Overview of Mechanical Thrombectomy Devices for Venous Disease

Wm. Britton Eaves, MD
WKHSC Bossier City, LA
Clinical Assistant Professor LSUHS
No Disclosures
Deep Vein Thrombosis (DVT) forms in the deep veins of the legs or arm.

- Lower extremity DVT is most common.
- Approximately 600,000 new cases each year.
Overview of Mechanical Thrombectomy Devices

Causes of DVT

- Injury/trauma
- Prolonged inactivity
- Extended plane or car travel
- Anticoagulation disorder
- Surgery
- Cancer
- Contraceptives/estrogen therapy
- Severe infection
DVT-associated massive pulmonary embolism (PE) result in 300,000 deaths annually in the US.

Leading cause of preventable hospital deaths.

Major pulmonary embolism is often undiagnosed ante mortem.
Overview of Mechanical Thrombectomy Devices for Venous Disease

- 47% of DVT patients develop PTS (Post Thrombotic Syndrome)
- Swelling
- Pain
- Dermatitis
- Varicose veins
- Ulceration fibrosis with atrophy
- Lymphedema
- Venous claudication
Overview of Mechanical Thrombectomy Devices for Venous Disease

Ambulatory Venous Pressures & Symptoms
- 28 mmHg – Asymptomatic
- 36 mmHg – Varicosities
- 41 mmHg – Edema
- 47 mmHg – Hyperpigmentation
- 60 mmHg – Ulceration
Overview of Mechanical Thrombectomy

Anticoagulation

• First line therapy
• Prophylaxis against further thrombus and allows natural fibrinolytic system to favor lysis of thrombus
• 95% successful in popliteal-tibial thrombosis
• 20% successful in iliofemoral thrombosis
• Associated sequela of long term anticoagulation
Overview of Mechanical Thrombectomy

Catheter Directed Thrombolysis (CDT)

Advantages
- Technologically simple
- Minimally invasive
- Resolves Thrombus
- Low Equipment Cost

Limitations
- Extensive exposure to thrombolytics
- Extended ICU Stay
- Post procedure care can be complicated
- Multiple visits to Procedural lab
Overview of Mechanical Thrombectomy

Thrombectomy

- Open surgical thrombectomy largely reserved for Phlegmasia or Venous Gangrene due to the high morbidity associated with the procedure
- Rapid mechanical debulking can result in faster recannalization
- Can be used as stand alone therapy in patients with contraindications to anticoagulation
- When used in combination with thrombolytics can provide rapid recanalization with reduced exposure to systemic thrombolytics
Overview of the Mechanical Thrombectomy
Society for Vascular Surgery and American Venous Forum Guidelines

• Early thrombus removal strategy is the treatment of choice in patients with limb threatening venous ischemia due to iliofemoral deep venous thrombosis with or without associated femoropopliteal venous thrombosis (phlegmasia cerulea dolens) (Grade 1A)

• With above criteria strategy pharmacomechanical thrombolysis may be selected over catheter based thrombolysis if expertise and resources available (Grade 2C)

• Early Thrombus removal in selected patients with (a) first episode of iliofemoral deep venous thrombosis, (b) symptoms <14 days duration, (c) a low risk of bleeding, (d) ambulatory with good functional capacity and acceptable life expectancy (Grade 2C)
Overview of Mechanical Thrombectomy
Considerations for Endovascular Interventions

- Acute <14 days (fresh thrombus)
- Sub-acute < 6 months duration (fibrin bound, more stable clot)
- Chronic > 6 months (organized thrombus, fibrin-rich stable and difficult to remove)
- Symptoms: pain, swelling, ambulatory pain, lifestyle impact
- Anatomy: Common femoral or higher, iliofemoral
Types of Thrombectomy Tools
Rotational Thrombectomy

- Indicated in grafts and fistulas
- Atraumatic sinusoidal wire conforms to vessel size
- Macerates thrombus
- Thrombus aspiration through introducer sheath

CLEANER XT™-Argon Medical
Types of Thrombectomy Tools
Pharmacochemical

- Occluding balloons isolate the thrombus
- Thrombolytics are infused into the isolated area
- Drive unit activates catheter to macerate thrombus and disperse lytic
- Thrombus and residual lytic is aspirated
Types of Thrombectomy Tools
Ultrasonic accelerated thrombolysis

- Enhanced catheter-directed thrombolysis
- Ultrasound energy facilitates dispersion of the lytic agent
- Increases efficiency and decreases total lytic dose
- Minimal trauma to the vessel

EkoSonic Endovascular System - Ekos Corporation
Overview of Mechanical Thrombectomy

BERNUTIFUL Trial Results:
Ultrasound-Assisted CDT vs Conventional CDT
“The addition of intravascular ultrasound did not facilitate thrombus resolution”

<table>
<thead>
<tr>
<th></th>
<th>CDT (N=24)</th>
<th>CDT + Ultrasound (N=24)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Post-CDT</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thrombus Load Reduction</td>
<td>54±12.7%</td>
<td>55±12.7%</td>
<td>0.91</td>
</tr>
<tr>
<td>Bleeding Complication Rate</td>
<td>8.3%</td>
<td>12.5%</td>
<td>&gt;0.99</td>
</tr>
<tr>
<td><strong>3 Months</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary Venous Patency</td>
<td>96%</td>
<td>100%</td>
<td>0.33</td>
</tr>
<tr>
<td>PTS Severity (Villalta score)</td>
<td>3.0±3.9</td>
<td>1.9±1.9</td>
<td>0.21</td>
</tr>
</tbody>
</table>

- Thrombus load and complication rates were similar after CDT or ultrasound-assisted CDT
- 3-month outcomes did not differ significantly between groups
  - Rates of adjunctive therapy use were similar between groups (angioplasty and stenting 83% vs 80%, P=0.99; adjunctive thrombus removal 46% vs 29%, P=0.37)

Types of Thrombectomy Tools
Rheolytic Thrombectomy

• Powerful saline jets create a low pressure zone around the catheter tip that causes a vacuum effect
• Thrombus is drawn into the catheter, where it is fragmented by the jets and then removed from the body
• Wide variety of catheter sizes and lengths

AngioJet system
(Boston Scientific Corporation)
AngioJet Power Pulse System

- AngioJet thrombectomy indicated for the controlled and selected infusion of physician-specified fluids, including thrombolytic agents
- Utilizing mechanical thrombectomy to power-infuse lytic solution directly into the clot
- Wait time followed by removal in the thrombectomy mode
- Combination of chemical and mechanical thrombolysis
Overview of Mechanical Thrombectomy

ZelanteDVT™ Catheter

- Venous only indication
- Directional control over thrombus removal
  - Single, larger inflow window
  - Total Inflow area similar to Solent™ Omni and Proxi Inflow
- 8F, 105 cm length, 0.035 inch (0.89 mm) guidewire
- 6 mm minimum venous diameter
- Power Pulse™ enabled
- Hemolysis profile (run times) similar to Omni
Overview of Mechanical Thrombectomy
Overview of Mechanical Thrombectomy Pearl Registry

• Determine efficacy of thrombus removal from baseline to final angiogram
• Evaluate clinical outcomes of treated patients at defined intervals of 3, 6, and 12 months
• Characterize clinical events
• Characterize treatment options used with the AngioJet® System
• Estimate rate of AngioJet Thrombectomy-related adverse events
Overview of Mechanical Thrombectomy
PEARL Registry: Venous Cohort

• 96% of patients had Grade II/III (50%-100%) clot reduction
• Clot reduction grade distribution not affected by symptom duration or treatment group
• Significant improvements over baseline in both physical & mental component scores of the SF-12 (P<.0001)
• 83% freedom from rethrombosis at 12 months
• 78% with continued clinical benefit (no recurrent thrombosis or worsened condition in the treated limb) at 12 months

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>AngioJet Thrombectomy alone (Rheolytic)</td>
<td>13 (4%)</td>
</tr>
<tr>
<td>AngioJet + Lytic by AngioJet (PMT)</td>
<td>115 (35%)</td>
</tr>
<tr>
<td>AngioJet Rheolytic + CDT</td>
<td>29 (9%)</td>
</tr>
<tr>
<td>AngioJet PMT + CDT</td>
<td>172 (52%)</td>
</tr>
</tbody>
</table>
Overview of Mechanical Thrombectomy

**Attract Trial** *(Acute Venous Thrombosis: Thrombus Removal with Adjuvant Catheter-Directed Thrombolysis)*

- Comparative effectiveness study
- Phase III, open label, multicenter RCT
- Objective:
  - Determine if the initial use of adjunctive Pharmacomechanical Catheter Directed Thrombolysis (PCDT) in symptomatic patients with proximal deep vein thrombosis (DVT) reduces the occurrence of Post-Thrombotic Syndrome (PTS) over 24 months follow-up
  - PCDT + standard therapy vs standard therapy alone
  - Determine whether pharmachomechanical CDT in patients with acute proximal DVT prevents post thrombotic syndrome and improves quality of life
Overview of Mechanical Thrombectomy Devices for Venous Disease

Case Study

• 16 year old female
• History of recent birth control use
• Slept with RUE positioned above her head
• Presented with painful edematous RUE
• No previous history of DVT
• Primary care planned to treat with anticoagulation only
• Avid soccer player
Overview of Mechanical Thrombectomy Devices for Venous Disease

Case Study

• Sheath was placed in the distal brachial vein
• 10mg tpa was administered into thrombus using Power Pulse Technique
• Dwell time was 30mins
• Angiojet was then used to remove the thrombus along with POBA
Overview of Mechanical Thrombectomy Devices for Venous Disease

Summary

• Mechanical Thrombectomy is a safe and efficient way to remove thrombus
• Removal of thrombus is important not only in restoration of flow, but also because it may reduce the incidence of PTS
• Standard care therapy with anticoagulation only is not sufficient to provide proper medical care for many patients
• Proper case selection and more aggressive treatment can lead to better outcomes
• We can do better!!
Thank You For Your Attention
Overview of Mechanical Thrombectomy Devices for Venous Disease

Wm. Britton Eaves, MD
WKHSC Bossier City, LA
Clinical Assistant Professor LSUHS