Rapid Detection of HIV-1 and 2 Antibodies by using Oral Fluid: A Multicentric Pilot Study in India

Nallan CSK Chaitanya, Pinakapani R, Pavan Kumar, Rajeshwari Annigeri, G Raghu Rama Rao, A Amareswar, Veena Ramanna

Assistant Professor, Department of Oral Medicine and Radiology, Mamata Dental College and Hospital, Khammam, Andhra Pradesh, India
Reader, Department of Oral Medicine and Radiology, Genesis Institute of Dental Sciences, Ferozepur, Punjab, India
Head, Department of Oral Medicine and Radiology, GITAM Dental College and Hospital, Visakhapatnam, Andhra Pradesh, India
Head, Department of Oral Medicine and Radiology, College of Dental Sciences, Davangere, Karnataka, India
Consultant, Department of Dermatology, Visakhapatnam, Andhra Pradesh, India
Medical Officer, King George Hospital, Visakhapatnam, Andhra Pradesh, India
Manager, Department of Operations, Translational Medicine India Pvt Ltd, Bengaluru, Karnataka, India

Correspondence: Nallan CSK Chaitanya, Assistant Professor, Department of Oral Medicine and Radiology, Mamata Dental College and Hospital, Khammam-577004, Andhra Pradesh, India, e-mail: nallanchaitanya@gmail.com

ABSTRACT

Introduction: Detection of HIV antibodies is done by the standard blood tests. Rapid tests provide results in few minutes. The OraQuick rapid HIV1/2 antibody test using oral fluid has not been tried in resource-limited settings in India. The aim was to evaluate the efficacy of the OraQuick test kit using oral fluid for HIV antibody detection in patients attending the dental hospitals.

Materials and methods: This multicentric pilot study was administered on 134 consenting subjects. Seventy subjects were randomly screened at Visakhapatnam and 64 at Davangere, by OraQuick test using oral fluid and other standard HIV screening tests. The subjects and the test administrators were enquired regarding the convenience of the oral fluid test and blood tests. The results were compared and conclusions were drawn.

Results: Seventy subjects were positive with both oral fluid and blood tests. Sixty-four subjects were negative with both the tests demonstrating 100% sensitivity and specificity. The oral fluid test was well accepted by all patients and test administrators.

Conclusion: Our study revealed that the OraQuick test using oral fluid was found to be highly accurate, noninvasive screening test which can be easily used in dental hospitals.

Keywords: HIV screening, Oral fluid, OraQuick test, Blood tests.

INTRODUCTION

Human immunodeficiency virus type 1 and 2 are the etiological agents of AIDS. A global summary of AIDS epidemic by WHO in 2008, estimated 33.4 (31.1 to 35.8) million people are living with HIV-1 worldwide, while about 2 million have already died in 2008. There could be still unknown, undiagnosed cases probably living with HIV virus. These estimates may mask the dynamic nature of this evolving epidemic in relation to temporal changes, geographic distribution, magnitude, viral diversity and mode of transmission.

The demographic features of spread of HIV in Asia are different from elsewhere. India stands second in the world with respect to people living with HIV. UN estimates project that India’s adult HIV prevalence will peak at 1.9% in 2019. About 2.3 million people are living with HIV infection by 2007. There is a declining trend in the epidemic in South Indian states.

The early detection assumes paramount importance at the present scenario. Diagnosis of HIV infection is based on the detection of specific antibodies, antigens or both. Serological tests are employed for the screening purposes.

The CDC recommends that diagnostic HIV testing and opt out HIV screening be a part of routine clinical care in all health care settings, while maintaining the individual concerned for not opting the testing for optimal clinical and preventive care.

Technological advances in the diagnosis of HIV infection provide the clinicians with greater opportunities to reduce HIV transmission rates. It estimates that increased awareness of serological status will decrease the number of new infections mainly by behavior modification of HIV-positive people and treatment that decreases viral loading in infected individuals.

To date, only traditional ELISA was available for detection of anti-HIV antibodies in serum. Overtime there have been improvements of performance of ELISAs from usage of viral lysates to usage of recombinant antigens, synthetic peptides or combination of these both. This has led to better sensitivity and specificity of these assays. The ELISA more recently has
been employed to detect HIV antibodies in whole blood, urine and salivary samples too. The Westernblot remains the gold standard in HIV antibody confirmation.12-14

The ELISA and Westernblot produce final results in 1 to 2 weeks. This is identified as ‘weak link in the chain’ of screening programs for HIV. This is more detrimental in case of pregnant women with late or no prenatal care. The chances of unavailability of patient to receive the results are also high.9

With the introduction of rapid HIV tests since 1992, by FDA, the above situation is slowly transforming. In 2002, FDA approved OraQuick rapid HIV-1 antibody test (OraSure Technologies Inc, Philadelphia, USA) for whole blood. It can also be used for oral fluids and serum.7,9,15-19

Oral rapid point of care HIV tests score over blood tests in their quality, rapidity, convenience, ease of sample collection and feasibility15. While these aspects were tested elsewhere, there is no known data from the dental set-up in India. We, hereby, report the results of oral fluid based OraQuick® HIV I and II antibody test on the cross section of South Indian population.

MATERIALS AND METHODS

The present multicentric study was conducted in Chegateri Government Hospital and Gitam Dental College and Hospital, between September 2009 and February 2010 in collaboration with College of Dental Sciences and Elizabeth Glaser Pediatric AIDS Foundation Project, Davangere. Various nongovernmental organizations working with HIV patient care in Visakhapatnam had directed randomly selected patients to Gitam Dental College and Hospital. Ethical clearance was obtained from the respective testing centers. A total of 134 patients were included in the study, with 70 patients at Visakhapatnam and 64 at Davangere centers. After appropriate counseling at both the centers and with written consent from all the subjects, preliminary test using OraQuick® rapid HIV I and II antibody test on the cross section of South Indian population.

RESULTS

The mean age of the study population with both males and females was 21 years and they were in the range of 17 to 60 years. Out of 134 subjects, 57% were females and 43% were males. Most of them (90%) were daily-wage workers (Table 1).

Fifty-two percent presented with signs and symptoms of HIV infection and the population groups assessed were of low-risk group. None of the participants were trusted for HIV infection in the past.

With the reference test results, the clinical staging was also attributed to each HIV-positive patient. Fifty-one percent belonged to stage I illness as per WHO criteria. Twenty-five percent and 21% belonged to stage II and III illness respectively, with least being stage IV of just 1% (Table 2).

All 134 patients tested by OraQuick test using oral fluid, reported to be convenient when compared to 32 patients (23%) who were apprehensive with the blood test involving the needle prick. Thus, there is 100% acceptability of OraQuick test using oral fluid.

The OraQuick test results were obtained within 20 to 40 minutes, while the EIA comb/Tri-dot/Combaids®-RS Advantage-ST test results using blood were available within 2 days. The test results by Lifeline-InTec® rapid test using whole blood was also obtained within 10 to 15 minutes. None of the test results showed ‘invalid’ results.

### Table 1: The percentage distribution of gender involved in the study

<table>
<thead>
<tr>
<th>Sex</th>
<th>Frequency</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>76</td>
<td>56.7</td>
</tr>
<tr>
<td>Male</td>
<td>58</td>
<td>43.2</td>
</tr>
<tr>
<td>Total</td>
<td>134</td>
<td>100.0</td>
</tr>
</tbody>
</table>

### Table 2: The percentage distribution of the HIV patients categorized under clinical staging

<table>
<thead>
<tr>
<th>Clinical stages</th>
<th>Frequency</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>36</td>
<td>51.4</td>
</tr>
<tr>
<td>II</td>
<td>18</td>
<td>25.7</td>
</tr>
<tr>
<td>III</td>
<td>15</td>
<td>21.4</td>
</tr>
<tr>
<td>IV</td>
<td>1</td>
<td>1.4</td>
</tr>
<tr>
<td>Total</td>
<td>70</td>
<td>100.0</td>
</tr>
</tbody>
</table>
The OraQuick oral fluid based test had sensitivity, specificity, the positive and negative predictive values were 100% (Table 3).

None of the test samples had shown false-positive and false-negative results when compared with the reference tests.

**DISCUSSION**

Rapid point of care HIV tests greatly aid in knowing sero-status by providing faster and accurate results in minutes. This can be used in areas with limited laboratory resources and they provide convenience in testing on site results by allowing the delivery of definite negative or provisional reactive results greatly enhancing interventional programs.

There are rapid HIV tests using oral fluid and whole blood. The efficacy of these tests has been evaluated individually and also by comparing both the tests.

In the present study, the OraQuick test demonstrated high sensitivity and specificity of 100% with oral fluid specimens as claimed by the manufacturer. These findings are in accordance with a previous study done in rural population in India, although there were conflicting reports of lower sensitivity and specificity of oral fluid-based tests elsewhere with high incidence of false-positive and false-negative results.

As depicted in our study, the OraQuick test using oral fluid seemed to be of patient’s preference than the blood-based test as it was a painless, simple and noninvasive procedure. This was also the test administrator’s preference over the conventional blood-based tests as it was rapid, safe with least occupational exposures, easier sample collection and simple to perform.

The test offers an immense benefit in pregnant patients without prenatal care and also in case of occupational exposures.

Dentists and emergency care providers are most commonly prone for infections from contact with patient’s blood and oral fluids. Due to lack of adequate sterilization measures and detection facilities, there is a greater chance of not only acquiring infection but also spreading it among other patients unwittingly.

Thus, incorporating this simple to perform test kit, using noninvasive means, can greatly reduce the risk of transmitting the infection.

There is a more recent study on this oral fluid-based test kit which demonstrated its utility for detecting infections due to HIV-1 subtypes and recombinants.

Although the present study demonstrated the usefulness of the oral fluid-based OraQuick® rapid HIV-1 and 2 antibody test, the disadvantage lies in its inability to specify whether the sample contained HIV-1 or HIV-2 antibodies specifically, HIV-2 being less prevalent than HIV-1.

We also stress the need for confirmation of the serological status of the patient using Westernblot, if found seropositive with this oral fluid-based HIV antibody detection test.

We conclude that this test kit is efficacious as an effective screening device of HIV antibody detection; further studies are warranted in larger group of population involving the dental set-up, emergency care units, pregnant patients and high-risk groups directed at its diagnostic accuracy and to introduce it as a routine office screening procedure.

**ACKNOWLEDGMENT**

We profoundly thank the subjects who had participated in the study. We would like to thank our technicians for their support. We thank OraSure technologies, Mr Quoc Pham for his constant support and for supplying the kits. We also thank Dr Prema, Dr Gangadhar Prasad and Dr Phanender Ketha for their inputs in the study. Our friends, Dr Rajanikanth and Dr Venkat Reddy need special mention for staying with us all through the study. The study has not been funded by any organization or individual.

**REFERENCES**


