AngioJet Thrombectomy Versus Catheter-Directed Thrombolysis for Lower Extremity Deep Vein Thrombosis: A Meta-Analysis of Clinical Trials

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Abstract
Early catheter-directed thrombolysis (CDT) for lower extremity deep vein thrombosis (LEDVT) can reduce post-thrombotic morbidity and the AngioJet thrombectomy is a new therapy that can be selected for the treatment of LEDVT. We performed a systematic review and meta-analysis of clinical trials comparing AngioJet versus CDT to assess the efficacy and safety of AngioJet thrombectomy. We systematically searched PubMed and Embase for clinical trials that published before November 1, 2020 and compared AngioJet thrombectomy and CDT in the treatment of LEDVT. We meta-analyzed effective rate of treatment, serious complications, PTS, Villalta score, duration of treatment and drug dose. AngioJet does not result in a significant difference in the effective rate (OR 1.00, CI 0.73-1.36, P = 0.98; I² = 0%) and complications (OR 1.16 CI 0.84-1.61, P = 0.36; I² = 39%) compare to CDT. And there was a statistically significant decrease in incidence of PTS (OR 0.58 CI 0.37-0.91, P = 0.02; I² = 0%) and Villalta score (OR −1.86 CI −3.49 to −0.24, P = 0.02; I² = 34%) for AngioJet compared to CDT. In addition, there was a statistically significant decrease in duration of the treatment (OR −2.45 CI −2.75 to −2.15, P < 0.0001; I² = 95%) and drug dose (OR −3.15 CI −3.38 to −2.93, P < 0.0001; I² = 98%) between AngioJet and CDT. AngioJet results in a low severity of PTS compared to CDT therapy. Moreover, the average duration of treatment and thrombolysis time was shorter in the AngioJet group compared to the CDT group. However, the AngioJet group was not significantly different in effective rate of treatment and serious complications compared to the CDT group.

Keywords
AngioJet, catheter-directed thrombolysis, deep vein thrombosis

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Introduction
Lower extremity deep venous thrombosis (LEDVT) is a common disease with an incidence of 1/1000 in adults each year and leads to significant morbidity and mortality.¹ The associated mortality could be as high as 14.6% each year.² It can impact the daily routine and lead to consequential complications, such as varicosity, limitation in activity, post thrombotic syndrome (PTS), and even pulmonary embolism (PE).³ The standard treatment of DVT includes anticoagulation and graduated compression stockings.⁴ However, anticoagulation can only prevent thrombus extension. It can’t eliminate existing thrombus, leading to venous valvular insufficiency and PTS.⁵

By contrast, catheter-directed thrombolysis (CDT) can rapidly obtain a more complete thrombolysis than that by anticoagulation because of direct thrombus clot lysis, but the potential risk of hemorrhage can be life threatening.⁶

Percutaneous mechanical thrombectomy (PMT) has been an alternative method for treatment of DVT. PMT include different percutaneous devices for removal of thrombus including suction, rotation, rheolytic thrombectomy, and ultrasound. AngioJet device is a method of rheolytic thrombectomy. It was inserted to the thrombus lesion and the operation continued

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with a solution of Urokinase. The design of AngioJet device is such that it allows for thrombus fragmentation and rapid evacuation through the effluent lumen.

The potential benefits of PMT include shorter procedural time, lower thrombolytic dosage, lower associated systemic effects, lower cost, and more complete resolution of the thrombus. However, no recommendations for PMT were made for the treatment of LEDVT in the tenth edition of the American College of Chest Physicians guidelines.

There have been a few meta-analysis of PMT for LEDVT. However different devices have disparate effects and are not suitable for discussion together. The aim of this meta-analysis was to summarize the application of AngioJet versus CDT in LEDVT and to assess the efficacy and safety of the treatment.

**Methods**

**Literature Search**

Literature published before November 1, 2020, was searched using PubMed and Embase. The search terms included the following: ((mechanical thrombectomy OR rheolytic thrombectomy OR percutaneous mechanical thrombectomy OR ANgioJet OR AngioJet) AND (Venous Thrombosis)) AND ((CDT OR Catheter-Directed Thrombolysis) AND Venous Thrombosis). No language restrictions were enforced. Inclusion criteria were studies comparing AngioJet (experimental group) with CDT (control group) and presence of intact clinical data.

The abstracts for potential inclusion in the study were assessed, and then the full texts of the studies were reviewed. The reference lists were also examined for potential additional studies. Two investigators independently extracted data: number of patients in experimental group and control group, study quality, time of follow-up, effective rate of treatment (the clearance rate of thrombotic ≥ 50% or complete improvement of symptoms), serious complications (Including acute kidney injury, limb loss, bacteremia and major bleed. Minor bleed and hemoglobinuria were not included in the study.), PTS, Villalta, duration in treatment and drug dose.

**Data Extraction and Quality Assessment**

Details of the publication, inclusion and exclusion criteria, demographics of the study participants, interventions, and outcomes were collected and reviewed. Risk of bias in the studies (including masking of participants, intention-to-treat analysis, incomplete or unclear data, and time to follow-up) was also assessed. Study quality was assessed by the Newcastle-Ottawa Scale (NOS). Disagreements between reviewers were resolved by consensus.

**Statistical Analysis**

Review Manager 5.3 software was used for meta-analysis. Outcomes were analyzed using odds ratios or standardized mean difference, and all effects were represented by 95% CI. The I² test was used to measure the statistical heterogeneity. A fixed-effects model was used when no significant heterogeneity (I² < 50%) existed among the studies. Otherwise, a random-effects model was used. Stata 12.0 (Stata Corporation, College Station, TX) was used to except for the risk of bias.

**Bias Analysis**

Funnel, Galbraith and L’abbe plot analysis was conducted for the studies with more than 10 articles. Begg-adjusted rank correlation test was used for quantitative analysis of funnel plots. Pr value >0.05 indicated no publication bias.

**Results**

**Description of the Studies**

The initial search strategy identified 146 articles; 12 trials satisfied the appropriate criteria for inclusion in the meta-analysis (Figure 1). These studies included experimental groups that received AngioJet therapy for DVT and control groups that received CDT therapy for DVT and all of them is retrospective review. Table 1 shows the baseline characteristics for each study. The qualities of trials were assessed by NOS score.

**Outcomes**

**Effective Rate of Treatment**

The judgments on efficacy are various, and the clearance rate of thrombotic ≥50% or complete improvement of symptoms is taken as the standard in our study. Ten trials reported the effective of treatment.

Meta-analysis indicated that AngioJet not result in a significant difference in the effective rate (OR 1.00, CI 0.73-1.36, P = 0.98; I² = 0%) compare to CDT. Results of the meta-analysis of the effective rate are shown in Figure 2.

As Figure 3 shows that Pr = 0.917 and indicates no publication bias in the effective rate.
## Table 1. Characteristics of Included Clinical Trials.

| Study       | Group   | Sample | Design   | Follow-up | Effective rate of treatment | Serious complications | PTS | Villalta score | Duration of treatment | Thrombolytic drug | Drug dose | NOS |
|-------------|---------|--------|----------|-----------|----------------------------|-----------------------|-----|----------------|-----------------------|-------------------|-----------|-----|
| Garcia, M. J. | AngioJet CDT | 115    | Retrospective | 12        | 109                         | NA                    | NA  | NA             | NA                    | Urokinase          | NA        | 7   |
| Huang, C. Y. | AngioJet CDT | 16     | Retrospective | 12        | 16                          | 0                     | NA  | 2.06 ± 2.95   | NA                    | Urokinase          | 17.973 ± 2.31 | 8   |
| Kuo, T. T.   | AngioJet CDT | 30     | Retrospective | 24        | 27                          | 14                    | 6   | 1.87 ± 2.7    | NA                    | Urokinase          | 27.635 ± 6.78 | 8   |
| Lin, P. H.   | AngioJet CDT | 52     | Retrospective | NA        | 39                          | 2                     | NA  | 1.27 ± 0.56   | 18 ± 8                | Urokinase          | NA        | 8   |
| Liu, X.      | AngioJet CDT | 52     | Retrospective | NA        | 44                          | 0                     | NA  | NA             | NA                    | Urokinase          | NA        | 8   |
| Pouncy, A. L. | AngioJet CDT | 70     | Retrospective | 12        | 55                          | 25                    | 55  | NA             | NA                    | Urokinase          | NA        | 7   |
| Wang, S.     | AngioJet CDT | 11     | Retrospective | 19.3      | 8                           | 0                     | NA  | NA             | NA                    | Urokinase          | NA        | 7   |
| Xu, Y.       | AngioJet CDT | 186    | Retrospective | 19        | 190                         | 19                    | 10  | NA             | NA                    | Urokinase          | 95.16 ± 45.89 | 7   |
| Yin, X.      | AngioJet CDT | 94     | Retrospective | 16        | 91                          | 12                    | 8   | 62.4 ± 28.8   | 163.2 ± 72           | Urokinase          | 15 ± 5    | 9   |
| Zhu, J.      | AngioJet CDT | 32     | Retrospective | NA        | 29                          | 6                     | NA  | 4.2 ± 1.7     | 73.6 ± 18.3          | Urokinase          | 0.264 ± 0.135 | 8   |
| Escobar, G. A. | AngioJet CDT | 52     | Retrospective | NA        | 15                          | NA                    | NA  | NA             | Urokinase              | NA                | 1.869 ± 0.528 | 6   |
| Morrow, K. L | AngioJet CDT | 15     | Retrospective | NA        | 3                           | NA                    | NA  | NA             | Urokinase              | NA                | NA        | 6   |
Serious Complications

The complications of AngioJet involve renal failure, PE, major bleeding, acute stent thrombosis, etc. CDT will be in such danger as PE, bacteremia, major bleeding and limb loss, etc. Hemoglobinuria, minor bleed and other complications that needn’t extra processing are excluded from the study.

The complications are show in Figure 4. Eleven studies\(^8,13-22\) included the results of complications. There was no result
in a significant difference in complications (OR 1.16 CI 0.84-1.61, $P = 0.36; I^2 = 39\%$) between AngioJet and CDT.

As Figure 5 shows that $P_r = 0.858$ and indicates no publication bias in the complications.

**PTS and Villalta Score**

Four studies$^{4,16,18,19}$ included the results of PTS, and 2 studies$^{13,14}$ included the results of Villalta score. There was a
statistically significant decrease in incidence of PTS (OR 0.58 CI 0.37-0.91, \(P = 0.02; I^2 = 0\%\)) and Villalta score (OR -1.86 CI -3.49 to -0.24, \(P = 0.02; I^2 = 34\%\)) for ANGIOJET compared to CDT. The results of the meta-analysis are shown in Figures 6 and 7.

**Discussion**

With the increase of age and risk factors, DVT has become the third most common vascular disease. Traditional anticoagulation can reduce the occurrence of PE and PTS. However, it cannot clear the thrombus, and the incidence of PTS within 2 years is as high as 40\%.\(^3\) PTS is the result of venous outflow obstruction, venous reflux, and calf muscle pump dysfunction after severe DVT. Treatment with thrombolysis is aimed to lower PTS morbidity.\(^2\)

With the accumulation of clinical experience and the development of scientific and technological devices, people’s treatment ideas for LEDVT are changing constantly. At present, the treatment of LEDVT is interventional therapy on the basis of traditional anticoagulation, so as to achieve the purpose of rapid removal of thrombus.

CDT is the most widely used method of thrombolysis, with an effective rate of 85\% \(\sim\) 90\%. Because it can quickly clear

**Table:**

| Study or Subgroup | AngioJet | CDT | Mean Difference IV, Random, 95% CI |
|-------------------|----------|-----|----------------------------------|
| Huang, C.Y.2015   | 2.06     | 2.95| -1.86 [-3.49, -0.24]             |
| Kuo, T.T.2017     | 1.87     | 2.7 | -1.26 [-2.69, 0.17]              |
| Total             | 46       | 49  | 100.00%                          |
| Heterogeneity: Chi^2 = 0.52, df = 1 (P = 0.22); P = 34% |
| Test for overall effect: Z = 2.26 (P = 0.02) |

**Figure 7.** Meta-analysis of Villalta score (OR -1.86 CI -3.49 to -0.24, \(P = 0.02; I^2 = 34\%\)).

**Figure 8.** Meta-analysis of duration of the treatment (OR -2.45 CI -2.75 to -2.15, \(P < 0.0001; I^2 = 95\%\)).

**Figure 6.** Meta-analysis of PTS (OR 0.58 CI 0.37-0.91, \(P = 0.02; I^2 = 0\%\)).

**Table:**

| Study or Subgroup | AngioJet | CDT | Std. Mean Difference IV, Fixed, 95% CI |
|-------------------|----------|-----|-------------------------------------|
| Lin, P.H.2006     | 1.27     | 0.56| -3.01 [-3.61, -2.41]                |
| Yin, X.2018       | 0.24     | 0.28| -1.91 [-2.27, -1.54]                |
| Zhu, J.2020       | 4.2      | 1.7 | -5.24 [6.28, -4.19]                 |
| Total             | 175      | 153| 100.00%                             |
| Heterogeneity: Chi^2 = 38.99, df = 2 (P < 0.00001); P = 95% |
| Test for overall effect: Z = 16.05 (P < 0.00001) |

**Figure 9.** Meta-analysis of drug dose (OR 3.15 CI 3.38 to 2.93, \(P < 0.0001; I^2 = 98\%\)) for Angiojet compared to CDT. The results of the meta-analysis are shown in Figures 8 and 9.

**Figure 8.** Meta-analysis of duration of the treatment (OR -2.45 CI -2.75 to -2.15, \(P < 0.0001; I^2 = 95\%\)).

**Figure 7.** Meta-analysis of Villalta score (OR -1.86 CI -3.49 to -0.24, \(P = 0.02; I^2 = 34\%\)).

**Figure 6.** Meta-analysis of PTS (OR 0.58 CI 0.37-0.91, \(P = 0.02; I^2 = 0\%\)).
the thrombosis, without damaging the valve and venous wall, and reduce the occurrence of complications, it has gradually become the preferred treatment method for clinicians. Xu y. and others through the CDT for 238 cases of acute lower extremity deep vein thrombosis patients treated, 198 patients (83.91%) thrombolysis rate of Grade II magnitude, only 23 cases (9.66%) of patients with bleeding complications, and no fatal complications.24 Jun Zhu et al treated 33 patients with deep venous thrombosis of lower extremities, and the majority of patients with thrombus dissolution was up to 97.20 It indicated that CDT had high safety and effectiveness in the treatment of LEDVT. However, its clinical application still has certain limitations. In the treatment process, patients need to undergo multiple angiography examinations to clarify the effect of thrombolysis, which increases the X-ray exposure and nursing cost of patients and operators, and the use of long-term urokinase also increases the risk of bleeding in patients.25

AngioJet is widely used. The device is divided into pulse and thrombectomy. Thrombectomy can quickly clear the thrombus and restore venous access. The operation is simple, the treatment efficiency is high, and will not cause serious damage to the vein wall and valve. However, bradycardia and hemoglobinuria may be caused due to the destruction of red blood cells by saline high-pressure injection, and the degree of hemolysis increases with the extension of operation time, leading to renal function injury in severe cases. Current studies have found that AngioJet has sufficient safety in the treatment of acute and subacute LEDVT, and can effectively remove thrombosis and reduce the operation time and complications.19,26

Although many studies have confirmed the advantages of AngioJet in LEDVT treatment, there are also many studies that have debated the advantages and disadvantages of the 2 approaches. Our meta-analysis, based on 12 comparative studies, compared AngioJet to CDT for the treatment of LEDVT.

Ten trials8,12-20 included the results of complications. AngioJet does not result in a significant difference in the effective rate (OR 1.39, CI 0.73-2.62, P = 0.31; I² = 66%) and complications (OR 1.16 CI 0.84-1.61, P = 0.36; I² = 39%) compare to CDT. Both methods are effective in treating LEDVT. They can clear blood clots rapidly and relieve patients’ symptoms. The complications of AngioJet mainly reflect in hemoglobinuria. The degree of hemolysis increased with the prolongation of operation time due to the destruction of red blood cells by saline high-pressure injection. CDT mainly involves minor bleeding attributed to the use of thrombolytic drugs. Neither hemoglobinuria nor minor bleeding requires additional treatment and will not bring greater burden to patients. So, they were not taken into account in our study. From the point of serious complications, there is no obvious difference between AngioJet and CDT.

Six trials reported the follow-up time. The mean time of it ranged from 12 months to 24 months. Our meta-analysis indicated that there was a statistically significant decrease in incidence of PTS (OR 0.58 CI 0.37-0.91, P = 0.02; I² = 0%) and Villalta score (OR −1.72 CI −2.69 to −0.50, P = 0.006; I² = 34%) for AngioJet compared to CDT. Our results showed that AngioJet reduced the severity of PTS compared to CDT. It may associate with the principle of AngioJet. The thrombosis is segmenting by thrombolytics, so that the thrombolytic drugs can be in full contact with the thrombosis and achieve better therapeutic effect.

AngioJet can quickly clear the thrombus and restore venous access. In our meta-analysis, duration of treatment (OR −3.31 CI −4.88 to −1.74, P < 0.0001; I² = 95%) and drug dose (OR −3.09 CI −4.64 to −1.53, P < 0.0001; I² = 98%) were significantly shorter in the AngioJet group compared to CDT. This may have been caused by the reduction in treatment time in the AngioJet group. The shorter duration of treatment stay may decrease the economic burden of patients without health insurance.

Our meta-analysis had limitations. There were no RCTs in this meta-analysis, and the quality of studies was not high. Therefore, the data from the non-RCTs with lower quality may affect the results of the meta-analysis. In addition, we did not carefully explore the sources of heterogeneity. And, study quality, sample size of the studies, and follow-up time may be important factors influencing the results of the meta-analysis. What’s more, because the criteria for each study were different, we simplified the results as effective rate of treatment and serious complications. It may bias the results of the study. So, High-quality RCTs are required to reduce heterogeneity and provide more reliable data.
Conclusion

This meta-analysis demonstrates that AngioJet results in a low severity of PTS compared to CDT therapy. Moreover, the average duration of treatment and thrombolysis time was shorter in the AngioJet group compared to the CDT group. However, the AngioJet group was not significantly different in effective rate of treatment and serious complications and compared to the CDT group.

Declaration of Conflicting Interests

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