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A COMPARATIVE STUDY OF A RAPID TEST AND ELISA FOR THE SEROLOGICAL DETERMINATION OF HIV INFECTION

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SUMMARY

In a comparative study, 460 serum samples were tested for the serological determination of human immunodeficiency vrius (HIV) using an ELISA kit and a Rapid Test kit. Results indicated that the Rapid Test is reliable for screening unkonwn samples when there is no special equipment for screening with immunoblotting and/or ELISA.

KEY WORDS: *AIDS; ELISA; Rapid Test.*

INTRODUCTION

The various enzyme immunoassays have been developed for screening the anti-human immunodeficiency virus antibodies (HIV-1, HIV-2). Conventional enzyme-linked immunosorbent assay (ELISA) has shown to have the accuracy more than 99.9% (1,2); however, the conventional ELISA is time consuming and needs expensive equipments. It also requires technical skills for the operation of the equipments.

Need for a test, which is rapid and simple tc perform and the one which does not require any special equipment and/or skilled operator, is an ever increasing phenomenon. Fortunately, a new generation of enzyme immunoassay tests, called Rapid Tests (sometimes referred to as physicians office diagnostics or do it yourself tests) is now available. These tests do not require any special equipment and can detect anti-HIV antibodies in less than ten minutes. These are designed to be used individually with a single sample or with a small number of samples. Most of these tests must be performed with serum, which requires centrifugation of the blood sample before testing, and thus intended to be used in small laboratories. Other tests, like the one we evaluated, can be used with whole blood or serum by non-medical personnel

which will detect the antibody to both HIV-1 and HIV-2 at the same time.

In an evaluation study, we examined one of the newest generation of the Rapid Tests that uses synthetic antigen instead of recombinant antigen. Synthetic antigen is more specific and harbors less false positive results (3). The kit requires one or two drops of either blood or serum for screening the presence of antibody to gp41 and gp36 corres--ponding to the transmembrane glycoproteins of HIV-1 and HIV-2, respectively.

MATERIALS AND METHODS

Commercial kits were: Rapid HIV-1, HIV-2 AB from Clonatec (Paris, France), Conventional ELISA kits from Organon Teknica (Brussels, Belgium). Blood samples and/or sera were supplied by Iranian Blood Transfusion Service, Department of Infectious Diseases at Imam Khomeini Hospital and Shahid Akbarabadi Hospital. Assays were done according to the manufacturer's procedures and recommen--dations.

RESULTS

In our first experiment, 400 samples were tested, using the Rapid Test, ELISA and immunoblot diagnostic kits. Sixteen positive cases were detected by all the three kits (Table 1) meaning that all the three tests were 100% comparable; therefore, they bear the same degree of sensitivity.

In our second experiment, we screened 60 samples of either whole blood or non-diluted serum. As shown in Table 2, six positive cases were detected by each of the three tests.

In order to examine the sensitivity of the kits, we diluted sera up to 1:100 and then tested them by the Rapid Test and ELISA. Results are summarized in Table 3. These results indicated the high sensitivity of both tests even following 100 fold dilution of the samples. It should be noted that we could not examine the endpoint dilution of the samples due to limitation of the available kits.

DISCUSSION

The results indicated that the Rapid Test, inspite of its rapidity and simplicity, has the same sensitivity and specificity as ELISA. This was not unexpected because, in principal, both tests have used the same technology, thus bearing the sensitivity of >99.9% (4). However, by using synthetic antigen for detection of antibody in the Rapid Test, it will increase the specificity of the test up to 99.69% (3). It should be noted that most of the published studies evaluating Rapid Tests were based on latex agglutination techniques (5,7). In this experiment, we studied a test that has used the newer technique which is a solid phase enzyme immunoassay (ELISA immunofiltration). It is a sandwich assay with synthetic transmembrane glycoproteins of HIV-1 and HIV-2. Generally speaking, this technology is preferred to the conventional ELISA, in which, they use recombinant antigen and polystyrene as a solid phase. The conventional ELISA bears higher incidence of false positive and background than that of the former.

Besides the improvement of specificity and comparable sensitivity, the built-in quality control in the Rapid Test kit is an advantage over the conventional kit because a non-medical personnel can detect testing errors and repeat the test. But, in the case of the conventional ELISA, there are too many variable sources of errors that cannot be easily identified; therefore, the frequency of the errors increase. Considering the seriousness of even one false negative due to assay error makes this test, with a built-in quality control, a better test for screening the test even with relatively large number of the samples. The simple procedure and rapid result reading make this test a choice for all physicians' and dentists' offices, emergency operating rooms, and blood transfusion services where there are no skilled technicians and/or reliable instrument for the conventional ELISA.

1) Postive samples in each experiment were taken from clinically proven cases.

Table 1. Anti-HIV antibody detection

Samples	No.	Rapid Test		ELISA		Immunoblot	
		+	−	+	−	+	−
Normal	141	0	141	0	141	0	141
Dial.*	108	0	108	0	108	0	108
Hemop.**	84	16	68	16	68	16	68
I.V.D.***	67	0	67	0	67	0	67

* Dial.= Dialysis patients' sera

** Hemop.= Hemophiliac patients' sera

*** I.V.D= Intravenous drug addicts' sera

Table 2. Anti-HIV antibody detection

Samples	No.	Rapid Test		ELISA		Immunoblot	
		+	−	+	−	+	−
Normal Blood	24	0	24	0	24	0	24
Hemop.* Blood	6	6	0	6	0	6	0
Normal Sera	24	0	24	0	24	0	24
Hemop. Sera	6	6	0	6	0	6	0

* Hemop.= Hemophiliac patients

Table 3. Anti-HIV antibody detection

Samples	No.	Dilution	Rapid test		ELISA	
			+	−	+	−
Normal Sera	24	1:10	0	24	0	24
Hemop.* Sera	6	1:10	6	0	6	0
Hemop. Sera	6	1:100	6	0	6	0

* Hemop.= Hemophiliac patients

REFERENCES

1) Francis, HL, Kabeya, M, Kaufman, *et al* (1988). Comparison of sensitivities and specificities of latex agglutination and enzyme-linked immunosorbent assay for detection of antibodies to human immunodeficiency virus in African sera. *J. Clin. Microbiol., 26,* 2462-2464.

2) Riggin, CH, Beltz, GA, Hung, CH, *et al* (1987). Detection of antibodies to human immunodeficiency virus by latex agglutination with recombinant antigen. *J. Clin. Microbiol., 25,* 1772-1773.

3) Zulaica, D, Cilla, G, & Perez-Trallero, E. (1989). Evaluation of sensitivity and specificity: Rapid method for detection of HIV-1 and HIV-2 infection. *V Inter. Conf. AIDS,* Montreal.

4) Baccard-Longeree, M, Genoulaz, O, Seigneurin, JM, *et al* (1998). L'immunocomb de PBS orgenics: Comparison de ce teste avec quatre techniques ELISA. *Feuillets de Biologie, 165,* 65-67.

5) Van de Perre, P, Nzaramba, D, Allen, S, *et al* (1988). Comparison of six serological assays for human immunodeficiecy virus antibody detection in developing countries. *J. Clin. Microbiol, 26,* 552-556.

6) Quinn, TC, Riggin, CH, Kline, RL, *et al* (1998). Rapid latex agglutination assay using recombinant envelope polypeptide for the detection of antibody to the HIV. *JAMA, 260,* 510-513.

7) Aubert, V, Erb, P, Perin, LH, Grob, PJ, & Frei, PC. (1991). Evaluation of commercial Rapid Tests for serological determination of HIV infection. *Lab. Med., 22,* 869-872.