Thrombolysis Device Removes Clots in DVT

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WASHINGTON — Isolated pharmaco-mechanical thrombolysis using the Trellis-8 peripheral infusion system achieved at least 50% thrombus removal with restored patency in over 90% of 827 limbs in 771 patients with deep vein thrombosis.

That finding was among the prospective data collected from Trellis manufacturer Bacchus Vascular’s patient registry presented by Dr. Gerard J. O’Sullivan at the annual meeting of the Society of Interventional Radiology.

Intended as an adjunct to anticoagulation, pharmaco-mechanical thrombectomy combines physical maceration of the clot and drug dispersal through the clot, followed by aspiration of the clot out of the body. In contrast to catheter-directed thrombolysis (CDT), which takes 2-3 days, usually requires a stay in intensive care, and incurs a 10%-20% risk of bleeding complications, pharmaco-mechanical thrombectomy can be done in a single setting in less than 2 hours with far less chance of bleeding, said Dr. O’Sullivan, an interventional radiologist with University Hospital, Galway, Ireland.

The data set included 827 venous limbs in 771 patients, with procedures performed between February 2005 and February 2008 at 362 centers in the United States, Canada, Ireland, and Belgium. Mean patient age was 54 years, with 51% female.

Clinical presentation of the clot—based on the Society of Interventional Radiology’s reporting criteria (J. Vasc. Interv. Radiol. 2006;17:417-34)—was acute (present for 14 days or less) in 74% (608) of the limbs, including 44% (360) in patients who also had venographic evidence of a previous deep vein thrombosis (DVT) that had been present for longer than 28 days (defined as chronic). Another 10% (87) had subacute DVT (15-28 days), 11% (89) had “subacute on chronic,” and 5% (43) had chronic DVT alone. The majority (85%) of clots were in a lower extremity. Of those 703, 79% (554) had iliac involvement. Among the upper extremity clots, most (90%) were subclavian only.

Outcomes were slightly better for acute than for chronic clots: Lysis of either grade II (5-9%) or grade III (95% or greater thrombus removal) or grade III (95% or greater thrombus removal) was achieved in 97% of the acute-only clots, in 94% of the “acute on chronic” clots, 95% of the subacute clots, 89% of the “subacute on chronic,” and in 91% of the chronic-only clots. Venous patency was established in all cases, Dr. O’Sullivan said.

Adjunctive therapies delivered during the primary procedure included percutaneous transluminal angioplasty (PTA) alone in 46%, stent alone in 4%, and PTA plus stent in 27%. In most of these cases, the reason for the adjunctive treatment was either underlying chronic obstruction or culprit lesion that would have greatly increased the likelihood of DVT recurrence if not treated, he explained.

More than 80% of all cases—ranging from 77% of the subacute and acute/chronic clots to 95% of the chronic—were completed in a single setting in less than 2 hours, with an average Trellis-8 use time of 22 minutes. Tissue plasminogen activator was the thrombolytic used in most (93%) of the cases, at an average lytic dose of 6.0 mg per run, 13.4 mg total per patient. These doses are considerably lower than those used with CDT, he noted.

No bleeding complications were reported in short-term follow-up. The percutaneous Trellis-8 peripheral infusion system, designed specifically for single-setting DVT thrombolysis, comprises an 8 French catheter with two occluding balloons and drug infusion holes between the balloons. With the clot isolated between the two balloons within a targeted vessel, the device mechanically disperses infused thrombolytic agents directly to it with a rotational motion (video is available at www.bacchusvascular.com).

All data for this study were obtained from the data registry maintained by the device manufacturer, Bacchus Vascular.