
HPV E6, E7 mRNA EXPRESSION IN ECTOCERVICAL CELLS (HPV ONCOTECT) PREDICTS DISEASE PROGRESSION IN WOMEN WITH LOW GRADE INTRAEPITHELIAL NEOPLASIA (LSIL)

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Background: Current cervical cancer screening relies on cytologic diagnosis combined with HPV DNA detection. This screening algorithm identifies women at risk for developing cervical cancer but does not provide any information on which women with low grade lesions (LSIL) will progress.

Objectives: To address this important deficiency in cervical cancer screening, we prospectively followed women with a cytologic diagnosis of LSIL.

Materials and Methods: Serial samples were frozen in ThinPrep PreservCyt medium at -80 °C until analysis. Study subjects were divided into Progressors (n=11) and Non-progressors (n=9) and samples were analyzed at baseline and at the time of progression. Non-progressor samples were analyzed at the same duration as Progressors relative to the baseline sample. To predict which subjects progressed and which subjects did not, we used HPV OncoTect (Invirion Diagnostics, Oakbrook IL, USA), an assay that quantifies on a cell-by-cell basis the overexpression of HPV E6, E7 mRNA, on all of the thawed, frozen specimens.

Results: Samples from the Progressor group had an average of 5.2% cells that overexpressed HPV E6, E7 mRNA relative to HPV negative control cells. Samples from the Non-progressor group averaged 1.6% cells that overexpressed HPV E6, E7 mRNA which is below the background cut-off of 2.0% determined on 100 HPV negative cervical cytology samples. The difference in the percentage of cells overexpressing HPV E6, E7 mRNA between the Progressor group and the Non-progressor group was statistically significant ($p = 0.008$).

Conclusions: Using a cut-off of 2.0%, HPV OncoTect correctly distinguished all Progressors from Non-progressors.