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Session A. Breast cancer

A41 Evaluation of safety and activity of everolimus plus exemestane in metastatic breast cancer: a single institution experience

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Background: Everolimus (EV) is an oral inhibitor of mammalian target of rapamicin (mTOR), recently approved in combination with exemestane (EX) for the treatment of hormonal positive metastatic breast cancer (MBC) progressed to a non steroideal aromatase inhibitor.

Patients and method: We retrospectively evaluated 63 consecutive patients (pts) treated with EV plus EX in our institution from July 2012 to April 2015. At the beginning of EV's therapy median age was 63 years (range 45-80); pts older than 70 were 15. Visceral metastases were present in 35 pts (56%) and 18 pts (28.6%) had more than two sites of metastasis. 19 pts (30%) and 18 (28.5%) had liver and lung involvement respectively. Pts received previous hormonal therapy for metastatic disease for a median number lines of 1 (range 0-4) and chemotherapy for a median line of 1 (range 0-5) respectively. EV plus EX was administered as first line in 10 pts (15.8%).

Results: Oral mucositis, observed in 45 pts (71%), was the most common toxicity: it presented with a grade 3 appearance in 10 pts (16%). Then in order of frequency: skin toxicity in 22 pts (35%), fatigue in 19 pts (30%) and transaminase increase in 18 pts (28.5%). Non-infectious pneumonitis was reported in 11 pts (17%) with only 1 case of grade 3; diarrhea in 12 pts (19%), in all cases of grade 1 or 2; hyperglycemia and hypercholesterolemia respectively in 15 (23.8%) and 10 pts (16%) respectively with a case of grade 3 in both. Other relevant observed toxicity were, anemia in 10 pts (16%) and piastrinopenia in 5 pts (7.9%). Overall, 27 pts (43%) reduced EV dosage to 5 mg per day. 15 pts (23.8%) were 70 years or older and among them 6 (43%) stopped treatment for toxicity and 8 (53%) decreased EV dosage. Furthermore, we admitted 2 pts for enteritis. The incidence of toxicity was similar in elderly patients, except for fatigue observed in 7 pts (46.6%). In the overall population median duration of treatment was 7.6 months (m) (range 1-25 m) and median progression free survival (PFS) was 7.9 m (1-23 m).

Conclusion: In our real life experience the activity and toxicity of EV plus EX treatment was comparable to BOLERO-2 study except for oral mucositis and metabolic disorder. A careful patient's proactive monitoring is strictly necessary in order to minimize the toxicity and obtained the best results of combination.