Clinical Characteristics of Chinese Patients with HR+/HER2- Early Invasive Breast Cancer Tested with MammaPrint: A Comparison with the MINDACT Cohort

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Abstract

This study compared clinicopathological characteristics between 1,900 Chinese patients and 6,693 patients from the MINDACT cohort, all with early invasive breast cancer tested using the 70-gene signature (MammaPrint®)[1]. Chinese patients were significantly younger at diagnosis and exhibited a higher prevalence of T2-stage tumors and Grade 2 histology compared to the MINDACT cohort. These distinct clinical profiles were consistent across all genomic risk subgroups. Notably, the proportion of clinical high-risk/genomic low-risk patients—a key group for potential chemotherapy de-escalation—was similar between the Chinese and MINDACT cohorts (24.0% vs. 23.2%). These findings highlight unique pathological features in Chinese breast cancer patients and emphasize the need to validate the 70-gene signature's predictive utility in this population. Further survival analyses and prospective studies based on this large cohort are warranted to confirm its clinical value in guiding treatment decisions for Chinese patients.

Introduction

The 70-gene signature (MammaPrint®) is a prognostic tool for predicting distant metastasis risk in early invasive breast cancer, particularly in HR+/HER2- patients with 0-3 positive lymph nodes. Although included in international guidelines, its performance in Chinese populations requires further validation. This study aims to compare clinicopathological features between a large Chinese cohort and the MINDACT cohort.

Methods and materials

We conducted a retrospective analysis of 1,900 Chinese patients with early breast cancer tested using MammaPrint®. Clinical risk (C-High [C-H] or C-Low [C-L]) was assessed using a modified Adjuvant! Online algorithm. Genomic risk was classified by MammaPrint® as High Risk (G-H) or Low Risk (G-L) and further subcategorized into quartiles: Ultra-Low (G-UL), Low but Not Ultra-Low (G-LNUL), High but Not Ultra-High (G-H1), and Ultra-High (G-H2). We compared G-H vs. G-L within the Chinese cohort and evaluated key characteristics (age, T-stage, grade, nodal status) across the overall population and four clinico-genomic risk groups (C-H/G-H, C-H/G-L, C-L/G-H, C-L/G-L) against the MINDACT cohort1 (n=6,693). Categorical variables were analyzed using Fisher's exact test, with a two-sided P < 0.05 considered statistically significant.

Results

- Within the Chinese cohort, significant differences were observed between genomic low-risk (G-L) and high-risk (G-H) patients. The G-H group exhibited more aggressive tumor characteristics, including a higher proportion of T2-stage tumors, advanced histological grade, low PR expression (≤20%), and elevated Ki-67 index (>14%). These findings confirm that the 70-gene signature effectively stratifies patients based on distinct clinicopathological profiles (Table 1).

Table 1. Baseline Characteristics That Significantly Differed by 70-Gene Signature Risk in the Chinese Cohort

	Genomic high-risk (G-H,N=780)	Genomic low-risk (G-L,N=1120)	P-value
Clinical_risk			<0.001
C-H	421 (54.0%)	456 (40.7%)	
C-L	359 (46.0%)	664 (59.3%)	
Grade			<0.001
1	57 (7.3%)	189 (16.9%)	
2	556 (71.3%)	887 (79.2%)	
3	167 (21.4%)	44 (3.9%)	
T-stage			<0.001
T1	398 (51.0%)	677 (60.4%)	
T2	364 (46.7%)	426 (38.0%)	
T3	18 (2.3%)	17 (1.5%)	
PR status			<0.001
<=20%	159 (20.4%)	111 (9.9%)	
>20%	621 (79.6%)	1009 (90.1%)	
Ki-67 status			<0.001
<=14%	132 (16.9%)	547 (48.8%)	
>14%	648 (83.1%)	573 (51.2%)	

- Comparison with the MINDACT cohort revealed that Chinese patients were significantly younger (proportion <50 years: 40.3% vs. 33.3%) and had higher frequencies of T2-stage disease (41.6% vs. 27.2%), Grade 2 tumors (75.9% vs. 49.1%), and lymph node positivity (23.7% vs. 21.0%). In the clinical high-risk/genomic low-risk (C-H/G-L) subgroup, Chinese patients showed markedly higher proportions of Grade 2 (86.8% vs. 64.2%) and T2-stage tumors (69.1% vs. 54.4%), and a lower proportion of T1-stage tumors (27.2% vs. 41.8%). The proportion of C-H/G-L patients was comparable between the Chinese and MINDACT cohorts (24.0% vs. 23.2%). The overall clinico-genomic concordance rate was 57.1% (Table 2 and Figure 1).

Table 2. Significant Differences in Baseline Characteristics Between Chinese and MINDACT Cohorts Across All Risk Subgroups

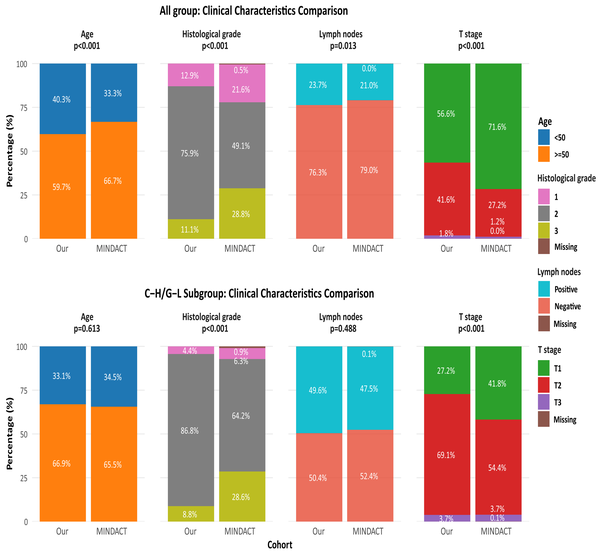
	All			C-H/G-L			C-H/G-H			C-L/G-H			C-L/G-L		
	Our N(%)	MNDACT N(%)	pvalue	Our N(%)	MNDACT N(%)	pvalue	Our N(%)	MNDACT N(%)	pvalue	Our N(%)	MNDACT N(%)	pvalue	Our N(%)	MNDACT N(%)	pvalue
Total	1900	6693		456 (24)	1550 (23.2)		421 (22.2)	1806 (27.0)		359 (18.9)	592 (8.8)		664 (34.9)	2745 (41.0)	
Age			p<0.001			p=0.613			p<0.001			p<0.001			p<0.001
<50	765 (40.3)	2226 (33.3)		151 (33.1)	534 (34.5)		130 (30.9)	716 (39.6)		179 (49.9)	178 (30.1)		305 (45.9)	798 (29.1)	
≥ 50	1135 (59.7)	4467 (66.7)		305 (66.9)	1016 (65.5)		291 (69.1)	1090 (60.4)		180 (50.1)	414 (69.6)		359 (54.1)	1947 (70.9)	
T stage			p<0.001			p<0.001			p<0.001			p<0.001			p<0.001
T1	1075 (56.5)	4795 (71.6)		124 (27.2)	648 (41.8)		118 (28.0)	943 (52.2)		280 (78.0)	581 (98.1)		553 (83.3)	2623 (95.6)	
T2	790 (41.6)	1819 (27.2)		315 (69.1)	843 (54.4)		285 (67.7)	843 (46.7)		79 (22.0)	11 (1.9)		111 (16.7)	122 (4.4)	
T3	35 (1.8)	78 (1.2)		17 (3.7)	58 (3.7)		18 (4.3)	20 (1.1)		0 (0.0)	0 (0.0)		0 (0.0)	0 (0.0)	
Mssing data	0 (0.0)	1 (0.0)		0 (0.0)	1 (0.1)		0 (0.0)	0 (0.0)		0 (0.0)	0 (0.0)		0 (0.0)	0 (0.0)	
Histological grade			p<0.001			p<0.001			p<0.001			p<0.001			p<0.001
1	246 (12.9)	1447 (21.6)		20 (4.4)	98 (6.3)		10 (2.4)	15 (0.8)		47 (13.1)	92 (15.5)		169 (25.5)	1242 (45.2)	
2	1443 (75.9)	3287 (49.1)		396 (86.8)	995 (64.2)		253 (60.1)	421 (23.3)		303 (84.4)	414 (69.9)		491 (73.9)	1457 (53.1)	
3	211 (11.1)	1927 (28.8)		40 (8.8)	443 (28.6)		158 (37.5)	1365 (75.6)		9 (2.5)	83 (14.0)		4 (0.6)	36 (1.3)	
Mssing data	0 (0)	32 (0.5)		0 (0.0)	14 (0.9)		0 (0.0)	5 (0.3)		0 (0.0)	3 (0.5)		0 (0.0)	10 (0.4)	
Lymph nodes			p=0.013			p=0.488			p<0.001			p=1.000			p=1.000
Positive	450 (23.7)	1404 (21.0)		226 (49.6)	737 (47.5)		173 (41.1)	477 (26.4)		9 (2.5)	15 (2.5)		42 (6.3)	175 (6.4)	
Negative	1450 (76.3)	5288 (79.0)		230 (50.4)	812 (52.4)		248 (58.9)	1329 (73.6)		350 (97.5)	577 (97.5)		622 (93.7)	2570 (93.6)	
Mssing data	0 (0.0)	1 (0.0)		0 (0.0)	1 (0.1)		0 (0.0)	0 (0.0)		0 (0.0)	0 (0.0)		0 (0.0)	0 (0.0)	

p-values were computed excluding missing data.

Discussion

This study represents a significant advancement in the validation of MammaPrint in Asian populations. Previous investigations in Japan[2] (n=102) and South Korea[3] (n=36) were limited by their small sample sizes. Building upon this foundation, our study has established the largest MammaPrint validation cohort in Asia to date (n=1900). We have demonstrated that Chinese patients undergoing MammaPrint testing exhibit distinct clinical characteristics, including a younger age at diagnosis, higher proportions of T2-stage and grade 2 tumors. Notably, MammaPrint may enable effective risk stratification in this population. We are currently collecting additional cases and follow-up data. Subsequent survival analyses and prospective studies based on this large cohort will ultimately define the prognostic and predictive value of MammaPrint for Chinese breast cancer patients.

Figure 1. Key Clinicopathological Features in Chinese vs. MINDACT Cohorts: Overall and C-H/G-L Subgroup



p-values were computed excluding missing data.

Conclusions

Significant differences in age (younger), T-stage (more T2), and grade (more Grade 2) were observed between the Chinese and MINDACT cohorts, and these differences persisted across all MammaPrint® risk subgroups. Our findings underscore the importance of validating the 70-gene signature's predictive value for chemotherapy decisions using data from Chinese patients. Survival analysis of this large cohort and future prospective studies will further evaluate its risk stratification performance and clinical utility in Chinese patients with HR+/HER2− early breast cancer.

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