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Titel des Beitrags: Randomized phase III study comparing irinotecan combined with 5-fluorouracil and folinic acid to cisplatin combined with 5-fluorouracil in chemotherapy naive patients with advanced adenocarcinoma of the stomach or esophagogastric junction.

Abstract: BACKGROUND: We aimed to establish the superiority (or noninferiority if superiority was not achieved) in terms of time to progression (TTP) of irinotecan/5-fluorouracil (IF) over cisplatin/5-fluorouracil (CF) in chemonaive patients with adenocarcinoma of the stomach/esophagogastric junction. PATIENTS AND METHODS: Patients received either IF: i.v. irinotecan 80 mg/m(2) 30 min, folinic acid 500 mg/m(2) 2 h, 5-fluorouracil (5-FU) 2000 mg/m(2) 22 h, for 6/7 weeks or CF: cisplatin 100 mg/m(2) 1-3 h, with 5-FU 1000 mg/m(2)/day 24 h, days 1-5, every 4 weeks. RESULTS: In all, 333 patients were randomized and treated (IF 170, CF 163). Patient characteristics were balanced except more IF patients had Karnofsky performance status 100%. TTP for IF was 5.0 months [95% confidence interval (CI) 3.8-5.8] and 4.2 months for CF (P = 0.088). Overall survival (OS) was 9.0 versus 8.7 months, response rate 31.8% versus 25.8%, time to treatment failure (TTF) 4.0 versus 3.4 months for IF and CF, respectively. The difference in TTF was statistically significant (P = 0.018). IF was better in terms of toxic deaths (0.6% versus 3%), discontinuation for toxicity (10.0%...
versus 21.5%), severe neutropenia, thrombocytopenia and stomatitis, but not diarrhea. CONCLUSION: IF did not yield a significant TTP or OS superiority over CF, and the results of noninferiority of IF were borderline. However, IF may provide a viable, platinum-free front-line treatment alternative for metastatic gastric cancer.