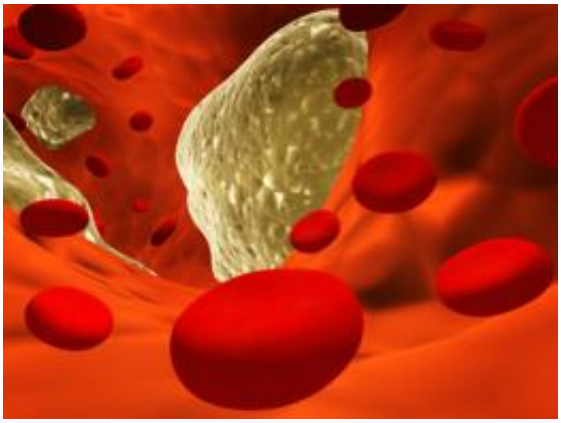
Treatment for stroke-related blood clots shows promise

January 31 2011, By Colin Poitras



A blood clot.

Devices for removing or destroying blood clots in stroke victims may improve medical outcomes for some patients, but further research is needed to show who might benefit most from the treatment and when it should be applied, according to a new report by University of Connecticut School of Pharmacy researchers and their peers at Hartford Hospital.

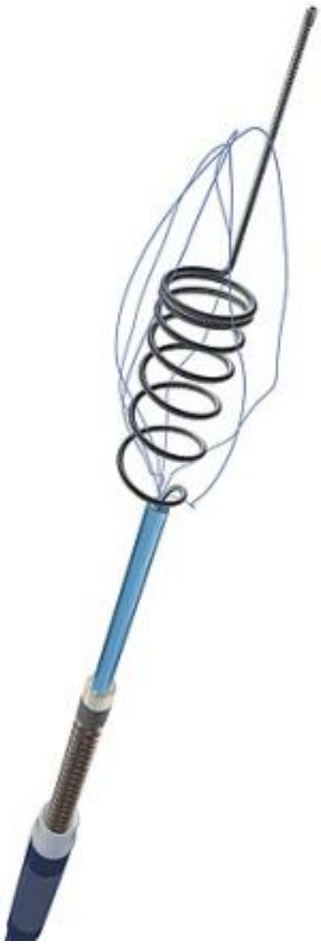
The “state-of-the-evidence” report appears online this month in the *Annals of Internal Medicine*. Produced by researchers at the University of Connecticut/Hartford Hospital Evidence-based Practice Center in Hartford, the report assesses the available evidence supporting the use of the technology.

The report focuses on devices that are inserted into the body via a catheter and used to remove or destroy blood clots from patients suffering from acute ischemic stroke, which is stroke caused by a thrombosis, or clot, in a small artery of the brain that deprives the brain of oxygen-enriched blood.

The Penumbra System uses a suction-like action to extract the blockage. Credit: Penumbra Inc.

Ischemic stroke is the most common of two broad classifications of stroke, the other being hemorrhagic stroke, which occurs when a blood vessel bursts inside the brain.
Stroke is the third leading cause of death in the United States behind heart disease and cancer, and the leading cause of long-term disability. An estimated 795,000 new or recurrent stroke events are reported annually.

Patients who arrive at the hospital within two to three hours of the onset of stroke symptoms are usually treated with medication in the form of a clot-buster drug known as a recombinant tissue plasminogen activator or rtPA. In recent years, doctors have used clot-removing devices in cases where stroke patients don't begin treatment until three to eight hours after their symptoms start, or who are otherwise unable to be treated with the rtPA medicine. The procedure involving the devices is known as "neurothrombectomy."



The MERCI Retrieval System uses a corkscrew-type application to attack a blood clot. Credit: Concentric Medical

Each procedure – the pharmacologic rtPA application and neurothrombectomy – comes with risks, says Craig Coleman, an associate professor in the School of Pharmacy, co-director of the practice center and one of the study's primary investigators. The clot-buster drug rtPA is extremely aggressive – much more so than widely-used blood thinners – and is used to break up a clot. But because it is so strong and cannot be targeted to a specific area, rtPA has been known to cause hemorrhagic stroke in blood vessels vulnerable to rupture. RtPA is indicated for use only within three hours after stroke symptoms appear.

The neurothrombectomy devices also pose risks, as they can tear or puncture blood vessels, break, or get stuck during the procedure.

“I think the most important conclusion of our study is that neurothrombectomy devices appear beneficial in a high-risk population with little other option for treatment,” says William L. Baker, an assistant clinical professor in the UConn School of Pharmacy and assistant professor of medicine at the UConn School of Medicine. “However, we do not currently have data regarding which device is best to use, and in what clinical situations these devices have maximum benefit and minimized risk.”

Baker served as co-author of the study with Coleman. Others working on the study included Dr. Isaac Silverman, co-medical director of the Stroke Center at Hartford Hospital and an assistant clinical professor of neurology at the UConn School of Medicine; and Dr. Jeffrey Kluger, director of Heart Rhythm Management in Hartford Hospital’s Department of Cardiology. UConn School of Pharmacy researchers Jennifer Colby, Vanita Tongbram, and Ripple Talati, as well as C. Michael White, director of the Evidence-based Practice Center and professor of pharmacy at UConn, also contributed to the study.

The study is a technical brief funded by the U.S. Department of Health and Human Services’ Agency for Healthcare Research and Quality (AHRQ). AHRQ’s Effective Health Care Program produces reports about emerging or developing technologies or treatments in order to highlight areas for further research. AHRQ’s Effective Health Care program sponsors the development patient-centered outcomes research to assist public- and private-sector organizations in their efforts to improve the quality of health care in the United States.

The bulk of the study focused on two neurothrombectomy devices that have been cleared by the U.S. Food and Drug Administration in recent

years. One is the MERCI Retriever made by Concentric Medical in Mountain View, Calif., and the other is the Penumbra System made by Penumbra Inc. of Alameda, Calif. The MERCI Retriever uses a corkscrew-type application to attack a blood clot. The Penumbra System uses a suction-like action to extract the blockage, Coleman says.

“Our report does not say device A is better than device B,” Coleman says. “What we have produced is a report that details what these devices do, what the results have been, what they are looking at in other studies, and what they aren’t looking at, to assist people in making future decisions.”

The researchers screened more than 1,600 abstracts and reviewed more than 377 scholarly articles before selecting 87 articles that best met their research goals and standards. The largest share of the articles (62) involved individual case reports, while there were 18 prospective single-group studies and seven noncomparative retrospective studies. The overwhelming majority of the studies centered on either the MERCI or Penumbra devices, although studies involving new ultrasonic technology, lasers, and snares also were reviewed.

The success rates of each device varied broadly in the different studies, according to the report. The rate of harm from the procedures also varied. Variables that influenced negative outcomes included older age, higher baseline systolic blood pressure, higher baseline scores on the National Institute of Health’s Stroke Scale (used in assessing stroke symptoms), prior history of stroke, longer procedure duration, and documented blockages of the internal cerebral artery. An inherent risk of neurothrombectomy is that it includes the need for intubation and heavy sedation, which may worsen outcomes, the report says.

The report notes that ongoing prospective, randomized studies may soon present more comprehensive data about the effectiveness and reliability

of the new devices.

One important question the researchers were unable to address is whether the risk of harm outweighs the benefits of neurothrombectomy more than eight hours after stroke symptoms appear when damage to brain tissue may already be irreversible. Another is whether stroke patients should consider neurothrombectomy within the first three hours of stroke when they have a choice between taking the rtPA medicine and/or neurothrombectomy. In the end, Coleman says, patients should be cautious until more research is done.

Provided by University of Connecticut