

Abstract

Objective: Asian breast cancer patients are often diagnosed at a younger age, with high Ki67, node positive tumors, with lower ER expression than the Western counterparts. Data on prognostication of Asian ER+/HER2- early stage breast cancer (EBC) patients is limited, intriguing and remains an unmet need. CanAssist Breast (CAB) - an immunohistochemistry and artificial intelligence based prognostic test was developed on Indian patient's tumors and validated in retrospective global studies in India, US, Spain, Germany, Austria, Italy, The Netherlands. CAB uses CD44, ABCC11, ABCC4, two cadherins as biomarkers plus 3 clinical parameters to segregate patients as low-risk (LR) or high risk (HR) for distant recurrence. CAB is in clinical use in South East Asia, UAE, Turkey, Iran for last 8 years. Here we showcase the usefulness of CAB in prognosticating Asian patients.

Methods: We analysed retrospective and prospective CAB user data over last ~8 years. Specifically, how does CAB help to segregate the slightly "clinically high" risk patients.

Results: CAB based prognostication is statistically significant in various subgroups tested. CAB identified 87% patients <48 years treated with ET as LR with 94% DMFS. In (0-3)node+ patients CAB segregated ~55% patients as LR treated with ET with 91% DMFS. In Low ER (1-20%) expressing patients CAB segregated 65% as LR with 91% DRFI and 35% CAB HR patients with much lower DRFI can benefit from additional therapies. In the intermediate Ki67 patients CAB segregated 73% as CAB LR with 94% DMFS. Prospectively, CAB has been used on 7000+ patients, over segregation across different histological subtypes in 72:28% (LR:HR). We observed overall treatment adherence to CAB risk category is at 92%.

Conclusion: CAB represents tumor biology of Asian patients with slightly aggressive features well and coupled with world-wide validation it presents as an accurate alternative for patients in Asia, Africa and Middle East (ME).

What Makes CanAssist Breast Test Unique?

- CanAssist Breast is India's first AI-driven immunohistochemistry test, providing crucial insights into breast cancer recurrence risk. By analyzing key tumor biomarkers, CAB helps oncologists assess whether a patient is at "low-risk" or "high-risk" for recurrence, guiding treatment decisions, including the need for chemotherapy.
- CAB has been in use for last 8 years in India and select countries internationally.

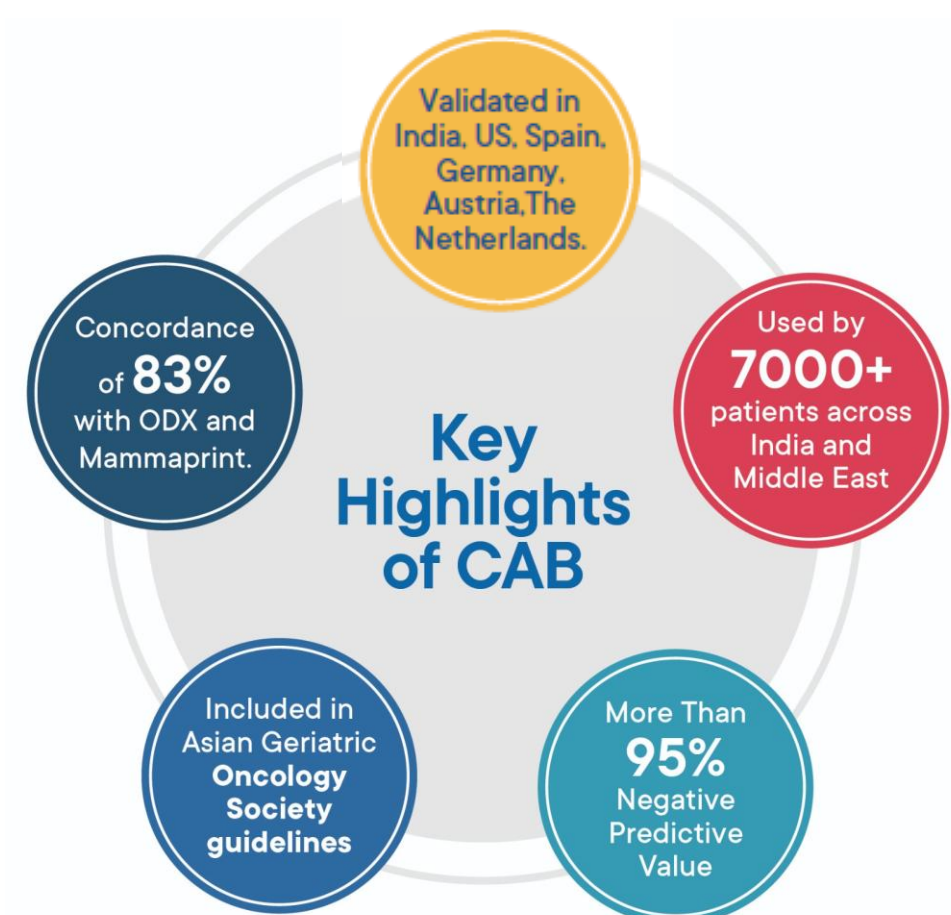


Figure 1: Key highlights of CanAssist Breast Test (CAB)

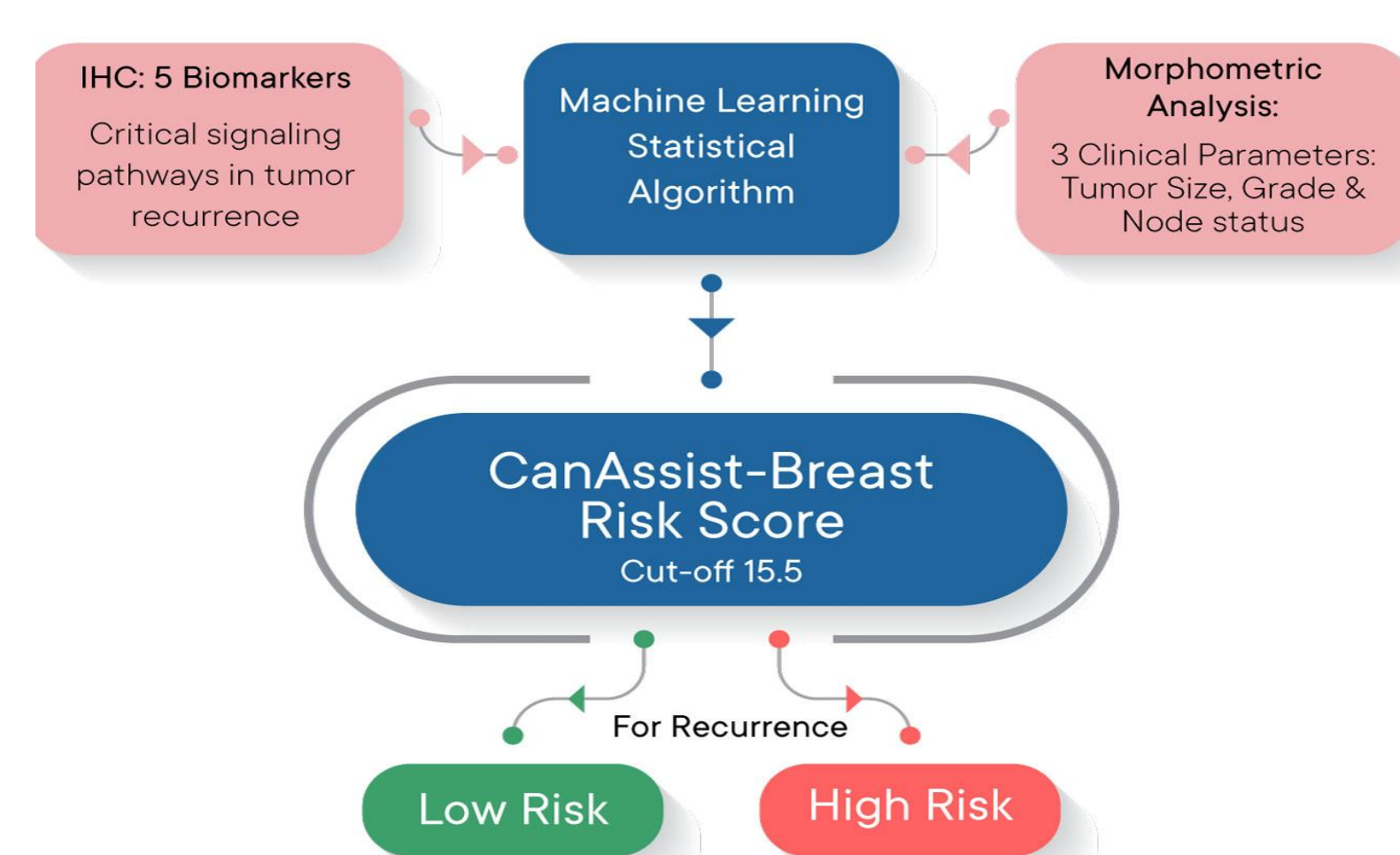


Figure 2: CanAssist Breast Test (CAB) risk prediction.

Results

Table 1: Distribution and CAB risk stratifications of patient demographics

Parameters	Clinical subgroups	%	CAB Low risk (%)	CAB High risk (%)
	Total (n=7075)	100	72%	28%
Gender	Female	99	72%	28%
	Male	1	70%	30%
Age at diagnosis (years)	≤ 48 yrs	22	75%	25%
	> 48 yrs	78	71%	29%
	Median age (years)		58	
Tumor size (cm)	0-2 cm	34	83%	17%
	> 2 cm	66	66%	34%
	Median T size (cm)		2.5	
Node status	Node negative (N0)	81	78%	22%
	Node positive (N+)	19	41%	59%
Histological grade	G1	16	93%	7%
	G2	65	80%	20%
	G3	19	25%	75%
Ki67	< 5%	8	81%	19%
	6-29%	63	76%	24%
	> 30%	29	60%	40%

Figure 3: CAB based risk stratification in entire validation cohort

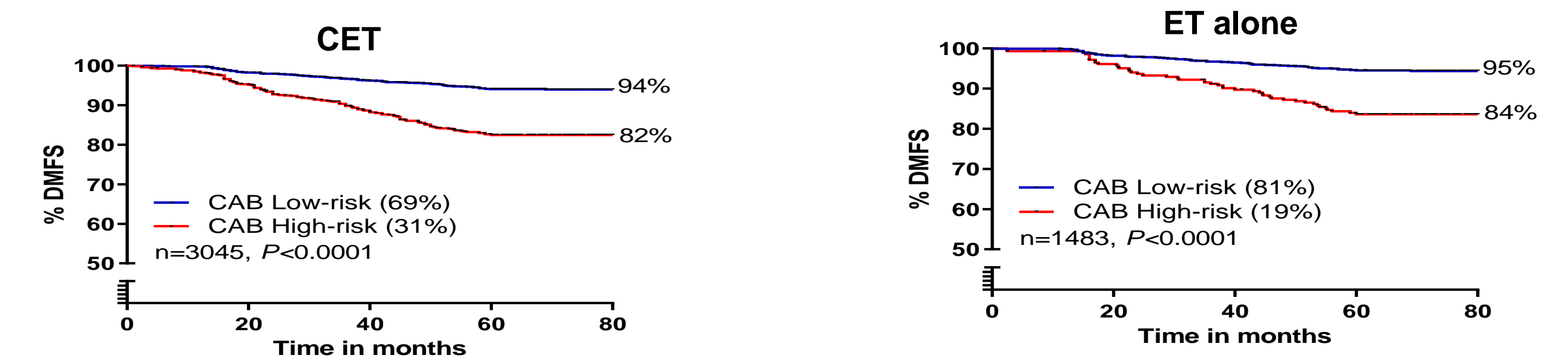


Figure 4: Chemotherapy benefit in CAB High Risk patients

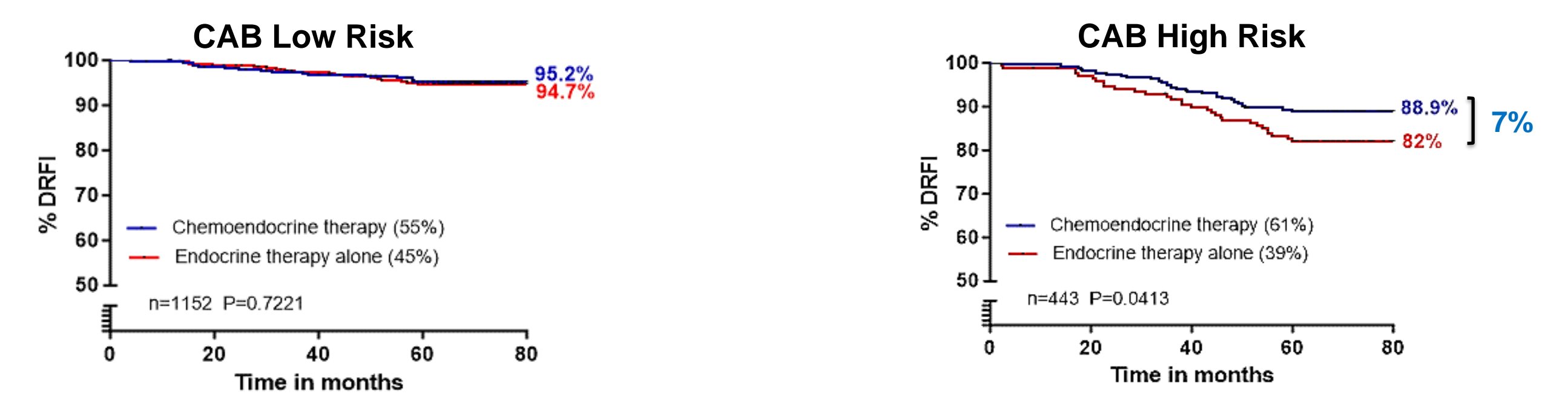


Figure 5: CAB stratification in young patients aged 48 years or below.

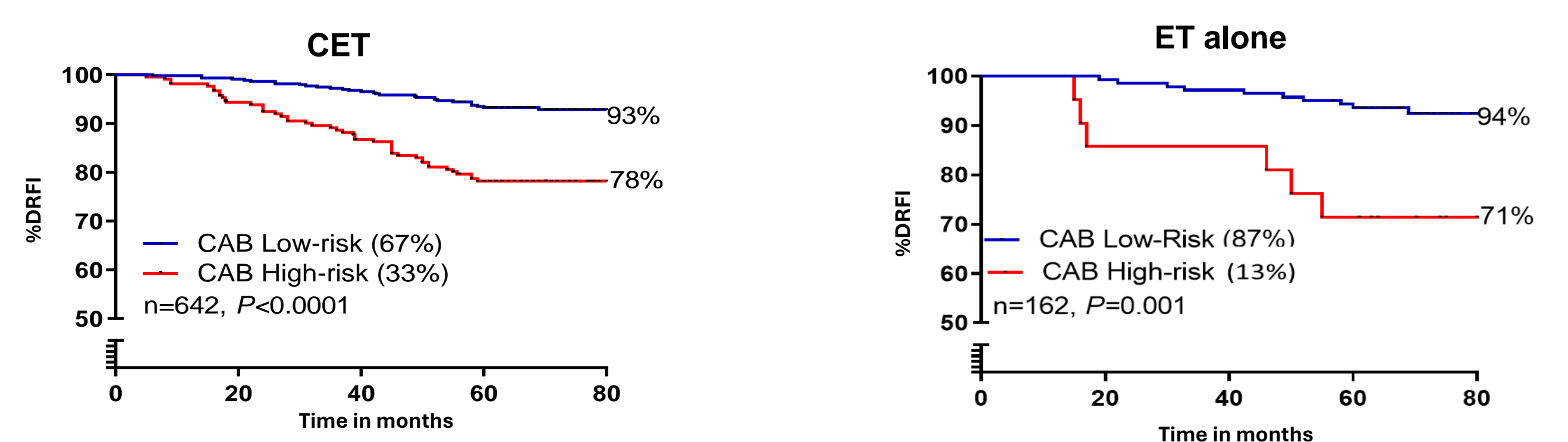


Figure 6: CAB stratification of patients with lymph node-positive disease (N+)

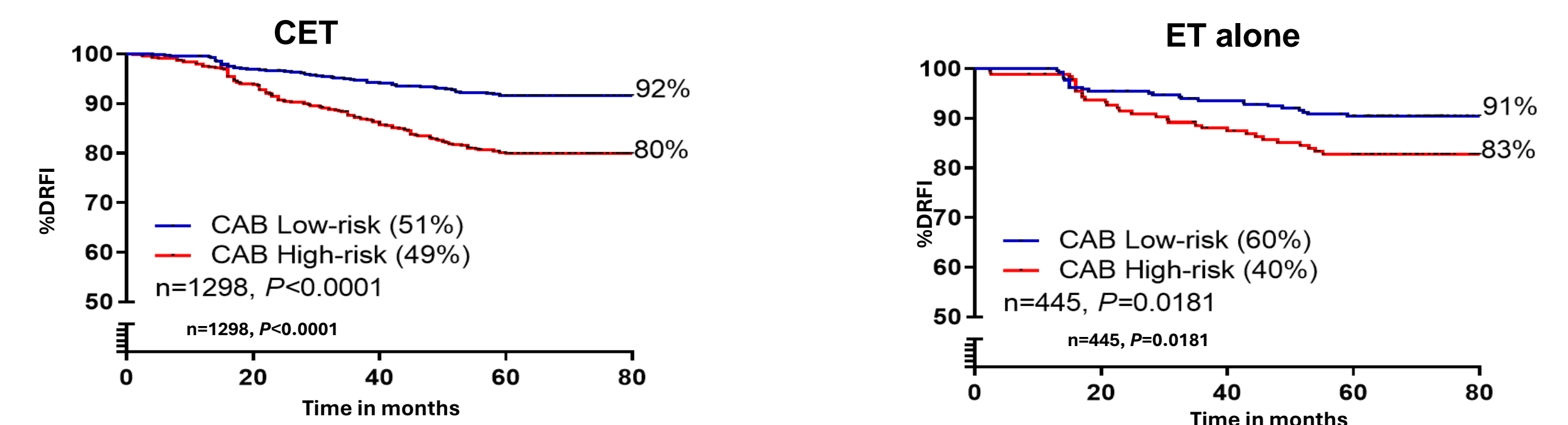


Figure 7: Risk stratification of low ER (1-20%) and high ER (>20%) patients by CAB

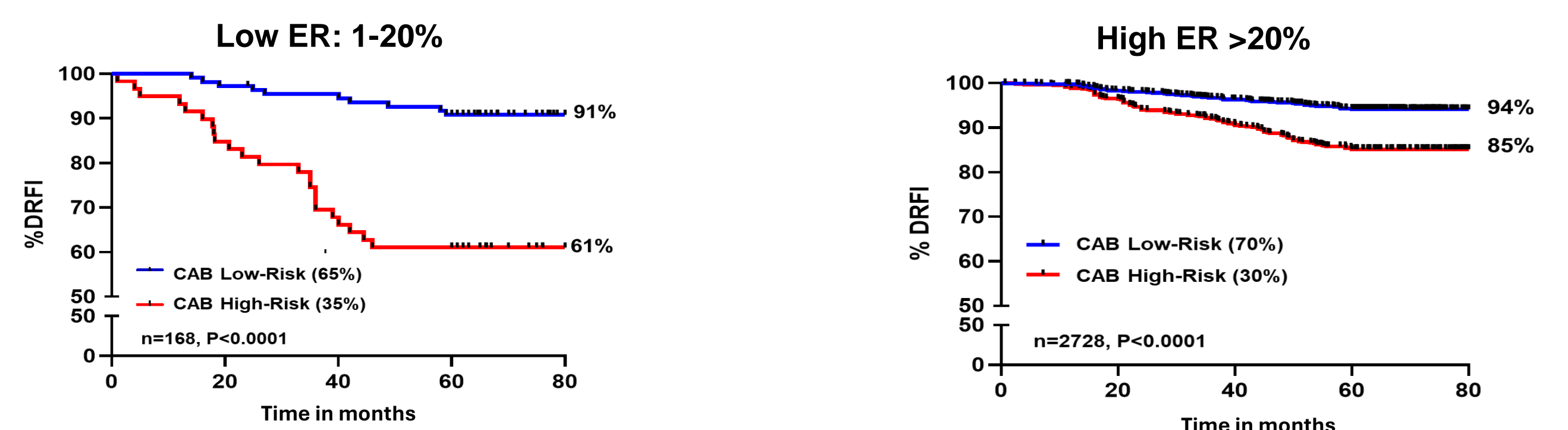
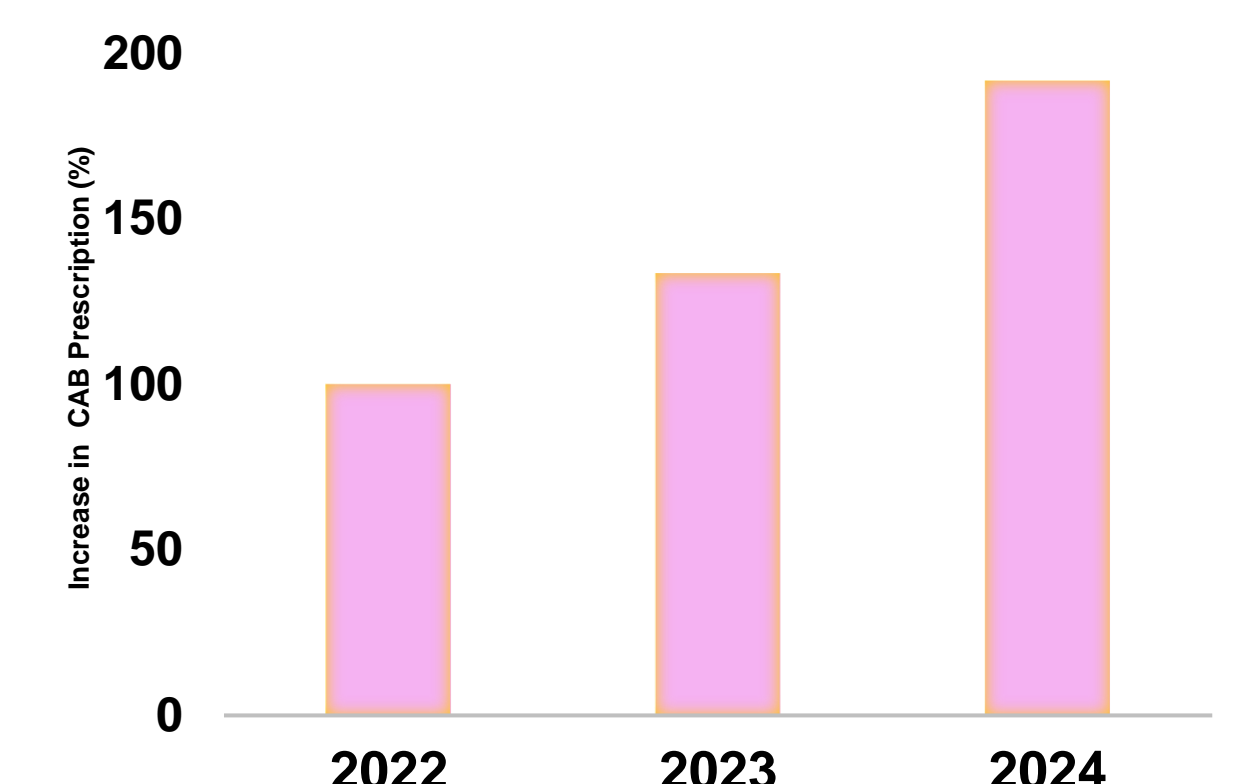


Figure 8: Real world reach of CanAssist Breast

Global reach of CanAssist Breast



Increase in CAB prescriptions/adoption year on year



The Real World NPV of CanAssist Breast is 97.5%

Conclusions

- CanAssist Breast (CAB)** is a pioneering prognostic test developed and validated on Asian patients and validated in a global study in USA, Germany, Spain, The Netherlands, Austria, Italy and Turkey.
- In Asia, Africa & ME incidence of breast cancer is often early with T2 tumors, and 1 involved node. CAB meaningfully stratifies these young patients, T2 and node positive patients showcasing usefulness of CAB in these patient populations.
- CAB stratifies tumors with intermediate Ki67 (6-29%) in a decisive manner thus helping with a treatment decision.
- CAB has been in clinical use for past 8 years and increase in prescriptions shows growing confidence of clinicians in CAB in India, Sri Lanka, Bangladesh, Turkey, UAE and Iran.
- Real world NPV of CAB is >95% showcasing its effectiveness and clinical utility.
- CAB offers a cost- effective and suitable alternative to western prognostic tests to patients in Asia, Africa and ME.

References

- "Real-World Evidence of the Impact of CanAssist Breast on Physician's Decision About the Use of Adjuvant Chemotherapy in Early Breast Cancer." *Cureus* vol. 16,12 e75622. 12 Dec. 2024. doi:10.7759/cureus.75622
- "Comparison of Risk Stratification by CanAssist Breast Test Performed on Core Needle Biopsies Versus Surgical Specimens in Hormone Receptor-Positive, Her2-Negative Early Breast Cancer." *Cureus* vol. 16,9 e70054. 23 Sep. 2024. doi:10.7759/cureus.70054
- "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 : Breast Cancer Research* vol. 25,1 40. 14 Apr. 2023. doi:10.1186/s13058-023-01643-2
- "A retrospective validation of CanAssist Breast in European early-stage breast cancer patient cohort." *The Breast (Edinburgh, Scotland)* vol. 63 (2022): 1-8. doi:10.1016/j.breast.2022.02.010
- "The usefulness of CanAssist Breast over Ki67 in breast cancer recurrence risk assessment." *Cancer Medicine* vol. 12,12 (2023): 13342-13351. doi:10.1002/cam4.6032
- "The usefulness of CanAssist breast in the assessment of recurrence risk in patients of ethnic Indian origin." *The Breast (Edinburgh, Scotland)* vol. 59 (2021): 1-7. doi:10.1016/j.breast.2021.05.007

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