

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

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Rational: Levels of serum bone-markers (BM) might be correlated with outcome in terms of skeletal related events (SRE), disease progression and death in patients (pts) with advanced renal cancer and bone metastases treated with zoledronic acid 4 mg IV/every 3-4 weeks (ZA).

Methods: Observational, prospective trial. All pts were not previously treated with bisphosphonates: Serum samples were measured at baseline and every 3 months (mo) for 24 mo. Bone specific alkaline phosphatase (BALP) was analyzed by ELISA (immunoenzymatic assay, IDS UK), carboxiterminal telopeptide of type I collagen (α CTX) and aminoterminal propeptide of type I collagen (P1NP) by automatised assay (Elecsys, Roche). We present preliminary results of an exploratory analysis of BM changes at 6 mo follow up.

Results: 45 pts were recruited. Median age was 65 years; median time from tumor diagnosis to detection of bone metastasis: 26 and 7 mo respectively; MSKCC risk group: intermediate: 60%, poor: 32%; previous nephrectomy: 84%; previous anti-cancer treatment: anti-VEGF targeted therapy: 56%, mTOR inhibitor: 23%; previous SRE: 60%. Pts had elevated baseline levels of: 60% CTX, 34% P1NP and 31% of BALP. At the time of this analysis 10 pts (29%) had a follow up of 6 mo.: 10 (100%), 7 (70%) and 9 (90%) had CTX, P1NP and BALP normalization respectively.

Conclusions: Elevation of baseline BM levels is frequently present in advanced renal cancer with bone metastasis. Preliminary data shows a normalization of BM levels in response to ZA. A longer follow up is needed to correlate these changes with pts outcomes.