Evaluation of the clinical utility of the Becton Dickinson ProbeTec Qx (BDQ) *Trichomonas vaginalis* molecular detection test in two large, urban GU medicine services

C Tipple¹, M Rayment², S Mandalia², Monica Rebec¹, L Walton¹, L Simonds¹, L Pitty¹, L O’Riordan¹, S O’Neill¹, J Murray¹, R Jones², D Wilkinson¹

¹Imperial College Healthcare NHS Trust, ²Chelsea and Westminster Hospital NHS Foundation Trust, London, UK

Background

Trichomonas vaginalis (TV) is a sexually transmitted protozoan infection. In 2011, there were 6264 incident cases reported in genitourinary medicine clinics in England.

The diagnosis of TV can be made using wet-prep microscopy (WPM), culture and, more recently, nucleic acid amplification tests (NAATs). A recent large prospective trial comparing TV culture, NAAT and WPM revealed sensitivities of 97.4%, 98.3% and 68.7%, respectively ($P < 0.001$).¹

Our clinics currently test for TV in symptomatic women only. At clinic A, testing comprises vaginal pH screening and WPM; in clinic B, WPM, and TV culture. We wished to evaluate the use of the BD Qx TV NAAT in all women attending our services. This assay simultaneously detects infection with TV, *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG) on a clinician taken endocervical or vulvo-vaginal swab, or self-collected vulvo-vaginal swab.

Aims and Objectives

1. Determine the prevalence of TV among female patients attending our GU medicine services both with and without symptoms
2. Identify epidemiological factors associated with TV infection in our clinic populations in order to inform better our testing strategies
3. Determine the proportion of TV cases undiagnosed with current screening and testing strategies (including sensitivity of both pH testing and WPM)
4. Describe laboratory pathways and result turnaround time
5. Describe the utility of NAAT test-of-cure (TOC) in patients treated with first line treatments

Methods

This was a prospective, cross-sectional study of women attending clinics A and B over a one month period, with a projected sample size of 900 women.

Inclusion criteria

- Aged 18 years or over at study entry
- STI screening recommended and accepted by the patient

Exclusion criteria

- Treatment with metronidazole, tinidazole or any other treatment for TV in the two weeks prior to presentation
- Use of vaginal foams or gels within 24 hours

Verbal consent was obtained for participation, and swabs were collected according to standard screening protocols. Symptomatic women underwent examination and near-patient testing as per current practice. Women with any positive TV result were treated according to BASHH guidelines, and all invited to attend for TOC.

Data collected prospectively: demographics, symptoms, results of near-patient tests and BD Qx for TV, CT NG. Data were collated in Excel and analysed in SPSS v20.

Results

Over the study period, 901 women had a TV NAAT test (451 at clinic A and 450 at clinic B): 472 (53%) were white (NHS ethnicity codes A-C), 143 (16%) black (codes D, E, M, N, P); median age 28yrs (range: 49 yrs). 499 (55%) were symptomatic. One woman was living with HIV-1 infection.

Infections detected by TV NAAT comprised: 11 TV (1.2% [95% CI: 0.49-1.91%]), 3 NG (0.3% [0.00-0.66%]) and 44 CT (4.9% [3.49-6.31%]). The prevalence of TV detected by NAAT was 1.4% (7/499; [95%CI 0.03-1.97%]) in symptomatic women and 1.0% (4/401; [95%CI 0.37-2.43%]) in asymptomatic women.

Of the 11 TV NAAT+ cases, 8/11 (73%) were black, and 7/11 (64%) were symptomatic. Of the symptomatic cases: 4/7 (57%) were WPM+, 4/4 (100%) had vaginal pH >4.5 (clinic A only), 7/7 (100%) Hay-Ison Grade 2, and 1/3 (33%) TV culture+ (clinic B only).

There were no negative TV NAATs in the presence of positive WPM or TV culture.

In a univariable logistic regression model including the whole study population, the only significant association with TV NAAT positivity was with black vs. non-black ethnicity (relative risk [RR]: 10.2 [95%CI 2.15-48.4]). In a sub-analysis of symptomatic women, black ethnicity remained predictive of TV NAAT positivity (RR 13.73 [95%CI 1.64-115.25]).

Mean turn-around time was 3.44 days (Std Dev: 1.48 days). All TV NAAT+ women received treatment and 9/9 (100%) were BDQ negative at TOC (mean time to TOC: 15 days [range: 7-42 days]).

Conclusions

We identified a prevalence of TV infection in our clinic populations of 1.2%. This exceeded that of NG infection in the same population by four-fold. The statistical power of the study was sufficient to demonstrate a clear association of TV infection with black ethnicity, but relatively few events may have limited the ability to detect other associations.

Whilst uptake was not collected prospectively, use of the triple NAAT meant the test was highly acceptable to patients and staff, and integrated well within existing pathways. This was demonstrated by very quick recruitment to target.

In symptomatic women, TV NAAT had a relative sensitivity of 100% and performed better than WPM and culture (57% and 33% sensitivity, respectively). We cannot state the sensitivity in the asymptomatic population. In particular sub-groups, the prevalence of TV infection was high, but we are limited in making firm conclusions by the relatively few events in the study. A larger prospective study may help us design clinically and economically effective TV screening algorithms in both asymptomatic and symptomatic populations.

Ethical Considerations and Funding:

This study received a favourable ethical opinion from the Bloomsbury REC (ref: 15LO 0457). Tests were provided free of charge for validation by Becton Dickinson Ltd. (NJ, USA). No further funding was received.

Reference [1]: Van der Pol *et al. J Clin Micro* 2014. 52(3):885-889