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CLINICAL INVESTIGATION

Endovascular Treatment of Phlegmasia Cerulea Dolens with Impending Venous Gangrene: Manual Aspiration Thrombectomy as the First-Line Thrombus Removal Method

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Abstract
Purpose Our purpose was to report the outcome of endovascular treatment with manual aspiration thrombectomy as the first-line thromboablative method for phlegmasia cerulea dolens.
Methods Between October 2006 and May 2010, seven consecutive patients (5 women, 2 men; age range, 31–80 years) with the diagnosis of phlegmasia cerulea dolens secondary to acute iliofemoral deep venous thrombosis had endovascular treatment with manual aspiration thrombectomy. Catheter-directed thrombolysis and stent placement were used as adjunctive procedures. Phlegmasia was left-sided in five and right-sided in two patients.
Results All patients had associated great saphenous vein thrombosis in addition to iliofemoral deep vein thrombosis (DVT). Aspiration thrombectomy completely removed the thrombus from the popliteal vein to the inferior vena cava (IVC) in all cases. Three patients with May-Thurner syndrome had stent placement in the left common iliac vein. Two patients had early recurrences. Repeated aspiration thrombectomy was unsuccessful in one patient. There were no complications related to the procedure. One patient who had been successfully treated died of sepsis and another patient who had unsuccessful repeated interventions had below-the-knee amputation. Overall, the clinical success and survival rates of patients in this study were 86%. On follow-up, three patients with successful treatment were asymptomatic with no deep venous insufficiency. One of these patients died during the 4-month follow-up period. Two patients had mild ankle swelling with deep venous insufficiency.
Conclusions Manual aspiration thrombectomy with adjunctive use of catheter-directed thrombolysis and stent placement is an effective endovascular treatment method with high clinical success and survival rates for phlegmasia cerulean dolens.

Keywords Venous intervention · Aspiration · Combined treatments · Endovascular treatment · Inferior vena cava filter (IVC) placement · Thrombectomy · Thrombolysis · Vein · Deep vein thrombosis

Introduction

Phlegmasia cerulea dolens (PCD) is an uncommon, but life-threatening complication of acute deep vein thrombosis (DVT). Phlegmasia refers to a characteristic clinical picture in which DVT causes massive swelling of the entire extremity. Phlegmasia alba dolens is massive swelling of the limb but is not associated with cyanosis. In contrast, phlegmasia cerulea dolens is associated with cyanosis and can lead to arterial insufficiency, compartment syndrome, venous gangrene, and limb amputation [1, 2]. It is characterized by total or near total occlusion of the limb veins, including the microvascular circulation. Arterial insufficiency due to severe venous edema causes severe pain depending on the degree of arterial ischemia. PCD is an

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emergency that requires prompt diagnosis and treatment if venous gangrene is to be prevented. A delay in treatment may lead to venous gangrene, amputation, and death of the patient. There is no consensus for treatment so far. Treatment methods that have been suggested include the following alone or in combination: anticoagulation with leg elevation, fasciotomy, surgical thrombectomy, and thrombolytic therapy. However, the treatment methods previously reported are mostly suboptimal and often patients require amputation despite treatment [1].

Mechanical thrombectomy methods are generally used to treat lower extremity DVT in combination with catheter-directed thrombolysis (CDT) to increase efficiency and decrease procedure time [3]. Percutaneous manual aspiration thrombectomy (AT) also is an effective method for thrombus removal but is seldom used for lower extremity DVT [4]. It has the advantage of rapidity and avoids bleeding complications compared with catheter-directed thrombolysis—the standard endovascular treatment for DVT. In this study, we present seven patients with PCD treated with AT for first-line thrombus removal method alone or in combination with catheter-directed thrombolysis and stent placement.

Materials and Methods

Patients

Between October 2006 and May 2010, seven consecutive patients (5 women, 2 men; mean age, 58 (range 31–80) years) who were diagnosed with acute deep venous thrombosis with phlegmasia cerulea dolens were treated with endovascular methods (Table 1). A diagnosis of DVT was established with color Doppler ultrasonography, which included the deep as well as the superficial veins, and was confirmed with venography performed during the endovascular procedure in all patients. The duration of symptoms ranged from 5 h to 7 days. The progress of the disease was very rapid in two patients compared with the other five patients. One patient had a bypass operation 15 days before the onset of the disease and another had previous ipsilateral crural DVT 15 years ago. Two patients had clinically mild pulmonary embolisms, which were detected by computed tomography at the time of diagnosis. All patients were admitted to the intensive care unit and supportive measures were undertaken immediately. Magnetic resonance imaging (MRI) of the involved leg was

Table 1 Demographic data and treatment outcome

Patients (#)	1	2	3	4	5	6	7
Sex	F	F	M	M	F	F	F
Age (year)	77	64	80	67	31	40	55
Location of PCD	Left	Right	Left	Left	Left	Right	Left
Duration of symptoms	8 h	7 days	5 days	1 day	5 h	5 days	4 days
Risk for DVT	None	None	None	Postoperative state	Previous DVT)	None	None
May-Thurner syndrome	Yes	NA	No	Yes	Yes	NA	No
Comorbidity	CHF	Morbid obesity	CHF	CAD	DM	–	DM
Type of DVT	Descending	Ascending	Ascending	Ascending	Descending	Ascending	Descending
IVC involvement	–	–	+	+	+	+	–
IVC filter	–	–	–	+	+	+	–
Arteriography	–	+	+	–	–	–	–
Stent size (mm)	12 × 90	–	–	12 × 90	14 × 60	–	–
CDT	–	–	–	–	–	+	+
Recurrence	–	–	–	–	–	2nd day	1st day
Procedure duration (min)	55	60	75	115	85	125	140
Treatment day	1	1	1	1	1	3	4
Complication	None	None	None	None	None	None	None
Follow-up	Asymptomatic	Asymptomatic	Ex in the hospital	Mild symptoms	Asymptomatic	Mild symptoms	Below-the-knee amputation
Femoral vein insufficiency	No	No	NA	Yes	No	Yes	NA

F female, *M* male, *PCD* phlegmasia cerulea dolens, *DVT* deep venous thrombosis, *IVC* inferior vena cava, *CDT* catheter-directed thrombolysis, *CHF* congestive heart failure, *CAD* coronary artery disease, *DM* diabetes mellitus, *NA* not applicable

performed if there was slow clinical improvement or clinical deterioration of the leg.

Standard heparin at a loading dose of 5,000 IU and infusion dose of 1,000 IU per hr to maintain an activated partial thromboplastin time between 60 to 90 s was initiated as soon as the diagnosis of DVT had been established. All patients were given detailed information on endovascular treatment, which is the treatment of choice for acute and subacute iliofemoral DVT in our hospital. Written, informed consent was obtained from each patient. Patients were scheduled for urgent treatment and all were treated the same day that they arrived at the hospital without delay. There was no exclusion criteria set for PCD. Contralateral limbs with iliofemoral DVT also were treated per our routine even though there were not PCD in these limbs.

Procedure

The patient was placed prone on the angiography table (GE, Innova IQ3100, USA). Punctures were made under ultrasound guidance with 9-MHz or 13-MHz transducers (Antares, Siemens, Erlangen, Germany) using 21-gauge or 18-gauge needles. First access to the vein was achieved with a high crural or low popliteal vein puncture in all patients. Access to the great saphenous vein (GSV) or posterior tibial vein (PTV) also was attempted, if deemed necessary. Venograms were obtained from every puncture site. A 10-Fr vascular sheath (Cordis Europa, Roden, the Netherlands) was placed in the popliteal vein for aspiration with a 8-Fr or a 9-Fr guiding catheter (Vista Brite, Cordis). A 6-Fr or a 7-Fr guiding catheter was used for aspiration of the thrombus in the GSV. A straight-tip guiding catheter was used to aspirate for veins with a straight course (popliteal, femoral, or GSV), and an angled multipurpose guiding catheter was used for veins with a curved course (e.g., iliac veins or saphenofemoral junction). Smaller, angled-tip guiding catheters (5-Fr or 6-Fr Envoy guiding catheter, Cordis) were used to aspirate from small-diameter veins (e.g., saphenous veins). If there were thrombi in the inferior vena cava (IVC) prone to embolization during endovascular treatment, a retrievable IVC filter was placed. The filter was removed as soon as possible. Catheter-directed thrombolysis was used to dissolve thrombus in the small veins where AT is not recommended or to dissolve residual thrombi after AT. Tissue plasminogen activator (Actilyse, Boehringer Ingelheim, Rhein, Germany) at a dose of 1 mg per hr was the thrombolytic drug used. Removal of the thrombus was regarded as complete if >95%, partial if 50 to 95%, and poor if <50% of the thrombus was removed. After thrombus removal with AT or CDT, additional pelvic venograms were always obtained for detailed evaluation of the iliac veins during the procedure. If there was significant compression with intraluminal webs consistent with iliac vein compression (May-Thurner) syndrome, or if there was irregularity or residual thrombus that could not be removed in the iliac veins or the IVC, a stent was placed and dilated with a balloon catheter.

Therapeutic-level heparin was administered during the procedure. The anticoagulant warfarin sodium was started after the procedure and continued for 6 months. Follow-up was performed at 1 week and 1, 3, 6, and 12 months, and then annually and included clinical examination and color Doppler ultrasonography.

Results

All patients had iliofemoral DVT with massive swelling of the limb, cyanosis, and pain. Pain was very severe in two patients. Four patients had skin blistering at the time of treatment. DVT was bilateral in four patients and unilateral in three patients, but PCD was unilateral (5 on the left, 2 on the right) in all patients. One patient previously had bilateral PCD but had undergone amputation of the right leg 3 days before his admission in another center for venous gangrene. Four patients had an ascending type of DVT in which venous thrombosis originated from the crural veins with involvement of crural, popliteal, femoral, and iliac veins. Two of these patients also had thrombi in the IVC. Three patients had a descending type of DVT in which crural and popliteal veins were patent. These three patients had involvement of the proximal femoral and iliac veins. Additionally, two of the patient with descending DVT also had involvement of the IVC. Thrombosis of the great saphenous vein was seen in all patients. A thrombus was present in the proximal GSV in four patients and the entire GSV in three patients. Three patients had iliac vein compression (May-Thurner) syndrome as diagnosed by venography during the procedure. Color Doppler ultrasonography examination revealed involvement of the deep femoral vein in four patients.

The first access to the venous system was through the popliteal vein in all patients. Four patients had additional GSV puncture below the knee and two patients had an additional PTV puncture at the ankle level because successful removal of thrombus in the popliteofemorocaval axis did not resolve significant leg swelling. The thrombus was removed completely (>95%) and uninterrupted venous flow was established in all patients from the puncture site up to the IVC at the first intervention (Figs. 1, 2). Aspiration of the whole thrombus required 15 to 30 passes of the catheter depending on the thrombus burden. Three patients with IVCS had stent placement in the left common iliac vein. Of the patients with stents, two patients had a 12 × 90 mm Wallstent (Boston Scientific, Natick, USA),

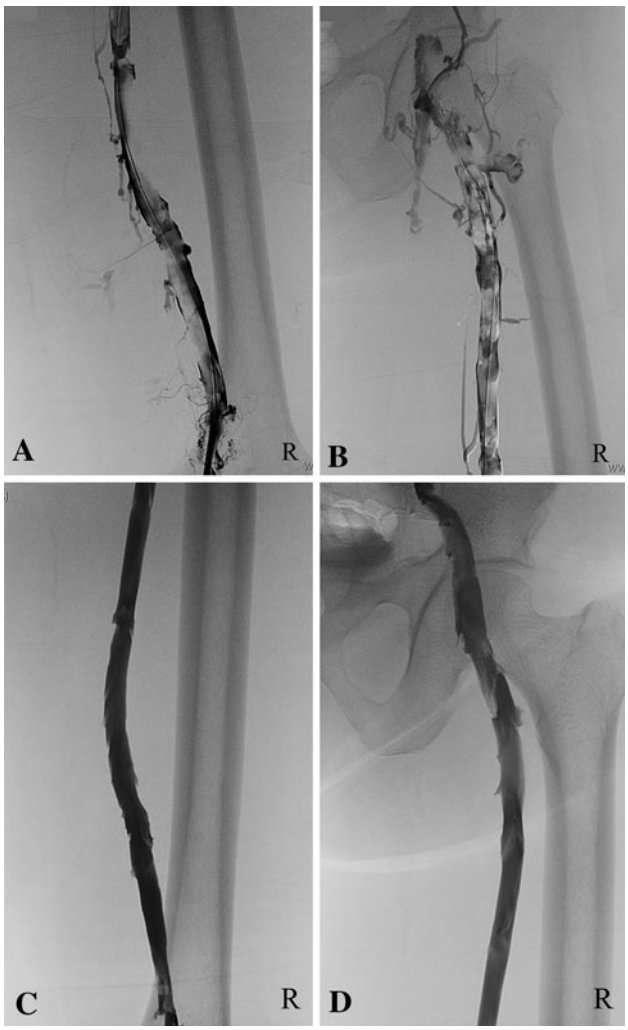

Fig. 1 Venograms obtained through the popliteal sheath while the patient is prone shows massive acute iliofemoral deep venous thrombosis (**A** and **B**). After 10 min of manual aspiration thrombectomy, there is complete removal of the thrombus (**C** and **D**)

and one patient had a 14 × 60 mm nitinol stent (Protégé, eV3, MN, USA). In two patients, contralateral limb DVT was the iliofemoral type and was treated with endovascular methods during the same session. One of these patients had AT alone and the other patient had AT with stent placement (Wallstent, 12 × 90 mm) in the common iliac vein. Three of four patients with IVC thrombosis had a filter placed in the infrarenal IVC without complication just before the treatment (Fig. 2). IVC filters were removed at the end of the first intervention in one patient and after 5 days in two patients. There were no thrombi entrapped in the filters.

The first five patients had successful treatment without recurrence. The sixth patient had heparin-induced thrombocytopenia and recurrent thrombosis on day 2. This patient underwent a second intervention through the popliteal vein. Aspiration thrombectomy was performed with success. To prevent recurrence and to increase blood flow to the femoral and iliac veins, the GSV and the PTV were punctured at the ankle level and tPA infusion was started at a dose of 0.5 mg/h from each port for 16 h. On the following day, there was complete dissolution of the thrombus in both venous segments. Aspirin (300 mg/day) was started on the first day after cessation of heparin, and warfarin (5 mg/day) was started after CDT and continued for 6 months. There were no additional recurrences. This patient had venous gangrene in all five toes at the time of admission and underwent planned amputation of all toes on day 7. The last patient (no. 7) had patent veins in the popliteal-iliac vein axis 1 day after treatment with persistent massive swelling of the limb distal to the knee. Both the saphenous veins and crural veins below the knee still had thrombi obstructing venous flow. The GSV and PTV were punctured. AT was performed for the GSV thrombosis with complete removal of the thrombus (Fig. 3). CDT was started in the PTV at 1 mg per day. The patency of the veins was restored after 20 h of thrombolytic infusion. This patient had recurrence of thrombosis 2 days later. The deep venous system was recanalized with AT, but flow could not be established at the end of the procedure. Blisters on the lateral side of the leg deteriorated. MRI of the leg did not reveal an infracted area in the muscle planes. This patient had good anticoagulation with expected target activated partial thromboplastin levels throughout the hospitalization period. A below-the-knee amputation was required on day 7.

Endovascular treatment with manual AT as the first-line treatment method and CDT as an adjunctive procedure resulted in clinical success and survival rates of 86%. The duration of treatment and the total procedure times are shown in Table 1. The fluoroscopy times ranged from 9–32 (mean, 17) min. Cyanosis disappeared the same day in every patient. Swelling progressively decreased within a day and was completely resolved after 72 h in the first five patients. Complete healing of skin blisters took approximately 15 days in three patients and progressed to gangrene and ultimately to amputation in one patient (no. 7). No complications occurred due to endovascular treatment in any of the patients. The patient with a previous right leg amputation died of sepsis on day 3 without PCD in the hospital. He was in the intensive care unit from the time of admission to his death. On long-term follow-up, one patient died of congestive heart failure 4 months after treatment. She was asymptomatic at the 3-month follow-up. Two other patients were asymptomatic without deep venous insufficiency at the 6- and 24-month follow-ups. Two patients had mild swelling around the ankle with deep venous insufficiency at the 12- and 36-month follow-ups. There was no recurrence of thrombosis or pulmonary embolism during the follow-up period.

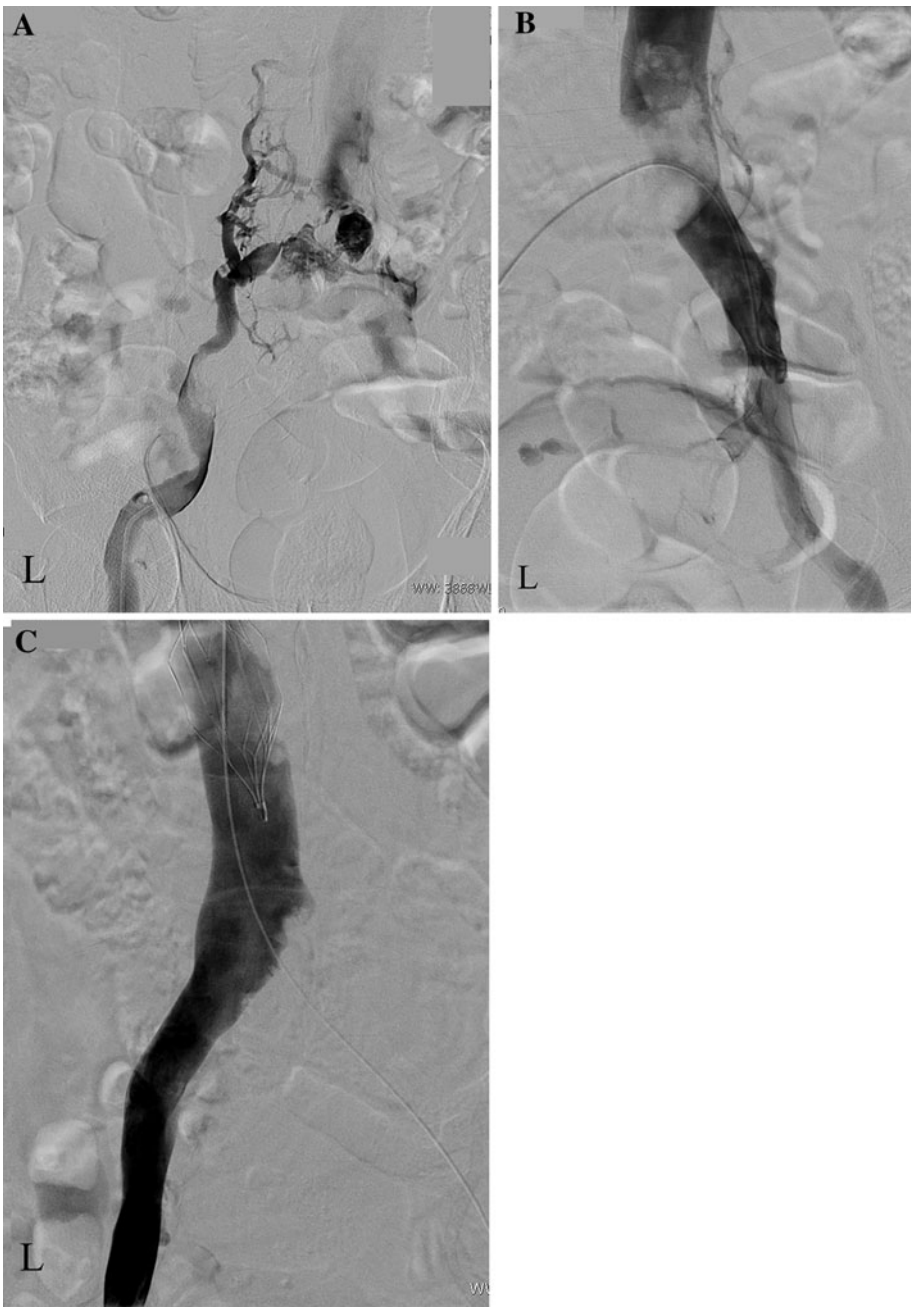

Fig. 2 Venograms in prone position show complete thrombosis of the iliac veins (**A**). After manual aspiration thrombectomy of the iliac veins, a catheter was advanced to the contralateral iliac vein to reveal extension of thrombus in the inferior vena cava (**B**). After seeing the location of the caval thrombus, a vena cava filter is placed from the same popliteal approach. The thrombus in the inferior vena cava was removed with aspiration thrombectomy alone. The venogram shows complete removal of the thrombus from the iliac vein and the inferior vena cava (**C**). A Wallstent was placed to the right common iliac vein of this patient during the same session (not shown)

Discussion

All patients in this study had iliofemoral DVT, and during the past 10 years no patients have been seen with distal (femoropopliteal) DVT presenting as PCD in our center. All patients in this study had involvement of the common femoral vein, which is the drainage junction of the femoral vein, great saphenous vein, and the deep femoral vein. All patients also had thrombosis of the great saphenous vein at least in the proximal segment that drains into the common femoral vein. Additionally, all patients who were examined with Doppler ultrasonography had thrombosis of the deep femoral vein. Four of seven patients had massive involvement of the IVC. Thrombus burden was very high in each patient, and these findings were not previously reported in detail for PCD in the literature. The rapidity of progression of venous thrombosis varied among patients. There was rapid progression to blister formation, indicating partial thickness necrosis and early venous gangrene within a few hours in two patients and more slow progression taking several days in the other five patients. Patients with rapid progression also had the most severe pain due to arterial ischemia. This was probably due to the rapidity with which the thrombus extended or the degree of occlusion of the

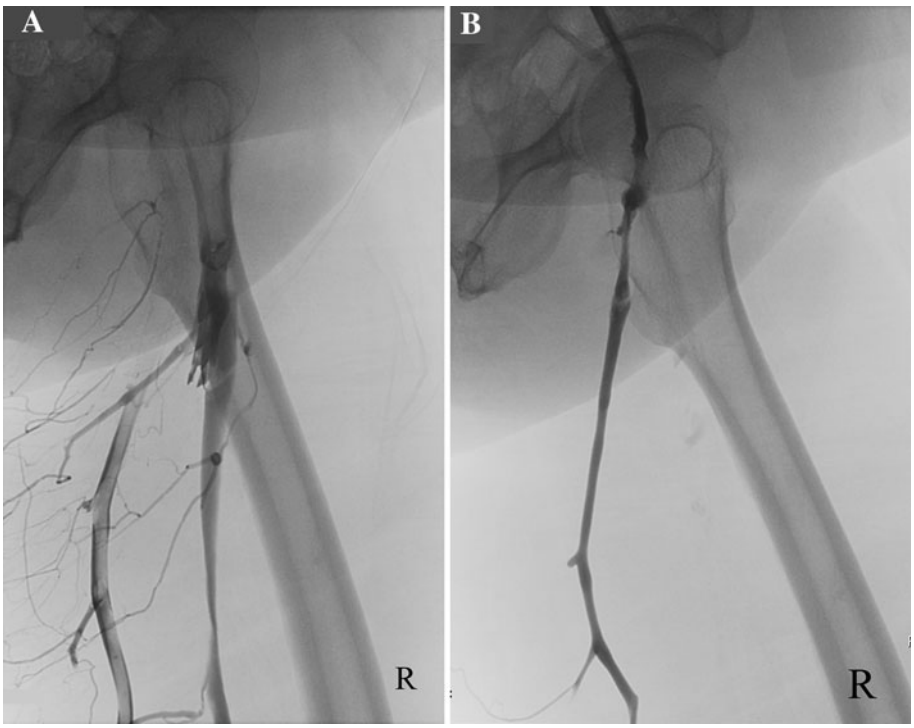

Fig. 3 Venogram through a sheath in the right great saphenous vein shows acute thrombosis of the vein (**A**). To improve the blood flow from the leg, a 7-Fr vascular sheath was placed in the saphenous vein at a level below the knee and the thrombus was aspirated with a 7-Fr guiding catheter (**B**)

main and collateral venous pathways. Complete or near complete occlusion of the common femoral vein and the two tributary veins (GSV and deep femoral vein) was probably the key factor in the development of PCD in our patient population. Endovascular treatment was successful in all patients with complete removal of the thrombus in the deep venous system after the first interventions. The recurrence rate (2/7) was high during the first 3 days. Thrombosis in one patient who had amputation of the left leg was quite aggressive and resistant or unresponsive to successful repeated endovascular treatments.

DVT presents with different severity of clinical manifestations depending on the extent of thrombus and degree of venous occlusion. PCD is the worst DVT clinical scenario apart from massive pulmonary embolism and requires emergency treatment. PCD denotes a reversible clinical stage but can progress to an irreversible stage of venous gangrene. The classical clinical triad of PCD consists of intense pain, significant edema, and cyanosis—hence the term phlegmasia cerulea dolens (blue, painful leg). The risk factors for PCD are the same as for DVT, but the postoperative state and malignancy rates are reported to be higher in patients with PCD [5]. PCD is mostly seen with iliofemoral DVT but also can be seen with femoropopliteal DVT. Bilateral involvement occurs in only 6.2% of cases of PCD. In unilateral cases of PCD, the left lower extremity is affected four times more often than the right. This is possibly the result of iliac vein compression syndrome, which also may occur with DVT. In venous gangrene, by contrast, the left lower extremity is affected only slightly more than the right (left 56%, right 46%) [5]. In addition, there are more bilateral cases of venous gangrene than PCD [5].

Extensive venous occlusion with a rapid increase in venous pressure is thought to cause massive extravasation of fluid into the surrounding tissue leading to resistance of arterial flow with associated reduction in tissue perfusion. This in turn may lead to arterial ischemia and ultimately gangrene [6]. The intravascular pressure has been shown to increase to 16–17 times the normal pressure within 6 h of occlusion [7]. Massive extravasation and sequestration of fluid in the leg can lead to significant hypovolemia with renal failure if fluid resuscitation is inadequate. Therefore, supportive treatment to reverse hypovolemia and hypovolemic shock is essential at the onset of the condition. It results in venous gangrene in almost half of the cases reported: pulmonary emboli in 22%, amputation in 12–50%, and death in 20–40% of patients [1, 2, 6, 8]. Blistering of the skin indicates partial-thickness necrosis and is considered early venous gangrene. Venous gangrene is full-thickness skin necrosis caused by ischemia. The development of tissue necrosis and venous gangrene is a late sign of PCD and carries a poor prognosis as opposed to the more favorable prognosis when tissue necrosis is not present.

In a review of articles from 1967 to 1985, treatment with intravenous heparin was 100% successful in 12 patients with PCD without venous gangrene, whereas it was completely ineffective in 12 patients of PCD with venous gangrene [1]. Surgical thrombectomy and thrombolysis

seemed to be more effective in patients without venous gangrene than in patients with venous gangrene. Because PCD progresses rapidly within hours, the clinical presentation mimics that of acute limb ischemia. Acute limb ischemia can follow a very rapid or slower course depending on the degree of arterial occlusion and presence of collaterals supplying the distal arterial tree. Limb swelling is the dominant differential among clinical features.

It is not known when and why acute DVT leads to complete occlusion severe enough to produce PCD and venous gangrene. Recent literature shows that proximal mechanical obstruction of the iliac veins and IVC, such as iliac vein compression syndrome, and previously placed IVC filter seems to be a risk factor for PCD but this is not well-established. The recent literature indicates that postoperative state does not seem to be a high-risk factor for PCD as was claimed in the past. This may be due to the fact that more patients get prophylaxis for operations having a high risk for DVT. On the other hand, the literature still suggests that malignancy is a high risk for PCD, although none of our patients had malignancy before PCD [1, 2]. IVC filters have been recently reported as a frequent risk factor for PCD [2, 9–12]. In some of these reports, DVT rapidly progressed to PCD after placement of IVC filters. Therefore, partial mechanical obstruction with an IVC filter in a patient with an aggressive venous thrombosis might actually be a trigger for the progression from DVT to PCD in some patients. Although the association of IVC filters and PCD has been previously reported, possible progression of DVT to PCD after IVC filter placement has not been emphasized. Based on this previous literature, IVC filters used in this study were removed as soon as possible. We did not have any patient with a previous IVC filter placement because endovascular treatment has been our routine treatment method for iliofemoral DVT during the past 10 years and we prefer to remove thrombi rather than place IVC filters to prevent pulmonary embolism. Aspiration thrombectomy provides the means to treat almost every patient with iliofemoral DVT, including those who cannot undergo anticoagulation or those who developed complications due to anticoagulation.

There is no consensus on the treatment of PCD due to the rarity of the condition, and therapeutic outcomes are suboptimal. The goal of therapy is to immediately arrest thrombus formation and progression and preserve patency of the venous collateral pathways. The recommended treatments for thrombosis are anticoagulation, systemic thrombolysis, catheter-directed thrombolysis, and surgical thrombectomy alone or in combination. Surgical thrombectomy with or without distal arteriovenous fistula creation has been advocated as the primary intervention for patients who have severe ischemia or impending venous gangrene due to DVT. With this treatment, mortality and recurrences were high and postoperative venous insufficiency (postthrombotic syndrome) was common [13, 14]. Anticoagulation and systemic thrombolysis in selected patients resulted in a fatal outcome in 4 of 12 patients [2]. Systemic thrombolysis with streptokinase or alteplase achieved resolution of pain and cyanosis, but massive swelling of legs on long-term follow-up persisted in most patients [15]. Catheter-directed thrombolysis (CDT) has been shown to be feasible and effective for treating acute lower extremity DVT [16]. The most important drawback of CDT was minor or major bleeding [16]. Limited case reports describe the use of CDT in the treatment of PCD with good limb salvage rates in most patients [2, 9, 17]. Although more effective than anticoagulation, infusion of a thrombolytic agent usually takes longer than 36 h and may take up to 72 h for successful thrombus removal. Although the technique is very good for patients who have slow progression of PCD, this period may be too long to avoid irreversible tissue necrosis in patients with a rapid course of progression. Therefore, CDT is not recommended for PCD patients with a very rapid disease course, which was the case in two of our patients. Pulse-spray thrombolysis for PCD requires additional long-term infusion of thrombolytic agent. Percutaneous mechanical thrombectomy devices can be combined with CDT. The main goal of all treatments used for DVT is to resolve the patient's symptoms by removing the thrombus to prevent pulmonary embolism and postthrombotic syndrome. One of the goals of DVT treatment should be to prevent development of PCD.

Manual aspiration thrombectomy was first described by Starck et al. and is applicable to emboli as well as thrombosis of iatrogenic or intrinsic origin [18]. It is the key technique of mechanical thrombectomy. It is simple to perform and easy to learn and is inexpensive and rapid [4]. It is therefore surprising that it is not more frequently used in clinical practice. Manual AT also has been used to treat lower extremity DVT in combination with thrombolysis [3, 19–21]. The effectiveness of AT as the primary thrombus removal method has been previously reported to be rapid and effective for one of our patients with PCD (patient 1) and in 27 patients with acute limb DVT without PCD. Flow was established using AT in 24 (88%) of these patients [22, 23]. There have been no other studies on the safety and effectiveness of AT as the first-line endovascular treatment of DVT with or without PCD. AT has the major advantage of effective thrombus removal with no bleeding complication. Our data suggest that AT should be considered as the first line of treatment when progression of the disease is rapid and administration of heparin or thrombolytic agents is contraindicated. In centers where endovascular treatment of DVT is not performed, surgical thrombectomy should be

considered in patients who are unresponsive to anticoagulation given the aggressive nature of the disease.

Phlegmasia cerulea dolens is an emergency and can rapidly progress to tissue necrosis and venous gangrene if left untreated. It occurs mostly in patients with acute iliofemoral DVT. The thrombosis is very extensive. The common femoral vein, the great saphenous vein, the deep femoral vein, and the IVC are involved in most or all patients. Disease progression is very rapid in some patients, therefore making the use of catheter-directed thrombolysis obsolete because of long infusion times. Manual AT can provide as rapid and effective of a treatment as surgical thrombectomy without the risk of morbidity, mortality, or recurrences after surgery or bleeding caused by thrombolytic administration. It should be considered as one of the first-line endovascular treatments, especially when the disease progression is rapid.

Conflict of interest The authors declare that they have no conflict of interest.

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