

## Multicenter, double-blind, randomized, intraindividual crossover comparison of gadobenate dimeglumine and gadopentetate dimeglumine for MR imaging of the breast (DETECT)

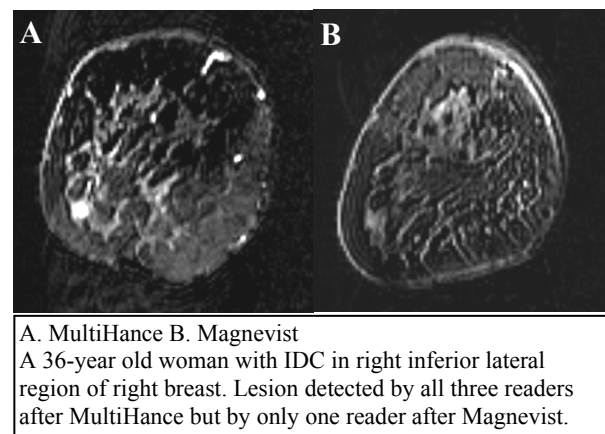
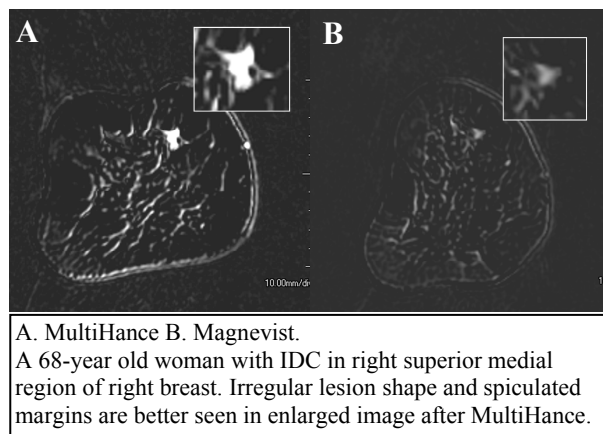
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**Purpose:** To intra-individually compare 0.1 mmol/kg doses of gadobenate dimeglumine and gadopentetate dimeglumine for contrast-enhanced breast MRI using a prospective, multi-center double-blinded, randomized protocol.

**Methods:** Institutional review board approval and patient informed consent was obtained. One hundred sixty-two women (52.8±12.3 years) enrolled at 17 sites in Europe and China between 07/07 and 05/09 underwent at least one breast MRI exam at 1.5T using 3D spoiled GRE sequences. Of these, 151 women received both agents in randomized order in otherwise identical exams separated by >2 but <7 days. Images, acquired at ≤2 min intervals after contrast injection, were evaluated independently by three blinded radiologists unaffiliated with enrolment centers. Histopathological confirmation was available for all malignant lesions (n=144), while benign lesions were confirmed either by histopathology (n=52) or by 12-month diagnostic follow-up (n=20) with mammography and/or ultrasound. Determinations of malignant lesion detection rates and diagnostic performance (sensitivity, specificity, accuracy, positive and negative predictive values [PPV and NPV]) were performed and compared (McNemar and Wald tests). A full safety assessment was performed.

**Results:** Each reader detected significantly more malignant lesions with gadobenate dimeglumine than with gadopentetate dimeglumine (132-136 of 144 [91.7-94.4%] vs. 115-120 of 144 [79.9-83.3%]; p≤0.0003). The cancer misdiagnosis rates were roughly double with gadopentetate dimeglumine for all three readers (4.9-11.9% vs. 2.6-4.0%). In terms of diagnostic performance significantly superior sensitivity, specificity and accuracy for breast cancer detection with gadobenate dimeglumine was noted by all three readers (91.1-95.2% vs. 81.2-84.6%; 96.9-99.0% vs. 93.8-97.8%; 96.7-98.2% vs. 92.8-96.1%; p≤0.0094). Likewise each reader noted significantly superior PPV (77.2-91.1% vs. 60.9-80.7%; p≤0.0002) and NPV (99.0-99.4% vs. 97.8-98.1%; p≤0.0003) with gadobenate dimeglumine. Three-reader agreement for assessing lesion nature was good (76.4%; κ=0.689) for gadobenate dimeglumine but only moderate (66.2%; κ=0.574) for gadopentetate dimeglumine. No safety concerns were noted with either agent.



**Conclusion:** Gadobenate dimeglumine at a dose of 0.1 mmol/kg bodyweight is superior to gadopentetate dimeglumine at equivalent dose for breast cancer diagnosis. The improved diagnostic performance with gadobenate dimeglumine may have important implications for breast cancer screening and diagnosis.