

# Mechanical clot removal may restore more function than medication alone after severe stroke

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Stroke patients previously considered unlikely to survive without severe

disability may regain far more function if the blood clots (which cause ischemic stroke) are mechanically removed in addition to standard medical therapy, according to preliminary late-breaking research presented today at the American Stroke Association's International Stroke Conference 2022, a world premier meeting for researchers and clinicians dedicated to the science of stroke and brain health, held in person in New Orleans and virtually, Feb. 9-11, 2022.

In 2018, the [American Heart Association's stroke treatment guidelines](#) were updated to recommend endovascular [therapy](#) (mechanical clot removal) for select [stroke patients](#) to improve the odds of functional recovery. Endovascular therapy involves threading a slim catheter through a vessel in the leg to mechanically remove a clot blocking a brain vessel.

A new study in Japan is the first randomized, controlled trial to demonstrate the effectiveness of endovascular therapy in patients who have severe strokes involving clots in one or more large brain arteries, interrupting blood flow to a large area of the brain. Effectiveness of the approach had previously been established for patients whose large-vessel clots disrupted blood flow to fewer areas of the brain, however, [clinical experience](#) was mixed for patients with more severe strokes.

Infarction area, or core area, estimates the volume of brain affected and describes the blockage location as seen on a brain CT. A lower number translates to a stroke affecting more core areas of the brain: 8-10=small core, 6-7=moderate core and 0-5=large core (larger, more severe strokes). Current U.S. stroke guidelines recommend conducting endovascular therapy for core areas 6-9. This study examined blockages that affected more core brain areas, specifically blockages that scored as 3-5. Strokes with blockages measuring 0-2 core areas are considered too severe and highly unlikely the patient would return to ambulatory independence.

"I have often encountered a dramatic improvement in a patient just after the mechanical clot removal procedure, even when the infarction area was large. Yet, patients sometimes also experienced severe hemorrhagic transformation [a life-threatening complication that occurs when blood from outside the brain crosses the blood-brain barrier and worsens stroke outcome] after the artery was reopened. So, in Japan, our stroke physicians are always cautious about endovascular therapy when the infarction area is large," said Shinichi Yoshimura, M.D., Ph.D., lead author of the study and professor of medicine in the department of neurosurgery at Hyogo College of Medicine in Nishinomiya, Japan.

In this randomized study, 203 stroke patients (average age of 76 years; 44% women) were treated at 45 hospitals in Japan. Most (71%) were examined and had magnetic resonance imaging or a CT scan of the brain within 6 hours after stroke symptoms were first noticed, the timeframe that patients are generally considered eligible for endovascular therapy. The other patients were seen between 6-24 hours after symptoms were noticed, and additional imaging showed areas of the brain that might benefit from prompt treatment.

On imaging, all patients were found to have clots blocking a large artery in the brain—either the internal carotid artery, the proximal middle cerebral artery or both. The strokes were rated as severe (median 22 on the National Institutes of Health (NIH) Stroke Scale, which assesses a patient's ability to perform normal functions such as speaking and moving) and involved disrupted blood flow to large areas of the brain (about 7 out of 10 regions).

After imaging, the patients were randomly selected to receive either standard medical care for stroke (providing intravenous fluids, controlling blood pressure and other risk factors, and administering clot-busting medications for select patients at lower risk of bleeding) or standard medical care plus endovascular therapy performed within an

hour after imaging to mechanically remove the clots. Due to bleeding concerns, intravenous clot-busting medications were sparingly administered to select patients in a similar proportion in both treatment groups (27 of those who received endovascular therapy and 29 who received standard care).

Comparing the 100 patients who received endovascular therapy with 102 on standard therapy alone, the analysis found:

- Patients who received endovascular therapy were 2.43 times more likely (31% vs. 13%) to be able to walk without assistance and to have a residual disability rated as none to moderate 90 days later.
- After 90 days, more of the patients (14% vs. 6.9%) who received endovascular therapy were considered functionally independent, meaning they were either able to carry out all their pre-stroke activities or to have a slight disability that did not require daily assistance.
- At 48 hours after treatment, more of the patients (31% vs. 8.8%) who received endovascular therapy had major early neurological improvement (improved ability to talk and move limbs).

"Our findings confirm that anyone who suffers from stroke should be transferred to a medical facility capable of endovascular therapy as soon as possible. The benefit of endovascular therapy is not limited by the severity or region of a stroke. These patients may have the chance to more fully recover from stroke and go back to their previous lives and activity levels," said Takeshi Morimoto, M.D., Ph.D., M.P.H., senior author of the study and professor of medicine in the department of clinical epidemiology at Hyogo College of Medicine in Nishinomiya, Japan.

Several outcomes were compared to evaluate the safety of adding

endovascular therapy to medical treatment, with researchers reporting:

- Within 48 hours, scans revealed that more of the patients who received endovascular therapy had experienced some bleeding within the brain (with or without symptoms), 58% vs. 31%, respectively.
- However, the number of patients who experienced other adverse outcomes was similar in the two treatment groups. The adverse events included brain bleeding within 48 hours that caused a worsening of neurological status (4 points or greater worsening on the NIH Stroke Scale); the need for surgery to relieve pressure on the brain in the first week; death within 90 days; or the recurrence of [ischemic stroke](#) within 90 days.

"The finding of more intracranial bleeding in the patients who received endovascular therapy is very important. However, there were hemorrhages with symptoms and some that caused no symptoms. The hemorrhages with no symptoms were detected on imaging conducted for this study in the endovascular treatment group, not in the standard practice group. Symptomatic intracranial hemorrhage still occurred more commonly among patients in the endovascular group, however, it was not a statistically significant difference from the standard care group," Morimoto said.

The results of this study may not be generalizable to the U.S. or western countries because the study was conducted in Japan, where there is less use of intravenous thrombolysis than in the U.S. and other western countries, and where more strokes are imaged with MRI than CT (perhaps leading to different estimates of how many brain regions are affected by the [stroke](#)). Due to these differences in treatment protocols, this study's results may over- or underestimate the effectiveness of endovascular therapy.

The researchers are currently performing sub-analyses to help identify factors that might signal which patients are more likely to have a greater return of function after the treatment. "In addition, tools, devices or rehabilitation methods that could potentially improve the likelihood for similar patients to recover with less disability should be investigated," Morimoto said.

Provided by American Heart Association

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