Detection of breast cancer in the symptomatic clinic using radio-wave technology - a multi-centre study

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Aims & Objectives

A commercially-available radio-wave breast imaging system (MARIA®,Micrima Limited, Bristol) has been deployed in multi-site symptomatic clinical. Interim results have been reported previously [1,2,4] including a higher lesion detection sensitivity to cancer in dense tissue than obtained for x-ray mammography [3]. However this is the first presentation of final statistics from the completed study of this volumetric, non-compressing modality which uses harmless radio-waves in the GHz spectrum to detect and characterize changes in the dielectric properties in the breast tissue which are associated with the presence of lesions.

Methods

Patients attending symptomatic clinics at 3 sites were identified by clinicians as having a palpable lump. Following informed consent eligible patients underwent this prone imaging technique. The bilateral reconstructed 3D images were correlated with clinical information and other imaging studies including ultrasound and/ or mammography and, when relevant, core biopsy results to determine sensitivity scores. [Ethics approval (Yorkshire & The Humber and South Yorkshire REC 15/YH/0084, ClinicalTrials.gov NCT02493595)].

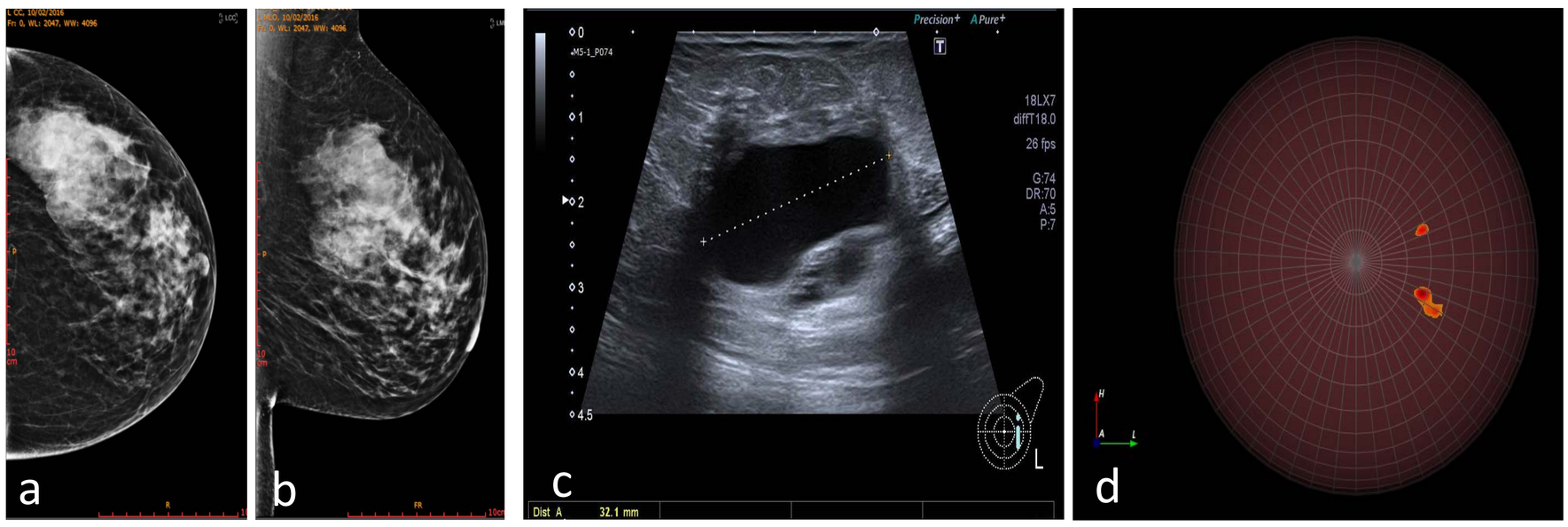
Results

From a total of 232 evaluated cases, 90 were confirmed as cancer by means of histology post-image guided biopsy. For these studies, MARIA's overall sensitivity was calculated as 76%. In pre-/peri-menopausal women sensitivity was 74%, in post-menopausal it was 79% & in women with dense breasts (BI-RADS c and d) it was 80% and 93% in BI-RADS D with 100% of cancers located though these are very small numbers. The cases highlighted in Figures 1 and 2 demonstrate that MARIA® can be a great asset for even the most senior radiologists to conclude a diagnosis.

	cases	Sensitivity score (ss)	Mean age yrs	Age range Yrs	Cysts ss	Cancer ss	Others ss
All	232	76%	50	16-89	62/82 (76%)	66/90 (73%)	48/60 (80%)
Pre/ Peri menopausal	163	74%	42	16-60	54/72 (76%)	27/39 (69%)	40/52 (77%)
Post menopausal (inc HRT)	68	79%	67	49-89	38/50 (76%)	38/50 (76%)	8/8 (100%)
BIRADS a+b	70	67%	59	34-89	33/47 (70%)	33/47 (70%)	8/12 (67%)
BIRADS c+d	110	80%	49	19-81	23/28 (82%)	23/28 (82%)	17/23 (74%)
BIRADS d	32	93%	49	23-81	16/18 (89%)	4/4 (100%)	8/9 (89%)

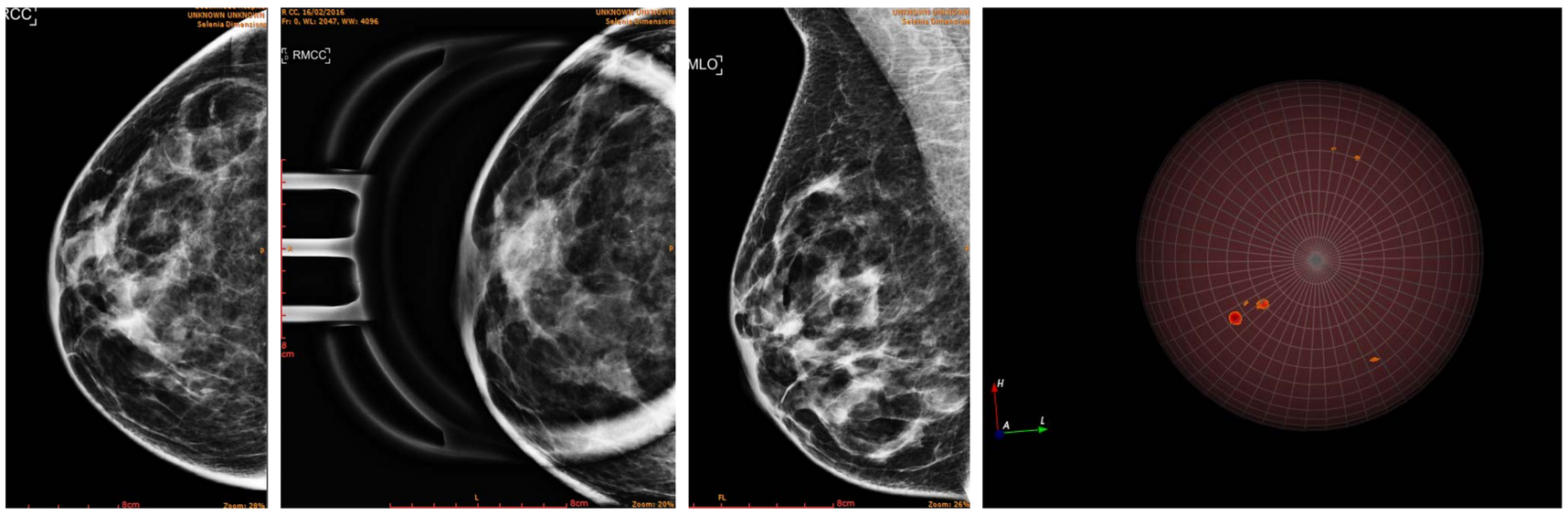
Case 1 – Figure 1

Clinical experience shows us that lesions can be found with MARIA® (Figure 1d) in a consistent manner when read by radiologists. The results show that MARIA® was able to identify the legions and correctly define their position to aid clinicians with their diagnosis.



Case 2 – Figure 2

This case demonstrates the ability for MARIA® to locate and identify a Grade ll invasive carcinoma in dense breast tissue. The technologies ability to work effectively regardless of breast density could provide additional clinical information to aid diagnosis and assist with additional procedure planning.



Conclusion

Results from the prospective use of MARIA® on this symptomatic cohort underline its effectiveness in detecting cancers, particularly in the dense breast, with its inherent advantages as a whole-breast, non-ionising modality. Further trials are due to commence to validate MARIA's performance on new patient populations.

References

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