607 Radioligand therapy with Lutetium 177-labeled PSMA-I&T for metastatic castration-resistant prostate cancer: Clinical experience with 100 consecutive patients

Eur Urol Suppl 2018; 17(2);e874

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Introduction & Objectives: To report our clinical 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).

Materials & Methods: All 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, previous taxane-based chemotherapy or ineligibility to 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, PSA progression-free survival (PSA-PFS), clinical progression-free survival (cPFS) and overall survival (OS) as well as toxicity.

Results: At baseline, median age was 72 years (range 46-85) and median PSA level was 164 ng/ml (range 0-6178). Bone, lymph node and visceral metastases were present in 94, 85 and 33 patients, respectively. The median number of previous treatment regimens for mCRPC was 3 (range 1-6) and 84 patients were pretreated with chemotherapy. At the time of evaluation, 286 cycles with ^{177}Lu-PSMA-I&T were applied (median 2 cycles per patient, range 1-6), while treatment was still ongoing in 27 patients. Overall, 4 and 6 cycles were applied in 33 and 15 patients, respectively. PSA decline ≥30%, ≥50% and ≥90% was achieved in 40, 32 and 9 patients, respectively. Median PSA-PFS was 3.4 months (95%CI 2.7-4.0), median cPFS was 4.1 months (95%CI 2.5-5.7) and median OS was 12.2 months (95%CI 8.8-15.7). Treatment-emergent hematologic grade 3/4 toxicities were anemia in 7, thrombocytopenia in 5 and neutropenia in 4 patients. Grade 3/4-non-hematologic toxicities were not observed. The main non-hematologic grade 1/2 toxicities were dry mouth in 18, fatigue in 16 and loss of appetite in 9 of patients.

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