

methods with relatively poor sensitivity compared to nucleic acid amplification methods. Our aim was to determine TV prevalence using the APTIMA TV Assay (ATV, Gen-Probe Incorporated) and the frequency of co-infections with *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoea* (NG) in the USA among women being screened.

Methods Samples from 7593 women aged 18–89 years undergoing routine CT and NG screening at obstetrics/gynaecology, emergency room, hospital in-patient, family practice, family planning, internal medicine, jail, and STD clinic populations in 21 states were collected. Consecutive samples previously tested for CT and NG by the APTIMA COMBO 2 Assay (Gen-Probe Incorporated) were retrospectively tested with the ATV assay. Endocervical, urine, vaginal swab and PreservCyt liquid Pap samples (Hologic Inc.) diluted into APTIMA specimen transport buffer were tested.

Results Overall prevalences of TV, CT and NG in surveyed women were 8.7%, 6.7%, and 1.7%, respectively. TV prevalence ranged from 7.5 to 8.6% in women age 18 to 39 yr, and increased to 9.8% in women age 40–44 yr. Highest observed TV prevalences were in women ages 45–49 yr (13.4%) and over 50 yr (13.0%). CT and NG prevalences were less than 2% in the 40+ age group and highest in women less than 30 years of age ranging from 5.2% to 14.3% for CT and 1.3%–3.3% for NG. TV was the more prevalent STD than either CT or NG in all age groups, except the 18–19 yr group (CT: 14.3%; TV: 8.5%). TV prevalence differed by race/ethnicity (20.2% blacks; 5.7% whites; 5.0% Hispanics; 3.8% Asians). TV prevalence was 14.4% in the Southeast, 9.5% in the Southwest and Midwest, and 4.3% in the Northeast and ranged from 5.4% in Family Planning clinics to 22.3% in jails. Co-infections in most age groups were <1%, and were highest in the 18–19 yr group (TV/CT: 2.1%; TV/NG: 0.88%).

Conclusions TV prevalence was highest in women over 40 years of age, in contrast to CT and NG prevalences which were highest in women under 30 years of age. Co-infection of TV with CT or NG was relatively low. The high TV prevalence in all age groups suggests that all women being screened for CT/NG should also be screened for TV. Routine TV screening should also be considered for at-risk sexually active women of any age.

03-S2.06 THE EFFECT OF *TRICHOMONAS VAGINALIS* (TV) INFECTION ON THE VAGINAL MICROBIOME

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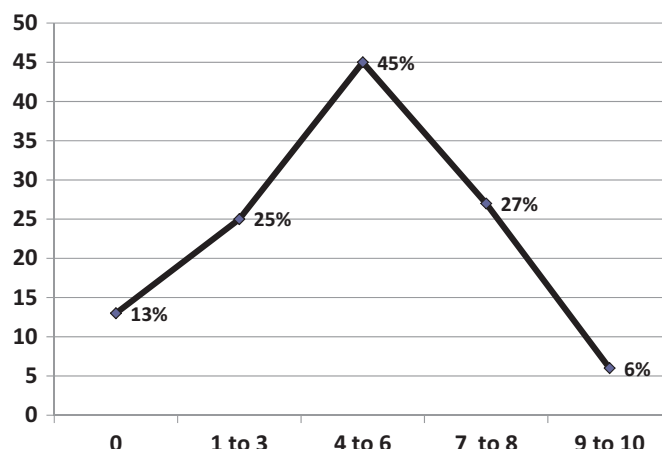
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Background Among pregnant women the prevalence of TV infection is highest in women who have intermediate Nugent scores (NS) compared to those with low and high scores reflective of normal and bacterial vaginosis (BV) types of vaginal flora. The goals of this study were to determine if this relationship held true for non pregnant women and to determine if TV infection was associated with changes in the vaginal microbiome.

Methods The study subjects were 394 women enrolled in a cross-sectional study of the aetiology of cervicitis in the New Orleans STD clinic. TV was diagnosed using the InPouch culture method. NS was determined using standard criteria. *C trachomatis* (CT), *N gonorrhoeae* (NG), and *M genitalium* (MG) were diagnosed using NAATs. DNA was extracted from a vaginal swab and stored. Associations between NS and STIs and NS and sexual behaviour were analysed for all 394 women. 454 pyrosequencing analyses were performed on vaginal DNA from 30 TV positive and 30 TV negative samples evenly divided between those with normal, intermediate, and BV flora as determined by NS.

Results 95% of enrolled women were African American and the mean age of the population was 25.6 years. The prevalence of TV

(y axis) by 5 NS categories (x axis) is shown in the Abstract O3-S2.06 figure 1. As opposed to TV, the prevalence rates for CT, GC, and MG were highest among women with NS of 7–10. Also there was no difference in high risk sexual behaviour between those with low and high NS. These data suggested that the striking decrease in TV prevalence observed among women with BV was the result of vaginal environmental factors, not decreased risk for STIs. A heat map based on pyrosequencing data showed that the vaginal flora of 18/30 of the women positive for TV had similar microbiomes which were distinctly different from those of the other 42 women. In the former group, *Mycoplasma spp.* and *Ureaplasma spp.* were more abundant than in the latter group while the reverse was true of *Megasphaera spp.* and *Gardnerella spp.*



Abstract O3-S2.06 Figure 1 *T. vaginalis* Prevalence by Nugent Score.

Conclusions Though published research shows that the incidence of TV is highest in women with BV, our data along with those from a previous study in pregnant women clearly establish that TV prevalence is highest in women with intermediate NS. These data in conjunction with our pyrosequencing results suggest that following infection TV modifies the vaginal microbiome by suppressing some of the BV associated organisms and enhancing the abundance of mycoplasmas.

Clinical sciences oral session 3—diagnostic testing: chlamydia & gonorrhoeae

03-S3.01 COMPARISON OF A NEW APTIMA SPECIMEN COLLECTION AND TRANSPORTATION KIT TO L-PAP FOR DETECTION OF *C TRACHOMATIS*, *N GONORRHOEA* AND *T VAGINALIS* IN CERVICAL AND VAGINAL SPECIMENS

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Background Control of sexually transmitted infections in women has focused on screening using cervical, vaginal or urine samples. The objective was to compare a new specimen collection and transportation (SCT) kit to PreservCyt (PC) and SurePath (SP) liquid-based Pap (L-Pap) for cervical sampling and self- and physician-collected vaginal samples.

Methods Women (n=562) attending a gynaecology clinic (GYC) (n=435) or a youth health clinic (YHC) (n=127) signed consent for a physician to collect two L-Pap samples with a Cervex broom, cervical (CSCT) and vaginal (VSCT) samples and a self-collected VSCT. All specimens were tested for *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG) by APTIMA Combo 2 (AC2) and

Trichomonas vaginalis (TV) by APTIMA TV on a TIGRIS instrument. Each patient was asked on a scale of one to five to express strength of agreement or disagreement with ease or comfort of the 6 step self collection process for the VSCT.

Results There were a total of 22 CT, 19 TV and 2 NG infections with dual infections in 6 people (one CT and NG, one NG and TV and four CT and TV). Prevalences were as follows: CT 3.9% (GYC 1.3% and YHC 12.6%); NG 0.3% (2.0% in YHC); TV 3.4% (GYC 0.4% and YHC 13.4%). Sensitivity for CT infections were CSCT 100%, PC 100%, SP 81.8%; VSCT-self 100%, VSCT-physician 95.4%: for TV infections CSCT 89.4%, PC 84.2%, SP 63.2%; both VSCT 100%: for NG all collections 100%. There were no false positives (% specificity 100). Results of the survey revealed that the majority of patients found opening the package, self sampling, insertion of the SCT swab into preservation media and uncapping and recapping the tube were relatively easy to perform. Eighty two per cent experienced no discomfort using the SCT kit for collection.

Conclusions APTIMA testing on the TIGRIS showed that the cervical and vaginal SCT and PC L-Pap samples were 100% sensitive in detecting CT and NG infections. VSCT samples detected all TV infections but cervical SCT and PC L-Pap were less sensitive. SP L-Pap samples showed reduced sensitivity for CT and TV. Overall, patients were in strong agreement with the ease of use of the VSCT and most found the process comfortable.

03-S3.02 PERFORMANCE OF THE BIO-RAD Dx CT/NG/MG ASSAY FOR SIMULTANEOUS DETECTION OF CHLAMYDIA TRACHOMATIS, NEISSERIA GONORRHOAE AND MYCOPLASMA GENITALIUM IN UROGENITAL SAMPLES

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Objectives To investigate the performance of the Bio-Rad Dx CT/NG/MG Assay with an internal control for the detection of *Chlamydia trachomatis* (CT) and *Mycoplasma genitalium* (MG) in urogenital samples in comparison with the Roche Cobas TaqMan CT test and an in-house TaqMan PCR test for MG. For *Neisseria gonorrhoeae* (NG), only positive PCR results were controlled by culture.

Methods In this prospective study, urogenital samples were obtained from symptomatic and asymptomatic patients attending the STI center of Bordeaux, France, from January to April 2010. For symptomatic women and men, two endocervical swabs and two urethral swabs were collected, respectively. All patients and women collected first-catch urines and two vaginal swabs, respectively. Two swabs per site were used, a flocked swab in the universal transport medium and the Bio-Rad flocked swab in its transport medium. For the Bio-Rad CT/NG/MG assay, the DNA was manually extracted and amplified according to the manufacturer's instructions. For the comparator PCR tests, DNA was extracted using the MagNa Pure LC instrument (Roche Diagnostics) and amplified with the Cobas TaqMan CT 48 assay (Roche Diagnostics) and with a MgPa-targeted PCR assay on an ABI Prism 7000 (Applied Biosystems) for MG. The patient was considered as infected if at least two of the 4 or 6 PCR tests performed according to the gender and characteristics of patients, were positive. For asymptomatic men, in case of discrepancy, the urine sample was retested by both methods and the patient was considered infected if at least two of the four PCR results were positive for the considered microorganism.

Results A total of 658 clinical specimens (259 male and 180 female urines, 191 vaginal, 21 cervix and seven urethral swabs) from 453 patients were analysed. The prevalence of CT and MG infections was 7.7% (20/260) and 1.9% (5/260) in men and 10.3% (20/193) and

2% (4/193) in women, respectively. The Bio-Rad Dx CT/NG/MG test sensitivity was 100% for CT and MG in men and women. In male urines, the specificity was 99.6% for CT and 100% for MG. In women, the specificity was 99.5% for swabs and 100% for urines for CT and MG. All 7 NG-PCR positive samples were positive by culture. Patients were co-infected in 5/56 (9%) with CT/MG in three cases and CT/NG in two cases.

Conclusion The Bio-Rad Dx CT/NG/MG Assay was found to be very effective for the simultaneous detection of CT, MG, and NG infections in urogenital specimens.

03-S3.03 DIFFERING NEISSERIA GONORRHOAE BACTERIAL LOADS IN THE PHARYNX AND RECTUM: IMPLICATIONS FOR GONOCOCCAL DETECTION, TRANSMISSION AND CONTROL

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Background To help improve our understanding of the potential transmissibility of gonococcal infections from the pharynx and rectum we measured gonococcal bacterial loads at these sites and examined clinical and laboratory determinants of these loads.

Methods Men who had sex with men were tested for pharyngeal and rectal gonorrhoea by culture using modified Thayer Martin medium and by two real-time quantitative qPCRs targetting opa gene, and porA pseudogene.

Results 1011 rectal and 1076 pharyngeal specimens were obtained from 1076 MSM. Forty three (3.9%) pharyngeal specimens were PCR positive of which 17 were culture positive (sensitivity 39%, 95% CI: 25% to 54%). Forty seven (4.6%) rectal specimens were PCR positive of which 25 were also culture positive (sensitivity 58%, 95% CI 44% to 71%). The median bacterial load among PCR positive rectal infections (18 960 copies per swab) was significantly higher than that for PCR positive pharyngeal infections (2,100 copies per swab) ($p=0.001$). The median bacterial load among men with symptomatic rectal infection was higher (278 800 copies per swab) than with asymptomatic men, PCR positive rectal infections (13,980 copies per swab, $p<0.001$). The median bacterial load of gonorrhoea was significantly higher in culture positive than culture negative specimens. This applied for both rectal ($p<0.001$) as well as pharyngeal infections ($p=0.03$).

Conclusion Higher bacterial loads of gonorrhoea were observed in rectal infections, particularly with symptomatic rectal infections. This has implications for gonococcal transmission and control.

03-S3.04 SELF-ADMINISTERED NEISSERIA GONORRHOAE AND CHLAMYDIA TRACHOMATIS TESTING IN THE PHARYNX AND RECTUM AMONG MEN WHO HAVE SEX WITH MEN IN WASHINGTON, DC

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Background Recent studies have demonstrated a high prevalence of pharyngeal (P) and rectal (R) *Neisseria gonorrhoeae* (GC) and *Chlamydia trachomatis* (CT) infections among men who have sex with men (MSM), which is concerning given the potential for harmful