

nation regimens have been investigated to improve results. Modiano et al (ASCO 1993; 12: 303) with the ELF regimen (etoposide, folinic acid, and 5-fluorouracil) plus interferon obtained 6/7 partial remissions in pts with APC. Considering these interesting results and the therapeutic activity of Epirubicin in this disease, we started a study (GOIM 9405) to verify the efficacy and safety of the ELFE regimen.

Patients: Twenty-three pts with APC received etoposide 80 mg/m² day 1-3, Folinic Acid (levo-isomer form) 100 mg/m² day 1-3, 5-Fluorouracil 340 mg/m² day 1-3, and Epirubicin 60 mg/m² day 1. Treatment was repeated every three weeks. The main characteristics of the 20 evaluable patients were: sex (M/F): 16/4; median PS (Karnofsky): 90; median age: 63 years; previous surgery: radical 3, biopsy 17; site of disease: primary tumor 17, liver 12, lymphnode 7, bone 2; multiple sites: 16.

Results: We obtained 3 PR (15%), 4 SD and 13 PD. The duration of responses were 3+, 6+ and 9 months, respectively. The median duration of survival was 4 months. Grade 3-4 toxicity (WHO criteria) were as follows: leukopenia 13%, diarrhea 17%, mucositis 22%, loss of hair 61%.

Conclusion: The ELFE regimen demonstrates scarce activity in pts with APC, with mild toxicity.

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POSTER

Helicobacter pylori infection and gastric carcinoma

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Purpose: *Helicobacter pylori* (H.p.) infection, though to be casually related to chronic gastritis or duodenal ulcer, may also be associated with an increased risk of gastric cancer.

Methods and Patients: To determine whether an association with gastric cancer does exist, we evaluated gastroscopic biopsies from 166 pts with histologically confirmed gastric adenocarcinoma, minimum 2 biopsies from antral mucosa, corporal mucosa and 4 biopsies around carcinoma from endoscopically unchanged mucosa were taken. These results were compared with 392 pts without gastroscopic changes at gastric mucosa. These samples were pathologically determined at H.p. with modified Giemsa stain. The risk of H.p. infection in the case patients relative to the control subjects was estimated with the use of Odds ratio (OR).

Results: H.p. were detected at antral mucosa in 65.68%, at corporal mucosa in 68.80% and at mucosa around carcinoma in 70.16% pts with adenocarcinoma. In pts without gastroscopically changes H.p. were detected at antral mucosa in 44.67% and at corporal mucosa in 42.76%. A significant association was found for H.p. infection and gastric carcinoma at antral and corporal mucosa (OR = 2.62, 95% CI = 1.91-3.60) and between H.p. infection and gastric carcinoma at mucosa around carcinoma (OR = 3.53, 95% CI = 2.30-5.43).

Conclusion: Our results support the hypothesis of a relationship between H.p. infection and the development of gastric adenocarcinoma.

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POSTER

CEF chemotherapy for advanced gastro-oesophageal cancer

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ECF chemotherapy is active in advanced gastric carcinoma with higher OR%, relapse free and overall survival compared to FAMTX. Infusional 5FU is associated with central venous catheter (CVC) complications resulting in line removal in 15% of patients (Webb et al. *J. Clin. Oncol* 15: 261, 1997), although complications were reported in 30% of pts previously. However, other investigators have reported higher CVC rates. We evaluated a combination of epirubicin 50 mg/m², cisplatin 60 mg/m² and 5 FU 600 mg/m² (CEF) given as a short infusion every 3 weeks. 23 patients were treated 18 M:5 F; median age 59 (30-73) with good PS WHO 0-11 pts; 1-6 pts and 2-6 pts. 7 pts had gastric, 13 gastro-oesophageal and 3 oesophageal carcinomas. 15 pts had poorly diff tumours. Measurable disease was predominantly lymphadenopathy (12 pts) and liver (7 pts). A total of 79 courses were given, a median of 3 cycles/pt. 5 pts achieved a PR (22.7%) with symptom improvement in 12/20 (60%) of pts. Median TTP of 4.5 mths with median survival 6 months (23% and 5% 1&2 year survival). 6 cycles were delayed due to myelosuppression with 1 neutropenic death. 2 pts developed grade 3/4 (WHO) thrombocytopenia and 1 pt grade 4 anaemia. Other toxicities were mild, 1 pt with grade 4 N&V.

The activity of this regimen was disappointing although many patients obtained symptomatic benefit. In comparison with ECF the patients received

less chemotherapy (median 3 cycles). CEF is an easy to administer regimen that offers good palliation in pts not suitable for intensive chemotherapy.

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POSTER

Recurrence and prognosis after curative resection for early gastric cancer

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Purpose: Even after curative resection of early gastric cancer (EGC), a small percentage of patients experiences local or distant recurrence.

Methods: Between 1969 and 1993 we treated 320 consecutive patients with EGC (153 submucosal and 143 mucosal carcinomas). For the follow up study we excluded 24 patients (7.5%) who died within 3 months after resection. There were 105 (35%) women and 191 (65%) men ranging in age from 25 to 87 years (median: 62). Follow up is complete until 31.12.95 for all 296 patients.

Results: 20 patients (6.8%) experienced disease recurrence: local recurrence appeared in 6 patients (2.0%), 12 patients (4.1%) suffered from distant metastases and 2 patients (0.7%) showed a combination of these. Except of 2 patients who died without tumor, 18 (6.1%) patients died of EGC recurrence.

Other carcinomas were apparent in 50 patients: 26 (8.8%) carcinomas metachronously (only 5 in the residual stomach) and 24 carcinomas synchronously or in the past. 26 patients (8.8%) died because of this malignancy.

At the end of follow up 140 patients of the total had died (47.3%). The death rate associated with other causes (120 patients, 40.5%) surpassed that of EGC recurrence (18 patients, 6.1%) significantly. Thus the cumulated 10-year-survival rate of the 246 patients without concurrent carcinomas was 98 ± 13%, this one of the remaining patients was 30 ± 18%.

Conclusion: It is rare for EGC to recur after curative resection and to die of it even more so. The results suggest the importance of other causes besides the cancer's recurrence in limiting the survival.

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PUBLICATION

Concurrent chemo-radiotherapy for epidermoid anal cancer treatment

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Since 1992 to 1996, 12 consecutive patients (pts) (median age: 62 years) with untreated epidermoid anal cancer: T2, 58%; T3, 42%; N+, 25%; have been treated with a simultaneous chemo-radiotherapy (CT-RT) treatment.

Methods: CT consisted of 24-hour i.v. infusion of 5-FU, 750 mg/m² days 1-4 and CDDP, 100 mg/m² i.v. infusion day 1; every 21 days. All the pts received 3 complete cycles of CT and concurrent RT given at a daily dose of 1.8 Gy up to a total dose of 36 Gy in 4 weeks, to the ano-perineal region, middle and lower pelvis, inguinal and external iliac nodes.

Results and Conclusion: an acceptable toxicity (leucopenia, proctitis and diarrhea) has been well controlled with topic or systemic treatments. A CR was assessed in 10 pts (83%), 2 pts in PR (N+) had a "Miles" operation. After a median follow-up of 3 years, 10 pts (83%) are alive without evidence of disease. In short, this regimen has been well tolerated and effective. Up to now, it represents the treatment of choice for anal cancer at all stages, while surgery must be used like a rescue treatment for pts in PR or with recurrence of disease.

1275

PUBLICATION

Intraarterial polychemotherapy and intraabdominal therapy with immobilized chemodrugs in radical treatment of patients with III-IV stage of gastric cancer

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Purpose: Systemic polychemotherapy in combine treatment of extensive gastric cancer has insufficient efficacy. The regional intraarterial chemotherapy (IACT) before surgical treatment and intraabdominal chemotherapy with immobilized cytostatics (IC) during operation was evaluated.

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.

1276

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)

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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)

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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

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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

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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.

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PUBLICATION

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

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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