Diagnosis of extra-genital chlamydia and/or gonorrhoea infections by Versant CT/GC DNA 1.0 Assay

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INTRODUCTION

Chlamydia trachomatis (CT) and *Neisseria gonorrhoeae* (GC) are the two most common bacterial sexually transmitted infections (STI) worldwide. Anal and/or pharyngeal intercourse are increasingly recognized as a component of the sexual repertoire of many couples, in particular in men who have sex with men (MSM). Although an accurate pharyngeal and rectal diagnosis is critical to STI control efforts, nucleic acid amplification techniques (NAATs) for testing extra-genital specimens have not been licensed yet. For that reason, many laboratories have performed their own validation studies in order to provide results for the clinical management.

In this study, Versant CT/GC DNA 1.0 Assay (Siemens) performances were evaluated by testing rectal and pharyngeal swabs collected from a high STI-risk population.

MATERIALS AND METHODS

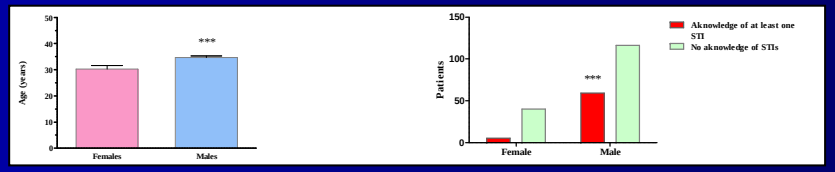
Study group. From February 2013 to October 2013, a prospective study was performed on 220 subjects attending the STI Outpatients Clinic of St. Orsola Hospital, Bologna. All patients were enrolled because of reporting unsafe receptive anal and/or pharyngeal sex intercourses. Data regarding gender, age, sexual orientation, symptoms and presence of other STIs, in particular HIV, syphilis, HPV, HBV and HCV, were recorded.

NAATs. All the specimens were tested by Versant CT/GC DNA 1.0 Assay. In case of a CT positive result by Versant CT/GC 1.0 Assay, the corresponding remnant DNA was collected from the extraction microplate and used as a template for *omp1* amplification by an in-house semi-nested PCR. Genotyping was performed by RFLP analysis of the PCR products, using *AluI*, *HinfI* and *DdeI* as restriction enzymes (Promega). All the specimens scored GC positive were retested by a "home-made" PCR assay, targeting *PorA* gene.

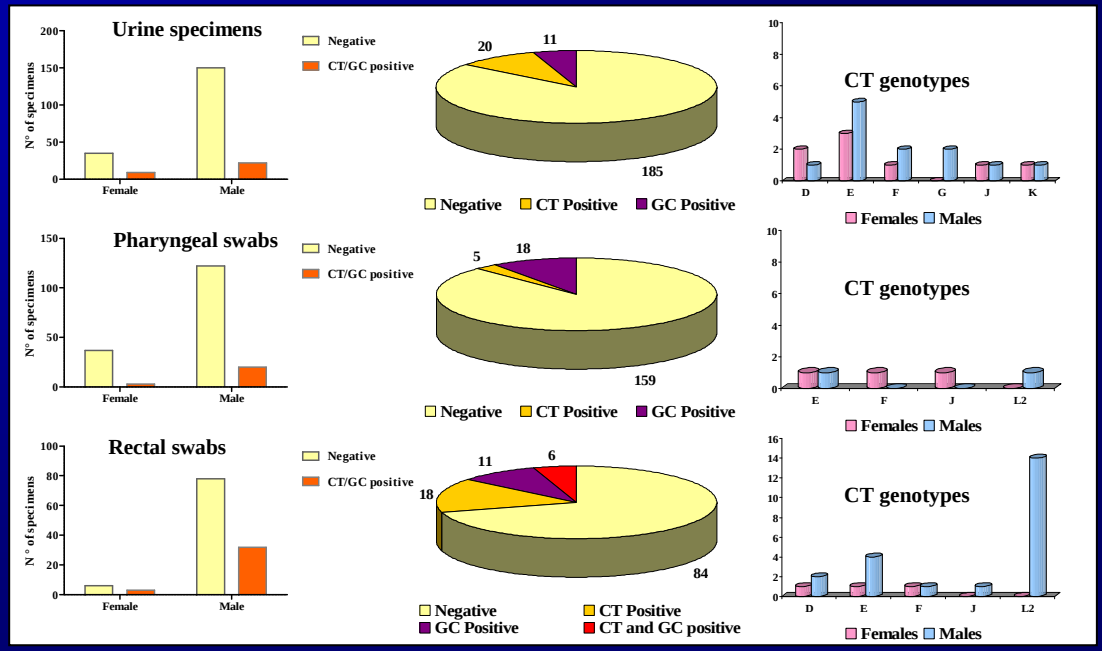
Statistics. Chi-square test and Student's t test were performed and a P value <0.05 was considered significant.

RESULTS

A total of 220 patients were enrolled for the study: in particular 45 heterosexual females, 146 men having sex with men (MSM) and 29 heterosexual males.



During the study period 216 urine samples, 182 pharyngeal swabs and 119 anorectal swabs were tested for CT/GC detection.



Considering patients with positive rectal swab results, we noticed that they were more likely symptomatic (P<0.01) and presented more STIs (P=0.007) than negative subjects.

Finally, all GC positive results obtained by Versant CT/GC DNA 1.0 Assay were confirmed by "home made" PCR testing, attesting an excellent specificity of the commercial test used.

CONCLUSIONS

In our experience Versant CT/GC DNA 1.0 Assay, for its performances and the easy of use, showed to be a very good choice for CT/GC laboratory diagnosis on extra-genital specimens.

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