48−84 years). Informed consent was obtained from all patients. Underlying pathology was squamous cell carcinoma (n = 24, 96%) and malignant melanoma (n = 1, 4%). The median total dose of radiotherapy to the primary tumor was 65 Gy (range, 60–70 Gy) given in 1.8 or 2.0 Gy single daily fractions. All patients were treated with concurrent chemotherapy consisting of two cycles of cisplatin or nedaplatin combined with 5-FU or docetaxel. All patients underwent FDG-PET scanning within several days of CRT completion. Maximum standardized uptake value (maxSUV) at the primary site was evaluated for CLR and LRFS in univariate and multivariate analyses. P values <0.05 were considered significant.
Results: See Table 1. Univariate analysis revealed that maxSUV cutoff values of 3.5 (P = 0.042) and 6.5 (P = 0.024) were significantly associated with CLR. Multivariate analyses showed that maxSUV > 3.5 was predictive of CLR. The log-rank test found that maxSUV cutoff values of 3 (P = 0.02), 3.5 (P = 0.014), 6.5 (P = 0.004), and 7 (P = 0.034) were related to LRFS. The multivariate Cox model revealed that maxSUV > 3.5 was significantly correlated with LRFS.
Conclusions: Early FDG-PET scans following curative CRT appears to be valuable in evaluating CLR and LRFS in esophageal cancer patients.

Table 1. Post-CRT FDG-PET assessment of clinical response at primary site[a]

SUV criteria	Sens. (%)	Spec. (%)	Accuracy (%)	P value	
				Univar.	Multivar.
SUV >2.0 vs. ⩽2.0	100	6	36	NS	NS
SUV >2.5 vs. ⩽2.5	100	18	44	0.527	0.953
SUV >3.0 vs. ⩽3.0	88	53	64	0.088	0.972
SUV >3.5 vs. ⩽3.5	88	59	68	0.042	0.029
SUV >4.0 vs. ⩽4.0	63	59	60	0.411	0.953
SUV >4.5 vs. ⩽4.5	50	65	60	0.667	0.928
SUV >5.0 vs. ⩽5.0	50	71	64	0.394	NS
SUV >5.5 vs. ⩽5.5	50	88	76	0.059	0.941
SUV >6.0 vs. ⩽6.0	38	88	72	0.283	0.946
SUV >6.5 vs. ⩽6.5	38	100	80	0.024	0.928
SUV >7.0 vs. ⩽7.0	25	100	76	0.093	NS

[a]Sens., sensitivity; Spec., specificity; Univar., Univariate analysis; Multivar., multivariate analysis; NS, not significant.

Abbreviations: CRT = chemoradiotherapy; FDG-PET = ^{18}F-fluorodeoxyglucose positron emission tomography; SUV = standardized uptake value.

3556 POSTER

The utility of PET in anal cancer

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Background: Functional imaging is becoming increasingly important in the staging and assessment of cancer patients. The aim of this study was to assess the utility of FDG-PET in anal cancer for staging, treatment response and detection of recurrent disease.
Methods and Materials: A retrospective study was performed on 50 patients that were identified with histopathologically confirmed epidermoid anal cancer referred to the Austin PET Center between 1996–2006. 45 patients were treated with curative intent (radical) mainly with combined chemo-radiation. The remaining 5 patients were treated with radiotherapy alone. PET imaging was initially performed on a Phillips Allegro PET scanner then subsequently on a Phillips Gemini PET-CT scanner from 2003. The median age of the patients was 58 years (36−85 years). The non-PET clinical staging including CT was of 8 Stage I (16%), 18 Stage II (36%), 22 Stage III (44%), and 2 Stage IV (4%) patients. PET was used in staging and following treatment to assess the response and detect recurrent disease. The PET results were correlated with clinical and pathological findings.
Results: Pre-treatment PET staging was performed in 48 patients. The primary tumor was excised in 7 patients and the PET scan was negative at primary site in all. In the 41 patients with a non-excised tumour, the primary tumor was strongly FDG avid in 40 (98%) patients compared to CT which detected 58%. PET upstaged 8 (17%) patients with unsuspected pelvic or inguinal nodal disease and downstaged 3 (6%). Post-treatment PETs were performed in 25 patients (median time of 17 weeks, range 9−28 weeks) of which there were 20 (80%) complete responses (CR) and 5 (20%) partial responses (PR). By 18 weeks, 15 of 16 scans (94%) performed showed a CR. The PRs were biopsy positive in 2 and negative in 3. At last follow-up, 10 of the 45 radical patients (22%) had developed recurrent disease of which 9 had PET scans. In seven patients, the PET scanning was used to confirm recurrence. In the remaining two patients, follow-up PET detected unsuspected recurrence where there was no prior clinical or radiological evidence of disease. All of the 9 PET detected recurrences were pathologically confirmed.
Conclusions: Anal cancer appears to be FDG avid and PET upstages nearly one fifth of patients. Therefore, PET is useful for staging of anal cancer and can assist in the identification of residual disease post-treatment and can aid in the detection of recurrent disease.

3557 POSTER

Phase I study of docetaxel, oxaliplatin and S-1 (DOS) for patients with advanced gastric cancer

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Background: Docetaxel, oxaliplatin and S-1 have shown significant single-agent efficacy in gastric cancer. These drugs have distinct mechanisms of action and no overlapped key toxicities. Furthermore, fluoropyrimidine and docetaxel or oxaliplatin have shown synergism in vivo studies and in clinical trials. We performed a phase I study of combination docetaxel, oxaliplatin and S-1 (DOS) to determine the maximum-tolerated dose (MTD), recommended dose (RD) and efficacy in advanced gastric cancer.
Methods: Eligible patients were those who had unresectable, locally advanced or metastatic, gastric adenocarcinoma. Both initially diagnosed and recurred patients with no previous history of chemotherapy except adjuvant chemotherapy were enrolled. The patients of age 18 to 70 with ECOG PS 0−2 were enrolled to this study. Docetaxel and oxaliplatin were administered intravenously on day 1 and S-1 was administered orally on days 1−14. Cycles were repeated every 21 days. Doses were escalated as follows: docetaxel/oxaliplatin/S-1, level −1A 52.5/80/60; level −1B 52.5/80/80; level 1A 52.5/105/80; level 1B 52.5/130/80; level 2A 60/105/80; level 2B 60/130/80; level 3A 67.5/105/80; level 3B 67.5/130/80; level 4A 75/105/80; and level 4B 75/130/80 (mg/m^2).
Results: Nine patients (male/female 6/3; median age 52, range 39−67; median ECOG PS 0) have been enrolled in this study. Five patients had recurred cancer after surgery and adjuvant chemotherapy and 4 patients were diagnosed as a metastatic disease. Tumor differentiation was 2 moderate, 5 poor and 2 unknown. Main sites of metastasis were 6 liver, 6 lymph node, 8 peritoneum, 1 bone and 2 others. One of 6 patients at level 1A and 2 of 3 patients at level 1B developed dose-limiting toxicity (grade 4 neutropenia with fever) during the initial 2 cycles. Therefore, the dose at level 1B and level 1A were determined as the MTD and RD, respectively. A total of 51 cycles were administered (median 7, range 1−9). All patients were evaluated for toxicity and response. The main toxicities were neutropenia (grade 1/2/3/4 = 0/0/2/7 patients) and neutropenic fever (grade 3 = 4 patients) that were easily manageable. There were 5 PR, 3 SD and 1 PD. The response rate was 56% and the disease control rate was 89%.
Conclusions: These data suggest that DOS regimen is safe and active in patients with advanced gastric cancer. Phase II study with RD will be started.

3558 POSTER

Metastatic small bowel adenocarcinoma: favourable outcome in patients with primary tumour resected – retrospective analysis of 44 cases

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Background: Small bowel Adenocarcinoma (SBA) is a rare disease with probably less than 400 new cases per year in Germany. Only limited data is available concerning the effect of palliative chemotherapy (CT) in this disease. Resection of the primary tumour is not routinely performed if distant metastases are present.
Material and Methods: We retrospectively evaluated the files of all patients (Pt) who received at least one cycle of palliative CT. Pt were classified to have the primary (PRI) or local recurrence (LR) surgically completely removed or not and whether they were offered a 2nd-line CT in case of failure or not.

Results: 44 Pt, age 32−72, median (M) 60 were identified; location of PRI: duodenum 24, jejunum 14, ileum 6. 21 Pt were initially resected in curative intent and suffered a distant and/or local relapse after 1–104 months (mo), M 11 mo. 25 Pt had no PRI/LR when palliative CT was started for distant metastases (DM) whereas the remaining had local tumor only (3) or in combination with DM (16). Pt received a broad variety of fluoropyrimidine-based regimens in 1 to 4 lines (mainly colorectal-like protocols). Several Pt with DM but without local tumour or peritoneal carcinosis (PER) experienced long lasting complete or partial remissions (12–111+ mo) in 1st- but also 2nd- and 3rd-line. Outcome was poor in general when local tumor (LT) was present and survival was significant worse: M 8 mo (LT present) vs. 40 mo (no LT), p = 0.003. Outcome from start palliative chemo was comparable if the PRI was resected in curative intent and DM occurred later or if palliative but complete resection was performed with DM present. 6 pt are still in remission following 1st-line chemotherapy. 22/38 Pt with PD received 2nd-line (colorectal like regimens). If 2nd-line was offered survival was significant longer (M 26 mo vs 8 mo).
Conclusions: Due to the retrospective character of the study one has to be cautious. But the effect of palliative CT in pt with metastatic SBA and no local tumor seemes impressive as compared to other types of upper GI cancer. In contrast outcome of Pt in our series, who had local tumor (PRI or LR) was poor. In this disease even in palliative intent surgical local tumor control appears to be essential for a favourable outcome. Strong bias might have had impact on the longer survival of Pt offerd 2nd-line.

3559 POSTER

A phase II study of gemcitabine in combination with oxaliplatin as first line chemotherapy in patients with inoperable biliary tract adenocarcinoma

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Background: The role of systemic chemotherapy in advanced biliary tract cancer is known to be very limited although various single-agent or combination therapies had been tested. The GERCOR study showed the promising result of gemcitabine in combination with oxaliplatin as first line chemotherapy in advanced biliary tract adenocarcinoma. Combination of gemcitabine and oxaliplatin has demonstrated activity in advanced pancreatic cancer.
Methods: This non-randomized phase II study evaluated the efficacy and safety of gemcitabine 1000 mg/m^2/d IV with fixed dose infusion rate of 10 mg/m^2/min on day 1 and oxaliplatin 85 mg/m^2/d IV as a 2-hour infusion on day 2 every 2 weeks as first line chemotherapy in patients with inoperable biliary tract adenocarcinoma. Patients with histologically proven, inoperable biliary tract adenocarcinoma and signed written informed consent were eligible. We report preliminary results in this paper and this study is going on now.
Results: From Sep 2006 to Apr 2007, 21 patients were prospectively enrolled. The median age was 65 years (47−77) and male: female ratio was 7:14. In total, 105 cycles were administered with a median of 4 cycles (1−12) per patients and 13 patients were evaluable for treatment response. The remaining eight patients were not assessable for response due to the following reasons: two patients died with asphyxia and unknown cause, respectively; one patient refused further treatment after thromboembolism event; five patients were too early for response assessment. In median follow up duration of 17.4 weeks (1.1−30.7), the objective response rate was 23.1% with no CR and 3 PR. The disease control rate was 69.2% including 6 SD and only 4 patients had PD. Median overall survival and time to progression was not evaluable yet. Median time to remission in 3 PR was 8 weeks. In total 105 cycles, grade 3/4 toxicities were seldom observed as follows: neutropenia (0.9%), thrombocytopenia (0.9%), nausea (0.9%), diarrhea (2.8%), general weakness (1.9%), fever (0.9%). Regarding peripheral neuropathy, just grade 2 toxicity was observed in 3 patients (14.2%) of all 21. Grade 3/4 pulmonary thromboembolisms were developed in 3 events of all cycles, but the relationship with chemotherapy was not clear.
Conclusion: Gemcitabine and oxaliplatin combination chemotherapy showed a very promising preliminary anti-tumor activity and was very well tolerated as a first line treatment for patients with inoperable biliary tract adenocarcinoma.

3560 POSTER

Bone loss after gastrectomy in patient with stomach cancer

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Background: Although bone disease is commonly associated with gastric surgery, the effect of gastrectomy on bone metabolism and mineral density are still unclear. The purpose of this study was to clarify the decrement of bone mineral density (BMD) after gastrectomy using dual-energy X-ray absorptionmetry (DEXA) and the pathogenesis of postgastrectomy bone disease by measurement of other bone-related serum marker.
Materials and Methods: This study was designed for prospective, one year follow-up after gastrectomy. The forty-six patient had been enrolled. The thirty-six patients were analyzed in the end. There were 24 men, 6 premenopausal women and 6 postmenopausal women, aged 48−68 years, mean 58 years. The bone mineral density of L2 – L4 spine and femur were measured using dual-energy X-ray absorptionmetry. In all patients, the blood was sampled to check the serum calcium, phosphorus, bone turn over marker. The serum PTH and 25(OH)-vitamin D levels were determined before and one year after gastrectomy.
Results: The mean bone loss in lumbar spine, total proximal femur, femoral neck, and the trochanter, which was calculated as the percentage change from the baseline to the level at one year, was 5.9% ($p < 0.05$), 5.3%($p < 0.01$), 6.4%($p < 0.01$) and 8.7%($p < 0.01$) respectively. The bone loss was generally higher in a group who received chemotherapy ($p < 0.05$). The serum calcium and phosphorus levels were not changed significantly and within the normal range throughout the observation period. After gastrectomy the level of type 1 carboxy-terminal telopeptide (CTP) and reached a peak at 1 month (9.6±2.9 ng/mL; $p < 0.01$ vs. baseline). Thereafter, it progressively declined; however the CTP levels were still higher compared to the baseline at 1 year after gastrectomy (6.6±3.0 ng/mL; $p < 0.05$ vs. baseline). During the observation period, there were no significant changes in the levels of osteocalcin. The level of 25(OH)-vitamin D at 1 year postgastrectomy was not significantly changed compared to the baseline. However, iPTH levels higher at 1 year than before gastrectomy (33.9±10.2 pg/mL, 49.4±20.5pg/mL; $p < 0.01$; mean percentage change, 61.6%). Albeit not significant, iPTH levels at 1 year postgastrectomy tended to be negatively associated with the percentage changes in the BMD of the lumbar spine from the baseline to 1 year. Conclusions: The data in this study provide evidence that propound bone loss occurs and increased bone resorption supervenes during the early postgastrectomy period. In addition, it is conceivable that gastrectomy related bone loss may be due, at least in part, to the overproduction of PTH.

3561 POSTER

A prospective study for serum REG4 protein in pancreatic cancer as a tumor marker

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Background: Pancreatic cancer (PC) shows the worst mortality rate in gastrointestinal tract cancers, with 5-year survival rate of 4%. The only way to cure the disease is surgical resection of early stage PC. Although carbohydrate antigen19−9 (CA19−9) is a good marker for monitoring PC, a screening strategy to detect early stage PC is not perfectly established. REG4, a member of the regenerating islet-derived (REG) family, are secreted proteins that play a role in tissue regeneration and inflammation in digestive organs. We reported overexpression of REG4 in PC cells and serum (Takehara A. et al. Cancer Science 2006), and preliminary data of the serum REG4 level of pancreatic disease patients including PC patients at Asian Pacific Digestive Week 2006. We conducted a prospective study to evaluate the role of serum REG4 in PC.
Methods: The series included 91 patients diagnosed pathologically as PC between November 2004 and June 2006. Serum REG4 was quantified by standard sandwich ELISA (Enzyme Linked Immunosorbent Assay) using original kit (MBL116: provided by Medical and Biological Laboratories Co., LTD, Japan) before treatment. The upper limit of the test was set at 4.22 ng/ml and was based on studies of serum from 69 healthy control subjects.
Results: With a specificity of 100%, the diagnostic sensitivity and accuracy were 61.5% and 78.1%, respectively. The ROC (receiver operating characteristic) analysis showed that area under the curve was 0.92. REG4 levels were a significant differences between PC and control ($p < 0.001$), between each T stage and control (T2, T3 or T4 v control), and between each TMN stage and control (stage 1+stage 2, stage 3 or stage 4 v