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Clinical performance of HPV16/18 genotyping, reflex cytology and CINtec® PLUS immunocytochemistry to triage of hrHPV+ women: Pilot nested in the Scottish PAVDAG study

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Background: The objective of this study is to examine clinical performance of HPV 16/18 genotyping, reflex liquid-based cytology (LBC) and CINtec® PLUS immunocytochemistry for triage of high-risk HPV positive (hrHPV+) women for detection of cervical intraepithelial neoplasia grade 2 or worse (CIN2+) in a Scottish population.

Methods: LBC samples of 536 hrHPV+ women identified in the papillomavirus Dumfries and Galloway (PAVDAG) study were processed for CINtec® PLUS immunocytochemistry. All women with positive CINtec® PLUS tests were invited to colposcopy if they had not been otherwise investigated through the PAVDAG protocol.

Results: Triage of hrHPV+ women with CINtec® PLUS was more sensitive for CIN2+ than LBC. However, the sensitivity of CINtec® PLUS for CIN2+ was relatively low (84.2%) in HPV16/18+ women. One in three (32%) women with CIN2+, who tested LBC negative were also CINtec® PLUS negative. Relative sensitivity and specificity of LBC vs. CINtec® PLUS in cervical and vaginal hrHPV+ women with other than HPV16/18 types (hrHPV other+) was 0.95 (0.73-1.23), 1.12 (1.09-1.12) and 1.00 (0.78-1.28), 1.07 (0.95-1.20) respectively.

Conclusions: CINtec® PLUS has better sensitivity for CIN2+ in non type-specific hrHPV+ women compared to LBC. However this difference is much smaller when HPV16/18+ women are referred for colposcopy directly and only hrHPV other+ women are triaged. These results are similar irrespective of the sampling method used (clinician collected cervical or self collected vaginal samples) for hrHPV detection. The optimal hrHPV based cervical screening should include HPV16/18 typing to allow direct referral to colposcopy for all HPV16/18+ women. Further triage of other than HPV16/18 hrHPV+ women should include LBC follow-by CINtec® PLUS testing of LBC women.

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Moving forward with the implementation of cytology based cervical cancer screening programs in eastern Europe and Central Asia

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Cervical cancer is one of the most common cancers among women in low and middle income countries, although the vast majority of cases could be prevented by well organized, population based cervical screening programs. At this time, the current trend in developed countries is to move from cytology (the Pap test) to the use of HPV testing for cervical screening. However, the use of HPV testing in many low and middle income countries is problematic because of the high prevalence of HPV infection combined with suboptimal adherence to or the complete absence of clinical guidelines for the triage and follow up of HPV positive women and the incentives to conduct these follow up and treatment procedures that are created by formal or informal payment to doctors. Therefore, cytology based cervical screening with a lower sensitivity but high specificity than HPV testing is likely to be a more cost effective and safer option for many low and middle income countries but particularly for Eastern European and Central Asian countries where cytology and cytopathology were highly developed during Soviet times. In recognition of these issues, this presentation will discuss the status of cytology and cytopathology in Eastern Europe and Central Asia during Soviet times; the current status of cervical screening in this region; the potential problems with using HPV testing in this region including HPV prevalence rates and the issues pertaining to clinical guidelines for the follow up and treatment of screen positive women; the process that is required to implement cytology based cervical screening programs in this region and the progress that has been achieved with the implementation of a cytology based cervical screening program in the Republic of Moldova.

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