EVALUATION OF A RAPID HUMAN IMMUNODEFICIENCY VIRUS TEST AT TWO COMMUNITY CLINICS IN KWAZULU-NATAL

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Objectives. To establish whether the Determine (Abbott, Tokyo, Japan) HIV antibody test is suitable as an on-site rapid HIV test at primary health care centres by determining its sensitivity and specificity compared with the standard enzyme-linked immunoassay (ELISA) test.

Design. Prospective field evaluation study of a rapid HIV test compared with an ELISA.

Setting. KwaDabeka clinic and St Mary's Hospital, urban primary health care clinics in the Durban western metropolitan area.

Subjects. Women attending antenatal clinics and those presenting at onset of labour.

Outcome measures. Performance of the rapid test versus conventional ELISA testing, sensitivity, specificity, feasibility of implementing the test at primary health care clinics, prevalence of HIV infection at study sites and its association with patient booking status.

Results. A total of 323 specimens were tested from patients from two community clinics, KwaDabeka (N = 159) and St Mary's (N = 164). The overall HIV prevalence was 45.5%. There was a significant difference in HIV prevalence (P < 0.001) between KwaDabeka (35.2%) and St Mary's (55.5%). Of the participants 49.2% were from KwaDabeka clinic and 50.8% from St Mary's Hospital. Overall, HIV prevalence among unbooked participants was 43.0%, and among booked participants 46.3%. This was not statistically different (P = 0.612) between the two clinics. The rapid test showed a sensitivity and specificity of 100% when compared with a conventional diagnostic ELISA test.

Conclusion. The Determine rapid HIV antibody test is sensitive, specific, easy to perform and provides a valuable method for HIV testing especially in settings with limited access to laboratory infrastructures and trained laboratory staff.

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Diagnostic HIV testing in South Africa mainly entails the use of a series (two or three) of automated enzyme-linked immunoassays (ELISAs).[1] This may be problematic for under-resourced institutions because of factors such as the long turnaround time for results, the large number of specially trained personnel involved in taking of blood specimens, specimen transportation, processing and dispatching of results, expensive equipment to process the specimens, hazards associated with transport of blood tubes and the fact that many of the individuals who have their blood collected do not come back for results.

Since the introduction of the first enzyme immunoassay for the detection of antibodies against HIV in 1985,[2,3] the most widely used testing algorithm has been the screening of specimens with ELISA and repeat testing of reactive specimens with the more specific Western blot assay. Although this algorithm works well, in resource-poor settings it is difficult to implement because it requires skilled laboratory personnel and specialised equipment. With the progression of the HIV epidemic in South Africa, more affordable options are required for HIV testing. Rapid HIV tests can enable health care providers to supply definitive negative and preliminary positive results to patients at the time of testing. The advantages of rapid on-site testing, however, depend on whether tests are reliable and accurately reflect the HIV status of the individual.

To date numerous investigations into the performance of rapid HIV kits have been performed, with varying findings.[1-9] Most of these investigations have centred on two important aspects, namely the specificity and sensitivity of the assay.[1] Also there have been some doubts regarding the accuracy of HIV serological tests on patients infected with HIV subtypes of African origin,[2] since most of the available commercial tests are not manufactured in Africa and have not been evaluated extensively against HIV subtypes encountered in southern Africa. Most studies show that specific combinations of two or more different rapid HIV assays can provide results that are as reliable as those from the ELISA-Western blot combination.[3]

According to the World Health Organisation (WHO), the choice of a testing strategy depends on the prevalence of HIV infection in the population and the presence or absence of HIV-associated symptoms.[4] However, these recommendations do not specify which combination of tests should be used or provide data validating the sensitivity and specificity of the proposed algorithms under field conditions.[9]

This study was done to establish whether the Determine (Abbott, Tokyo, Japan) rapid HIV antibody test can be used for less expensive on-site rapid screening for the detection of HIV antibodies in primary health care settings by comparing its performance with that of an ELISA (Abbott Axsym HIV-1/2 go; Abbott, Delkenheim, Germany) test currently used widely in South African national laboratories for the diagnosis of HIV infection.

MATERIALS AND METHODS

The study was approved by the Ethics Committee of the Faculty of Medicine, University of Natal, Durban. All the patients participated after having received appropriate information about the study and having signed written informed consent.

Selection of Abbott Determine rapid test

Choice of this particular rapid test was based on the fact that it has given satisfactory results in other settings,[9] it is able to discriminate between HIV-1 and HIV-2, it is readily available and reasonably priced, it can be performed using a variety of specimens (plasma or whole blood), and it has a long shelf life.

Study sites

Two primary health care facilities which are existing Medical Research Council (MRC) study sites were chosen for this study. KwaDabeka clinic is a 24-hour urban health care centre, which caters for a population of about 52 000 people from the townships of Clermont and KwaDabeka outside Durban. KwaDabeka clinic is the only facility in that area which offers antenatal care and delivery facilities for this population.

The second site, St Mary's Hospital, is a district hospital situated about 20 km from KwaDabeka clinic. It serves as the referral centre for KwaDabeka clinic and other surrounding clinics on the outskirts of Pinetown and the inner west of Durban.

Subjects

Initial sample size calculations were based on the current estimated HIV prevalence level in KwaZulu-Natal of 32% (1998 antenatal clinic survey, Department of Health). We wished to show the sensitivity of a rapid test of at least 97% with a 95% confidence interval (CI): 92 - 99%. Based on calculations with EPI-Info version 6, we calculated that we would require 313 women for a rapid test of 97% sensitivity compared with the standard 100% sensitivity on the ELISA. The power of the study was therefore quite low enabling us to show only a 10% difference between a rapid test and the standard ELISA.

All women presenting at onset of labour from December 1999 to June 2000 who agreed to participate in the study at both clinics were enrolled until we had the total sample size required.

Study procedure

Women presenting in labour and at the antenatal care clinic who did not know their HIV status were offered free HIV counselling and testing. This was followed by collection of blood from the consenting participants into ethylene-diaminetetraacetic acid (EDTA) anticoagulated test tubes. The Determine rapid HIV antibody test was then performed and the results recorded. Preliminary results were given to the participants and they were told to return on a designated day for results of a confirmatory ELISA test. Blood specimens were then centrifuged and the plasma frozen at –20°C. Confirmatory testing on these specimens was performed at the virology laboratory at King Edward VIII Hospital, Durban, using the Abbott Axsym automated microparticle ELISA system (MELISA). Testing was done in accordance with the manufacturer's instructions.

ANALYSIS OF RESULTS

The results were analysed using the statistical analysis system (SAS version 6.12, Carry, NC) and SPSS version 9.0 computerised statistical packages. Univariate analysis was done using the two-sided Pearson's chi-square test of significance. The sensitivity of the rapid test was expressed as the ratio of the patients testing positive by the rapid test over those testing positive by confirmatory test. The specificity was calculated as the ratio of the negative rapid tests over the negative ELISA confirmatory test. The positive and negative predictive values were calculated as the proportions of patients with positive and negative rapid tests that were truly positive and truly negative (i.e. by confirmatory test).

RESULTS

Of the total 323 specimens tested, 147 (45.5%) tested positive with both the rapid test and the ELISA, and 176 (54.5%) were negative by both methods (Table I). The sensitivity of the rapid test compared with the ELISA was 100%. There were no discordant results among the 147 HIV-positive patients or the 174 HIV- negative patients between the two tests. Since there was no discordance between the rapid test and the ELISA confirmatory test in this small pilot study, the sensitivity and the negative predictive values were equal. Similarly, the specificity and the positive predictive values were also equal. However, it should be noted that both the positive and negative predictive values are dependent on the population disease prevalence, which is high in South Africa for HIV compared with developed countries.

Of the 323 patients tested, 159 (49.2%) were from

Table I. Comparison of the rapid test strategy with the ELISA test strategy (*N* = 323)

	HIV-positive	HIV-negative	%
Determine rapid test	147	176	
ELISA confirmatory test	147	176	
Sensitivity			100
Specificity			100

Table II. Patient characteristics at KwaDabeka clinic and St Mary's Hospital

	No. of patients (%)		HIV-positive No.	%	HIV-negative No.	%	Prevalence (%)	Booked No.	(5)	Unbooked No.	(%)
Kwa-Dabeka	159	(49.2)	56	35.2	103	64.8	35.2	115	47.1	44	55.7
St Mary's	164	(50.8)	91	56.5	73	44.5	55.5	129	52.9	35	44.3
Total	323	(100)	147	45.5	176	54.5	45.5	244	75.5	79	24.5

KwaDabeka clinic and 164 (50.8%) from St Mary's (Table II). The overall prevalence of HIV infection at these two sites was 45.5%. There was a significant association between the HIV status and site ($P < 0.0003$), with the rate higher at St Mary's than at KwaDabeka clinic (Fig. 1). The high prevalence could be that many patients who came for testing at St Mary's Hospital were potential high-risk patients seeking inclusion in a concurrent study conducted at this site. There was no significant association between the booking status of the participants and the sites ($P = 0.291$), with St Mary's having a higher number of booked patients (52.9%), than KwaDabeka clinic (47.1%).

The prevalence of HIV between booked and unbooked patients showed no major difference, with a rate of 43% among the unbooked group, i.e. women enrolled at the onset of labour, and 46.3% among those enrolled at antenatal clinics ($P = 0.612$).

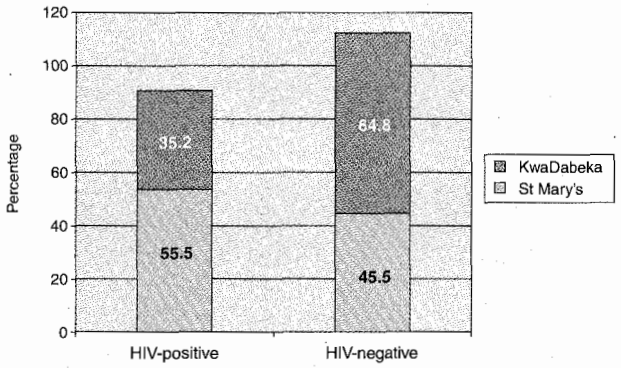

Fig. 1. Prevalence of HIV at KwaDabeka clinic and St Mary's Hospital.

Discussion

Rapid tests with immediate results are appropriate for HIV screening in primary health care settings in South Africa. People who test negative are able to learn their status and receive counselling in a single visit, thereby reducing the psychological stress of waiting for results, and saving time and resources. Provision of preliminary positive results increases the number of infected people who learn their infection status and can be referred for medical treatment and other prevention services. This is particularly important in the light of the possible introduction of antiretrovirals by the South African government to prevent mother-to-child transmission (MTCT) of HIV infection. Although there was no significant association between the patient booking status and the prevalence of HIV infection in this study, it is generally accepted that unbooked mothers are at higher risk and are more likely to have sexually transmitted diseases[9] such as syphilis among others. Therefore it is generally accepted that these high-risk women should be offered HIV testing, and introduction of a rapid test will be of great significance in the management of these patients.[10]

The sensitivity and specificity of the Determine rapid assay are comparable to those of a conventional ELISA. A negative test does not require further testing, and counselling can be provided at the initial visit.

Wilkinson *et al.*[5] used a prospective comparison of two testing strategies, namely double rapid test on site versus central ELISA-based testing. However, a single rapid test seems to be an ideal solution for use in resource-poor settings as it provides a cheaper alternative than a double testing strategy. Double rapid tests may increase the costs, and if two tests are done, they may be more expensive than conventional ELISAs, which are performed in batches in a laboratory.

The Determine test strip is essentially a three-step process and the results are read visually and available in 15 minutes. A built-in control ensures the test validity and essentially no specialised equipment is required. The benefits of rapid testing are greatest for settings that serve a population with a high prevalence of HIV.

This study shows that the use of the Determine rapid test yields results that are as accurate as those of the conventional ELISA test. This was very useful at the two clinics where these MTCT studies were being performed. The test was a straightforward procedure that could be performed easily by the nursing staff and other personnel with minimum training. Rapid tests will undoubtedly enhance the implementation of MTCT programmes at various institutions and could save money and other resources, which would otherwise be wasted, should these programmes be introduced in South Africa.

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THE RADIOLOGICAL OUTCOME OF LUMBAR SPINAL FUSION USING A SOUTH AFRICAN-DEVELOPED DYNAMIC SPINAL FIXATION SYSTEM

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Objectives. To investigate the radiological outcome of the use of a new Cape Town-developed spinal fixation system.

Design. One hundred and fifty-five patients underwent posterior lumbar spinal fusions with this fixation system and autogenous bone graft more than a year ago. Of these 121 were available for radiological follow-up.

Setting. Spinal pedicle fixation systems are in common use in spinal fusion surgery. Most systems use rigid screws with a high rate of implant failure.

In South Africa most spinal implants are imported and expensive, and this prompted the development of a locally manufactured dynamic spinal fixation system with the aim of producing a cheaper and more effective system with a lower risk of implant failure.

Outcome measures. A visual assessment of 1-year post-surgery radiographs by a qualified independent observer looking particularly at the rate of fusion and the incidence of implant failure.

Results. Bone fusion rates were comparable to all other pedicle fixation systems but implant failure rates were considerably less than in systems using rigid screws and more comparable to a similar dynamic spinal fixation system.

Conclusions. This spinal fixation system is safe and effective in aiding bone fusion. It has a low rate of implant failure and is currently cheaper than all imported spinal fixation systems. It has therefore achieved the objectives that prompted its inception.

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The efficacy of lumbar pedicle screw fixation as an adjunct particularly in long lumbar spinal fusions is now well accepted.[1] This success is reflected in the multitude of such devices developed over the last decade. Early plate and screw constructs were soon superseded by more versatile rod and screw systems. Initially all fixation systems employed rigid screws which necessitated very accurate rod contouring to accommodate sagittal coronal and torsional distortions of the spine. Failure to achieve a precise fit between the screw and the rod would result in preloading of the system with the risk of subsequent failure. Even where an adequate fit is obtained there is still a significant incidence of instrumentation failure[2-17] such as screw breakage, rod breakage or failure at the bone-metal interface with loosening of the screws in bone (Table I).

Recognising the inherent defects in implant design von Strempel *et al.*[18] developed a unique implant (segmental spinal correction system) whereby the head and shank of the screw are connected via a hinge to allow permanent uni-axial articulation — a so-called dynamic fixation system. At first glance this seems contradictory since the purpose of the implant is to achieve rigid fixation. Biomechanical testing in von Strempel's own laboratory[2] as well as in an independent laboratory[19] showed that the dynamic system was as rigid *in vitro* as one utilising fixed screws.

A review of patients treated with this method of fixation showed that the bony fusion rate was as good as with any rigid system, and importantly that the instrumentation failure rate was considerably reduced.[20]

This system has the further advantage that precise rod contouring to achieve a perfect fit between the rod and the screw head is largely eliminated by the perpetual mobility of the screw head which readily accommodates non-