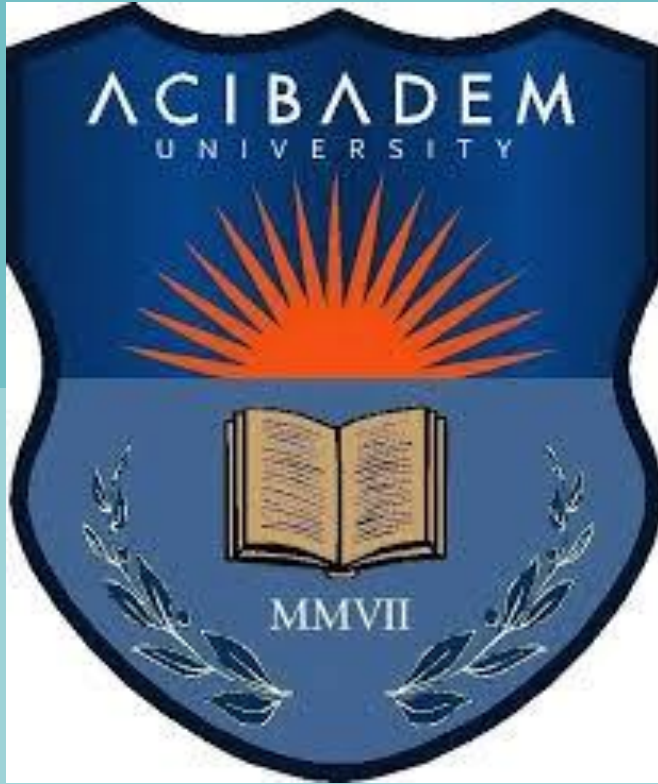


Concordance of CanAssist Breast with Oncotype Dx and Mammaprint in Patients with Early-Stage Hormone Receptor-Positive Breast Cancer



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ABSTRACT

Background: CanAssist-Breast (CAB) is an immunohistochemistry based prognostic test which utilizes expression of five biomarkers (CD44, ABCC4, ABCC11, N-Cadherin and Pan-Cadherin) and three clinical parameters including tumor size, grade, and node status to categorize patients as 'low or high' risk for distant recurrence within 5 years of diagnosis using an AI based algorithm. Oncotype DX (ODX) and MammaPrint (MP) tests are prospectively validated genomic prognostic tests which use 21 and 70 genes, respectively. All these prognostic tests are used for early breast cancer patients with hormone receptor (HR) positive, HER2 negative tumors to predict risk of distant recurrence. In this study, we aimed to analyze the concordance of CAB test with ODX and MP.

Methods: The pathological specimens of 107 patients for whom ODX and MP were requested as a part of their clinical management were also tested with CAB test prospectively between June 2022 and December 2024. The treatment was planned based on either ODX or MP risk categorization. The threshold for high versus low-risk ODX categories is selected as 25 since there were few numbers of patients with ODX scores < 11 and 18. A cut off 15.5 is used to stratify the patients into low-risk (≤ 15.5) and high-risk (>15.5) for CAB test.

Results: There were 53 patients with ODX and 54 patients with MP risk scores. Median age was 46 (range 25-78), and 64% of patients were premenopausal. Among 107 patients, 47% had Stage I disease, 34% had node positive, 80% had grade 2 disease. All patients received endocrine therapy (ET), 44% received chemo endocrine therapy while 56% were treated with ET alone. Out of the ODX cohort, 81% and 79% patients were stratified as low-risk by ODX and CAB respectively. Amongst MP cohort, 52% and 65% were stratified as low-risk by MP and CAB respectively. 77%, 75% and 82% concordance was observed between CAB and ODX in low-risk patients in overall, pre-and post-menopausal patients respectively. Additionally, in N0 patients 80% and 88% concordance was found in low-risk categories of CAB and ODX in pre- and post-menopausal patients respectively. With MP, concordance of CAB was 75%, 71% and 79% in overall, pre- and post-menopausal patients while 100% and 50% concordance was observed in N0 and N+ patients.

Conclusion: In the first ever prospective comparison of CAB with established prognostic tests, CAB demonstrated high concordance ($>75\%$ overall) with ODX and MP for low-risk patients and hence can be a useful prognostic tool for HR+/HER2- early-stage breast cancer patients. The clinical outcomes of these patients which will be followed in the next few years will substantiate the prognostic value of CAB.

INTRODUCTION

- CanAssist Breast (CAB) is an immunohistochemistry (IHC) and ML-based prognostic test that utilizes the expression of five biomarkers integrated with three clinical parameters to stratify patients into two categories based on their 5-year risk of distant recurrence.
- CAB has been validated in retrospective global studies in India, the US, Spain, Germany, Austria, Italy, and in a prospective, randomised, completed TEAM trial in the Netherlands.
- Since mid-2016, CAB has been in clinical use in Southeast Asia, Turkey, UAE, and is accredited by CAP and ISO 13485.

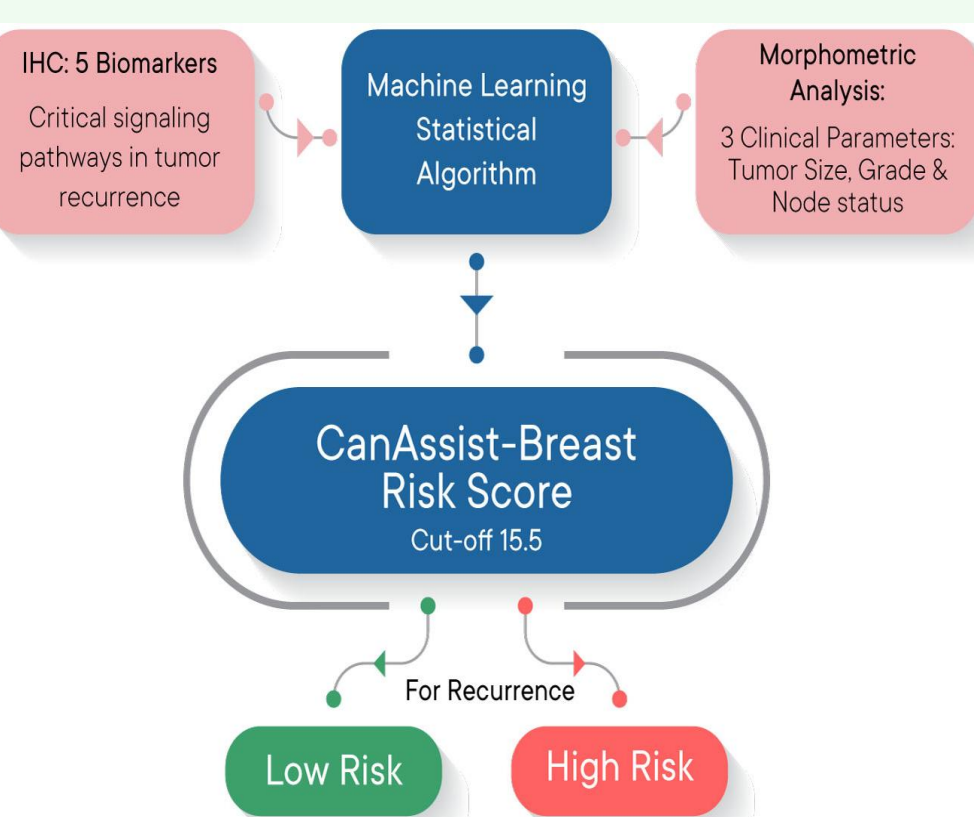


Figure 1: CanAssist Breast Test (CAB) risk prediction.

BACKGROUND OF CAB

Figure 2: Global validation data of CAB based risk stratification in patients treated with chemotherapy and endocrine therapy (A) and patients treated with endocrine therapy alone from CAB validation studies (B)

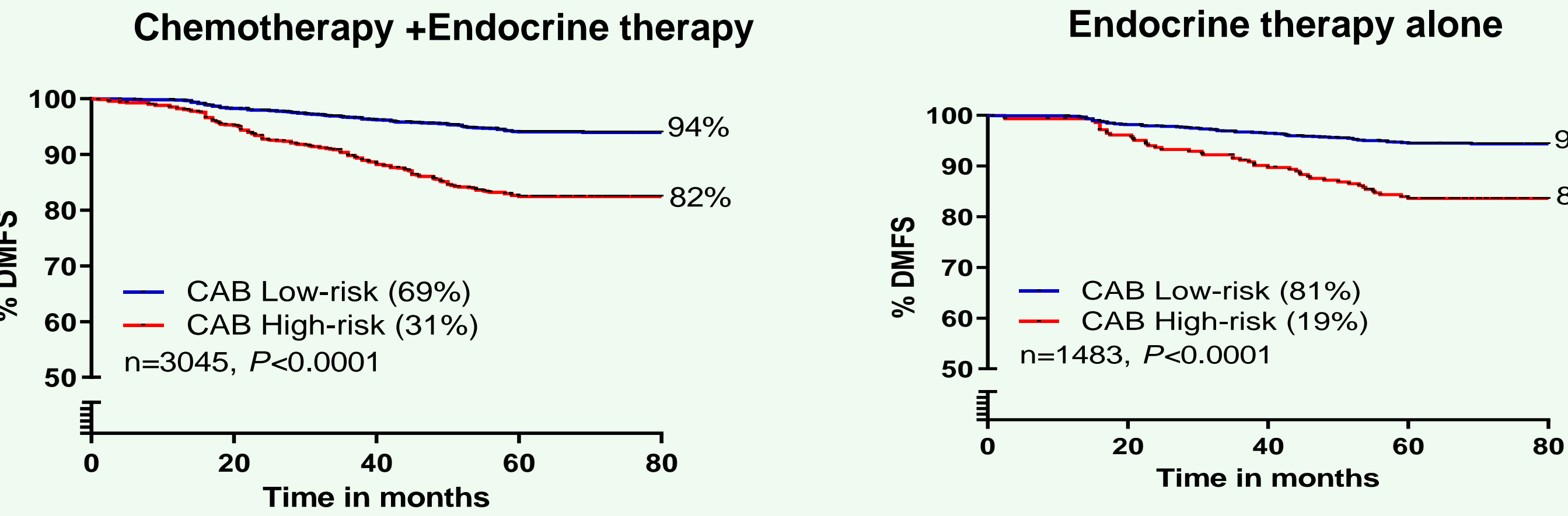
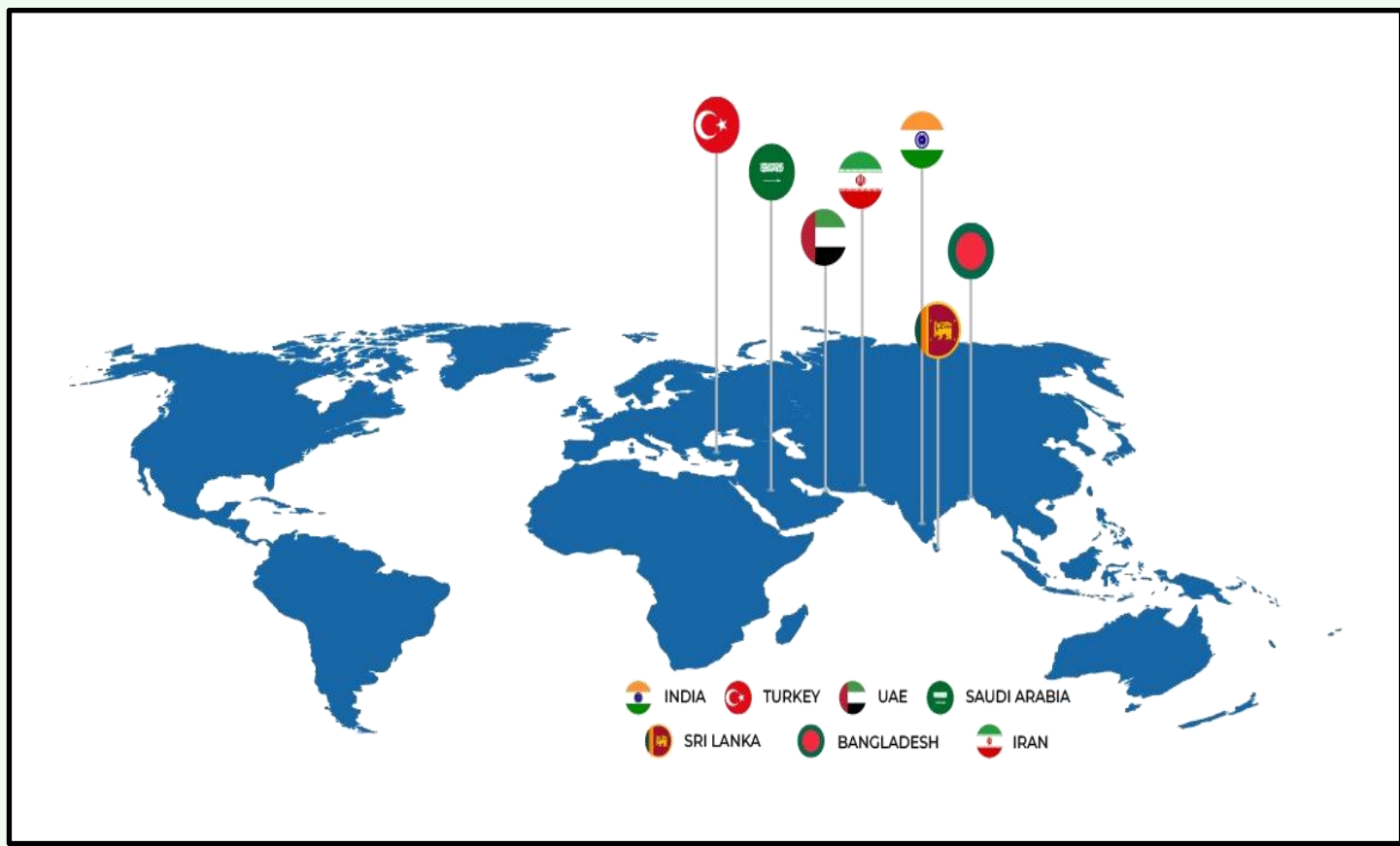


Figure 3: Global sales of CanAssist Breast



RESULTS

Table 1. Demographics of the patients for the current study

Parameters	Clinical subgroups	Overall (%)	ODX (%)	MP (%)
Total		107	53	54
Menopausal status	Pre-	64	74	56
	Post-	36	26	44
T size (cm)	T1	69	74	65
	T2	31	26	35
Node status	N0	66	77	56
	N1	34	23	44
Histological grade	G1	6	6	6
	G2	80	85	76
	G3	14	9	19
TNM status	T1N0	47	60	33
	T2N0	20	17	22
	T1N1	22	13	31
	T2N1	11	9	13
*Treatment given	Chemotherapy +Endocrine therapy	44	38	50
	Endocrine therapy alone	55	60	50

* Treatment information not available for 1 patient

CONCLUSIONS

- This study is the first ever prospective comparison of CanAssist Breast test with established prognostic tests Oncotype DX and Mammaprint.
- In low-risk patients, CAB demonstrated high concordance ($>75\%$ overall) with ODX and MP and hence can be a useful prognostic tool for HR+/HER2- early-stage breast cancer patients.
- The clinical outcomes of these patients will be monitored over the coming years, which would further help substantiate the prognostic value of CAB.

METHODOLOGY OF THE CURRENT STUDY

This prospective study was approved by Acibadem University Medical Research Assessment Committee (ATADEK 2022-09/31) and is being conducted adhering to ethical guidelines after obtaining informed consent from all the patients.

For this current study, patients were recruited between June 2022 and December 2024, and ODX and MP were requested as part of their clinical management prospectively.

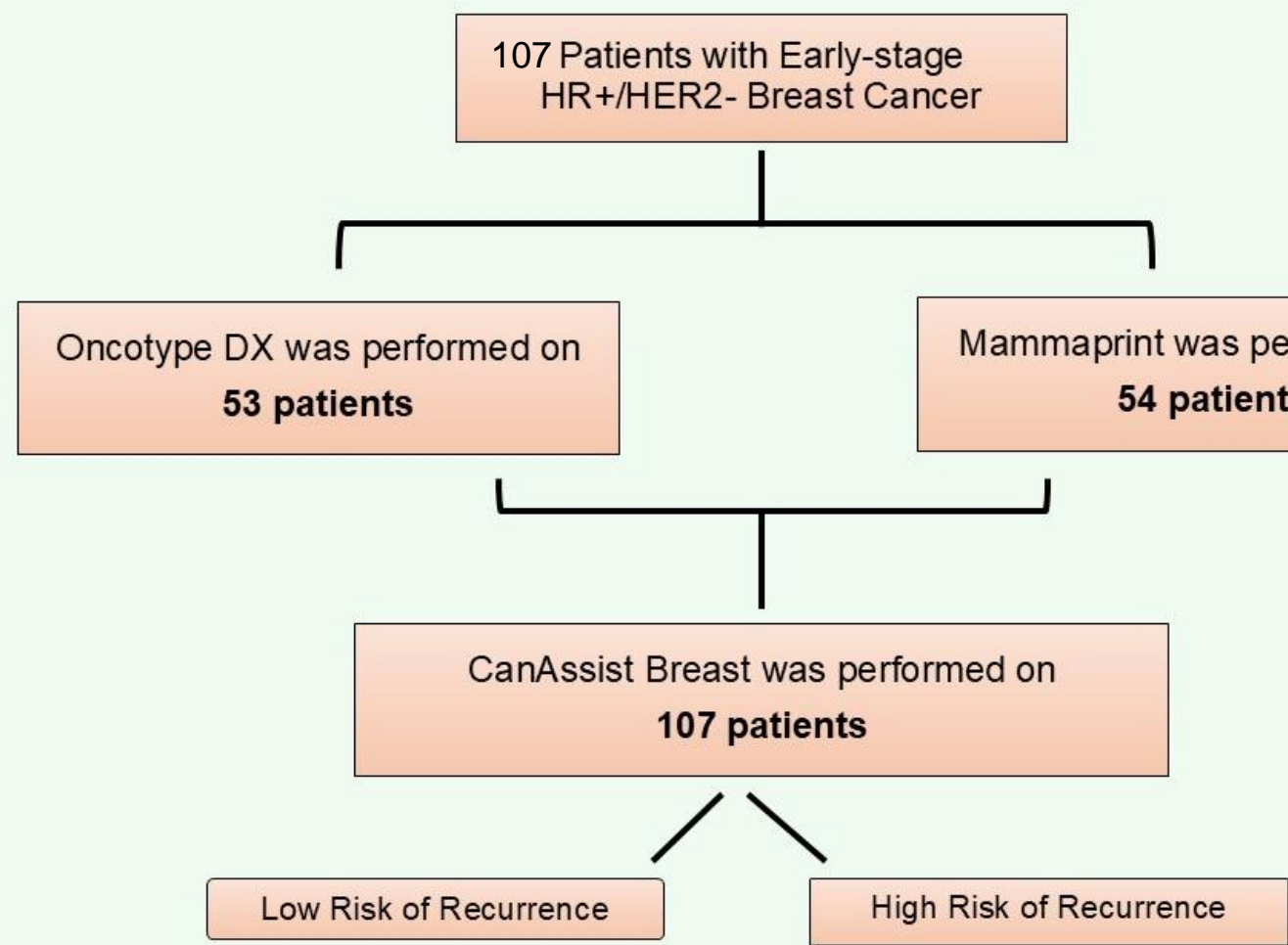
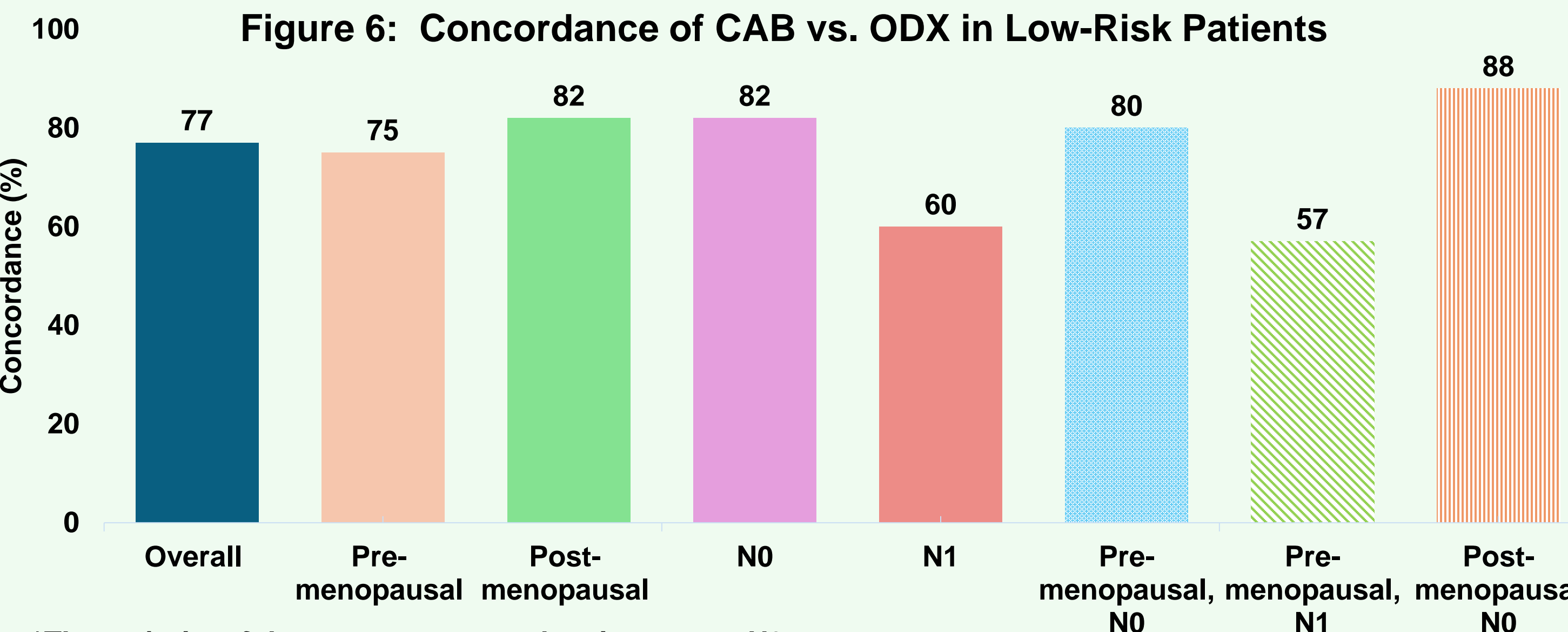
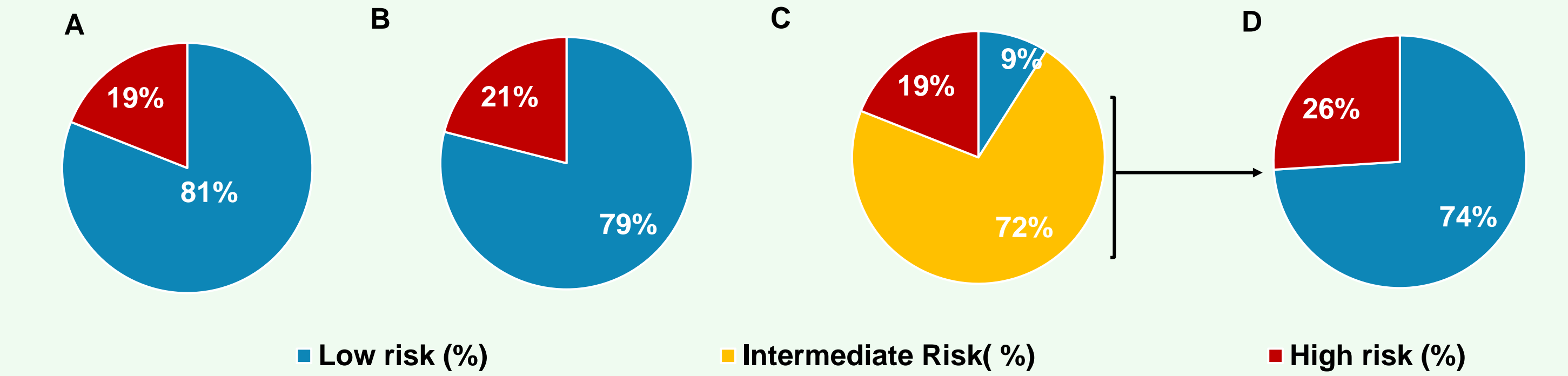


Figure 4: Study Methodology

Figure 5: Risk stratification of ODX (cut-off 25) (A) and CAB (B) in ODX cohort; Risk Stratification of ODX (cut-off 10) (C); CAB Re-stratification of ODX-intermediate risk category (D) (%)



*The majority of the post-menopausal patients were N0

Figure 7: Risk stratification of MammaPrint (A) and CAB (B) in MammaPrint cohort

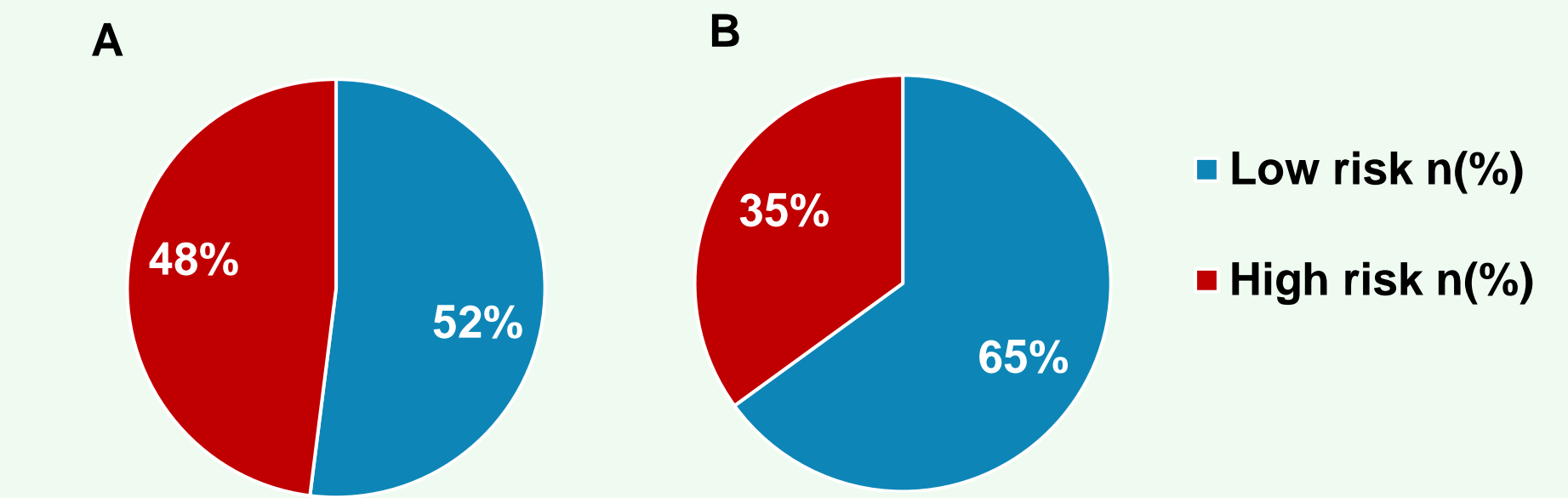
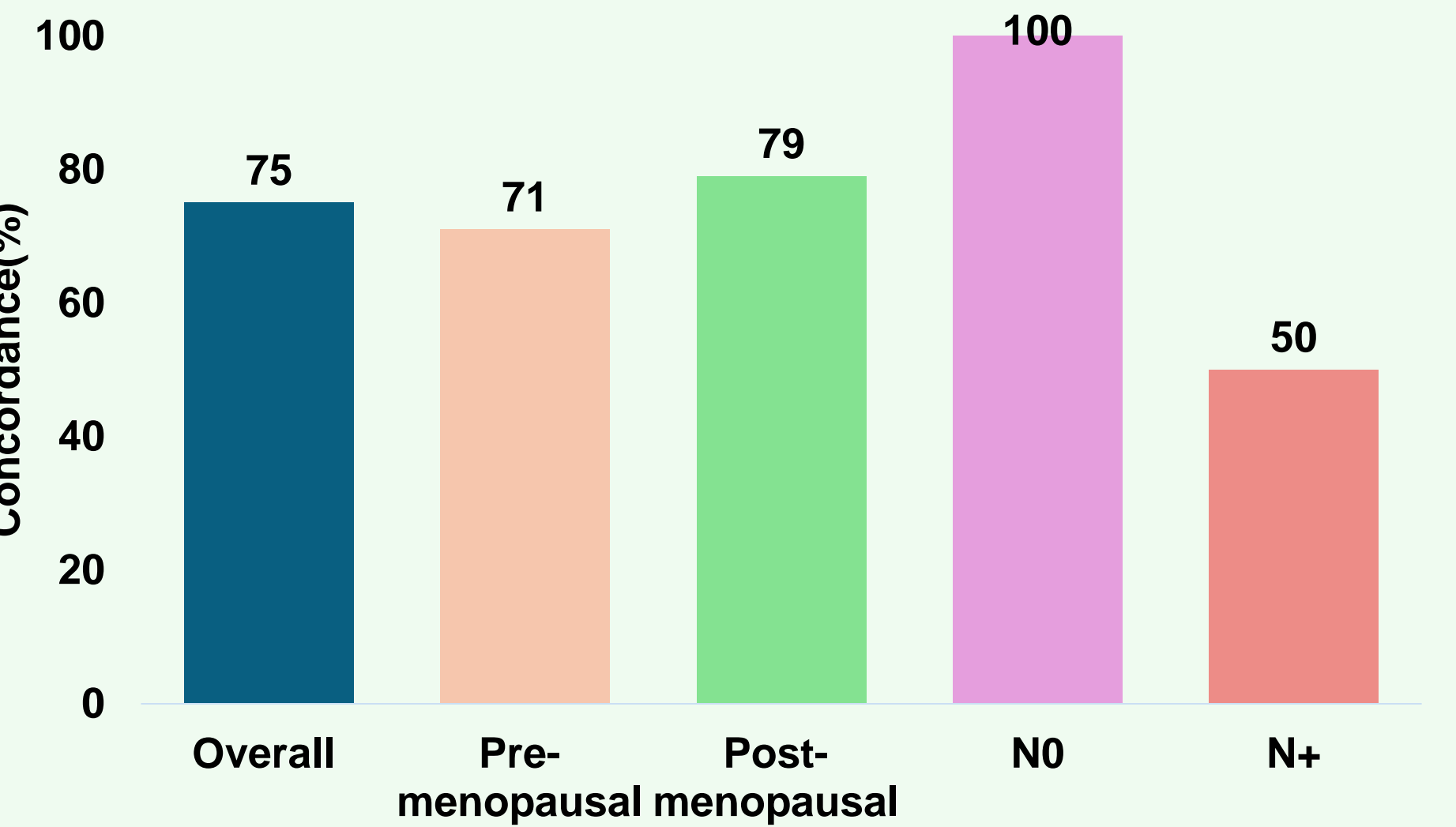


Figure 8: Concordance of CAB vs. MP in Low-Risk Patients



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