I–II mucositis in 1.4%, grade I–II nephropathy in 2%, grade I–II emesis in 33%, grade III–IV emesis in 2%, grade I–II abdominal pain in 19% and grade III–IV abdominal pain in 2% of courses. 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.

Median follow-up was 16 months. There were 8 (21%) intraabdominal and 10 (26%) systemic recurrences. Metastatic sites were liver in 5 patients, lung in 1 patient and local + liver in 4 patients. Five patients died without determination of recurrence site. Twenty-one patients were dead and 16 patients are alive without evidence of disease. Median disease free survival (DFS) and overall survival (OS) were 13 and 16 months. Cumulative 3 year DFS and OS were 40.5% (SD ± 8.7) and 42.2% (SD ± 8.9) respectively.

IPCT seems feasible and tolerable, but its efficacy should be evaluated in randomized trials.

556 PUBLICATION

Gemzar (GEM) + Mitimycin C (MMC) in patients with advanced pancreatic cancer (APC)

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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 58.5 age. Karnofsky PS 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, weekness – 19. Thirteen pts received palliative surgi-cal treatment. 16 pts were treated MMC 5–10 mg/m^2 i.v. day 1, GEM 1000 mg/m^2 i.v. 1, 8, 15 days. Nine pts received regimen MMC 8 mg/m^2 i.v. day 1, GEM 1000 mg/v2 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 38%.. The duration of effect varied from 8 to 29+ weeks. 11 pts have SD. During of chemotherapy clinical benefit response was observed in 60% pts. Toxicity gr. III–IV for 1-st regimen: neutropenia – 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 – 38%, edema – 20%.

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

557 PUBLICATION

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-mogenesis, 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.

Metods: 128 patients were examined: 80-with GC and 48 with AG. In all the cases X-ray and endoscopic diagnosis was verified morphologically. ER level in the tissues was detected with the radioligand 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 fmol/1 mg of protein. In tumours the ER level was higher (85.0 &61617; 8.0 fmol/1 mg of protein) then ER level in GM in patients with AG (21.0&61617; 4.0 fmol/1 mg of protein).

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

558 PUBLICATION

Phase II trial of epirubicin, uracil-tegafur and leucovorin (ELV) in advanced gastric cancer

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Purpose: Phase II trial to evaluate the therapeutic potential and tolerance of the combination epirubicin-UFT-leucovorin in advanced gastric cancer.

Patients: 33 untreated patients with histologically proven gastric adeno-carcinoma were included. The mean age was 60 years (35–73), there were 8 women and 25 men. ECOG performance status: 0 in 5 patients, 1 in 18 and 2 in 10. Two patients (6%) had a locally inoperable advanced tumor and 31 metastatic disease (11 in 1 site, 20 in two or more sites)

Treatment: Oral UFT 195 mg/m^2/12 h days 1–14, i.v. leucovorin 500 mg/m^2 day 1, oral leucovorin 15 mg/12 h days 1–14, i.v. epirubicin 75 mg/m^2 day 1. Courses every 28 days on an outpatient basis for a minimum of 3 courses. Therapy was maintained until progression or severe toxicity appeared.

Results: 3 patients had a complete response (9%) and 9 a partial response (27%), for an overall response rate of 36% (95% CI 17.5–67-5%). 207 courses were administered, a median of 6 per patient. The main toxicities were gastrointestinal and hematological. WHO grade 3–4 toxicities: nausea/vomiting 4 patients (12%), diarrhea 8 (24%), fever 2 (6%), mucositis 1 (3%), anemia 1 (3%). Median time to progression was 6 months and overall survival 9 months.

Conclusion: these results suggest that the combination epirubicin-UFT-leucovorin is active in patients with advanced gastric cancer with an accept-able toxicity.

559 PUBLICATION

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/m^2 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 GEM as a second line chemotherapy, 20 patients were chemotherapy naive.

Results: The number of cycles applicated 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 with a primary non-resectable 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 leukopenia, 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 withdrawl of the treatment.

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

560 PUBLICATION

Phase II trial of gemcitabine in advanced gallbladder cancer

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