Aim: Achieving an initial relevant and rapid tumor shrinkage may be an important objective in mCRC pts. The triplet FOLFOXIRI is a highly active regimen. The aim of the present analysis is to explore the impact of FOLFOXIRI plus BV or anti-EGFRs in determining tumor response in RAS and BRAF wt pts treated in clinical trials by the GONO group.

Methods: 37 and 64 RAS and BRAF wt pts treated with FOLFOXIRI plus panitumumab and FOLFOXIRI plus cetuximab in TRIP and MACBETH trial respectively and evaluable for response were included in the anti-EGFR group (N = 101); 62 RAS and BRAF wt pts treated with FOLFOXIRI plus BV in the TRIBE trial and evaluable for response were included in the BV group. Best response according to RECIST, early tumor shrinkage (ETS) and deepness of response (DoR) in the two groups were analysed. Pts achieving a >20% reduction in the sum of longest diameters of RECIST target lesions at week 8 compared to baseline were defined as early responders. Since pts in TRIBE and TRIP trials received up to 12 cycles of treatment, while pts in MACBETH trial received up to 8 cycles, DoR was defined as the relative change in the sum of longest diameters of RECIST target lesions at the nadir within the first 8 cycles of treatment, compared to baseline.

Results: 83 pts (82%) in the anti-EGFR group and 44 pts (71%) in the BV group achieved a RECIST response (p = 0.120). Early response was reported in 70 out of 95 evaluable pts (74%) and in 36 out of 58 evaluable pts (62%) in the anti-EGFR and in the BV group, respectively (p = 0.150). The median ETS in the anti-EGFR group was significantly higher than in the BV group (40.8% vs 26.4%, p = 0.003). A significantly better DoR was achieved in the anti-EGFR group as compared to the BV group (median DoR: 48.6% vs 37.8%, p = 0.005).

Conclusions: Both FOLFOXIRI plus BV and FOLFOXIRI plus an anti-EGFR allow to achieve impressive results in terms of RECIST response rate (71% and 82% respectively) in the first-line treatment of RAS and BRAF wt mCRC pts. According to the present exploratory analysis the use of anti-EGFRs may be associated with an higher extent of ETS and a better DoR.

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