A major advance in treating strokes, but few get it in time
By Henry L. Davis
Published Mon, Mar 20, 2017
Buffalo News

Larry Beck was in his office one afternoon when, feeling unbalanced, he wobblingly walked to the bathroom, splashed water on his face and collapsed a few steps away.

As an ambulance raced the Buffalo architect to the hospital, he slipped in and out of consciousness. He couldn’t move his right side. He tried to speak, but the words didn’t come out.

“I’m talking gibberish,” Beck thought to himself.

A clot the size of a raisin blocked a blood vessel in his brain, depriving it of oxygen. Every minute that passed, two million nerve cells died, increasing the odds of death or the kind of long-lasting impairments that send patients into nursing homes. He was having a stroke and, as the saying goes in stroke, time is brain.

When Beck reached Gates Vascular Institute, everything was ready. Dr. Elad Levy, who sped to the hospital with a police escort, threaded a tiny tube to Beck’s brain to grab the clot with a device known as a stent retriever. Within moments, Beck could talk.

The next day he could walk.

The day after that he went home.

A new generation of devices is transforming stroke treatment. The advance is viewed as sea change in treatment, yet only about 10 percent of potential candidates get it in time. The optimal window to be effective stands at about six hours from the start of symptoms, so success depends on a race against the clock.

Neurosurgeons in Western New York and elsewhere face a major challenge – how to get the right patients to hospitals capable of offering the highly complex procedure in time for them to benefit.

This won’t be easy. Change will require improved public education about the signs of stroke, better stroke detection in the field by emergency medical personnel, fewer delays in transferring patients from one hospital to another, and regional protocols detailing when it’s appropriate to bypass the closest hospital to go directly to a facility that offers these endovascular procedures.

It also will require cooperation among the big hospital systems here competing for stroke patients.

“We need an equitable way to fix this. There is a lot of historical baggage out there among the hospitals, and no discussions in Western New York about what to do about it,” said Dr. Adnan Siddiqui, director of the neurosurgical stroke service for Kaleida Health.
The stakes are high. Stroke is like a heart attack in the brain. It ranks as the third-leading cause of death in the United States, with 140,000 people dying each year, and remains the leading cause of disabilities, including paralysis. The problem remains especially acute in this region, where mortality rates from stroke are among the highest in the state.

The devices treat a type of stroke in which there is a clot blocking blood flow. There was little doctors could do for ischemic stroke, which accounts for 85 percent of the 795,000 stroke cases each year in the nation, until 1996. That’s when the Food and Drug Administration approved the clot-busting drug tPA for use in strokes.

But tPA must be given within four and half hours from the onset of symptoms, is unsafe in some patients and doesn't work well in large clots. The vast majority of patients eligible for the drug don't get it.

Manufacturers and physicians have been investigating devices like the stent retriever to restore blood flow similar to the way physicians clear clots near the heart by maneuvering devices with a catheter through blood vessels. However, until recently, trials of the devices for stroke offered mixed results.

That's completely changed. Studies in the past year or so offered convincing evidence that mechanically removing clots from blocked arteries in certain patients like Beck with large blockages works significantly better than using clot-busting drugs alone.

“It’s extremely time-sensitive technology that requires intensive expertise. We’ve shown the therapy works. The next step is organizing care so patients can get it as fast as possible,” said Siddiqui.

Physicians at Kaleida Health’s Gates Vascular Institute and the University at Buffalo played a key role in developing the technology. In 2006, they were the first to use a self-expanding stent to restore blood flow in an ischemic stroke patient. They were the first, as well, to gain FDA approval for a study in 2009 of stenting for acute stroke, and in 2015 led the U.S. portion of one of the key trials showing the benefits of what’s known as mechanical thrombectomy, using one of the newer generation of stent retrievers.

That study, known as SWIFT PRIME, was stopped early because of the positive results: 60 percent of the patients who received tPA in combination with a stent retriever were functionally independent in three months compared to 35 percent of the patients who just got the drug.

“The benefit of stent retrievers is overwhelming, and we are still relatively early in the game,” said Levy, co-director of the Kaleida Health Stroke Center.

Procedures with the retriever and similar devices, like any surgery, carry risks, such as bleeding from perforation of a blood vessel. But, with the advances in technology and technique, doctors talk about a revolution in stroke care. The procedures can prevent or minimize disability.
Other changes helped, as well, including more careful selection of patients and faster time to treatment once patients enter the hospital. Now, a key area of focus is improving regional systems of care to significantly shorten delays before a patient arrives.

Beck, who was 65 when he suffered his stroke in 2015, illustrates the advantage of quick action. After recuperating at home, he’s back at work at TRM Architecture, Design & Planning with little after effect.

---

**Too many delays in care**

Stroke care generally is built around a two-tier system designed to deliver the clot-busting drug. Higher-level comprehensive stroke centers offer around-the-clock access to tPA and stroke procedures. Primary stroke centers don't perform the procedures but can administer the clot-busting drug, the first treatment stroke patients should get. In New York, those distinctions are made by accrediting organizations and not by the state.

Two comprehensive stroke centers – Kaleida Health’s Gates Vascular Institute and Catholic Health’s Mercy Hospital – provide the majority of stroke care in the Buffalo Niagara region. Eight hospitals operate primary stroke centers, including Kaleida Health’s Millard Fillmore Suburban and Catholic Health’s Sisters and Kenmore Mercy facilities.

Kaleida Health does about 51 percent of the stroke care here and Catholic Health about 37 percent, according to statistics from Gates Vascular doctors. Publicly available federal data indicates that Kaleida Health’s current death rate among Medicare stroke patients – 15.6 percent – is considered no different than the national average, and Mercy Hospital’s at 19.5 percent is worse than the national average. Both hospitals rank near the national average for how often stroke patients must be readmitted within 30 days of discharge.

Efforts to diagnose and treat stroke quickly are not new. Many states and regions have systems in place, and a medical culture amplified by hospital marketing has grown around the concept of “drip and ship,” getting patients to the closest stroke center for the clot-busting drug and, if needed, transferring them to a comprehensive stroke center.

Despite these efforts, delays in emergency transport and hospital transfers remain common, Siddiqui and others said. An analysis by physicians at Gates Vascular of their patients found that, on average, across the region four hours and 41 minutes slips by from the moment patients recognize a stroke to when emergency medical services receives a call. Then, on average, more than an hour passes before an ambulance reaches the stroke center.

Doctors estimate there are only about 400 patients a year in Western New York eligible for the procedures based on current criteria, generally patients with large clots that don’t respond to the clot-busting drug. The number could increase as the technology improves. Solutions to get the patients to the right place in time will mean answering some tough questions.
Can more patients be diagnosed and given the clot-busting drug in the field and sent directly to a comprehensive stroke center? Can primary stroke centers shorten the time it takes to identify candidates for mechanical thrombectomy, a process that requires an advanced CT scan with dye to visualize the clot? Can the two competing comprehensive stroke centers collaborate to develop regional policies?

“We have adversarial stances between two well-entrenched hospital systems. But we need criteria and standards. We need to have that discussion. The community should demand the best care possible,” said Siddiqui.

New guidelines from the American Heart Association and American Stroke Association recommend that doctors use devices within six hours of the start of symptoms in select patients after trying the clot-busting drug. Neurosurgeons see an access problem. An estimated 240,000 patients in the U.S. are considered candidates, but doctors perform only about 22,000 procedures a year, according to medical device maker Medtronic.

“It’s complicated. Delay is the biggest issue. But we’re talking about a small number of patients, and every region of the country will be different because of geography, weather and travel times,” said Dr. William Powers, the University of North Carolina physician who led the panel that wrote the new guidelines.

Powers said communities should seek agreement on ways to reduce delays. But he voiced less certainty about policies on when to bypass a closer primary stroke center for tPA to transport a patient to a comprehensive stroke center, saying such decisions will require much better data in the field by emergency medical services about the severity of a patient's stroke.

He said it remains unclear when it is better to take a stroke patient to a nearby hospital that can only start a clot-busting drug, potentially delaying treatment with a device, or transport the patient farther to a facility able to provide tPA and the procedures.

All of which leads to another tough question some physicians raise: Should just one medical center, similar to the way trauma care works for the worst injuries, get the candidates for the stroke procedures?

---

Creating a system of care

Doctors at Kaleida Health say it’s a topic at least worth discussion, citing their research work, larger volume of cases and availability of clinical trials for stroke. But Siddiqui said what’s most important is that hospitals put aside differences and work together to ensure as many patients as possible get the right care as soon as possible.

At the Catholic Health system, the idea of giving up stroke procedures is a non-starter, but there is interest in talking to the competition about what's best for patients.
“Competition is a good thing. It raises the bar. We challenge each other,” said Dr. Lee Guterman, medical director of neurosciences.

He said his preference is the system in which patients go to the closest stroke center, get tPA and an advanced CT scan. Patients who will benefit from a procedure, if not already at a comprehensive stroke center, can then be transferred there, he said.

"I question the impetus to follow a trauma model for stroke because all hospitals need to be able to treat stroke, and a minority of patients need the procedures," Guterman said.

To Guterman, the greatest opportunity for collaboration centers around pre-hospital triage by EMS.

"Let’s better understand what signs and symptoms should mean going directly to a comprehensive stroke center,” he said. “The biggest bang for the buck would be standardized EMS protocols, education for EMS and better communication with EMS to prevent delays. Should we be talking to our competitors about this? Yes.”

Dale Jerge’s case shows how things go well with minimal delay.

A year and a half ago, he was preparing to leave his Amherst home for a business trip, when his wife, Susan, found him sitting on the bed incoherent and unable to move his left side. She quickly recognized stroke from her experience as a certified nurse’s aide and sought help.

Little more than an hour later, he was wheeled into the emergency room at Buffalo General Medical Center, where Jerge vaguely recalls doctors and nurses rushing toward him like firefighters responding to an alarm. The hospital’s stroke team had been alerted as he was en route.

Today, Jerge, a consultant on occupational safety, is back to normal after doctors at Gates Vascular used a minimally invasive procedure to clear a clot that had traveled from his heart to the brain.

“I’ve got no side effects, nothing,” he said.

But figuring out who should go where when an ambulance arrives isn’t always clear. EMS personnel use assessments to diagnose stroke, but identifying the type, size and severity in the field remains an inexact science without a CT scan for confirmation.

Opening more comprehensive stroke centers isn’t the answer either. They require enormous investment and expertise, and the thinking goes that hospitals that do more cases tend to achieve better outcomes. A few regions in the U.S. are experimenting with mobile stroke units outfitted with a CT scanner, but the units cost as much as $1 million and have not yet shown they provide a significant benefit.
Dr. Joseph Bart, director of EMS Operations for the UB|MD Emergency Medical Services Division, said the state doesn’t differentiate between types of stroke centers, meaning EMS can’t write protocols that distinguish between them. Regardless, he said, a regional consensus on protocols is an admirable goal.

“It’s definitely worth discussion,” he said. “We now do stroke screening when we arrive. Then it’s up to family, the patient and hospital marketing as to where the patient goes.”

http://buffalonews.com/2017/03/20/major-advance-treating-strokes-get-time/