EPIGENETIC MARKERS ALLOWING FOR EARLY RISK DETERMINATION FOR CERVICAL NEOPLASIA AND CANCER*

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Objectives

Cervical cancer develops slowly from lesions, so-called cervical intraepithelial neoplasias (CIN) as a consequence of persisting HPV infection. Neither at the primary HPV infection stage, nor at the manifestation of the different premalignant lesions current cervical cancer screening methods allow to distinguish between infections and lesions that will clear and those that may persist and develop into cancer. Markers with prognostic potential would allow for successful treatment of those lesions that may develop into cancer, at an early stage, which increases the chances for full cure. Whereas women with lesions that have the potential to regress, will profit from such a test, as they will not undergo long-term watchful waiting and eventual unnecessary treatment.

Methods

In a retrospective, longitudinal study cervical scrapes from 30 patients with final histopathologically assured diagnosis CIN_3, for whom samples from visits even before the diagnosis CIN_3 were available, were analysed for methylation of the three markers contained in the GynTect® test for cervical cancer diagnostics, ASTN1, DLX1, and ZNF671. The methylation status of the three markers was determined using methylation-specific PCR and correlated to histopathological and cytological findings.

Results

In the small longitudinal study comprising 30 patients detection (up to six years) of the markers ZNF671, DLX1, and ASTN1 was obtained in 50%, 40% and 30% of all cases at a time point where no histopathological signs of a lesion were determined. In some of these cases the markers were detected more than 2 years before CIN_3 was diagnosed. In a control group comprising 552 patient samples with Pap I findings, the detection rate was significantly lower with 0.9%, 11.1% and 3.6%, respectively.

1

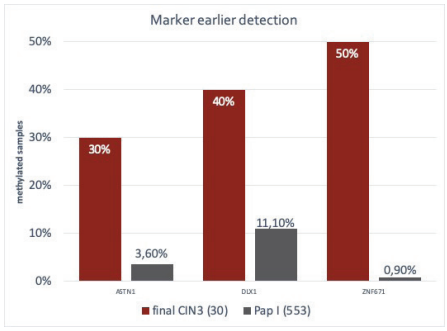

Fig. 1: Methylation of the markers ASTN1, DLX1, ZNF671 in 30 patients with later diagnosis CIN_3, compared to women with no abnormal cytology finding (Pap I, 553 patients).

2A

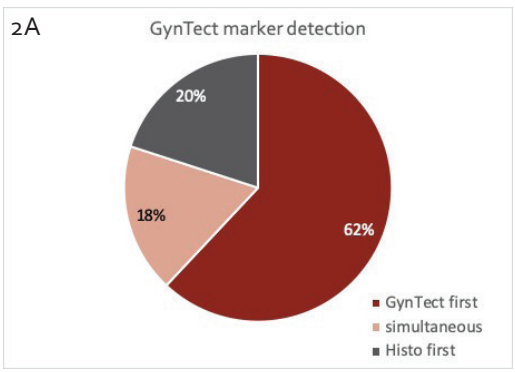

Fig. 2A: GynTect marker detection among 119 women with final histopathology HSIL/CIN_3.

2B

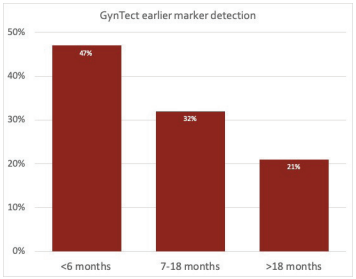

Fig. 2B: Time of earlier detection in those 62% of cases where GynTect markers were detected before the CIN_3 hsitopathology finding..

Conclusion

The results of this study underscore the prognostic value of the markers for severe cervical dysplasia. With the prospective trial GynTect-PRO we aim to confirm the prognostic value of all six GynTect® methylation markers.

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