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Pancreatic cancer: The analysis of prognostic factors in patients with pancreatic cancer with distant metastasis

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Purpose: Because of difficulties in early detection of pancreatic cancer, significant number of patients are diagnosed with distant metastatic lesions. Pancreatic cancer with distant metastas is a rapidly progressive disease, and candidates of systemic chemotherapies should be selected under consideration of their short survival time. We analyzed prognostic factors in patients with pancreatic cancer with distant metastasis retrospectively to identify the significant prognostic factors.

Methods: 69 patients with pancreatic cancer who admitted to the center from Oct. 1992 to Dec. 1997 with distant metastasis but without any therapies. They were histologically or cytologically diagnosed as adenocarcinoma of the pancreas. Twenty-nine patients received systemic chemotherapies with or without radiation therapy and the others received the symptomatic treatment. Pretreatment clinical variables (age, sex, performance status (WHO), location of primary tumor, site of metastasis, presence of ascites, pain, chemotherapy, total bilirubin, hemoglobin, platelet count, albumin, total cholesterol, cholinesterase (ChE), tumor markers (CEA, CA19-9), prothrombin activity) were examined by using univariate analysis. Significant variables were analyzed in Cox proportional hazards model to identify the independent prognostic factors.

Results: The overall median survival time (MST) of all patients was 61 days, and 1 year survival rate was 0%. Significant poor prognostic factors were over the age of 60 years old, the presence of ascite, a total bilirubin >2 mg/dl, a prothrombin activity <70%, a ChE <180 mg/dl, and a performance status >1 ($p < 0.01$). The presence of pain, having chemotherapies, metastatic hepatic lesions or a higher level of tumor makers (CEA, CA19-9) were not significantly related to MST. The independent poor prognostic factors using Cox proportional hazards model were a presence of ascites, a serum ChE level of <180 mg/dl, and a age > 60. Higher hazard ratios were recognized as the following order: ascites, ChE, and age factors. MST of the patient without ascites was 85 days and, that of with ascites was 25 days. MST of those with a serum ChE level of <180 mg/dl were 34 days, and a age over 60 was 45 days respectively.

Conclusion: This study indicated that patients who had poor prognostic factors such as a presence of ascites, ChE < 180 mg/dl, or age > 60 should not be eligible for chemotherapies because of their extremely short survival time.

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Selective arterial cytostatic infusion combined with chemoembolization in hepatic tumors

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Purpose: Liver is a very frequent site of malignant tumors with a conventionally low success rate of treatment locally and low survival generally. Thus, an alternative therapy is to be initiated rather than i.v. chemotherapy or major hepatic surgery.

Material and Methods: In 53 patients in 132 cycles all together 708 cytostatic infusion was given combined with 120 chemoembolization.

Results: In 41 patients the progression of the malignant process stopped or regressed. In 9 cases the progression was not effected and in 3 (very much advanced diseases) a deterioration was observed. The complication rate was very low of 2% (14 cases of 708 cycle). The most common result of the treatment was the decrease or halt of the spread and growth of the focal intrahepatic disease frequently with signs of necrosis.

Conclusion: Intraarterial anticancer chemotherapy is indicated in focal hepatic malignancies based on its acceptable clinical results and low morbidity being comparable to those of intravenous chemotherapy.

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Neoadjuvant radiotherapy and chemiotherapy for advanced esophageal cancer

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Purpose: To determine the results of radiotherapy alone and combined with chemotherapy in the treatment of stage III esophageal carcinoma.

Methods: From 1990 to 1998 42 patients with stage III esophageal cancer, mean age 65.3 years, were treated in the Department of Radiation Therapy at the University of Rome "La Sapienza". Twentytwo patients underwent concomitant radiochemotherapy with external beam radiation, 45–50 Gy; 1.8 Gy 5/W, and chemotherapy, 5 FU 750 mg/m^2; day 1–5 and CDDP 50 mg/m^2 day 1. Twenty patients received radiotherapy alone, 50–60 Gy; 1.8 Gy 5/W. In selected patients, a boost of intraesophageal brachytherapy with 192 Ir, 10–20 Gy was administered.

Results: Of the 22 patients received radiochemotherapy, 9 have been subsequentely operated, 6 were pT0, nine patients had a complete response and 4 a partial response. Among 20 patients submitted to radiotherapy alone, 10 had complete response, 4 of them developed distant metastases after 4–7 months and 10 had a partial response. Acute toxicity particulary esophagitis (grade III: 3 cases) and hematologic side effects (grade III: 4 cases) were observed in patients treated with chemoradiotherapy (33%) and in patients treated with radiotherapy alone (25%).

Conclusion: Radiotherapy alone seems to have a significative local control in the advanced esophageal cancer, combined with chemotherapy even decreases the rate of distant metastases.

582 PUBLICATION

Weekly gemcitabine (GEM) and 5-fluorouracil (5-FU) in pancreatic carcinoma. Phase I-II study

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Introduction: 5-FU and GEM are the most active drugs in the treatment of pancreatic cancer. A randomized study comparing GEM and 5-FU showed an improvement of RR and clinical benefit in the group of pts treated with GEM. In order to evaluate toxicity dose limiting (TDL), the maximum tolerated dose (MTD), the efficacy of the association 5-FU and GEM also in term of clinical benefit, we began a phase I–II study with escalating doses of both drugs.

Methods: Inclusion criteria were: locally advanced or metastatic measurable adenocarcinoma of pancreas; PS (ECOG) = 2; normal hematological, hepatic, renal and cardiac function; life expectancy more than 3 months. Previous chemotherapy was not allowed. Three steps of 7 patients were projected. Chemotherapy was administered on days 1, 8, 15 every 4 weeks. I step: GEM 1000 mg/mq IV + 5-FU 1000 mg/mq IV bolus. II Step: GEM 1000 mg/mq IV + 5-FU 2000 mg/mq IV in 24 hours ci. III Step: GEM 1200 mg/mq IV + 5-FU 2250 mg/mq IV in 24 hours continous infusion. Up to now 17 pts were enrolled, 14 in the first 2 steps and 3 in the third step. All pts are evaluable for toxicity and clinical benefit, 14 are evaluable for response. Their main characteristics are: median age 54 y, 10 M/7 F, 5 stage IVA, 12 IVB, median PS (ECOG) 1.

Results: Altogether 77 courses of chemotherapy were delivered (37 step I, 33 step II, 7 step III); chemotherapy in day 15 was omitted in 5% of courses of step I and in 9% of the courses of step II. Grade 3–4 toxicity was observed only in step II: neutropenia in 12%, anemia in 6%, ALT/AST increase in 6% of courses. We observed 4 PR (2 in step I, 1 in step II e 1 in step III). Ten out of the 17 pts showed a clinical benefit from chemotherapy.

Conclusions: This schedule appears feasible at all the steps until now evaluated. Toxicity was accettable, clinical benefit was significant, response needs further evaluation.

583 PUBLICATION

Phase II trial of gemcitabine-UFT-leucovorin (ILV) in advanced carcinoma of the pancreas: Preliminary results

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Purpose: to evaluate the therapeutic activity and the tolerance of the combination Gemcitabine-UFT-LV in patients with advanced pancreatic cancer.

Patients and Method: 25 patients were included since sept-97, median age 59 (limits 45–71), male/female 14/11. Five patients (20%) had locally advanced disease and 20 (80%) metastatic disease. Fifteen patients (60%) had a performance status of 60–70, 14 (56%) moderate to severe pain and 17 (68%) weight loss greater than 5%.

Treatment consisted of gemcitabine 1500 mg/m^2 on days 1 and 14, i.v. l-LV 250 mg/m^2 in 2 hours on day 1 followed by oral l-LV 7.5 mg/12 hours for 14 days, and UFT 390 mg/m^2/day for 14 days. Courses were repeated every 28 days for a minimum of 3 per patient.