coverage. Compared with 3D-CRT, Tomo-IMRT reduced IDs to the rectum, the bladder and normal tissue (NT) by 14.8%, 6% and 16.7% respectively.
Conclusions: Tomotherapy is superior to 3D-CRT in regard to the delivery of high dose radiation and coverage of target volume while meeting the dose constrains of surrounding organs at risks and reduction of NTID. In our practice, helical tomotherapy is the IMRT-delivery of choice for treatment of localized prostate cancer.

7053 POSTER

Epirubicin, carboplatin and 5-fluorouracil as second-line chemotherapy in castration resistant prostate cancer

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Background: This single institution study evaluated epirubicin/carboplatin/5-fluorouracil (E-Carbo-F) as second-line chemotherapy for castration resistant prostate cancer (CRPC) progressing after docetaxel.
Methods: Men with CRPC who received at least 2 cycles of E-Carbo-F as second-line chemotherapy after first-line chemotherapy with docetaxel at University College London Hospital, were retrospectively identified. Patients treated with E-Carbo-F received epirubicin 50 mg/m^2 on day 1, carboplatin area under the curve (AUC) 5 on day 1 and 5-fluorouracil 440 mg/m^2 on days 1 and 15 in 28-day-cycle.
Results: The study included 20 patients with median age 68 years at the start of E-Carbo-F. Decline of prostate specific antigen (PSA) level of > 50% was observed in 6 patients (30%) and the median duration of PSA response was 5.5 months. Median time to PSA progression was 4.5 months (8 months in PSA responders and 2.5 months in non-responders). Median overall survival in those patients who died by the time of results evaluation (n = 14) was 15 months, while 6 patients were still alive with median length of follow-up 14.5 months. Response to first-line chemotherapy with docetaxel did not predict response to E-Carbo-F. The median number of E-Carbo-F treatment cycles was 6 (8 in PSA responders and 4 in non-responders). 13 patients were treated with full dose and 7 with reduced dose from the beginning (either carboplatin AUC 4 and full dose epirubicin and 5-fluorouracil, or all 3 agents reduced by 10−20%). 5 patients out of 20 required dose reduction during the course of treatment.
Conclusions: Carboplatin with epirubicin and 5-fluorouracil is an active regimen in men with CRPC, whose disease has progressed during or after docetaxel. Selection of patients with good performance status is required and individual adjustment of dose often needed.

7054 POSTER

High-dose-rate brachytherapy combined with external beam radiotherapy for localized prostate cancer: correlation between clinical and dosimetric parameters and the incidence of Grade 2 or worse rectal bleeding

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Background: Several investigations have revealed that the alpha/beta ratio for prostate cancer is atypically low, and that hypofractionated radiotherapy or high-dose-rate brachytherapy (HDR-BT) regimens using appropriate radiation doses are expected to improve the local control rate for localized prostate cancer. However, the increase in the total biological effective dose may cause an increase in the severity and incidence of normal tissue complications. The purpose of this study was to investigate if the clinical and dosimetric factors affected the incidence of Grade 2 or worse rectal bleeding after HDR-BT combined with external beam radiotherapy (EBRT).
Material and Methods: Between March 2001 and October 2007, 90 patients with localized prostate cancer were treated by HDR-BT combined with EBRT at Kochi Medical School Hospital. The fractionation schema for HDR-BT and EBRT was prospectively changed. The distribution of the fractionation schema used in the patients was as follows: 6 Gy × 3 (HDR-BT) + 2 Gy × 20 or 1.8 Gy × 25 (EBRT) in 16 patients (Group 1); 9 Gy × 2 + 2 Gy × 20 in 57 patients (Group 2); and 9 Gy × 2 + 3 Gy × 13 in 17 patients (Group 3). The median follow-up duration was 38 months (range 18−97 months). The toxicities were graded based on the National Cancer Institute-Common Terminology Criteria for Adverse Events v3.0.
Results: Six patients (7%) developed Grade 2 rectal bleeding. There were no patients with Grade 3 or worse rectal bleeding. All of those six patients belonged to Group 2 or 3. The more the prescribed biologically effective dose increased, the more the incidence of Grade 2 rectal bleeding increased. However, regarding the correlation with dosimetric factors, no significant differences were found in the average percentage of the entire rectal volume receiving 10%, 30%, 50%, 70%, and 90% of the prescribed radiation dose from both HDR-BT and EBRT between those with bleeding and those without in each Group. The presence of a history of the antiplatelet therapy was statistically significant risk factor for the occurrence of Grade 2 rectal bleeding.
Conclusions: A history of antiplatelet therapy was the statistically significant risk factor for the occurrence of Grade 2 rectal bleeding, although the rectal dose from both HDR-BT and EBRT was also associated with the risk of rectal bleeding.

Oral presentations (Tue, 22 Sep, 09:00−11:00)
Genitourinary malignancies − Renal and Other

7100 ORAL

High-dose sequential chemotherapy versus conventional-dose chemotherapy as first-line treatment for advanced poor prognosis germ-cell tumors: a multicenter Phase III Italian trial

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Background: Upfront high-dose chemotherapy for poor prognosis germ-cell tumors (GCTs) showed promising results in preliminary studies. We started a phase III randomized trial to assess the efficacy of high-dose sequential chemotherapy (HDS) followed by autologous hematopoietic stem-cells transplant (ASCT) over standard chemotherapy (CT).
Patients and Methods: IGCCCG poor prognosis GCT pts were randomly assigned to receive 4 cycles of PEB (cisplatin, etoposide, bleomycin) (arm A) or 2 cycles of PEB followed by a sequence of high-dose (HD) cyclophosphamide (7 gr/m^2), 2 courses of PEB with HD-VP16 2.4 gr/m^2 each and HD-carboplatin (AUC 25 mg/ml × min) rescued by ASCT (arm B). In both arms, post-CT surgery was planned on residual resectable masses. Primary endpoint (EP) was 2-yrs overall survival (OS). We planned to accrue 50 pts/arm to detect a 20% improvement in pts receiving HDS with an α of 5% and 80% power. Due to the prolonged accrual time and the results at interim analysis, the study was stopped anticipately.
Results: From 12/1996 to 04/2007, 89 pts were randomized: 46 in arm A and 43 in arm B. 84 pts (94%) were evaluable for response and outcome (43/41). 41 (95%) and 36 (88%) pts completed the program. Median follow-up was 50 mos (range 1−129). In an intent-to-treat analysis, major responses [complete responses (CR) + partial responses with normal markers (PRm-)] were 31 (67%) after PEB ± surgery while 30 (70%) after HDS ± surgery. OS and progression-free survival (PFS) at 2-yrs were not significantly different (66.8 vs 60.5% – Log-Rank p = 0.42 and 58.5 vs 55.8 – Log-Rank p = 0.94). 18 (39%) and 19 pts (44%) relapsed/progressed, respectively. 3/18 and 2/19 have been rescued by further conventional-dose salvages. Progressions occurred within a median time of 4 (1−8) and 5.5 (3−25) mos, respectively. Mean administered CDDP dose-intensity was significantly different between the 2 arms: 17.04 mg/m^2/w for arm A vs 20.62 mg/m^2/w for arm B ($p < 0.0001$ at unpaired t-test). At univariate analysis, no differences have been observed for primary EP between the 2 arms as for baseline markers level, tumor primitivity and sites of disease. There was one treatment-related death (arm A).
Conclusions: In our study, the administration of front-line HDS in poor prognosis GCTs did not improve treatment outcome. Novel treatment strategies are needed to improve results in this cohort of pts.