Ultrasound Catheter Speeds Peripheral Clot Lysis

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Miami Beach — A catheter that delivers ultrasound energy while infusing a lytic drug led to fast clot lysis and artery recanalization, and a low rate of major bleeds in a series of 66 patients with peripheral artery occlusions treated at 13 medical centers in the United States.

Faster clot lysis makes same-day treatment possible and lowers treatment cost. The findings also suggest that by lowering the rate of major bleeds, the Lysus Infusion Catheter System "serves to overcome one of the major psychological barriers" to clot-lysis therapy, Dr. Thomas O. McNamara said at the 18th International Symposium on Endovascular Therapy.

For peripheral vessel occlusions, "the future of lysis is to shorten it. If we can reduce the duration of thrombolysis we can probably cause less bleeding," said Dr. McNamara, chief of the interventional radiology service at the University of California, Los Angeles.

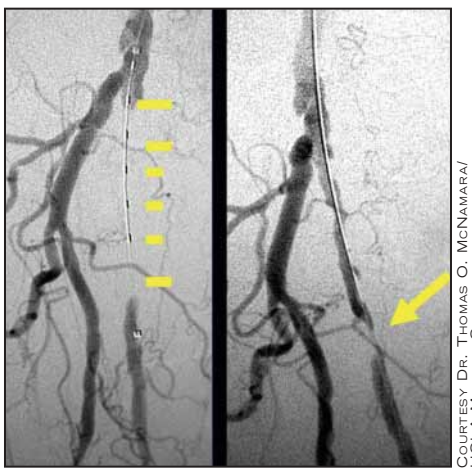
The Lysus catheter is a 5-French diameter device that comes in 6- to 50-cm lengths. It contains channels for infusing a drug along the entire length, as well as spaced transducers that produce ultrasound pulses at 2.2 MHz for every 1 cm of catheter length. So far, a variety of thrombolytic drugs have been used: tenecteplase (TNKase), reteplase (Retavase), alteplase (Activase), and urokinase. The lytic agent is selected at the discretion of each treating physician.

The catheter received FDA approval in 2004, but widespread marketing did not start until this year. Dr. McNamara is a consultant to Ekos, which makes the Lysus catheter.

By December 2005, 145 patients had been treated with the catheter at 13 centers in the United States. The total included 77 patients with peripheral arterial occlusions, 40 patients with deep vein thrombosis, and the remaining 28 with other occlusions, including some patients with strokes.

Dr. McNamara presented results for 66 patients who had complete follow-up information available. The 66 patients had occlusions that had been in place for 3-180 days.

For all 66 participating patients, follow-up angiographic assessments were done an average of 17.5 hours after the start of treatment. At follow-up, complete clot lysis had occurred in 58 patients (88%), with 1 patient (1.5%) having a major bleed (a bleeding event that required transfusion, surgery, or cessation of treatment) and 1 patient (1.5%) with distal embolization. Among all 145 patients who had been treated with the ultrasound catheter through the end of last year, 3 patients (2.1%) had major bleeds.



Courtesy Dr. Thomas O. McNamara/UCLA Medical Center

Severe claudication is shown before (left) and 4.5 hours after treatment.

As a comparison, Dr. McNamara cited data collected for conventional thrombolysis with urokinase in the Thrombolysis or Peripheral Arterial Surgery (TOPAS) trial, the results of which were published in 1998. The study established catheter-based thrombolysis as an alternative to surgery for peripheral occlusions (N. Engl. J. Med. 1998;338:1105-11).

In TOPAS, the average angiographic follow-up was after 24.4 hours of treatment, at which time 68% of the 243 treated patients had complete clot lysis. The rate of major bleeds was 12.5%, and the rate of distal embolization was 14.6%.

A subgroup of 27 patients treated with the Lysus catheter system were assessed by angiography 2-8 hours after treatment, and 82% had complete clot lysis.

Among the arterial patients treated with the ultrasound catheter so far, 70% had their treatment finished on the same day it started, and in this subgroup 76% were discharged on the same day. ■

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