grade II to I, 6 from grade II to 0, 2 from grade I to 0 and 1 from III to II), whilst in one patient there was deterioration. Response was graded as significant (complete or near complete resolution of symptoms) in 16 patients, moderate (partial but noticeable improvement) in 9 and no response (minimal or no improvement) for 4. For those patients that received Alfuzosin during RT for more than 2 weeks, this response was maintained in 16 patients, but was not maintained in 4 patients. Multivariate analysis showed an association of response with prostate volume ($p = 0.041$).
Conclusion: This study confirms that alfuzosin significantly reduces LUTS arising during RT for prostate cancer, and may also improve QoL. This data supports further investigation with a randomized alfuzosin versus placebo study in patients undergoing radical RT for prostate cancer.

868 POSTER

Chemotherapy for teratoma with malignant transformation

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Background: Germ cell tumors (GCT) with a non GCT malignant component is a rare phenomenon called teratoma with malignant transformation (TMT). In the literature, the largest series of patients (pts) with TMT treated with chemotherapy comprises for 12 pts (J Clin Oncol 2003, vol 21, No 23). We report our experience of chemotherapy in 14 patients with TMT.
Patients and methods: Sarcoma was the most frequent histologic type of TMT, identified in 9 pts, with rhabdomyosarcoma ranking first among the subtypes (4/9). Other histological types included adenocarcinoma (4) and bronchoalveolar carcinoma (1). Chemotherapy was administered to 14 pts with TMT, including 10 with measurable disease. Each patient received chemotherapy regimens based on the specific malignant cell observed in the transformed histology.
Results: 7/10 pts with measurable disease achieved a partial response, with the duration of response ranging between 4 and 17 months. Two patients did not respond to treatment and one patient had stable disease. All pts with sarcoma-containing TMT received a cisplatin-doxorubicin based chemotherapy. 9 pts had a resection of residual masses. With a median follow-up of 72 months, 4/14 pts (%) are alive, including 3 who are disease-free.
Conclusion: This is by far the largest reported European experience of chemotherapy in TMT. Although TMT has a poor prognosis compared to GCT, its management may be improved by adapted chemotherapy associated with surgical resection of residual masses.

869 POSTER

Prognostic significance of early predicted time to normalization (TTN) of tumor markers in advanced nonseminomatous germ cell tumors (NSGCT): validation study

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Purpose: K. Fizazi et al. have shown the decline rate of serum AFP and hCG during the first 3 weeks of chemotherapy (CT) predict the outcome in NSGCT pts with poor-prognosis (JCO, Vol.22 (19), 2004). In our validation study we retrospectively studied the prognostic relevance of early predicted TTN in advanced NSGCT.
Patients and methods: During 1984–2002, in the study were included 312 NSGCT chemotherapy (CT)-naïve pts with known tumor markers levels at the beginning of first and second cycles of CT. They were treated with modern cisplatin-etoposide-based CT in our department. Decline rates were calculated using a logarithmic formula and expressed as TTN. Pts with both TTN of AFP <9 wks and hCG <6 wks were defined as favorable group.
Results: Median f.-up time was 36 (range, 12–156) months. Progression-free survival (PFS) and overall survival (OS) were similar in good and intermediate IGCCCG groups irrespective of predicted TTN. In poor prognostic group there was a trend of worsening in 3-years OS in pts who had unfavorable TTN (50%) than favorable TTN (71%, $p = 0.11$). Separate analysis of prognostic relevance of TTN AFP and hCG shown that only unfavorable TTN of AFP predicted lower OS in poor prognostic group in comparison with favorable TTN – 42% and 65% ($p = 0.016$), respectively. According to IGCCCG prognosis OS was entirely identical in pts with favorable or unfavorable TTN of hCG.
Conclusions: The analysis showed that decline rates of AFP but not hCG during the first 3 weeks of CT predict outcome in NSGCT pts with poor-prognosis according to the IGCCCG.

870 POSTER

A pilot study: potential role of nutrient vitamin D in prostate cancer patients with rising PSA after definitive therapy

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Objective: To assess the effect of nutrient vitamin D (cholecalciferol) on the rate of PSA rise and PSA levels in prostate cancer patients with rising PSA after definitive therapy. Optimal management for patients with PSA relapse alone (with no evidence of distant metastasis or local progression) after surgery and/or radiotherapy remains uncertain. Although androgen ablation (AA) has been traditionally the standard treatment for these patients, there are several concerns related to implementing AA in earlier stage of PSA relapse. These include: 1. a finite duration of effectiveness and potentially significant side effects of AA. 2. no randomized study suggesting the benefit of immediate AA for PSA relapse alone, compared with delayed application at the time of clinical evidence of tumor progression. Thus many clinicians choose to observe asymptomatic patients with PSA relapse alone. On the other hand, it is distressful to a patient to be idle in the presence of rising PSA. Therefore it is desirable to have an agent with low toxicity that can inhibit or decrease the rate of tumor progression before consideration of AA. Vitamin D may be such an agent.
Methods: A prospective, single arm, study. Fifteen asymptomatic patients (median age: 68) with PSA relapse alone after surgery and/or radiotherapy were treated with simple, nutritional vitamin D 2000 IU per day orally. All had an evidence of PSA relapse with at least 3 successive PSA rises over a minimum of 9 months after definitive therapy. Patients were followed every 2–3 months for PSA levels and toxicity. The rates of PSA rise and absolute PSA levels were compared between before and after the initiation of vitamin D.
Results: Median follow-up after the start of vitamin D was 8 months (range:4–21). 8/15 had a decrease in PSA (sustained from 5 to 17 months) after the start of vitamin D. In one additional patient, PSA levels fluctuated around the baseline for 21 months. After the start of vitamin D, 14/15 had a decrease in the rate of PSA rise, which was statistically significant ($p = 0.005$). PSA doubling time increased from a median of 14.3 months before vitamin D to 25 months after vitamin D. None had side effects from vitamin D.
Conclusion: Simple, nutrient vitamin D appears an effective agent that can moderate the rate of PSA rise, which may suggest the retardation of tumor progression. This was achieved with very low cost ($2.00/month) and no adverse effects. A confirmatory study is needed.

871 POSTER

Urinary ICAM-1 levels can predict response in superficial bladder cancer treated with intravesical immunotherapy

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Aim: The present study investigated the value of urinary ICAM-1 as a prognosticator of response in patients with superficial bladder cancer treated with different immunotherapeutic modalities.
Material and methods: 34 patients with histologically proven superficial recurrent bladder cancer (except carcinoma in situ) were included in the study. The patients received intravesical instillations of bacillus Calmette-Guérin (BCG), interferon-α-2b and interferon-γ-1b. Three fresh-voided urine specimens were collected from every patient at each instillation; one before the instillation, one 12 hours after the instillation and one 24 hours after the instillation. ICAM-1 measurements in the urine were performed using a commercially available enzyme-linked immunosorbent assay (ELISA) kit. Response to treatment was evaluated with cystoscopy and routine urine cytology every 3 months for a period of 12 months. Patients without evidence of recurrence were considered as responders, whereas those with recurrent disease were considered as non-responders.
Results: Mean urinary soluble ICAM-1 levels at each instillation were calculated from the three pertinent measurements. Concentrations in the

'b' and 'c' samples were significantly higher than in the 'a' samples at the first instillation ($p < 0.01$). The Kruskall-Wallis test resulted in a significant difference of mean sICAM-1 levels at the 6th instillation between responders and non responders ($p < 0.05$). Regression analysis showed significant correlation between ICAM-1 levels at the 6th instillation and response to treatment. This correlation was not dependent on the type of administered immunotherapy. By setting a cut-off value of 338.2 ng/mL, ICAM-1 sensitivity was 85%, specificity 84.6% and negative predictive value was 88.5%.
Conclusions: Soluble ICAM-1 urine levels at the 6th instillation seem to be an independent predictor of response to intravesical immunotherapy with high sensitivity and specificity. Correlation with disease progression would require a larger patient population and is currently in progress.

872 POSTER

10 year experience in using a modified field size in hemibody irradiation for metastatic prostate cancer

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Introduction: This retrospective review was carried out to assess whether patients receiving modified hemi-body irradiation (HBI) required further treatment to sites outwith the radiation field, namely the skull and lower leg, and whether the treatment outcome was successful – in terms of pain control, or subsequent treatment for pain or new skeletal events within the treated area.
Method: 103 patients with widespread bony metastases from prostate cancer received modified HBI in a consecutive 10 year period, using the same radiotherapy (RT) technique and dose. The treatment field for the upper hemi-body excluded the region above the ramus of the mandible, and for the lower hemi-body the region below the knee was excluded. A successful outcome of HBI was determined by assessing whether pain was better, the same or worse in combination with any change in analgesia intake. This was assessed for the first outpatient review at 6 weeks post HBI and again at the final documented outpatient follow up to see whether the successful outcome was sustained.
Results: 45 patients received sequential (upper and lower) modified HBI, of whom 33/45 patients (73.3%) had a successful outcome at their first review (87.9% sustained this success at last review), with only 3/45 patients receiving further RT to the skull (2/45) and lower leg (1/45). 20 patients received upper modified HBI alone, of which 17/20 patients (85%) had a successful outcome at first review (94.1% sustained this success at last review), with no RT required to the skull. 38 patients received lower modified HBI alone, of which 26/38 patients (68.4%) had a successful outcome at first review (80.8% sustained this success at last review), with no further RT to the lower leg. Toxicities were minimal, with 6/103 patients experiencing nausea, 1/103 had diarrhoea, and pneumonitis was not seen. Post HBI, 25/103 patients (24.3%) required a blood transfusion while no patients required a platelet transfusion. 5/103 patients (4.8%) developed new skeletal events in the treated area.
Conclusions: HBI provides successful and sustained relief in the majority of patients with bone pain in metastatic prostate cancer. Modifying the field size, as not to include the skull and lower leg, does not appear to have any significant impact on the final outcome of treatment, namely pain control and the need for additional RT. A low incidence of side effects was associated with modifying the field size, for the patients reported here.

873 POSTER

Organ preservation in urinary bladder cancer: conservative treatment with radiochemotherapy for fragile patients. Mono-institutional experience.

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Introduction: Conservative treatment allows the anatomical and functional organ preservation in some oncology patients. In this way, there are some radiochemotherapy protocols in the treatment of muscle-invasive urinary bladder cancer. They can conduce to a similar survival of patients, with vesical conservation without cystectomy in great number of the same.
Purpose: to assess the efficacy of a multidisciplinary treatment protocol for muscle-invasive bladder cancer in fragile or elderly patients. The protocol comprising rigorous transurethral resection (TUR) and chemo-radiotherapy, evaluating local control and survival.
Patients and methods: thirty six patients treated in the period 2002–2004, aged mean 70 years (49–78) were enrolled in this study. All of them with a diagnosis of muscle invasive bladder cancer stage: T2a-T4a. The treatment protocol consisted on maximal TUR of the bladder tumors, followed by two cycle's chemotherapy with Carboplatin plus Gemcitabine, administered previous conformal 3D radiation therapy: 45 Gy on pelvis volume and total dose of 65 Gy in bladder, concomitant with a weekly dose of carboplatin (total dose of 50 mg) as radio sensitizer. Response was evaluated by restaging transurethal resection. Cystectomy was considered when persistent tumour or local relapse was achieved.
Results: with a median follow-up of 31 months (ratio 8–44), actuarial 3 years cancer specific and overall survival rates are 70% and 61%. Conserve the bladder 89% (32/36) and 87% (28/32) of them are free of local relapse. Two patients underwent early cystectomy because of no response, and two patients underwent delayed cystectomy. The combined treatment is excellently tolerated and therefore with high index of fulfilment (79%). Toxicity has been very low.
Conclusions: the results of this study show that bladder-sparing radiotherapy with neoadyuvant and concurrent chemotherapy is feasible in elderly or fragile patients (mean aged of 70 years) with excellent results in terms of local control and survival. Most of them can conserve functional bladder without important side-effects.

874 POSTER

Gemcitabine monotherapy in the treatment of locally advanced/metastatic bilharzial-related bladder cancer: a follow up report

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Background: In Egypt, bladder cancer represents 18.2% of all cancer types. Its high incidence is potentially related to the domestic prevalence of bilharziasis, which causes pathologic changes rendering this disease more resistant to chemotherapy and radiotherapy. The activity of gemcitabine in transitional cell carcinoma (TCC) is well studied in western countries; therefore, we conducted this phase II study to evaluate the efficacy of gemcitabine in locally advanced/metastatic bilharzial-related bladder cancer.
Methods: Eligible patients had locally advanced/metastatic (T3b, T4/N2–3/M1) bilharzial-related bladder cancer, were aged 18–75 years, and had WHO performance status (PS) of 0–2. No prior chemotherapy or radiotherapy was allowed, but prior surgery was acceptable if disease recurred. Adequate bone marrow reserve and organ function, a life expectancy >6 months, and informed consent was required. Patients received gemcitabine 1200 mg/m^2 via 30-minute infusion on days 1, 8, and 15 of a 28-day cycle.
Results: From March 1999 to October 2001, 20 patients were enrolled in the study. Ten (50%) had locally advanced disease; 7 (35%) had metastatic disease; and 3 (15%) had recurrent disease. Metastatic sites were liver (2 patients) and bone, lung, supraclavicular lymph nodes, liver and bone, and iliac and para-aortic lymph nodes (1 patient each). Among the 15 evaluable patients, 14 (93%) were male, and 11 (73%) had TCC. Nine patients (60%) had a WHO PS of 2. One patient had a complete response (CR) (7%), and 5 had partial responses (PRs) (33%) for an overall response rate of 40%; all responders had TCC. Five (33%) had stable disease, and 4 (27%) had progressive disease (PD). The only toxicities reported were grade 3 neutropenia in 3 patients (20%) and grade 3 anemia in 2 patients (13%). After a 1-year follow-up of the responders, the CR was maintained, and another 2 patients achieved CR (1 after cystoscopy and radiotherapy and 1 after a liver nodule assessment that was determined irrelevant to the disease). One patient maintained a PR, while 2 patients died of PD. After 2 years, 2 CRs and 1 PR (20%) remained.
Conclusion: In a multimodality approach, gemcitabine monotherapy can be used in patients with bilharzial-related bladder cancer of the TCC type who cannot tolerate platinum compounds or who have a poor performance status to achieve long-term, complete remission.

875 POSTER

Concurrent radiochemotherapy with Gemcitabine for locally advanced bladder cancer

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Background: Combined chemo-radiotherapy may improve local control, organ preservation rate and long term survival in patients with locally advanced bladder cancer.
Gemcitabine shows certain activity in bladder cancer. Several studies confirmed that Gemcitabine have radiosensitizing properties. We proposed in this study to evaluate the efficacy and toxicity of the concurrent radiochemotherapy with Gemcitabine in locally advanced bladder cancer.
Material and methods: From March 2002 to May 2004 27 patients with locally advanced bladder cancer were enrolled onto this study. Patients characteristics: there were 21 male and 6 female, median age 53 years