**4019** POSTER

**Phase III, randomized, open-label study of triweekly docetaxel (tT) vs. biweekly docetaxel (bT) as treatment for advanced hormone refractory prostate cancer (HRPC): findings from an interim safety analysis**

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**Background:** Docetaxel given every third week is a standard treament for advanced HRPC. We conducted this study to investigate if a biweekly schedule would be better tolerated in a palliative setting with often elderly patients.
**Patients and Methods:** This planned interim analysis was conducted when between March 2004 and May 2006, 148 pts of a planned 354 pts were randomized to receive either T 75 mg/m$^2$ i.v. d1 q 3 wks (tT) or T 50 mg/m$^2$ i.v. d1 and d 14, q 4 wks (bT). Both groups received prednisolon 10 mg p.o. daily. Pts groups were well balanced; WHO performance status 0 in 23% and 22%, 1 in 67% and 67%, 2 in 10% and 11% of the pts in the tT and bT arms, respectively, and the mean ages were 69 years (range 44−86) and 68 years (range 46−84), and PSA 117 μg/l (range 11–964) and 103 μg/l (range13–1490), respectively.
**Results:** Altogether 511 tT cycles were given to 75 pts and 435 bT cycles to 73 pts. A larger proportion of pts were still receiving the study treatments 6 months after randomization in the bT arm than in the tT arm (28 pts, 38.4% vs. 17 pts, 22.7%, P = 0.029). Serious adverse events were more frequently reported in the tT group (53 times, 10.4% of cycles) than in the bT group (27 times, 6.2%, P = 0.018). One patient died due to coronary infarction and in one patient an acute myelocytic leukemia was diagnosed after two cycles; both cases were in the biweekly group. In general the treatments were well tolerated and the most common reported Grade 3−4 adverse events (expressed as %/cycles) were: neutropenia 20% in tT and 14% in bT, infection with/without neutropenia 8% vs. 3%, leucocytes 8% vs. 3%, elevation of serum alkaline phosphatase 2% vs. 4%, fatigue 3% vs. 3%, febrile neutropenia 2% vs. 1%, bone pain 2% vs. 1%, and pain 1% vs. 2%, respectively.
**Conclusions:** Both triweekly and biweekly docetaxel treatments are generally moderately well tolerated in this mostly elderly patients with advanced HRPC. The biweekly schedule appears better tolerated and a larger proportion of patients continued to receive the biweekly treatment 6 months after randomization.

**4020** POSTER

**Toxicity and quality of life in the GETUG 06 randomized trial comparing 70 Gy and 80 Gy for localized prostate cancer**

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**Background:** Following a phase II trial of a 80 Gy-level dose in the treatment of prostate cancer, a randomized trial was conducted to compare outcomes after 70 or 80 Gy. The study was conducted on the behalf of the PHRC.
**Material and Methods:** From 1999 to 2002, 306 patients were randomized to receive 70 Gy (153 pts) or 80 Gy (153 pts) in 17 centres. Patients had intermediate prognosis tumour. When risk of lymph node involvement was >10%, lymphadenectomy was performed. In case of trans-urethral resection (22 pts) radiotherapy was delayed of 2 months. No adjuvant androgene deprivation was allowed. Toxicity was graded with the RTOG scale (Lawton 1991). Quality of life was scored with the EORTC QLQ-C30 and PR-25 questionnaires.
**Results:** The mean of follow-up was 57 months. The rate of biological relapse was 27%. 20 patients were dead, only 7 dead of disease, none of toxicity. We report toxicity on the whole group and quality of life for patients with available questionnaires before and 5 years after treatment: 44 patients in the 70 Gy group, 38 patients in the 80 Gy group.
In RTOG scale, at 70 and 80 Gy, grade 1, 2, 3 rectal toxicities were 23, 12, 2% versus 25, 16, 6%. Urinary toxicity of grade 1, 2, 3 was 22, 8, 2% at 70 Gy and 27, 16, 1% at 80 Gy. There was no statistically significant difference between the two arms for rectum toxicity but bladder toxicity was more frequent at 80 Gy level (p = 0.04).
Comparing QLQ-C30 questionnaires, there was no difference between 70 Gy and 80 Gy groups for functioning and symptoms scales before treatment and after 5 years. For 82 patients, physical, cognitive and social functions decreased slightly during the follow-up with mean scores of 92, 86, 94 before treatment and 88, 80, 90 at 5 years. During the same time dyspnea score increased from 13 to 19 (p < 0.0002)and sleep disturbance score from 17 to 20 (p < 0.002). Diarrhea remainded unchanged. PR-25 analysis showed a significant increase in symptom scales between inclusion and 5-year questionnaires: urinary trouble score from 13 to 17 (p = 0.000), bowel trouble score from 6 to 8 (p = 0.0004), treatment related symptom score from 6 to 14 (p = 0.0000). Libido and sexual function changes were not significant. There were no difference between 70 and 80 Gy treatment group. When RTOG toxicity occurred (cumulative registration), 5-year diarrhea QLQ score, urinary and bowel PR-25 scores were increased (p = 0.04).
**Conclusion:** Tolerance of the conformal definitive radiotherapy was comparable in both arms.

**4021** POSTER

**Testosterone recovery following prolonged adjuvant androgen blockade in localized prostate cancer: is there an effect on outcome?**

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**Background:** Testosterone recovery (TR) after prolonged androgen suppression is variable and some patients may remain castrated indefinitely. We examined the impact of testosterone recovery in the outcome of patients with high risk prostate cancer treated by curative RT and prolonged adjuvant androgen ablation (AA) as compared to similarly treated patients in which testosterone levels remained at castrate levels after cessation of hormonal therapy.
**Methods:** From May 1992 to December 2001, 83 patients (median age 67 years) with high-risk prostate cancer treated with pelvic RT (median dose 72 Gy) and prolonged AA (minimum of 24 months) were retrospectively studied. Patients were followed every 3−6 months and had PSA and testosterone levels measured before treatment and throughout the period after cessation of hormones.
**Results:** The median duration of hormonal therapy was 36months (24−96). The median follow up from the end of hormonal therapy is 52 months (6–128). A total of 70 patients (84%) achieved a castrate level of testosterone defined as <0.5 nmol/L, 77(93%) achieved a testosterone level of <1nmol/l, while 80(96%) achieved a level of <2nmol/l at some point during their treatment. Overall, only 36 (43%)of patients recovered their normal testosterone level (10nmol/L). The median time to TR was 17 months. In those patients achieving a castrate level of <0.5nmol/L, TR to normal level was only achieved in 27 (40%) of them. Of the 36 patients who fully recovered their testosterone level, 10 of them (28%) went on to develop biochemical failure compared to 33% of the patients who never recovered their normal testosterone level (p = 0.82). There was a 31% biochemical relapse rate in patients who achieved a castrate testosterone level (<0.05 nmol/L) compared with 16% in those who were never castrated (p = 0.36).
On multivariate analysis, factors significantly associated with non-recovery of the testosterone was a castrate level of <0.5nmol/L (P = 0.003), age >67 years (P = 0.049) and duration of hormones for more than 36 months (p = 0.05).
**Conclusions:** our data suggest that testosterone recovery after at least 2 years of androgen ablation is not certain and its occurrence did not predict for biochemical relapse. Testosterone recovery after prolonged androgen blockade in itself is not a useful tool in prognosticating biochemical outcome.