Learning objectives. At the conclusion of this activity, the participant should be able to: 1) describe how mechanical thrombectomy may alleviate symptoms and decrease the incidence of post-phlebitic syndrome in patients with deep venous thrombosis (DVT); 2) discuss how DVT leads to chronic venous insufficiency and why clot removal with mechanical thrombectomy may be better than standard anticoagulation alone; and 3) discuss the benefits of combined mechanical thrombectomy with thrombolytic therapy.

ABSTRACT: Multiple sequelae may occur after deep venous thrombosis (DVT) including acute limb symptoms, such as swelling and pain, valvular damage and reflux leading to chronic symptoms, and, the most serious, pulmonary embolism and death. Conventional therapy consists of anticoagulation with heparin and warfarin in the setting of an acute DVT, which prophylaxes against clot propagation and pulmonary embolism but does not relieve thrombus burden. The delayed complications of DVT, known as the post-phlebitic syndrome, are due to valvular damage from chronic thrombus and scarring. Endovascular management utilizing percutaneous mechanical thrombectomy alone or in combination with pharmacological thrombolytic agents is safe and effective in relief of thrombus burden. Along with possible preservation of venous valve function, inciting anatomic lesions may be treated simultaneously. This article explores the use of percutaneous mechanical thrombectomy in the treatment of venous thrombotic disease.

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Introduction

The incidence of deep vein thrombosis (DVT) alone is approximately 48 per 100,000 persons per year in large community-wide studies, with an in-hospital case-fatality rate from complications of thromboembolism at 12 percent. Thus, 300,000 hospitalizations per year can be directly attributed to venous thrombotic disease with studies reporting as many as 90 percent of patients traditionally admitted to the hospital. Venous thromboembolic disease, both DVT and pulmonary embolus (PE), is an under-diagnosed medical problem that may result in high rates of significant patient morbidity and mortality. Most studies cite inadequate venous thromboprophylaxis in surgical and medical patients as a causative factor in DVT and PE. DVT with or without subsequent PE can negatively impact patient outcomes and increase healthcare costs. Patients with multiple venous segment involvement, particularly in the iliofemoral veins or with extension of a calf vein DVT, are among those most frequently presenting for treatment.

In the acute setting, venous obstruction of the lower extremity may lead to leg swelling and pain. If progressive, phlegmasia cerulean dolens may develop with signs and symptoms of limb-threatening ischemia. Conventional initial therapy includes heparin or enoxaparin (or other low molecular-weight heparin) followed by oral warfarin for several months; the exact length of treatment is controversial. Anticoagulation therapy, the current standard of care, for iliofemoral DVT may inhibit further clot propagation and prevent pulmonary embolism. However, it does not in itself prevent chronic post-thrombotic complications.

Chronic Venous Insufficiency

The consequences of chronic deep venous insufficiency, the post-thrombotic or post-phlebitic syndrome, is a major medical problem and often results in a significant compromise of lifestyle for an affected patient. DVT can render the venous valves incompetent, resulting in a spectrum of clinical presentations ranging from varicose veins to chronic lower-extremity pain and edema to venous skin changes and ulceration. Chronic venous insufficiency (CVI) secondary to post-phlebitic syndrome occurs in 66 percent of patients at five years following an episode of DVT and accounts for up to 75 percent of all cases of venous ulcerations. Following extensive lower-extremity DVT, the post-phlebitic syndrome may manifest immediately or take several months or years to full patient debilitation.

This disease complex occurs secondarily as a result of chronic venous hypertension and venous valvular insufficiency and reflux. Hemodynamic derangements may result from a combination of abnormalities, such as valvular incompetence, venous obstruction with flow diversion through high resistance collaterals, or residual venous stenoses causing flow resistance. Techniques aimed at valve preservation and restoration of venous patency should theoretically decrease venous hypertension, reducing the incidence and degree of post-thrombotic symptoms. Improvements in venous hemodynamics should lead to overall improved clinical symptoms. Venous valvular reflux is the dominant cause of CVI. This valvular incompetence has been shown to result directly from DVT. Furthermore, patients with deep venous obstruction have more severe valvular insufficiency, calf muscle pump dysfunction, and ambulatory venous hypertension than patients without evidence of obstruction.

The ability of interventions, such as anticoagulation therapy, thrombolytic therapy, and surgical/endovascular thrombectomy, to restore venous patency, alleviate obstruction, and ultimately...
decrease reflux in a diseased extremity can be used to return patients to their normal way of life free of pain, swelling, ulceration, and in the ideal case, free of the need for elastic support.

**Surgical Thrombectomy**

Surgical thrombectomy with distal arteriovenous fistula creation for acute DVT is mainly of historical interest only because of its associated operative morbidity primarily related to blood loss. However, surgical thrombectomy may still be used in the clinical setting of venous gangrene with impending limb loss. The best reported results are from a 1999 study by Juhan, et al. These authors demonstrated an improvement in long-term results following surgical venous thrombectomy for acute iliofemoral DVT in their personal series. In a review of 77 patients, principally young trauma victims, valvular competency was preserved at five years in 80 percent, while 90 percent of limbs had either mild symptoms of CVI or no symptoms at all. Additionally, Meissner and colleagues reported their results of venous thrombectomy with arteriovenous fistula in 30 patients. Other series have demonstrated only average results for this all but abandoned technique.

**Catheter-Directed Thrombolysis**

The delivery of a pharmacologic lytic agent directly into an existing venous thrombosis has overtaken systemic thrombolysis due in part to more complete clot lysis combined with a lower rate of bleeding complications. By using one of many commercially available multiple side hole infusion catheters for lytic agent delivery, high drug concentrations are able to be concentrated at the location of the thrombus. Catheter-directed thrombolysis has been advocated because of its theoretical advantage of complete and rapid clot dissolution. Multiple studies have documented the efficacy of several lytic agents in the treatment of acute DVT, with total infusion times needed for thrombus removal ranging from hours to days. An association between time to lysis and the development of venous reflux was evaluated in patients using serial duplex scans following a DVT episode. With the exception of the posterior tibial vein, early lysis and rapid venous recanalization appears to protect valve integrity in the lower extremity. Though thrombolytic therapy for DVT has excellent outcomes with thrombus clearance and thus may lower the incidence of post-phlebitic syndrome by preservation of valvular function, the complication profile of the treatment secondary to the lytic agent and the infusion times may be limitations for widespread use.

**Percutaneous Mechanical Thrombectomy**

Relief of clot burden by directly extracting thrombus surgically or via lytic dissolution should hypothetically decrease the risk of PE and also that of post-phlebitic syndrome resulting in manifestations of CVI. Primarily because of the bleeding risks of catheter-directed thrombolysis, percutaneous mechanical thrombectomy (PMT) has emerged as an advantageous option for the treatment of acute DVT. Table 1 summarizes various thrombectomy catheters and the mechanism of clot removal. A full discussion of each of the catheters is beyond the scope of this article. The catheters fall into one of two categories for clot extraction mechanism: microfragmentation or thrombo-aspiration (so-called Venturi effect). Several PMT catheters may be used in combination with adjunctive thrombolytic agents for more complete and rapid thrombus removal with lower mean lytic infusion doses and durations. Reducing the dosage and/or time for complete thrombolysis should translate into cost savings and decreased bleeding complications. Furthermore, inciting lesions leading to thrombosis may be unmasked with PMT with
or without adjunctive lysis. Venous stenoses could be treated following thrombectomy in the same operative setting, resulting in more efficient patient care.

Several authors have evaluated multiple PMT catheters in the treatment of DVT. However, to date, there is no prospective, randomized trial data available. In one review, Vedantham, et al., used PMT and tested several devices, including Amplatz® (Microvena, White Bear Lake, Minnesota); AngioJet® (Possis Medical, Inc., Minneapolis, Minnesota); Trerotola® (Arrow International, Reading, Pennsylvania); and Oasis® (Boston Scientific/Meditech, Natick, Massachusetts) with CDT for the treatment of lower-extremity DVT.22 Procedural success was achieved in 82 percent with underlying culprit stenoses uncovered and stented in 15 patients (18 limbs). These authors reported substantial thrombus removal with the two techniques combined compared to either alone. Another group (Delomez), using only the Amplatz thrombectomy device, reported successful recanalization of the thrombosed segment in 83 percent of patients with proximal DVT.23 At 29.6 months follow up, 10 patients had minimal symptoms relating to the episode, and only one patient had developed post-thrombotic sequelae.

In a retrospective review of the management of DVT, Kasirajan demonstrated the efficacy of the rheolytic thrombectomy catheter (RTC), AngioJet®, in thrombus removal, venous patency restoration, maintenance, and symptom relief.24 The RTC is designed to produce an area of extremely low pressure at the catheter tip by controlled high velocity saline jets. Via this mechanism, thrombus surrounding the catheter tip is macerated and rapidly evacuated via an effluent lumen into a collection chamber. In this study, only four (23.5%) patients achieved greater than 90-percent thrombus clearance with PMT alone. Adjunctive thrombolytic agents were used in 9 of 17 patients, those that had a lesser amount of clot extracted with the use of the PMT catheter. Often the thrombolytic catheter was left in place, and the average duration of lytic therapy was 20.2 hours. Clinical symptomatic improvement was seen in 82 percent over a follow-up time frame of 11 months. No complications were seen directly related to the RTC itself. The authors’ experience is with the RTC system; the authors will describe the system and their personal results.

**RTC System Description**

The RTC system consists of three components: a single-use catheter, a single-use pump set, and a pump drive unit. The 6 Fr Xpeedior catheter has a working length of 120cm, is introduced via a percutaneous approach (6 Fr sheath), and operates over a 0.035-inch guide wire. The dual lumen catheter design consists of one lumen supplying pressurized saline to the distal catheter tip and a second lumen incorporating the first lumen, guide wire, and thrombus particulate debris. The drive unit/pump generates high pressure (approx. 10,000 psi) into the catheter as well as generating pulsatile saline flow that exits the catheter tip through multiple retrograde-directed jets. These high-velocity jets create a localized low-pressure zone (Bernoulli effect) for thrombus aspiration and maceration. The jets also provide the driving force for evacuation of thrombus particulate debris through the catheter. The Xpeedior catheter design also has a means for radially directed low velocity fluid recirculation to assist with dislodgment from the vessel wall and direction to the catheter tip for evacuation. The RTC system works in an isovolumetric manner: the saline infusion flow rate (60cc/min) is in balance with the evacuation rate of thrombus particulate debris.

The infusion solution of saline may be replaced with saline mixed with a thrombolytic agent (1000 L saline combined with 250,000 u urokinase). A three-way stopcock is placed on the catheter outflow lumen between the catheter and the aspiration tubing. The stopcock can be positioned in the “off” setting, thus converting the thrombectomy catheter into a high pressure infusion—labeled “power pulse spray” by interventionalists who use this technique (Figure 1). After lacing the thrombus with the pharmacological agent and waiting an appropriate period of time (average 20 minutes), the stopcock is resumed in the open position and aspiration performed (Figure 2). If concern exists for
pulmonary embolism during this procedure, a dual-purpose removable/permanent vena caval filter may be placed at the beginning prior to PMT.

**Technique of PMT for the Treatment of DVT**

The techniques described herein represent preferences of the authors based on experience, not recommendations from a manufacturer. This is considered an off-label use of this catheter, which is approved for use in hemodialysis grafts and infrainguinal arteries. Subsequent interventions, such as endovascular stenting, depend upon the judgment of the treating physician.

All procedures are performed in a fully equipped operating room with endovascular capabilities. The patients are placed in a prone position and the ipsilateral popliteal vein is cannulated using ultrasound guidance. After the initial ascending venogram is performed, the RTC is advanced over a guide wire and through the thrombosed vein segment. It is at this point that an adjunctive thrombolytic agent is added to the infusion solution. A stopcock is added to the catheter outflow lumen as previously described and placed in the “off” position to close the outflow. One slow pass, withdrawing the catheter, is made to lace the thrombus with the lytic drug. After waiting 10 to 20 minutes to allow for more complete lysis, the outflow lumen is opened and mechanical thrombectomy performed to remove any residual clot burden (Figures 3 and 4). This sequence may be repeated in the event that significant residual thrombus remains on subsequent venograms.

With this method, venous patency should be able to be restored in the operating room or interventional suite, decreasing the need for intensive care unit stays or multiple trips for repeat venography. Furthermore, in the authors’ experience, lower total doses of thrombolytic agent are used than with catheter-directed thrombolysis. This translates into lower overall cost and a reduction in potential hemorrhagic complications. Adjunctive endovascular techniques, such as balloon angioplasty with or without stent placement, may be performed in the same setting of pharmaco-mechanical thrombectomy.

![Figure 3](image1.png)  
(A, B) Initial ascending venogram demonstrating complete occlusion of the common femoral vein, iliac veins, and proximal superficial femoral vein. (C) Venogram following pharmaco-mechanical thrombectomy with RTC and power-pulse spray method. A stenosis was uncovered in the common iliac vein. (D) Subsequent angioplasty and stent placement in the common iliac vein.

![Figure 4](image2.png)  
Completion venogram showing no residual thrombus and excellent flow into the inferior vena cava.
Table 1. Commercially available devices

<table>
<thead>
<tr>
<th>Catheter Name</th>
<th>Mechanism of clot extraction</th>
<th>Clot suctioning capability</th>
</tr>
</thead>
<tbody>
<tr>
<td>AngioJet (Possis, Inc.)</td>
<td>Venturi</td>
<td>Yes</td>
</tr>
<tr>
<td>Hydrolyser (Cordis, Inc.)</td>
<td>Venturi</td>
<td>Yes</td>
</tr>
<tr>
<td>Oasis (Boston Scientific/Meditech)</td>
<td>Venturi</td>
<td>Yes</td>
</tr>
<tr>
<td>Amplatz (Microvena)</td>
<td>Microfragmentation</td>
<td>No</td>
</tr>
<tr>
<td>Helix (EV3)</td>
<td>Microfragmentation</td>
<td>No</td>
</tr>
<tr>
<td>Treterotol (Arrow International)</td>
<td>Microfragmentation</td>
<td>No</td>
</tr>
<tr>
<td>Castañeda and Cragg Brush (Micro Therapeutics)</td>
<td>Microfragmentation</td>
<td>No</td>
</tr>
<tr>
<td>Trellis infusion catheter (Bacchus Vascular)*</td>
<td>Microfragmentation</td>
<td>Yes</td>
</tr>
</tbody>
</table>

*a withdrawn from market

Conclusions

Theoretically, early and rapid thrombus removal should preserve venous valve patency. Additionally, patients should have immediate symptomatic relief from pain and swelling associated with an acute DVT. These initial clinical benefits should be followed by a reduction in the incidence of long-term CVI. Only long-term prospective randomized studies comparing this technique to others or to standard anticoagulation will provide definitive data to support this hypothesis.

References

4. Anand SS. Comparison of 3 and 6 months of oral anticoagulant therapy followed by a reduction in the incidence of long-term CVI. Only long-term prospective randomized studies comparing this technique to others or to standard anticoagulation will provide definitive data to support this hypothesis.

References

Mechanical Thrombectomy in Deep Venous Thrombosis

Learning objectives. At the conclusion of this activity, the participant should be able to: 1) describe how mechanical thrombectomy may alleviate symptoms and decrease the incidence of post-phlebitic syndrome in patients with deep venous thrombosis; 2) discuss how DVT leads to chronic venous insufficiency and why clot removal with mechanical thrombectomy may be better than standard anticoagulation alone; and 3) discuss the benefits of combined mechanical thrombectomy with thrombolytic therapy.

Learning assessment. Successful completion of this CME activity entails completing the entire answer and evaluation form (on next page), sending it to the correct address listed below, and scoring at least 70% on the learning assessment. Certificates will be mailed to those who successfully complete the learning assessment by March 6, 2005. Fax the completed form to (610) 560-0501 or mail it to: Trish Levy, CME Director, HMP Communications, 83 General Warren, Blvd., Suite 100, Malvern, PA 19355. This article is accredited for 1 credit hour in Category 1 of the Physician’s Recognition Award of the American Medical Association. Please see accreditation and designation statements on page 2 of this supplement.

1. Which of the following is a consequence of DVT?
   (a) Pain
   (b) Edema
   (c) Skin changes, induration
   (d) All of the above

2. All of the following are considered adequate for initial treatment of acute DVT except?
   (a) Heparin
   (b) Low-molecular weight heparin (enoxaparin)
   (c) Oral warfarin
   (d) Aspirin

3. Rapid removal of lower-extremity thrombus with mechanical thrombectomy techniques may:
   (a) Decrease the time the patient is on warfarin therapy
   (b) Eliminate the risk of recurrent DVT
   (c) Preserve venous valvular function
   (d) Allow for early patient ambulation after DVT

4. What is the usual time frame for development of chronic venous insufficiency after a DVT?
   (a) Variable, months to years
   (b) Immediately
   (c) Rarely occurs following DVT

5. What percentage of patients will develop chronic venous insufficiency at five years after a DVT?
   (a) 5 percent
   (b) 50 percent
   (c) 66 percent
   (d) 100 percent

6. What is the current standard of care for DVT?
   (a) Percutaneous mechanical thrombectomy
   (b) Anticoagulation with heparin and warfarin
   (c) Thrombolytic therapy
   (d) Compression stockings

7. Percutaneous mechanical thrombectomy is beneficial in what way for the treatment of DVT?
   (a) Rapid relief of thrombus burden
   (b) May reveal an inciting lesion, such as May-Thurner syndrome
   (c) Therapy may be accomplished in one procedure
   (d) Lessen the time needed for adjunctive lytic therapy
   (e) All of the above

8. Why does chronic venous insufficiency occur after a DVT?
   (a) Venous valvular damage and reflux
   (b) Persistent occlusion of the deep venous system
   (c) Venous hypertension
   (d) Both A and C
Mechanical Thrombectomy in Deep Venous Thrombosis

Answer, Evaluation, and Registration Information: (PLEASE PRINT CLEARLY)

Name

Degree

Position/Title

Organization/Institute

Department

Mailing Address for Certificate (Home or work):

Street Address

City

State

Zip Code

Email Address

Social Security Number

Phone (area code)

Fax (area code)

Answers: Circle one letter for each answer:

1. A B C D
2. A B C D
3. A B C D
4. A B C

5. A B C D
6. A B C D
7. A B C D E
8. A B C D

Evaluation: (circle one) Excellent (4) Good (3) Satisfactory (2) Poor (1)

Accuracy and timeliness of content: 4 3 2 1

Relevance to your daily practice: 4 3 2 1

Impact on your professional effectiveness: 4 3 2 1

Relevance of the content to the learning objectives: 4 3 2 1

Effectiveness of the teaching/learning methods: 4 3 2 1

Avoided commercial bias or influence: 4 3 2 1

Evaluation, Part 2: Now that you have read this article, can you: (circle one)

1) Describe how mechanical thrombectomy may alleviate symptoms and decrease the incidence of post-phlebitic syndrome in patients with deep venous thrombosis? YES NO

2) Discuss how DVT leads to chronic venous insufficiency and why clot removal with mechanical thrombectomy may be better than standard anticoagulation alone? YES NO

3) Discuss the benefits of combined mechanical thrombectomy with thrombolytic therapy? YES NO

What questions do you still have?

How will you use what you have learned from this activity?

Answers:

1. A B C D
2. A B C D
3. A B C D
4. A B C
5. A B C D
6. A B C D
7. A B C D E
8. A B C D