Gadovist® 1.0
Gadobutrol

Valuable Diagnostic Imaging for Multiple Sclerosis

Improving Our Picture of MS with Gadovist®1*

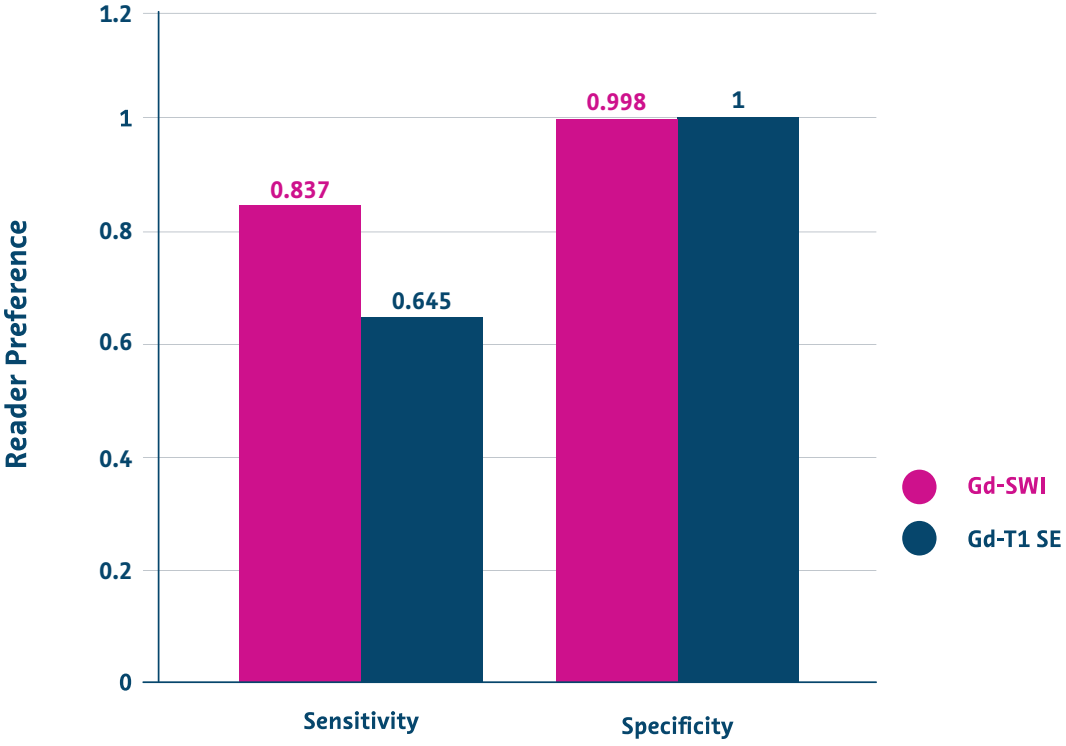
Research has shown that increasing susceptibility-weighted imaging (SWI) sequence applications in clinical practice can improve our knowledge of multiple sclerosis.[1]

Gadovist®-enhanced SWI detects significantly more active Multiple Sclerosis (MS) lesions than T1 SE,[1] leading to a more reliable disease assessment.

- More accurate knowledge of active inflammation on MS plaques is crucial for evaluating the extent of BBB dysfunction.
- Additionally, Gadovist®-enhanced SWI is able to depict the “central vein sign.” This is regarded as a promising imaging biomarker of inflammatory demyelination, adding MS specificity to the diagnosis.

* Gadovist® product monograph. September 2021.

Nearly one-third sensitivity increase compared to T1 SE[1]



Adapted from do Amaral et al, AJNR Am J Neuroradiol, 2019, 40;614-19

Study details

- 15,756 white matter lesions in 170 MRI examinations with Gadovist® @1.5T
- Gadovist®-enhanced SWI showed 265 Gd-enhancing lesions, compared to 183 lesions with Gadovist®-enhanced T1 SE
- Sensitivity increase of approximately 29.7% compared to T1 SE

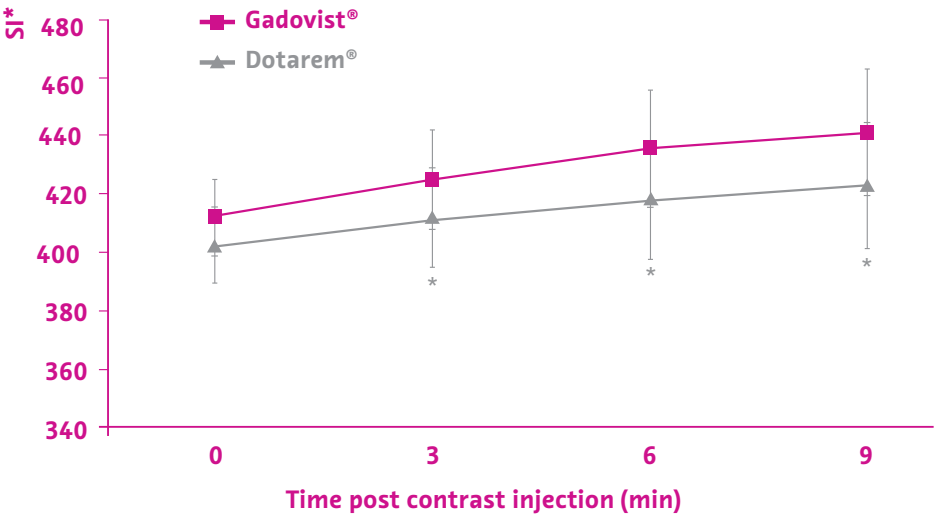
Clinical Benefit

- More accurate knowledge of active inflammation on MS plaques.
- Improved evaluation of BBB dysfunction.

This shows that, by improving the detection of MS lesions, Gadovist® can enhance much more than just the image, by helping to improve the patient journey and clinical outcomes.

› **Saake M et al. 2016** – A prospective, multicenter, randomized, intra-individual comparison study.

Increased Enhancement in MS Lesions With Gadovist® vs. Dotarem®[2]



Measured SI of MS lesions after GBCA injection. Asterisk indicates statistically significant difference ($p < 0.05$). Bars show standard deviations. Gadovist® generated higher lesion SI at all time points.

> Significantly higher mean lesion enhancement for Gadovist® ($p < 0.05$)

> Subjective preference showed non-significant tendency in favor of Gadovist®

* SI = Signal Intensity

GADOVIST® 1.0 mmol/mL solution for injection. **Composition:** GADOVIST 1.0 is a clear, sterile, aqueous solution. Each mL of GADOVIST 1.0 contains 604.72 mg (1.0 mmol) of gadobutrol, 1.211 mg trometamol, 0.013 mg sodium (0.00056 mmol), and 0.513 mg calcium sodium butrol in water for injection. The pH of GADOVIST 1.0 is adjusted to between 6.6 and 8.0 with hydrochloric acid. **Indications:** GADOVIST 1.0 (gadobutrol) is a medicinal product for diagnostic use only. GADOVIST 1.0 (gadobutrol) is indicated in adults and children of all ages including term newborns for: contrast enhancement during cranial and spinal MRI investigations and for contrast-enhanced magnetic resonance angiography (CE-MRA); contrast enhanced MRI of the breast to assess the presence and extent of malignant breast disease, and MRI of the kidney. GADOVIST 1.0 is particularly suited for cases where the exclusion or demonstration of additional pathology may influence the choice of therapy or patient management, for detection of very small lesions and for visualization of tumours that do not readily take up contrast media. GADOVIST 1.0 is also suited for perfusion studies for the diagnosis of stroke, detection of focal cerebral ischemia and tumour perfusion. **Contraindications:** GADOVIST 1.0 should not be administered to patients who have experienced a life-threatening reaction to GADOVIST 1.0 previously. **Serious warnings and precautions for use:** Gadolinium-based contrast agents (GBCAs) increase the risk for Nephrogenic Systemic Fibrosis (NSF) in patients with: chronic severe renal insufficiency (glomerular filtration rate <30 mL/min/1.73m^2), or acute renal failure / acute kidney injury. In these patients, avoid use of GBCAs unless the diagnostic information is essential and not available with noncontrast-enhanced magnetic resonance imaging (MRI). NSF may result in fatal or debilitating systemic fibrosis affecting the skin, muscle, and internal organs. Screen all patients for renal dysfunction by obtaining a history and/or laboratory tests. When administering a GBCA, do not exceed the recommended dose and allow a sufficient period of time for elimination of the agent from the body prior to any readministration. **Adverse reactions:** Patients with a history of previous reaction to contrast media, allergic disorders or bronchial asthma suffer more frequently from hypersensitivity reactions than others. As with other contrast media, delayed allergoid reactions occurring hours or days after administration have been observed, though rarely. Anaphylactoid reactions may occur. Transient sensations of taste or smell perversion may occur during or immediately after injection of GADOVIST 1.0.

Literature:

1. LLF do Amaral et al., “Gadolinium-Enhanced Susceptibility-Weighted Imaging in Multiple Sclerosis: Optimizing the Recognition of Active Plaques for Different MR Imaging Sequences,” AJNR Am J Neuroradiol 40, no. 4 (Apr 2019): 614-619.
2. Saake M, Langner S, Schwenke C, et al. MRI in multiple sclerosis: an intra-individual, randomized and multicentric comparison of gadobutrol with gadoterate meglumine at 3 T. Eur Radiol. 2016;26(3):820–828

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Bayer Inc.
2920 Matheson Blvd. East
Mississauga, ON L4W 5R6
Phone: (800) 268-1432
Fax: (800) 567-1710

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