Advanced gastric cancer (AGC) has a poor outcome and chemotherapy has mainly a palliative effect. Despite many years of chemotheraphy, there are no definite data to suggest that 5-FU alone is inferior to other treatment. The TTD group carried out two consecutive phase II trials in patients with biopsy proven AGC with measurable disease. Performance Status (PS) < 3 and normal liver, kidney, heart and marrow function. In the first one 5-FU was given as a single agent in 48-hours continuous infusion (3 g/m²/sub) weekly. In the second trial cisplatin (9 g/m²/sub) was added every week. In the second trial cisplatin increased significantly the response rate (CR). However, there are no differences in time to progression (TTP) depending on specific guidelines given by the EORTC.

Method:

To assess MRI as a means of detecting early tumour recurrence and of describing the late normal tissue effects in the perianal soft tissue and perineum.

Purpose:

To observe MRI as a means of detecting early tumour recurrence and of describing the late normal tissue effects in the perianal soft tissue and of describing the late normal tissue effects in the perianal soft tissue and perineum.

Results:

Of those pts showed documented tumor progression within 3 weeks of last chemotherapy. Median number of organs involved: 3. Symptomatic improvement: 50%. Out of 3 pts who had PR as best response to CPT-11, 1 achieved TTP and OS was 4.4 and 0.8 months, respectively. The addition of cisplatin increases significantly the response rate (CR). However, there are no differences in time to progression (TTP) depending on specific guidelines given by the EORTC.

Conclusion:

MRI in the long term follow up of patients treated with 5-FU alone. Overall response rate (ORR) was 18% (10-26, Cl at 95%), with 4% CR. Time to progression (TTP) and OS was 4.8 and 9.2 months, respectively. The addition of cisplatin increases significantly the response rate (CR). However, there are no differences in time to progression (TTP) depending on specific guidelines given by the EORTC.

Quality of Life (QoL) has become an important issue in modern quality management to measure health outcome in tumor surgery. Since September 1998 patients with GI tumors have been assessed pre- and postoperatively for their health related Quality of Life in daily clinical routine in our department. Development of the QoL modules used in this trial takes time and is depending on specific guidelines given by the EORTC.

From 1987–89 in a prospective pre-study QoL in 74 patients with GI tumors was measured at the Dep. of surgery at the University hospital of Hamburg. In open interviews patients were asked for symptoms before, during and after therapy. This list of symptoms was completed by consulting experts and literature review. All subjectively experienced symptoms were worded into simple questions and tested for clarity. These modules were used in two main studies with 500 (300 + 200) patients from 1990–96. Patients answered the questionnaires one day before surgery (70), one day after discharge (Z1) and one year after radical surgical treatment (Z2). This main study was followed by a psychometric analysis to measure reliability and to reduce the number of items on the questionnaire. Validity was assessed by medical records. The questionnaires presented show good reliability and validity and can be filled out by patients in less than 20 minutes.

Development of tumor specific questionnaires for patients with GI tumors according to the guidelines of the EORTC are presented. Results from our prospective and retrospective studies underline the good reliability and satisfactory validity of those GI-modules in combination with the EORTC-QLQ-C30.

Adjuvant intraperitoneal chemotherapy with cisplatinum, mitoxantrone, 5-fluorouracil and calcium folinate in stage II–III gastric cancer

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Despite numerous trials of postoperative chemotherapy following potentially curative gastric resection, the value of adjuvant therapy is uncertain. Adjuvant chemotherapy is not a standard therapy after complete gastric resection, but there are many trials evaluating the role of adjuvant therapy. The feasibility, efficacy and toxicity of adjuvant intraperitoneal chemotherapy (IPC) were evaluated in patients with stage II–III gastric cancer.

After complete tumor resection, cisplatin 60 mg/m², mitoxantrone 12 mg/m², 5-fluorouracil 900 mg/m² and calcium folinate 60 mg/m² were administered in 2 L normal saline intraperitoneally via temporary or semi-permanent catheter every 4 weeks for 6 courses to 39 patients and were not removed from the peritoneal cavity. Characteristics of patients were median age 50 (25–66), female 13, male 26, stage II (23%) and stage III (77%).

IPC courses were given. Twenty-seven (69%) patients had received the total of 6 courses. Remission of the peritoneal patient was 6. (range 1–6). Toxicity grading was done according to WHO criteria. The toxicity was mild. Non-hematological toxicity included: grade 3 anemia and 2 cases of stomatitis.

Conclusion: By the given MR criteria, MRI supported the clinical and endoscopic impression of local tumour control. No MR evidence of femoral head or AVN was seen in this sample of patients. MRI has highlighted the varying degrees of architectural distortion of the anal complex at one year post chemo-radiation. This discriminating morphological scoring of these changes will permit correlation with functional outcome. Yearly examination are ongoing for this purpose.
Gastro-intestinal

I-II mucostas in 1.4%, grade I-II neopropathy in 2%, grade I-II emisie in 33%, grade III-IV emisie in 2%, grade I-II abdominal pain in 19% and grade III-IV abdominal pain in 2% of cases. Catheter obstruction occurred in 3 patients with permanent catheter, and colon puncture in 4 patients with temporary catheter. No grade III-IV hematological toxicity has occurred.

3 patients with permanent catheter, and colon puncture in 4 patients with...

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Purpose: GEM is the new agent with activity in APC, and clinical benefit re-sponse is reported 26-45% pts. by several investigators. We assessed an effi-cacy of combination GEM + MMC in pts with APC.

Methods: 25 pts (13 men and 12 women) with measurable APC were included in trial. The average age of the patients was 56.5 years. Karnofski score was from 60 up 90 (60-10; 70-5; 80-9; 90-1). The most of pts have severe symptoms of disease: pain – 20, loss weight – 19, weakness – 19. Thirteen pts received palliative surgical treatment. 10 pts were treated MMC 5-10 mg/m² i.v. day 1, GEM 1000 mg/m² i.v. 1, 8, 15 days. Nine pts received regimen MMC 8 mg/m² i.v. day 1, GEM 1000 mg/m² i.v. 1, 8, 21, 29 days. The interval between the cycles was 2 weeks.

Results: 23 pts were evaluated for toxicity and 21 pts for efficiency. Two pts had early progressive disease. OR for combinations GEM + MMC was 50%. The duration of onset varied from 6 to 29: wools. 11 pts have SD. During of chemotherapy clinical benefit response was observed in 60% pts. Toxicity gr. III-IV for 1-st regimen: neutro-penia - 45.2%, trombocytopenia-54%, pulmo-nary toxicity 20%, it was a reason to correct regime, for 2-nd regimen: neutro-penia - 12.3%, trombocytopenia - 4%, pulmonary toxicity - 1 pts from 9, flu-syndrome - 30%, edema - 20%.

Conclusion: the combination GEM + MMC has shown efficiency in treatment of patients with APC. Clinical improvement was registered in 60% patients. Second regimen of treatment demonstrated satisfactory efficacy and less toxicity.

Clinical significance of estrogen receptors investigation in patients with atrophic gastritis and gastric cancer

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Purpose: Estrogen receptors (ER) participate in regulation process of gastric mucosa (GM) functioning, as well as in the process of its blasto-magenesis, thus stomach can be considered as a target for estrogens. In a perspective study GM estrogen reception characteristics in patients with atrophic gastritis (AG) and gastric cancer (GC) were evaluated.

Methods: 320 patients were examined: 60-with GC and 40 with AG. In all the cases X-ray and endoscopic diagnosis was verified morphologically. ER level in the tissues was detected with the radiologic method by Lippman and Huff.

Results: ER were detected both in GM of patients with AG and GC cytosol fraction. Their level varied from 10 to 236 fmoi/1 mg of protein. In tumours the ER level was higher (85.0 ±6.1517; 9.0 fmoi/1 mg of protein) then ER level in GM in patients with AG (21.0±6517; 4.0 fmoi/1 mg of protein).

Conclusion: GC characterized with higher estrogen reception then AG, that is probably due to transition of cancer cells to the pathological endocrine regulatory mechanism.

Phase II study of gemcitabine in patients with nonresectable cancer of the biliary system

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The biliary-system shares the embryologic origin with the exocrine pancreas. Therefore we investigated the effect of gemcitabine in patients with non resectable cancer of the biliary system.

Methods: Between January ’97 and September ’98 21 patients with non resectable cancer of the biliary system were enrolled. Patients were treated with Gemzar 1000 mg/m² i.v. over 30 min once per week. The first cycle included 7 applications followed by one week rest. The following cycles consisted of 3 applications only, followed by one week rest. Staging was performed after each cycle. Only one patient received Gemzar as a second line chemotherapy, 20 patients were chemotherapy naive.

Results: The number of cycles applied varied from 1 cycle to 7 cycles (median 3 cycles). Five patients achieved a partial remission (PR 24%) and 11 patients had a stable disease. Three out of 16 patients without an objective response had a clinical benefit, defined as >10% gain of performance status and/or body weight. So far, the median time to progression was 17.4 weeks in 12 eligible patients. Two patients are still in partial remission (35 and 10 weeks after beginning of treatment). One patient won a primary non- resecatable CCC underwent surgery (R0-resection) after 5 cycles of Gemzar because of his partial response. One patient with progressive disease under high dose 5-Fu/leucovorin, developed a stable disease for 21 weeks. Overall the regimen was well tolerated. Side effects (WHO) included 10 cases of grade 2 leukenemia, 2 cases of grade 4 anemia, 4 cases of grade 2 flue like syndrome and 7 cases of grade 2/3 nausea. One patient developed a hemolytic-uremic syndrome which resulted in the withdrawal of the treatment.

Conclusion: Our results indicate that the treatment of cancer of the biliary system with GEM is effective, well toleraded and leads to clinical benefit of some patients.

Phase II trial of gemcitabine in advanced gallbladder cancer


Gallbladder cancer (GC) is the leading cause of death from malignant neoplasia in women in Chile. Most patients (pts) present locally advanced or metastatic disease, the median survival being only 12 weeks. Blasted