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POSTER

Quality of life in patients with cervical cancer during concomitant radio-chemotherapy

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Background: The benefit of radio-chemotherapy with cisplatin in cervical cancer was proved in many studies, the indicated cisplatin schedules remains to be decided. As consequences in Institute of Oncology Cluj-Napoca, in 2003 a randomized phase three trial was initiated, which compares two single-agent cisplatin regimens, one of the aims being the quality of life evaluation.

Material and methods: Between March 2003 and November 2004, this study included 300 patients with cervical cancer stage IIB (143), IIIA (101) and IIIB (56). The patients were randomly assigned in one of the two arms of the protocol: (A) cisplatin 20 mg/m² × 5 days, every 21 days (149 patients) and (B) cisplatin 40 mg/m²/weekly (151 patients), administered concomitant with the radiotherapy. After 46 Gy on the pelvis patients with good response were operated (radical hysterectomy with pelvis lymphadenectomy) and the others continued radio-chemotherapy until 64 Gy. The patients' quality of life from the two arms of the protocol was measured using the European Organization for Research and treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C 30, v.3.0) at randomization and in the 3rd and 5th week during radio-chemotherapy.

Results: The compliance rate at start-line (baseline) was 94%, in the 3rd week 91% and in the 5th week 78%. In arm (A) a significant improvement of global health status ($p < 0.01$) and a decrease in pain ($p < 0.01$) were observed, while in arm (B) fatigue increased ($p = 0.01$) and role functioning diminished ($p = 0.05$). In both treatment arms depression and feel tense (emotional functioning) ($p < 0.01$ and $p = 0.05$), nausea and vomiting ($p < 0.01$), and diarrhea intensified ($p < 0.01$).

Conclusions: Concomitant radio-chemotherapy with cisplatin = 20 mg/m² × 5 days, every 3 weeks offers improved quality of life for patients with cervical cancer. In the future these data are going to be analyzed in comparison with objective results.

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The importance of interval from debulking surgery to the beginning of chemotherapy in ovarian cancer patients

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Background: Ovarian cancer has a poor prognosis, with 5-year survival ranging from 50–85% for early stage tumours (FIGO stages I-II) to 5–20% for advanced stage disease (FIGO stages III-IV). The standard therapy for advanced disease is debulking surgery followed by platinum-based therapy. The timing of chemotherapy initiation after debulking surgery is a matter of concern and patients are often excluded from clinical trials if they cannot commence chemotherapy within 6 weeks of surgery. However, no studies have shown significant differences in survival among patients who received chemotherapy sooner or later after surgery. This work was designed to ascertain whether there is any influence of the interval from surgery to the beginning of chemotherapy on survival in patients with ovarian cancer treated with platinum-based chemotherapy.

Material and methods: We analysed patients from our database. For the last 7 years we have recorded clinical data on all patients coming through the ovarian cancer clinic. Univariate survival analyses were executed using the log-rank test. Multivariate analyses were performed using Cox regression model.

Results: We analysed 525 patients with epithelial ovarian cancer who underwent surgery and post-operative chemotherapy. The mean age of the sample was 57 years old. Most patients (65%) had stage 3 or 4 disease as well as macroscopic disease after debulking surgery (58%). The median follow up was 24 months. We stratified the interval from surgery to chemotherapy in 3 groups: patients who received chemotherapy within 4 weeks from surgery (group 1; $n = 72$), between 4–8 weeks after surgery (group 2; $n = 349$), and more than 8 weeks after surgery (group 3; $n = 102$). In the multivariate analysis we have found no significant statistical differences in survival among the 3 groups. Bulk of residual disease after surgery ($p < 0.0001$), performance status ($p = 0.010$) and post-chemotherapy CA-125 ($p < 0.0001$) were independent prognostic variables.

Conclusions: This study suggests that the interval between debulking surgery and beginning of chemotherapy is not an independent prognostic factor for overall survival. It is important to emphasize that we analysed the survival of patients that have started chemotherapy more than 8 weeks after surgery.

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Randomized trials comparing chemotherapy and hormonal therapy regimens for advanced endometrial cancer: biases and evolution over time

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Background: Several chemotherapy and hormonal therapy regimens have been proposed for the treatment of women with advanced endometrial cancer. We systematically evaluated the available data from randomized trials and examined whether there is evidence for any superior efficacy of specific regimens in overall survival or whether biases could be detected in this literature.

Material and Methods: We searched MEDLINE, EMBASE and the COHRANE Library until April of 2005 for randomized controlled trials evaluating various chemotherapy or hormonal therapy regimens in patients with locally advanced or metastatic endometrial cancer. We focused on survival outcomes and examined trial characteristics pertaining to quality and potential biases.

Results: Across 17 eligible trials (3,006 patients randomized in 34 arms), only 4 regimens were involved in more than 1 trial, and only two trials had used the same comparison of regimens. A statistically significant effect in survival was seen only in one recent trial, but it was borderline ($p = 0.032$) and amounted to only 3 months difference in median survival. Only 3 trials (17%) described an appropriate mode of randomization, only 8 (47%) described an appropriate mode of allocation concealment, only 8 (47%) did not clearly violate intention-to-treat and none of the trials were blinded. Median survival was seemingly longer in more recent compared with older trials, but this was entirely attributed to the inclusion of significantly fewer patients with poor performance status in more recent trials.

Conclusion: Randomized trials of systemic treatment in advanced endometrial cancer suffer from fragmentation of research efforts and there is evidence for several biases plaguing their results. Transparent efforts should be made to improve the situation, if any real progress is to be made.

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Outcome after combined modality treatment for uterine papillary serous carcinoma: a rare cancer network (RCN) multicenter study

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Background: There are no established guidelines for treatment of uterine papillary serous carcinoma (UPSC), either in the adjuvant setting or in advanced disease. The aim of this retrospective, multi-center study was to analyze the outcome of patients (pts) with UPSC treated with combined modalities.

Methods: This was a cooperative study within the framework of the RCN. Charts of patients with UPSC diagnosed between 1972 and 2003 were reviewed. Pts were followed for 3–294 months (median 33). Treatment included surgery, chemotherapy, and/or radiation therapy (RT) according to the discretion of the treating physician.

Results: 110 pts, 37–87 yrs old (median 67) were included. Histology features: mixed histology containing UPSC elements and typical adenocarcinoma was found in 23 pts (21%), pure UPSC in 87 pts (79%). Stage distribution: stage I 43 pts (39%), II 16 pts (15%), III 29 pts (27%), IV 21 pts (19%), no data 1 pt. 103 pts had surgery, 5 pts biopsy only. 62 pts (56%) were treated with RT in an adjuvant setting, 9 pts irradiated for palliation, and 7 for pelvic recurrence. 38 pts (35%) received platinum-based adjuvant chemotherapy (CT). In 41 pts CT was given for persisting disease, resulting in 46% response rate (6 complete and 13 partial responders). 38 pts (35%) are alive and NED, 7 (6%) are alive with disease, 53 (48%) died of disease, 11 (10%) died of other causes, and one died of toxicity.