of at least six cycles of carboplatin (AUC 5) and docetaxel 75 mg/m$^2$ d1q22. Hemoglobin levels were obtained before each cycle of the therapy. Study objectives were response, time-to-progression and overall-survival (OAS). Univariate analysis and cox-regression studies were undertaken to evaluate the prognostic impact of the hemoglobin level before und during chemotherapy.

**Results:** Median age of the patients was 57 years. The majority of the patients was diagnosed at stage III ovarian cancer and had received best cytoredutive surgery. 415 cycles of four different carboplatin-based chemotherapy regimen were administered (Mean 6, range 3–20). Mean hemoglobin level before therapy was 11.5 g/dl, during therapy 11.2 g/dl and after therapy 10.8 g/dl. In cox-regression analysis hemoglobin levels before and during chemotherapy showed a prognostic relevance in terms of time-to-progression (p < 0.01). In addition, univariate analysis revealed a statistical trend for hemoglobin levels before (p = 0.09) and during (p = 0.06) chemotherapy to have prognostic relevance in terms of time-to-progression.

**Conclusions:** The pretherapeutic hemoglobin level seems to have prognostic relevance for patients with primary ovarian cancer undergoing carboplatin-based chemotherapy. Though the majority of these patients is diagnosed in advanced tumor stages the therapeutic intention is curative. For that reason further prospective trials should be undertaken to prove the prognostic impact of hemoglobin levels before and during chemotherapy. Based on these data the role of anemia correction as standard supportive therapy should be discussed in the treatment of patients with primary ovarian cancer.

## 937                                                                                POSTER
**Analysis of predictors of toxicity in patients with stage III endometrial cancer confined to the pelvis treated with external-beam radiotherapy**

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**Purpose:** Patients with stage III endometrial cancer often receive pelvic radiotherapy (RT). This study assesses predictors of acute and late adverse events in these patients.

**Methods:** Records of 121 patients with pathologic stage III endometrial adenocarcinoma treated between 1990 and 2003 were reviewed. External beam RT was delivered to 66 patients with a median dose of 45 Gy in 25 fractions. Fifty patients (76%) also received high-dose-rate brachytherapy as a boost, typically 6 Gy in one session. Adjuvant chemotherapy (CT) was delivered to 8 patients (12%). The influence of age, body mass index (BMI), history of smoking, diabetes, hypertension, inflammatory bowel disease, previous bowel obstruction, previous abdominal and pelvic surgery, radiation dose, beam energy, field arrangement and size, and treatment with CT was evaluated as potential predictors of toxicity.

**Results:** The median follow-up is 39 months. Five-year overall survival is significantly improved in patients treated with adjuvant RT (68%) compared to those with resection alone (50%; p = 0.029). Five-year disease-free survival in patients treated with or without RT was 67% and 37%, respectively ( p = 0.004). Acute and late lower GI and GU toxicities are shown in the table. Only grade 1 or 2 upper GI toxicities were seen in 8% of patients. Treatment with CT was found to significantly correlate with the acute upper GI toxicity. Acute lower GI toxicity significantly correlated with BMI and number of radiation fields. Acute GU toxicity significantly correlated with history of pelvic surgery. In addition, there was a trend for correlation between acute GU toxicity and beam energy ( p = 0.069). Treatment with CT significantly correlated with the development of hematological toxicity, although grade 2 or higher adverse events was not observed. Late GI toxicity was found to significantly correlate with history of small bowel obstruction, previous pelvic surgery, and number of radiation fields. No treatment-related deaths were observed.

**Conclusions:** Radiotherapy improves survival in patients with stage III endometrial cancer confined to the pelvis and is well-tolerated. Patients with higher risk for developing late complications were identified. Advanced techniques, such as intensity-modulated radiotherapy, may be beneficial in the treatment of these selected patients.

| Grade | Acute | | Late | |
|-------|----------|---------|----------|---------|
|       | Lower GI | GU      | Lower GI | GU      |
| 1     | 14 (21%) | 11 (17%)| 6 (9%)   | 2 (3%)  |
| 2     | 32 (48%) | 3 (5%)  | 3 (5%)   | 0 (0%)  |
| 3     | 1 (2%)   | 2 (3%)  | 0 (0%)   | 0 (0%)  |
| 4     | 1 (2%)   | 0 (0%)  | 2 (3%)   | 0 (0%)  |

## 938                                                                                POSTER
**A biweekly schedule of pegylated liposomal doxorubicin (C), can it reduce the skin toxicity? Results of a phase-II study of heavily pre-treated patients with recurrent ovarian cancer**

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**Background:** C is a pegylated liposomal doxorubicin formulation and has been approved for the treatment of recurrent ovarian cancer. Palmar-plantar erythrodysesthesia (PPE) has been reported as being the dose-limiting toxicity and effects patients' quality of life. We conducted this phase-II trial based on the encouraging results of a biweekly schedule of C in patients with AIDS-related Kaposi's sarcoma.

**Methods:** A multi-institutional phase-II study was performed to analyze the toxicity profile of PLD (20 mg/m$^2$/q 14d) in heavily pre-treated patients with ROC. Eligibility criteria: ROC, prior treatment with Platinum and Taxan. Statistic: 2-Step-Design, in case of a positive first step (n = 26): > 2 response+<6 events of PPE (CTC Grade III/IV), a total number of 60 patients must be recruited; power: 80%, p < 0.05, based on a 10% reduction of PPE (95%CI). Eligibility criteria: relapsed epithelial ovarian cancer, prior treatment with platinum- and paclitaxel-containing chemotherapy, ECOG status 0–2, organ function (e.g. cardiac, liver) within normal range, written informed consent.

**Results:** A total of 64 patients were recruited (10/2001–02/2004). 553 courses (median: 7, range: 1–35) were evaluable. Median age was 59 (38–81). Patients were generally heavily pretreated: Only 13 patients has been in second-line, most of the patients were in third- or fourth-line. Ten patients were in fifth-line. Overall, the treatment was well tolerated. 30 patients developed skin toxicities: 18 patients with grade I, 9 with grade II and only 3 patients with grade III. These side effects occurred after a median of 5 courses. Haematological toxicity profile was unincisive: only in three patients anaemia grade III and in one patient thrombocytopenia grade III was observed. Clinical response were evaluable by CA-125-monitoring and radiological measurements. Two patients achieved complete response, further five patients partial response and 13 stable diseases as best response criteria. The progression-free survival for these heavily pre-treated patients was median 6.4 months. The overall survival was median 13.4 months.

**Conclusion:** These results of heavily pre-treated patients shows, that the biweekly schedule of C is effective, secure and well tolerated, with a low incident of skin toxicity.

Supported by ESSEX Pharma Germany

## 939                                                                                POSTER
**Management of sarcomas of female genital tract**

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**Aim**: Sarcomas of the female genital tract are presented with poor clinical picture and a wide spectrum of histological findings. Only a third of patients go for surgery with an established diagnosis. Currently, the main method of treatment of sarcomas of the female genital tract is surgery. The efficacy of chemotherapy and radiotherapy are questionable. Surgery remains the main mode of treatment. So, the aim of our study is to establish the optimal treatment modalities for these tumors.

**Methods:** 406 patients treated at the NNBRCRC from 1970 to 2002 were retrospectively analized: 168 patients with leiomyosarcoma, 88 – endometrial stromal sarcoma, 113 – carcinosarcoma, 34 – rabdomyosarcoma, 2 – adenosarcoma, 1 – liposarcoma. All patients were analyzed according to two basic parameters: histological structure and tumor site. Surgical treatment, as independent method, was performed to 189 patients, chemotherapy – 4 patients, radiotherapy – 8 patients. Combined treatment, including surgery and postoperative chemotherapy was performed to 76 patients, surgery+radiotherapy – 60 patients. Complex treatment (surgery+chemotherapy+radiotherapy) was performed to 60 patients.

**Results:** local recurrences and distant metastases after the initial treatment occurred in 188 patients (46.3%), 80% from them were multiple lesions. Site of the metastases correlated with the histological structure of the sarcoma. Uterine sarcomas (92.2%) are the most common in our material. Sarcoma of the cervix, ovaries, vulva, vagina are rare and compose only 7.8%. Histologically, smooth cell tumors – leiomyosarcomas (41.4%) are the most common. Immunohistochemistry and electronmicroscopy play a major role in establishing the diagnosis. One of the most important prognostic factors of sarcomas of the female genital tract is the morphological structure of the tumor: 5 year overall survival of patients with leiomyosarcoma – 48.3+4.2%; low-grade endometrial stromal sarcoma-85.8+5.3%; high-