72 hours; the duration of HT-session was 45–50 min. In the 5th group (36 patients) we used HG 30–50 mmoll/l during 90–100 min. combined with HT after RT. Surgery was earned out after 14–16 day rest in all groups except 1st.

Results: Simultaneous application of RT, HT and HG intensified tumour damage, but increased the level of postoperative complications. The resection rate of the S, RT, RT + IBT, RT + HT and RT + HT + HG groups was 33.3%; 58.8%; 78.7%; 70.0% and 85.7%. The 3-year survival rates of the resected groups were 19.1%; 24.6%; 34.1%; 29.7% and 27.8%; accordingly.

Conclusion: The additional application of intracavitary irradiation is the most effective and safe proposed regimens.

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Concurrent chemoradiotherapy using low-dose continuous infusion of 5-fluorouracil for stage 2–3 esophageal cancer: A 3-year follow-up report

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Purpose: To improve local control of locally-advanced esophageal cancer, concurrent chemoradiotherapy with 5-fluorouracil (5-FU) infusion was tried under the cooperation of the Niigata RCT Research Group.

Material and Methods: 31 patients with stage 2–3 esophageal cancer were treated with the concurrent chemoradiotherapy using continuous infusion of 5-FU (250~300 mg/m^2 per 24 hours) for 5 days per week given over 25 to 35 days (RT + FU group). Treatment results were compared with the historical control of 27 patients treated with radiotherapy alone (RT group).

Results: The chemoradiotherapy regimen was well tolerated. Response rate (CR + PR) of 94% in the RT + FU group was significantly higher than 63% in the RT group ($p = 0.01$). Median local progression-free time of 31.2 months in the RT + FU group was significantly higher than 4.0 months in the RT group ($p = 0.02$).

Conclusion: This chemoradiotherapy regimen is significantly superior to conventional radiotherapy alone in locoregional control of stage 2–3 esophageal cancer.

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Intra-arterial chemotherapy (iaCT) combined with radiation (RT) for advanced pancreatic cancer

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Purpose: To evaluate the efficacy of intra-arterial infusion of cytostatic drugs combined with radiation in the treatment of patients with locally advanced and metastatic pancreatic cancer.

Methods: 29 patients were included in the trial. Catheters were inserted angiographically into celiac axis (18 pts.) or a.lienalis (11 pts.) and left in place for 4 consecutive days for each cycle. 5-FU (2–2.5 g/m^2), ADR (50–60 mg/m^2) and cis-DDP (40–50 mg/m^2) were infused over 120 min for 4 consecutive days. Radiation was started 3 days later and given in 5 daily fractions (2.5 Gy) per week (total dose 30 Gy). Combined treatment was given in a median of three cycles.

Results: Ten (34%) partial response was observed, as were thirteen cases (45%) of stable disease and six (21%) of progressive disease. Median disease free survival was 11.3 months. Toxicity was generally mild to moderate; leucopenia (8/29), nausea and vomiting (12/29) predominated.

Conclusion: iaCT with RT is feasible and well tolerated. This combination results in the improvement of local control in patients with advanced pancreatic cancer.

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Combination therapy with Oxaliplatin + Gemcitabine in advanced pancreatic cancer

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Encouraged by treatment results with a combination of oxaliplatin + 5-FU/FA in 10 patients suffering from colorectal and gastric cancer with 3/10 PR, 1 MR and 4 SD (8/10 second line, 8/10 tumor recurrences) we now treated in a pilot study 9 patients (2 m, 7 f, age 38–76) with advanced pancreatic cancer (n = 3 locally advanced recurrence (LR), n = 3 T3N1 tumors, 1 of these 3 tumors with ascites, and n = 2 with LRM1 and T3N1M1 tumors resp.), without prior chemotherapy, with a combination of Gemcitabine (G) + Oxaliplatin (Ox) by systemic i.v. application: G (mean 700 mg/m", 30 min. infusion) + Ox (mean 70 mg/m", 4 h infusion) on day 1 and 700 mg/m" Gemcitabine (30 min. infusion) on day 8, followed by a new cycle every 2 weeks. Treatment duration: 5, 5, 5, 6, 6, 6, 7, 8, >10 months. In case of allergic reactions, severe neuropathy or tumor progression therapy was partly continued by Gemzar-monotherapy or 5-FU/FA or Campto and Caelix resp. Diagnosis was confirmed by clinical signs, imaging methods, operation and/or histology. Efficacy was evaluated by clinical signs, US, CT, in special cases by MR and PET, and tumor markers, mostly CA 19-9 (determined every 4 weeks). Treatment resulted in 4 PR, 2 MR and 3 SD over more than 3 months (CT and US), and in 1 CR, 4 PR, 1 MR and 1 SD of the tumor markers (n = 2 TM negative). Progression free survival in the imaging methods 5, 6, 6, 6, 9, >9, >10, >10, >12 months. Survival since beginning of therapy: >9, 10, >10, 11, >11, >12, >12, >12, >16 months. As in studies with Mitomycin-C + Gemcitabine (R. Klapdor et al, J. Cancer Res Clin Oncol 124, 1998, R11) the relevant tumor markers, in most cases CA 19-9, more rapidly reflected tumor response and tumor relapse than the imaging methods, offering themselves as relevant parameters for control and evaluation of efficacy of palliative treatment regimens of pancreatic cancer in individual patients. Side effects: 2 allergic reactions about 5 months after beginning of treatment, in most cases transient neuropathy (grade I, II and II–III in 5, 2 and 1 cases).

Conclusions: The results offer a combination therapy with gemcitabine + oxaliplatin as a potentially active and well tolerated regimen for a phase II study.

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Local effect of cisplatin/epinephrine injectable gel on intrahepatic lesions of hepatocellular carcinoma (HCC)

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Purpose: To evaluate a novel intratumoral chemotherapy with cisplatin/epinephrine injectable gel (CDDP/epi gel) in patients with HCC. The gel formulation is designed to deliver high drug concentrations for extended periods.

Methods: Patients with histologically proven HCC with ≤3 tumors (≤7 cm maximum diameter, ≤200 cm^3 total volume) and no major vessel involvement or extrahepatic disease were enrolled. CDDP/epi gel (1 mL contains 4 mg CDDP, 0.1 mg epi) was administered with percutaneous intratumoral injection under ultrasound control. Up to 10 mL CDDP/epi gel was given 1×/wk for 4 treatments within 6 wk. Tumors were evaluated with magnetic resonance imaging (MRI) 2 wk before and after treatment to assess tumor necrosis as a marker of response. Hyperintense lesions depicted at the arterial phase of gadolinium-enhanced, turbo spin-echo T1-weighted sequence were considered viable tumors.

Results: Seven patients (12 intrahepatic lesions) for whom liver resection was contraindicated due to previous hepatectomy (1) or poor liver reserve (6) were treated. Before treatment, median tumor volume was 12.6 cm^3 (range 4–32 cm^3). After one or two cycles of CDDP/epi gel, MRI showed no viable tumor in 11 of 12 lesions and only 11% viable tumor in one. Side effects (in 36 treatment sessions) included fever (10), chills and rigor (4), abdominal pain (8), and nausea or vomiting (11); all were mild to moderate in severity and subsided with conservative management.

Conclusion: Initial evaluations by MRI suggest that intratumoral CDDP/epi gel appears effective in eradicating viable intrahepatic HCC. Further follow-up will determine the association of treatment-related tumor response, as measured by both MRI and 3-phase CT scans, and effect on patient survival or disease progression.