observed: obstipation 6/0, diarrhoea 6/0, CNS/mood 2/2, pain/myalgia 8/2, dyspnoea 8/0, thrombosis 4/0 and infections 5/0. Due to toxicity, an alteration of the cycle became necessary for 4% of cycles. The intensity of dosage reached 90.5% for C and T, and 72.8% for G. The latter was due to the reduction of dosage on day 8 (level 1) in cycles 2-6.

Conclusions: Since the moderate haematological and mild non-haematological toxicity proved to be controllable the analysis were lead into an international, GCIG (Gynecologic Cancer Intergroup), randomized phase III intergroup study (*Ovar- 9*) that compares the standard therapy (T/C) with the triple combination. The study has been active since August 2002.

165 POSTER

Gemcitabine (G) plus carboplatin (C) in patients whose epithelial ovarian carcinomas (EOC) relapsed ≥6 months after platinum-containing first-line therapy: Preliminary results of a phase II study

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Background: Ovarian cancer, over 90% of which is epithelial in origin, remains the leading cause of gynecologic cancer deaths, accounting for 4% of all cancer diagnoses in women and 5% of all cancer-related deaths, collectively.

Objectives: The primary objective of this study was to determine the overall response rate (ORR) of G plus C in patients with EOC that relapsed e 6 months after discontinuation of first-line platinum therapy. Secondary objectives were to assess toxicity, duration of response, time to progressive disease, time to treatment failure, and survival time.

Methods: During each 21-day cycle, patients received G 1000 mg/m^2 on days 1 and 8 and C AUC 4.0 on day 1 (after G).

Results: From July 2001 to November 2002, 40 patients enrolled at 4 sites. The median age was 54.5 years (range, 38-79). Patients' World Health Organization (WHO) performance statuses were 0 (80%) or 1 (20%). Eighty percent of pts received prior paclitaxel in combination with a platinum. A total of 234 cycles were delivered (median 6; range, 2-8). Based on Southwest Oncology Group (SWOG) response criteria, 6 patients (15%) had complete responses, 18 patients (45%) had partial responses, and 1 patient (2.5%) had a partial response in nonmeasureable disease, for an ORR of 62.5% (95% CI, 45.8%-77.3%). CTC grade 3/4 toxicities were primarily hematologic, consisting of neutropenia (42.5%/35.0%), leukopenia (30.0%/0.0%), thrombocytopenia (15.0%/2.5%), and anemia (15.0%/0.0%). Two (5.0%) patients had grade 3 infection with grade 3/4 neutropenia. Other grade 3 toxicities were febrile neutropenia, anorexia, gastritis, epistaxis, abdominal pain, nausea, and vomiting (all in 1 patient each). No patients died on-study or within the 30-day post-study follow-up period.

Conclusion: These preliminary results show that G plus C has activity in EOC cancer, and a toxicity profile that is expected and manageable. Although analyses are ongoing, G plus C appears to be a promising treatment option for relapsed EOC in platinum-sensitive patients. Final data, including time-to-event results, will be available at the meeting.

166 POSTER

Ct scan-generated small bowel dvh's, and small bowel toxicity profiles, in post-operative gynaecological cancer patients. a prospective study assessing the impact of a bellyboard device

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Aims: 1) To see if small bowel volumes in radiation portals were reduced by treating prone on a bellyboard versus supine without.This would be analysed using CT-planning 3D imaging and DVH's. 2) To establish relationships between small bowel DVH's and patients' RTOG/LENT-SOMA acute bowel toxicity scores, which were recorded prospectively.

Methods: 45 Post-op gynae. cancer patients to be prospectively assessed, first underwent conventional simulation supine and prone, as for standard 3 or 4 field pelvic radiotherapy. Planning CT scans were then done in the above two treatment positions. Small bowel was outlined on all slices, and DVH's acquired for both positions. The volume of small bowel in the radiation portals was analysed for supine and prone. Actual treatment was delivered prone, and acute bowel toxicity recorded prospectively. Observations:1.) Small bowel in the lateral radiation portals significantly reduced when prone on the bellyboard - 6-111cc reduction at 95% CI; p=0.04. 2.) Patients with no or negative reduction when prone had significantly smaller abodomino-pelvic volumes as calculated by CT planning; p, E. Wong, J. Chen, T. Coad, G. Rodrigues, M. Lock, G. Bauman (Canada)

Background: Whole pelvic IMRT is complex, requiring multiple fields, often with field splitting and junction problems. We developed an Intensity Modulated Arc Therapy (IMAT) radiation technique that simplifies treatment planning and delivery.

Materials and Methods: Five women with high-risk carcinoma of the endometrium received 4-6 cycles of paclitaxel and carboplatin sequentially with radiotherapy. Using axial CT slices, the tumor bed, iliac and pre-sacral vessels, ± lower para-aortic region were contoured as GTV. A CTV with 5-10 mm margin and PTV with 7 mm margin were generated. The small bowel, iliac crests, femoral heads, bladder and rectum were contoured as critical organs. Balancing the complexity of the arc technique with normal organ sparing, two anterior intensity modulated arcs, from 300° to 30° (IEC convention) and 330° to 60° were used. DVH, dose distribution, dynamic MLC patterns, and comparisons to conventional treatment and 5-field IMRT inverse plans were generated.

Results: Using the IMAT, 95% of the tumor volume received dose above 45 Gy, the nodes 40-45 Gy and bladder/ rectum ≤ 45Gy. This technique allowed sparing of the small bowel, iliac crests and femoral heads. The dose to the iliac crests was reduced compared to conventional radiation therapy and similar to IMRT. The volume of small bowel receiving dose above 45Gy was 80%, 10%, 15% for conventional, IMRT, and IMAT technique respectively. Treatment has been well tolerated with no significant acute toxicities.

Conclusions: IMAT provides an effective technique to treat the tumor bed and regional nodes while allowing a conformal avoidance of the bone marrow and small bowel compared with conventional radiation therapy. While critical structure sparing is similar to multi-field IMRT, our method is simpler to plan and deliver and was well tolerated. Ongoing work will assess both the clinical outcome and long term toxicity of this multi-modality treatment strategy.

167 POSTER

Is 5-year survival rate a real measure of outcome in cervix cancer patients treated by radiotherapy? Long-term results in patients treated with external beam radiation therapy and high dose rate brachytherapy

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Background: To evaluate the long-term outcome of patients with carcinoma of the cervix treated with a combination of external beam radiation therapy (EBRT) and high dose rate brachytherapy (EBRT).

Material and Methods: From 1984 and 1977, a total of 283 previously untreated patients (pts) with cervix cancer were treated with a combination of EBRT and HDRB. The median age was 62 years and there were 23 pts with stage IB disease (9%), 50 with IIA (18%), 116 with IIB (43%), 7 with IIIA (3%) and 77 with IIIB (27%). EBRT consisted of irradiation to the whole pelvis to a median dose of 46 Gy (range: 40-54.6 Gy) and HDRB typically in 3 insertions given weekly, each insertion delivering a dose of 8 Gy to point A. Chemotherapy was not given to any of these pts. The primary endpoints assessed in this analysis were survival, pelvic control and toxicity. In an attempt to determine predictive variables for survival and pelvic control, multivariate analyses, using a Cox proportional hazardous model were performed. Variables investigated were stage, age (<47 vs >47 years), overall duration of treatment (<47 vs >47 days), HDRB scheduling (<25th vs >25th day) and total dose (<98 Gy vs >98 Gy).

Results: At a median follow-up time of 84 months for pts at risk, the 5-, 10- and 15-year overall survival rates are 60%, 55%, and 49%, respectively. There was a continuous decrease in survival from cervix cancer with longer follow-up. The long-term survival rates and pelvic control rates for the different stages are shown in the table below. A total of 78 pts (24%) failed in the pelvis. On multivariate analysis, stage ($p < 0.0001$), age ($p = 0.019$) and treatment duration ($p = 0.057$) had a significant impact in survival, while stage, age, treatment duration and brachytherapy scheduling

Stage	5-year Survival/ Pelvic Control	10-year Survival/ Pelvic Control	15-year Survival/ Pelvic Control
Overall	60%	55%	49%
IB	62%/78%	62%/78%	62%/78%
IIA	75%/90%	67%/86%	57%/86%
IIB	70%/80%	63%/74%	58%/74%
IIIB	48%/55%	40%/55%	40%/55%