Conclusion: In our series of IBC, C followed by ACT has been associated with a reduction in the risk of relapse and death, particularly in patients with extravesical disease or N+.

7168 POSTER

Prognostic factors for survival in patients (pts) with metastatic nonseminomatous germ cell tumors (mNSGST) relapsed after modern induction chemotherapy (CT)

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Purpose: Despite high efficacy of induction platinum-based CT, 20−30% pts with mNSGCT relapse and only minority of them might be cured. There is no commonly used prognostic classification for relapsed mNSGST like IGCCCG classification for CT-naive pts. The aim of this study was to define prognostic factors for survival in mNSGST pts relapsed after platinum+etoposide-based induction CT.
Patients and Methods: We analyzed data of 698 CT-naive pts with advanced NSGCT who had been treated in our department from 1986 to 2006 with etoposide- and cisplatin-based regimens (EP, BEP, C-BOP-3BEP and T-BEP) followed by resection of residual tumors. With median follow-up time 32 (range, 3−215) months 181 (26%) pts had relapsed. Pts with mature growing teratoma syndrome were not included in the analysis. The salvage CT was administered to 138 pts, 71 (51.7%) of them were treated with ifosfamide-cisplatin-based conventional CT (VeIP, TIP or VIP regimens). Multivariate step-wise Cox' regression analysis was performed to determine prognostic factors in the 71 relapsed pts treated with ifosfamide-cisplatin-based CT.
Results: The 5-year overall survival (OS) rate for pts treated with ifosfamide-cisplatin-based CT was 32% (95% CI, 25−41%). In the univariate analysis, following negative factors were determined: initial poor IGCCCG prognostic group, mediastinal primary tumor, morphology of primary tumor (yolk sac tumor), AFP level $\geqslant$10,000 U/ml and LDG level $\geqslant$1.5 ULN before induction CT, absolute cisplatin-refractory relapse, progression-free interval $\leqslant$ 2 years and LDG level $\geqslant$2 ULN at relapse. Four prognostic factors remained in the multivariate analysis: morphology of primary tumor (yolk sac tumor), LDG level $\geqslant$1.5 ULN before induction CT, absolute cisplatin-refractory relapse, LDG level $\geqslant$2 ULN at relapse. According the analysis pts could be classified into three prognostic groups. Good prognostic group (no negative factors) – 10/71 (14%) pts, 3-year OS – 100%. Intermediate prognostic group (1 negative prognostic factor) – 33/71 (46.5%) pts, 3-year OS – 50.2%. Poor prognostic group – ($\geqslant$2 negative prognostic factors) – 28/71 (39.5%) pts, 3-year OS – 6.7%.
Conclusion: Our classification allows dividing pts with relapsed mNSGCT into groups with different prognosis. This way of stratification is urgently needed for further trials. New regimens of salvage CT is demanded for pts with poor prognosis.

7169 POSTER

Association of preoperative sodium concentration with prognosis in renal cell carcinoma

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Background: Renal cell carcinoma has a variable natural history, and determining individual prognosis is important to guide management. A single recent report in a small UK series suggested that pre-operative hyponatremia might be a prognostic factor in renal cell carcinoma. We aimed to validate this finding in an external series of patients from a single Asian centre.
Methods: We retrospectively analyzed a series of patients undergoing nephrectomy for newly diagnosed RCC between 1991 and 2008. Clinical, pathologic, and laboratory data were recorded in each case.
Results: A total of 447 RCC patients formed our study population, with a median survival of 41.2 months. It was found that cancer specific survival correlated well with pre-operative sodium levels (HR 2.06, 95% CI 1.31−3.22, p = 0.001 by log-rank testing), with 5-year survival estimates to be 71.0% (95% CI 64.5−75.4) and 82.8% (95% CI 79.1−85.9) respectively, with poorer prognosis predicted in patients with relative hyponatremia. This same relationship can be seen using the outcomes of overall survival (p = 0.003) as well as disease-free survival in patients with non-metastatic disease (p = 0.069). Multivariate analysis showed that the effect of sodium levels was independent of clinical staging (HR 1.74 95% CI 1.11−2.73, p = 0.016). This was also seen with reference to other variables such as pre-operation serum creatinine levels, histological grade and ECOG performance status.
Conclusions: We confirm that a pre-operative serum sodium level is an independent prognostic factor in an external Asian series of RCC patients. We are currently conducting analysis to elucidate the cause of the hyponatremia.

7170 POSTER

Clinical practice guideline impact on referral and treatment rates of neoadjuvant chemotherapy for muscle-invasive bladder cancer: a comparative analysis between two Canadian tertiary care centres

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Background: Level I evidence recommending neoadjuvant chemotherapy (CT) for muscle invasive bladder cancer exists. A Clinical Practice Guideline (CPG) was developed in Alberta, Canada based on this evidence. The primary objective of the current study was to examine the impact of this CPG on referral rates and treatment-offered rates for patients with muscle invasive bladder cancer. We then assessed the degree to which two tertiary health centres in the province of Alberta differed with respect to CPG uptake. Secondarily, the impact of neoadjuvant CT on pathologic response of the disease was examined.
Methods: The study was a retrospective cohort analysis of pooled data from patients who underwent radical cystectomy (RC) for presumptive clinical stage $\geqslant$ T2 bladder cancer at two tertiary care centres in Alberta. Patients receiving care within a 5-year period encompassing the CPG release date were identified and separated into one of two cohorts (pre-CPG [n = 129] from 2.5 to 0.5 years before the release, and post-CPG [n = 107] from 0.5 to 2.5 years after the release). Referral to medical oncology and actual treatment rates were ascertained for each cohort in each of the two centres. Rates of pathologic response among the RC only group and CT plus RC group were also analyzed.
Results: Referral to medical oncology for neoadjuvant CT occurred in 2 out of 129 (1.5%) patients and 23 out of 107 (21.5%) patients in the pre- and post-CPG groups, respectively (RR 13.9, 95% CI 3.3 to 57.5, p < 0.001) with a difference of 6% and 25% between centres. Neoadjuvant cisplatin and gemcitabine (CG) CT was offered to 0 out of 2 (0%) patients and 18 of 23 (78.3%) patients in the pre- and post-CPG groups, respectively (p = 0.02) with a difference of 0% and 7% difference between centres. Four out of 13 (30.6%) patients and 12 out of 223 (5.4%) patients who received neoadjuvant CT plus RC and RC alone, respectively, had a complete pathologic response (pT0) (p < 0.001). Pathologic downstaging (ie, pT < cT) occurred in 8 out of 13 (61.5%) patients who received combined therapy compared to 52 out of 223 (23.3%) patients who had RC alone (p = 0.002).
Conclusions: Referral and treatment-offered rates improved significantly after the release of the CPG. However, these rates are low. The uptake of the CPG between the two tertiary centres varied considerably, indicating a non-uniform and incomplete dissemination of the guideline. The pT0 rate of the CG regimen used in this study was comparable to existing data using a methotrexate, vinblastine, doxorubicin, and cisplatin regimen.

7171 POSTER

Chemoradiotherapy with cisplatin (C) and gemcitabine (G) plus concurrent irradiation (XRT), for the conservative treatment of invasive transitional bladder cancer (ITBC) patients – clinical outcome and long term follow-up in a monoinstitutional experience

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Background: C and G have synergistic activity when used in combination and are both potent radiosensitizers. In a dose finding trial, conducted in our hospital on 16 T2−4 N0 ITBC patients using C and G combined with concurrent XRT, after maximum transurethral resection, the maximum tolerated dose (MTD) of G was 400 mg/sqm (IJROBP 2003; 57: 1310−16). On this basis, we have designed a formal multi-institutional phase II trial, in order to confirm the promising results observed in the previous study. The trial however, was prematurely closed, due to low accrual, so we have

updated and are presenting now the long-term clinical outcome of the 16 patients involved in the dose-finding trial, together with that of the 9 pts enrolled in the phase II study.
Materials and Methods: from June 1999 to December 2004, we have treated in our institution a consecutive series of 25 T2−4 N0 ITBC pts (median age 67 yrs, range 51−80). After macroscopically radical TUR, all pts received XRT (54 Gy in 30 fractions over 6 weeks) and concurrent C (100 mg/sqm on days 1, 22). In dose finding study G was given weekly from 200 to 500 mg/sqm: since unacceptable toxicity was observed in two cases (one death for toxicity), at the dose of 500 mg/sqm/week, and considering the treatment toxicity profile, the recommended G dose for phase II trial was 400 mg/sqm on day 1.8 q 21 for 2 courses together C and XRT. At the trial closure, 9 pts have received such treatment.
Results: Except the pt who died for toxicity before the end of treatment, all the remaining 24 pts were microscopically disease free at the cystoscopic re-evaluation performed within 8 weeks after the treatment. Seven local and 2 distant relapses have been observed so far, at a median follow-up of 66 mos. Presently, 67% of pts is alive and disease-free, with one patient died for lung cancer. All pts alive have retained their bladder, with a normal organ function, in absence of any relevant long-term toxicity. The median survival has not been reached yet, while the OS at 7 years is 66%. The 5-year DFS, local DFS and survival without cystectomy, were 62%, 70%, and 95% respectively.
Conclusions: in our experience G + C with concurrent XRT in ITBC pts, appears encouraging, even at long-term follow-up. Considering the 100% of complete response observed after the treatment, this combination may be of interest in enhancing the disease control of C plus XRT that is today the treatment of choice in the conservative therapy of ITBC.

7172 POSTER

Feelings of loss and shame after having lost a testicle: a population-based long-term follow-up of testicular-cancer survivors

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Background: Knowledge about the reactions and feelings among men who have lost a testicle due to testicular cancer is rather limited.
Materials and Methods: We identified 1173 eligible men diagnosed with non-seminomatous testicular cancer treated according to the national cancer-care programs SWENOTECA I-IV between 1981 and 2004. During an 18-month qualitative phase we constructed a study-specific questionnaire, primarily on cognitive functioning in every-day life. In addition, we also asked the men about their feelings after having lost one testicle.
Results: We obtained information from 960/1173 (82 percent) testicular-cancer survivors 3 to 26 years after diagnosis. We found that 32 percent of these men miss or have missed their ablated testicle and that 26 percent have or have had feelings of shame related to their body because of the ablated testicle. These feelings were more common among younger men (20−34 years old) than among older (44−74 years old) men. Relative risk for younger men of having or having had feelings of loss was 1.5 (95% confidence interval, CI 1.2 to 1.9) and of shame 1.8 (95% CI 1.3 to 2.3). Furthermore, we found that a greater percentage of singles missed the testicle (RR 1.7; 95% CI 1.3 to 2.3) and had feelings of shame related to their body (RR 1.9; 95% CI 1.3 to 2.7) than did non-singles. We did not find that feelings of loss and shame were less common among those who had, compared to those who did not have, a prosthesis. However, we found it was more common for men who had never been offered a prosthesis to report feelings of loss (RR 1.7; 95% CI 1.3 to 2.2) and shame (RR 1.3; 95% CI 1.0 to 1.8) than for men who had been offered but rejected one.
Conclusion: A substantial amount of Swedish testicular-cancer survivors treated between 1981 and 2004 have or have had feelings of loss and shame due to having lost one testicle due to testicular cancer. These feelings are more common among younger men and single men. Feelings of loss and shame are not less common among men who have a prosthesis than among those without a prosthesis. However, these feelings are more common among men who never were offered a prosthesis than among men who were offered but rejected a prosthesis.

7173 POSTER

Combination ifosfamide, bleomycin, etoposide and cisplatin (IBEP) as first line chemotherapy in patients with intermediate and poor prognosis advanced cancer of the testis

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Background: Patients with intermediate and poor prognosis advanced testis cancer according to the International Germ Cell Consensus Classification (IGCCC) have a rather dismal long-term outcome (five-year survival roughly 80% and 50% respectively) when treated with the standard initial chemotherapeutic combination of Bleomycin, Etoposide and Cisplatin (BEP). Therefore, the use of more aggressive approaches in the context of clinical studies is recommended.
Aim: The estimate of effectiveness and toxicity of combination IBEP as first line chemotherapy in patients with advanced cancer of the testis of intermediate and poor prognosis.
Patients and Methods: Patients are treated with IBEP chemotherapy with Ifosfamidie 1.2 g/m^2 for 3 days, Bleomycin 15 mg for 3 days, Etoposide 80 mg/m^2 for 5 days and Cisplatin 20 mg for 5 days with support with hydration and mesna. Primary endpoints are overall survival (OS) and the Disease-free survival (DFS).
Results: 75 patients were treated in 9 centres. The median age of patients was 27 (16−54) years, while in the 83% of patients had non-seminomatous tumours. Apart alopecia, the main toxicities were nausea - vomiting, anaemia, leucopenia-neutropenia, thrombocytopenia and neurotoxicity. With a median follow-up of 56 months, in the initial analysis, the three-year survival is 84% and three-year DFS 72%. Detailed analysis, including 5-year outcome separately for each category of patients is under way in order to be presented during the congress.
Conclusion: Combination IBEP as first line chemotherapy in the advanced cancer of the testis of intermediate and poor prognosis is safe and relatively well tolerated, while the initial long-term results expressed as overall and Disease-free survival appear encouraging.

7174 POSTER

Bleomycin-induced pulmonary toxicity in patients with advanced germ-cell tumours: comparison of bolus administration vs 72-hour continuous infusion

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Background: The standard chemotherapy regimen for advanced germ-cell tumours (aGCT) consists of bleomycin as a bolus, etoposide and cisplatin (BEP). Retrospective evidence suggests that bleomycin-induced pulmonary toxicity (BIPT) may be decreased by the administration of bleomycin as a continuous infusion (CI). The aim of the study was to compare BIPT between bolus administration and CI in patients with aGCT treated with BEP.
Materials and Methods: male patients with testicular germ-cell tumors considered for BEP for 3 or 4 cycles were randomized to receive bleomycin as a bolus or as a 72-hour CI. High resolution CT (HRCT) scans of the lungs were obtained at baseline at every 2 cycles. BIPT was defined using Kazerooni scale, which assigns independent scores (0−5) for alveolar damage (ground-glass opacities) and interstitial damage (fibrosis) in patients with idiopatic pulmonary fibrosis. BIPT was defined as an score $\geqslant$ 2 for alveolar damage and/or >1 for interstitial damage. Expected incidence of BIPT was 40% with bolus bleomycin. We hypothesized that bleomycin administered as a CI could decrease BIPT to 20%. To detect this difference with 80% power and 5% α error, 127 patients were needed. The study was approved by the institutional ethics committe of the two institutions where patients were recruited.
Results: Between 03/2005 and 10/2006, 44 patients signed informed consent. Forty-one patients had at least one HRCT and were evaluable. Median age was 23 (17−41). According to the International Germ Cell Consensus Classification, 11 patients had good prognosis, 10 had