

Methods: For realizing of IACT a catheterization of gastric blood vessels was used. IACT was performed in 3–5 days before surgical treatment with 30 mg/m² adriablastin and 0.5 g/m² 5-fluoruracil. Intraabdominal chemotherapy was performed during operation after resection of tumor using by immobilized on siliconorganic matrix adriablastin (40–80 mg) and 5-fluoruracil (2.5–3.0 g).

Results: The all analyzed groups a radical operation have been made. The results of 18-month survival of patients were:

Treatment	n	Survival, %
1. Surgical	165	47.2 ± 7.2
2. IACT + surgical	49	69.5 ± 5.6
3. IACT + surgical + intraabdominal IC	37	86.4 ± 3.7

Conclusion: The results of laboratory examination of therapy toxic effect, clinic observation of patients and 18-month survival suggest that combination surgical treatment with intraarterial chemotherapy and intraabdominal chemotherapy with immobilized cytostatics is the most effective treatment of gastric cancer of III–IV stage.

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PUBLICATION

Contribution of chemotherapy (CMT) to the survival (S) of patients (P) with advanced gastric cancer (AGC). A retrospective comparative study of patients who received and those who refused treatment (Tx)

N. Tsavaris, P. Kosmidis, C. Kosmas, M. Katsikas, Ch. Bacoyiannis, N. Mylonakis, E. Papalambros, C. Koufos, E. Bastounis, M. Sechas. *Departments of Pathophysiology, Medicine, and Surgery, Laikon General Hospital-Athens University, Athens; Second Department of Medical Oncology, Metaxas Cancer Hospital, Piraeus, Greece*

The purpose of the present study was to evaluate whether combination CMT benefits P with AGC. 280 P were studied. P with severe cardiac, respiratory and renal dysfunction, as well as P unable to receive solids/liquids by mouth, and those with a KPS < 70 were excluded. Two groups were formed: A (those refusing Tx) = 162 and B (Tx group) = 138. Each group was separated in those who were operated and subsequently relapsed (SxRel), those operated with advanced disease (SxAD) and those deemed inoperable (noSx). Both groups of P (A/B) as well as subgroups of A or B were balanced for clinical characteristics. P in group B received CMT with FAM ± FA. Median S: A = 5.6 (1–11), B = 8.1 (1–16), [P = 0.04], A-SxRel = 5.1 (3–9), B-SxRel = 7.2 (2–12), [P = 0.05], A-SxAD = 3.8 (1–7), B-SxAD = 4.7 (2–12), A-noSx = 4.4 (1–7), B-noSx = 9.2 (2–16) mo, [P = 0.03].

Conclusion: Irrespectively of response, CMT with FAM demonstrates a modest (+3 mo) but significant improvement of S in AGC. The new CMT regimens for AGC are expected to have a greater impact in improving S.

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PUBLICATION

Adjuvant chemotherapy of gastric cancer with etoposide Doxorubicin and cis-platinum combination (EAP)

P. Papacostas, N.A. Malamos, G.F. Samelis, E. Papazachariou, G.P. Stahopoulos. *Hippokraton Hospital, Athens, Greece*

Adjuvant chemotherapy in gastric cancer has been attempted by several studies and the results are controversial. The aim of the present study was to attempt EAP combination as adjuvant taking on account high responses that EAP combination gave in advanced carcinoma of the stomach.

Material: 22 patients have been enrolled. Median age 51 (23–74). Male 14, Female 8. They all had locally advanced disease and metastases to the regional lymph nodes.

Treatment: Cis-platinum 90 mgs/m², Doxorubicin 45 mgs/m² day 1 and Etoposide 120 mg/m² days 1–3. Patients had six courses after the gastrectomy. Toxicity myelotoxicity Grade 1–3.

Results: Median follow-up 50 months (12–64). 12 patients showed recurrence (54.5%). Median recurrence time since treatment's beginning 21 months (7–42). Disease free survival 22 months (7–59 months).

Median survival 28 months (10–59).

Conclusion: Preliminary results suggest that EAP adjuvant chemotherapy in gastric cancer is effective. Large number of patients need to confirm it.

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PUBLICATION

Efficacy of intrahepatic chemotherapy for liver metastases of rare gastrointestinal tract and other rare cancers

G.H. Leder, K.H. Link, A. Formentini, U. Widmaier, J. Pillasch, H.G. Beger. *Department of General Surgery, University of Ulm, Germany*

Purpose: Intrahepatic chemotherapy for non-resectable liver metastases of rare GI-tract and other cancers with no standardized therapy available was performed.

Methods: 14 patients with liver metastases from carcinoids of the GI-tract (4), renal cell cancers (3), non-ductal pancreatic cancer (2), unknown primary (2), gastric cancer (2), thyroid cancer (1) were infused with 8 mg/m² NOV (day 1), 480/170 mg/m² 5-FU/FA (day 1–5) and 7 mg/m² MMC (day 5) via the hepatic artery using a port-catheter system. 5 Patients received 60 mg/m² CDDP instead of MMC and one 25 mg/m² EPI instead of NOV, when in vitro chemosensitivity results became available. Treatment was repeated after 4 weeks. Liver-CTs were performed prior to therapy and at every 3rd cycle and evaluated according to WHO criteria.

Results: 43% of all patients showed a PR (6/14) and another 43% (6/14) a NC while only 2 progressed during the first 3 cycles. After 6 cycles there were 44% PRs (3/9) and CRs (1/9), 44% NCs (4/9) and 1 PD. Side effects (WHO ≥ 2) were leukopenia (5/14), thrombocytopenia (3/14), anemia (1/14), nausea/vomiting (4/14), GI-toxicity (3/14) and alopecia (1/14).

Conclusions: Intrahepatic chemotherapy with usually a combination of NOV, 5-FU, FA and MMC prevents progression of liver metastases in more than 80% of patients with rare gastrointestinal tract and other rare cancers during a 3 and 6 months period, respectively, at tolerable toxicity.

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PUBLICATION

C reactive protein and albumin in pancreatic cancer

P. Pugliese¹, M. Girino¹, A. De Medici², A. Riccardi¹, E. Ascani¹. ¹Medical Oncology; ²Surgery II, Univ. and IRCCS S. Matteo, Pavia, Italy

Purpose: To determine whether serum C reactive protein (CRP) and albumin are useful markers and potential targets for therapeutic strategies in patients with pancreatic cancer.

Methods: Fifty patients with resectable and unresectable pancreatic cancer was included in this study. Six patients had stage I, 32 patients had stage II–III, 12 patients had stage IV disease (41 head, 9 body-tail). CRP and albumin were measured using standard automated laboratory techniques.

Results: The median of CRP was 0.4, 3.7, 3.6 mg/dl (v.n. < 0.6 mg/dl) respectively in stage I, II–III and IV; the median of acute-phase protein was higher in tumors of body-tail (head: 3.7 mg/dl; body-tail: 13.8 mg/dl). The median of albumin was 4.0, 3.5, 3.4 gr/dl respectively in stage I, II–III, IV; albumin was slightly decreased, but no differences were observed between head and body-tail pancreatic cancer.

Conclusions: Although the mechanism whereby patients with cancer develop an acute-phase protein response is not clear, the results of this study suggest that measurement of serum CRP may be a useful parameter for clinical evaluation of patients with tumor of the pancreas and for stratification of patients into prognostic and therapeutic categories.

1280

PUBLICATION

Intraperitoneal 5-fluorouracil treatment in patients with non resectable pancreatic carcinoma

M. Öman¹, P.J. Blind¹, B. Gustavsson², L. Hafström¹. ¹Department of Surgery, University Hospital of Umeå; ²Department of Surgery, Sahlgrenska Hospital of Gothenburg, Sweden

Purpose: Intraperitoneal administration of cytotoxic agents for the treatment of gastrointestinal malignancies results in a greater total drug exposure in the peritoneal fluid than in plasma. Lyppressin, a synthetic vasopressin analogue, which gives a significant constriction of the vessels of the splanchnic circulation.

The aim of the present study was to explore the feasibility of i.p. 5-FU administration for patients with advanced pancreatic carcinoma and if reduced splanchnic bloodflow may increase the dose intensity in the abdominal cavity and reduce systemic drug exposure.

Methods: Nine patients (five men) median age 61 (53–67 years), with a non-resectable pancreatic carcinoma (stage III and IV) were treated with intraperitoneal instillation of 750 mg/m² 5-FU daily for 2 days every 3rd week through an intraperitoneally placed port-a-cath until tumour progression. The i.p. distribution was controlled by Tc-99 scintigraphic method. An infusion of 0.1 units/min of lyppressin was administered i.v. during 180 min at every

second treatment. The serum concentration of 5-fluorouracil was measured with HPLC and related to the modification of the splanchnic circulation with lypressin. Tumour effects was analyzed with repeated CT scans.

Results: In one patient a limited tumour regression was observed and in four patients the disease was stable for 3 months or more. The median survival time was 6 months (2–16 months). 5-FU in plasma was lower when lypressin was administered.

Conclusion: 5-FU i.p. has an effect on pancreatic cancer.

1281

PUBLICATION

Combination bendamustin (B), mitomycin (M), 5-FU (FU) and prednisolon (P) in advanced gastrointestinal tumours with progress under chemotherapy

K. Ridwelski, St. Rudolph, J. Fahike, Th. Gebauer, H. Lippert. *Clinic of Surgery, University of Magdeburg, Germany*

We developed a new chemotherapy treatment regime especially for those patients with gastrointestinal tumours, which were progressed under the accepted protocols for this kind of tumour. The protocol based on Bendamustin, a Benzimidazol – derivative with a N-Lost group. Patients: Between 10/92 and 10/96 28 patients with a median age of 57 years were included. The Karnofsky index ranged between 50 and 80%. The primary tumor was located: 19x colon/rectum, 4x pancreas, 3x stomach and 2x gall bladder. All patients had a wide spread metastatic disease by primary "standard" chemotherapy. 18 patients had also second line chemotherapy this included also high dose 5-FU infusion. Measurable lesions were assessed by ultrasound and computed tomographic scans, repeated every 3 cycles or sooner, if there was any evidence of progression on clinical or biochemical grounds. The tumour-markers were measured after every cycle.

Protocol: Our treatment regimen consists of 8 mg/m² Mitomycin C i.v. (30'), 100 mg/m² Bendamustin i.v. (30') and 800 mg/m² 5-FU (i.v. over 2 h), given as an outpatient treatment. To avoid toxic side effects in the lung a premedication with 50 mg Prednison p.o. was given 30 min before treatment started. Cycle was repeated at day 29.

Toxicity: Regimen was always well tolerated, no toxicity greater WHO 2° occurred.

Results: We saw 1 CR (4%) and 4 PR (14%). 9 patients (32%) have had a SD for 6 months. The other 14 patients (50%) have had a primary progressive disease.

Summary: The regimen is active (CR + PR = 18%, SD = 32%) in patients with disseminated metastatic gastrointestinal cancer under accepted standard chemotherapy protocols. Now we estimate this protocol in a first line therapy.

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PUBLICATION

Etoposide, leucovorin and fluorouracil (ELF) in advanced gastric cancer: Our experience

A. Scimone, V. Adamo¹, A. Altavilla¹, G. Chillà, G. Chiofalo, A. Laudani¹, R. Maisano, G. Toscano, S. Pergolizzi, G. Ferraro¹. *Istituto Nazionale per la Ricerca sul Cancro, Genova, Sez. Dec. Messina; ¹Istituto di Clinica Oncologica Università di Messina, Italy*

Purpose: To evaluate the efficacy and toxicity of ELF regimen in patients (pts) with histologically-proven advanced or metastatic gastric cancer.

Methods: between 1/94 and 7/96, 26 pts (19 M and 7 F) median age 62 years (range 49–75), 5 locally advanced and 21 metastatic, received ELF regimen: VP-16 100 mg/mq, LV 150 mg/mq, 5FU 500 mg/mq; d 1–3; q: 3 w. According to the Lauren classification 15 pts had diffuse-type, 8 intestinal-type and 5 mixed-type gastric cancer. 5 pts were treated in the adjuvant setting (Stage IIIa or b). 21 were treated for metastatic disease. Metastatic sites were: liver, peritoneum, lymph nodes and bone. 95 cycles (range 1–6 per pts., median = 3.5) were administered.

Results: of 19 pts valuable with metastatic disease 5 pts (29%) had partial response (PR), 6 pts (31%) had stabilization of disease (SD) and 8 had progression disease (PD). Responsive sites were liver (2/8), lymph nodes (2/12), and peritoneum (1/4). Median survival (months) in this setting of pts. was: 7 (range 3–15) in RP pts, 4 (range 2–7) in SD pts. Median overall survival was 7 months (range 2–15). Five pts with stage III a or b disease completed six cycles and none have relapsed at 8, 10, 14, 14 and 18 months. Toxicity was acceptable: grade III leukopenia in 20% of pts, grade III mucositis in 5% of pts, grade III alopecia in 40% of pts. No treatment related death occurred.

Conclusion: the ELF regimen is an effective, well tolerated and safely administered combination in advanced gastric cancer

1283

PUBLICATION

Helicobacter pylori associated stomach cancer elicits specific germline encoded IgM response

F. Hensel, J. Dämmrich, B. Illert¹, W. Burghardt², H.K. Müller-Hermelink, H.P. Vollmers. *Institut für Pathologie, ¹Chirurgische Klinik, ²Medizinische Klinik, Universität Würzburg, Denmark*

Purpose: *H. pylori* infections of the stomach mucosa are believed to be involved in generation of stomach cancer. We investigated the humoral response to *H. pylori* infection on the IgM level, by selecting those cross-reacting with *H. pylori* and stomach cancer cell line 23132.

Methods: We isolated monoclonal IgM antibodies from stomach cancer patients and selected them for reaction with *H. pylori* lysates in Western-Blots. The antibodies were tested in proliferation assays and analyzed by sequencing the antibody variable regions. Also we examined the IgM fraction from sera of stomach cancer patients by proliferation assay and Western Blots analyses.

Results: The monoclonal antibodies showed a strong reaction with *H. pylori* lysates. We found a predominantly expression of IgMs homolog to germline gene DP-49. Stimulation of gastric cancer cells was observed by the MTT-proliferation assay. Western Blotting and proliferation assay with sera from gastric cancer patients revealed similar properties.

Conclusion: Our data indicate a functional role of IgM antibodies and we believe that these antibodies play an important role in the initiation and progression of stomach cancer and can also be used as a marker of disease.