Planned interim analysis of the intergroup FFCD-GERCOR-FNCLCC-AERO phase III study comparing two sequences of chemotherapy in locally advanced or metastatic gastric cancers.

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Abstract:

Background: There are several standard chemotherapies in locally advanced or metastatic gastric or cardia adenocarcinoma, including ECF. Methods: Patients (pts) with a gastric or cardiac adenocarcinoma, locally advanced or metastatic, not surgically curable, with a WHO PS ≤ 2 and evaluable or measurable lesions, were randomized (1:1) according to the following sequences: ECC (epirubicin 50 mg/m² D1+ cisplatin 60 mg/m² D1 + capcitabine 2000 mg/m² D2 to D15, every 3 weeks) in 1st line, then FOLFIRI (IRI 180 mg/m² D1, leucovorin 400 mg/m² D1, bolus 5FU 400 mg/m² D1 and continuous 5FU 2400 mg/m² in 46h, every 2 weeks) in 2nd line (Arm A) vs the reverse sequence (Arm B) with a stratification for center, PS, adjuvant treatment, site, limits and measurable disease. To show an improvement in median time to treatment failure for the 1st line (TTF: time between randomization and progression, or treatment discontinuation or recurrence or death) of 15 to 20 weeks for arm B (α bilateral 5%; β 20 %), 381 failures and 416 pts are required in 4-year period. An interim analysis is planned when at least 190 failures are observed (ITT). TTF is estimated according to the Kaplan Meier method and compared with a Log-rank test.

Results: In arm A and B, 174 and 175 pts were included respectively, between 17/06/05 and 21/12/07. Pts characteristics are: PS 1: 51%, med. age 60 years, gastric 67%, M+ 88%, resected primary tumor 27% and linitis 23%. In arms A and B respectively, 141 and 147 pts received at least one dose in 1st line and 61 and 44 pts in 2nd line. Toxicities during the first line is more frequent in the ECC than in the FOLFIRI arm: grade 3/4 (88 vs 68% - p ≤ 0.0001) and grade 3/4 hematotoxicities (69 vs 36% - p ≤0.001). In 2nd line, toxicities frequency is not different in both arms. The median TTF in 1st line (n = 310 pts) is 4.7 months [3.8 - 5.7] for ECC and 5.2 months [4.4-6.0] for FOLFIRI (Log Rank p = 0.78). Regarding the 252 failures observed (67% of the required events), the significance level to reject H0 is p = 0.012 (EAST V5). Conclusions: It is not possible yet to conclude to the superiority of FOLFIRI in 1st line; the final analysis after observation of 381 failures is required. Regarding toxicity, hematotoxicity is more frequent with ECC in 1st line.

Abstract Disclosures
Faculty and Discussant Disclosures
Annual Meeting Planning Committee Disclosures
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