Catheter Guided Thrombolysis of Acute Peripheral Deep Vein Thrombosis

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Disclosure

• Cook Speakers Bureau
Scope of Problem: United States Acute DVT

- 600,000 Americans Acute DVT/yr
- Incidence <15 yr: <5/100,000
- Incidence 80 yo: 500/100,000
- 7% recurrence DVT @ 6 months
- ↑winter, caucasian / african-american

The epidemiology of venous thromboembolism
Treatment Of Acute DVT

Diagnosis

• Venous Duplex US (Vein Compress)
• D – Dimer: Acute vs. Scar “old DVT”
  – Hx. DVT
  – No Symptoms, Incidental finding
• CT Vgram: Central Extent (e.g. IVC / Iliac V.
• Chest CT: Dx. PE if intervene DVT
Treatment Of Acute DVT
Initial: Anticoagulate

- Prevent DVT Propagation
- Prevent PE
- Not Recanalize vein
- Endogenous Thrombolytics effect lysis
- $\uparrow\uparrow\uparrow$ thrombus load, $\downarrow\downarrow$ clot clearance
- No Clearance, No Patent Vein
Treatment Of Acute DVT
Initial: Anticoagulate

- Patent Vein Theory
  - Open lumen, facilitate drainage
  - Decrease CVI symptoms
- Reflux: Venous Valve Insufficiency
  - Part of the CVI story
  - Less critical than previously thought
  - Minimal treatment options
Treatment Of Acute DVT

Injected: Anticoagulation

- **IV Heparin**: rapid reversal
  - Titration Challenge
  - Failure => sub-optimal PTT

- **LMWH** (e.g. enoxaparin)
  - Predictable dosing & response
  - EGFR < 30 ml/min; “black box”
Treatment Of Acute DVT
Oral: Anticoagulation

- **Coumadin**: Inexpensive
  - Titrate INR, Frequent blood draw
  - Dietary Limitations

- **Novel Oral Anti-Coagulant (NOAC)**
  - NOAC ≠ Coumadin / Enoxaparin
  - e.g. Xeralta, Eliquis, Pradaxa
  - No blood draw, No dietary limits
  - Untested for post-intervention
Treatment Of Acute DVT
Anticoagulation Post Intervention

- Total Anticoagulation 6 months
- Enoxaparin (lovenox) – 4 weeks
- Oral anticoagulation choice - 5 months
  - NOAC
  - Coumadin if $ issue
Uncomplicated Acute DVT
Site of Treatment: Inpatient

- Pt. Can’t Walk due to pain/edema
- Phlegmasia Cerulea Dolens (Rare)
- Needs IV Heparin
- Another Medical Reason for Admission
Uncomplicated Acute DVT
Site of Treatment: Outpatient

• 95% of Pts: Coumadin / NOAC / LMWH
• Follow-up - Critical!!
• Patient Clinically improving?
  – 1-3 weeks: Window to Change treatment
• Convert Acute DVT to Chronic Disease
  – Post-Thrombotic Syndrome
Deep Venous Anatomy of the Leg

Proximal DVT

Inferior vena cava
Common iliac vein
External iliac vein
Common femoral vein
Internal iliac vein
Great saphenous vein
Deep femoral vein
Femoral vein
Popliteal vein
Gastrocnemius vein
Anterior tibial veins
Soleus vein
Posterior tibial veins
Peroneal veins

Courtesy Dr. Hal Welch
Uncomplicated Acute DVT
Site of Intervention: Inpatient

• Follow-up: Change Treatment?
  – Occlusive DVT Iliac / Common Femoral V.
    • Thromblysis; 1-14 days
Deep Venous Anatomy of the Leg

Distal DVT
Uncomplicated Acute DVT
Site of Treatment: Outpatient

- Follow-up: Change Treatment?
  - Occlusive DVT Iliac / Common Femoral V.
    - Thromblysis; 1-14 days
  - Occlusive DVT Femoral / Popliteal V.
    - Not Improved w/ AC / Time
    - Inpatient: Thrombolysis 7-14 days
Deep Venous Anatomy of the Leg

Calf Vein DVT
Uncomplicated Acute DVT
Site of Treatment: Outpatient

- Follow-up: **Change Treatment?**
  - Occlusive DVT Iliac / Common Femoral V.
    - Thromblysis; 1-14 days
  - Occlusive DVT Femoral / Popliteal V.
    - Not Improved w/ AC / Time
    - Thrombolysis 7-14 days
  - Calf Vein: Monitor Duplex US 1 week
    - Anticoagulate if progress => TP trunk / Popliteal V.
Uncomplicated Acute DVT
Duration Treatment

• Follow *Chest Guidelines* (2016)
• Provoked acute DVT: 3 months
• Unprovoked acute DVT: 3-6 months
• Post Thrombolysis / Thrombectomy:
  – Anticoagulation Duration as above
Acute DVT
Thrombolysis / Thrombectomy

Why is it So Important?
DVT Age
1-2 weeks

Cut-away view of vein
Pathophysiology Post-Thrombotic Syndrome (PTS)

- Acute DVT: inflammation & occlusion
- Valve damage, reflux, obstruction
- Venous HTN $\Rightarrow$ edema, tissue hypoxia & ulceration
- Combined proximal v. reflux / obstruction $\Rightarrow$ worst PTS

Pathophysiology Post-Thrombotic Syndrome (PTS)

- Proximal veins
  - (i.e. Iliac, CFV, FV)
- Worst PTS
  - Combine obstruction & reflux

Prospective Evaluation of Health-Related Quality of Life in Patients with DVT

- Multi-center prospective study
  - 359 DVT patients, all on an anticoagulation regime

- *1 month* QOL scores pts.
  - lower than pts w/ chronic lung disease & arthritis
  - similar to pts w/ angina

- *4 months* QOL scores for DVT
  - similar to pts. w/ COPD & arthritis

Kahn et al, Arch Intern Med 2005
Postthrombotic Syndrome
Signs & Symptoms

Signs & Symptoms
• Edema, Heaviness & Pain
• Stasis Dermatitis
• Hyperpigmentation
• Open or Healed Ulcer

*Trying for Pt.
Deep Venous Anatomy of the Leg
Proximal Acute DVT

Courtesy Dr. Hal Welch
Acute DVT by History
Acute / Subacute DVT 1 => 4 Weeks

- Catheter Thrombectomy Specimen
- Fresh red thrombus
- Organizing white tissue
The Face of Chronic DVT
> 6 month

Scar and Synechiae in PTS

Cross-section of CFV lesion
National Quality Forum
JCAHO 2012

• Plan for Prevention and Treatment of DVT for Inpatients
• Treat selected patients with mechanical thrombolysis
• Prevent Post-Thrombotic Syndrome
• Vascular Surgery Consultation on inpatients with DVT
Surgical Thrombectomy 10 Year Follow-Up

- Prospective, Randomized trial
  - Iliofemoral DVT Treated w/
    - Medical: Anticoagulation (AC) (n=17)
    - Surgical: Thrombectomy, AVF, AC (n=13)
- Increased Iliofemoral vein patency
- ↓ Severity of Post-Phlebitic syndrome vs. AC
  - 76% vs. 46% severe

Eur J Vasc Endovasc Surg, 1997
Iliofemoral Deep Vein Thrombosis: Conventional Therapy Versus Lysis and PTA and Stenting

- Single center study, 51 pts. w/ iliofemoral DVT,
- Anticoagulation vs. Anticoagulation & Thrombolysis
- Life-table analysis: Primary patency
  - 24% primary patency anticoagulation
  - 83% for the intervention group at 1 year
- Long term freedom from symptoms
  - 30% anticoagulation
  - 78% anticoagulation & lysis

CaVenT Study

<table>
<thead>
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<th>Table 2: Short-term and long-term outcomes</th>
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<td>Additional catheter-directed thrombolysis (n=90)</td>
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<td>Post-thrombotic syndrome at 24 months†</td>
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<td>Iliofemoral patency at 6 months†‡</td>
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<tr>
<td>Post-thrombotic syndrome at 6 months§</td>
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Post-thrombotic syndrome defined as Villalta score of 5 points or higher. *χ² test. †Co-primary outcomes. ‡Five patients had inconclusive patency assessments and one was lost to follow-up at 6 months. §Secondary outcome.

- First RCT clinically significant decrease in PTS after Lysis vs. AC

ATTRACTION Trial
Acute Leg DVT

- Multi-Center NIH sponsored Trial
- Randomized
  - Thrombolysis + AC Vs. AC alone
  - 2 Arms: Iliac/CFV or Femoral-Popliteal DVT
- 2 yr. F/U to Identify PTS
- Results: Reported next week
Thrombolysis for Acute DVT

- Tissue Plasminogen Activator (TPA)
- Infuse into Thrombus
- Dissolve DVT
- Restore Vein Patency
- Preserve Valve Fx.
- Reduce Patient Sxs/PTS
Catheter Directed Thrombolysis
US Assisted ThrombolysisEkos:
AngioJet
Mechanico-Chemical Thrombolysis
Mechanical-Chemical Thrombolysis

6 mg rt-PA for 15 minutes
High Risk DVT for Lysis
DP Introduction

- 59 yo w female w/ stage IV Cervical Ca
- Lung Metastases, Normal Function
- 24 hours Severe leg swelling / pain
- Duplex US - FV, CFV, EIV occlusive DVT
- 7 days Bed Rest, Heparin
- Swelling / Pain persists, minimal improvement
Case Study #1: (5-14 days)
DVT Right Leg CFV, SFV, POP

*Case Duration: 2 hours
AK Introduction

- 16 yo white female
- 3-4 days of LLQ pain & leg swelling
- ER - Venous US w/ iliofemoral DVT
- Home on lovenox
- *CT - No Mass, No extension into IVC
- Mechanical-Thrombolysis next day
AK1: Iliofemoral DVT and May-Thurner Syndrome
AK2: Residual stenosis
Chronic Iliac & FV DVT

Pt. D/C’d home 6 hours later w/ no leg swelling or pain
No Recurrence, Reflux, or SXs 6 mos later
Percutaneous Thrombectomy
Acute DVT Leg

- Aspirate acute DVT from Vein
- No TPA / Lysis
- Expand Pt. Population treatable
AngioVac
Need Cardiac Pump
Figure 3. The Indigo CAT8 device with separator (A). Extracted clot from the case.
ClotTreiver Acute DVT Thrombectomy System

- No TPA
- Post-op patients
- TPA contraindicated
- Single Setting Treatment
Continued pulling of system through the clot forces clot into braided net.

ClotTriever System: Mechanism of Action

1. Patient's head
2. ClotTriever pulled through clot
3. Patient's feet
“New Technology”
Mechanical Thrombectomy & Thrombolysis

Percutaneous
• Mechanically Debulk Clot
• Shorten Lysis time if any; (Hours)
• Shorten or Remove Systemic Exposure
• Markedly Reduce Bleeding Complications
• Restore Vein Patency & Valve Function
ISOL-8 Registry Study
Iliofemoral Acute DVT

Freedom from VCSS Symptoms

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<tr>
<th></th>
<th>Edema</th>
<th>Pain</th>
<th>Varicose Veins</th>
<th>Skin Changes</th>
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<tr>
<td>N</td>
<td>106</td>
<td>83</td>
<td>62</td>
<td>23</td>
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<td>1 mos</td>
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Results: Thrombus Classification

Initial thrombus classification underestimated the presence of chronic disease
ISOL-8 Registry Study
Results: Freedom From VCSS Symptoms by Thrombus Age

- Acute: 89% (1 Month), 88% (12 Month)
- Subacute: 100% (1 Month), 100% (12 Month)
- Chronic: 60% (1 Month), 50% (12 Month)
DVT

Pulmonary Embolus

Immediate Impact on Quality of Life

Anti-Coagulation

Early Clot Removal

Long Term Sequelae (Post-thrombotic Syndrome, etc.)
Overcoming a tough chronic venous obstruction

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Southern CT Vascular Center
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Total Deep Vein Occlusion
Post Thrombotic Syndrome

- Prior DVT > 2 months - years?
- Deep veins occluded by dense scar
  - CFV, EIV, CIV, IVC
- Patient
  - CEAP 3-6
  - Diminished Quality of Life
  - Lost work / productivity
What are we up against?

Scar and Synechiae in PTS

Cross-section of CFV lesion

Courtesy Dr. Comerota
Crossing Long Segment Occluded Deep Veins

- Angled Glide Wire into occlusion
- Glide Catheter Tip Hangs Up
- Quick Cross Catheter not pushable
- Long Sheath Tip Hangs Up
- Limited Success
- Catheter / Sheath Not Track
- No advance wire, no support
Chronic Occluded Deep Vein

occluded ➔
collateral ➔
collateral ➔
Successfully Crossed Lesion

- Place working .035 wire
  - Amplatz
  - Bentson
- PTA / Dilate Serially / Stent
- IVUS for adequate lumen gain
- Once adequate lumen and flow
- Go Home!
Case 1

• 60 yo Caucasian Female
• Orthopedic surgery 2012
• IVC Filter Placed for DVT
• RLE Edema / Pain
• Interrupts Activities of Daily Living
• DUS: Occluded R EIV / CIV
Finding the Way Through #1

JH
Finding the Way Through #2

JH
Finding the Way Through #3

JH
Finding the Way Through #4

JH
Finding the Way Through #4

JH
Intervene #1 JH

Serial PTA

Serial PTA / Stent
Intervene #2 JH
Epilogue 1

- Pt. on anticoagulation / antiplatelet
- Edema and Pain Resolved
- No Compression Therapy
- Patent and well at 10 months
- Very Grateful Patient!!!
Case 2

- 70 yo Caucasian Female
- Recurrent Left Leg DVT 1998 / 2003
- LLE Edema / Heaviness daily
- Interrupts Activities of Daily Living
- DUS: Occluded L EIV / CIV
Diagnostic #1

VZ
Diagnostic #2

VZ
Finding Way Through #1

VZ

CXI ➔
Flexor ➔
Finding The Way Through #2
VZ

- CXI tip →
- Flexor tip →
- IVC ←
Intervene #2

VZ

Channel Created
PTA

Patent Vein / Brisk Flow
Post Stent

↩ CIV

↩ EIV
Conclusion

- Revascularize chronic occluded CFV / Iliac veins possible
- **TriForce** simplifies crossing occlusions
- Decrease Time / Radiation for Pt. / MD
- Pts experience immediate & marked clinical improvement
- “Try (Triforce) you’ll like it!”
Chronic Femoral-Popliteal DVT / Scar

ACCESS Study
Chronic Femoral-Popliteal Vein DVT / Scar

ACCESS Study
Chronic Femoral-Popliteal Vein DVT / Scar

ACCESS Study

VCSS Score Improvement, 6 months
Summary

• Acute DVT:
  – Treatment Algorithm more than AC / Filter
  – Consider Thrombolysis
• Chronic Post-Thrombotic Syndrome
  – Consider Intervention by Specialist
• Improve QOL
• Improve Patient Productivity / Happiness
Time Check

One More Time!
Non Thrombotic Iliac/CFV Vein Occlusive Disease
Non Thrombotic Iliac Vein Occlusive Disease
Stenting for IlioFemoral Obstruction; Post-Thrombotic & NIVL
Long-Term Outcomes (8 yrs)

- 1997 – 2005
- 982 chronic obstructive Iliofemoral vein disease; Diagnosed with IVUS & stented
- 93% CEAP 3-6
- F/U 94% of pts., mean 22 mos. (1-107 mos)
- Thrombosis -1.5% (<30 days); 3% long-term

Tx. of NonThrombotic Iliac Vein Lesions (NIVL)

Results

• 2.5 years after stent w/ reflux & w/out reflux
  – complete relief of pain up to 82%,
  – complete ulcer healing up to 76%,
  – complete relief of swelling up to 53%,

• Conclusions:
  – NIVL common, pts. W/ CEAP 3-6
  – Stent placement often provides relief

  Raju et al, J Vasc Surg, 2006
Chronic Venous Outflow Obstruction

VIDIO Study
LB History/PE

CEAP 4

History

• 65 yo Caucasian Female Left leg complaints
• 3 yrs reversible swelling, heaviness, ache
• No DVT, Vein Surgery, CAD, CHF, CRI

Physical Exam

• moderate calf edema; stasis dermatitis
Diagnostic Venogram
Iliofemoral Veins
IVC / Iliac Vein
Diagnostic IVUS
Measurement images of CSA/Diameter with IVUS of Veins

EIV stenosis

Dilated Caudal EIV

75-80% stenosis
IVUS Post-Stent
Compressed EIV
LB Follow-up
1 week & 24 months

“Can see my ankle again”

• Heaviness and achiness resolved
• Dermatitis resolved
• Venous Duplex:
  • No Deep Vein Thrombosis
Summary

- CEAP 4-6 Severe Chronic Venous Insufficiency (CVI)
- Iliac vein compression common
- Permissive to acute DVT
- Percutaneous stent placement
  - Resolve CVI
  - Improve outcomes after Thrombolysis DVT
Thank You!

One More Time!
Thank You!

One More Time!
Thank You!

One More Time!
Thank You!

One More Time!
Thank You!

One More Time!
Thank You!

One More Time!