New strategy for endovascular treatment of the obstructed common femoral vein

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Disclosure

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I have the following potential conflicts of interest to report:

- [ ] Consulting: Plusmedica, Optimed, BTG
- [ ] Employment in industry
- [ ] Stockholder of a healthcare company
- [ ] Owner of a healthcare company
- [ ] Other(s): Reserach grant: Sanofi, Bayer

- [ ] I do not have any potential conflict of interest
Swiss Venous Stent Registry

Long term follow up (mean 796 days) of 121 patients treated for postthrombotic syndrome

- 35 (29%) with IVC stents
- 119 (98%) with iliac stents
- 86 (71%) stents below the inguinal ligament
- 36 (30%) bilateral interventions
Swiss Venous Stent Registry
Stent patency at 3 years for acute iliofemoral DVT versus PTS

Primary Patency Rate

- Postthrombotic Syndrome (n=121)
- Acute iliofemoral DVT (n=122)

Secondary Patency Rate

- Postthrombotic Syndrome (n=121)
- Acute iliofemoral DVT (n=122)

<table>
<thead>
<tr>
<th>Condition</th>
<th>Primary Patency Rate</th>
<th>Secondary Patency Rate</th>
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<tbody>
<tr>
<td>Postthrombotic Syndrome</td>
<td>61% (95% CI 52-70)</td>
<td>89% (95% CI 83-95)</td>
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<tr>
<td>Acute iliofemoral DVT</td>
<td>74% (95% CI 66-82%)</td>
<td>95% (95% CI 91-99%)</td>
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p = 0.003
p = 0.256
Endovascular treatment of PTS
Stent thrombosis

May Thurner Anatomy

Stent below inguinal ligament

Long Rank (Mantel-Cox): p = 0.03

Long Rank (Mantel-Cox): p = 0.77

PERMANENT STENT MALFUNCTION
• 5/10 patients with stents below CVF
Issues with treatment of common femoral vein occlusions

• Often combined with postthrombotic leg inflow veins (FV, DFV)
• No dedicated CFV stent available
• Laser cut nitinol stents or woven steel alloy stents in CFV may be associated with stent malfunction, stent restenosis, stent thrombosis, stent fractures, groin discomfort
• Few and debatable results for endophlebectomy of common femoral vein
Stent fractures at and below inguinal ligament
Ideal stent for common femoral vein occlusions

- Highly flexible throughout stent length
- High radial and restistive force in areas where needed (e.g. the ligament area)
- No stent fractures
- No groing pain or discomfort
- Patency and freedom from PTS
Blueflow Venous Stent for common femoral vein (plusmedica)

First braided venous nitinol stent

- Push-Pull Delivery-System for „packing“ the stent during deployment (increase in radial force)
- Re-sheathable for allowing better deployment precision
Blueflow Venous Stent for common femoral vein (plusmedica)

- Braided meshed stent made of two 0.22mm electropolished nitinol wires
- Braiding technique with two wires enables closed loop design
- Each wire loops back when it reaches the stent tip, thus creating 14 radial force stable end loops
- Two wires are welded together at two points in the center of the stent
Blueflow case: 1
68 y, male with phlegmasia
Occlusion of the common femoral vein due to iatrogenic intramural CFV hematoma
Treatment: 12 x 100 mm Blueflow Stent
Blueflow case: 2

- 48 y, male with severe PTS and leg ulcers
- History of i.v. heroin injections CFV
- Treatment: 14 x 150 mm Blueflow Stent
Blueflow Venous Stent for common femoral vein (plusmedica)

- Two centers (Arnsberg, Zurich) initiated a post-market introduction follow-up plan in February 2018
- Overall, 36 patients were treated with the blueflow stent between February and December 2018, mainly for PTS
- No device-related complications were reported
- Overall, 19 patients had complete 3 month-follow up data in December 2018

Primary patency: 89.5% (17 of 19 patients)
Secondary patency: 94.7% (18 of 19 patients)
Summary

- Endovascular treatment of PTS often requires stent placement in the common femoral vein.
- Conventional stents (laser cut nitinol or woven steel alloy) may cause problems when placed in the common femoral vein.
- The blueflow stent was specifically designed for the CFV.
- Initial experience shows promising results.
- Further evidence is required to confirm efficacy and safety of the blueflow stent.
Thank you for your attention!
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