Aim: Although breast cancer is a tumor sensitive to drug therapy, there is an urgent need for an effective treatment for pts with TNmBC. The study was performed to assess the efficacy and safety of CP combination in TNmBC.

Methods: Eligibility criteria included measurable TNmBC, multiple metastases to visceral organs ≥2, ECOG ≤2, adequate liver, kidney and bone marrow function, no brain metastases. P was administered 175 mg/m² on D1 and C AUC5 on D1 q3w up to 6 cycles. Treatment was continued until progression or unacceptable toxicity. Endpoints include response rate, OS, PFS and safety.

Results: Between 2009-2013 81 pts with TNmBC were recruited. Mean age was 54.9 ± 3.4 yrs. All pts had multiple synchronous metastases to visceral organs ≥2 disease sites: lung 64.2% (52), lymph nodes 54.3% (44), bones 59.3% (48), liver 72.8% (59), 35.8% (29) pts received the 1st line and 64.2% (52) - the 2nd line chemotherapy (CT). RR was 80.2% (65) including 6.2% CR (5), 24.5% PR (20) and 49.4% SD (40). Most common toxicities were: nausea 1/2Gd-51.9%(42), vomiting 2Gd-13.6%(11), fatigue 1/2Gd-54.3%(44), bone pain 1/3Gd-69.1%(56), neutropenia 2/3Gd-32.1%(26). All kinds of toxicities were controlled by symptomatic medication if necessary and did not lead to CT delay. In the 1st CT line OS was 13.3 ± 2.4mos, PFS - 7.4 ± 1.5mos. In the CT 2nd line OS was 8.2 ± 1.8mos, PFS - 4.6 ± 0.9mos.

Conclusions: CP combination had a satisfactory efficiency and well-controlled toxicity. The favorable RFS and OS allow its use widely as clinical option in the 1-2 line of treatment of TNmBC pts with massive visceral metastases.

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