Paper demonstrates benefits of stenting for stroke

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UB neurosurgery team led groundbreaking research into stenting for stroke. (L to R) Adnan Siddiqui, Elad Levy, L. Nelson "Nick" Hopkins", Credit: Kenneth Snyder

A *New England Journal of Medicine* (*NEJM*) paper published today and co-authored by University at Buffalo neurosurgeons reports that stroke patients have a much better chance of surviving and returning to normal function when they receive clot-busting drugs in conjunction with a wire mesh stent device, than when they receive the medications alone.

The results from the international SWIFT PRIME trial were previously reported during the International Stroke Conference in Nashville in February.

"This is exactly a game-changer," said Elad Levy, MD, professor and chair of the Department of Neurosurgery at UB, medical director for neuroendovascular services at Gates Vascular Institute (GVI) and co-author of the NEJM study. Adnan Siddiqui, MD, PhD, professor and vice chair of neurosurgery at UB and site principal investigator for the trial at GVI also was co-author. Jeffrey Saver of UCLA and Mayank Goyal of the University of Calgary were first authors.

The study found that 88 percent of patients treated with tissue Plasminogen Activator (tPA) in conjunction with Solitaire, a wire-mesh stent device, experienced successful revascularization – much higher than the 35 percent rate of tPA alone. Of those patients, 60 percent regained final independent function, higher than what has been seen with other endovascular interventions.

But this "game-changer" was long in coming, according to Levy, Siddiqui and other UB neurosurgeons, who, under the direction of L. Nelson "Nick" Hopkins, MD, SUNY Distinguished Professor and former chair of the UB Department of Neurosurgery, pioneered many of these techniques back in the 1990s.

Hopkins and his colleagues had begun exploring how to use minimally invasive stroke treatments that take advantage of the body's circulation

system by threading micro-thin devices through an artery in the groin to reach blocked vessels in the brain where they are then treated with stents.

At first, the neurosurgeon community was less than enthused. "They ridiculed us, they called us cowboys," said Levy, recalling the response to a presentation at a scientific meeting he made on stenting for strokes. "Physicians in the audience got up out of their seats to tell us how absurd it was to think that we could use stents for acute stroke. They called it unproven, untested and dangerous."

But Hopkins and his colleagues at UB and Kaleida forged ahead, in part inspired by the success cardiologists had seen using stents to treat coronary heart disease.

"We're at the dawn of a new era in stroke," Hopkins said recently.

Right now, that new era is coming to select hospitals and stroke centers, like the GVI, explained Levy.

"These results were achieved at the very best centers in the US and Canada," he said, "and much of it has to do with workflow systems and how we move stroke patients through the Emergency Room (ER). Why do stroke treatments fail? Because patients sit in the ER. So here in Buffalo, we don't let stroke patients sit anywhere, we keep them constantly moving through the ER."

The UB/GVI team is continually reviewing procedures, searching for ways to further optimize them and identifying and eliminating any potential inefficiencies.

While Levy said stroke treatment shouldn't only be viewed as a race against time, he notes that there's no way around the fact that speed is a

key factor. Swift Prime's target was to take 70 minutes or less to progress from acquisition of a qualifying image – where the occlusion is confirmed – to groin puncture. Of all 36 study centers in the trial, the UB/GVI team had the fastest pace and was presented with a certificate for that achievement. In one case, the Buffalo team achieved the feat in just 18 minutes.

Conducted with 196 patients at 36 sites, the study stopped enrolling patients last November when results from a similar study found that endovascular therapy with clot-busting drugs significantly benefitted patients.

Levy said some patients who were treated with tPA plus the wire-mesh stent were able to leave the hospital after just a few days, in stark contrast to what has been standard of care, where patients spend several days in the intensive care unit then additional time at a rehabilitation facility.

Another advance the UB/GVI team helped pioneer is the use of CT perfusion imaging, which allows physicians to visualize where the clot is located and what portion of the brain is not receiving blood. "About 10 or 15 years ago, people thought CT perfusion imaging was of no value and that time was the only parameter in treating acute stroke," said Siddiqui, "now we wouldn't think of doing a stroke treatment with this kind of imaging."

Siddiqui explained: "CT perfusion along with CT angiography allowed for critical assessments to be made for clinical decision-making, reserving MRI for patients who did not need immediate intravenous tPA or mechanical thrombectomy."

In addition to vindicating the work that neurosurgeons at UB and Kaleida Health have developed on stenting for stroke, the results also

demonstrate the value of the collaborative clinical science model exemplified by the Gates Vascular Institute/CTRC building. Opened in 2012, it was designed to help researchers bridge the gap between basic biomedical discoveries and clinical treatments. The collaborative environment was expected to reduce barriers between academic disciplines and between institutions, resulting in exceptional clinical and translational advances in medicine.

"The SWIFT PRIME trial is a big win for this building," said Levy. "It proves the value of having UB research upstairs and the operating rooms downstairs. You can take the elevator from research and translation to innovation and the clinical forum."

The research was conducted to determine if patients who experienced an ischemic stroke experienced better outcomes with the intravenous clot-busting drug tissue Plasminogen Activator alone versus tPA in conjunction with the use of a wire mesh stent device called Solitaire, made by Covidien. The trial examined the use of the Solitaire™ FR (Flow Restoration) Revascularization Device within six hours of symptom onset. The primary study outcome measure was the degree of disability at 90 days.

Solitaire is a wire-mesh stent device that is inserted through a tiny incision in the groin and threaded through the femoral artery by catheter to the vessel in the brain that's blocked. When the mesh device is opened, it captures the clot and pulls it out as the catheter is removed. Normal flow to the brain is restored and damage to the brain due to lack of blood is mitigated.

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