Intrathecal Injection of Ionic Contrast Material Is Sometimes Fatal

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PROBLEM: A 31-year-old man died after being injected with the wrong contrast medium during an outpatient myelogram (spinal radiography). Myelography is safely performed when non-ionic water-soluble radiographic agents are used, as indicated for this route of administration. However, the intrathecal misadministration of ionic contrast media can result in a syndrome of spasms and convulsions, often leading to death.

In this case, it was clear within an hour after the patient received the intrathecal injection that something was terribly wrong. The patient was transferred to the emergency department, and a neurologist was consulted. After visiting the radiology department to investigate, the neurologist discovered that an ionic contrast medium, contraindicated for intrathecal use, had been administered in error. The patient was quickly transferred to another hospital for treatment, but he died.

Many radiological contrast agents are neurotoxic and should not be given by the intrathecal route. Oil-based agents (e.g., ioophendylate [Pantopaque]) were introduced many years ago for intrathecal use, but a lack of fine-image detail (because of cohesiveness) and the need to remove the dye (to prevent arachnoiditis and post-spinal headaches) made these agents suboptimal.

Later, ionic watersoluble media (e.g., iothalamate meglumine [Conray]) were developed. However, they are unsuitable for direct contact with neural tissue; such contact can lead to severe muscle spasms, seizures, cerebral edema and hemorrhage, coma, paralysis, hypotension, hyperthermia, rhabdomyolysis, multisystem organ failure, and death.

An intact blood–brain barrier appears to protect the nervous system when ionic agents are given intravenously. Even then, these agents may cause limited disruption of the blood–brain barrier, particularly when they are given in high concentrations. This may account for the occasional neurological complications associated with intravenous (IV) use.

Over the last two decades, non-ionic watersoluble agents (e.g., metrizamide [Amipaque]; ioheol [Omnipaque]) have been developed that are significantly less neurotoxic than the ionic water-soluble agents. Some of these agents are suitable for both IV and intrathecal administration.

Similar errors have been reported in the literature, and most patients have died as a result of the neurotoxic effects of ionic contrast media. However, one study suggested that immediate recognition of a mistake and prompt aggressive treatment may lessen the likelihood of harm or death.5

A 65-year-old man who underwent surgery for a laminectomy had an intraoperative myelogram to confirm complete spinal decompression. The surgeon mistakenly used an ionic agent instead of a non-ionic agent. Three hours later, the patient began experiencing painful clonic spasms in his lower extremities (symptoms are often delayed for one to six hours after administration). The spasms increased in frequency and quickly involved his trunk, upper extremities, and face. The patient became obtunded and was intubated. These symptoms, along with hyperthermia and an elevated creatine kinase level, led to the quick recognition of the error and prompt, aggressive treatment. Fortunately, the patient recovered with no long-term sequelae.

The Food and Drug Administration (FDA) issued a warning about this problem on February 3, 1994. The agency ordered manufacturers to place a boxed warning on the carton, vial, and package insert for each iodinated contrast product that was not intended for intrathecal use. As a result, shipping cases, vial labels, and package inserts for these products today must include the words “Not for Intrathecal Use” or “Not for Myelography.” Although these warnings were intended to prevent the types of errors like those described in this article, they have not been wholly effective. Because the warnings are not always prominent or centered on the vials, they are easy to overlook.

SAFE PRACTICE RECOMMENDATION:
The use of contrast materials should be a prime target for failure mode and effects analysis (FMEA). Along with the potential for fatal outcomes associated with the inadvertent intrathecal administration of ionic contrast media, other potentially serious adverse events (allergic reactions, extravasation, and air emboli during administration), clearly suggest that these products warrant a closer look, as follows:

1. During the analysis, the pharmacy’s role in the distribution of contrast media should be evaluated. These products are not just standard floor stock items; they should be given as much attention as other injectable drugs.

2. If the radiology department requisitions the products, a pharmacist—not a technician or an employee in the purchasing department—should evaluate the request and should double-check all products before they are dispensed.

3. The pharmacy should consider placing prominent auxiliary labels on ionic contrast media that should not be used for myelography.

4. It must be determined where the products are to be stored. Contrast agents may be used in operating rooms, cardiac catheterization laboratories, and other areas as well as radiology departments.

5. It must be established how the media are being stored. One pharmacist reported the potential for confusion between look-alike vials of ionic diatrizoate meglumine (Hypaque), which is used in cerebral angiography, and non-ionic ioheol (Omnipaque 300), which is used

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in myelography. Both agents are made by the same manufacturer.

6. Each type of contrast media should be stored separately according to its use. For example, the hospital where the error occurred now stores the non-ionic product, which is intended for myelograms, in a locked box in an examining room that is used strictly for intrathecal procedures. No other contrast media are stored there. Another hospital packages special kits for myelograms that include the appropriate contrast media.

7. Pharmacists should visit storage areas periodically to evaluate the potential for errors in drug selection. The staff should perform an independent double-check of all products that are used.

8. Staff training is vital. Staff members who work in these areas should understand the proper indications and routes of administration for each contrast agent in use. It might help to post charts about all product in areas where they are used.6

9. Employees must be prepared to deal with the deleterious effects of an error. Prompt recognition of a mistake and timely treatment may prevent a fatal outcome.5

REFERENCES


The reports described in this column were received through the USP–ISMP Medication Errors Reporting Program (MERP). Errors, close calls, or hazardous conditions may be reported on the ISMP (www.ismp.org) or the USP (www.usp.org) Web site or communicated directly to ISMP by calling 1-800-FAIL SAFE or via e-mail at ismpinfo@ismp.org.