

DRH1 – EVALUATING A BLOOD-BASED MARKER FOR HPV16-INDUCED OROPHARYNGEAL CARCINOMA

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INTRODUCTION

The past decade has seen a steady rise in the incidence of HPV-induced cancers. In the USA, the incidence of HPV16-induced oropharyngeal carcinoma has recently surpassed that of cervical cancer. In this study, we assessed the performance of a novel blood-based assay in the detection and post-treatment monitoring of HPV16-induced oropharyngeal carcinoma.

METHODS

This non-interventional, prospective study included 34 tumor patients (oropharyngeal carcinoma or CUP syndrome) and 1064 CRP-negative controls.

Patient sera were collected at the time of diagnosis and over a 28-month follow-up period after treatment initiation, resulting in a total of 166 samples for analysis. The samples were analyzed for the presence of anti-HPV16 L1 antibodies using a newly developed rapid test based on the HPV16-L1-specific monoclonal antibody clone DRH1. DRH1 antibody levels in patient sera were monitored following treatment and correlated with clinical observations. Samples obtained at the time of diagnosis were used to assess the sensitivity of the assay in detecting HPV16-induced oropharyngeal carcinoma. To confirm HPV status, tumor specimens were checked for the presence of HPV DNA and p16 expression. CRP-negative control sera were used to establish the diagnostic specificity of the assay.

RESULTS

A total of 20 tumors were found to be positive for HPV16 DNA. 19 of these 20 were also tested positive with the immuno-assay used here (DRH1 antibody concentrations of 1,000-28,000 ng/mL), resulting in a sensitivity of 95%. The diagnostic specificity of the assay was found to be 99.36% in men and 99.29% in women over 30 years. The majority of the patients with confirmed HPV16-induced carcinoma showed a decrease in DRH1 antibody levels of 30-100% after treatment. A rise in DRH1 antibody levels from 2,750 ng/mL to 12,000 ng/mL was observed in one patient during follow-up. A clinical diagnosis later confirmed disease recurrence (lung metastasis) in this patient.

CONCLUSION

The presence of HPV16 L1 DRH1 epitope-specific antibodies in patient blood is an indicator for HPV16-induced malignant growth. The immuno-assay used here provides a promising tool to track treatment response and may be used for the early detection of disease recurrence.