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Original Article

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Early and mid-term outcomes of patients treated with catheter-directed thrombolysis combined with percutaneous rotational mechanical thrombectomy for deep vein thrombosis

Abstract

Aim: Deep vein thrombosis (DVT) is an important disease that may cause serious morbidity and mortality. In the current study, we aimed to evaluate the employability of the mechanical thrombectomy and combination of it with catheter-directed thrombolysis in selected patients with acute and/or subacute DVT.

Material and Methods: We applied mechanical thrombectomy and catheter-directed thrombolysis in the patients who admitted with an index diagnosis of lower extremity acute and/or subacute DVT. The thrombus in the femoral vein and iliac vein was intervened by intervention from the popliteal vein. Afterwards, mechanical thrombectomy and catheter-directed tPA infusion for 24 hours were applied. In follow-up, patients were evaluated through physical examination and Doppler ultrasonography on the 1st-, 6th-, 12th-, and 18th-month follow up, and scored with Villalta.

Results: The mean age was 59.9 years. Twenty-six and 21 of the 47 patients were male and female, respectively. In the 1st-month follow-up visit, there was ≥50% patency in 43 patients, and ≥90% patency in 30 patients. During the 18-month follow-up period, while three patients had recurrent DVT, one patient had a new DVT episode in the contralateral extremity. According to Villalta score, three patients were found to have post-thrombotic syndrome (PTS) at the end of 18 months.

Conclusion: We think that; pulmonary embolism (PE) and PTS rates would decrease with the concomitant application of percutaneous interventions to medical treatment in patients with index DVT diagnosis. Additionally, although the cost of percutaneous interventions seems to be high, it would be much more cost effective in the long-term when the complications related to DVT are taken into account. We also think that lowering the burden of thrombus in the acute period would preclude development of long-term complications.

Keywords: Rotational thrombectomy, iliofemoral deep vein thrombosis, post-thrombotic syndrome

INTRODUCTION

As a description, deep vein thrombosis (DVT), which is more common in lower extremity than that of upper extremity, expresses obstruction and decreasing of blood flow due to thrombosis in the deep veins (1). Venous duplex ultrasonography (USG) is the most easily applied and effective means of diagnosis. As the most important complication of DVT is pulmonary embolism (PE), the most important morbidity is post-thrombotic syndrome (PTS). Post-thrombotic syndrome leads to serious problems due to impairment of quality of life and high treatment costs in the long-term (2).

The aim of treatment in VTE is to prevent development of pulmonary thromboembolism (PTE), chronic pulmonary hypertension (PHT), recurrence of VTE, and PTS. Anticoagulation is the mainstay in treatment of DVT. PTE develops in 20% of the patients with proximal DVT who was not treated, and is fatal in

10-20%. The rate of mortality would be decreased 5-10 folds with aggressive anticoagulation (3).

The first choice of standard treatment in DVT is initiation with heparin or low-molecular-weight heparin (LMWH), accompanied by oral warfarin sodium until the target INR is achieved, which is followed by discontinuation of heparin or LMWH and continuation with oral warfarin (4). Because of the recent advancements, direct oral anticoagulants (DOAC) are in use which has a lower major bleeding complication rate in comparison to warfarin, and has a similar efficiency (5). However, it was shown in studies that the thrombus is not cleared away sufficiently with standard treatment of anticoagulation, and PTS risk does not reduce (6). The increasing experience and successful interventions of vascular surgeons in interventional treatment methods in our country have led to less use of open surgical interventions on the lower extremities (7). Accordingly, it is important to reveal the importance of showing the efficiency of concomitant treatment modalities of endovenous treatment methods (pharmaco-mechanical thrombectomy, catheter-directed thrombolysis, inferior vena cava filters) with standard medical treatment.

In the current study, we presented our early- and mid-term results of treatments in the patients in whom combination of rotational thrombectomy catheter and catheter-directed tPA infusion were applied.

MATERIAL AND METHODS

The study was approved by the Ethical Committee of Non-invasive Clinical Research at Eskisehir Osmangazi University Faculty of Medicine on 25 January 2021 (Approval number: E-25403353-050.99-137439).

Patient Selection

Between January 2018 and March 2020, 49 patients with acute or subacute iliofemoral DVT who received Mantis Rotational Thrombectomy catheter (RD Global Health Inc, Invamed) and Viper pharmaco-mechanical thrombectomy system (RD Global Health Inc, Invamed) were included in the study. Two patients were excluded due to discontinuation to the post-interventional out-patient follow-up visits. Of the patients, 26 were male, 21 were female, mean age was 59.9 years (range 24 – 96 years). All of the patients were either admitted to emergency department or to our out-patient clinic, or consulted with us while staying in-hospital in another clinical ward, and had lower extremity pain, swelling, and/or hyperemia/local temperature rise. The patients who were suspected to have DVT were diagnosed with lower extremity venous Doppler USG.

Endovascular Procedure

The patients in whom an endovenous intervention was planned were admitted to ward and routine investigations were made. Informed consent was obtained from all patients before intervention. The intervention was performed in operating theatre while heart rate, systemic blood pressure, and saturation were monitored in all patients. The procedure was performed under local anesthesia with the advent of a C-arm fluoroscopy. The popliteal vein of the ipsilateral side of DVT was percutaneously punctured in prone position under Doppler USG guidance, and a 0.35 inch guidewire was advanced in it. The patient was positioned to supine. Then, under Doppler USG guidance, contralateral side femoral vein was punctured and an 8 French sheath was placed through the guidewire into the femoral vein. In order to prevent pulmonary embolism during intervention, all patients received a temporary inferior vena cava filter which was placed through the contralateral femoral vein and advanced just before connection of renal vein to inferior vena cava (IVC) (Figure 1).

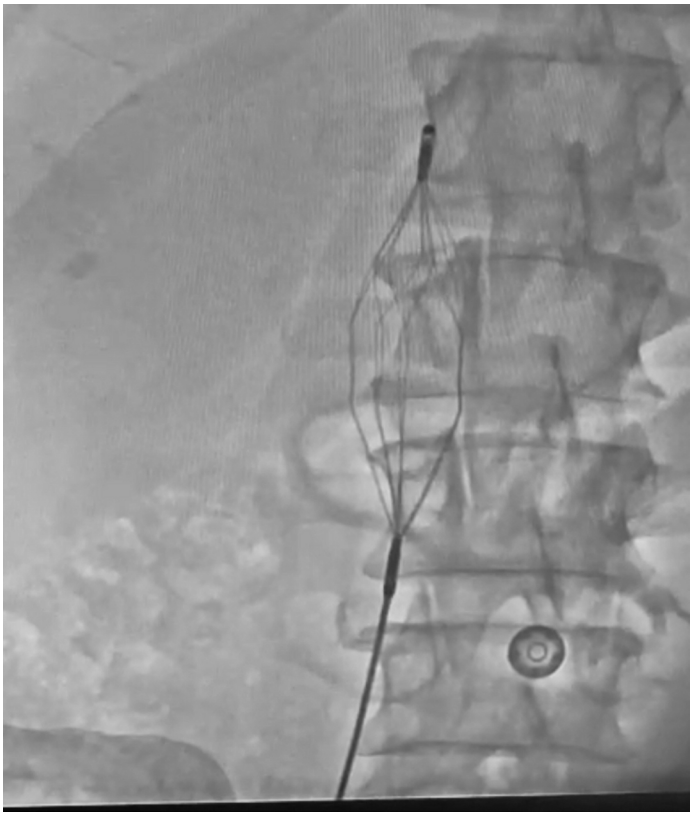

Figure 1. The inferior vena cava filter placed within the inferior vena cava

Following placement of IVC filter, the obstructions were visualized with contrast medium that was administered through the sheath in popliteal vein (Figure 2). Afterwards, a 7 French Mantis rotational thrombectomy catheter was advanced, and once the catheter comes out of sheath within vein, the tip of the catheter was opened and thrombectomy was initiated (Figure 3). Thrombectomy was applied to popliteal vein, superficial femoral vein, common femoral vein, external iliac vein, and common iliac vein, respectively. Checking venogram was done with contrast medium, and the patency of the obstructed vein segments were evaluated (Figure 4).

Figure 2. The view of contrast indentation indicating femoral vein stenosis

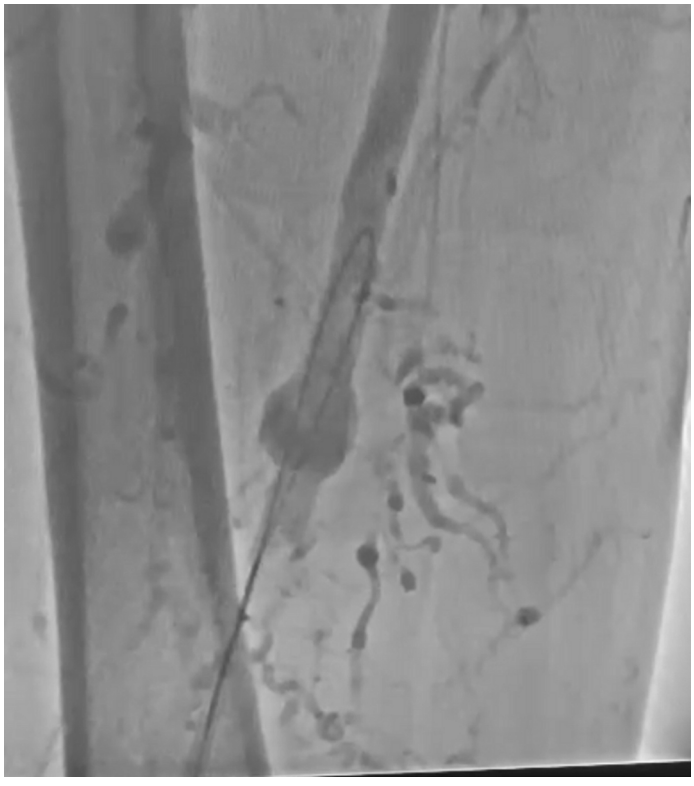

Figure 3. The running view mechanical thrombectomy catheter within the vein

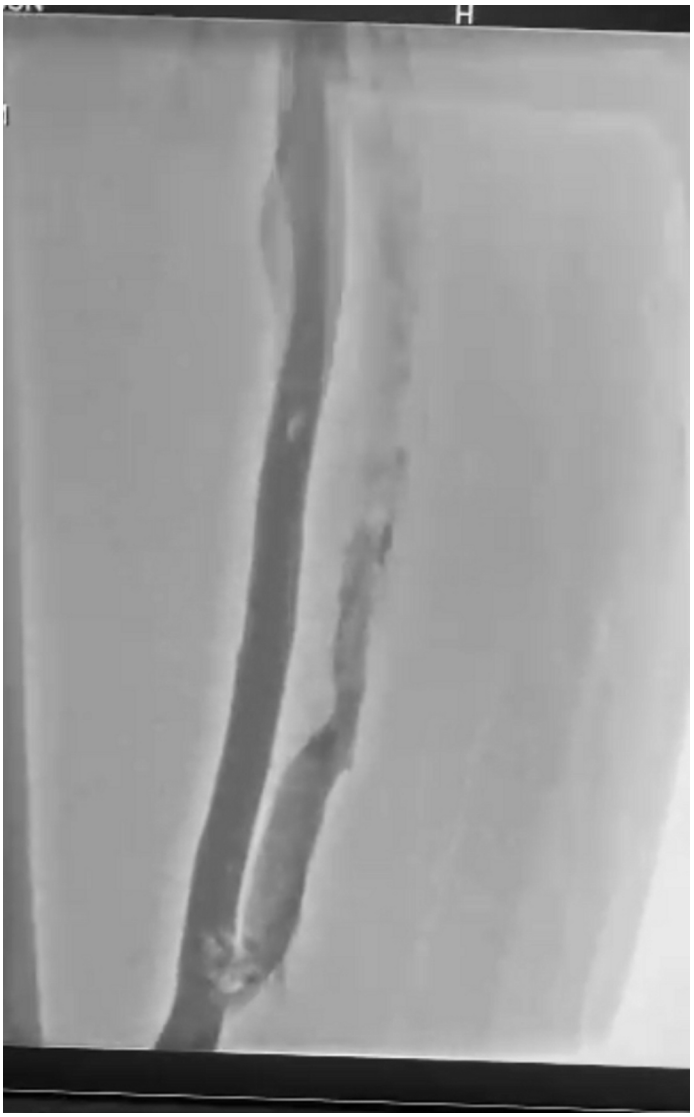

Figure 4. The view of the relief of femoral vein stenosis following thrombectomy

If the vein patency was not adequate, thrombectomy was reapplied. Then, the procedure was finished after a Viper catheter was placed where the tip of it was advanced at the uppermost part of the thrombus near the IVC filter.

All the patients were transferred to intensive care unit, and elevation of lower extremity was applied while tPA infusion through the Viper catheter and concomitant intravenous infusion were commenced. In the patients who had a long-segment venous obstruction, the Viper catheter was pulled back every six hours so as to apply tPA infusion throughout the obstructed segment. After 24-hour period of tPA infusion treatment, the Viper catheter, the sheath in the ipsilateral popliteal vein, temporary IVC filter, and the sheath in the femoral vein were removed, respectively. Following removal of the catheters, patients were transferred to ward. The patients were closely followed-up in regards to complications during and after the procedure, and the complications that developed were noted. Throughout the

ward admission, patients were followed for aPTT, and received IV heparin, lower extremity elevation, and limited mobilization. During the admission period, patients were evaluated for the development of circumference difference, temperature, hyperemia, pain, and stiffness. Patients were discharged with LMWH for one month, and recommended intermediate-pressure compression stockings.

All patients' LMWH treatment were stopped at one month and started to have NGOA treatment for 6-months. Patients were invited for out-patient visits at 1st, 6th, 12th, and 18th months after discharge. Pain, cramp, numbness, edema, hyperpigmentation, venous ectasia, hyperemia, cutaneous induration, and venous ulcer were evaluated in every visit. Additionally, patients were evaluated with Doppler USG for duration of reflux flow and patency of deep veins, and the findings were noted.

Statistical Analysis

In this study, continuous variables were presented as mean±standard deviation. Descriptive statistics were one using SPSS (SPSS Inc., Chicago, Illinois) software version 18.

RESULTS

The demographic and clinical characteristics of the patients are revealed in Table 1. Among the included patients, 26 were male and 21 were female. While the initiation of the symptoms in all patients was less than 28 days, 38 patients admitted in acute period (0-14 days). Thirteen patients were already under treatment for cancer. All the included patients had thrombosis at iliac vein, common femoral vein (CFV), deep femoral vein (DFV), and popliteal vein (PV). The d-dimer was increased in all patients. At the time of admission, patients had pain, edema, hyperemia, and increase in circumference. None of the patients had phlegmasia cerulea dolens.

In the physical examination performed in the first post-interventional day, there was a decrease in circumference more than 3 cm in 32 patients, 1-3 cm in 13 patients, and less than 1 cm in 2 patients. While there was no hyperemia in 42 patients, five patients had hyperemia. The duration of hospital stay in 39 patients was less than five days.

The patients were followed-up for 18 months. All patients were evaluated by means of Doppler USG on the 1st, 6th, 12th, and 18th months. The findings and characteristics of physical examination, follow-up findings, and Doppler USG are revealed in Table 2. While three patients had recurrent DVT in the same lower extremity, one patient had recurrent DVT in contralateral lower extremity. Among the three patients with recurrent DVT, one patient had intra-abdominal mass, one had myasthenia gravis, and one had May-Thurner syndrome. In Doppler USG evaluations throughout the 18-month follow-up period, there was an improvement in the rates of patency and reflux flow in deep veins. The evaluation performed at the 18th month revealed near-complete patency in 80% and more than 50% patency in 93% of the patients. While there was moderate to severe (≥2 seconds) reflux flow in 6.3% of the patients, there was mild (around 1 second) reflux flow in 34% of the patients. There was no reflux flow in the 18th month evaluation in the remaining patients.

Table 1. Demographic and clinical characteristics of the patients

Age	59.9±13.2
Gender	
Female	21
Male	26
Side	
Right	14
Left	33
Duration of Symptom	
0-14 days (acute)	38
14-28 days (subacute)	9
Predisposing Factors	
Malignancy	13
Hypertension	9
Diabetes mellitus	7
Dyslipidemia	1
Previous surgery	7
Previous DVT	1
Previous trauma	1
Previous CVA	1
Hemodialysis/central venous catheter application	1
Use of oral contraceptives	1
Symptoms on admission	
Pain	34
Hyperemia	12
Diameter difference	45

DVT: deep vein thrombosis, CVA: cerebrovascular accident

The complications occurred during and after intervention were summarized in Table 3. While there was shortness of breath in two patients during the intervention, there were catheter-related complications in five patients. In four of the five patients, the rotational thrombectomy catheter led to venous trauma because it wrapped around the thrombus that was adherent to the femoral vein wall. In another patient, the catheter of IVC filter haunted at the femoral vein entrance site and led to difficulty at removal. There was 2x2 cm in size thrombus in the IVC filter, and it was thought that the thrombus precluded the folding of the IVC filter into the catheter, and this was the reason of difficulty of catheter removal. This patient's femoral vein was evaluated on table with a C-armed fluoroscopy, and there was no extravasation. In the post-interventional period, acute renal failure developed in one patient that does not necessitate hemodialysis. There was gingival hemorrhage in one, and intramural hematoma in the

Table 2: Postoperative follow-up and early-mid-term results

Decrease in diameter difference on day 1	Number of patients
Less than 1 cm	**2**
Between 1-3 cm	**13**
More than 3 cm	**32**
Hyperemia on day 1	
Yes	**5**
No	**42**
Pain on day 1	
Yes	**33**
No	**14**
Length of hospitalization	
5 days or less	**39**
More than 5 days	**8**
1st month USG control	
90% or more clearance	**30**
50% or more, less than 90% clearance	**13**
Less than 50% clearance	**4**
Reflux flow	
No	**21**
Mild	**20**
Moderate	**4**
Severe	**2**
6th month USG control	
90% or more clearance	**36**
50% or more, less than 90% clearance	**8**
Less than 50% clearance	**3**
Reflux flow	
No	**27**
Mild	**15**
Moderate	**4**
Severe	**1**
12th month USG control	
90% or more clearance	**37**
50% or more, less than 90% clearance	**7**
Less than 50% clearance	**3**
Reflux flow	
No	**28**
Mild	**16**
Moderate	**2**
Severe	**1**
18th month USG control	
90% or more clearance	**38**
50% or more, less than 90% clearance	**6**
Less than 50% clearance	**3**
Reflux flow	
No	**28**
Mild	**16**
Moderate	**2**
Severe	**1**
Recurrense	**3**
Contralateral DVT development	**1**

USG: ultrasonography, DVT: deep vein thrombosis

femoral region in another patient, but there was no extravasation in femoral imaging. There was gastrointestinal hemorrhage in one, retroperitoneal hemorrhage in one, and alveolar bleeding in another patient. The patient that had alveolar bleeding was intubated due to respiratory insufficiency, and died on postoperative day one. There was no PE observed in any of the patients.

Table 3. Intraoperative and postoperative complications

Intraoperative	Number of patients
Shortness of breath/difficulty breathing	**2**
Catheter-related complication	**5**
Extravasation	**0**
Postoperative	
Acute kidney failure	**1**
Minor bleeding	
Gum/nose bleeding	**1**
Hematoma	**1**
Major bleeding	
Gastrointestinal bleeding	**1**
Alveolar bleeding	**1**
Retroperitoneal bleeding	**1**
Pulmonary Embolism	**0**
Death	**1**

In order to evaluate the clinical effects of PTS, one of the most important complications of DVT, we applied Villalta scoring, and the scores are revealed in Table 4. It was found that PTS occurred at the end of 18 months in 36.1% of the patients of which the PTS was significant in 6.4%. There was stasis ulcer in one patient. The most common symptoms in patients in whom PTS occurred were pain, camp, color chance when standing, and numbness. There was cutaneous hyperpigmentation in 11 patients, and induration in five patients.

Table 4. Villalta scoring results

	Number of patients (n:47) (%)
No PTS	30 (%63.8)
Mild PTS	9 (%19.1)
Moderate PTS	5 (%10.7)
Severe PTS	3 (%6.4)

PTS: post- thrombotic syndrome

DISCUSSION

Because of the outcome of morbidity and mortality, DVT is a cardiovascular disorder in which the importance of early diagnosis and treatment is important. Along with the Protein C, S, anti-thrombin deficiencies and factor V Leiden mutation as hereditary risk factors, immobilization, surgery, trauma, pregnancy, estrogen treatments, hospitalization, and existence of antiphospholipid antibody play important role in the etiology of DVT (8). In DVT treatment, along with medical treatment, particularly in acute and subacute DVT patients, percutaneous interventional methods aim at lowering DVT-related morbidity and mortality. While performance of the intervention in the early period provides advantage in regards to risk of PE, providing rapid recovery, better prevention of venous functions, and reducing the venous reflux rate, it has disadvantages, for instance; all patients are not eligible to receive it, high costs, and invasiveness (9). Thus, we applied a combination therapy of Mantis rotational thrombectomy and Viper catheter-directed tPA infusion in selected 47 patients who were diagnosed with acute or subacute iliofemoral DVT.

The success of percutaneous pharmaco-mechanical treatment is defined as more than 50% resolution of thrombus (10). In the article of Shi et al. in which 16 patients were treated with catheter-directed thrombolysis combined with percutaneous pharmaco-mechanical thrombectomy treatment, more than and equal to 50% patency at the end of 13 months was found to be 75% (n=12), and none of the patients had PE (11). The rate of ≥90% patency rate in our series throughout the 18-month follow-up period using Doppler USG was 80%. While the immediate-term patency rate of ≥50% was 91%, the rate in mid-term was 93.6%. Yet, the rate of the patients with moderate and severe reflux flow in the immediate-term was 12%, and at the end of 18 months, it dropped to 6%. None of our patients had PE in the post-interventional period.

Among the catheter related complications, while stuck of the catheter within the vein wall during the rotational run of it is a complication related to no detachment of the Mantis rotational thrombectomy catheter from the guidewire, it has a potential risk factor for serious complications. In order to solve this problem, the connection of the device was reversed to detach the catheter form the vein wall among the four patients in whom this complication occurred. We think that in order to prevent stuck of the catheter to vein wall during procedure, these issues should be considered; advancement of the catheter into smaller side branches, and to prevent injury to the vein wall, use of a hydrophilic catheter for tPA infusion after thrombectomy procedure is completed.

In the literature, there is conflicting evidence in regards to the routine use of IVC filter before percutaneous mechanical thrombectomy and/or catheter-directed thrombolysis. In the study by Protack et al., among patients in whom catheter-directed thrombolysis was applied, the selected 20% of the patients received IVC filter and none of the patients developed PE after intervention (12). In another study conducted by Kölbel et al., all the patients that received catheter-directed thrombolysis were routinely implanted temporary IVC filter, and an apparent thrombus formation was observed in 45% of the patients after intervention. Thus, they recommend routine use of IVC filter (13). In the current study, all of the patients were implanted a temporary IVC filter before intervention. Following a 24-

hour period of catheter-directed thrombolysis treatment after thrombectomy procedure, thrombolysis catheter was removed followed by removal of the IVC filter at last. We observed that there was apparent thrombus material in 19 of 47 patients (40.4%) (Figure 5). We experienced difficulty removing the IVC filter due to the 2x2 cm in size thrombus material in one patient. Because the aim of IVC filter is capturing the thrombus material, we observed that large-sized thrombus materials would preclude collection of the IVC filter into the sheath during removal step of the procedure. According to the potential of the thrombus material to cause difficulties for closure of the IVC filter, we conclude that the IVC filters would be delivered through larger sheaths or there would be systems that would be integrated to the delivery system to aspirate the thrombus just before removal of the IVC filter. Additionally, as it is seen in our findings, because 40% of the patients had thrombus material in the temporary IVC filter, we think that IVC filters should routinely be applied particularly in the patients that will receive thrombolytic treatment after rotational thrombectomy.

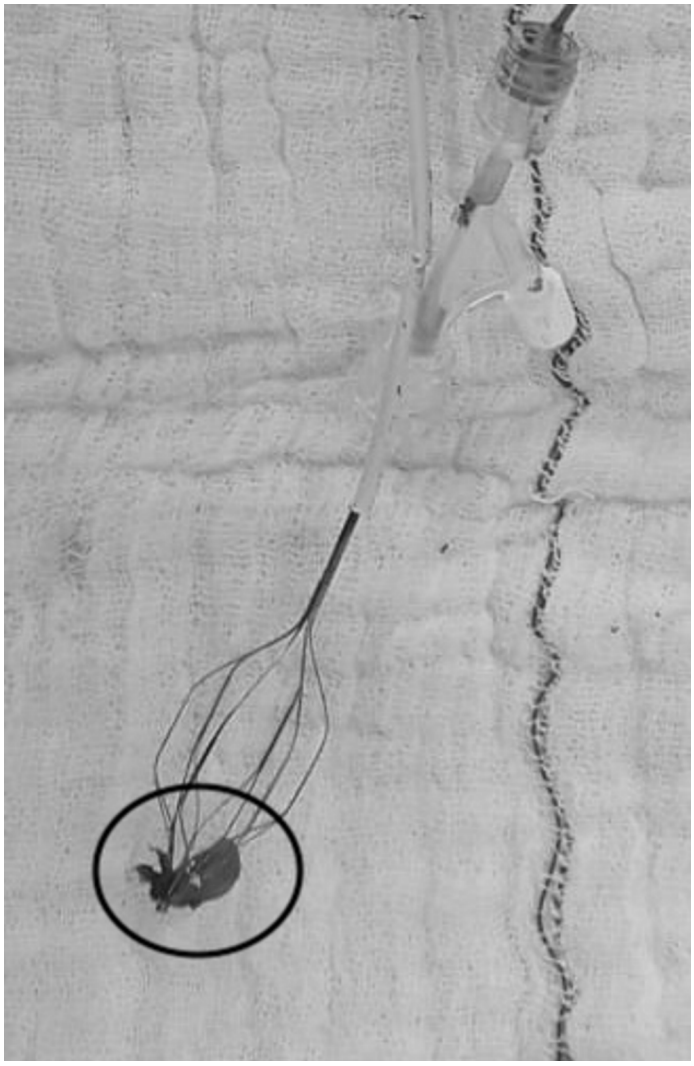

Figure 5. The view of thrombus stuck in the inferior vena cava filter

When the post-interventional symptomatology of the patients is taken into account, it was reported by Chauldry et al. and Rao et al. that the rate of decrease in regards to clinical complaints and success of intervention were between 70% and 95% in the patients in whom pharmaco-mechanical thrombectomy was applied (14,15). In our study 95% of the patients' complains were subsided in the post-interventional first day, and this finding was compliant with the literature.

Post-thrombotic syndrome is the most important late-term complication of DVT that lead to significant morbidity. PTS develops within 2 years around 20-50% of the patients with DVT, and it is severe in 5-10% of the patients (16). Likewise in our study, compliant with the literature, based on the Villalta scoring, severe and moderate PTS developed in three (6.4%) and five (10.7%) patients, respectively. Additionally, 63.9% of the patients did not have PTS. One of the main aims of DVT treatment is to prevent development of PTS in the long-term because it results in high costs in treatment and poor quality of life. In this regard, the CaVenT study, which was conducted in 2021, is the randomized controlled study comparing the treatment outcomes of anticoagulant treatment and catheter-directed thrombolysis. In this study, while one group was given only anticoagulant treatment, the anticoagulant treatment in the other group was accompanied by the catheter-directed thrombolysis. At the end of follow-up period of 24 months, PTS rate was found to be significantly lower in the group of patients who received anticoagulant treatment and catheter-directed thrombolysis (55.6% versus 41.1%, p=0.047) (17). A scarce side of the CaVenT study is that none of the patients received mechanical or pharmaco-mechanical thrombectomy. Additionally, in another randomized controlled study conducted by Vedentham et al. in 2017, the results of the CaVenT study were confirmed (18). In this study, the study groups were separated into two groups; that one group received pharmaco-mechanical thrombolysis and anticoagulation, and the other group was treated with anticoagulation alone. In 24-month follow-up, there was no reduction in the rate of recurrent VTE and development of PTS. However, it was found that the PTS score in the group who received pharmaco-mechanical thrombectomy was found to be lower. Moreover, a significant reduction in terms of pain and edema in the pharmaco-mechanical thrombolysis group in 10 and 30 days after intervention were reported. In the study of Grewal et al., they reported that the catheter-directed thrombolysis, alone or in combination with mechanical thrombectomy would lower the thrombus burden and reduce the development of PTS (19). In our study, highly likely due to the reduction in thrombus burden, we also observed rapid clinical relief of symptoms and decline in the development of PTS in our patients during the 18-month follow-up. We also concluded that the mild symptoms of the patients during the follow-up were related to the reflux flow.

When we compare our treatment strategy with isolated anticoagulation treatment, while the near complete patency rate was 38% at 6th month follow-up in proximal DVT patients who

received isolated anticoagulation (20,21), this rate in our study at 6th month follow-up was 80%. This finding indicates that in the patients with acute and subacute DVT, combined rotational mechanical thrombectomy and catheter-directed thrombolysis is superior to anticoagulation treatment in terms of patency rate. We think that providing the patency in the immediate-term would decrease the risk of PE and preclude the development of complications through prevention of the venous vessel wall in the late-term. The situation that none of the patients in the current study developed PE although there were high-risk patients included in the current study also supports our above-mentioned idea.

CONCLUSION

According to the results presented in the current study, in comparison to the outcomes with the use of other catheters, a similar outcome was achieved with the treatment method applied herein in the immediate- and mid-term. In comparison to solitary medical treatment, the patency rates and the conditions of morbidity and mortality like PE and PTS rates are favorable in the current treatment. Although the treatment seems costly, the treatment methods applied through percutaneous access cost less when compared with the long-term treatment costs of PTS and PE.

The application of the catheter-directed percutaneous intervention method in DVT treatment is safe, easy, and effective. We think that these methods are hopeful in regards to lowering the serious complication rates with lower morbidity and mortality rates through reducing the thrombus burden. Additionally, we think that these methods should be used and improved in the future.

Conflict of Interests: The authors declare that there are no conflict of interests.

Financial Disclosure: The authors declare that there is no financial support.

Ethics Committee Approval: The study was approved by the Ethical Committee of Non-invasive Clinical Research at Eskisehir Osmangazi University Faculty of Medicine on 25 January 2021 (Approval number: E-25403353-050.99-137439).

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