failure. 12 patients were operated. Operative procedures were Pancreatico-duodenectomy, extended hemi-hepatectomy with bile duct resection, and bile duct resection were 6 cases, 4 cases, and 1 case, respectively. One patient was not resected by dissemination, which was found after laparotomy. 7 patients were operated with R0-resection, 4 patients were R2-resection. The factors of R2 were mainly distant metastases, this means NACRAC provided good local control. Based on Intention to treat (ITT) analysis, R0-resection rate was 57.1% (8 /14). This has possibilities to meet the primary end point, and then we continue P-2.
Conclusions: Three-years results after Phase I showed no severe adverse events, and P-2 showed acceptable effect as previously estimated. Neoadjuvant chemoradiation therapy with conventional resections appears to be effective and well tolerated. The study is continued as scheduled, to further evaluate the benefit of this regimen.
Trial registration: UMIN Clinical Trials Registry (UMIN-CTR) UMIN UMIN000000992 and UMIN000001754

6523 POSTER

Intraperitoneal Paclitaxel Combined With S-1 Plus Intravenous Paclitaxel for Gastric Cancer With Peritoneal Metastasis − a Report of 100 Cases

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Background: Peritoneal metastasis is the most life-threatening metastasis in patients with gastric cancer, and no standard therapy has been established in spite of recent advances in chemotherapy. We previously verified the safety and efficacy of S-1 plus intravenous (IV) and intraperitoneal (IP) paclitaxel (PTX) in phase I and II studies (Oncology 2009, Ann Oncol 2010). We hereby report the results of 100 patients treated with this regimen at the University of Tokyo Hospital.
Materials and Methods: Gastric cancer patients with macroscopic peritoneal metastasis were implanted with peritoneal access ports, and received combination chemotherapy of S-1 plus IV and IP PTX. PTX was administered IV at 50 mg/m^2 and IP at 20 mg/ m^2 on days 1 and 8. S-1 was administered at 80 mg/ m^2/day for 14 consecutive days, followed by 7 days rest. Radical gastrectomy was performed when macroscopic curative resection was made achievable after the chemotherapy. Efficacy and safety were evaluated in all the patients.
Results: Between February 2005 and January 2011, 100 patients with peritoneal metastasis were treated, including 80 with primary tumours, 10 after palliative gastrectomy, and 10 with peritoneal recurrence. The median number of courses was 8 (range 1−48). The median survival time (MST) was 22.6 months (95% CI, 17.9–28.9 months). The MSTs of subgroups were as follows: Metastasis to the adjacent peritoneum, 49.6 months (n = 10); metastases to the distant peritoneum, 19.7 months (n = 90). Ascites negative, 39.3 months (n = 29); ascites positive, 19.0 months (n = 71). With primary tumours, 20.6 months (n = 80); after palliative gastrectomy, 49.6 months (n = 10); with peritoneal recurrence, 22.6 months (n = 10). Out of 80 patients with primary tumours, 37 patients underwent gastrectomy after response to chemotherapy, and had a MST of 34.9 months. The frequent grade 3/4 toxic effects included neutropenia (36%), leukopenia (20%) and anemia (8%). Infection and obstruction of peritoneal access device were observed in 7 and 6 patients, respectively. There were no treatment-related deaths.
Conclusions: Combination chemotherapy of S-1 plus IV and IP PTX is well tolerated and active in gastric cancer patients with peritoneal metastasis.

6524 POSTER

Does the Addition of FDG-PET to the Standard Pre-operative Work up of Pancreatic Cancer Change Management − a Prospective Study

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Background: Patients with resectable pancreatic ampullary and distal bile duct (PAB) carcinomas are candidates for surgery with curative intent. Following surgery the majority of patients relapse and die of their disease. Improved patient selection is desirable. Small series have suggested that positron emission tomography with 2-Fluoro-2-deoxy-D-glucose (PET) improves detection of metastases and helps avoid futile surgery in up to 15% of patients. We prospectively evaluated the impact of the addition of PET to the standard work up of PAB carcinomas.
Materials and Methods: Prospective single-arm single institution study. Included patients had suspected or proven resectable PAB carcinoma. Resectability was determined by standard imaging and multi-disciplinary team discussion. Following this, patients underwent PET scan. The primary outcome was to determine the percentage of patients in whom there was a change in management plan due to PET.
Results: To date 33 patients have been recruited, 31 with PAB (84% pancreas, 13% distal bile duct, 3% ampulla), 2 with benign pathology. Median age 63 (range 35−84), 76% male. The sensitivity of PET for the primary carcinoma was 61%. PET changed the management in 3 of the 31 patients with carcinoma (9.7%, 95% CI 2.0% to 25.8%). In these 3 patients PET detected metastases not demonstrated on prior imaging (liver 2, retroperitoneal node 1). In 3 further patients PET failed to detect metastases; in 2 patients metastases were detected intraoperatively (liver 1, peritoneum 1), and in one patient non-FDG-avid liver lesions rapidly progressed post-pancreaticoduodenectomy. In 5 patients the carcinoma was unresectable at laparotomy due to local invasion. PET did not detect this or change management in any of these patients. Twelve patients had locoregional node metastases in the resection specimen, none of which were FDG-avid. In 6 patients (18%) PET detected independent pathology; 3 patients required additional investigations − skin biopsy (squamous cell cancer), axillary biopsy (benign), colonoscopy (tubular adenoma).
Conclusion: PET had low sensitivity for detecting the primary PAB tumours. It does not appear useful in identifying locally advanced tumours or locoregional nodes. PET can detect distant metastases not otherwise apparent resulting in a change of management in 9.7% of patients. Hence it may not be useful as a routine staging tool. Additional investigations may be initiated due to incidental abnormalities found on PET.
Trial registry number ACTRN12607000604404.

6525 POSTER

A Phase I Study of Triapine and Radiation in Patients With Locally Advanced Pancreas Cancer

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Background: Pancreas cancer is one of the leading causes of cancer death in the world. Chemoradiation provides modest improvement in outcome in locally advanced pancreas cancer (LAPCA). Triapine, an inhibitor of the M2 subunit of ribonucleotide reductase, was shown to be a potent radiosensitizer in preclinical and early clinical studies.
Materials and Methods: This is a dose escalation trial with 3 dose levels of triapine (24 mg/m^2, 48 mg/m^2, 72 mg/m^2) administered concurrently with 50.4 Gy of radiation in 28 fractions. Patients received triapine within 30 minutes of radiation on Monday, Wednesday and Friday of every other week for 5$\frac{1}{2}$ weeks. Primary endpoint was maximum tolerated dose (MTD) of triapine in combination with radiation. Secondary endpoints included response and radiographic correlates with dynamic contrast enhanced (DCE) MRI.
Results: Twelve patients were treated. Three patients were non-evaluable (NE) for the primary endpoint. Four patients (1 NE) were enrolled at dose level 1, 3 patients at dose level 2, and 5 patients (2NE) at dose level 3. The last patient is undergoing treatment at dose level 3. No DLTs have been observed. Grade 3 thrombocytopenia was seen in 1 patient at dose level 2. Two patients (18%) achieved a PR and 5 patients (45%) had SD. One patient underwent successful surgical resection after therapy. mOS is 7.5 months (range 1.3−20 months, 95% CI 3–15.8). DCE MRI was found to be a predictor for early response to therapy.
Conclusion: The combination of triapine and radiation is safe and tolerable in patients with LAPCA with evidence of promising preliminary activity. Triapine should be considered to be part of future combinatorial studies with gemcitabine or a fluoropyrimidine with radiation in LAPCA. DCE MRI is a potentially useful imaging tool to predict early response to therapy in patients with LAPCA and deserves further investigation.