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Efficacy and safety of neoadjuvant chemotherapy plus trastuzumab and pertuzumab in non-metastatic HER2-positive breast cancer in real life: NEOPEARL study

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Background: In HER2+ breast cancer (BC) patients (pts) the pathological complete response (pCR) is associated with improved survival. With regimens based on the combination of trastuzumab (T), pertuzumab (P) and chemotherapy, pCR rates are slightly over 48%. We conducted a retrospective analysis on HER2+ BC pts to describe the outcomes of neoadjuvant combination of P+T and chemotherapy in the real-life setting.

Methods: Our cohort included 64 pts treated between Sept 2015 and Mar 2018 in 15 Italian Cancer Centers. Treatment outcomes were analyzed in terms of pCR (defined as ypT0/Tis, ypN0i-) and toxicities, recorded according to National Cancer Institute Common Toxicity Criteria. Statistical analysis was performed with T di Student test and $\chi 2$ test.

Results: Overall, in the 55 evaluable pts median age was 50 (range 28-77) and 29 pts (53%) were pre-menopausal. 24 pts (45%) were ER-/PgR-, 12 (21%) ER+/PgR-, 16 (29%) ER+/PgR+, median ki67 was 40. 9% of pts were cT1, 73% cT2, 13% cT3 and 5% cT3; 42 pts (76%) were cN+. All pts received 4 cycles of T (8 mg/kg loading dose, followed by 6 mg/kg every 3 weeks) and P (loading dose 840 mg, followed by 420 mg every 3 weeks). In 42 pts T+P were administered with docetaxel (75 mg/mq every 3 weeks), in 8 pts with paclitaxel (80 mg/mq) and 5 pts received docetaxel and carboplatin (AUC5). In 13 pts also 3 cycles of anthracyclines, according to the FEC scheme, were administered. A pCR was achieved in 29 pts (53%). No significant associations were found between pCR and baseline characteristics or treatments schedule. Seven out of 55 (13%) pts reported G3-G4 toxicities (5 pts neutropenia G3-G4, 1 pt vomiting G3, 1 pt diarrhoea G3, 1 pt anemia G3). Three out of 4 pts treated with docetaxel, carboplatin and P+T reported G3/G4 toxicities. A significant association was found between chemotherapy schedule and toxicities (p = 0.004).

 $\label{lem:conclusions:} Conclusions: The association of P+T+chemotherapy improved pCR rate in HER2+BC pts treated in the real-life setting. Our results showed that the selection of chemotherapy that will be associated with the dual blockade of HER2 is of paramount importance in order to avoid severe toxicities and increase the compliance with treatment.$

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