Aptima TV NAAT Test Performance in GUM Clinics & Primary Care in the UK

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Background:
The Aptima TV NAAT has been approved for use for the detection of *Trichomonas Vaginalis (TV)* and is more sensitive (~100%) than wet mount (54%) or culture (75%)[1] Asymptomatic women attending genitourinary (GUM) clinics and patients in primary care are often not tested for TV, as the prevalence is assumed to be too low for testing to be cost effective.

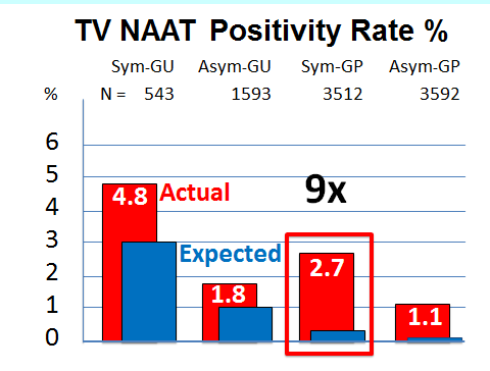
Methods:
9241 unselected patients attending a sexual health clinic and primary care were tested using the Aptima TV NAAT test alongside existing testing methods. Our aim was to determine

- TV positivity rates among clinic attendees with and without symptoms using the Aptima TV NAAT
- Whether targeted testing on the basis of ethnicity is feasible using the Aptima TV NAAT
- How many additional cases of TV are identified with the Aptima TV NAAT
- Whether self-taken and clinician-taken swabs are equivalent

Results

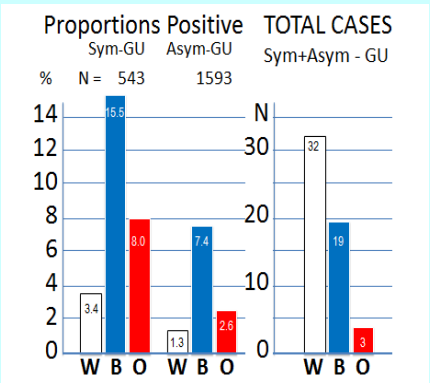
What is the positivity rate for TV in both settings?

Using TV NAAT, actual positivity rates were significantly higher than expected in all groups, especially in those with symptoms attending primary care



Is TV positivity linked to ethnicity in this sample?

Positivity rates for TV were high in patients from black ethnic minority groups with and without symptoms at 15.5% (9/58) and 7.4% (10/135) respectively in the GUM clinic population



The positivity rate in the white clinic population with symptoms was higher than expected 3.4% (15/444).
In terms of absolute numbers of TV positives,

65% (35/54) identified as non-black

Thus targeted testing based on ethnicity alone would miss two thirds of all cases in this population

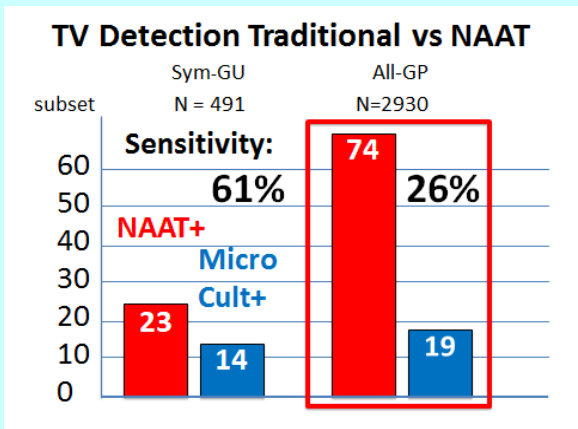
Test Performance

Is the TV NAAT a better test in this sample?

TV NAAT significantly outperforms our existing testing methods.

In a subset of 491 GUM patients in whom all tests were performed, 14/23 (61%) TV NAAT positives were identified on wet prep or culture (p=0.004)

In a subset of 2930 primary care patients in whom all tests were performed, 19/74 (26%) TV NAAT positives were identified on wet prep or culture (p<0.00001). This is likely to be due to deterioration of specimens in transport



Are self-taken swabs comparable to clinician-taken swabs for the Aptima TV NAAT?

- 26 out of the 530 symptomatic GUM patients for whom we had paired swabs, tested positive for TV NAAT on any swab
- 25 tested positive on self swab and 21 on clinician taken swab

Self-taken vaginal swabs are equivalent in sensitivity to clinician taken swabs (McNemar Test p=0.51) and may prove superior in a larger sample. This has important implications for those patients who do not require examination

1. Aptima TVNAAT product information www.hologic.com

Conclusions:

- The positivity rate for TV using the Aptima TV NAAT is higher than expected particularly in primary care in those with symptoms
- Although TV positivity is associated with black ethnicity, targeted testing based on ethnicity may miss the majority of cases
- The Aptima TV NAAT identifies significant numbers of additional cases and is likely to be cost effective for patients with symptoms
- The Aptima TV NAAT outperforms our existing testing methods wet prep and culture particularly in primary care. This is likely to be due to deterioration of specimens in transport. Conventional testing methods for TV in primary care are unlikely to be useful on this basis
- Self - taken swabs are of equivalent sensitivity to clinician - taken swabs and may be used for non invasive testing