Neoadjuvant Nivolumab Plus Chemotherapy Followed By Response-Adaptive Therapy for HPV+ Oropharyngeal Cancer: A summary of ctHPV-DNA findings from JAMA publication

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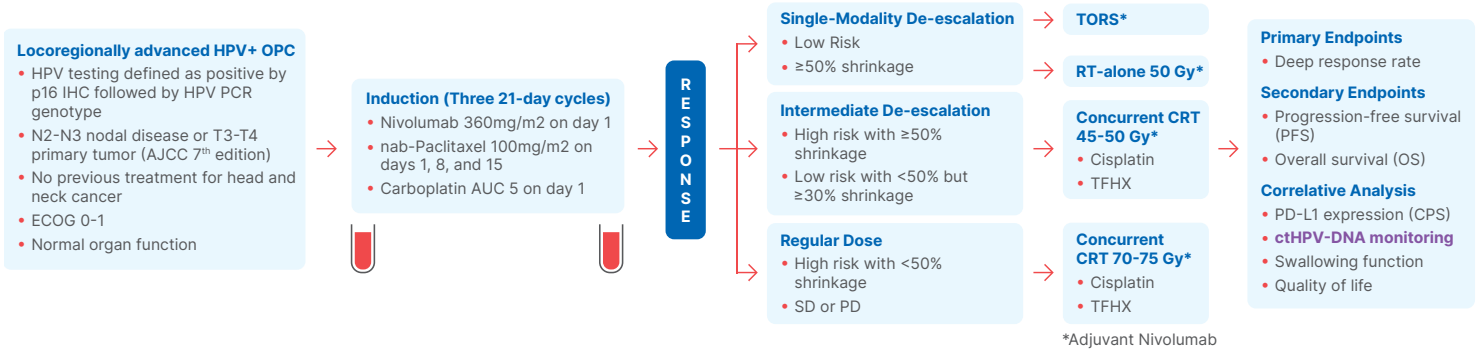
Background

Circulating tumor human papillomavirus DNA (ctHPV-DNA) is a promising non-invasive biomarker that has the potential to significantly enhance the clinical management of patients with HPV-associated cancers. This biomarker can be utilized at various stages of the cancer care continuum: for accurately determining HPV status to aid in patient risk stratification, monitoring treatment response, and conducting surveillance to detect recurrences early.

In a new clinical study published in JAMA Oncology, researchers from the University of Chicago Medicine Comprehensive Cancer Center assessed the use of ctHPV-DNA monitoring in a novel clinical trial of immunotherapy, nivolumab plus neoadjuvant chemotherapy (The OPTIMA IIB; NCT03107182). Clearance of ctHPV-DNA predicted improved survival in an inclusive cohort of patients with HPV-associated oropharyngeal cancer (HPV+ OPSCC). An ultrasensitive, NGS-based HPV-SEQ assay, was utilized to monitor ctHPV-DNA, and assess its relationship with standard of care diagnostic modalities such as radiography and efficacy outcomes such as progression-free survival.

Study design: OPTIMA II Phase 2 Open-Label Nonrandomized Clinical Trial



*Adjuvant Nivolumab

Key results

- All 31 patients with paired samples at baseline and after 2-3 cycles of neoadjuvant therapy had detectable and quantifiable ctHPV-DNA at baseline and quantitative reduction of ctHPV-DNA with neoadjuvant therapy along with radiographic response.
- Of the 31 patients, 26 had clearance of ctHPV-DNA during neoadjuvant therapy, while 5 patients had detectable ctHPV-DNA after 6-9 weeks of neoadjuvant treatment.
  - 2-year PFS was significantly improved for patients with neoadjuvant clearance of ctHPV-DNA as compared with those with persistent ctHPV-DNA (p=0.0018).

Key takeaways

DNA clearance	ctHPV-DNA clearance, monitored using HPV-SEQ assay, predicted improved survival in an inclusive cohort of HPV+ OPSCC patients treated with neoadjuvant nivolumab with chemotherapy.
Sensitivity	ctHPV-DNA may be utilized clinically as a sensitive biomarker for patient selection in HPV+ OPSCC.
Treatment response	ctHPV-DNA clearance may act as an improved non-invasive biomarker to grade treatment response to neoadjuvant therapy and may pose a better strategy to select patients for de-intensification which is currently under investigation in ongoing clinical trials at multiple institutions (NCT05108870, NCT04988074).
Dynamic biomarker	Both deep response and ctHPV-DNA clearance are dynamic biomarkers, which may offer advantages and complementary information compared with baseline, static biomarkers.

Learn more: sysmex-inostics.com/cfhpv-dna-assay

References: Rosenberg AJ, Agrawal N, Juloori A, et al. JAMA Oncol. 2024;10(7):923-931. doi:10.1001/jamaoncol.2024.1530.

Improve patient care outcomes and optimize drug development using HPV-SEQ

HPV-SEQ: Ultra-sensitive, CLIA-validated NGS-based assay for accurate detection and quantification of cell-free HPV-DNA in HPV-associated cancers.

Key features of HPV-SEQ

- **Ultra-sensitive Detection:** High analytical and clinical sensitivity, with the ability to reliably and consistently detect as low as 2 copies of HPV 16 and HPV 18 DNA.
- **Robust Clinical Evidence:** cfHPV-DNA clearance monitoring using HPV-SEQ has shown to correlate with radiographic response and predict survival in patients with HPV+ OPSCC.
- **Clinical Utility in HPV+ cancers:** Non-invasive biomarker for accurate determination of HPV status to aid in patient risk stratification, monitoring treatment response, and conducting surveillance to detect recurrences early.

97.6%

Clinical sensitivity of detecting cfHPV-DNA in pretreatment baseline using HPV-SEQ was 97.6% (95% CI, 91.5% – 99.7% [80 of 82 tests])

Learn more: sysmex-inostics.com/cfhpv-dna-assay

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