Gadolinium-based Contrast Agents for Magnetic Resonance Imaging (MRI): Drug Safety Communication - FDA Evaluating the Risk of Brain Deposits With Repeated Use

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FDA 目前正在調查重複使用含釓類顯影劑(gadolinium-based contrast agents, GBCAs)於核磁共振攝影造成腦部沉積的風險。近期的研究指出，GBCAs 引起的腦部沉積主要發生於進行核磁共振攝影四次以上的病人，目前仍不清楚 GBCAs 引起的沉積是否有害。

FDA 與美國國家毒理學研究中心將進一步分析其風險可能性，並與研究人員及工業界確認釓滯留的機轉與對健康所造成的危害。因目前仍需要更多的資訊證實此不良反應，因此 FDA 暫不要求製造商更改含釓類顯影劑的產品標籤內容。

建議

FDA 建議，為了降低釓蓄積的可能性，醫療人員應考慮限制臨床上含釓類顯影劑的使用，並重新評估重複使用含釓類顯影劑於核磁共振攝影的必要性。病人、家屬及照護者如對含釓類顯影劑及核磁共振攝影相關資訊有任何問題，需與醫療照護人員確認。

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AUDIENCE: Radiology

ISSUE: FDA is investigating the risk of brain deposits following repeated use of gadolinium-based contrast agents (GBCAs) for magnetic resonance imaging (MRI). Recent publications in the medical literature have reported that deposits of GBCAs remain in the brains of some patients who undergo four or more contrast MRI scans, long after the last administration. It is unknown whether these gadolinium deposits are harmful or can lead to adverse health effects.

FDA, including its National Center for Toxicological Research (NCTR), will study this possible safety risk further. FDA is working with the research community and industry to understand the mechanism of gadolinium retention and to determine if there are any potential adverse health effects. Based on the need for additional information, at this time, FDA is not requiring manufacturers to make changes to the labels of GBCA products.

BACKGROUND: After being administered, GBCAs are mostly eliminated from the body through the kidneys. However, trace amounts of gadolinium may stay in the body long-term. Recent studies conducted in people and animals have confirmed that gadolinium can remain in the brain, even in individuals with normal kidney function. Available information does not identify any adverse health effects.

RECOMMENDATION: To reduce the potential for gadolinium accumulation, health care professionals should consider limiting GBCA use to clinical circumstances in which the additional information provided by the contrast is necessary. Health care professionals are also urged to reassess the necessity of repetitive GBCA MRIs in established treatment protocols.

Patients, parents, and caregivers should talk to their health care professionals if they have any questions about the use of GBCAs with MRIs. This issue affects only GBCAs; it does not apply to other types of scanning agents used for other imaging procedures, such as those that are iodine-based or radioisotopes.

Table 1. FDA Approved GBCAs

Brand name	Generic name
Ablavar	gadofosveset trisodium
Dotarem	gadoterate meglumine
Eovist	gadoxetate disodium
Gadavist	gadobutrol
Magnevist	gadopentetate dimeglumine
MultiHance	gadobenate dimeglumine
Omniscan	gadodiamide
OptiMARK	gadoversetamide injection
ProHance	gadoteridol