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breast cancer

F50 Eribulin vs. Eribulin + Bevacizumab in advanced-line treatment of Her-2 negative metastatic breast cancer

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Background: in this phase II study we compared the efficacy and safety of Eribulin monotherapy (arm A) with the association of Eribulin and Bevacizumab (arm B) in patients with metastatic breast cancer.

Patients and methods: We included all the patients with metastastic breast cancer, Her2-negative, hormone receptor-positive, who have already received at least 2 lines of therapy for metastatic disease. Patients in Arm A received Eribulin 1.23 mg/m2 on days 1 and 8 every 3 weeks as monotherapy, whereas patients in Arm B received the same regimen associated with Bevacizumab 15 mg/kg day 1 triweekly. Patients in the protocol underwent hematologycal assessment, with urine analysis and markers dosing on day 1 of every cycle, a total body CT scan every 4 months (or for any evidence of progression of disease). The primary endpoint was PFS. Secondary endpoints were the OS and the toxicity profile.

Results: From February 2013 to April 2016 were enrolled 30 patients; 18 in the arm A, 12 in the arm B. Patients characteristics did not differ between the arms in terms of grading, age, Ki67, number of metastases. After a median follow up of 11 months a total of 19 patients developed progression of disease (respectively 14 in arm A and 5 in arm B) and 10 patients died (respectively 7 in arm A and 3 in arm B). PFS in Arm A was 5,34 +/- 0,74 months, (95% CI 3,87-6,80) and in Arm B 8,20 +/- 1,04 (95% CI 6,14-10,25), with a p value of 0,034. OS in Arm A was 24,45 +/- 3,63 months (95% CI 17,32-31,58), while in Arm B 17,81 +/- 3,15 (95% CI 11,61-24,01) with a p value of 0,726, probably due to the insufficient follow up period. The most common adverse events related to Bevacizumab were hypertension (grade 3-4 in 3 patients), controlled with antihypertensive therapy, and epistaxis (grade 3-4 in 2 patients). Febrile neutropenia was not observed. The addition of Bevacizumab has not significantly worsened the toxicity profile.

Conclusions: The combination chemotherapy seems to improve PFS compared to Eribulin monotherapy in patients with metastatic breast Her2-negative already heavily pretreated, although it does not affect OS. Further studies with a greater number of patients and a long follow up are needed to support these data.