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.

7059 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.

7060 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 whole blood circulating endothelial (CEC), progenitors (EPC: CD34+45-) and hematopoïetic 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.

7061 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 = 3.3nmol/l) and TRAP (md = 1.55UI/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 ⩽130UI/l (HR = 0.26), P1NP <100 μg/l (HR = 0.38), TRAP <1.55UI/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.

7062 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

prostate cancer who had undergone, or were planed for curative intended radiotherapy between December 2006 and March 2010. The QLQ-INFO25 consists of questions regarding the level of perceived information about the disease (4 items), medical tests (3 items), treatment (6 items) and other services (4 items) and 8 single items (different places of care, things you can do to help yourself get well, written information, information on CD tape/video, satisfaction with received information, wish for more or less information and if the information overall had been helpful). For 21 items the response format was a four-point scale from 1 ("Not at all") to 4 ("Very much") and for 4 items "Yes" or "No". Item scores were transformed to a 0 to 100 scale. Higher scores represent higher level of information received, higher information wishes and higher satisfaction.
Results: A total of 601 (91%) patients responded to the INFO-25 questionnaire. The mean value and standard deviation (SD) for perceived information about the disease was 55.0 (22.6). Corresponding figures for perceived information on medical tests and treatment were 70.1 (23.6) and 64.6 (21.9). Most patients, 69% were satisfied with the information (42% "quite a bit" and 27% "very much"). Analysis is ongoing and data will be presented on associations between levels of perceived information, information needs, satisfaction with information and time since treatment.
Conclusion: Most patients were satisfied with the information, although lack of information concerning information about the disease, medical tests and treatment were observed.

7063 POSTER

Bone Scan is of Doubtful Value as a First Staging Test in Prostate Cancer

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Background: Although reported as having lower sensitivity and specificity than MRI scanning, nuclear bone scanning is still the commonest initial staging test for patients with newly diagnosed prostate cancer. With the hypothesis that primary bone metastases are always in the pelvis or lumbar spine, we wished to assess if bone scan could be replaced by axial imaging as the primary staging test in newly diagnosed prostate cancer (CaP).
Materials and Methods: We reviewed all bone scans (n = 1201) identified as being carried out in newly diagnosed prostate cancer patients from 2000 to 2010. Patient age, ethnicity, PSA at diagnosis of CaP, TNM stage, Gleason score and serum Alkaline Phosphatase were recorded for multivariate analysis. The mean age was 72 years (41−96). 57% were white and 38% black. PSA mean PSA was 268.95 (0.5–106931). Gleason 7 was the most common reported (39.38%), followed by Gleason 6 (22%). Mean Alkaline phosphatase was 166 (7–2755). Patients were assigned to one of four groups according to possible bony metastases.
Results: See the table.

Results of initial analysis by possible bone metastases diagnosed by bone scan

Group 1	No metastases	818	68.11%
Group 2	Metastases only in pelvis and/or lumbar spine	136	11.32%
Group 3	Widespread metastasis including pelvis and lumbar spine	223	18.57%
Group 4	Distant metastases without pelvic or lumbar spine abnormalities	24	2%

The 24 patients in group 4 were analyzed in detail: 15 were shown by other imaging to be false positives, 6 were found to have had prior hormone therapy, 1 was diagnosed with multiple myeloma, and another had Paget's disease. Only one had disease that was detected only outside the pelvic and lumbar spine (4% of this group but 0.08% of the total), unfortunately there were not enough images to decide.
Conclusions: Bone scan is a useful investigation to confirm and monitor metastasic prostate cancer. However this data suggests that axial imaging is a more appropriate primary staging study, and that bone scan is unnecessary if CT or MRI of the pelvis and abdomen are clear of metastases.

Oral Presentations (Sat, 24 Sep, 11:15−12:30)
Genitourinary Malignancies − Prostate and Other

7100 ORAL

Prostate-specific Antigen and Long-term Prediction of Prostate Cancer Incidence and Mortality in the General Population

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Background: It is largely unknown whether prostate-specific antigen predicts long-term risk of prostate cancer incidence and mortality in the general population. We tested the hypothesis that baseline prostate-specific antigen levels predict long-term risk of prostate cancer incidence and mortality.
Materials and Methods: Using a prospective study, we examined 4383 20−94 year old men from the Danish general population followed in the Copenhagen City Heart Study from 1981 through 2009. We measured baseline prostate specific antigen and assessed prostate cancer incidence and mortality as a function of prostate specific antigen using Kaplan–Meier plots of cumulative incidence and Cox proportional hazard models, adjusted for potential confounders.
Results: During 28 years of follow-up, 170 men developed prostate cancer and 94 died from prostate cancer. For prostate cancer incidence, the age-adjusted hazard ratio was 2.5 (95% confidence interval 1.6−3.9) for a prostate-specific antigen level of 1.01–2.00 ng/ml, 5.0 (3.1−8.2) for 2.01–3.00 ng/ml, 6.1 (3.2−11) for 3.01–4.00 ng/ml, 12 (7.7−19) for 4.01–10.00 ng/ml, and 44 (26−74) for >10.00 ng/ml versus 0.01–1.00 ng/ml. For prostate cancer mortality, corresponding hazard ratios were 1.8 (1.0−3.1), 3.3 (1.8−6.0), 3.8 (1.6−9.1), 4.7 (2.4−9.2), and 12 (5.0–26.0). For men with prostate-specific antigen levels of 4.01–10.00 ng/ml, absolute 10-year risk of prostate cancer was 11% for age <50 years, 19% for 50−60 years, 21% for 60−70 years, 22% for age >70 years; corresponding values for levels >10.00 ng/ml were 37%, 68%, 73%, and 79%, respectively.
Conclusions: Stepwise increases in prostate-specific antigen predicted a 3−44 fold increased risk of prostate cancer and a 2−12 fold increased risk of prostate cancer mortality. Also, absolute 10-year risk of prostate cancer was 11−22% in those with prostate-specific antigen levels of 4.01–10.00 ng/ml and 37−79% in those with levels >10.00 ng/ml. These results may be useful during revisions of guidelines on use of prostate-specific antigen testing in healthy men.

7101 ORAL

Variations in Androgen Dependent Clinical Progression Kinetics in Locally Advanced Prostate Cancer

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Trial Name: TROG 96.01: Short-term neoadjuvant androgen deprivation (NADT) and radiotherapy (RT) for locally advanced prostate cancer (PC). Registration No: Australian New Zealand Clinical Trials Registry AC-TRN12607000237482. Status: Closed 31 August 2010 after minimum 10 years follow-up. Sponsors: Australian Government National Health and Medical Research Council; Hunter Medical Research Institute (Newcastle, Australia); AstraZeneca Pty Ltd (Sydney, Australia); Schering-Plough Pty Ltd (Sydney, Australia).
Design: Phase III randomised clinical trial.
Objective: To determine whether 3 or 6 months NADT reduces mortality after RT.
Endpoints: Clinical progression, mortality.
Background to the present study: To understand the impact of short term NADT on distant progression after RT for locally advanced PC.
Methods: Between 1996 and 2000, 802 eligible men with T2b, T2c, T3, and T4 N0 M0 prostate cancers were randomly allocated radiotherapy alone to 66 Gy (RT), 3 months NADT or 6 months NADT before RT. NADT comprised of goserelin 3.6 mgs monthly sc and flutamide 250 mgs tds orally. Cumulative incidences and interval hazards of local and distant progression were derived and compared across trial arms. Competing risks