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FDA warns of risk from medical fragments

By CYNTHIA WASHAM

Physicians beware — a notice the U.S. Food and Drug Administration (FDA) issued in January warning physicians about broken medical device fragments left in patients strengthens patients' malpractice claims if a fragment causes harm.

"From now on you need to know better, because of the warning," said Kenneth Goodman, director of the bioethics program at the University of Miami.

Physicians who in the past might have blamed the manufacturer when a catheter or other device breaks may find themselves shouldering the blame.

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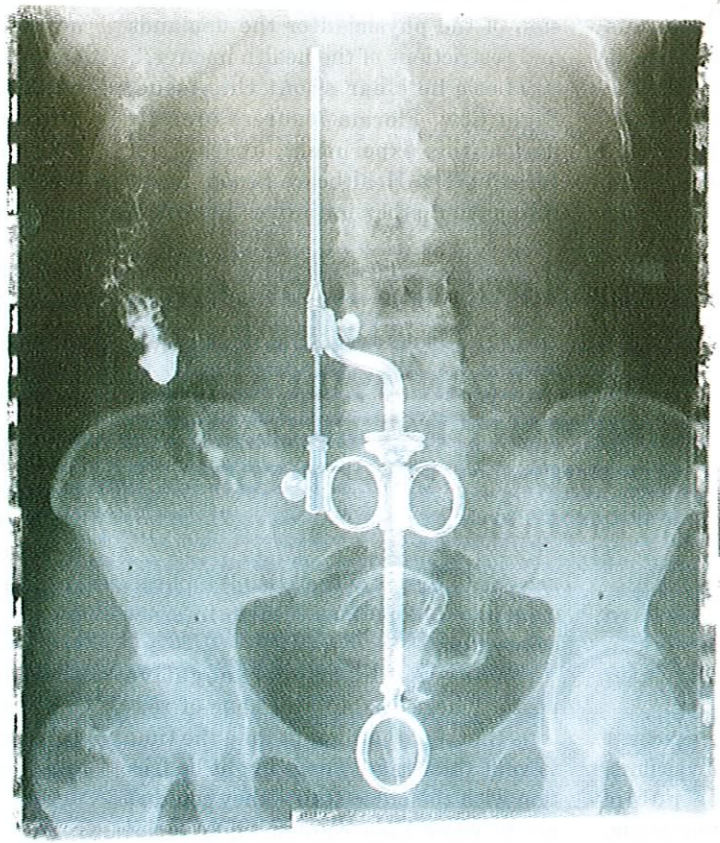
The notice warns physicians that unretrieved medical fragments have caused serious problems including infections, internal tissue damage, blocked or perforated blood vessels and death. One of the major risks comes from MRI. The magnet used in MRI imaging can cause metal fragments to move. Radiofrequency waves can heat the metal enough to burn surrounding tissue.

Adverse events

Every year, the FDA's Center for Devices and Radiological Health receives nearly 1,000 reports of "adverse events" related to fragments from more than 200 different devices, especially guidewires and broken catheter tips. Hospitals are required to report to the FDA whenever a device fragment causes serious injury or death. The agency encourages them to report broken fragments even if they cause no injury. A 1998 physician survey revealed, though, that only five percent of adverse events are reported to the agency.

The FDA notice doesn't claim breakage is the fault of the physician rather than the manufacturer. Yet it suggests responsibility ultimately lies with the physician. Recommendations include one to "Inspect devices prior to use for damage during shipment...that might increase the likelihood of fragmentation..." Another recommendation is to "Inspect devices immediately upon removal from the patient for any signs of breakage..."



Whether or not a fragment is likely to cause problems, attorneys agree physicians must inform their patients.

"If you make a mistake, you must tell the patient," Goodman said. "Patients don't sue over mistakes. They sue over what they're not told. People prefer to be given the whole story."

Leave nothing hidden

The FDA's advisory recommends physicians tell their patients the size, location and composition of the fragment, the risk of injury, and procedures to avoid, such as MRI. This information also should be included in the patient's record. The agency acknowledges that physicians might knowingly leave an apparently benign fragment in a patient to avoid the risk of removing it surgically.

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— plaintiff's attorney Stuart Ratzan, Miami

Although the notice does not address radiologists, Ratzan says they have a responsibility to question patients about fragments and other internal medical devices before conducting an MRI.

"The burden is on the radiologist as well in taking the patient's history," he said. ◆