XX CONGRESSO NAZIONALE AIOM 2019

The outcome of metastatic (M) or locally advanced (LA) gastric cancer (GC) is not improved by a new docetaxel (DOC)-based triplet regimen as compared with an epirubicin (EPI) standard triplet regimen: a GISCAD trial.

Labianca R, Rosati G, Fazio N, Cavanna L, Ferrari D, Di Bartolomeo M, Mosconi S, Giordano M, Silvestris N, Artioli F, Iaffaioli V, Veltri E, Amoroso D, Ciarlo A, Barni S, Davite C, Di Sanzo A, Casolaro A

Background: in advanced gastric cancer EOX (EPI + oxaliplatin-OHP + capecitabine-CAPE) is one of the standard regimens, but the role of EPI is under discussion and DOC substituted it in many centers. An innovative DOC-based regimen was developed, aiming at increasing the outcome vs EOX without the important side-effects of the conventional DOC combination.

Methods: from 1/2013 to 11/2018, 169 chemo-naive patients (pts) with M (87,6%) or LA GC were randomized by 23 institutions between low-TOX (arm A) and EOX (arm B):

- Arm A: DOC: 35 mg/m2 iv, d 1 and 8 + OHP: 80 mg/m2 iv, d 1 + CAPE: 750 mg/ m2 x2 daily p.o. for 2 weeks
- Arm B: EPI: 50 mg/m2 iv, d 1 +OHP: 130 mg/m2 iv, d 1 +CAPE: 625 mg/m2 x2 daily p.o. for 3 weeks

Both regimens recycled q 21 days

If no PD or heavy toxicity, pts were programmed on therapy for a maximum of 5 (if CR) or 6 courses (if PR or SD). The primary endpoint was PFS, the secondary OS, ORR, DCR and tolerability. The study was designed to detect a 35% (80% power at a two side 5% significance level) PFS increase with low-TOX and an interim analysis for futility was planned after the first 127 events (75% of expected).

Results: At the cut-off date of interim analysis, 164 pts (median age 62 y; 63,9% male; ECOG PS: 0 in 75,7%) have available data for primary efficacy analysis. The median PFS was 5.8 months (m) (95% CI: 5.0 – 7.8) in arm A vs 6.5 m (95% CI: 5.0 – 8.9) in arm B, without statistical difference (NS). Also OS was comparable: 12.2 (95% CI: 8.6 -16.0) vs 12.8 m (95% CI: 9.1-21.0). ORR were 22% and 35.4% and DCR 59.8% and 65.9%, again NS.

The median number of courses per pt was 6 and treatment modification was higher in arm A (90,2% vs 78%) with a weakly higher number of CTC ≥ 3 AE in arm A (54 vs 41).

Conclusions: On the basis of these results, it is unlikely that low-TOX regimen can reach the target of improvement vs EOX, both in efficacy/activity and in tolerability. Therefore, if clinicians decide for a triplet (i.e. in aggressive or very symptomatic disease), EOX could remain a standard option.