Neoadjuvant chemotherapy in the treatment of early breast cancer - results of a real-world study.

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Background: Pathologic complete response (pCR) following neoadjuvant chemotherapy (NAC) has been proposed as a surrogate endpoint for of long-term clinical benefit, such as disease-free survival, event-free survival (EFS) and overall survival (OS) in patients (pts) with early breast cancer (BC). A pCR is dependent on clinical-pathological characteristics and molecular subtypes.

Methods: The aim of the study was to evaluate real-world treatment outcomes in a multidisciplinary setting managing early breast cancer patients.
We retrospectively analyzed real-world data of 273 pts undergoing taxane and/or anthracycline, +/- trastuzumab based NAC. Luminal A was documented in 12 pts, Luminal B in 55 pts, Her-2^+ in 44 pts and triple negative breast cancers (TNBC) in 162 pts. Pathological complete response was defined as the complete disappearance of the invasive cancer in the breast and absence of tumor in the axillary lymph nodes.

Results: The pCR rate of the entire cohort was 48%. At 4 years 96% of pts who attained a pCR were disease free compared to 74% of pts who did not attain a pCR (log rank test Chi^2 =19.78, $p < 0.0000$).
On univariate analysis factors associated with higher pCR included molecular subtype (TNBC 60%, Her-2^+ 61%, Luminal A - none and Luminal B 15%, Chi^2 =48, $p<0.00000$), primary tumor size (T1=66% vs. T2=49% vs. T3=19% vs. T4=27%, Chi^2=19,70, $p<0.0002$), nodal disease (N0=56% vs. N1=40%, Chi^2=7.05, $p<0.007$), age (< than 50 years = 55% vs. ≥ 50 years = 43%, Chi^2 = 3.75, $p<0.05$) ER receptor status (negative=61% vs. positive=26%, Chi^2=31.56 $p<0.00000$), PR receptor status (negative=59% vs. positive=19%, Chi^2=33.95 $p<0.00000$), Ki67 (≥40=60% vs.14-39=41% vs. ≤14=5%,Chi^2=27.11 $p<0.00001$) and Stage (I= 77% vs. IIA=55% vs. IIB=40% vs. III=24%, Chi^2=23.89 $p<0.00003$). Menopausal status, ethnicity, extra-nodal spread and lympho-vascular invasion were not associated with a higher pCR rate. In a logistic regression model Ki-67 as a continuous variable ($p<0.007$) and biological subtype ($p<0.0002$) retained its significance; while tumor size, stage of disease, nodal status, ER and PR loss significance.

Conclusion: This data highlights the importance of breast care multidisciplinary management in early disease. TNBC and HER-2+ subsets were associated with a higher pCR rate. Our results are similar to those reported in a clinical trial setting.