Background

Type specific serologic tests for herpes simplex virus (HSV)-1&2 are used for sero-epidemiological studies. Its early application has also been shown to be of benefit in testing for primary & recurrent infections in diagnosis and patient management. The present study was conducted to evaluate the role of type specific HSV-1&2 antibody detection as a diagnostic modality in patients with clinically suspected genital herpess.

Methods

Sera obtained from 44 patients with clinically suspected genital herpess attending the STD clinic of our institution over last 7 months were tested for type specific HSV-1&2 IgG antibody by glycoprotein G based ELISA (HerpeSelect 1&2, Focus Diagnostics, USA). Direct Fluorescent Antibody testing (DFA) (BIO-RAD laboratories, USA) was used for identification and typing of HSV-1&2 in genital ulcer specimens in all cases.

Results

There were 21 cases of primary & 23 cases of recurrent genital ulceration. DFA was positive in 68% samples (43% only HSV-2, 9% only HSV-1, 16% both HSV-1&2). On comparison with DFA, the sensitivity, specificity, positive and negative predictive value of HSV-2 IgG ELISA in primary herpetic ulcer was 8%, 75%, 33%, 33%, while it was 79%, 89%, 92%, 73% in recurrent genital ulceration. The sensitivity, specificity, positive predictive and negative predictive values of HSV-1 IgG ELISA in primary herpetic ulcer was 50%, 67%, 37.5%, 77%, while it was 80%, 39%, 27%, and 87.5% in recurrent genital ulceration.

Conclusion

Our results highlight the importance of HSV-2 IgG detection in strengthening the diagnosis of recurrent HSV-2 disease, while absence of HSV-2 IgG antibody helps in excluding genital herpes as a likely cause of recurrent genital ulceration. The identification of HSV-1 IgG antibody may not be useful for diagnosis in patients of genital ulcer disease highlighting the need for typing HSV-1 strains from the genital lesion.

COPAN ESWAB™, A LIQUID BASED MICROBIOLOGY DEVICE, CAN BE USED FOR THE PRESERVATION OF NEISSERIA GONORRHOEAE FOR CULTURE AND FOR DETECTION OF CT/NG BY GEN-PROBE® APTIMA® COMBO 2 ASSAY

Background

Copenhagen Amies Elution Swab (ESwab™) Collection and Transport System incorporates maintenance medium which can sustain the viability of Neisseria gonorrhoeae (NG). Swab specimens placed in the tube and stored at room temperature (RT) can be cultured within 24 hours, and aliquots for nucleic acid amplification tests (NAATs) can be processed within five days.

Methods

Clinicians at a Baltimore City Health Department STD clinic used standard-of-care aluminium shaft swabs with polyester tips to collect urethral swabs from men, smeared a slide for Gram stain, and placed NG positive (by smear) swabs into investigational ESwab™ tubes. The ESwab™ collection swab applicator was then broken off into the tube and the cap was closed. Culture was performed after tube sat from 5 to 28 hours at RT. Tube was vortexed for 5 seconds; 100 μl was inoculated to MTM plate, streaked for isolation, and incubated in appropriate conditions for 48–72 hours; 100 μl was placed into Gen-Probe® Unisex transport tube for testing by APTIMA® COMBO 2 assay.

Results

Of 35 swabs, 26 (74%) were culture positive for presumptive NG (Gram negative diplococci, oxidase positive). Colony counts ranged from 1 to > 500 colonies. 35 (100%) swabs were positive for NG by Gen-Probe® APTIMA® COMBO 2 assay. Six (17%) were also positive for Chlamydia trachomatis (CT) by Gen-Probe® assay.

Conclusion

Although quality of collected clinical specimen and quantity of NG on the swab are significant variables in obtaining reliable culture results, the ESwab™ System was able to maintain NG viability for at least 24 hours, and stabilised nucleic acids for Gen-Probe® testing. The ability to maintain culture viability of NG up to 24 hours until NAAT testing is completed could eliminate the necessity to perform cultures on all patients who are being screened for NG, with cultures maintained only for susceptibility testing for NAAT + patients.

EVALUATION OF ELECSYS® IMMUNOASSAY SYSTEM FOR DETERMINATION OF TYPE-SPECIFIC IGG ANTIBODIES TO HSV-1 AND HSV-2

Background

HSV-1 strains from the genital lesion.

Methods

were tested for type specific HSV-1&2 IgG antibody by glycoprotein G based ELISA (HerpeSelect 1&2, Focus Diagnostics, USA). Direct Fluorescent Antibody testing (DFA) (BIO-RAD laboratories, USA) was used for identification and typing of HSV-1&2 in genital ulcer specimens in all cases.
Background HSV infections during pregnancy are generally asymptomatic and associated with high rate of neonatal morbidity and death. Differential serologic diagnosis of HSV infections in pregnancy is important for the correct assessment of the infection status. The aim of this study was to evaluate the performance of Roche Elecsys® assays for the type-specific determination of HSV-1 and HSV-2 IgG antibodies.

Methods A total of 800 samples obtained from sexually active adults (n = 400), pregnant women (n = 400) and herpes infection suspected patients (n = 100) were analysed using Roche Elecsys® HSV-1 and HSV-2 assays and commercially available Focus Diagnostics HerpeSelect, Radim HERPES S.V and Diasorin LIAISON type specific ELISA assays.

A commercially available Western Blot assay was used for the resolution of the discrepant results.

For further confirmation of the type-specific detection performance of the Elecsys® HSV-1 and HSV-2 assays 310 potentially cross-reactive samples for HSV-2 and 123 samples for HSV-1 were analysed.

Results The Elecsys® HSV-1 IgG assay showed a relative sensitivity of 95.6 to 100%. The relative specificity was between 97.6 and 100%. The Elecsys® HSV-2 IgG assay showed a relative sensitivity of 92.6 to 100%. The relative specificity was between 98.7 and 99.6% (95% CI: 98.8–100) and 96.6% (95% CI: 93.9–98.4) and a specificity of 95.5% (95% CI: 93.1–97.3) and 100% (95% CI: 99.1–100) for Focus and Kalon respectively.

Conclusion Although our study confirms the assay performance findings of previous studies in Sub-Saharan countries, we found less pronounced differences in terms of sensitivity and specificity of both assays using the cut-off as prescribed by the manufacturers. The prevalence of HSV-2 found in our study corresponds to previously reported results.

P5.073 COMPARISON OF COBAS® 4800 HPV ASSAY TO DIGENE HYBRID CAPTURE 2, ROCHE LINEAR ARRAY, AND AMPLICOR IN THE DETECTION OF HIGH-RISK HUMAN PAPILLOMAVIRUS GENOTYPES IN WOMEN WITH PREVIOUS ABNORMAL PAP SMEARS


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Introduction Cobas® 4800 HPV assay has been evaluated as a screening and triage application recently. The aim of this study was to evaluate the performance of the Cobas® 4800 HPV assay for the detection and identification of high-risk (HR) HPV genotypes after treatment of high grade lesion by comparison with the Hybrid Capture 2® (HC2), Amplicor (Amp), and Linear Array (LA) HPV tests.

Methods Four hundred and six PreservCyt® specimens from women undergoing management for a high-grade Pap abnormality were evaluated and results compared with the HC2, Amp, and LA HPV test results, in addition to histological diagnosis of a contemporaneously collected biopsy.

Results The sensitivity in detection of underlying high-grade histological diagnosed by Cobas® 4800 HPV was 90.6%, for HC2 86.1%, whilst for Amp and LA 92.9% and 91.8% respectively. Restricting detection of Cobas® 4800 HPV to only types 16 and 18 resulted in sensitivity of 60.0%. Detection of HR genotypes by Cobas® 4800 HPV showed a concordance of 86.9%, 96.1%, and 96.3% compared to HC2, Amp and LA HPV tests respectively.

Conclusion The performance of Cobas® 4800 HPV was equivalent to the Amp and LA HPV tests for HR HPV detection. Cobas® 4800 HPV identified more underlying histologically-confirmed high-grade lesions than the HC2 HPV test, with the added advantage of identifying HPV 16 and 18 genotypes present.