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Basic Data Underlying Clinical Decision-Making in Endovascular Therapy

Basic Data Related to Thrombolytic Therapy for Acute Venous Thrombosis

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Background: Treatment guidelines for thrombolysis in iliofemoral deep venous thrombosis (DVT) are based on a limited number of observational and prospective studies. The acute venous thrombosis: thrombus removal with adjunctive catheter-directed thrombolysis (ATTRACT) trial will be the first large, multicenter randomized control trial to evaluate the relative advantages of several current treatment strategies. The objective of this study was to summarize the existing data that inform the use of catheter-directed thrombolysis (CDT) or pharmacomechanical thrombectomy in the management of acute iliofemoral DVT.

Methods: A search of the current literature was done using PubMed, Ovid, and Cochrane databases for all available articles published up to December 2013.

Results: Of those studies, which included at least 25 patients, 19 case series were identified from 1996 to 2012. Treatment groups included anticoagulation, surgical thrombectomy, pharmacomechanical thrombectomy, and CDT. Cases observed in each ranged from 26 to 101. Three studies were identified which derived data from national multicenter registries. Only 2 randomized control trials were identified from 2002 to 2012. Both support the use of CDT over anticoagulation alone for treatment of iliofemoral DVT.

Conclusions: Present treatment guidelines for acute iliofemoral DVT have been in flux and are derived from a relatively small amount of clinical data. They are summarized here in anticipation of results from the ongoing ATTRACT trial.

INTRODUCTION

The goals of therapy for acute deep venous thrombosis (DVT) are 1) to prevent pulmonary embolism and 2) to reduce the incidence of postthrombotic syndrome. Conventional anticoagulant therapy, aimed at prevention of pulmonary embolism and recurrent venous thromboembolism, has been largely ineffective at treating postthrombotic syndrome. Late manifestations of postthrombotic syndrome result from a combination of valvular incompetence and residual venous occlusive disease.[1,2]

The Society for Vascular Surgery along with the American Venous Forum recently published a set of guidelines on early thrombus removal strategies that can potentially restore venous patency and preserve valve function, thereby reducing postthrombotic morbidities (Table I).[2] Current recommendation on treatment of iliofemoral venous thrombosis (for patients meeting criteria as listed in Table I) is percutaneous catheter-directed thrombolysis (CDT, either pharmacologic or pharmacomechanical) as first-line therapy.[2–5] CDT can rapidly dissolve venous thrombus, providing quicker symptomatic relief and preserving venous valvular function. Of the numerous thrombolytic agents currently available (Table II), streptokinase is the

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Table I. Summary of guidelines for venous thrombosis management

Venous thrombosis level	Recommendation
Iliofemoral deep venous thrombosis: • First episode of acute iliofemoral deep venous thrombosis, • Symptoms <14 days in duration, • Low risk of bleeding, and • Ambulatory status with good functional capacity and an acceptable life expectancy	*Early thrombus removal options:* • Catheter-directed thrombolysis, • Pharmacomechanical thrombolysis, and • Surgical thrombectomy (if thrombolytic therapy is contraindicated)
Phlegmasia cerulea dolens	Early thrombus removal (as listed previously)
Isolated femoropopliteal deep venous thrombosis	Standard anticoagulation with unfractionated or low-molecular-weight heparin

Table II. Dosing of thrombolytic agents when used for catheter-directed therapy

Generic name	Trade name(s)	Dose
Alteplase	Activase	0.25–2 mg/h
Reteplase	Retavase	0.75 U/h
Tenecteplase	TNKase	0.25–5 mg/h
Urokinase	Kinlytic	250,000 IU bolus, then 100,000–140,000 IU/h

Adapted from Rutherford Vascular Surgery, 7th edition

Table III. Mechanical thrombectomy devices

Device	Mechanism	Thrombus extraction
Hydrodynamic		
AngioJet Xpeedior	Venturi effect	Yes
Hydrolyser	Venturi effect	Yes
Oasis	Venturi effect	Yes
Rotational		
Amplatz	Microfragmentation	No
Arrow-Trerotola	Microfragmentation	No
Castañeda brush	Microfragmentation	No
Cragg brush	Microfragmentation	No
Helix	Microfragmentation	No
Ultrasound-assisted		
EKOS	Ultrasound/infusion	No
OmniWave	Ultrasound/cavitation	No
Others		
Trellis	Fragmentation/mixing	Yes

Table IV. Advantages of pharmacomechanothrombectomy

- Local administration of thrombolytic agent
- Reduced thrombolytic dose
- Reduced thrombolytic infusion time
- Decreased bleeding complications
- Reduced ICU stay
- Reduced overall hospital treatment cost

ICU, intensive care unit.

only Food and Drug Administration–approved agent but it is rarely used in the United States. Off-label use of other thrombolytics is the rule with tissue plasminogen activator being the agent most commonly used. CDT is more commonly complicated by bleeding complications than systemic anticoagulation alone and also requires procedural access and angiographic guidance. These factors have, in some institutions, limited the adoption of CDT for acute iliofemoral venous thrombosis.

Pharmacomechanical thrombectomy (PMT) is the combination of mechanical thrombectomy and thrombolytic agents. These devices are classified as hydrodynamic, rotational, and ultrasound-assisted devices (Table III).[6] PMT potentially reduces thrombolytic dose and infusion time while minimizing bleeding complications (Table IV).[7] Current guidelines recommend the use of PMT for venous thrombosis if expertise and resources are available.[8–13] Surgical venous thrombectomy is considered when thrombolytic therapy is contraindicated or not available, but not as a first-line therapy.

The data from which the previously mentioned recommendations are based are derived from a multitude of observational case series, venous registries, and small randomized studies. A comprehensive list of the case series describing the use of CDT and/or PMT for treatment of acute DVT is shown (Table V).[14–32] Only studies consisting of at least 25 patients are included. Most of the studies describe high thrombolysis success and low morbidity and mortality rates after CDT and/or PMT.

In addition to observational studies, venous registries have been established to collect the data on endovascular management of venous thrombosis (Table VI).[33–35] The American Venous Registry, a multicenter registry developed in 1995, is a

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