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ONCOTYPE DX[®] IN THE SISTEMA ÚNICO DE SAÚDE DO BRASIL (SUS): RESULT OF 125 CASES

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Objectives: OncotypeDx[®] is a diagnostic test that uses the qRT-PCR (Reverse Transcript polymerase chain reaction quantitative real time) technique in the evaluation of 21 genes and the result is given as Recurrence Score (RS) ranging from 0 to 100. The RS was validated in data from the NSABP B-14 study which examined the benefit of adjuvant tamoxifen in patients with hormone receptor positive and lymph node-negative breast cancer. In patients classified as low risk by RS (RS <18), only 7% relapsed despite adjuvant tamoxifen compared to high risk patients (RS > 31), of whom 31% relapsed. The TailorX study, updated in 2018, included 9,719 HER2 negative hormone receptor patients with tumors ranging from 1.1 to 5.0 cm and was designed to evaluate the benefit of chemotherapy in patients considered to be at intermediate risk (RS between 11 and 25). Thus, 6,711 patients in the intermediate group were randomized to receive chemotherapy followed by hormone therapy or only hormone therapy. After data analysis (follow-up of 96 months for overall survival) it was concluded that chemotherapy had no benefit in patients older than 50 years old up to RS 25, but those under 50 years could have an additional benefit depending on the value of the RS (6.5% benefit in score from 21 to 25 and 1.6% from 16 to 20). To evaluate the change of conduct after the test result (OncotypeDx[®]) in SUS. **Methodology:** 125 patients from 08/08/2018 to 03/25/2019, post-surgery with T1 and T2 tumors, with up to 3 axillary lymph nodes involved, luminal (HER 2 negative and ER positive), candidates for adjuvant systemic therapy. Before the test, it was determined which systemic therapy would be prescribed, and after the result, that was actually performed. **Results:** The mean age of the patients was 57.4 years (34–78), 41 had axillary lymph nodes involved and 76% were postmenopausal. Before the test, 122 of the 125 patients had, by clinical criteria, indication of chemotherapy. After the test was performed, there was a modification in CT indication in 68.8% (84 patients that would receive CT by clinical indications did not receive it and received only HT, and 2 patients that were not going to receive CT had to receive it because of the recurrence score). Using the criteria defined in the MINDACT study for the classification between high and low clinical risk, we observed that 48.8% of our patients were at high risk and only 36% of them (22/61) received chemotherapy. Regarding low-risk patients according to clinical criteria, 21.9% underwent chemotherapy (19/64). **Conclusion:** Recruitment remains active and, initially, we have already evaluated the advantage of applying the test in reducing the indication of chemotherapy with benefits to both the patient and the health system. Clinical criteria have not been able to adequately predict which patients benefit from chemotherapy.