TPS6116 Poster Session

Reduction of postoperative radiotherapy in head and neck squamous cell carcinoma: A single-arm, phase II trial (REPORT-HNSCC study).

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Background: Postoperative radiotherapy (PORT) significantly enhances the prognosis for high-risk patients with locally advanced squamous cell carcinoma of the head and neck (LA HNSCC). However, elective nodal irradiation (ENI) in low-risk areas can lead to serious acute and long-term toxicities, which negatively impact quality of life. In a study by Contreras (NCT00593840), 72 patients with LA HNSCC experienced a remarkable 97% regional control rate at five years after eliminating PORT to the pathologically negative (pN0) neck. Additionally, patients who responded well to neoadjuvant therapy showed better local control rates, suggesting a possible reduction in the need for radiotherapy. The RAVD study (NCT01133678) demonstrated that the elimination of ENI in patients with good response to neoadjuvant chemotherapy did not appear to compromise outcomes and resulted in significantly decreased late toxicity. Preclinical studies have also suggested that the elimination of ENI may preserve beneficial T cells in normally draining lymph nodes, enhancing the efficacy of radioimmunotherapy. The study was designed to evaluate regional control rates and quality of life in LA HNSCC patients undergoing sequential elimination of ENI to the pN0 neck by neoadjuvant chemo-immunotherapy. **Methods:** REPORT-HNSCC is a phase 2, single-arm, single-center trial assessing patients with newly diagnosed LA HNSCC. Patients receive neoadjuvant chemo-immunotherapy (flexibility in regimens and cycles). This trial targets patients with an ipsilateral and/or bilateral pN0 neck, while surgical resection will be guided by the surgeon's discretion. Key treatment components include 60 to 66 Gy to the primary tumor bed (CTVtb), 60 Gy to CTV1, and 54 to 60 Gy to CTV2, with appropriate expansion margins to optimize target volume. Eliminating ENI (that is, CTV2) to the pN0 neck. A symmetric 0.3-cm expansion around the CTV defined the corresponding planning target volume (PTV). Radiation doses were prescribed to the PTV. Intensity-modulated radiotherapy (IMRT) will be administered to all patients, while select patients with positive surgical margins or extranodal extension receive concurrent chemotherapy. The primary endpoint is 2-year region-free recurrence survival rate. Secondary endpoints include 2-year PFS, 2-year OS, 2-year DMFS, 2-year LRFS, acute and late toxicities, and quality of life. We will also explore predictive biomarkers for better understanding of responses and survival. As of January 2025, we have enrolled 14 of the planned 50 patients since the study began in October 2024, with results expected by December 2029. Clinical trial information: NCT06630780. Research Sponsor: None.