Conclusions: vWF:Rcof levels during CMT and basal levels of Fibrinogen might both predict response to treatment and TTP in advanced GC pts.

6582 POSTER

Long-term results of surgical treatment of recurrent gastric cancer

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Background: To improve the treatment effect of recurrent gastric cancer by using repeated surgical procedures.
Materials and Methods: 82 patients with recurrent gastric cancer operated because of antral zone cancer in general surgery and oncological hospitals have been made over 2000 to 2008. The patients aged from 24 until 76 years old. Men prevailed 65 (79.3%), women 17 (20.7%). Patients operated were divided into 2 groups: 1-st consisted of 33 (40.2%) patients operated in volume of distal subtotal resection by Billrot-I, 2-nd consisted of 49 (59.8%) patients operated in volume by Billrot-II. In 1-st group relapse-free time was 6.1±0.3 mth, in 2nd – 12.8±0.2 mth. Morphological structure of 29% tumour observations were presented high and moderate differentiated adenocarcinoma, in 71% – low-grade differentiated adenocarcinoma. In all 82 cases lymphodissection corresponed to volume D1, and just in 24 cases to volume D2. By growth form infiltrative form 44 (53.7%) was the most occurred, endophytic form was in 27 (32.9%) cases, and in exophytic form was in 11 (3.4%) cases. Tumour localized in antral zone in 14 (17.1%) patients, 39 (47.6%) in antral zone transiting on lower third gastric body, 29 (35.3%) in antral zone with transition on middle third gastric body. Of 82 patients only 36 (43.8%) ones were performed repeated operative procedures, 23 (63.8%) of them were made radical surgery. 12 (52.2%) of them were made combined surgery. If unresectable, considering stenosis of gastroenteroanastomosis 10 (27.8%) patients were made draining surgery. In 3 (8.3%) cases because of spread of tumour process explorative laparatomy was performed.
Results: Frequency of complications after recurrent cancer gastric surgery being 19.4%, lethality 8.3% (3 patients). The most highest respectability was 66.7% after gastric resection by Billrot-II, after resection by Billrot-I – 33.3%. After radical surgery the median of survival rate in groups was: in 1 group 14.2±0.7 mth, and in 2 group 22.3±0.6 mth.
Conclusions: Resectability by Billrot-I surgery was twice less than by Billrot-II. Relapse-free time is twice less than in Billrot-II. Experience showed that there is the need to develop the principles of early diagnostics to improve the radical surgery results for patient with recurrent gastric cancer.

6583 POSTER

Ways of optimization of principle splenectomy in extensive gasterectomy

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Background: to work out modern approaches to principal splenectomy performance in surgical treatment of gastric cancer.
Materials and Methods: there made comparative analysis of direct results of surgical treatment of 137 patents with gastric cancer over 2000–2007. Patients were divided in 2 groups: 1) patients subjected extensive gasterectomy in volume D2 with splenectomy and resection of tail part of pancreas (n = 70), 2) subjected to extensive gasterectomy in volume D2 with preservation of pancreas (n = 67). As known intensity and direction of metastasis in lymph nodes, identify the properties of initial tumor invasion, localization, form growth, histological structure. To identify the need of removal 10 groups of lymph nodes we studied the frequency of damage of these group lymph nodes depending on different prognostic factors.
Results: when analyzed 70 extensive gasterectomy metastasis damage of regional lymph nodes (N+) revealed in 68 (9.2%) cases. From them the metastasis of operated patients were in N1–100%, N2−91.4%. In morphological study of 10 groups of lymph nodes metastasis were revealed in 28.5%. Metastatic damage of pancreas reported in 2.8% cases. Metastasis analysis in lymph nodes of pancreas portal in the depending on tumor localization showed that in 45.0% (9/20) cases of metastasis noted in proximal part of stomach cancer, in 25.0% (5/20) cases in stomach tumor and in 30.0% (6/20) in total stomach affection. Metastasis in lymph nodes of pancreas portal was not observed in affection of antral zone of stomach. No metastases were in 10th group of lymph nodes in exophytic form growth. The more frequent metastatic process was revealed in diffuse type of stomach cancer and made 40.9% in ulcerate infiltrative form, 54.5% – diffuse infiltrative tumor growth. Metastases in 10th group of lymph nodes observed in low-grade differentiated tumors up to 86.4% cases.
Conclusion: the performance of principle splenectomy in extensive gasterectomy has been induced in the following cases. Cancer of proximal part of stomach T3-T4, low differentiated structure, infiltrative growth, stomach cancer of total affection; infiltrative form of diffuse type structure stomach cancer, any localization.

6584 POSTER

A phase III study of CapeOx +/− lapatinib in HER2 positive locally-advanced/metastatic upper gastrointestinal adenocarcinoma: interim safety results

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Background: HER2 overexpression or amplification is associated with worse prognosis in locally advanced/metastatic adenocarcinoma of the upper gastrointestinal (UGI). Fluoropyrimidine plus platinum-based treatment is the backbone therapy for the treatment of this disease with a median survival rate of less than a year. LOGiC/TRIO-13 is a phase III global trial in HER2 positive UGI adenocarcinoma randomizing patients to capecitabine and oxaliplatin (CapeOx) with lapatinib or placebo (PBO) designed to evaluate safety and efficacy. A preplanned interim analysis of safety was conducted to evaluate tolerability of this novel regimen.
Methods: CapeOx was administered in a 3-week cycle. Oxaliplatin (130 mg/m^2) was administered on day 1; capecitabine (850 mg/m^2/BID) on day 1−14; and lapatinib (1250 mg) or PBO daily on day 1 onward. The safety analysis was performed after twenty randomized subjects completed 1 cycle of therapy.
Results: From September 2008 to February 2009, 22 subjects with metastatic gastric/GEJ/esophageal (n = 17/3/2, respectively) were randomized; median age 59 (range: 43−80; 17 males); ECOG PS 0 (n = 10), 1 (n = 11), 2 (n = 1);); 21 pts comprise the safety population (1 pt withdrew prior to study therapy); of these, 2 subjects reported significant toxicities defined as severe adverse events. The most common treatment emergent adverse events (TEAE) included neuropathy (gr1, n = 8), diarrhea (g1−2, n = 9; gr3, n = 2 pts); nausea (g1−2, n = 8; g3, n = 3); vomiting (g1−2, n = 9); anorexia (g1−2, n = 4; gr3, n = 2). Additional g3 events included asthenia (n = 1); dehydration (n = 1); pulmonary embolism (n = 1), renal failure (g3−4, n = 2); No unexpected toxicities occurred.
Conclusion: Twenty-one subjects received at least 1 cycle of treatment. Only 2 had significant toxicity, similar to expected based on studies with CapeOx alone. No unusual toxicities were observed. The regimen CapeOx plus lapatinib/PBO appears well-tolerated in patients with HER2-positive UGI cancers.

6585 POSTER

Changes in body composition following Whipple's procedure in patients with pancreatic cancer

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Background: Pancreatic cancer (PC) is a devastating disease with surgical resection providing the only possible cure. The Whipple's Procedure (WP) is one of the most common resection procedures performed in PC patients. Recovery following a WP may be determined by the patient's nutritional status. The restoration of protein and fat losses should improve the patient's response to adjuvant therapy, which is mandatory when margins are involved. It is, therefore, important to investigate the effect(s) of margin involvement on long-term nutritional status through detailed and comprehensive body composition analysis.
Aims: The primary aim of this project, therefore, was to investigate and describe the detailed body composition (BC) changes that occur during the first six months after a WP for PC as well as determining the differences in BC of patients with Clear Margins (CM) and Unclear Margins (UCM) during this period.
Methods: 27 (14 males, 13 females) consecutive PC patients undergoing WP were recruited. Surgery resulted in 10 patients with UCM and 17 with CM. BC measurements were performed at base-line and then at 2, 5, 14, and 26 weeks post-operative time-points. BC measurements included Fat Mass (FM), Nitrogen Index (NI), Lean Body Mass (LBM), Total Body Water (TBW), Total Body Potassium (TBK) weight and Body Mass Index (BMI). Changes in BC within as well as between the groups were measured and compared statistically.
Results: There were significant differences between the groups in BMI (p = 0.048l; p = 0.035), FM (p = 0.027; p = 0.044), and weight (p = 0.047; p = 0.041) at the base-line and two weeks post-operative time-points,

respectively. At the 26 weeks, there were significant differences between the groups in NI ($p = 0.027$), TBW ($p = 0.015$), and all BIA-derived LBMs. Compared to base-line, there were significant changes in weight ($p = 0.006$), BMI ($p = 0.005$), FM ($p = 0.007$), %Body Fat (%BF) ($p = 0.016$), TBK/Ht ($p = 0.021$), LBM_{TBK} ($p = 0.023$), $LBM_{VanLoan}$ ($p = 0.034$), and LBM_{Segal} ($p = 0.038$) at the 14 weeks as well as the FM ($p = 0.012$), %BF ($p = 0.003$), and BMI ($p = 0.027$) at the 26 weeks time-point.
Summary and Conclusions: Results suggest a deviation between the two groups in their TBN, LBM and TBW content observable in a long term setting and FM in the relatively shorter-term. Also, although the UCM has lower body composition values than the CM, both groups seem to begin to gradually "equalise" around the 14 weeks time-point. This may suggest that regardless of whether a curative or a palliative surgery is performed on patients with PC, at least by around 14 weeks, their body composition statuses can become relatively similar.

6586 POSTER

Patterns of radiotherapy practice for pancreatic cancer in Japan: results of the Japanese radiation oncology study group (JROSG) survey

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Background: To determine the patterns of radiotherapy practice for pancreatic cancer in Japan.
Materials and Methods: A questionnaire-based national survey of radiotherapy for pancreatic cancer treated between 2000 and 2006 was conducted by the Japanese Radiation Oncology Study Group (JROSG). Detailed information on 870 patients from 34 radiation oncology institutions was accumulated.
Results: Median age of all patients was 64 years (range, 36−88), and 80.2% of patients had good performance status. More than 85% of patients had clinical T3−4 disease, and 68.9% of patients had unresectable disease at diagnosis. Concerning radiotherapy, 49.8% of patients were treated with radical external beam radiotherapy (EBRT) (median dose: 50.4 Gy), 44.4% of patients were treated with intraoperative radiotherapy (IORT) (median dose: 25 Gy) ±EBRT (median dose: 45 Gy), and 5.9% of patients were treated with postoperative radiotherapy (median dose: 50 Gy). Treatment filed was primary tumor (bed) only in 55.6% of patients. Computed tomography-based treatment planning and conformal radiotherapy were used in 93.1% and 83.1% of patients treated with EBRT, respectively. Chemotherapy was used for 691 (79.4%) patients (before radiotherapy: 66 patients; during radiotherapy: 531 patients; after radiotherapy: 364 patients), and gemicitabine was the most frequently used drug, followed by 5-fluorouracil.
Conclusion: This study describes the general patterns of radiotherapy practice for pancreatic cancer in Japan. Most patients had advanced unresectable diseases, and not only radical EBRT but also IORT±EBRT were frequently employed. Concerning chemotherapy, gemicitabine was commonly used in conjunction with radiotherapy during the survey period.

6587 POSTER

The comparison of the conformal radiotherapy (CFRT – 2, 3 and 4 fields) and intensity modulated radiotherapy (IMRT) in adjuvant radiochemotherapy for patients with pancreas cancer

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Purpose: To compare CFRT – 2, 3, 4 fields (F) and IMRT in planning of adjuvant radiochemotherapy in patients with pancreas cancer after Whipple operation.
Materials and Methods: A treatment planning study was performed to compare CFRT (2F, 3F, 4F) and IMRT for fifteen patients with pancreas cancer. For each patient from this group four treatment plans were performed: 3 for CFRT and 1 – IMRT. The CFRT plans consisted of two opposite fields (2F), two opposite fields and one oblique fields (3F), two lateral and two oblique fields (4F) and the IMRT plan.
The treatment plans were performed to achieve the minimum dose for PTV no lower than 95% of total dose. Treatment plans were compared using dose-volume histograms and plots of median doses for left and right Kidney (K) V_{20}, Liver (L) V_{30}, D max for Spinal Cord (SC) and D max for Intestines (IN). For the evaluation of statistical significance the nonparametric Wilcoxon's test was performed.
Results:
– Minimum dose in PTV (PTV min) for 2F plan was: 42.70 Gy, 3F – 42.70 Gy, 4F – 43.19 Gy and in IMRT – 43.23 Gy ($p = 0.006$).
– D max for SC was acceptable in all plans (3F – 40.4 Gy, 4F – 34 Gy, IMRT – 44 Gy) except in 2F – 46.5 Gy (2F vs IMRT $p = 0.00065$, 3F vs IMRT $p = 0.95$, 4F vs IMRT $p = 0.005$).
– The median volume for each kidneys V_{20} was comparable for all conformal plans. For left kidney 44.7%, 41%, 40% for 2F, 3F and 4F respectively and 11.3%, 10.7%, 9.2% for right kidney. The V_{20} for left kidney was 18% and 6% for right kidney using the IMRT plans ($p < 0.002$).
– Liver V_{30} was comparable for each of the performed plans: 2F – 8.3%, 3F – 8%, 4F – 7% and IMRT – 7%. (2F vs IMRT $p = 0.015$, 3F vs IMRT $p = 0.04$, 4F vs IMRT $p = 0.36$)
– D max for intestines was acceptable in all plans 2F – 48.5 Gy, 3F – 47.0 Gy, 4F – 46.7 Gy, IMRT – 48.0 Gy ($p = 0.001$).
Conclusions:
1. All plans fulfill ICRU 50 recommendation for PTV min.
2. DVH demonstrated better protection of the kidneys in IMRT as compared to CFRT.
3. Similar and acceptable protection of liver and intestines in all performed techniques.

6588 POSTER

A phase II trial of cationic liposomal paclitaxel in combination with gemcitabine in patients with advanced pancreatic cancer

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Background: EndoTAG™-1 is a novel cationic liposomal formulation of paclitaxel being developed for the treatment of solid malignancies. It acts by targeting activated negatively charged endothelial cells of tumor blood vessels. Its safety and efficacy in combination with gemcitabine has been evaluated in a randomized, controlled phase II trial in patients with advanced pancreatic cancer (PC).
Methods: Patients with advanced PC were randomized to 1st line treatment with weekly gemcitabine (GEM: 1000 mg/m^2) and twice weekly infusions of EndoTAG™-1 (E) at 3 different dose levels (E_{low}: 11 mg/m^2, E_{med}: 22 mg/m^2, E_{high}: 44 mg/m^2) or GEM monotherapy. Patients were treated for 7 weeks and followed up for overall survival (OS) for at least 1 year. After finishing study treatment, any anti-tumor therapy was allowed. A subgroup of patients who had at least stable disease according to RECIST had the option to receive repeated cycles of combination therapy until disease progression.
Results: Of the 200 patients enrolled, 80% had metastatic and 20% had locally advanced disease. Median OS was substantially higher in the GEM+E_{med} and GEM+ E_{high} groups than in the GEM monotherapy group with 12-month survival rates of 36% (GEM+E_{med}) and 32% (GEM+E_{high}) compared to 17% in the GEM group. Adjusted hazard ratios for OS were 0.72 (95% CI 0.45−1.13) for the GEM+E_{med} and 0.67 (0.42−1.07) for the GEM+ E_{high} group. Adding E to GEM was also associated with prolonged progression-free survival and a higher rate of disease stabilization after 7 weeks. Treatment with EndoTAG™-1 and gemcitabine was generally well tolerated. Adverse events related to combination therapy with E were predominantly chills and pyrexia of mild or moderate intensity.
Conclusion: This phase II trial indicates a considerable survival benefit for patients with advanced PC receiving EndoTAG™-1 in combination with gemcitabine and a favourable safety profile warranting further development of EndoTAG™-1 in this indication.