No distant metastasis, no pretreatment and no second malignancies were allowed.

Localisation: head 88% (n = 79), corpus 11% (n = 10), tail 1% (n = 1) of the pancreas.

Grading (n = 81): G1: 12.5% (n = 10), G2: 33.5% (n = 27), G3: 48% (n = 39), G4: 6% (n = 5)

Radiotherapy: Total dose 44.8 Gy to the 90% isodose in 28 fractions of 1.6 Gy each applied in 2 fractions a day.

Chemotherapy: FA 300 mg/m^2, 5-FU 600 mg/m^2 (day 1–3 of radiotherapy), repetition 4 weekly.

Results: Median progression-free interval: 7.8 mts
Median survival time (all patients): 12.8 mts
One-year-survival-rate: 52.7%
Severe side effects (WHO-grade 3 and 4):
nausea/vomiting: 14.5%
diarrhea 0.0%
leuco-/thrombocytopenia: 10.0%
mucositis: 7.2%

Conclusions: This combined modality treatment improves the median survival rate to 12.8 mts for all patients comparable to other studies. The treatment duration could be reduced in comparison with similar treatments. Continuing this study and modulation of the therapy schedule will show more information about this effective palliative treatment.

1252 POSTER

Early postoperative intraperitoneal chemo-immunotherapy after curative gastrectomy for stomach cancer

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This prospective randomized study of the patients with primary stomach cancer was designed to determine clinical results of early intraperitoneal chemo-immunotherapy after curative gastrectomy. 53 pts with morphologically proven gastric cancer of stage II or III were treated surgically (gastrectomy). After operation (from the 5th day) all pts have received 5-FU 1 g/m2 + TNF-α 2 × 10^6 IU/m^2 + ds-RNA 8 mg intrapentoneally during ten days. Control group (74 pts) underwent surgical treatment without intraperitoneal chemo-immunotherapy. In pts group who were treated with chemo-immunotherapy three years survival rate was 64.2%, in control group three years survival rate was 55.4%. We observed 12 pts (22.6%) with relapses in chemo-immunotherapy group and in control group there were 36 pts (48.6%) with relapses. This difference was statistically significant. So, we conclude that early postoperative chemo-immunotherapy in pts with stomach cancer is effective. This method decreased the count of relapses in pts after surgical treatment.

1253 POSTER

Computer-assisted optimization of pancreatic treatment

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Purpose: Pancreatic cancer represents a particular challenge for treatment planning and was chosen to test the hypothesis that computer-aided optimization using a genetic algorithm can reliably produce treatment plans which meet or exceed the results of standard planning techniques.

Methods: Patients were planned according to a consistent protocol: 50 Gy to the target isocenter with beams having a 2.0 cm margin around the clinical target volume. Dose volume constraints applied were as follows: ≤18 Gy to 33% of the kidneys, ≤30 Gy to 33% of the liver, ≤45 Gy to 100% of small bowel, ≤45 Gy to the spinal cord. A score function was developed that favored target dose uniformity and simultaneously penalized distributions violating the dose constraints. Plans were optimized using a genetic alorithm (GA Ezzell, Med Phys 23: 293–305. 1996). Axial and non-axial beam arrangements were compared to a standard three-field distribution.

Results: Optimized plans consistently scored higher than standard plans. Non-axial plans tended to score higher than axial plans.

Conclusion: These results demonstrate that computer-aided optimization can improve conventional planning using a feasible number of beams and standard treatment equipment.

1254 POSTER

Long follow-up of gastric lymphoma

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Purpose: Gastric lymphoma is classified as low-grade MALT (mucosa-associated lymphoid tissue) and high-grade primary gastric lymphoma (PGL) a difference that may be more apparent than real. We analyzed the clinical characteristics and survival of 27 patient with PGL diagnosed in our hospital between February 1982 and December 1995.

Results: At a mediam follow-up of 56 m (17–155) 25 of the 27 patients are alive. Overall survival at 7 y is 93% and relapse free survival (RFE) 87%. We do not find any statistically significant difference in survival between low, medium and high-grade neither between MALT and no-MALT PGL nor Helicobacter pylori positive or negative.

Male/female	13/14
Median age	56 y (18–82)
Fenotype B	27/27
MALT/No MALT	14/13
Helicobacter (+)	9/18
Stage IE	8 (30%)
IIE	11 (41%)
IIIE	1 (3%)
IVE	7 (26%)
Grade. High	11 (41%)
Medium	4 (15%)
Low	12 (44%)
Treatment: Surgery (S)	5 (18.5%)
Chemotherapy (QT)	6 (22%)
S+QT	13 (48%)
RT+QT	2 (7%)
S+QT+RT	1 (4%)

Conclusion: Primary gastric lymphomas, in any of its clinical presentations have a very favorable behavior. We do not find overall survival difference between Malt and no-Malt gastric lymphomas. (P = 0.7)

1255 POSTER

Paclitaxel (T) plus 5-fluorouraciL (5-FU): A novel and very active regimen for advanced gastric cancer (AGC). A phase II trial

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Purpose: To better explore the activity of T in AGC, and a possible synergism between T and 5-FU and their low toxicity profile.

Methods: Patients with AGC, CT naive, measurable disease, KPS > 50, life expectancy ≥3 months receive on outpatient basis: T −175 mg/m2 i.v. in a 3 hour infusion on day 1 with premedication and 5-FU −1.5 g/m2 i.v. in a 3 hour infusion on day 2, every 21 days (maximum of 7 cycles). A system to assess clinical benefit (CB) based on KPS, pain and weight gain was used in this trial.

Results: 31 patients were enrolled (20 male and 11 female) and 27 are eligible for evaluation. Median age was 61 (31–70). Median KPS 70 (60–80). 160 cycles of CT were given. There were 17 (63%) objective responses (95% C.I.: 44%–81%), including 5 (18.5%) CRs and 12 (44.57%) PRs. 2 patients had a minor response, with a great subjective clinical improvement. 3 CRs with extensive liver involvement had the response confirmed pathologically. 2 gastric CRs were confirmed by endoscopy and biopsy. The median overall survival is 12 months (1–19+). 1-year overall survival is 58%. The regimen was very well tolerated. Alopecia WHO grade 2 occurred in 2 patients and 3 in 24. Neutropenia grade 2 in 9% and 3 in 3%; infection grade 2 in 3%; allergy grade 1 in 2.5%; anemia grade 2 in 7% and grade 3 in 2.5%; oral grade 1 in 10%; neuropathy grade 1 in 33% and 2 in 1.7%; mialgia grade 1 in 26% and grade 2 in 4% and vomiting grade 1 in 12% and 2 in 4% of the cycles. CB responses were observed in 16 (59%) patients. Our in vitro studies with culture of gastric cell lines and so far some synergism between the two drugs has been demonstrated. This novel regimen is very effective in AGC, producing a high rate of ORs, at the cost of a very acceptable toxicity profile. It translated into clinical benefit and excellent palliation for the majority of the patients.

1256 POSTER

Surgical therapy of the squamous cell carcinoma of the thoracal esophagus

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Purpose: These carcinomas mostly are detected in an advanced disease. Thus there is a poor prognosis in survival for the patients.

Methods: Between 1986 and 1995 we treated 512 consecutive patients (450 men (88%) median age 59 years) with squamous cell carcinoma of the thoracal esophagus (upper:middle:lower third Δ 81 (15%): 167 (32.6%): 147 (28.7%) patients, other Δ 117 (22.9%) patients).

Results: 106 patients (20.7%) were resected curatively (R0 resection), 23 (4.5%) patients underwent noncurative resection and 383 patients (74.8%) had palliative therapy. At the time of the initial diagnosis in 48 patients (45.3%) of the 106 R0 resected regionary lymph node metastases were evident (the border lymph node in 16 patients (15.1%)). The category pT0/T1 was shown in 32 patients (30.2%), pT2 in 16 patients (15.1%) and pT3 in 52 patients (49.1%).

The overall 5-year-survival rate was the best for the lower third, followed by the middle and the upper third: 18 ± 10% vs. 12 ± 6% vs. 10 ± 8%. This one for the nonresected differed with 3 ± 3% significantly. It also differed significantly from this one of the R0 resected patients, who survived in 28 ± 8%. Within the group last named there still is a significant difference according to the pT category: pT1 Δ 68 ± 19 years, pT2 Δ 29 ± 35 years and pT3 Δ 24 ± 15 years.

Conclusion: The sole therapeutic option for an acceptable survival is R0 resection of the tumor in the category pT0/T1. Thus the main problem seems to be the early detection of this kind of cancer. Another important approach might be the (neo)adjuvant therapies, but our absolute number of patients treated in this way still is too small for a final assessment.

1257 POSTER

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

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Purpose: To evaluate the safety and therapeutic activity of continuously infused MMC in metastatic gastric cancer patients with disease recurrence or progression following first-line chemotherapy (ctx).

Patients and Methods: Pts were treated with MMC 20 mg/m² i.v. over a time period of 120 h followed by a 3-weeks rest under prophylacticlly applied prednisone 50 mg p.o. for 5d. 13 pts were enrolled and all were assessable for toxicity and 11 for response (2 pts evaluable but not measurable). Pts characteristics: Median age: 53 years (32–68); Sex (m/f): 10/3; Karnofsky status: 65% (50–90); Previous ctx: Bolus 5-FU/FA n = 5 (38%), ELF n = 4 (31%), EAP n = 3 (23%), c.i. 5-FU/FA/DDP n = 1 (8%); Resection of primary tumor n = 5 (38%); Site of metastases: hepar n = 12 (92%), locally advanced n = 7 (54%), peritoneum n = 7 (54%), pulmo n = 4 (31%), bone n = 1 (8%).

Results: In 11 evaluable pts 1 CR and 4 PRs were observed (ORR: 45% [$CI_{95\%}$: 15.4–75.4%). The median response duration was 3.5 mon (2–6), the median survival 4.8 mon (2.7–8.6). Median number of treatment cycles was 2 (1–6). WHO °III/IV mucositis, diarrhea and fever/infection occurred each in 1 pts. Cumulative thrombo- and leukocytopenia (WHO °III/IV) were observed in 3 and 1 pts and treatment had to be stopped early in 1 case. No severe renal dysfunction, pulmonary toxicity or evidence of hemolytic uremic syndrome was observed. Fatigue during the 120 h-infusion of MMC was common (5/13 pts).

Conclusion: The incidence of severe and cumulative thrombocytopenia was 15% in 13 pretreated pts receiving 120 h c.i. of MMC as salvage ctx. Other side-effects were rare. No renal side effects or hemolytic uremic syndrome occurred Based on a small number of pts c.i. infusion of MMC has favourable single-agent activity in advanced gastric cancer progressing during or shortly after 5-FU- (ELF, 5-FU/FA) or anthracycline-(EAP) based ctx.

1258 POSTER

Liver resection and liver transplantation for primary hepatocellular carcinoma

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Purpose: In case of still circumscribed hepatocellular carcinomas (HCC), the sole curative therapeutic option providing a reliable prolongation of live, is surgical removal. We compared different surgical approaches.

Methods: Between 1980 and 1994 we treated 181 consecutive patients with HCC, 93 patients between 1980 and 1989 (first group), and 88 patients between 1990 and 1994 (second group). There were 34 (19%) women and 147 (81%) men ranging in age from 22 to 81 years (median: 61 years). The median follow up time was 75 months.

Results: The resection rate for the first group was 37% (34/93) and for the second group 59% (52/88) (p = 0.02) whereas the postoperative mortality was reduced from 35% to 19% (n.s.). Two of 13 (13%) patients of the second group died after liver transplantation. The 5-year-survival rate of the total 181 patients (without postoperative mortality) for the second group (n = 77) was significantly better than for the first one (n = 78) (32 ± 31% versus 12 ± 7%).

This result was significantly influenced by the kind of therapy and the possibility for curative resection. For the curative resected a significant correlation was shown for pT classification, pathological stage and grade of malignancy. A cirrhotic liver and multiple tumours in one lobe were of no significant influence.

Conclusion: The results after liver resection or liver transplantation for HCC nearly approach the survival rates for other gastrointestinal carcinomas. Thus, only if curative treatment is not possible because of concomitant factors, palliative therapies may be employed.

1259 POSTER

A phase II study of chronomodulated (CHR) 5-fluorouracil (5-FU) and leucovorin (LV) in combination with epirubicin (EPIDX) and Cis-Platin (CDDP) in the treatment of metastatic gastric carcinoma (MGC)

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PELF is an active regimen in MGC although is associated with moderate to severe toxicities. Some studies have demonstrated that a circadian infusion pattern of 5-FU and LV can improve antitumor activity while reducing toxicity. In preclinical studies we have demonstrated that the administration of CDDP after 5-FU improves the synergism of the two drugs. Based on these studies we have treated 23 patients affected by MGC with a modified schedule of PELF. Patients characteristics were as follows: M/F: 19/4, median age 60 years (range 34–71), single metastatic sites in 16 pts and multiple in 7. The initial treatment was Epidx 75 mg/m² day 1 i.v. bolus, Cis-Platin 75 mg/mq day 8 i.v. bolus and 5-Fu 200 mg/m²/day +LV 5 mg/m²/day as a i.v. continuous CHR infusion (g.1- > 14), with 68% of 5-FU and LV dose administered between 4 pm and midnight. Cycles were repeated every 28 days. After the initial 10 pts 5-FU dose was reduced to 150 mg/mq/day, Epidx and CDDP dose to 60 mg/mq because of severe mucositis in 40% of pts and 2 toxic deaths (both because of grade 4 mucositis and sepsis). Total cycles administered were 69 (range 1–6) and all the patients are evaluable for toxicity. In the initial schedule (10 pts) toxicity gr. 3–4 was the following: stomatitis in 4 pts (40%), diarrhoea in 2 pts (20%), vomiting in 1 pts (10%), leucopenia in 3 pts (30%) and thrombocitopenia in 1 pts (10%). In the reduced schedule (13 pts) the only grade 3–4 toxicity observed was stomatitis in 2 pts (15%). 13/23 pts are evaluable for response: 5 CR, 2 PR, 1 MR and 5 PD were observed (RR 53% and 95% confidence limit interval 25–91). Median time to progression was 4.5 months. Although the study is ongoing, preliminary results seem to support that CHR PELF we used has elevated activity in MGC and the reduced schedule is well tolerated.

1260 POSTER

Surgical therapy of gastric carcinoma in the elderly

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Purpose: Due to increased life expectancy, the number of elderly patients suffering from gastric carcinoma is continuously rising. We analysed our