Indications and Outcomes of Iliac Vein Stenting

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DISCLOSURES

• No financial disclosures
• Site PI Cook Vivo trial
• Site Co-I Veniti trial
Venous outflow obstruction plays a significant role in CVI, especially those who fail to respond to conventional treatment

- Primary cause of ambulatory venous HTN
- 29-82% associated with post thrombotic syndrome
- 67% of patients have ulcer recurrence
- Recurrent DVT are common

For the past 2 decades, treatment of patients with CVI has focused on addressing axial reflux with little attention placed on the obstructive component

- Recent focus on iliac angioplasty and stenting
Iliac Vein Obstruction: Etiology

- **Non-thrombotic Obstruction**
  1) May Thurner Syndrome
  2) Venous webbing, synechiae
  3) Agenesis/atresia
  4) Pelvic mass
  5) Idiopathic

- **Chronic CVI**

- **Thrombotic Occlusion**
  - most common
    1) DVT
    2) Stent or IVC filter occlusion
    3) Radiation
    4) Trauma
    5) Prothrombotic state

- **DVT, Acute or chronic**
Iliac venous obstruction

- Veins behave differently than arteries
  - The elastic recoil is much higher
    - Low-pressure systems
- Although the patency after iliac arterial angioplasty is close to but not quite as good as that for iliac arterial stenting, patency after angioplasty of iliac veins is poor.
- Virtually all patients who present with acute or chronic iliofemoral disease will require a stent.
Iliac Vein Stenting recommended

- High failure rate with thrombolysis alone
- High failure rate with angioplasty alone
- 1-year patency significantly better in limbs treated with iliac stents (74%) than in limbs without stent placement (53%)

Stent patency - iliofemoral outflow obstruction

Razavi et al. Meta-Analysis of Venous Stents

NT - non-thrombotic
AT - acute thrombotic
CPT - chronic post thrombotic
Stenting of Chronic Pathology

Balloon Dilation and Stenting of Chronic Iliac Vein Obstruction: Technical Aspects and Early Clinical Outcome

Peter Neglén, MD, PhD; and Seshadri Raju, MD
River Oaks Hospital, Jackson, Mississippi, USA

- 94-96% tech success
- 81% symptom improvement
- 79% primary patency - chronic
- 84% secondary patency - chronic
- Procedural success dependent on quality of inflow and outflow, rigor of anticoagulation

Chronic Iliac Vein Occlusion: Midterm Results of Endovascular Recanalization

Tilo Kölbl, MD, PhD; Mats Lindh, MD; Michael Åkesson, MD; Johan Wassèlius, MD, PhD; Anders Gottsäter, MD, PhD; and Krassi Ivancev, MD, PhD
Vascular Center, Malmö University Hospital, Malmö, Sweden.

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Non-Thrombotic Venous Outflow Obstruction

Endovascular Management of Nonmalignant Iliocaval Venous Lesions

Brian G. DeRubertis, Ali Alkaif, Juan Carlos Jimenez, David Rigberg, Hugh Gelabert, and Peter F. Lawrence, Los Angeles, California

• Non-thrombotic lesions-
• 69-82% complete symptom relief at final follow-up
• 64-82% resolution of edema
• 71-81% ulcer healing
• 96% primary patency 1 year
• 99% secondary patency 1 year

Endovascular Management of May-Thurner Syndrome

Wael Ibrahim, MD, PhD, Zakareya Al Safran, MD, Hosam Hasan, MD, and Wael Abu Zeid, MS

Changing Strategies to Treat Venous Thrombotic Occlusions of the Upper and Lower Extremities Secondary to Compressive Phenomena

Adam Spivack MD1, Doug Troutman DO1, Matthew Dougherty MD1, and Keith Calligaro MD1

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Stenting across the inguinal ligament

- Comparison of secondary patency between limbs treated for thrombotic occlusion and those with thrombotic non-occlusive obstruction at 32 months revealed no difference whether or not the stent was placed across the inguinal ligament
  - Thrombotic occlusion 77% and 77%, P=NS
  - Thrombotic non-occlusive obstruction 96% and 95%, P=NS
Stenting across the inguinal ligament

• Contrary to arterial stenting, stents can be safely placed across the inguinal crease with no risk of stent fractures, in-stent restenosis, and no effect on long-term patency.

• Patency rate is not related to the length of stented area or the placement of the stent across the inguinal ligament, but is dependent upon the etiology and whether the treated postthrombotic obstruction is occlusive or not.
Anatomic and functional outcomes of pharmacomechanical and catheter-directed thrombolysis of iliofemoral deep venous thrombosis.

Hager E¹, Yuo T², Aygerinos E², Naddaf A², Jeyabalan G², Marone L², Chaer R².

Author information

Abstract

OBJECTIVE: Pharmacomechanical thrombolysis (PMT) and catheter-directed thrombolysis (CDT) are commonly used for the treatment of iliofemoral deep venous thrombosis (DVT). The purpose of this study was to examine the short- and long-term venous patency and venous valvular function as well as clinical outcomes of patients treated for iliofemoral DVT by PMT and CDT.

METHODS: A retrospective review of all patients with symptomatic DVT treated between 2006 and 2011 with PMT or CDT was performed. All patients were treated by local tissue plasminogen activator delivered with PMT or CDT. Patients were divided into two groups on the basis of initial treatment modality: patients treated by PMT alone (group 1), and those who underwent PMT and CDT or CDT alone (group 2). Group comorbidities, initial presenting symptoms, and Clinical, Etiologic, Anatomic, and Pathologic (CEAP) classification scores were compared. Postprocedural duplex ultrasound was used to assess valve function and treated vein patency rates. At all visits, Villalta and CEAP scores were recorded and compared. Group demographic and procedural results were analyzed by Fisher exact test for dichotomous variables and Kruskal-Wallis equality-of-populations rank test for the ordinal and continuous data. Kaplan-Meier survival estimates were used to assess preserved valve function as well as primary and secondary patency rates.

RESULTS: There were 79 patients with 102 limbs treated for extensive iliofemoral DVT (median age, 51.5 years; range, 16.6-83.8 years). There were 18 patients in group 1 and 61 patients in group 2 (PMT + CDT [n = 54] or CDT alone [n = 7]). There were no differences in demographics or comorbidities between groups aside from malignant disease, which was more common in group 1 (35.3% vs 11.5%; P = .03). A total of 102 limbs were analyzed, 24 in group 1 and 78 in group 2. Patients in group 1 had a shorter symptom duration compared with group 2 (7 days vs 16 days; P = .011). The median number of procedures in group 1 was lower than in group 2 (P < .001). At last clinical follow-up, there was no significant difference between the Villalta and CEAP scores or the rate of clinical improvement in symptoms between groups. By Kaplan-Meier analysis, there was no difference in primary patency, secondary patency, and treated valve function at 48 months.

CONCLUSIONS: This study suggests that PMT as a stand-alone therapy is as effective as CDT with or without PMT in preserving valve
OBJECTIVES

• Examine anatomic and functional outcomes of pharmacomechanical thrombolysis (PMT) alone and compare it to catheter directed thrombolysis (CDT) with or without PMT
  – Initial success rates
  – Complication rates
  – Long term anatomic and functional outcomes
    • Preserved valve function
    • Vein/stent patency
GROUP 1
27 Patients
PMT alone

GROUP 2
57 Patients
PMT/CDT or CDT alone

84 Patients (107 LIMBS)
## Initial Outcomes

<table>
<thead>
<tr>
<th></th>
<th>Group 1</th>
<th>Group 2</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Group</strong></td>
<td>(n=27)</td>
<td>(n=57)</td>
<td></td>
</tr>
<tr>
<td><strong>Initial Symptom Relief</strong></td>
<td>95%</td>
<td>96%</td>
<td>NS</td>
</tr>
<tr>
<td><strong>Median duration of symptoms</strong></td>
<td>13 days</td>
<td>6 days</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td><strong>Iliac stenting</strong></td>
<td>63%</td>
<td>41%</td>
<td>NS</td>
</tr>
<tr>
<td><strong>Lysis &gt;50%</strong></td>
<td>80%</td>
<td>93%</td>
<td>NS</td>
</tr>
</tbody>
</table>

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Follow-up @ up to 4 years

Long term stent primary patency 91% in the iliac segment

<table>
<thead>
<tr>
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<th>Group 1 (n=27)</th>
<th>Group 2 (n=57)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Length of follow-up</td>
<td>25 months (5.3-51.7)</td>
<td>19 months (6.1-47.2)</td>
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<tr>
<td>Preserved valve function</td>
<td>71%</td>
<td>73%</td>
<td>NS</td>
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<tr>
<td>Stent Thrombosis</td>
<td>4%(n=1)</td>
<td>4%(n=2)</td>
<td>NS</td>
</tr>
<tr>
<td>Treated vein secondary patency</td>
<td>90%</td>
<td>80%</td>
<td>NS</td>
</tr>
<tr>
<td>Symptom relief</td>
<td>97%</td>
<td>95%</td>
<td>NS</td>
</tr>
</tbody>
</table>

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Long term patency of iliac stents used for acute or chronic obstruction

- Range 67-100%
- Low rate of re-intervention
- Predictors of failure: male sex, younger age, recent trauma, common femoral disease, extent of inflow/outflow disease


Outcomes of endovascular intervention for May-Thurner syndrome.

Hager ES1, Yuo T2, Tahara R3, Dillavou E2, Al-Khoury G2, Marone L2, Makaroun M2, Chaer RA2.

Abstract

BACKGROUND: Endovascular interventions for May-Thurner syndrome (MTS) have become first-line therapy, often performed in a young patient population despite the lack of robust supportive data. This article reports on long-term outcomes from a large series of patients treated in the setting of de novo or postthrombotic presentation.

METHODS: A retrospective review of MTS patients treated between 2006 and 2010 was conducted at two institutions. Patients who presented with acute iliofemoral deep vein thrombosis (DVT) were treated with either catheter-directed thrombolysis (CDT) and/or pharmacomechanical thrombolysis and identified as having a venous stenosis by venogram or intravascular ultrasound (IVUS). Patients who presented with chronic venous insufficiency symptoms or recalcitrant ulceration but no DVT and evidence of MTS on duplex ultrasound, magnetic resonance venography, or computerized tomography venography were evaluated by venography. IVUS was selectively utilized. Stenting of the iliofemoral junction was performed in all patients with a >50% diameter stenosis by IVUS or venogram.

RESULTS: Seventy patients with MTS underwent 77 lower extremity interventions. They were divided into two groups: postthrombotic (group 1) and de novo presentation of chronic swelling/pain or ulceration but no DVT (group 2). There were 56 extremities in group 1 and 21 extremities in group 2. Both groups were comparable in terms of gender distribution and comorbidities, but hypercoagulable state was more common in group 1 (P = .014), and average CEAP and Villalta scores on presentation were higher in group 2 (P < .001). There were left-sided symptoms in 40 (78%) patients in group 1 and 15 (79%) in group 2 (P = 1.00). Female patients were more likely to have left-sided symptoms compared with male patients (odds ratio, 4.88; 95% confidence interval, 1.49-15.89; P = .014). The average stent size was significantly different among the groups (P < .027), with different types used in each group. There was one patient in group 1 who had significant
May Thurner Syndrome -

- Compression of left common iliac vein against the 5th lumbar vertebrae by the right common iliac artery
- Secondary webbing formation
- Found in younger females
- May involve the right limb

_treat if symptomatic, C3 and higher, failed compression_
Non-Thrombotic Iliac Vein Obstruction
• 70 patients, 77 extremities
• Two groups: postthrombotic (group 1) and de novo presentation of chronic swelling/pain or ulceration but no DVT (group 2).
• Mean follow up was 29.7 months in group 1 (range, 18.4-58.3 months) and 22.4 months in group 2 (range, 17.1-42 months).
• Complete or partial symptom relief was reported for 52 (92.9%) extremities in group 1 and 20 (95.2%) extremities in group 2 (P = 1.00).
• Primary patency of group 1 at 36 months by life-table analysis was 91% with a secondary patency of 95%.
• Primary and secondary patency for group 2 was 91% at 36 months.
Outcomes of Iliac Vein Stents Following Pregnancy

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²RANE Center, Jackson, MS
³Allegheny Vein & Vascular Center, Bradford, PA

Eastern Vascular Society 2016
Methods

- Review of three-center prospectively maintained database
- 7-year study period (2007-2014)
- Female patients of reproductive age (18-45 years old) at time of iliocaval stenting for DVT or May-Thurner Syndrome
- Pregnancy post-stenting identified through chart review and/or written/phone follow-up
Results

- 310 women of reproductive age received iliacaval stenting
- 4% (n=12) had at least one pregnancy post-stenting
- Mean age at time of stenting: 28 years
- Mean time from stenting to pregnancy: 23.3 months
<table>
<thead>
<tr>
<th>#</th>
<th>Age at 1st Procedure</th>
<th>DVT vs. MTS</th>
<th>Hypercoagulable State</th>
<th>Stent Location</th>
<th># of Pregnancies Post Stent Placement</th>
<th>Time to 1st Pregnancy Post Stent (months)</th>
<th>Adverse Events</th>
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<tr>
<td>1</td>
<td>26</td>
<td>DVT</td>
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<td>CIV/EIV</td>
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<td>12</td>
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<td>28</td>
<td>DVT</td>
<td>No</td>
<td>CIV/EIV</td>
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<td>CIV/EIV</td>
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<td>No</td>
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<td>5</td>
<td>31</td>
<td>MTS</td>
<td>No</td>
<td>CIV/EIV</td>
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<td>3</td>
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<td>6</td>
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<td>DVT</td>
<td>No</td>
<td>CIV/EIV/Femoral vein</td>
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<td>36</td>
<td>Asymptomatic stent compression 1 year post 2nd delivery</td>
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<td>8</td>
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<td>DVT</td>
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<td>CIV/EIV/Femoral Vein</td>
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<tr>
<td>9</td>
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<td>DVT</td>
<td>Factor V Leiden</td>
<td>CIV/Iliocaval junction</td>
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<tr>
<td>10</td>
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<td>DVT</td>
<td>No</td>
<td>CIV/EIV</td>
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<tr>
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<td>Factor V Leiden</td>
<td>CIV/EIV/Femoral vein</td>
<td>1</td>
<td>24</td>
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</table>
Conclusions

- Pregnancy does not negatively impact stent patency of iliocaval stents for DVT or MTS indications
  - Given LMWH prophylaxis during pregnancy

- Iliocaval stenting is not contraindicated in women of reproductive age

- Close-follow up is warranted intra and post-partum
GUIDELINES
Societal Support

- ACCP ±
- Society of Interventional Radiology
- Society for Vascular Surgery
- AHA

• 2.9. In patients with acute proximal DVT of the leg, we suggest anticoagulant therapy alone over CDT (Grade 2C)

• Patients who are most likely to benefit from CDT and attach a high value to prevention of PTS and a lower value to the initial complexity, cost, and risk of bleeding with CDT are likely to choose CDT over anticoagulation alone
• Patients who are most likely to benefit from CDT have iliofemoral DVT, symptoms for ≤14 days, good functional status, life expectancy of ≥1 year, and a low risk of bleeding.

• If CDT has been successful but there are residual lesions in the common femoral or more proximal veins, balloon angioplasty and stenting often are used to relieve obstruction.
AHA guidelines

- CDT or PMT should be given to patients with IFDVT associated with limb-threatening circulatory compromise (i.e. phlegmasia cerulea dolens)
- CDT or PMT is reasonable for patients with IFDVT associated with rapid thrombus extension despite anticoagulation
- CDT or PMT is reasonable as first-line treatment of patients with acute IFDVT to prevent PTS in selected patients at low risk of bleeding complications.
- Stent placement in the iliac vein to treat obstructive lesions after CDT, PCDT, or surgical venous thrombectomy is reasonable

Mark H. Meissner, MD, a Peter Gloviczki, MD, b Anthony J. Comerota, MD, c Michael C. Dalsing, MD, d Bo G. Eklof, MD, e David L. Gillespie, MD, f Joann M. Lohr, MD, g Robert B. McLafferty, MD, h M. Hassan Murad, MD, i Frank Padberg, MD, j Peter Pappas, MD, k Joseph D. Raffetto, MD, l and Thomas W. Wakefield, MD, m Seattle, Wash; Rochester, Minn; Toledo, Ohio; Indianapolis, Ind; Helsingborg, Sweden; Rochester and New York, NY; Cincinnati, Ohio; Springfield, Ill; Newark, NJ; West Roxbury, Mass; Ann Arbor, Mich

Background: The anticoagulant treatment of acute deep venous thrombosis (DVT) has been historically directed toward the prevention of recurrent venous thromboembolism. However, such treatment imperfectly protects against late manifestations of the postthrombotic syndrome. By restoring venous patency and preserving valvular function, early thrombus removal strategies can potentially decrease postthrombotic morbidity.

Objective: A committee of experts in venous disease was charged by the Society for Vascular Surgery and the American Venous Forum to develop evidence-based practice guidelines for early thrombus removal strategies, including catheter-directed pharmacologic thrombolysis, pharmacomechanical thrombolysis, and surgical thrombectomy.
Management of Iliac Venous Obstruction

• Arterial techniques NOT directly transferrable

• Basic principles
  • Contrast imaging sometimes inadequate
  • IVUS a useful adjunct
  • Angioplasty alone inadequate
  • Recoil always requires stenting
  • Stent ALL disease

No venous stents are currently approved in the US. Off label use.
Intravascular Ultrasoundography (IVUS)

- Diagnostic test of choice
- Quantification of stenosis
- Detection of
  - Webs / synechea
  - Intimal thickening
  - Extrinsic compression
Venous Interventions - Guidelines

• Avoid contralateral femoral approach
• Preferred approaches
  • Right IJV
  • Ipsilateral CFV
  • *U/S guided femoral (SFV) or popliteal*
• Lesion crossed with hydrophilic 5 F catheter / angled glide wire combination
Venous Interventions - Guidelines

- Primary stenting always required
- Self expanding stents preferred
  - CFV & external iliac - 12 mm
  - Common iliac - 14 to 16 mm
  - IVC - 20 to 25 mm (Gianturco)
- Stent entire area of disease
- Assure stent apposition with IVUS

No venous stents are currently approved in the US. Off label use.
Iliac venous obstruction

• Wallstents have been the mainstay technology with the largest pool of experience and longest follow-up of any stent.

• Some idiosyncrasies with which younger endovascular specialists are less comfortable, such as a significant degree of foreshortening (30% minimum), a tendency to straighten over time, and lack of vessel conformability.
  – Variable patency depending on pathology

• With the newer venous stent technologies, there is less foreshortening, better vessel conformability, and more precise placement.
Requirements for stents per segment

- The vein geometry should dictate the shape of the stent and not the opposite
- Flexibility
- The stent must be able to treat the underlying pathology
- Radial Force
  
  Location dependent: IVC: High radial force, low flexibility, large diameter.
  
  CIV, EIV and CFV: High radial force, high flexibility, large diameters
Shortcomings of current stents

• Compression of stent (radial force to low)
• Straightening
  – Kinking of stent (high rigidity)
  – Stent rigidity
• Tapering
New stent designs

- Improved flexibility
- Improved radial force
# New venous Stents

<table>
<thead>
<tr>
<th>Type</th>
<th>Radial force</th>
<th>flexibility</th>
<th>placement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zilver Vena</td>
<td>+</td>
<td>++</td>
<td>++</td>
</tr>
<tr>
<td>Veniti</td>
<td>++</td>
<td>+</td>
<td>++</td>
</tr>
<tr>
<td>Sinus Venous</td>
<td>++</td>
<td>++</td>
<td>+</td>
</tr>
<tr>
<td>Sinus XL flex</td>
<td>++</td>
<td>+</td>
<td>++</td>
</tr>
</tbody>
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Minimizing stent related complications

- Improve flexibility
- Optimize alignment
- Prevent need for anticoagulation
- Improve radial force
- Prevent compression
- Prevent straightening
- Prevent kinking
- Prevent fractures
- Prevent stent material sticking into the lumen
- Optimize delivery
- Prevent shortening
- Allow repositioning
The optimal venous stent

- Accurate deployment
- Minimal shortening
- Good radial force
- Good visibility
- Flexible
- Non-thrombogenic
- MRI compatible
- Wide diameter, length range, low profile
- Inexpensive!

Goals within current reach!
Future designs. Food for thought

- Beveled/fenestrated stents for confluence stenting

- Hybrid stent: rigid top to resolve CIV compression and flexible body to accommodate the EIV

- Different stents for thrombotic (micromesh design? Heparin bonding?) or non-thrombotic lesions (drug eluting technology?)
Iliac Venous Stenting

• Required to treat culprit lesions in the setting of acute DVT or chronic obstruction
  – Prevent recurrence
  – Maintain symptom relief

• Outcomes very durable

• Current stents has resulted in excellent outcomes but dedicated venous stents will hopefully address some of the shortcomings of current designs
Thank you for your attention

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