

Selected Summaries

Oral fluid-based rapid HIV 1/2 antibody test

Pant Pai N, Joshi R, Dogra S, Taksande B, Kalantri SP, Pai M, Narang P, Tulsy JP, Reingold AL. (Immunodeficiency Service, Montreal Chest Institute, McGill University Health Centre, Montreal, Canada; Mahatma Gandhi Institute of Medical Sciences, Sewagram, Maharashtra, India; Acharya Shri Chander College of Medical Sciences, Jammu, India; Department of Epidemiology, Biostatistics and Occupational Health, McGill University, Montreal, Canada; Department of Internal Medicine, University of California at San Francisco, San Francisco, California, USA; Division of Epidemiology, University of California at Berkeley, Berkeley, California, USA.) Evaluation of diagnostic accuracy, feasibility, and client preference for rapid oral fluid-based diagnosis of HIV infection in rural India. *PLoS ONE* 2007;2:e367.

SUMMARY

This cross-sectional, hospital-based study was done on 450 patients to evaluate the diagnostic accuracy, feasibility and client preference for a rapid, oral fluid-based diagnostic test for HIV infection in rural India. The OraQuick rapid HIV 1/2 test was used to test oral fluid and finger-stick blood. Parallel testing with ELISA and western blot was done for confirmation. Pre- and post-test counselling and face-to-face interviews were conducted to determine client preference. One hundred forty-six participants were deemed to be seropositive for HIV (a seropositivity rate of 32%). The OraQuick rapid HIV 1/2 test was found to perform better on oral fluid specimens, with a sensitivity of 100% (95% CI: 98–100) and a specificity of 100% (95% CI: 99–100), as compared with testing of finger-stick blood samples, which had a sensitivity of 100% (95% CI: 98–100) and a specificity of 99.7% (95% CI: 98.4–99.9). Client preference for the modality of HIV testing was evaluated using face-to-face interviews after testing on oral, finger-stick and venepuncture specimens. The oral fluid-based test was preferred by 87% of participants for first-time testing and by 60% of participants for retesting.

COMMENT

The HIV epidemic has been particularly explosive in India. As of August 2006, the National AIDS Control Organization (NACO) reported 124 995 cases of AIDS in India.¹ The UNAIDS report on the global AIDS epidemic states that India has 5 700 000 people living with HIV/AIDS.²

Rapid, point-of-care HIV testing remains an important component of HIV control initiatives and programmes. In resource-constrained settings as in rural India, a non-invasive, simple, rapid test has the potential to make a major impact on HIV screening programmes. Such a test opens up the possibility of home-based HIV testing, which would drastically reduce the manpower costs associated with screening programmes. It would also have the potential to provide personal privacy during testing, and thus possibly shield seropositive individuals from likely social ostracism.

This study examined the OraQuick Rapid HIV 1/2 test, a rapid test that can be done with oral fluid, finger-stick blood as well as whole blood and plasma obtained by venepuncture. The aims were:

1. To evaluate the diagnostic accuracy of the test
2. To determine if subjects would prefer this method
3. To ascertain if this would be a feasible modality of testing for HIV in rural and resource-constrained settings.

Recruitment of participants was done from patients attending the Internal Medicine and Sexually Transmitted Disease clinics. It was based on inclusion criteria that were dependent on presenting symptoms suggestive of HIV infection and the presence of risk factors. The sampling was based on convenience. The participants were initially tested with one OraQuick oral fluid test, one OraQuick finger-stick test and an ELISA. If the ELISA was reactive, a second ELISA, followed by a western blot test were done on the sample. The technician doing the ELISA and western blot tests was blinded to the OraQuick oral fluid and finger-stick tests. Had logistics permitted, blinding of the person doing the Oraquick oral fluid test with the OraQuick finger-stick test might have added more strength to the study.

While the OraQuick oral fluid test had a 100% specificity and sensitivity in this study, the OraQuick finger-stick test had a sensitivity of 100% and a specificity of 99.7%, with one false-positive test. Previous studies reported sensitivities ranging from 75% to 100%, and specificities ranging from 99.9% to 100%.^{3–6} The wide variation in sensitivity can be partly explained by the fact that these studies had participants from other settings, for example, pregnant women and patients from emergency departments and correctional facilities. On the other hand, given that these studies had sample sizes ranging from 1258 to 135 724 participants, which were larger than that of the current study, it is possible that their results reflect a wider spectrum of factors influencing the test. In addition, the authors of this study state that they have used a new and improved OraQuick rapid HIV 1/2 test. They do not mention what the improvements are. It is probable that some, or all, of the previous studies used a different version of the test, and this might explain some of the differences in diagnostic accuracy.

In this study, the participants had an 87% preference for the oral fluid-based test for initial testing, while only 60% preferred it for repeat testing. Though this level of client preference is the highest as compared with previous studies,^{7,8} it is not clear why 13% of the participants did not prefer the test for initial testing and 40% for retesting. Details of the reasons would help understand factors influencing client preferences in different cultures.

The term 'oral fluid' requires some clarification, and so does the methodology of collection of the sample. Oral fluid is not saliva. It is fluid present in the oral cavity, which is like a plasma transudate, and has a high concentration of IgG. The sample is collected by gently swabbing the absorbent pad (attached to the kit) around the gingival capillary margin. This allows the oral fluid to soak the pad, after which it is put into the test solution provided with the kit. It works as a lateral flow immunoassay, showing a visible colour change in the test area, if the test is positive.

On the whole, this study is well designed and ably conducted. It addresses a felt need, given the rate of HIV seroconversion in India. The participants were chosen from a rural area—this is important because the utility of OraQuick tests would be very high in resource-constrained rural areas. This test performed well in a

population with a high pretest prevalence of HIV infection and it would be worthwhile to explore its potential for use as a home-based test in such a population. Further studies would also be needed to look at the performance of the oral fluid-based test if it is done by the clients themselves.

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