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breast cancer

F44 **Subcutaneous Trastuzumab (scT) and metronomic oral Vinorelbine (mVRL) combination in HER2 + ve advanced breast cancer (ABC) patients (pts): a pilot evaluation of toxicity. Preliminary results of the VICTOR-4 study**

F. Cicchiello[1], F. Riva[2], M.E. Cazzaniga[2], N. Digiacomo[2], D. Pelizzoni[2], R. Longarini[2], S. Capici[2], P. Bidoli[2]
[1]*Asst- Monza, Monza*
[2]*Asst-Monza, Monza*

Background: The combination of Trastuzumab (T) and Vinorelbina (VRL) is wildly administered in metastatic HER2 + ve breast cancer. This combination is associated to a high incidence of grade 3-4 neutropenia compared to taxane-based treatment. Recent data demonstrated that scT is not-inferior to ivT in terms of efficacy, with a similar pharmacokinetic and safety profile. In a previous study (VICTOR-1), we tested the metronomic administration (low-dose, continuing schedule) of VRL, demonstrating an incidence of grade 3-4 toxicities below 5%. The easier schedule of mVRL, together with the preference for scT by pts, suggest the possibility to combine these two schedules in HER2+ pts. Here we present the preliminary results of toxicity in an unselected group of HER2+ pts, as a pivotal experience for a Phase II study.

Materials and methods: HER2+ ABC pts were treated with VRL 40 mg thrice a week continuously + scT 600 mg fixed dose every 3 weeks, until progression or unacceptable toxicity. Drug-related toxicity was collected at the beginning of each scT administration. Tumor radiological assessment has been planned every 3 cycles (1 cycle = 3 weeks), according to the clinical practice.

Results: From August 2014 to March 2016, 10 pts entered this pivotalstudy. At the moment of the present analysis, a total of 93 cycles are evaluable for toxicity. Median age of the pts was 69 years; 9 pts have been previously treated with taxanes; 2 patients received mVRL + scT as 1stline,4 pts as 2nd, 2 pts as 3rd and 2 pts as 4th line of treatment. Table 1 summarizes the incidence of side effects. Grade 3 toxicity was observed in 3.2% of the cycles; no Grade 4 toxicity has been reported. Results regarding efficacy are too early at the moment to be presented.

Conclusion: In this pilot evaluation, scT and mVRL combination seems to be feasible with a low incidence of toxicity, in comparison to what observed in the TRAVIOTA Trial. Further evaluation of a greater number of cycles is needed to confirm these preliminary results.

Table: F44

	G1	G2	G3	G4
Nausea	1	3	1	0
Diarrhoea	2	0	0	0
Vomiting	0	1	0	0
Abdominal pain	1	0	0	0
Myalgia	1	1	0	0
Neuropathy	2	0	0	0
Neutropenia	0	3	1	0
Asthenia	2	0	1	0
Total	9	8	3	0