Safety and efficacy of pharmacomechanical thrombolysis for acute and subacute deep vein thrombosis patients with relative contraindications

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**Abstract**

To evaluate the safety and efficacy of pharmacomechanical thrombolysis (PMT) performed for patients with relative contraindications. From June 2014 to December 2016, 112 patients with acute or subacute proximal deep vein thrombosis (DVT) were enrolled in this study. 60 patients (including 27 acute DVT patients and 33 subacute DVT patients) were treated with catheter-directed thrombolysis (CDT), and 52 patients with relative contraindications (including 25 acute DVT patients and 27 subacute DVT patients) with PMT. Assessment of venous recanalization was conducted using venography the time inferior vena cava filter is removed, and complications were used to compare safety and efficacy between the groups.

The outcomes of acute DVT patients no matter which kind of therapy performed, CDT or PMT, were significant better than subacute DVT patients ($P_{\text{CDT}} = .04$ and $P_{\text{PMT}} = .01$). However, there was no significant difference between CDT acute group and PMT acute group or between CDT subacute group and PMT subacute group ($P_{\text{acute}} = .80$ and $P_{\text{subacute}} = .84$). For complications of all patients, there was no mortality and major bleeding occurred.

PMT could be a safe and effective management for DVT patients with relative contraindications, and the acute DVT may achieve better outcomes when they receive CDT or PMT.

**Abbreviations:** CDT = catheter-directed thrombolysis, DVT = deep vein thrombosis, PMT = pharmacomechanical thrombolysis, PTA = percutaneous angioplasty, SAH = subarachnoid hemorrhage.

**Keywords:** catheter-directed thrombolysis, deep vein thrombosis, efficacy, pharmacomechanical thrombectomy, safety

1. Introduction

Deep vein thrombosis (DVT) is a common cardiovascular condition with an incidence of approximately 1 to 2 per 1000 persons per year, which is considered to be a significant source of mortality and morbidity. Anticoagulation is the standard management for DVT to prevent pulmonary embolism and recurrence of DVT, however its ineffectiveness at thrombus removal may prolong venous obstruction which may lead to post-thrombotic syndrome (PTS) even long-term morbidity.

Furthermore, there are 25% to 40% patients with DVT developing PTS within 2 years of the DVT episode, which may not only lead to high economic burden but also significantly reduce patients’ quality of lives. Especially iliofemoral or iliocaval DVT, with proportion up to 28% to 38%, may be related to more risk of pulmonary embolism and worse risk of PTS.

So far, catheter-directed thrombolysis (CDT) has been demonstrated to be an excellent way to effectively remove thrombus and significantly reduce the risk of PTS. However, CDT could be chosen to treat for only selected patients with iliofemoral DVT symptoms for <14 days, good functional status, life expectancy of >1 year, and low risk of bleeding. For patients with relative contraindications such as major trauma, major surgery, or aging patients, pharmacomechanical thrombolysis (PMT) may be a better option.

Based on former studies and our clinical experiment, this study was carried out aiming to evaluate safety and efficacy of PMT performed for patients with relative contraindications.

2. Materials and methods

This study was approved by the Institutional Committee of Ethics in Research. From June 2014 to December 2016, consecutive patients with DVT in Third Hospital of Hebei Medical University were prospectively enrolled in this study. Patients were included based on the following criterions:

1) with a definite diagnose of unilateral iliopoplantar or iliocaval DVT diagnosed using color duplex ultrasound imaging or ascending venography;
2) acute DVT (<15 days) or subacute DVT (15–30 days);
3) informed consent form obtained. CDT was chosen for treating patients with iliofemoral DVT symptoms, good functional status, age <70 and low risk of bleeding.
4) Moreover, based on the Clinical Practice Guideline of the Society for Vascular Surgery and the American Venous Forum as well as American College of Chest Physicians Guidelines on Antithrombotic Therapy, PMT was chosen for treating patients with contraindications defined as recent cerebrovascular event (including transient ischemic attacks), neurosurgery (intracranial, spinal), or intracranial trauma (<3 months); recent major surgery, obstetrical delivery, or major trauma (<10 days); and age >70.14–16

Low-molecular-weight heparin (LMWH) was routinely administered for each patient daily after admission and interventional therapies were performed as soon as possible. Inferior vena cava filter insertions were performed to prevent fatal pulmonary embolism. Balloon dilation and stent implantation would be performed after thrombolysis if there was an underlying iliac vein stenosis greater than 50% or occlusion. Postoperative systematic anticoagulant would be utilized for 3 to 6 months generally and it may extend to 6 to 12 months if iliac vein stent was implanted.

2.1. Interventional therapy

2.1.1. CDT. Percutaneous access was performed through popliteal vein or posterior tibial vein under guidance of ultrasound or venography. A 5F or 6F sheath was inserted and ascending venography was obtained to examine the extent and location of thrombus after puncture. A suitable multiple-sidehole infusion catheter was chosen and placed within the thrombosis vessel with the aid of fluoroscopy. Urokinase was infused through catheter at a dose of 200,000 U within 15 to 20 minutes intra-operatively, which would continue to be infused at a rate of 600,000 U to 1,200,000 U per day postoperatively. Unfractionated heparin was infused simultaneously through the access sheath at a dose of 125 U/h to prevent thrombus formation. The activated partial thromboplastin time (aPTT), hemoglobin, fibrinogen level, and platelet count were examined every 4 to 8 hours. Moreover, venography was performed via the sheath daily, based on types and doses of anticoagulation were modified. (Fig. 1)

2.1.2. AngioJet Ultra Thrombectomy. AngioJet system was performed by standard procedure. AngioJet catheter was inserted into the thrombosis vessel through the guide wire and thrombolytic therapy (200,000 U urokinase per 50 mL saline) was infused for 20 minutes. Then PMT was performed as catheter’s first Mark near the thrombosis vessel at a rate of 2 mm/s.

In each procedure, percutaneous angioplasty (PTA) was performed when significant stenosis existed. And if there was residual stenosis of over 70% after repeat PTA, stenting could be adapted. (Fig. 2)

2.1.3. Assessment of venous recanalization. The outcome assessments were conducted by using venography the time Inferior vena cava filter being removed. Definition of successful recanalization is that residual thrombus has no influence on patency after clot lysis. The results of thrombolysis based on the residual thrombus in venous including popliteal vein, femoral vein, external iliac vein, and iliac vein, which were categorized as follows: level I means total length or multi-segment cumulative length of residual thrombus less than 1 cm with no influence on patency; level II means total length or multi-segment cumulative length of residual thrombus was more than 1 cm and less than 2 cm.

Figure 1. A 49-year-old man, who received internal fixation treatment for right femoral neck fracture 22 days ago, was diagnosed as subacute proximal DVT based on color duplex ultrasound imaging. It was confirmed by ascending venography, and CDT was performed after IVC implantation. (a) Initial venography revealed irregular stenosis of right superficial femoral vein. (b) After 5-day CDT treatment, venography was performed and there was almost no irregular stenosis except a residual thrombus less than 2 cm. This patient achieved successful recanalization with level II after treatment. CDT = catheter-directed thrombolysis, DVT = deep vein thrombosis, IVC = inferior vena cava.
cm with no influence on patency; level III means total length or multi-segment cumulative length of residual thrombus more than 2 cm and less than 3 cm with no influence on patency; level IV means total length or multi-segment cumulative length of residual thrombus more than 3 cm and less than 4 cm with no influence on patency; level V means total length or multi-segment cumulative length of residual thrombus more than 4 cm with a slight influence on patency and the reduction effect with thrombolysis achieved; level VI any length of residual thrombus means significant influence on patency with no reduction effect.

2.2. Complications
The safety outcomes were evaluated by the occurrence of bleeding complications.[17] Major bleeding was defined as obvious bleeding enough leading to death, surgery, cessation of therapy, or blood transfusion including intracranial hemorrhage, gastrointestinal bleeding and retroperitoneal hematoma. It was considered as minor bleeding complications that other less severe bleeding events could be manageable with local compression, sheath upsizing, or dose alterations of a pharmacologic thrombolytic agent anticoagulant, or antiplatelet drug.

2.3. Statistical analysis
Statistical analysis was performed using SPSS 22.0 software (IBM Corp., Armonk, NY). Continuous data including age and durations were reported as means ± standard deviation, and their significant difference was verified using Student t test. Nominal data including clinical characteristics and predisposing factors of patients were reported as the number of subjects and were analyzed using Wilcoxon–Mann–Whitney test. Statistical significance was defined a P value of <.05.

3. Results
One hundred twelve patients including 59 males and 53 females were enrolled in our study. 60 patients with 27 acute DVT and 23 subacute DVT were performed with CDT. 52 patients with relative contraindications such as major surgery recently including 25 acute DVT and 27 subacute DVT were treated with PMT.

Table 1
Patients demographics.

|                | CDT (n=60) | PMT (n=52) |
|----------------|------------|------------|
|                | Acute (n=27) | Subacute (n=33) | Acute (n=25) | Subacute (n=27) |
| Age            | 59.04±7.23  | 59.45±6.79  | 64.40±13.37 | 65.11±12.99   |
| Sex (M/F)      | 15/12      | 17/16      | 14/11       | 15/12         |
| Psubacute      | .97        | .75        | .42         | .93           |
| Side (L/R)     | 17/10      | 18/15      | 13/12       | 15/12         |
| Duration       | 6.44±3.70  | 20.52±5.30 | 7.04±3.28   | 20.15±3.54    |
| Psubacute      | .54        | .75        | .54         | .75           |

Psubacute presents the difference between CDT acute group and CDT subacute group. Pacute presents the difference between PMT acute group and PMT subacute group. PMT = pharmacomechanical thrombolysis.
significant difference was not found for age between acute DVT patients and subacute DVT patients (both CDT and PMT groups). There was no significant difference in duration between CDT acute group and PMT acute group or between CDT subacute group and PMT subacute group. However, durations of CDT subacute group and PMT subacute group were significantly longer than CDT acute group and PMT acute group.

As listed in Table 2, significant difference was not found in comparison of comorbidities among the groups with respect to hypertension, CAD, dyslipidemia, diabetes, thrombophilia, or May-Thurner syndrome. Clinical characteristics of patients receiving PMT were listed in Table 3. There was no significant difference between those 2 groups regarding to total knee arthroplasty (TKA), total hip arthroplasty (THA), femoral fracture, pelvic fracture, >70 years, or subaracnoid hemorrhage.

Assessments of venous recanalization were listed in Table 4. The outcomes of acute DVT patients with CDT or PMT were significantly better than subacute DVT patients (both CDT and PMT groups). The thrombectomy outcomes of acute DVT patients were better than subacute DVT patients in both therapeutic methods.

4. Discussion
The most important finding of our study is that patients with relative contraindications treated by PMT may achieve a similar thrombectomy efficacy with regular patients treated by CDT, and the thrombectomy outcomes of acute DVT patients were better than subacute DVT patients in both therapeutic method. Therefore, a better thrombectomy outcome would be achieved is the time PMT applied in acute phase for iliofemoral or iliocaval DVT patients with relative contraindications. A clinical significance of management for iliofemoral or iliocaval DVT patients with relative contraindications may happen.

### Table 2
Clinical characteristics and predisposing factors of patients.

|                     | CDT (n = 60)                  | PMT (n = 52)                  | *p*<sub>acute</sub> | *p*<sub>subacute</sub> |
|---------------------|------------------------------|------------------------------|---------------------|-------------------------|
|                     | Acute (n = 27)               | Subacute (n = 33)            |                     |                         |
| Smoking             | 7                            | 5                            | 6                   | 8                       | .33 | .65 |
| Immobilization      | 5                            | 8                            | 6                   | 6                       | .28 | .19 |
| Hypertension        | 10                           | 8                            | 9                   | 11                      | .73 | .17 |
| CAD                 | 3                            | 5                            | 3                   | 4                       | .61 | .28 |
| Dyslipidemia        | 11                           | 15                           | 12                  | 10                      | .77 | .51 |
| Diabetes            | 5                            | 7                            | 5                   | 8                       | .71 | .42 |
| Thrombophilia       | 1                            | 2                            | 0                   | 0                       | .72 | .04 |
| May-Thurner syndrome| 8                            | 6                            | 9                   | 6                       | .30 | .27 |

### Table 3
Clinical characteristics of patients received PMT.

|                  | Acute (n = 27) | Subacute (n = 27) | *p*<sub>acute</sub> |
|------------------|----------------|-------------------|---------------------|
| TKA              | 4              | 3                 | .61                 |
| THA              | 6              | 7                 | .99                 |
| Femoral fracture | 7              | 6                 | .63                 |
| Pelvic fracture  | 5              | 5                 | .89                 |
| >70 years        | 4              | 5                 | .81                 |
| Subaracnoid hemorrhage | 1 | 3 | .34 |

*p*<sub>CDT</sub> presents the difference between CDT acute group and CDT subacute group.

*p*<sub>PMT</sub> presents the difference between PMT acute group and PMT subacute group.

*p*<sub>acute</sub> presents the difference between CDT acute group and PMT acute group.

*p*<sub>subacute</sub> presents the difference between CDT subacute group and PMT subacute group.

CDT = catheter-directed thrombolysis, PMT = pharmacomechanical thrombolysis, TKA = total knee arthroplasty, THA = total hip arthroplasty.
PTS is 1 of the most common sequelas of iliofemoral or iliocaval DVT, which may result from venous valvular incompetence, VO obstruction, and calf muscle pump dysfunction following an acute episode of DVT.\(^{11}\) The severity of PTS relates to the recovery of venous obstruction and developments of collateral bypass veins.\(^{11}\) The rates of PTS following iliofemoral DVT was ranging from 25% to 46% when they are conservatively treated by anticoagulation.\(^{7,20}\) Although application of CDT has been demonstrated rapid and effective dissolution of thrombus and significantly reducing rates of PTS,\(^{19}\) according to guidelines of the American College of Chest Physicians, CDT can be chosen for treating patients with iliofemoral DVT symptoms for <14 days, good functional status, life expectancy of >1 year, and low risk of bleeding.\(^{14}\) In clinic, some contradictions exist.

With an aged population as well as expanding indications, there is expected increase in the number of aged patients receiving orthopedic surgery such as arthroplasty, especially in our hospital specialized in orthopedic. As for orthopedics, the rates of DVT are relatively high even in the absence of prophylaxis.\(^{21}\) When it comes to the aging patients undergoing orthopedics surgery, the rates may be much higher. Therefore, for DVT patients with >70 years, subarachnoid hemorrhage (SAH), or undergoing arthroplasty, it is a real severe problem to avoid PTS.

There are different kinds of PMT devices with their own advantages each,\(^{21}\) and the Angiojet rheolytic thrombectomy system (Boston Scientific) might still be a widely utilized thrombectomy device introduced in 1996. Bunch of studies have been done to determine the outcome of PMT (most were Angiojet) with inspiring results. Tzu-Ting Kuo et al found that CDT and PMT have similar venous outcomes in patients with acute iliofemoral DVT, although PTS is less severe following PMT than after CDT.\(^{18}\) The study of Eric Hager et al suggested that PMT may have the same efficiency as CDT in preserving valve function and preventing PTS.\(^{22}\) Study of Chun-Yang Huang et al showed that there is a similar treatment efficiency for PMT with CDT, but the rate of PTS was lower.\(^{23}\) What is more, David Vogel et al also found a similar conclusion that PMT may have advantages in protecting valve function compared with CDT.\(^{24}\) Studies mentioned above are much more focused on the comparison between CDT and PMT.\(^{23}\) Only few authors isolated patients with relative contraindications including >70 years, subarachnoid hemorrhage (SAH), or undergoing arthroplasty. Based on our promising results, those patients treated by PMT could have the same thrombus removal efficacy as patients without contraindication treated by CDT.

For the diagnosis of DVT mostly based on symptom duration, duplex ultrasound imaging and D-dimer level,\(^{23}\) the diagnosis time of the lower extremity DVT may be later than its occurrence. Current DVT staging system is based on symptom duration and the definition of DVT stages might be relative. However, it could significantly affect safety and efficacy of thrombolysis that stratifies patient selection criteria and timing of intervention. Treatment of acute DVT could result in a better outcome than subacute DVT,\(^{24}\) the same result as our study. No matter what kind of therapy they received, thrombus removal of most acute DVT patients achieved level I or level II, while subacute DVT patients level III or level IV.

|          | I     | II    | III   | IV    | V     | VI    | P     |
|----------|-------|-------|-------|-------|-------|-------|-------|
| CDT      |       |       |       |       |       |       |       |
| Acute    | 7 (25.9%) | 9 (33.3%) | 4 (14.8%) | 2 (7.4%) | 1 (3.7%) |       | \(P_{\text{CDT}} = .04\) |
| Subacute | 2 (6.1%)  | 4 (12.1%) | 10 (30.3%) | 8 (24.2%) | 7 (21.2%) | 2 (6.1%) | \(P_{\text{CDT}} = .04\) |
| PMT      |       |       |       |       |       |       |       |
| Acute    | 10 (40.0%) | 8 (32.0%) | 3 (12.0%) | 2 (8.0%) | 2 (8.0%) | 0 (0.0%) | \(P_{\text{CDT}} = .01\) |
| Subacute | 2 (7.4%)  | 4 (14.8%) | 3 (29.6%) | 7 (25.9%) | 4 (14.8%) | 2 (7.4%) | \(P_{\text{CDT}} = .04\) |

\(P_{\text{CDT}}\) presents the difference between CDT acute group and CDT subacute group.
\(P_{\text{PMT}}\) presents the difference between PMT acute group and PMT subacute group.
\(P_{\text{Subacute}}\) presents the difference between subacute group.

\(\text{CDT} = \text{catheter-directed thrombolysis, PMT = pharmacomechanical thrombolysis.}\)

### Table 4

**Assessment of venous recanalization.**

### 5. Conclusions

PMT could be a safe and effective management for DVT patients with relative contraindications, and the acute DVT may achieve better outcomes when they receive CDT or PMT.

### Author contributions

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