on data demonstrating effectiveness of gemcitabine (GEM) in pancreatic carcinoma and the common embryologic origin of the exocrine pancreas and gallbladder, we decided to study the effectiveness of GEM.

Between July 1997 and February 1999, 20 pts with advanced GC were treated with GEM 1000 mg/m$_2$ i.v. for 30' weekly for 3 weeks out of every 4 in a phase II study. Patients were treated on an outpatient basis. All pts had measurable locally or metastatic GC with hystological proof; no prior chemotherapy; mean age, 50.8 years (38–68); 13 were females and 7 males. They all had performance status (WHO) 0–2, twenty were evaluable for toxicity and 16 for response (3 too early 1 dropped out). A mean of 4 courses were given (1–14). There was no complete response but 8 partial responses, for a global response rate of 50% (8/16). Mean follow-up was 23.8 weeks. The median survival time was 19 weeks; 40% of all pts survived longer than 6 months. Side effects were mild: no gastrointestinal toxicity or grade 3–4 (WHO) hematological episodes were recorded.

It is concluded that GEM appears to be highly active and well tolerated. This agent might have a significant clinical benefit not only on response rate and survival but on quality of life, which warrants new trials especially in combination regimens.

561 PUBLICATION

Continuous 120 hours-infusion (CI) of mitomycin C (MMC) as salvage treatment in progressive or rapidly recurrent gastric cancer (GC)

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Purpose: To evaluate the safety and therapeutic activity of continuously infused MMC in metastatic GC patients (pts) following first-line chemotherapy (ctx).

Methods: Pts were treated with MMC 20 mg/m^2 i.v. over a time period of 120 h followed by a 3-weeks rest. 22 pts were enrolled. All were assessable for toxicity and 20 pts for response evaluation. Pts characteristics: Median age: 63 years (39–76); Sex (m/f): 13/9; Karnofsky status: 70% (50–100); Previous ctx: Bolus 5-FU/FA n = 6 (27%), ELF n = 4 (18%), EAP n = 3 (14%), CI 5-FU/FA/DDP/paclitaxel n = 9 (41%); Resection of primary tumor n = 12 (55%); sites of metastases: hepar n = 17 (77%), locally advanced n = 10 (45%), peritoneum n = 13 (59%), pulmo n = 5 (23%), bone n = 3 (14%), lymph nodes 14 (64%).

Results: 1 CR and 5 PRs were observed (ORR: 27.2% [CI$_{95\%}$: 6.3–48.1%). The median response duration was 2.1 mort (range, 2–5), the median survival 3.6 mon (CI$_{95\%}$: 1.2–6.0); $\frac{1}{2}$-year survival rate was 30%. Responding pts had a statistically significant overall survival advantage (3.1 vs. 8.6 mon, p = 0.03). There was a trend of a prolonged survival in pts who had not received aggressive 1st line-therapy (p = 0.06). Thrombo- and leukocytopenia (WHO °III/IV) were observed in 4 (18%) resp. 2 pts (9%), and treatment had to be stopped early in 2 cases (9%).

Conclusion: CI of MMC over 5d was feasible on an outpatient basis revealing an acceptable toxicity. MMC demonstrated activity in advanced GC, pts but had only limited efficacy after platin/paclitaxel-containing ctx.

562 PUBLICATION

Chemoimmunotherapy protocol for advanced gastric cancer

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Introduction: Treatment of gastric cancer is still controversial. Modulation of 5-FU cytotoxicity with different chemotherapeutics and immunomodulators is still under investigation.

Material and Method: We tested in a prospective Phase II study a chemo-immunotherapy protocol in advanced gastric cancer patients. The regimen consisted of Cisplatin 50 mg/m^2 D1, 5-FU 375 mg/m^2 D1-3, Folinic Acid 20 mg/m^2 D1-3, IFN- a 2b 3Mio U sc. D1-3, every 28 d; and IFN- a 2b 3Mio U sc. 3 times weekly between the cycles. The treatment was given for 6–8 cycles. Twenty-four patients were included (18 males, 6 females). Mean age was 53.46 yr. (25–76). Five presented with locally advanced disease, and 19 had metastatic disease (Distant lymph nodes: 12, Liver: 5, Lung: 2). Initial performance status was 0: 3 patients., 1: 12 patients, 2: 9 patients. Response rate was 33% (1 CR, 7 PR). Median overall survival was 9 months (95% CI 4–14 months). The toxicity profile of this regimen was: G I-II Fever: 14 patients, G II Neutropenia: 3 patients, G I Renal toxicity: 2 patients. We conclude that, this regimen is well tolerated on an outpatient basis, and effective in advanced gastric cancer patients.

563 PUBLICATION

Survival after curative gastric resection

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Between December 91 and March 97, 55 patients submitted to curative gastric resection in the Clínica Oncológica I of the Portuguese Institute of Oncologie entered in a Phase III Clinical Trial of adjuvant chemotherapy with FAMTX. These are the results of a single institution experience. Overall 5-year survival rate was 57.4%.

In the control arm 5-year survival was 59.7%. In the FAMTX arm 5-years survival 55.7%. Pathologic staging was an important prognostic factor with a survival rate of 84.4% and 47.9% for stages II and III/IV respectively.

Conclusion:

(1) Pathologic staging is an important prognostic factor in curative gastric resection.
(2) Adjuvant treatment with FAMTX has no effect in survival.

564 PUBLICATION

Pancreatic carcinoma: Simultaneous radiochemotherapy with gemcitabine and cisplatin. A pilot study

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Purpose: to determine feasability and toxicity of simultaneous RCT using GEM & cDDP in a pilot study.

Methods: Between 4/98 and 1/99, 10 pts with locally advanced pancreatic carcinoma were recruited. 3d-conformal Rx was administered with 1.8 Gy SD daily. Primary tumor, metastatic nodes and high risk nodes were irradiated with a TD of 50.4 Gy, followed by a conedown to 55.8 Gy. Cx consisted of cDDP (20 mg/m^2 IV, d1–5 & 29–33) and GEM (600 mg/m^2 IV, d −2, 5, 12, 19, 26, 33, (40). Acute toxicity for Rx (RTOG) and Cx (NCI) were recorded.

Results: 18/20 courses cDDP could be administered (1/18 with 50% dose reduction). 54/68 courses GEM were given (1/54 with 50% dose reduction) Reasons for canceling Cx in almost all cases were leuco- a/o thrombopenia. Critical GEM courses were d12 & 19. Substantial acute toxicity: leucopenia 7/10 stage (st.) III; 2/10 st. IV; thrombopenia 3/10 st. III, 4/10 st. IV; upper GI tract (nausea, vomiting) 3/10 st. III, 0/10 st. IV; diarrhea 0/10 st. III/IV. One pt with combined leucothrombopenia st. IV had received COPP-ABV 10 yrs ago for Hodgkin's dz. 2/3 potentially resectable pts were assessed resectable at restaging. One of them was resected (R0), the other one refused surgery.

Conclusions: Simultaneous RCT (GEM/cDDP) is feasible, however hematotoxicity is substantial. Therefore Cx dose should be reduced. Efficacy in a neoadjuvant setting seems to be promising.

565 PUBLICATION

"Docetaxel-cisplatin, an effective palliativ therapy concept in advanced gastric carcinoma?"

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Objective: The aim of this study was to analyse the response rate, survival time, time to progression and toxicity for patients with advanced gastric carcinoma and therapy with Docetaxel and Cisplatin.

Patients/Methodes: From 1/97 to 1/99 we treated 47 patients (32 m., 15 f.) with a median age from 62.4 years (39–75 years) suffering from advanced gastric carcinoma 21 patients had a primary C. and 26 patients a recurrency. From the 47 patients 20 (42.5%) had liver metasases, 10 (21.2%) lymph-node metasases, 8 (17.1%) peritoneal carcinosis and 9 (19.1%) without metastases.

Treatment regime: 75 mg/m^2 Docetaxel, i.v., 1 h, day 1; 75 mg/m^2 Cisplatin, i.v., 1 h, day 1. The cycle was repeated at day 21 × 6.

Results: Of these 47 patients we analysed 43 patients. We observed 3 CR (6.9%), 13 PR (30.2%), 1 MR (2.5%), 14 SD (32.5%) and 12 patients with a progress (27.9%). The ORR was 17/43 patients (39.5%). The median survival time was 13.1 months and the time to progression in median 5.1 months. We observed haematological side effects ≥ grade III (WHO) 21.3% and a nadir after 5 to 7 days. Other side effects were nausea/vomiting ≥ grade III (WHO) 8.6% and alopecia ≥ grade III (WHO) 7.6%.