had prolonged progression free-survival and/or survival, despite an initial unfavorable clinical and/or histopathological presentation. The toxic profile consisted in infrequent grade 3 toxicity and was easily manageable. So far G+D associated with G-CSF could be an option in first line treatment for sarcomatoid tumors where anti angiogenics have no efficacy or when rapid progressions, whatever the histopathologic types, occur following targeted therapies.

4534 POSTER

Phase II study of single-agent vinflunine in platinum-refractory transitional cell carcinoma of the urothelium (TCCU)

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Background: Vinflunine (VFL) is a new microtubule inhibitor of the vinca alkaloid class with clinical activity in TCCU (S. Culine, BJC 2006). This trial was conducted to define VFL activity in platinum-refractory TCCU patients (pts).
Methods: Global, multicenter, single-arm study. Primary endpoint: response rate (Independent Review; modified WHO criteria). Planned sample size: 150 pts. Main pt eligibility: at least one measurable lesion; documented progression within 12 months of last dose of platinum-containing regimen; calculated creatinine clearance (Cr Cl) >20 mL/min. VFL (320 mg/m^2 IV infusion over 20 minutes) was administered every 3 weeks. In pts with poor performance status, prior pelvic irradiation, or renal impairment (Cr Cl 20−60 mL/min), initial dose (ID) was 280 mg/m^2, escalated to 320 mg/m^2 if well tolerated.
Results (first 114 pts treated; 7 [5 PR, 2 SD] treatment ongoing): Baseline pt characteristics: Male 77%; female 23%. Median age: 66 years (range 40−83). Renal impairment: 40%. Prior chemotherapy: cisplatin: 66%; carboplatin: 44%, gemcitabine: 89%. Refractory status: 77%. Total of 425 VFL cycles administered (range: 1−14+). 320 mg/m^2 ID: 34 pts; 280 mg/m^2 ID: 80 pts. Main toxicity was hematologic (Grade [G] 3/4): neutropenia: 20%/39%; thrombocytopenia: 4%/0%; anemia: 16%/1%; febrile neutropenia: 7% (no pts withdrawn from study). Main non-hematologic toxicities (G 3/4): constipation: 13%/1%; fatigue: 11%/0%. Severe diarrhea or vomiting was infrequent. Only 1 atypical G3 peripheral neuropathy was noted (no G4). IRC response rate was 14.9% (95% CI: 8.9%-22.8%) with median duration of response: 6.8+ months. Stable disease in 42% of pts.
Conclusions: VFL has demonstrated activity and a manageable toxicity profile in pts with platinum-refractory TCCU.

4535 POSTER

Pronostic factors in seminoma

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Purpose: To determine the prognostic factors and to assess the relationship between selected pretreatment characteristics and survival in patients with seminoma.
Patients and Methods: 714 patients with seminoma diagnosed at INEN, Lima-Peru from 1990 to 2005 and were the subjects of the study. We describe the clinic behavior, response to treatment, follow up and survival. The overall patterns were compared in relation to clinical characteristics with Logrank/Breslow test. We identified the prognostic factors through the Cox model. The statistical evaluation was performed with 5% significance level. The results were processed with SPSS v. 12.0 program.
Results: The median age was 33 years (15−80y). The presentation of the primary site was testicular (97.2%), mediastinum (2.2%) and retroperitoneum (0.6%). 54.6% of them were CS I, 29.6% CS II, 15.8% CS III. The involved sites were lungs (4.2%), liver (2.4%) and Central Nervous System (0.6%). According to the IGCCCG risk classification, 83% were low risk (LR) and 17% intermediate risk (IR). The median follow up was 65 months. The patients with CS I, who received para-aortic radiotherapy (RT), had overall survival (OS) at 10 years of 98% in relation to 85% in patients with observation ($p \leqslant 0.001$). In CS II−III patients who received chemotherapy (CT), the OS at 5 and 10 years were 98% and 86% in LR, 73% and 72% in IR respectively. The prognostic factors for the OS were: age >50 years ($p = 0.023$, RR = 2.8), CS II ($p < 0.001$, RR = 19.3), CS III ($p < 0.001$, RR = 54.0) and liver metastasis ($p = 0.025$, RR = 3).
Conclusions: In our study the survival was related with prognostic factors such as age, clinical stage and liver metastasis. The risk qualification was not prognostic factor in our population. We observe that in CS I, radiotherapy was significant in relation to observation in survival. Further studies of tumor biology, including genetic analysis are required to identify other parameters that may correlate with survival.

4536 POSTER

Salvage chemotherapy in patients with recurrent germ cell tumors (GCT)

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Background: Patients (pts) with relapsed or refractory GCT may be cured by salvage chemotherapy with gemcitabine and paclitaxel. Optimal treatment is unknown.
Methods: Retrospective review of 35 consecutive pts treated with gemcitabine and paclitaxel at Thomayer Teaching Hospital in Prague from 1999 to 12/2006. Highly pretreated patients (chemoterapy BEP – average 4 cycles per patient, chemotherapy VeIP – average 3 cycles per patient, high-dose MTX was applied in 5 pts, high dose chemotherapy Carbopec in 24 pts) were treated with paclitaxel 175 mg/m^2 D1 and gemcitabine 1000 mg/m^2 D1+5, int. 3−4w.
Results: toxicity was quite low, hematological toxicity was manageable with growth factors and replacement of platelets, neurological toxicity grade III was observed in 3 patients, ototoxicity grade III was observed in 1 patient. 9 pts attained CR, 6 pts PR, 11 patients had stable disease, progressive disease was observed in 9 pts. Median OS was 16.2 months.
Conclusion: salvage chemotherapy with paclitaxel and gemcitabine is effective treatment with acceptable toxicity in highly pretreated patients with recurrent germ-cell tumors.
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4537 POSTER

Late recurrences (LR) in germ cell testicular tumours (GCTT): a population-based experience over 23 years

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Background: Sparse data are available with regard to incidence, clinical characteristics, therapeutic management and prognosis of pts with GCTT, who relapsed >2 years (y) after initial treatment.
Methods: A review of 1633 pts treated from 1980 to 2003 was conducted. 1504 of 1633 pts (92.1%) who received 1st line treatment were relapse free at 2 y. Among these 1504 pts [710 seminoma (S), 794 nonseminoma (NS)], 37 pts (2.5%) developed LR [10 S (1.4%), 27 NS (3.4%)].
Results: Median age at 1st presentation was 34 y and 27.2 y in S and NS, respectively. Intervals to LR were 31.8 months (mo) (range 25−48) in S and 59.6 mo (range 25–180) in NS. A total of 74.1 of NS but only 40% of S had disseminated disease (ds) at 1st presentation ($p < 0.01$). 25 pts (92.6%) with NS had initially received chemotherapy (cht) vs only 4 pts (40%) with S ($p < 0.01$). AFP was the dominant serum tumor marker elevated. Lymphogenic spread was the predominant pathway of LR metastasis [symptomatic in 17 pts (45.9%)]. The majority of pts presented with far advanced metastatic ds (80% and 88.9% in S and NS, respectively). Of 10 pts with S alive with NED are 7 pts (70%) for MFU of 84.4 mo (range 27–138), whereas 1 pt is alive with stable ds and 2 pts died of ds. Management included radiotherapy (2), cht (5) and surgery (3, combined with CHT in 2 pts) [1 teratoma (T), 2 vital carcinoma (VC)] (multiple procedures in 1 pt). 14 pts (51.8%) with NS are alive and free of ds (AFD) after treatment of LR at MFU of 82.6 mo (range 6–204). 13 pts died (11 of ds, 2 of cht related toxicity). Only 1 of 8 pts (12.5%) managed with CHT alone (PEB, PVI/PEI, CARBOPEC, paclitaxel combined regimens, oral VP 16) is AFD at 36 mo. 13 pts underwent successful surgery for LR, following previous salvage cht in 3 pts, for MFU of 82.6 mo (range 6–204). Cure failed in 1/13 pts (7.7%) with T and in 5/6 pts (87%) with VC (log rank test = 0.0015). Salvage surgery included RPLA (8), redo RPLA (11), neck dissection (1), lung (3) and liver (2) metastasectomy (multiple procedures in 3 pts).Overall AFD are 21/37 pts (56.8%) at MFU of 84.4 mo (range 6–204). Predictive factors for long term CR/NED included extent of ds, AFP < 100 ng/ml, no

extraretroperitoneal dissection, complete resection, good prognostic group and absence of VC at surgery. Overall AFD are 21/37 pts (56.8%) at MFU of 84.4 mo (range 6–204).
Conclusion: GCTT pts require long term follow-up. Cht alone seems to be of minor curative potential. At the time of LR, surgical resection remains our preferred therapy.

4538 POSTER

Phase II study of concurrent chemoradiotherapy (CCRth) for bladder preservation in the treatment of muscle invasive bladder cancer

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Background: Multimodality treatment aiming at organ sparing has become the standard of care for many malignancies, therefore the question has arisen as to whether cystectomy in the treatment of muscle invasive bladder cancer (MI BLC) could be replaced by an organ sparing treatment option. Phase II trials using chemotherapy (Cth) and radiotherapy (Rth) in different sequences in patients (pts) with MI BLC have reported different results, however the highest complete response rate was achieved in pts who received concurrent Cth and Rth compared with sequential administration of both.
Accordingly we have conducted this study in order to evaluate the combination of gemcitabine (Gem), cisplatin (Cis) and Rth after Transuretheral resection (TUR) of bladder tumors aiming at bladder preservation and to determine the outcome of this regimen. The study end points were response rate (RR), disease free survival (DFS), overall survival (OS) and toxicity (Tox).
Methods: After undergoing macroscopically complete TUR, Pts staged T2a, T2b and T3a received 60 Gy of fractionated Rth over 6 weeks with Cis (75 mg/m^2 q3w) starting on day 1 of Rth concomitant Gem (300 mg/m^2 on days 1, 8 and 15 q3w) for 2 cycles. Response was assessed after 4−6 weeks after the end of treatment by cystoscopic evaluation with multiple biopsies of the initial tumor site.
Results: This study included 30 pts of whom 27 pts showed CR (90%), one pt (3%) died after 25 settings of Rth and 2 pts (7%) showed progressive disease at the cystoscopic reevaluation, with a median follow up of 18 months, 10 pts developed infiltrating bladder recurrence and they were managed surgically by radical cystectomy. Hematologic tox in the form of anemia (G3) due to Cth was observed in one pt (3%) during treatment, 5 pts (17%) developed cystitis (G3) due to Rth. Updated analysis of DFS and OS will be presented.
Conclusion: After TUR, CCRth using Gem in combination with Cis and Rth have shown promising activity with acceptable tox, follow up of pts to evaluate DFS and OS is still ongoing.

4539 POSTER

Monitoring of serum levels of angiogenin, PDGF and MCP-1 in patients with renal carcinoma in the course of the treatment

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Background: Monitoring of angiogenin, PDGF (plateled-derived growth factor) and MPC-1 (monocyte chemotactic protein-1) levels for the purpose of determining malignant potential of renal cell carcinoma (RCC).
Materials and Methods: In order to determine the level of angiogenic factors, protein array method of the RayBiotech Company (USA), RayBio Human Angiogenesis Antibody Array I, was used. The results were expressed as relative values of concentrations of individual proteins in comparison to controls. RCC was diagnosed in 32 patients (11 women and 21 men, with the average age of 65.9 years). Eight resections and 24 nephrectomies were carried out. The diagnosis was confirmed histologically. Patients were divided into 3 groups based on TNM classification (10th revision, 2002). The first group included 15 patients with stages I and II RCC, the second group consisted of 8 patients with stage III RCC and the third group, 9 patients with stage IV RCC. Patient sera were obtained by repeated peripheral venous blood collections which were carried out on the day of surgery, 7 days and 8 weeks after surgery. Control serum were obtained from 14 healthy blood donors of similar age.
Results: Serum levels of angiogenin were significantly higher before surgery in patients with RCC in comparison to healthy blood donors and persisted 7 days (and as late as 8 weeks) after tumour removal. No significant differences in angiogenin levels were seen among individual disease stages. MCP and PDGF serum levels of patients with stage I-III RCC were significantly elevated in comparison to the group of healthy donors. Patients with advanced RCC (stage IV) had lower serum levels of MCP and PDGF. This finding may be considered the manifestation of immune insufficiency in case of advanced tumorous disease.
Conclusion: eight weeks after tumour removal, a decrease in MCP and PDGF was seen but there was no decrease in angiogenin. Both factors, MCP-1 and PDGF, seem to reflect as increase in the intensity of anti-tumour response as neoangiogenesis.
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4540 POSTER

Cyclophosphamide and cisplatin is an effective treatment in patients with stage II and III seminoma

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Objective: To determine the efficacy of Cisplatin + Cyclophosphamide (PC), an alternative regimen to BEP (Bleomycin–Etoposide–Cisplatin) in terms of response rate (RR), disease-free-survival (DFS) and overall survival (OS) in patients with diagnosis of Seminoma.
Patients and Methods: 237 patients with diagnosis of stage II and III, testicular cancer, Seminoma, who received chemotherapy with either PC (134) or BEP scheme (103) between 1990 and 2005, were evaluated at INEN. PC scheme consisted in 4 cycles of Cisplatin 100 mg/m^2 + Cyclophosphamide 10000 mg/m^2 each 3 weeks, and BEP in 4 cycles of Bleomycin 30 mg days 2, 9, 16 + Etoposide 100 mg/m^2/d $\times$ 5 days and Cisplatin 100 mg/m^2. The clinical characteristics, response to treatment and overall survival were evaluated with Chi square test. We estimated the overall curves with Kaplan-Meier and compared them with Logrank or Breslow test.
Results: The median age was 35 years (18−63) for PC and 31 years (15−51) for BEP. The primary sites were testis in 223 (94%), mediastinum in 11 (4.6%) and retroperitoneum in 3 (1.3%). The clinical stage was II (70%) and III (30%); according to the IGCCCG risk classification, 67% had low risk and 32% intermediate risk. The sites of disease were retroperitoneum lymph nodes (23%), mediastinum lymph nodes (9%), lungs (8%), soft tissues (3%), liver (2%) and central nervous system (0.8%). The clinical characteristics did not show statistical difference. The complete response (CR) rate was 72% in PC and 81% in BEP ($p = 0.115$). The median follow-up was 53 months. The DFS at 10 years was 87% in CP group vs. 95% in BEP group ($p = 0.229$). The OS at 5 and 10 years was 84 and 82% in CP group vs. 88 and 88% in BEP group ($p = 0.503$).
Conclusions: 4 cycles of Cisplatin + Cyclophosphamide is an effective treatment for clinical stage II–III Seminoma. We did not find statistically significance difference in RR, DFS and OS comparing with the BEP scheme.