PostScript

LETTERS

A case of a false positive result on a home HIV test kit obtained on the internet

There are two major reasons to diagnose asymptomatic HIV infection: to facilitate timely initiation of antiretroviral therapy, and to reduce the chance of onward transmission. A negative test offers an opportunity for preventive health promotion. All these aspects of testing require follow up by suitably trained personnel. We describe a case illustrating the hazards of self testing for HIV.

A 31 year old British heterosexual man attended the genitourinary medicine clinic requesting an HIV test. His last sexual contact was 3 weeks earlier with a female partner of 3 months. He had recently learnt that she had had a previous male partner who had had African sexual partners and therefore may be at higher risk of having HIV infection. He obtained a home HIV test kit ("Discreet" HIV Home Test Kit, Seville Marketing Ltd) from a Canadian based internet site and this result was positive. On further inquiry he gave a history of sore throat and swollen cervical lymph nodes 2 months previously, although these symptoms had largely resolved. He had never tested for HIV before and had no other significant risk factors.

We requested an HIV test on the patient; the result was negative. We repeated the test after 3 months and again it was negative, confirming that the patient was not infected at the time he performed the home HIV test. The current HIV screening test used by our centre uses both HIV antibody and p24 antigen detection and is known to detect HIV infection 3–12 weeks after infection. Given that he was now symptom free with negative syphilis serology and at low risk for acquiring HIV, no further investigations were undertaken.

The patient had disposed of the test kit and it was not available for inspection. Unlike oral fluid kits recently licensed in the United States,¹ this kit required a fingerprick and a drop of blood to be applied to a reagent strip. The company claimed "99.4% accuracy" for the kit's results. From discussion with the patient it seemed that the result displayed by the testing kit evolved over time and had to be read between 3 minutes and 8 minutes after applying the drop of blood. The time dependency of the reaction made the kit liable to be misread.

We performed an internet search and found that websites selling the kit were no longer active. Furthermore, a US Federal Trade Commission restraining order had been placed on the kit 2 days before the patient presented to our clinic. As well as finding the company to be in breach of US law by selling the kit in the United States, the Centers for Disease Control and Prevention had tested the accuracy of the kit. "Results of the testing, based on the package instructions, 'changed dramatically' during the 15 minutes that the results were reported. After 3 minutes, 15.4% of the kits gave erroneous readings; after 8 minutes, 29.6% registered

inaccurate results; after 15 minutes, 59.3% of the kits gave inaccurate results. Moreover, the kits showed both inaccurate HIV positive results and inaccurate HIV negative results."²

This case is important because the use of the internet to obtain HIV test kits is likely to increase. One study in California found fairly high levels of interest in instant home HIV tests³ and it is not difficult to locate kits for HIV testing and other diagnostic services on the internet. A home HIV test kit using oral fluid has been licensed in the United States and a home blood collection and telemedicine system is also available,^{4,5} but these are not available legally in the United Kingdom or Europe. All healthcare professionals involved in counselling and testing patients for HIV should be aware that self taken HIV tests may be inaccurate and confirmatory testing in an appropriate laboratory should be performed before making a diagnosis of HIV infection.

Although access problems to sexual health services have rightly engendered innovative approaches to diagnosis and management, there should be a note of caution on using new HIV technologies of rapid testing in non-healthcare settings and legalisation of home and over the counter HIV testing kits.⁶ It is imperative that clinical governance issues are addressed. Medico-legal consequences are important, but of greater significance is the distress to individuals and their partners who are wrongly diagnosed or inappropriately reassured through the use of poorly performing kits.

Contributors

LH saw the patient before and after testing and wrote the case report; AR suggested the case be reported and reviewed/redrafted the manuscript.

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Jane Sudlow counselled the patient and commented on the case. Julian Tang provided advice on HIV testing and confirmation.

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Primary HIV infection masquerading as Munchausen's syndrome

Since 1986 there have been several case reports describing factitious HIV infection.¹ We have seen two acute presentations where the patients claimed to have chronic HIV infection, were found to be HIV antibody negative but on closer evaluation were found to be seroconverting with primary HIV infection (PHI). We believe that the patients were motivated by the psychological need to assume the sick role, fulfilling the principal feature of a factitious disorder, rather than malingering.

Case 1

A 40 year old homosexual man presented to HIV services with an acute diarrhoeal illness, claiming to have been diagnosed as HIV positive at another hospital 2 years previously. A third generation HIV test, Abbott AxSYM HIV 1/2 gO (antibody only), was negative. He returned 1 month later, still denying any sexual risk, and requested a repeat HIV test, which was again antibody negative but reactive with the fourth generation assay, Abbott HIV Ag/Ab Combo (antibody and p24 antigen combined).

Case 2

A 39 year old homosexual man presented to the accident and emergency department with fever, ulcerative gingivitis, and maculopapular rash, claiming to have been diagnosed HIV positive 4 years previously. He reported safer sex with 30 casual male partners in the previous 3 months and stated that his regular male partner was HIV negative. He was found to have had four negative HIV tests in the previous 2 years at this hospital and numerous negative HIV tests at other hospitals. The third generation HIV test was negative. The following day, however, a fourth generation test was reactive.

Comment

The ability to diagnose PHI has always required a high index of suspicion and a keenly taken history, and if missed the next opportunity for testing may not be until years later when the patient presents in ill health, with symptomatic HIV or even AIDS.² Clearly, a missed diagnosis of PHI may have a deleterious effect on the individual's prognosis, but there may also be significant public health consequences, as early infection is a core factor in the propagation of an epidemic^{3,4} because of high viral burden and de facto risk taking sexual behaviour. Indeed, early detection of PHI probably represents the

single most important method of slowing the spread of HIV within populations, with mathematical modelling indicating that eliminating high infectivity in early infection has more effect than at any other disease stage.⁵

Thus, the diagnosis of PHI in at-risk individuals has considerable advantages in both individual and public health terms. These two cases demonstrate how easy it can be to disregard such patients as having factitious HIV infection and are a gentle reminder that a negative antibody test does not necessarily exclude PHI. Healthcare professionals must continue to be alert to the less common clinical manifestations of PHI, be aware of the particular assays used in their own laboratory, and because no combination of symptoms is 100% sensitive or specific, diagnostic procedure must be broad and inclusive.⁶

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Chlamydia trachomatis PCR positivity and inflammatory changes on cervical cytology

The presence of genital infection does not increase the likelihood of an inadequate Papanicolaou (Pap) test.¹ Conversely, testing for *Chlamydia trachomatis* at the time of routine cytological screening presents an opportunity to detect asymptomatic genital tract infection.² The PreservCyt fixative fluid (Cytoc Corporation, Boxborough, MA, USA) used for the ThinPrep Pap test (Cytoc Corporation) can be used for detection by the polymerase chain reaction (PCR) of *C. trachomatis*.^{3–4} This presents an opportunity to study the correlation between the chlamydia result and the Pap test finding.

We retrospectively reviewed all routine requests for chlamydia PCR on ThinPrep samples sent to our laboratory over a year. Data were collected on the woman's age, chlamydia PCR result, result of genital tract cultures if performed on the same date, and Pap test result. Data on the Pap test result included presence or absence of an epithelial cell abnormality either high grade (HGEA) or low grade (LGEA), whether the Pap was inflammatory and the presence or absence of recognisable pathogens. Cervical specimens collected in PreservCyt transport medium were processed for *C. trachomatis* using the automated Cobas Amplicor (Roche Diagnostic Systems) and the method by Bianchi et al.³

Over the study period, 733 samples were received, of which 23 (3.1%) had *C. trachomatis* DNA detected by PCR. Comparison of the women with chlamydia infection, with those without chlamydia infection is shown in table 1. There was no statistical difference in the presence of high or low grade epithelial abnormalities, recognition of other pathogens, or age of the women; however, 26% of women with chlamydia had an inflammatory Pap test compared to 9% of women without chlamydia ($p < 0.01$).

Complementary therapy and genital warts

Complementary therapy (CT) is now the second biggest growth industry in Europe (after IT). Up to 20% of the UK population visit a complementary therapist each year and as much as £5 billion is spent annually on such therapies.¹ In the United States this figure is \$30 billion. The National Institutes of Health in the United States are keen to fund good scientific studies showing efficacy of CT, in order to "disseminate authoritative information to the public and professionals".² Objective data gathering is all the more important as a large majority of physicians view CT very negatively.³

Five years ago we were approached by a group of Reiki therapists to undertake a study showing the efficacy of Reiki healing on STIs. Reiki healing (RH) is a hands-on healing method that may be undertaken as distance healing.⁴ There is a precedent for CT therapies being used in the form of yoga for patients

with infection—in particular a well designed randomised trial showing efficacy in tuberculosis.⁵ In view of this we undertook a study of the effect of RH at a distance on genital warts. The study had local ethics committee approval.

Patients with anogenital warts who were awaiting surgical treatment initially had their wart size and number assessed by a nurse using standard techniques.⁶ Waiting time from this point to surgical removal of the warts averaged 6 weeks (plus or minus 1 week). Another nurse, who was blind to the initial wart visualisation, photographed the back of patient's head and then allocated each patient to a treatment (RH) or no treatment group according to a random code. Twelve Reiki healers were then each sent the photographs and undertook RH on them at a distance on a daily basis for about 10 minutes. Thus, half the patients received RH and the other half did not. Just before surgical removal of the warts the size and number of the warts was again assessed by the original nurse.

Considering a difference between a 35% reduction in wart volume for the Reiki treated group and a 10% reduction for the placebo (90% power 0.05) it was considered that 130 patients would be needed (65 in each arm); in fact, only 27 patients were enrolled into the study. Ten were lost to follow up. Of the 17 who completed the study nine received RH and eight did not. Two patients who received RH and one who did not totally cleared their warts. Seven who received RH and two who did not had an increase in wart mass/number. No patient who received RH and five who did not showed some degree of decrease in wart mass/number. These rates of regression are similar to those described in the placebo arms of recent double blind trials.^{7–8}

Although this is a small study, we believe it was well designed but we failed to enrol large enough numbers. We also think it failed to show any efficacy for RH. Undertaking well designed trials of CT in the STI arena is important—not least because a majority of patients attending STI clinics may already be using them, and open discussion about them can help patients to make informed decisions as well as avoid drug interactions.⁹

In terms of common skin warts, efficacy of Reiki healing has not been shown to be effective.¹⁰

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Table 1 Comparison of women with and without chlamydia infection

	Positive <i>C trachomatis</i> PCR	Negative <i>C trachomatis</i> PCR	p Value
Median age	24 (range 19–40)	28 (range 15–68)	0.182
LGEA/HGEA	5 (22%)	106 (15%)	0.37
Other pathogens	1 (17%)	12 (18%)	NS
Inflammation on Pap test	6 (26%)	65 (9%)	<0.01

LGEA, low grade epithelial abnormalities; HGEA, high grade epithelial abnormalities.

The association of inflammation on Pap testing and chlamydial infection has been previously examined with variable methodologies and findings.⁵ We utilised the same sample (ThinPrep) for determining both the presence of inflammatory changes on Pap test and chlamydia infection and found a positive association between the two despite a low prevalence population. Our study confirms the feasibility of performing chlamydia PCR from liquid based cytology samples in a routine diagnostic setting. Testing for chlamydia should be considered in women with inflammatory Pap tests for which there is no other explanation.

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Cardiovascular syphilis in HIV infection: a case-control study at the Institute of Sexually Transmitted Diseases, Chennai, India

It is known that HIV co-infection with syphilis may accelerate the onset of gummatous and neurosyphilis and increase their severity. However, this has only been reported for cardiovascular syphilis in two previous cases.^{1,2}

This case-control study deals with a total of 14 HIV seropositive and 100 HIV 1 and 2

seronegative individuals with syphilis, who were seen in our clinic between June 2000 and May 2001. Of the 14 HIV seropositive individuals, 12 were reactive for VDRL (venereal diseases reference laboratory) and TPHA (*Treponema pallidum* haemagglutination assay) and two had primary syphilis confirmed by dark field examination for *T pallidum*. Of the 100 HIV seronegative individuals, 85 had reactive VDRL and TPHA and 15 had primary syphilis confirmed by dark field examination. The prevalence of cardiovascular syphilis in the HIV seropositive and seronegative groups was 14.3% and 2%, respectively (OR 8.2; 95% CI 1.1 to 61.5).

Two HIV seropositive individuals with cardiovascular syphilis had aortic root dilatation while the two HIV seronegative individuals had aortic aneurysm. The HIV seropositive individuals were asymptomatic with regard to cardiac status but one HIV seronegative individual had chest pain and the other was asymptomatic. None in the HIV seronegative group had aortic root dilatation ($p < 0.01$). There was a theoretical possibility that aortic root dilatation could be a manifestation of HIV or opportunistic infections involving the heart. A parallel study done on cardiovascular involvement in HIV seropositive individuals from the same institute during the same time interval had revealed that none of the 61 non-syphilitic HIV seropositive individuals had aortic root dilatation, compared with 2 out of 14 with syphilis ($p < 0.01$; paper in preparation).

The mean duration of diagnosing cardiovascular syphilis from the time of acquiring syphilis was 40 months (27 and 53) in the HIV seropositive group and 102 months (84 and 120) in the HIV seronegative group. The mean age of the HIV seropositive individuals who had cardiovascular syphilis was 31.5 years (29 and 34) and that of HIV seronegative individuals was 45.5 years (44 and 47).

The shorter duration for diagnosing cardiovascular syphilis from the time of acquiring syphilis for the HIV seropositive group (40 months) compared with the HIV seronegative group (102 months) ($p < 0.003$) could be explained by the fact that HIV hastens the progression to late syphilis,³ which might be due to an alteration to the immune system. It could also be possible that HIV infected individuals seek medical attention because of opportunistic infections, which might have led to the earlier diagnosis of cardiac lesions because the two individuals with aortic root dilatation were asymptomatic with regard to cardiac status. The difference in the clinical manifestation of cardiovascular syphilis between these two groups could not be explained at this point of time.

Contributions

MM designed the study, collected the data, interpreted the results, and analysed the

results and statistics; SKG contributed to collecting data, interpretation of results and laboratory collaboration.

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Antiretroviral therapy – alternative uses

Recently, while speaking to a patient from Nigeria I was very concerned to discover that she had been taking combivir for breast enhancement. On closer questioning it appears that she had accessed this drug, passed to her in individual sachets with no information insert etc, via a friend. Her friend, knowing that my patient wished for larger breasts, had passed her the combivir to use on an as required basis for breast enhancement. My patient claims that the drug did work to enlarge her breasts.

The drugs were apparently prescribed by a doctor in Nigeria at the cost of about US\$250 for six sachets and the pharmacist dispensing them had been asking why the girls were taking them. Apparently the sachets did not come with any leaflets or drug information inserts.

My patient and her friends appeared to be totally unaware of the fact that the combivir was for use in HIV therapy and were unaware of any potential side effects from the drug. It was only when my patient was surfing the web that she found out about the licensed use for combivir.

My patient, sadly, acquired HIV from a blood transfusion in Africa and on primary resistance testing showed very broad nucleoside reverse transcriptase inhibitor resistance and apparent full sensitivity to protease inhibitors and non-nucleoside reverse transcriptase inhibitors (NNRTIs). Resistance to

NNRTIs was only confirmed after weeks of unsuccessful therapy by further resistance testing.

My patient has alerted all her friends in Nigeria as to the real nature of combivir and advised them to stop using it for breast enhancement. She has also told me that she believes the doctor in Nigeria who prescribed these drugs may have had this activity terminated.

Because no one I have spoken to has come across this particular misuse of antiretroviral therapy I felt it was worth highlighting to a wider audience in the hope that such practises may be addressed.

Acknowledgements

This patient has agreed to publish details of her case to help prevent recurrent misuse of this drug.

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CORRECTION

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The order of the authors of the paper by Götz *et al* on page 24 of the February 2005 issue (HM Götz *et al*. A prediction rule for selective screening of Chlamydia trachomatis infection. *Sex Transm Infect* 2005;**81**:24–30) were wrong. The order should have been as follows: HM Götz, JEAM van Bergen, IK Veldhuijzen, J Broer, CJPA Hoebe, EW Steyerberg, AJJ Coenen, F de Groot, MJC Verhooren, DT van Schaik, and JH Richardus.