group 2] and 28 TCPs received ⩾2 cycles of chemotherapy (⩾2 cycles with BEP or EP; group 3). An individual change in performance from baseline to follow-up on each neuropsychological test measure was assessed using a standardized regression-based model (SRB), fitted first to group 1 (reference). All test scores at follow-up were compared to their predicted values using this SRB-model. The SRB-model could not be applied for skewed test scores (4 out of 18 test measures) and these test scores were categorized, and an individual change of category from baseline to follow-up was registered. Based on all these analyses, the individual overall change in neuropsychological test performance from baseline to follow-up was classified as either "no change", "improved" or "declined".
Results: We found no statistically significant difference between the three groups in the proportions that exhibited decline or improvement on neuropsychological test performance. Data from all patients evaluated at follow-up until September 2009 (approx. 90% of the included TCPs) will be presented at the congress.
Conclusions: Our preliminary results do not support the hypothesis that systemic chemotherapy may affect cognitive function in TCPs; however type II statistical errors cannot be excluded.

7165 POSTER

The value of PET/CT with F-18-FLT and F-18-FDG in the therapeutic management of metastatic germ cell tumours

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Background: To assess the ability of F-18-FLT ([F-18]-3'-Fluoro-3'-deoxythymidin), a cell proliferation marker, for early response monitoring and prediction of histology of residual tumor masses in patients (pts) with metastatic germ cell tumors (GCT) in comparison to the standard tracer F-18-FDG (2-fluoro-2-deoxy-D-glucose), CT scans and serum tumor markers.
Material and Methods: Eleven male patients (pts), aged between 23 and 48 years, with metastatic GCT were evaluated with both F-18-FDG-PET/CT and F-18-FLT-PET/CT prior to chemotherapy (CTh), after the first cycle (early response) and 3 weeks after completion of induction CTh. PET was analyzed retrospectively visually and quantitatively. The results were validated by histopathology of resected residual masses after CTh in 7 pts or by clinical-radiological follow-up for at least 6 months in 4 pts. Presence of necrosis was judged as responder, as well as CR/PRm- within a minimum progression-free interval (PFI) of 6 mos. In case of multiple resections, the worse histology was taken into account. Regarding early tumor response EORTC criterias were used.
Results: Eight out of 11 pts had a PFI >6 mos (range, 206−1337 days). Examination of resected masses revealed necrosis in 3/7, teratoma in 2/7 and viable tumor in 2/7 pts. Prior to CTh the reference lesions showed increased FDG uptake ($SUV_{mean/range}$ 8.8/2.9−15.0) in all pts but moderate FLT uptake ($SUV_{mean/range}$ 3.7/1.7−9.7) in 10 out of 11 pts. Decrease of SUV_{mean} after 1 cycle of CTh was 64% in responders and 60% in non-responders (p=.8) for FDG, as well as 58% vs. 48% for FLT (p=.5), respectively, and 85% vs. 73% (FDG, p=.1) and 68% vs. 65% (FLT, p=.8) in the final monitoring. Results of early and final response were inconsistent in 6/11 pts in FDG and in 4/10 pts in FLT-PET. The 2 pts with teratoma presented false negative results in both FDG- and FLT-PET. The sensitivities, specificities, positive and negative predictive values (%) of FDG- and FLT-PET for early and final response monitoring were 60/33/43/50, 60/80/75/67, 20/100/100/60 and 0/100/0/50, respectively.
Conclusions: PET negative residual masses after CTh of metastatic GCT still require resection, since the low negative predictive value of F-18-FDG-PET cannot be improved by application of the proliferation marker F-18-FLT.

7166 POSTER

Predicting and preventing thrombo-embolic events in patients with germ-cell tumors receiving cisplatin-based chemotherapy

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Purpose: We previously demonstrated that patients with germ-cell tumor (GCT) receiving cisplatin-based chemotherapy are at a high risk of thrombo-embolic event (TEE) compared to patients of a same age with other cancers and receiving a similar treatment. Serum lactate dehydrogenase (LDH) and body surface area (BSA) were identified as independent predictive factors for TEE (Piketty et al. Br J Cancer 2005; 93: 909−14). The aim of this study was to prospectively validate these predictive factors and to assess the impact of a thrombo-prophylaxis policy in patients at risk of TEE.
Patients and Methods: From 2001 to 2007, 144 patients received first-line cisplatin-based chemotherapy for GCT at Institut Gustave Roussy. Preventive anticoagulation with low molecular weight heparin was recommended in patients with elevated serum LDH and/or BSA > 1.9 m^2. Incidence of TEE during the 6 months following the initiation of chemotherapy was assessed. Ten patients with evidence of TEE before starting chemotherapy were excluded from the analysis.
Results: Among 134 eligible patients, a TEE occurred in 16 (12%) including deep venous thrombosis (DVT) (n = 9) and superficial thrombophlebitis (STP) (n = 7). The incidence of TEE was 14% in 92 patients with one or both risk factors (9 DVT and 4 SVT) and 7% (3 STP) in the 42 patients with no risk factor. Of note, all 9 DVT occurred in patients with risk factors (9% vs 0%). Most (6/7) STP were located in the patients'arms used for peripheral venous access. The outcome was favorable in all 7 STP. Overall 24 patients (26%) with risk-factors received primary thromboprophylaxis, and this rate increased with time and with the availability of the results of our previous study (Br J Cancer 2005; 93: 909−14): 18% and 38% before and after 2005, respectively. The incidence of DVT slightly decreased from 11% to 8% during this period, respectively. Thromboprophylaxis was not associated with haemorrhage toxicity in this population.
Conclusion: This study confirms that patients with GCT receiving chemotherapy and either elevated serum LDH or a high BSA or both factors are at risk of developing TEE, specifically DVT. The use of a primary thromboprophylaxis was feasible in these patients and its systematic implementation is now an ongoing process in our institution.

7167 POSTER

Adjuvant chemotherapy (ACT) in patients with invasive bladder carcinoma (IBC): multivariate analysis of a cohort study

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Background: The use of ACT for IBC is only supported by retrospective nonrandomized studies or underpowered randomized trials. Additional information from metanalysis or observational studies can help to better define its role.
Patients and Methods: Since 1988, our institutional policy for patients (p) with IBC who underwent radical cystectomy (C), was to offer ACT to those patients who agree after they have been informed about their risk factors for relapse, toxicity of ACT, and status of the art at that moment. P treated with C or C+ACT were then followed according to the standard clinical practice. In this study we have retrospectively collected data in order to analyze the effect of ACT on the outcome of these two cohorts.
Results: From 1988−2008, 447 p having a radical cystectomy for IBC were identified (277 only C, 170 ACT). Chemotherapy consisted of 3 courses of MVAC (90 p) or, mainly from year 2000, 4 courses of CDDP 70 mg/m^2 d1 – gemcitabine 1 gr/m^2 d1,8 (73 p) or carboplatin – gemcitabine (7 p). There were no toxic deaths. Median follow-up was 63 m. As expected, there was a clear unbalance against the ACT cohort respect to important prognostic variables. Thus (C vs ACT): AJCC 2002 staging (pII, pIII, pIV: 56.7%, 33.6%, 9.7% vs 18.2%, 32.9%, 48.8%); histology (papillary/solid: 41.5%/58.5% vs 21%/79%), grade (G3: 91% vs 96.5%), surgical complications (39 % vs 28%) andperiod of treatment (until 1999/2000 and later: 57%/43% vs 39%/61%); p < 0.05 for all comparisons. Age was unbalanced in the pIII subgroup; 90% were male in both groups. Despite that, there were no statistically significant differences either in crude progression-free survival (PFS), overall survival (OS) or cancer-specific survival (CSS) in both cohorts. A multivariate Cox analysis including the above variables was fit to estimate the hazard ratio (HR) of relapse and death (ACT/C). We found interaction between stage and type of treatment, so results are presented stratified by pathological stages in the following table:

	PFS		SCS		OS	
	HR	95% IC	HR	95% IC	HR	95% IC
Unadjusted	1.18	0.9−1.6	1.10	0.82−1.50	0.98	0.76−1.27
Multivariate						
pII	1.01	0.53−1.91	0.88	0.42−1.8	0.77	0.42−1.43
pIII	0.58	0.35−0.96	0.64	0.37−1.1	0.55	0.34−0.88
pIV	0.28	0.16−0.50	0.31	0.16−0.60	0.28	0.15−0.50