Validation of a recombinase polymerase amplification assay for the diagnosis of female genital schistosomiasis in Zambian women using cervicovaginal lavage and vaginal self-swab samples

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What is the research?

Female genital schistosomiasis (FGS), caused by infection with *Schistosoma haematobium*, is associated with a range of adverse reproductive health outcomes such as destruction of the cervicovaginal mucosa, infertility, ectopic pregnancy and abortion. Further to these sequelae, FGS is now recognised as an important contributor to the transmission of sexually transmitted bacterial and viral infections (STIs). Of particular concern is the impact of FGS on HIV transmission owing to a range of characteristic genital tract pathologies known to augment HIV acquisition. Overall, FGS is believed to increase a woman’s chance of contracting HIV by up to four times.

The World Health Organization estimates that approximately 56 million women currently experience from some form of FGS, though this is widely considered a vast underestimate owing to difficulties in both diagnosing infection with *S. haematobium* and in observing any genital pathology caused by infection. One diagnostic approach involves the use of polymerase chain reaction (PCR) to detect sequestered *S. haematobium* egg-derived DNA collected within cervicovaginal lavage (CVL) samples. Though promising, CVL sampling is invasive and requires specialist health personnel working within a clinical setting. In addition, PCR-based diagnostics are currently unsuited for use in endemic field settings and so typically cannot be used at the point-of-care.

Because of this, the BILHIV (Bilharzia and HIV) study, led by Dr Amaya Bustinduy at the London School of Hygiene & Tropical Medicine, was formed and aims to explore the innovative role of vaginal and cervical self-swabs for the diagnosis of FGS. Self-sampling with swabs is not only far less invasive than CVL sampling but can also be performed by the patient within the home. As part of the BILHIV study, it was recently shown that self-swab samples may be as sensitive, if not more sensitive, than CVL sampling when using qPCR to detect DNA derived from eggs sequestered throughout the genital tract.

The recently developed recombinase polymerase amplification (RPA) assay is a field-deployable DNA amplification technology and alternative to PCR. Here, we assessed the use of RPA for the detection of sequestered egg-derived DNA within CVL and vaginal self-swab samples; comparing RPA performance to that of qPCR. Our work suggests that RPA may be a viable alternative to qPCR for the diagnosis of FGS and, if used in conjunction with self-swab samples, may provide a scalable solution in resource limited areas for the diagnosis of FGS at the point-of-care.

Why is this research necessary?

Currently, there is no rapid and reliable method for detecting FGS-associated symptoms within schistosomiasis-endemic areas. Further development and assessment of the RPA assay for use with vaginal and cervical self-swab samples may provide a viable means for self-swabbing and rapid point-of-care diagnosis, empowering women, relieving stigma and enabling targeted treatment and/or intervention.

What is the research impact?

Reliable detection of FGS at the point-of-care will better our understanding of FGS prevalence and epidemiology in schistosomiasis-endemic areas, contribute to the improved health and wellbeing of those suffering from FGS-related pathologies and may even help towards the reduced transmission of sexually transmitted infections such as HIV.

Human exposure to schistosomiasis relies on freshwater contact.

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