Neuroimaging Sorts Out Eclampsia-Like Conditions

BY CHRISTINE KILGORE
Contributing Writer

Neuroradiologic studies can provide valuable diagnostic information in women who present during pregnancy or the puerperium with apparent eclampsia or similar neurologic manifestations, British investigators have reported.

A host of less common neurologic conditions and manifestations may mimic or resemble eclampsia and, because signs and symptoms are often nonspecific, it can be difficult to differentiate these conditions "on clinical grounds alone," they said in a recently published pictorial review.

"Neuroimaging in a clearly defined case of eclampsia may not be necessary but, if there is focal neurology or deterioration in neurological status, imaging should be performed," said Dr. R. Dineen of the department of neuroradiology at Queen's Medical Centre in Nottingham, England, and his associates.

Without it, the diagnosis of various conditions—from intracranial hemorrhage and other cerebrovascular conditions, to intracranial tumors and various pituitary and metabolic conditions—may be delayed as women are mistakenly treated for eclampsia, they said.

In women with true eclampsia, the most frequent abnormality detected on cranial MRI is high-signal change on T2-weighted and FLAIR images. Lesions are commonly seen in both deep and subcortical white matter, often with a posterior circulation distribution, and within the basal ganglia.

Lesions also occur within the pons and brainstem, and correspond to low-attenuation areas on CT scanning. The majority of lesions are reversible but some may progress to infarction, they said.

Several "overlap syndromes"—postpartum cerebral angiopathy, hypertensive encephalopathy, and reversible posterior leukoencephalopathy syndrome—may show neuroimaging features that are similar to or indistinguishable from those of eclampsia, they said (Clin. Radiol. 2005;60:1156-70).

Neuroimaging features are more distinct with other neurologic emergencies, such as the cerebrovascular disorders that can occur in pregnancy or the puerperal period: arterial ischemia and infarction, intracranial hemorrhage, venoocclusive disease, and vasculitis.

The mainstay for investigating ruptured intracranial aneurysms—the most common cause of subarachnoid hemorrhage and a cause of intracerebral hemorrhage—is CT with either CT angiography or conventional angiography. Magnetic resonance angiography, however, can be used to assess aneurysms without the need for ionizing radiation or contrast media.

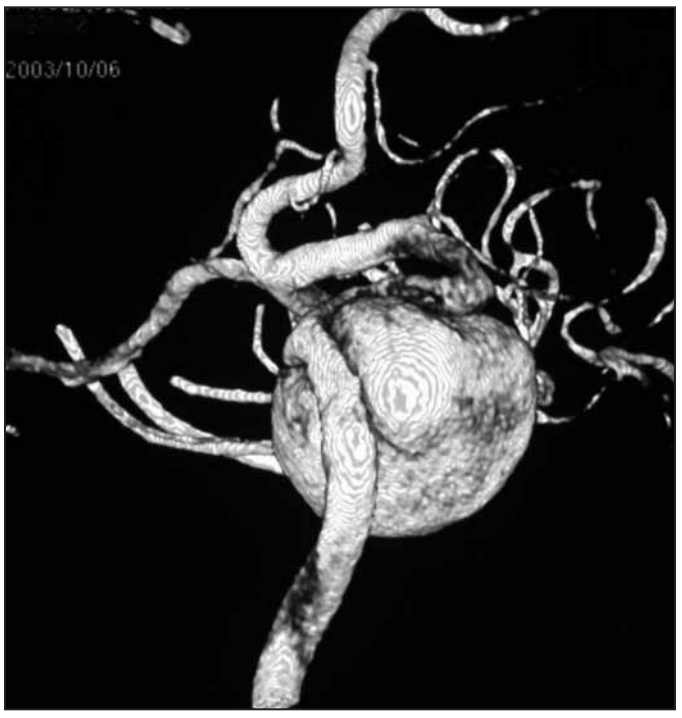
Neuroimaging may not be necessary in clear eclampsia, but if there is focal neurology or deterioration in neurologic status, it should be done.

Just as the risk of ruptured intracranial aneurysms increases for women who are pregnant or in the puerperal period, compared with nonpregnant women, the risk of intracranial venoocclusive disease is particularly increased around the puerperal period. Intracranial venoocclusive disease also can occur in women with preeclampsia.

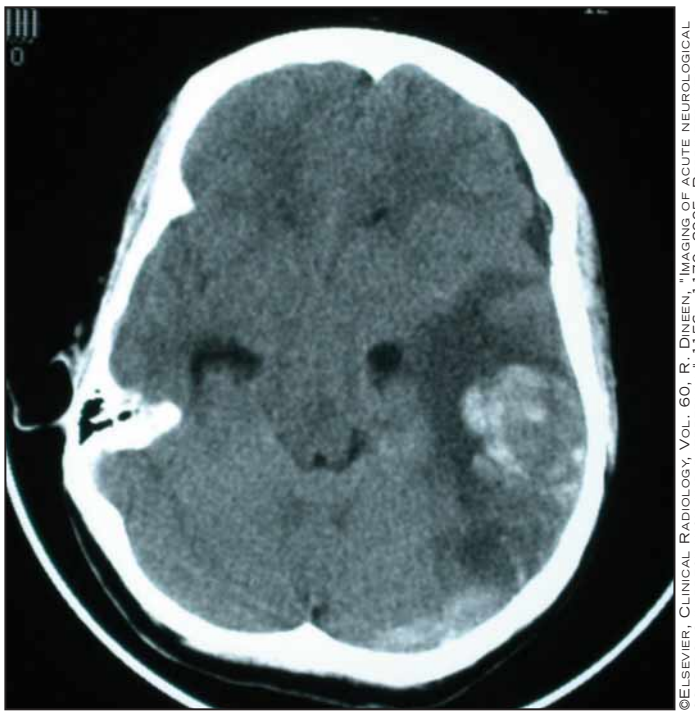
Women with the condition present with headache, confusion, decreased consciousness level, papilledema, seizures, and often, focal deficits.

CT scanning shows hyperdensity in the venous sinuses, cortical veins, or deep cerebral veins. When venous infarction develops, areas of low attenuation are seen. Patterns of venous infarction on MRI "do not conform to the contours expected from an arterial occlusion," the investigators note. T2-weighted images show high-signal change involving the white matter with absent flow void in the related cortical vein or dural venous sinus.

Precautions should be taken to limit fetal exposure to ionizing radiation, but "fetal exposure to ionizing radiation from CT of the maternal head is extremely low, and the risk to the fetus is likely to be considerably less than the risk to both the fetus and mother from an acute neurological condition," the investigators reported. ■



An internal carotid catheter angiogram shows a giant intracavernous aneurysm at the underside of the C4 segment.



A CT shows high density in the left transverse sinus and hemorrhagic venous infarction in the left temporal lobe.

Physician Certification Required

STAN *from page 2*

Dr. Julia Carey-Corrado, the FDA's clinical reviewer of the device application, said the FDA is requiring the manufacturer to submit annual reports that address a specified list of adverse events, including rates of perinatal death, neonatal encephalopathy, acidemia, and acidosis; the rate of device malfunction; the number of monitors sold; the number of institutions using the monitors; the proportion of patients monitored with STAN as opposed to standard EFM; and the number of physicians credentialed.

"The reports [will provide for] a more systematic, intense review" than normally occurs through the FDA's standard adverse event reporting requirements, Dr. Carey-Corrado said.

"The approval is unique in that we have been very explicit [in our conditions]," she said. "And having a denominator [on the extent of the device's use] will allow us to interpret the significance of outcomes."

The FDA will not, however, require the manufacturer to submit data on operative delivery rates, which is something its advisory panel recommended in June.

According to Colin Pollard, chief of the FDA's ob.gyn. devices branch, the agency decided not to require collection of this data, largely because it felt the issue of operative delivery rates had been addressed in the pivotal study.

The FDA will not require the manufacturer to submit data on operative delivery rates, which is something its advisory panel recommended in June.

In the pivotal Swedish randomized trial, the rate of operative delivery decreased significantly with the use of the STAN system. The rate of cesarean section for fetal distress was not significantly lower when all enrollees were included (the intent-to-treat analysis), but it was significantly lower when only those with adequate recordings were included.

Under the FDA's requirement for training, clinicians must be certified based on a written test and credentialed based on an oral exam that is administered after successful completion of at least five "practice cases," according to Dr. Carey-Corrado.

Physician certification is something the FDA's advisory panel called for in June, and the FDA deliberately structured its training requirement to resemble the training that was required of clinicians in the U.S. bridging studies, she said.

Dr. Hankins questioned how such a requirement could be enforced and said that training is ultimately "under local purview."

When asked about enforcement, the FDA's Mr. Pollard acknowledged the validity of the question and said that the agency's authority "does not extend beyond the labeling."

The STAN S31 system is indicated for use in patients with planned vaginal delivery, greater than 36 weeks of gestation, a singleton fetus, vertex presentation, and ruptured amniotic membranes.

Simon Grant, CEO of Neoventa, the monitor's Swedish manufacturer, said the company intends to partner with a U.S. company to introduce the device to the U.S. market this year. The STAN S31 system includes a standard EFM component and can be used with the ECG component turned on or off, he said.

In the second, larger bridging study, trained clinicians used the STAN system to manage 530 women in labor. Their decisions on when and why to intervene were compared with those of experts in Sweden who independently viewed the STAN tracings.

In 37 of the 530 cases, the experts indicated cause for concern and a need for intervention; in 31 of those cases, there was agreement by the U.S. clinicians. In the cases in which the experts and new users disagreed, the U.S. clinicians had access to information that the experts did not have; the U.S. clinicians were determined to have made appropriate decisions, Dr. Carey-Corrado said. ■