and 150 mg/m^2 respectively for 5 weeks concomitant with radiotherapy. All patients had received pelvic external beam radiotherapy to dose of 50 Gy/25fraction/5 weeks by four field box technique followed by intracavitary radiotherapy (3 sessions, each 7 Gy to point A).
Results: Median follow up noted was of 8.5 months (range 3−36 months) and 10.9 months (range 2−49 months) in cisplatin arm and gemcitabine arm respectively. At first follow up, 68.8% in cisplatin arm and 70% in gemcitabine arm had achieved complete response. Similar response rate was noted in different stages in both arms. None of the patients except one had developed grade 4 toxicity. Similar toxicity profiles were observed in both arms. In comparison to cisplatin arm, a higher number of patients in gemcitabine arm had developed grade 3 and 4 anemia (4/20 vs. 2/16), neutropenia (2/20 vs. 0/16) and thrombocytopenia (2/20 vs. 0/16). Grade 1/2 nausea was commoner in cisplatin arm as compared to gemcitabine arm (14/16 vs. 5/20). Local disease control, distant disease free survival and overall survival was 68.8% vs. 70%, 93.8% vs. 85%, 68.8% vs. 60% in cisplatin and gemcitabine arm respectively. None of patient in cisplatin arm had failed after achieving complete response. In gemcitabine arm, three patients had pelvic/ distant failure after achieving complete response.
Conclusion: Weekly gemcitabine had similar disease control and tolerable toxicity profile like cisplatin. Cisplatin arm was found to have edge over gemcitabine arm in longer follow up with sustained results. Gemcitabine may be used as alternative to cisplatin in patient with compromised renal function.

8049 POSTER

Cisplatin-based combination chemotherapy (CTX) consisting of docetaxel and cisplatin (DP) is still effective for patients with relapsed ovarian carcinoma (ROC) resistant or refractory to carboplatin-based CTX (TC: taxol/carboplatin)

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Purpose: To evaluate the efficacy and toxicity of DP for patients (pts) with relapsed EOC.
Methods: Eligible pts had histologically-confirmed serous, endometrioid, or transitional cell carcinoma of the ovary measuring more than 2 cm in diameter, age ⩽75 yrs, WHO PS ⩽ 3, adequate pulmonary, cardiac, hematopoietic, liver and renal functions, and written informed consent. The DP regimen was as follows: docetaxel, 60 mg/m^2 infused over 1 hr, days 1 and cisplatin 15 mg/m^2 infused over 2 hrs, days 1−5. The treatment was repeated at 4-week intervals.
Results: Forty eligible pts were enrolled in this study. The median age was 51 yrs (range, 41−64). All pts received more than 6 cycles of TC. Thirty-four of 40 pts (85%) had 1 or more previous chemotherapy other than TC. Histologic types were serous (33 pts), endometrioid (5 pts), and transitional (2 pts). After a median of 4 cycles (range, 2−10), we observed objective responses in 28 pts (70%), with 4 (10%) CRs and 24 (60%) PRs, and 12 (30%) NCs. Median overall survival time (MOS) for all 40 pts was 24.3 months (mo) (range, 4 to 78). MOS of pts achieving CR, PR, and NC were “not reached”, 23.6 mo, 8.2 mo, respectively (Log-rank, $p < 0.001$). The most frequent Grade 3−4 hematologic toxicities were; neutropenia 57.8%, anemia 43.3%, and thrombocytopenia 14.4%. Alopecia (Grade 1−2) occurred in 91.3%, but there was no grade 2 or 3 peripheral neuropathy, nephrotoxicity, or cardiotoxicity.
Conclusion: The DP regimen had a significant anti-tumor activity with acceptable toxicity and appreciable response duration for pts with relapsed OC resistant or refractory to TC. Several studies have demonstrated that cisplatin is more effective than carboplatin in almost all platinum-sensitive disease except OC (Lokich J: Cancer Invest 19; 756: 2001). In OC, carboplatin was reported to be equal to cisplatin in anti-tumor activity in “optimal” disease (GOG 158, AGO), but the equivalency was not demonstrated in “suboptimal” disease. We must reappraise cisplatin is an agent that should be included in the first line for platinum-sensitive OC.

8050 POSTER

Usefulness of FDG-PET/CT guided brachytherapy planning in patients with uterine cervical cancer

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Background: To evaluate the feasibility of FDG-PET/CT guided conformal brachytherapy treatment planning in patients with cervical cancer and compare dose-volume parameters with conventional treatment planning.
Materials and Methods: Seven patients with cervical cancer were included in this study. Brachytherapy simulation was done at external beam radiation therapy dose of 36 Gy. Patients underwent FDG-PET/CT scans with placement of the tandem and ovoid applicators. A target volume was determined and a treatment plan was generated that included dose–volume histograms and three dimensional (3-D) dose distribution displays. For each patient, comparison between conventional point A plan with PET/CT guided volume based plan was done. A PET/CT guided volume based plan was designed to cover clinical target volume (CTV), which included entire cervix shown on CT and residual tumor represented by FDG uptake on PET. The percent of volume receiving 100% prescribed dose (V100) and 90% prescribed dose (V90) were analyzed for CTV, bladder, and rectum.
Results: Five patients presented with FDG uptake on tumor and 2 patients had no discernable uptake. The median V100 and V90 of CTV in point A plan were 73.7 and 79.9%, respectively. CTV coverage was significantly improved in PET/CT guided plan with 88.0 and 92.5% of median V100 and V90 ($p = 0.06$, $p = 0.06$), respectively. V100 and V90 of both bladder and rectum were not significantly different.
Conclusions: The visual target localization was facilitated by using CT with PET fusion. PET/CT guided brachytherapy plan was superior to conventional point A plan in terms of the target coverage without increasing the dose to the bladder and rectum, making optimized 3-D brachytherapy treatment planning possible.

8051 POSTER

Final results of a phase I study of pegylated liposomal doxorubicin + gemcitabine in prolonged infusion in patients with recurrent ovarian cancer less than one year

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Background: We present the final results of a phase I study with the combination of Pegylated liposomal doxorubicin (PLD) (standard treatment) and Gemcitabine (G) in a prolonged infusion (PI) (10 mg/m^2/min) in order to know if we can enhance the therapeutic index of this association in patients with platinum-resistant ovarian cancer.
Materials and Methods: Eligible criteria included: recurrent epithelial ovarian cancer (REOC) with a platinum-taxane free interval <1 year, primary or secondary treatment with platinum and taxane, age <80 years, Karnosky ⩾ 60% and normal organ function.
The starting dose of G was 1500 mg/m(2) PI q 2 weeks (± 250 mg/m^2 in PI G titration depending on toxicity) followed by PLD 35 mg/m^2 q 4 weeks. Pharmacokinetic and pharmacogenomic analyses were performed on days 1 and 15 of the first cycle. The primary end point was to determine the dose-limiting toxicity (DLT), the maximum tolerated dose (MTD) and the recommended dose. The toxicity was studied only in patients who received almost two cycles.
Results: From December 2005 to July 2008, 36 patients (pts) were registered. 1 pts was not eligible and 6 were non-evaluable for toxicity due to early progression. In the first step, 2 out of 4 pts had DLT consisting on grade 4 neutropenia and grade 3 stomatitis. 5 pts entered in the next step, G1250/PLD35, with different tolerance between “frail pts” (heavily-pretreated pts (> 6 cycles) and/or >70 years) and “non frail pts” so we divided pts up into two groups. Frail pts were treated with G1000/PLD35 and 3 of 12 pts experienced DLT while non frail pts were treated with G1250/PLD35 and 4 of 10 developed DLT. Dose reduction was necessary due to late toxicity (stomatitis (85%) and dermatitis (61%)). The most common grade 3/4 adverse effects were neutropenia (43%), stomatitis (35%), dermatitis (21%) and hand-foot syndrome (14%). PLD did not affect the pharmacokinetic of G or its metabolites. Response rate: 17% complete responses (6/35), 26% partial responses (9/35) and 20% stable disease (7/35). The median time to progression and median overall survival were 230 days (95% CI, 65−394) and 417 days (95% CI: 281−552), respectively.
Conclusions: Preliminary results suggest that Gemcitabine 1000 mg/m^2 in a prolonged infusion q 2 weeks + Pegylated liposomal doxorubicin 35 mg/m^2 q 4 weeks is an active combination with tolerable toxicity so these are the recommended doses for a phase II study in REOC.

8052 POSTER

Weekly paclitaxel in the treatment of relapsed ovarian and primary peritoneal cancer - Royal Marsden Hospital experience

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Background: Single agent weekly paclitaxel has been reported to have significant activity in patients with ovarian and primary peritoneal cancer,