1 gm/m^2 on days 1–4 and days 29–32 and a bolus dose of mitomycin C 10 mg/m^2 on day 1.

Results: A total of 96 patients satisfied the inclusion criteria, 70% female. The median age was 62 years (range 33–86). T stages at presentation were: Tx 2%, T1 18%, T2 50%, T3 9%, T4 21%. Thirteen patients (14%) had involved inguinal nodes. Disease persisted after chemoradiation in 10%. At 10 years following commencement of radiotherapy a further 19% were estimated to have suffered locoregional relapse, 6% distant metastases and 19% death without known progression, leaving 46% surviving failure-free at 10 years. Estimated overall survival was 91% at 2 years, 72% at 5 years and 59% at 10 years. There were no significant differences in failure-free survival between T stages-T1, T2, T3, T4, between N0 and N1–3, between T1–2N0 and T3/T4/N1–3. Patients with tumours <4 cm survived significantly longer without failure than patients with larger tumours (P = 0.006). In terms of overall survival, there were no significant differences between T stages, between N0 and N1–3, between T1-2N0 and T3/T4/N1–3, or between <4 cm and >4 cm tumours.

Conclusion: In our experience, TNM stage for carcinoma of anus does not predict failure-free survival or overall survival in patients treated with chemoradiation.

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A phase II study of hypofractionated radiotherapy in combination with Gemcitabin in the palliative treatment of advanced pancreatic carcinoma

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Purpose: To evaluate the toxicity and palliation of hypofractionated radiotherapy in combination with gemcitabine in advanced inoperable pacreatic carcinoma.

Patients and Methods: A total number of 21 patients with recurrent disease after resection, primary irresectable and/or metastatic tumours were included. Gemcitabine (300 mg/m^2) was given at day 1, 8 and 15 at the same day of radiotherapy. CT-assisted radiotherapy consisted of 3 fractions of 8 Gy, once a week on the macroscopic tumour. From day 22, gemcitabine (1000 mg/m^2) was continued weekly. The mean number of courses was 12 (3–21). Al most all patients suffered from intractable abdominal pain.

Results: Treatment was generally well tolerated. Seventeen patients experienced mild nausea and vomiting and 7 patients experienced mild abdominal pain. In 7 patients, an increase of pre-existing pain was noted shortly after radiation. In 1 patient gemcitabine was not given before the third fraction because of hematological toxicity and in 6 patients dose reduction was needed. No significant changes of liver enzymes and renal function were noted. A significant reduction of the tumour marker CA 19.9 was observed in 14/17 patients (82%). Palliation of pain was observed in 13/18 patients (72%). Pain medication could be reduced in 11/15 patients (73%). The median survival was 16.2 months.

Conclusion: Hypofractionated radiotherapy in combination with gemcitabine in irresectable pancreatic carcinoma is well tolerated and offers good palliation.

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Phase I/II study of irinotecan combined with mitomycin-C in patients with advanced gastric cancer

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Purpose: Irinotecan (CPT-11) is a new active drug for advanced gastric cancer (AGC). Preclinical synergism has been reported in combination of CPT-11 and mitomycin-C (MMC) in human gastric cancer cell lines. To determine the maximum tolerated dose (MTD), the dose limiting toxicity (DLT), and preliminary anti-tumor activity, we conducted a dose escalation study of CPT-11 and MMC in patients with AGC.

Methods: MMC was administered as i.v. bolus, and then immediately followed by intravenous infusion of CPT-11 over 90 minutes. The treatment was repeated every other week. Granisetron was administered to prevent nausea and vomiting. The prophylactic use of granulocyte colony-stimulating factor was not planned. The planned dose escalation schedule for MMC/CPT-11 (mg/m^2) of each dose level was as follows; level-1, 5/100; level-2, 5/125; level-3, 5/150; level-4, 7/150; level-5, 10/150. MTD is determined when the incidence of critical toxicity (either grade 4 neutropenia "4 days, febrile grade 4 neutropenia, non-hematological toxicity "grade 3, or treatment delay due to any toxicity >7 days) exceeds 50% (2/3 or 3/6 patients).

Results:: Twenty-one patients was entered (3 at level-1, 7 at level-2, 6 at level-3, 3 at level-4, and 2 at level-5, respectively) and 20 patients were evaluable for toxicity. Patient characteristics were following; median age 61 yrs [range 46–73]; sex 18 male, 3 female; PS 0–4, 1–15, 2–2; macroscopic type; diffuse –4, non-diffuse –17; microscopic type; diffuse –19, intestinal –2. At level-1, no critical toxicity was observed. At level-2, the critical toxicity was observed in 2 of 7 patients (administration delay due to persistent leukopenia and grade 4 diarrhea). At level-3, the critical toxicity was observed in 2 of 6 patients (grade 4 neutropenia "4 days and grade 3 diarrhea). At level-4, no critical toxicity was observed. At level-5, the critical toxicity was observed in 2 patients (administration delay due to hematological toxicity and grade 3 diarrhea). At the present, partial responses were achieved in 8 of 16 patients evaluated (response rate; 50%). In eight chemotherapy-naive patients, partial responses were obtained in 6 patients (response rate; 75%). The chemotherapy could be continued on the outpatient-basis in all patients.

Conclusions: We determined that the maximum tolerated dose of CPT-11 and MMC was 150 mg/m^2 and 10 mg/m^2, respectively and that the recommended dose of CPT-11 and MMC for a phase II trial was 150 mg/m^2 and 7 mg/m^2, respectively. Additionally, the present study suggested the combination chemotherapy with CPT-11 and MMC should be very active against advanced gastric cancer. We will soon start a phase II study of this regimen.

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Stage-adapted radio-chemotherapy in anal canal carcinoma

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Purpose: The optimal combination of radio-chemotherapy in anal canal carcinoma has yet to be established. The advantages of stage-adapted therapy and the merits of different radio-chemotherapy combinations in advanced stages are analyzed.

Methods: 56 patients with anal canal carcinoma with a median age of 64 years (range 29–92) were treated. Median follow-up was 28 months (range 10–75 months). 8 patients with early stages received only local irradiation up to 60 Gy, 19 patients with T2 N0 stages were treated with a combination of 5-FU and 50 Gy, 29 patients with advanced stages received 50 Gy combined with 5-FU and Mitomycin C (14 patients) or 5-FU and Cisplatin (15 patients).

Results: Overall-survival was 80%, disease-survival 60% at 5 years. The local recurrence rate was 22%. None of the patients treated with a combination containing Cisplatin developed distant metastasis as compared to 36% in the Mitomycin C group.

Conclusion: Early stage patients can be successfully treated with irradiation alone or combined only with 5-FU. Advanced cases seem to profit more from a combined radio-chemotherapy regimen containing Cisplatin.

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Hepatocellular carcinoma: Adjuvant chemotherapy postliver transplant

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Background: Transplantation is sometimes recommended for hepatocellular carcinoma (HCC). Patients with cirrhosis in stage II to IVA have a median survival of 12 months following surgical resection or other local therapies. More than 86% of patients have a recurrence within the following 2 years. Liver transplantation has been occasionally used in these patients, with or without complementary chemotherapy.

Materials and Methods: Between 1992 and 1998, 9 patients underwent transplantation and subsequently received weekly doses of adjuvant doxorubicin 10 mg/m^2, for 20 weeks. All patients had hepatocarcinoma. Eight patients had cirrhosis (44.4% C virus, 0% B virus, 22.2% alcoholic, 22.2% cryptogenic, 0% metabolic hepatopathy). One patient had chronic active hepatitis. Classification was 33.3% stage II, 22.2% stage III, and 44.4% stage IV-A. Major vascular invasion was seen in 11.1%, microscopic invasion in 22.2%, and 44.4% had capsular invasion (11.1% pT2). Single tumorous nodules were found in 33.3%, multiple tumorous nodules in 1