

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 seems 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 offered 2nd-line.

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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/m²/d IV with fixed dose infusion rate of 10 mg/m²/min on day 1 and oxaliplatin 85 mg/m²/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.

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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 absorptiometry (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 absorptiometry. 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 ± 20.5 pg/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.

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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

control), but were not a statistical significance with T stage (T2 v T3 v T4), M stage (M0 v M1) or TNM stage (stage 1+stage 2 v stage 3 v stage 4) in PC patients. The diagnostic sensitivity and accuracy of CA19-9 (>50U/ml) was 69.2% and 82.5%, respectively. No significant correlation was demonstrated between REG4 and CA19-9 (coefficient of determination R-squared = 0.11).

Conclusions: This study shows the potential of serum REG4 as a screening test for PC, especially for early PC. REG4 is considered to be a more useful marker in combination with CA19-9.

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POSTER

Results of laparoscopic lymphadenectomy in gastric cancer

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Background: A D2 lymphadenectomy is a prerequisite for curative surgery of gastric cancer (GC). In the present paper our experience and results of laparoscopic D2 lymphadenectomy are reported.

Material and Methods: Between Jan 2001 and Oct 2006 54 consecutive patients with GC underwent a laparoscopic operation. Preoperative workup included endoscopy with biopsies, upper gastrointestinal series, abdominal ultrasound and computed tomography scan in all series. D2 lymph node dissection was performed in all but 8 patients (14.8%) who underwent because of carcinosis and/or poor general conditions D1 lymphadenectomy. All the patients had gastric adenocarcinoma, located in the upper, medium, and lower third of the stomach in 33.3%, 29.7%, 37.0% patients, respectively. We performed 18 total gastrectomies, 23 subtotal gastrectomies, 4 residual gastrectomies, 5 partial resections, 4 gastrectomies. A Roux-en-Y reconstruction was performed in 22 cases (40.7%), in 23 cases Hoffmeister (42.6%), in 9 cases (16.7%) with B-I reconstruction.

Results: Major complication rate was 12.5%. The most common complication has been pancreatic juice leakage or pancreatitis, which resolved after positioning of drainages in 5 cases whereas in 3 resolved with laparoscopic toilette or drainage of pancreatic abscesses. This complication is related to lymph node dissection along the upper margin of the pancreas and the Fredet fascia. Mean operative time for the laparoscopic procedure was 256±87 minutes with no significant difference between the procedures. The clear margin from the tumor was 5.4±0.5 cm (range 5–7). The mean number of dissected lymph nodes was 29 with a range of 9 to 65 (D1 12.76±3.7 vs D2 34.87±17.4; p<0.001).

Conclusions: If laparoscopic gastric operation for EGC with D1 dissection has been accepted for its good results, several authors claimed that this technique isn't feasible for advanced GC due to the technical difficulties of laparoscopic D2 resection. In our opinion D2 resection is the gold standard treatment for advanced GC since D2 lymphadenectomy was found to decrease locoregional recurrence to 33% of all recurrences. An R0 resection is by far the most important prognostic factor. Our study demonstrates that laparoscopic technique for advanced GC with a correct D2 lymphectomy is feasible and safe producing long-term good results.

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POSTER

Sentinel node mapping during laparoscopic distal gastrectomy for gastric cancer

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Background: Lymph node metastasis is one of the most important prognostic factors in patient with gastric cancer. Therefore, gastrectomy with D2 lymphadenectomy is the standard surgical procedure in gastric cancer despite some authors demonstrated that D2 lymphadenectomy does not influence patient survival, especially in early-stage gastric cancer. Although the risk factors for lymph node metastasis have been clarified, it remains difficult to precisely predict the presence or absence of lymph node metastasis both before and during surgery. Recently, several studies evaluated the feasibility of sentinel node biopsy for gastric cancer. If sentinel node navigation surgery could be applied to such patients, then minimally invasive surgery with personalized lymphadenectomy might be possible. The next important issue in this field is the introduction of laparoscopic surgery in the treatment of gastric cancer, particularly for early-stage disease. Laparoscopic modified surgery based on sentinel node status

would be the goal of a minimally invasive approach for pathologically node negative early gastric cancer. We developed and have used a blue dye sentinel node mapping for laparoscopic sentinel node detection. The aim is evaluate feasibility and accuracy of sentinel node (SN) mapping with endoscopic submucosal blue dye injection during laparoscopic distal gastrectomy for gastric cancer.

Methods: 34 cases of gastric adenocarcinoma without serosal invasion and distant metastasis were prospectively enrolled in our preliminary study. At the start of the surgery, 2 ml of 2% patent blue was endoscopically injected into the submucosal layer at four points around the site of the primary tumor. Sentinel nodes were defined as nodes that stained the blue dye within 5 to 10 minutes after the dye injection. After identification and removal of sentinel lymph nodes, each patient underwent laparoscopic distal gastrectomy with D1 (n=2) or D2 (n=32) lymphadenectomy.

Results: Out of the 34 patients, 14 had positive nodules (41%). The mean number of dissected lymph nodes per patient was 31±10 (range 16–64). SNs were detectable as blue nodes in 27 (80%) of 34 patients. The mean number of blue nodes per patient was 1.5 (range 1–4). Only five (sensitivity 35%) of 14 N(+) patients had at least 1 metastatic lymph node among the SNs identified. Nevertheless, in early gastric cancer (n=18), three patients had lymph nodes metastasis. These early gastric cancer patients had at least 1 metastatic lymph node among the SNs identified (sensitivity 100%). There were no false negatives in early gastric cancer.

Conclusions: Intraoperative SN mapping in gastric cancer is technically feasible. Blue dye SN mapping during laparoscopic distal gastrectomy seems to be an accurate diagnostic tool for detecting lymph node metastasis in patients with early-stage gastric cancer. Validation of this method requires further studies on technical issues, including selection of the tracers.

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POSTER

Histological response as potential prognostic factor after neoadjuvant chemotherapy (Ch) and chemoradiotherapy (CRT) for locally-advanced pancreatic cancer: preliminary results

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Background: Histological response to preoperative therapy has been found to be a positive prognostic factor in several gastrointestinal malignancies. The present study analyses the histological response after a combined protocol of Ch and CRT followed by surgery and its potential value as prognosis factor.

Material and Methods: 22 patients with diagnosis of non-metastatic pancreatic cancer were included. Median age was 60 years. Patients were staged with CT scan and endoscopic ultrasound (EUS). Treatment protocol consisted on three cycles of neoadjuvant Ch (gemcitabine 1,000 mg/m² and oxaliplatin 85 mg/m² day 1, and capecitabine 625 mg/m² bid x 7 days, every 14 days) followed by CRT: 50–54 Gy in 5–6 weeks with concurrent weekly oxaliplatin 50 mg/m² and daily capecitabine 825 mg/m² bid Monday to Friday. After 4–6 weeks patients were re-staged and surgical treatment indication was considered. Histological response was evaluated and categorised according to tumor necrosis, grade of fibrosis and residual tumor load. Major tumor response grade (TRG) was interpreted as presence of <10% of residual tumor cells in the surgical specimen, without metastatic lymph nodes.

Results: All of the 22 patients completed the planned neoadjuvant segment of treatment. None grade 3–4 adverse effects were observed during the neoadjuvant Ch. Median dose of radiotherapy was 53 Gy. During CRT 18% of patients developed any grade 3–4 toxicity. Clinical downstaging was achieved in 41% of patients after Ch and CRT. Twelve patients underwent radical surgery. Major TRG was observed in 5/12 (42%) patients. Most of these patients did not received postoperative adjuvant chemotherapy. Median time of follow-up for patients underwent surgery was 14 months. Median time to progression was 8.4 months for patients achieving major TRG and 5.1 months for those patients who did not reach major response. At time of last follow-up, all the patients with major TRG are alive, but 2/7 patients without major TRG are died.

Conclusion: Although preliminary data are presented, rates of major TRG after neoadjuvant chemo and CRT for resectable pancreatic cancer are encouraging. Histological response as measured by residual tumor load after neoadjuvant treatment may be useful as prognostic factor and additional investigation is warranted.