EVALUATION OF BD MAX™ VAGINAL PANEL FOR THE DETECTION OF VAGINOSIS/VAGINITIS

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Aim:

To compare the performance of BD MAX Vaginal panel for the diagnosis of bacterial vaginosis (BV), candidiasis and Trichomonas vaginalis (TV) with the current standard tests in a specialist sexual health service.

Methods:

Women with abnormal vaginal discharge, who had not used douches or vaginal treatment in preceding 48 hours.

Sampling

Each woman had 2 introital NAATs swabs taken: one for chlamydia and gonorrhoea using the Roche Cobas™ PCR and one for candida, BV and TV using the BD MAX™ QS Vaginal Panel performed on the BD MAX System.

Speculum examination was then performed and routine vaginal swabs taken for:

- Assessment of vaginal pH
- Microscopy of vaginal secretions
 - Gram-staining for BV using Hay/Ison criteria and candida
 - Wet-mount for detection of TV
- Culture for candida if negative on Gram stain

Results

196 women with symptoms of vaginal discharge were included in the study. 1 sample could not be processed due to the sample size being too small. In addition to altered discharge 84 (43%) women complained of itch, 40 (21%) burning, 84 (43%) odour and 98 (50%) a range of other symptoms. The average age was 29.1 with a range 15 – 70 years. 91 (46.7%) were aged 25 or under.

46/196 women were negative for all 3 infections on the vaginal panel. 93 were positive for BV, 70 for candida on NAATS, of whom 3 (4.3%) were reported with C. glabrata and 9 had TV detected. 36 women tested positive for both BV and candida on NAATs.

Candida	NAATs+ve	NAATs-ve
Microscopy positive +/- culture +ve	47	8
Standard tests negative, clinically candida	4	2
Microscopy negative, culture not done, Clinically not candida	17	12
Microscopy and culture negative. Clinically not candida	2	103
		95% CI
Sensitivity	83.6%	71.91%-91.85%
Specificity	85.8%	78.75%-91.24%

Bacterial vaginosis	NAATs+ve	NAATS-ve
BV positive:	67	4
Hay Ison 3 or Hay Ison 2, clinically BV		
BV negative:	26	98
Hay Ison 1 or 2, clinically not BV		
		95% CI
Sensitivity	94.37%	86.20% to 98.44%
Specificity	79.03%	70.81% to 85.82%

TV	NAATs+ve	NAATS-ve
TV +ve wet prep	7	2
TV -ve wet prep	2	184

Concurrent STIs

37 (19%) Women were diagnosed with 44 acute STIs. In addition to the 11 cases of TV (of whom 2 also had gonorrhoea and chlamydia) there were 11 diagnoses of pelvic inflammatory disease, 11 chlamydia infections, 4 gonorrhoea infections, 1 mycoplasma genitalium, 3 1st episode genital warts, 3 1st episode genital herpes. Additionally one woman had a urinary tract infection and 2 were contacts of chlamydia or gonorrhoea.

Discussion

This is the first evaluation of the BD Max vaginal panel in a sexual health clinic. The lower specificity and sensitivity for candida is not unexpected as a proportion of women carry low levels of asymptomatic candida. The sensitivity for BV was good but specificity is lower than previously described¹. Residual samples were not available for repeat testing. However 18/26 women who were NAATS positive but microscopically and clinically did not have BV, had other STIs including gonorrhoea, mycoplasma and chlamydia which potentially altered the vaginal microbiome.

The NAATs do not provide the immediate results that are available from microscopy in a specialist sexual health service but were easy to perform and process and offer benefits over the traditional high vaginal swab where a microscope is not available

1. Gaydos CA et al. Clinical Validation of a Test for the Diagnosis of Vaginitis. Obstet Gynaecol 2017;130:181-189