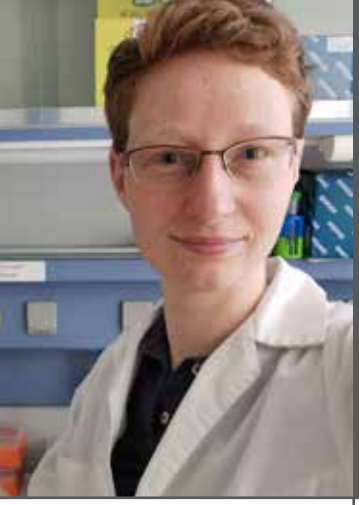

Clarification testing/triage of women tested HPV DNA-positive in cervical cancer screening using a DNA methylation marker-based test as well as an HPV mRNA test*

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oncgnostics GmbH

Talk FC05
10/04/22
13.30-15.00
Room 16B

Objectives

HPV-testing is more and more implemented in cervical cancer screening resulting in a higher sensitivity. This is at the expense of specificity, which may result in overtreatment and higher screening costs.

Aim: Assess DNA methylation marker-based testing and HPV mRNA testing as reliable triage methods for clarification of HPV DNA-positive women. Additional testing may provide a suitable tool especially with respect to keeping false-positive rates low.

Methods

Cervical smear samples (n = 231) with cytology findings ≥Pap III, in liquid-based cytology medium (BestPrep®; CellSolutions). For all samples results from HPV DNA testing (Roche Cobas HPV test) were available.

GynTect® (oncgnostics):
DNA methylation assay for the detection of six tumour-specific DNA methylation marker

Aptima HPV mRNA assay (Hologic):
in vitro detection of mRNA of the oncogenes E6/E7 from 14 hrHPV types allows detection of active infection

Results

	Pap III (170)			Pap IV (53)			Pap V (5)		
HPV group (number)	samples	GynTect-positive	HPV mRNA-positive	samples	GynTect-positive	HPV mRNA-positive	samples	GynTect-positive	HPV mRNA-positive
HPV 16/18 (94)	56	42.9% (24/56)	67.9% (38/56)	35	85.7% (30/35)	85.7% (30/35)	3	100.0% (3/3)	100.0% (3/3)
HPV others (108)	90	13.3% (12/90)	76.7% (69/90)	17	70.6% (12/17)	88.2% (15/17)	1	100.0% (1/1)	100.0% (1/1)
HPV-negative (26)	24	12.5% (3/24)	4.2% (1/24)	1	0.0% (0/1)	0.0% (0/1)	1	invalid	negative

Table 1: Positivity of GynTect and Aptima HPV in relation to cytology findings

The number of positively tested samples increases between PAP III and PAP IV for both tests. In the group of Pap III samples the rate of positivity for the HPV mRNA test (Aptima) is much higher than for the DNA methylation assay GynTect® (Figure 1).

The difference between Aptima and GynTect® is most pronounced in women with Pap III cytology, infected with other types than HPV16/18 (Tab.1). Lesions based on infections with HPV types other than HPV16/18 have lower progression potential. Also samples from patients with high-grade histopathology-confirmed lesions based on infections with HPV types other than HPV16/18 are much less frequently Gyn-Tect-positive.

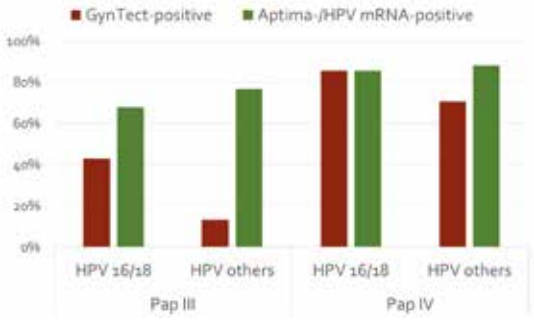

Figure 1: Positivity in relation to cytology and HPV DNA

Conclusion

Detection of mRNA of the HPV oncogenes E6 and E7 provides a sign for a persisting infection with HPV. In contrast, the DNA methylation markers comprising GynTect® are a direct sign for carcinogenesis. Triage using GynTect may show much higher specificity than using HPV mRNA. The main difference in positivity of both tests is seen in the group of samples that are HPV DNA-positive and show a cytology Pap III. Thus, GynTect may help to clarify the malignancy status of HPV-positive women with cytological signs of max. mild dysplasia.

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