Oral rapid test: an alternative to traditional HIV screening in Chile

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Suggested citation Irarrazábal LP, Ferrer L, Cianelli R, Lara L, Reed R, Levy J, et al. Oral rapid test: an alternative to traditional HIV screening in Chile. Rev Panam Salud Publica. 2013;33(6):427–32.

ABSTRACT

Objective. *To compare the sensitivity and specificity of an Oral Rapid Test (ORT) to that of the Enzyme-Linked Immunosorbent Assay (ELISA) for HIV testing in Santiago, Chile; to track the number of study participants returning for ELISA testing results; and to analyze the participants' perceptions of the ORT compared to the ELISA.*

Methods. *A total of 497 people were recruited in Santiago, Chile: 153 had previously tested positive for HIV, and 344 were of unknown status. Participants were tested for HIV using both the ELISA and the ORT to examine and compare specificity and sensitivity. Qualitative data were collected from 22 participants to compare perceptions of the testing experience with ORT versus ELISA.*

Results. *The ELISA reported 184 (37%) of the 497 participants as being "positive" for HIV antibodies; the ORT showed 181 (36.4%) as being "reactive" for HIV. The ORT showed a sensitivity of 98.4% (95.7%–99.9%, 95% Confidence Interval) and specificity of 100%. The Kappa test produced K = 0.983 (*$P < 0.0001$*). Of the 344 participants whose HIV status was unknown at the start of the study, 55 failed to return for their ELISA results. Participants positively perceived ORT as having reduced both waiting time and anxiety over obtaining their test results. ORT oral swabbing appeared more practical and less invasive than drawing blood for the ELISA.*

Conclusions. *The ORT and ELISA were statistically equal in specificity and sensitivity. ORT provides quicker results, potentially ensuring that more people receive them, and does not require handling of or exposure to potentially hazardous blood products.*

Trial number ClinicalTrials.gov identifier: NCT01733927.

Key words HIV infections, diagnosis; AIDS serodiagnosis; HIV seroprevalence; clinical laboratory techniques; disease prevention; Chile.

Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome (HIV/AIDS) continues to be one of the most devastating worldwide pandemics. The latest United Nations Global Report (1) indicates that in 2010 a total of 33.3 million people were living with HIV, and of these, 2.6 million were new cases. Of the Latin American countries, Chile historically has had one of the lowest HIV prevalence rates (2). Unfortunately, since 1991 the country has seen an increase of notified cases of HIV/AIDS in certain areas such as Arica, Metropolitana, Parinacota, Tarapaca, and Valparaiso (3). Currently, Chile has an annual HIV rate of 6.0 cases per 100 000 inhabitants and an annual AIDS rate of 5.1 per 100 000 inhabitants (3). The metropolitan area in which Santiago is located has one of the highest rates in the country with 25.1 per 100 000 inhabitants (4).

In response to the AIDS epidemic, in 2010 the Joint United Nations Program on HIV/AIDS (UNAIDS) urged countries to increase the number of people who know their HIV status, thereby potentially reducing HIV transmission and increasing treatment (1). An effective

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country response is to increase voluntary testing and counseling, particularly among at-risk populations (3). Ensuring that patients receive their test results is essential to these efforts.

While the Chilean government offers free screening for HIV using the Enzyme-Linked Immunosorbent Assay (ELISA) (4), accurate reports on the rates of HIV testing are unavailable in Chile (5). In addition, many Chileans fail to return for their test results, as do other individuals worldwide (6). Data from 2004–2008 in Chile, combining statistics from both private and public sectors (7), documented that 104 (10%) of 4 043 people who tested HIV-positive failed to return for their results. Due to a lack of information, ascertaining if another 415 people with a positive test received their results during the study period was impossible (6). In the United States, the Center for Disease Control and Prevention (Atlanta, Georgia, United States; CDC) reported that when using the "gold standard of HIV testing" (the ELISA), 30% of people with negative results and 39% of people with positive results did not return for their test results (8).

In many countries, the use of rapid testing technology instead of the traditional ELISA to identify HIV 1 and 2 has increased the percentage of people who are aware of their serological status (8–11). Granted, neither the rapid testing nor ELISA yield a definitive diagnosis; further confirmation testing with the Western Blot is required to rule out false-positive results (12). Nonetheless, by providing quick turn-around, rapid testing helps to increase the probability that those with a positive result will be quickly referred to appropriate health services for confirmatory testing and treatment.

The United States Food and Drug Administration (Silver Spring, Maryland, United States; FDA) currently has approved six different rapid tests to clinically detect HIV 1 and 2. However, only one of these is an Oral Rapid Test (ORT): OraQuick® ADVANCE Rapid HIV-1/2 Antibody Test (OraSure Technologies Inc., Bethlehem, Pennsylvania, United States). Examination of pooled results from a systematic review and meta-analysis of the scientific literature showed the sensitivity of ORT to be 98.03% with oral samples, compared to 99.68% using blood. The specificity of the tests was statistically the same at 99.74% for oral samples and 99.91% for blood (13). The ORT presents a competitive edge to the gold standard of ELISA testing by permitting simpler administration without exposure to hazardous blood products. The ORT merely requires a single swab of oral mucosa between gums and teeth using a testing device resembling a lollypop stick. The testing device is inserted into a manufacture-supplied buffer; results are available in 20–40 minutes as either nonreactive (HIV-negative) or reactive (HIV-positive).

In addition to decreasing clients' time spent waiting for results and removing the need to handle blood samples, ORT testing can be conducted in geographic locations where ELISA-capable laboratory facilities are unavailable. Thus, HIV screening programs that adopt ORT can extend their reach far beyond previous locations.

Despite ORT's growing success and popularity in many different settings globally (11, 14–20), Chile has yet to accept ORT as a viable alternative to ELISA testing. According to Carlos Pérez, a Chilean physician and specialist in infectious diseases at the Pontificia Universidad Católica de Chile, Rapid HIV diagnostic testing using blood samples is available in Chile for urgent situations, such as during childbirth, but rapid testing has not been approved by the Public Health Institute of Chile for standard screening (personal communication, 28 February 2013) (21). The Government of Chile has delayed approval of ORT adoption pending additional evidence that it offers advantages over the ELISA, with equal specificity. Of concern is that at least one study conducted in the United States saw increased false-negative results using ORT, though this affected less than 1% of the total results (13). The Institute of Public Health in Chile, which is responsible for ORT approval, has requested further research into the efficacy and efficiency of ORT versus the ELISA.

This study, conducted in Santiago, Chile, was designed to compare the sensitivity and specificity of ORT to that of the ELISA; to track the number of study participants that returned for their ELISA results; and to analyze perceptions among participants of ORT compared to ELISA testing for HIV screening.

MATERIAL AND METHODS

This was a mixed-method, cross-sectional study. Quantitative analysis of results from 497 participants compared the sensitivity and specificity of ORT to the ELISA in screening for HIV. Focus groups and semi-structured interviews with a subsample of 22 participants examined participants' perceptions of ORT compared to ELISA testing. The Institutional Review Board of the Nursing and Medical Schools of the Pontificia Universidad Católica de Chile (Santiago, Chile; PUC) approved the study for the protection of human subjects.

Recruitment and sampling

A convenience sample was recruited from two outpatient centers in the PUC Health Network and two nongovernmental organizations (NGO) in the Chilean capital of Santiago. The city has a population of 6 061 185, with a national HIV prevalence of 0.4% among individuals 15–49 years of age; 20.3% among males who have sex with males (5); and 2.3% HIV/AIDS cases per 1 000 habitants (2).

Sample size was statistically powered to assume a recommended testing sensitivity and specificity of approximately 98% (22). With a 2-point percentage margin of error and a 95% Confidence Interval (95%CI), a total sample of at least 376 individuals (188 HIV-positive and 188 HIV-negative) was estimated to be needed. Overall, 497 people participated in the study, of which 119 (34%) were recruited from the PUC Network and 378 (66%) through the NGOs.

The sample was recruited in two groups. Group 1 consisted of 344 participants of unknown HIV status; Group 2 consisted of 153 participants previously confirmed with a Western Blot test to be HIV-positive. Both serostatuses are needed to compare test specificity. Study participants had to be at least 18 years of age and either seeking ELISA testing to learn their HIV status (Group 1) or had been confirmed HIV-positive through Western Blot testing and were not currently on antiretroviral medication (Group 2).

In recruiting Group 1, laboratory staff members invited clients who had just completed HIV counseling and had provided a blood sample (for ELISA)

to participate. Those possibly interested were encouraged to go directly to nearby research staff who provided more detailed information and enrolled those willing to participate.

For Group 2, either a PUC health care provider or one of the NGOs recruited participants. Group 2 included a subset of 47 individuals who had tested HIV positive in an initial pilot study conducted by the senior author using the same inclusion criteria and research procedures as this study at one of the current participating sites. Snowball sampling was used to recruit additional Group 2 members by asking research participants to invite friends living with HIV to join the study and be ORT tested.

Qualitative subsample

Using convenience sampling, 22 participants were recruited using the ORT consenting process described above. Of the 22 participants, 6 participated in direct interviews while the remaining 16 were divided into two focus groups of 8 participants each. Recruitment for interviews and focus group sessions continued until data saturation was achieved. Both the interviews and focus groups were conducted at the health care clinic where participants were tested.

ORT consent form procedure

During the recruitment process, participants were informed about the nature of the test, the length of time for results, and what procedures would be involved in self-administering the ORT. Each participant provided written, informed consent for ORT testing and their ELISA results to be made available to the researchers. Also, participants could indicate if they were interested in being contacted at a later date to participate in a focus group discussion or interview about their testing experience and perceptions of both tests. They also were advised that their ELISA test results would be available within a specified time; whereas, results from the ORT would not be disclosed since the test was still in the experimental phase in Chile.

ORT testing procedures

Research team members were trained and certified in administering the ORT through the World Health Care Infrastructure and AIDS International Consortium (Philadelphia, Pennsylvania, United States). After being instructed according to the manufacturer's directions, participants demonstrated their ability to properly take an ORT sample using a popsicle stick as a proxy for the testing device. If practiced successfully, they were instructed to obtain their own oral fluid sample under staff supervision using the testing device in the ORT kit. Following testing, participants were thanked and compensated with $2 000 Chilean Pesos (approximately US$ 4) for their time.

Project team members, certified to interpret ORT results, registered each test outcome on a data form using the same anonymous code number that the participant was assigned for the ELISA test. To protect patient privacy, only certain clinic employees who also read the ELISA test results had access to the confidential information linking the code to the participant.

Statistical analysis

Performance of the ORT for HIV detection was assessed by directly comparing its results with that of the ELISA. The *sensitivity* of the test was obtained by comparing the positive results of the ORT test to the positive results of the ELISA (proportion of true positives identified by the test). The concordance between results was used to identify the level of sensitivity of the rapid test. *Specificity* refers to the concordance of each test in relation to true negatives (proportion of the true negatives identified by the test). Bayes Theorem calculations were used to estimate positive and negative predictive values, based on the sensitivity, specificity, and an estimate of HIV prevalence in Chile. In addition, a descriptive statistical analysis and Kappa test using the statistical packet PAWS18 also were conducted. A margin of error of 2 percentage points was assumed with 95%CI.

In contradictory cases, where the ELISA test indicated a positive result and the ORT test showed negative, a Western Blot test was performed. When the ELISA was negative and the ORT positive, the result yielded by the ELISA test was considered the Gold Standard.

Qualitative analysis

Data gathered from the interviews and focus groups were transcribed *verbatim* and entered into the Non-numerical Unstructured Data Indexing Searching & Theorizing (NUD*IST) software program (QSR International, Melbourne, Australia). Using content analysis, a coding sheet was developed to help identify emerging themes based on participants' perception of their experience with ORT versus ELISA. Bracketing and member check were used to improve the accuracy, credibility, and validity of the findings.

RESULTS

The mean age of the participants was 31.36 ± 11 years old; males (409) greatly outnumbered females (88). Based on the Chilean Institute of Public Health's recommendations for validating a rapid test, the ORT results were directly compared to the matching results of the ELISA test. The following outcomes resulted: the ELISA reported 184 (37%) of the 497 participants as "positive" for HIV antibodies, and the ORT showed 181 (36.4%) as "reactive" for HIV (Table 1). No statistically significant discrepancies existed between the two tests. Meanwhile, comparison of the negative and nonreactive results of the two tests initially revealed 3 cases for which test

TABLE 1. Contingency tests comparing results for the Enzyme-Linked Immunosorbent Assay (ELISA) and Oral Rapid Test (ORT) for HIV (*n* = 497), Santiago, Chile, 2011

	ELISA test results					
	Positive		Negative		Total	
ORT results	No.	%	No.	%	No.	%
Reactive	181	98.4	0	0	181	36.4
Non-reactive	3	1.6	313	100.0	316	63.6
Total	184	100.0	313	100.0	497	100.0

outcomes did not match. Thus, results for the ORT showed a sensitivity of 98.4% (95.7%–99.9%, 95%CI) and specificity of 100%, versus the ELISA with sensitivity and specificity of 99%.

Of the 344 participants who reported unknown HIV status, 55 (16%) failed to return for their ELISA results. Assuming that all study participants would have received their ORT results if they had been made available at the testing, the Wilcoxon test analysis provided a statistically-significant difference in receiving results ($P < 0.05$). Moreover, the correlation measure with the Kappa test was K = 0.983, and was significant with $P < 0.0001$.

In terms of acceptability, participants in the interview sessions identified three perceived advantages of the ORT over the ELISA. First, ORT offered quicker access to test results. Participants mentioned that the waiting time with the ELISA was long and could be emotionally stressful. The ORT was perceived as the more psychosocially positive, obtaining—its results only required about 20 minutes. As one participant explained:

> I think [the ORT] is a good idea because of the fact that it delivers a faster result. Also, there's anxiety with the ELISA test because it takes a week, or a couple of weeks, for the result. The fact that [ORT] is something instant, just 15 or 20 minutes, is a plus.

The second perceived advantage was that ORT swabbing appeared less physically invasive than the blood-draw required for ELISA testing. As one participant observed,

> . . .you have to take a number [to take the ELISA], you have to administer the test [ELISA], then there is the issue of sting and pain [drawing blood].

The third perceived advantage of the ORT was that it appeared more practical to administer than the ELISA. Participants appreciated the increased access and availability of being able to simply orally swab:

> [The ORT] by design is much more practical, easy enough for anyone to use, it doesn't have to be done by. . .someone who is a health expert.

Not all comments about ORT were positive. Some participants questioned the validity of its results in comparison to the ELISA:

> The issue here is that it is so easy to take it [ORT] and this may cause a bit of distrust in the final results, or maybe the test can be manipulated, or maybe the results will vary, but as a screening test I think it can be a valid test to take.

Possibly, as this participant's words suggest, the ease with which the ORT is administered may undermine confidence in its results. Also, as another participant explained, "I do not know if it's just something in my head, but for me, it's always going to seem that blood is going to be more valid."

DISCUSSION

Comparing matched results from both tests showed that the ORT identified true HIV-negative patients with a specificity of 100% and a sensitivity of 98.4%. This outcome echoes comparison studies, one by the FDA (22) and another by the manufacturer of ORT in collaboration the CDC (8), which both show a sensitivity of 99.3% and specificity of 99.8%.

As a word of caution, care should be taken when using HIV rapid testing in populations with a lower prevalence than Chile's, due to the increased likelihood of obtaining false positive results (13, 23). In low-prevalence countries, when a positive result is obtained through rapid testing, an immediate finger-prick test followed by a confirmatory Western blot test is recommended (24). According to the World Health Organization (WHO), the decision on whether to use blood or oral testing should be made according to the advantages each can provide to the population and the logistics of its screening needs (25, 26).

Findings from this study lend evidence to substantiate that the ORT is equal in specificity to the ELISA in screening for HIV in the Chilean population. Despite their advantages in providing initial screening, both the ELISA and ORT must be followed with confirmatory Western Blot testing prior to a definitive diagnosis of HIV.

HIV testing programs commonly encounter participants who fail to return after ELISA testing to learn their status. Of the 344 participants of unknown status in this study, 55 (16%) did not return for their ELISA results. This finding coincides with data on HIV testing available from the Ministry of Health in Chile (7). Assuming that most of those, if not all, who take the ORT learn their results in the same visit, there would be a substantial, national increase in the number of individuals who know their HIV status. Also, the number of HIV-positive cases referred for appropriate care would likely increase while possibly decreasing the frequency of transmission.

As study participants and others noted (27), the ORT provides HIV results within 20–40 minutes of being swabbed. This quick turn-around can greatly reduce the associated stress and anxiety of waiting. Moreover, the ORT is noninvasive and painless when compared to the blood draw required for the ELISA. Both the rapidity of obtaining ORT results and its relatively benign specimen collection may encourage more people at risk to seek HIV testing and referral to services if needed (19, 27–29).

The ORT also can be performed by a finger-prick (drop of blood) with 99.3% sensitivity. Use of the finger-prick method possibly could increase confidence in HIV rapid testing technology among those who perceive blood as a medium superior to mucosal swabs (16). The oral swabbing method was selected for this study because of the advantages of not requiring staff trained to handle blood and being noninvasive (30); however, the ORT finger-prick may prove to be the better choice with some clients.

Study limitations

Comparison of the two types of testing was conducted under experimental conditions. As a WHO report (18) observes, test outcomes for both rapid testing and the ELISA may show lesser sensitivity and specificity when used in low-resource settings or administered by untrained staff (20). Translational research using the test in nonexperimental practice settings is needed to provide guidelines that would help to ensure that both tests perform well when used in resource-restricted environments.

Conclusions

These study results provide much needed information on the potential use of ORT, which could help to inform social policy debates and decisions in

Chile and other countries. As a diagnostic screening tool, ORT proved to statistically meet the ELISA's high standards of specificity and sensitivity in HIV screening. Also, the qualitative data suggests that Chilean clients possibly perceive the ORT as a more feasible and acceptable HIV screening method than the ELISA. Among its advantages, the ORT can be administered in locations without specialized laboratories or staff; the wait time for obtaining results is considerably shorter; and the test itself is relatively noninvasive when compared to the ELISA. Although evaluations of various rapid HIV tests show that they perform well under research conditions (15), their performance may lessen when adopted for use in low-resource countries with inadequately trained staff, poor laboratory infrastructure, and weak quality assurance programs (26). WHO recommends a three-step performance evaluation for use in resource-limited settings to ensure that rapid tests function as demonstrated under more optimal experimental conditions and also when used in countries where great HIV-1 genetic diversity exists (18).

In sum, the ORT technology holds great promise for increasing the number of people who seek testing, and subsequently, learn their HIV status. For these reasons, UNAIDS recommends its use (1). The findings from this study support its adoption for use in the Chilean government's HIV screening system, including in primary health care clinics and in mass campaigns. Increased awareness of HIV status could result in reduced virus transmission, thereby helping to curb the epidemic in Chile.

Acknowledgements. This research was funded by the 2009 Interdisciplinary Research Special Contest of the Faculty of Medicine, Pontificia Universidad Católica de Chile (PUC; Santiago, Chile). The authors wish to thank the clinical nurses at PUC Clinics and the NGO staff who made this project possible. Also, the senior author received support in preparing this manuscript and advisory assistance from the United States National Institutes of Health-funded Chicago Developmental Center for AIDS Research (P30 AI 082151).

Additional support in preparing the manuscript for publication was provided by the Chicago Developmental Center for AIDS Research (Chicago, Illinois, United States), which is funded by the United States National Institute of Health (P30 AI 082151; Bethesda, Maryland, United States) and through the principal author's doctoral traineeship from the Fogarty AIDS International Training and Research Program at the University of Illinois at Chicago (5D43TW001419-12; Chicago, Illinois, United States).

Finally, a special thank you to Natalia Villegas and Luis Villarroel who participated as external reviewers.

Conflict of interest. None declared by the authors.

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Manuscript received on 29 August 2012. Revised version accepted for publication on 12 March 2013.

RESUMEN

Prueba oral rápida: una alternativa al tamizaje tradicional del VIH en Chile

Objetivo. Comparar la sensibilidad y la especificidad de una prueba oral rápida con las del análisis de inmunoadsorción enzimática (ELISA) para la detección del VIH en Santiago de Chile, Chile; hacer un seguimiento del número de participantes en el estudio que regresan para saber los resultados del ELISA; y analizar las percepciones de los participantes con relación a la prueba oral rápida en comparación con el ELISA.

Métodos. Se incluyeron 497 personas en Santiago de Chile: 153 tenían resultados positivos para el VIH, y la situación de las restantes 344 era desconocida. Se sometió a los participantes a pruebas de detección del VIH tanto mediante el ELISA como mediante la prueba oral rápida, con objeto de analizar y comparar la especificidad y la sensibilidad. Se recopilaron datos cualitativos de 22 participantes para comparar sus impresiones con relación a la experiencia de someterse a la prueba oral rápida en comparación con el ELISA.

Resultados. Mediante el ELISA se notificó que 184 de los 497 participantes (37%) obtuvieron un resultado "positivo" en las pruebas de detección de anticuerpos contra el VIH; mediante la prueba oral rápida 181 participantes (36,4%) fueron "reactivos" para el VIH. Esta prueba demostró una sensibilidad de 98,4% (intervalo de confianza de 95%: 95,7–99,9%) y una especificidad de 100%. El coeficiente kappa (K) fue de 0,983 ($P < 0,0001$). De los 344 participantes cuyo estado con respecto a la infección por el VIH era desconocido al comienzo del estudio, 55 no regresaron para conocer los resultados del ELISA. Los participantes percibieron positivamente la prueba oral rápida debido al período de espera más breve y la reducción de la ansiedad por conocer los resultados de la prueba. La obtención de una muestra oral mediante hisopo resultó más práctica y menos invasora que la extracción de sangre necesaria para llevar a cabo un ELISA.

Conclusiones. La prueba oral rápida y el ELISA se mostraron estadísticamente equivalentes en cuanto a especificidad y sensibilidad. La primera proporciona resultados más rápidos, garantiza que más personas puedan conocerlos, y no requiere el manejo o la exposición a hemoderivados potencialmente peligrosos.

Número de ensayo Identificador de ClinicalTrials.gov, NCT01733927.

Palabras clave Infecciones por VIH, diagnóstico; serodiagnóstico del SIDA; seroprevalencia de VIH; técnicas de laboratorio clínico; prevención de enfermedades; Chile.