From the Eastern Vascular Society

Fast-track thrombolysis protocol: A single-session approach for acute iliofemoral deep venous thrombosis

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ABSTRACT

Objective: Catheter-directed thrombolysis in the treatment of acute iliofemoral deep venous thrombosis (IFDVT) often requires more than one interventional session to yield successful outcomes. Catheter-directed thrombolysis is generally expensive, requiring prolonged hospital stay that may be associated with increased local and systemic hemorrhagic complications. We developed the fast-track thrombolysis protocol (FTTP) to address these issues. The goal of FTTP is to restore patency during the initial session of thrombolysis, thereby minimizing costs and complications associated with prolonged thrombolysis.

Methods: A retrospective analysis of 38 patients treated for acute IFDVT using FTTP at our institution from January 2014 to February 2019 was performed. The protocol includes periadventitial injection of lidocaine at the venipuncture site under ultrasound guidance, contrast venography of the entire target segment, pharmacomechanical rheolytic thrombectomy of the occluded venous segment, tissue plasminogen activator infusion along the occluded segment, balloon maceration of the thrombus, and, if indicated, venous stent placement in areas of significant (≥50%) stenosis refractory to thrombolysis and balloon angioplasty. Once the thrombus was cleared, patients were prescribed oral antithrombotic therapy.

Results: Thirty-eight primary FTTPs (45 total interventions) were performed in 38 patients. The median age was 66 years (range, 39-93 years); 60.5% were female. Initial venous access was most often obtained through the popliteal vein, followed by the femoral and great saphenous veins. The mean operative time was 122 minutes (range, 59-249 minutes), and the median volume of tissue plasminogen activator infused was 10 mg (range, 4-20 mg). The median cost per procedure, including devices and medication, was $5374.45. Median postoperative length of stay was 1 day (range, 1-45 days). Successful single-session FTTP, as determined by completion venography, was accomplished in 81.5% (n = 31/38) of cases. The remaining seven cases (18.5%) required one additional session. Of the 38 patients, 30 (79%) required iliac vein stenting. Periprocedural complications consisted of one patient with retroperitoneal hemorrhage that was managed conservatively. No patients experienced rethrombosis within 30 days of FTTP. During the 5-year study period, there were no cases of pulmonary embolism, significant local or systemic hemorrhage, limb loss, or mortality.

Conclusions: FTTP, as presented herein, appears to be a safe, effective, and cost-effective technique in the resolution of acute IFDVT. (J Vasc Surg: Venous and Lym Dis 2019;7:773-80.)

Keywords: Deep venous thrombosis; Post-thrombotic syndrome; Catheter-directed thrombolysis; Iliac vein stenting; Pharmacomechanical thrombectomy; AngioJet

Iliofemoral deep venous thrombosis (IFDVT) is associated with severe short- and long-term physical, psychosocial, and financial sequelae for affected patients and their families.[1] Short-term complications associated with IFDVT include pulmonary embolism (PE), phlegmasia cerulea dolens, severe pain, and interference with activities of daily living. A common long-term complication of both untreated and unresolved IFDVT is post-thrombotic syndrome (PTS), an entity that results in significant disability and impaired quality of life and carries a substantial economic impact.[2]

Catheter-directed thrombolysis (CDT)[3,4] and thrombectomy[5] of IFDVT are associated with an increased quality of life, improved venous patency, decreased edema, and reduction in the incidence of PTS. Pharmacomechanical CDT (PCDT), a newer technology that combines CDT and rheolytic mechanical thrombectomy, has demonstrated excellent safety and efficacy with a further reduction in PTS and concomitant decrease in bleeding risk compared with CDT alone; however, recent data have questioned the extent of this benefit.[6] These techniques often require multiple sessions with

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Author conflict of interest: none.

Presented as an Plenary session presentation at the Thirty-third Annual Meeting of the Eastern Vascular Society, Pittsburgh, Pa, September 5-7, 2019.

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The editors and reviewers of this article have no relevant financial relationships to disclose per the Journal policy that requires reviewers to decline review of any manuscript for which they may have a conflict of interest.

2213-333X

https://doi.org/10.1016/j.jvsv.2019.06.018

intermittent lytic infusions and are associated with prolonged hospital stays that increase costs and the risk for complications.[7]

We have developed a novel, single-session technique—a fast-track thrombolysis protocol (FTTP)—to address these issues. The goal of FTTP is to restore iliofemoral venous patency during the initial session of thrombolysis, thereby minimizing costs and complications associated with prolonged thrombolytic exposure. This investigation documents the technical aspects and clinical outcomes of our 5-year experience with FTTP for acute IFDVT.

ARTICLE HIGHLIGHTS

- **Type of Research:** Single-center retrospective study
- **Key Findings:** Thirty-eight patients with iliofemoral deep venous thrombosis underwent treatment by our novel fast-track thrombolysis protocol. Thirty-one procedures resulted in complete thrombus resolution in a single session, which resulted in no intensive care unit stays, decreased utilization of tissue plasminogen activator, and lower costs when compared to procedures that necessitated overnight thrombolytic infusion.
- **Take Home Message:** Acute iliofemoral deep venous thrombosis can be successfully managed in a single-session approach, which reduces costs and length of stay and results in excellent long-term patency. During the 5-year study period, there were no cases of pulmonary embolism, significant local or systemic hemorrhage, limb loss, or mortality.

METHODS

Overview. This retrospective analysis of operative data was initially collected as part of a clinical quality improvement initiative. However, during the period covered in this investigation, our Institutional Review Board guidelines changed, and therefore we sought approval, following the principles outlined in the Declaration of Helsinki, for both retrospective and prospective data collection. A waiver for informed consent was granted as this investigation was of low risk and retrospective in its methodology. A review of our institution's electronic medical record database from January 2014 to February 2019 was performed, and all patients who underwent our novel FTTP for occlusive IFDVT were included.

Patient variables included in analysis were age, sex, comorbidities, thrombus laterality, and thrombus grading (Table I). Operative data points included venous access site, procedure duration, and number of operative sessions. Postoperative outcomes evaluated in this study were any 30-day complications, 30-day rethrombosis, major adverse limb events, PE, intracranial or retroperitoneal hemorrhage, and all-cause mortality. The primary procedure end point was radiographic evidence of thrombus resolution. Cases were excluded from analysis if they involved thrombolysis of any arterial, pulmonary, or arteriovenous segments. Isolated femoropopliteal deep venous thrombosis (DVT) was an exclusion criterion, and these cases were not analyzed.

FTTP. An algorithm for our FTTP in the management of IFDVT can be found in Fig 1. Immediately after diagnosis of IFDVT by clinical examination and duplex ultrasound (DUS), patients were systemically anticoagulated with a weight-based (100 units/kg) intravenous infusion of unfractionated heparin (UFH). All ultrasound results were independently reviewed by the operating surgeon and graded according to thrombus extent (Table II). Systemic anticoagulation with UFH was continued throughout all procedures. Once patients arrive to the operating suite, the affected limb is once again evaluated with DUS to identify the optimal percutaneous access site.

All patients receive intravenous conscious sedation, with the specific anesthetic agents left to the discretion of the attending anesthesiologist. Urinary catheterization is routinely performed after the initiation of sedation but before sterile preparation of the patient to closely monitor fluid and hemodynamic status in the setting of thrombolysis.

Before venous access is obtained, ultrasound-guided periadventitial administration of local anesthetic is performed to provide adequate pain control throughout the procedure. Our access technique involves standard ultrasound-guided puncture within a compressible segment of the vein in the thrombosed limb with eventual upsizing to an 8F sheath to accommodate all potentially necessary devices for mechanical thrombectomy and balloon angioplasty. When stenting was deemed necessary, the short sheath was upsized to a 10F sheath to accommodate 18- to 24-mm Wallstents (Boston Scientific, Marlborough, Mass). For extent 2 and extent 3 thrombi (Table II), we prefer a behind-the-knee popliteal vein approach with the patient situated in the prone position. After an access sheath is placed, another weight-based bolus (100 units/kg) of UFH is administered in addition to the concurrent maintenance infusion (18 units/kg per hour). Next, contrast venography is performed to ensure proper venous access, to confirm the extent of thrombus visualized on DUS, and to guide further therapeutic intervention. Intravascular ultrasound (IVUS) was not used during any FTTP procedure owing to its lack of availability at our institution. However, we do recommend the use of IVUS if possible because of its superiority to venography alone in the diagnosis of caval and iliofemoral obstruction.[8] Because of this limitation, our group has previously described suprainguinal venographic findings that allow accurate diagnosis of iliofemoral stenosis without the use of IVUS[9]; however, we consider IVUS to be mandatory when it is available.

In all cases, the rheolytic thrombectomy feature of the AngioJet (Boston Scientific) pharmacomechanical

Table I. Patients' demographics and comorbidities

Parameter	Female	Male	*P* value
Cases	23 (60.5)	15 (39.5)	.06
Average age, years (range)	68.8 (39-93)	57.1 (43-67)	.14
Thrombus laterality			
LLE	14 (60.8)	9 (60)	.96
RLE	9 (39.2)	6 (40)	
Thrombus grade[a]			
1	10 (43.5)	7 (46.6)	.53
2	10 (43.5)	7 (46.6)	
3	3 (13.0)	1 (0.67)	
Hypertension	13 (56.5)	9 (60)	.83
Diabetes	5 (21.7)	3 (20)	.89
Hyperlipidemia	8 (34.7)	5 (33.3)	.93
Renal insufficiency or failure	2 (8.6)	0 (0)	NA
Asthma or COPD	2 (8.6)	0 (0)	NA
Congestive heart failure	1 (4.3)	0 (0)	NA
Coronary artery disease	5 (21.7)	1 (6.6)	.21
Cerebrovascular disease	2 (8.6)	1 (6.6)	.82
Peripheral artery disease	2 (8.6)	1 (6.6)	.82
Prior DVT	7 (30)	2 (13)	.22
Contralateral	3	1	
Ipsilateral	4	1	
No significant PMHx	3 (13)	3 (20)	.57

COPD, Chronic obstructive pulmonary disease; *DVT,* deep venous thrombosis; *LLE,* left lower extremity; *NA,* not applicable; *PMHx,* past medical history; *RLE,* right lower extremity.
Categorical variables are presented as number (%).
[a]As defined in Table II.

thrombectomy catheter is used to perform an initial debulking of any fresh thrombus. We prefer the AngioJet ZelanteDVT catheter; however, before 2015, this option was not available, and therefore we used a properly sized AngioJet Solent system. Next, the Power Pulse feature of the AngioJet catheter is used to uniformly deliver 10 mg (diluted in 100 mL of saline) of tissue plasminogen activator (tPA) directly into the thrombus. After the pulsed delivery of tPA, the thrombus burden is immediately macerated with a low-pressure balloon (Atlas or Conquest; Bard Peripheral Vascular, Tempe, Ariz), which is sized whenever possible to the diameter of a patent adjacent vein. If the iliac veins are totally thrombosed, we use a 14 × 60-mm balloon inflated to 4 to 6 mm Hg. Rarely, higher inflation pressures are required. As the balloon is inflated, one needs to carefully observe for the presence of severe stenosis as outlined by the deformity of the contrast material inside the balloon (balloon contouring). This maneuver is repeated alongside the occluded segments of the common and external iliac veins.

Balloon maceration is a key step in the FTTP algorithm that accomplishes several important tasks. It increases the surface area of the target thrombus; facilitates direct contact of tPA against the target lesion; fractures the clot into smaller pieces, allowing more efficient suction thrombectomy; and aids in the identification of any underlying venous stenosis that could have potentially played a role in development of the initial IFDVT (Fig 2, *B* and *C*).

After balloon maceration, tPA is allowed to dwell for 10 minutes. The AngioJet catheter is then used for a repeated pass of rheolytic thrombectomy to further debulk and remove any remaining thrombus. Repeated balloon venoplasty is performed whenever large amounts of thrombus are seen on completion venography after mechanical thrombectomy. This is necessary to address resolution of resilient thrombus and to confirm areas of venous stenosis or compression. This step may be avoided with IVUS use; however, owing to the lack of IVUS availability at our institution, balloon expansion is used as an adjunctive measure in addition to contrast venography to identify any residual stenoses or thrombus burden. If a significant stenosis or residual thrombus within the iliofemoral veins is found to continue to cause impedance of flow, an appropriately sized, self-expanding Wallstent is deployed within the problem area (Fig 3, *A*) with balloon venoplasty to ensure proper expansion (Fig 3, *B* and *C*).

We avoid the routine placement of inferior vena cava filters in our FTTP algorithm as current guidelines and recent research do not support their use in the setting of isolated IFDVT without contraindications to anticoagulation.[10,11] The routine placement of retrievable inferior vena cava filters during the minimally invasive management of iliofemoral thrombosis has not been widely accepted and in our experience has been unnecessary.

Completion venography (Fig 3, *D*) is performed after any intervention (ie, mechanical thrombectomy, balloon venoplasty, stent placement) to assess for clearance of thrombus, to confirm restoration of iliofemoral venous outflow, and to identify any extravasation. Restoration of venous inflow and outflow is characterized as physiologic venous return from below to above the inguinal ligament, through all previously diseased segments, as visualized on contrast venography. Patients with complete or near-complete resolution of residual thrombus are discharged to the postanesthesia care unit, then to a regular surgical floor, and discharged to home once prior authorization for oral anticoagulation has been confirmed. In the interim, patients are anticoagulated with intravenous UFH until an oral anticoagulant can be officially prescribed and administered. In some instances, such as if the case ran late into the afternoon or evening, case managers, social workers, and insurance offices were not available to facilitate a "same-day" discharge. In these situations, patients are discharged the next morning, once the appropriate support is available to do so.

If persistent thrombus is present after completion of FTTP, lysis is continued through an appropriately sized

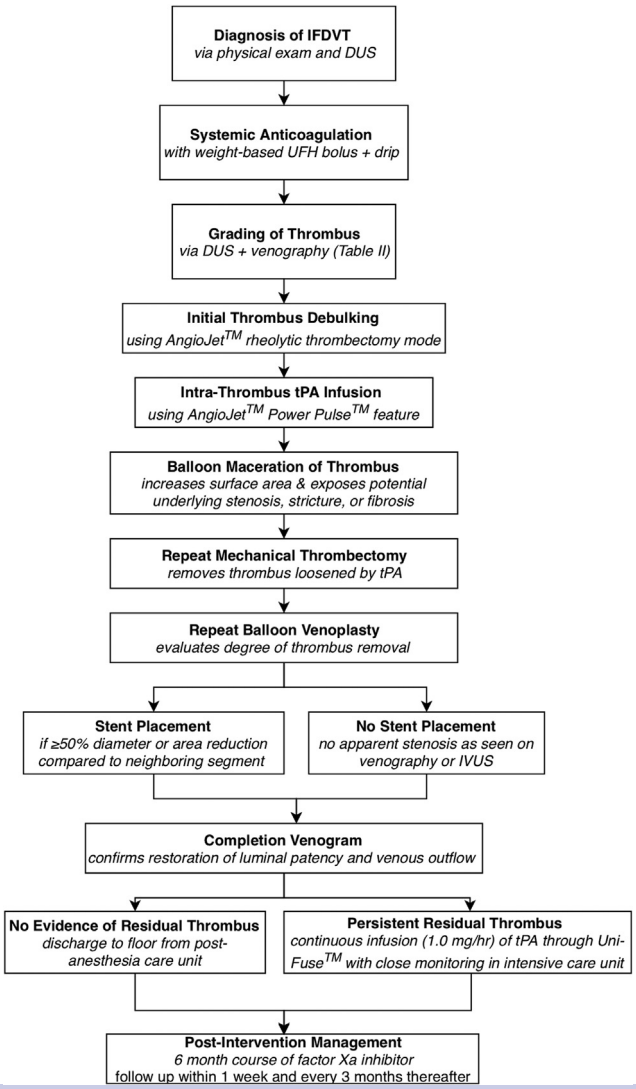

Fig 1. Fast-track thrombolysis protocol (FTTP) for iliofemoral deep venous thrombosis (*IFDVT*). *DUS,* Duplex ultrasound; *IVUS,* intravascular ultrasound; *tPA,* tissue plasminogen activator; *UFH,* unfractionated heparin. AngioJet and Power Pulse are registered trademarks of Boston Scientific (Marlborough, Mass). Uni-Fuse is a registered trademark of AngioDynamics (Latham, NY).

multihole infusion catheter (Uni-Fuse; AngioDynamics, Latham, NY) with the patient closely monitored for signs of hemodynamic instability or hemorrhage in the surgical intensive care unit or, if beds are unavailable, in the post-anesthesia care unit. Alteplase is infused at a rate of 1.0 mg/h through the Uni-Fuse catheter, with a concomitant heparin infusion of 500 units/h through the sheath to prevent sheath thrombosis. As the sole purpose of the heparin infusion is to prevent sheath thrombosis, the infusion dose is subtherapeutic and standardized regardless of thrombus burden and the patient's weight, and therefore parameters such as activated partial thromboplastin time are not routinely monitored. Venography and further intervention, if indicated, are typically repeated at 12-hour intervals until evidence of angiographic thrombus resolution is appreciated.

Single-session intervention was defined as successful completion of the FTTP in a single trip to the operating suite. If the patient required more than one trip, this was considered failure of the FTTP.

Postintervention medical management. Postoperative medical management for all patients consists of a 6-month regimen of an oral factor Xa inhibitor, for which insurance availability typically dictates choice of a specific agent.

We use a 6-month regimen of oral anticoagulation therapy for the combined purpose of DVT treatment and prevention of stent thrombosis. After this, patients were maintained on antiplatelet therapy for life. Rivaroxaban is initially dosed at 15 mg twice daily for 21 days, then 20 mg once daily thereafter for 6 months. Apixaban is initially prescribed at 10 mg twice daily for 7 days and then 5 mg twice daily thereafter for 6 months. These recommendations were tailored to the individual patient if the patient had a sensitivity to either agent, was already prescribed an antithrombotic regimen for another reason, or had issues obtaining either medication.

Postintervention follow-up. All patients were evaluated in the office or hospital-based outpatient vascular clinic within 1 week of intervention and every 3 months postoperatively thereafter with a physical examination and DUS evaluation of the inferior vena cava and lower extremity veins.

Data collection and statistical analysis. All procedures were documented in a single database registry, with collected variables including the patient's age, sex, and comorbidities (Table I); extent of thrombus (Table II); etiology of DVT (Table III); and duration of intervention, access site, volume of tPA and heparin, devices used, and 30-day and long-term outcomes (Table IV), which included recurrent thrombosis and reintervention. Statistical analysis was performed with χ^2 and unpaired *t*-tests (Excel 2017 with Data Analysis ToolPak; Microsoft Corp, Redmond, Wash).

Before September 2016, the cost of tPA at our institution was $121.57 per 2-mL vial. Starting in September 2016, this cost changed to $143.00 per 2-mL vial. The cost of tPA per patient was determined by taking the total tPA used in a patient, in milliliters, dividing it by 2, then multiplying by the cost of a vial, depending on the date of each intervention.

RESULTS

During the 5-year evaluation period, 38 primary FTTP procedures were performed in 38 individual patients. The median age of the patient cohort was 66 years, ranging from 39 to 93 years. There were more women (n = 23 [60.5%]) than men (n = 15 [39.5%]); however, there were no differences in thrombus laterality by sex. Similar

Table II. Definitions of thrombus extent

Thrombus grade	Definition	Patients, No. (%)
Extent 1	Thrombus involves external or common iliac vein only	17 (44.7)
Extent 2	Thrombus involves both iliac and femoral veins	17 (44.7)
Extent 3	Thrombus extension from iliac to popliteal vein	4 (10.5)

results were seen in thrombus grade (Table II) between the female and male patients. Furthermore, there were no differences in medical comorbidities between the men and women who received FTTP for IFDVT (Table I).

The primary indication for FTTP in this cohort was the presence of IFDVT. The majority of IFDVTs treated with FTTP were unprovoked, followed by stent thromboses. A full distribution of IFDVT etiology can be found in Table III. The initial access site varied between the popliteal, femoral, great saphenous, small saphenous, and tibial veins, with a full distribution found in Table IV. Mean operative time was 122 minutes, ranging from 59 to 224 minutes, with a median total tPA and heparin dose per procedure of 10 mg (4-20 mg) and 5000 units (3000-7000 units), respectively. Thirty (79%) needed stenting with an appropriately sized Wallstent. The median cost per intervention, including both endovascular devices and medication, was $5374.45. The tPA cost per primary FTTP session was $848.16.

Median postintervention length of stay (LOS) was 1 day (range, 1-45 days). The single patient with an extended LOS (45 days) developed IFDVT during prolonged hospitalization for the treatment of behavioral health problems and an uncontrolled seizure disorder. The extended stay was unrelated to the single-session FTTP thrombolysis session.

Successful thrombus clearance, defined as patent iliofemoral venous inflow and outflow at discharge, occurred in all cases (38/38 [100%]). Single-session FTTP thrombolysis was accomplished in 81.5% of cases (31/38). The remaining seven cases required a return trip to the operating suite for planned lysis check (18.5% failure rate). The mean cost of tPA for all interventions, as calculated through an intention-to-treat analysis, including overnight lysis and returns to the operating room, was $697.37.

At 30-day follow-up, no patients in the FTTP cohort required unplanned thrombolysis or readmission. On extended surveillance of cohort patients presenting for 6- and 12-month follow-up, there were no additional thrombotic events.

The rate of periprocedural complications was low. A single patient experienced retroperitoneal hematoma attributed to access site bleeding; this particular case was managed conservatively with blood transfusion and close monitoring. No patients experienced PE, intracranial hemorrhage, or limb loss. There has been no procedure-related or all-cause mortality in the cohort to date.

DISCUSSION

The presence of acute IFDVT is a vascular emergency that necessitates prompt endovascular therapy to reduce the incidence of PE and PTS. As demonstrated through numerous trials, systematic reviews, and meta-analyses, both CDT and thrombectomy improve clinical and angiographic outcomes compared with anticoagulation alone.[3-7] However, there is a lack of consensus on the technique and timing of these interventions. A common protocol used in modern practice

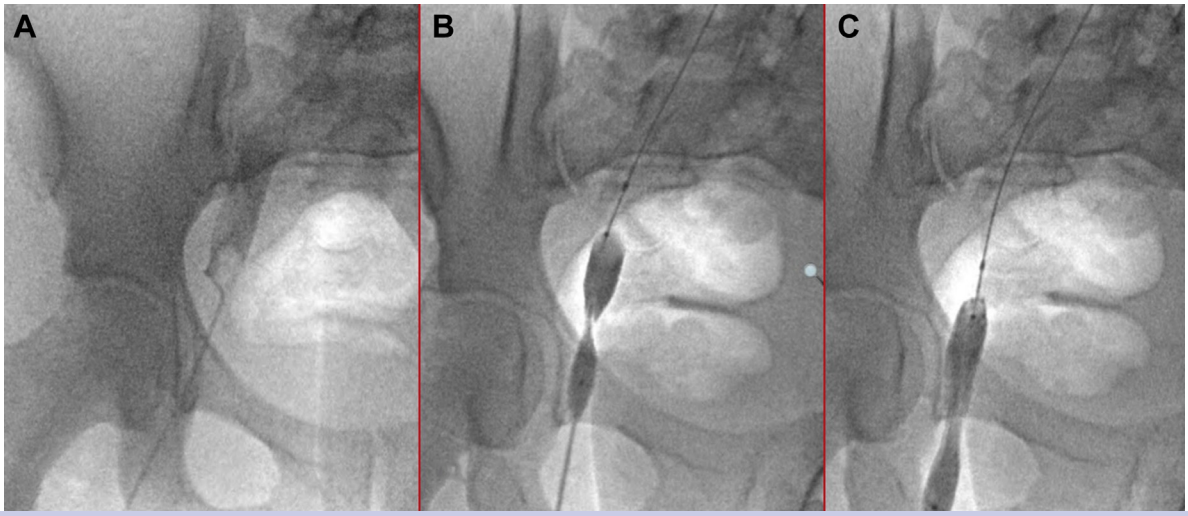

Fig 2. Contrast venography revealing iliofemoral deep venous thrombosis (IFDVT; **A**), with subsequent balloon maceration of thrombus revealing underlying stenoses **(B** and **C)**.

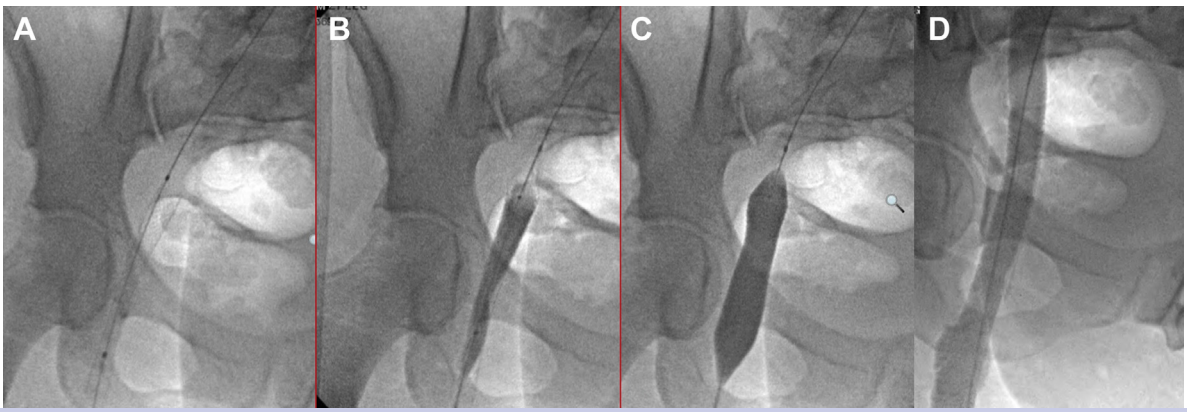

Fig 3. Self-expanding stent placement **(A)** with postdeployment balloon venoplasty to ensure proper expansion in an area of persistent stenosis **(B** and **C)** and resultant completion venogram **(D)**.

involves an initial session of PCDT followed by lytic infusion during an extended period, with one or more repeated angiograms to assess for target lesion patency. This practice, although effective, prolongs LOS, heightens costs, and is associated with increased risk of hemorrhagic complications.

The FTTP approach combines the well-established benefits of PCDT[7] and iliac vein stenting[12,13] into a complementary and highly effective approach for the endovascular management of acute IFDVT. Furthermore, the low incidence of bleeding complications seen in patients undergoing FTTP (n = 1) challenges that of trials evaluating the efficacy of PCDT plus extended thrombolytic infusion, which report a similarly low incidence.[7,14] Compared with standard CDT, our single-session protocol uses a lower volume of lytic agent (mean, 10 mg) for a finite amount of time (mean, 122 minutes), under direct visualization and hemodynamic monitoring. We believe that repeated balloon maceration, which increases the surface area for tPA to dissolve thrombus and reveals underlying culprit stenoses, is the major factor associated with the technical success of FTTP. By maximizing the interaction of tPA with the target thrombus, a single-session approach is feasible for most (81.5%) patients with acute IFDVT. The speed at which the procedure is conducted, along with the short exposure to tPA, seems to eliminate the feared—and potentially fatal—complications associated with PE[15] and intracranial hemorrhage.

Whenever it is indicated, placement of stents to eliminate residual stenosis or extrinsic compression is a critical step of the FTTP algorithm. In our study, 79% (30/38) of patients underwent placement of a self-expanding stent deemed necessary for restoration of adequate venous outflow. Because we did not use IVUS, we could not ascertain for sure whether all areas of luminal narrowing in the iliac vein were caused by extrinsic compression, short segment of poor recanalization, acute-on-chronic thrombus, webbing, or synechiae. We believe this important question should be further investigated by prospectively constructed trials. In the meantime, to avert rethrombosis of the iliac vein, it is imperative to eliminate the area of stenosis by effectively stenting the appropriate segment. Otherwise, localized venous stasis and endothelial damage could lead to an increased risk of DVT formation.[16] Failure to address underlying residual stenoses, similar to leaving behind residual thrombus, is a risk factor for DVT recurrence and increases the severity of PTS.[17,18]

Table III. Etiology of deep venous thrombosis (*DVT*) treated with fast-track thrombolysis protocol (FTTP)

Etiology of DVT	No. (%)
Unprovoked	19 (50)
Stent thrombosis	16 (42)
Postsurgical	2 (5)
Prolonged immobilization	1 (3)

FTTP shows advantages in several specific value-metrics important in the current health care landscape, including cost containment, reduction in LOS, and avoidance of readmission. Furthermore, a single session of FTTP eliminates the need for ongoing lysis and the incurred costs of surveillance in the intensive care unit and repeated laboratory monitoring.[19] Whereas PCDT is associated with decreased costs compared with CDT alone,[20] we believe that FTTP, at an average cost of $5374.45 per session, offers significant economic benefit with equivalent safety and efficacy.

The median LOS for our cohort was 1 day, which is substantially lower than the national average of 5 days for all IFDVT-related hospitalizations.[21] There were no 30-day readmissions for any patient receiving FTTP compared with the national average of 15.1% in 2010,[20] and no patients included in analysis during the 5-year study period experienced rethrombosis or needed subsequent thrombolysis.

Results of the Acute Venous Thrombosis: Thrombus Removal with Adjunctive Catheter-Directed Thrombolysis (ATTRACT) trial, comparing standard-of-care anticoagulation plus adjunctive PCDT vs anticoagulation alone for

Table IV. Procedural details, technical parameters, and outcomes

Parameters	
Mean procedure time, minutes	122
Female	109
Male	142
Access site	
Popliteal vein	20
Femoral vein	12
Great saphenous vein	3
Small saphenous vein	2
Posterior tibial vein	1
Single-session protocol	31 (81.5)
≥1 session with overnight lysis	7 (18.5)
Median operative expense (USD)	$5374.45
Mean tPA cost (USD)	$697.37
30-day rethrombosis	0
PE	0
Intracranial hemorrhage	0
Limb loss	0
Retroperitoneal hemorrhage	1 (2.6)
All-cause mortality	0

PE, Pulmonary embolism; *tPA*, tissue plasminogen activator; *USD*, U.S. dollars.
Categorical variables are presented as number (%).

acute lower extremity DVT, were recently published with much controversy. The ATTRACT investigators concluded that adjunctive PCDT did not reduce the incidence of PTS compared with anticoagulation alone.[22,23] Critics of the investigation argue that one of the major faults of the study lies in its evaluation of the primary PTS end point. Instead of assessing PTS as a continuous variable based on Villalta scoring, the ATTRACT investigators designed a binary end point system. Patients were simply defined as "having PTS" if they had a Villalta score >5, instead of assessing symptom severity as a scale of symptom severity.[24] Furthermore, although it is widely used as a marker of PTS severity, some authors have argued that the Villalta score has minimal data supporting real-world use and heavily weights visible cutaneous findings while drastically under-representing actual quality-of-life measures, such as pain and weight gain.[24] This reliance on physical examination signs, such as skin changes, is worrisome as there is weak correlation between physical examination findings and patient-reported symptoms.[25] Furthermore, the Villalta scoring system has been found to poorly detect severe post-thrombotic disease.[26]

Subgroup analysis of the IFDVT cohort data revealed that adjunctive PCDT resulted in improved venous-related quality of life, reduced symptom severity, and lower average Villalta scores and that it reduced the proportion of patients who developed moderate to severe PTS.[23,27] Another added benefit of adjunctive PCDT in treating IFDVT was more rapid symptom resolution within 30 days of intervention compared with anticoagulation alone. One of the most controversial issues surrounding the authors' conclusions of the ATTRACT trial was the inclusion of isolated infrainguinal femoropopliteal DVT lesions, which are often treated medically as they carry a lower risk of PE and PTS compared with IFDVT. The inclusion of femoropopliteal DVT lesions in an attempt to increase the population size probably underpowered the IFDVT arm, which may have led to the "negative" trial conclusion.[25] Regardless of the authors' published conclusions, ATTRACT was a large-scale and—despite the aforementioned shortcomings—a relatively well designed study that remains a landmark trial in the endovascular-first era.

The limitations of this study are consistent with its single-center and retrospective methodology. A modest sample size of 38 patients limits the generalizability of our results; however, we believe the large range of ages and comorbidities is a strength. The lack of prospective and follow-up Villalta scoring prohibits long-term analysis of PTS incidence; however, our data collection regarding long-term FTTP outcomes remains a work in progress.

CONCLUSIONS

FTTP appears to be a safe, efficacious, and cost-effective approach in restoring iliofemoral venous outflow in the presence of acute IFDVT. From a technical standpoint, FTTP does not require any specialized devices or training that is not already available to the modern surgeon or interventionalist. FTTP minimizes blood loss, reduces costs, does not require general anesthesia, forgoes the need for surgical exposure, and in most cases does not require prolonged tPA infusion.

AUTHOR CONTRIBUTIONS

Conception and design: EA
Analysis and interpretation: EA, JC, AP, NM, AH, PK
Data collection: JC, AP, PK
Writing the article: EA, JC, AP, NM, AH, PK
Critical revision of the article: EA, JC, AP, NM, AH, PK
Final approval of the article: EA, JC, AP, NM, AH, PK
Statistical analysis: AP, PK
Obtained funding: Not applicable
Overall responsibility: EA

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Submitted Apr 12, 2019; accepted Jun 25, 2019.