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Preliminary application of Acostream percutaneous aspiration thromboembolectomy sequential low-dose alteplase in the treatment of lower extremity deep vein thrombosis

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Abstract: Objective To investigate the efficacy and safety of Acostream percutaneous aspiration thromboembolectomy (PAT) sequential low-dose alteplase (rt-PA) in the treatment of lower extremity deep vein thrombosis (LEDVT). **Methods** The clinical data of 22 patients with LEDVT admitted to the Affiliated Nanjing First Hospital of Nanjing Medical University from June 2022 to March 2024 were retrospectively analyzed. Data on procedure-related parameters, parameters of combined low-dose rt-PA use, hospital stay, thrombus clearance rate, swelling rate of the affected limb, hemoglobin changes at 48 h after operation, and complications were recorded. **Results** The thrombus aspiration time was （2.1±1.0） min. Immediate post-PAT grade Ⅲ thrombus clearance was achieved in 3 cases (13.6%), grade Ⅱ clearance in 18 cases (81.8%), and grade Ⅰ clearance in 1 case (4.5%). Sequential rt-PA thrombolysis had a thrombolytic time of （51.1±14.6）h and a dose of （26.7±9.0）mg, with grade Ⅲ clearance in 14 cases (63.6%), grade Ⅱ clearance in 7 cases (31.8%), and grade Ⅰ clearance in 1 case (4.5%). The hospital stay was （10.4±3.2）d. After thrombolytic therapy, the reduction in thigh circumference was （1.7±0.8）cm, and the reduction in calf circumference was （0.9±0.5）cm. Small bleeding events occurred in 7 patients during hospitalization. No new renal function impairment, allergic reactions, or severe complications were observed. After 6 months of follow-up, thrombosis recurred in 1 patient after the initial treatment, and 1 patient developed mild post-thrombotic syndrome 6 months post-procedure; the mean Villalta score was 1.5±1.3 for the 22 patients. **Conclusion** Acostream mechanical thrombectomy followed by low-dose rt-PA can rapidly reduce thrombus burden and restore limb blood flow, and it is preliminarily assessed as a safe and effective treatment for LEDVT patients.

Keywords: Acostream; Percutaneous aspiration thromboembolectomy; Alteplase; Lower extremity deep vein thrombosis

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Lower extremity deep venous thrombosis (LEDVT) is a common vascular disease, affecting approximately 0.1% of the global population [1]. LEDVT thrombus detachment can lead to pulmonary embolism, which can be life-threatening in severe cases. Current treatment methods for LEDVT include anticoagulation therapy, catheter-directed thrombolysis (CDT), percutaneous mechanical thrombectomy (PMT), percutaneous intraluminal angioplasty (PTA), and stent implantation [2]. Anticoagulation therapy is foundational, as standard anticoagulation can reduce the risk of thrombus propagation and decrease the likelihood of recurrence. However, due to the lack of endogenous fibrinolytic activity, anticoagulation therapy prolongs the presence of the thrombus, thus increasing the risk of chronic complications such as venous insufficiency and post-thrombotic syndrome (PTS) [3-4]. Studies have shown that early thrombus removal can reduce the risk of chronic complications [5], and endovenous intervention allows for early thrombus removal.

Endovenous interventions have been applied in the treatment of deep venous thrombosis (DVT) for many years. In recent years, with advancements in technology and new equipment, there has been a growing range of options for endovenous treatment [6]. Acostream, a novel percutaneous aspiration thrombectomy (PAT) device, has been explored, but there is limited research on its use in conjunction with sequential low-dose alteplase (rt-PA) for treating acute iliac-femoral and femoro-popliteal venous thrombosis. Therefore, this study aims to investigate the safety and efficacy of Acostream mechanical thrombectomy combined with sequential low-dose rt-PA in the treatment of acute iliac-femoral and femoro-popliteal venous thrombosis.

1 Materials and methods

1.1 General information

This retrospective study collected data from patients who underwent Acostream mechanical thrombectomy followed by sequential low-dose rt-PA treatment for LEDVT at Nanjing Municipal First Hospital between June 2022 and March 2024. All patients signed informed consent forms prior to treatment. Patients received Acostream sequential low-dose rt-PA treatment for acute

iliac-femoral or femoro-popliteal venous thrombosis. The study included baseline data, thrombus location, LEDVT risk factors, surgical-related parameters, postoperative low-dose rt-PA parameters, hospital stay, thrombus removal rate, limb edema reduction, hemoglobin changes 48 hours post-surgery, and complications. A total of 22 patients were included in this study, including 11 men and 11 women, with an age range of 18-78 (55.5 ± 17.9) years, and a body mass index (BMI) of 21.5-31.0 (25.2 ± 2.9) kg/m². All patients were diagnosed with iliac-femoral or femoro-popliteal venous thrombosis prior to surgery. Baseline characteristics and clinical features of the patients are shown in **Table 1.**

1.2 Treatment methods

All patients immediately began anticoagulation therapy after diagnosis, with subcutaneous low-molecular-weight heparin (LMWH) at 100 units/kg every 12 hours or adjusted apixaban standard anticoagulation treatment. Preoperative blood tests, coagulation, and renal function were completed. Preoperative lower limb venography was performed to determine the thrombus location and load. All patients received inferior vena cava filter placement to reduce the risk of pulmonary embolism during CDT or PAT.

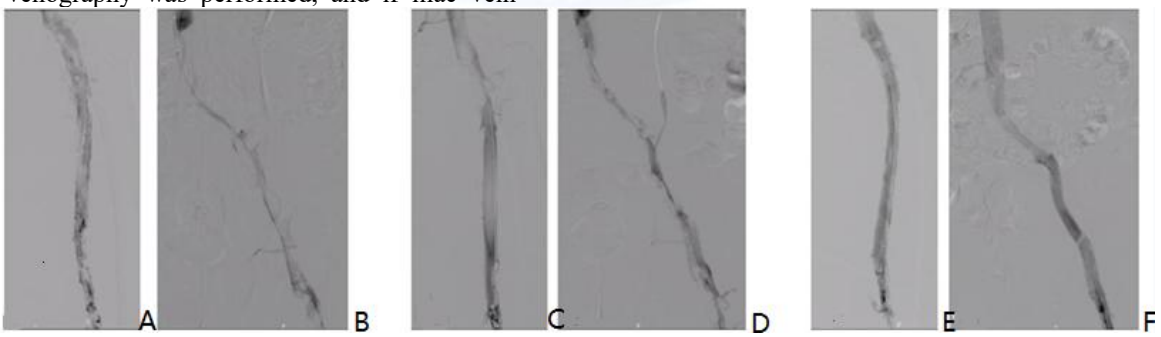
During the procedure, blood pressure, heart rate, oxygen saturation, and electrocardiogram were monitored. The patient was placed in the supine position, and after local anesthesia, a 4F vascular sheath (Terumo, Cook) was inserted via the healthy side femoral vein. After inferior vena cava venography, a filter was placed below the renal vein level on both sides. Based on thrombus location and load, an Acostream catheter was selected, and either a Terumo was used from the healthy side to the upper end of the thrombus segment or a short sheath was inserted via the puncture of the affected popliteal vein under local anesthesia. After heparinization, an Acostream catheter was introduced via a 0.035-inch exchange wire (Terumo) to the thrombus segment. The Acostream catheter was controlled and advanced slowly through the thrombus segment at a speed of 3-5 mm/s for 2-3 passes to reduce thrombus load. The operator monitored the patient's blood pressure, heart rate, oxygen saturation, and electrocardiogram for abnormalities. Post-PAT venography was performed, and if iliac vein stenosis or occlusion was found, balloon angioplasty and iliac vein stent implantation were performed either simultaneously or electively. The CDT approach was the same as PAT, using a 0.035-inch exchange wire to pass through the thrombus, followed by the introduction of a thrombolytic catheter. The catheter selection was based on thrombus extent and load.

Once the thrombolytic catheter was successfully placed, the sheath and thrombolytic catheter were retained in the sickroom. If there were residual thrombus or incomplete thrombus removal with a score lower than Grade I post-PAT, sequential low-dose rt-PA thrombolysis was considered. If plasma fibrinogen was >1.0 g/L, rt-PA was administered in a reduced dose: 20 mg rt-PA was infused through the reserved thrombolytic catheter at a rate not exceeding 0.01 mg/(kg•h), with a maximum infusion rate <1.0 mg/h, and the total dose did not exceed 40 mg within 72 hours. If plasma fibrinogen was ≤1.0 g/L, rt-PA infusion was stopped, and fibrinogen supplementation was administered as necessary. Regular venography or dorsalis pedis venography was performed to assess thrombus dissolution during thrombolytic therapy. A typical image of an LEDVT patient during different treatment stages was shown in **Figure 1**.

After excluding thrombus risk, all patients underwent inferior vena cava filter removal during follow-up. Upon discharge, patients were prescribed oral warfarin for 3-5 days, followed by dose adjustment to maintain an international normalized ratio (INR) of 2.0-3.0, or rivaroxaban 20 mg orally once daily for at least 6 months. Patients were also advised to wear compression stockings for at least one year post-discharge.

Tab.1 Basic information and clinical characteristics of patients

Item	Case (%)
Age(year, $\bar{x}\pm s$)	55.5±17.86
Male	11(50.0)
BMI（kg/m², $\bar{x}\pm s$）	25.2±2.88
Left-side thrombosis	15(68.2)
Thrombosis extent	
Inferior vena cava, iliac-femoral vein + femoro-popliteal vein	3(13.6)
Iliac-femoral vein + femoro-popliteal vein	14(63.6)
Femoro-popliteal vein	5(22.7)
LEDVT risk factors	
History of DVT	4(18.2)
Rheumatologic diseases	3(13.6)
Postoperative or traumatic immobility	7(31.8)
Active tumors	3(13.6)
May-Thurner syndrome	4(18.2)
Unknown etiology	3(13.6)



Note: A, B were catheter-directed venography showing thrombosis in the femoro-popliteal and iliac-femoral veins; C, D were post-Acostream mechanical thrombectomy showing reduced thrombus load on catheter-directed follow-up; E, F were post-sequential low-dose rt-PA showing near-complete resolution of thrombus on follow-up.

Fig.1 Images of typical LEDVT patients at different treatment stages

1.3 Evaluation of efficacy and safety

1.3.1 Efficacy

Thrombus clearance rate was evaluated by preoperative and postoperative venography. Thrombus clearance levels were graded according to the standards in the LEDVT vascular intervention report [7]: Grade III (thrombus clearance rate>95%), Grade II (thrombus clearance rate 50%-95%), and Grade I (thrombus clearance rate <50%). Thrombus clearance rate was calculated by scoring the thrombus load in the inferior vena cava, common iliac vein, external iliac vein, femoral vein, superficial femoral vein proximal and distal, and popliteal vein [8]. Complete occlusion was scored as 2 points, partial occlusion as 1 point, and complete patency as 0 points. The total score before and after thrombectomy was calculated and the difference divided by the preoperative total score to determine the thrombus clearance rate. Limb edema was assessed by measuring the difference in circumference between the affected and unaffected thighs (15 cm above the patella) and calves (10 cm below the patella) before and after treatment. The reduction in circumference difference was used to calculate the limb edema reduction rate.

1.3.2 Safety

Changes in hemoglobin and complications during treatment were recorded. Postoperative success rates and complications of combined procedures were assessed. Complications included allergic reactions, bleeding, renal dysfunction, pulmonary embolism, and death. Minor bleeding events were defined as those controlled by pressure or cessation of thrombolysis, such as puncture site bleeding or oral bleeding. Severe complications included hemoglobin drop ≥2 g/dL requiring ≥2 units of red blood cell transfusion, intracranial hemorrhage, retroperitoneal hemorrhage, symptomatic pulmonary embolism, and death. Clinical success was defined as thrombus clearance ≥Grade II without severe complications.

1.4 Postoperative follow-up

All patients were followed for at least 6 months post-discharge. Follow-up included clinical assessment and ultrasound or lower limb venous CT venography (CTV) to evaluate vascular patency. The Villalta score was used to assess the presence and severity of PTS: normal (0-4), mild (5-9), moderate (10-14), and severe (≥15).

1.5 Statistical methods

SPSS 22.0 software was used for all data. The measurement data were expressed as $\bar{x}\pm s$, and the count data were expressed as case (%).

2 Results

2.1 Efficacy

Among the 22 patients, 3 had inferior vena cava, iliac-femoral, and femoro-popliteal venous thrombosis; 14 had iliac-femoral and femoro-popliteal venous thrombosis; and 5 had femoro-popliteal venous thrombosis. Filters were successfully implanted in all patients, with 12 patients receiving OptEase filters (Cordis), 6 receiving Denali filters (Bard), and 4 receiving Aegisy filters (Lifetech).

During the procedure, there were no significant abnormalities in blood pressure, heart rate, oxygen saturation, or electrocardiogram. The thrombus aspiration time was 2.10 ± 1.00 minutes, with Grade III thrombus clearance achieved in 3 cases (13.6%), Grade II in 18 cases (81.8%), and Grade I in 1 case (4.5%). All patients received sequential low-dose rt-PA thrombolysis, with thrombolysis time of 51.1 ± 14.6 hours and total rt-PA dose of 26.7 ± 9.0 mg. After sequential rt-PA, Grade III thrombus clearance was achieved in 14 cases (63.6%), Grade II in 7 cases (31.8%), and Grade I in 1 case (4.5%). Hospital stay averaged 10.4 ± 3.2 days. Post-thrombolysis, the average reduction in thigh circumference was 1.7 ± 0.8 cm, and calf circumference reduction was 0.9 ± 0.5 cm. Fifteen patients received balloon angioplasty, and 2 patients received iliac vein stent implantation.

2.2 Safety

Among the 22 patients treated with PAT + CDT, 7 patients experienced minor bleeding events during hospitalization, including 4 cases of puncture site bleeding, 2 cases of oral bleeding, and 1 case of both puncture site and oral bleeding. No new renal dysfunction or allergic events were observed. No serious complications such as intracranial hemorrhage, gastrointestinal bleeding, or death occurred.

2.3 Follow-up

All 22 patients completed at least 6 months of follow-up. One patient experienced thrombus recurrence after initial treatment, and one patient developed mild PTS at 6 months. The average Villalta score for all 22 patients was 1.5 ± 1.3 points.

3 Discussion

In patients with acute lower extremity deep vein thrombosis (LEDVT), especially those with iliac-femoral and femoro-popliteal venous LEDVT, the condition can cause obstruction of the main venous return, potentially leading to unilateral limb pain, swelling, skin discoloration, venous hypertensive ulcers, and venous claudication [10-11]. Compared to below-knee DVT, iliac-femoral and femoro-popliteal LEDVT is associated with higher incidences of pulmonary embolism, thrombus recurrence, and PTS. Early thrombus clearance can

alleviate obstruction, restore venous valve function in the affected segment, prevent the development of venous valve insufficiency in the unaffected distal veins, and help reduce the occurrence of PTS [12]. Therefore, rapid thrombus removal is especially important in the treatment of iliac-femoral and femoro-popliteal venous DVT, with active management of existing iliac vein pathology to promptly improve symptoms and reduce complications.

Although CDT has been proven to be effective in rapidly removing thrombus, improving vessel patency, and reducing the incidence of PTS [13], it carries relatively long bed rest periods, thrombolysis time, and bleeding risks, while also extending hospitalization. For some rapidly progressing and severe LEDVT cases, CDT may be inadequate to prevent disease progression, increasing the likelihood of PTS occurrence [14]. In contrast, PAT uses negative pressure to rapidly clear thrombus, reduce the dosage of thrombolytic agents, and lower the risk of bleeding, gradually being applied to the treatment of venous thromboembolism [15-16]. The results of this study showed that Acostream mechanical thrombectomy followed by sequential rt-PA treatment in LEDVT patients achieved an immediate success rate of 95.45% (21/22), with an average thrombolytic agent dose of (26.70±9.04) mg. This indicates that Acostream thrombectomy provides a fast and effective technical approach for the treatment of acute LEDVT and can be considered as a first-line thrombectomy method for this group of patients. Based on the rapid and effective PAT, single-session endovenous treatment is technically feasible.

Currently, the main PMT devices available in China include the AngioJet and Aspirex thrombectomy systems. While these devices can rapidly clear thrombus, reduce thrombolytic agent dosage and time, and decrease bleeding risks, they may damage venous valve function and the vessel wall, potentially increasing the risk of secondary thrombosis. Additionally, during PMT suction, red blood cell destruction is unavoidable, and the released hemoglobin is excreted through the kidneys, potentially leading to hemoglobinuria [17-18]. Mechanical damage to red blood cells can increase plasma hemoglobin levels, which then decompose into heme and globin. High heme levels may affect glomerular filtration rate through their bioactivity and pro-oxidative effects, posing a potential risk of worsening kidney damage, particularly in patients with pre-existing renal conditions [18].

In this study, no significant arrhythmias were observed during PAT thrombectomy, and postoperatively, there was no notable hemoglobinuria or increase in serum creatinine levels. Seven minor bleeding events occurred after sequential rt-PA treatment, which were managed by reducing the rt-PA infusion rate and applying pressure to achieve hemostasis. Although the sample size in this study was limited, the results suggest that Acostream mechanical thrombectomy has a low-risk, high-reward potential. In patients with May-Thurner syndrome, thrombus removal followed by percutaneous transluminal angioplasty (PTA) and stent placement can help alleviate symptoms and improve quality of life.

Due to the rapid pharmacological decline of rt-PA, continuous infusion was maintained using an infusion pump after PAT to sustain the drug concentration [19]. Based on clinical experience with rt-PA and the characteristics of LEDVT, and after considering the potential increased bleeding risk, this study restricted rt-PA use to the following parameters: (1) infusion rate ≤ 0.01 mg/(kg•h), with a maximum flow rate ≤ 1.0 mg/h; (2) infusion duration ≤ 72 hours; (3) total rt-PA dose not exceeding 40 mg; (4) rt-PA infusion only when plasma fibrinogen >1.0 g/L. Following Acostream mechanical thrombectomy with low-dose rt-PA, satisfactory therapeutic efficacy and safety were achieved without significant dose-dependent major bleeding events. The combined use of low-dose rt-PA further enhanced thrombus clearance, partially due to Acostream thrombectomy reducing thrombus load in the affected limb.

In the acute venous thrombosis ATTRACT randomized trial, mechanical thrombectomy significantly reduced the incidence of PTS compared to anticoagulation therapy starting at 6 months. After 12 months, the reduction was slightly attenuated but still >20% [20]. In this study, the 6-month follow-up showed a relatively low incidence of PTS. However, due to the short follow-up period and the lack of a control group, longer follow-up data and further controlled studies are needed.

In conclusion, Acostream mechanical thrombectomy followed by sequential low-dose rt-PA can rapidly reduce thrombus load, restore blood flow in the affected limb, and can be safely and effectively applied to the treatment of LEDVT patients.

Conflict of interest None

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·论　著·

Acostream 机械性血栓抽吸序贯低剂量阿替普酶在下肢深静脉血栓治疗中的初步应用

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摘要：目的　探讨 Acostream 机械性血栓抽吸术（PAT）序贯低剂量阿替普酶（rt-PA）治疗下肢深静脉血栓（LEDVT）的有效性和安全性。**方法**　回顾性分析南京市第一医院 2022 年 6 月至 2024 年 3 月收治的 22 例 LEDVT患者的临床资料，记录手术相关参数、联合低剂量 rt-PA 使用参数、住院时间、血栓清除率、患肢消肿率、术后 48 h 血红蛋白变化、并发症等资料。**结果**　血栓抽吸时间为 1.7（1.4，2.7）min，PAT 术后即刻Ⅲ级血栓清除率 13.6%（3 例），Ⅱ级血栓清除率 81.8%（18 例），Ⅰ级血栓清除率 4.5%（1 例）；序贯 rt-PA 溶栓，溶栓时间为（51.1±14.6）h，溶栓剂量 21.0（20.0，36.5）mg，Ⅲ级血栓清除率 63.6%（14 例），Ⅱ级血栓清除率 31.8%（7 例），Ⅰ级血栓清除率4.5%（1 例）。住院时间为（10.4±3.2）d。溶栓治疗结束后，患者大腿周径减少（1.7±0.8）cm，小腿周径减少 0.8（0.5，1.3）cm。住院期间 7 例患者出现小出血事件。无新增肾功能损伤、过敏事件和严重并发症发生。随访 6 个月，1 例患者在初次治疗后血栓复发，1 例患者术后 6 个月发生轻度血栓后综合症；22 例患者 Villalta 评分为 2（1，2）分。**结论**　Acostream 机械性血栓抽吸术序贯低剂量 rt-PA 可快速降低血栓负荷，恢复患肢血流，初步评估可安全有效地应用于 LEDVT 患者的治疗。

关键词： Acostream；机械性血栓抽吸术；阿替普酶；下肢深静脉血栓；溶栓
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Preliminary application of Acostream percutaneous aspiration thromboembolectomy sequential low-dose alteplase in the treatment of lower extremity deep vein thrombosis

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Abstract: Objective　To investigate the efficacy and safety of Acostream percutaneous aspiration thromboembolectomy (PAT) sequential low-dose alteplase (rt-PA) in the treatment of lower extremity deep vein thrombosis (LEDVT). **Methods**　The clinical data of 22 patients with LEDVT admitted to Nanjing First Hospital from June 2022 to March 2024 were retrospectively analyzed. Data on procedure-related parameters, parameters of combined low-dose rt-PA use, hospital stay, thrombus clearance rate, swelling rate of the affected limb, hemoglobin changes at 48 h after operation, and complications were recorded. **Results**　The thrombus aspiration time was 1.7 (1.4, 2.7) min. Immediate post-PAT grade Ⅲ thrombus clearance was achieved in 3 cases (13.6%), grade Ⅱ clearance in 18 cases (81.8%), and grade Ⅰ clearance in 1 case (4.5%). Sequential rt-PA thrombolysis had a thrombolytic time of (51.1±14.6) h and a dose of 21.0 (20.0, 36.5) mg, with grade Ⅲ clearance in 14 cases (63.6%), grade Ⅱ clearance in 7 cases (31.8%), and grade Ⅰ clearance in 1 case (4.5%). The hospital stay was (10.4±3.2) d. After thrombolytic therapy, the reduction in thigh circumference was (1.7±0.8) cm, and the reduction in calf circumference was 0.8 (0.5, 1.3) cm. Small bleeding

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events occurred in 7 patients during hospitalization. No new renal function impairment, allergic reactions, or severe complications were observed. After 6 months of follow-up, thrombosis recurred in 1 patient after the initial treatment, and 1 patient developed mild post-thrombotic syndrome 6 months post-procedure; the mean Villalta score was 2 (1, 2) for the 22 patients. **Conclusion** Acostream mechanical thrombectomy followed by low-dose rt-PA can rapidly reduce thrombus burden and restore limb blood flow, and it is preliminarily assessed as a safe and effective treatment for LEDVT patients.

Keywords: Acostream; Percutaneous aspiration thromboembolectomy; Alteplase; Lower extremity deep vein thrombosis; Thrombolytic

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下肢深静脉血栓形成(lower extremity deep venous thrombosis, LEDVT)是一种常见的血管性疾病,约占世界人口的 0.1%[1]。LEDVT 血栓脱落可导致肺栓塞,严重时可危及生命。目前,关于 LEDVT 的治疗方法,包括抗凝、经导管接触性溶栓治疗(catheter directed thrombolysis, CDT)、经皮机械性血栓清除术(percutaneous mechanical thrombectomy, PMT)、经皮腔内血管成形术(percutaneous transluminal angioplasty, PTA)及支架植入术等[2]。抗凝治疗是基础,标准抗凝可以降低血栓扩散风险、减少血栓复发可能,但由于其缺乏内源性纤溶活性,导致血栓存在时间延长,从而增加了慢性并发症发生的风险,包括静脉功能不全和血栓后综合征(post-thrombotic syndrome, PTS)[3-4]。研究表明早期血栓清除可降低慢性并发症发生的风险[5],血管内介入治疗可实现早期的血栓清除。

血管内介入治疗在深静脉血栓的治疗中已经应用多年。近年来,随着许多不同的技术进步和新的设备的出现,血管内治疗的选择越来越多[6]。Acostream 作为一种新型经皮机械性血栓抽吸(percutaneous aspiration thromboembolectomy, PAT)装置,目前关于 Acostream 机械性血栓抽吸术序贯低剂量阿替酶(rt-PA)治疗急性髂股和股腘静脉血栓患者的研究仍较少。因此,本研究探讨 Acostream 机械性血栓抽吸术序贯低剂量 rt-PA 治疗急性髂股和股腘静脉血栓患者的安全性和有效性。

1　资料与方法

1.1　*一般资料*　本研究回顾性收集 2022 年 6 月至 2024 年 3 月南京市第一医院接受 Acostream 机械性血栓抽吸术序贯 rt-PA 治疗的 LEDVT 患者资料,所有患者均在术前签署治疗知情同意书,应用 Acostream 序贯低剂量 rt-PA 治疗急性髂股静脉或股腘静脉血栓。患者的基线资料、血栓部位、LEDVT 风险因素、手术相关参数、术后联合低剂量 rt-PA 使用参数、住院时间、血栓清除率、患肢消肿率、术后 48 h 血红蛋白变化、并发症被纳入分析。共有 22 例患者纳入本研究,其中男 11 例,女 11 例;年龄 18~78 (55.5±17.9)岁;BMI 21.5~31.0(25.2±2.9)kg/m^2;术前均明确有下肢髂股或股腘静脉血栓。患者的一般资料及临床特点见表 1。

表 1　患者一般资料及临床特点　[例(%)]
Tab. 1　General data and clinical characteristics of patients　[case(%)]

项目	参数	项目	参数
年龄(岁,$\bar{x}\pm s$)	55.5±17.9	LEDVT 风险因素	
男性	11(50.0)	既往 DVT 病史	4(18.2)
BMI(kg/m^2, $\bar{x}\pm s$)	25.2±2.9	风湿免疫性疾病	3(13.6)
左侧血栓	15(68.2)	术后或外伤制动	7(31.8)
血栓累及范围		活动性肿瘤	3(13.6)
下腔静脉、髂-股静脉+股-腘静脉	3(13.6)	May-thurner 综合征	4(18.2)
髂-股静脉+股-腘静脉	14(63.6)	病因不明确	3(13.6)
股-腘静脉	5(22.7)		

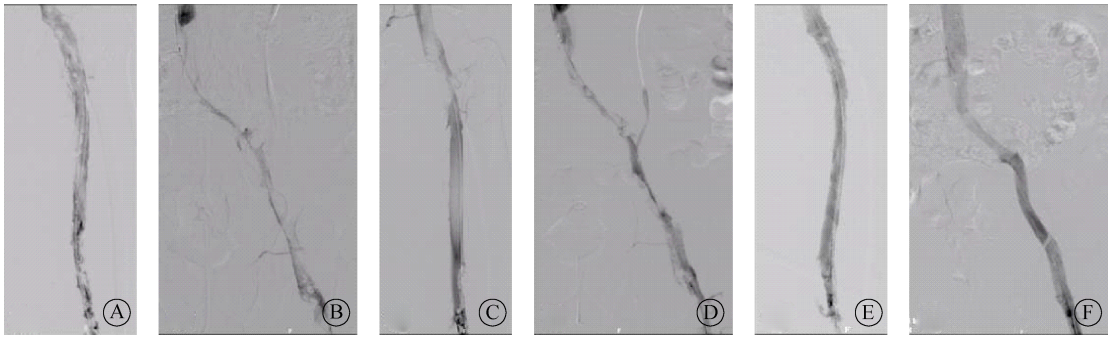
1.2　*治疗方法*　所有患者确诊后立即开始抗凝治疗,皮下注射低分子肝素,剂量为 100 单位/kg,每 12 h一次,或调整阿加曲班标准抗凝治疗,完善术前血常规、凝血、肾功能等检查。术前行患侧下肢顺行静脉造影明确血栓部位及血栓负荷量。所有患者均行下腔静脉滤器置入以降低 CDT 或 PAT 期间发生肺栓塞风险。

术中监测患者血压、心率、血氧饱和度和心电图。患者取仰卧位,局麻后穿刺健侧股静脉置入 4F 血管鞘组(Terumo、Cook),插入猪尾导管行下腔静脉造影后于双侧肾静脉水平以下置入下腔静脉滤器。然后根据血栓部位及负荷量选择 Acostream 导管型号,选择翻山鞘(Terumo)由健侧至患侧血栓段上端,或局麻下穿刺患侧腘静脉置入短鞘。经鞘管全身肝素化,经 0.035 英寸交换导丝(Terumo)引入 Acostream 导管至血栓段。固定导丝,操控 Acostream 抽吸导管以

3~5 mm/s 左右的速度由远心端向近心端缓慢通过血栓段 2~3 次以达到减轻血栓负荷的目的。手术医师需要注意观察患者血压、心率、血氧饱和度、心电图是否异常。PAT 术后立即行造影复查，若发现髂静脉狭窄闭塞，则同期或择期行球囊血管成形术+髂静脉支架植入术。CDT 穿刺入路的选择同 PAT，使用普通 0.035 英寸交换导丝通过血栓后，经交换导丝引入溶栓导管准确置于血栓段内。溶栓导管型号及规格的选择由手术医师根据血栓范围及血栓负荷量作出决定。

溶栓导管放置成功后，患者保留鞘管及溶栓导管返回病房。PAT 术后有残余凝块或血栓清除分级在Ⅰ级以下，可考虑序贯低剂量 rt-PA。当血浆纤维蛋白原>1.0 g/L 时，给予 rt-PA 减量溶栓治疗：单次 20 mg rt-PA经预留溶栓导管以不超过 0.01 mg/(kg·h)的速度输注，最大输注速度<1.0 mg/h。总剂量≤40 mg，输液时间在 72 h 内；当血浆纤维蛋白原≤1.0 g/L 时，停止输注 rt-PA，必要时补充人纤维蛋白原。溶栓治疗期间，定期行溶栓导管内造影或足背顺行造影，评估血栓溶解程度。1 例典型 LEDVT 患者不同治疗阶段图像如图 1 所示。

所有患者均在复查时排除血栓风险后取出下腔静脉滤器。并在出院后予华法林口服，疗程 3~5 d，随后调整剂量，维持国际标准化比值 2.0~3.0 或者直接口服利伐沙班片 20 mg，每日 1 次，连续治疗至少 6 个月。同时建议患者出院后穿医用弹力袜至少 1 年。



注：A、B 为经导管左下肢静脉造影示股腘静脉和髂股静脉血栓形成；C、D 为 Acostream 机械性血栓抽吸术后即刻经导管复查示血栓负荷减少；E、F 为序贯低剂量 rt-PA 后经导管复查示血栓基本消失。

图 1　典型 LEDVT 患者不同治疗阶段影像

Fig. 1　Images of typical LEDVT patients at different treatment stages

1.3　疗效和安全性评价

1.3.1　疗效　血栓清除率根据患者术前顺行造影及术后造影复查结果评定。血栓清除等级根据 LEDVT 血管内治疗报告标准内记录的分级方法进行分级[7]：Ⅲ级为血栓清除率>95%；Ⅱ级为血栓清除率 50%~95%；Ⅰ级为血栓清除率<50%。血栓清除率的计算[8]：对下腔静脉、髂总静脉、髂外静脉、股总静脉、股浅静脉近端、股浅静脉远端、腘静脉按照血栓负荷量进行评分，静脉完全闭塞时为 2 分，部分闭塞时为 1 分，完全通畅时为 0 分。抽栓前与抽栓后 7 个节段静脉的评分相加为术前与术后的总评分，然后将它们的差值除以术前的总评分得到患肢的血栓清除率。记录患者治疗前大腿（髌上 15 cm）和小腿（髌下 10 cm）患侧与健侧周径差，治疗结束复测大小腿周径差，以周径差变化程度来评估患肢消肿程度。计算患者患肢消肿率，该值为溶栓治疗后患侧大腿及小腿周径差较治疗前减少的值。

1.3.2　安全性　记录治疗过程中患者血红蛋白变化以及并发症的发生。对联合手术的术后成功率及并发症进行评估，并发症包括过敏反应、出血、肾功能损伤、肺栓塞和死亡。小出血事件定义为可通过单纯压迫或停止溶栓控制的出血事件，如穿刺点出血、口腔内出血等；严重并发症包括血红蛋白下降≥2 g/dL 致需要输注≥2 u 红细胞悬液、颅内出血、腹膜后出血、症状性肺栓塞和死亡[9]。临床成功定义为治疗后血栓清除率达到Ⅱ或Ⅲ级，且无严重并发症发生。

1.4　术后随访

所有纳入本研究的患者出院后均接受至少 6 个月的随访，复诊时进行临床评估及超声检查或行下肢静脉 CT 造影（CTV），评估血管通畅情况。采用 Villalta 评分评估有无 PTS 及其严重程度：正常 0~4 分，轻度 5~9 分，中度 10~14 分，重度≥15 分。

1.5　统计学方法

所有数据均采用 SPSS 22.0 软件，计数资料以例（%）表示，正态分布的计量资料用 $\bar{x}\pm s$ 描述，非正态分布的计量资料以 $M(P_{25}, P_{75})$ 表示。

2 结 果

2.1 疗效 22 例患者中,3 例下腔静脉、髂股静脉和股腘静脉血栓;14 例髂股和股腘静脉血栓,5 例股腘静脉血栓。所有患者均成功置入滤器,其中 12 例置入 OptEase 滤器(Cordis 公司),6 例置入 Denali 滤器(Bard 公司),4 例置入 Aegisy 滤器(Lifetech 公司)。

所有患者术中血压、心率、血氧饱和度、心电图均无明显异常。血栓抽吸时间为 1.7(1.4,2.7)min,其中 PAT 术后即刻Ⅲ级血栓清除率为 13.6%(3 例),Ⅱ级血栓清除率为 81.8%(18 例),Ⅰ级血栓清除率为4.5%(1 例)。所有患者均序贯低剂量 rt-PA 溶栓治疗,溶栓时间为(51.1±14.6)h,溶栓剂量为 21.0(20.0,36.5)mg,序贯 rt-PA 溶栓后达到Ⅲ级血栓清除率 63.6%(14 例),Ⅱ级血栓清除率 31.8%(7 例),Ⅰ级血栓清除率 4.5%(1 例)。住院时间为(10.4±3.2)d。溶栓治疗结束后,患者大腿周径减少(1.7±0.8)cm,小腿周径减少 0.8(0.5,1.3)cm。15 例患者接受球囊血管成形术,2 例患者接受髂静脉支架植入术。

2.2 安全性 PAT+CDT 治疗的 22 例患者中,术后住院期间 7 例患者出现小出血事件,4 例为单纯穿刺点出血,2 例为单纯口腔出血,1 例患者同时出现穿刺点出血和口腔出血。无新增肾功能损伤和过敏事件发生。均无颅内出血、消化道出血、死亡等严重并发症发生。

2.3 随访 22 例患者均完成至少 6 个月的随访,1 例患者在初次治疗后血栓复发。1 例患者术后 6 个月发生轻度 PTS,22 例患者 Villalta 评分 2(1,2)分。

3 讨 论

急性 LEDVT 患者中,尤其是髂股和股腘静脉 LEDVT,可引起主干静脉回流障碍,进而可能导致单侧肢体疼痛肿胀、皮肤变色、静脉高压性溃疡和静脉跛行[10-11]。其与膝下 DVT 相比,有更高的肺栓塞、血栓复发及 PTS 发生率。而早期血栓清除可减轻血栓阻塞,恢复血栓段的静脉瓣膜功能,防止未受累的远端静脉瓣膜功能不全发生,有助于减少 PTS 的发生[12]。因此,在髂股和股腘静脉 DVT 治疗中,快速清除血栓尤为重要,并且同时积极处理存在的髂静脉病变,这样才能迅速改善症状,减少并发症的发生。

虽然 CDT 的疗效目前比较确切,可迅速清除血栓,增加血管通畅性,降低 PTS 发生率[13],但其有相对较长的卧床时间、溶栓时间和出血风险,同时延长了住院时间。对于一些进展迅速、病情严重的 LEDVT,CDT 难以阻止病情发展,增加了 PTS 发生的可能性[14]。而 PAT 利用负压快速清除血栓,减少溶栓药物剂量,降低出血风险,已逐渐应用于静脉血栓形成的治疗[15-16]。本研究结果示,Acostream 机械性血栓抽吸术序贯 rt-PA 治疗 LEDVT 患者,术后即刻成功率为 95.45%(21/22),溶栓剂量为 21.0(20.0,36.5)mg。表明 Acostream 血栓抽吸术不仅为急性 LEDVT 的治疗提供了一种快速有效的技术手段,而且其可作为这组患者的一线取栓方法,基于 PAT 的快速有效,单次血管内治疗在技术上是可行的。

目前进入国内 PMT 装置主要有 AngioJet 和 Aspirex 血栓清除系统等。PMT 装置虽然也可以快速清除血栓,减少溶栓剂量和时间,降低出血风险,但其可能对静脉瓣膜功能和血管壁造成血栓,反而增加继发性血栓的风险。此外,在 PMT 抽吸过程中,不可避免地破坏红细胞,释放的血红蛋白通过肾脏排泄导致血红蛋白尿[17-18]。同时红细胞机械性损伤可提高血浆血红蛋白水平,并分解为血红素和珠蛋白,其中高血红素水平可通过其生物反应性和促氧化作用影响肾小球滤过率,尤其原有肾脏疾病的患者,有潜在加重肾脏损伤的风险[18]。

本研究中 PAT 术中抽吸时患者未发现明显的心律异常,术后未见明显血红蛋白尿,未见明显的肌酐升高,序贯 rt-PA 后出现 7 例小出血事件,减少 rt-PA 流率并在压迫后止血。虽然本研究中样本数量有限,但本研究表明,Acostream 机械性血栓抽吸术具有低风险与高回报的可能性。伴 May-Thurner 综合征患者,清除血栓后行 PTA 和支架植入术有助于改善症状,提高生活质量。

本研究中,由于 rt-PA 的快速药理衰减的特点,PAT 术后使用输液泵进行连续灌流以维持持续的药物浓度[19]。根据临床使用 rt-PA 的经验和 LEDVT 疾病的特点,在权衡可能增加的出血风险后,本研究使用 rt-PA 限制为:(1)输注速度≤0.01 mg/(kg·h),最大流速≤1.0 mg/h;(2)输注时间≤72 h;(3)rt-PA总剂量不超过 40 mg;(4)仅在血浆纤维蛋白原>1.0 g/L 时输注 rt-PA。Acostream 机械性血栓抽吸术联用低剂量 rt-PA 后,取得了较为满意的疗效和安全性,且无剂量依赖性大出血发生。联用低剂量 rt-PA 后,可达到更进一步的血栓清除效果,部分归因于 Acostream 机械性血栓抽吸术降低了患肢血栓负荷。

在急性静脉血栓 ATTRACT 随机试验中,与抗凝

治疗相比，从 6 个月开始，机械性血栓清除治疗可显著降低 PTS 的发生率。12 个月后，这一降低幅度略有下降，但幅度仍>20%[20]。目前本研究中 6 个月随访已呈现较低的 PTS 发生率，但由于随访时间较短，缺乏对照组，需要获得更长时间的随访数据，开展进一步对照研究。

综上所述，Acostream 机械性血栓抽吸术序贯低剂量 rt-PA 可快速降低血栓负荷，恢复患肢血流，初步评估可安全有效地应用于 LEDVT 患者的治疗。

利益冲突　无

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