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Percutaneous mechanical thrombectomy combined with catheter-directed thrombolysis in the treatment of symptomatic lower extremity deep venous thrombosis

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Abstract

Purpose: To evaluate the efficacy of percutaneous mechanical thrombectomy (PMT) combined with catheter-directed thrombolysis (CDT) in the treatment of massive symptomatic lower limb deep venous thrombosis (DVT).

Materials and methods: One hundred and three clinically confirmed DVT patients were discharged from our institution. Sixteen patients with massive lower limb DVT were included in this retrospective study. After prophylactic placement of inferior vena cava filters (IVCFs), percutaneous mechanical thrombectomy (ATD, $n = 10$; Straub, $n = 6$) and catheter-directed thrombolysis were performed in all patients. Complementary therapy included percutaneous transluminal venous angioplasty (PTA, $n = 3$) and stent placement ($n = 1$). The doses of thrombolytic agents, length of hospital stay, peri-procedure complications and discharge status were reviewed. Oral anticoagulation was continued for at least 6 months during follow-up.

Results: The average hospital stay was 7 days. The technical success rate (complete and partial lysis of clot) was 89%, the other 11% patients only achieved less than 50% clot lysis. The mean dose of urokinase was 3.3 million IU. There were no significant differences of clinical outcome between the ATD and Straub catheter group. The only major complication was an elderly male who experienced a fatal intracranial hemorrhage while still in the hospital (0.97%, 1/103). Minor complications consisted of three instances of subcutaneous bleeding. No transfusions were required. Vascular patency was achieved in 12 limbs during follow-up. No pulmonary emboli occurred. There is one recurrent DVT 4.5 months after the treatment.

Conclusions: Percutaneous mechanical thrombectomy combined with catheter-directed thrombolysis is an effective and safe method for the treatment of symptomatic DVT. A randomized prospective study is warranted.

Keywords: Deep venous thrombosis; Therapy; Interventional; Anticoagulation; Percutaneous mechanical thrombectomy; Catheter-directed thrombolysis

1. Introduction

Deep venous thrombosis (DVT) is a significant cause of morbidity and mortality. It has been estimated that the yearly incidence of DVT is as high as 250,000 cases in the United States alone and as many as 100,000 individuals die annually from pulmonary emboli (PE) [1] In addition to early risk of PE, later morbidity may develop from recurrent thrombosis and post-thrombotic syndrome [2].

Inferior vena cava filters (IVCFs) can effectively decrease the incidence of fatal pulmonary emboli. Although conventional anticoagulation therapy has been proven effective in the treatment of DVT and PE, the incidence of recurrent DVT (2–10%) and post-thrombotic syndrome (20–50%) is fairly high after the first episode [3,4]. Moreover, venous valvular insufficiency is not uncommon: there are reports in the literature of incidences as high as 100% after the primary DVT event [2]. Complete removal of the thrombus can improve clinical outcomes. Percutaneous mechanical thrombectomy (PMT) combined with catheter-directed thrombolysis (CDT), a comprehensive interventional therapy, can quickly minimize the burden of thrombus in the treatment of symptomatic massive DVT (many phlegmasia cerulea dolens), reduce the thrombolysis drug use, avoid venous gangrene and decrease the high post-thrombotic syn-

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drome rate [5]. The purpose of this retrospective study was to evaluate the efficacy of combined therapy with percutaneous mechanical thrombectomy and catheter-directed thrombolysis in patients with lower extremity DVT.

2. Materials and methods

From January 2004 to September 2006, 103 consecutive clinically confirmed DVT patients were discharged from our hospital. Among them, 16 symptomatic massive DVT patients who underwent percutaneous mechanical thrombectomy combined with catheter-directed thrombolysis had complete follow-up data. We retrospectively analysed the records of these 16 patients. Inclusion criteria are as follows: patients who had overwhelming symptoms of lower extremity swelling, incapacitating pain, or phlegmasia dolen. Or patients presented with a high risk of pulmonary embolism, extensive iliocaval or iliofemoral thrombus that compromised lower limb blood flow. Exclusion criteria are that patients with asymptomatic DVT who underwent conventional anticoagulation treatment at our constitution; patients had contraindication to anticoagulation therapy and patients follow-up data were not available. The study was approved by our institutional review board. Informed consent was obtained from each patient.

This study included 9 males and 7 females, with a mean age of 53.3 ± 15.6 years (range 32–81 years). Acute DVT was present in 18 limbs (left, 13 limbs; right, 5 limbs) of 16 patients (Table 1). The thrombi were located in the iliofemoral-popliteal veins (left, 11 limbs; right, 3 limbs), inferior vena cava and bilateral iliofemoral-popliteal veins (2 patients). The average DVT age (time from the onset of lower limb symptoms or signs suggestive of DVT to the time of a definitive diagnosis) was 4.9 ± 3.9 days (range 1–15 days). In this group, risk factors for DVT included malignancy ($n = 3$), trauma ($n = 2$), recent surgical operation ($n = 4$), and hypercoagulable state ($n = 4$). All patients underwent venography and five patients received color Duplex Doppler ultrasound exams prior to admission to the hospital [6,7].

Intravenous administration of non-fractionated heparin (heparin sodium, Changzhou Qianhong Bio-Pharma Co. Ltd., Changzhou, China) at the rate of 12,500 IU qd and subcutaneous injection of low molecular weight heparin (Fraxiparine, Glaxo Smith Kline, Suzhou, China) at the rate of 0.4 ml q 12 h were utilized for the initial anticoagulation treatment. Each patient's international normalized ratio (INR), coagulation function, and platelet count were monitored every 2 days.

All interventional radiologic procedures were performed by experienced interventional radiologists (H.S., Y.H., T.S., Q.X.). Under sterile conditions, prophylactic inferior vena cava filters were placed in the angiography suite under local anesthesia through the right jugular vein or contralateral superficial femoral vein in 15 cases (11 Trapease Filters, Cordis, Miami; 1 Optease filter, Cordis; 1 Simmon nitinol filter, Bard, Crawley, UK; 2 Gunther-Tulip filters, Cook, Bloomington, IN). In one case, a Trapease filter was placed under general anesthesia in a patient with Stage IV rectal cancer, who had compulsive position and suffered severe pain caused by diffused metastatic lesions.

Percutaneous mechanical thrombectomy was conducted with the 8F Amplatz thrombectomy device (ATD, Microvena, White Bear Lake, MN) via ipsilateral popliteal vein access in the first 10 patients. The ATD catheter used was comprised of a double inverted helix rotating at 150,000 revolutions per minute (rpm) in a protective sleeve. It is driven by compressed air controlled by a foot pedal (working pressure 5–6 bar). This device is advanced through the thrombus at a speed of 15 cm/min.

6 F Straub-Rotarex catheter rotational thrombectomy (Straub Medical, Wangs, Switzerland) was performed in the final six cases via ipsilateral popliteal vein ($n = 4$) and bilateral popliteal veins ($n = 2$, bilateral DVTs). The design of the Straub-Rotarex catheter is based on a coated stainless steel spiral that rotates

Table 1
Patients' characteristics and treatment results

Patient no.	Age/sex	DVT age (days)	Predispose factors	Urokinase dose (million IU)	Treatment duration (h)	Procedural outcome (grade)	Complementary procedures	Follow-up
1	52/M	1		5.75	12	2		Partial
2	81/M	3	HP, DM	3.80	144	3	PTA	Died
3	38/F	3	Infection	5.25	48	3		Complete
4	60/F	10		2.50	36	3		Complete
5	80/F	1	Operation	1.80	36	3		Complete
6	74/F	1		4.20	48	1		Recurrent
7	43/M	1	Operation	4.50	36	3		Complete
8	68/M	4	Bone tumor, HP	3.70	48	3		Partial
9	44/M	7	Operation	2.70	24	3	PTA	Complete
10*#	32/M	7	Abdominal pain	1.50	24	1		Partial
11#	53/F	7	Rectal cancer	4.50	36	2	PTA, stent	Died
12	56/F	3	Operation	2.75	24	3		Complete
13	48/F	6	Pelvic trauma	3.00	30	3		Complete
14	49/M	15	Head injury	0.25	12	3		Complete
15*	42/M	2	Colon cancer	5.40	48	2		Partial
16	33/M	7	Ex-DVT	1.00	12	2		PTS

Abbreviations: *, bilateral DVT; #, vena cava and iliac thrombosis; HP, hypertension; DM, diabetes mellitus; PTA, percutaneous transluminal angioplasty; partial, partial patency; complete, complete patency; PTS, post-thrombotic syndrome.

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at 40,000 rpm; the catheter and motor drive are connected by a magnetic clutch. At the tip of the catheter, the spiral communicates with the vessel lumen through two oval slits. The spiral allows the passage of a 0.020-in. guide wire (Schneider, Saint Quentin en Yvelines, France). Furthermore, it is crucial that gentle forward and backward movements be applied during thrombus removal so that the regular interruption of clot transportation allows the passage of blood. The catheter is advanced at a rate of 1 cm every 2–4 s.

The infusion catheter was placed through the PMT access vein site after up to 6 passes of PMT at the discretion of the radiologists. Then catheter-directed thrombolysis (Mewissen, Boston Scientific, Natick, MA, USA) was performed with urokinase (Shenyan Eversright Pharma, China) using the power bolus injection technique where the urokinase was infused into the thrombus at a rate of 250,000–400,000 IU/6–8 h. Heparin 5000 IU qd was administered simultaneously through the catheter with a mini-pump. The tip of the catheter was adjusted with the surveillance venography every 24 h [8].

The INR was maintained between 2 and 3 in all patients. Complementary therapy included percutaneous venous transluminal angioplasty (PTA) in three individuals (patients 2, 9, and 11) and stent placement (Smart, Cordis, Miami, USA) in one patient (patient 11) with May–Thurner syndrome. Urokinase doses and the circumferences of the affected limb were recorded. We measured the thigh circumference at 15 cm above the knee joint and that of the calf at 10 cm below the tibial tuberosity. We used venograms through the thrombolysis catheter to investigate venous patency during therapy. Venous patency was classified into three groups for analysis: grade 1 for less than 50% patent, grade 2 for 50–99% patent, grade 3 for 100% patent, i.e. complete lysis [8]. Peri-procedure complications were recorded. In the clinical ward, each patient was in the 30 reverse Trendelenberg position on the bed and instructed to move the ankle joint at regular intervals. After discharge, oral anticoagulation with warfarin was continued concomitant with the use of graduated elastic compression stockings. All patients were followed for at least 6 months. Clinical follow-up by the referring physician included physical exam, abdominal plain films, color Duplex Doppler US and INR in all patients.

2.1. Statistical analysis

Statistical analysis was performed using SPSS, Version 11.0 (SPSS, Inc., Chicago, IL, USA). Continuous variables are reported as the mean ± standard deviation. The figures were generated in Microsoft Excel. Unpaired *t*-test was used for comparisons between ATD and Straub groups. A probability value ≤ 0.05 was considered to indicate statistical significance.

3. Results

Successful placement of the IVCFs was achieved in 100% of patients. Average procedure time was 64 min (ranged 45–90 min), including IVCF deployment, PMT activation time and infusion catheter placement time. There was no blood loss in ATD group. The blood loss for Straub catheter was mean 150 ml (range 120–200 ml). The thrombi extracted from the mechanical catheter varied from 5 to 30 g; all specimens were sent for pathologic examination. Post-PMT procedure, there were various sizes of remnant thrombi or irregular intimal surface, thus the CDT continued. The mean urokinase dose during thrombolysis was 3.3 ± 1.6 million IU (range 2.5–5.8 million IU). The catheter was deployed in the affected extremities for a mean duration of 39.4 ± 30.7 h (range 12–144 h). At hospital, grade 3 or complete lysis was achieved in 55.5% (10/18) of DVTs treated. Grade 2 or partial lysis was achieved in 33% (6/18), while 11% (2/18) achieved grade 1 lysis.

In our series, the mean activation time of ATD $n = 10$ and Straub $n = 6$ was 3.5 ± 1.5 min and 4.2 ± 2.4 min, respectively ($P \leq 0.05$). Meanwhile, there were no significant difference between ATD and Straub group in terms of thrombolysis agents dose, infusion catheter placement time and clot lysis grade (Table 2).

One retrieval filter (Gunther-Tulip) was removed 10 days after placement following complete dissolution of the thrombus, small clots were detected from the retrieved filter; no adverse events occurred in this case, who had a complete venous patency during follow-up (Fig. 1).

The mean hospital stay was 7.0 ± 2.5 days. Most patients reported symptom relief 2–7 days after the procedure. The thigh circumference decreased an average of 8.1 cm on the second day following treatment while the calf circumference decreased by an average of 5.4 cm (Fig. 2). During the hospital stay, platelet counts remained above 10×10^{12} per L in all patients. D-Dimer levels decreased significantly from 850 ± 273 μg/L at the time of admission to 380 ± 145 μg/L at the time of discharge. We performed a total of 39 venograms and 9 color Duplex Doppler studies during hospital stay.

Three patients experienced minor subcutaneous hemorrhage at the venous access site ($n = 1$), pedal vein puncture site ($n = 1$) and gingiva ($n = 1$). An 81-year-old male (patient 2), who had a long history of hypertension and diabetes, suffered a fatal cerebellar hemorrhage at a urokinase dose of 3.8 million IU. No patients required blood transfusion during the hospital stay. One patient (patient 8) experienced high fevers peaking at 39 °C during thrombolysis, with no positive bacterial culture. He was managed with hydration and steroids.

One man (patient 11) died of advanced-stage rectal cancer 1 month after discharge. His ultrasound demonstrated that the

Table 2
The clinical outcomes of ATD and Straub catheter group

Group	Age (years)	DVT age (days)	Activation time (min)	Urokinase dose (million IU)	Catheter placement time (h)	Lysis grade
ATD $n = 10$	57.2 ± 17.9	3.8 ± 3.2	3.5 ± 1.5	3.57 ± 1.4	45.6 ± 36.6	2.5 ± 0.85
Straub $n = 6$	46.8 ± 8.3	6.7 ± 4.5	5.2 ± 2.4	2.8 ± 1.9	27.0 ± 14.1	2.5 ± 0.55

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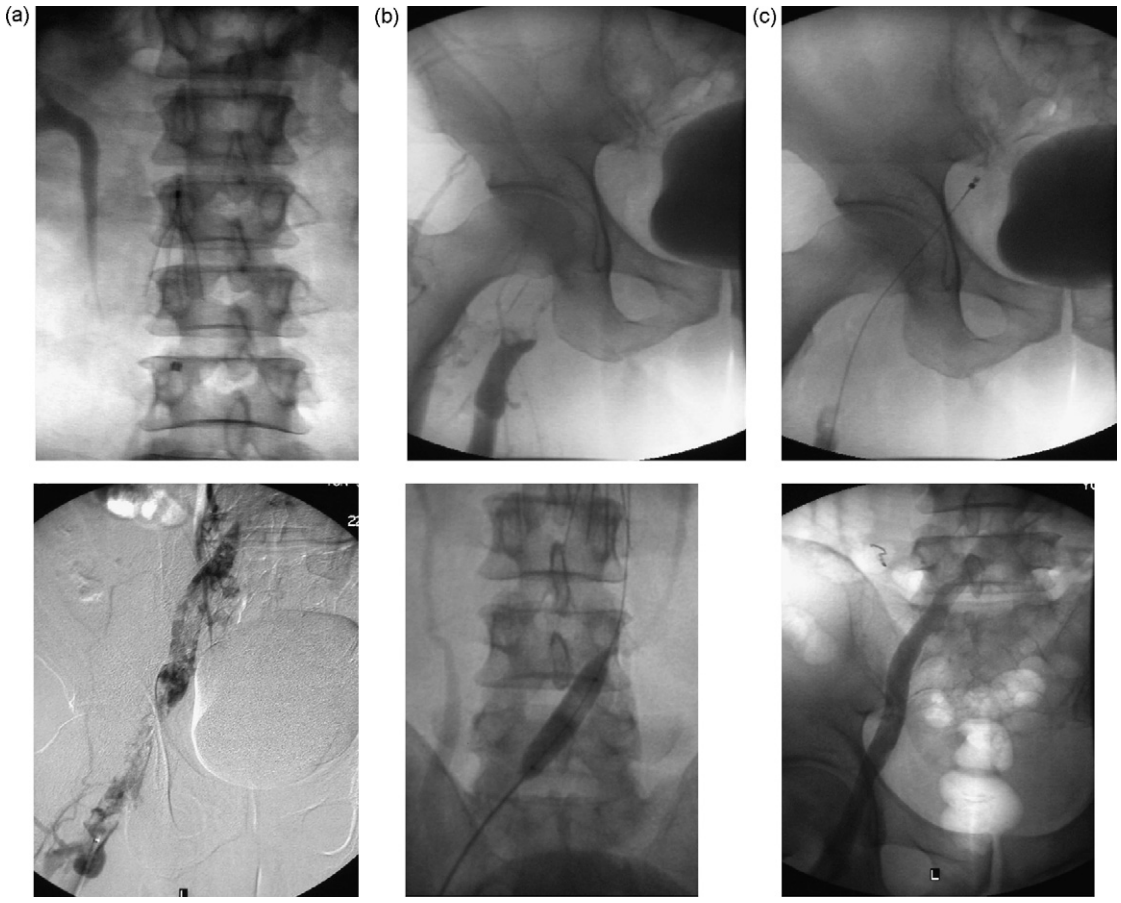

Fig. 1. Patient 9, male, 44 years old, who had left lower extremity DVT with a 2 weeks history of cholecystectomy, underwent PMT and CDT therapy. (a) A retrievable IVCF (Gunther-Tulip) was implanted before PMT and CDT. (b) Venographs obtained before and during PMT (ATD) concomitant with venous angioplasty through left popliteal vein access (prone position); catheter-directed thrombolysis not shown on these pictures. (c) Venography post PMT and CDT (prone position).

affected venous remained patent 1 week post-discharge. Mean follow-up was 13 months (range 6–35 months) for the remaining 14 patients. Plain abdominal films showed no migration of the IVCFs. Activated partial thromboplastin time (APTT) was elevated 1.5–2.5 times of normal level. Goal INR was between 2 and 3. No other patients had clinical or CT angiography evidence of pulmonary emboli. No hemorrhagic events occurred during the follow-up period. Twelve patients (12 limbs) achieved venous patency—8 complete and 4 partial patency (removal of 50% or more of thrombus burden) as documented by Duplex Doppler US with no symptoms during the follow-up period [9]. There was one recurrent DVT in our study. The elderly female (patient 6) developed another DVT 4.5 months following cessation of oral anticoagulation therapy. Another young male (patient 16) with thrombophilia had initially presented with portal venous thrombosis. During systemic thrombolysis, he developed massive gastrointestinal bleeding, so lysis and anticoagulation was stopped. Subsequently, he was presented with distal inferior vena cava thrombosis 6 months later, and underwent PMT with CDT after IVC filter prophylaxis. Post-procedure his caval patency was at grade 1. Unfortunately, 4 months later, he then underwent ilectomy for symptoms of intractable abdominal pain and significant weight loss with imaging verified intestinal obstruction. He developed post-thrombotic syndrome 10 months after operation. All the other patients had no serious symptoms.

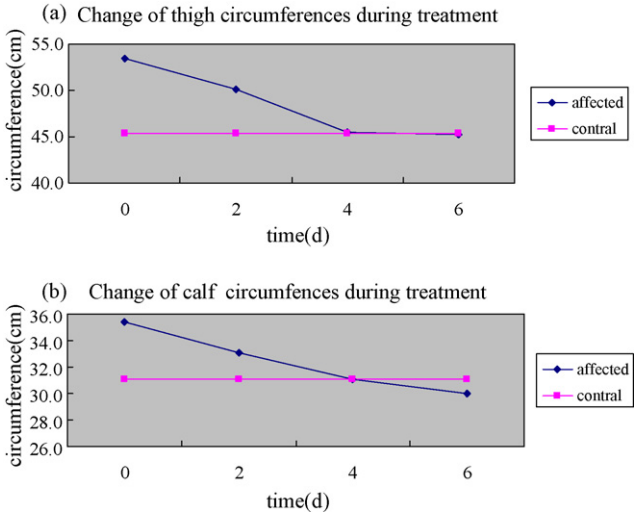

Fig. 2. Patients' affected (a) thigh and (b) calf circumferences change during treatment.

4. Discussion

The objective of treatment for DVT is to diminish the severity and duration of lower limb symptoms, prevent pulmonary emboli and post-thrombotic syndrome and minimize the risk of

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recurrent venous thrombosis [2]. Although IVCFs do not prevent deep vein thrombosis, they prevent pulmonary emboli and their catastrophic sequelae. Many centers therefore advocate prophylactic IVCF placement in critically ill surgical patients, because trapped clots are noted in the filters [10,11]. In this study, for issues of patient safety, we placed prophylactic IVCFs before the interventional procedures. Though there are only 3 retrievable filters used in this study, the authors recommend to use more retrievable filters in future, as some patients may have long life expectancy and only require short-term pulmonary emboli prophylaxis [12].

Anticoagulation with unfractionated heparin or low molecular weight heparin is currently recognized by many physicians as the gold standard therapy in the management of DVT and PE. However, as anticoagulation alone cannot diminish the inflammatory response to thrombosis and is rarely able to lyse clots adequately, the incidences of recurrent DVT and post-thrombotic syndrome remain fairly high following an initial diagnosis of DVT [13,14].

There is published evidence that thrombolytic drugs, even when administered systemically, are superior to standard anticoagulation therapy for achieving early lysis of thrombi. Catheter-directed thrombolysis has been demonstrated to be effective in clot lysis in multi-center trials (the National Venous Thrombosis Registry) [7], and it is routinely practiced in many centers for selected candidates. The mechanism of CDT involves increasing the regional concentration of thrombolytic agents and exposing more surface of the clot to these agents [15]. However, Mewissen et al. reported that major bleeding complications occurred in 54 patients (11%); six patients (1%) developed PE; and two deaths (<1%) of PE and intracranial hemorrhage. Puncture site bleeding (even use rt-PA) was the most serious complication and as many as 25% (6/24) of treated patients may require transfusions, symptomatic reocclusion occurred in 4 patients. Moreover, some thrombi cannot be completely removed by this method [8,16].

Aggressive thrombus elimination techniques include surgical embolectomy using Fogarty catheter and temporary creation of an arteriovenous fistula. Though large-bore sheath aspiration thrombectomy is less expensive than mechanical thrombectomy device, it is associated with the risk of pulmonary embolism and residual thrombus [17,18].

Mechanical thrombectomy is a minimally invasive endovascular technique for the management of acute and chronic symptomatic DVT, which removes thrombi by mechanical fragmentation and/or aspiration. There are many thrombectomy devices currently available. Mechanistically, these thrombectomy recirculation devices fall within 2 categories: wall contact and hydrodynamic. The wall contact mechanical thrombectomy devices use a high-speed rotating basket to fragment the thrombus. Hydrodynamic, or "rheolytic" recirculation devices are based on the Venturi effect, created by high-speed saline jets moving in a retrograde fashion. The jets fragment the thrombus and the material is then aspirated into the device. Devices based on this mechanism might possibly produce less valvular or endothelial damage than rotational thrombectomy devices, but this has not yet been evaluated in clinical trials [2]. A limiting factor of all currently available hydrodynamic thrombectomy devices is their inability to treat wall-adherent and organized thrombus sufficiently.

The mechanical thrombectomy devices used in this study are both wall contact ones. Amplatz thrombectomy device has no central aperture and therefore is not introduced over a guide wire. The system is prevented from overheating by means of continuous perfusion of cold saline solution under pressure. The rapid rotation of the helix gives rise to negative pressure in the catheter (vortex effect), which sucks the clot inside the distal end, macerates it and recirculates the slurry via three side ports. Blood and thrombotic materials are not removed from the circulation [19]. In vitro experiments show that the Straub-Rotarex catheter is able to remove large volumes of thrombus with a limited risk of embolization. The Straub-Rotarex catheter can recanalize the native arterial or bypass-graft occlusion with promising long-term results. Nevertheless, its compatibility with a guide wire lessens the potential risk of vascular injury as compared with other high-speed rotational devices. The high rotational speed creates a negative pressure at the catheter distal side holes which brings the occlusion materials in contact with the spiral; the fragments are transported by the spiral to the proximal side port and discharged into a plastic bag [20,21]. With a guide wire leading, the catheter can negotiate tortuous vessels. In short, ATD is a liquid volume balance device but its limitation is potential of developing distal embolization, vascular injury and hemolysis. While Straub catheter is a feasibility one with guide wire control, however, its drawback is having procedure-related blood loss.

However, with PMT, some fragments of the thrombus may still remain; damage to venous valves is a potential sequelae. Here, in our study, we used PMT with antigrade access fashion to clear clots, which may do the least harm to the valves. Therefore, CDT combined with PMT may be the best way to clear the thrombus; it also decreases the dose of thrombolytic drugs required and shortens the duration of hospital stay compared to medication and single interventions. Muller-Hulsbeck et al. demonstrated that simultaneous rt-PA-enhanced thrombectomy is feasible in vitro. [22]. In our study, the urokinase dose was only 3.3 million IU, compared to doses of 7.8 million IU reported in the literature using catheter-directed thrombolysis. Additionally, the mean infusion time (39.4 h) was shorter than that previously reported (53.4 h). Furthermore, there was no major hemorrhage at the venous access site and no transfusions were required in our series. Other than a single episode of intracranial hemorrhage (0.97%, 1/103) during treatment, this therapy is well tolerated in massive lower limb DVT patients. Our study demonstrated a promising 75% (12/16) venous patency during the 13 months follow-up which is better than that seen in Mewissen's 1 year primary patency of 60% [8]. Post-thrombotic syndrome occurred in only 1 patient (6.2%), much better than the literatures used anticoagulation alone [3,4]. PMT combined with CDT has been reported to achieve better outcomes than mechanical thrombectomy alone, as the authors have noted five reocclusion occurred within the first 48 h (5/11) [9].

Lin et al. demonstrated that pharmacomechanical thrombectomy (the same mechanism as our therapy) is an effective

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treatment modality in patients with significant DVT. When compared with CDT, this treatment provides similar treatment success with reduced ICU, total hospital length of stay, and hospital costs [23]. Our mean lytic time and mean urokinase dose are similar with Kim et al.'s reports of catheter-directed thrombolysis with Angiojet (Possis Medical, Minneapolis, MN) percutaneous rheolytic thrombectomy [24].

This series showed the results of 3 malignancy patients: one died, two partial patent during follow-up. Patients whose DVT was secondary to underlying malignancy may have the worst prognosis. Therefore, catheter-directed thrombolysis with PMT seems not to be recommended as first-line therapy in such patients [25].

There are several limitations of our study. This study was not a double-blind prospective randomized case-controlled trial. Rather, it was a single-center retrospective study involving only a small number of subjects. There may have also been a patient selection bias, most of our patients have acute proximal DVTs rather than chronic ones. Some individuals who received this therapy but lost during follow-up cannot enrol the study. Based on these data alone, we cannot determine which of the two mechanical thrombectomy devices is superior. Therefore, a further prospective case-controlled study is warranted.

In conclusion, PMT with catheter-directed thrombolysis is to be effective and safe for the treatment of systematic DVT. Adjuvant therapy including venous PTA, stenting is necessary in selected cases.

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