Updated analysis: observational cohort study of 1st line bevacizumab combined with chemotherapy in metastatic colorectal cancer (HGCSG0802): Comparison of Infusional FU/oxaliplatin (OX) + BV and oral FU/OX + BV


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Aim/Background: Some studies had reported that oral FU/Oxaliplatin (OX) was non-inferior to infusional FU/OX as 1st line treatment for metastatic colorectal cancer (mCRC). We conducted observational cohort study (HGCSG0802) which investigated Japanese patients (pts) treated with bevacizumab (BV) containing regimen. Therefore, we had performed analysis in order to investigate whether there was a difference in safety and efficacy of infusional FU/OX (mFOLFOX6 + BV: iFU) and oral FU/OX (CapeOX/SOX + BV: oFU) using the HGCSG0802 database.

Methods: The key eligibility criteria of HGCSG0802 were with evaluable lesions, older than 20 years, ECOG PS 0-2, and this analysis used the cohort treated with OX-based regimens. In this analysis, pts characteristics, RR and safety were compared using Fisher’s exact test. PFS, TTF and OS were compared using log-rank test for comparison of the iFU and oFU.

Results: Of 108 pts (the full analysis set), 95 pts were evaluable for treated with OX-based regimens. Forty-eight pts (50.5%) were treated with iFU and 47 pts (49.5%) were treated with oFU (CapeOX + BV 42 pts/SOX + BV 5 pts). The pts characteristics between those were generally balanced except for PS 0-1 (72.9% in iFU/93.6% in oFU; p = 0.012) and synchronous liver metastases (93.8% in iFU/78.8% in oFU; p = 0.040). Adverse events ≥ Grade 3 were balanced except for leucopenia (25.0% in iFU versus 2.1% in oFU; p = .002) and neutropenia (43.5% in iFU and 10.9% in oFU; p = .001). Hand-foot skin reaction was not different between two cohorts. RR was 62.5% in iFU versus 71.1% in oFU (p = 0.835). The median PFS was 8.3 months in iFU versus 8.2 months in oFU (p = 0.970) and median OS was 18.3 months in iFU versus 23.5 months in oFU (p = 0.247).

Conclusions: As a result of this analysis, in Japanese daily practice, efficacy was no significant difference between iFU and oFU, and the profiles of adverse events varied from each regimens. This analysis had been presented at the European Cancer Congress 2015 (Nakatsumi H, et al. Abstract number was 2 092).


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