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EDITORIAL

FDA Investigates the Safety of Brain Perfusion CT

On October 8, 2009, the US Food and Drug Administration (FDA) issued an initial notification regarding a safety investigation of facilities performing brain perfusion CT (PCT) scans. This alert indicated that the FDA had become aware of radiation overexposures during PCT imaging performed to diagnose stroke at a single, particular facility. Because of incorrect settings on the CT scanner console, more than 200 patients over a period of 18 months received radiation doses that were approximately 8 times the expected level. While this event involved a single kind of diagnostic test at 1 facility, the magnitude of these overdoses and their impact on the affected patients were significant. About 40% of the patients lost patches of hair as a result of the overdoses.

This episode highlights the importance of CT quality assurance programs. These should include regular reviews of CT protocols by a specialized CT physicist, testing scan protocols on dose phantoms, and the monitoring of actual doses received by patients for each type of CT protocol. Some institutions have chosen to designate a dedicated CT technologist in charge of ensuring that all CT protocols respect the ALARA (as low as reasonably achievable) principle. CT quality assurance programs should not be restricted to PCT protocols, but should be applied to all CT protocols, both neuro and nonneuro. Indeed, although the incident reported above involved PCT (which may be more prone to substantial radiation overexposure if performed incorrectly due to the cine nature of the acquisition), any CT protocol might have been involved, as was demonstrated in a recent unrelated incident at a community hospital in Arcata, California.[1] CT protocols with inappropriate acquisition parameters—for whatever reasons—might nonetheless be saved on scanner consoles, and subsequently applied by technologists to multiple patients before protocol errors are detected and corrected. Such errors can be difficult to discover,[2] especially considering that overexposed CT protocols are unlikely to decrease image quality (rather the opposite!), and hence can go unnoticed unless specific attention is paid to the technical scan parameters. Moreover, if patients receive higher than "reasonably achievable" CT radiation doses, but not sufficiently high to produce obvious epilation, there may be no other indication of potentially increased risk of long-term radiation effects. Importantly, the American College of Radiology (ACR) has established a voluntary CT accreditation program in which institutions are invited to submit patient and phantom images, along with dose measurements, from their proposed CT protocols, to demonstrate that they abide by ACR dose guidelines (ACR CT Accreditation Program Requirements, 2007). Along these lines, it might be desirable for neuroimagers to create a repository of optimized CT protocols, representing all types of CT scanners from all vendors, as well as all types of CT studies, which would be freely shared by the radiology community at large.

Radiologists and technologists should be familiar with and aware of the dose indices normally displayed on the CT scanner console. These indices include the volumetric CT dose index ($CTDI_{vol}$) and the dose-length product (DLP). The $CTDI_{vol}$, which was introduced to take into account the pitch of helical acquisitions, represents the average dose delivered within the reconstructed section, and is calculated as the weighted CTDI divided by the pitch.[3] The DLP is the $CTDI_{vol}$ multiplied by the scan length expressed in centimeters. It gives an indication of the energy imparted to organs, and can be used to assess overall radiation burden associated with a CT study. CT scanners now routinely record the $CTDI_{vol}$, and, in some cases, the DLP. Although the $CTDI_{vol}$ is not the dose to a specific patient, it is an index of the average radiation dose from a CT series.[3] For each protocol selected, and for each patient, the dose indices displayed on the control panel should be carefully monitored and determined to be within a reasonable range to prevent accidental overexposure. Radiologists and technologists should also become acquainted with dose modulation software[4] and, in the immediate future, with iterative reconstruction algorithms, which can replace filtered back projection, and have the potential to decrease image noise, while maintaining signal intensity, at a lower radiation dose.[5]

Hence, there is a need for continued, increased knowledge and awareness among radiologists and technologists regarding radiation dose, its measurement, and what can be done to decrease the risks associated with it. Radiologists have a responsibility as patient advocates to educate their clinical colleagues so that radiation dose is an important consideration in determining if an imaging study is warranted, especially when multiple, serial CT or flouroscopic studies may be required during a single admission. In a published case report of radiation overexposure resulting in epilation, for example, the patient had actually received four 120 kV PCT studies with CT-angiograms (CTAs), and 2 conventional digital subtraction angiograms, all within a 2-week period.[6] The need to keep serial studies involving ionizing radiation to a minimum is increasingly being underscored at many centers, most notably for critically ill patients in neurologic intensive care units who may receive multiple unenhanced CT, CTA, PCT, and fluoroscopic examinations.[7,8]

PCT studies should be performed at 80 kVp[9] and no more than 200 mAs. When using such parameters, the effective radiation dose associated with a single slab PCT study is approximately equal to that of an unenhanced head CT, roughly 2–3 mSv.[10,11] A comprehensive stroke CT protocol that includes an unenhanced and postcontrast head CT, PCT, and CTA of the cervical and intracranial arteries may deliver a mean effective dose up to 6 times that of a standard, unenhanced head CT.[12] Not every scan sequence, however, need be performed for every patient. Dedicated stroke protocols should be tailored to specific clinical indications, and radiation reduction strategies such as adaptive dose modulation, not to mention MR imaging scanning when feasible, should be implemented as appropriate.

Finally, as noted in the FDA alert that prompted this editorial, it is important to bear in mind that "while unnecessary radiation exposure should be avoided, a medically needed CT scan obtained with appropriate acquisition parameter has benefits that outweigh the radiation risks." Increasingly, indications for performing PCT include evaluation of patients

with signs and symptoms of acute stroke, vasospasm following aneurysmal subarachnoid hemorrhage, and chronic vascular occlusive disease (cerebrovascular reserve assessment with acetazolamide challenge). In stroke patients, especially those for whom MR imaging cannot be obtained, PCT permits more accurate assessment of infarct core (irreversibly ischemic tissue) than does unenhanced CT.[13,14] A recent publication by Lin and colleagues, for example, has shown that PCT is significantly more sensitive (64.6% versus 26.2%, $P < .0001$) and accurate (76.0% versus 52%, $P < .0001$), and has a better negative predictive value (59.6% versus 42.2%, $P = .032$) than does unenhanced CT in the detection of acute brain ischemia within 3 hours of symptom onset.[15] In another study, PCT detected abnormalities consistent with stroke/transient ischemic attack in many patients (32%) for whom no occlusion was identified on CTA; negative PCT/CTA predicted good outcome in most patients.[16] PCT findings may not only help select patients for thrombolytic therapy beyond the currently standard 3–4.5 hour time window for IV treatment, but might also prove to be of value in patient management within the first 3 hours of stroke onset. Since 2000, the American Heart Association has twice issued guidelines and recommendations for acute stroke imaging that have included extensive discussion of the role of PCT.[17,18]

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