

Understanding

stroke



Concentric
MEDICAL



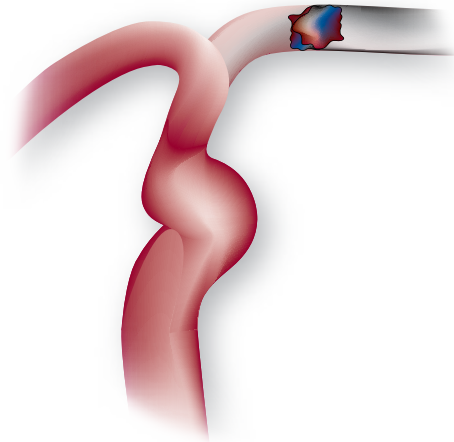
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What is stroke?

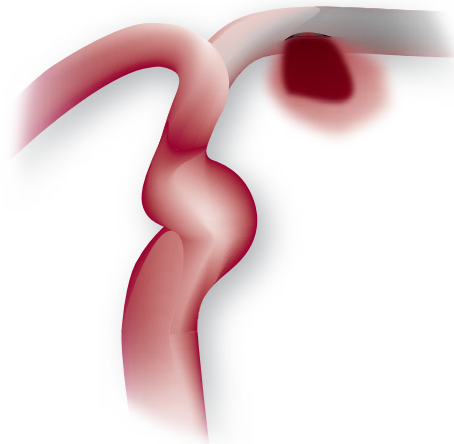
A stroke or cerebrovascular accident (CVA), occurs when blood flow to the brain becomes disrupted through either a blockage or excessive bleeding. Blood vessels carry blood, oxygen and nutrients throughout the body and to the brain. During a stroke, a blood vessel in the brain may become blocked (ischemic stroke) or may rupture or burst (hemorrhagic stroke). An ischemic stroke, or one caused by the blockage of blood flow, is the most common type of stroke and is often caused by a clot. Over 85% of strokes are of this type. When the brain is deprived of blood and oxygen it fails to work properly, and in some cases the affected tissue of the brain dies. Depending on the severity of the stroke and the area of the brain affected, loss of function or death can occur. Similar to a heart attack, a sudden-onset ischemic stroke is sometimes referred to as a brain attack. Time is of the essence and acting quickly can make a big difference for a patient. This booklet focuses primarily on the prevention of and options for acute ischemic stroke patients.

U.S. Stroke Statistics¹

- Stroke is the 3rd leading cause of death and the number one cause of long term disability
- Each year, it is estimated that 795,000 people will suffer a new or recurrent stroke
- 75% of strokes are new or first-time strokes
- 87% of strokes are "ischemic" meaning they are caused by a blood clot
- Every 40 seconds, someone suffers a stroke



Ischemic Stroke



Hemorrhagic Stroke

What are the effects of stroke?

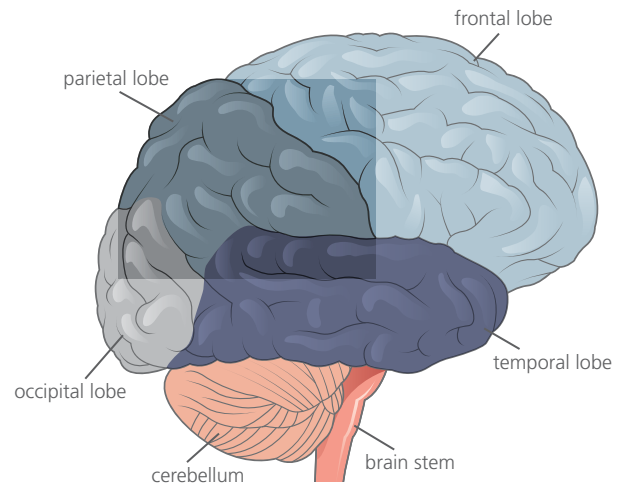
The brain controls a multitude of functions that allow us to perform every-day tasks and are often taken for granted. The ability to smoothly lift a coffee mug to take a sip is controlled by the motor areas of the brain. The ability to process and act on multiple pieces of information, such as driving a car, is managed by various areas of the brain. The abilities to swallow, stand, see and speak are each controlled by other, specific areas of the brain. If the blood flow to any of these areas is blocked or interrupted suddenly, that particular ability is diminished or lost completely. The brain stem is also an important part of the brain. It controls breathing and other vital functions for life. Blockage to this area is more frequently fatal if left untreated.

The effects of stroke are widely varied depending on the type of stroke, the area of the brain affected and the extent of the brain injury. Brain injury from stroke can cause:

- Difficulty with motor activity (movement of arms or legs). The symptoms can vary from complete paralysis to mild weakness, generally on one side of the body
- Facial droop on one side
- Slurring, difficulty with speech or the ability to understand speech
- Vision changes such as blurred vision or double vision
- Changes in sensation (such as touch or awareness of body positioning)
- Changes in behavior and thought patterns

- Changes in memory and emotions
- Persistent vegetative state (locked-in syndrome) or death

Skills and Functions Associated with the Different Areas/Lobes of the Brain



Frontal Lobe

- Voluntary initiation of movement
- Attention
- Emotional, social, sexual control
- Verbal expression
- Judgment
- Decision making

Temporal Lobe

- Short-term memory
- Language comprehension
- Face recognition
- Behavior (aggressive)

Parietal Lobe

- Awareness of body parts
- Academic skills
- Object naming
- Right/Left organization

- Eye-hand coordination

Occipital Lobe

- Visual perception
- Visual processing
- Reading

Cerebellum

- Coordination of voluntary movement
- Gross and fine motor coordination
- Postural control
- Balance and equilibrium
- Eye movement

Brain Stem

- Autonomic nervous system (heart rate, breathing, etc.)
- Arousal and sleep regulation
- Swallowing food and fluid
- Balance and movement

What are the risk factors for stroke?

Some risk factors for stroke are hereditary while others are a result of a person's lifestyle.

While you cannot change hereditary risk factors, you can modify and treat lifestyle risk factors with the help of a healthcare professional.

It's possible to have multiple risk factors for stroke, even if you aren't feeling sick. Because many risk factors for stroke don't present with symptoms, you should consult your physician to assess your risk. The best way to prevent a stroke is to reduce your stroke risk factors.

Risk Factors for Stroke that Cannot Be Changed

- Increasing Age
- Gender
- Family History
- Race
- Prior Transient Ischemic Attack (TIA – “mini” or “warning” stroke), Stroke or Heart Attack

Risk Factors for Stroke that Can Be Modified or Controlled

- High Blood Pressure
- High Cholesterol
- Cigarette Smoking
- Diabetes Mellitus
- Physical Inactivity or Obesity
- Atrial Fibrillation (A-Fib) or other Heart Disease
- Carotid artery stenosis or other cardiovascular disease

What are the warning signs for stroke?

Since stroke involves a sudden disruption of blood flow, the symptoms of stroke are generally a noticeable loss or rapid change in the ability to perform specific functions. In some cases, however, symptoms can fluctuate. In either case, stroke is a medical emergency and requires immediate attention. While prevention is important, it is equally important to understand the warning signs or symptoms of a stroke so that a patient or patient's family may act quickly to seek medical attention. People often do not recognize when they are having a stroke; or if they notice symptoms, they may expect them to subside and may not act quickly enough to receive treatment. Similar to a heart attack, seeking immediate medical attention is critical for a chance for a positive outcome and/or survival. It is also critical to understand that stroke does not only affect the elderly. Young persons are also at risk for stroke, especially if they have risk factors for clotting, diabetes, undiagnosed heart conditions or other hereditary factors.

Stroke warning signs include the sudden onset of:

- Numbness or weakness of the face, arm or leg - usually on one side of the body
- Difficulty speaking or understanding; sluggish speech
- Blurred vision or trouble seeing in one or both eyes
- Unexplained dizziness, confusion or loss of balance and coordination
- Sudden or extremely severe headache with no known cause

Call 9-1-1 Immediately

If you notice any of the above symptoms, call 9-1-1 immediately! Stroke is a medical emergency.

Although other diseases or conditions may cause some of these symptoms, sudden onset is a key factor, and immediate medical attention is recommended to rule out a serious condition such as a stroke.

If you suspect that a family member or loved one of any age is suffering a stroke, it is important to act **F.A.S.T.** Ask the person to do the following:

- **F**ace — Check for facial droop on one side or an uneven smile.
- **A**rm — Ask the person to raise both arms. Observe if one arm lags behind, or is not raised as high as the opposite arm. Also check to see if the person is unable to maintain both their arms at equal height for several seconds.
- **S**peech — Ask them to repeat a simple sentence, such as “the cow jumped over the moon.” Check to see if the person's speech is altered or slurred, or if they have difficulty understanding.
- **T**ime — Call 9-1-1 and get to the hospital immediately.



Any one of these signs may be indicative of a stroke. If the person has one or more of these signs, call 9-1-1 immediately.

IMPORTANT: Do NOT attempt to transport the person on your own to the hospital. Call 9-1-1 and ask the EMS driver to take the person to a certified stroke center in the area. Hospitals can vary widely on their ability to recognize and treat acute stroke and the options that they offer in acute care of a stroke patient. Your EMS crew may be able to properly assess those capabilities and send the person to the appropriate center.

options

in the Care of Acute Ischemic Stroke

Understanding stroke means understanding options in the care and treatment of the disease. Planning ahead by recognizing the symptoms and understanding the treatment options and where they are offered may benefit you and your family.

Ischemic Stroke

In ischemic stroke, the blockage is usually caused by a clot, also called a thrombus or embolus. The primary goal in treating ischemic stroke is to restore blood flow to the brain. This can be done by removing the clot, dissolving the clot or by otherwise disrupting the blockage that is occurring in one or more vessels in the brain. Clinical data confirm that restoring blood flow to the brain correlates with improved outcomes and increased chance of survival for ischemic stroke patients. Clots may or may not respond to drugs, or pharmaceutical options. Based on the patient's symptoms, the blockage location, and other diagnostic testing, the treating physician will decide the best and safest method for treating a stroke.

Restoring the Blood Flow

When 33 clinical articles were analyzed, the data showed that patients who had blood flow restored were more likely to survive and be able to function on their own. The data showed that 58% percent of patients with restored blood flow were functioning independently at a 90-day follow up visit with their doctor. This compared to only 25% of those who did not have blood flow restored. The survival rate was also higher for those who had their blood flow restored; 42% of patients with restored blood flow survived, versus just 14% of those who did not have blood flow restored.²

Clot Busting Drugs or Lytics

Intravenous Infusion of Lytic (Infused through a vein in the arm)

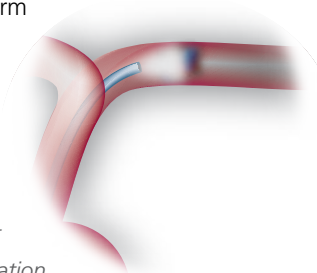
If diagnosis occurs within 0-3 hours from the onset of symptoms, your physician may administer Activase® (Alteplase) also referred to as IV tPA (Intravenous tissue Plasminogen Activator). Activase was FDA approved for the treatment of acute ischemic stroke in 1996. Some centers have extended their protocol to allow for treatment with IV tPA to 4.5 hours from the onset of symptoms. While not officially FDA-approved, the time window expansion is supported by a highly regarded clinical study published in 2008 and by a scientific advisory council recommendation.

Activase is part of a family of drugs called lytics, or “clot busters,” and is usually given intravenously through a vein in the arm. If the clot is of average or small size, the drug may be successful in dissolving the clot completely. In large vessel stroke, the size of the clot (clot burden) may be too big for the drug to be effective and the patient may require additional intervention.

Some patients may not be eligible for IV tPA due to serious illness, recent surgery, clotting disorders or other conditions; and sadly, since most patients do not reach the hospital before 3 hours, only 3-4% of those who suffer an acute ischemic stroke actually receive this treatment.^{4,5,6} In these cases, other treatments may be necessary.

Intra-arterial Infusion of Lytic (Infused directly into the clot)

Lytic medication may also be infused directly into the clot through a minimally invasive surgical (endovascular) procedure. The term endovascular (within the vessels) refers to types of procedures that are performed using vessels in the body to access the treatment site. In this



*Dissolving a clot
with lytic medication.*

procedure, a small incision is made in the femoral artery in the upper leg, and a catheter (small tube) is threaded into the artery where the clot is lodged. The lytic medication is then passed through the tube and into the clot. This procedure may be done alone, or may be performed as adjunctive treatment, meaning in combination with another endovascular attempt to disrupt the blockage or retrieve the clot. IA lytic infusion is usually performed within 6 hours of the onset of a patient's symptoms. While this option is not FDA approved, it has become widely accepted by physicians and physician societies as an option in acute ischemic stroke care.

As with any surgery, endovascular procedures involve risks that include but may not be limited to: infection, vessel perforation or puncture with or without subsequent bleeding or worsening of symptoms, vessel dissection, and even death.

What are the risks involved with lytics?

The primary risk associated with lytic agents is hemorrhage or bleeding in the brain. The NINDS trial found that this occurred in 6.4% of patients who were given an IV (intravenous) infusion of the drug within 0-3 hours of symptom onset.⁷

The other consideration with infusion of IV tPA is the effectiveness of the drug on clots of varying size. Some studies suggest that smaller clots tend to respond more favorably to this therapy, while larger clots may require additional intervention. In large vessel strokes, the recanalization rate of those that were eligible to receive IV tPA, has been shown to be approximately 33%.⁸

For patients taken to the angiography lab, the rate of restoring blood flow when lytic was infused directly into the clot in a commonly affected blood vessel (Middle Cerebral Artery) was reported to be 66% vs. 18% for those who did not receive the medication. Other, larger vessels of the brain were not studied for this therapy and may require more aggressive treatment.

Mechanical Endovascular Procedures

For some patients, endovascular intervention may be recommended. Endovascular surgery is a minimally invasive method of treating disease by accessing the blood vessels of the brain and other areas of the body. These procedures are performed using tiny wires, tubes and other devices that are delivered into the patient's blood vessels through a small puncture in the femoral artery in the upper leg. Once in the arteries, the physician uses x-ray technology to visualize the area and tiny instruments to treat the patient's condition.

Merci Retrieval Procedure

Mechanical thrombectomy or the Merci Retrieval Procedure is an endovascular procedure using the Merci Retriever® to mechanically remove the clot. If a patient does not respond to lytic therapy (using a "clot-busting" agent) or if they are ineligible for the drug (either due to medical conditions or arrival to the hospital after 3 hours from experiencing symptoms), the treating physician may suggest this surgical option. The Merci Retriever is a minimally invasive, catheter-based device that was cleared by the FDA in 2004 to restore blood flow in the brain by removing clots in patients experiencing an ischemic stroke. The Merci Retriever is used in the larger vessels of the brain, and has been used up to 8 hours past the start of symptoms, and sometimes longer, based upon physician discretion.

The Merci Retriever is a tiny corkscrew or spring-shaped device that works by wrapping around the clot and trapping it. The clot is then retrieved and removed from the body. Over 13,000 patients world-wide have undergone this procedure and it has been performed at over 500 U.S. hospitals. Not all hospitals perform the Merci Retrieval Procedure.

Merci Retrieval Procedure

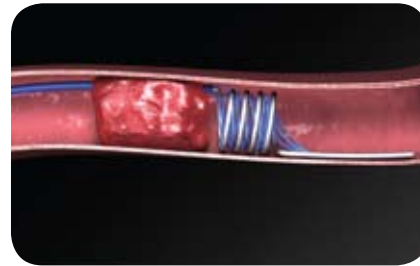


Figure 1.
The Merci Retriever is deployed past the clot.

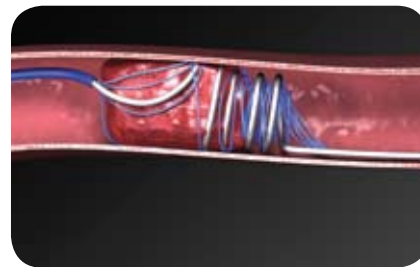


Figure 2.
The Merci Retriever ensnares the clot.

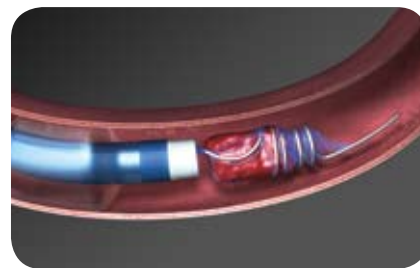


Figure 3.
The Merci Retriever pulls the clot out of the body.

What are the risks involved with the Merci Procedure?

As with any surgery, the Merci Retrieval procedure is not without risk. Endovascular procedures are a minimally invasive form of surgery and risks include: infection, vessel perforation or puncture with or without subsequent bleeding or worsening of symptoms, vessel dissection, and even death. Acute stroke is an emergency situation and decisions often must be made quickly. A treating physician can further explain the risks and benefits involved with the Merci Retrieval Procedure.

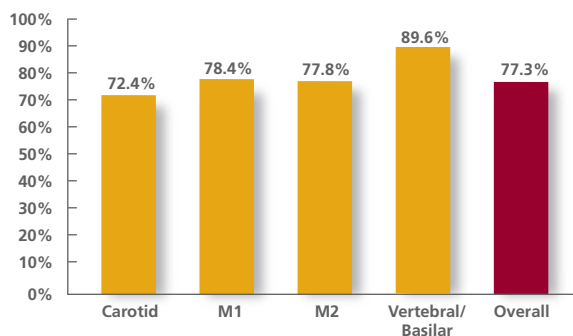
Clinical Data and Outcomes of the Merci Retrieval Procedure

Clinical data show a strong correlation between restoring blood flow to the brain and better overall outcomes for stroke patients. This means that those who have blood flow restored are more often functioning independently and with less disability.

Restoring blood flow is a principal goal when treating ischemic stroke patients. In the Multi MERCI trial, the Merci Retriever was demonstrated to restore blood flow in 55% of patients when used alone, and 68% of the time when used in conjunction with IA lytic. For every 3 patients treated with the Merci Retriever, blood flow was restored in approximately 2 patients, and of those 2 patients, one had little or no disability. Specifically, of the patients who had blood flow restored, 49% were functioning independently at their 90-day follow up with the doctor.¹⁰

In the Merci Registry, an extensive collection of cases in which the Merci Retriever was used, the revascularization rate is approximately 77% overall and is shown by vessel below.¹¹

Percent of Patients that Had Blood Flow Restored in Four Large Vessels of the Brain Using the Merci Retrieval Procedure



M1 = Middle Cerebral Artery
M2 = Distal Branch of Middle Cerebral Artery
Vert/Bas = Vertebral & Basilar Arteries

Mechanical Embolectomy Provides an Option for Stroke Patients.

Time From Stroke Onset	0-3 hrs	0-4.5 hrs	0-6 hrs	0-8+ hrs
IV tPA [†]	→			
IA tPA [‡]	→			
M e r c i [¶]	→			

[†] FDA approval is for 0-3 hours only

[‡] Not an FDA-approved indication

[¶] Approved for use in the 0-3 hour window for patients who are ineligible for IV tPA or who fail to respond to IV tPA ; Indication for use does not have a time window upper limit

Stenting or Balloon Angioplasty

This endovascular procedure involves inflating a small balloon to crush the clot against the artery walls. While not FDA approved for the treatment of acute ischemic stroke, this option has been used to successfully restore flow in the occluded vessel in certain cases. A stent may also be placed to hold clot or plaque against the wall after balloon angioplasty if there is evidence of atherosclerotic disease (i.e. the build-up of plaque on the vessel wall). If a patient has plaque occluding a vessel, a physician may recommend this treatment in the context of a clinical study, as it is still being investigated for acute stroke treatment.

Aspiration of Clot

In this endovascular procedure, the physician delivers a catheter through the vessels to the affected area of blockage and attempts to aspirate the obstruction using suction. This procedure has not been studied in as many patients as the Merci Retrieval procedure, but it has been found to be effective and some devices are FDA-cleared. As with any surgery, this procedure is not without risk. Endovascular procedures are a minimally invasive form of surgery and risks include: infection, vessel perforation or puncture with or without subsequent bleeding or worsening of symptoms, vessel dissection, and even death. Acute stroke is an emergency situation and decisions often must be made quickly. A treating physician can further explain the risks and benefits involved with this type of procedure.

Care

After a Stroke

What resources are available for stroke caregivers and stroke patients?

There are a significant number of stroke support websites that offer resources such as support groups, stroke hotlines, discussion boards, magazines and other literature for both stroke survivors and stroke caregivers. Please visit the Patient Resources section on our website at www.concentric-medical.com for a complete listing.

It is important to work with your medical professional to understand any possible long term disabilities in order to provide the best post-stroke care.

Prevent a Recurrent Stroke

If you have suffered a stroke, you are at greater risk for suffering another stroke, one with a higher rate of disability or death. But you can take steps toward preventing a recurrent stroke.

Visit: www.stroke.org and search the term “STARS” to learn more about the Steps Against Recurrent Stroke program. You can also contact the National Stroke Association for information on this program by calling: 1-800-STROKES (1-800-787-6537)

Preventing Another Stroke

1 in every 5 individuals who have a stroke will go on to have a secondary or recurrent stroke.¹²

Whether or not you have already suffered a stroke, taking steps toward a healthier lifestyle can play a big part in decreasing your risk for having a stroke in the future. Some things you can do immediately include the following:

- Stop smoking
- Engage in physical activity on a regular basis; work with your physician to determine what is best for you
- Maintain a healthy weight
- Eat a healthy diet; this includes a low sodium diet if you have high blood pressure
- Maintain a healthy blood pressure; work with your doctor to control high blood pressure
- If you have a heart condition, including valve disease or irregular heart beat (called a-fib or atrial fibrillation), work with your physician to monitor and control it
- Take your medication as directed by your physician.

Glossary of Terms

Angiography – (n.) X-ray of the blood vessels after injection of contrast (a radiopaque substance that appears on x-ray). This test allows a physician to visualize the vessels of the brain to determine the best method of treatment. (syn: arteriography, angiogram, arteriogram)

Aspiration – (n.) To draw or remove by suction. To remove (a fluid) from a body cavity by use of an aspirator or suction syringe.

Clot – (n.) a coagulated mass of blood.

Clot Buster – See Lytic.

CT Scan – (n.) Computed Tomography Scan – a cross sectional view of the body completed via computed tomography. This allows a physician to visualize the tissues of the brain to determine the method of treatment.

CT Angiography – (n.) A type of imaging to look at the vessels inside the body. Intravenous dye is used, which contains iodine, and a CT scan is performed to view the cerebral arteries. While the use of catheters is not necessary (this test may be considered “noninvasive”), there are still some risks involved. In people allergic to iodine, pretreatment with medications is necessary to prevent allergic reactions to the dye. In people with abnormal kidney function and/or diabetes, the dye may affect kidney function.

CT Perfusion – (n.) A type of computer-enhanced imaging used to identify the extent to which areas of the brain are affected by an occlusive or ischemic stroke. The interpreted scan may help a physician understand the extent of brain tissue death that has already occurred and the tissue that is still alive, but at risk for death if blood flow is not restored.

Cerebrovascular accident (CVA) – (n.) a stroke

Embolus – (n.) An abnormal particle, such as a clot, circulating in the blood vessels. An embolus may cause a stroke if it becomes lodged in one of the brain vessels and disrupts normal flow of blood.

Endovascular – (adj.) A surgical approach considered to be minimally invasive. Endovascular procedures are performed through a small incision or access site in an artery and tiny devices are used to complete the surgery within the vessels. Visualization of the

work is done via angiography or x-ray technology.

Ischemia – (n.) Deficient supply of blood and oxygen to a body part like the heart or brain that may be due to obstruction of the inflow of arterial blood. The obstruction may be caused by a clot, the narrowing of arteries, spasm or disease.

Ischemic – (adj.) Describing a type of condition where oxygen is deficient.

IV tPA – (n.) Intravenous tissue plasminogen activator. A drug given by injection or infusion, into a vein, to dissolve blood clots.

Lytic – (n.) a drug (such as streptokinase, activase or tissue plasminogen activator) used to dissolve blood clots.

Mechanical Thrombectomy or Embolectomy – (n.) Endovascular removal of an obstruction from a vessel. See also: Endovascular and Merci Retriever.

Merci Retriever® – (n.) A tiny, corkscrew or spring-shaped medical device used in endovascular procedures to remove an obstruction, including clots, from arteries of the brain. The device was cleared by the FDA in 2004 and has been used in over 13,000 patients around the world.

Stroke – (n.) The sudden loss of sensation, voluntary motion or other senses caused by rupture or obstruction of a blood vessel of the brain – also called a brain attack or cerebrovascular accident.

Hemorrhagic Stroke – (n.) Stroke caused by the rupture of a blood vessel that results in bleeding into the tissue of the brain.

Ischemic Stroke – (n.) Stroke caused by a clot (thrombus or embolus).

Thrombus – (n.) Blood clot that accumulates in a blood vessel. If a thrombus becomes dislodged and circulates, it is called an embolus.

Transient Ischemic Attack (TIA) – (n.) A brief episode of cerebral ischemia that is usually characterized by temporary blurring of vision, slurring of speech, numbness, paralysis, or syncope (fainting) and that is often predictive of a serious stroke. Also called a mini-stroke.

Merci Retriever®

Device Description

The Merci Retriever® (with filaments) consists of a flexible, tapered core wire with helical loops and polymer filaments at the distal end. Platinum coils at the distal end allow fluoroscopic visualization. There are gaps between adjacent coils that may appear radiolucent under fluoroscopy. Retriever dimensions are indicated on product label. The Retriever has a hydrophilic coating to reduce friction during use. The Retriever has a shaft marker to indicate proximity of Retriever tip relative to Microcatheter tip. A torque device is provided with the Retriever to facilitate manipulation. The torque device is marked to facilitate counting the number of revolutions. An insertion tool is provided to introduce the Retriever into a Merci Microcatheter.

Indications for Use

Merci Retrievers are intended to restore blood flow in the neurovasculature by removing thrombus in patients experiencing ischemic stroke. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment. Merci Retrievers are also indicated for use in the retrieval of foreign bodies misplaced during interventional radiological procedures in the neuro, peripheral and coronary vasculature.

Complications

Procedures requiring percutaneous catheter introduction should not be attempted by physicians unfamiliar with possible complications which may occur during or after the procedure. Possible complications include, but are not limited to, the following: air embolism; hematoma or hemorrhage at puncture site; infection; distal embolization; vessel spasm, thrombosis, dissection, or perforation; emboli; acute occlusion; ischemia; intracranial hemorrhage; false aneurysm formation; neurological deficits including stroke; and death.

Procedure Quick Reference

- Deploy all Retriever loops distal to thrombus, anatomy permitting.
- Pull back to engage thrombus.
- Position Microcatheter tip just proximal to loops.
- Inflate balloon.
- SLOWLY pull back Retriever and Microcatheter while aspirating. Maintain Microcatheter tip just proximal to loops.

Safety and Effectiveness Information

In the Multi MERCI (Multinational Mechanical Embolus Removal in Cerebral Ischemia) clinical trial, patients meeting the following enrollment criteria were treated with the Merci Retriever L5.

Inclusion Criteria:

- Clinical signs consistent with ischemic stroke.
 - Acute ischemic stroke treated with intravenous thrombolytic therapy where vascular imaging (TCD, CTA, MRA, angiography) shows a persistent occlusion after the end of the infusion treatment.
 - Acute ischemic stroke where thrombolytic treatment is contraindicated.
- Treatment within 8 hours of symptom onset.
- Patients \geq 18 years of age.
- NIHSS \geq 8.
- Angiogram shows occlusion in ICA, M1/M2 MCA, or vertebrobasilar arteries.

Exclusion Criteria:

- Pregnancy.
- Glucose $<$ 50 mg/dL.
- Excessive tortuosity that prevents placement of Retriever or Balloon Guide Catheter.
- Known hemorrhagic diathesis, coagulation factor deficiency, or oral anticoagulant therapy with INR $>$ 3.0.

- Heparin within 48 hours with PTT $>$ 2 times lab normal.
- Platelets $<$ 30,000.
- Sustained severe hypertension (systolic blood pressure $>$ 185 mmHg or diastolic blood pressure $>$ 110 mmHg).
- Angiogram shows arterial stenosis ($>$ 50%) proximal to the embolus.
- CT or MRI shows significant mass effect with midline shift.
- History of severe allergy to intra-arterial contrast medium.

One hundred and thirty one (131) patients were treated with the Merci Retriever L5 in the Multi MERCI clinical trial. The median age and NIH Stroke Scale Score at time of treatment were 72 years and 18, respectively. The successful revascularization rate following use of the Merci Retriever L5 for the patient cohort was 57.3% (75/131). Post-procedure, 69.5% (91/131) were revascularized. The procedure-related serious adverse event rate was 9.9% (13/131). Three (3) of these events (2.3%) were possibly related to the Merci Retriever. The symptomatic intracranial hemorrhage rate within 24 hours of treatment was 9.9% (13/131). The percentage of patients experiencing a good outcome (Modified Rankin \leq 2) at 90 days was 37.0% (47/127). The mortality rate through 90 days was 33.6% (43/128).

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Notes:

Rx Only.

Merci, Merci Retriever and Concentric are registered trademarks of Concentric Medical, Inc.

These products may be covered by one or more of the following patents: 5,895,398; 6,436,112; 6,485,497; 6,530,935; 6,692,508; 6,692,509; 6,663,650; 6,638,245; 6,702,782; 6,730,104; 6,824,545; 7,058,456; Europe: 0880341. Australia: 758524; 2003204826. Canada: 2248226. Israel: 125612.

Other U.S. and foreign patents pending.

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