Endovascular Management of Ili-Femoral DVT with Percutaneous Thrombectomy and Thrombolysis: Indications, Techniques and Results

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Veith 2015

Faculty Disclosure

- Consultant Medtronic, Boston Scientific, Cardinal Health, Volcano

Venous Thromboembolism (DVT & PE)

- >2 million Deep vein thrombosis
- >200,000 deaths from pulmonary embolism
- Even after 6 months of anticoagulation following first VTE event, risk of subsequent VTE is increased by 5-12% annually.

Pathophysiology


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Virchow’s Triad 1856

Rudolf Virchow 1821~1902

Growing Wall
Thrombosis

Hypercoagulable State

Deep vein of calf

Dilated vein

Pulmonary embolism

Venous lower leg, knee

Crossing of vein and vessel

Clotting of vessel

Growth of thrombus (RBCs, fibrin, platelets)
Deep Vein Thrombosis

- **Hematologist:** view DVT as a disorder of hematology and biology.
- **Vascular Surgeon and Interventional Radiologist:** view DVT from an Anatomical and Functional perspective.

Ilio-Femoral DVT

Endovascular Specialists:

- View ilio-femoral DVT as fundamentally different from physiologic considerations as well as more severe disease manifestation
- BUT it is rarely distinguished from other forms of DVT by other physicians.

Not All Clots Are Created Equal

Venous Thrombosis ≠ Peripheral Arterial Thrombosis ≠ Coronary Artery Thrombosis

Indications for Endovascular Therapy

- Functional patient with ilio-femoral DVT
- No Major risk factors for the use of thrombolytics
- “But” can use Mechanical Thrombectomy
- Pilegmasia Cerulea Dolens

Post thrombotic syndrome

- Most physicians treat all cases of proximal DVT the same.
- MUST differentiate between iliofemoral DVT and infragenital DVT.
- Iliofemoral DVT → Virulent post-thrombotic morbidity.

20 - 40% of Pts with DVT
800,000/Yr cases of Post-Thrombotic Syndrome

Natural History of Ilio-Femoral DVT

Associated with Severe Post Thrombotic Morbidity
Post Thrombotic Syndrome

- Chronic leg heaviness
- Leg aching
- Venous claudication
- Edema
- Venous varicosities
- Chronic skin changes
- Ulceration

Iliofemoral DVT
Natural History

Associated with Severe Postthrombotic Morbidity!

O'Donnell T Mavor GE Beyth RJ

Iliofemoral DVT
Long Term Clinical Status and QOL

Conclusions

- Venous claudication developed in almost 50%
- Limited ambulation in 15%
- Marked hemodynamic impairment
- Markedly reduced QOL

Delis KT et al

Iliofemoral DVT
Treatment Objectives

- Minimize or eliminate the Embolic potential of the existing Thrombus
- Prevent further Thrombosis
- Restore Venous Patency (remove obstruction)
- Preserve Venous Valvular function
Anticoagulation

**DOES**
- Minimize or eliminate the Embolic potential of the existing Thrombus
- Prevent further Thrombosis

**DOES NOT**
- Restore Venous Patency (remove obstruction)
- Preserve Venous Valvular function

Post Thrombotic Syndrome (PTS)
- Venous Hypertension
- Venous Capacitance is reduced
- Calf pump ejection fraction is reduced

Ambulatory Venous Hypertension

**Components**
- Obstruction
- Valve incompetence
- Obstruction and valve incompetence
  - ...Highest venous pressure
  - ...Most severe morbidity

Ilio-Femoral DVT

**Improved Outcome with Early Resolution**

Randomized Trial: Iliofemoral DVT
Venous Thrombectomy vs. Anticoagulation
(Follow-up @ 6 mos, 5 yrs, 10 yrs)

- Patients randomized to thrombectomy showed:
  1. Improved patency \( P < 0.05 \)
  2. Lower venous pressures \( P < 0.05 \)
  3. Less leg swelling \( P < 0.05 \)
  4. Fewer post-thrombotic symptoms \( P < 0.05 \)

Compared to anticoagulation
Management of Ilio-Femoral DVT

- Anticoagulation
- Surgical Thrombectomy
- Catheter Directed Thrombolysis
- Pharmacomechanical Thrombectomy

Combination of Mechanical Thrombectomy and Thrombolysis

- Combination therapy is even more powerful
- Initially reduces more thrombus burden
- Exposes a greater area of the thrombus surface to lytic agent
- Decrease dose and infusion time for thrombolytic drugs
- One retrospective study, PMT greatly reduced both time of lysis (40% reduction) and Lytic drug dose (60% reduction).

Ilio-Femoral DVT Treatment Objectives

- Minimize or eliminate the Embolic potential of the existing Thrombus
- Prevent further Thrombosis
- Restore Venous Patency (remove obstruction)
- Preserve Venous Valvular function

Endovascular Intervention

1. Access
2. Device/Techniques

Access

- Popliteal Vein
- Small Saphenous vein
- Post Tibial Vein
- Contralateral Femoral vein
- JJ Vein

Popliteal Vein
Small Saphenous Vein

PT Vein Access

Small Saphenous Vein

PT Vein Access

Contralateral Femoral Vein

Adjunctive Procedures
- Placement of Foley catheter during procedure
- Keep symptomatic leg elevated with placement of Venodyne sequential compression boot
- PCA pump for pain
- For continued thrombolysis use 0.5 mg/hr TPA with 500 units thru the sheath

Device/ Techniques

Treating DVT with AngioJet
**AngioJet® Power Pulse® Delivery System**

- Power-infuse lytic solution directly into the clot
- Combination of chemical and mechanical thrombolysis

**Solent™ Family**

**AngioJet® Catheters for Peripheral Vessels**

- **SOLENT Proxi** - 90 cm length
- **SOLENT Omni** - 120 cm length

- Thrombectomy power similar to DVX®
- Compatible with 6FR sheath and 0.035" guidewire
- Guidewire swapability
- Contrast injection port
- Power Pulse® Delivery enabled

**Trellis- PMT System**

- Thrombus isolated between 2 occluding balloons, reducing embolization risk
- Local delivery of lytic allows minimal dose needed to achieve high concentration
- Sinusoidal wire disperses lytic, mechanically disrupts thrombus
- Aspiration following treatment
- Often requires only single treatment setting

**EKOS Lysis System**

- >99% of US energy passes through valves
- 3 drug delivery lumens
- US core wire
- Thermocouple
- Central coolant lumen

**EKOS US-Assisted CDT**

- 3 drug delivery lumens

**AngioJet® Thrombectomy System**
May-Thurner Syndrome

Natural Filter!

PEARL Registry

- Prospective, multi-center registry collecting patient history, procedural information, adjunctive treatments, outcomes and adverse events. All pts treated with AngioJet® Thrombectomy catheters.
- Pts divided into arterial, venous & dialysis access
- PEARL I (January 2007 thru April 2010): Followed patients for 3 months with documentation of symptomatic improvement after rheolytic thrombectomy (with mid-length catheters).
- PEARL II (March 2010 thru June 2013): Followed patients outcomes through 12 months after thrombectomy using any AngioJet® Catheter

Registry Objectives

- Determine efficacy of thrombus removal from baseline to final venogram
- Evaluate clinical outcomes of treated patients at defined intervals of 3, 6 & 12 mos.
- Characterize clinical events
- Characterize treatment options used with the AngioJet® System
- Estimate rate of AngioJet Thrombectomy related adverse events

AngioJet® Mechanism of Action

The Bernoulli Effect explains the relationship between velocity and pressure.

Pressurized saline jets travel backwards to create a low pressure zone causing a vacuum effect.

Cross-Stream® windows optimize the drawing action for more effective thrombus removal.

Thrombus is drawn into the catheter where it is fragmented by the jets and evacuated from the body.

PEARL Enrollment

N = 952

DVT 140 (15%)
LI 371 (39%)
HA 410 (43%)
Other 26 (3%)

Mark J. Garcia, MD, MS, Robert Luviano, MD, Rahul Mathoria, MD, All Arrini, MD, RVT, Lawrence A. Billing, MD, Daniel A. Lewin, MD, Eugene J. Simonini, MD, and Peter A. Stuckel, MD
DVT Age
From Signs/Symptoms Onset

<table>
<thead>
<tr>
<th>Acute</th>
<th>≥ 24 Hours</th>
<th>&gt; 24 Hours and ≤ 7 Days</th>
<th>&gt; 7 Days and ≤ 14 Days</th>
<th>256/371 (69%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sub-Acute</td>
<td>&gt; 14 Days and ≤ 30 Days</td>
<td>≥ 30 days and ≤ 3 Months</td>
<td>&gt; 3 Months and ≤ 6 Months</td>
<td>6 (1%)</td>
</tr>
<tr>
<td>Chronic</td>
<td>&gt; 6 Months</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

69% of patients report symptom onset of < 14 days.

PEARL Results
Duration of treatment

<table>
<thead>
<tr>
<th>Time Period</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤ 6 Hrs</td>
<td>133 (35%)</td>
</tr>
<tr>
<td>&gt; 6 Hrs &amp; ≤ 12 Hrs</td>
<td>37 (10%)</td>
</tr>
<tr>
<td>&gt; 12 Hrs &amp; ≤ 24 Hrs</td>
<td>97 (27%)</td>
</tr>
<tr>
<td>&gt; 24 Hrs</td>
<td>88 (25%)</td>
</tr>
</tbody>
</table>

38% completed in ≤ 6 hrs
75% completed in < 24 hrs

PEARL Results
# of sessions

<table>
<thead>
<tr>
<th># of Sessions</th>
<th>N(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>123 (34%)</td>
</tr>
<tr>
<td>2</td>
<td>189 (53%)</td>
</tr>
<tr>
<td>3</td>
<td>40 (11%)</td>
</tr>
<tr>
<td>&gt;3</td>
<td>7 (2%)</td>
</tr>
</tbody>
</table>

87% had 2 or less sessions

PEARL Results
Lab Test Comparisons

<table>
<thead>
<tr>
<th>Analyte</th>
<th>Pre-procedure Mean</th>
<th>Post-procedure Mean</th>
<th>Mean Difference*</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemoglobin (N=266)</td>
<td>12.4</td>
<td>11.2</td>
<td>1.3</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>BUN (N=235)</td>
<td>16.8</td>
<td>16.4</td>
<td>0.4</td>
<td>0.1030</td>
</tr>
<tr>
<td>Creatinine (N=239)</td>
<td>1.1</td>
<td>1.2</td>
<td>0.1</td>
<td>0.0084</td>
</tr>
</tbody>
</table>

*Paired analysis

Wilcoxon Signed Rank Test

PEARL Results
Venographic Results
N = 1295 vessels treated (p<0.0001)

- Improved: 97%
- Unchanged: 3%
- Worsened: <1%

Venographic Results by Technique Subgroups (p<0.0001)
N = 1295 # vessels treated

- Improved: 100%
- Unchanged: 97%
- Worsened: 94%
**Venographic Results**

clot age by Sx Onset (p<0.0001)

- **ACUTE DVT**
  - <=24 Hrs: 100% Improved
  - 1-7 Days: 97% Improved, 3% Unchanged, 0% Worsened
  - 7-14 Days: 97% Improved, 3% Unchanged, 0% Worsened

- **SUBACUTE CHRONIC**
  - 14-30 Days: 97% Improved, 7% Unchanged, 0% Worsened
  - 30-90 Days: 93% Improved, 7% Unchanged, 0% Worsened
  - >3 Mos: 100% Improved

**Freedom from Rethrombosis***

- 90 Days: 94%
- 180 Days: 88%
- 365 Days: 84%

**Maintained Clinical Benefit***

- 90 Days: 93%
- 180 Days: 82%
- 365 Days: 78%

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**SF 12 QOL (Pii Only)**

Baseline: 44.0
3 Mon: 48.9
6 Mon: 48.1
12 Mon: 48.9

**Adverse Events**

During Hospitalization

16/78 (20%) events were related to the overall procedure. Of these, 2% were related to the AngioJet® thrombectomy. This thrombectomy could not be ruled out as a possible contributing factor - all resolved except 1 CVA.
PEARL Comparison  
Treatment of LE DVT

<table>
<thead>
<tr>
<th>PEARL</th>
<th>Venous Registry*</th>
<th>CaVenTT**</th>
</tr>
</thead>
<tbody>
<tr>
<td># of Patients</td>
<td>329</td>
<td>287</td>
</tr>
<tr>
<td># of Sites</td>
<td>35</td>
<td>63</td>
</tr>
<tr>
<td>Prior DVT</td>
<td>40%</td>
<td>31%</td>
</tr>
<tr>
<td>Primary Treatment</td>
<td>AngioJet Thrombectomy With or Without PPS/RL</td>
<td>CDT CDT LMWH</td>
</tr>
<tr>
<td>Primary access</td>
<td>Popliteal</td>
<td>Popliteal</td>
</tr>
<tr>
<td>#</td>
<td>Male=57%; Female=43%</td>
<td>Male=48%; Female=52%</td>
</tr>
<tr>
<td>Age (mean)</td>
<td>52.2 yrs</td>
<td>47.5 yrs</td>
</tr>
<tr>
<td>Treatment Location</td>
<td>Iliofemoral – femoral pop</td>
<td>Iliofemoral – femoral pop CFV or iliofemoral</td>
</tr>
<tr>
<td>Limbs Involved</td>
<td>Left=62%; Right=38%</td>
<td>Left=61%; Right=39%</td>
</tr>
</tbody>
</table>

Onset of DVT Symptons:
- Acute: 67% (≤14 days) 66% (≤10 Days) 100% ≤21 days
- Chronic: 33% (>14 days) 16% (>10 Days) NA

Primary Lytic TPA Urokinase TPA NA
CDT Drip Times (mean) 17 hrs 48 hrs 57.6 hrs (2.4 days) NA

Left Ilio-Femoral DVT
- 49 Yr old female S/P Left foot surgery. Few days later started with left leg swelling which got worse and now involves the thigh
- PMH: No HTM, DM, No meds, No smoking
- Venous duplex scan: Left ilio-femoral DVT
- On heparin drip and received 2 doses of coumadin

Conclusions
- PEARL Registry is the first prospective registry studying the safety and efficacy of AngioJet® catheters for treatment of Deep Vein Thrombosis
- Immediate improvement was achieved in 97% of the treated vessels with the majority of patients (75%) successfully treated in 24 hours or less
- Maintenance of clinical benefit at the 12 month follow up is 78%
- Freedom from re-thrombosis at the 12 month follow up is 84%
- The majority of operators are currently utilizing combination therapy (pharmacomechanical)
- The procedural adverse events are primarily minor with >99% permanently resolved
- The mean CDT drip time of 17 hrs was significantly lower than either the Venous Registry or CaVenTT Trial
- This technology appears to be safe & effective for acute, subacute & chronic deep vein thrombosis
Lesser Saphenous Vein
Popliteal Vein

Thrombus
Patent IVC

Power Pulse® Delivery
- Power Pulse with TPA 10 mg in 50-100 cc of saline

Remove Clot
Early thrombus resolution with Endovascular Intervention is associated with improved outcome!

(Especially iliofemoral DVT)

Summary: Acute Ilio-Femoral DVT

- Medical management is associated with higher PTS compare to endovascular management.
- There is increasing evidence that early thrombus resolution with endovascular intervention is associated with improved outcome.
- Pharmacomechanical decreases procedure time, decrease amount of thrombolytic used.

GOAL

Thank You