

RESEARCH ARTICLE

Concordance in Cervical HPV Detection between Hybrid Capture 2 and HPV GenoArray Tests

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Abstract

HPV type-specific detection may promote cervical screening program and vaccination development worldwide. We conduct a study comparing HPV Hybrid capture II (HC II) Test and HybriBio GenoArray test, a newly developed HPV type-specific assay, in patients with cervical epithelial neoplasm. Results showed a good concordance in cervical HPV detection between two tests (kappa value 0.80, $p < 0.05$, McNemar test). Our study may promote utilization of type-specific HPV detection that is helpful for cervical cancer screening and vaccination.

Keywords: Human papillomavirus - cervical cancer - hybrid capture

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Introduction

Cervical cancer is one of the most prevalent malignancies affecting women worldwide while human papillomavirus (HPV) infection is the most important risk factor of this disease. In China, there were approximately 58,000 new cases and over 20,000 deaths every year which causes an important public health problem (Li et al., 2011). HPV detection mainly relies on molecular biological techniques using nucleic acid probes. Type-specific detection may promote cervical screening program and vaccination development. Hybrid capture II (HC II) test is a widely used HPV test approved by the Food and Drug Administration (FDA) of United States (Hubbard, 2003). By using in vitro nucleic acid hybridization for qualitative detection, it can accurately detect 13 types of high-risk HPV DNA; however, it does not provide any genotype-specific information (Raiv et al., 2014). The recently developed HPV type-specific assay, GenoArray HPV Test, is now used in Asia and Europe. Little is known about the accuracy of this test. Here we report a study comparing the agreement of HC II and GenoArray tests.

Materials and Methods

A total of 110 patients with cervical intraepithelial neoplasm (CIN) were recruited from West China Second Hospital, Sichuan University. Cast-off cells were scraped from cervical lesions and used for both HC II (Digene Inc, Gaithersburg, USA) and GenoArray tests (HybriBio Limited, Hong Kong, China). For the HC II test, a sample was considered positive if the relative light units (RLU) more than 1.0. The study was approved by the Hospital

Table 1. Concordance between the Results for High Risk HPV detection in the 110 Samples Tested by the HC2 HPV test and the HybriBio GenoArray Test

HC II HPV test	HPV GenoArray test			Agreements between the two assays
	Negative	Low risk HPV	High risk HPV	
Negative	16	7	2	23/25(92.0%)
Positive	3	3	79	79/85(92.9%)

*Kappa vale: 0.804, $p < 0.05$ (McNemar test)

Ethical Committee and informed consent was obtained from the patients. Cohen's kappa statistics and the nonparametric McNemar test were used for statistical analysis. Statistical significance was assumed at $p < 0.05$.

Results

High-risk HPV detection rate was 77.3% (85/110) and 73.6% (81/110) by HC2 test and GenoArray test in CIN patients, respectively. The overall agreement in high-risk HPV detection between the two assays was 92.9% with the kappa value of 0.80 ($p < 0.05$, McNemar test), suggesting a good consistency in high-risk HPV DNA detection (Table 1).

Discussion

Primary screening by HPV DNA testing is proved an effective and better method for cervical cancer screening than cytology (Junyangdikul P, 2013; Wang JL, 2013). As a PCR-based HPV type-specific assay, GenoArray test utilizes L1 consensus primers to simultaneously amplify 21 HPV genotypes, including 7 low-risk types (6, 11, 42, 43, 44, 53 and 81) and 14 high-risk genotypes (16, 18, 31,

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33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68), followed by flow-through hybridization with immobilized genotype-specific probes (Hubbard, 2003). This assay has been granted certificate by State Food Drug Administration of China (SFDA) and Verification of Conformité Européenne, but not FDA. Several recent studies have shown that this assay is sensitive and specific for the HPV test and genotyping (Grisaru D, et al., 2008; Liu SS, et al., 2010). Our present study shows a good agreement of the test to HC II in high-risk HPV detection. The results may promote utilization of type-specific HPV detection that is helpful for cervical cancer screening and vaccination.

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