TPS5621 Poster Session

ANA trial: Development of a diagnostic test and dynamic evaluation of ctDNA to optimize follow-up and tailor treatment in patients with HPV-related cervical and anal tumors.

Renata Colombo Bonadio, Camila M. Venchiarutti Moniz, Letícia Vecchi Leis, Pedro Hashizume, Maria Luiza Nogueira Dias Genta, Raelson Rodrigues Miranda, Laura Sichero, Lara Termini, Maria Aparecida Azevedo Koike Folgueira, Paulo Marcelo Hoff, Maria Del Pilar Estevez-Diz; Instituto do Câncer do Estado de São Paulo, Faculdade de Medicina da Universidade de São Paulo, São Paulo, Brazil

Background: Cervical and anal cancers treated with definitive radiotherapy (RT), with or without chemotherapy, frequently exhibit persistent disease or recurrence. Post-treatment imaging—the current gold standard for assessing response—faces limitations due to local inflammatory processes, necessitating repeated imaging and invasive biopsies, which increase complexity and costs. Circulating tumor DNA (ctDNA) has emerged as a promising biomarker for assessing recurrence or disease progression in HPV-associated cancers. This study proposes the development of a low-cost HPV ctDNA test. Additionally, it aims to evaluate ctDNA's accuracy compared to standard imaging and its role in guiding immunotherapy for patients at high risk of recurrence. **Methods:** ANA trial seeks to establish a novel, affordable diagnostic approach to optimize follow-up and treatment strategies for HPV-associated cancers, potentially improving outcomes while reducing costs. This is a prospective, single-center study with two components: 1. Non-interventional phase: Development and validation of a low-cost HPV ctDNA test. The test's accuracy will be compared with commercially available ctDNA tests and standard imaging in monitoring patients with HPV-associated cervical and anal cancers post-definitive RT or chemoradiotherapy. 2. Interventional phase (Phase II trial): A single-arm study evaluating the efficacy of early complementary immunotherapy in patients with persistent ctDNA positivity post-treatment. Eligibility criteria include patients with HPV-positive cervical or anal cancers undergoing definitive RT or chemoradiotherapy. The study will enroll 110 participants, stratified into two groups based on post-treatment ctDNA results: 68 ctDNA-negative patients for serial ctDNA monitoring and 16 ctDNA-positive patients for Phase II immunotherapy intervention. In this phase, patients will receive Pembrolizumab 200mg IV every 3 weeks for twelve months. Endpoints: The primary endpoint for the non-interventional phase is the sensitivity and specificity of the HPV ctDNA test compared to commercial ctDNA tests and imaging. Secondary outcome is cost-effectiveness of HPV ctDNA as a follow-up tool. For the interventional phase, the primary endpoint is the 6-month disease progression rate in ctDNA-positive patients receiving immunotherapy. Secondary outcomes include recurrence rates, and survival outcomes. Clinical trial information: NCT06640283. Research Sponsor: National Council for Scientific and Technological Development (CNPq); Process No. 444027/2023-8.