51ST VEITH symposium

Session 104: MORE IMPORTANT DEEP VENOUS CONCEPTS

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Indications, Technical Aspects, And Outcomes Of Stent Placement In Chronic Iliofemoral Venous Obstruction

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UPMC

Disclosures

None

Special issue on iliofemoral venous stenting

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Special issue

Contemporary Role of Iliofemoral Venous Stenting

Last update 5 June 2024

Endovenous techniques to correct symptomatic iliofemoral venous obstruction in patients who have failed conservative therapy have become the standard of care in both acute and chronic settings. This 6-article special issue on iliofemoral venous stenting written and reviewed by experts in the field aims to cover the breadth of the subject and serve as a go-to guide for the reader. Each article covers a particular topic in-depth and guides the reader on how to apply the information in their day-to-day practice. We hope that the readers will enjoy this collection as much as we have enjoyed putting it together.

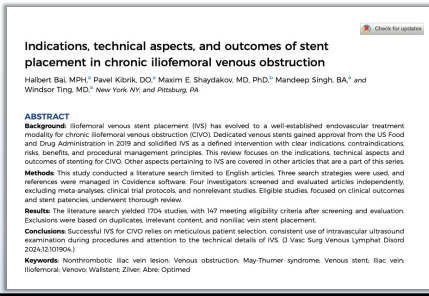
Guest Editors:

Arjun Jayaraj
The Rone Center, Jackson, Mississippi

Houman Jalaie
University Hospital Aachen, Aachen, Germany

Special issue on iliofemoral venous stenting

Special issue on iliofemoral venous stenting



Indications, technical aspects, and outcomes of stent placement in chronic iliofemoral venous obstruction

Halbert Bai, MPH,[a] Pavel Kibrik, DO,[a] Maxim E. Shaydakov, MD, PhD,[b] Mandeep Singh, BA,[b] and Windsor Ting, MD[a] *New York, NY, and Pittsburg, PA*

ABSTRACT

Background: Iliofemoral venous stent placement (IVS) has evolved to a well-established endovascular treatment modality for chronic iliofemoral venous obstruction (CIVO). Dedicated venous stents gained approval from the US Food and Drug Administration in 2019 and solidified IVS as a defined intervention with clear indications, contraindications, risks, benefits, and procedural management principles. This review focuses on the indications, technical aspects and outcomes of stenting for CIVO. Other aspects pertaining to IVS are covered in other articles that are a part of this series.

Methods: This study conducted a literature search limited to English articles. Three search strategies were used, and references were managed in Covidence software. Four investigators screened and evaluated articles independently, excluding meta-analyses, clinical trial protocols, and nonrelevant studies. Eligible studies, focused on clinical outcomes and stent patencies, underwent thorough review.

Results: The literature search yielded 1704 studies, with 147 meeting eligibility criteria after screening and evaluation. Exclusions were based on duplicates, irrelevant content, and noniliac vein stent placement.

Conclusions: Successful IVS for CIVO relies on meticulous patient selection, consistent use of intravascular ultrasound examination during procedures and attention to the technical details of IVS. (J Vasc Surg Venous Lymphat Disord 2024;12:101904.)

Keywords: Nonthrombotic iliac vein lesion; Venous obstruction; May-Thurner syndrome; Venous stent; Iliac vein; Iliofemoral; Venovo; Wallstent; Zilver; Abre; Optimed

Methodology

Systematic search in

PubMed, Embase, Scopus, Cochrane

I. "venous stent" **AND** "iliac vein" **OR** "iliofemoral vein"

II. "Venovo" OR "Vici" OR "Wallstent" OR "Zilver" OR "Abre" OR "Optimed" OR "DUO" **AND** "iliac vein" OR "iliofemoral vein"

III. "nitinol stent" **OR** "bare metal stent" **OR** "elgiloy stent" **AND** "iliac vein" OR "iliofemoral vein"

acute venous thrombosis
non-iliac vein stenting

1704 studies

147 studies included

meta-analyses,
clinical trial protocols, reviews,
case reports, editorials, letters,
commentaries, and abstracts

Indications

>50% iliac vein stenosis **+** **symptoms**

50% stenosis: postthrombotic disease

Multifocal disease

Bilateral disease

Long segment stenosis

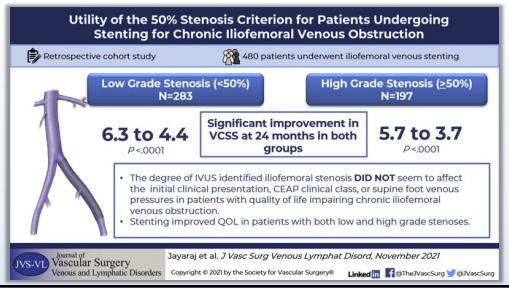
50% stenosis: NIVL

>61%

iliac vein stenosis

Gagne PJ. Analysis of threshold stenosis by multiplanar venogram and intravascular ultrasound examination for predicting clinical improvement after iliofemoral vein stenting in the VIDIO trial. J Vasc Surg Venous Lymphat Disord. 2018 Jan;6(1):48-56.e1.

50% stenosis



Venous-specific symptoms?

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The online version of this article is located at http://www.minervamedica.it
International Angiology 2016 August;35(4):374-98

SPECIAL ARTICLE

Venous symptoms: the SYM Vein Consensus statement developed under the auspices of the European Venous Forum

Michel PERRIN [1], Bo EKLÖF [2], Andre VAN RIJ [3], Nicos LABROPOULOS [4], Michael VASQUEZ [5], Andrew NICOLAIDES [6, 7], Werner BLÄTTLER [8], Didier BOUHASSIRA [9], Eliete BOUSKELA [10], Patrik CARPENTIER [11], Katy DARVALL [12], Marianne DE MAESENEER [13], Mieke FLOUR [14], Jean-Jérôme GUEX [15], Claudine HAMEL-DESNOS [16], Stavros KAKKOS [17], Robert LAUNOIS [18], Marzia LUGLI [19], Oscar MALETI [19], Armando MANSILHA [20], Peter NEGLÉN [21], Eberhard RABE [22], Evgeny SHAYDAKOV [23]

Venous-specific symptoms?

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Valvular reflux

1. Evans CJ et al. Prevalence of venous reflux in the general population on duplex scanning: the Edinburgh vein study. J Vasc Surg. 1998 Nov;28(5):767-76.
2. Robertson LA et al. Incidence and risk factors for venous reflux in the general population: Edinburgh Vein Study. Eur J Vasc Endovasc Surg. 2014 Aug;48(2):208-14.

Indications: individualized approach

- ✓ **Suspected** chronic venous obstruction
- ✓ **Severe** persistent signs or symptoms (pain, edema, ulcers)
- ✓ **VCSS, Villalta, CIVIQ-14, CIVIQ-20, VEINES QoL**
- ✓ **Failed** adequate conservative treatment (elevation, compression, exercise, antithrombotic therapy) with acceptable compliance
- ✓ Appropriate **ambulatory status**
- ✓ Reasonable **life expectancy**
- ✓ **Abnormal** iliofemoral axis on imaging

Indications: individualized approach

expect improvement
not
complete resolution of symptoms

Setting

Office-based lab (OBL) = [1,2] **Ambulatory surgery center (ASC)**

1. Aurshina A et al. Safety of vascular interventions performed in an office-based laboratory in patients with low/moderate procedural risk. J Vasc Surg. 2021 Apr;73(4):1298-1303.
2. Satwah I et al. Iliac vein stenting is safe when performed in an office based laboratory setting. J Vasc Surg Venous Lymphat Disord. 2022 Jan;10(1):60-67.

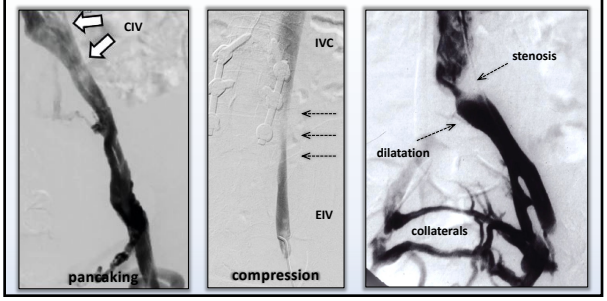
Anesthesia

General anesthesia = **Moderate sedation**

Access

- **Supine**
- **CFV / FV** (unless chronically occluded)
- **9-10F**
- **Heparin 60-100 U/kg**, ACT>250 sec

Venogram



Venogram

fails to detect >50% stenosis
in 1/4 patients

misses the exact location
in 2/3 patients

Gagne PJ, et al. Venography versus intravascular ultrasound for diagnosing and treating iliofemoral vein obstruction. J Vasc Surg Venous Lymphat Disord. 2017 Sep;5(5):678-687.

IVUS: the gold standard

25-30%
higher sensitivity
to detect significant lesions

10-15%
more accurate
estimate of severity

Gagne PJ, et al. Venography versus intravascular ultrasound for diagnosing and treating iliofemoral vein obstruction. J Vasc Surg Venous Lymphat Disord. 2017 Sep;5(5):678-687.

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Precise localization
of stenosis

Stent sizing

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Precise localization
of stenosis

Precise localization
of the iliac confluence

Stent sizing

Landing zones

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Precise localization
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Stent sizing

Landing zones

Reduces
contrast and radiation

Gagne PJ, et al. Venography versus intravascular ultrasound for diagnosing and treating iliofemoral vein obstruction. J Vasc Surg Venous Lymphat Disord. 2017 Sep;5(5):678-687.

IVUS: the gold standard

30-day patency
98.5% vs 89.4%
(P=.02)

2-year patency
90.3% vs 78.7%,
(P=.03)

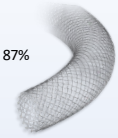
HR=0.22
95% CI: 0.07-0.71, P = .01

Tran LM et al. Intravascular ultrasound evaluation during iliofemoral venous stenting is associated with improved midterm patency outcomes. J Vasc Surg Venous Lymphat Disord. 2022 Nov;10(6):1294-1303.

Wallstent

Wallstent (Boston Scientific)

- FDA 2020
- Braided elgiloy closed cell
- Conformable / durable
- n=77
- Primary patency at 72 months – 87%



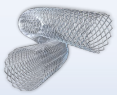
Gagne PJ, Gagne N, Kucher T, Thompson M, Bentley D. Long-term clinical outcomes and technical factors with the Wallstent for treatment of chronic iliofemoral venous obstruction. J Vasc Surg: Venous and Lymphatic Disorders . 2019;7:45e55.

Dedicated venous stents

Sinus-Obliquus (Optimed)

Sinus-XL (Optimed)

Blueflow (Plus Medica)



Sinus-XL Flex (Optimed)

Dedicated venous stents

Abre (Medtronic)

Venovo (BD)

Zilver Vena (Cook Medical)

DUO Hybrid / Extend (Philips)

Dedicated venous stents

Abre (Medtronic)

- FDA 2020
- Open cell
- Flexibility / conformability
- **ABRE study** (n=200)
- Primary patency at 12 months – 88%

Venovo (BD)

- FDA 2019
- Open cell, 3mm flared end
- Maximize apposition / prevent migration
- **VERNACULAR study** (n=170)
- Primary patency at 12 months – 89%

Zilver Vena (Cook Medical)

- FDA 2020
- Open cell
- Flexibility / minimal foreshortening
- **VIVO study** (n=35)
- Primary patency at 12 months – 88%

DUO Hybrid / Extend (Philips)

- FDA 2023
- Open cell
- Hybrid design (strength ---> flexibility)
- **VIVID study** (n=162)
- Primary patency at 12 months – 90%

Dedicated venous stents

Abre (Medtronic)

88%

Venovo (BD)

89%

Zilver Vena (Cook Medical)

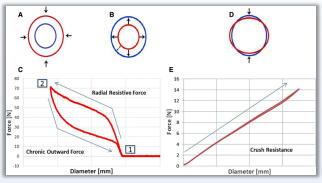
88%

DUO Hybrid / Extend (Philips)

90%

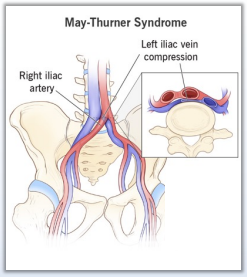
Mechanical properties are different

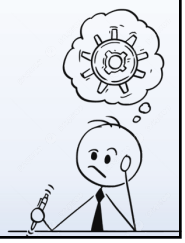
- **Crush resistance**
- **Chronic outward force**
- **Radial resistive force**



Dabir D. Physical Properties of Venous Stents: An Experimental Comparison. Cardiovasc Intervent Radiol. 2018 Jun;41(6):942-950.

How about the outcomes?





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Predilation to the intended stent diameter

allows **adequate stent expansion** after deployment

per IFU of most stents

serial dilatation may be required

can verify stent sizing

Stent sizing

From good **inflow** to good **outflow**

Maintain **deep femoral vein inflow**

Inflow **luminal area** on IVUS

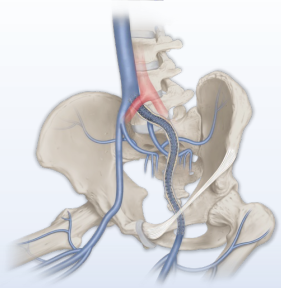
Distal to proximal, **overlap 2-3cm**

Minimal extension to IVC

Postdilation

the **maximal resistive force** of nitinol
is not achieved
until dilatation to its **nominal diameter**

Stenting across the inguinal ligament

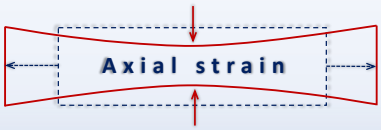


Venogram: post-stenting

Poisson's effect

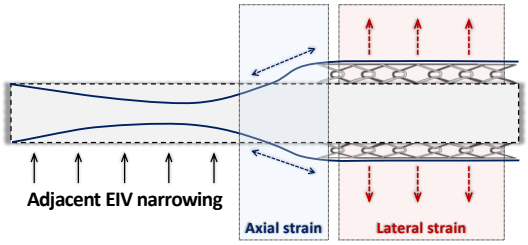
deformation of a vein wall perpendicular to the loading direction

$$\mu = \frac{d\varepsilon_{transverse}}{d\varepsilon_{longitudinal}} = \frac{\text{Lateral strain}}{\text{Axial strain}}$$



Maxim E. Shaydakov, MD PhD; Eric S. Hager, MD FACS; University of Pittsburgh Medical Center

Poisson's effect



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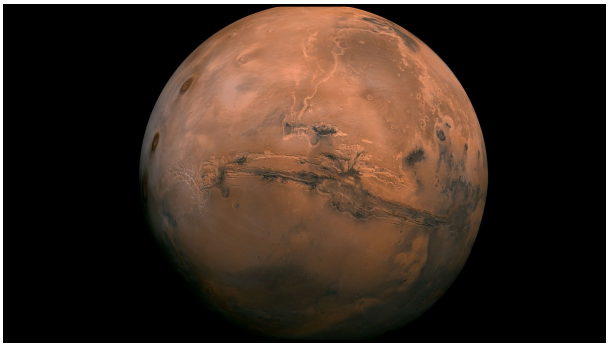
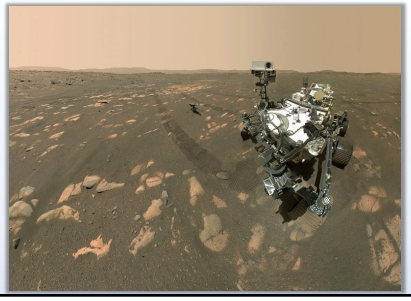
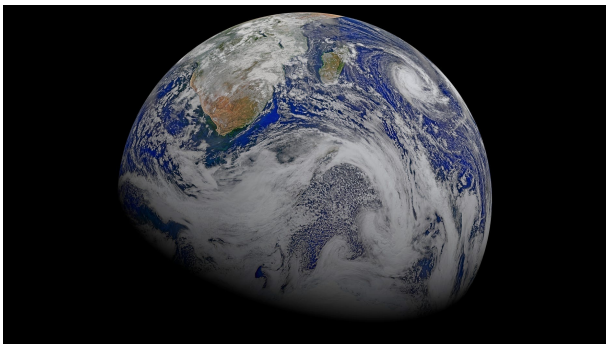


Mars 2020 Perseverance Rover





Antithrombotic therapy

<1 month **>12 months**

Antithrombotic therapy

<1 month **>12 months**

no therapy, Aspirin, Clopidogrel,
LMWH, Apixaban, Rivaroxaban, Dabigatran, Warfarin,
Dipiridamole, Acenocoumarol, Cilostazol… or any combination

Long-term patency (pooled data)

NIVL	PTS (non-occlusive)	PTS (occlusive)
>90%	~80%	<70%

Complications

- Back pain
- Stent migration (<60mm length, <14mm diameter)
- Acute thrombosis (residual stenosis, kinking, angulation, PTS, impaired inflow)
- In-stent restenosis / stent compression **~80%**

Snow C, Pappas S, Sulakvelidze L, Kennedy R, Lakhanpal S, Pappas PJ. Nitinol stents placed in iliac veins are not associated with prolonged back pain. Phlebology . 2023;38:44e50.
Gibson K. Iliac vein stenting: best practices for patient safety and successful outcomes. Endovascular Today . 2021.
Gagne PJ, Gagne N, Kucher T, Thompson M, Bentley D. Long-term clinical outcomes and technical factors with the Wallstent for treatment of chronic iliofemoral venous obstruction. J Vasc Surg: Venous and Lymphatic Disorders . 2019;7:45e55.

Limitations

- Most studies are retrospective
- High heterogeneity in design and outcomes evaluation
- High patient diversity (race, ethnicity, gender)
- Reflux not evaluated
- Compression therapy not reported
- Practice setting, volume… and more

Thank you!