## *Poster presentations* (Wed, 2 Nov)
## GI – non-colorectal cancer

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### Preliminary results of hypofractionated proton beam therapy for hepatocellular carcinoma

N. Fukumitsu[1], K. Tokuuye[1], T. Hashimoto[1], S. Sugahara[2], K. Kagei[1], M. Hata[1], K. Ohara[2], Y. Akine[1]. [1]*University of Tsukuba, Proton Medical Research Center, Tsukuba, Japan;* [2]*University of Tsukuba, Department of Radiation Oncology, Tsukuba, Japan*

**Purpose/Objective:** We have previously shown that proton beam therapy is effective and safe for patients with various conditions of hepatocellular carcinoma (HCC). The purpose of this study is to evaluate the efficacy and safety of hypofractionated proton beam therapy for HCC.
**Materials/Methods:** We treated patients having HCC with proton beam therapy to give 60 Gy in 10 fractions over 2 weeks when they met following criteria: patients had liver functions of Child-Pugh class A or B, had a solitary HCC less than 10 cm in maximal diameter and whose tumor was located more than 2 cm apart from the porta hepatis or digestive tract. Thirty-six out of 105 HCC patients, who were treated by proton beam therapy at University of Tsukuba from Sept. 2001 to Dec. 2003, met the criteria. The remaining 69 patients who were irradiated with other irradiation regimen such as 66 Gy in 22 fractions, 70 Gy in 35 fractions were excluded from this study. Of the 36 patients, 22 patients were men and 14 women. The median age was 66 years (26–85 years old). Twenty-six patients had Child-Pugh class A and 10 had B. The median tumor maximal diameter was 3 cm (0.8–9.3 cm). The patients were followed by CT or MRI every 3 months for 2 years after proton beam therapy and every 6 months after that. Two-year survival and local control rates were calculated from the beginning of proton beam therapy using the Kaplan-Meier method.
**Results:** The median observed period was 19 months (5–34 months). Thirty-one patients are alive and 5 dead at March 2005. The two-year survival rate was 70.3%. Local recurrence was observed in 2 patients at 16 and 18 months after the beginning of proton beam therapy, respectively. Two-year local control rate was 88.1%. Late complications of grade 2 or more were observed in 2 patients: one patient suffered from radiation pneumonitis (grade II) and rib fracture at 1 and 27 months after proton beam therapy; The other suffered from rib fracture at 8 months after proton beam therapy.
**Conclusions:** The irradiation regimen of a total dose of 60 Gy in 10 fractions appears effective and feasible for patients with HCC.

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### Postoperative chemoradiotherapy in gastric cancer – results of two parallel phase I-II studies of a fixed radiotherapy regimen with escalating doses of cisplatin and capecitabine

E.P.M. Jansen[1], H. Boot[2], A. Cats[2], R. Dubbelman[2], M.P. Saunders[3], V.S. Khoo[3], T.D.L. Crosby[4], H. Bartelink[1], M. Verheij[1]. [1]*Netherlands Cancer Institute, Radiotherapy, Amsterdam, The Netherlands;* [2]*Netherlands Cancer Institute, Gastroenterology, Amsterdam, The Netherlands;* [3]*Christie Hospital NHS Trust, Radiotherapy, Manchester, United Kingdom;* [4]*Velindre Hospital, Radiotherapy, Cardiff, United Kingdom*

**Background:** The prospectively randomized Intergroup Study INT-0116 has demonstrated that postoperative 5FU-based chemoradiotherapy improves survival and locoregional control in gastric cancer. These results stimulated us to evaluate whether treatment outcome could be further improved using increasing doses of the radiosensitizing drugs cisplatin and capecitabine during radiotherapy.
**Methods:** Between December 2002 and May 2005, 70 patients with $T_{2-4}N_{0-3}M_0$adenocarcinoma of the stomach or distal esophagus were enrolled in two parallel running phase I-II studies. Treatment started in both studies within 60 days after surgery with capecitabine 1000 mg/m$^2$ bid on days 1–14. Thereafter radiation started to a total dose of 45 Gy in 25 fractions of 1.8 Gy to the original tumor site, anastomoses and adjacent lymph nodes on weekdays during weeks 4 through 8. In the first study capecitabine given concurrently with radiation was escalated in groups of 20 patients per dose level from 600 to 900 mg/m$^2$ bid (planned maximum 1000 mg/m$^2$ bid). In the second study, both cisplatin and capecitabine were given concurrently with radiation. Cisplatin was administered in an escalating daily dose of 3 to 6 mg/m$^2$ (iv) and capecitabine was escalated from 250 to 650 mg/m$^2$ bid in groups of at least 3 patients per dose level.
**Results:** Up to May 2005, 47 patients have completed treatment with capecitabine only; one withdrew early due to anxiety. The full radiation and capecitabine dose were delivered to all patients. No grade III/IV toxicity was observed. In the cisplatin-capecitabine study 21 patients have completed treatment; one had to stop due to cisplatin allergy. Grade III toxicity consisted of neutropenia (n = 1); dysphagia (n = 1) and hand–foot syndrome (n = 1). One patient developed grade IV leucopenia (cisplatin 5 mg/m$^2$; capecitabine 575 mg/m$^2$ bid). In 3 additional patients in this dose level, no other DLT's have occurred. In the next dose level (cisplatin 6 mg/m$^2$; capecitabine 650 mg/m$^2$ bid) one patient developed grade IV trombopenia, so 3 extra patients will be accrued. There were no toxicity-related deaths.
**Conclusions:** In these two ongoing dose escalating studies with capecitabine and cisplatin given concurrently with radiation in postoperative chemoradiotherapy in gastric cancer, no non-manageable acute toxicity was observed until so far. Final results of acute toxicity are anticipated in the near future.

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### Late renal toxicity following post-operative chemoradiotherapy in gastric cancer

M. Verheij[1], H. Boot[2], A. Cats[2], B. Van Asselen[1], J. Stroom[1], M.P. Saunders[3], V.S. Khoo[3], R.A. Valdes Olmos[4], H. Bartelink[1], E.P.M. Jansen[1]. [1]*The Netherlands Cancer Institute, Radiation Oncology, Amsterdam, The Netherlands;* [2]*The Netherlands Cancer Institute, Gastroenterology, Amsterdam, The Netherlands;* [3]*Christie Hospital NHS Trust, Radiation Oncology, Manchester, United Kingdom;* [4]*The Netherlands Cancer Institute, Nuclear Medicine, Amsterdam, The Netherlands*

**Background:** Recent data indicate that post-operative chemoradiotherapy (CRT) improves clinical outcome in gastric cancer and that acute toxicity is acceptable. Data on late side effects, however, are scarce. Renal functional impairment represents one of the most serious late complications following abdominal radiotherapy. The aim of this study is to prospectively analyze renal function in patients receiving post-operative CRT for gastric cancer.
**Patients and methods:** Between December 2002 and April 2005, 77 consecutive patients with T2–3N0–3M0 adenocarcinoma of the stomach received post-operative CRT. Radiation (AP-PA technique) was given in 25 fractions of 1.8 Gy to a total dose of 45 Gy in 5 weeks. For plan comparison, dose distribution was recalculated in a subset of patients using an intensity-modulated radiotherapy (IMRT) set up. Concurrent chemotherapy consisted of 5FU (n = 12), capecitabine (n = 41) or capecitabine/cisplatin (n = 24). The relative renal function was assessed by $^{99m}$Tc-MAG-3 renography before and every 6 months after treatment.
**Results:** The mean volume (±SD) of the left and right kidney receiving *30 Gy (V30) was 62±25%, and 14±13%, respectively. The mean dose (±SD) to the left and right kidney was 31±9 Gy and 11±6 Gy, respectively. IMRT reduced the mean dose and V30 to the left kidney with 37% and 69%, respectively, while the dose to the right kidney and liver remained within the same range. With this IMRT technique an adequate dose coverage of the target volume was ensured. At the time of analysis, 28 out of 77 patients had received a baseline and at least 1 post-treatment renography. Baseline renal tests were normal in all patients. At 12 months after CRT the relative left kidney function had decreased to a mean (±SD) of 73±23% of pretreatment value.
**Conclusions:** At 1 year after CRT for gastric cancer a more than 25% decrease in left renal function is observed. Given the progressive nature of radiation nephropathy, this functional impairment will continue to increase over time. Therefore, IMRT should be used to minimize the dose to the kidneys and limit late renal toxicity in these patients.

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### Mature results of the French collaborative Phase II trial FFCD 9704-SFRO: preoperative concurrent chemoradiation in resectable pancreatic adenocarcinoma

F. Mornex[1], M. Ychou[2], N. Bossard[3], D. Smith[4], J.F. Seitz[5], C. Partensky[6], P. Rouanet[2], B. Chauffert[7]. [1]*Centre Hospitalier Lyon Sud, Radiation Oncology, Lyon Pierre Bénite, France;* [2]*Centre Val d'Aurelle, Oncology, Montpellier, France;* [3]*Centre Hospitalier Lyon Sud, Statistician, Lyon Pierre Bénite, France;* [4]*Hôpital Saint André, Gastroenterology, Bordeaux, France;* [5]*Institut Paoli Calmettes, Gastroenterology, Marseille, France;* [6]*Hôpital Edouard Heriot, Gastro-intestinal Surgery, Lyon, France;* [7]*Hôpital du Bocage Fondation Francophone de Cancérologie Digestive, Oncology, Dijon*

Over 80% of patients (pts) who undergo a potentially curative resection for pancreatic cancer develop local or distant recurrence. Neoadjuvant chemoradiotherapy might offer several potential advantages to these pts. In order to allow for further investigations in the neoadjuvant setting, we prospectively explored the feasibility of a chemoradiation regimen to pts with biopsy proven, potentially resectable pancreatic adenocarcinoma. The treatment scheme consisted of concomitant radiotherapy (50 Gy within 5 weeks directed at the pancreatic tumor and regional lymphatics)