Percutaneous Manual Aspiration Thrombectomy Followed by Stenting for Iliac Vein Compression Syndrome with Secondary Acute Isolated Iliofemoral Deep Vein Thrombosis: A Prospective Study of Single-session Endovascular Protocol

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WHAT THIS PAPER ADDS

Single-session endovascular treatment with MAT as the first-line thrombus removal method is feasible, safe, and effective for IVCS with secondary acute isolated iliofemoral DVT, and can result in more efficient patient care.

Objective: To evaluate the feasibility, safety, and effectiveness of single-session endovascular treatment with manual aspiration thrombectomy (MAT) as the first-line method of thrombus removal for iliac vein compression syndrome (IVCS) with secondary acute isolated iliofemoral deep vein thrombosis (DVT).

Methods: This was a prospective clinical study. Twenty-six patients (19 women, 7 men, mean age 54 years) with left-sided acute iliac—common femoral DVT secondary to IVCS were enrolled. All patients presented with leg swelling or pains. Endovascular treatment, consisting of MAT, balloon angioplasty, and stent placement, was performed in the same setting. Overnight antegrade thrombolysis was performed in patients with residual thrombus after MAT. Patients were followed up by ultrasonography. The mean follow-up period was 17.8 months (12—25 months).

Results: Single-session endovascular procedures were performed successfully in all patients. The mean procedure time was 67 minutes (ranging from 45 to 90 minutes). Complete thrombus removal, including almost 100% of removal in 24 patients and little residual thrombus (<5%) in two, was achieved after repeated MAT. Thrombolysis was used in these two patients. Complete symptomatic relief was achieved in 25 patients (96%) and partial relief in one. The hospital stay ranged from 2 to 4 days (mean 2.7 days). Recurrent thrombosis within the stent was observed in one case and recanalized with thrombolysis. The 1-year primary and secondary patency rate was 96% and 100%, respectively. No symptomatic pulmonary embolization, bleeding, and venous reflux were observed. Five patients complained about transitory low back pains during balloon angioplasty.

Conclusion: Single-session endovascular treatment with MAT as the first-line thrombus removal method is feasible, safe, and effective for IVCS with secondary acute isolated iliofemoral DVT. Although limited, our experience suggests that patients thought to be at high risk of bleeding may be candidates for the present single-session endovascular protocol.

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INTRODUCTION

Iliac vein compression syndrome (IVCS), also known as May—Thurner syndrome, is believed to be caused by extrinsic compression of the left common iliac vein between the overlying right common iliac artery and the vertebral body, and it has been considered an anatomic risk factor for the left-sided deep vein thrombosis (DVT).[1—3] Approximately 50—60% of patients presenting with left-sided iliofemoral DVT are found to have common iliac vein synechiae or intraluminal web resulting from vein wall contact and compression.[4] The rate of recurrence (73%) is high in patients with acute left-sided iliofemoral DVT when the IVCS is not treated with stent placement.[5] This group of patients may be put at particularly high risk for post-thrombotic syndrome (PTS) and late disability.

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Endovascular treatments, consisting of catheter-directed thrombolysis (CDT), percutaneous mechanical thrombectomy (PMT), and stent placement, are currently considered to be the mainstay for DVT secondary to IVCS.[6,7] Although it may enhance thrombus lysis and prevent PTS, CDT has some specific disadvantages, such as the risk of bleeding, the long time to lysis, long hospital stay, and heavy economic cost incurred by the need for close monitoring, which may impede its widespread utilization.[6—10] PMT may increase the efficiency of thrombus clearance and lower the infusion dose and time of the thrombolytic agent,[11—13] but it may cause damage to vessel walls and valves, and even have the risk of pulmonary embolization (PE).[6] Besides, PMT devices may cause hemolysis and hemoglobinuria.[14]

Manual aspiration thrombectomy (MAT) is an effective and rational option for thrombus removal due to its advantages of rapidity and avoidance of bleeding complications.[15,16] Theoretically, MAT can result in more efficient patient care. The purpose of the present study was to prospectively evaluate the feasibility, safety, and effectiveness of single-session endovascular treatment with MAT as the first-line thrombus removal method for the treatment of IVCS with secondary acute isolated iliac—common femoral DVT.

MATERIALS AND METHODS

Patient population

This study was approved by the institutional review board and the ethics committee of our university. From July 2010 to June 2012, 26 consecutive patients with left-sided acute (1—14 days) isolated iliac—common femoral DVT due to IVCS were enrolled in the present prospective study based on the following inclusion and exclusion criteria. DVT was diagnosed based on the clinical and imaging findings. Color Doppler ultrasonography (CDU) was the most commonly used for imaging findings of DVT. IVCS were diagnosed by spiral computed tomographic (CT) venography. The patients were included in the study if they had stenosis or occlusion of the left common iliac vein (≥50% luminal diameter reduction) caused by compression of the right common iliac artery and the vertebral body demonstrated by CT images (including cross-sectional images and images after three-dimensional construction using curved planar reformation and volume rendering) (Fig. 1), and thrombosis in any part of the iliac vein and/or the common femoral vein (Fig. 2). The patients were excluded from the study if they had thrombosis in the femoral vein, popliteal vein, or inferior vena cava (IVC), active internal bleeding, a recent cerebrovascular accident, allergy to thrombolytic agents, recent

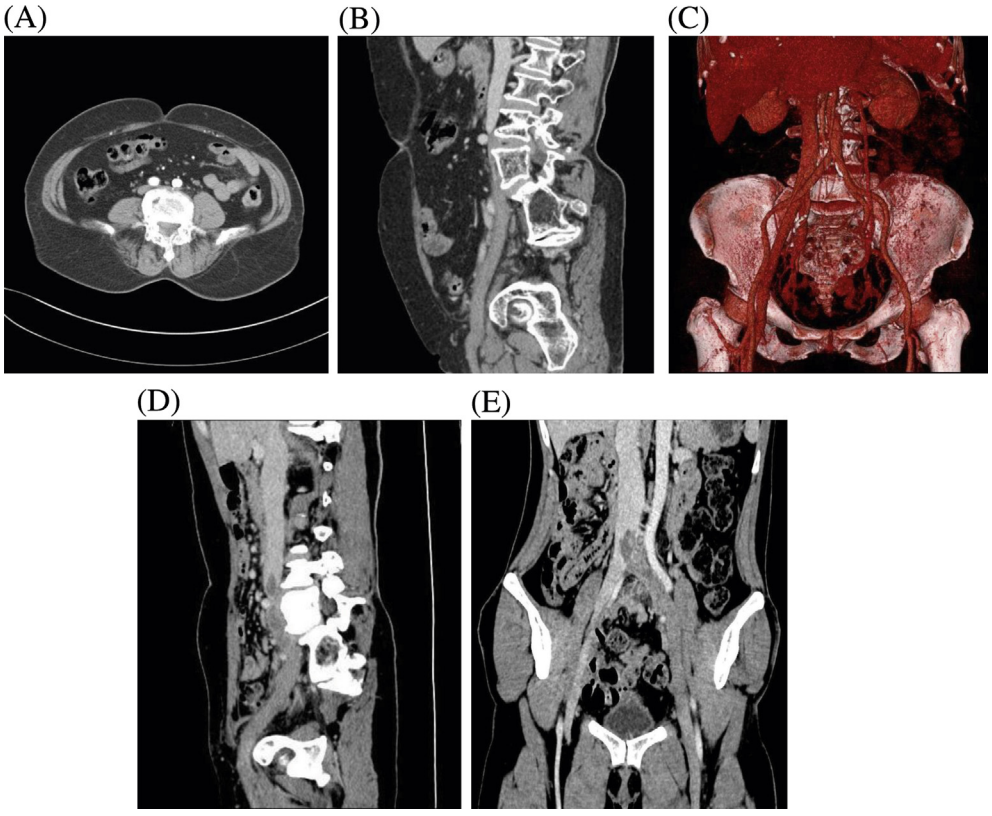

Figure 1. Computed tomography (CT) evaluation of the underlying stenosis or obstruction and the extent of thrombus. (A) Cross-sectional image demonstrates considerable compression of the left common iliac vein by the right common iliac artery. (B) Curved planar reformation along the left iliofemoral vein demonstrates extrinsic compression of the left common iliac vein between the right common iliac artery and the spine. (C) Volume-rendered image shows lack of visualization of the left iliofemoral vein. (D, E) CT images demonstrate stenosis of the left common iliac vein caused by compression of the right common iliac artery and the vertebral body, and thrombus extension to the inferior vena cava.

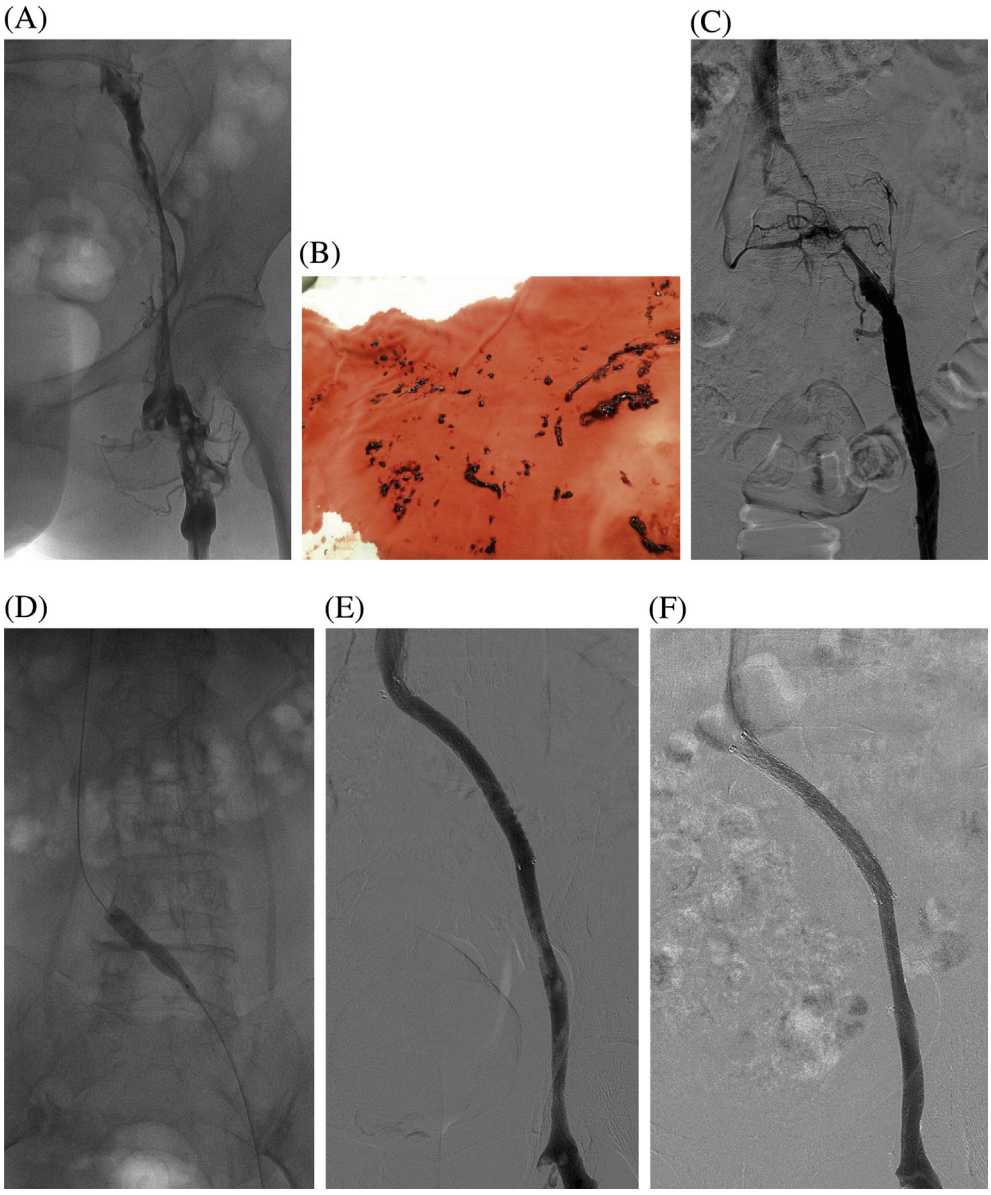

Figure 2. A 72-year-old woman with acute pain and leg swelling in the left lower extremity due to acute iliofemoral deep vein thrombosis (DVT) secondary to iliac vein compression syndrome. (A) Initial venography in the prone position shows acute iliofemoral DVT. (B) Clinical photograph shows the thrombus aspirated out. (C) A venogram after manual aspiration thrombectomy shows stenosis of the common iliac vein and collateral formation. (D) The stenotic iliac vein was dilated with an angioplasty balloon. (E) A venogram after stent deployment shows a patent common iliac vein, good antegrade flow, abolition of collaterals and little residual thrombus. (F) The final venogram shows a patent common iliac vein and no residual thrombus was shown after overnight thrombolysis.

serious gastrointestinal bleeding, recent serious trauma, severe hypertension, pregnancy, coagulopathy, malignancy with less than 1-year estimated survival, or contraindications to the use of anticoagulation or contrast media.

Among the enrolled 26 patients, there were 19 women and 7 men with a mean age of 54 years (aged between 33 and 79 years). All patients presented with leg swelling or pains in the left lower extremity. The duration of symptoms ranged from 1 to 11 days (average 5.2 days). Four of them presented with symptoms for 4 days after hysterectomy because of hysteromyoma. Other risk factors for development of DVT, except IVCS, included immobilization ($n = 8$), bony fractures ($n = 3$), postpartum state ($n = 3$), while no other obvious risk factors were found in eight of them (Table 1). Hematologic abnormalities such as protein S or protein C deficiency, or Factor V Leiden mutation were not routinely searched in the present study.

Single-session endovascular procedures

Informed consents were obtained from all the patients prior to procedures. All authors have experience in interventional radiology of more than 5 years. All of the endovascular procedures, including MAT, balloon angioplasty, and stent placement, were performed in the same setting. Prophylactic IVC filter placement was not planned in this group of patients.

Table 1. The characteristics of deep vein thrombosis secondary to iliac vein compression syndrome and the outcome of single-session endovascular treatment.

Pt. no.	Age (sex)	Symptom duration (days)	Other risk factors	Thrombus location	Procedure time (min)	Complications	Thrombus removal	Clinical outcome	Hospital stay (days)	Follow-up duration (months)
1	51/F	2	Immobilization	Iliac vein and common femoral	68	None	Nearly 100%	Complete	3	25
2	62/F	5	Unknown	Iliac vein and common femoral	75	None	Nearly 100%	Complete	2	24
3	66/F	4	Bony fracture	Iliac vein and common femoral	90	None	Nearly 100%	Complete	3	24
4	57/M	2	Unknown	Iliac vein	50	None	Nearly 100%	Complete	3	23
5	79/M	9	Immobilization	Iliac vein and common femoral	72	Transitory pain	Nearly 100%	Partial	3	22
6	43/F	4	Surgery	Iliac vein and common femoral	55	None	Nearly 100%	Complete	2	22
7	49/F	7	Surgery	Iliac vein and common femoral	86	None	Nearly 100%	Complete	2	21
8	42/M	3	Immobilization	Iliac vein and common femoral	82	Transitory pain	Nearly 100%	Complete	2	21
9	56/F	4	Immobilization	Iliac vein	48	Transitory pain	Nearly 100%	Complete	3	20
10	33/F	5	Postpartum	Iliac vein and common femoral	62	None	Nearly 100%	Complete	3	20
11	66/F	5	Unknown	Iliac vein and common femoral	48	None	Nearly 100%	Complete	2	19
12	57/F	3	Unknown	Iliac vein and common femoral	75	None	Nearly 100%	Complete	2	18
13	35/F	4	Bony fracture	Iliac vein and common femoral	76	Transitory pain	Nearly 100%	Complete	3	17
14	75/M	1	Immobilization	Common iliac	45	None	Nearly 100%	Complete	2	17
15	73/M	11	Unknown	Iliac vein and common femoral	85	None	<5% residual	Complete	4	16
16	46/F	4	Surgery	Iliac vein and common femoral	72	None	Nearly 100%	Complete	2	16
17	55/F	4	Immobilization	Iliac vein and common femoral	76	None	Nearly 100%	Complete	3	15
18	35/F	10	Postpartum	Iliac vein and common femoral	70	None	Nearly 100%	Complete	4	15
19	70/M	8	Unknown	Iliac vein and common femoral	66	None	Nearly 100%	Complete	4	15
20	68/F	6	Bony fracture	Iliac vein	55	None	Nearly 100%	Complete	2	14
21	49/F	10	Unknown	Iliac vein and common femoral	82	Transitory pain	<5% residual	Complete	4	14
22	65/F	2	Immobilization	Common iliac	50	None	Nearly 100%	Complete	3	14
23	57/F	6	Surgery	Iliac vein and common femoral	63	None	Nearly 100%	Complete	2	13
24	46/M	4	Immobilization	Iliac vein and Common femoral	70	None	Nearly 100%	Complete	2	13
25	35/F	5	Postpartum	Iliac vein and common femoral	68	None	Nearly 100%	Complete	3	12
26	54/F	7	Unknown	Iliac vein and common femoral	58	None	Nearly 100%	Complete	3	12

Patients were placed in the prone position on the angiographic table. The ipsilateral popliteal vein was punctured under ultrasonography after the left popliteal fossa had been prepared in a sterile manner. A 21-gauge micropuncture needle set (Cook, Bloomington, IN, USA) was used to access the vein. After placement of a 10F vascular sheath (Cordis, Amsterdam, the Netherlands), an ascending venography was performed (Fig. 2A). Then a 9F guiding catheter (Vista Brite, Cordis) used for MAT was introduced into the thrombus-filled iliac—common femoral vein via a guidewire. The guiding catheter was gently moved back and forth and rotated to aspirate the thrombus while negative pressure was maintained using a 20-mL syringe. During the dynamic movement of the aspiration catheter, a large thrombus could be remodeled and aspirated out (Fig. 2B). If blocked up a by large thrombus, the guiding catheter had to be pulled out of the sheath. Suitable negative pressure was maintained during this process. Repeated MAT was performed until the thrombus within the aspiration catheter was washed out. Venography was performed to evaluate the thrombus burden in the process of aspiration, and repeated aspiration was performed until more than 95% of the thrombus was cleared up before reconstruction of the iliac vein (Fig. 2C). After crossing the lesion with a hydrophilic guidewire, the stenotic or occlusive iliac vein was dilated using a balloon catheter (C.R. Bard, Murray Hill, NJ, USA) (Fig. 2D) and then a self-expandable nitinol stent (Luminexx, C.R. Bard) was placed. A final venography was performed to confirm that antegrade in-line flow from the popliteal vein to the IVC was restored, and the stenosis or occlusion of the iliac vein was eliminated (Fig. 2E). Overnight antegrade thrombolysis through the popliteal sheath with urokinase (total 800,000 units, lasting for 12 hours) was performed if little residual thrombus was shown (Fig. 2E). Another venography was performed to assure complete clearance of the residual thrombus (Fig. 2F).

Periprocedural management and follow-up

Low molecular weight heparin (Nadroparin, GlaxoSmithKline, Tianjin, China) 4,100 IU twice a day for 5—7 days and warfarin sodium 1.25—5 mg once per day were administered when DVT was diagnosed. After endovascular therapy, anticoagulation therapy with warfarin sodium for a minimum course of 6 months was conducted to maintain the international normalized ratio in the range of 2.0—3.0. All patients were to be followed-up at the interventional radiology outpatient clinic at 1, 3, 6, and then every 6 months for the first 2 years, and once every year thereafter. At each clinical visit, CDU was performed to detect the patency of the stent and the deep vein system, and to detect any reflux present. All patients were present at all of the follow-up visits.

Assessment of treatment and definitions

Treatment efficacy and safety were assessed based on the guidelines published by the American Society of Interventional Radiology on lower extremity deep vein thrombosis.[17] Clinical success, technical success, and primary and secondary patency were defined according to the guidelines. Procedure time was counted from the point when the popliteal vein was punctured to the point when the final venography was performed after the stent was placed. Removal of the thrombus by $<$50% after repeated MAT was scaled as minimal (grade I); by 50—95%, as partial (grade II); and by $>$95%, as complete (grade III).

Complications were defined as procedure-related complications such as major vessel wall damage and blood loss secondary to MAT, symptomatic PE, acute thrombosis in the stent, stent migration, and thrombolysis-related complications such as bleeding and hematoma. Major vessel wall damage could be identified when contrast agent stagnation in the vessel wall or diffusion outside the vessel was observed in venography. The major bleeding-associated complications were intracranial bleeding, and severe bleeding necessitating transfusion or surgery, or causing death or cessation of thrombolytic therapy. Minor complications included minimal bleeding or hematoma, fever, pain, and nausea and vomiting.

Statistical analysis

Data were expressed as the mean $\pm$ standard deviation for continuous variables and percentages for categorization. Hemoglobin levels before and right after endovascular procedures were compared using the paired Student *t* test. Statistical analyses were performed using SPSS version 16.0 (SPSS, Chicago, IL, USA).

RESULTS

Efficacy outcomes

Single-session endovascular procedures were performed successfully in all patients, with a technical success rate of 100%. The procedure time varied from 45 to 90 minutes (average 67 minutes). Complete thrombus removal, including nearly 100% in 24 patients and little residual thrombus ($<$5%) that disappeared from our observation overnight in two patients, was achieved after repeated MAT. The thrombus in the four patients who underwent hysterectomy was completely removed without the use of thrombolytic agents (Table 1). Venography after thrombus removal demonstrated collateral formations in the distal iliac veins. Stenosis of the iliac vein was observed in 24 patients and occlusion in two patients. Recanalization of the left iliac vein was successful in all patients and a total of 26 stents, 10—14 mm in diameter and 60—100 mm in length, were placed.

Complete symptomatic relief was achieved in 25 patients (96%) and partial relief in one patient within a week after procedures. The hospital stay ranged from 2 to 4 days (average 2.7 days) (Table 1). During the follow-up periods, recurrent thrombosis in the stent was detected in one patient 11 months after the procedures. After CDT, successful restoration of antegrade in-line flow within the stent was obtained. Overall, primary and secondary patency rates

were 96% and 100% at 1 year. The follow-up periods ranged from 12 to 25 months (average 17.8 months).

Safety outcomes

Major damage to the vessel wall related to the MAT was not observed. None of the patients in this group experienced symptomatic PE and bleeding complications. No reflux was detected in any of the patients. The mean decrease in the hemoglobin level after procedures was 1.2 g/dL and there was no significant difference compared with the preprocedural level ($p = .00$). Five patients complained of transitory low back pain during balloon angioplasty.

DISCUSSION

Although quality improvement guidelines for the treatment of lower extremity DVT have been published by the American Society of Interventional Radiology and the Society for Vascular Surgery,[7,14] catheter-based endovascular methods differ from center to center. CDT plus anticoagulant therapy is an acceptable initial treatment strategy for many patients with acute iliofemoral DVT because of its consistent success in the removal of thrombus and the potential to prevent PTS. A pooled analysis revealed that major bleeding, due to administration of large dosages of thrombolytic agents and prolonged infusion time, was the most frequent major complication of CDT and was observed in approximately 8% of patients undergoing treatment.[8] Adjunctive PMT devices, such as Angiojet, ATD, Trellis-8, EKOS Endowave, have been designed to offer an appealing endovenous solution for aggressive thrombus removal. A systemic review demonstrated that a technical success of 82—100% was achieved with grade II or III lysis (≥50% luminal patency) in 83—100% of patients.[13] As well as disadvantages mentioned before, PMT devices are significantly costly.

The results of the present study demonstrated that MAT can not only provide a rapid and effective means for the treatment of acute isolated iliac—common femoral DVT due to IVCS, but also be adopted as a first-line thrombus removal method for this appropriately selected group of patients. Based on the rapidness and effectiveness of MAT, single-session endovascular treatment is technically feasible. Following MAT, the underlying iliac stenosis or occlusion can be treated in the same setting, which may contribute to more efficient patient care. Another advantage of the current technique is the excellent performance—price ratio. Fresh thrombus and relatively lower thrombus burden result in good response to MAT alone. Compared with that of CDT, the effectiveness of MAT was predominant in this patient group,[17] so that administration of urokinase was limited in only two patients, and bleeding complications were thus not observed. In this study, two patients presented with symptoms 4 days after hysterectomy, which was considered a contraindication to the use of thrombolytic agent. However, complete removal of the thrombus was achieved by MAT alone.

PE risks, vessel wall and valve damage, hemolysis, and hemoglobinuria are the potential procedure-related complications of PMT.[6,14] In the present study, major damage to the vessel wall related to the MAT manipulation was not observed. To date, it is difficult to evaluate damage to valves and minor damage to vessel walls, such as damage to endothelium. The present authors deduce that damage to valves or vessel walls due to MAT may not be clinically significant, as illustrated in part by the fact that no reflux or valve dysfunction was detected by CDU in the 1-year follow-up. Long-term effects on the valvular function remain to be evaluated in the future. Based on our results and those of Oguzkurt L et al.,[16] MAT is promising for removing the thrombus in the femoral or popliteal vein.

Symptomatic PE was not observed in this study. We deduce that the incidence of PE is probably lower because the intraluminal synechiae may act as a simple obstructive barrier in preventing the passage of large volumes of thrombus into the IVC. Whether prophylactic IVC filter placement is necessary or not in the treatment of acute DVT due to IVCS remains controversial; during enrollment of patients for this study, we had cases with thrombus extension to IVC, even though evidently underlying venous stenosis at the left common iliac vein was observed on CT images (Fig. 1D, E).

The anatomy of deep veins, the extent of thrombus, and the underlying stenosis or obstruction is important information in the management of DVT, especially for left-sided cases with a high index of suspicion of IVCS. It is very difficult to accurately evaluate the underlying stenosis or obstruction in patients with extensive acute iliofemoral DVT by ascending venography alone, unless the thrombus has been removed. In recent years, CT has proved to be useful in evaluating the underlying anatomic abnormalities in patients with left-sided DVT.[18,19] CT venography and three-dimensional construction images are useful in selecting patients appropriate for the present single-session endovascular treatment (Fig. 1). Our results demonstrated that a CT scan could provide great important information in treatment planning for DVT.

Various studies have revealed that endovascular treatment of DVT due to IVCS is feasible and effective, with 79—100% primary patency rates in 1—2 years.[3,5,20,21] Our results are similar to those of previously reported series. Patency during the long term, however, has to be assessed in the future.

This study has certain limitations. We had a relatively small study group with a single arm; larger groups and comparative studies must be performed to firmly establish the interventional protocol. The follow-up period was short, and long-term follow-up is needed to confirm safety and effectiveness.

In conclusion, single-session endovascular treatment with MAT as the first-line thrombus removal method is feasible, safe, and effective for the treatment of IVCS with secondary acute isolated iliac—common femoral DVT. Although limited, our experience suggests that patients thought to be at a high risk of bleeding may be suitable candidates for the present single-session endovascular protocol.

FUNDING

None.

CONFLICT OF INTEREST

None.

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