Mechanical Thrombectomy with Trerotola Compared with Catheter-directed Thrombolysis for Treatment of Acute Iliofemoral Deep Vein Thrombosis

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Background: Mechanical thrombectomy (MT) of acute deep vein thrombosis (DVT) is safe and effective in reducing thrombus burden. MT utilizing a percutaneous thrombectomy device confers a great advantage because it may reduce both the dose of the thrombolytic agent and the overall procedure time compared with a conventional catheter-directed thrombolysis (CDT). We examined the results of MT using the Trerotola device and evaluated factors affecting patient outcome.
Methods: This retrospective study was performed using data from a database of patients who had undergone treatment for an acute iliofemoral DVT from January 2005 to December 2011, at 2 institutions. The patients' clinical characteristics and procedures were compared, and the outcomes of treatment with the Trerotola in the MT group were compared with those obtained with CDT.
Results: There were a total of 98 DVTs (left 76; right 22) in 90 patients (34 men); 53 DVTs were treated with MT and 45 with CDT. There were no statistical differences in the clinical characteristics among the MT with CDT, MT only and CDT group. Inferior vena cava filters were placed in 93 DVTs (95%), and iliac vein stenting was used in 64 (65%). Symptom improvement was seen in 78% (18 limbs) of the MT group, 80% (24 limbs) of the MT with CDT group, and 71% (32 limbs) of the CDT group ($P = 0.498$). The procedure time was shorter in the MT with CDT group (18.2 ± 8.2 hr) or in the MT only group (2.7 ± 2.0 hr) compared with the CDT group (29.3 ± 9.4 hr; $P < 0.001$). Urokinase dose was lower in MT only (0 million units) or in the MT with CDT group (5.13 ± 3.72 million units) than in the CDT group (7.51 ± 4.54 million units; $P < 0.001$). There was no difference in complications during the procedures or in primary patency rate during the follow-up period (mean 16.0 ± 19.1 months; range: 0–78 months).
Conclusions: MT with the Trerotola device for acute iliofemoral DVT required shorter procedure times and lower urokinase doses than conventional CDT, while providing the same results.

INTRODUCTION

Anticoagulation therapy, the current standard of care for deep vein thrombosis (DVT), inhibits thrombus propagation and provides prophylaxis against pulmonary embolism (PE).[1] However, it neither removes existing thrombus nor prevents post-thrombotic syndromes (PTSs). PTS is characterized by pain, swelling, a sensation of heaviness, edema, pigmentation, and deterioration of the

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skin to include venous ulcers in severe cases.[2] Endovascular management with catheter-directed thrombolysis (CDT) or percutaneous mechanical thrombectomy (MT) is safe and effective in reducing PTS and thrombus burden.[3]

Recently, there has been more broad-based interest in removing thrombus from the deep veins in patients with acute DVT. Endovascular treatment has advanced considerably, so this therapy can now be delivered efficiently and safely, removing the thrombus, maintaining patency to the deep venous system, and preserving valvular function. This not only improves quality of life but result in return of normal life for many of those successfully treated. In particular, CDT has shown to improve the clinically relevant long-term outcome after iliofemoral DVT by reducing PTS compared with conventional treatment with anticoagulation and elastic compression stockings alone in a randomized trial.[3] There are fewer randomized trials about MT than CDT but several studies have reported shorter treatment times and lower doses of lytic agent in patients treated with MT compared with CDT.[4–6] When thrombolytic agents such as urokinase is contraindicated, MT is a useful treatment without the need for CDT.[7] Almost all the previous reports of CDT with MT used AngioJet (Possis Medical, Minneapolis, MN), Trellis (Bacchus Vascular, Santa Clara, CA), or an ultrasound-assisted lysis catheter system (Ekos Corp, Bothell, WA) as the thrombectomy device.[4,5] The Trerotola device (Arrow International, Redding, PA) is a MT device initially designed for the treatment of thrombosed dialysis arteriovenous fistulae or grafts.[8] Favorable clinical results have been reported regarding the usefulness of the Arrow-Trerotola device in thrombosed hemodialysis grafts or native accesses.[8] MT using the Trerotola device in iliofemoral DVT is an off-label use. Studies of MT using the Trerotola device are limited to one study.[9] The study was a case series without direct comparison between MT and CDT, and to our knowledge, no study has investigated MT with Trerotola device compared with CDT. Thus, the comparison between MT and CDT remains poorly understood. Therefore, we report on our experience with the clinical outcomes of MT with Trerotola compared with CDT alone in patients with acute iliofemoral DVT.

METHODS

Patients who underwent CDT or MT for treatment of an acute iliofemoral DVT (with symptoms of leg swelling, pain or redness, and duration <3 weeks)[3] were identified through the vascular surgery registries of Inha University and Seoul Catholic University Hospital. The medical records of patients treated between January 2005 and December 2011 were retrospectively reviewed.

For analysis, the patients were divided into 3 groups: those who had been treated with CDT alone, those who had been treated with CDT after MT, and those who had been treated with MT alone. We limited our study population to patients who had been treated only with urokinase as the thrombolytic agent and with Trerotola as the MT device. Initial PEs were diagnosed by computed tomography (CT) venography. We did not offer MT or CDT for cases of symptomatic PE. There was no symptomatic PE in our study.

For each patient, a retrospective chart review was used to collect demographic data and information on immediate clinical efficacy, including the degree of thrombus reduction, treatment duration, total urokinase dose, and periprocedural complications.

All patients were admitted for vascular procedure after lower extremity DVT was identified using CT venography. Contraindications to CDT included recent stroke, surgery, serious gastrointestinal bleeding, primary or metastatic central nervous system malignancy, and coagulopathy.[10] Treatment decisions were made by the preference of individual attending surgeons. Patients in all groups were initially anticoagulated with a continuous intravenous infusion of unfractionated heparin, adjusted to maintain an activated partial thromboplastin time between 80 and 100 sec from diagnosis. Systemic heparin was switched to an oral anticoagulant (warfarin) after MT or CDT. The patients received anticoagulation for 6 months. The target international normalized ratio was 2–3 for most patients.

In 93 (95%) patients, an inferior vena cava (IVC) filter (OptEase; Cordis Europa, Roden, The Netherlands or Tulip; Cook Medical, Bloomington, IN) was inserted via the right jugular vein or the contralateral femoral vein before MT or thrombolysis was performed.

Percutaneous access was achieved via popliteal vein access under ultrasound guidance. With a 7F sheath, we crossed the clots with a 5F hydrophilic hockey-stick catheter (Terumo, Somerset, NJ) and a 0.035-inch hydrophilic guidewire (Terumo). Venograms were obtained using an iodine contrast agent through the sheath or catheter (Fig. 1A).

The device used in this study was a 7F Arrow-Trerotola device with 0.025-inch guidewire compatibility (Arrow international). The basic concept of this device has been described in previous reports.[11]