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Trial shows better function after stroke if clots removed

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A technique that removes blood clots from large brain blood vessels reduced disability after stroke in a trial conducted in Catalonia, Spain, and co-led by an expert from the University of Pittsburgh School of Medicine. The findings will be announced today at the annual meeting of the European Stroke Organisation in Glasgow, Scotland, and published online in the *New England Journal of Medicine*.

The results of the trial, known as REVASCAT, echo findings from other recent large studies that were stopped early when the technique, called endovascular therapy or stent retriever thrombectomy, appeared to be highly effective, said co-principal investigator Tudor Jovin, M.D., associate professor of neurology and neurological surgery, and director of the UPMC Stroke Institute. Originally, the REVASCAT trial expected to enroll nearly 700 participants.

"This is a giant step forward that will change the way we approach triage and treatment of stroke patients," Dr. Jovin said. "After an interim analysis once 25 percent of the original participant sample size were enrolled, the data safety monitoring board of the study recommended stopping the trial as it became clear that it was no longer ethically justified to randomly assign patients to receive only conventional therapy. "And, as other studies found, removing blood clots from the brain did indeed lead to better outcomes for patients."

Endovascular therapy is performed by inserting a thin tube into a groin artery to thread it through the aorta and into the brain vessels using X-

ray-guided imaging. A retrievable stent opens the blocked vessel to restore blood flow and then is withdrawn, pulling the clot out with it. Dr. Jovin discusses and demonstrates the treatment in this video: http://youtu.be/s7wY9RgAFTk.

For the study, conducted at four large designated stroke centers in Catalonia, Spain, between November 2012 and December 2014, the researchers treated and monitored 206 patients whose stroke symptoms began not more than eight hours earlier and who had evidence of vessel blockage in imaging studies. For the 70 percent of patients who received an intravenous dose of the clot-busting drug tPA, or alteplase, imaging studies conducted 30 minutes after tPA administration had to confirm the vessel was still blocked. Half the patients were randomly assigned to receive medical therapy alone and the other half to medical therapy plus stent retriever thrombectomy.

The researchers found a 1.7 fold reduction in disability and a 15.5 percent increase in the rate of return to functional independence in the endovascular therapy group compared to the medical intervention-alone group.

Because the Catalan Department of Health keeps a registry of all stroke patients treated with clot busting therapies (intravenous or intra-arterial) , the researchers were able to determine that nearly all eligible patients who were treated at participating centers and in Catalonia over the duration of the trial were actually enrolled in REVASCAT. This unique feature distinguished the trial from other similar recently published randomized studies, removing any lingering concerns that endovascular therapy for stroke is only beneficial for a minority of eligible patients, Dr. Jovin noted.

"We now have five global studies that provide an overwhelming body of clinical evidence in support of stent retriever thrombectomy. Based on

these findings, it is time for the stroke community to come together to re-evaluate stroke treatment guidelines and to look for systems to facilitate the access of treatable patients to specialized centers," said co-principal investigator Antoni Dávalos, M.D., Ph.D., of Hospital Universitari Germans Trias i Pujol, and professor of neurology at the Universitat Autònoma de Barcelona in Spain.

The researchers say that more work needs to be done to determine whether the technique is effective when performed more than eight hours after stroke onset, in vessels that are smaller and in different locations in the brain than those treated in REVASCAT, and in the very elderly.

The study team included researchers from Barcelona, Spain; the University of Calgary in Canada; and the Dresden University of Technology in Germany. The project was funded by the Fundació Ictus Malaltia Vascular through an unrestricted grant from device manufacturer Covidien, and by a grant from the Spanish Ministry of Health co-financed by FEDER (Instituto de Salud Carlos III).

Published the same day in the NEJM and presented at the European Stroke Organisation Meeting, researchers announced further results of another large stroke trial of nearly 200 patients called SWIFT PRIME. That study showed endovascular treatment within six hours of stroke onset led to increased functional recovery and decreased 90-day disability. The Pitt arm of SWIFT PRIME, led by Dr. Jovin, was the second-leading enroller in the trial.

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