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## Development and validation of a liquid biopsy test for HPV associated oropharyngeal cancer

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There are two major risk factors for oropharyngeal cancer. It is well known that tobacco smoking and alcohol consumption causes oral cancer but there is an increasing prevalence of oropharyngeal cancer that is associated with human papillomavirus (HPV) infection. Disease control and survival are significantly better when HPV infection is involved. HPV status is routinely used for prognosis and is beginning to influence treatment decisions. An easily available biological sample and a sensitive method for HPV detection is a need to check HPV status before, during, and after completing therapy. We have designed and validated an ultrasensitive droplet digital PCR and TaqMan probe-based assay to detect and quantify HPV (subtypes 16, 18, 31, 33 and 35) in liquid biopsy samples. Plasma circulating tumor HPV16 DNA (ctHPV16DNA) was evaluated serially over time in patients who completed 6 weeks of de-intensified chemo-radiotherapy to analyze HPV status in our ongoing prospective phase II clinical trial. The HPV status was compared with the treatment response. Baseline plasma circulating tumor HPV-16 DNA (ctHPV16DNA) was detectable in 81 out of 102 patients in the study cohort (79%). Baseline ctHPV16DNA levels were highly variable and did not significantly correlate with any standard clinical factors including T stage, N stage, or smoking status. However, there was a good correlation between plasma ctHPV16DNA density and tumor HPV copies. ctHPV16DNA was cleared by week 6 of the treatment from the majority of the HPV16 positive patients. HPV variant strains were detected in many patients with undetectable baseline HPV16. We report ctHPV16DNA kinetics and disease control. Our data suggest plasma ctHPV16DNA profiles may be a useful biomarker of disease control. Undetectable ctHPV16DNA, low ctHPV16DNA, HPV variants, and delayed clearance kinetics may reflect worse disease prognosis compared to patients with high ctHPV16DNA that is rapidly cleared during treatment.

### Biography

Sunil Kumar is a scientist working in the area of precision medicine and biomarker discovery. He graduated from Indian Institute of Technology Bombay and has Postdoctoral experience from University of North Carolina at Chapel Hill. His research is focused on finding novel biomarkers for head and neck cancer and breast cancer. His study has shown the utility of liquid biopsy method in cancer patient care and surveillance. He has shown the significance of using Human papillomavirus (HPV) as an important biomarker for prognosis and surveillance of oropharyngeal cancer patients. His breast cancer research aims to find biomarkers and early drivers of metastatic breast cancer. He has an entrepreneurial mindset. He had founded one company just after completing his doctoral study and filed a patent application on using liquid biopsy for patient care..

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