831P Clinical experience with 100 consecutive patients treated with Lu-177-labeled PSMA-I&T radioligand therapy for metastatic castration-resistant prostate cancer: Final analysis

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Background: Final analysis of our experience with ^{177}Lutetium-labeled prostate-specific membrane antigen-ligand (^{177}Lu-PSMA-I&T) for systemic radioligand therapy in 100 consecutive patients with metastatic castration-resistant prostate cancer (mCRPC).

Methods: Patients were treated under a review board-approved compassionate use protocol. Eligibility criteria for ^{177}Lu-PSMA-I&T therapy included previous treatment with abiraterone or enzalutamide, taxane-based chemotherapy or unsuitability for taxanes as well as positive ^{68}Ga-PSMA tracer uptake of metastases in a prior PET-scan. Intravenous treatment with ^{177}Lu-PSMA-I&T was given 6- to 8-weekly with an activity of 7.4GBq up to 6 cycles in patients without clinical or radiographic progression. We report prostate-specific antigen (PSA) decline, clinical progression-free survival (cPFS), overall survival (OS), subgroupanalysis and toxicity.

Results: Median age was 72 years (range 46-85) and median PSA level was 165 ng/ml (range 0-6178). Bone, lymph node and visceral metastases were present in 96%, 87% and 35% of patients. The median number of previous treatment regimens for mCRPC was 3 (range 1-6) and 82% of patients were pretreated with chemotherapy. At the time of evaluation, 319 cycles with ^{177}Lu-PSMA-I&T were applied (median 2 cycles per patient, range 1-6). No treatment was ongoing. 4 and 6 cycles were applied in 44 and 20 patients. PSA decline $\geq$30%, $\geq$50% and $\geq$90% was achieved in 47%, 38% and 11% of patients. Median cPFS was 4.1 months (95%CI 2.5-5.7) and median OS was 12.9 months (95%CI 9.9-15.9). In the subgroupanalysis visceral metastases were associated with a worse prognosis concerning PSA decline >50% (26 vs. 44%, $p = 0.06$), median cPFS (3.1 vs. 5.9 months, $p < 0.01$) and median OS (8.0 vs. 14.0%, $p = <0,05$). Treatment-emergent hematologic grade 3/4 toxicities were anemia (9%), thrombocytopenia (4%) and neutropenia (6%). Grade 3/4-non-hematologic toxicities were not observed. The main non-hematologic grade 1/2 toxicities were dry mouth (24%), fatigue (20%) and loss of appetite (10%).

Conclusions: Radioligand therapy with ^{177}Lu-PSMA I&T appears to be safe and active in late-stage mCRPC.

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