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base of 1595 gastric cancer admissions from 1985–1995. Relevant factors were analyzed by the Kaplan-Meier method and Log-rank test. Significant factors (p < 0.05) were subjected to Cox's multivariate analysis. Survival in a separate group of 288 patients explored but not resected served as a bench mark for comparison.

**Results:** The median age was 64 years and the male:female ratio 2.3:1. There were 145 R2 resections and 85 R1 for a median follow up time of 7 months (range 0–88) and overall median survival of 9 months. Median survival was 11 months for R1 and 8 months for R2 (p = 0.009) and 5.7 months for the 288 unresected patients. Median survival was 6 months for those with residual disease in visceral sites vs 11 months for non-visceral sites (p < 0.001). Multivariate analysis identified only R1 vs R2 resection and visceral vs non-visceral residual disease as being significant.

Conclusion: Palliative, R1 or R2, operations are of minimal, if any, value and in such the indication for operation should be confined to the relief of symptoms alone. Only patients with limited peritoneal or nodal metastasis showed some small survival advantage from non-curative gastrectomy over no operation at all.

1247 POSTER

### Gastric cancer: The value of limited lymph node dissection for early stage gastric cancer

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Purpose: In Japan, standerd lymph node dissection has been D2. However we have performed, limited lymph node dissection for especially early stage of gastric cancer. Limited lymph node dissection is D1 with #7, 8 a lymph node dissection and/or #9, 10, 11 lymph node sampling. The purpose of this study was to evaluate limited lymph node dissection in 130 gastric cancer in our institution.

**Results:** The age ranged 41 to 84 with an average of 63. Eighty three were male and 47 were female. Surgical procedure; 83 distal gastrectomy, 31 total gastrectomy and 12 inoperable. Lymph node dissection; D1:10, D1+ $\alpha$ :79, D2:26. The frequency of positive lymph node metastasis and positive lymphatic permeation based on the depth of invasion were summarized as follows.

| Depth of invasion    | m  | sm | pm | 88 | se | si |
|----------------------|----|----|----|----|----|----|
| total No.            | 39 | 27 | 14 | 11 | 28 | 7  |
| positive LN. meta    | 0  | 2  | 5  | 6  | 20 | 5  |
| lymphatic permeation | 0  | 11 | 8  | 10 | 23 | 6  |

Conclusion: Lymphatic permeation was positive in almost half of sm cases, however, lymph node metastasis was rarely positive, therefore, D1 or D1+ $\alpha$  could be a standard procedure for early stage gastric cancer.

1248 POSTER

# p53 Status as potential predictor for response to chemotherapy in locally advanced gastric cancer

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**Purpose:** Inactivation of p53 has been reported to be associated with resistance to chemotherapy. The significance of p53 status on clinical outcome of chemotherapy was assessed in locally advanced gastric carcinoma (LAGC).

Methods: 25 chemotherapy-naive patients with LAGC received a weekly administration of CDDP 30 mg/m<sup>2</sup>: epi-doxorubicin 35 mg/m<sup>2</sup>; 5 fluorouracil 500 mg/m<sup>2</sup>; 65-leucovorin 250 mg/m<sup>2</sup> and glutathione 1,500 mg/m<sup>2</sup>. After 8 chemotherapeutic administrations, patients were assessed for response. Biopsy specimens of primary tumors were analyzed for p53 status using monoclonal antibody Bp53-12.

Results: Characteristics of patients were: median age, 65 years (range 44–70); 16 males and 9 females; PS (ECOG) 0, 10; 1, 13; 2, 2; histology, 11 differentiated, 14 undifferentiated; site, cardias 7; body 8; antrum 10. Response rate (assessed with CT scan and endoscopy) among patients with not overexpressing p53 was significantly higher than that with overexpressing p53 (85.7% vs 14.3%, p = 0.007). Multivariate analysis showed an independent predictor for response for not overexpressing p53.

Conclusions: p53 status analysed before chemotherapy seems to be associated with response to treatment in LAGC. This may provide a useful guide to deciding upon neoadjuvant chemotherapy in patients with LAGC.

1249 POSTER

### Can surgery be replaced by radio-chemotherapy in the treatment of esophageal cancer?

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Purpose: Surgery claims to be the only radical treatment method for resectable cancer of the esophagus. Non-surgical treatment results in unresectable situations doubt the position of the surgeons.

Methods: Our protocol consists of external radiotherapy to the esopahgus (single dose 2 Gy, total dose 56-60 Gy) and chemotherapy (5-FU 1000 mg/m2/d, cisplatin 25 mg/m2/d) during week 1 and 5. The percutanous radiation follow 2 HDR-brachytherapy applications, 5 Gy each/0.75 cm distance from the applicator surface.

Between Jan 91–June 96 30 pat. have been treated, median age 59 y (41–76). 25 pat received the whole treatment course; 5 pat. did not receive brachytherapy because of acute oesophagitis (2) or refusal of esophagoscopy (3). Median tumor length was 7 cm (3–12), 26/30 pat. corresponded to tumor class cT3 or cT4.

Results: 24/30 pat had endoscopically complete response. 4 pat. developed a local recurrence after 5, 6, 12 and 20 months. In 9/30 pat. we observed hematogenic metastases. Median survival was 21 months, 1-and 2-year survival rates were 74% (48%–88%) and 48% (22%–69%).

Conclusion: This non-surgical treatment is not only a substitute method for treatment of esopahgeal cancer but it can be a true alternative with similar results concerning loco- regional tumor control.

1250 POSTER

# Pylorus preserving partial duodenopancreatectomy for ductal pancreatic carcinoma

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In a study compiling the data in a prospective manner, the validity of the pylorus preserving duodenopancreatectomy (PPPD) in comparison to the partial duodenopancreatectomy (PD) in patients suffering from ductal pancreatic carcinoma were assessed concerning postoperative morbidity, mortality and overall prognosis of the disease. From May 1990 to April 1995 130 patients entered the study. 61 underwent PD, 69 patients had a PPPD. The patients were regularly followed-up every 6 month and the median follow-up period for all patients was 36 months. The PPPD in patients with ductal pancreatic head carcinoma without infiltration of the duodenum is the technically simpler and faster operation method with significantly less blood loss. Moreover, PPPD did not lead to increased postoperative complications. The median survival rate of patients in the PD group was 10.8 months, in the PPPD groups 21 months. This significant difference derives from the fact that the tumor stages were unevenly distributed. Regarding the most common stage (stage III according to UICC) the median survival times were almost identical (in the PD group: 10.1 months, in the PPPD group 11.2 months). Therefore, the PPPD operation seems to be a sufficient radical procedure which does not worsen the prognosis of the disease.

1251 POSTER

Feasibility and phase II study of combined modality treatment with accelerated radiotherapy and chemotherapy in patients with locally advanced inoperable carcinoma of the pancreas

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Purpose: This study was developed to evaluate a palliative therapy for prolonging survival and stabilizing quality of life because of the unfavourable prognosis of advanced, inoperable adenocarcinoma of the pancreas.

Methods: From 8/90 to 12/96 90 Patients (33 female/57 male) with locally advanced, inoperable and histologically proven adenocarcinoma of the pancreas were included. The mean age was 61.8 years.

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<sup>2</sup>, 5-FU 600 mg/m<sup>2</sup> (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- $\alpha$  2  $\times$  10 $^6$  IU/m² + 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 pylor positive or negative.

Male/female 13/14 Median age 56 y (18-82) Fenotype B 27/27 MALT/No MALT 14/13 9/18 Helicobacter (+) Stage IE 8 (30%) 11 (41%) ШE 1 (3%) IVE 7 (26%) Grade. High 11 (41%) Medium 4 (15%) 12 (44%) Low 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.