vestigated the addition of CAP to GEM in patients with advanced pancreatic cancer

**Methods:** Patients (pts) with histologically or cytologically confirmed, inoperable or metastatic pancreatic cancer were included in this open multicenter study. GEM was given at a fixed dose of 1 g/m² on days 1 + 8. CAP was given q12hrs for 14 days. The regimen was repeated every 3 weeks. Starting dose for CAP was 1 g/m²/d (level 1), escalating to 1.3 g/m²/d and 1.6 g/m²/d (level 2 and 3 resp.). Maximum tolerated dose (MTD) was defined as the dose causing dose limiting toxicity (DLT) in  $\geq$ 1/3 of a cohort of 6 pts. DLT was defined as neutro- or thrombocytopenia grade 4, mucositis  $\geq$  grade 3, hand-foot-syndrome grade 3, all according to NCIC CTC. At the recommended dose level (one level below MTD) an additional 10 pts. were included.

**Results:** 35 pts were included. DLT occurred in 2/6 pts at level 3 consisting of myelotoxicity and stomatitis. Hand-foot-syndrome and alopecla were not observed and other toxicities were mild. Thus, in this regimen the recommended dose of CAP is 1.3 g/m²/d.

Of 24 pts: with measurable disease, so far 1 complete and 6 partial remissions (RR 29%) and several highly significant drops in CA 19-9 have been observed.

Conclusions: GEM and CAP is a highly active and well tolerated drug combination in advanced panoreatic cancer. It is presently compared to GEM-monotherapy in a phase III trial.

## Gynaecological cancer

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## Factors determining acute normal tissue reactions of postoperative radiotherapy in endometrial cancer

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Purpose Our aim was to evaluate the influence of patient- and treatment-related factors on the risk of acute reactions during postoperative radiotherapy (RT) in endometrial cancer (EC) patients (pts).

Methods This series included 247 EC pts treated between 1974 and 1991 with surgery followed by RT consisting of Cs or Ra brachytherapy (BRT) and external beam RT (XRT). Mean BRT dose rate at 0.5 cm was 0.75±0.49 Gy/h and mean BRT dose was 50.1±11.7 Gy at 0.5 cm. Mean XRT dose within the target volume was 44.5±3.4 Gy given with a mean daily traction of mean 1.82±0.15 Gy. Normalised Total Doses (NTD including XRT and BRT doses, were calculated based on linear-quadratic equation. EORTC/RTOG scale was used to score acute reactions.

Results Acute rectal reactions (of any grade) occurred in 188 pts (76%) and acute urinary bladder reactions - in 101 pts (41%). Severe (grade 3 and 4) acute rectal and bladder reactions were observed in 14 pts and 1 pt (5%), respectively. In univariate analysis, XRT dose (p=0.018) and total NTD in the prescription point (p=0.047) and in the rectum (p=0.037) were significantly correlated with the risk of acute rectal reactions, whereas age was of borderline significance (p=0.07). Multivariate analysis showed that NTD (p=0.007) and XRT dose (p=0.003) were independent risk factors for acute rectal injury. BRT dose (p=0.049), BRT dose rate (p=0.002), XRT fraction dose (p<0.001) and use of Cs (p<0.001) were in univariate analysis correlated with the risk of acute bladder injury, whereas parity (p=0.074) and NTD (p=0.063) were of borderline significance. In multivariate analysis none of these factors was significantly correlated with the risk of acute bladder injury. Interestingly, no clinical factor (age, parity, FIGO stage, diabetes, hypertension), neither RT time and surgery-RT interval was independently associated with acute rectal and/or bladder injury.

Conclusions The risk of acute normal tissue reactions depends mainly on treatment-related factors (NTD, XRT dose), whereas the impact of patient-related variables is negligible. Precise treatment prescription, planning and verification are of paramount importance.

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Adequacy of small pelvic irradiation instead of whole pelvic irradiation for a subgroup of lymph-node negative patients in postoperative radiotherapy for cervical carcinoma

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Purpose: In postoperative radiotherapy (postop RT) for cervical carcinoma, a whole pelvic irradiation (WP) which includes pericervical regions and the lymphatic system up to common iliac lymph node (LN) regions has been used irrespective of nodal status. We clinically verified logical adequacy of using a small pelvic irradiation (SP) for LN negative patients; SP includes pericervical regions only and in consequence covers external and internal iliac LN regions. Methods: 85 patients with stage I or II cervical squamous cell carcinoma treated by postop RT between 1990 and 1998 were eligible. The patients had any of risk factors of deep stromal invasion, lymph-vascular infiltration, close surgical margin, and LN metastasis. RT doses ranged from 48.0 to 54.0 Gy, with or without another boost doses. WP was used for a group of 42 LN positive patients and SP for another group of 43 LN negative patients. Survival rate (SR), disease free rate (DFR), and pelvic disease free rate (PFR) were calculated by the Kaplan-Meier method to make a comparison between two groups. Results: 4 patients showed recurrence and 3 died of disease in SP group, whereas 15 showed recurrence and 12 died of disease in WP group; 3 and 4 showed pelvic recurrence in respective groups. SR and DFR were significantly higher for SP group than for WP group: 2-year SR being 93% vs 83% (p=0.0124) and 2-year DFR being 91% vs 69% (p=0.0029), respectively. In contrast, PFR did not differ between SP group and WP group: 2-year PFR being 93% vs 88% (p=0.2532), respectively. Conclusion: Use of SP is sufficient for LN negative patients in whom pericervical regions are the main sites of recurrence.

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## Does palliative chemotherapy provide a palliative effect in cervical carcinoma? A review of the literature

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**Purpose:** To review whether palliative chemotherapy has an evidence-based palliative effect (on pain, discharge, bleeding, fatigue etc), besides the limited effect on survival.

**Method:** 69 palliative chemotherapy studies were identified in Medline during 1987-2000. Data on type of treatment, response rate, response duration, side-effects, and effect on symptoms and quality of life were registered.

Results: Response rates were often in the range of 10-40%, with a short duration. Only in 12/69 studies there were any approach to evaluate a possible palliative effect on pain, subjective improvement of other cancer related symptoms (bleeding, discharge, oedema, breathlessness etc.) or improvement of performance status using a defined instrument. The scarce data indicate that palliative chemotherapy might have a good effect on symptoms, but the strict evidence-base is poor.

**Discussion:** Pain, discharge, haemormage, fatigue and dyspnoea are frequent problems in recurrent cervical cancer. Convincing data show that objective tumour response and duration of response is limited. Still, patients might benefit from palliative chemotherapy as regards improvements in symptom control and quality of life. Studies that are designed to evaluate such true palliative effects are needed.

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## Therapeutic outcome in the radiotherapy of relapses of cervical carcinoma

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**Objective:** The purpose of this study was to evaluate the efficacy of radiotherapy in patients with relapses of cervical carcinoma.

Methods: A retrospective analysis was undertaken of 27 consecutive patients who underwent radiation therapy for relapses of cervical carcinoma between 1989 and 1999. The median follow up was 14 months (1-61). 17 patients had inoperable tumors or macroscopic residual tumor following surgery of the recurrence. 4 patients had a microscopically incomplete surgery, 6 patients had a complete tumor resection. Radiation