Redefining MRI:
From Image to Insight

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MR Contrast Agents

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Gadopiclenol: What We Know from Phase III and RWD

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Gadopiclenol is a non-ionic macrocyclic gadolinium-based contrast agent (GBCA) characterized by high longitudinal relaxivity, primarily attributed to its hydration number of 2. This physicochemical property enhances T1 shortening, allowing for adequate signal intensity at reduced gadolinium concentrations. As a result, gadopiclenol can be administered at a dose of 0.05 mmol/kg, addressing increasing discussions regarding cumulative gadolinium exposure, particularly in patients requiring repeated magnetic resonance imaging (MRI).

The clinical performance of gadopiclenol has been evaluated in two phase III randomized, double-blind, intraindividual crossover studies (PICTURE and PROMISE), comparing gadopiclenol 0.05 mmol/kg with gadobutrol 0.1 mmol/kg across central nervous system (CNS) and body MRI. Across both studies, gadopiclenol demonstrated non-inferiority to gadobutrol for key endpoints, including lesion border delineation, internal morphology, and contrast enhancement. In CNS imaging, quantitative analyses indicated higher lesion-to-background contrast with gadopiclenol, and blinded reader assessments showed a greater preference for gadopiclenol-enhanced images, suggesting improved lesion conspicuity. In body MRI, diagnostic performance was consistent across abdominal, pelvic, breast, and musculoskeletal indications, with no clinically meaningful differences observed. Reader evaluations generally indicated comparable image quality between the two agents.

Safety outcomes were further supported by postmarketing data from the United States. Among more than 880,000 administrations, no serious adverse events were reported, and the incidence of non-serious adverse events was low (0.0036%), with most events being mild and transient. These findings are consistent with results from controlled clinical trials.

In conclusion, gadopiclenol provides diagnostic performance comparable to standard-dose gadobutrol while using half the gadolinium dose. It demonstrates consistent efficacy across CNS and body MRI, with potential advantages in contrast characteristics in CNS imaging. Together with its favorable safety profile, these findings suggest that gadopiclenol may be a useful option for optimizing gadolinium exposure without compromising diagnostic quality.

Keywords: *Gadopiclenol, Gadolinium-based contrast agent, MRI, Phase III, Efficacy, Safety, Relaxivity*