

## Prevalence of HIV Infection among Individuals Referred to Consult Center of Behavior Diseases, West Health Center in Tehran, Iran

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### Abstract

**Background:** Rapid test and conventional ELISA are common immunological assays used for the detection of HIV infection. In this study, we evaluated the prevalence rate of HIV infection by rapid test used for screening HIV infection and then confirmed the positive cases with ELISA and western blot tests.

**Materials and Methods:** In this analytical descriptive study, 1964 out of 6923 patients who were referred to the Consult Center of Behavior Diseases, West Health Center (Valfajr Clinic), Iran University of Medical Sciences were subjected to rapid test for screening HIV infection from July 2012 to September 2014.

**Results:** Thirty seven out of 1964 (1.88%) cases were confirmed as positive by rapid HIV test. All of the positive cases confirmed by rapid test were also confirmed as positive by ELISA and western blot tests. According to the data analysis of this study, among people diagnosed as HIV positive using rapid test, 12 (32.4%) cases had unsafe heterosexual contact, followed by 10 (27%) cases of IDUs with a history of prison, shared injection, and unsafe heterosexual contact.

**Conclusion:** The use of rapid test as a screening test for diagnosing HIV infection and the confirmation of all the positive and suspected negative cases by the ELISA test or western blot is recommended.

**Keywords:** Prevalence, HIV, Rapid test, IR Iran

### 1. Background

Early understanding of human immunodeficiency virus (HIV) serostatus in patients is a critical factor for further prevention and interventional treatment of HIV infection (1).

There are different diagnostic methods for diagnosing HIV infection. Some of which detect antibody, and the other ones detect antigen or virus nucleic acid (2). We need to use methods which are based on the recognition of antigen and nucleic acids in order to be able to identify disease at its early stages when antibody is not detectable, although the isolation of nucleic acid-based methods are expensive and not available in some laboratories (3).

Enzyme Linked Immunosorbent Assay, ELISA is an easy method which can detect antigen, antibody, or both of them. This technique has been developed from the first-generation tests using viral lysate to detect immunoglobulin G (IgG), the second-generation tests using recombinant or synthetic peptide antigens, the third-generation tests that detect IgG and IgM, and finally the third-generation tests that also detect HIV-1 group O (4). Antibody is detectable between 6-12 weeks after the HIV infection using first and second-generation kits, and the time is shortened into 3-4 weeks using third-generation kits (5). The use of p24 antigen in diagnostic kits can detect the antibody about 2 weeks after the HIV infection, and the methods based on the nucleic acid assay detect the infection one week after the HIV infection (6).

Fourth-generation ELISAs have been constructed to detect anti-HIV immunoglobulin and protein p24 antigen (7). The detection of p24 antigen by ELISA is a simple and cost-effective method for diagnosing HIV infection (4).

Rapid HIV test is a simple method used for screening blood for transfusions, monitoring voluntary counseling and testing, and perinatal preventive programs. The advantages of these tests are as follow: minimal equipment requirements, immediate test results, and cost effectiveness (8); however, rapid tests have some limitations such as producing false negative results for acute HIV infection or window phase, serologically negative results and false positive results for uninfected participants injecting HIV vaccine, and infants born from HIV seropositive mothers with passive maternal antibodies (9).

Sensitivities and specificities of rapid tests are nearing to 100%; however, false positive or negative results may be occurred. In order to decrease the number of invalid results, it is better to use accessory tests in combination with rapid test (10). In 2004, CDC was recommended to approve all positive rapid HIV test results obtained using either HIV-1 Western blot or HIV-1 IFA (11), so the current strategies of rapid antibody testing suggest the use of an additional test such as detection of HIV nucleic acids, the use of western blot test, and immune assay method in order to approve positive rapid HIV test results (9).

## 2. Objective

In this study, we evaluated the prevalence rate of HIV infection by rapid test used for screening HIV infection and then confirmed the positive cases with ELISA and western blot tests among the individuals referred to the Consult Center of Behavior Diseases, West Health Center in Tehran, Iran.

## 3. Materials and Methods

In this analytical descriptive study, 6923 subjects were referred to the Consult Center of Behavior Diseases, West Health Center, Iran University of Medical Sciences from July 2012 to September 2014. During the study period, patients were referred to the clinic by a physician or referred by own to the counselors to examine rapid HIV test kits as described by World Health Organization testing guidelines (12-13).

This study was approved by the Ethics Committee of Iran University of Medical Sciences in accordance with Helsinki Declaration and guidelines.

The HIV counselors are trained in diagnostic techniques, and people who need help immediately receive basic information about the HIV screening test provided by hotline section of West Health Center during the work hours.

Individuals enrolled in this study were consisted of 1964 patients with unsafe sexual contact, intravenous drug user (IDU), sex workers, and people who had blood transfusion and tattoo or prison experience. These people were subjected to rapid HIV test for screening HIV infection if 3 months passed from these conditions.

### 3.1. Rapid HIV antibody test

Venipuncture specimens were collected in EDTA tubes, and rapid HIV test was carried out using SD BIO LINE HIV- $\frac{1}{2}$  3.0 with 100% sensitivity and 99.87% specificity, recommended by WHO, then the positive rapid tests were

approved by an additional test. All patients with positive rapid HIV test were confirmed by using DSI ELISA Screening KIT (DSI HIV-AgAb kit, Milan, Italy) according to the manufacturer's protocol, and finally, HIV Western blot was done for detecting antibodies against viral proteins like p24, gp41, gp120/160.

## 4. Results

A total of 1964 patients eligible for rapid HIV test, including 1353 male (68.9%) and 611 females (31.1%), were examined by HIV rapid test. The mean age of the sample population was 31.88. Among the risky behaviors of this group, unsafe heterosexual contact (1503, 76.5%) was more prevalent, followed by a history of prisons (472, 24%), and a history of shared injection among drug user (197, 10%).

Thirty seven out of 1964(1.88%) cases were positive in rapid HIV test, including 23 men and 14 women. The chi-square statistic was 0.7965 with a *p*-value of 0.372157, and there was not statistically significant difference between comparing groups. All of the positive cases diagnosed with rapid test were also approved to be positive by ELISA and western blotting tests.

The frequency of HIV positive cases among referral patients to consult center of behavior diseases, west health center using rapid test are shown in Fig 1. As it is observed in Figure 1, there are 12(32.4%) cases with unsafe heterosexual contact, 1 (2.7%) case with a history of unsafe homosexual contact, 1 (2.7%) case with a history of blood transfusion, 1 (2.7%) case with a history of prison and needle stick injury with a blade, 5 (13.5 %) wives diagnosed as HIV positive husband, 10 (27%) cases of IDUs with a history of prison and shared injection and unsafe heterosexual contact, 3(8.1%) cases with a history of prison and unprotected heterosexual contact, 4 (10.8%) cases of IDUs with shared injections and a history of prison,

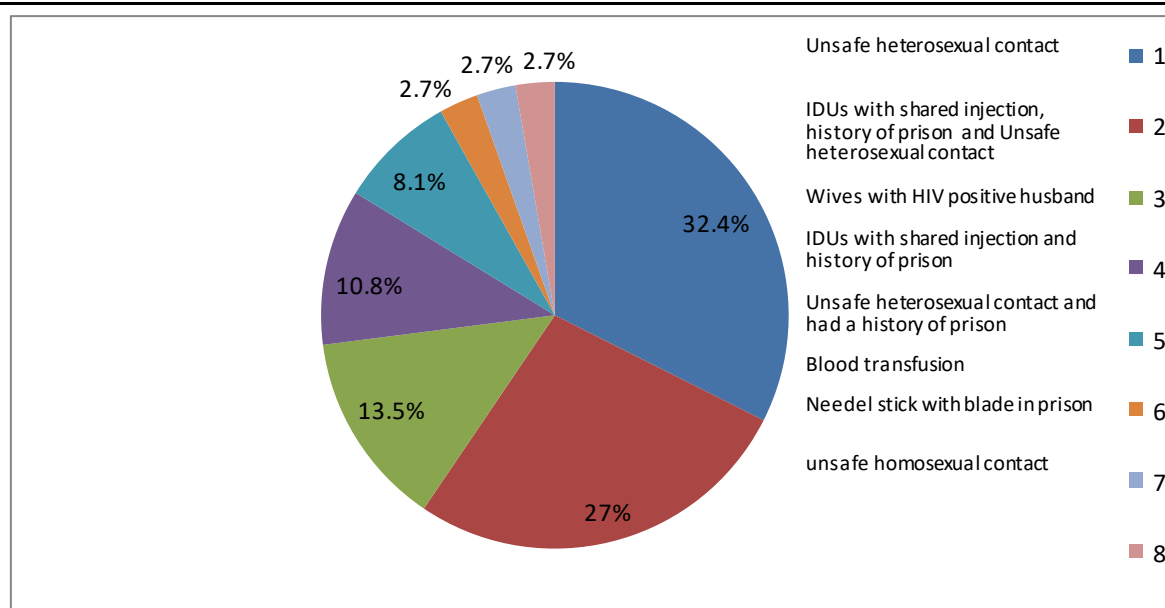


Figure 1. Frequency of HIV positive cases among referral patients to Consult Center of Behavior Diseases, West Health Center by using rapid test.

## 5. Discussion

According to the reports of Disease Management Center, Ministry of Health and Medical Education, over 69% of the HIV positive cases have been reported to be among injection drug users (IDU) (14). An important method for prevention of HIV infection is disease identification in its early stage (15). The benefits of using HIV testing services are clinical care, receiving combination antiretroviral therapy (cART), effective prevention of mother to child transmission (PMTCT) and prevention of opportunistic infections by prescribing prophylaxis antibiotics. The program provides ART for mothers to stop their infants from acquiring the virus, antenatal services including infant feeding and HIV testing during pregnancy and postnatal healthcare services (16-17).

Rapid test and conventional ELISA are common immunological assays for the detection of HIV infection, although there are differences between the results of the two methods (18). Rapid HIV-1/2 antibody based tests are the worldwide standard tests for HIV testing with high sensitivity and specificity, particularly in the developing world (9).

Some studies have shown that the performance of some rapid test to detect HIV is weaker than the ELISA, and it is likely that the actual detection of some positive cases to be lost. It's essential that the result of HIV negative rapid test be confirmed by another test. The failure of rapid test in diagnosing HIV infection may be because of inadequate coating of antigens, the nature of antigens used in some kits, and genetic heterogeneity of virus (19).

In a study, rapid test as a screening test was compared with ELISA in diagnosing HIV infection. Forty out of 787 samples evaluated by ELISA were HIV positive, all positive cases were also approved as positive by western blot, and 9 of which were reported as negative by rapid test while positive by ELISA so interpreted as false negative; also, 5 samples were positive by rapid test while negative by ELISA and regarded as false positives. The sensitivity, specificity, and negative and positive predictive values of the rapid test were 77.5, 99.3, 98.8, and 86.1%, respectively, in comparison with ELISA as the gold standard. So rapid test is insufficient as a screening assay and need to be approved by an additional test like ELISA and western blot (18).

In another study, sensitivity and specificity of rapid test in comparison with ELISA in diagnosing HIV infection was 43.33 and 56.66%, respectively, because rapid test was not able to identify 17 out of 40 HIV positive infections which were confirmed by ELISA (19).

In general, various sensitivities in different studies may be due to the nature of applied antigens and inadequacy in antigen coating in some rapid tests (19).

In our study, from a total of 1964 samples evaluated using rapid test and ELISA, 37(1.88%) cases were positive by rapid test, and all of the positive cases were also confirmed as positive by ELISA and western blot. According to the data analysis of this study among people diagnosed as HIV positive using rapid test, there were 12(32.4%) cases with the highest risk code or unsafe heterosexual contact, followed by 10 (27%) cases of IDUs with a history of prison and shared injection and unsafe heterosexual contact.

In a study, HIV prevalence rate was reported as 24.4% among male injection drug users in Tehran, Iran, and the use of an opioid in jail and older age are factors associated with HIV infection (20).

Prevalence rate of HIV-1 infection among male drug users in treatment centers in Tehran, Iran has been reported

to be 15.2%, with a history of shared injection inside the prison (21).

In another study, the difference in the abilities of rapid tests to distinguish HIV infection in recently infected individuals was taken into account (22). Regarding the different sensitivities in rapid tests, the use of different rapid HIV detection tests with high sensitivity is recommended.

Limitations of rapid test in diagnosing HIV infection should be eliminated using ELISA as a second screening assay, applying p24 antigen as another screening assay, and the confirmation of the results by western blot in order to reduce the false results.

Face to face counseling in health centers and hospitals, phone consultancy, and community education with a focus on at risk population are advised. Because of the limitations of this study in evaluating specificity, it is suggested that another study to be carried out regarding the positive and negative results of the rapid test compared with the ELISA and western blot tests.

## 6. Conclusion

The use of rapid test with high sensitivity as a screening test for diagnosing HIV infection and the confirmation of all positive and suspected negative cases by the ELISA or western blot tests is recommended.

## Conflict of interests

The authors declare that there is no conflict of interests.

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## Authors' Contributions

Mahin Jamshidi Makiani designed and supervised the study, Maryam Hosseiny- Rad prepared and supervised the study, Khadijeh Khanaliha prepared and supervised the manuscript, Sholeh Tavkoli and Samira Sohrabi performed laboratory work and analysis of study, Haleh Ahmadnia and Susan Taghizadeh were responsible for study management. All of the authors contributed in preparing the final version of manuscript.

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