Dedicated ring-design Stent

Patency rates and clinical results

Rick de Graaf, MD PhD
Interventional Radiologist
r.de.graaf@MUMC.nl
Disclosure

Speaker name:

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I have the following potential conflicts of interest to report:

- Consulting: Cook medical; Optimed GmbH; Bard; Volcano/Philips; TVA Medical; Vesper Medical;

- Employment in industry

- Stockholder of a healthcare company

- Owner of a healthcare company

- Other(s)

- I do not have any potential conflict of interest
Stent design

- Designed as a dedicated venous stent
  - Not from arterial platform

- Segmented ring design
Demands for a venous stent

- **Flexibility**
  - Will it bend?
  - Effortless follow anatomy

- **Radial force/crush resistance**
  - Enough, not as high as possible
Anatomical considerations
Venous ≠ arterial!!

- Not atherosclerosis
  - Fatty instable plaque

- Fibrosis
  - Collagen fibers
Rationale
Earlier assumptions...

Objectives: to compare the results and complications of endovascular surgery in limbs with post-thrombotic and non-thrombotic disease and to detail some technical aspects of the procedure.

Design: a single centre, prospective study.

Materials and methods: between March 1997 and August 1999, 139 consecutive lower extremities with chronic iliac venous obstruction (61 limbs with primary disease [MTS] and 78 with post-thrombotic disease [PTS]) were treated by balloon dilation and stenting. History, clinical examination, procedure and follow-up data were recorded.

Results: mortality was zero. Non-thrombotic complication rate was only 3%. Postoperative (8%, 6/78) and late occlusion (3%, 2/69) occurred only in post-thrombotic limbs. Primary, primary-assisted and secondary cumulative patency rates of the stented area at 2 years were 52%, 88% and 90%, respectively, in the PTS group as compared to 60%, 100% and 100% in the MTS group. Clinical improvement in pain and swelling was significant in both groups. Half of active venous ulcers healed after the procedure.

Conclusions: chronic iliac vein obstruction appears to be a symptomatic lesion that can be treated safely and effectively by endovascular surgery regardless of aetiology. Generous use of IVUS is suggested in both diagnosis and treatment since phlebography is unreliable. The clinical improvement was significant in both groups; however, more excessive neointimal hyperplasia and a higher early and late occlusion rate were observed in post-thrombotic disease. Stenting after balloon dilation is advised in all venoplasties; stents should be inserted well into the IVC when treating ilio-caval junction stenosis. A wide-diameter (16 mm) stent is recommended. The stent should cover the entire lesion as outlined by the IVUS.

Neglen et al. . Eur J Vasc Endovasc Surg 2000
Venous ≠ arterial!!
Results of ring-design venous stent

Short-Term Clinical Experience with a Dedicated Venous Nitinol Stent: Initial Results with the Sinus-Venous Stent

M.A.F. de Wolf a,*, R. de Graaf b, R.L.M. Kurstjens a, S. Penninx a, H. Jalaie c, C.H.A. Wittens a,c

a Department of Vascular Surgery and Cardiovascular Research Institute Maastricht, Maastricht University Medical Centre, Maastricht, The Netherlands
b Department of Radiology, Maastricht University Medical Centre, Maastricht, The Netherlands
c Department of Vascular Surgery, University Hospital RWTH Aachen, Aachen, Germany

WHAT THIS PAPER ADDS
Endovascular treatment in patients with deep venous occlusive or obstructive disease, by PTA and stent placement, is an emerging field; however, dedicated venous stents have only recently become available. This study describes a first experience with one such device, the sinus Venous stent. This device distinguishes itself from previously used stent designs aimed at the arterial system by increased radial force and flexibility, and greater diameter and length. It is postulated that dedicated venous stents will become the new standard for treatment of venous compression and post-thrombotic syndromes in the future.
Demographics

• Age: 45 (range 18-77) years

• 65% female

• 88% one or more prior DVTs

• 47% NIVL; 53%PTS
Clinical Scoring

- CEAP
  - 28% class C4-C6 disease

- Villalta
  - 33% mild
  - 28% moderate
  - 33% severe

- Venous claudication: 53%
Patency rates unilateral PTS

- Primary patency
- Assisted primary patency
- Secondary patency

Subjects at risk | Baseline | 3 months | 6 months | 9 months | 12 months
--- | --- | --- | --- | --- | ---
Primary Patency | 40 | 26 | 17 | 10 | 7
Assisted primary patency | 40 | 25 | 17 | 10 | 7
Secondary patency | 40 | 26 | 18 | 11 | 8

Patency rate iliac vein compression syndrome

Subjects at risk | Baseline | 3 months | 6 months | 9 months | 12 months
--- | --- | --- | --- | --- | ---
Primary Patency | 35 | 25 | 18 | 12 | 7
Results

• Clinical scoring improvement
  • 64.6% (NIVL); 76.2% (PTS)

• Venous claudication reduction
  • 87% (NIVL); 72% (PTS)

• Ulcer healing
  • 50%
Further experience

• 2012-2016

• Exclusion of acute, hybrid, bilateral and IVC cases

• 312 patients
  • 89 compression syndrome
  • 223 chronic obstruction
Further experience

• **Primary (assisted) patency**
  - NIVL 93.1(100)%; PTS 72.5(83.1)%

• **Secondary patency**
  - NIVL 100%; PTS 91.7%

• **Clinical scoring improvement**
  - 68.1% (NIVL); 79.7% (PTS)
Conclusions

- Sustained technical success and clinical improvement
- No stent integrity loss
- Operator dependent patency loss in NIVL

..........or stent related..........
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