

Original Article

Early outcomes of mantis pharmacomechanical thrombectomy system combined with catheter-directed thrombolysis for treatment of acute iliofemoral deep vein thrombosis

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Abstract

Aim: The purpose of this research was to investigate the early outcomes of pharmacomechanical thrombectomy (PMT) with the Mantis device and adjunctive catheter-directed thrombolysis (CDT) for the treatment of acute iliofemoral deep vein thrombosis (IFDVT).

Material and Methods: Twenty patients with symptomatic acute IFDVT were successfully treated with the Mantis rotational thrombectomy device and CDT, between August 2020 and March 2021. Patients' demographical, clinical and follow-up data were obtained and analysed retrospectively. Villalta and Pain Severity scores were utilized to assess the patients for the occurrence of post-thrombotic syndrome (PTS).

Results: The procedural success rate was 100%. All cases presented early clinical improvement. No device related complications were encountered. Reocclusion was observed in 3 (15%) patients. Pre-procedural median pain score was 7 (range: 6–8) and 1 (range: 0–7) at 12-month following thrombectomy ($P < .001$). Pre-procedural median Villalta score was 7 (range: 3–11) and 1 (range: 0–13) at 12-month following thrombectomy ($P < .001$). At 12-month follow-up, no PTS was reported in 15 (75%) patients, mild PTS was reported in 2 (10%) patients, moderate PTS was reported in 2 (10%) patients and no severe PTS was observed.

Conclusion: The Mantis PMT system with CDT seems to be an efficient treatment approach for acute IFDVT with encouraging early results.

Keywords: Deep venous thrombosis, pharmacomechanical thrombectomy, catheter-directed thrombolysis, post-thrombotic syndrome, balloon angioplasty

INTRODUCTION

Venous thromboembolic disease is a serious public health concern involving high rates of morbidity and death [1]. Iliofemoral DVT (IFDVT) leads to serious consequences such as venous ulcers, post-thrombotic syndrome (PTS), and even quite dangerous pulmonary embolism (PE) [2]. Despite the fact that oral anticoagulant therapy is the conventional therapeutic approach for the treatment of IFDVT, randomized studies have reported the occurrence of PTS in about 50% of individuals

following the initial course of symptomatic DVT [3].

Active removal of thrombi located in the deep veins during the acute phase of DVT has been confirmed by randomized controlled studies to be useful in preventing PTS [4]. In recent years, alternative and new methods like pharmacomechanical thrombectomy (PMT) with catheter-directed thrombolysis (CDT) have gained popularity as a result of their excellent results [5,6]. These procedures reduce post-thrombotic morbidity, maintain venous valve competency and also provide early clot

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elimination. After the procedure, endovascular techniques such as balloon angioplasty and stent implantation may be applied to treat the remaining ilio-caval stenoses [7]. Mantis (Invamed, Ankara, Turkey) is a percutaneous rotational mechanical thrombectomy device that works atraumatically in the vein. The primary advantage of this device is that it may be used periodically together with lytic injection and vacuum-assisted suction from the side port.

The aim of this paper was to evaluate the safety and effectiveness of PMT using Mantis device and adjunctive CDT in the treatment of acute IFDVT.

MATERIAL AND METHODS

Study design

Twenty patients (14 female and 6 male), who were admitted to cardiovascular surgery department with acute symptomatic IFDVT and who underwent PMT with Mantis device and CDT, between August 2020 and March 2021, were retrospectively analysed. The original hospital and patient records were used to collect all clinical, perioperative, and demographic data. Color Doppler ultrasonography (CDUS) was performed as the first diagnostic method in all patients to confirm acute IFDVT. Contrast venography was used before the procedure to identify the size and extent of the affected deep veins. The research included patients with IFDVT who had acute symptoms (existing for less than 14 days). The following were the study exclusion criteria: Patients under the age of 18, isolated femoral or popliteal DVT, recurrent or chronic DVT, contraindications for thrombolytic therapy (a history of major trauma or surgery in the last 7 days, pregnancy, hemorrhagic disorders), patients with a life expectancy lower than 1 year, patients with a total vena cava occlusion, contraindications for using radiation and symptoms lasting longer than 2 weeks. Prior to the operation, all patients who underwent PMT were fully informed about the technique and they signed consent forms.

These procedures were not applied in IFDVTs developed in patients who were pregnant and who had a history of major trauma within 7 days. PMT+CDT hybrid procedures were successfully applied to 2 female patients who had IFDVT in the 1st month postpartum and 2 female patients under chemotherapy treatment (Breast cancer, Rectal cancer). A special thrombolytic regimen was not administered to these patients.

Procedural details

PMT procedures were carried out under local anesthetic in the hybrid surgical suite by a single vascular surgeon. Interventions were performed under ultrasound guidance. Initially, a temporary thrombolysis catheter with inferior vena cava (IVC) filter (Figure 1A, TPS Thrombolysis Catheter, 8 French (F), 50cm, 30mm filter diameter, Invamed, Ankara, Turkey) was inserted into the infrarenal segment via femoral access (Figure 2A). Following

this, a 7F sheath was inserted into the thrombosed side's popliteal vein. Following the insertion of a 7F sheath, intravenous heparin was administered to achieve an active clotting time (ACT) of 180 to 200 seconds. Contrast material (240 mg iodine/mL) was diluted with 50 to 100 mL of saline and administered in order to record serial fluoroscopic images of the deep venous system (Figure 2B). The Mantis rotational thrombectomy device (Figure 1B, 7F, 90 cm, Invamed, Ankara, Turkey) was introduced into the sheath and delivered to the thrombosed segment of the deep venous system gently (Figure 3A). Following the activation of Mantis, the device's side injection port was used to administer a mixed dose of Alteplase (Actilyse, Boehringer Ingelheim, Germany) and saline (1:10 ratio). The device was used periodically with lytic infusion and macerated thrombus was suctioned via vacuum-assisted aspiration from the side port. Through segmental PMT, 1 mg tissue plasminogen activator (tPA) solution with saline mix (1:10) was applied for every five cm of the vessel for 5 to 6 minutes. Control venograms were used to assess all thrombosed segments, and the procedure was repeated until there were no thrombosed vein segments. Moreover, the Dovi thrombus aspiration catheter (Figure 1C, 8F, 90cm, Invamed, Ankara, Turkey) was utilized to extract the residual thrombus mixture in all cases. When the results were suboptimal, or in the presence of residual thrombus, the procedure was repeated once more. Following the PMT, all patients were treated with plain old balloon angioplasty (8–14 mm) for post-thrombotic strictures (Figure 3B). Finally, post-interventional venogram was conducted and analyzed following the procedure (Figure 3C) (Figure 4). Viper thrombolysis catheter (Figure 1D, 6F, 90cm, Invamed) was inserted to all cases, and tPA was infused at 1mg/hr through the Viper for 20-24 hours to remove residual thrombus.

Follow-up assessments

Following the procedure, the patients were taken to the intensive care unit. They were closely monitored for potential complications on the first day. All patients were mobilized wearing compression stockings on both legs. Approximately 24 hours after the procedure, the Viper device was removed and anticoagulant treatment was started. Subcutaneous low molecular-weight heparin was administered for all individuals before switching to the oral anticoagulant. On the second day, the IVC filter was removed. Following the procedures, all patients were given oral anticoagulants for six months. The clinical results and the physical examination findings of all patients were documented at the 1st, 6th, and 12th month follow up. The PTS severity was determined using the patients' Pain Severity Scores and Villalta scores. CDUS was also carried out during each follow-up to assess venous patency, residual thrombus, and venous valve dysfunction. Re-intervention was decided in patients who showed symptomatic worsening and who had stenosis in the iliofemoral segment of more than 70% remaining as a result of pelvic and lower extremity computed tomography venography (CTV) examinations.

Study endpoints

The Villalta scale (range 0-33) is frequently utilized to evaluate the course of PTS following DVT.[8] Patients' complaints, examination findings, and the presence or absence of venous ulcers were scored at baseline and twelve months to assess the severity of PTS. Severity of post-thrombotic symptoms was classified as follows: no PTS (score 0-4), mild PTS (score 5-9), moderate PTS (score 10-14) or severe PTS (score 15, or presence of ulcer). A pain severity score (range: 0-10) was evaluated after 12 months. Secondary endpoints were thrombolysis time, duration of intensive care unit and hospital stay, complications, hemorrhagic events, reocclusions and reintervention rates. CDUS examination determined the venous patency rates during the 6 and 12-month follow-ups.

Statistical analysis

SPSS version 22.0 software was used for statistical analysis (SPSS Inc., Chicago, IL, USA). The compatibility of the variables to normal distribution was examined using visual (histogram) and analytical methods (Kolmogorov-Smirnov / Shapiro-Wilk Tests). Descriptive statistics were given as median (minimum-maximum), frequency distribution and percentage for non-parametric evaluations. Group comparisons were made using Wilcoxon Signed Rank Test. GraphPad Prism version 8.0.3 (GraphPad Software, La Jolla, CA, USA) was used to create the graphs. $P < .05$ was considered significant.

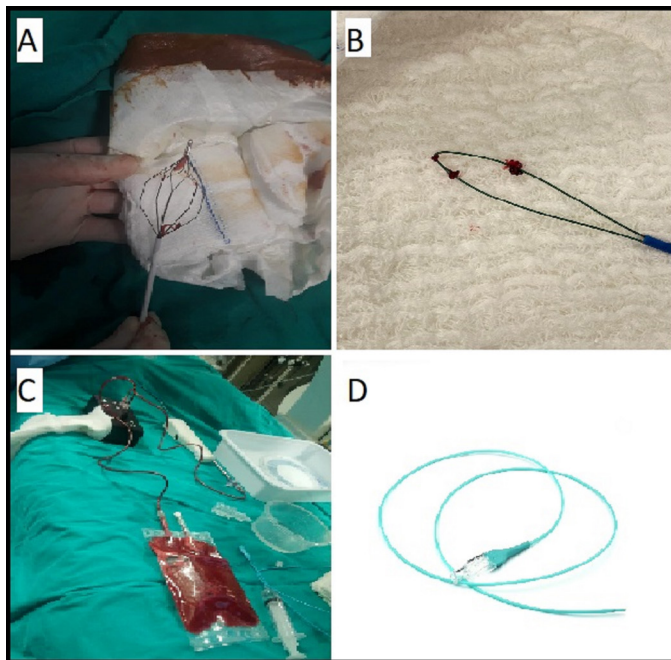


Figure 1. (A) Temporary thrombolysis catheter with inferior vena cava (IVC) filter. (B) Mantis thrombectomy device. (C) Dovi thrombus aspiration device. (D) Viper catheter-directed thrombolysis device

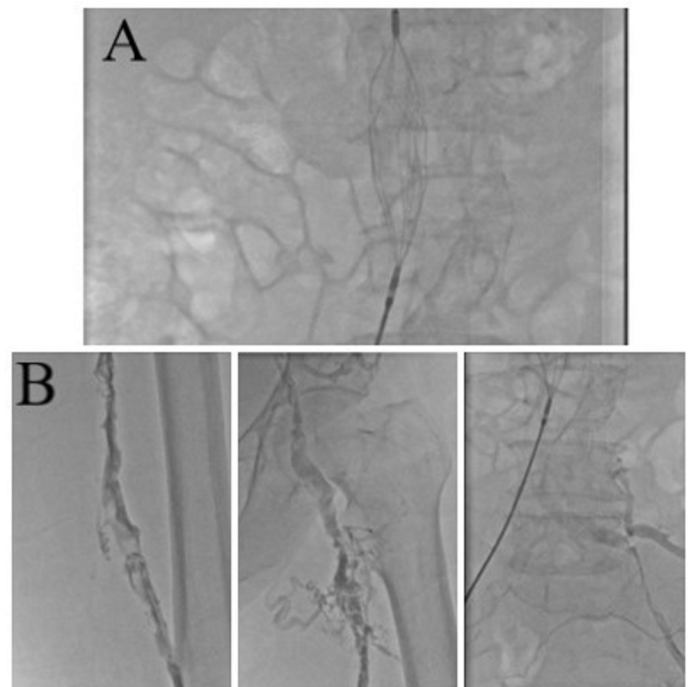


Figure 2. (A) Insertion of IVC filter before PMT. (B) Initial ascending venograms demonstrate occlusions of common femoral vein, and iliac veins

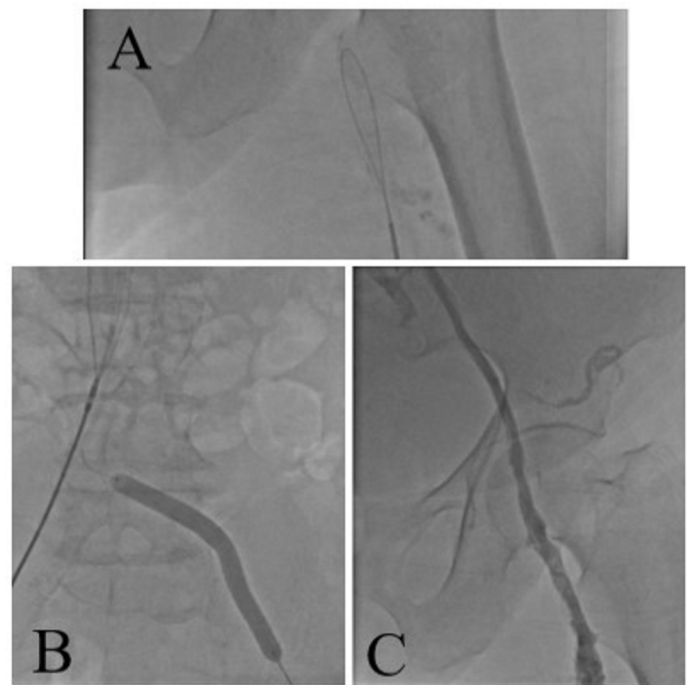


Figure 3. (A) Pharmacomechanical thrombectomy (PMT) catheter in the femoral segment. (B) Balloon angioplasty was performed due to residual venous stenosis. (C) Completion venogram shows no residual thrombus and excellent flow into the inferior vena cava

RESULTS

Patient demographics and risk factors of IFDVT were summarized in Table 1. The median age was 51 (range, 21–77) years. The median time lapse between onset of complaint and procedure was 6 days (range: 2-13 days). The IFDVT site was unilateral (12 on the left side (60%), 8 on the right side (40%)). A temporary

thrombolysis catheter with IVC filter was inserted in all patients. The puncture site was the popliteal vein in all patients. Following PMT, all patients were treated with balloon angioplasty (8-14 mm) for post-thrombotic strictures. The procedural success rate was 100%. During the procedure, there was no deterioration in the oxygen saturation and hemodynamics of the patients.

Table 1. Patient Demographics and Risk Factors of DVT^a

Data	DVT, n=20, %
Age, years	51 (range: 21-77)
Sex	Male 6 (30) Female 14 (70)
Comorbidity	Arterial hypertension 7 (35) Diabetes mellitus 3 (15) COPD 2 (10) History of major surgery (>1 month) 3 (15)
Risk factors	History of VTE 1 (5) Use of oral contraceptive 2 (10) History of pregnancy 2 (10) Immobilization 3 (15) Chemotherapy for malignancy 2 (10)

Abbreviations: COPD, chronic obstructive pulmonary disease; DVT, deep venous thrombosis; VTE, venous thromboembolism. ^aData are presented as median + counts (%)

Table 2. Procedural and Post-Procedural Data^a

Data	n=20
DVT side	Right 8 (40)
Anesthesia type	Left 12 (60) Local 20 (100) General 0 (0)
Procedure time	70 min (range, 31-110)
Technical success	20 (100)
Early clinical improvement	20 (100)
ICU stay	1 (range, 1-5)
Hospital length of stay	6 (range, 4-12)
Complications	Minor bleeding / hematoma 6 (30) Major bleeding 1 (5) Pulmonary thromboembolism 0 (0)
Reocclusion	3 (15)
Reintervention	2 (10)
Mortality	1 (5)

Abbreviations: DVT, deep venous thrombosis; ICU, intensive care unit. ^aData are presented as median + counts (%)

Table 3. Outcomes of the Study Group

	Baseline	12 th month	Z value	P value
	Median	Median		
	(min-max)	(min-max)		
Villalta scores	7 (3-11)	1 (0-13)	3.351	<.001*
Pain scores	7 (6-8)	1 (0-7)	3.851	<.001*

*Wilcoxon Signed Ranks test

All cases presented early clinical improvement. The removable IVC filters were successfully retrieved without any complications in an average of 2 days. Pulmonary thromboembolism was not observed in any of the patients during the follow-up. A 77-year-old male patient died due to major gastrointestinal bleeding during the ICU follow-up. Hence, follow-up was completed with 19 patients. No device related complications were encountered. Three (15%) patients had reocclusions throughout the follow-up period. The reason for reocclusion was identified as immobilization in 1 patient and irregular anticoagulant use in 2 patients. Two cases required repeat intervention with balloon angioplasty during the follow-up period.

Procedural and post-procedural details of patients are shown in Table 2. Venous patency rates during the 6- and 12-month follow-up were 85% and 80%, respectively. Three patients who developed reocclusion and one patient who died were not

included in the Villalta and Pain scorings. However, both of these patients showed improvements in symptoms and scoring after reintervention. Median pain score was 7 (range: 6–8) before the procedure and 1 (range: 0–7) at 12th month following thrombectomy ($P<.001$). Median Villalta score was 7 (range: 3–11) prior to intervention and 1 (range: 0–13) at 12th month following thrombectomy ($P<.001$). The changes in Pain scores and Villalta scores are shown in Table 3. Comparison of the Villalta and pre-intervention and post 12-month pain scores of the patients following the procedure revealed a significant difference between the Villalta and pain severity scores. At 12-month follow-up, no PTS was reported in 15 (75%) patients, mild PTS was reported in 2 (10%) patients, moderate PTS was reported in 2 (10%) patients. Furthermore, no severe PTS was observed. Variations of Pain scores and Villalta scores for each patient are shown in (Figure 5).

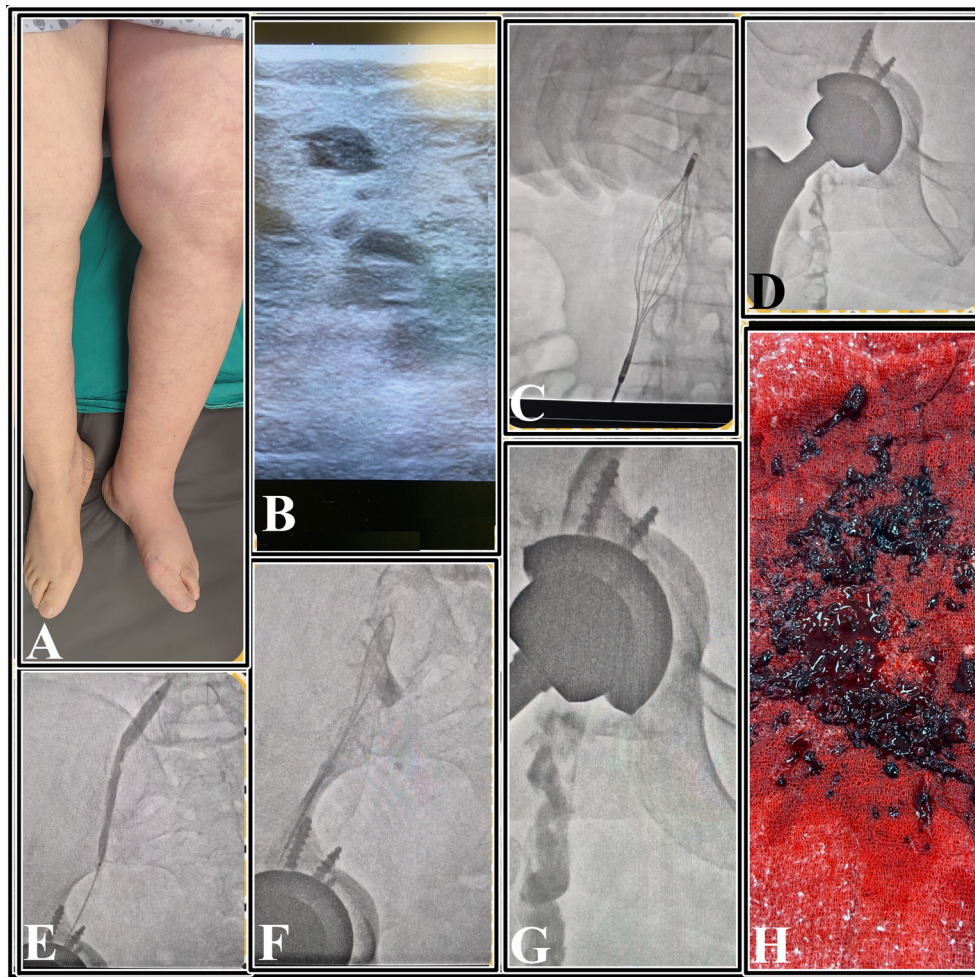


Figure 4. (A) An elderly female patient with a history of hip replacement surgery a month ago, who presented with warmth, discoloration, pain and swelling in her left leg. (B) Thrombus material in the femoral vein on ultrasonography. (C) Insertion of IVC filter. (D) Initial ascending venograms demonstrate significant occlusions of iliofemoral veins segments. (E) Plain old balloon angioplasty was performed due to residual venous stenosis following PMT. (F) Mantis catheter in the iliofemoral segment. (G) Completion venogram shows good flow into the vein segments. (H) Aspirated thrombus materials

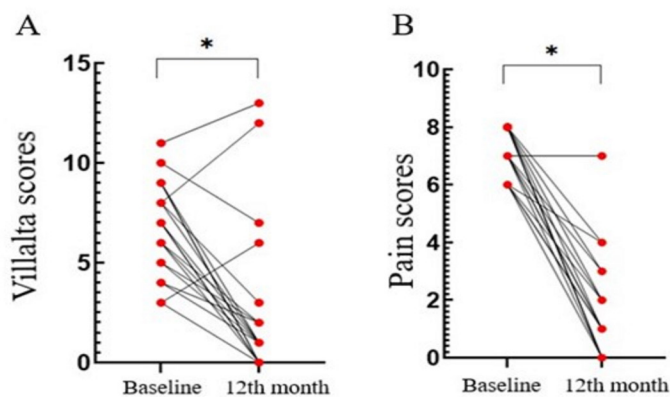


Figure 5. (A) Variation of Villalta scores for each patient * $p < .001$, Wilcoxon Signed Ranks test. (B) Variation of Pain scores for each patient * $p < .001$, Wilcoxon Signed Ranks test

DISCUSSION

The key point for treating IFDVT is reducing venous thrombosis complications, immediately alleviating symptoms, and improving patients' quality of life [9]. According to the current guidelines, anticoagulation is both the initial and the gold standard therapy for DVT [10]. Previous research demonstrated that PE might develop in 50% of untreated IFDVT cases, while PE can occur even if individuals are on anticoagulant treatment for DVT. [11] Furthermore, PTS may develop in 20%- 50% of cases with IFDVT, even when optimal anticoagulation therapy is used [4].

In the last ten years, PMT has been utilized as an alternative therapeutic option to CDT and open surgical thrombectomy to prevent the development of PTS. While these procedures are not advised in patients with a life expectancy of less than one year, or recurrent DVT, they may be preferred generally in active and younger patients with acute IFDVT [12,13]. The long-term outcomes of PMT have not been investigated. Nevertheless, there is significant amount of research reporting the efficacy outcomes of combined PMT and CDT. In a multicenter, randomized-controlled CAVENT trial, CDT was performed on 189 patients with IFDVT, and it was demonstrated that CDT reduced PTS in cases at follow-up, with major complications developing in 3% in the study cohort [5]. Furthermore, in the ATTRACT study, which was conducted to determine PMT and CDT in preventing the development of PTS in 692 individuals with IFDVTs, it was shown that both the severity of PTS as well as leg pain and swelling were significantly improved in patients who underwent PMT and CDT [14,15]. In other small cohorts undergoing PMT for IFDVT, Bozok et al. reported the rate of developing PTS as 19.8% in their case series consisting of 91 patients [16]. Many studies with a limited number of patients demonstrated rapid clinical improvement of more than 75% of patients and venous patency rates of over 80% for 12 months without any major complications [1,17-19]. In addition, Karthikesalingam et

al. investigated 16 retrospective studies for PMT with a total of 481 cases and reported a procedural success rate ranging from 82% to 100% without any major complications [20]. In addition, Köksoy et al. reported a study with a technical success rate of 97.6% [21]. A recent report by Kuetting et al. revealed one year primary patency rate after PMT as 94% [22] in patients with acute IFDVT. In the present study, procedural success was achieved in all patients. However, our patency rates (at 6- and 12-month follow-up) were 85% and 80% and relatively lower compared to previous studies. This may be due to the age and comorbid conditions of the patients.

The severity of PTS, as evaluated by the Villalta score was shown to be substantially correlated to the postoperative thrombus score and the degree of venous stenosis [8]. Early clinical improvement was seen in all cases following successful procedure of the deep venous system in the present study. However, based on the Villalta score at 1-year follow-up, no PTS was reported in 15 (75%) patients, mild PTS was reported in 2 (10%) patients, and moderate PTS was reported in 2 (10%) patients. No severe PTS was observed. According to these results, it is promising that after 12 months of follow-up among 19 patients, mild to moderate PTS was observed in 4 patients and no serious PTS developed in any of the patients. The statistically significant decrease in the Villalta and Pain scores compared to the pre-procedure values of the patients is a remarkable data. It is very important in terms of both the patients' quality of life and the prevention of major complications caused by DVT. Finally, it is promising in terms of long-term results.

Retrievable IVC filters are critical for preventing PE and capturing embolus. There is no consensus about the prophylactic use of these filters in studies [23]. In the present study, despite the aspiration system of the Mantis device, IVC filters were used routinely in all cases and successfully retrieved in an average of 2 days. As a consequence, no patients suffered from pulmonary embolism, puncture site complications, renal ischemia, filter migration, or vein trauma.

Systemic thrombolysis surely possesses substantial side effects, such as major bleeding and complications. Local or systemic bleeding is the most often reported complication of PMT and CDT procedures, occurring in 5% to 11% of patients [24]. Since the PMT technique requires less time and amount of thrombolytics, the risk of bleeding complications is decreased even more as compared to standard isolated CDT therapy [25]. In the present study, access site minor bleeding or hematomas were seen around the popliteal puncture site in 6 patients (30%). Compression therapy was adequate for these cases, and no blood transfusions were required. Nevertheless, a 77-year-old male patient died in the ICU due to major gastrointestinal bleeding after the procedure. No device related complications were encountered. Bearing in mind the age and the comorbid factors of the patient before the PMT procedure may be helpful

in preventing complications that may develop.

It should be essential to discuss and recommend some home notes. Despite publications related to isolated PMT, isolated CDT or rheolytic thrombectomy in the literature, hybrid methods may also be applied in selected patients and successful results may be obtained [12-25]. However, the current publication and results are only the initial experience. The crucial points in the procedural principle of the Mantis PMT device are that the thrombus can be mechanically fragmented with a single catheter. It allows easy manipulation in all segments, ease of use with single hand, and simultaneous administration of thrombolytic agents. However, another advantage of this device is that macerated thrombus can be suctioned from the side port via vacuum-assisted aspiration. In some cases, the Mantis may have difficulty breaking up a macerated thrombus. Therefore, the Dovi aspiration catheter can be used to aspirate residual thrombi. Since this catheter is thicker and multi-holed, it allows us to aspirate the residual thrombus a few more times. Of course, these procedures extend the duration of the procedure to some extent. In general, PMT may be ineffective in the common iliac vein segment. PMT in this segment may cause vein damage and catastrophic complications. Therefore, residual stenosis in this segment can be overcome with simultaneous plain old balloon angioplasty. Finally, it can be aimed to completely clear free or adherent thrombi in the venous pathway with CDT. The decision to add CDT method may be modified according to the clinical experience of the vascular surgeon and the patient's risk and comorbidity factors. Of course, the success of this hybrid method will enable us to make a healthier and safer interpretation after comparing it with other methods. Moreover, in the current study, it is important to mention that 3 patients had reocclusion, and 2 of them underwent reintervention at the 12-month follow-up. The reocclusion in these patients was due to immobilization and irregular use of anticoagulant drugs. In addition, these cases had a relatively longer procedural time than the others with a higher Villalta score. Furthermore, all patients in the study received effective anticoagulant treatment both before and after the intervention. This is also another key aspect for improving overall patency and reduced reintervention rates following the procedures.

Limitations of the study

The current study has some limitations, including its retrospective design, single-center nature, and small sample size. In addition, it is difficult to comment on the cost effectiveness of the hybrid procedure since there is no publication in the literature. The outcomes and efficacy of the Mantis device should be compared with other devices in order to establish definite conclusions.

CONCLUSIONS

The Mantis device combined with CDT appears to be an effective treatment approach for acute IFDVT, with encouraging

early results. This research also demonstrated that this technique provides quite satisfactory thrombus removal in acute IFDVT patients and significant symptomatic improvement at mid-term follow-up. More comparative, prospective, long-term, and randomized studies are required.

Ethics Committee Approval: The study protocol was approved by the Bozok University, Faculty of Medicine Ethics Committee (No: 2017-KAEK-189_2022.05.12_03). 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: Study development, data collection, design, interpretation, writing and editing the manuscript – G.Y.

Conflict of Interest: The author declared no conflicts of interest with respect to the authorship and/or publication of this article.

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