

phosphatase. No serious AEs, deaths, or discontinuations due to AEs were reported.

Conclusions: These results demonstrate the potential for AA to inhibit the CYP2D6 metabolic pathway and caution should be used when AA is coadministered with medications that are known CYP2D6 substrates. There was no apparent DDI between AA and T, a CYP1A2 substrate. The safety profile of AA was consistent with known toxicities.

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POSTER

Incidence and Outcomes of Brain and Meningeal Metastases (BMm) in Patients With Castration-resistant Prostate Cancer (CRPC) in the Era of Docetaxel (DOC)

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Background: The occurrence of BMm has been usually viewed as an exceptional event in the history of prostate cancer (PC) patients (pts). In two large retrospective series the incidence of BMm in PC pts was about 0.5%. Since the recent introduction of DOC as first line treatment has improved survival of CRPC pts, we have retrospectively evaluated the occurrence of BMm in such setting of pts, to explore whether this survival prolongation has changed the incidence of BMm.

Materials and Methods: The clinical records of a consecutive series of 943 pts with CRPC treated in our Institutions from 2002 to 2010 were reviewed. All pts met the definition of CRPC according to international guidelines: all pts received or were eligible for DOC-based treatment.

Results: We collected a series of 31 pts with BMm (incidence 3.3%). The median age at the diagnosis of PC was 62 yrs (range 51–78). Twenty-one pts had a median number of 1 brain metastases (range 1–8) and neurological symptoms were present in 16 cases. Ten cases presented meningeal metastases: in this case all but one pt were symptomatic. After BMm diagnosis, local treatment were proposed in 16 pts: 5 pts underwent metastasectomy (M) + external brain irradiation (BI), 1 M alone, 9 BI alone, 1 gamma-knife. Eleven pts received chemotherapy after BMm, while the remaining received only best supportive care. The median interval from the PC diagnosis and the achievement of castration resistance was 23 mos (range 7–141) while the appearance of BMm was documented after 6–173 mos (median 43.5). The median survival after BMm was 4 mos (range 1–29) with 6 pts surviving more than 1 year. These long-term survivors had brain metastases in 5 cases and meningeal metastases in 1 case and were managed with surgery in 3 cases, radiotherapy in 2 cases and DOC in 1 case.

Conclusions: It appears from our data that in the DOC era 1) the incidence of BMm in CRPC pts is higher than in the historical reports; 2) the interval from PC diagnosis and the appearance of BMm is clearly longer (43.5 mos) compared to that reported in historical series (28 mos). These findings could be related to the changes in survival of CRPC, produced by DOC introduction in the clinical practice. A special attention should be reserved to the appearance of neurological symptoms in a long-term CRPC survivor due to a possible relation with BMm.

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POSTER

Assessment of Angiogenic Factors and Hematopoietic Stem Cells and Their Relevance as Prognostic Factors for Overall Survival (OS) in Metastatic Castration-resistant Prostate Cancer (mCRPC) Patients (pts): a Prospective Study

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Background: Circulating biomarkers identification could be useful in predicting early response to sunitinib in pts with mCRPC, especially while blood circulating endothelial (CEC), progenitors (EPC: CD34+45-) and hematopoietic stem (HSC: CD34+45low) cells, as well as plasma levels of angiogenic factors (AF) VEGF-A, bFGF, SDF-1, sVEGFR-1&2 (soluble form).

Materials and Methods: A single arm phase 2, multicentre study, continuous regimen of sunitinib (37.5 mg once daily), was subject to CEC, EPC, HSC and AF level assessment at baseline (bsl). CEC, EPC, AF were respectively assessed by immunomagnetic isolation, flow cytometry and ELISA. This abstract presents results of bsl prognostic factor for

OS. Multivariate analysis was performed using a Cox stepwise regression model. Bsl ECOG-performance status, hemoglobin, polymorphonuclear neutrophil and platelets were considered as adjustment factors.

Results: Upon 50 patients accrued, AF and CEC/EPC/HSC were available for 40 and 14 pts, respectively. Median OS (months, [CI95%]) for AF sub-group was 15.4 (10.9–23.5). Bsl ECOG: 0=18 and 1–2=22. In univariate analysis, VEGFR-1, HSC and HSC/KDR+ were predictive of OS (respectively p=0.02, p=0.016 and p=0.01), a high level of sVEGFR-1 and high count of HSC or HSC/KDR+ were associated with poor prognosis (3 pts with bsl HSC/KDR+ count >80 presented with the shortest survival). sVEGFR-1 and VEGF-A levels were correlated (r=0.41, p=0.009, Spearman); a VEGFR-1/VEGF-A ratio >1.5 (median) was associated with longer OS (HR=0.4, CI95%:0.16–1.0). In multivariate analysis sVEGFR-1 and HSC were the main prognostic factors for OS (respectively p=0.001 and p=0.01), a HSC count of less than 1250 (median) being related to good prognosis (HR=0.16 CI95%:0.03–0.8).

Conclusions: Baseline HSC, HSC/KDR+ and sVEGFR-1 were independent factors associated with poor prognostic in mCRPC pts. Analysis of these markers for early prediction of response to sunitinib is ongoing.

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POSTER

Assessment of Bone Remodeling Markers and Their Relevance as Prognostic Factors for Overall Survival (OS) in Metastatic Castration-resistant Prostate Cancer (mCRPC) Patients (Pts) Treated With Sunitinib (S) After Docetaxel Failure – a Prospective Study

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Background: Circulating biomarkers identification could be useful in establishing prognostic for survival and prediction of early response in mCRPC pts treated with S. Three bone remodeling markers (BM) were assessed: P1NP, Tartrate-Resistant Acid Phosphatase 5b isoform (TRAP) and beta Collagen 1 carboxy terminal telopeptide (CTX).

Materials and Methods: A single arm phase 2, multicentre study, S continuous regimen (37.5 mg once daily), was subject to BM level assessment at baseline (bsl) and after 3 months of S (% change from bsl). Data also considered at bsl were: ECOG-performance status, total alkaline phosphatases (PAL), bone metastasis (BO), bisphosphonates received within 6 months prior to S (PH6). Total serum calcium, 25-OH Vit D and PTH levels were considered as potential confusion factors in multivariate analysis.

Results: Upon the 50 pts accrued, BM levels at bsl and after 3 months of S were available for 35 and 29 pts, respectively. Observed: 26/35 deaths, median (md) survival 15.4 months [CI95%: 7.3–24.2]. Bsl ECOG 0: N=13 and 1–2: N=22, BO N=30 and PH6 N=6. P1NP (md=100 µg/l), CTX (md=3.3 nmol/l) and TRAP (md=1.55 UI/l) were correlated (r=0.7, p<0.0001, Spearman), both at bsl and after 3 months. In univariate analysis, factors associated (p<0.1) with good prognostic were PAL ≤130 UI/l (HR=0.26), P1NP <100 µg/l (HR=0.38), TRAP <1.55 UI/l (HR=0.4), ECOG=0 (HR=0.55), no BO (HR=0.28), no PH6 (HR=0.51), CTX <3.3 nmol/l (HR=0.47). Multivariate analysis (stepwise Cox regression) was performed excluding bsl total PAL which was correlated to P1NP (r=0.8, p<0.0001, spearman) and not specific of bone formation. P1NP was the only independent factor associated with OS (HR=0.39 [CI95%:0.17, 0.90]). No BM was predictive of response to S at 3 months, this time lapse could be too short with regard to the mean cycle time of bone remodeling.

Conclusions: Baseline P1NP ≥100 µg/l is associated with poor prognostic and should be taken into account for treatment of mCRPC patients and could considered as a possible stratification factor for future studies.

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POSTER

Patients' Perception of Information During and After Radiotherapy for Localized Prostate Cancer

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Background: There is a lack of studies on patients' perception of information during and after radiotherapy for localized prostate cancer. Knowledge about areas where patients perceive the information to be sparse can help in improving information to this patient group. Patients' perception of received information and its relation to quality of life were studied as well as information needs and satisfaction with information at different time points from diagnosis.

Material and Methods: Between February 8 and April 15 in 2010, the EORTC QLQ-C30 and QLQ-INFO25 were sent to 660 patients with