PERFORMANCE OF HPV E6/E7 mRNA AND DNA TESTS FOR THE DETECTION OF CIN 2 OR WORSE: RESULTS FROM A MULTICENTRE CANADIAN STUDY

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Background: Testing for HPV E6/E7 expression is likely to have greater clinical specificity for the detection of cervical pre-cancer/cancer than testing for the presence of HPV DNA. An ongoing multicentre study is assessing the performance of E6/E7 mRNA-based tests and biomarkers in comparison with HPV DNA testing.

Objectives: This study assessed the clinical sensitivity and specificity of different HPV tests for the detection of > CIN 2 in colposcopy referral and routinely screened populations.

Methods: The study populations were enrolled from 6 centres, representing 6 of the 10 Canadian provinces. The APTIMA® HPV Assay (Gen-Probe) and Pre-Tect HPV Proofer® (Norchip) tests were used for E6/E7 mRNA testing, the HC2® (Qiagen) and AMPLICOR ® (Roche) tests for DNA testing, and the Linear Array® test (Roche) for genotyping. Histology confirmed > CIN 2+ served as the gold standard.

Results: Of 831 referral cases, 240 were diagnosed with > CIN2 (Disease prevalence, 28.9%). In this population, the clinical sensitivity and specificity were 94.6% and 46.7%, respectively, for APTIMA versus 77.9% and 75% for PreTect Proofer; this compared with 95% and 38.1% for HC2. In a second subset of 478 referral cases, 107 were diagnosed with > CIN 2 (Disease prevalence, 22.4%). In this population, the clinical sensitivity and specificity were 91.6% and 61.7%, respectively, for APTIMA versus 96.3% and 43.4% for AMPLICOR; this compared with 90.7% and 50.1% for HC2. Of 1120 routinely screened subjects, 7 were diagnosed with > CIN 2 (Disease prevalence, 0.6%). In this population, the clinical sensitivity was 100% for both APTIMA and HC2. Among those with < CIN1, a lower proportion tested positive by APTIMA compared with HC2, i.e., 138 vs 174 ($p < 0.05$).

Conclusions: The APTIMA E6/E7 mRNA test showed equal clinical sensitivity and a higher clinical specificity compared with the HC2 DNA test. When compared with these two tests, the AMPLICOR DNA test showed a higher clinical sensitivity but a lower specificity whereas the opposite was true for the Pre-Tect Proofer test.