One of the major co-receptor of HIV-1 and HIV-2 for entry into the human macrophages during initial infection is the cysteine-cysteine chemokine receptor type 5 (CCR5) [10].

However, the serological investigation of the HIV in the community enables early guidance of antiviral treatment for carriers of the disease, and there are insufficient statistics on the sero-positivity of HIV in Sudan. So, this study was aimed to evaluate serological diagnosis of HIV1 and HIV2 using Rapid diagnostic Test (RDT)) and to confirm HIV1 and HIV2 using enzyme linked immune sorbent assay (ELISA).

Materials and Methods

This was a cross-sectional laboratory based study, carried out at Khartoum and Wad Medani Antiretroviral Treatment Centers in central Sudan, and this study was conducted within two years (2019-2021) to determine HIV antibodies status in Sudanese Patients. A total of 400 Patients were enrolled in this study. Blood sample was collected from each patient in plain container and then Immune-chromatography test (ICT) was done for each sample, and serum was separated and tested for (HIV) M and IgG by using ELISA.

Procedure of Immune-chromatography Test (ICT)

- According to the manufacturer instruction, 20 µl of plasma were added using a micropipette to the sample well of the test device.
- 3 drops of assay diluents were added into the sample well of the test device.
- The test results were read within 10 to 20 minutes.

ELISA Procedure

HIV-1 antibodies were tested using ELISA EUROIMMUN (Germany); semi quantitative analysis was done according to manufacturer instruction as following:

1. 100 µl of the calibrators, positive control, negative controls and diluted patients' samples were transferred to micro plate wells and incubated for 30 min at 32co.
2. 300 µl of working strength wash buffer was used to Wash micro plate wells. And this process repeated three times.
3. 100 µl of enzyme conjugate was pipetted into each of the micro plate wells and incubated for 30 min at room temperature.
4. The micro plate wells were washed again as previously described in step two.
5. 100 µl of chromogenic substrate was pipetted into each micro plate wells and incubated for 30 minutes at 32Co.
6. 100 µl of stop solution was pipetted into each micro plate wells and incubated for 5 min.
7. Results were recorded at 450 nm wavelength filters and also at 650 nm for reference reading by ELISA reader.
8. Results were recorded at 450 – 650 nm wavelength filters and calibrator 2 was measured to evaluate the results according to following formula:

$$\text{Ratio} = \frac{\text{Extinction of the control or patient sample}}{\text{Extinction of calibrator 2}}$$

Specimens with antibody concentrations >18 U/ml above the mean concentrations of negative controls were considered as positive.

Data Management and Analysis

Data and results were kept confidentially and entered in Excel sheet and then were analyzed by using the Statistical Package for the Social Sciences (SPSS) computer program version 20

Ethical Consideration

Ethical approval for this study was obtained from IRB of the Faculty of Medical Laboratory Sciences. Also, permission was taken from the local health authorities in Gezira and

Khartoum states, and the study participants informed by the study objectives and a written consent were taken from them.

Results

Data were collected from 288 Patients suffered from HIV, as indicated in Tables 1, 2&3, majority of participants were males (185/288), most of them in age group 39-49 years and most of them were single (186/288). The educational status of the enrolled patients was basic, 187/288 (Table 4). The RDT results showed that 287 of them had HIV-1 positive while 1 sample were negative, while 288 had positive by ELISA test (Tables 5, 6 & 7).

Gender	Frequency	Percent
Male	185	64%
Female	103	36%
Total	288	100%

Table 1: Distribution of Gender among Study group.

Age group	Frequency	Percent
less than 17 years	6	2%
17-27 years	58	20%
28-38 years	72	25%
39-49 years	94	33%
50-60 years	47	16%
more than 60 years	11	4%
Total	288	100%

Table 2: Distribution of age group among study group.

Status	Frequency	Percent
Married	93	32%
Single	186	65%
Widowed	9	3%
Total	288	100%

Table 3: Distribution of social Status among case.

Educational level	Frequency	Percent
University	16	5%
Secondary	85	30%
Basic	187	65%
Total	288	100%

Table 4: Distribution of Educational status among studied group.

Study population	RDT results		Total
	HIV-1	HIV-2	
Study group	287	0	288
Total	288	0	288

Table 5: Distribution of RDT results among study group.

Study population	ELISA results		Total
	HIV-1	HIV-2	
case	287	0	288
Total	288	0	288

Table 6: Distribution of ELISA results among study group.

RDT	ELISA		Sensitivity %	Specificity %
	Positive	Negative		
Positive	287	0	99.70%	100%
Negative	1	0		
Total	288	0		

Table 7: Comparison of RDT versus ELISA for HIV-1.

Discussion

Both ELISA and RDTs (Rapid Direct tests) such as RDT are widely employed immunological assays for sero-diagnosis of HIV1/2 infection [11]. The performance of HIV Antigen/antibody combination-based HIV ELISA continuously to ensure the correct diagnosis of HIV infection especially by HIV ELISAs. The fourth generation HIV ELISAs are made in a way that HIV p24 antigen is combined with anti-HIV-1 and anti-HIV-2 for early diagnosis of HIV infection. The present evaluation determined the performance characteristic of the HIV Antigen/antibody ELISA. In the current study which conducted among 288 Sudanese suspected individuals of HIV-1/2 as Study group, RDT results reveals that 284 were HIV1 and there is no HIV2 but 4 tests read invalid. However, ELISA results showed that 288 of participant had HIV1 positive. As of gender the results show that the majority of participant (64%) were male, while most of individual are young were (30.5%) in age group 39-49 years and most of them were single (65%). There about 47% were married. The younger age group in the study group is probably due to economic conditions or low education level. There were 65% with basic education, 5% with University degree while 30% with Secondary education. In study done in West Africa, rapid HIV assays are often used for the diagnosis of HIV-1 or HIV-2 or dual HIV-1/HIV-2 infection. This strategy is based on the demonstration of virus-specifics antibodies using enzyme-linked immune-sorbent assay-based technique [12-15]. In the West African region, current serological tests for

the diagnosis of HIV-2 include: 1) for screening purposes: Determine, ELISA Final confirmation is made when available with PeptiLAV (Bio-Rad), Western Blot, HIV DNA PCR. HIV-2 may be underreported because antibody cross-reactivity between HIV-1 and HIV-2 is common and frequently results in misdiagnosis of HIV-2 as HIV-1 or dual infection [16,17]. Therefore, screening tests need high sensitivity for HIV-2, while confirmatory testing may require multiple steps in order to reliably distinguish between HIV-1, HIV-2, and HIV-1/HIV-2 dual infection. In the current study which conducted among 288 Sudanese suspected individuals of HIV-1 as Study group, all patients sample tested by RDT and all of them were presented as HIV -1 positive while HIV-2 were negative that mean in Sudan HIV-1 was predominant and HIV-2 was rare.

Conclusion

This study of HIV-2 and HIV-1 infection suggests that routine clinical diagnosis and care is less than optimal and that management and treatment of HIV.

Conflict of Interest: The authors declare no conflicts of interest

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