The Selective Personalized Radio-Immunotherapy for Locally Advanced NSCLC Trial (SPRINT)

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The Selective Personalized Radio-Immunotherapy for Locally Advanced NSCLC Trial (SPRINT)

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Purpose/Objective(s): Standard therapy for unresectable locally advanced non-small cell lung cancer (LA-NSCLC) is concurrent chemoradiotherapy (chemoRT), which is usually followed by adjuvant durvalumab. We performed a prospective trial testing sequential pembrolizumab and risk-adapted radiotherapy without chemotherapy for biomarker-selected LA-NSCLC patients.

Materials/Methods: Patients with AJCC version 8 stage III NSCLC or unresectable stage II NSCLC and ECOG performance status 0-1 were eligible for this trial. Subjects with PD-L1 tumor proportion score (TPS) ≥ 50% received three cycles of induction pembrolizumab (200 mg, every 21 days), underwent restaging FDG-PET/CT, received risk-adapted thoracic radiotherapy (55 Gy delivered to tumors or lymph nodes with metabolic tumor volume exceeding 20 cc and 48 Gy delivered to smaller lesions, all in 20 daily fractions), and then received up to 13 cycles of additional pembrolizumab. Subjects with PD-L1 TPS < 50% received concurrent chemoRT, and adjuvant durvalumab was recommended for patients without disease progression. The primary study endpoint was one-year progression-free survival (PFS) for subjects treated with pembrolizumab and radiotherapy (pembroRT), which we hypothesized would exceed 65%. Other study endpoints included 1-year overall survival (OS) and rates of clinician-scored (pembroRT) and patient-reported (PRO-CTCAE) adverse events observed over one year.

Results: Twenty-five subjects with PD-L1 TPS ≥ 50% and 12 subjects with PD-L1 TPS < 50% from three institutions were enrolled between August 2018 and November 2021. Median age was 70. Twenty-four subjects had stage II-IIIA disease, and 13 had stage IIIB-IIIC disease. Except for PD-L1, no significant differences were observed across treatment groups. Ten out of the 12 subjects with ChemoRT received adjuvant durvalumab, and one received adjuvant osimertinib for EGFR mutation. The median follow-up duration is 15 months. Compared to patients treated with chemoRT, treatment with pembrolizumab and radiotherapy has yielded numerically higher 1-year PFS (72% v. 46%, log rank p=0.232) and OS (91% v. 73%, log rank p=0.069). Similar rates of grade 3 physician-scored adverse events have been observed with pembrolizumab (24%) and chemoRT (25%). Less severe patient-reported adverse events occurred with pembrolizumab compared to chemoRT (See Table).

Conclusion: Treatment with pembrolizumab and risk-adapted radiotherapy without chemotherapy is a promising approach for LA-NSCLC patients with PD-L1 TPS ≥ 50%. In addition to yielding high disease control rates, this strategy appears to reduce patient-reported adverse events compared to standard chemoRT and adjuvant therapy.

Abstract 147 – Table 1: Average PRO-CTCAE grades and t-test p-values for PembroRT vs ChemoRT

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>PembroRT</th>
<th>ChemoRT</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dysphagia</td>
<td>1.5</td>
<td>2.3</td>
<td>0.056</td>
</tr>
<tr>
<td>Dyspnea</td>
<td>1.4</td>
<td>1.9</td>
<td>0.111</td>
</tr>
<tr>
<td>Cough</td>
<td>1.4</td>
<td>2.4</td>
<td>0.005</td>
</tr>
<tr>
<td>Wheezing</td>
<td>1.2</td>
<td>2.1</td>
<td>0.017</td>
</tr>
<tr>
<td>Dermatitis</td>
<td>0.9</td>
<td>1.9</td>
<td>0.028</td>
</tr>
</tbody>
</table>

(Continued)