VALIDATION OF A NEW HPV DNA TEST FOR CERVICAL AND SELF-COLLECTED VAGINAL SAMPLES IN THE MULTICENTRIC PROSPECTIVE TRACE TRIAL IN HUNGARY

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Objectives

The clinical performance of the CONFIDENCE HPV™ test (NEUMANN Diagnostics Ltd.) as a first-line primary cervical cancer screening test from cervical samples collected in ThinPrep® (Hologic, Inc.) and from self-collected vaginal samples taken with the Qvintip® device (Aproxis AB) was assessed in the multicentric prospective TRACE (Triage and Risk Assessment of Cervical Precancer by Epigenetic Biomarker) trial in Hungary. Further subject of our analysis was the HPV viral load measured in the cervical samples with different clinical endpoints.

Methods

The CONFIDENCE HPV™ test is a multiplex real-time PCR DNA assay which detects HPV16 and HPV18 separately and 12 other high risk types in group. The DNA extraction and PCR setup was performed on Tecan EVO® liquid handling platform and 5-plex quantitative real-time PCR was performed on the QuantStudioTM 6 Flex platform in 384-well plate format in four reactions per sample.

In the comparison of the CONFIDENCE HPV™ test with a clinically validated reference test, the cobas® HPV test (Roche) was used (n=3,150). (Figure 1.)

The CONFIDENCE HPV™ test for the Qvintip® self-collected vaginal sample was clinically validated by comparing the CONFIDENCE HPV™ test results of the clinician collected cervical sample with the self-collected vaginal sample of the same women (n=281). (Figure 2.)

Results

In comparison with the cobas® HPV test the CONFIDENCE HPV™ test results showed 92.3% overall agreement for hrHPV detection and 0.99% relative sensitivity and 0.97% relative specificity for CIN2+ cases. (Figure 3.)

The comparison results of the CONFIDENCE HPV™ test from cervical and vaginal samples showed 89.0% overall agreement for hrHPV detection, 0.89% relative sensitivity and 0.92% relative specificity for CIN2+ cases. (Figure 4.)

Distribution of the normalized HPV viral load in samples with CIN2+ cases (n=75) and in women with no evidence of a CIN2+ lesion (n=713) detected by CONFIDENCE HPV™ is shown in Figure 5.

Conclusions

The clinically validated CONFIDENCE HPV™ test is nearly as accurate on self-samples as on clinician-collected samples. The quantitative result of the HPV viral load in cervical samples may further characterize the cervical cancer risk of the patient.

Figure 1. TRACE study for CONFIDENCE HPV™ and CONFIDENCE Marker™ test clinical validation.

Figure 2. TRACE study for CONFIDENCE HPV™ test clinical validation on Qvintip® self-collected vaginal samples.

Figure 3. CONFIDENCE HPV™ test results compared to cobas® HPV test (n=3,150).

(A) Absolute and relative sensitivity, specificity, PPV, NPV results of CONFIDENCE HPV™ test on Qvintip® and Thinprep®.

(B) Agreements of the CONFIDENCE HPV™ test results (any, 16, 18, other) on Qvintip® and Thinprep®.

Figure 4. CONFIDENCE HPV™ test results on self-collected vaginal (Qvintip®) compared clinician-collected cervical samples (Thinprep®) (n=281).

(A) Absolute and relative sensitivity, specificity results of CONFIDENCE HPV™ test on Qvintip® and Thinprep®.

(B) Agreements of the CONFIDENCE HPV™ test results (any, 16, 18, other) on Qvintip® and Thinprep®

Figure 5. Distribution of normalized HPV viral load tested by CONFIDENCE HPV™ in LBC sample of women aged 30 years or older from the baseline sampling of the TRACE study. CIN2+ cases versus women with no evidence of a CIN2+ lesion.