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***Original Article** / Özgün Makale*

Combined pharmacomechanical thrombectomy with selective catheter-directed thrombolysis in patients with acute proximal deep vein thrombosis

Proksimal akut derin ven trombozu olan hastalarda kombine farmakomekanik trombektomi ve kateter aracılı selektif tromboliz

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ABSTRACT

Background: The aim of this study was to evaluate the characteristics and the outcomes of combined percutaneous pharmacomechanical thrombectomy with selective catheter-directed thrombolysis for acute iliofemoral deep vein thrombosis.

Methods: Between March 2018 and February 2020, a total of 37 patients (21 males, 16 females; mean age: 55±13.8 years; range, 21 to 79 years) with symptomatic acute iliofemoral vein thrombosis who underwent combined percutaneous pharmacomechanical thrombectomy and catheter-directed thrombolysis were retrospectively analyzed. All patients received a three-step therapy: *(i)* insertion of a temporary inferior vena cava filter, *(ii)* percutaneous pharmacomechanical thrombectomy via rotational mechanical thrombectomy device with an adjuvant 0.15 mg/kg recombinant tissue-type plasminogen activator alteplase, and *(iii)* catheter-directed thrombolysis with continuous 1 mg/h tissue-type plasminogen activator alteplase. Data including demographic characteristics of the patients, bleeding complications, technical success, and adjuvant angioplasty rates were analyzed. The Kaplan-Meier analysis was used to evaluate freedom from re-thrombosis at 3, 6, and 12 months of follow-up was calculated.

Results: The majority of the patients had left-sided (n=22, 59.4%) proximal deep vein thrombosis. Successful insertion of the inferior vena cava filter was achieved in 97.2% (n=36) of patients. The technical success rate was 89.1% (n=33). Adjuvant venous angioplasty was performed in four patients (10.8%) and no venous stents were used. No major bleeding was occurred, while minor bleeding was observed mostly in the form of hematuria (n=12, 32.4%). No mortality was observed. The 3, 6, and 12-month freedom from re-thrombosis rates were 96.3%, 92.6%, and 86.0%, respectively.

Conclusion: Combined percutaneous pharmacomechanical thrombectomy and catheter-directed thrombolysis seems to be an effective and safe treatment of the iliofemoral acute deep vein thrombosis with acceptable minor bleeding complications post-interventionally.

Keywords: Acute iliofemoral deep vein thrombosis; catheter-directed thrombolysis; percutaneous pharmacomechanical thrombectomy; thrombolytic.

ÖZ

Amaç: Bu çalışmada, akut iliofemoral derin ven trombozunda kateter aracılı selektif tromboliz ile birlikte yapılan perkütan farmakomekanik trombektominin sonuçları değerlendirildi.

Çalışma planı: Mart 2018 - Şubat 2020 tarihleri arasında, semptomatik akut iliofemoral derin ven trombozu nedeniyle kombine perkütan farmakomekanik trombektomi ve kateter aracılı tromboliz uygulanan toplam 37 hasta (21 erkek, 16 kadın; ort. yaş: 55±13.8 yıl; dağılım 21-79 yıl) retrospektif olarak incelendi. Tüm hastalara üç aşamalı tedavi uygulandı: *(i)* geçici inferior vena kava filtresinin yerleştirilmesi, *(ii)* 0.15 mg/kg rekombinant doku tipi plazminojen aktivatör alteplaz ile rotasyonel mekanik trombektomi cihazı aracılığıyla perkütan farmakomekanik trombektomi ve *(iii)* sürekli 1 mg/saat doku tipi plazminojen aktivatör alteplaz ile kateter aracılı tromboliz. Hastaların demografik özellikleri, kanama komplikasyonları, teknik başarı ve adjuvan anjiyoplasti oranları dahil olmak üzere veriler incelendi. Kaplan-Meier analizi, 3, 6 ve 12 aylık takiplerde yeniden tromboz olup olmadığını değerlendirmek için kullanıldı.

Bulgular: Hastaların çoğunda sol taraflı (n=22, %59.4) proksimal derin ven trombozu saptandı. Hastaların %97.2'sinde (n=36) inferior vena kava filtresi başarılı bir şekilde yerleştirildi. Teknik başarı oranı %89.1 (n=33) idi. Dört hastaya (%10.8) adjuvan venöz anjiyoplasti uygulandı ve venöz stent kullanılmadı. Majör kanama görülmemekle birlikte, minör kanama daha çok hematüri şeklinde izlendi (n=12, %32.4). Mortalite gözlenmedi. Üç, altı ve 12 aylık yeniden tromboz görülmeme oranları sırasıyla %96.3, %92.6 ve %86 idi.

Sonuç: Akut iliofemoral derin ven trombozu olan hastalarda kombine kateter aracılı tromboliz ve perkütan farmakomekanik trombektomi tedavisi, girişim sonrası kabul edilebilir minör kanama komplikasyonları ile etkili ve güvenli bir tedavi olarak değerlendirebilir.

Anahtar sözcükler: Akut iliofemoral derin ven trombozu, kateter aracılı tromboliz, perkütan farmakomekanik trombektomi, trombolitik.

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Deep venous thrombosis (DVT) is a common cause of cardiovascular mortality and morbidity that can induce a life-threatening pulmonary embolism (PE) or post-thrombotic syndrome (PTS), affecting almost 0.16% of the global population.[1]

Proximal (iliofemoral) DVT is defined as venous thrombus involving the common femoral and/or the iliac veins, with or without extension the inferior vena cava (IVC). Proximal DVT of lower extremity represents about 25% of all DVT cases.[2] More frequent and severe PTS or lifestyle-limiting venous claudication may occur in patients with iliofemoral DVT and is associated with decreased quality of life and higher health costs.[3,4]

The main goal of the treatment of acute DVT is an early thrombus removal and the practice guidelines recommend an early and rapid clot removal for patients with proximal DVT who have symptoms less than 14 days in duration, with good functional ability, and a life expectancy of >1 year and have a low risk for bleeding complications.[5-8]

While there is no consensus in the endovenous treatment protocol for the patients with acute DVT, percutaneous pharmacomechanical thrombectomy (PMT) has been shown to be an effective and safe treatment modality.[9] The second option for the removal of clot is catheter-directed thrombolysis (CDT), which allows direct delivery of a fibrinolytic agent to the thrombus site via an infusion catheter.[10]

Notably, several randomized-controlled with large sample size studies, including the Catheter-directed Venous Thrombolysis (CaVenT) and Thrombus Removal with Adjunctive Catheter-Directed Thrombolysis (ATTRACT), evaluated the efficiency of CDT, and to date, the role of alone CDT in acute DVT remains controversial.[8,11,12]

Recent studies regarding comparing of PMT with alone conventional anticoagulation therapy have demonstrated that PMT does not result in a lower risk of the PTS, but results in a higher risk of procedural complications and PMT alone is sometimes less successful than CDT.[12,13] Therefore, the trend of endovenous treatment strategy of iliofemoral DVT tends to combine CDT with PMT. However, there is a limited number of data regarding the clinical outcomes and the effectiveness of combined PMT and CDT for the treatment of iliofemoral acute DVT up to date.[1]

In the present study, we aimed to report the characteristics and the outcomes of combined PMT and CDT in patients with acute iliofemoral deep vein thrombosis.

PATIENTS AND METHODS

This single-center, retrospective study was conducted at Bahçeşehir University School of Medicine, VM Medicalpark Pendik Hospital, Department of Cardiovascular Surgery between March 2018 and February 2020. A total of 37 patients (21 males, 16 females; mean age: 55±13.8 years; range, 21 to 79 years) with symptomatic acute iliofemoral vein thrombosis who underwent combined PMT and CDT in our clinic were included. Inclusion criteria were as follows: patients with iliofemoral DVT which was confirmed by Duplex ultrasound (US); DVT symptom onset not prior to 14 days; and patients who had no contraindication for systemic thrombolytic treatment. The patients with a contraindication to anticoagulation therapy or systemic thrombolysis, or with a massive inferior vena thrombus, or without iliofemoral involvement were excluded from the study.

The medical records and the clinic charts of the patients were examined from the hospital database retrospectively. The data obtained in this study included patients' demographics, predisposing risk factors, affected limb side, concomitant diseases, clinical presentations and determination of the involved vessels. The complications including intracerebral bleeding, major bleeding requiring blood transfusion, minor hemorrhage as a hematoma, epistaxis and hematuria were noted. Mortality and morbidity regarding the combined procedure were evaluated. Technical success rate, adjuvant angioplasty rate and the 3, 6, and 12-month freedom from re-thrombosis were calculated.

Surgical technique

All procedures were performed by experienced two cardiovascular surgeons in a standard angiography labor set-up. The combined therapy included three sequential steps: *(i)* implantation of the IVC filter, *(ii)* PMT via popliteal vein with aspiration of the thrombosis, and *(iii)* CDT using alteplase.

Before all procedures and prior PMT, a 7F 30-cm recoverable permanent IVC filter (Reya Venocat, Biolas Health Inc., Ankara, Türkiye) was routinely placed via contralateral femoral vein puncture under local anesthesia using US guidance to prevent a potential PE (Figure 1a). The IVC filter was released below of the infrarenal level (Figure 1b). In case of presence of a massive inferior cava thrombus or other anatomical issues (such as IVC aneurysm) that disallowed to inserting filter in IVC, the procedure was aborted. All these IVC filters were

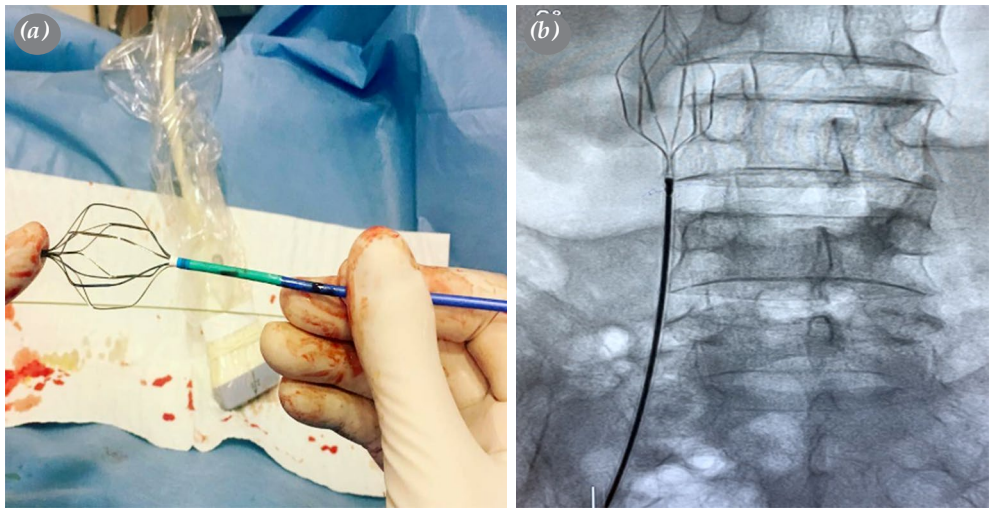


Figure 1. (a) Recoverable permanent inferior vena cava filter placed via contralateral femoral vein puncture under local anesthesia using ultrasound to prevent a potential pulmonary embolism. **(b)** The inferior vena cava filter was released below of the infrarenal level.

successfully retrieved within three days after the interventional therapy and the control venography under fluoroscopy.

As the second step, the patient was laid in prone position to allow puncture of the popliteal vein under local anesthesia using US guidance for the application of the PMT procedure. A standard 8F introduction sheath was placed into the ipsilateral popliteal vein with the Seldinger technique. In case of presence of thrombus in the popliteal vein, a micro-puncture technique was used before the standard sheath placement. The Reya mechanical thrombectomy system consists of three main parts: a single recoverable IVC filter, a catheter which allows to perform a rotational mechanical thrombectomy, a standard aspiration catheter. This system was used in all patients, for the intervention. After the ipsilateral popliteal vein cannulation in the affected limb under US, an ascending venography was performed in all patients to evaluate the extent and the feature of the thrombus (Figure 2a). The thrombectomy catheter (7F, 90 cm) was introduced and advanced through the thrombus until to the common iliac vein or IVC. As an adjunctive thrombolytic agent, 0.15 mg/kg recombinant tissue-type plasminogen activator alteplase (tPA) (Actilyse®, Boehringer Ingelheim Pharma GmbH & Co. KG. Biberach/Riss. Germany) with a contrast agent was delivered into the thrombus through the mechanical thrombectomy catheter. Mechanical thrombectomy was, then, performed from iliac veins to popliteal veins, until

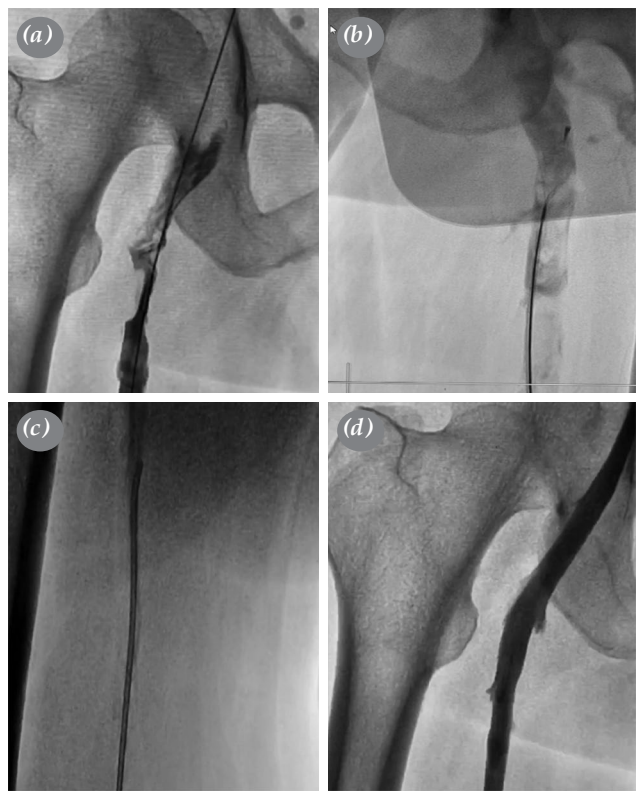


Figure 2. (a) Ascending venography demonstrated the acute iliofemoral deep vein thrombosis and total occlusion of the vessel, **(b)** Mechanical thrombectomy via popliteal vein cannulation, **(c)** Selective catheter-directed thrombolysis under fluoroscopy, **(d)** Control venography after combined percutaneous pharmacomechanical thrombectomy and catheter-directed thrombolysis showing a successful recanalization of iliofemoral vein.

a significant recanalization of the vessel could be seen in sequential venography (Figure 2b). For the thrombus removal and aspiration, a 7F aspiration catheter compatible with the 0.035-inch guidewire was used.

As the last step of the procedure an infusion catheter with multi-side-holes at the distal part was inserted into the iliofemoral vein for the selective CDT under fluoroscopy (Figure 2c).

Technical success was defined as successful removing the thrombus via endovenous therapy.

Medical treatment regimen and monitoring

All patients were followed in cardiovascular intensive care unit during the CDT. The thrombolytic regimen for the CDT included a continuous infusion of 1 mg/h alteplase (Actilyse, Boehringer Ingelheim Pharma GmbH & Co. KG. Biberach/Riss. Germany) through the infusion catheter for 24 h after PMT intervention. In addition, a continuous intravenous infusion of unfractionated heparin (10 U/kg per h) via the introducer sheath port was given to keep an activated clotting time (ACT) between 180 and 250 to escape thrombosis at the insertion site and thrombus generation overall. The patients were monitored with ACT and fibrinogen levels every 6 h after the intervention.

After 24-h CDT, the patients underwent control venography (Figure 2d). In case of residual thrombosis which prevents venous flow into the IVC, an adjunctive angioplasty was performed in selected patients. In these cohort, no venous stents were inserted. Low-molecular-weight heparin was reintroduced together with an oral anticoagulant after completion of combined PMT and CDT procedure. After discharge, all patients were treated with direct oral anticoagulant agent (rivaroxaban) for six to nine months together with compression stocking (20 to 40 mmHg) therapy against to prevent established PTS, according to the current guidelines. Follow-up was performed by clinical evaluation and Doppler US control at the postoperative three and six months from the treatment and on a yearly basis, thereafter.

Table 1. Baseline and demographic characteristics of patients (n=37)

Variables	n	%	Mean±SD	Range
Age (year)			55±13.8	21-79
Onset of symptoms (day)			6.5±3.7	2-14
Sex				
Male	21	56.8		
Comorbidities and risk factors				
Hypertension	14	37.8		
Diabetes mellitus	11	29.7		
Smoking	11	29.7		
Recent major surgery	6	16.2		
Malignancy	4	10.8		
Hypercoagulopathy	3	8.1		
IVC aneurysm	1	2.7		
Symptoms				
Swelling	35	94.6		
Pain	34	91.9		
Phlegmasia	2	5.4		
DVT-affected limbs				
Left	22	59.4		
Right	14	37.8		
Bilateral	1	2.7		
Involved vessels				
Inferior vena cava	1	2.7		
Common iliac vein	21	56.7		
External iliac vein	15	40.5		
Femoral vein	37	100		

SD: Standard deviation; IVC: Inferior vena cava; DVT: Deep venous thrombosis.

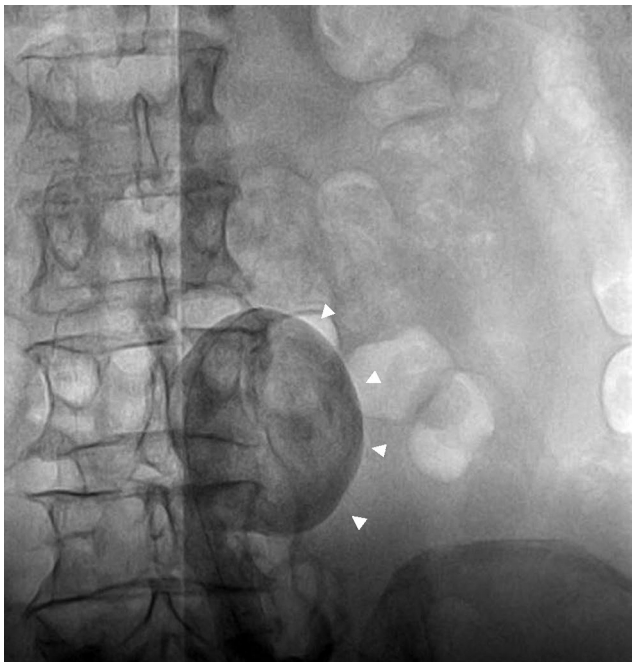


Figure 3. Huge inferior vena cava aneurysm that could not allow to deploy an inferior vena cava filter.

Statistical analysis

Statistical analysis was performed using the IBM SPSS version 22.0 software (IBM Corp., Armonk, NY, USA). Continuous data were presented in mean ± standard deviation (SD) or median (min-max), while categorical data were presented in number and frequency. The freedom from re-thrombosis during the first-year follow-up was analyzed using the Kaplan-Meier analysis in patients who underwent a successful combined therapy with follow-up (n=29). A *p* value of <0.05 was considered statistically significant.

RESULTS

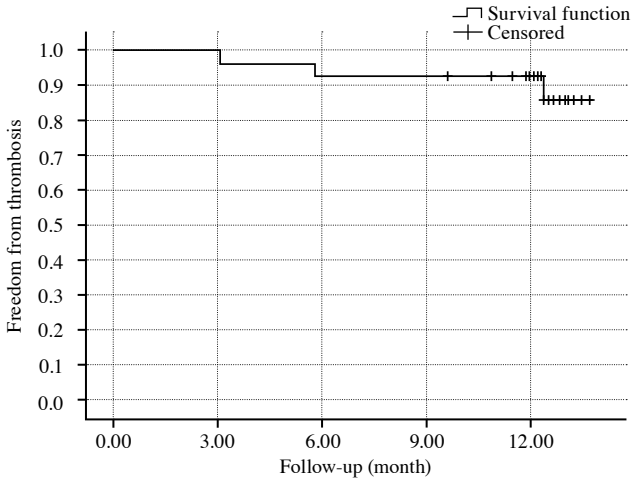
The mean time from the onset of DVT symptoms or a definitive diagnosis with US was 6.5±3.7 (range, 2 to 14) days. In the cohort, risk factors for DVT included recent surgical operation (n=6, 16.2%), malignancy (n=4, 10.8%), recognized thrombophilia (n=3, 8.1%), and aneurysm of IVC (n=1, 2.7%). The predisposing risk factors were unknown in 23 (62.1%) patients. The most common comorbidity was hypertension (n=14, 37.8%), and 11 (29.7%) patients had diabetes mellitus. Demographic and preoperative variables are given in Table 1.

While majority of the patients had left-sided limb proximal DVT (n=22, 59.4%), 14 (37.8%) patients had right-sided iliofemoral acute DVT and one (2.7%) patient had bilateral proximal DVT. Although the most presented symptom of the DVT was swelling of the affected limb (n=35, 94.6%), only two patients were suffered from phlegmasia (n=2, 5.4%). Regarding involved deep veins, while all patients had common femoral vein involvement, 21 (56.7%) patients had extension to common iliac veins and 15 (40.5%) patients had external iliac vein extension. One (2.7%) patient had both IVC aneurysm and a massively thrombus of IVC.

Table 2. Procedural and clinical features (n=37)

Variables	n	%	Mean±SD	Range
Hospital stay (day)			3.4±0.9	2-5
ICU stay (day)			1.3±0.5	1-4
Technical success	33	89.1		
Adjuvant angioplasty	4	10.8		
Complications				
Hematuria	12	32.4		
Popliteal hematoma	3	8.1		
Epistaxis	2	5.4		
Major bleeding	0	0		
Total	17	45.9		
Follow-up				
No follow-up	4	10.8		
Freedom from re-thrombosis rates (n=29)				
3rd-month	96.3			
6th-month	92.6			
12th-month	86.0			

SD: Standard deviation; ICU: Intensive care unit.



Month	0	3	6	9	12
Number at risk	29	26	25	23	13
Freedom from thrombosis (%)	100	96.3	92.6	92.6	86.0

Figure 4. Kaplan-Meier estimate of freedom from re-thrombosis during the first-year follow-up.

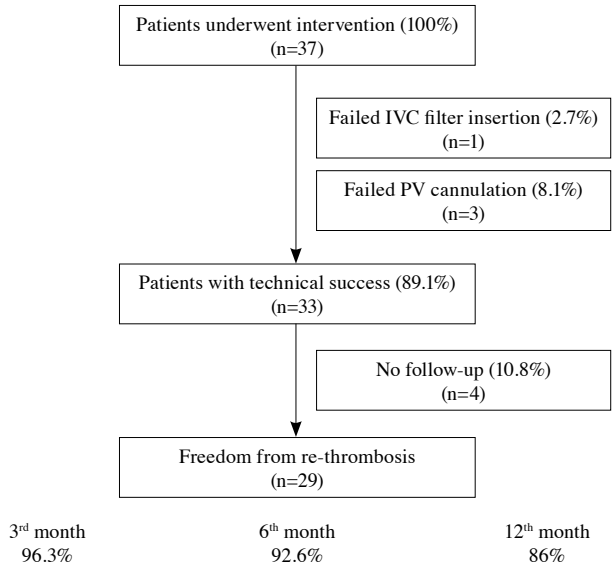


Figure 5. Study flow chart and follow-up data.
IVC: Inferior vena cava; PV: Popliteal vein.

Successful insertion of the IVC filter was achieved in 97.2% (n=36) of patients. The venography during IVC filter placement in a female patient who was admitted with bilateral acute iliofemoral DVT demonstrated a huge IVC aneurysm that could not allow to deploy a IVC filter (Figure 3). In this patient, a combined interventional therapy could not be performed. In three (8.1%) patients, a successful PMT or CDT catheter could not be inserted via ipsilateral popliteal vein. Those patients were treated with conventional anticoagulant medical therapy with rivaroxaban. The technical success was 89.1% (n=33). While adjuvant venous angioplasty was performed in four (10.8%) patients, no venous stents were used during the combined procedures.

No major bleeding complication occurred during hospitalization, but minor bleeding that not requiring transfusion were observed in the form of epistaxis in two (5.4%) patients and popliteal hematoma at the venous access site in three (8.1%) patients. The common complication due to the combined therapy that observed was hematuria in 12 (32.4%) patients. No intracerebral hemorrhage, thrombocytopenia, or mortality was observed during the hospital stay.

The mean hospital und intensive care unit stays were 3.4±0.9 (range, 2 to 5) days and 1.3±.0.5 (range, 1 to 4) days, respectively. Most patients reported symptom relief two to five days after the combined interventional therapy. In the study period, four patient lost follow-up and three patients had a recurrent or residual DVT during the first-year follow-up. The clinical and procedural features are summarized in Table 2. The 3, 6, and 12-month freedom from re-thrombosis rates were 96.3%, 92.6%, and 86.0%, respectively. The Kaplan-Meier analysis is shown in Figure 4. The study flowchart regarding follow-up and interventional success is given in Figure 5.

DISCUSSION

In the present study, the combined interventional therapy of iliofemoral DVT with PMT and CDT was evaluated in terms of outcomes. The study population comprised 37 patients who underwent combined therapy in a single center. Our study demonstrated that combined therapy (PMT+CDT) of iliofemoral DVT was an effective and safe treatment modality with acceptable complication rates.

While anticoagulation with warfarin or direct oral anticoagulant agents is considered the gold standard in the mainstay treatment of chronic iliofemoral DVT, the main goal of treatment of these patients should be to prevent the extension of thrombus, avoiding massive PE and PTS. Nevertheless, there is no a certain consensus about the interventional treatment of acute and subacute proximal DVT. In the recent ATTRACT study, the combination of PMT to anticoagulation (CDT with/or adjuvant intra-thrombus tPA) resulted in a higher major bleeding complication (1.7% *vs*. 0.3%, p=0.049) without a favorably decrease

of presence of PTS in patients with acute DVT.[12] However, the study had limited power to evaluate the treatment effects within subgroups. The authors reported that only 57% of total patients had DVT extends into common femoral vein or iliac vein and the number of the solely iliofemoral acute DVT was uncertain. In addition, the duration of anticoagulant therapy with compression stocking therapy was lower than 60% of the total cohort and 25% of the patients had a previous DVT or PE. However, in our study, we evaluated the patients who had a certain extension into the iliac vein without any prior DVT or PE and this study demonstrated that combination of PMT to CDT resulted in an acceptable risk of bleeding with higher long-term rate of freedom from re-thrombosis.

In their study, Tayfur et al.[14] reported the outcomes of 30 consecutive patients with acute iliofemoral DVT who were treated via a rotational thrombectomy device, Cleaner (Rex Medical, Fort Worth, TX, USA). Their study resulted with a 97% patency rate at the end of the first year in follow-up. While no major bleeding and mortality were reported by the authors, only two post-interventional punction site hematoma were observed in the cohort. In our study, the 12-month freedom from re-thrombosis rate was 86%, In addition, the most common complication due to the intervention was hematuria in 12 (32.4%) patients. Likewise, Shi et al.[15] noted an 89% technical success of PMT with CDT in their study that consist of 16 cases. In their study, only three minor subcutaneous bleeding which required no transfusion was observed. To compare the technical success rates, regrettably, there is a limited number of data in the current literature which report the outcomes of CDT+PMT. According to technical success rates of Shi et al.,[15] we achieved a similar rate of technical success, but according to Liu et al.'s[6] study, our rate of technical success in combined therapy remained lower. We believe that, with the improvement the learning curve, the rate of technical success can be escalated.

Recently, Rabuffi et al.[16] published their results of PMT with CDT (with an 80,000 IU/h urokinase infusion over nightly) via the Aspirex (Straub Medical, Wangs, Switzerland). The authors analyzed 22 patients who had iliofemoral acute (<21 days) DVT retrospectively. Their study demonstrated 95.5% patency at 12 months of follow-up without major or minor complications after the combined PMT and CDT. In brief, Rabuffi et al.[16] confirmed the positive findings of our study, as well as the results of the five-year CaVenT trial.[11,17]

Although several devices have been used for PMT, Liu et al.[18] performed mechanical thrombectomy by manual rotation and aspiration using pigtail catheters with CDT. In our study, we used the Reya mechanical thrombectomy system and the outcomes in terms of hematuria were higher than other previous reported studies.[19,20]

A retrievable IVC filter plays a crucial role, as it prevents PE and is recommended for the therapy of the iliofemoral DVT via Reya system in patients who have scheduled for interventional treatment.[21] Nonetheless, the patients who have contraindication to replace a IVC filter such as aneurysm of IVC, which reported rarely in the literature,[22-25] cannot be treated via a combined PMT and CDT therapy. In our series, a huge aneurysm of IVC was observed and the combined therapy failed due to an abortive IVC filter insertion (Figure 3).

This study is limited by the fact that it was retrospectively designed and reports the experience of a single center showing in-hospital events, and follow-up outcomes with long-term freedom from re-thrombosis rates. The other major limitation of present study was the lack of the PTS results due to a relative short follow-up and the lack of a control group that allow to compare the combined PMT and CDT versus alone interventions. In addition, some of the cases were lost-to-follow-up. Finally, the study has a relatively small sample size.

In conclusion, although the technical success rate of combined pharmacomechanical thrombectomy with selective catheter-directed thrombolysis in our series was 89.1%, this study also showed that the one-year freedom from re-thrombosis was 86% and no major bleeding complications were observed post-interventionally in patients with acute iliofemoral deep venous thrombosis. Further large-scale, prospective, randomized-controlled studies using other thrombectomy devices are needed.

Ethics Committee Approval: The data was used with permission from the hospital administration. The study was conducted in accordance with the principles of the Declaration of Helsinki.

Patient Consent for Publication: A written informed consent was obtained from each patient.

Data Sharing Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

Author Contributions: Conceived and designed the analysis, collected the data, contributed data or analysis tools, wrote the paper - M.A., U.C.; performed the analysis - MA.

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