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Scientific Abstract

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Dose Finding Study of Gadopiclenol, a New Macrocyclic Gadolinium-Based Contrast Agent, in MRI of the Central Nervous System

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Objectives

To determine a safe and effective dose of gadopiclenol, a new high relaxivity macrocyclic GBCA, based on the Contrast-to-Noise Ratio (CNR) as compared to gadobenate dimeglumine.

Methods and Materials

This double-blind, randomized, dose-parallel group and cross-over study included patients with known or highly suspected focal areas of disrupted blood brain barrier. Patients were randomized to one of the four doses of gadopiclenol (0.025, 0.05, 0.1, 0.2 mmol/kg) and to one series of two MRIs: gadopiclenol and then gadobenate dimeglumine at 0.1 mmol/kg or vice versa. Three independent blinded readers performed the signal intensity measurements off-site. Adverse events were collected up to one day post second MRI.

Results

The study population included 272 patients (58.5% females) with a mean±SD age of 53.8±13.6 years. The superiority of gadopiclenol over gadobenate dimeglumine was statistically demonstrated at 0.2 and 0.1 mmol/kg for all readers with an increase in CNR>30%. At 0.05 mmol/kg, gadopiclenol showed a similar CNR as gadobenate dimeglumine at 0.1 mmol/kg. The relationship between CNR and dose of gadopiclenol was linear for all readers. Similar results were observed for the other quantitative assessments (lesion-to-brain ratio and contrast enhancement percentage).

Rates of adverse reactions were comparable with gadopiclenol (11.7%) and gadobenate dimeglumine (12.1%).

Conclusion

When compared to gadobenate dimeglumine at the standard dose of 0.1 mmol/kg, the doses of 0.05 and 0.1 mmol/kg can be considered as effective and safe clinical doses of gadopiclenol.