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