SIOG 2017 - Abstract Submission

Track 1: Solid tumours in the elderly and basic science

Colorectal & GI cancers

O14

BEVACIZUMAB + CHEMOTHERAPY VERSUS CHEMOTHERAPY ALONE IN OLDER PATIENTS WITH UNTREATED METASTATIC COLORECTAL CANCER: A RANDOMIZED PHASE II TRIAL - PRODIGE 20 STUDY RESULTS

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Introduction: Metastatic colorectal cancer frequently occurs in older patients. Bevacizumab in combination with front line chemotherapy is a standard treatment but some concerns were raised about tolerance of bevacizumab in the older patients.

Objectives: The purpose of PRODIGE 20 was to evaluate tolerance and efficacy of bevacizumab according to specific endpoints in this population.

Methods: Patients aged 75 and over were randomly assigned to bevacizumab + chemotherapy (BEV) versus chemotherapy (CT). LV5FU2, FOLFOX and FOLFIRI regimen were prescribed according to investigator's choice. The co-primary composite endpoint, assessed 4 months after randomization, was based on efficacy: tumor control and absence of decrease >2 points of the Spitzer QoL index and safety: absence of severe cardiovascular toxicities and unexpected hospitalization. Efficacy in more than 20% and safety in more than 40% of the patient were the lower thresholds expected at 4 months. A geriatric assessment was performed at randomization and at each evaluation. The predictive value of geriatric and oncologic factors was determined for the combined co-primary composite endpoint assessing safety and efficacy of treatment (BEV and/or CT) simultaneously and also progression-free survival (PFS) and overall survival (OS).

Results: 102 pts were randomized in this trial (51 BEV and 51 CT), median age was 80 years (range 75-91). The primary endpoint was met for efficacy in 50.0% [90% CI: 37.1 ; 62.9] and 57.8% [90% CI: 44.4 ; 70.3] and for safety in 60.9% [90% CI: 47.7 ; 73.0] and 71.1% [90% CI: 58.0 ; 82.0] of patients in BEV and CT respectively. Median PFS was 9.7 months in BEV and 7.8 months in CT. Median OS was 21.7 months in BEV and 19.8 months in CT. The 36-month OS rate was 27.0% [95% CI: 15.7-39.7] in BEV and 10.1% [95% CI: 3.1-22.0] in CT. Severe toxicities grade 3/4 were observed in 80.4% and 63.3% in BEV and CT respectively. On multivariate analysis, baseline normal independent activity of daily living (IADL) score and no previous cardiovascular disease predicted the combined co-primary endpoint. High (vs low) baseline Köhne score predicted short PFS and baseline Spitzer quality of life (QoL) score <8, albumin level ≤35 g/L, CA19.9 >2 ULN and high baseline Köhne score predicted short OS. Survival without deteriorated QoL and autonomy were similar with BEV and CT treatment. On subgroup analyses, the trend for a better PFS and OS with BEV was maintained in patients with baseline impaired IADL or nutritional status.

Conclusion: Both arms met the primary safety and efficacy criteria. Normal IADL score was associated with a good efficacy and safety of both BEV and CT treatments. Köhne criteria may be relevant prognostic factors in older patients. Adding BEV to CT did not impair patient autonomy or QoL.

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