Gynaecological Cancer

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Gynaecological cancer (1)

5000 ORAL

Quality of life after radiotherapy for endometrial cancer: first results from the randomized PORTEC-2 trial

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Background: Reported data on quality of life (QoL) after treatment for endometrial cancer have suggested that patients who undergo pelvic radiation (RT) have lower role functioning and higher diarrhoea and fatigue scores than the general population, but similar social functioning and global health/QoL scores. In the PORTEC-2 trial, patients with intermediate risk endometrial carcinoma were randomly assigned to external beam pelvic RT or vaginal brachytherapy, and QoL was evaluated using EORTC QLQ C-30 and subscales for bladder and bowel symptoms from PR25 and sexual symptoms from OV28.
Material and Methods: PORTEC-2 included 427 randomized patients, of whom 345 (81%) were evaluable for QoL. QoL questionnaires were filled in before RT (baseline), after RT, and 6−12 monthly until 5 years. Patient accrual closed October 2006. Two-year QoL outcomes were analysed.
Results: At baseline, after surgery, global QoL was at the lowest level and did not differ significantly between the treatment groups. From 6 to 12 months QoL gradually increased in both treatment arms, to reach a plateau between 12 and 24 months. From 6 months onwards global QoL scores were significantly higher in the vaginal brachytherapy group ($p < 0.01$). Symptom ratings showed significantly less acute bowel symptoms (e.g. diarrhoea) and less fatigue in the vaginal brachytherapy group (both $p < 0.001$), and this difference remained significant during further follow-up. Reported sexual symptoms, such as reduced sexual interest and vaginal dryness, did not differ between the treatment groups, $p = 0.36$.
Conclusions: Global QoL after radiotherapy for endometrial cancer was lowest at baseline, and increased thereafter to plateau after 12 months. From 6 months onwards patients in the vaginal brachytherapy group reported significantly better global QoL, and significantly less bowel symptoms and fatigue. This QoL benefit is an important factor to take into account when balancing risks and benefits of pelvic radiation and vaginal brachytherapy. Final outcome of the PORTEC-2 trial is awaited and will evaluate the efficacy of vaginal brachytherapy for intermediate risk endometrial carcinoma, and determine whether pelvic radiation can be replaced by brachytherapy to ensure local control with less morbidity and better quality of life. Updated results will be presented.

5001 ORAL

Intraperitoneal administration of the trifunctional antibody catumaxomab for treatment of malignant ascites due to ovarian carcinoma: Results of a phase II/III study

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Background: Malignant ascites in ovarian carcinoma patients (pts.) is associated with a poor prognosis and reduced quality of life. Catumaxomab (anti-EpCAM x anti-CD3) is known to effectively eliminate tumor cells within ascites by simultaneously activating T cells and Fc gamma-receptor I/III cells and redirecting them against the tumor.
Materials and Methods: A total of 129 ovarian cancer pts. with recurrent symptomatic malignant ascites containing EpCAM+ tumor cells were enrolled in the study; 85 were randomized to treatment with catumaxomab (paracentesis plus 4 intraperitoneal infusions of 10, 20, 50 and 150 µg within 11 days), and 44 to the control arm (paracentesis alone). The primary endpoint was puncture free survival (time to first need for paracentesis after treatment or time to death, which ever occurred first).
Results: Pts. characteristics were well balanced in both arms. Median puncture free survival was 52 days for catumaxomab vs. 11 days for control ($p < 0.0001$) whereas the median time to first need for paracentesis was 71 days vs. 11 days ($p < 0.0001$). There was a pronounced decrease of tumor cell load accompanied by a distinct increase of leukocyte count during catumaxomab treatment within the ascites fluid. Overall and progression free survival data suggest longer survival for catumaxomab-treated pts. compared to control. 11 months after the last patient entered the trial, 9 patients of the catumaxomab group and one patient of the control group who also received catumaxomab as a cross-over option, are still alive. Detailed survival analysis will be presented. The most frequent AEs were symptoms related to cytokine release (pyrexia, nausea, vomiting). These were generally mild to moderate in intensity, and fully reversible. Transient increases in liver enzymes and bilirubin, and transient WBC abnormalities such as leukocytosis, neutrophilia and a decrease in peripheral lymphocytes were regularly observed as abnormal laboratory values but rarely considered clinically significant.
Conclusions: Intraperitoneal therapy with catumaxomab resulted in a significant and clinically relevant improvement of puncture-free survival time, decrease of tumor cell load, and prolonged time to first need for puncture compared to the control group of best available treatment. The safety profile reflects catumaxomab's mode of action and reveals a low and acceptable toxicity.

5002 ORAL

Results from a Phase II randomized, placebo-controlled, double-blind trial suggest improved PFS with the addition of pertuzumab to gemcitabine in patients with platinum-resistant ovarian, fallopian tube, or primary peritoneal cancer

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Background: Pertuzumab is a humanized monoclonal antibody that blocks HER2's ability to heterodimerize with HER/ErbB receptors. As a single agent, pertuzumab has demonstrated clinical activity in relapsed/refractory epithelial ovarian cancer (EOC). Since platinum-resistant EOC remains a