A randomized phase III study of adjuvant platinum/docetaxel chemotherapy with or without radiation therapy in patients with gastric cancer.

Bamias A, Karina M, Papakostas P, Kostopoulos I, Bobos M, Vourli G, Samantas E, Christodoulou Ch, Pentheroudakis G, Pectasides D, Dimopoulos MA, Fountzilas G.

Source

Department of Clinical Therapeutics, University of Athens School of Medicine, Athens, Greece. abamias@med.uoa.gr

Abstract

The optimal adjuvant treatment for gastric cancer remains controversial. We compared the efficacy of a docetaxel and platinum adjuvant chemotherapy regimen, in patients with high-risk gastric cancer, with that of the same chemotherapy plus radiation therapy (RT). In addition, we evaluated the prognostic and/or predictive value of a panel of molecular markers. Patients with histologically proven, radically resected gastric cancer, stage > or =T3 and/or N+ were randomized to 6 cycles of docetaxel with cisplatin, both at 75 mg/m2 every 3 weeks (arm A) or the same treatment with RT (arm B; 45 Gy). Due to excessive nausea and vomiting, cisplatin was substituted by carboplatin at AUC (area under the curve) of 5 after the first 45 patients (22 group A, 23 group B). The prognostic value of EGFR, ERCC1, HER2, MET/HGFR, MAP-Tau, and PTEN expression was also studied in a subset of 67 patients using immunohistochemistry on tissue microarrays (TMAs). A total of 147 patients were randomized. After a median follow-up of 53.7 months, no differences in overall (OS) and disease-free survival (DFS) were found between the two arms. The most common grade 3/4 toxicities for arms A and B (excluding alopecia) were non-febrile neutropenia (11 and 17%, respectively), febrile neutropenia (9 and 7%) and diarrhea (7 and 4%, respectively). Patients with ERCC1 positive tumors had significantly longer median DFS (33.1 vs. 11.8 months, Wald P = 0.016) and OS (63.2 vs. 18.8 months, Wald P = 0.046). Our results indicate that the addition of RT to platinum/docetaxel adjuvant chemotherapy does not appear to improve survival in high-risk, radically resected gastric cancer. However, the possibility that a benefit by the addition of RT was not detected due to decreased power of the study should not be excluded.

Comment in

- Cancer Chemother Pharmacol. 2011 Jan;67(1):243-4; author reply 245.
- Cancer Chemother Pharmacol. 2010 May;65(6):1005-7.