246 Proffered Papers

selection of patients who might avoid unnecessary cancer treatments that are associated with serious sequelae.

854 POSTER

Chemotherapy vs. radiotherapy in clinical stage CSA and B1/B2 seminomatous testicular tumours: the two institutions experience

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Background: Radiotherapy (RT) applied to retroperitoneal and ipsilateral pelvic nodes represent standard treatment in CSA and B1/B2 seminomatous testicular tumours (STT), promising results have been reported with chemotherapy (CHT). The aim of the prospective non-randomized study was to analyze the survival, relapses, acute and late side effects following RT and CHT.

Material and methods: Between 1982 and 2003, 456 patients (pts) in CSA and B1/B2 STT were divided into 2 groups according to primary tumour treatment. Group A (1997–2003) CSA (n = 177): 170 pts received 2 cycles of CHT with carboplatin (CBDCA). CS B1/B2 (n = 17) underwent induction CHT (platinum (P) and etoposide (E)). Complete response (CR) to CHT was defined as complete radiographic resolution of metastasis or a <3 cm stable residual mass (rm). Partial response (PR) to CHT was defined as >3 cm stable rm followed by delayed selective consolidation with retroperitoneal lymph adrenalectomy. Group B (1982–1997), 286 pts (247 in CSA and 39 in CS B1/B2) received RT in majority of pts by linear accelerator (8 pts were treated using Co unit), applied to retroperitoneal and ipsilateral pelvic nodes. The prescribed dose at midplane was 30 Gy/18 fractions.

Results: Group A – after median follow-up (mfu) of 4 years all pts in CSA are alive and free of disease (afd). 1 pt (0.6%) relapsed in the retroperitoneal nodus at 28 months (m) and achieved CR with PE CHT. All pts in CS B1/B2 entered in CR following PE CHT (2 pts with RM <3 cm). 1 pt relapsed at 12 m in retroperitoneal lymph nodes and achieved CR with salvage CHT. All pts are afd after mfu of 55 m. Group B – after mfu of 10 years afd are 98% and 91% in CSA and B1/B2, respectively. Relapses were registered in 14 pts (4.9%) within mfi of 10 m. 9 (64.3%) relapsing pts achieved CR with CHT and/or RT: 7/10 in CSA and 2/4 in CS B1/B2. 7 pts died (4 of STT, 3 of intercurrent disease). 7 pts developed second malignancy within mfi of 160 m (lung 3 pts, non-Hodgkin lymphoma 1 pts, bladder 1 pts, opposite testis 2 pts)

Conclusions: Orchidectomy followed by RT for CSA and B1/B2 seminoma resulted in an excellent survival and low rate of complications and relapses. CBDCA CHT appear to be an acceptable alternative approach in CSA STT: application is easy, side effects are mild, relapse rate and late sequels are lower than after RT. However, primary CHT in CSA + B1/B2 STT necessitate long term follow-up studies in order to determine more precisely late events.

855 POSTER

Differences in degree and duration of bone protection with intravenous bisphosphonates in prostate cancer patients receiving androgen deprivation therapy (adt): results of a placebo-controlled trial

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Background: Although androgen deprivation therapy (ADT) is the gold standard of treatment for hormone-refractory prostate cancer (HRPC), the associated bone demineralization increases the risk of osteoporosis, osteopenia, and related skeletal fractures. Because of their beneficial effects on bone turnover, bisphosphonates have been investigated as a potential treatment to maintain bone integrity in such patients.

Methods: This prospective, placebo-controlled study included 97 men who were randomly assigned to 1 of 3 treatment groups after undergoing androgen ablation (LHRH-agonist therapy or orchiectomy). The treatment groups included: monthly intravenous (IV) clodronate infusions (n = 39); monthly IV zoledronate infusions (n = 27), or no bone protection (control; n = 34). Efficacy evaluations included PSA, serum testosterone, x-ray, bone scintigraphy, and dual-energy x-ray absorptiometry (DEXA) scans with densitometry performed every 6 months. Patients were followed for a minimum of 36 months.

Results: The average patient age was 63 years. Bisphosphonate treatment maintained bone mineral density to a greater extent than the control, with clodronate providing greater protection against osteopenia than zoledronate. The average time to development of osteopenia after ADT was 6 months in the control group, vs 24 months and 18 months in the IV clodronate and IV zoledronate groups, respectively. Likewise, the average

time to develop osteoporosis was 24 months in the control group, compared with 28.3 months and 28.5 months in the IV clodronate and IV zoledronate groups, respectively.

Conclusions: Bisphosphonates should become the standard of care to maintain bone integrity in those patients receiving ADT for the treatment of HRPC. In this study, IV clodronate provided greater protection against osteopenia than IV zoledronate.

## 856 POSTER

## Prostate size and the effect of hormonal manipulation

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Background: To evaluate prostate gland length and volume in a large population of men diagnosed with localized prostate cancer. Furthermore, to assess the effect of hormonal manipulation (HM), specifically the difference between luteinizing hormone releasing hormone (LHRH) agonist therapy alone (LHRH) compared to total androgen blockade (TAB).

Materials and methods: 3370 men with presumed organ confined prostate cancer underwent 1125/Pd 103 prostate brachytherapy (PB) at a single institution from October 1997 through January 2003. Prior to PB, transrectal ultrasound prostate sagittal and transverse image based volume studies (VS) were performed at least once on all patients. A B-K medical systems ultrasound machine and biplanar probe was used for each VS. 363/3370 (10.8%) patients required a repeat VS specifically because they were considered suboptimal candidates for PB secondary to excessive prostate volume. Subsequently, this group was subjected to HM for the purpose of decreasing prostate size (cytoreduction) in preparation to PB. 313/363 (86.2%) of these patients were given cytoreduction with LHRH while 50/363 (13.8%) patients received TAB. TAB consisted of biclutamide 50 mg p.o. q day times 3 months in addition to LHRH 7.5 mg depot IM q 1 month ×3. After three months of cytoreductive therapy, a repeat VS was performed.

Results: The mean sagittal length and prostate volume for the entire group of 3370 patients was  $38.6\pm6.5~\mathrm{mm}$  and  $41.9\pm18.4~\mathrm{cm}^3$ , respectively. The mean prostate volume for the 313 patients who received LHRH only and the 50 patients who received TAB prior to any hormonal manipulation was  $70.1\pm19.8~\mathrm{cm}^3$  and  $76.9\pm24.5~\mathrm{cm}^3$ , respectively. The mean prostate volume for the 313 patients who received LHRH only and the 50 patients who received TAB after receiving hormonal manipulation was  $49.4\pm16.0~\mathrm{cm}^3$  and  $49.7\pm16.6~\mathrm{cm}^3$ , respectively. There was a significant difference in the mean percent decrease in prostate volume for those receiving LHRH versus TAB ( $28.9\%\pm14.6\%$  vs.  $34.1\%\pm14.2\%$  (p= 0.022)).

Table 1: Prostate size results

Patient group	Original		Repeat	
(# patients)	Sagittal length (mm) (mean±SD)	Prostate volume (cm <sup>3</sup> ) (mean±SD)	Sagittal length (mm) (mean±SD)	Prostate volume (cm <sup>3</sup> ) (mean±SD)
All (3370)	38.6±6.5	41.9±18.4	N/A	N/A
LHRH (313)	47.2±6.8	$70.1 \pm 19.8$	41.1±6.6	49.4±16.0
TAB (50)	47.8±6.9	76.9±24.5	40.9±5.8	49.7±16.6

Conclusions: Whether for therapeutic benefits or strictly for prostate cytoreduction, the use of HM remains prevalent prior to PB. Controversy has existed regarding the use of LHRH versus TAB. This study strongly suggests that patients undergoing TAB experience a significantly higher reduction in overall prostate volume than those who receive LHRH agonist alone.

857 POSTER

Weekly paclitaxel plus carboplatin in patients with metastatic transitional cell carcinoma of the urothelium who failed MVAC: Phase II trial

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Backgrounds: Though MVAC is one of the standard care for *transitional cell carcinoma* (TCC), this regimen might be toxic for pretreated or elderly pts. There is no standard salvage treatment for pts who failed MVAC. Paclitaxel(P) is active agent for TCC and Carboplatin(C) has synergistic activity with P. P plus C is safely manageable and effective regimen for ovarian or lung cancer. Weekly administration of P plus C can be not only less toxic treatment for these pretreated pts but also more