Stroke scans and radiation risk

News reports between autumn, 2009, and summer, 2010, claimed that several hospitals across the USA had been overdosing patients with radiation during routine CT perfusion brain scans. Lawsuits are in progress against hospitals and scanner manufacturers, and promises have been made to increase staff training and improve machine safety, but should CT perfusion scanning be a routine procedure at all? Ruth Williams investigates.

For the **Glendale press release** see http://www.glendaleadventist.com/body.cfm?id=10&action=detail&ref=59

At the end of September, 2009, a concerned doctor contacted Richard Patterson, a lawyer in Los Angeles, California. The doctor described the symptoms of one of his patients with stroke, and his concern was that these symptoms—dizziness, loss of equilibrium, modified gait, stupors of thought, loss of memory, and particularly hair loss—did not tally with the relatively mild stroke that the patient had had.

A few days later, Cedars-Sinai Medical Center in Los Angeles contacted the patient to tell her she had received a radiation overdose during a CT perfusion scan. A few days after that, the *Los Angeles Times* broke a story claiming that between February, 2008, and August, 2009, Cedars-Sinai hospital had exposed over 200 patients to excess radiation. A press release from Cedars-Sinai confirms the claim.

November and December brought more reports: another two hospitals in California—Glendale Adventist Medical Center and Providence St Joseph Medical Center in Burbank—were claimed to have given radiation overdoses during CT perfusion scans. And in July this year, the *New York Times* reported that the problem was yet more widespread. From its investigations, the newspaper alleged that eight hospitals across three states had given more than 400 patients overdoses during CT perfusion scans. In addition to Cedars-Sinai, Glendale, and Providence, those hospitals were identified as Los Angeles County-University of Southern California Medical Center (LAC-USC), California; Bakersfield Memorial Hospital, California; Huntsville Hospital, Alabama; South Lake Hospital, Orlando, Florida; and an unnamed hospital. A press statement from Glendale confirms that ten of its patients were exposed to excess radiation, while Providence states that 37 of its patients underwent scans before the hospital revised its protocol in accordance with FDA radiation dose recommendations. LAC-USC confirmed to *The Lancet Neurology* that two of its patients may have been overexposed. South Lake denied the *New York Times'* claims. Huntsville and Bakersfield did not respond to queries.

For the **FDA alert on radiation doses** see http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm193293.htm

CT perfusion brain scans are used at some hospitals to help with the diagnosis of stroke. Patients are given an intravascular contrast agent—iodine—and their brains are scanned repeatedly over the course of a minute or so. The resulting images produce a movie of blood flow in the brain. CT perfusion exposes patients to considerably more radiation than does a single CT scan, which itself is equivalent to about 200 radiographic procedures. The overdosed patients at Glendale received three to four times the normal dose, according to the hospital's press release, while in another case the FDA reported: "Patients at a particular facility received radiation doses that were approximately eight times the expected level."

How could some hospitals have got it so wrong? And, more importantly, could this happen at other hospitals across the USA, or the world?

Stanley Goldsmith, director of nuclear medicine at New York-Presbyterian Hospital, says he didn't take the claims lightly: "I realised that this was bad news for everyone, that you can't just be smug about it and say, well it can't happen here." At New York-Presbyterian, Goldsmith explains, managers and radiologists had an emergency review to discuss their protocols. "Everyone felt that it couldn't possibly happen", he says, adding: "It is hard to understand how you could overexpose someone to that degree."

So, how could it happen? At the hospitals concerned, two types of scanner were used, made by either Toshiba or GE Healthcare, and none of the machines was reported to have malfunctioned. However, Stephanie Hall, chief medical officer at LAC-USC, says that technicians followed the manufacturer's (Toshiba's) guidelines, yet two patients are thought to have been overexposed. Toshiba did not respond to queries. In this case, neither patient reported ill effects. A press statement from Cedars-Sinai suggests an auto-setting on their GE scanner "delivered a higher than expected level of X-ray radiation" but Ken Denison, a spokesperson for GE Healthcare claims that, "Changes were made from the reference protocols that we send out with the system…and those were what resulted in the dose being increased to the patient."

Denison adds: "[The users] see the dose that is going to be delivered by the machine in the upper right hand corner of the screen, and it is constantly updated with every change that [the users] make." He also explains that when multiple scans are to be taken of the same part of the body, as occurs in CT perfusion, a warning message appears asking if the user is sure they want to proceed. "They would have to dismiss that message in order to start the perfusion scan", says Denison.

It can be relatively easy to click "OK" when a message appears on a computer screen, so it is important to ensure that users understand the consequences of that action through sufficient training. Also important is that supervising radiologists and neurologists pay attention to technicians' reports and undertake regular checks.

According to their press statement, Cedars-Sinai has introduced new procedures and policies for CT, including reviews and validations of new protocols, additional checks of radiation dose, and additional staff training. Patricia Aidem, a spokesperson for Providence St Joseph, says new policies and expanded staff training have been implemented there also. At LAC-USC, Hall says the staff now do more thorough assessments of new CT protocols.

These revised procedures should help prevent mistakes from being made in the future, but given the relative ease with which they were made in the past, the Medical Imaging and Technology Alliance, which represents Toshiba, GE, and other manufacturers, has also made a commitment. Future CT scanners will include a new software safety feature called dose check. Denison explains that this will allow health-care providers to define a dose limit in their scanner, beyond which either a further alert message would appear or a password would be required. "Starting late this year, early next, every CT scanner that ships will have this feature", says Denison. GE will also retrofit the software to technically compatible models, worldwide.

In the UK, the risk of a radiation overdose is already very low, because scanners are rarely used for CT perfusion. "There is very little drive [in the UK] to start doing them, because there is no evidence that the information that a CT perfusion scan gives you should in any way be influencing the way we practise", says Tony Rudd, professor of stroke medicine at Guy's and St Thomas' NHS Foundation Trust, London. Louis Caplan, senior neurologist at the Beth Israel Deaconess Medical Center in Baltimore, MD, USA, agrees: "It's an experimental test...the utility of it is unknown."

Given CT perfusion's apparently experimental nature, should patients be routinely receiving CT perfusion scans at all? The question is one for debate, although George Lantos, associate professor of neurology and radiology at Albert Einstein College of Medicine in the Bronx, NY, has a clear standpoint. He writes in a letter to the *New York Times*, "The problem is that there is no FDA-approved therapy that uses the information from perfusion scans in the setting of acute stroke", and goes on: "My stroke neurologists and I have decided that if treatment does not yet depend on the results, these tests should not be done outside the context of a clinical trial, no matter how beautiful and informative the images are."

Michael Lev, director of the Emergency Neuroradiology and Neurovascular Lab, Massachusetts General Hospital, Boston, MA, argues that absence of evidence does not mean the technique does not work. He adds: "We do things in medicine all the time that don't have this very high level of evidence, and we don't think twice about them." He stresses that there is evidence to support use of CT perfusion as a differential diagnostic tool, albeit weak.

"The idea behind the [CT perfusion] test is a very good one...it was a direct sequel to the MRI diffusion which people have used", says Caplan. But Rudd points out, "CT perfusion does not substitute effectively for MRI-DWI [diffusion weighted imaging]." And Lev does not disagree: "If you can get a diffusion MR scan, you should, but when you can't, [CT perfusion] often becomes the next best alternative." Most emergency rooms do not have an MRI machine, he explains.

A properly performed CT perfusion scan will not make a patient's hair fall out: although the radiation dose is high, it is thought to be safe. However, because the risk for cancer is cumulative, and because CT perfusion scans deliver an especially large radiation load, limiting their use might be considered. "It always comes down to balancing risk and benefit", says Lev, adding that with CT perfusion, "you are balancing the risk and the benefit in a population of patients who in general are older and sick to begin with". Increasing an older person's risk of cancer slightly might be deemed a chance worth taking in a life-threatening situation. But many young people also have strokes, or stroke-like symptoms, and many hospitals give them CT perfusion scans. Indeed, a number of the reported overdose victims were in their twenties, says Patterson.

While the debate about the use and usefulness of CT perfusion continues, at least the chance of the procedure causing an overdose should now be much reduced. In December, 2009, the FDA published a list of recommendations for undertaking CT perfusion scans, and in February this year they published an initiative to reduce unnecessary radiation exposure in medical imaging.

Sadly, these recommendations come too late for the unlucky patients who Patterson and other lawyers now represent. "What these people are really suffering from", says Patterson, "is the question of, am I going to die from this."

Ruth Williams

Simon Fraser/Science Photo Library

For the **Medical Imaging and Technology Alliance statement on the dose check feature** see http://www.medicalimaging.org/2010/02/nation%E2%80%99s-ct-manufacturers-unveil-new-industry-wide-medical-radiation-patient-safety-features/

For the **FDA recommendations for undertaking CT perfusion scans** see http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm185898.htm

For the **FDA initiative to reduce unnecessary radiation exposure from medical imaging** see http://www.fda.gov/Radiation-EmittingProducts/RadiationSafety/RadiationDoseReduction/ucm199994.htm