

**BONE-MARKER LEVELS AND POTENTIAL CORRELATION WITH OUTCOMES IN PATIENTS WITH PROSTATE CANCER AND BONE METASTASIS: PRELIMINARY RESULTS OF TUGAMO TRIAL**

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**RATIONAL:** Serum bone-markers (BM) levels might be correlated with outcome in terms of skeletal related events (SRE), disease progression and death in patients (pts) with advanced prostate cancer, bone metastases and no previous or short time exposition to treatment treated with zoledronic acid 4 mg IV/every 3-4 weeks (ZA).

**METHODS:** Observational, prospective trial. Pts were not previously treated with bisphosphonates, were hormone naïve (new) or hormone treated (pre) for no longer than 6 months (mo). Bone specific alkaline phosphatase (BALP) analyzed by ELISA (immunoenzymatic assay, IDS), carboxiterminal telopeptide of type I collagen ( $\beta$ CTX) and aminoterminal propeptide of type I collagen (P1NP) by automatized assay (Elecsys, Roche) were measured every 3 mo for 24 mo. We present demographics, baseline BM and BM levels with 6 mo follow-up.

**RESULTS:** 80 pts were recruited, 35 (44%) new and 45 (56%) pre. Median age was 71 years; ECOG 0-1: 90%. Most frequent symptom at diagnosis was pain (42%); 77% were high PSA, median time from diagnosis to inclusion: 3.8 mo. Baseline metastasis (Soloway classification): 90% and 62% less than 20 category in new and pre respectively; 50% of pts had elevated baseline levels of  $\beta$ CTX, 40% P1NP and 33% of BALP. At the time of this analysis 31 pts had a follow up of 6 mo: 20 (65%) had  $\beta$ CTX normalization, 18 (58%) BALP and P1NP respectively.

**CONCLUSIONS:** Consistent BM levels normalization in response to ZA in highly hormone sensitive patients with bone metastasis. Longer follow up is needed to correlate with outcomes.