

## AB002. OS01.02. A phase ii study of chemotherapy concurrent with radiotherapy in patients with unresectable advanced thymic tumors

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**Background:** Thymic malignancies are rare, and treatment options for unresectable thymic epithelial tumors (TET) are limited. We conducted a prospective phase II study of cisplatin plus etoposide concurrent with intensive modulated radiotherapy (IMRT) in patients with unresectable stage III or IV thymic epithelial tumors, to determine the efficacy and tolerability of the combination therapy.

**Methods:** Patients were eligible if they had histologically confirmed unresectable thymic epithelial tumors, an Eastern Cooperative Oncology Group (ECOG) performance status (PS) of 2 or lower, measurable disease, and adequate organ function. No patient had previously undergone chemotherapy, radiotherapy, or surgery. Patients were treated with cisplatin (25 mg/m<sup>2</sup>) and etoposide (75 mg/m<sup>2</sup>) on day 1 to day 3 of a 4-week cycle for 2 cycles, concurrent with a median dose of 60 Gy (range, 40–66 Gy) thoracic IMRT. Two cycles consolidate chemotherapy was given after IMRT. The primary endpoint of this study was objective response rate (ORR), and the secondary endpoints included toxicity, progression free survival (PFS), and overall survival (OS). The trial was registered with ClinicalTrials.gov, number NCT02636556.

**Results:** Forty-eight patients were enrolled, 31 with thymic carcinoma and 17 with thymoma. The median age was 52 years (range, 21–76 years), 24 patients (50%) were male. Sixteen patients had stage III disease, 14 patients had stage IVA, and 18 patients had IVB. The median number of chemotherapy cycles was 4 (range, 1–6). One patient with thymic carcinoma was deemed ineligible after enrolment and did not receive protocol

treatment. The median follow-up times were 18 months [interquartile range (IQR) 9.5–31.5]. Of 30 assessable patients with thymic carcinoma, 23 (76.7%) had partial responses and 7 (23.3%) achieved stable disease. Of 16 assessable patients with thymoma, 12 (75%) had a partial response, 3 (18.8%) had stable disease, and 1 (6.3%) had progressive disease. The most common treatment-related adverse events were grade 1 and 2 neutropenia [27 (58.7%) of 46 patients], and grade 3 and 4 neutropenia [14 (32.6%) of 46 patients]. The other common acute toxicity was esophagitis in 39.1% of patients with RTOG grades 1–2, and in 2.2% with RTOG grade 3. RTOG grades 1–2 radiation pneumonitis developed in 36.9% of patients. Nine patients (19.6%) developed pulmonary fibrosis RTOG grade 1 or grade 2. The median PFS for all 46 patients was 24 months (95% CI, 12.66–35.34); similarly, the median PFS for patients with thymic carcinoma was 24 months (95% CI 15.92–32.08). The 3-year PFS was 37.3% for all 46 patients, and 35.4% for the patients with thymic carcinoma. The 3-year PFS was 51.1% for stage III patients, and 31.9% for stage IV patients. The 3-year OS was 73.8% for all the patients, and particularly, it was 62.2% for those with thymoma and 74.3% for those with thymic carcinoma. The 2-year local control rate and 2-year metastasis rate were 57.7% and 36.4% for all patients, respectively.

**Conclusions:** These data suggest that the combination of cisplatin and etoposide with IMRT is highly effective and tolerable for the treatment of unresectable stage III and stage IV thymic epithelial tumors. Although advanced disease, we can acquire an excellent outcome of survival by the more positive concurrent chemoradiotherapy.

**Keywords:** Phase II clinical trial; thymic epithelial tumors (TET); chemoradiotherapy; unresectable stage III and stage IV

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