CLINICAL STUDY

Pharmacomechanical Thrombolysis of Symptomatic Acute and Subacute Deep Vein Thrombosis with a Rotational Thrombectomy Device

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ABSTRACT

Purpose: To retrospectively evaluate the efficacy and safety of pharmacomechanical thrombolysis (PMT) with the use of a rotational thrombectomy device for symptomatic deep vein thrombosis (DVT).

Materials and Methods: Between July 2012 and August 2013, 41 patients with acute or subacute DVT underwent PMT. The Cleaner thrombectomy device was used in a single-session technique for patients with lower-extremity DVT. Based on contrast venography, the extent of lysis was graded from I (< 50%) to III (complete).

Results: Sixteen patients (39.0%) had a femoropopliteal thrombosis and 25 (61.0%) had an iliofemoral venous thrombosis. The mean duration of symptoms was 11.0 days (range, 3–25 d). The mean quantity of tissue plasminogen activator was 20.7 mg (range, 10–50), and the mean duration of the procedure was 74.3 minutes (range, 30–240 min). At the end of the PMT procedure, 29 patients (70.7%) had complete (grade III) thrombus resolution. Grade I and II lysis were noted in one (2.4%) and 11 (26.8%) patients, respectively. Thirty-eight of the 41 patients were treated with PMT in a single session, and three (7.3%) required an additional lytic infusion as a result of residual thrombi. The overall grade III, II, and I thrombus resolution rates, including the supplemental thrombolysis, were 73.2% (n = 30), 22.0% (n = 9), and 4.9% (n = 2), respectively. There was no mortality.

Conclusions: Use of the Cleaner thrombectomy device is a promising alternative to current treatment modalities for the management of DVT in a single session of PMT.

ABBREVIATIONS

CDT = catheter-directed thrombolysis, DVT = deep vein thrombosis, IVC = inferior vena cava, PMT = pharmacomechanical thrombolysis, PTS = postthrombotic syndrome, TPA = tissue plasminogen activator

Deep vein thrombosis (DVT) affects a significant proportion of the population, many of whom go on to develop postthrombotic syndrome (PTS) (1). During the past decade, PMT has emerged as an effective alternative to open surgical thrombectomies and catheter-directed thrombolysis (CDT) in patients with acute DVT (2). Pharmacomechanical approaches have been suggested as viable and possibly preferable approaches to the management of acute DVT (3). Although several observational studies have demonstrated the successful implementation of PMT (4–6), no multicenter, randomized controlled trials have yet demonstrated the long-term effects of this therapy.

Several PMT devices have been developed during the past two decades (5–7). The Cleaner thrombectomy device (Argon Medical Devices, Plano, Texas) is a battery-operated percutaneous mechanical thrombectomy catheter that functions by spinning a flexible "S"-shaped guide wire within the vessel to be treated (**Fig 1**). This function allows the clot to be macerated and aspirated through an introducer sheath. Information about the efficacy of this device is limited. Therefore, the aim of the present study was to evaluate the efficacy

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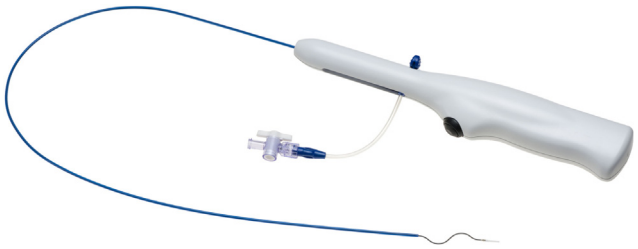

Figure 1. The Cleaner thrombectomy device. (Available in color online at www.jvir.org.)

and safety of pharmacomechanical thrombectomies performed with the use of this rotational thrombectomy device for the treatment of DVT.

MATERIALS AND METHODS

Patients

Following institutional review board approval, consecutive patients who underwent PMT with recombinant tissue plasminogen activator (TPA) for a symptomatic lower-extremity DVT over a 1-year period between July 2012 and August 2013 were identified from one clinical database combined from four nationwide centers. The records were retrospectively reviewed for demographic data, indications for treatment, periprocedural complications, clinical outcomes, and follow-up with duplex ultrasound (US) imaging, and reporting was done in accordance with the Society of Interventional Radiology (SIR) reporting standards for the endovascular treatment of lower-extremity DVT (8). Based on these criteria, symptom duration was defined as acute ($\leq$ 14 d), subacute (15–28 d), or chronic ($>$ 28 d).

Records of 41 symptomatic patients with acute or subacute lower-extremity DVT were reviewed. All patients had leg swelling, pain, or symptoms related to phlegmasia cerulea dolens. The patients consisted of 29 men and 12 women, with a mean age of 54.9 years $\pm$ 19.6 (range, 17–84 y). The initial diagnosis of DVT was made in all patients with venous duplex imaging. The definitive delineation of the extent of the involved venous segments was established by venography at the time of intervention.

To be included in the study, patients required first-time verified acute or subacute symptomatic DVT involving the femoropopliteal, iliofemoral, or iliocaval segments. The criteria excluded patients who were not 16–85 years of age; patients with an upper-extremity thrombosis, established PTS, severe renal failure, or active gastrointestinal bleeding; patients who could not receive tPA or anticoagulation therapy; terminally ill patients; and patients with contraindications to thrombolytic treatment, such as hemorrhagic stroke or other intracranial diseases, recent ($<$ 10 d) major trauma or surgery, pregnancy, recent obstetric delivery, bleeding disorder, and prolonged traumatic cardiopulmonary resuscitation. Patients who did not meet the inclusion did not undergo PMT.

PMT Technique

Before the procedure, a retrievable inferior vena cava (IVC) filter (Option retrievable vena cava filter; Argon Medical Devices) was placed via contralateral femoral or internal jugular vein access. Under local anesthesia, a percutaneous 6-F sheath was placed in an antegrade fashion into the popliteal or posterior tibial vein under US guidance. Unfractionated heparin was administered into a peripheral vein, with a target of two- to threefold activation of the partial thromboplastin to provide anticoagulation at the lytic site and in the systemic circulation.

Venography was performed, and the location of the thrombus was established. Then, a 6-F Cleaner thrombectomy device was inserted through the introducer sheath. A recombinant form of TPA (alteplase; Actilyse; Boehringer Ingelheim, Ingelheim am Rhein, Germany) was delivered through the side port of the device. The device was activated to spin the S-shaped wire, which was then advanced in an antegrade fashion (Fig 2). Following a 2–5-minute thrombolysis, the device was deactivated and temporarily withdrawn. The macerated thrombus and residual lytic agent were suctioned through the sheath, and control venograms were obtained to evaluate the treated segments. The device was then reinserted and repositioned into the upper thrombosed segment. Thrombolysis was performed in a segmental antegrade fashion. The most cranial portion was lysed last to prevent the embolization of a thrombus fragment. The vein was treated in approximately 5–10-cm intervals by injecting 10 mL of saline solution containing 1 mg of the TPA solution for 2–5 minutes; the rate depended on the patient's condition and weight and the size of the thrombus. This procedure was repeated until the end of the thrombus was reached. Finally, the device was removed, and a completion venogram was obtained. When the extent of the thrombus resolution was less than 50% of the occluded segment, the device was reinserted and activated for an additional pass. If the control venogram revealed a residual occluding or significantly obstructing thrombus after the second or third pass, the procedure was terminated or a 4-F infusion catheter (Cragg McNamara valved infusion catheter; ev3, Irvine, California) was inserted, and an infusion of 1 mg/h TPA was initiated for 24 hours.

Percutaneous transluminal angioplasty and venous stent placement were performed selectively to treat underlying severe stenoses or nonresponding iliocaval obstructions. If there was a significant compression of the left common iliac vein or if there was severe stenosis as a result of a residual thrombus that could not be removed with the device or a following CDT in the iliac veins or the IVC, self-expanding stents were placed. With use of the same access, large (16–18 mm in diameter) Wallstents (Boston Scientific, Natick, Massachusetts) were placed with at least 1–2 cm at the stent joints after predilation to normal vein caliber for the location.