



ECR2016: Gadolinium Contrast Agent Safety: Facts and Myths



Over the past 25 years, gadolinium-based contrast agents (GBCA) have been recognised to have exceptional safety profiles with minimal side effects, as three researchers showed in their presentations at the European Congress of Radiology (ECR 2016) in Vienna.

Dr. [Richard Semelka](#) of the Department of Radiology, University of North Carolina at Chapel Hill, said in his keynote address during a satellite symposium hosted by Bracco Imaging, that “the accumulated safety record is outstanding, with serious adverse reactions occurring in about 0.03% of all GBCA administrations.”

GBCAs are virtually indispensable in clinical trials for the detection and characterization of tumours, the detection of inflammation and fibrosis, assessment of organ perfusion, and the delineation of vessels.

“However, as with all other drugs used in clinical practice, GBCAs should be evaluated for risk versus benefit, such as when considering the potential risk from MRI with GBCAs compared to alternative imaging strategies, with iodine-based contrast enhanced CT,” Semelka said.

“Adverse reactions to GBCA are infrequent and in most cases not life threatening. The best resource for comparing acute adverse events between agents is the published phase III studies on those agents, and the product inserts,” he added.

“Summarising these materials, one finds that there are essentially negligible differences between agents, recognising the subjective variations between describing mild acute adverse events which include such factors as cultural/national levels of tolerance.”

“Major licensing bodies such as the FDA in the U.S. and the European Medicines Agency recognise these variabilities, hence their focus generally on these agents has not been comparing acute adverse events between them, but looking for warning signs in individual agents.

“On a practical level, we recommend that when evaluating the introduction of a new contrast agent into the institutional formulary, double blind comparison between the existing and new agent is optimal.”

Posing the question of “what do we know and should we be concerned about Gadolinium deposition,” Dr. [Cesare Colosimo](#) of the Institute of Radiology, Diagnostic Imaging at the Policlinico Universitario A. Gemelli Foundation in Rome said that “radiologists must play an active role in defining real justification for the administration of the GBCAs, especially in patients with benign or chronic inflammatory diseases.”

“Radiologists must refuse to accept GBCA injection as a routine uncontrolled procedure, based solely on a

generic referral. They should regain their clinical role and go back to evaluate the need to administer GBCAs on a case-by-case basis,” Colosimo said.

“Moreover, given the evidence of a direct relationship between cumulative dose and the amount of deposition, the radiologist must use the minimum amount of GBCA necessary to obtain diagnostic results. This may be achieved by reducing the standard approved dose in selected instances. Such reduction may be possible if GBCAs with higher relaxivity and sufficient stability are used, as demonstrated in the peer-reviewed literature.”

Towards the end of the symposium, Prof. [Johannes Heverhagen](#) of the University Institute of Diagnostic, Interventional and Pediatric Radiology at the University Hospital, University of Bern, said “there is an extremely low risk of developing nephrogenic systemic fibrosis (NSF) for patients whose eGFR lies above 30ml/min/1.73sq.m.”

“However, since a risk still exists, the lowest possible GBCA dose should be administered. For the contrast agents belonging to the high-risk group, a warning applies to patients with moderate renal impairment, therefore, these agents should be used only after a careful risk-benefit analysis.”

In conclusion, the use of contrast agents with compromised renal function should always be weighed carefully. During their administration, the lowest possible dose required to obtain an acceptable diagnostic result should be utilised.”

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