

P16/Ki-67 Dual Stain in the triage of PAPIII/IIID cytology in cervical cancer screening

Kisser A, Zechmeister-Koss I

Each year around 30 000 women in Austria receive a PAPIII or PAPIIID cytology result during routine cervical cancer screening. Roughly equivalent to ASC-US or LSIL cytology according to Bethesda classification, this result means that equivocal cell anomalies or mild to moderate dysplasia were detected in their pap smear. The risk of progression to cancer of these results is unclear and requires further diagnostic investigation: this induces emotional stress to the patients and causes a high number of unnecessary procedures, including biopsies and conisations.

The p16/Ki-67 Dual Stain test (CINtec® PLUS) claims to detect virally induced oncogenic molecular changes in the cell through the immune cytochemical double staining of the tumour suppressor gene p16INK4a and the proliferation marker Ki-67 and thereby to improve the triage of women with equivocal cytological results.

We have conducted a systematic review of the studies assessing utility of the p16/Ki-67 Dual Stain test in the triage of equivocal or mild to moderate dysplasia results in cervical cancer screening. We could not identify any studies assessing clinical outcomes such as mortality or morbidity and only one high quality study assessing diagnostic accuracy of the test: the evaluation of the clinical utility of the test was therefore not possible. Consequently the test was not recommended for inclusion in the benefits catalogue of public health insurances.

The full German version is available

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