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Real-World Evidence on the Use of the 21-Gene Assay in Patients with HR+/HER2– Early Breast Cancer in Japan
A Nationwide Claims Database Analysis

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BACKGROUND

- Oncotype DX® (21-gene assay) provides prognostic information and predicts adjuvant chemotherapy (CT) benefit in HR+, HER2- early breast cancer. (1-5)
- Oncotype DX test has been reimbursed in Japan since September 2023 to support adjuvant treatment decision-making. (6,7)
- Real-world evidence (RWE) on its clinical use in Japan remains limited.
- This study presents the first large-scale RWE study in Japan using a nationwide claims database providing insights into the clinical application and utilization of Oncotype DX test.

METHODS

- **Design**: Retrospective cohort study
- **Data source**: Claims database from Medical Data Vision Co., Ltd. (Tokyo, Japan) including approximately 230 acute care hospitals
- **Study period**: Sept 2023 – Dec 2024
- **Population**: Breast cancer (BC) patients who underwent Oncotype DX test were identified. Among these, CT and endocrine therapy (ET), classified as neoadjuvant or adjuvant, were described in patients with at least 6 months of follow-up after Oncotype DX test.

STUDY COHORT

- **3,837 BC patients** who underwent Oncotype DX test post-reimbursement
- Median age: 57 years [IQR 49–67]; including 17 male patients (0.4%). Age distribution: ≤39 years (n=151, 3.9%), 40–49 (n=907, 23.6%), 50–59 (n=1,100, 28.7%), 60–69 (n=929, 24.2%), 70–79 (n=704, 18.4%), 80–89 (n=44, 1.1%), 90–99 (n=2, 0.1%).
- Median BMI: 22.6 [IQR 20.3–25.7]
- TNM clinical classification: T1 (55%), T2 (40%), node-negative (N0: 87%), node-positive (N1:12%)
- Clinical Stage: IA (50%), IIA (39%), IIB (7%), Stage III/IV (1.3%)
- 88% of patients were treated at designated cancer care hospitals; of these, 53% were at large hospitals (≥500 beds) and 46% at mid-sized hospitals (200–499 beds)

DISCUSSION & CONCLUSIONS

DISCUSSION

- A 23% adjuvant CT rate is similar to pre-Oncotype DX test rate (8), but whether this reflects changes in treatment decisions due to test use is unclear.
- Median times from surgery indicate timely testing and therapy initiation in routine clinical practice in Japan.
- Limitations include lack of Recurrence Score® results and clinical outcomes.
- Future research will identify patients eligible for Oncotype DX test who did not undergo test and analyze their clinical characteristics and treatment patterns.

CONCLUSIONS

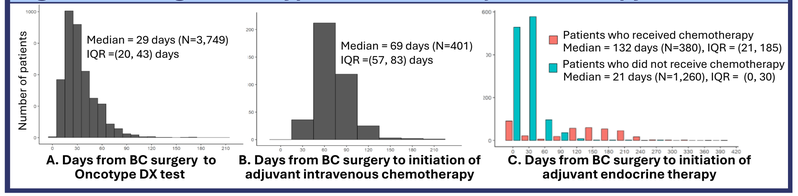
- This is the first nationwide RWE study on the clinical use of the Oncotype DX test after its reimbursement in Japan.
- Findings on the use of Oncotype DX test are consistent with current guidelines for personalized treatment.

Table 1. Patient Characteristics

Characteristics	All patients* (N = 3,837)	Patients with 6-month FU** (N = 1,725)
Age†, Median (IQR)	57 (49 , 67)	56 (48 , 66)
BMI, Median (IQR)	22.6 (20.3 , 25.7)	22.6 (20.3 , 25)
CCI, Median (IQR)	2 (2, 3)	2 (2 , 3)
Sex		
Female	3,820 (99.6%)	1,717 (99.5%)
Male	17 (0.4%)	8 (0.5%)
cT		
T0	1 (0.0%)	1 (0.1%)
T1	1,980 (55.1%)	891 (54.7%)
T2	1,451 (40.4%)	665 (40.8%)
T3	42 (1.2%)	20 (1.2%)
T4	27 (0.8%)	11 (0.7%)
Tis	90 (2.5%)	40 (2.5%)
cN		
N0	3,138 (87.4%)	1,429 (87.8%)
N1	444 (12.4%)	195 (12.0%)
N2	7 (0.2%)	3 (0.2%)
N3	1 (0.0%)	1 (0.1%)
cM		
M0	3,507 (99.9%)	1,590 (99.9%)
M1	5 (0.1%)	2 (0.1%)
Clinical Stage		
0	86 (2.5%)	39 (2.5%)
IA	1,739 (49.9%)	779 (49.4%)
IB	17 (0.5%)	7 (0.4%)
IIA	1,350 (38.7%)	628 (39.8%)
IIB	245 (7.0%)	104 (6.6%)
III/IV	47 (1.3%)	21 (1.3%)
Hospital scale		
~ 199 beds	35 (0.9%)	13 (0.8%)
200 ~ 499 beds	1,756 (45.8%)	813 (47.1%)
500 beds ~	2,046 (53.3%)	899 (52.1%)
DCC Hospital	3,369 (87.8%)	1,519 (88.1%)

* All patients who received Oncotype Dx test from Sept 2023 – Dec 2024
** Patients who had at least 6 months follow-up after Oncotype DX test
† Age at Oncotype DX test
Abbreviations: FU, follow-up; IQR, Inter-quartile range; CCI, Charlson Comorbidity Index; DCC, Designated Cancer Care

Figure 1. Timing of Oncotype DX test and Adjuvant Therapy



A. Days from BC surgery to Oncotype DX test
B. Days from BC surgery to initiation of adjuvant intravenous chemotherapy
C. Days from BC surgery to initiation of adjuvant endocrine therapy

RESULTS

- Among **1,725 patients** with at least 6 months of follow-up, 23% received adjuvant CT.
- The most common regimens were Anthracycline and Taxane (48%), and Taxane plus Cyclophosphamide (43%).
- ET was administered to 9% as neoadjuvant and 95% as adjuvant therapy.
- Adjuvant ET consisted mainly of aromatase inhibitors (60%), followed by SERMs alone (22%) and LHRH agonists + SERMs (16%).
- 37% of patients received radiation therapy.
- Median times from BC surgery to: Oncotype DX test, 29 days (IQR 20–43); adjuvant IV CT, 69 days (IQR 57–83); and adjuvant ET, 21 days (IQR 0–30) without CT and 132 days (IQR 21–185) with CT.

Table 2. Treatment Patterns

	Patients who had at least 6 months follow-up after Oncotype DX test (N = 1,725)				
	Preoperative therapy			Postoperative therapy	
Chemotherapy	3 (0.2%)		401 (23.2%)	(100.0%)	
Anthracycline w/o Taxane	2 (0.1%)		20 (1.2%)	(5.0%)	
Anthracycline and Taxane	0 (0.0%)		194 (11.2%)	(48.4%)	
Taxane and Cyclophosphamide	0 (0.0%)		174 (10.1%)	(43.4%)	
Others	1 (0.1%)		13 (0.8%)	(3.2%)	
Endocrine therapy	157 (9.1%)	(100.0%)	1,640 (95.1%)	(100.0%)	
AIs, SERMs + AIs	80 (4.6%)	(51.0%)	989 (57.3%)	(60.3%)	
AIs + LHRHs, AIs + LHRHs + SERMs	1 (0.1%)	(0.6%)	33 (1.9%)	(2.0%)	
SERMs	64 (3.7%)	(40.8%)	358 (20.8%)	(21.8%)	
LHRHs + SERMs	11 (0.6%)	(7.0%)	260 (15.1%)	(15.9%)	
LHRHs	1 (0.1%)	(0.6%)	0 (0.0%)	(0.0%)	
S-1, CDK4/6, PARP, Capecitabine	1 (0.1%)		541 (31.4%)		
S-1	0 (0.0%)		503 (29.2%)		
CDK4/6	0 (0.0%)		37 (2.1%)		
PARP	0 (0.0%)		4 (0.2%)		
Capecitabine	1 (0.1%)		1 (0.1%)		
Radiation	3 (0.2%)		637 (36.9%)		

Percentages are based on all patients for the first column and on each therapy group for the second.
Abbreviations: LHRHs, luteinizing hormone-releasing hormone agonists; SERMs, selective estrogen receptor modulators
CDK4/6, cyclin-dependent kinase 4 and 6 inhibitors; PARP, poly (ADP-ribose) polymerase inhibitors

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