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Innovative Canadian stroke trial targets brain hemorrhage

OTTAWA, Oct. 3, 2011 – Canadian stroke researchers have teamed up to launch a multisite clinical trial of an image-guided treatment strategy for a serious form of stroke caused by bleeding in the brain. If proven successful, their protocol could lead to the first effective emergency treatment for intracerebral hemorrhage, the deadliest and most disabling type of stroke.

“We are trying to find a way to stop bleeding in the brain during the critical first few hours of a hemorrhagic stroke. With no approved emergency treatments for patients with intracerebral hemorrhage, there is a pressing need for this kind of research,” said Dr. David Gladstone, principal investigator of the SPOTLIGHT trial and scientist in the Brain Sciences Research Program at Sunnybrook Research Institute in Toronto. Dr. Gladstone presented his findings at the Canadian Stroke Congress here today.

The researchers will test a strategy that uses imaging technology to identify the stroke patients at highest risk of further bleeding in the brain as soon as they get to the emergency department. These patients will then be randomly assigned to either a treatment or control group. Patients in the treatment group will get an injection of recombinant activated coagulation Factor VII, a drug that has shown promise to treat bleeding. Researchers will evaluate if this novel pairing of imaging and therapy can improve outcomes in these high-risk patients.

The trial will test if this treatment protocol can be administered rapidly and safely to stroke patients in the emergency department, and whether it can effectively reduce bleeding in the brain. “The hope is that treatment to reduce brain bleeding, if administered quickly enough and to the right patients, can translate into improved recovery and reduced disability,” said Gladstone, who is also director of the Regional Stroke Prevention Clinic at Sunnybrook Health Sciences Centre and assistant professor in the Department of Medicine at the University of Toronto.

The SPOTLIGHT trial builds upon the imaging discovery of the “spot sign,” identified by Dr. Richard Aviv, and further characterized by Dr. Andrew Demchuk, both of whom are co-principal investigators on the trial. The spot sign is seen using computed tomography (CT) angiography, a technology that can visualize bleeding blood vessels in the brain.

“The spot sign method has become the most rapid, accurate and reliable way to predict which patients are actively bleeding and at highest risk of worsening due

to hemorrhage expansion,” said Aviv, who is a neuroradiologist at Sunnybrook and researcher at SRI. “This imaging advance is going to significantly improve patient selection for clinical trials,” said Demchuk, director of the Calgary Stroke Program and professor at the University of Calgary.

Recombinant Factor VIIa is used for other life-threatening bleeding conditions, but is still under study as a therapy for brain hemorrhage. Although it has shown promise in treating this condition, a major limitation of previous trials is that they have not focused on the highest-risk patients, the active bleeders, who are the ones most likely to benefit from the therapy. This trial is designed to overcome that limitation. It is the first Canadian study to test the therapy in patients specifically selected using CT angiography because they have the spot sign.

Looking ahead, the hope is that this therapy could become a first-line treatment in the future, said Gladstone. “For years, intracerebral hemorrhage has been considered an untreatable type of stroke, with a dismal prognosis for many patients. If this new image-guided approach proves successful, then it could revolutionize how such patients are treated worldwide,” he said.

The randomized controlled trial received Health Canada approval and was awarded a top-rated research grant from the Canadian Institutes of Health Research (CIHR). The study, coordinated at the Li Ka Shing Knowledge Institute of St. Michael’s Hospital in Toronto, will recruit patients from hospitals across Canada that are members of the Canadian Stroke Consortium, a network of leading stroke centres.

The SPOTLIGHT trial is funded by CIHR, the Ontario Stroke Network and the Ontario Ministry of Research and Innovation.

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