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The efficacy of modified docetaxel, cisplatin and 5-fluorouracil in advanced stage gastric carcinoma

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Background: Patients with advanced gastric carcinoma have still had bad prognosis despite advances in the treatment era. Palliative combination chemotherapy including docetaxel, cisplatin, 5-fluorouracil (DCF) is a standard and effective but highly toxic regimen for advanced cases. In this study, we modified the standard doses of DCF (mDCF) to evaluate the effectiveness and side effects.
Material and Methods: From July 2005 to July 2008, 37 advanced gastric cancer patients treated with at least one course of mDCF protocol as first-line treatment were included. The mDCF protocol included 60 mg/m^2 docetaxel and cisplatin for one day and 600 mg/m^2/day, 5-flourouracil infusion for 5 days, repeated every 3 weeks. None patients used prophylactic granulocte-colony stimulating factor.
Results: Of the patients 28 were male and 9 were female; the median age was 53 (23−65) years. At the time of diagnosis, 24.3% had undergone curative and 40.5% palliative surgical intervention. Of the patients, 83.8% received at least 4 courses of chemotherapy and 64.9% completed the preplanned 6 courses of treatment. Eleven (29.7%) of those patients who received mDCF in the first-line treatment used the FOLFIRI (5-FU, folinic acit, irinotekan) regimen for the second-line treatment. Responses were evaluated according to RECIST criteria in 30 out of 37 patients. The median follow-up time was 7.1 months. The longest follow-up time was 19.9 months. Two patients (5.4%) had complete response, 9 (21.6%) had partial response, and 14 (37.9%) had stabilized disease; overall, the disease was controlled in 25 patients (64.9%) whereas 5 patients (13.5%) had progression. Median time to progression was 6.7 months and overall survival was 10 months. The assessment of patients for grade 3−4 toxicity revealed that while 5.4% had anemia and 8.1% had neutropenia, 5.4% nause and 5.4% diarrhea. Neutropenic fever developed in two patients that required hospitalization. G-CSF was used in 3 patients. Two patients with neutropenic fever and 2 with severe anemia (total number 4; 10.8%) received delayed chemotherapy. Dose reduction was required in 4 patients (10.8%), 1 due to neutropenia, 1 due to nephrotoxicity and 2 due to nausea. None patient died due to chemotherapy toxicity.
Conclusion: This retrospective assessment including a small number of patients suggested that mDCF was as effective as DFC with much lower toxicity. However, the small number of patients and retrospective nature of the study should be considered when interpreting the results.

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Phase II study of preoperative chemotherapy with paclitaxel (PTX) plus cisplatin (CDDP) for advanced gastric cancer

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Buckground: The purpose of this trial is to evaluate the efficacy and safety of preoperative chemotherapy with PTX plus CDDP for advanced gastric cancer which may not be completely resectable without neoadjuvant chemotherapy or for one with poor prognosis even after curative resection.
Methods: Preoperative staging was confirmed by laparoscopy. Eligibility criteria included 1) histologically proven gastric cancer, 2) stage II or higher and M0 except for positive peritoneal cytology or resectable peritoneal metastasis adjacent of stomach, 3) clinical stage IIIB-IV, type 4 tumor or large type3 ($\geqslant$8 cm), or with esophageal invasion, 4) PS 0.1 and 20−80 years old. Patients (Pts) received PTX (80 mg/m^2) and CDDP (25 mg/m^2) on day 1, 8, 15 every 4 weeks for 2 to 4 courses depending on the response and resectability, followed by gastrectomy with D2 lymphadenectomy. Pts having tumor response were to receive 2 courses of the same chemotherapy. The primary endpoint was pathological response rate (pRR) which was defined as degeneration occupied more than 1/3 of the cross sectional surface area of tumor. Sample size of 50 was required when the expected pRR was over 25% and threshold pRR was set at 10% with one-sided alpha of 0.05, beta of approximately 0.2.
Results: 52 pts were enrolled and all pts were eligible. The median age was 65 (range 36−80); male/female: 32/20; PS0/1: 45/7. The pRR was 34.6% (95%CI, 22.0−49.1%) and the null hypothesis (pRR < 10%) was rejected ($p < 0.0001$). Fourty-three pts (82.7%) underwent surgery, in whom curative resection was done in 33 pts (63.5%; 95%CI, 49.0−76.4%), and 31 pts completed the protocol treatment. The response of preoperative chemotherapy was CR in 1 (1.9%), PR in 22 (42.3%), and PD in 6 (11.5%); with response rate of 44.2% (95%CI, 30.5−58.7%). Three year survival rate could not yet be calculated. % of CTC grade 3 or higher hematological or non-hematological toxicities were 32.7% and 4.6%, respectively, and grade 2 or higher operative morbidity was 18.6%.
Conclusion: The combination of PTX and CDDP was well tolerated and promising as a preoperative chemotherapy regimen for patients with advanced and M0 gastric cancer.

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Audit of patients undergoing primary radical chemoradiotherapy treatment for oesophageal cancer at the KCH Oncology Unit

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Background: There is increasing evidence that oesophageal cancer responds to combination chemotherapy regimens based on cisplatin. Response rates before surgery of 40−60% for squamous carcinoma and 30−40% for adenocarcinoma, and 2-year survival rates of 30−40% with preoperative chemotherapy plus surgery, have been reported.
Materials and Method: We performed a retrospective study of patients with localised oesophageal carcinoma treated with primary radical chemoradiotherapy at the Kent Oncology Center in Canterbury, Kent. 12 patients with localised oesophageal carcinoma and stage T3N0M0 or T3N1M0 received primary chemoradiotherapy. Patients were assessed for treatment related toxicities and overall survival.
Results: The most common indications for radical radiotherapy treatment were inoperability (72% of referrals) and co-morbidities (28% of referrals). Our practice fluctuated significantly regarding the type and the schedule of neoadjuvant chemotherapy used. Patients received neo-adjuvant chemotherapy with a number of different cisplatin based combinations. Radical chemoradiotherapy was generally well tolerated with 13% of patients experiencing G3 toxicities and 26% of patients experiencing G2 toxicities. Dysphagia and neutropenia were the commonest toxicities reported. All patients completed treatment. Our 1 year survival rate was 62%. We plan to re-audit our practice next year, in order to get a 2 year survival rate as well.
Conclusion: Over the last 2 years we have noticed a marked increase in the number of oesophageal cancer patients receiving treatment with primary radical chemoradiotherapy. The main indication for referral was advanced stage, inoperable disease, whereas comorbidities accounted for nearly a quarter of referrals. Radical chemoradiotherapy was well tolerated and all out patients completed treatment. Our 1 year survival rate was 62% and is similar to the 1 year survival rate of patients on the OEO2 trial which was 69%.

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Phase I study of concurrent selective lymph node late course accelerated hyper-fractionated radiotherapy and pemetrexed, cisplatin for locally advanced esophageal squamous cell carcinoma

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Background: Concurrent chemoradiotherapy (CRT) is now a standard of care in locally advanced esophageal cancer. However, the prognosis was still poor and the toxicity was severe. To improve the outcome, we evaluated a new regimen of CRT with pemetrexed.
Materials and Methods: Patients with a T3−4N0−1M0−1A SCC of thoracic esophagus were included. Intensity modulated radiotherapy (IMRT) was carried out using a two-phase irradiation schedule. In the 1st radiation (RT) phase, treatment target included primary tumor with 5 cm expanding superiorly and inferiorly, metastatic lymph nodes, and selective high risk lymph node areas. The RT dose was delivered as 40 Gy in fractions of 2.0 Gy/day for 4 weeks. In the 2nd RT phase, the targets were adjusted as the selective high risk lymph node metastatic areas being spared, and the primary tumor with 3 cm expanding craniocaudally. The dose was delivered at 1.4 Gy/fraction, twice daily with a minimum interval of 6 hours, to 19.6 Gy/14fractions. The concurrent chemotherapy protocol was as following: cisplatin 10 mg/m^2 on days 1−5 and 22−26, pemetrexed in escalating doses, from the base level of 500 mg/m^2 administered as a 10-min i.v. infusion once every 21 days. Primary objectives were to study the feasibility and to determine the maximum tolerated dose

(MTD)/recommended Phase II dose (RD) and DLTs. Secondary end points included determination of preliminary radiographic response rates.
Results: 3 patients were enrolled at the following dose levels of pemetrexed: 500 mg/m^2 (Level 1), 400 mg/m^2 (Level 0), respectively. All of the IMRT plans met the optimization criteria. At dose level 1, DLTs (grade 3 neutropenia/esophagitis/vomiting) occurred in two of three patients. However, none of the patients entered into Level 0 developed DLT. The preliminary radiographic response rates were evaluated. The complete response (CR) and partial response (PR) were observed in 5 and 1 patients, respectively. Furthermore, no patient experienced cancer progression with a median follow-up of 7 months (range 1.5−11 months).
Conclusions: The concurrent selective lymph node LCAF IMRT and chemotherapy is feasible. DLT was mainly observed at Level 1 (pemetrexed 500 mg/m^2). The MTD of pemetrexed in this regimen was 500 mg/m^2 once every 21 days for two cycles and RD for phase II trial was 400 mg/m^2. Although the toxicities were common, the protocol was safe and well-tolerated, as well as achieving an encouraging outcome for locally advanced SCC of esophagus.

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Modified left side mobilization of stomach during extended-combined gastrectomy

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Background: To evaluate the effectiveness of combined resection of the involved organs with regard to survival in patients with locally advanced gastric cancer.
Material and Methods: We developed and offered the left side mobilization (LSM) and lymph dissection during total gasterectomy due to gastric cancer with germination to the pancreas. The essence of the offered way consists that process extended-combined gasterectomy begins with LSM of the stomach. 87 patients randomized from 2000 to 2006. In the 1st group 45 patients were undergone to the gasterectomy with LSM. In the 2nd group 42 patients were undergone to the total gasterectomy with traditional mobilization. In 12 (26.6%) patients of the 1st group and in 11 (26.2%) patients of the 2nd group the operation were combined with splenectomy and resection of pancreas tail, in 7 (15.5%) cases of the 1st group and in 5 (11.9%) cases of the 2nd group there were performed hemipancreatectomy. In 12 (26.6%) cases of the 1st group and 13 (30.9%) cases of the 2nd group there were performed superficial resection of the body and head of pancreas.
Results: Postoperative complications developed in 8 (17.8%) patients of the 1st group and in 8 (19%) patients of 2nd group. Unsupperative pleuritis in 2, after operation pancreatitis in 2 in both groups, pancreatic fistula in 1 of the 1st group and in 2 of the 2nd group, pancreonecrosis in 1 patient of the 2nd group, inconsistence esophago-intestinal anastomosis in 1patient in both groups, tromboembolia of pulmonary artery in 1 of the main group and cardiac-pulmonary insufficiency in 1 of the main group. Though postoperative complications turned out to be alike in both groups, LSM have some advantages. 1) LSM more suitable for estimation the process invasion to pancreas and for making the identical volume of resection. 2) Volume of blood lost turned out to be at the average less on +100 ml under LSM in comparison with usual way of mobilization. 3) Time of operations was abbreviated on 20 minutes under LSM in comparison with usual way of mobilization. 4) R0-ressections were achieved in 42 (93.3%) cases in the 1st group and in 33 (78.5%) cases in the 2nd group.
Conclusion: LSM and lymph dissection shortens the time of operation and blood lost. Meanwhile method is enough suitable and less traumatical. Curative (R0) resection improves prognosis and even long-term survival can be achieved in selected individual cases.

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Prospective study of docetaxel in combination with cisplatin and an oral fluoropyrimidine in patients with gastric and esohagogastric junction adenocarcinoma

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Background: Docetaxel in combination with cisplatin and 5-FU is an approved regimen for the treatment of advanced gastroesophagic cancer (AEGC) in patients who have not received prior chemotherapy for advanced disease. It is based on the results of a randomized multinational phase III study (TAX-325). Two phase III trials (REAL-2 and ML17032) have evaluated capecitabine in combination with other agents in patients with AEGC with positive results in comparison to 5-FU. Based on these results, we designed a prospective study to evaluate the efficacy and safety of an oral fluoropyrimide (capecitabine or tegafur) in combination with docetaxel and cisplatin as the first-line treatment in consecutive patients with AEGC.
Material and Methods: Patients with histologically confirmed adenocarcinoma or undifferentiated carcinoma of the gastroesophagic junction or stomach with no prior treatment (except in adjuvant setting) were included. Normal hepatic, renal and haematological parameters were required. Each cycle of treatment lasted 21 days, consisting of docetaxel 75 mg/m^2 day 1, cisplatin 60 mg/m^2 day 1 and an oral fluoropyrimidine on days 2−15 (either capecitabine 825 mg/m^2 bid or tegafur 500 mg/m^2 bid and continuous levofolinic acid 25 mg/m^2). Patients were assessed for response by RECIST criteria every 3 cycles and treatment was maintained until progression or unacceptable toxicity. Dose adjustments were made according to the CTCAE v3.0.
Results: 46 patients, 34 men with median age 64 years (31−78), were included from 2003 to 2008. Thirty-one patients were assessable for efficacy and 41 for toxicity. Forty-five patients had metastatic disease (40% liver, 32% peritoneal, 35% ganglionar). Seventy-five percent received 6 cycles, with a mean of 4.5 cycles per patient. Dose reductions were required in 21% and 36% needed G-CSF support. Grade 3−4 adverse events included neutropenia (26%), asthenia (17%), diarrhoea (8%) and nausea/vomiting, stomatitis and hand-food syndrome (6%). ORR was 61% (7 complete responses, 12 partial responses). PFS was 5.2 months (0.1−14.6) and median OS was 10.0 months (0.2−41). A non-statistically significant trend to a better OS and PFS was found in patients treated with capecitabine versus tegafur.
Conclusions: The efficacy results and toxicity profile of the combination of docetaxel, cisplatin and an oral fluoropyrimidine in the first-line treatment of AEGC are comparable to previous trials using 5-fluorouracil. Oral fluoropyrimidines provide convenience to patients who can swallow with a similar toxicity profile to 5-FU. The combination with capecitabine has a trend to a better OS and PFS than tegafur.

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A retrospective study of first-line platinum-based combination chemotherapy in patients with recurrent and advanced gastric cancer

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Background: Cisplatin-based chemotherapy, in combination with fluoropyrimidines or taxanes, have demonstrated efficacy against advanced gastric cancer (AGC). This retrospective study was performed with the data obtained from our cancer chemotherapy registry.
Methods: In 2008, a total of 252 AGC patients were treated with cisplatin-based doublet chemotherapy in the first-line setting: capecitabine plus cisplatin (XP, n = 78), S-1 plus cisplatin (SP, n = 76), docetaxel plus cisplatin (DP, n = 67), and 5-fluorouracil plus platinum (FP, n = 31). The primary endpoints were response rate and progression-free survival (PFS).
Results: Median follow up duration was 4.8 months (95% CI, 5.1−6.0) and median delivered number of chemotherapy cycles were XP: 4 (95% CI, 3.6−4.6), SP: 5 (95% CI, 3.9−5.2), DP: 5 (95% CI, 4.0−5.2) and FP: 3 (95% CI, 3.9−6.9), respectively. Objective tumor responses were achieved in 60.5%, 39.5%, 37.3% and 22.6% patients who were treated with XP, SP, DP and FP. Median PFS was 5.1 months (95% CI: 3.6−6.7) for XP, 5.7 months (95% CI, 3.0−8.4) for SP, 3.9 months (95% CI, 3.3−4.5) for DP, and 2.8 months (95% CI, 0.5−5.2) for FP.
Conclusion: All of the cisplatin-based doublet chemotherapy regimens appear to be active as first-line chemotherapy for AGC.

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Cyfra21−1 and CEA are useful markers for predicting the sensitivity to chemoradiotherapy of esophageal carcinoma

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Background: Esophageal cancer is a common malignant neoplasm throughout the world. The common practice is esophagectomy for surgically resectable tumors and chemoradiotherapy (CRT) for locally advanced, unresectable tumors. Sensitivity of tumors to CRT differs from one case to another and may be influenced by the expression of biological molecules. Some reports have revealed that patients who responded well to CRT had favorable outcomes while poor responders conversely showed a worse