series of resectable gastric carcinoma (n = 616, April 1986–July 1995) to look for the results of surgical therapy in elderly patients.

Methods: One hundred twenty six patients older than 75 years (20.5% male, n = 69, female n = 57, mean age 77.8 ± 3.5 years) were operated. All patient data were retrospectively studied with special regard to perioperative morbidity, mortality and survival (Kaplan-Meier, log-rank-test, $p < 0.05$).

Results: The majority of patients had at least two risk factors (69.8%, n = 88) in particular cardiovascular and lung disease. 26 patients had no risk-factors. Of all resections, 62.7% (n = 88) were classified as curative resection (R0). Postoperative morbidity and mortality rates were 26.2% and 4.1% respectively. Median survival after resection was 45 ± 4.4 months with statistically significant differences ($p < 0.05$) for R-classification and tumor stage.

Conclusion: Due to improved perioperative management, resection of gastric carcinoma in elderly patients is the treatment of choice. Although these patients often have age-related cardiovascular and pulmonary risk factors, postoperative morbidity and mortality even after extensive resection is low. Survival rates are comparable to younger patients and the prognosis is best after R0 resection, which therefore should be the goal of surgery for gastric carcinoma in elderly patients.

1261 POSTER

Double biochemical modulation of cisplatin, leucovorin and 5-fluorouracil in advanced gastric cancer

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Purpose: This phase II study was designed to evaluate the activity, safety and tolerability of weekly cisplatin (CDDP), leucovorin (Lv) and 5-fluorouracil (5-FU) in patients (pts) with advanced gastric cancer (AGC).

Methods: Between 9/93 and 8/96 28 patients (pts) with AGC were treated with CDDP 33 mg/m^2 as a 1-hour infusion, Lv 300 mg/m^2 in bolus and 5-FU 500 mg/m^2 in bolus, days 1.8 and 15 every 28 days, in an outpatient clinic. All but one had measurable disease by CT scan. Median age was 58 years (range 44–79). Nine were female and 19 male. Six pts were performance status (PS) 0, 18 pts PS 1 and 4 pts PS 2. Thirteen pts had primary metastatic disease. 17 pts had liver metastasis. All were evaluable by WHO criteria for toxicity and 24 for response (4 pts died of intercurrent disease). A median of 4 cycles were given (−9).

Results: Intent to treat analysis (N:28): Three pts (11%) had CR, 12 (43%) had PR, for an overall response rate of 54% (95% CI: 36%–72%), and 5 (18%) pts had stable disease. Median survival was 45 weeks for all the group (range 2–170+). Severe toxicity included neutropenia grade 3 in 8 pts and grade 4 in 2 pts, thrombocytopenia grade 3 in one and diarrhea grade 3 in 2 patients. Minor toxicity was grade 1 neuropathy in 11 and grade 2 in 2; grade 2 stomatitis in 2; grade 2 diarrhea in 5; grade 1 asthenia in 3; grade 2 nausea and vomiting in 12. Eight pts required blood transfusion.

Conclusion: This outpatient regimen has showed remarkable responses with excellent tolerability in AGC, survival ranks equally with more toxic regimens.

1262 POSTER

Treatment of hiliar cholangiocarcinoma (Klatskin's tumour). Our experience

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Between 3/89 until 1/97, 50 patients (pts) (30 males and 20 females) with hiliar cholangiocarcinoma (HCC) have been treated in our Hospital. In 33 pts (66%) the treatment were a palliative cutaneus transhepatic biliary drainage tube (group 1). In 17 pts (34%), radical surgical resection were performed (group 2): 7, all of them with Bismuth IV, liver transplantation (LT) and the rest, biliary resection +/− partial hepatectomy. Combined chemotherapy (5Fluorouracil+ Mytomicin C) and radiotherapy was performed in 13 pts: 2 of group 1 and 11 of group 2 after surgical resection.

Results: Secondary complications to the treatment were: Group 1: 21 pts (64%) (15 cholangitis, 4 septic shock, 4 biliary blockage, 4 gastrointestinal hemorrhage, 4 pancreatitis). Group 2: 12 (70%) (4 abdominal abscess, 3 biliary fistulae, 2 septic shock, 3 others) without postoperative mortality. Median survival was: Group 1, 5 +/− 5 months (range 0–15); group 2, 17 +/− 14 months (range 0–51) ($p \approx 0.015$). Patients with LT had a median survival of 27 +/− 12 m (range 18–51) whereas pts with biliary resection 11 +/− 11 m (range 0–33) (non statistically significance).

Conclusions: Surgical resection is the treatment of choice for HCC, with a significance increase of survival without a high morbimortality. Although the number of pts is low, LT is an effective new approach to the treatment of Bismuth IV HCC.

1263 POSTER

Proposal for an international multi center study: E-cadherin mutationspecific antibody to detect exon deletion in diffuse type gastric cancer

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Background: E-cadherin, a membrane bound homophilic adhesion molecule, was shown to be mutated in diffuse type gastric cancer. Due to splice site mutations, Exon 8- and Exon 9-deletions were detected in 39% of the patients using RT-PCR and direct sequencing of the E-cadherin gene in malignant tissue. Monoclonal antibodies were subsequently generated against the fusion site of exon 8 and exon 10, that recognize only cells with exon 9 deleted E-cadherin, whereas wildtype E-cadherin is not recognized. On this basis a mutationspecific detection of malignant cells is possible. Due to the location of the mutated protein (transmembrane protein with presentation of the mutated part extra cellular) it might be a target for antibody based therapy. Additionally there are possibilities to prime the immune system to mutated protein by peptide vaccination.

Aim: Due to the small number of patients carrying the mutation we propose an international multi center study to evaluate:

1. Epidemiology of E-cadherin exon 9 deletion in high risk countries for gastric carcinoma 2. Prognostic impact of E-cadherin exon 9-deletions and possible correlation to clinical data 3. Planning of future trials concerning a) toxicological background of the underlying reason for the mutation and b) therapeutic approach using monoclonal antibodies, immunotoxins and peptide based vaccination.

1264 POSTER

Phase II study with 5-fluorouracil and Ginkgo Biloba extract in patients with pancreas CA

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Purpose: To evaluate the efficacy, tolerability and quality of life (QL) of 5-FU combined with Ginkgo Biloba extrakt (GBE 761 ONC).

Methods: 46 pts with pancreas ca were treated in a prospective phase II study. The treatment (day 1–6) was repeated every 3 weeks until PD. Response to therapy was evaluated after 2 and 4 treatment courses.

Results: At present 46 pts were included, 25 pts were evaluable for response up to now. All pts were assessed for tolerability and QL. We observed a complete response (CR) in 1 patient, a partial response (PR) in 1 patient, an no change (NC) in 12 patients and a progressive disease (PD) in 11 patients. 7 patients are still on study. 5-FU + GBE was well tolerated. The toxicity consisted mainly of myelosuppression and gastrointestinal symptoms judged as 5-FU related.

Conclusions: The combination 5-FU and GBE is well tolerated, the objective response rate is in the range already known from 5-FU alone therapy. Overall survival data presentation are in progress.

1265 POSTER

Teniposide, mitomicin C and cisplatin combination in treatment of advanced gastric cancer

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A pilot study was performed to assess the efficacy and toxicity of the combination – teniposide (Vm-26), mitomycin C (MMC) and cisplatin (DDP) in patients with advanced gastric cancer.

Patients and Methods: Twenty-four patients (Sex: M-14, F-10. Mean age 50.1.) with measurable advanced gastric cancer received MMC 5 mg/m2 i.v. 1 and 7 ds.; DDP 40 mg/m2 i.v. 2 and 8 ds.; Vm-26 60 mg/m2 i.v. 4, 5, 6 ds.. Interval 28 ds.. A mean number of cycles were four.

Results: 21 pts. are evaluated for response and toxicity. The overall response rate was 42.7% (CR-5/21 (14.2%); PR 6/21 (28.5%)). 6 out of