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,

and is well tolerated; this study assessed the outcomes of using weekly paclitaxel in routine clinical practice in a tertiary cancer center.
Methods: We performed a retrospective audit of 136 patients with recurrent ovarian or primary peritoneal cancer treated with weekly paclitaxel (80−90 mg/m^2) over a 5 year period (Nov 2003−Nov 2008). Toxicity was assessed using Common Toxicity Criteria, and response was evaluated using radiologic and CA-125 criteria.
Results: Patients had a median age of 67 (range 37−88) and had previously received a median of 3 treatments (range 1−7). A median of 13 (range 1−39) weeks of weekly paclitaxel were given. The mean dose intensity actually received (as a result of dose delays and reductions) was 74 mg/m^2/week. The response rate was 50% by radiologic criteria and 68% by CA-125 criteria. The commonest grade 3 toxicities observed were neutropenia (8%) and fatigue (8%). Grade 4 neutropenia was seen in 2%. The median progression-free survival was 5.7 months and median overall survival was 12 months. The response rate by CT criteria was not significantly different (55 vs. 47%, P = 0.42) for patients who had never received previous paclitaxel compared to those that had; there was also no difference in efficacy for patients with platinum-free or treatment-free intervals of less than 6 months compared to 6 months or more.
Conclusions: Weekly paclitaxel is well tolerated and represents one of the most active regimens in patients with recurrent ovarian cancer.

8053 POSTER

Impact of FDG PET/CT images in GTV delineation of recurrent or post-surgical residual gynaecologic cancer

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Background: Geographical uncertainties in gross tumour volume (GTV) delineation in recurrent or partially resected gynaecological cancer are high using either CT or MRI. We therefore evaluated the impact of (18) F-fluorodeoxyglucose positron emission tomography (FDG PET/CT) in radiotherapy (RT) treatment planning in these tumors.
Materials and Methods: Between September 2006 and December 2008, 11 patients with recurrent (n = 6) or/with post-surgical residual disease (n = 5) were planned for RT treatment using FDG PET/CT. The primary tumour side was cervix in 3, uterus in 3, vulva in 2, vagina in 1 and ovaries in 2 patients. Four experienced radiation oncologists defined the GTV based on contrast enhanced CT (GTV_{CT}) and in a second time using the fused PET/CT datasets ($GTV_{PET/CT}$). All clinical history and previous imaging studies were provided. The GTV was also delineated using the signal-to-background ratio-based adaptive threshold (GTV_{SBR}). Overlap analysis was conducted to assess geographic mismatch between the GTVs delineated using the different techniques.
Results: The inclusion of the FDG PET findings changed the GTVs significantly in 7 patients compared with the GTV_{CT}. The wilcoxon matched-pairs signed rank test showed that $GTV_{PET/CT}$ were significantly smaller than the GTV_{CT} but $GTV_{PET/CT}$ added substantial tumor extension outside the $GTV_{CT.}$ Interobserver variability for GTV delineation was high using CT images only and could be significantly reduced using the fused PET/CT. GTV_{SBR} were usually smaller than the $GTV_{PET/CT}$ but not significantly different.
Conclusion: The use of fused PET/CT images for target volume delineation of recurrent or post-surgical residual gynaecologic cancer reduced interobserver variability significantly with respect to CT only and alters RT treatment techniques in a majority of patients.

8054 POSTER

18FDG-PET/CT findings in patients with gynaecologic cancer suspected for relapse, with increased serum tumour markers and inconclusive or negative findings on CT/MRI

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Purpose: to determine the incremental information provided by ^{18}FDG-PET/CT in patients with gynaecologic cancer suspected for relapse, with increased serum tumour markers and inconclusive or negative CT/MRI.
Patients and Methods: This is a retrospective study of 124 women with a previous history of treated gynaecological malignancies (52 with ovarian cancer, 41 with cervical cancer, 12 with endometrial cancer, and 9 with various gynaecologic malignancies), 23−86 years old (average: 55.46±6.8y), who underwent whole-body 18FDG-PET/CT in our institution from January 2007 to January 2009. All patients' outcomes were reviewed from our medical records and compared to the interpretation of the PET/CT scans. PET/CT findings in 32/35 patients were confirmed by laparotomy, histopathology, or clinical follow up.
Results: Thirty five of 124 patients (28%) had increased serum CA-125/CEA/CA15−3/aFP and inconclusive or negative CT/MRI. This patient group consisted of 26 patients with ovarian cancer, 3 with endometrial cancer and 7 with cervical cancer. One patient had two gynecological cancers and two patients had an additional breast cancer. In 7/35 patients (20%) PET/CT studies were negative and in 28/35 (80%) increased ^{18}FDG uptake was noted: In13 (37.1%) in peritoneal implants, in 15 (48.5%) in lymph nodes (LNs) - in 3 patients in LNs above the diaphragm, in 10 patients in LNs below the diaphragm and in 2 in LNs above and below the diaphragm. Foci of increased ^{18}FDG uptake in other metastatic sites were found in 8 patients. In 3 patients PET/CT revealed local recurrence, and in one patient a new malignancy (pancreatic adeno-ca) was diagnosed.
Conclusion: ^{18}FDG-PET/CT may be a additional useful diagnostic tool in relapse monitoring patients with gynaecological cancer, increasing tumor markers and negative or inconclusive conventional imaging.

8055 POSTER

The impact of prophylactic prolonged carboplatin infusion on risk of hypersensitivity reactions during carboplatin retreatment in epithelial ovarian cancer

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Background: Treatment with carboplatin in ovarian cancer patients (pts) with recurrent, platinum-sensitive disease remains the most effective strategy available today. Increased exposure to carboplatin can lead to sensitization resulting in the development of hypersensitivity reactions (HSR). At MSKCC, an increasing proportion of pts are prophylactically converted to an extended schedule after 8 cycles of carboplatin.
Methods: We performed a retrospective electronic medical record review of pts with recurrent ovarian cancer retreated with carboplatin at MSKCC from 1/1/1998−12/1/2008.
Results: 707 pts with relapsed ovarian cancer were retreated with carboplatin. Of the 590 pts who did not develop HSR, 168 (28%) received the extended long-infusion schedule and the remainder the standard 30-minute infusion. 117 pts (16%) with a median age of 60yrs and median no. of 2 comorbidities developed HSR. In this group, 54% pts received carboplatin with AUC 4 and 41% AUC 5. Only 5% of HSR pts received the extended carboplatin schedule. The first HSR episode occurred after a median of platinum treatments in the standard schedule pts & a median of 17 cycles in extended schedule pts. In the standard schedule group HSR occurred on 2nd, 3rd & 4th retreatment cycles in 89pts (80%), 19 (17%) and 3 (3%), respectively with a median 19.4 mos interval from the preceding platinum regimen to the HSR. In the extended schedule group, HSR occurred in 1 pt (33%) on the 2nd, 3 (50%) on 3rd and 1 (17%) on 4th retreatment cycle with a median interval of 18.3 mos. 100 pts (90%) in the standard group developed ⩾3 gr HSR (12.6% 4 gr, 0% 5 gr). In the extended schedule group there were no grade ⩾4 reactions, but 3 pts (50%) experienced gr 3 HSR. In the standard schedule group 36 pts (32%) developed chest pain, 18 (16%) hypotension, 7 (6%) unresponsiveness. 7 pts (6%) from the standard group required ⩾1 dose of epinephrine and 12 pts (11%) hospitalization (2/12 to the ICU). 92% and 50% of pts in the standard group and 67% and 17% in the extended group required IV diphenhydramine & steroids, respectively. Using the Fisher-exact test there was an association with a reduced incidence of HSR with the extended infusion (p-value of <0.001).
Conclusion: The extended infusion schedule was associated with a reduction in the incidence and severity of HSR. Prospective validation is warranted to determine if the prophylactic conversion to the extended schedule of administration after 8 cycles of carboplatin (and/or the use of pre-medications) reduces the incidence of HSR.