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Symptomatic skeletal related events (SSE) and SSE-free-survival in real world castration-resistant prostate cancer (CRPC) patients: Results from CAPRI

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Background: Bone metastases are common in CRPC patients and these patients (pts) are at risk for symptomatic skeletal related events (SSE). Bone directed therapy and early initation of a life-prolonging drug (LPD) therapy can prevent or prolong time to SSEs. The objective is to evaluate whether delay in LPD has adverse outcome in CRPC pts and a shorter SSE-free interval.

Methods: CAPRI is an investigator-initiated, observational study in 20 hospitals in the Netherlands. All treated CRPC pts are retrospectively included in subgroups based on type of first line treatment: LPD (docetaxel, abiraterone, enzalutamide or radium-223) or non-LPD (other drugs as anti-androgens, prednisone). SSEs are defined as the occurrence of either radiotherapy (RT) to the bone, surgery to the bone, pathological fracture or spinal cord compression (SCC).

Results: 1,618 pts were included in this analysis. Median follow-up was 26 months (IQR 15-39). 466 (29%) were treated with LPD (mostly docetaxel 15%) and 1,152

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(71%) with non-LPD (mostly bicalutamide 62%) in first line. In the non-LPD subgroup, LPD was postponed in 712 patients. The LPD subgroup had frequent bone metastases, worse ECOG and, higher LDH, ALP and PSA at the start of first line therapy. 36% of all patients experienced a SSE during follow-up (32% RT to the bone, 4% surgery to the bone, 4% pathological fracture and 6% SCC). There was a small difference in total SSEs between subgroups (39% for LPD vs 35% for non-LPD, p=0.064). Median SSE-free survival was 13.0 vs 21.2 months for LPD and non-LPD respectively (HR 1.626, p=0.007). Correction for prognostic factors showed that type of first line therapy (LPD/non-LPD) was not associated with SSE-free survival (HR 1.021, p=0.817). Worse ECOG and presence of bone metastases were significant predictors for worse SSE-free survival.

Conclusions: Approximately 40% of CRPC-patients developed a SSE during follow-up. Worse patient and disease characteristics probably influenced timing of LPD. These factors were also related with worse SSE-free survival. Delay in the initiation of a LPD at castration-resistant state does not appear to influence outcome related to time-to-SSE. Clinical trial identification: The CAPRI study is registered in the Dutch Trial Registry as NTR3591.

Legal entity responsible for the study: Institute for Medical Technology Assessment, Erasmus University Rotterdam.

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