

Clinical Efficacy Evaluation of a Novel Tactile Imaging Device For Early Detection of Breast Cancer in the Developing World

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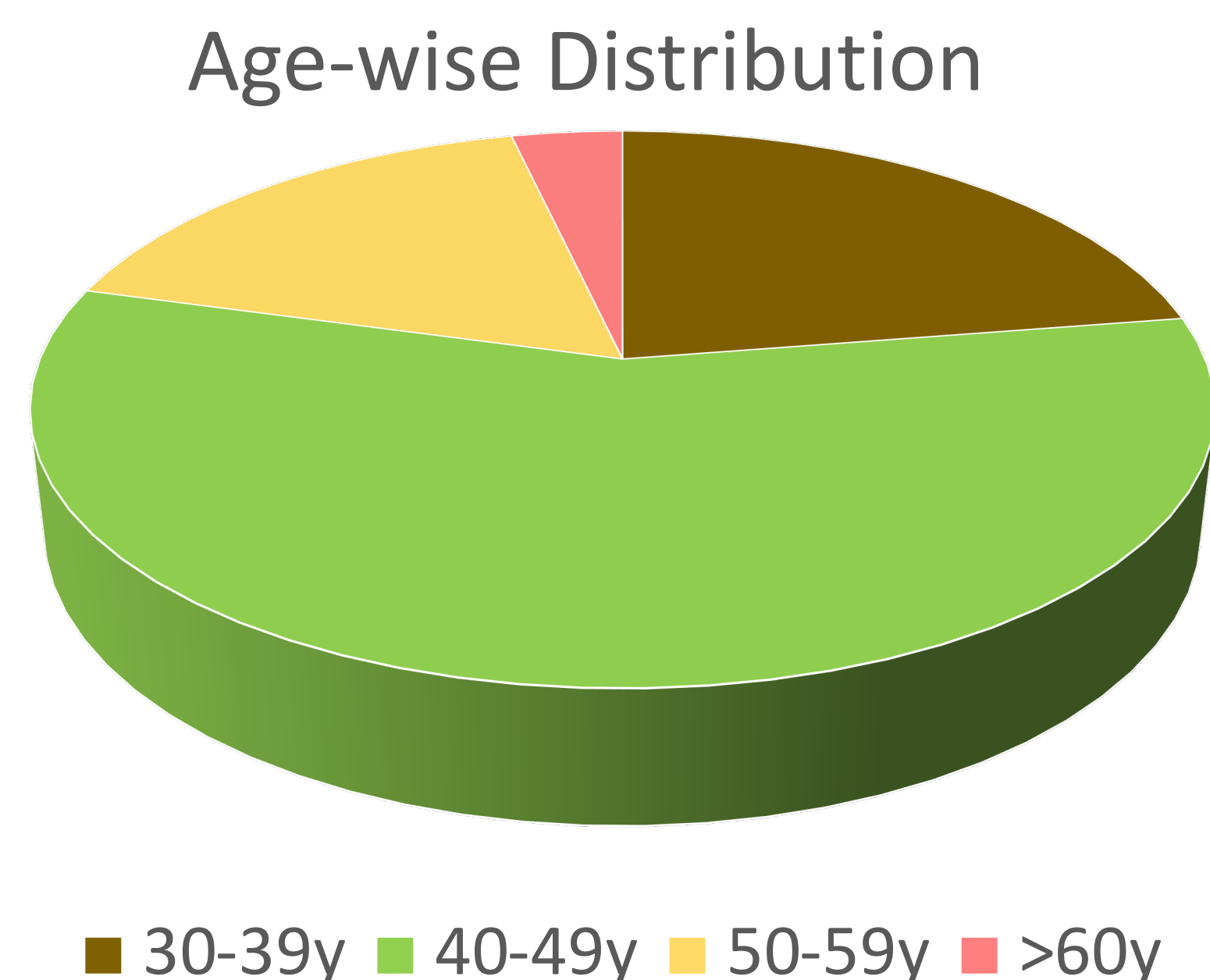
BACKGROUND

- Breast cancer is the most common cancer in women worldwide, disproportionately affecting low-and-middle income countries (LMICs).
- 52.6% of new breast cancer cases occur in LMICs, and this is expected to grow to 70% by year 2020¹.
- 5-year survival rate is 40-60% in most LMICs as compared to 80-90% in High Income Countries² (HICs).
- Organized screening mammography is expensive and resource intensive.
- iBreastExam (iBE) is a Low-cost, user-friendly technology that can help equip minimally trained community health workers to administer standardized breast exams without any special infrastructure, with the goal to down-stage breast cancer.**
- The aim of this study is to evaluate the clinical efficacy of the lower cost, non-invasive, portable device iBreastExam in the detection of clinically relevant breast lesions.**

METHODS

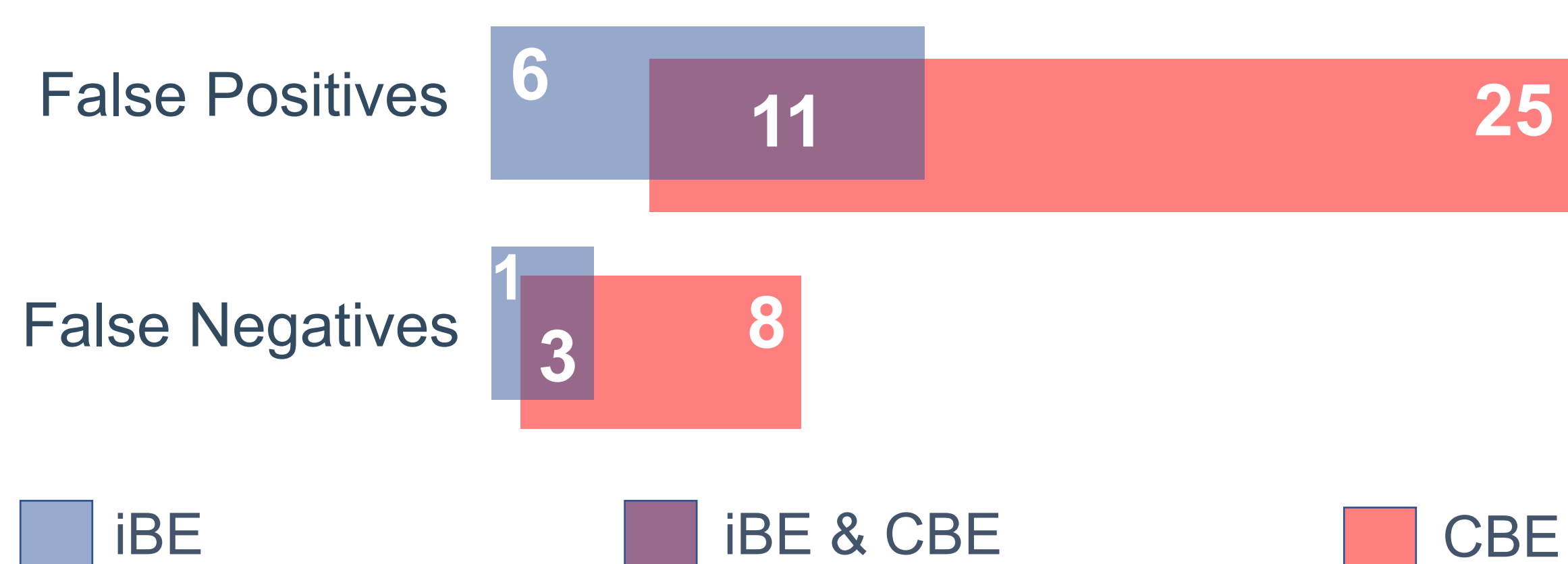
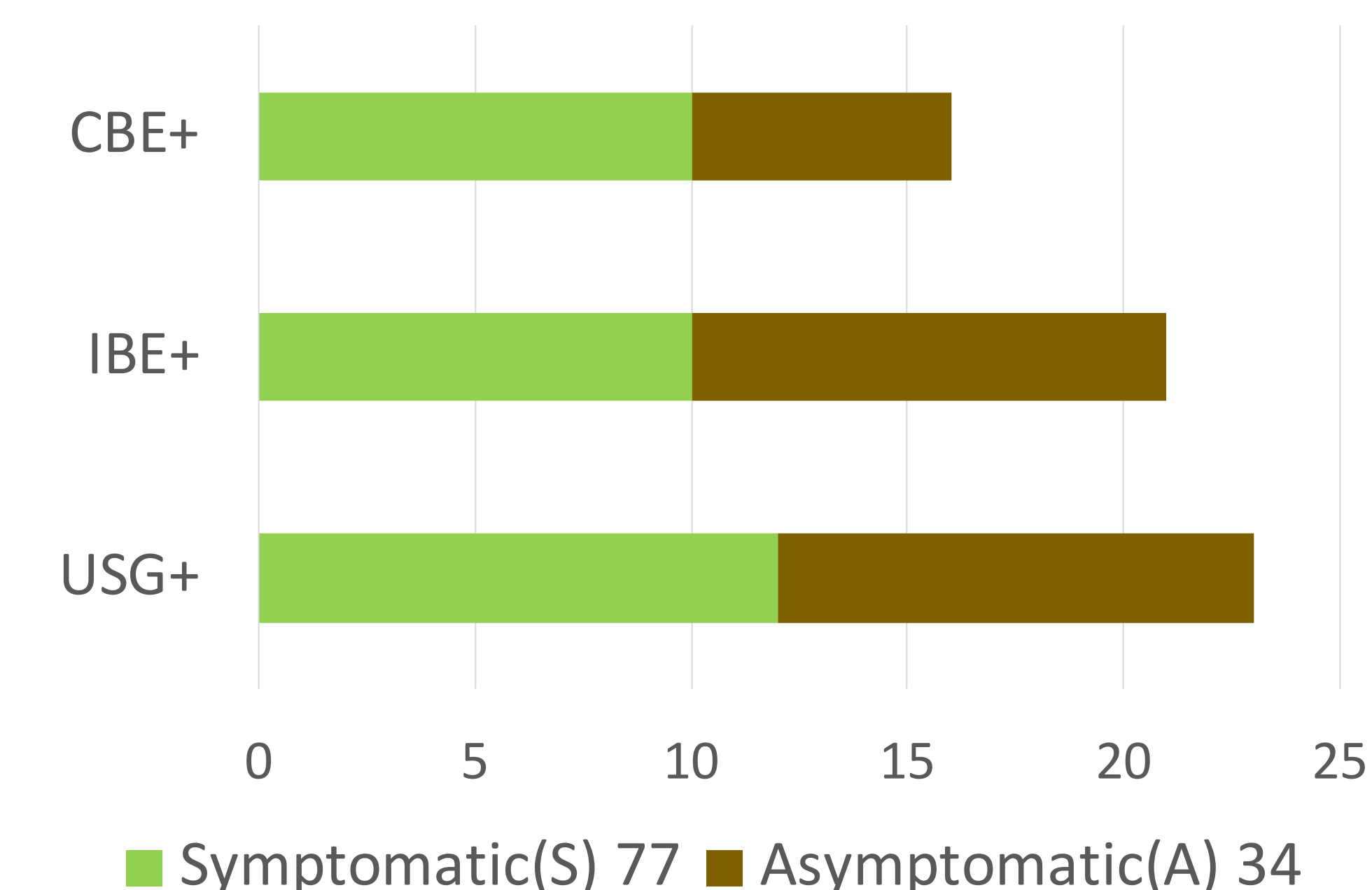
- A prospective non-interventional study** was conducted in Udupi district, Karnataka, India.
- 1200 Non-pregnant Consenting women of Age 30 years and above, seeking routine screening were enrolled.
- Additional 63 women presenting with some breast related symptom, seeking follow-up breast diagnostic evaluation were also enrolled.
- Each woman received an iBE palpation test and Clinical Breast Examination(CBE) blinded to each other. Women detected with any breast lesion on any of these tests were followed up with age appropriate diagnostic imaging.
- Each breast was considered an independent result for the sake of analysis for a total of 222 breasts.
- To assess accuracy of iBE and CBE to detect lesions, the sensitivity and specificity were calculated compared to diagnostic imaging.**
- Standard of truth was established as a positive Mammogram BIRADS 3-5 or a positive Ultrasound(US) as BIRADS 3-5.**

RESULTS



USG/MAMMO	IBE +	IBE -	TOTAL
BIRADS 1	9	75	84
BIRADS 2	0	3	3
BIRADS 3	15	2	17
BIRADS 4	5	1	6
BIRADS 5	1	0	1
	30	81	111

RESULTS



Sensitivity	86%
Specificity	91%
NPV	98%
PPV	57%

Sensitivity	63%
Specificity	82%
NPV	94%
PPV	32%

CONCLUSIONS

- iBreastExam demonstrated significantly (23%) higher sensitivity and moderately (9%) higher specificity to detect breast lesions as compared to CBE.
- Lower FP rates compared to CBE reduces the pool of women requiring further diagnostic follow-up.
- iBreastExam requires minimal training and provides objective breast examination with digital documentation.
- iBreastExam may enable community health worker led triaging to detect clinically relevant breast lesions in LMIC settings.