Patterns of OncotypeDX use in early HR+/HER2- Breast Cancer: clinical-pathological comparison of tested versus untested patients followed at the Breast Unit of Parma

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Background

OncotypeDX (ODX) test in early-stage hormone receptor-positive (HR+)/ Epidermal growth factor receptor2 negative (HER2-) breast cancer (BC) helps clinicians in evaluating patients' prognosis and defining adjuvant treatment. In Emilia-Romagna (Italy), the indication for conducting ODX is determined by the multidisciplinary breast unit team. However, the criteria for test reimbursement remain broad.

Methods

We performed a comparative analysis of the clinical and pathological characteristics of patients treated at the Parma Breast Unit from July 2020 to July 2024, comparing those who underwent ODX testing with those who, despite being potentially eligible, were not offered the test.

We excluded for analyses patients with

Low risk BC Luminal BC (indication at only endocrine therapy) 5 characteristics	HIGH RISK Luminal BC (indication at adjuvant chemotherapy and endocrinte therapy) At least 4 charatcteristics:
• G1 • pT1(a,b) – for T1a and other 2 criteria, no indication for ODX • ki67 < 20% • ER > 80% • N0	• G3 • T3-4 • ki67 > 30% • N+ (more than 3 positive nodes, no indication at test)

Results

ODX test was proposed to 139 patients (pts), with a median age at diagnosis of 56 years (range 36–74). Among these, 60% (84 pts) presented with T1 (< 2 cm) tumors, 39% (54 pts) had no nodal involvement (N0), 62% (86 pts) had grade 2 (G2) tumors, and 35% (48 pts) showed an intermediate Ki-67 proliferation index (15–29%).

Conversely, the test was not performed in 894 patients who otherwise met potential criteria for ODX testing. The median age in this group was 61 years. Of these, 240 patients were excluded from further analysis due to age >75 years (including 171 aged ≥80 years).

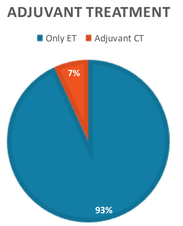
Among the remaining 654 patients, 64% (536 pts) had T1 tumors, 78% (512 pts) were N0, 62% (405 pts) had G2 tumors, and 57% (375 pts) exhibited a low Ki-67 (<15%).

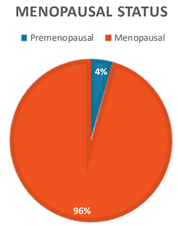
		ODX group	No ODX group
pT	T1a	1 (1%)	4 (1%)
	T1b	16 (11%)	234 (36%)
	T1c	67 (48%)	298 (45%)
	T2	55(40%)	118 (18%)
pN	N0	54 (39%)	512 (78%)
	N1	84(60%)	114 (18%)
	Nx	1(1%)	28 (4%)
Grading	G1	19 (14%)	190 (29%)
	G2	86 (62%)	405 (62%)
	G3	34 (24%)	59 (9%)
Ki67	Low (< 15%)	32 (23%)	375 (57%)
	Intermediate (15-29%)	48 (35%)	199 (30%)
	High (≥ 30%)	59 (42%)	76 (12%)
	Unkonwn	-	4 (1%)

Table 1. table shows main differences between 2 groups

30% (41 pts) of the patients who underwent ODX testing received adjuvant chemotherapy due to a high recurrence score (RS).

Among patients who were not tested with ODX, only 7% (45 pts) received adjuvant chemotherapy; of these, 62% (28 pts) were premenopausal and 64% (29 pts) had nodal involvement (N1).







Patients in the ODX-tested group typically presented with multiple intermediate-risk features (3 or 4 risk factors), whereas those not tested generally had fewer risk factors (usually 1 or 2).

Conclusions

Our real-world analysis reveals a substantial discrepancy between potential eligibility for ODX and its actual use in early-stage HR+/HER2- BC patients. Patients who underwent ODX testing more frequently exhibited multiple risk factors, which justified the genomic assessment and allowed for a more personalized decision-making process regarding adjuvant chemotherapy.

Considering the high cost of the assay and the limited availability of healthcare resources, a more precise selection of patients is essential to ensure cost-effective and clinically appropriate use of genomic testing, avoiding unnecessary expenses and improving treatment personalization.

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