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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, $P = 0.98$; $I^2 = 0\%$) and complications (OR 1.16 CI 0.84-1.61, $P = 0.36$; $I^2 = 39\%$) compare to CDT. And there was a statistically significant decrease in incidence of PTS (OR 0.58 CI 0.37-0.91, $P = 0.02$; $I^2 = 0\%$) and Villalta score (OR -1.86 CI -3.49 to -0.24, $P = 0.02$; $I^2 = 34\%$) for AngioJet compared to CDT. In addition, there was a statistically significant decrease in duration of the treatment (OR -2.45 CI -2.75 to -2.15, $P < 0.0001$; $I^2 = 95\%$) and drug dose (OR -3.15 CI -3.38 to -2.93, $P < 0.0001$; $I^2 = 98\%$) 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 Urokinasee. 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.[7,8] However, no recommendations for PMT were made for the treatment of LEDVT in the tenth edition of the American College of Chest Physicians guidelines.[9]

There have been a few meta-analysis of PMT for LEDVT.[10] 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).[11] 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 I^2 test was used to measure the statistical heterogeneity. A fixed-effects model was used when no significant heterogeneity ($I^2 < 50\%$) 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.

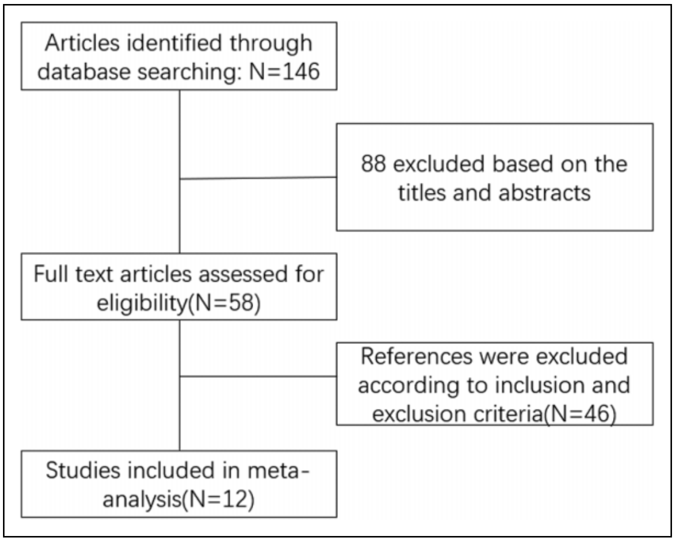

Figure 1. Flow diagram of literature review.

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[8,12-20] 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, $P = 0.98$; $I^2 = 0\%$) 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	115	Retrospective	12	109	NA	NA	NA	NA	Urokinase	NA	7
	CDT	29			27							
Huang, C. Y.	AngioJet	16	Retrospective	12	16	0	NA	2.06 ± 2.95	NA	Urokinase	NA	7
	CDT	18			18	1		5.06 ± 4.07				
Kuo, T. T.	AngioJet	30	Retrospective	24	27	14	6	1.87 ± 2.7	NA	Urokinase	17.973 ± 2.31	8
	CDT	31			25	7	6	3.13 ± 3			27.635 ± 6.78	
Lin, P. H.	AngioJet	52	Retrospective	NA	39	2	NA	NA	1.27 ± 0.56	Urokinase	NA	8
	CDT	46			32	3			18 ± 8			
Liu, X.	AngioJet	52	Retrospective	NA	44	0	NA	NA	NA	Urokinase	NA	8
	CDT	60			48	0						
Pouncey, A. L.	AngioJet	70	Retrospective	12	55	25	55	NA	NA	Urokinase	NA	7
	CDT	81			67	38	67					
Wang, S.	AngioJet	11	Retrospective	19.3	8	0	NA	NA	NA	Urokinase	NA	7
	CDT	25			21	2						
Xu, Y.	AngioJet	186	Retrospective	19	150	19	10	NA	NA	Urokinase	95.16 ± 45.89	7
	CDT	238			198	23	31				293.76 ± 42.71	
Yin, X.	AngioJet	94	Retrospective	16	91	12	8	NA	62.4 ± 28.8	Urokinase	15 ± 5	9
	CDT	76			70	11	9		163.2 ± 72		26.5 ± 7	
Zhu, J.	AngioJet	32	Retrospective	NA	29	6	NA	NA	4.2 ± 1.7	Urokinase	0.264 ± 0.135	8
	CDT	33			32	6			73.6 ± 18.3		1.869 ± 0.528	
Escobar, G. A.	AngioJet	52	Retrospective	NA	NA	15	NA	NA	NA	Urokinase	NA	6
	CDT	50				4						
Morrow, K. L.	AngioJet	15	Retrospective	NA	NA	3	NA	NA	NA	Urokinase	NA	6
	CDT	18				0						

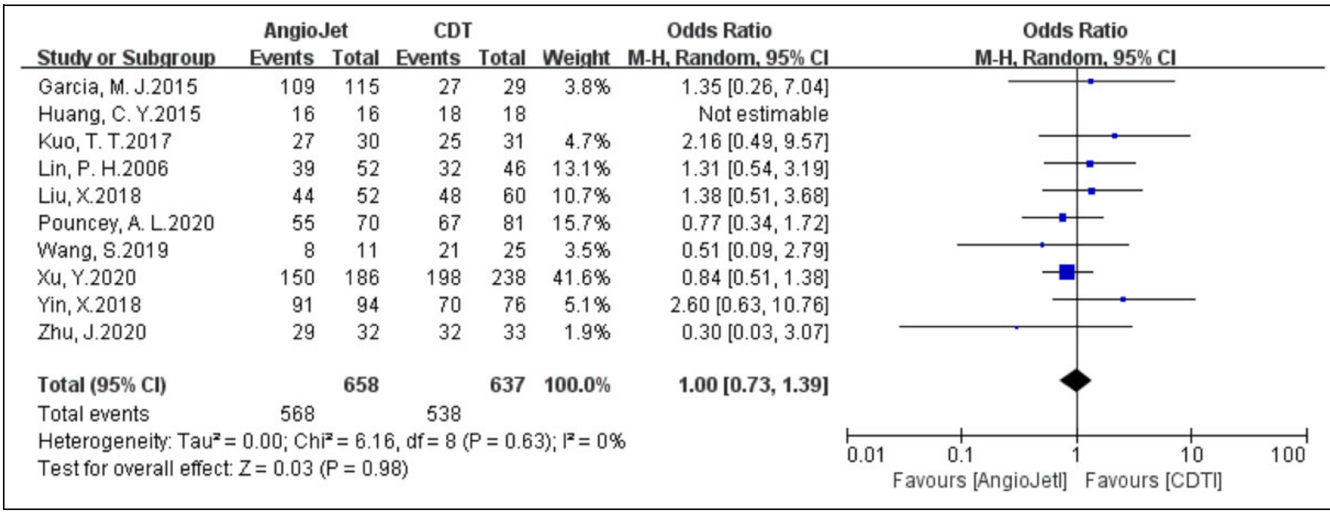

Figure 2. Meta-analysis of effective rate of treatment (OR 1.00, CI 0.73-1.39, $P = 0.98$; $I^2 = 0\%$).

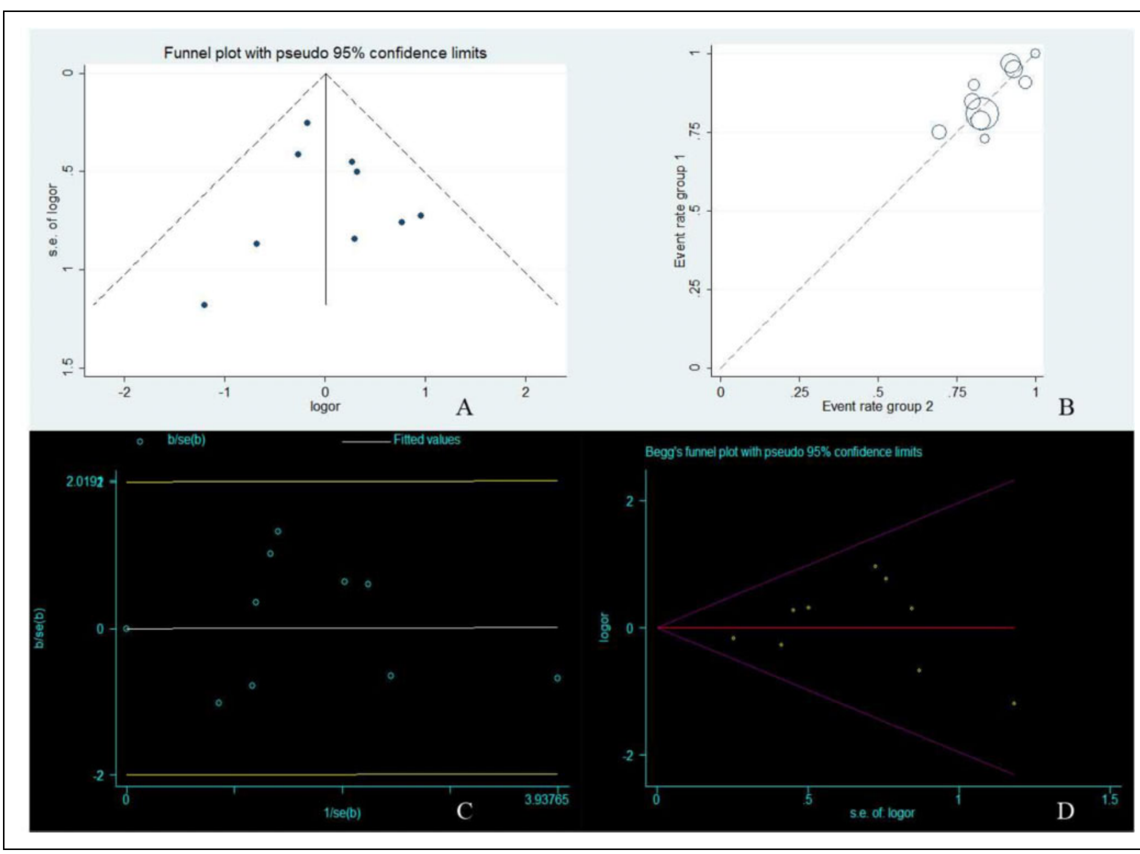

Figure 3. Bias of effective rate. (A) Funnel plot: the OR value of the effect size is scattered in the center and is basically symmetric. The effect points of small samples are basically distributed at the bottom, while the effect points of large samples tend to be in a narrow range at the top, showing an inverted funnel shape. (B) L'abbe plot: the distribution of each point is dense indicating that the heterogeneity is small. (C) Galbraith plot: the studies lie between 2 regression lines indicating that the heterogeneity is small. (D) Begg's funnel plot: $Pr = 0.917$.

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

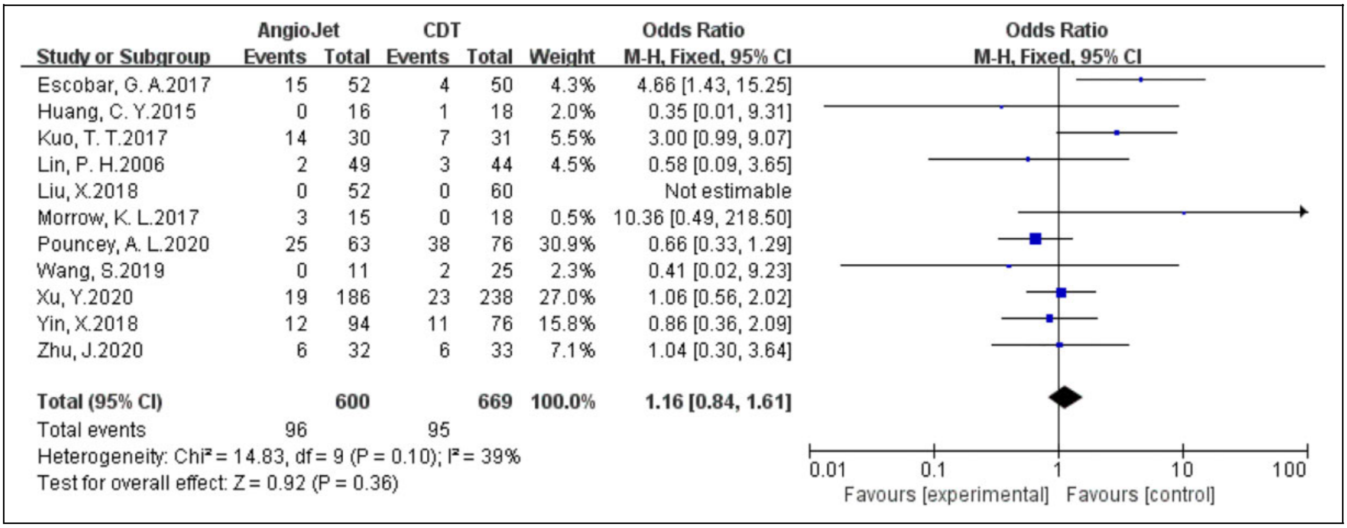

Figure 4. Meta-analysis of serious complications (OR 1.16 CI 0.84-1.61, $P = 0.36$; $I^2 = 39\%$).

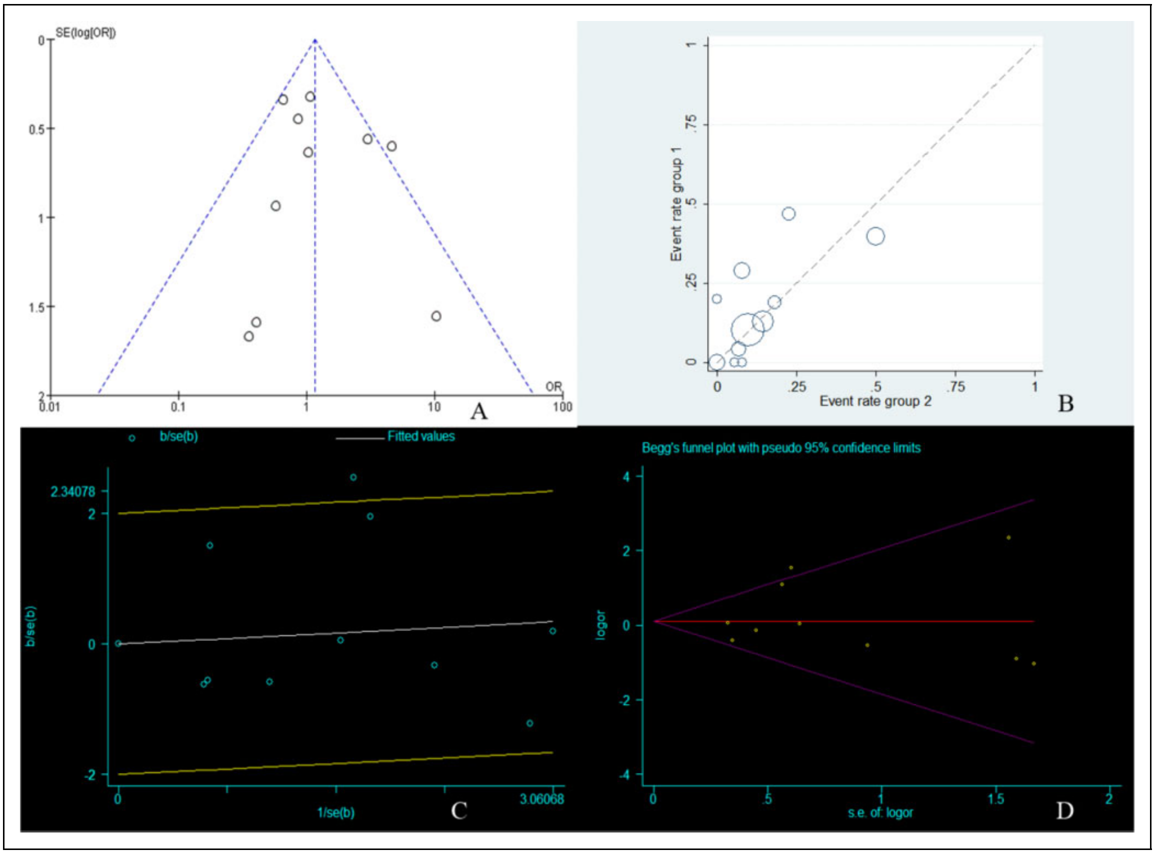

Figure 5. Bias of effective rate complications. (A) Funnel plot: the OR value of the effect size is scattered in the center and is basically symmetric. The effect points of small samples are basically distributed at the bottom, while the effect points of large samples tend to be in a narrow range at the top, showing an inverted funnel shape. (B) L'abbe plot: the distribution of each point is dense indicating that the heterogeneity is small. (C) Galbraith plot: the studies lie between 2 regression lines indicating that the heterogeneity is small. (D) Begg's funnel plot: $Pr = 0.858$.

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 $Pr = 0.858$ and indicates no publication bias in the complications.

PTS and Villalta Score

Four studies[14,16,18,19] included the results of PTS, and 2 studies[13,14] included the results of Villalta score. There was a

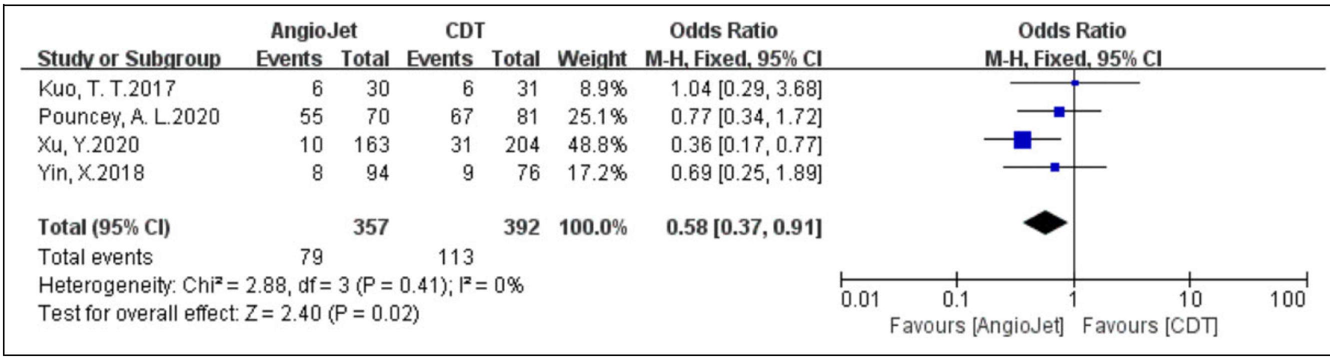

Figure 6. Meta-analysis of PTS (OR 0.58 CI 0.37-0.91, $P = 0.02$; $I^2 = 0\%$).

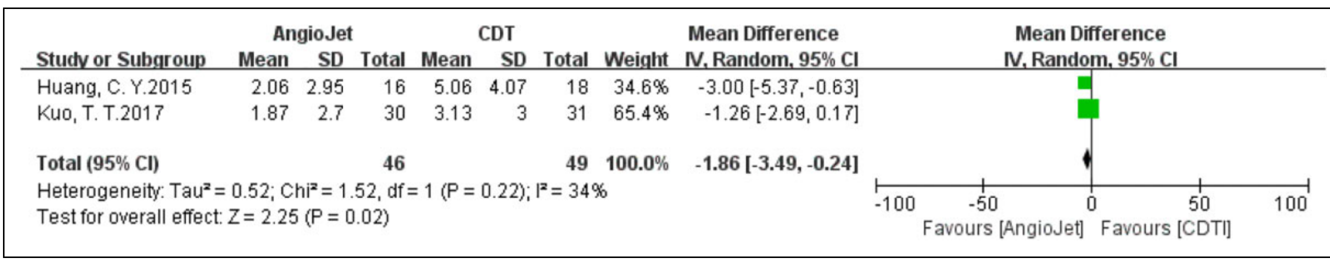

Figure 7. Meta-analysis of Villalta score (OR −1.86 CI −3.49 to −0.24, $P = 0.02$; $I^2 = 34\%$).

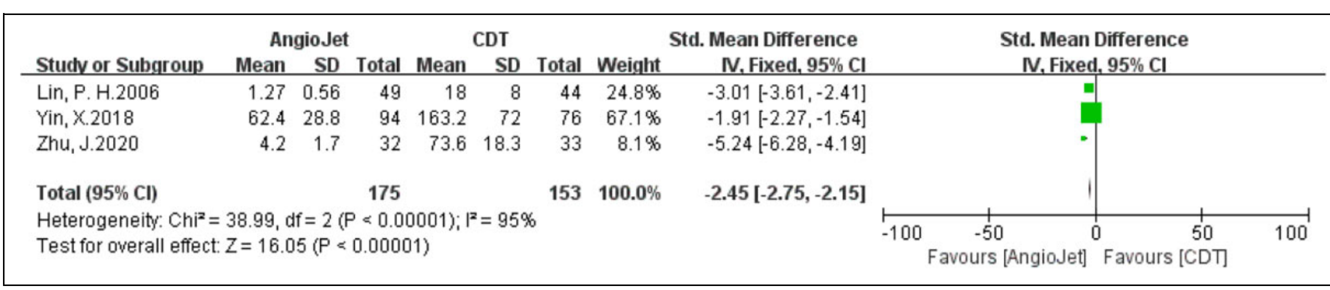

Figure 8. Meta-analysis of duration of the treatment (OR −2.45 CI −2.75 to −2.15, $P < 0.0001$; $I^2 = 95\%$).

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.

Duration of Treatment and Drug Dose

Duration of treatment include operative time and thrombolysis time. All of the studies used urokinase as thrombolytic drug. Three studies[8,19,20] reported the duration of treatment and 4 studies[14,18-20] included drug dose.

Meta-analysis indicated that there was a statistically significant decrease in duration of the treatment (OR −2.45 CI −2.75 to −2.15, $P < 0.0001$; $I^2 = 95\%$) and 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.

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.[23]

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% ∼ 90%. Because it can quickly clear

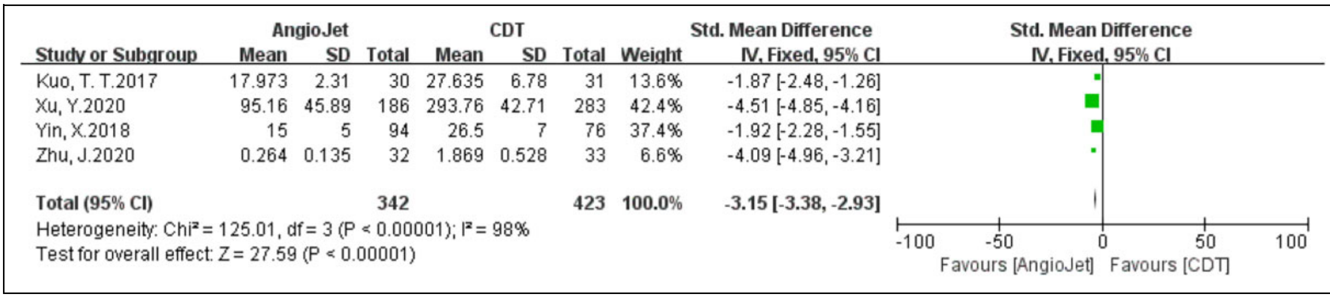

Figure 9. Meta-analysis of drug dose (OR −3.15 CI −3.38 to −2.93, $P < 0.0001$; $I^2 = 98\%$).

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 trials [8,12-20] reported the effective of treatment and 11 studies [8,13-22] 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, $P = 0.31$; $I^2 = 66\%$) and complications (OR 1.16 CI 0.84-1.61, $P = 0.36$; $I^2 = 39\%$) 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, $P = 0.02$; $I^2 = 0\%$) and Villalta score (OR −1.72 CI −2.69 to −0.50, $P = 0.006$; $I^2 = 34\%$) 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, $P < 0.0001$; $I^2 = 95\%$) and drug dose (OR −3.09 CI −4.64 to −1.53, $P < 0.0001$; $I^2 = 98\%$) 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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