Proffered Papers

Poster presentations (Mon, 21 Sep, 14:00-17:00) **Genitourinary malignancies - Other**

7161 POSTER

Stage I seminoma: can 18Flurorodeoxyglucose positron emission tomography (FDG-PET) predict occult dissemination? Preliminary results of a phase II study

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Adjuvant radiotherapy, adjuvant chemotherapy, and surveillance with treatment in case of a relapse, with high cure rates of 99–100% being achieved, whatever the option. With the evidence of long-term toxicity, sparing useless treatment has become a priority in patients with stage I seminoma. FDG-PET was demonstrated to be an accurate technique to evaluate post-chemotherapy residual masses in patients with advanced seminoma. Therefore, we evaluated the utility of FDG-PET to identify occult dissemination in stage I seminoma.

Patients and Methods: After orchiectomy and a signed informed consent, patients with testicular seminoma and no evidence of metastases on CT scan of the pelvis, abdomen, and thorax (stage I) underwent a PET-CT. PET-negative patients were offered surveillance or adjuvant treatment by radiotherapy or chemotherapy.

Results: 56 eligible patients participated to this program from March 2004 to June 2008. Six patients (11%) had a positive PET-CT, with abnormalities in the retroperitoneum. These 6 PET-positive patients were treated by either immediate (n = 4) or differed (after a rapid relapse, n = 2) chemotherapy and none relapsed thereafter. Among 50 PET-negative patients, 7 requested adjuvant chemotherapy and did not relapse. Of the remaining 43 PET-negative patients, 5 relapsed, all in the retroperitoneum, with a delay of 6, 8, 10, 16, and 18 months respectively. These patients achieved a continuous disease-free status after radiotherapy (n = 1) or chemotherapy (n = 4). With a median follow-up of 31 months, the overall survival rate is 100%.

Conclusion: This study confirms that post-orchiectomy treatment can be avoided in a majority of patients with stage I seminoma. It also suggests that PET-CT may help identifying about half (6/11) patients with disseminated seminoma that was not detected by CT-scan. Pending validation, PET-CT may therefore help better selecting patients that are candidate for surveillance.

7162 POSTER

Post-chemotherapy residual masses <15 mm in patients with metastatic non seminomatous germ cell tumors: is resection required?

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Background: Management of patients (pts) with metastatic non seminomatous germ cell cancer (NSGCT) with residual masses <15 mm in diameter after cisplatin-based chemotherapy is controversial although retroperitoneal lymph node dissection (RPLND) is usually advocated. Methods: Data from all pts with stage II-III NSGCT treated with cisplatinbased chemotherapy from 1991 to 2008 at IGR were collected. Pts with residual mass <15 mm managed by careful surveillance were reviewed. Results: Sixty two pts (BEP = 43; EP = 15; others = 4) fulfilled these criteria. The median age was 29 years (15-47). According to the IGCCCG classification, pts were initially classified as good- (n = 52), intermediate-(n = 6), and poor prognosis (n = 4). All pts had retroperitoneal lymph node metastases with a median diameter of 20 mm (range10-160 mm) before chemotherapy. After chemotherapy, the median diameter of residual masses was <5mm (n = 39), 5-10 mm (n = 10), 10-15 mm (n = 12). With a median follow-up of 5 years, 3 pts experienced a recurrence (4.8%), including two with relapse in the retroperitoneum (3%), who were subsequently rendered long-term disease-free by chemotherapy and surgery, and 1 with a brain relapse without retroperitoneal relapse. No late relapse was observed.

Conclusions: Pts with residual masses <15 mm after primary chemotherapy for metastatic NSGCT may be managed without systematic post-chemotherapy surgery. This data requires confirmation by other groups.

163 POSTER

Phase II study of eribulin (Halichondrin B analogue, E7389) in patients with advanced urothelial cancer (AUC) – California Cancer Consortium led NCI/CTEP-sponsored trial

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Introduction: There is a major unmet need for efficacious non-platin drugs in AUC, particularly for patients with renal dysfunction. Microtubule directed agents (taxanes) have activity in UC. We previously undertook a first in human phase I study of eribulin, a microtubulin modulator derived from black Pacific sea sponge toxin (T. Synold, ASCO A2054, 2005); <10% of eribulin/metabolites are renally excreted. Encouraging activity was evident in AUC. Phase II dose was 1.4 mg/m² in a weekly dose schedule.

Methods: The phase II component of this study accrued patients with normal creatinine or calculated CrCl \geqslant 59 mL/m, AUC: any histological type & no prior cytotoxic therapy for advanced disease (neo/adjuvant allowed). Eribulin 1.4 mg/m² was given IV on d 1 & 8, 3-week cycle. Endpoints: response rate (RR) >20% was deemed interesting in a 2-stage design requiring \geqslant 2 responses/21 pts to proceed to total 41 pts; PFS and OS.

Results: In the phase II component, 40 pts evaluable: 35 with TCC, 3 adeno, 1 SCC and 1 small cell AUC. Median age: 66.2 yrs (37.4-86.8); 68% male; KPS ≥90% in 60%, ≤80% in 40%. 72.5% had prior neo/adjuvant chemotherapy. Bajorin risk groups: 0: 25%, 1: 48%, 2: 28%. Response criteria: 1 CR +13 PR from 40 pts assessable, RR 35% 95% CI: (21%, 52%). In addition, of 10 pts with SD as best response, 2 pts had uPR on 6 wk scans only to have PD at 12 wks. All responses occurred in pts with TCC (RR 40% in this subgroup). At median follow-up 15.8 months, median PFS 3.9 months (2.7, 5.1; 35 pts progressed), median OS 10.0 mo (7.0, 17.4; 19 pts dead). PFS was associated with Bajorin risk group (p = 0.01 for trend). 20 pts experienced Gr 3/4 neutropenia, no febrile neutropenia. Sensory neuropathy: 23 pts (22 Gr 1/2). Other non-hematologic toxicities: hyperglycemia, hyponatremia, alopecia, leg fatigue & aching. In a concurrent phase I study in renal dysfunction, pts with CrCl 40--59 mL/m tolerated 1.4 mg/m² without DLT and accrual is ongoing for pts with CrCl <40 mL/m.

Conclusions: Eribulin has activity in AUC at doses tolerated by patients with normal, moderate & severe RD. Further analysis will be undertaken to place these phase II data in historical context especially pertaining to Bajorin prognostic criteria and prior neo/adjuvant therapy, which is associated with OS ~6 months (Dorff TB et al WJU 27:39, 2009). Early reports of responses to eribulin are encouraging esp given its limited toxicity to date.

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7164 POSTER

A prospective study of cognitive function in testicular cancer patients – preliminary results

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Background: Based on cross-sectional studies it has been discussed if systemic chemotherapy may have negative impact on cognitive function in some testicular cancer patients (TCPs). So far no relevant prospective study of cognitive function in TCPs has been published. We report preliminary results from such an ongoing prospective study.

Material and Methods: At baseline 129 newly diagnosed TCPs (median of 35 days after orchidectomy; before start of any additional treatment) were tested with a neuropsychological test battery with a total of 18 measures across different domains of cognitive function. So far 78 TCPs have been re-tested at follow-up at a median of 13 months after end of treatment; 23 TCPs received no chemotherapy (surveillance or radiation only; group 1), 27 TCPs received one cycle of chemotherapy [one treatment with carboplatin or one cycle with bleomycin, etoposide and cisplatin (BEP);