

Background

Prognostic tests play an essential role in informing treatment decisions for Hormone receptor-positive (HR+), HER2-negative (HER2-) early breast cancer (EBC); however, validation of existing tests is mostly confined to Western patients. Often diagnosed nearly a decade earlier, Asian EBC patients present with a marginally higher tumor burden, often at Stage II, indicating variations in the tumor behaviour from Western patients. Limited data on the prognostication of Asian patients are intriguing and remain an unmet clinical need. To address this, CanAssist Breast (CAB), a proteomic and ML-based prognostic test, was developed using Indian patient data to represent Asian tumor biology better. CAB has been extensively validated in retrospective global studies across India, the US, Spain, Germany, Austria, Italy, and in a prospective-randomised completed TEAM trial in the Netherlands. The inclusion of CAB in the Asian Geriatric Oncology Society (AGOS), Indian Society of Medical and Paediatric Oncology (ISMPO) and Association of Breast Surgeons of India (ABS) EBC treatment guidelines marks an important milestone. CAB has been in clinical use on ~10000+ patients in India, Turkey, UAE, Sri Lanka, Bangladesh, and Iran for the past 8 years, since 2016.

Objective

In this study, we demonstrate the usefulness of CAB prognostication and its impact on treatment decisions in real-world clinical settings.

Methodology

- In our retrospective cohort analyses, we examined how effectively CAB predicted distant recurrences at 5 and 10 years after diagnosis.
- We further examined the prospective CAB data from 2016 to June 2025 to assess the performance of CAB in real-world clinical settings.

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

Results

CanAssist Breast Accurately Predicts Disease Recurrence at 5 Years

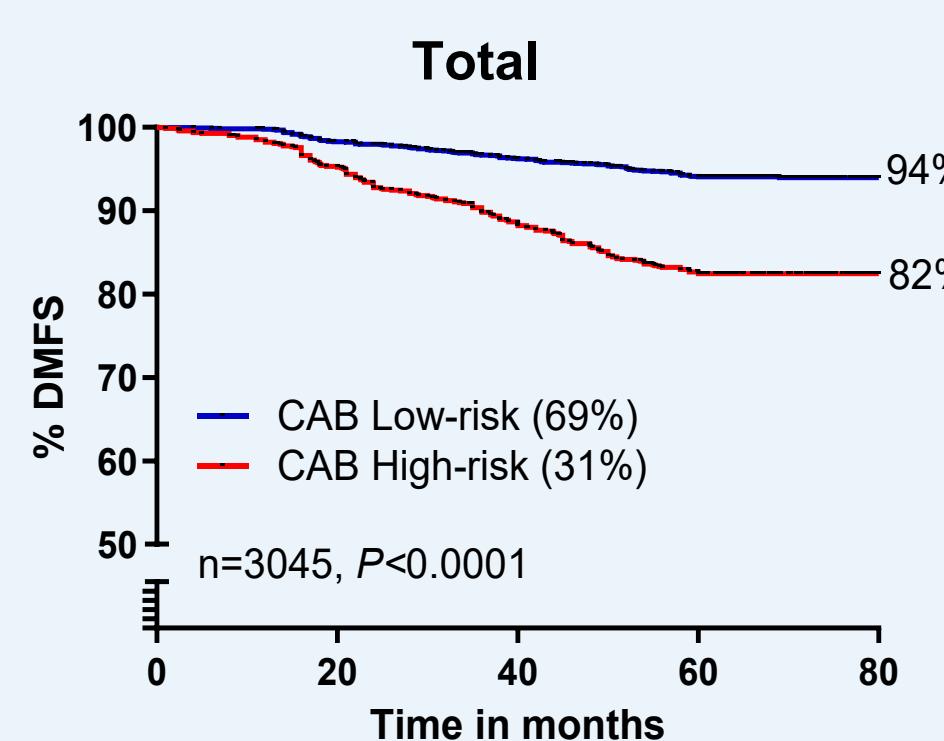


Figure 2: CAB stratification in the **total validation cohort**

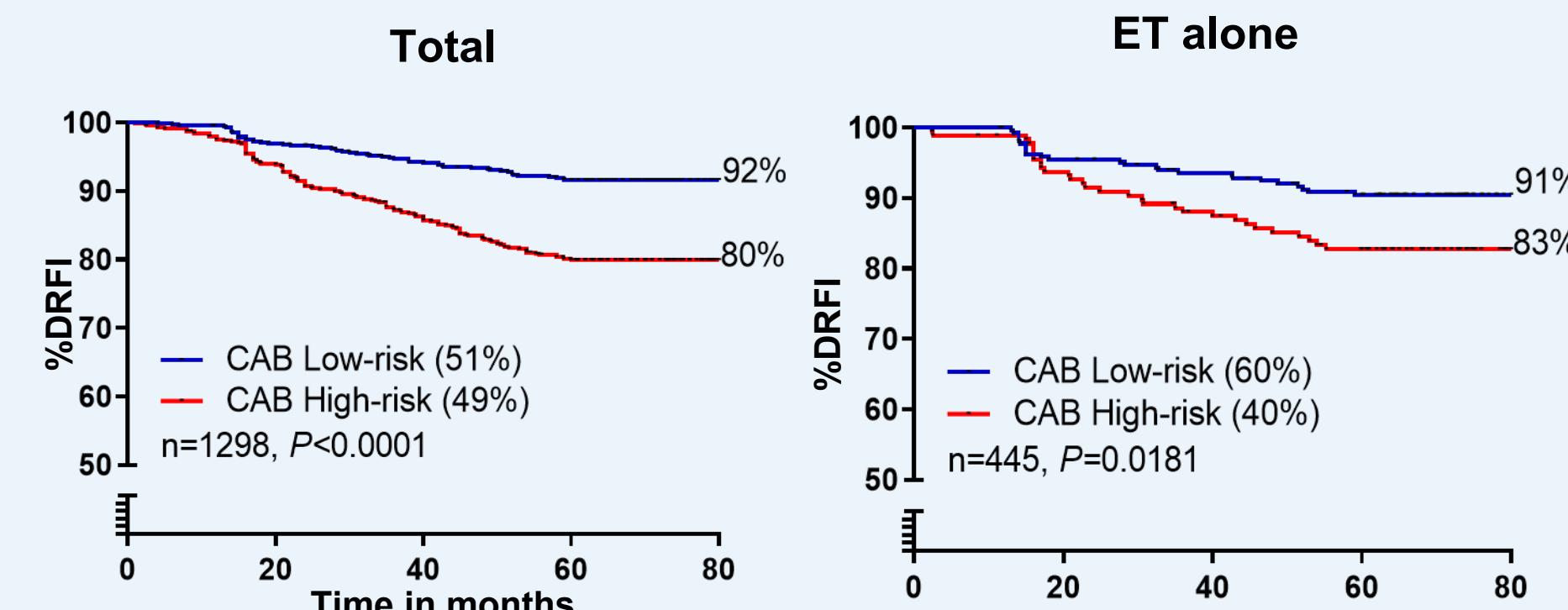


Figure 3: CAB stratification of patients with **lymph node-positive (N+)** disease

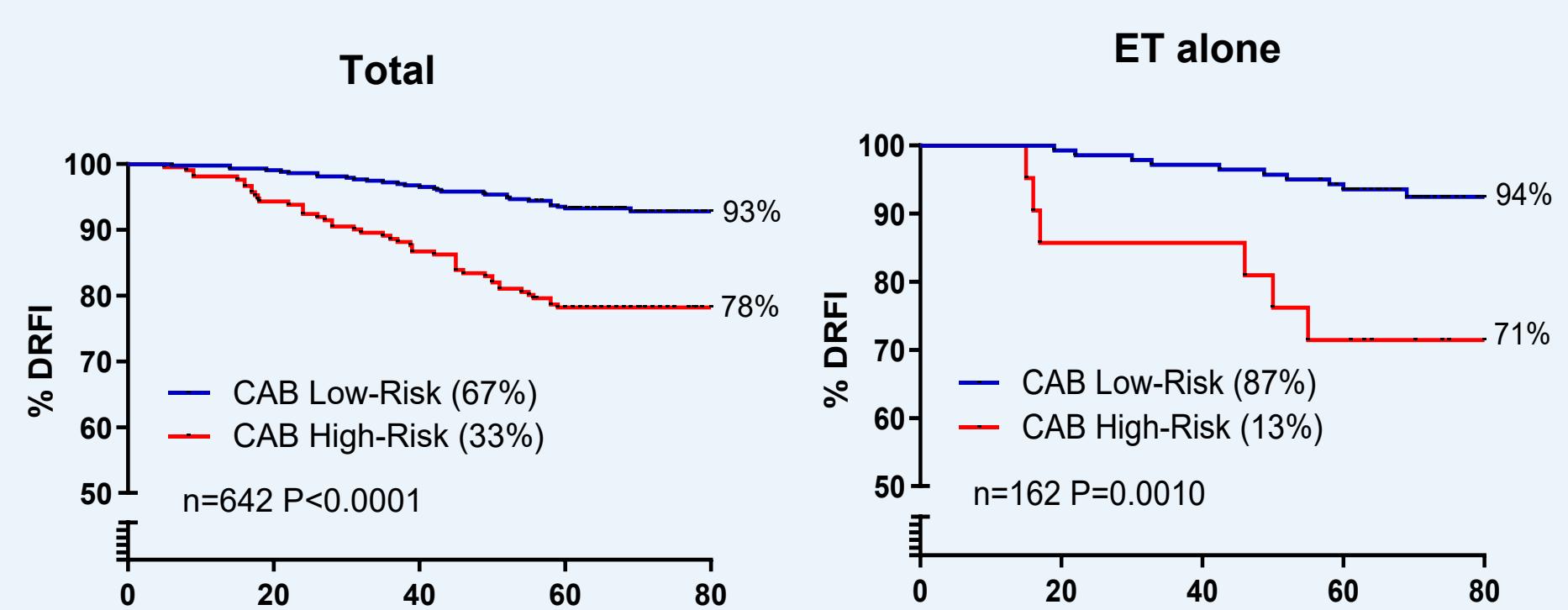


Figure 4: CAB stratification in young patients **aged 48 years or below**.

References

1. CanAssist Breast provides additional insightful prognostic information in retrospective, pooled secondary analysis in clinically low/high-risk patients with HR+/HER2-EBC." *Clinical Breast Cancer* (2025).
2. Real-world data of CanAssist Breast-first immunohistochemistry and AI-based prognostic test." *Scientific reports* 15.1 (2025): 30430.
3. CanAssist Breast-based prognostication in low-intermediate estrogen receptor positive (ER1%-20%) early-stage breast cancer patients helps guide treatment decisions." *Therapeutic Advances in Medical Oncology* 17 (2025): 17588359251342218.
4. Ten-year distant-recurrence risk prediction in breast cancer by CanAssist Breast (CAB) in Dutch sub-cohort of the randomized TEAM trial." *Breast Cancer Research* 25.1 (2023): 40.

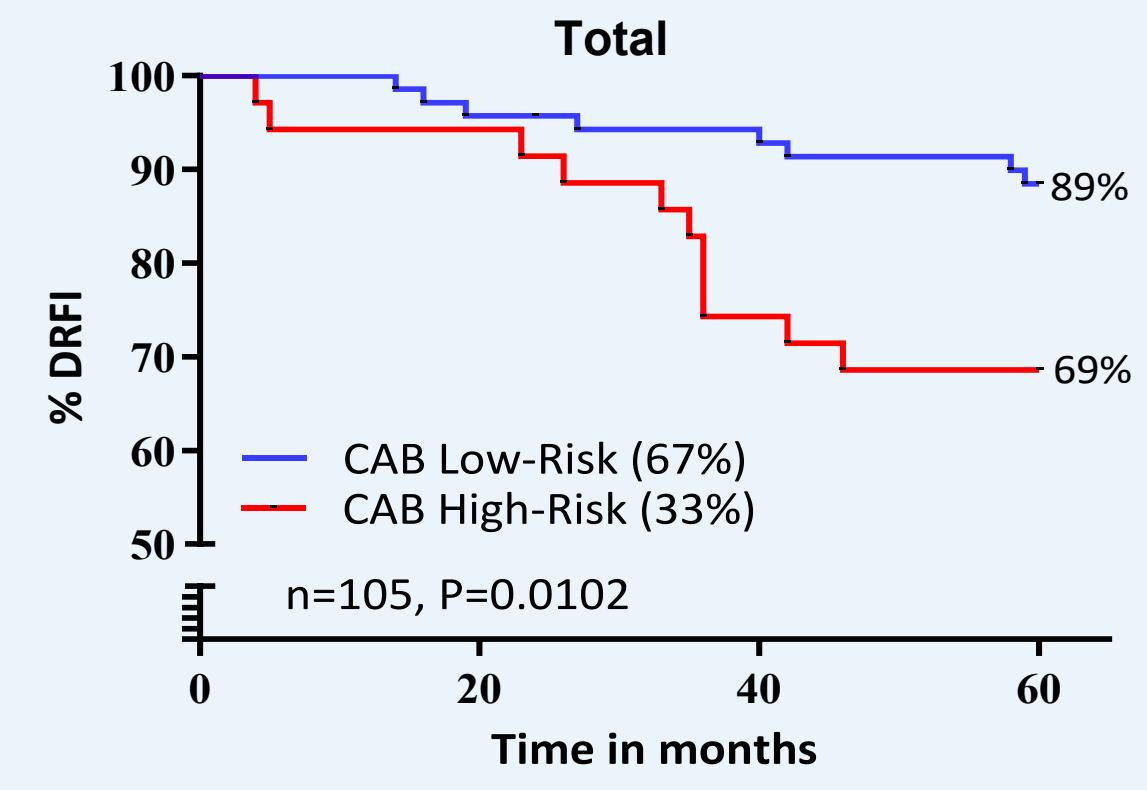


Figure 5: CAB stratification in patients with **low ER (1-10%) tumors**

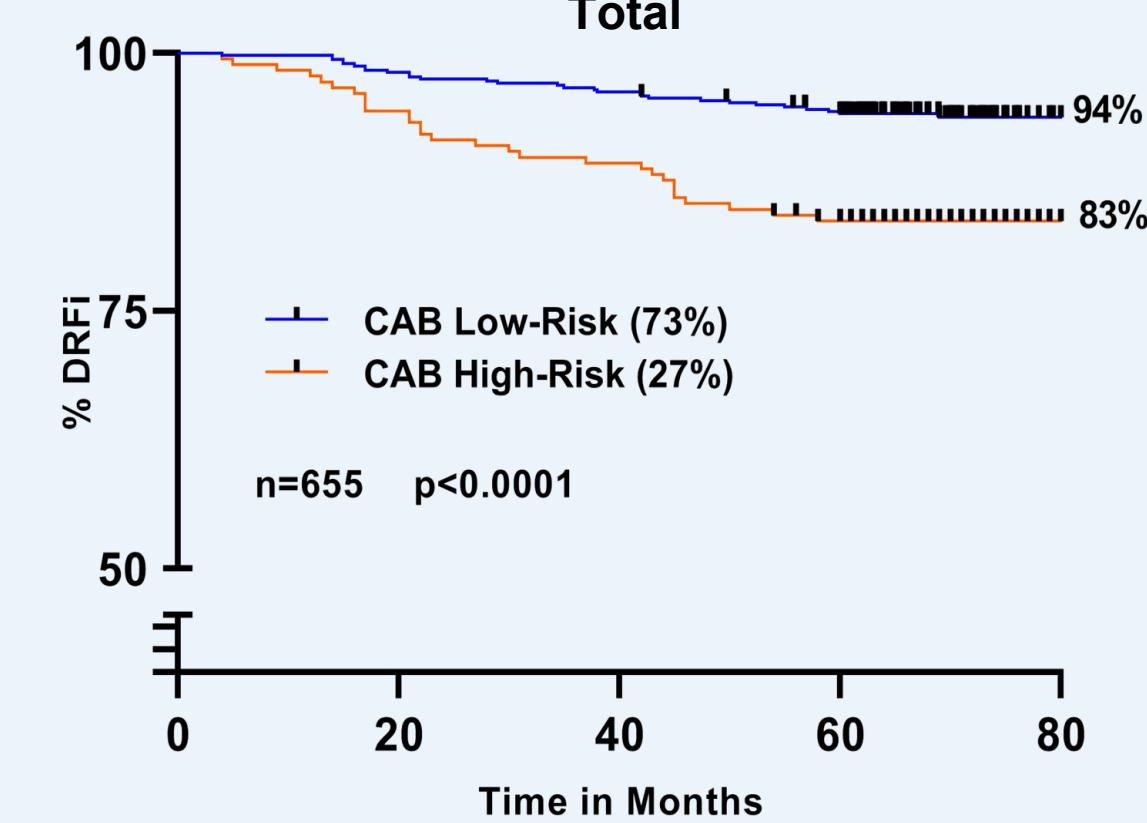


Figure 6: CAB stratification in patients with **intermediate Ki67 (>5-≤30)**

CanAssist Breast Predicting Recurrence at 10 Years: TEAM trial

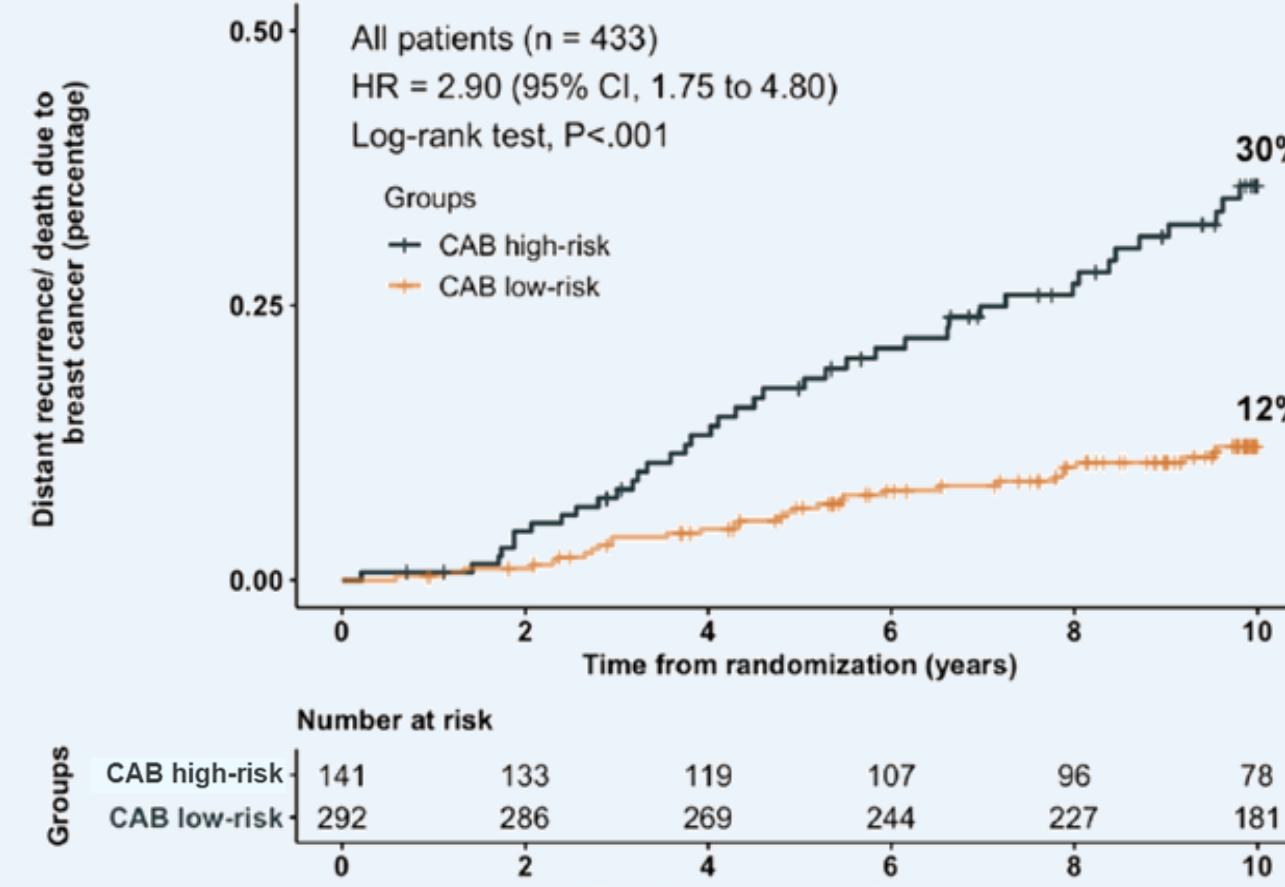


Figure 7: **Distant recurrence** for the total cohort

CanAssist Breast in the Real World: Real Patients, Real Impact

Table 1: Patient demographics

Parameters	Clinical subgroups	Numbers (n)	%
	Total	8242	100
Gender	Female	8185	99
	Male	57	1
Age at diagnosis (years)	≤ 48	1850	22
	> 48	6392	78
	Median age	58	
Tumor size (cm)	T1	2787	34
	T2	5272	64
	T3	183	2
	Median T size	2.5	
Node status	Node negative (N0)	6719	82
	Node positive (N+)	1523	18
Histological grade	G1	1323	16
	G2	5329	65
	G3	1590	19
CAB risk categories	CAB low risk	5879	71
	CAB high risk	2363	29

Acknowledgements

Dr Deepthi K S, Dr Naveen Krishnamoorthy, Dr Rahul Bhagat, Mr. Manjunatha G, Mr. Dinesh Babu P, Mr. Harishkumar N, Mrs. Prathima R from OncoStem Diagnostics, Bangalore for helping us with IHC experimentation, histopathological and data analysis, respectively.

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Conclusions

- CAB showcased statistically significant prognostication of HR+/HER2- EBCs in **global validation** studies:
 - i. In **young, N+, low-ER and ET-alone treated** patients
 - ii. Prospective-randomised TEAM trial (completed trial data)
 - iii. **Real-world** usefulness on ~10000+ patients with early **NPV >95%**.
- Backed by the data, **CAB** emerges as a **reliable and cost-effective solution** for patients in India and worldwide.

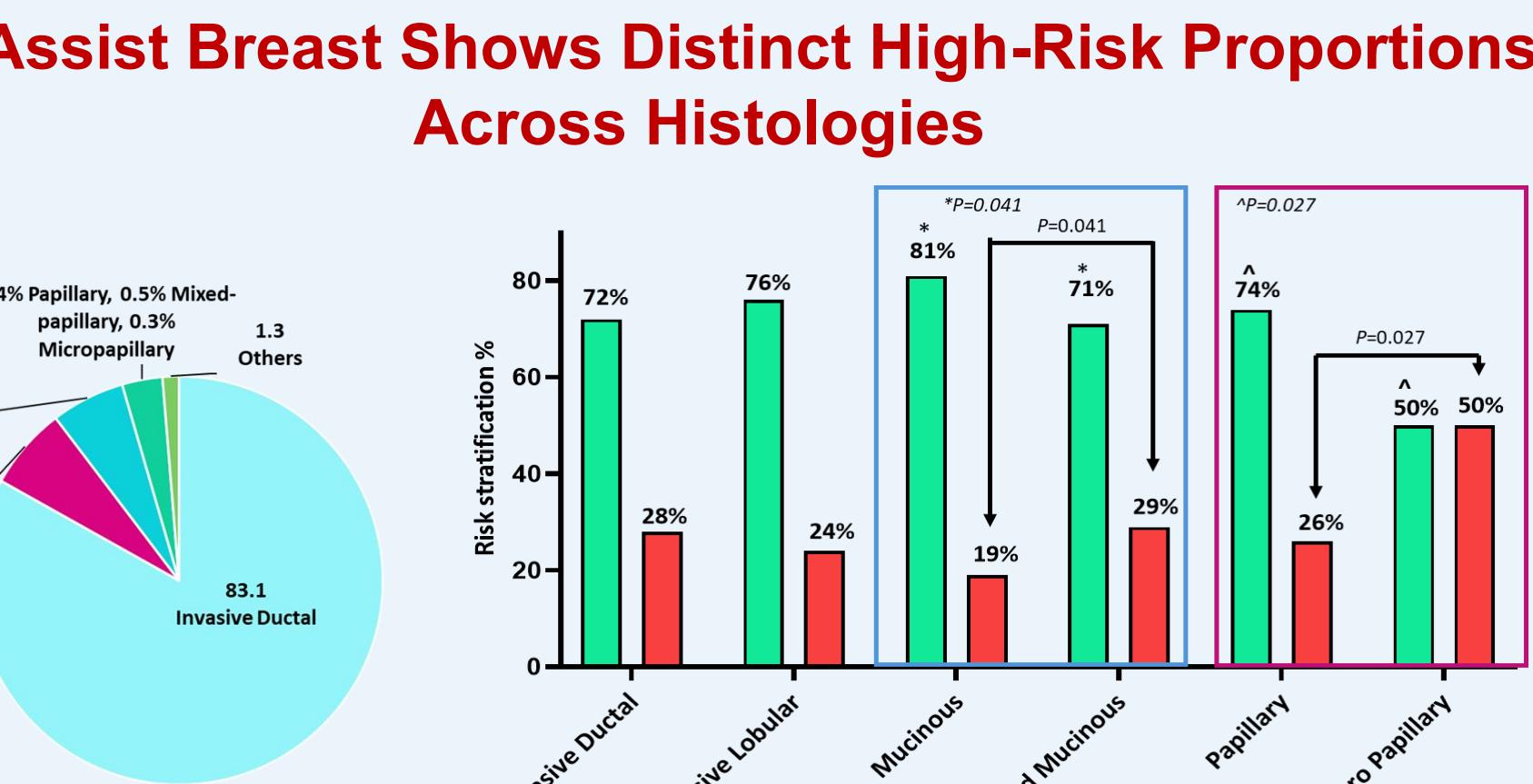


Figure 8: Distribution and CAB risk stratification in **histological subtypes**

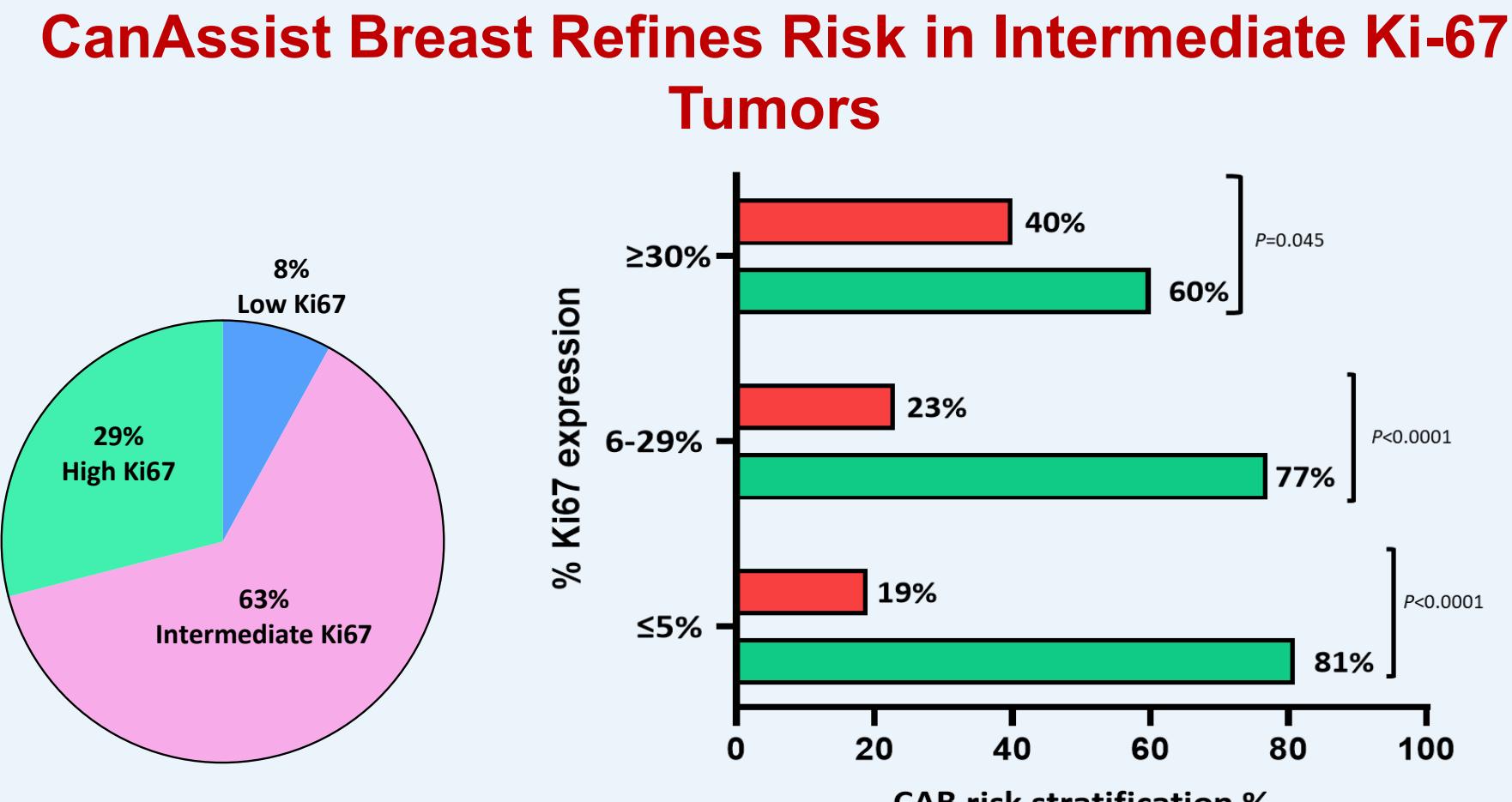


Figure 9: **Ki67** Distribution and CAB Risk Stratification

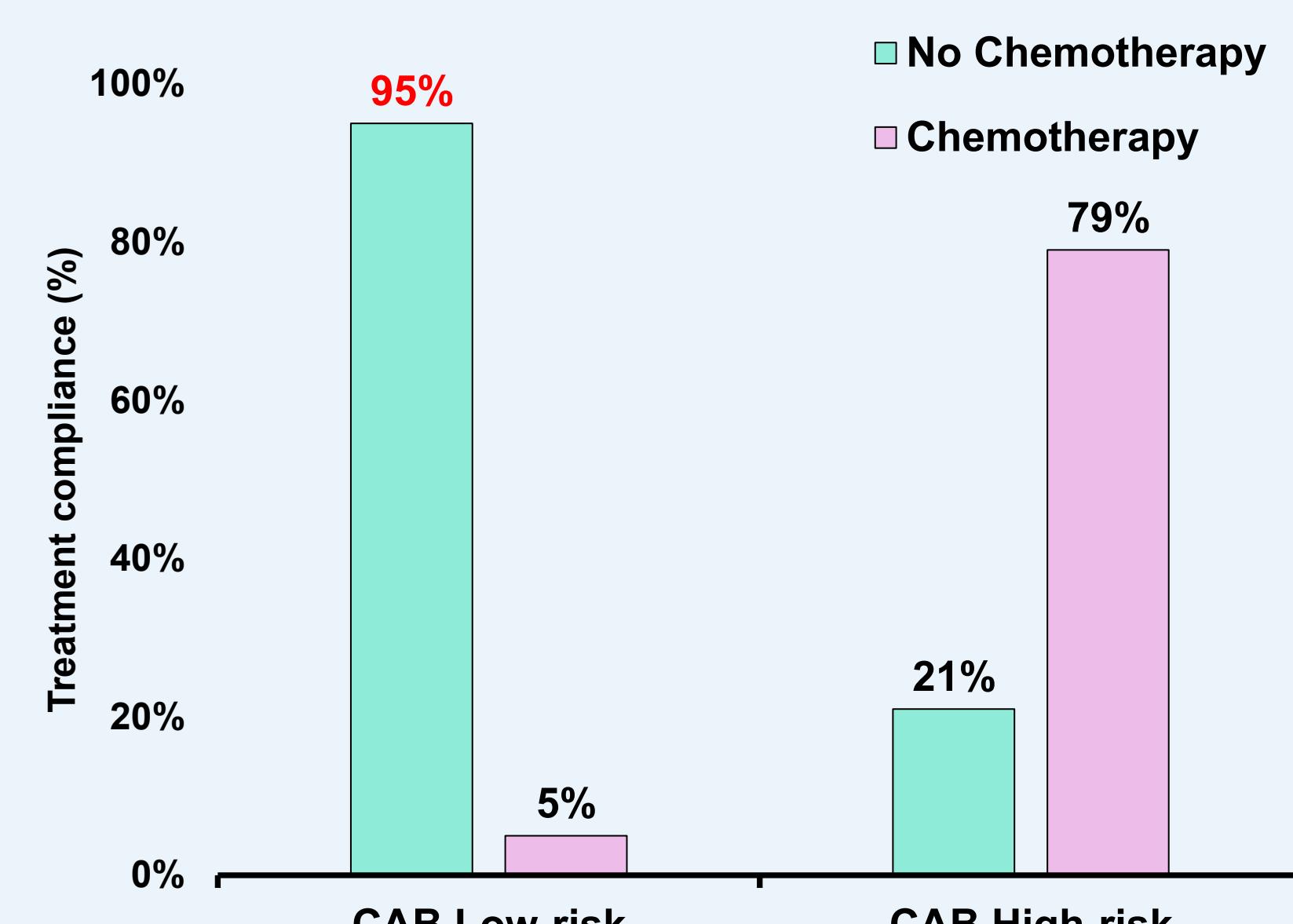


Figure 10: **Adherence** to CAB treatment recommendations by physicians



Figure 11: **Global reach** of CanAssist Breast