**7049** POSTER

**Early results of a phase II trial of second line chemotherapy with oxaliplatin (Ox) and capecitabine (Cp) in hormonorresistant metastatic prostate cancer**

J. Gasent Blesa[1], V. Alberola Candel[2], O. Juan Vidal[2], P. Cerezuela Fuentes[3], V. Giner Marco[4]. *[1]Hospital Marina Alta. Denia, Oncología, Denia (Alicante), Spain; [2]Hospital Arnau de Vilanova, Oncología, Valencia, Spain; [3]Hospital Virgen del Rosell, Oncología, Cartagena, Spain; [4]Hospital de Sagunt, Oncología, Sagunt, Spain*

**Introduction:** Docetaxel plus prednisone (DP) is the current standard of care in first line chemotherapy for metastatic hormone-refractory prostate cancer. However, there is no agent proven as effective after progression to standard DP therapy. Platins and capecitabine have shown activity in this setting. Here we present our early results of a phase II trial with the combination of Ox and Cp.
**Patients and Methods:** Between May 2004 and Feb 2009, 17 PS0–1 patients (pts) were included in this prospective, multi-centre trial. All pts had progressed to first line DP chemotherapy. Pts received Ox 100 mg/sqm on D1 and Cp 1000 mg/sqm/bid on days 1–14 every 21 days.
**Results:** A total of 94 cycles were administered; mean 5.5; range 3–8.3. Mean initial PSA was 561 ng/ml (27–4893). Mean postreatment PSA was 357 (range 3.2–2840). 10 of the treated pts presented with a PSA decrease compatible with biochemical response, 4 pts presents stable disease, and 3 pts presented progressive disease. In responding pts, mean PSA decrease was of 80% (range 50–99%). TTP was of 18.5 weeks (censored data). It is remarkable that 2 of the included pts progressed during DP therapy. No unexpected toxicity was observed. Only grade 3 toxicity reported was grade 3 anemia. 5 of the 17 pts presented grade 2 neuropathy.
**Conclusions:** Management of HRPC remains controversial. There is no standard treatment after DP progression. It is important to find well tolerated and active chemotherapy regimens for this situation. Platinum-based combinations, due to its lack of crossover resistance with antimicrotubule agents, could be a valid therapeutic alternative in this setting. Although ours is a small series, the results justify the study of this combination in a larger number of pts, to more precisely determine the effect of the combination and thus be able to evaluate the benefits that platinum-based combinations could bring to these pts, for whom there is no valid therapeutic alternative. We are still recruiting patients.

**7050** POSTER

**Evidence of psa decrease with fulvestrant acetate in androgen independent prostate cancer (AIPC) patients**

J. Gasent Blesa[1], V. Alberola Candel[2], O. Juan Vidal[2], V. Giner Marco[3], P. Cerezuela Fuentes[4]. *[1]Hospital Marina Alta. Denia, Oncología, Denia (Alicante), Spain; [2]Hospital Arnau de Vilanova. València, Oncología, València, Spain; [3]Hospital de Sagunt, Oncología, Sagunt, Spain; [4]Hospital Virgen del Rosell, Oncología, Cartagena, Spain*

**Introduction:** Preclinical evidence supports the role of estrogen receptor (ER) signaling in prostate cancer. Fulvestrant (FVT) belongs to the SERD class of ER antagonists and has shown no estrogen-agonist activity in either preclinical or clinical studies. FVT binds competitively to the ER, inhibits receptor dimerization and reduces the ER half-life increasing protein turnover. ER are expressed prostate cancer established cell lines. Targeting the AR for down-regulation or degradation could be a useful approach for decreasing AR-dependent prostate cancer cell growth and for treating AIPC. This strategy has been proven in preclinical models. A potential dose-response co-relation has also been suggested for FVT.
**Patients and Methods:** Between June 2008 and February 2009, a total of 7 AIPC prostate cancer patients (pts) were treated inside a compassionate use treatment following the Spanish requierements. FVT was administered im, with a loading dose of 500 mg every 2 weeks during the first month, followed by 250 mg im monthly thereafter.
**Results:** Median baseline ECOG was 1 (0–2), median age was 73.7 years (range 54–83). Mean baseline PSA was 534 ng/ml (21–2462 ng/ml). Mean previously no. of hormonotherapy lines was 3.4 (range 2–5). Four pts had received chemotherapy, mean no. of lines was 1.75 (range 1–3). 5 of the treated pts presented with PSA decrease, mean 72.8% (range 40–99%). In 2 of the pts the PSA level increased despite the treatment with FVT. Time to treatment Failure was of 11.14 weeks (censored data). 3 of the pts that presented with PSA decrease, have developed biochemical failure. No relevant side effect has been recorded.
**Conclusions:** Under our knowledgement, this is the first treated cohort of AIPC pts that have presented with PSA decrease when treated with FVT. Our cohort is a heavily pretreated one, and the observed activity is exciting. Under our point of view it is justified to continue with the development of FVT in metastatic prostate cancer.

**7051** POSTER

**Clinical predictors of late gastrointestinal and genitourinary toxicity after three-dimensional conformal radiotherapy using seven coplanar fields to localize prostate cancer**

K. Takeda[1], Y. Ogawa[1], H. Ariga[1], M. Kotoh[1], T. Sakayauchi[1], K. Fujimoto[1], M. Kubozono[1], K. Narazaki[1], Y. Takai[2], S. Yamada[1]. *[1]Tohoku University, Radiation Oncology, Sendai, Japan; [2]Tohoku University, Radiological Sciences, Sendai, Japan*

**Background:** Dose escalation of radiotherapy (RT) improves the treatment outcome of localized prostate cancer (LPC); however, late toxicity may limit the extent to which the dose may be escalated safely. This study estimated the late gastrointestinal (GI) and genitourinary (GU) toxicity after three-dimensional conformal RT (3DCRT) using seven coplanar fields for LPC and assessed the correlated clinical factors.
**Material and Methods:** At our institution, 88 LPC patients underwent 3DCRT between March 2004 and May 2007. The total dose was 74 Gy in 2 Gy daily fractions for each patient. The median patient age was 71 years (range 52–80). According to the National Comprehensive Cancer Network (NCCN) risk group classification, 6, 45, and 37 patients were low, intermediate, and high risk, respectively. There were 39, 34, and 15 patients at stages T1 to T3, respectively. Fifty-six patients were given androgen deprivation therapy (ADT). There was coexisting hypertension (HT) in 17 patients, diabetes mellitus (DM) in 10, and gastrointestinal (GI) disease in 12. Four patients had undergone previous abdominal surgery. Twelve patients were treated with anticoagulants/antiaggregants (A/A) for pre-existing vascular disease. The Radiation Therapy Oncology Group/European Organisation for Research and Treatment of Cancer (RTOG/EORTC) toxicity score was used to analyze late GI and GU toxicity of grade 2 or higher at 3 years. The relationships between the following variables and late GI and GU toxicity were accessed: NCCN risk, use of ADT, presence of HT or DM, A/A treatment, coexisting GI disease, and history of abdominal surgery.
**Results:** The median follow-up was 23 months (range 5–47 months). Late GI toxicity of grades 2 and 3 occurred in one patient each. Grade 2 late GU toxicity occurred in one patient. There was no grade 4 or higher late toxicity. Late GI and GU toxicity of grade 2 or 3 at 3 years occurred in 3 and 1.8% of the patients, respectively. In the univariate analysis, A/A treatment was correlated with grade 2 or 3 late GI toxicity and grade 2 late GU toxicity. Coexisting GI disease was significantly correlated with grade 2 or 3 late GI toxicity.
**Conclusions:** Coexisting GI disease was correlated with grade 2 or 3 late GI toxicity. A/A treatment appears to predict grade 2 or 3 late GI and GU toxicity.

Univariate analysis results for grade 2 or 3 late GI and GU toxicity (*P*-values)

| Late GI toxicity | Late GU toxicity | |
|---|---|---|
| NCCN risk | 0.25 | 0.67 |
| ADT | 0.76 | 0.25 |
| HT | 0.49 | 0.66 |
| DM | 0.068 | 0.75 |
| A/A | 0.0006 | 0.014 |
| Coexisting GI disease | 0.0005 | 0.75 |
| Prior abdominal surgery | 0.74 | 0.81 |

**7052** POSTER

**Comparison between Tomotherapy and 3D-CRT for localized prostate cancer in regard to integral dose**

A. Navran[1], R. Westendorp[1], C.J.M. Hoekstra[1], J.J.F.M. Immerzeel[1], A. Minken[1]. *[1]RISO, Radiotherapy, Deventer, The Netherlands*

**Background:** This study was designed to evaluate the three-dimensional conformal radiotherapy (3D-CRT) and intensity modulated RT by helical Tomotherapy (Tomo-IMRT) in regard to integral dose (ID) for treatment of localized prostate cancer.
**Material and Methods:** Fifteen radiation treatments plans using Tomo-IMRT (6MV) as well as 3D-CRT (Linac, 6 and 10 MV), were generated for patients with localized prostate cancer. The ID (mean dose × tissue volume) was calculated from dose-volume histogram. The total prescribed dose was an equivalent of 82 Gy (2 Gy daily fraction, EQD2) in 35 fractions for each patient.
**Results:** The percentage difference (PD) of mean ID of all planning target volumes (PTVs) between tomotherapy and 3D-CRT was (+0.073) and hence, the plans with both techniques were equivalent in the term of PTV