Vascular Specialist International
Vol. 36, No. 3, September 2020
pISSN 2288-7970 • eISSN 2288-7989

Original Article

Safety and Efficacy of Aspiration Thrombectomy or Pharmacomechanical Thrombectomy after Catheter-Directed Thrombolysis for the Treatment of Acute Iliofemoral Deep Vein Thrombosis

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Purpose: To evaluate the safety and efficacy of additional aspiration thrombectomy (AT) or pharmacomechanical thrombectomy (PMT) after catheter-directed thrombolysis (CDT) for the treatment of acute iliofemoral deep vein thrombosis (AIFDVT).

Materials and Methods: Between May 2017 and December 2018, 40 patients with AIFDVT were enrolled. Twenty underwent AT after CDT (CDTAT), while the remaining 20 underwent PMT using an AngioJet™ device after CDT (CDTPMT). Thrombus clearance was assessed using computed tomography venography at 1 week after the procedure, as follows: grade I, ≤50%; grade II, 51% to 75%; grade III, >75%. Grade III was considered a successful outcome. Treatment outcomes (thrombus clearance, thrombolytic therapy duration, urokinase dose, major complications, residual filter thrombosis, and Villalta score) were compared between the groups.

Results: Successful thrombus clearance was achieved in 95% of the patients in both groups. Significant decreases in the thrombolytic therapy duration (P=0.018) and urokinase dose (P=0.014) were noted in the CDTPMT group. Major complications were not noted in both groups. Residual filter thrombi >10 mm were found in 6 filters in the CDTAT group and in 1 filter in the CDTPMT group (P=0.038). The Villalta scores at 6 months were 1.47±1.24 and 1.12±0.92 in the CDTAT and CDTPMT groups, respectively (P=0.372).

Conclusion: Both methods may be safe and effective management options for patients with AIFDVT. CDTPMT can reduce urokinase dosage, time and remained filter thrombus compared to CDTAT. Studies conducted in the future should compare the effects of overnight CDT followed by PMT with those of single-session PMT on patients with AIFDVT.

Key Words: Therapeutic thrombolysis, Mechanical thrombolysis, Aspiration thrombectomy, Deep vein thrombosis

Received June 15, 2020
Revised July 21, 2020
Accepted September 3, 2020

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Vasc Specialist Int 2020;36(3):144-150 • https://doi.org/10.5758/vsi.200041

INTRODUCTION

Acute iliofemoral deep vein thrombosis (AIFDVT) accounts for approximately 20% to 25% of all cases of deep vein thrombosis (DVT) and is associated with an increased risk of pulmonary embolism (PE) and post-thrombotic syndrome (PTS) [1]. Conventional therapy, which includes systemic heparin followed by oral anticoagulation, is considered the current standard of care for DVT. However, the thrombus removal rate is low when only anticoagulants are used, and the treatment duration may be as long as at least 3 months. This regimen is effective for thrombus propagation and prophylaxis against PE. However, the existing thrombus is not removed with this treatment, and the development of PTS is not prevented [2,3]. Accordingly, catheter-based interventions, including catheter-directed thrombolysis (CDT) and aspiration thrombectomy (AT) with a large-bore catheter, which may improve venous patency and preserve valve function and show strong potential for preventing PTS, have been widely accepted as treatment strategies for DVT, especially AIFDVT [4]. However, some significant limitations are associated with CDT, such as the risk of bleeding owing to prolonged thrombolytic agent exposure. AT also has some specific disadvantages, such as the need for large vascular sheaths and catheters, periprocedural blood loss, and vessel wall damage [5,6]. At times, it is difficult to effectively treat DVT with AT alone. These limitations have prompted the development of various thrombectomy devices. In particular, pharmacomechanical thrombectomy (PMT) using an AngioJet™ device (Boston Scientific, Marlborough, MA, USA) is a recent treatment option that is associated with lower systemic bleeding complication rates [7]. Moreover, a previous study has reported that treatment of residual blood clots with CDT after PMT reduced thrombolytic therapy duration and thrombolytic agent dose and showed relatively satisfactory results in the patients [8]. However, severe hemoglobinuria and renal dysfunction after PMT have been reported. It is possible that cell lysis induced with the use of the AngioJet mechanical thrombectomy device may have led to a sudden increase in the serum uric acid levels leading to uric acid nephropathy. Aggressive use of the AngioJet device may increase the risk of inducing red cell lysis, significant hemoglobinuria, and acute renal failure. In addition to known complications, such as bradycardia, hemorrhage, embolism, dissection, and perforation, the risk of acute renal failure should be considered when using the AngioJet device [9]. This study aimed to compare the treatment outcomes of additional AT using a large-bore catheter after CDT (CDTAT) and PMT using an AngioJet catheter after CDT (CDTPMT) for AIFDVT.

MATERIALS AND METHODS

1) Patient selection and evaluation

We retrospectively reviewed the medical records of all patients who had AIFDVT and underwent endovascular treatment between May 2017 and December 2018. Patients presenting with the first DVT episode in the femoral or a more proximal vein with symptoms for ≤14 days were enrolled. The AngioJet device has been used for treating DVT in our hospital since June 2018. Therefore, patients who underwent endovascular treatment before May 2018 were treated with CDTAT, while those who underwent treatment after June 2018 were treated with CDTPMT. Forty patients were included in this study. Of these patients, 20 (mean age, 66 years) were treated with CDTAT, while the remaining 20 (mean age, 68 years) were treated with CDTPMT. In all cases, DVT was diagnosed using computed tomography (CT) venography.

The degree of thrombus clearance was assessed using CT venography at 1 week after the procedure and graded as follows: grade I, ≤50% thrombus clearance; grade II, 51% to 75% thrombus clearance; grade III, >75% thrombus clearance. Grade III clearance was considered a technical success.

2) Complications

The safety outcomes were evaluated according to the development of bleeding complications. Major bleeding was defined as enough obvious bleeding to lead to death, surgery, cessation of therapy, or blood transfusion, including intracranial hemorrhage, gastrointestinal bleeding, and retroperitoneal hematoma. Minor bleeding was defined as less severe bleeding that could be managed with local compression, sheath upsizing, or dose alterations of the pharmacologic thrombolytic agent, anticoagulant, or antiplatelet drug [10].

3) Ethics

Before initiation of the study, ethical approval was obtained from the Institutional Review Board of Wonkwang University Hospital (IRB no. WKUH 2020-04-029).

4) Interventions

First, a retrievable inferior vena cava (IVC) filter was routinely placed. Next, the patient was positioned in the prone position; the ipsilateral popliteal vein was punctured under ultrasonographic guidance, and an 8-Fr hemostatic sheath

https://doi.org/10.5758/vsi.200041

was inserted. Subsequently, a 0.035-inch hydrophilic guidewire was passed through the lesion, and a multi-side-hole catheter (Boston Scientific) was placed in the thrombosed venous segment. Urokinase was used as the thrombolytic agent, and overnight CDT was performed with infusion of urokinase through the multi-side-hole catheter. In most cases, urokinase was administered continuously at 30,000 to 50,000 units/hour.

After overnight CDT, thrombectomy was performed using one of the following two methods: AT using an 8-Fr shuttle sheath (Cook, Bloomington, IN, USA) or PMT using an AngioJet thrombectomy catheter. AT was performed, as described below. After ascending venography was performed, an 8-Fr shuttle sheath was advanced over a 0.035-inch guidewire. The shuttle sheath was gently moved back and forth while maintaining a negative pressure using a 50-mL syringe. If the thrombus was not effectively removed, it was aspirated using an 11-Fr modified Arrow sheath (Teleflex, Morrisville, NC, USA). If a residual thrombus was found after the procedure, CDT was repeated for 4 hours or overnight.

PMT was performed, as described below. After ascending venography was performed using a hemostatic sheath, an 8-Fr AngioJet ZelanteDVT™ thrombectomy catheter was advanced into the thrombosed venous segment. The power pulse mode was initially used with 200,000 units of urokinase diluted in 200 mL of normal saline. PMT was performed using an AngioJet catheter. According to the manufacturer's instructions, the total activation time of the AngioJet catheter should not exceed 230 seconds. After thrombolysis, the stenotic lesions or residual thrombi in the iliac vein were treated using balloon angioplasty and stent insertion. The stent length and diameter were determined on the basis of the venography findings. Follow-up CT venography was performed at 1 week after the procedure. The IVC filter was removed when no thrombus was observed in the iliac or common femoral vein. Oral anticoagulants (rivaroxaban or edoxaban) were routinely administered for at least 6 months.

5) Clinical follow-up

Clinical follow-up was conducted at the outpatient clinic. At the 6-month follow-up visit, the symptoms and signs of PTS were examined by 2 vascular specialists and assessed using the Villalta score [11].

6) Statistical analysis

All statistical analyses were performed using IBM SPSS for Windows, version 20.0 (IBM Corp., Armonk, NY, USA). The data were presented as mean±standard deviation for continuous variables and as percentages for categorical variables. P-values <0.05 were considered statistically significant.

RESULTS

1) Patient and procedural characteristics

The clinical characteristics of the patients are presented in Table 1. The mean age, affected limb, and symptom duration did not differ between the groups. All baseline characteristics, except a history of malignancy were similar between the groups. In the CDTPMT group, DVT extended to the IVC in 9 (45.0%) patients. The procedural details are shown in Table 2. All patients underwent retrievable IVC filter insertion. Celect™ (Cook) and OPTEASE™ (Cordis, SantaClara, FL, USA) filters were used. In most patients, vascular access was achieved through the ipsilateral popliteal vein. However, vascular access was achieved through the ipsilateral femoral vein in 2 patients in the CDTPMT group

Table 1. Baseline characteristics of the patients and lesions

Characteristic	CDTAT (n=20)	CDTPMT (n=20)	P-value
Age (y)	66.85±14.050	68.7±15.9	0.699
Sex, female	9 (45.0)	12 (60.0)	0.527
Affected limb, right	3 (15.0)	3 (15.0)	1.0
Symptom duration (d)	6.4±5.78 (1-21)	5.4±5.6 (1-20)	0.584
Risk factor			
Malignancy	1 (5.0)	6 (30.0)	0.037
Previous stroke	1 (5.0)	1 (5.0)	1.0
Pulmonary embolism	10 (50.0)	8 (40.0)	0.525

Values are presented as mean±standard deviation, number (%), or median range.
CDTAT, aspiration thrombectomy after catheter-directed thrombolysis; CDTPMT, pharmacomechanical thrombectomy using an AngioJet™ device after catheter-directed thrombolysis.

Table 2. Procedural characteristics

Characteristic	CDTAT (n=20)	CDTPMT (n=20)	P-value
IVC filter insertion	20 (100.0)	20 (100.0)	1.0
Approach site			
Ipsilateral popliteal vein	20 (100.0)	18 (90.0)	
Ipsilateral femoral vein		2 (10.0)	
Duration of thrombolysis (h)	35.3±18.2	21.7±16.5	0.018
Total amount of urokinase (million IU)	2.03±0.96	1.32±0.75	0.014
Stent insertion	14 (70.0)	15 (75.0)	0.723
Self-expandable nitinol stent	11 (78.6)	4 (26.7)	
Wallstent	3 (21.4)	11 (73.3)	
Mean stent diameter (mm)	14.1±1.6	15.4±1.7	0.039
Mean stent length (mm)	7.2±1.5	7.4±1.4	0.741
Thrombus clearance rate			
Grade I: ≤50%	0	0	1.0
Grade II: 51%-75%	1	1	
Grade III: >75%	19	19	
Major complication (death, acute renal failure)	0	0	1.0
Villata score (6 months)	1.47±1.24	1.12±0.92	0.372

Values are presented as number (%) or mean±standard deviation.

CDTAT, aspiration thrombectomy after catheter-directed thrombolysis; CDTPMT, pharmacomechanical thrombectomy using an AngioJet™ device after catheter-directed thrombolysis; IVC, inferior vena cava.

because they could not tolerate the prone position.

Iliac vein stent implantation was performed in 29 patients. In our hospital, Wallstents (Boston Scientific) have been used for treating DVT since 2018. Accordingly, self-expandable nitinol stents (Protégé; ev3 Endovascular, Inc., Plymouth, MN, USA) were mainly used in the CDTAT group, and Wallstents were mainly used in the CDTPMT group. Therefore, the stent diameter was larger in the CDTPMT group than in the CDTAT group.

2) In-hospital outcomes

With respect to the efficacy outcomes, the degree of thrombus clearance was assessed using CT venography at 1 week after the procedure, as follows: grade I, ≤50%; grade II, 51% to 75%; grade III, >75%. Grade III clearance was considered a successful outcome. Successful thrombus clearance was achieved in 95% of the patients in both groups. As shown in Table 2, the thrombolytic therapy duration and total urokinase dose were significantly lower in the CDTPMT group than in the CDTAT group.

With respect to the safety outcomes, minor bleeding at the sheath insertion site in 2 (10.0%) patients in the CDTAT group was controlled by the application of a compression bandage. Gross hemoglobinuria from hemolysis caused by the AngioJet catheter was observed in 17 (85.0%) patients in the CDTPMT group; however, the urine color returned to normal within 24 hours after hydration. There were no significant changes in the serum creatinine levels. Bradycardia was observed in 1 (5.0%) patient. Other major complications, such as major bleeding, renal dysfunction, symptomatic PE, or mortality, were not observed.

The IVC filters were retrieved from all patients. During hospitalization, DVT recurrence was not observed in either group.

3) Clinical outcomes during follow-up

The mean follow-up duration was 14.3±5.3 months (range, 6 to 24 months). As the AngioJet has been used at our hospital since June 2018, the mean follow-up duration for the CDTPMT group (mean, 9.8±1.9 months) was shorter than that for the CDTAT group (mean, 18.8±3.3 months). Three patients (2 patients in the CDTAT group and 1 patient in the CDTPMT group) were lost to follow-up. With respect to primary patency, 1 patient in the CDTPMT group experienced recurrent DVT after self-discontinuation of oral anticoagulants at 5 months after the procedure. This patient was successfully treated with repeated CDTPMT. Therefore, the primary patency rates at 6 months were 100% and 95% in the CDTAT and CDTPMT groups, respectively, indicating no statistically significant difference (P=0.317; Fig. 1). With respect to PTS, the mean Villalta scores were 1.47±1.24 (range, 0 to 5) and 1.12±0.92 (range, 0 to 3) in the CDTAT

https://doi.org/10.5758/vsi.200041

and CDTPMT groups, respectively (P=0.372).

The IVC filters were removed at 1 to 3 weeks after their insertion. Filters removed from the CDTAT group showed relatively more thrombi than those removed from the CDTPMT group (Fig. 2). Follow-up CT venography at 6 months showed no recurrent thrombus formation in both groups.

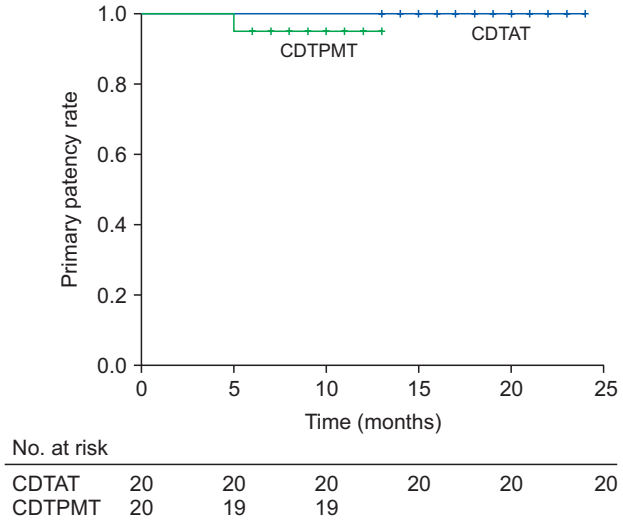

Fig. 1. Primary patency rates at 6 months were 100% and 95% in the CDTAT and CDTPMT groups, respectively, indicating no statistically significant difference. CDTAT, aspiration thrombectomy after catheter-directed thrombolysis; CDTPMT, pharmacomechanical thrombectomy using an AngioJet™ device after catheter-directed thrombolysis.

DISCUSSION

PMT or AT has been used as the initial approach for thrombus debulking or following CDT for residual thrombus removal. However, in our study, CDT was used as the initial approach for thrombus clearance followed by AT or PMT for residual thrombus removal. These treatment methods were found to be safe with respect to the risk of bleeding complications and effective with respect to the degree of thrombus clearance and prevention of PTS.

Manual AT using the pullback technique is an attractive approach for DVT treatment. However, pulmonary embolization of a small fragment is commonly noted during AT [12]. Additional CDT can be considered in cases in which AT is insufficient [13], as observed in the present study. Therefore, there was an increase in the thrombolytic therapy duration and total urokinase dose for the CDTAT patients in this study.

PMT using the AngioJet catheter is one of the latest treatment options for DVT that is associated with lower complication rates, especially the risk of systemic bleeding. The efficacy of AngioJet thrombectomy alone for DVT has previously been reported, although there is a wide disparity in the reported thrombus clearance rates (23.5% to 90.0%) [14]. Therefore, in many cases, additional CDT has been performed to remove the residual thrombi after PMT with the AngioJet device.

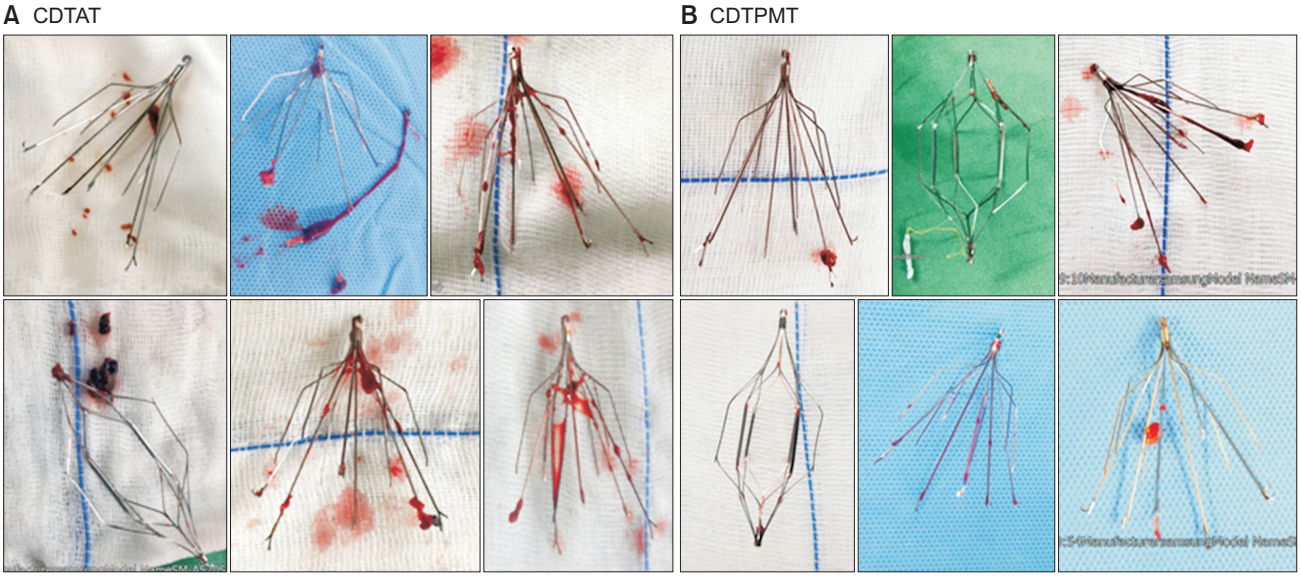

Fig. 2. Many thrombi were observed in the retrieved inferior vena cava (IVC) filters. (A) CDTAT, thrombi >10 mm were observed in 6 filters. (B) CDTPMT, a thrombus >10 mm was observed in 1 filter. CDTAT, aspiration thrombectomy after catheter-directed thrombolysis; CDTPMT, pharmacomechanical thrombectomy using an AngioJet™ device after catheter-directed thrombolysis.

It is known that the longer the duration of AngioJet use, the higher is the risk of severe hemoglobinuria and acute renal failure. To minimize these complications and maximize treatment efficiency, CDT was used as the first treatment approach in the present study. The thrombus was sufficiently dissolved using urokinase, and the residual thrombus was then effectively removed using AT or PMT. The total urokinase dose and thrombolytic therapy duration were significantly lower in the CDTPMT group than in the CDTAT group. Moreover, although the duration of AngioJet use was 150±20 seconds, effective thrombus removal was possible.

Major complications were not observed in both groups in this study. In some previous studies, patients undergoing CDT showed a major bleeding rate of 2% to 4% [15] and a minor bleeding rate of 14.6% [16]. In the present study, 2 (10.0%) patients in the CDTAT group experienced minor bleeding at the sheath insertion site, which was controlled by the application of a compression bandage, while no patient in the CDTPMT group experienced minor bleeding. Gross hemoglobinuria from hemolysis caused by the AngioJet catheter was observed in 17 (85.0%) patients in the CDTPMT group. However, the urine color returned to normal within 24 hours after hydration. A previous study reported major complications (acute renal failure, major bleeding, and uncontrolled severe hematuria) in patients after PMT [9]. However, major complications were not observed in patients after CDTPMT in the present study. This may be because of the short duration of AngioJet use (150±20 seconds) in the patients.

In this study, we used IVC filters as prophylaxis against serious PE. The IVC filters were inserted in all patients and then removed after 2 weeks of treatment. The number of residual thrombi in the retrieved IVC filters differed between the groups. A greater number of residual thrombi was observed in the IVC filters retrieved from patients in the CDTAT group than in those retrieved from patients in the CDTPMT group. Statistically, 6 blood clots larger than 10 mm were found in CDTAT and 1 in CDTPMT each filter (P=0.038; Fig. 2). This finding suggests that CDTPMT using the AngioJet device may provide better protection against distal thrombus embolization than does CDTAT; however, this suggestion should be validated by further studies. In PMT devices, a rheolytic system is used, and the Bernoulli effect is created that leads to thrombus maceration and aspiration through the holes on the sides of the catheter, thus, preventing distal embolization; however, with AT, the thrombus may be pushed distally while moving the large-bore catheter back and forth. Therefore, DVT patients with iliac vein stenosis (May–Thurner syndrome) may be treated with PMT using the AngioJet catheter after CDT without using IVC filters.

There are several limitations of this study. This was a single-center retrospective analysis with a small sample size and inherent selection bias. Moreover, the malignancy rates significantly differed between the groups. In addition, the follow-up period was relatively short, and only data regarding the 6-month outcomes were available. Deep vein reflux could not be assessed because vascular sonography was not performed during the follow-up. There were temporal changes in the devices used. Half of the enrolled patients underwent CDTAT with self-expanding stents (Protégé; ev3 Endovascular, Inc.) before May 2018, while the other half underwent CDTPMT with Wallstents after June 2018. Therefore, stent diameters was larger in the CDTPMT group than in the CDTAT group.

Owing to the availability of limited resources, we could not perform single-session PMT with a thrombolytic infusion and preferred overnight CDT followed by PMT. Our study protocol including overnight CDT may lead to higher rates of bleeding, and patients have to undergo 2 sessions of intervention rather than one. Furthermore, patients may experience discomfort from having a catheter in their popliteal area for the whole night without being able to flex their knees or change positions. However, compared to the effects of overnight CDT followed by PMT, the effects of single-session PMT in patients with AIFDVT are not clear to date. Moreover, major bleeding did not develop in the patients who underwent overnight CDT, which proved the safety of overnight CDT.

CONCLUSION

CDTAT and CDTPMT are safe with respect to the risk of bleeding complications and effective with respect to the degree of thrombus clearance and PTS prevention in management for patients with AIFDVT. In particular, CDTPMT can reduce the urokinase dose, time and filter-captured thrombus compared to CDTAT. Studies conducted in the future should compare the effects of PMT after overnight CDT with those of single-session PMT on patients with AIFDVT patients.

FUNDING

This paper was supported by Wonkwang Unversity in 2020.

CONFLICTS OF INTEREST

The authors have nothing to disclose.

https://doi.org/10.5758/vsi.200041

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AUTHOR CONTRIBUTIONS

Concept and design: JKL, SJB, KYK. Analysis and interpretation: SJB, KYK. Data collection: JKL, KYK. Writing the article: JKL, KYK. Critical revision of the article: SJB, KYK. Final approval of the article: all authors. Statistical analysis: none. Obtained funding: SJB. Overall responsibility: SJB.

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