Medical Safety & Global Health
ISSN: 2574-0407

Bianchi et al., Med Saf Glob Health 2017, 6:2
DOI: 10.4172/2574-0407/1000135

Research Article Open Access

Exposure to HIV: When Laboratory Investigation Time is Gold

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Abstract

To offer a rapid investigation on potential source of infection in case of worker exposure (needle stick) to reduce anxiety and to offer an accurate assessment we stressed the analytical performances of two commercial HIV point of Care (POCT). This strategy could suggest to give or not a retroviral therapy in less than 4 hours, the expected time to have the optimal infection's prophylaxis. 60 selected serum samples were previously analyzed, confirmed and classified for HIV positivity/negativity by conventional laboratory procedure: HIV Combo Ag/Ab Abbott diagnostic®, USA; Western Blot Matrix HIV 1/2 Abbott®, USA. Suddenly we investigated all samples by the new POCT test (HIV 1/2 Ag/Ab Combo InvernessMedical®, Chiba Japan) 60 selected serum are classified 40 as negative and 20 as positive. We analyzed our data by quantify agreement with kappa (Choen's kappa coefficient) and we registered a poor strength of agreement between two immunocromatographic HIV tests but a perfect strength of agreement (Kappa=1.000) between CMIA test and Immunocromatographic Ag/Ab HIV and PNV, VVP, sensitivity and specificity are 100%. All acute healthcare settings should expect to have an access to an urgent HIV screening assay result ideally within four hours, and definitely within 24 hours, to provide optimal support for exposure incidents. POCT can give a rapidly diagnostic evaluation on a possible source of infection enabling to give an accurate indication for a prophilactic treatment.

Keywords: POCT; Infection; Virus; Diagnosis; Prophylaxis

Introduction

Since their introduction in 1985, the performance of human immunodeficiency virus (HIV) screening assays has continued to improve.

Investigation of virological and serological events that occur during the very early phase of HIV infection indicate that, following local replication in proximity of the inoculation site, a high title viremia occurs, generally, during the second to third week after exposure [1]. A protein component of the virus core, p24 antigen (p24Ag), is usually detectable within a few days of the onset of viremia [2]. The p24Ag usually becomes undetectable until degradation of the host immune system associated with progressive HIV related disease, typically around 10 years leather. In most of cases HIV RNA remains detectable, but usually at levels much lower than in the acute phase. Detection of p24Ag in the absence of anti-HIV antibody may be used as a marker of recent infection although its presence is unreliable and short-lived (1 or 2 weeks) and therefore not very useful for measuring incidence [3].

Standard commercial screening (based on the detection of antibodies) and confirmatory tests (based on antibody and/or antigen detection and/ or virus genotype research) are mostly unable to distinguish long-standing from recent infections. The windows period between infection and antibody detection has been shortened (14 days) by the introduction of a third generation antigen- sandwich assays [4]. In order to offer a rapid result in case of workplace exposure, during night work weekends it is currently possible to use a rapid commercial test. This can diagnose that an individual has been infected or not in less than 30 minutes, but this approach necessitates a rapid laboratory test with good analytical performances. This strategy could also suggest whether to give retroviral therapy in less than 4 hours, the expected time for optimal infection's prophylaxis. We want to evaluate a new immunocromatographic test on card that propose a selective and combined detection of HIV 1/2 Antigen and Antibodies.

Materials and Methods

Samples

We conducted the present study using serum samples from 60 HIV-positive persons who had been diagnosed with HIV infection at the IRCCS Humanitas Hospital, Rozzano Milano, Italy. In particular, the serum samples were taken from all 370.890 serum samples of persons these arrive, for screening, in our withdrawals hospital room in latest 20 months. All samples were previously tested by all conventional laboratory procedures (CMIA test, Western Blot and p24 antigen). We registered: 20 positive (two for antigen and 18 for antibodies) and 40 negative. All 60 samples were then tested by two rapid cardbased immunochromatographic tests. Between 20 samples 16 were men and 4 were female (Table 1).

HIV-1/2 ag/ab Combo Inverness Medical®

The HIV-1/2 Ag/Ab Combo Inverness Medical is a qualitative immunochromatographic test for the simultaneous detection of HIV

New positive cases	Patients
Incidence	5.4 per 100.000
Median age of male	43 years
Median age of female	50 years
Male/female ratio	4.0

Table 1: Characteristics of our outpatients.

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Received August 29, 2017; **Accepted** September 01, 2017; **Published** September 08, 2017

Citation: Bianchi P, Maura F, Motta LM, Montanelli A, Monari M (2017) Exposure to HIV: When Laboratory Investigation Time is Gold. Med Saf Glob Health 6: 135. doi: 10.4172/2574-0407/1000135

p24 antigen (Ag) and anti24061976 bodies (Ab) to HIV-1 and HIV- 2 in human serum, plasma, or wool blood. The 50 µl sample is applied to the sample pad and kept for 30 minutes. The specimen mixes with a biotinylated antip24 antibody and selenium colloid-antigen conjugate. This mixture continues to migrate through the solid phase to the immobilized avidin, recombinant antigens and synthetic peptides at the patient's window sites. To ensure assay validity, a procedural control bar is incorporated in the device and is labelled control. If this bar is not red the test is invalid.

Three different results are possible:

-Red bars appear in the control window, Ag window and in Ab window. In this case the double presence of Ab and Ag suggests an early stage of infection and the test is considered positive;

-If only a red bar appears in Ag window, this suggests an early infection and the test is considered positive;

-The last one is a red bar in the Ab window, in this case it is a past infection and the test is considered positive.

Core HIV1/2 Core Diagnostic®, U.K.

This is a qualitative two site sandwich immunoassay for detection of antibodies to HIV 1-2 virus in human serum, plasma and wool blood. A mixture of highly purified recombinant antigen of gp41, recombinant p24 combinated to subtype O specific synthetic peptide, representing HIV-1 and recombinant gp36 representing HIV-2 are coated on the membrane in the test region and anti-rabbit antiserum in the control region.

Three different results can be obtained:

-positivity if HIV/1 or HIV/2 antibodies are present and two colored bands appear at test and control region;

-negativity if there are no antibodies and only one colored control band appears;

-the test is invalid if the control band is not visible despite the presence or absence of other colored bands (Table 2).

Results

Twenty samples previously classified as positive by conventional laboratory procedures are confirmed by the HIV1-2 Ag/Ab rapid immunocromatographic test: 15 for Ab presence, 2 for Ag presence and 3 for Ab and Ag presence.

Otherwise 18 of 20 samples previously classified as positive are confirmed by the HIV 1-2 Ab rapid immunocromatographic test (Table 3).

For HIV1-2 Ag/Ab rapid test on card we registered a total concordance with previous samples conventional laboratory classification: PNV, VVP, sensitivity and specificity of 100%. (Table 4) For HIV 1-2 Ab rapid tests on card we obtained as expected a slightly lower sensitivity due to impossibility to detect the presence of the antigen alone.

Assay	Results	Sensibility	Specificity	Time for results
HIV Ag/Ab Abbott	≥ 1 S/co	99.5%	94.8%	18'
HIV-1/2 Ag/Ab Combo Inverness Medical	Presence/ absence of band	100%	100%	15'
Core HIV1/2 Core Diagnostic	Presence/ absence of band	100%	100%	15'

Table 2: Comparison of the three different HIV assays compared.

	HIV1-2 Ag/Ab Rapid test	HIV1-2 Ab Rapid test
Positive % N=20	20	18
Negative% N=40	40	42
Indeterminate results %	0	0

Number of observed agreements: 62 (51.67% of the observations)
Number of agreements expected by chance: 60.0 (50.00% of the observations)
Kappa=0.033
SE of kappa=0.085
95% confidence interval: From -0.133 to 0.200

Table 3: Comparison of the HIV rapid immunocromatographic assays.

	HIV1-2 Ag/Ab Rapid test	HIV Ag/Ab CMIA
Positive % N=20	20	20
Negative% N=40	40	40
Indeterminate results %	0	0

Number of observed agreements: 60 (100.00% of the observations)
Number of agreements expected by chance: 33.3 (55.56% of the observations)
Kappa=1.000
SE of kappa=0.000
95% confidence interval: From 1.000 to 1.000

Table 4: Comparison of the HIV rapid immunocromatographic Ag/Ab assay and CMIA Test.

Discussion

Despite ongoing prevention and education efforts, many new infections are caused by individuals unaware of their HIV infection [5]. Rapid testing can be expanded to medical settings: this can provide greater access to testing, prevention, and care so as to reduce the number of new infections and lead to reductions in HIV associated morbidity and mortality [6]. To break down barriers for early diagnosis of HIV disease and increase access to treatment and prevention (this is very important in the presence of occupational exposure) it is necessary to reduce diagnosis times [7].

All acute healthcare settings should have access to an urgent HIV screening assay result ideally within four hours, and definitely within 24 hours, to provide optimal support for exposure incidents. Routine out-put test results should be available within 72 hours, therefore point of care (POCT) is recommended in the following scenario [8]: clinical settings where a rapid turnaround of testing results is desirable as community testing sites, urgent source testing in cases of exposure incidents and in circumstances when venipuncture is refused.

Because an individual exposed to HIV must be treated within 4 hour of exposure, we propose the use of a combined Ag/Ab immunochromatographic card test to detect the possible presence of HIV presence in the source of infection.

Our rapid kit gives results in less than 30 minutes, enabling us to indicate any eventual treatment, we do not register false negative or false positive results (diagnostic accuracy of 100%).

The complete concordance between the rapid and conventional tests that detect the antigen and antibody of HIV, offer us the possibility to use POCT with great safety. In this way, we can eliminate the inappropriate chemiotherapeutic prophylaxis usually administrated during the lengthy waiting periods required by conventional laboratory investigations. Rapid point-of-care would seem to be an optimal approach for screening.

A potential advantage could be that, as more infected individuals learn their status and reduce risk behaviours, HIV transmissions will dop [9]. We suggest that today possible uses of rapid test on card, with good safety margins, are the screening of women in labor who have not already had HIV testing during pregnancy; the investigation of source patients for occupational exposures to start or limit postexposure prophylaxis; in remote areas; in counselling centres for drug addicts, for sexually transmitted disease and for family planning.

References

1. Busch MP, Lee LL, Satten GA, Henrard DR, Farzadegan H, et al. (1995) Time course of detection of viral and serological markers predicting human immunodeficiency virus type 1 seroconversion: implications for screening of blood and tissue donors. Transfus 35: 91-97.
2. Busch MP, Satten GA (1997) Time course of viremia and antobody seroconversion following human immunodeficiency virus exposure. Am J Med 102: 117-124.
3. Murphy G, Parry JV (2008) Assays for the detection of recent infections with human immunodeficiency virus type 1. Euro Surveill 13: 537-545.
4. Constantine NT, Van der Groen G, Balsey EM, Tamashiro H (1994) Sensitivity of HIV–antibody assays determined by seroconversion panels. AIDS 8: 1715-1720.
5. Greenwald J, Burstein GR, pincus J, Branson (2006) A rapid review of rapid HIV antibody tests. Curr Infect Dis Rep 8: 125-131.
6. Janssen RS, Holtgrave DR, Valdiserri RO, Shepherd M, Gayle HD, et al. (2001) The serostatus approach to fighting the HIV epidemic: prevention strategies for infected individuals. Am J Public Health 91: 1019-1024.
7. Gliddon HD, Peeling RW, Kamb ML, Toskin I, Wi TE, et al. (2017) A systematic review and meta-analysis of studies evaluating the performance and operational characteristics of dual point-of-care tests for HIV and syphilis. Sex Transm Infect sextrans-2016.
8. Winter AJ, Sulaiman Z, Hawkins D and The british association for sexual health and HIV clinical governance committee (2006) BASHH clinical governance committee guidance on the appropriate use of HIV point of care tests. Int J STD & AIDS 17: 802-805.
9. Higgins DL, Galavotti C, O'Reilly KR, Schenell DJ, Moore M, et al. (1991) Evidence for the effects of HIV antibody counselling and testing on risk behaviours. Jama 266: 2419-2429.