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Pharmacomechanical Thrombectomy for Acute Symptomatic Lower Extremity Deep Venous Thrombosis

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ABSTRACT

Background: The purpose of this study was to evaluate the efficacy and safety of pharmacomechanical thrombectomy performed by using a rotational thrombectomy device for the treatment of deep vein thrombosis.

Methods: Between April 2012 and November 2014, 17 patients with acute deep vein thrombosis underwent pharmacomechanical thrombolysis. The thrombectomy device was used in a single-session technique for patients with lower-extremity deep vein thrombosis. After the procedure, the effect of thrombolysis was evaluated in 3 grades venographically. Grade I showed lysis of under 50%, and grade III showed complete lysis.

Results: Ten patients (58.8%) had an iliofemoral thrombosis and 7 (41.2%) had a femoropopliteal venous thrombosis. At the end of the pharmacomechanical thrombectomy procedure, 12 patients (70%) had complete (grade III) thrombus resolution. Grade I and II lysis were noted in 2 (12%) and 3 (18%) patients, respectively. Additionally, four (23.5%) 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 82.2% (n = 14), 12% (n = 2), and 5.8% (n = 1), respectively. There was no mortality.

Conclusion: Based on the present data, use of the Cleaner thrombectomy device may prove to be a safe and feasible single-session pharmacomechanical thrombectomy method for the treatment of acute deep vein thrombosis. To prove the effectiveness of this type treatment, a more extensive large-scale studies are needed.

INTRODUCTION

Deep vein thrombosis or deep venous thrombosis (DVT) is the formation of a blood clot within a deep vein, predominantly in the legs. Pain, swelling, redness, warmness, and engorged superficial veins are non-specific signs of DVT. DVT is prevalent in approximately 48 persons of 100,000 persons per year in large community-based studies and an in-hospital case fatality rate from complications of thromboembolism is 12%. Pulmonary embolism (PE) is a potentially life-threatening complication, caused by an embolization of a clot that travels to the lungs. Venous thromboembolic disease, including both DVT and PE, is an under-diagnosed medical problem that results in high rates of significant morbidity and mortality [Anderson Jr 1991]. Death occurs within one month of an episode in about 6% of those with DVT and 10% of those with PE [van Korlaar 2004; Bush 2004; Cushman 2004]. Postthrombotic syndrome (PTS), another complication, significantly increases the health-care cost of DVT (in 20-50% of patients after a first DVT). It has been associated with persistent symptoms of ambulatory venous hypertension, chronic edema, and venous ulceration.

Understanding the risk factors of venous thrombosis is necessary in order to maximize the prevention of this disease in persons and groups of patients who are at high risk. The major risk factors of thrombosis include endogenous patient characteristics such as obesity, genetic factors, myeloproliferative disease, anti-phospholipid syndrome, older age, and triggering factors such as immobility, trauma, postmenopausal hormone therapy, major surgery, and pregnancy [Pini 2006; Samama 2000].

The purpose of interventions and treatments (such as anticoagulation therapy, thrombolytic therapy, catheter-directed thrombolysis (CDT), and surgical or endovascular thrombectomy) are to restore venous patency, to remove obstruction, and ultimately to decrease the incidence and severity of reflux in a diseased extremity. These can be used to return patients to their normal way of life. During the last decade, pharmacomechanical thrombectomy (PMT) has emerged as an effective alternative to open surgical thrombectomies and CDT in patients with acute DVT [Vedantham 2012]. Pharmacomechanical approaches have been suggested as viable and possibly preferable for the management of acute DVT [Vedantham 2006].

The purpose of the present study was to evaluate the efficacy and safety of PMT performed by using this rotational thrombectomy device for the treatment of DVT.

MATERIALS AND METHODS

After ethics committee approval, between April 2012 and November 2014, 17 patients with lower-extremity acute

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DVT underwent PMT using a Cleaner thrombectomy device (Cleaner Rotational Thrombectomy System, Argon Medical Devices, Plano, TX) with recombinant tissue plasminogen activator (t-PA). Their records were retrospectively reviewed for demographics data, periprocedural complications, clinical outcomes, and were followed up with Duplex ultrasound (DUS) imaging. The symptoms that remained for less than 14 days were considered as an acute DVT.

All treated patients were severely symptomatic despite therapeutic anticoagulation and most commonly presented with a combination of incapacitating pain and limb swelling related to venous thrombosis. The patients consisted of 9 men and 8 women. All patients were diagnosed with physical examination and venous DUS imaging. Preintervention and postintervention venograms obtained the degree of thrombus reduction. All consecutive adult patients with acute DVT (femoropopliteal and iliofemoral segments) were included in the study. Patients were excluded from the study due to any of the following: not between 16-85 years of age; upper-extremity thrombosis; established PTS; severe renal failure; active gastrointestinal bleeding; could not receive t-PA or anticoagulation therapy; terminally ill; and contraindications to thrombolytic treatment (such as hemorrhagic stroke or other intracranial diseases, recent major trauma or surgery, pregnancy, recent obstetric delivery, bleeding disorder, and prolonged traumatic cardiopulmonary resuscitation).

Inferior vena cava (IVC) interruption with temporary filters was performed selectively at the beginning of the procedure via contralateral femoral or internal jugular vein. All PMT procedures were performed in a fully equipped operating room with capability for endovascular intervention by vascular surgeons. Patients were placed in a prone position, and the ipsilateral popliteal vein was cannulated under ultrasound guidance with a micropuncture technique under local anesthesia. Unfractionated heparin (100U/kg dose) was administered into a peripheral vein to provide anticoagulation at the lytic site and in the systemic circulation. Venograms were performed to determine the localization of the thrombus (Figure 1). A 6-F Cleaner thrombectomy device was inserted through the introducer sheath. A recombinant form of t-PA (Alteplase, San Francisco, CA; 5-10 mg per segment) was delivered through the side port of the device. The device was activated to spin the S-shaped wire, which was advanced in an antegrade way. This function allowed the clot to be macerated and aspirated through an introducer sheath (Figure 2). After thrombolysis was performed for 3-5 minutes, the device was stopped and temporarily withdrawn, and control venograms were ensured to assess the treated fields. After the device was reinserted, thrombolysis was performed as segmental with approximately 5–10 cm intervals by injecting 10 mL of saline solution containing 1 mg of the t-PA solution. This procedure was repeated until the thrombus disappeared completely. Finally, the device was removed, and the last venogram was obtained (Figure 3). If the control venogram revealed a residual occluded thrombus after the second or third attempt (more than 50% of the segment occluded), t-PA was initiated for 24 hours of dose infusion of 1 mg/h. Percutaneous transluminal angioplasty and venous stent placement were performed selectively to treat underlying severe venous stenosis or non-responding femoroiliac obstructions.

After the interventional treatment, patients continued to receive subcutaneous low molecular weight heparin, with a subsequent conversion to oral warfarin. The therapy was adjusted to attain an International Normalized Ratio in the range of 2–3. The IVC filters were removed within 1 month. Posttreatment ultrasound imaging of the affected leg was performed in weekly intervals during month 1 and then monthly. Patients were evaluated in the terms of recurrent DVT, PTS, and pulmonary embolisms during follow-up.

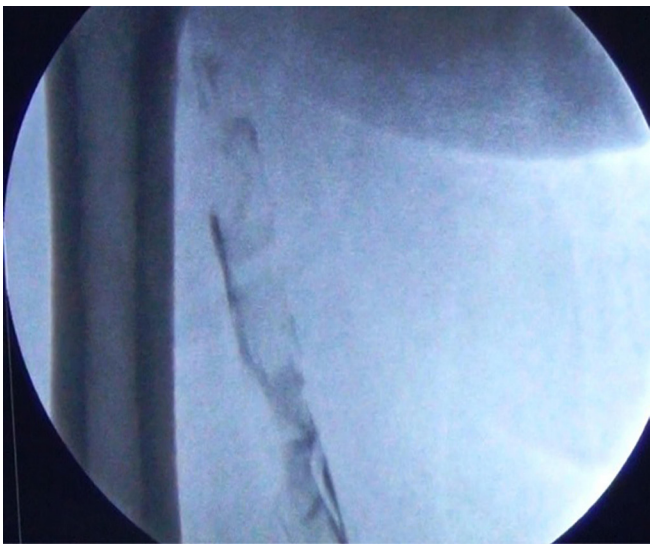

Figure 1. Venogram shows acute iliofemoral deep vein thrombi and venous obstruction.

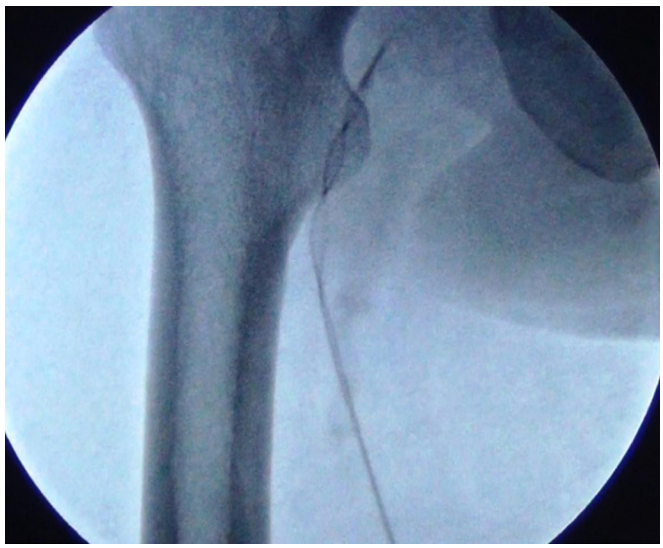

Figure 2. Percutaneous rotational thrombectomy device that functions by spinning a flexible S-shaped guide wire.

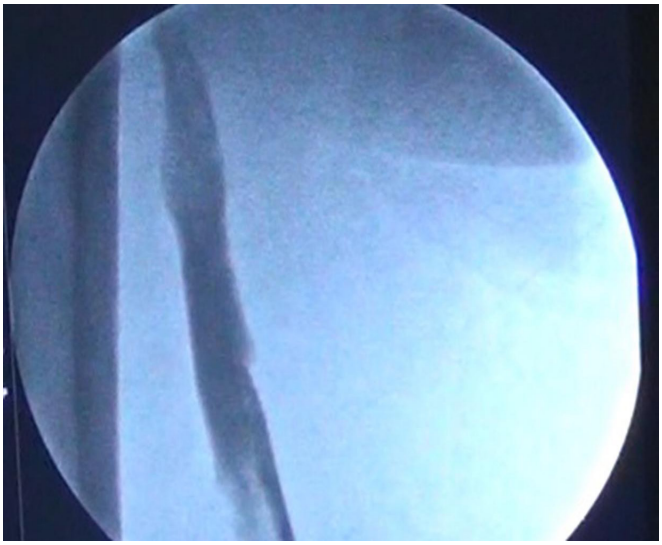

Figure 3. Iliofemoral deep vein without thrombi after pharmacomechanical thrombectomy procedure.

The venograms were graded according to the quantity of the thrombus extraction compared with the venograms by the same intervening person who performed the procedure, before and after the treatment. Our technical success was defined as >50% lysis as visualized on venography. The extent of the lysis was graded from I to III. Grade III lysis was defined as the complete resolution of the thrombus on a visual assessment of the venogram. Grades II and I lysis were defined as a thrombus resolution of 50-99% and less than 50%, respectively [Mewissen 1999]. The study terminated depending on the extent of clot lysis, major bleeding, and PE during follow-up.

Statistical Analysis

Statistical analysis was performed by using SPSS version 18.0. The data have been summarized as the mean ± standard deviation for continuous variables and as percentages for categorical data. Nominal data are reported as the number of subjects.

RESULTS

All patients had acute symptoms. There was no phlegmasia cerulean dolens among patients. Ten patients (58.8%) had an iliofemoral thrombosis and 7 (41.2%) had a femoropopliteal venous thrombosis. The patients were taken to angiography approximately within 16 h ± 8. After IVC filter, the PMT device was inserted via posterior tibial vein or the popliteal. The features relating to preintervention and intervention are shown in Table 1.

At the end of the PMT procedure, 11 of the 17 patients were treated in a single session. The second or third applications were performed in patients with unresolved thrombus (second intervention in 3 patients, third intervention in 3 patients). We used iliac stents for only one of the 10 patients with an iliofemoral venous thrombosis. This patient had iliac vein compression that was resistant to lytic therapy. After all attempts, 12 patients (70.7%) had complete (grade III) thrombus resolution. Grade I and II lysis were noted in 2 (11.7%) and 3 (17.6%) patients, respectively, who had varying degrees of partial thrombus extraction. The additional lytic infusion was required in 4 patients (23.5%) as a result of residual thrombi. The overall grade III, II, and I thrombus resolution rates, including the supplemental thrombolysis, were 82.2% (n = 14), 12% (n = 2), and 5.8% (n = 1), respectively. There were no device failures or adverse effects associated with the device. The DUS imaging that was performed before discharge demonstrated patent veins in all patients. The mean follow-up was 2.8 months ± 2.1 (range, 2-6 months).

Significant clinical improvement was seen in 16 patients (94.2%), as marked by a decrease in pain or swelling of the affected extremity within 24 hours of treatment. One patient had occlusions of the femoral vein without recurrent symptoms, and this patient was given medical treatment including anticoagulant therapy. DUS imaging also showed that the iliac stents in one patient were patent.

A hematoma under the skin developed as major bleeding in the interventional field of 1 patient (0.5%), who required a

Table 1. Characteristics and Data Associated with PMT Procedure

Preinterventional characteristics	Iliofemoral DVT	Femoropopliteal DVT
No. of patients (n = 17)	10 (58.8%)	7 (41.2%)
Mean age	45 ± 11	42 ± 12
Sex		
Male (n = 9)	6	3
Female (n = 8)	4	4
Hypertension, n	2	3
Smoker, n	3	2
COPD, n	1	1
Malignancy, n	1	1
Immobility, n	2	2
Mean duration of symptoms, days	7.3 ± 1.2 (range, 0-11)	8.1 ± 1.0 (range, 1-9)
Interventional data		
Entry places		
Posterior tibial vein, n	1	1
Popliteal vein, n	9	6
Mean amount of TPA, mg	28.3 ± 10.6 (range, 21-44)	25.7 ± 11.1 (range, 22-40)
Mean procedure duration, min	62.1 ± 22.7 (range, 42-108)	54.9 ± 28.1 (range, 33-102)
Length of ICU stay, hours	6 ± 0.7 (range, 3-9)	5 ± 0.6 (range, 2-7)
Duration of hospital stay, days	3 ± 0.7 (range, 1-4)	3 ± 0.4 (range, 1-3)

Table 2. Pre- and Post-procedural Complications

	Number of patients
Periprocedural death	0
Hospital deaths	0
Early and midterm mortality	0
Symptomatic pulmonary embolisms	0
Trapped thrombi in the IVC filter	0
Vascular injury	1 (0.5%)
Skin infection	1 (0.5%)
Bleeding complications	
Hematoma	1 (0.5%)
Subcutaneous bleeding not requiring transfusion	1 (0.5%)
Gingival bleeding	1 (0.5%)

blood transfusion. A popliteal hematoma and bleeding developed as a result of the very short period of compression at the popliteal access site. The skin infection was treated with antibiotics and superficial debridement. The large defect in the posterior tibial vein was repaired with end-to-end anastomosis. Complications of the procedure are shown in Table 2.

DISCUSSION

Anticoagulant therapy, surgical thrombectomy, or lytic therapy, or a combination of the 2 or 3 methods is essential for the rapid relief of thrombus burden. The purpose of these treatments is to decrease the risks of PE and PTS resulting in manifestations of chronic venous insufficiency.

Clinically, thrombolysis is fully dissolution of the clot. Comerota et al [Comerota 2007a; Comerota 2007b] showed that direct thrombus dissolution (thrombolysis) is more effective than anticoagulant therapy alone. In his study, complete lysis was achieved in 45% of patients who underwent thrombolysis, but this rate was 4% in patients treated with anticoagulation therapy alone. In several retrospective series and ongoing multicenter studies, there is evidence in favor of thrombolysis for iliofemoral DVT [Lin 2006; Enden 2007; Elsharawy 2002].

CDT was used as another treatment method in patients with acute DVT. CDT has been demonstrated to be more effective than conventional treatment methods in acute DVT. These reports cite improved short-term and long-term venous patency, with patency rates ranging from 54% to 89% at 1 year, as well as sustained symptom resolution or improvement [Mewissen 1999; Elsharawy 2002; AbuRahma 2001; Bjarnason 1997].

In the last decade, PMT has emerged as an effective alternative to surgical thrombectomy and catheter thrombolysis, and as a result of the hemorrhagic complications associated with CDT in patients with acute DVT. Although a few studies have shown that PMT can be successfully utilized, long-term benefits of this treatment have not yet been shown in studies [O'Sullivan 2007; Cynamon 2006]. These PMT catheters may be used in combination with adjunctive thrombolytic agents for more complete and rapid thrombus disposal. These combination therapies provide lower mean dosage and duration of lytic infusion. When it is compared with the studies, which used CDT alone, reducing the dosage or time for complete thrombolysis results in lower overall cost and reduction in hemorrhagic complications in our limited study [Bush 2004; Lin 2006]. Although the one-time cost of PMT is higher, it has advantages (such as minimizing treatment duration, and reducing the duration of intensive care and hospital stay) that are cost-effective compared with CDT [Lin 2006]. In addition, reducing the socioeconomic cost of postthrombotic complications after DVT is significant. Venous ulceration emerges in up to 80-90% of patients with acute DVT over the years and so patients have required repeat hospitalizations and miscellaneous medical and surgical methods to alleviate complaints. Moreover, patients with chronic venous disease resulted in labor loss. We preferred to use the Cleaner thrombectomy device in our patients with acute DVT. This device is a battery-powered percutaneous thrombectomy catheter that functions by spinning a flexible S-shaped guide wire within the vessel to be treated. This device softened and aspirated the clot through an introducer sheath. PMT with added lytic agents restores venous patency in the operating room or intervention suite, obviating the need for intensive care unit stays or multiple transfers for repeat venography. Though we did not make a cost analysis, it can be observed that the cost of PMT is less in the immediate and long-term compared with other DVT treatment modalities.

Vedantham et al reported that 31% of patients with iliofemoral DVT treated with PMT achieved grade III lysis, whereas 2 other studies had complete thrombus removal rates of 100% and 70% with PMT application for DVTs [Lin 2006; Vedantham 2004; Lee 2006]. Although the treatment methods and shapes are different in these 3 studies, the main treatment goal in the current high-risk series was not necessarily complete lysis, but significant lysis (>50%). In our patients, with the use of this device, a greater than 50% thrombus resolution was achieved in 94.2% of patients, without significant morbidity. This rate is comparable with the success rates reported by others [Lin 2006; Rao 2009; Hirsh 2008]. In a retrospective study of patients receiving CDT [Grewal 2010], patients who had greater than 50% clot removal with CDT were protected from PTS and had better quality of life than patients whose CDT did not achieve substantial clot removal [Grewal 2010]. These factors have therefore led to the emergence of PMT as a potentially faster, less invasive, safer alternative to venous thrombectomy or CDT [Bush 2004; Lin 2007], promising to limit the dose and duration of treatment. It has been well-studied recently [Lin 2006; Vedantham 2004; Lee 2006], with comparable or better success rates compared with CDT, and it has been shown to provide shorter hospital and intensive care stay and decreased costs [Lin 2006].

Bleeding is the most feared complication of thrombolysis. PMT is advocated over anticoagulation alone in patients with acute (<14-day-old) iliofemoral DVT who have low risk of

bleeding, to lessen postthrombotic symptoms [Hirsh 2008]. Major bleeding is estimated to occur in 2-4% of patients receiving CDT [Vedantham 2012]. We did not encounter any systemic bleeding complications among our patients. Although we noted 2 bleeding complications, there was only a need for blood transfusion in one of the patients. A retrospective study by Rao et al [Rao 2009] demonstrated that thrombolytic agent doses and infusion durations were reduced with PMT compared with conventional CDT. PMT may also decrease the risk of hemorrhagic complications because of its shorter infusion intervals and lower doses of thrombolytic agents, making it a more attractive modality in high-risk cases in postoperative patients [Dasari 2012].

We placed stents in only one of our patients. This is markedly less than rates reported in the literature, where up to 75% of patients treated for venous occlusive disease undergo iliac stenting [Neglen 2000].

The placement of a prophylactic IVC filter before thrombolytic procedures is still controversial. Protack et al [Protack 2007] report no increase in pulmonary emboli in patients who undergo CDT without filter placement. In a large prospective study with proximal DVT undergoing infusion CDT (without percutaneous mechanical thrombectomy) [Mewissen 1999; Sharifi 2012], symptomatic pulmonary embolisms occurred in only six patients (1.3%), one of whom died (0.2%). Retrievable VCI filters are efficacious in preventing pulmonary embolus and in trapping embolus. In our patients, we saw no associated complications, such as insertion site thrombosis, filter migration, symptomatic pulmonary embolisms, or vena cava injury. Our practice has therefore evolved to include the placement of temporary filters if there is caval or iliac vein involvement.

The present study has several limitations, including the nature of a retrospective analysis of one combined database, the small number of patients, and a heterogeneous study population in terms of the duration of symptoms and the locations of the thrombi. Randomization or direct comparisons between mechanical thrombectomy with lysis to mechanical thrombectomy alone were not part of this limited preliminary study. Also, the mean follow-up of the study is too short to evaluate a problem such as PTS, which develops over a number of years. During the follow-up duplex examinations, we did not attempt to record venous valve function, focusing instead on the veins' patency.

Although this study is not comparative with other methods of treatment type, PMT may be a preferable treatment method in patients with acute DVT in terms of immediate thrombus-dissolving activity, and a benefit of reducing bleeding risk, reducing hospital costs and the duration of hospitalization, and shortening treatment times. Based on the present data, use of the Cleaner thrombectomy device may prove to be a safe and feasible single-session pharmacomechanical thrombectomy method for the treatment of acute deep vein thrombosis. Demonstration of the effectiveness of this type of treatment will require larger studies with long-term follow-up.

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