

Learn about a clinical study of carotid artery disease

**ACT** /

AGAINST

**CAD**  
Carotid Artery Disease

A LEADING CAUSE OF STROKE

## Carotid artery disease

Carotid artery disease occurs when fatty material (plaque) builds up inside the major blood vessels—the carotid arteries—along the front of the neck.

These arteries are the main pathways for blood to flow from the heart to the brain, carrying oxygen and essential nutrients.



Patient information provided by Abbott Vascular, Inc., sponsor of the ACT I study.

## What is a stroke?

A stroke can happen when plaque blocks the flow of blood in the carotid arteries, or when pieces of plaque break free and block smaller blood vessels within the brain. When blood can't reach brain tissues, neurons are damaged or destroyed. Depending on where in the brain the blockage occurs, a stroke can affect speech, vision, movement, and other abilities.

Stroke is often called a “brain attack” because its cause is similar to that of a heart attack—and like a heart attack, stroke can result in disability or death. It is a major health risk, as the facts below show.<sup>1</sup>

- Stroke is the third leading cause of death in the United States, after heart disease and cancer
- Each year, about 700,000 people experience a stroke
- Each year, about 46,000 more women than men have a stroke

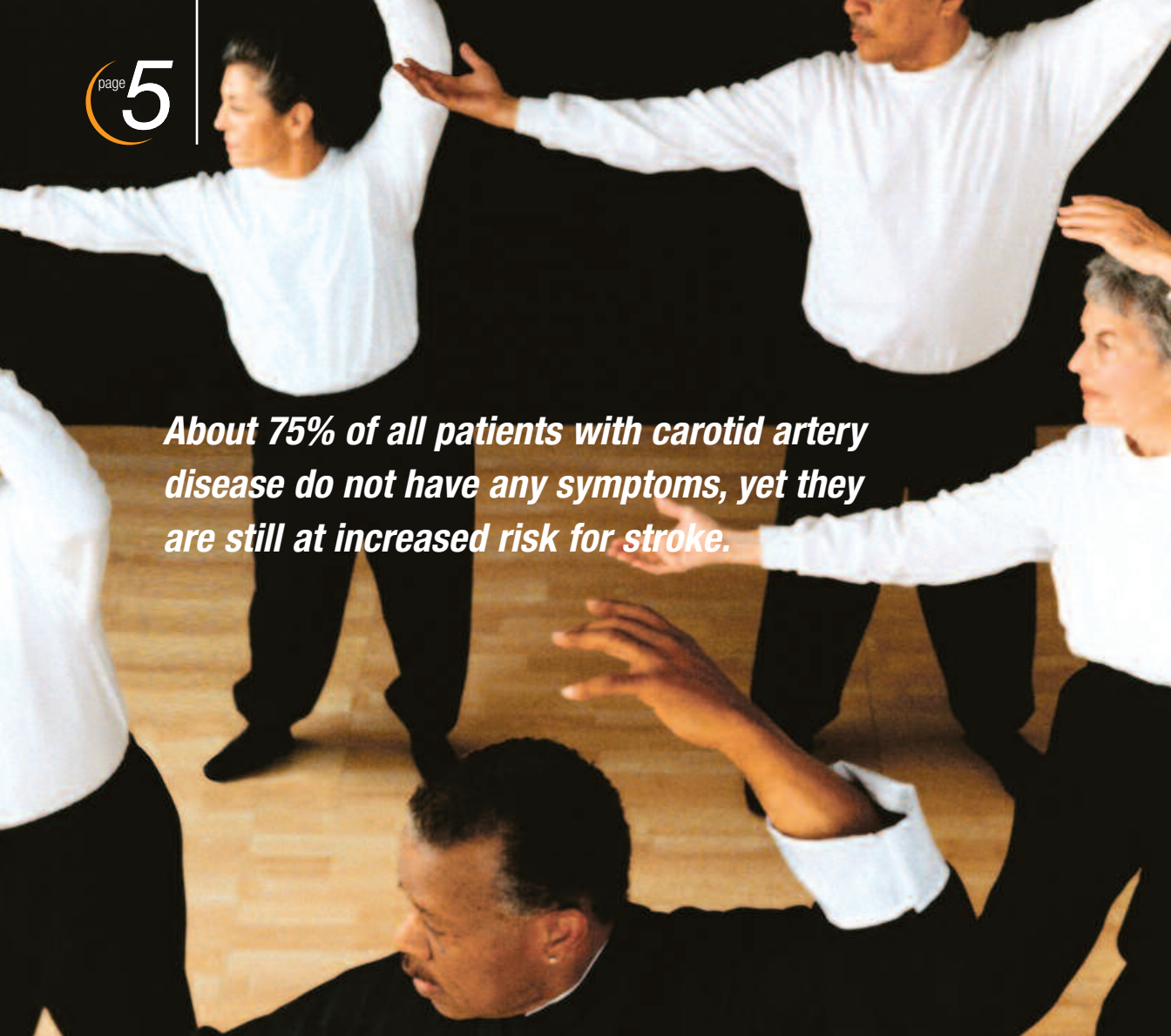


- People of African-American, Hispanic, Native American/Alaska Native, and Asian/Pacific Island descent tend to have strokes at younger ages than Caucasians

## Carotid artery disease and stroke symptoms

For some people, the first sign of carotid artery disease is a major stroke that happens without warning. Other people have symptoms that can signal the presence of carotid artery disease and the risk of stroke, including:

- Weakness, tingling, or paralysis in the arms, legs, or face
- Trouble swallowing
- Blurred vision, or temporary loss of eyesight
- Sudden severe headache with no known cause
- Dizziness, confusion, or fainting



***About 75% of all patients with carotid artery disease do not have any symptoms, yet they are still at increased risk for stroke.***

## Who is at risk for carotid artery disease?

Carotid artery disease is associated with many of the same risk factors as stroke, including

- Family history of stroke
- Family history of coronary artery disease
- Advanced age (over 70 years)
- Plaque buildup (atherosclerosis) in other areas of the body
- Peripheral arterial disease
- High blood pressure
- Diabetes
- Smoking
- Irregular heartbeat (atrial fibrillation)



## Questions and answers about diagnosis and treatment

### How is carotid artery disease diagnosed?

A physician can detect carotid artery blockage by holding a stethoscope to the neck and listening for a “swooshing” sound called a bruit (BROO-ee). The diagnosis can be confirmed with an ultrasound test. If a severe blockage is present, treatment may be necessary to restore blood flow to the brain. The physician will explain specific risk factors and the treatments that may be appropriate.

### How is carotid artery disease treated?

Depending on the patient’s health, carotid artery disease has traditionally been managed with medication and/or surgery called surgical carotid endarterectomy.

- Drug therapy usually involves the use of blood-thinning medications such as aspirin

- Endarterectomy is a surgical treatment that usually is performed while the patient is under general anesthesia; a surgeon makes an incision in the patient’s neck, opens the carotid artery, and removes plaque from artery walls in order to restore blood flow

An alternative procedure called carotid artery stenting, or CAS, is now available and has been shown to be as safe and effective as endarterectomy in some patients at high risk for neck surgery. CAS offers the following minimally invasive advantages:

- Reduces the risks associated with general anesthesia
- Reduces the risk of nerve damage
- Reduces the risk of scarring on the neck



### How does CAS work?

The physician makes a small incision in the patient's leg and inserts a catheter, which carries a small metal mesh tube called a stent to the site of a blockage. Once the stent is in place, a small balloon may be used to expand it and hold the artery open. A special filter catches any particles of plaque that may be dislodged and keeps them from reaching the brain.

### Who can receive a carotid artery stent?

Currently, CAS procedures are approved for patients with or without symptoms who are at high risk if they undergo carotid endarterectomy.

### Can a patient who has no symptoms and is not at high risk for surgery receive a stent instead of undergoing surgery?

At this time, CAS is not approved for patients with carotid artery disease who are not at high risk for surgery. However, patients may choose to participate in a new clinical study that could offer the possibility of being treated with a stent. Leaders in vascular surgery, interventional cardiology,

interventional radiology, and other specialties will perform the procedures and record the outcomes.

### The ACT I study: Exploring a new frontier in carotid artery disease treatment

Medical centers throughout the US are now enrolling patients in this groundbreaking clinical study. ACT I will involve at least 50 hospitals and will include up to 1,858 patients. The purpose of the study is to determine whether stenting is as effective as surgery in patients who do not have symptoms and are at standard risk for surgery.

*All patients in the study will receive treatment for their carotid artery disease.*

Unlike other studies, where one group of patients does not receive treatment, the ACT I study will provide treatment to both groups. Participants will receive either the stent or endarterectomy for their severe carotid artery disease.



### What exactly will the study measure?

The ACT I study will compare the current treatment, surgical carotid endarterectomy, to a potential new treatment using the Emboshield® Embolic Protection System with the Xact® RX Carotid Stent System.

Patients will have follow-up examinations at 30 days, six months, and one year after their procedures and will have annual exams for up to five years. Any stroke, heart attack, or other complication will be recorded.

### Who can participate?

Both men and women are being recruited for the study. Patients may qualify to participate if they:

- Are at least 18 years old but less than 80 years old
- Have been diagnosed with severe carotid artery disease and require treatment



- Have not had symptoms related to carotid artery disease in the past six months
- Are not at high risk for surgery

### Will everyone in the study receive a stent?

About three-fourths of the people who participate in the ACT I study will receive a stent—or three out of every four patients. Participants will be chosen at random to receive either the stent or surgical treatment. This will ensure that comparisons between the two treatment options will be objective and fair. As explained above, all study participants will receive treatment for their severe carotid artery disease.



## Learn more about the ACT I study

Your doctor may be participating as an investigator in the ACT I study. If so, you can ask him or her for more details about the goals of the study and the requirements for participation.



You can also obtain additional information by visiting [www.act1trial.com](http://www.act1trial.com).

Complete information about the study can also be found by searching for the keyword **ACT I** at [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

### Reference

1. American Heart Association. *Heart Disease and Stroke Statistics—2006 Update*. Dallas, Tex: American Heart Association; 2006.

## The study site in your area is:



Carotid stenting is not currently approved by the FDA for asymptomatic patients who are at standard risk for surgery.

CAUTION: Investigational device. Limited by Federal (or United States) law to investigational use.





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