Introduction/Background The use of trastuzumab in the treatment of HER2-positive breast cancer has changed the natural history of this disease. Trastuzumab was approved as a component of neoadjuvant treatment as well as adjuvant and metastatic. Biosimilars demonstrate chemical similarity and clinical efficacy to a reference product and are an option to provide access to high-quality systemic therapy alternatives.

Methodology This is a retrospective observational study revising patients treated with neoadjuvant therapy with trastuzumab (proposed biosimilar or trastuzumab) between January 2017 (period of introduction of the drug in our institution) - January 2020. All patients were treated with the same trastuzumab biosimilar drug.

Results Twenty-two patients (n=22) were included, with mean age at diagnosis of 55 years (range 31-84). Fifteen (n=15) patients were treated with proposed biosimilar and 7 patients with trastuzumab. Regarding histologic type, 82% (n=18) of patients had invasive carcinoma of no special type (NST), 5% (n=1) apocrine, 5% (n=1) invasive lobular and 5% (n=1) mucinous carcinomas. Sixteen patients had HER2 positive, hormone receptor (HR) positive tumors and 6 patients a HER2 positive, HR negative tumors. Regarding treatment, 86% of patients were treated with anthracyclines and in 5% (n=1) pertuzumab was used. In the trastuzumab group, 2 patients presented grade 1 toxicity (heart failure); in the proposed biosimilar group, 2 patients presented grade 1 toxicities (heart failure and dyspnea). Infusion reactions were not documented, namely hyperthermia. Axillary pCR was achieved in 86% (n=6) and 53% (n=8) in trastuzumab and proposed biosimilar groups respectively. Breast pCR was achieved in 86% (n=6) and 33% (n=5) in trastuzumab and proposed biosimilar groups respectively. There was no statistically significant difference between the proposed biosimilar versus trastuzumab for toxicities, achievement of axillary and breast pCR.

Conclusion The use of trastuzumab compared with the proposed biosimilar resulted in an equivalent axillary and breast pCR. Our results are concordant with the clinical trial results performed and support the evidence for their continued use.

Disclosures No disclosure.

Introduction/Background Breast cancer is the most common cancer of the female, and the second most common cancer overall. While chemotherapy is standard of care for many patients with this type of cancer, it is associated with various side effects that require supportive care. In addition to standard medical therapies, patients may benefit from complementary treatments, such as sport therapy or Reiki. Reiki is a far eastern method that promotes healing on a physical, mental and emotional level and activates self-healing powers. Aim of this study was to compare the efficacy of Reiki versus Sport as supportive care during primary systemic therapy of early breast cancer within the REASSURE study.

Methodology REASSURE was a prospective, randomized, controlled, two-armed clinical trial, in which patients with breast cancer received chemotherapy and Reiki (18 times) or chemotheraphy and sport (18 times). This evaluation specifically focused on patients who received neoadjuvant chemotherapy with four cycles of Epirubicin and Cyclophosphamide followed by 12 cycles of a Taxane. All patients were enrolled in the REASSURE-study and randomized before their first chemotherapy cycle. While sport therapy was delivered as conventional phyiotherapy, Reiki was delivered by a trained Reiki practitioner. We conducted a statistical analysis using Wilcoxon Rank sum tests to compare incidence of adverse events (febrile neutropenia (FNP), fever, infection, blood count variation, hospitalization), dose modifications (therapy discontinuation, dose interruption, dose reduction) and use of conventional medical supportive care treatments (G-CSF, antibiotics, blood transfusion, platelet transfusion).

Results A total of 48 subjects were included, of which 27 received Reiki and 21 received sport treatment. When comparing FNP events between both groups, we found 3 events in the sport group, whereas there were none in the Reiki group (p = 0.047). The median number of GCSF-application was 4 (range 0 to 8) in the sport group versus 0 (range 0 to 8) in the Reiki group (p = 0.006). For all other parameters, calculation of 95 percent confidence intervals showed no clinically significant difference between the two groups.

Conclusion Reiki may pose a viable alternative medical treatment option to sport as a supportive therapy option to combat side effects of neoadjuvant Epirubicin, Cyclophosphamide and Taxane chemotherapy for breast cancer treatment. To better understand the beneficial influence of this therapy, further research is needed to compare Reiki with a control group receiving no additional therapy.

Disclosures REASSURE Studie - This study is a collaborative study between Frauenklinik Rechts der Isar, Frauenklinik des Rotkreuzklinikums, Frauenklinik der München Klinik Harlaching, and ProReiki – Berufsverband e.V. There was no funding.

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