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Biweekly treatment with Docetaxel-Gemcitabine and Erlotinib in patients with metastatic and/or unresectable pancreatic cancer offers a survival benefit

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Background: Pancreatic cancer represents 2% of all cancers as the 4th leading cause of cancer-related deaths worldwide. Patients (pts) with unresectable and metastatic pancreatic adenocarcinoma had a median survival no longer than 2 months. This is a treatment challenge due to poor outcomes with current treatment modalities.
Materials and Methods: Chemotherapy naïve pts with histologically confirmed unresectable pancreatic cancer and documented extrapancreatic metastases, received docetaxel 75 mg/m^2 on day 1, gemcitabine 1250 mg/m^2 on day 1and daily erlotinib 100 mg p.o., in a biweekly schedule cycle. Pts were monitored every 4 cycles with CT scans and monthly serum CA19−9 measurements. 23 pts (14 males, 9 females, median age 71 years, range 41−80, ECOG PS: 0−2) were enrolled; all pts were eligible for the study. Pts received a total of 146 cycles with a median of 8.33 cycles (2−22).
Results: 8 pts remain alive and undergoing the study treatment. 10 pts discontinued therapy, 7 pts died due to disease progression and 3 pts due to cumulative grade III asthenia. Fatigue had 9/23 pts (36%), cumulative fluid retention edema had 11/203 pts (44%) docetaxel-related that resolved with diuretics and corticosteroids. Onycholyshis 10/23 (40%). Skin toxicity (rash) 15/23 pts (60%) after 6 cycles. Nausea and vomiting 4/23 (16%). 10/23 (40%) had improvement in their pain control and stop to take analgesics after a mean of 6 cycle of chemotherapy. 9/23 (39.1%) had amelioration of their performance status. 1 patient (5.5%) achieved CR, 3 (16.6%) PR and 4 (22.2%) showed stabilization in measurement disease. The median progression-free survival was 4 (2−13) months and the median survival was 8.4 (2−49+) months.
Conclusions: Biweekly chemotherapy with docetaxel, gemcitabine and daily erlotinib is effective for pain control and amelioration of the quality of life in pts with inoperable and/or metastatic pancreatic cancer and offered a median survival of 8.4 (2−49+) months and a reduction >50% in the CA19−9 in 50% of the pts.

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A phase II study of erlotinib plus gemcitabine in Japanese patients with unresectable pancreatic cancer

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Background: In PA.3, erlotinib plus gemcitabine (E+G) improved survival and progression-free survival (PFS) over gemcitabine alone in patients (pts) with unresectable pancreatic cancer (PC) (Moore et al. JCO 2007). We conducted a phase II study (JO20302, closed, CHUGAI Pharmaceutical Co.) to evaluate the safety and efficacy of E+G in Japanese pts.
Materials and Methods: Eligible pts were aged 20−80 years with histologically proven PC and ECOG performance status (PS) 0−2. Pts entered a two-step study to assess safety (dose limiting toxicity [DLT] in $\leqslant$2 pts) and PK in step 1 (6 pts), and to confirm efficacy and safety in step 2 (94 pts). E at 100 mg/day (p.o.) +G at 1000 mg/m^2 (i.v., days 1, 8, 15) were administered in a 28-day cycle. The primary endpoint was safety, and efficacy endpoints were also evaluated.
Results: 106 pts were treated with E+G. In step 1, a DLT (grade 3 diarrhea) occurred in one patient; the study therefore continued to step 2. Baseline characteristics were: median age 62 years (range 36−78); male/female 53/47%; stage IVa/IVb (Japanese Pancreas Society) 15/85% and ECOG PS 0/1/2 75/25/0%. The most common adverse event (AE) was RASH (rash, acne, exfoliative rash, dermatitis acneiform, erythema, eczema, dermatitis and pustular rash) in 93.4% (grade 1/2/3, 30.2/57.5/5.7%). Other grade 3/4 AEs were neutrophils (34.0%), WBC (28.3%), γ-GTP (17.9%), amylase (15.1%), anorexia (15.1%), haemoglobin (14.2%), lymphopenia (14.2%) and ALT (13.2%). Treatment-related interstitial lung disease (ILD)-like events occurred in nine pts (8.5%; grade 1/2/3, 3.8/2.8/1.9%): most were grade 1 or 2; two were grade 3. There were no grade 4/5 ILD-like events and all pts recovered or improved. There was one treatment-related death due to gastrointestinal haemorrhage. The incidence of erlotinib discontinuation due to AEs was 23.6%, that of erlotinib dose reduction was 14.2% and that of erlotinib dose interruptions longer than 7 and 14 consecutive days was 33.0% and 14.2%, respectively. Median overall survival was 9.2 mos (95% CI: 8.3−10.8 mos), with a 1-year survival rate of 33% (95% CI: 24−42%) and the median PFS was 3.5 mos (95% CI: 2.6−3.8 mos). The response rate was 20.3% (95% CI: 11.3−32.2%) for 64 evaluable pts.
Conclusions: This study shows a promising efficacy and safety profile of E+G in Japanese pts with unresectable PC.

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The role of PET/CT imaging in patients with suspected recurrence of pancreatic cancer

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Background: The goal of the study was to determine the value of ^{18}F-FDG PET/CT in patients (pts) with suspected recurrence of pancreatic cancer.
Materials and Methods: Twenty pts (M/F = 10/10, age 44−81, median 63 y) with increasing levels of CA 19−9 and/or CEA during follow-up and negative or equivocal CT scan were included. Sixteen pts were asymptomatic and 4 pts had mild symptoms. Previous treatment included pancreaticoduodenectomy in 14 pts and distal pancreatectomy in 6 pts. Adjuvant chemoradiation was given to 9 pts and was planned for additional 6 pts, while 5 pts were on follow-up. Tumor markers first increased 1 to 24 months after the operation. CT scan was done within one month later in all pts, and found to be normal in 12 pts and equivocal in 8 pts. PET/CT was then performed within one month (12 pts), 2 months (5 pts) and 3 months (3 pts). A final diagnosis of recurrence was confirmed by histopathology or by further clinical and radiologic follow-up.
Results: Of the 20 pts, 17 exhibited PET/CT findings consisted with recurrent cancer. Increased tracer uptake fused with anatomical CT findings were found in 10 pts in whom previous CT scan was defined as normal. Main sites of recurrence were tumor bed – 3 pts and distant (liver, bone and omentum) – 7 pts. PET/CT was also positive in 7 pts with equivocal CT findings (4 in tumor bed, 2 in omentum and 1 in liver+cervical lymph node). Chemotherapy was instituted for 19 pts following PET/CT findings. It was followed by radiation therapy and surgery in 3 and 1 pts with local recurrence, respectively. One pt underwent resection of an isolated abdominal recurrence. In 4 of the 6 pts planned for adjuvant chemoradiation the treatment was changed to systemic chemotherpy after the demonstration of distant metastases by PET/CT. Three pts had false negative PET/CT test, as proved by the clinical course of progressive recurrent disease.
Conclusions: PET/CT is a useful tool for detecting recurrent pancreatic cancer, and has an impact on patient management as well. Its value regarding the clinical course of the recurrent disease should be further evaluated.

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Prognostic model to predict outcomes in pancreatic adenocarcimoma patients who received surgical resection with curative intent

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Purpose: To identify prognostic factors for long term survival of pancreatic adenocarcinomas and devise a prognostic model based on clinical parameters in single centre's experience.
Patients and Methods: Between 1995 and 2007, 292 patients who had undergone surgery for pancreatic adenocarcinoma with curative intent,