On Which Criteria Do You Select Your Stent for Ilio-femoral Venous Obstruction?

North American Point of View

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Conflict of Interest

None
Venous Thromboembolism

- Incidence: 1 per 1000 in the US, increases with age
- ~ 201,000 first life-time cases diagnosed annually
- 7 day mortality is 25%
Iliofemoral Venous Thrombosis

- **Incidence:**
  
  1 in 10,000 of the population/year

- **Post-thrombotic syndrome:**
  
  25% of patients, even with anticoagulation and compression stockings
Criteria for Stents in Iliofemoral Venous Obstruction

• Etiology
• Clinical presentation
• Anatomy
• Risks/benefits of endovascular intervention
Etiology

- Acute iliofemoral deep vein thrombosis
  - With or without May-Thurner Syndrome
  - Stent thrombosis
Etiology

- Acute iliofemoral deep vein thrombosis
  - With or without May-Thurner Syndrome
  - Stent thrombosis
- Chronic obstruction
  - Non-thrombotic iliac vein stenosis or occlusion (May-Thurner Syndrome)
  - Chronic post-thrombotic occlusion
  - Chronic occlusion of iliac or ilio-femoral stent
Clinical Presentation

• Acute
  • Pain
  • Leg swelling
  • Phlegmasia alba/coerulea dolens
Clinical Presentation

- **Acute**
  - Pain
  - Leg swelling
  - Phlegmasia alba/coerulea dolens

- **Chronic**
  - Pain
  - Swelling
  - Venous claudication
  - Abdominal wall, lower extremity and suprapubic varicosity
  - Skin changes, venous ulcerations
  - Symptoms of pelvic venous congestion
Anatomy

• Inflow

• Outflow

• Obstruction
  • can be crossed
  • can be dilated
Anatomy
Anatomy
Anatomy
Anatomy

[Image of an anatomical diagram, possibly of the pelvis or hip area, with an arrow pointing to a specific part, labeled "LEFT"]
Patient Selection for Stenting

• Good inflow to common femoral vein or
  • Endophlebectomy with patch angioplasty
  • Stenting of the profunda femoris vein
Increased Risks of Intervention

- Chronic renal failure
- Underlying thrombophilia
- Sedentary or bedridden patient
- High cardiac and pulmonary risk
- Retroperitoneal fibrosis
- Previous radiation
- Previous stenting
37 studies, 2869 patients
(nonthrombotic, 1122; acute thrombotic, 629; and chronic post-thrombotic, 1118)

Technical success rates: 94% - 96%
• Periprocedural mortality: 0.1% - 0.7%
• Early thrombosis: 1.0% to 6.8%
• Major bleeding: 0.3% - 1.1%
• Pulmonary embolism: 0.2% - 0.9%
Preoperative Diagnostic Evaluation

- Duplex scanning
- Magnetic resonance venography
- Computed tomographic venography
- Direct contrast venography with venous pressure measurements
- Intravascular Ultrasound (IVUS)
May – Thurner Syndrome
May – Thurner Syndrome
May – Thurner Syndrome
Stents

A

B

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Stents
Current Commercially Available Stents

Wallstent
Boston Scientific
Marlborough, MA
Current Commercially Available Stents

- Gianturco Z-Stent
  Wilson-Cook Medical
  Winston-Salem, NC

- Wallstent
  Boston Scientific
  Marlborough, MA

- Smart
  Cordis Endovascular
  Warren, NJ

- Protégé
  ev3, Plymouth, MN

- Luminexx
  Angiomed/Bard
  Karlsruhe, Germany
Stents in Europe

AndraStent
Reutlingen, Germany

Sinus-XL

Sinus Venous stent

Optimed, Ettlingen, Germany
Two ongoing iliofemoral stent RCTs

To assess safety and efficacy

• The Veniti VIRTUS study
  Symptomatic patients with non-malignant iliofemoral venous obstruction

• Zilver Vena VIVO Study
  Symptomatic patients with iliofemoral venous obstruction
# Results from United States

## Single center

<table>
<thead>
<tr>
<th>Author, year</th>
<th>Study period</th>
<th>Stented segment</th>
<th>No of patients/limbs</th>
<th>Type of stents</th>
<th>Technical success (%)</th>
<th>Follow-up (month) (range)</th>
<th>Year</th>
<th>PP (%)</th>
<th>PAP (%)</th>
<th>SP (%)</th>
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<tbody>
<tr>
<td>Neglén, 2007</td>
<td>1997-2005</td>
<td>Iliofemoral and caval</td>
<td>870/982</td>
<td>Wallstent Other nitinol stents</td>
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<td>22 (1-107)</td>
<td>6†</td>
<td>79</td>
<td>100</td>
<td>100</td>
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<td>Titus, 2011</td>
<td>2005-2009</td>
<td>Iliofemoral</td>
<td>36/40</td>
<td>--</td>
<td>--</td>
<td>10.5 (0-38)</td>
<td>0.5</td>
<td>88</td>
<td>93</td>
<td>100</td>
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<td>Kurklinsky, 2012</td>
<td>2003-2008</td>
<td>Iliofemoral</td>
<td>87/91</td>
<td>Wallstent Other nitinol stents</td>
<td>100</td>
<td>11.3 (0.8-72)</td>
<td>1</td>
<td>81</td>
<td>94</td>
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*: non-thrombotic disease; †:thrombotic disease
# Results from European Countries

## Single center

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<th>Study period</th>
<th>Stented segment</th>
<th>No of patients/limbs</th>
<th>Type of stents</th>
<th>Technical success (%)</th>
<th>Follow-up (month) (range)</th>
<th>Year</th>
<th>PP (%)</th>
<th>PAP (%)</th>
<th>SP (%)</th>
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<tr>
<td>Oguzkurt, 2008 Turkey</td>
<td>2003-2006</td>
<td>Iliofemoral</td>
<td>36/36</td>
<td>Wallstent Protégé</td>
<td>94</td>
<td>18 (3-48)</td>
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<td>85</td>
<td>80</td>
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<td>Hartung, 2009 France</td>
<td>1996-2008</td>
<td>Iliocaval</td>
<td>89/89</td>
<td>Wallstent</td>
<td>98</td>
<td>33 (1-144)</td>
<td>1.3</td>
<td>89</td>
<td>83</td>
<td>94</td>
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<td>Rosales, 2010 Norway</td>
<td>2000-2009</td>
<td>Femoroliocaval</td>
<td>34</td>
<td>Wallstent</td>
<td>94</td>
<td>33 (1-196)</td>
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<td>76</td>
<td>90</td>
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<td>de Graaf, 2015 The Netherlands</td>
<td>2009-2014</td>
<td>Biiliocaval</td>
<td>40/40</td>
<td>Sinus XL Sinus venous Zilver Vena Andrastent</td>
<td>100</td>
<td>15 (0.2-56)</td>
<td>1</td>
<td>79</td>
<td>70</td>
<td>908</td>
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<td>de Wolf, 2015 Germany</td>
<td>2012-2014</td>
<td>Iliofemoral</td>
<td>75/75</td>
<td>Sinus venous</td>
<td>100</td>
<td>5.4 (1-18)</td>
<td>0.25</td>
<td>99</td>
<td>96</td>
<td>99</td>
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*PP, primary patency; PAP, primary assistant patency; SP, secondary patency*
Safety and Effectiveness of Stent Placement for Iliofemoral Venous Outflow Obstruction
Systematic Review and Meta-Analysis

Mahmood K. Razavi, MD; Michael R. Jaff, DO; Larry E. Miller, PhD

Background—Endovenous recanalization of iliofemoral stenosis or occlusion with angioplasty and stent placement has been increasingly used to maintain long-term venous patency in patients with iliofemoral venous outflow obstruction. The purpose of this systematic review and meta-analysis was to determine safety and effectiveness of venous stent placement in patients with iliofemoral venous obstructions.

Methods and Results—We searched the literature for reports of stent placement in patients with iliofemoral venous obstruction. A total of 45 studies were included in the review. In non-thrombotic patients (n=1,122), primary patency rates were comparable among groups for major bleed complications, symptom relief, and complications, reporting 45 treatment effects with success rates ranging from 1.0% to 6.0% for primary patency. Year, primary and secondary patency rates were 94% and 99% for chronic post-thrombotic syndrome.

Conclusions—Stent placement for iliofemoral venous outflow obstruction was associated with reduced complication rates regardless of the stent type.
Secondary Patency at 5 Years

- NT: 99%
- CPT: 94%
- AT: 89%
Stent placement for iliofemoral venous outflow obstruction results in high technical success and acceptable complication rates regardless of cause of obstruction.
Reinterventions for nonocclusive iliofemoral venous stent malfunctions

Seshadri Raju, MD, Paul Tackett Jr, BS, and Peter Neglen, MD, PhD
Jackson and Flowood, Miss

Background: Percutaneous iliofemoral venous stenting has been shown to be effective, safe, and durable in both nonthrombotic iliac vein lesion (NIVL) and postthrombotic disease. A small fraction of stented limbs require reintervention to correct stent malfunction. This manuscript examines the reasons for reintervention, types of procedures performed, and outcome.

Methods: Femoro-ilio-caval stenting was performed in 1085 limbs over a 10 year period from 1997 to 2007 (NIVL/postthrombotic limb ratio 1:1). Reinterventions were categorized into four types: (1) stent revised to correct inflow problems; (2) additional stenting to correct inflow problems; (3) additional stenting for occlusion; and (4) additional stenting for nonocclusive stent malfunction.

Results: Median time of intervention after initial stent was 15 months. Reinterventions were performed in 13.7% of the limbs. Most (31%) were performed for stent abnormalities, with the remainder for recurrent symptoms (69%). Of reinterventions, 77% were single and 23% were multiple.

Indications
- Stent abnormalities: 31%
- Recurrent symptoms: 69%

Reinterventions
- Median time: 15 months
- Single: 77%
- Multiple: 23%
Editor’s Choice — A Systematic Review of Endovenous Stenting in Chronic Venous Disease Secondary to Iliac Vein Obstruction

M.J. Seager, A. Busuttil, B. Dharmarajah, A.H. Davies
Department of Surgery and Cancer, Imperial College London, Charing Cross Hospital, London, UK

WHAT THIS PAPER ADDS
This review demonstrates that quality of evidence behind the use of deep venous stenting to treat obstructive chronic venous disease is weak. However, the consistent effects and marked changes to disease course mean that it should be considered as an acceptable treatment. This review includes a Supplemental Information section so clinicians and vascular teams are aware of this, and it will serve to direct future randomized controlled trials.

Objectives: Deep endovenous stenting to relieve chronic venous disease in non-thrombotic iliac vein obstruction is becoming an accepted treatment. The Cochrane review and the one systematic review on the topic are based on a single centre study analysis of the available data, reported in the PeriphEat Analyses guideline.

Methods: MEDLINE, EMBASE, and the Cochrane Library were searched.

Results: Systematic reviews were included (14 before this review). There were 16 studies reporting treatment effects in 2,586 post-thrombotic or nonthrombotic limbs (2,373 patients) were included.

• Persistent ulcer healing rates: 56% - 100%
• Primary patency: 32% - 98.7%
• Secondary patency: 66% - 96%
• Major complication rate: 0 - 8.7%

The quality of evidence to support iliac vein stenting is weak
Mayo Clinic Experience with Stenting in 66 Complex Iliocaval Obstructions
Primary Patency

Time (months)

Primary patency

- 87% at 8 months
- 78% at 24 months
- 69% at 50 months
Secondary Patency

92%  
87%

Time (months)
Guidelines 4.17.0 and 4.18.0 of the American Venous Forum on Endovascular Reconstruction for Primary and Post-thrombotic Iliac Vein Obstruction

<table>
<thead>
<tr>
<th>Guideline No.</th>
<th>GRADE of recommendation</th>
<th>Level of evidence</th>
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<td>4.17.1 4.18.1</td>
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We recommend endovenous stenting as the current “method-of-choice,” for treatment of symptomatic primary and post-thrombotic iliac vein obstruction.
THANK YOU!