

6527

POSTER

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

N. Ozdemir Yildirim¹, H. Abali², B. Oksuzoglu¹, B. Budakoglu¹, D. Uncu¹, T. Guler¹, H. Odabasi¹, S. Cihan¹, N. Zengin¹. ¹Ankara Numune Education and Research Hospital, Medical Oncology, Ankara, Turkey; ²Adana Baskent University, Medical Oncology, Adana, Turkey

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/m² docetaxel and cisplatin for one day and 600 mg/m²/day, 5-fluorouracil infusion for 5 days, repeated every 3 weeks. None patients used prophylactic granulocyte-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 acid, irinotecan) 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% nausea 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 DCF with much lower toxicity. However, the small number of patients and retrospective nature of the study should be considered when interpreting the results.

6528

POSTER

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

N. Nagata¹, A. Tsuburaya², H. Cho², N. Hirabayashi³, M. Kobayashi⁴, T. Matsui⁵, Y. Munakata⁶, Y. Kamada⁷, K. Oba⁸, J. Sakamoto⁹. ¹Kitakyushu General Hospital, Surgery, Kitakyushu, Japan; ²Kanagawa Cancer Center, Surgery, Yokohama, Japan; ³Hiroshima City Asa Hospital, Surgery, Hiroshima, Japan; ⁴Kochi Medical School, Surgery, Nankoku, Japan; ⁵Aichi Cancer Center Aichi Hospital, Surgery, Okazaki, Japan; ⁶Nagano Municipal Hospital, Surgery, Nagano, Japan; ⁷Kanagawa Cancer Center, Pathology, Yokohama, Japan; ⁸Kyoto University, Epidemiological & clinical Research, Kyoto, Japan; ⁹Nagoya University, Young Leaders Program, Nagoya, Japan

Background: 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 (≥8 cm), or with esophageal invasion, 4) PS 0.1 and 20–80 years old. Patients (Pts) received PTX (80 mg/m²) and CDDP (25 mg/m²) 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). Forty-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.

6529

POSTER

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

C. Mikropoulos¹, M. Cominos¹. ¹Kent Oncology Center, Oncology, Canterbury, United Kingdom

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%.

6530

POSTER

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

B. Li¹, H. Gong¹, W. Huang¹, Y. Yi¹, Z. Zhang¹, H. Li¹, Z. Wang¹, H. Sun¹. ¹Shandong Province Cancer Hospital, Radiation Oncology, Jinan, China

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/14 fractions. The concurrent chemotherapy protocol was as following: cisplatin 10 mg/m² on days 1–5 and 22–26, pemetrexed in escalating doses, from the base level of 500 mg/m² 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