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COMPARISON OF VARIOUS MOLECULAR METHODS FOR DETECTING HUMAN PAPILLOMA VIRUS FROM CLINICAL SPECIMENS

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Background

Persistent infection with one or more carcinogenic types of human papilloma virus (HPV) is an important etiologic factor in the development of cervical intraepithelial neoplasia and the progression to cervical cancer, the third common cause of cancer mortality in women worldwide. Cytopathology has provoked the marked reduction of cervical cancer mortality but its sensitivity is actually lower than that of HPV DNA assays. Until now, various molecular methods for HPV detection have been introduced and we evaluated the performance of hybrid capture assay, real-time polymerase chain reaction, fragment analysis, nucleic acid sequence based amplification (NASBA) and restriction fragment mass polymorphism (RFMP) analysis.

Methods

Out of 6,322 submitted clinical specimens from April in 2010 to June in 2012, 545 specimens were used for the evaluation of Hybrid Capture HPV DNA (HC2) assay, Abbott RealTime High Risk HPV test and fragment analysis using Seeplex HPV 18 ASE genotyping kit. Fragment analysis was performed when either HC2 or real-time PCR was true. The concordance among HC2 and RealTime High Risk HPV test was considered as True positivity or negativity. When the results were not concordant, the results of fragment analysis were regarded as true. Additionally, NASBA was simultaneously performed with fragement analysis and RFMP was performed using Bruker RFMP HPV PapilloTyper from January 2012 to June 2012.

Results

In 545 specimens, one or both of HC2 and real-time PCR showed positive results and fragment analysis was performed simultaneously. Positivity for high risk HPV using fragment analysis was shown in 486 specimens(89.2%, 7.7% of total specimens). The concordance rates of HC2 and real-time PCR in true positive results were 84.2%(409/486) and 99.0%(481/486). For NASBA, type 16, 18, 31, 33 or 45 were detected in 167 cases and the concordance rate between fragment analysis and NASBA was 56.3%(94/167). RFMP tests and fragment analysis were performed for 32 specimens and in 53.1%(17/32), the results were identical.

Discussion

We evaluated the performance of four molecular methods for HPV detection compared with fragment analysis. Other than NASBA, there were no significant differences in performance. But, using only single method seems to be insufficient for HPV detection and genotyping. HC2 was not as sensitive as real-time PCR and RFMP showed relatively poor performance, compared with real-time PCR or HC2. To provide the more accurate results, the combination of more than two molecular methods would be necessary.