Post Thrombotic Disease:
The relevance of long term follow up

Marzia Lugli
Endovascular outflow obstruction correction

2002 – Raju and Neglen  Venoplasty/stenting
Open surgery of iliocaval segment is limited to oncologic patient
PTS is a main cause of CVI (CEAP C3 – C6): what is the clinical impact of outflow obstruction treatment?
Clinical results

<table>
<thead>
<tr>
<th></th>
<th>Raju 2013</th>
<th>Qiu 2018</th>
<th>Zachary 2020</th>
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<tr>
<td>Pain relief %</td>
<td>86 - 94</td>
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<td>Swelling relief %</td>
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<tr>
<td>Ulcer healing %</td>
<td>58 - 89</td>
<td>75.7</td>
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</table>
Why such a wide range of outcomes?

First – There is a wide spectrum of PTS lesions
Monolateral non-occlusive obstruction
Extensive iliocaval occlusive lesions
Why such a wide range of outcomes?

*First* – There is a wide spectrum of PTS lesions

*Second* – There are a wide variety of results
Adequate
....... inadequate
The residual deep reflux after obstruction correction is still symptomatic in 50% of cases.
It proves difficult to compare so different cases and the analysis of literature data reflects this problem.
Systematic Review and Meta-Analysis of Iliofemoral Stenting for Post-thrombotic Syndrome


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WHAT THIS PAPER ADDS
Endovascular stenting is relevant to the management of post-thrombotic syndrome with chronic obstruction in iliofemoral venous segment. Although this systematic review demonstrates that the quality of evidence for iliofemoral stents is weak, venous stenting has the potential to be effective, with extremely rare occurrences of peri-operative complications. This review may assist in clinical decision making and guide future research.

Objective: Stent placements are considered as a treatment for post-thrombotic syndrome (PTS) with iliofemoral obstruction, but the application of these iliofemoral venous stents has also caused a lot of controversy. The purpose of this systematic review and meta-analysis was to summarise the efficacy and safety of venous stents in PTS with obstruction in iliofemoral venous segments.

Methods: MEDLINE, EMBASE, and the Cochrane Central Register for Controlled Trials databases and key references were searched up to 15 January 2018. The main relevant outcomes included technical success, peri-operative complications, symptom resolution, a change of symptom scores, and long-term patency of the stents.

Results: Overall, 504 limbs of 489 patients from seven studies were included in this study. A GRADE assessment showed the quality of the evidence was “very low” for 11 relevant outcomes. The technical success rate was 95%. The pooled rate of complications including 30 day thrombotic event, peri-operative venous injury, and back pain was 3.4%, 18.14%, and 52%, respectively. The rates of ulcer healing, pain and oedema relief were 75.66%, 52%, and 42%, respectively. The primary, assisted primary and secondary patency rates were 83.36%, 90.59%, and 94.32%, respectively, at 12 months and 67.98%, 82.26%, and 86.10% respectively, at 36 months.

Conclusions: Endovenous stenting has the potential to be effective and has a low risk of peri-operative complications. The quality of evidence to support this treatment is very low. Endovenous iliofemoral stenting should be considered a treatment option for PTS with iliofemoral obstruction.

504 limbs/489 pts
12 month
Primary 83.36
Assisted 90.59
Secondary 94.32

36 month
67.98
82.26
86.10
A systematic review of venous stents for iliac and venacaval occlusive disease

Zachary F. Williams, MD, and Ellen D. Dillavou, MD, Durham, NC

ABSTRACT

Objective: Endovascular stenting of the deep venous system is increasingly used to treat stenotic and occluded veins. This article reviews the efficacy and safety of venous stenting for lower extremity occlusive disease.

Methods: The Ovid portal was used to search the MEDLINE database for English-language randomized controlled trials and case series published between January 1, 2005, and December 31, 2018, involving venous stenting for lower extremity and inferior venacaval occlusive and compressive disease. Studies were eligible for inclusion if they contained at least 30 patients with at least 6 months of follow-up. Clinical outcomes, long-term patency, complications, and postoperative anticoagulation regimens were reviewed. Also included are nationally presented trial results of dedicated venous stents that may not have been formally published yet.

Results: Relevant studies were too heterogeneous for a formal meta-analysis to be performed. We analyzed 3812 stented limbs from 23 published studies and two national presentations. Dedicated venous stents were used in 740 patients, and standard stents were used in 3072 patients. The overall major complication rate was <1%. Median symptomatic improvement and ulcer healing were seen in 79% and 71% of the standard stented limbs, respectively. For standard stents, the median primary, assisted primary, and secondary patency rates were 71%, 89%, and 91%, respectively, with a median study follow-up of 23.5 months. Dedicated venous stents had an overall primary patency of 78.8% at 12 months, with lower patency (73%) seen in post-thrombotic vs compressive (96%) disease.

Conclusions: Whereas the quality of evidence remains weak, iliofemoral venous stenting appears to be a safe and effective treatment of chronic venous disease. In early results, dedicated venous stents appear safe and demonstrate results that are as good as or better than those of historically used devices. (J Vasc Surg. Venous and Lym Dis 2020;8:145-53.)

Keywords: Chronic venous disease, Post-thrombotic syndrome, Nonthrombotic iliac vein lesions, Stents
### Non dedicated stents

**23.5 mo. median FU**

<table>
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<tr>
<th>Study</th>
<th>Symptom relief, %</th>
<th>Ulcer healing, %</th>
<th>Primary patency, %</th>
<th>Primary assisted patency, %</th>
<th>Secondary patency, %</th>
<th>Median follow-up, months</th>
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Primary: 71
Assisted: 89
Secondary: 91
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<tr>
<th>Author</th>
<th>Stent name</th>
<th>Material</th>
<th>Study type</th>
<th>No. of patients</th>
<th>CEAP C5 or C6</th>
<th>12-month primary patency</th>
<th>QoL score change</th>
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<td>Van Vuuren, 2018</td>
<td>sinus-Venous</td>
<td>Open cell, laser cut, self-expanding nitinol</td>
<td>Single-center retrospective</td>
<td>200: 48 NIVL, 103 PTS, 49 hybrid</td>
<td>10.5%</td>
<td>68% (92% NIVL, 71% PTS)</td>
<td>−3 VCSS</td>
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<td>Marston, 2019</td>
<td>VICI</td>
<td>Self-expanding nitinol closed cell</td>
<td>Prospective multicenter single arm</td>
<td>200: 50 NIVL, 150 PTS</td>
<td>25.4%</td>
<td>84% (98.2% NIVL, 79.8% PTS)</td>
<td>−4.4 VCSS</td>
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<td>Black, 2018</td>
<td>VICI</td>
<td>Self-expanding nitinol closed cell</td>
<td>Single-center retrospective</td>
<td>88 PTS</td>
<td>15%</td>
<td>59% PTS</td>
<td>−6 Villalta</td>
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<td>Lichtenberg, 2019</td>
<td>VICI</td>
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<td>Single-center retrospective</td>
<td>82: 40 NIVL, 42 PTS</td>
<td>15%</td>
<td>94% (100% NIVL, 87% PTS)</td>
<td>−3 VCSS</td>
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<td>Dake, 2018</td>
<td>Venovo</td>
<td>Self-expanding nitinol closed cell</td>
<td>Prospective</td>
<td>170: 72 NIVL, 84 PTS</td>
<td>NA</td>
<td>88.3% (96.9% NIVL, 81.3% PTS)</td>
<td>−1.7 VCSS</td>
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<td>All</td>
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<td>Average 78.8% (95.8% NIVL, 73.4% PTS)</td>
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Dedicated stents
12 mo. median FU

Primary 73.4
Peripheral Vascular Disease

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 outflow obstruction.

Methods and Results—We searched MEDLINE and EMBASE for studies evaluating safety or effectiveness of stent placement in patients with iliofemoral venous outflow obstruction. Data were extracted by disease pathogenesis: nonthrombotic, acute thrombotic, or chronic post-thrombotic. Main outcomes included technical success, periprocedural complications, symptom relief at final follow-up, and primary/secondary patency through 5 years. A total of 37 studies reporting 45 treatment effects (nonthrombotic, 8; acute thrombotic, 19; and chronic post-thrombotic, 18) from 2869 patients (nonthrombotic, 1122; acute thrombotic, 629; and chronic post-thrombotic, 1118) were included. Technical success rates were comparable among groups, ranging from 94% to 96%. Complication rates ranged from 0.3% to 1.1% among groups for major bleeding, from 0.2% to 0.9% for pulmonary embolism, from 0.1% to 0.7% for periprocedural mortality, and from 1.0% to 6.8% for early thrombosis. Patient symptom relief data were reported inconsistently. At 1 year, primary and secondary patency were 96% and 99% for nonthrombotic, 87% and 89% for acute thrombotic, and 79% and 94% for chronic post-thrombotic.

Conclusions—Stent placement for iliofemoral venous outflow obstruction results in high technical success and acceptable complication rates regardless of cause of obstruction. (Circ Cardiovasc Interv. 2015;8:e002772. DOI: 10.1161/CIRCINTERVENTIONS.115.002772.)
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1118 patients
1 year FU

Primary 79
Secondary 94

1122 NIVL procedures !!!!
Modena experience on PTS endovascular recanalization

- 538 PTS cases (2007 – 2019)
- 13 years follow up
Focus on patients follow up > 10 years

- period 2007-2010

- 76 patients

- follow up 120–148 months
76 pts
  3 died
  8 lost at follow up

65 pts
  8 iliocaval
  57 monolateral
  18 below inguinal ligament (27.7 %)
11 restenosis

14 occlusion monolateral (no cava occlusion - but 3 limbs)

Patency 61.5%

14 re-intervention

13 endo
7 extension below ligament
3 extension up to CIV
3 PTA

1 hybrid procedure
Patency (secondary)

78.5% at more than 10 years
Patency (secondary)

78.5% at more than 10 years

what did we learn?
First

Inflow is key
Second

PTS is an evolving disease.

Follow up and reintervention can improve long term results.
Conclusion
after 2 years

after 4 years
thank you
Post Thrombotic Disease:
The relevance of long term follow up

Marzia Lugli