Annals of Oncology 25 (Supplement 4): iv167–iv209, 2014
doi:10.1093/annonc/mdu333.21

gastrointestinal tumours, colorectal

518P FOLFOXIRI WITH OR WITHOUT BEVACIZUMAB (BEV) AS FIRST-LINE TREATMENT OF METASTATIC COLORECTAL CANCER (MCRC): A PROPENSITY SCORE-BASED ANALYSIS

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Aim: A phase III trial by the GONO group showed that the triplet FOLFOXIRI increased RECIST response rate (RR), PFS and OS, as compared to an irinotecan-based doublet. More recently, the TRIBE trial demonstrated that first-line FOLFOXIRI plus bev improves PFS, RR and OS, compared to FOLFIRI plus bev. Also the early response rate and the deepness of response were significantly improved with the triplet plus bev. No direct comparison of FOLFOXIRI with or without bev is available, so that the impact of the addition of bev to the triplet has been never investigated.

Methods: From May 2001 to April 2005 122 mCRC patients received first-line FOLFOXIRI in the phase III trial by the GONO (FOLFOXIRI group) and from July 2008 to May 2011 252 patients received first-line FOLFOXIRI plus bev in the TRIBE trial (FOLFOXIRI plus bev group). A propensity scoring method was adopted to estimate the impact of adding bev to FOLFOXIRI. All comparisons were adjusted accordingly.

Results: Compared to the FOLFOXIRI group, in the FOLFOXIRI plus bev group more patients had ECOG PS 0 ($p < 0.001$) and synchronous disease ($p = 0.031$), less patients had received a prior adjuvant chemotherapy ($p = 0.012$), had the primary tumor resected ($p < 0.001$) and a high Kohne score ($p < 0.001$). In the FOLFOXIRI plus bev group a significantly longer PFS (median PFS: 12.1 vs 9.8 months, HR: 0.75 [95%CI: 0.58-0.96], $p = 0.022$) was reported, as well as a strong trend toward longer OS (median OS: 31.0 vs 23.4 months, HR: 0.76 [95%CI: 0.57-1.02], $p = 0.067$). No significant differences in terms of RECIST RR (65% vs. 56%; Odds Ratio: 1.19 [95%CI: 0.73-1.95], $p = 0.494$), early response rate (cut-off: 20%; 63% vs 58%; Odds Ratio: 1.19 [95%CI: 0.69-2.07], $p = 0.532$) and deepness of response (42.2% vs 53.8%, $p = 0.486$) were reported.

Conclusions: According to the present propensity score-based analysis, the addition of bev to first-line FOLFOXIRI provides a clear benefit in terms of PFS and improves OS with a trend toward significance, while no significant differences in terms of response are observed. Though in the absence of a randomized comparison, the present results support the addition of bev to FOLFOXIRI as first-line treatment of mCRC.

Disclosure: C. Cremolini: Advisory board: Roche; F. Loupakis: Advisory board and research funding: Roche; A. Falcone: Advisory board and research funding by Roche, Merck, Amgen, Sanofi Aventis Advisory board: Bayer, Celgene. All other authors have declared no conflicts of interest.