

difference in short axis of the measured nodes between the two imaging techniques was <2 mm in all cases.

**Conclusion:** The quality of low dose CT images is adequate for retroperitoneal nodal surveillance in stage I testicular germ cell tumours and allows a reduction in cumulative radiation exposure. This technique may be safely adopted in surveillance schedules.

# **7109 POSTER DISCUSSION** **An Individualized Dose/Schedule Strategy for Sunitinib in Metastatic Renal Cell Cancer (mRCC) May Improve Progression Free Survival (PFS) – Correlation With Dynamic Microbubble Ultrasound (DCE-US) Data**

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**Background:** Sunitinib area under the curve (AUC) correlates with response and PFS (Houk et al). Current recommendations for dose modification do not take this into account.

**Material and Methods:** A single center retrospective review identified mRCC patients (pts) where individualized (individ) sunitinib dose/schedule modifications (DSM) were used to maximize dose and minimize time off therapy (Rx). Pts were started on 50 mg 28 days (d) on/14d off. DSM were done to keep toxicity (fatigue, skin, GI) at ≤ grade-2. DSM-1 was 50 mg 14d/7d with individ increases in d on Rx based on toxicity. DSM-2 was 50 mg 7d/7d with individ increases in d on Rx. DSM-3 was 37.5 mg continuously with individ 7d breaks. DSM-4 was 25 mg continuously with individ 7d breaks.

**Results:** In 172 pts; median age was 60 y; 20% good, 60% intermediate, 20% poor prognosis by Heng criteria; 80% had nephrectomy; 79% clear cell histology; 60% were previously untreated. At a median follow-up of 12.9 months (mo), overall median PFS was 8.9 mo. All 20 pts still on therapy are on a DSM Rx. Pts were allocated to three groups based on the dose/schedule used for the longest time. The PFS/response% (PR+SD) for each group was 4.9 mo/64.1% (standard 50 mg 28d/14d; 39 pts), 10.4 mo/77.5% (DSM-1/DSM-2; 71pts) and 11.9 mo/82.3% (DSM-3/DSM-4; 62 pts) with improved PFS (p = 0.0002) in both DSM groups vs. the standard schedule but no difference in response. In 20 responding pts studied by DCE-US at baseline, and after 7d and 14d on Rx or after 14d and 28d on Rx, tumour blood volume decreased at d7 and again at d14 vs. baseline but was stable or increased at d28 vs. d14. A rebound was seen after 14d off Rx.

**Conclusions:** Based on the US data, previous pharmacokinetic data (steady state at 10–14d) and this clinical data, starting pts on 50 mg 14d/7d followed by individ DSM may be safe and active. This DSM strategy was associated with a favorable toxicity profile, apparent improvement in PFS and a good PR+SD rate in a group of unselected mRCC pts, warranting confirmation in a prospective trial. Pts that tolerate 50 mg 28d/14d with minimum toxicity may need dose escalation and/or less time off therapy to optimize PFS.

# **7110 POSTER DISCUSSION** **A Phase II Trial of Docetaxel, Cisplatin, 5-Fluorouracil (TPF) in Locally Advanced and Metastatic Carcinoma of the Penis (CRUK/09/001)**

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**Background:** Chemotherapy for penis cancer is used mainly as palliation of metastatic disease. It also has a role in treatment for locally-advanced disease but the rarity of the disease has hampered attempts

to define an evidence base for this. The combination of cisplatin (P) and 5-fluorouracil (F) has been used for treatment of squamous cell carcinoma (SCC) of the penis since 1990. Pathological similarities to head and neck SCC suggest that the addition of docetaxel (T) to an established platinum-based regimen may enhance therapeutic benefits.

**Materials and Methods:** A single-stage, single-arm academically-sponsored phase II trial was conducted. Eligible patients (pts) had histologically proven SCC of the penis staged as M1; or T4, any N, M0; or any T, N3/inoperable N2, M0; or any T, N1, M0 where chemotherapy was offered as first-line therapy after MDT discussion. All pts had measurable disease. Treatment consisted of three 21-day cycles of: T 75 mg/m<sup>2</sup> day 1, P 60 mg/m<sup>2</sup> day 1, F 750 mg/m<sup>2</sup>/day (days 1–5). The recruitment target was 26 evaluable pts. Fourteen or more responses were required to conclude a response rate of 60% or more (p0=0.35, p1=0.60, α=0.1, β=0.2; Fleming-A'Hern exact methods). The primary endpoint was overall response rate at completion/discontinuation of trial treatment. Secondary endpoints included safety, tolerability, progression-free and overall survival.

**Results:** 29 pts were recruited from 9 UK centres between September 2009 and December 2010. Median age was 61 years; 19 pts had performance status (PS) 0, 10 PS1, 1 PS2. Three pts discontinued treatment early for reasons other than progression. Dose reductions or delays were reported for 13 pts. With a median follow-up of 7 months, 19 pts remain in follow-up and 10 pts have died. Toxicity data are available for 28 patients: 19 (68%) experienced toxicity at grade 3/4, with neutropenia most common (n = 13, 46%). 8 pts (29%) experienced febrile neutropenia and/or sepsis.

Central independent review of response will be completed in April 2011. Full analysis of the primary endpoint, overall response rate, will be presented.

**Conclusions:** UK clinicians successfully recruited to a multi-centre trial in penis cancer. A network of centres has been established for future studies. Toxic effects of TPF were common but within acceptable limits. Response data are awaited.

# **7111 POSTER DISCUSSION** **High-dose Chemotherapy With Autologous Stem-cell Support in Patients With Metastatic Non-seminomatous Testicular Cancer – a Report From the Swedish Norwegian Testicular Cancer Group (SWENOTECA)**

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**Background:** Within the SWENOTECA IV study on patients with metastatic non-seminomatous testicular cancer, 55 men were treated with high-dose chemotherapy (HDCT) in three clinical situations: A) insufficient response to standard-dose intensified chemotherapy (BEP with addition of iphosphamide), B) histologically vital cancer at surgery following intensified chemotherapy, C) relapse after intensified chemotherapy. In situation A and C two HDCT cycles and in situation B one HDCT cycle was recommended. This study presents survival and toxicity data for these patients.

**Material and Methods:** From 1995 to 2007 situation A was the reason for HDCT in 36 patients, B in 7 patients and C in 12 patients. The first HDCT cycle consisted of carboplatin 28x(GFR+25) mg, cyclophosphamide 6000 mg/m<sup>2</sup> and etoposide 1750 mg/m<sup>2</sup>, all divided in four daily doses. For the second cycle etoposide was replaced by tiotepa 480 mg/m<sup>2</sup>.

**Results:** In total 33 men (59%) received two high-dose cycles, of whom 27/36 (75%) in situation A and 4/12 (33%) in situation C received two cycles. The main reasons for only one HDCT cycle was serious toxicity (n = 7, 32%), according to protocol (n = 5, 23%), and progressive disease (n = 4, 18%). After a median follow-up of 7.5 years, overall survival in situation A, B and C were 72%, 100% and 58%, respectively, whereas failure-free survival was 64%, 71% and 42%, respectively. In Cox regression analysis stratified for treatment indication, increasing age (HR 1.09, 95% CI 1.03–1.15) and being marker positive prior to HDCT (HR 2.47, 95% CI 1.20–5.11) was associated with increased risks for death due to any cause, while having received only one HDCT cycle (HR 2.84, 95% CI 0.83–9.77) tended to be associated. Three patients (5.5%) died during HDCT of renal failure or intracerebral hemorrhage, all treated before 2000. Nephrotoxicity was the most common non-hematological grade 4 toxicity, affecting 5 (9%). The time interval between cycle one and cycle two was median 55 days (range 30–84). Hematological toxicity was not more pronounced during the second vs. the first HDCT cycle. The hospitalization