Medtronic

Engineering the extraordinary

Redefining the management of Pelvic Venous Disorders

Let’s get started

Medtronic

Engineering the extraordinary

Redefining the management of Pelvic Venous Disorders

1 New SVP classification to precisely characterize PeVD

Find out more

2 New CVI guidelines with PeVD treatment recommendations

Find out more

3 Medtronic solutions to address PeVD patient needs

Find out more

Women can live with undiagnosed PeVD for many years

This could be because there are many conditions that PeVD can be mistaken for, due to several non-specific symptom

1. https://thewhiteleyclinic.co.uk/wp-content/uploads/The-Impact-of-Pelvic-Congestion-Syndrome-Report

Historical nomenclature failed to provide a unified and comprehensive framework to diagnose and characterize Pelvic Venous Disorders

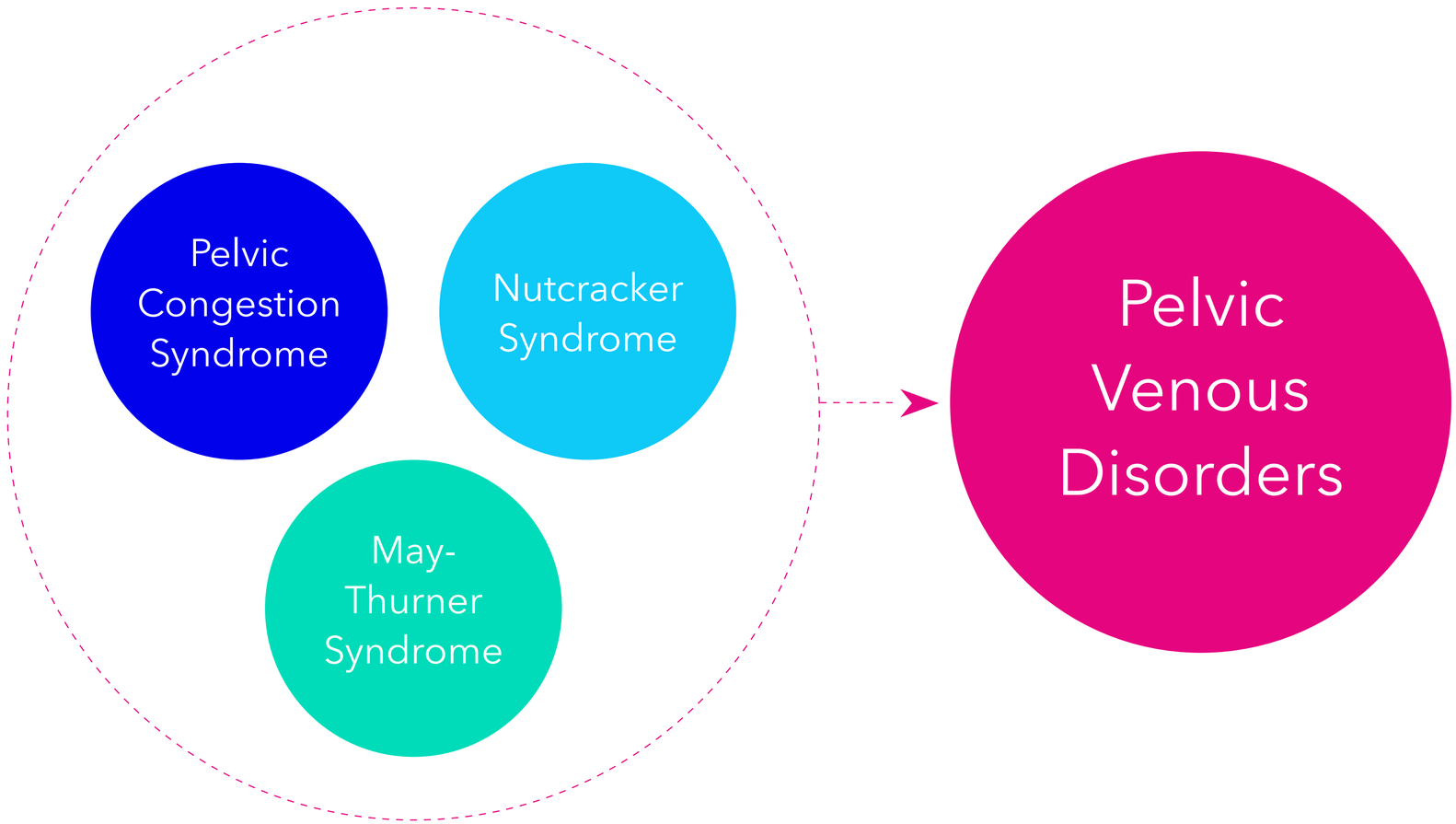
Misleading historical nomenclature, such as the **May-Thurner, pelvic congestion** and **nutcracker syndromes**, often fails to recognize the interrelationship of many pelvic symptoms and their underlying pathophysiology.

Historical nomenclature for pelvic venous disorders:

- Fails to recognize the **complex** and **interrelated pelvic venous circulation**
- Contributes to **misdiagnosis** and **poor treatment outcomes**
- Hinders **clinical research**

Source: Meissner MH, Khilnani NM, Labropoulos N, et al. The Symptoms-Varices-Pathophysiology classification of pelvic venous disorders: A report of the American Vein & Lymphatic Society International Working Group on Pelvic Venous Disorders. Phlebology. 2021;36(5):342-360. doi:10.1177/0268355521999559

A new classification supports the identification and characterization of Pelvic Venous Disorders (PeVD)



New SVP Classification

S: Symptoms

V: Varices

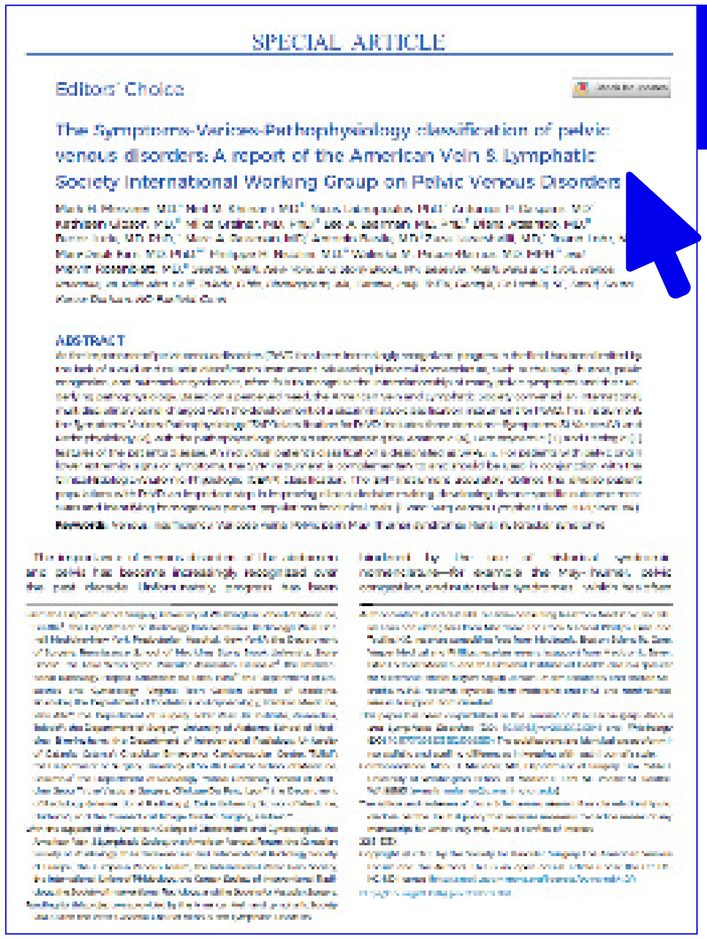
P: Pathophysiology
- A: Anatomy
- H: Hemodynamics
- E: Etiology

Source: Meissner MH, Khilnani NM, Labropoulos N, et al. The Symptoms-Varices-Pathophysiology classification of pelvic venous disorders: A report of the American Vein & Lymphatic Society International Working Group on Pelvic Venous Disorders. Phlebology. 2021;36(5):342-360. doi:10.1177/0268355521999559

The SVP classification was endorsed by vascular surgery and interventional radiology societies in both Europe and USA

SVS Society for Vascular Surgery

CIRSE Cardiovascular and Interventional Radiological Society of Europe

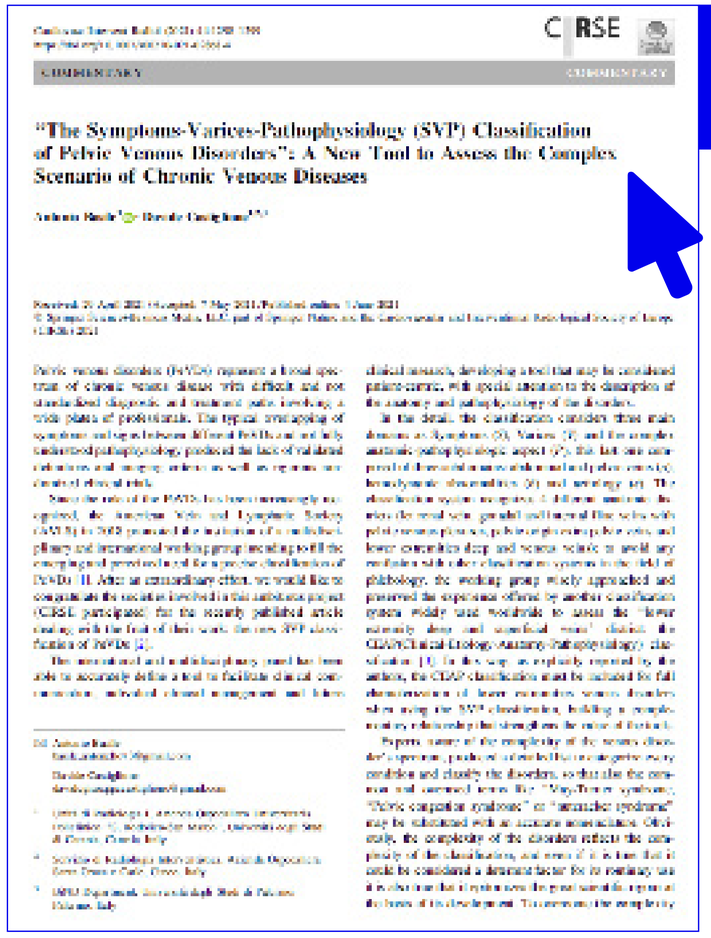

SPECIAL ARTICLE

Editors' Choice

The Symptoms-Varices-Pathophysiology classification of pelvic venous disorders: A report of the American Vein & Lymphatic Society International Working Group on Pelvic Venous Disorders

ABSTRACT

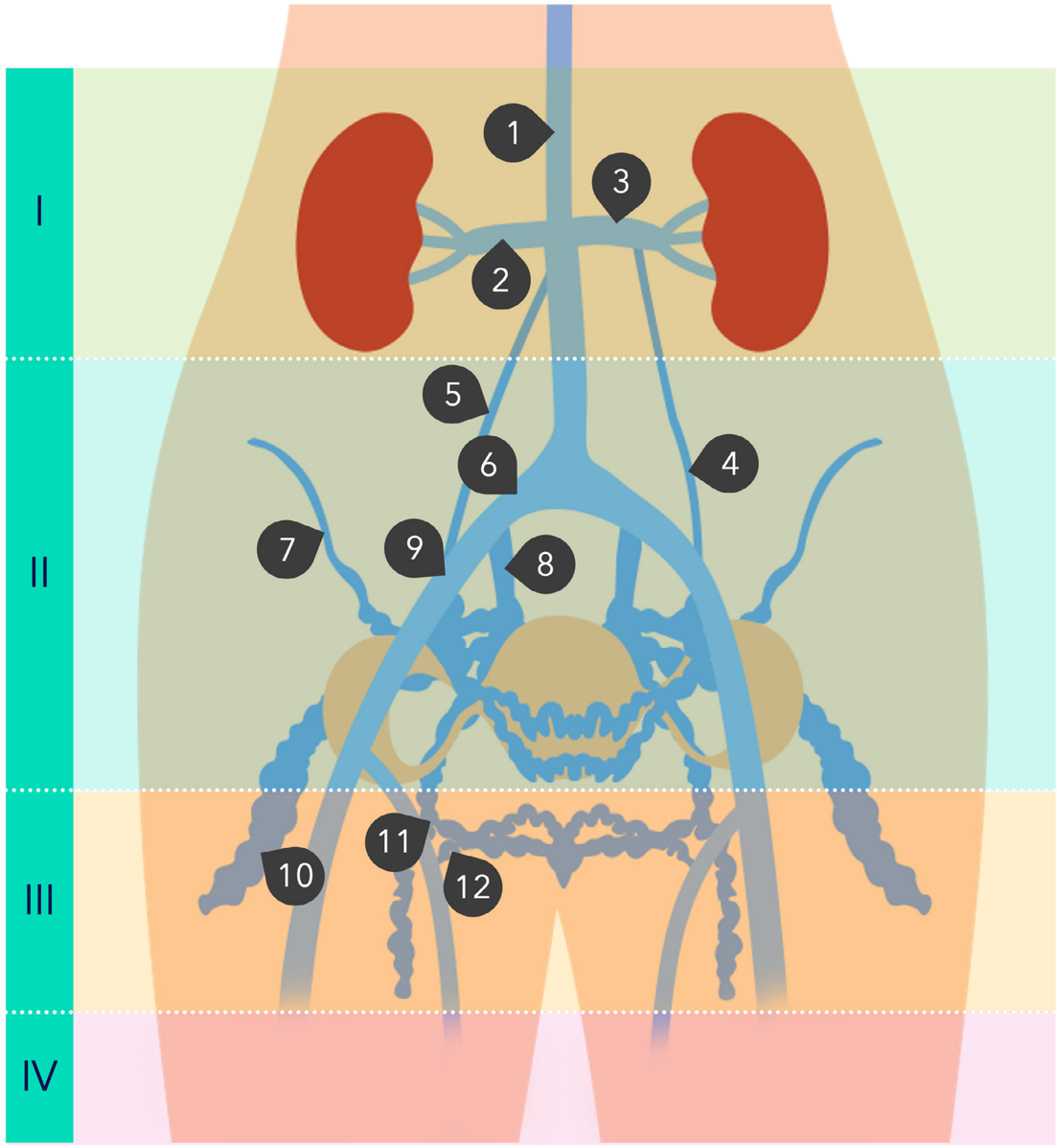
JAN 2021


"The Symptoms-Varices-Pathophysiology (SVP) Classification of Pelvic Venous Disorders": A New Tool to Assess the Complex Scenario of Chronic Venous Diseases

JUNE 2021

The SVP classification distinguishes between 4 anatomic zones

	Zone		Anatomical location	
Abdomen and pelvis	I	Left renal vein	1	Inferior vena cava
			2	Right renal
			3	Left renal
			4	Left ovarian
	II	Gonadal and internal iliac veins with pelvic venous plexuses	5	Right ovarian
			6	Common iliac
			7	Right superior gluteal
			8	Right internal iliac
			9	Right external iliac
	III	Pelvic origin extra-pelvic veins	10	Right inferior gluteal
			11	Right internal pudendal
			12	Right external pudendal
	IV	Lower extremity deep and superficial veins		



Source: Meissner MH, Khilnani NM, Labropoulos N, et al. The Symptoms-Varices-Pathophysiology classification of pelvic venous disorders: A report of the American Vein & Lymphatic Society International Working Group on Pelvic Venous Disorders. Phlebology. 2021;36(5):342-360. doi:10.1177/0268355521999559

The SVP classification precisely captures each aspect of PeVD by combining Symptoms, Varices and Pathophysiology related descriptors: Example

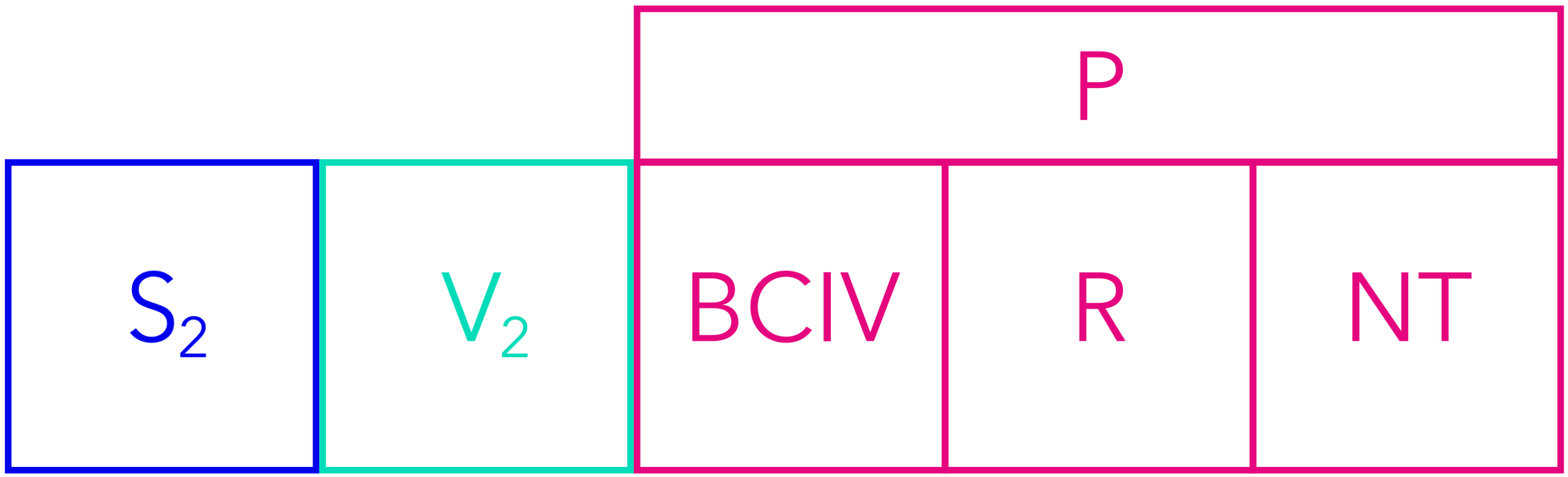
Symptoms (S)	
S_1	No symptoms of a PeVD (no renal, pelvic pr extrapelvic symptoms)
S_2	Renal symptoms of venous origin
S_3	Chronic pelvic pain of venous origin
A	Localized symptoms associated with veins of the external genitalia
B	Localized symptoms associated with pelvic origin, nonsaphenous veins of the leg*
C	Venous claudication*

Varices (S)	
No abdominal, pelvic, or pelvic origin extrapelvic varices on clinical or imaging examination	
V_1	Renal hilar varices
V_2	Pelvic varices
V_3	Pelvic origin extrapelvic varices
a	Genital varices (vulvar varices and varicocele)
b	Pelvic origin lower extremity varicose veins arising from the pelvic escape points and extending onto the thigh.*

Pathophysiology (P)					
Anatomy (A)		Hemodynamics (H)		Etiology (E)	
Abbreviation	Expansions				
IVC	Inferior vena cava	Obstruction (O)	Thrombotic or non-thrombotic (venous compression) venous obstruction	Thrombotic (T)	Venous reflux or obstruction arising from a previous episode of DVT
LRV	Left renal vein				
GV	Gonadal (testicular, ovarian) veins				
LGV	Left gonadal vein				
RGV	Right gonadal vein				
BGV	Bilateral gonadal veins				
CIV	Common iliac veins				
LCIV	Left common iliac vein			Non-thrombotic (NT)	Reflux arising from a degenerative process of the vein wall or proximal obstruction, obstruction arising from extrinsic compression
RCIV	Right common iliac vein				
BCIV	Bilateral common iliac veins				
EIV	External iliac veins	Reflux (R)	Thrombotic or non-thrombotic reflux	Congenital (C)	Congenital venous or mixed vascular malformations
LEIV	Left external iliac vein				
REIV	Right external iliac vein				
BEIV	Bilateral external iliac veins				
IIV	Internal iliac veins				
LIIV	Left internal iliac vein				
RIIV	Right internal iliac vein				
BIIV	Bilateral internal iliac veins			DVT	Deep vein thrombosis
PELV	Pelvic escape veins22 (“escape points”); inguinal, obturator, pudendal, and/or gluteal				

* Must include CEAP classification for full characterization or lower extremity varices.

The SVP classification precisely captures each aspect of PeVD by combining Symptoms, Varices and Pathophysiology related descriptors: Example



2022 CVI guidelines from ESVS

Taken from the European Society for Vascular Surgery (ESVS) 2022 Clinical Practice Guidelines on the Management of Chronic Venous Disease of the Lower Limbs

Recommendation 86	New
For patients with varicose veins of pelvic origin without pelvic symptoms requiring treatment, local procedures for varicose veins and related pelvic escape points should be considered, as initial therapeutic approach.	

Class	Level	References	ToE
IIa	C	Carston et al. (2007)	478
		Castonmillar et al. (2013)	480
		Hartung et al. (2015)	479
		Gavrilov et al. (2017)	471
		Delfrate et al. (2019)	477

Recommendation 87	New
For patients with varicose veins of pelvic origin without pelvic symptoms, pelvic vein embolization as initial treatment should not be performed.	

Class	Level	References	ToE
III	C	Carston et al. (2007)	478
		Castonmillar et al. (2013)	480
		Hartung et al. (2015)	479

Recommendation 88	New
For patients with varicose veins of pelvic origin with pelvic symptoms requiring treatment, pelvic vein embolization should be considered to reduce symptoms.	

Class	Level	References	ToE
IIb	B	Hartung et al. (2015)	479
		Champaneria et al. (2016)	476
		Brown et al. (2018)	475

Source: https://www.ejves.com/article/S1078-5884(21)00979-5/fulltext

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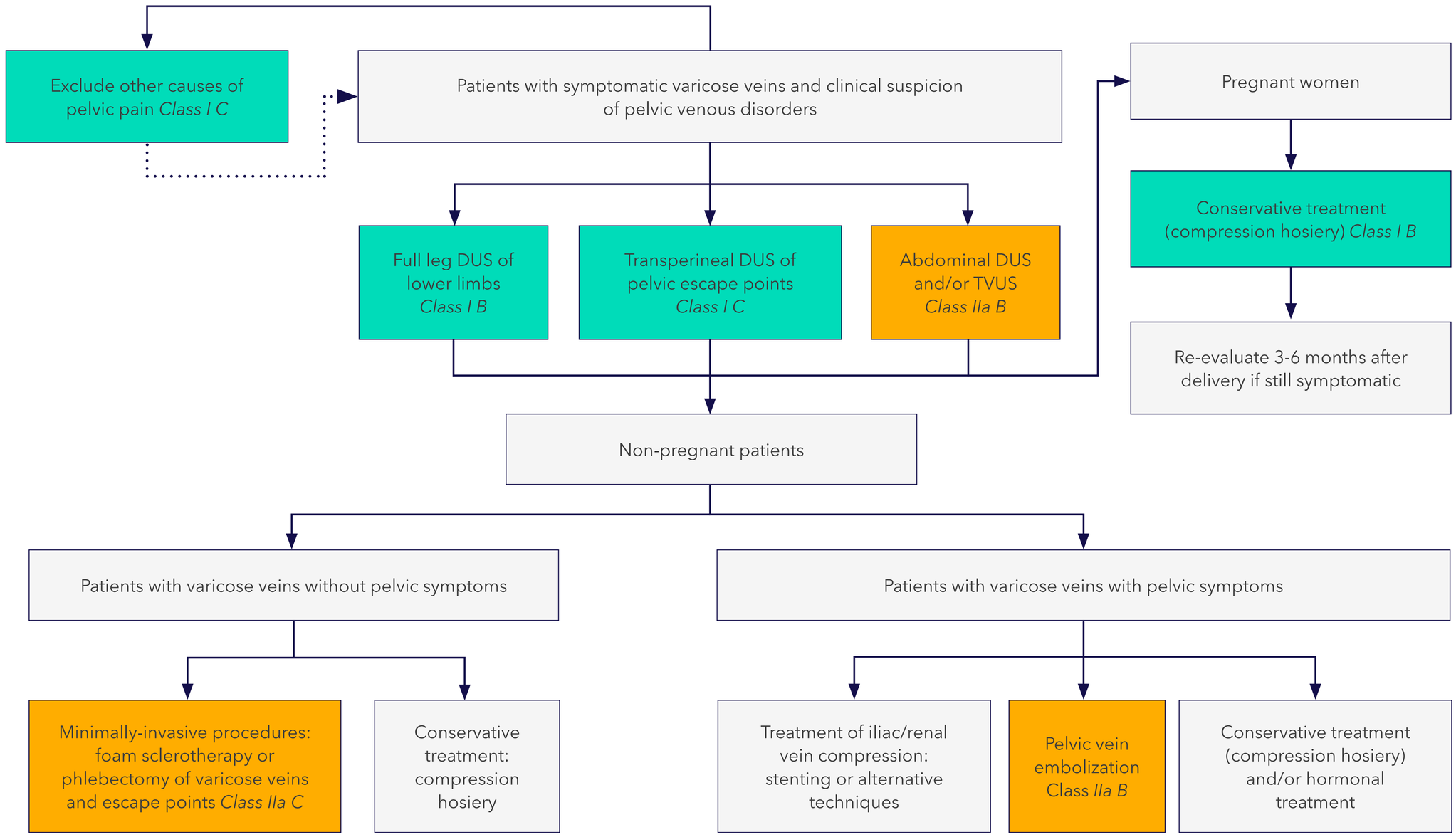


Figure 15: Management of patients with symptomatic varicose veins and clinical suspicion of pelvic venous disorders.
DUS = duplex ultrasound; TVUS = transvaginal ultrasoundSource: https://www.ejves.com/article/S1078-5884(21)00979-5/fulltext

2022 CVI guidelines from ESVS

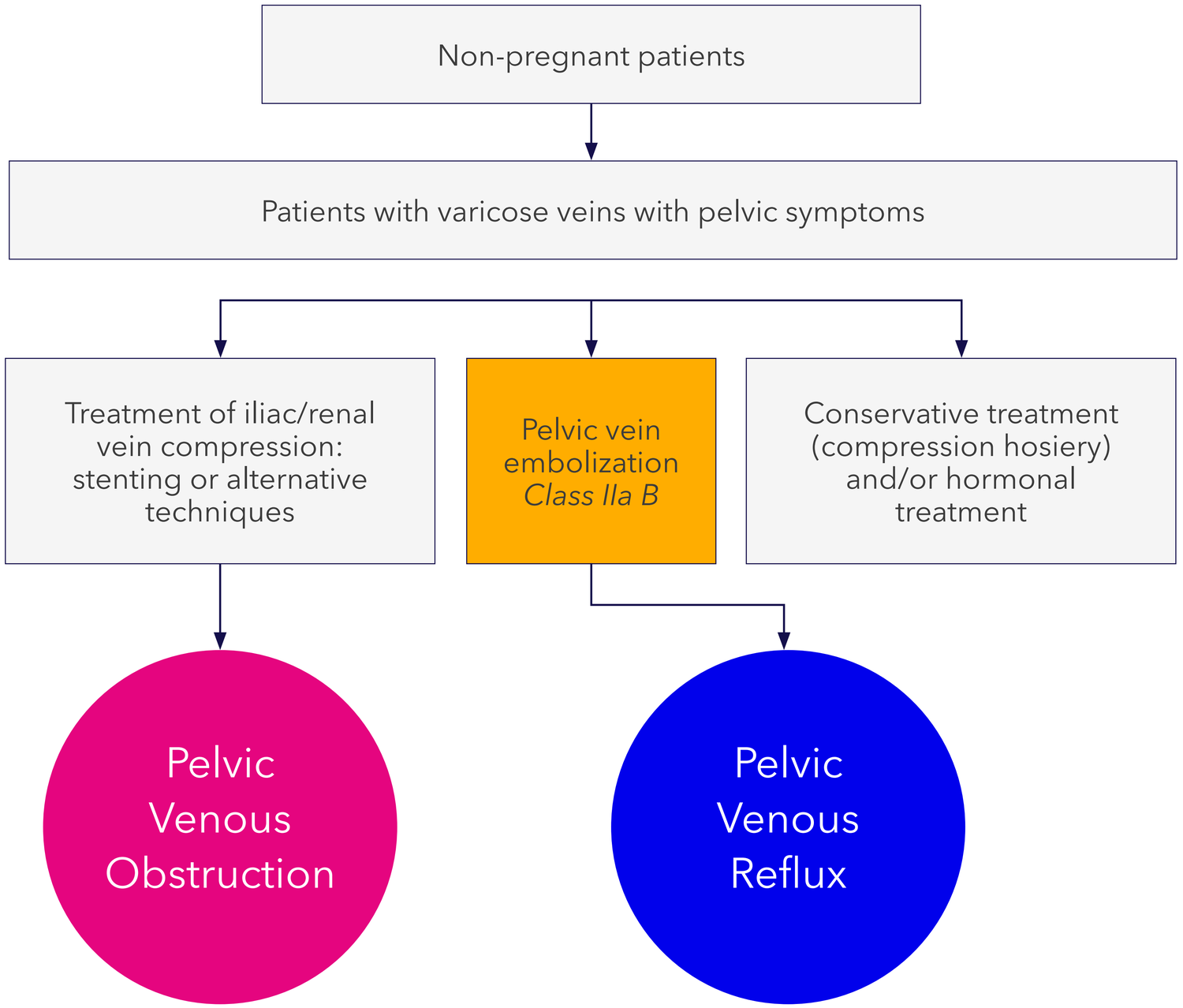
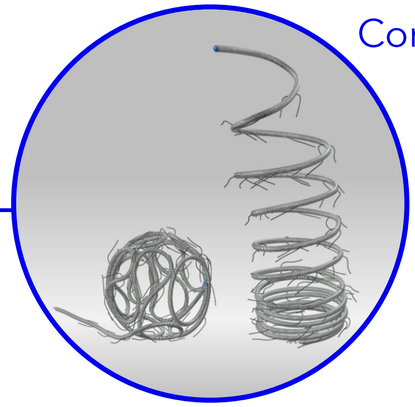


Figure 15: Management of patients with symptomatic varicose veins and clinical suspicion of pelvic venous disorders.
DUS = duplex ultrasound; TVUS = transvaginal ultrasoundSource: https://www.ejves.com/article/S1078-5884(21)00979-5/fulltext

Our solutions to treat each aspect of PeVD

Pelvic Venous Reflux

Onyx™



Concerto™

Pelvic Venous Obstruction

Abre™

Extrapelvic Varices

Genital

Lower extremity

VenaSeal™

ClosureFast™

Embolization of Pelvic Venous Reflux

Onyx™ Liquid Embolic System

The advantage of time, the power of control

- The Onyx™ Liquid Embolic System is an ethylene vinyl alcohol (EVOH) copolymer that provides complete filling and distal penetration[1] of peripheral lesions
- Its non-adhesive properties permit more distal nidus embolization without significant risk of catheter entrapment, while higher viscosities allow for controlled deployment[2]

1 Jose Urbano, MD, PhD Selective Arterial Embolization with Ethylene-Vinyl Alcohol Copolymer for Control of Massive Lower Gastrointestinal Bleeding: Feasibility and Initial Experience. J Vasc Interv Radiol. 2014.

2 Ricardo Yamada, Andre Uflacker. Austin Bourgeols. Joshua D. Adams. Marcelo Guimaraes. 'EVOH/DMSO In Peripheral Application' In Embolization Therapy: Principles and Clinical Applications, ed. Marcelo Guimaraes, Riccardo Lencioni, and Gary P. Siskin (Philadelphla, Wolters Kluwer, 2015), 582 pp

Embolization of Pelvic Venous Reflux

Concerto™ Detachable Coil System

Softness with smooth navigation

- Soft coils track easily through tortuous anatomy to access distal locations*
- Soft distal pusher reduces microcatheter kickback during deployment*

Enhanced thrombogenicity

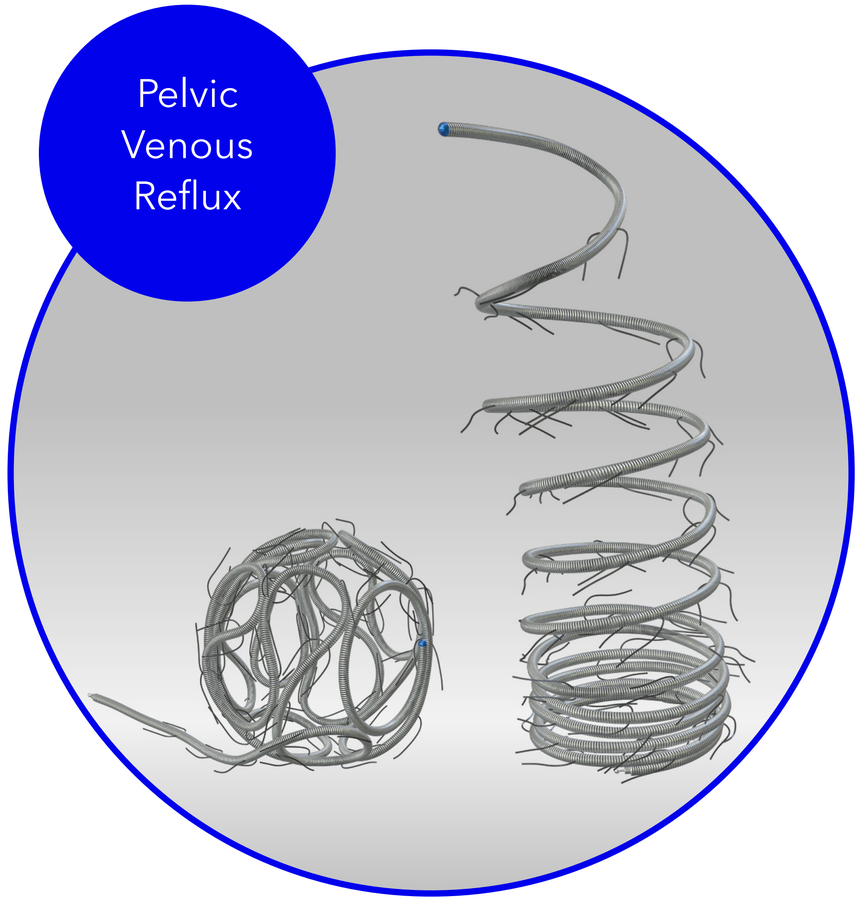
- Fibers increase thrombogenicity of the coil compared to bare metal equivalent[1]
- Nylon and PGLA fibers system features the unique LatticeFX™ technology which promotes thrombotic response1

Reliable deployment

- Fully re-sheathable, after complete or partial deployment, and is easily repositionable*
- Coil detaches instantaneously with proven reliability*

Optimal framing with a complex shape

- Conformable 3D shape with excellent stability*
- Designed to create a complex frame for filling*



* Medtronic internal reports: TR13-067 rev B / TR13-081 Rev A / TR12-054 REV A / TR14-061 Rev A / TR14-062 Rev A / TR14-065 Rev A.

1. Girdhar G.et al. In-vitro thrombogenicity assessment of polymer filament modified and native platinum embolic coils. Journal of the Neurological Sciences. 2014;339(1-2):97-101.

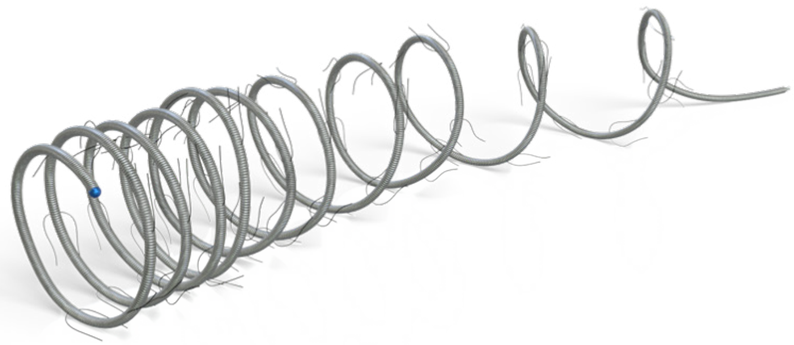
Embolization of Pelvic Venous Reflux with Onyx™ and Concerto™

incathlab

Case report

62-year-old woman with pelvic pain for 3-4 years

- Previous surgery for varicose veins in right leg
- Recurrence of pain in the groin
- A scan showed pelvic varices, mainly on the left
- Right femoral vein puncture performed
- Embolization performed with a combination of
  - **Onyx™** Liquid Embolic System
    and
  - **Concerto™** Detachable Coil System
- Procedure carried out under
  local anesthesia with same-day discharge



Embolization of Pelvic Venous Reflux with Onyx™ and Concerto™

incathlab

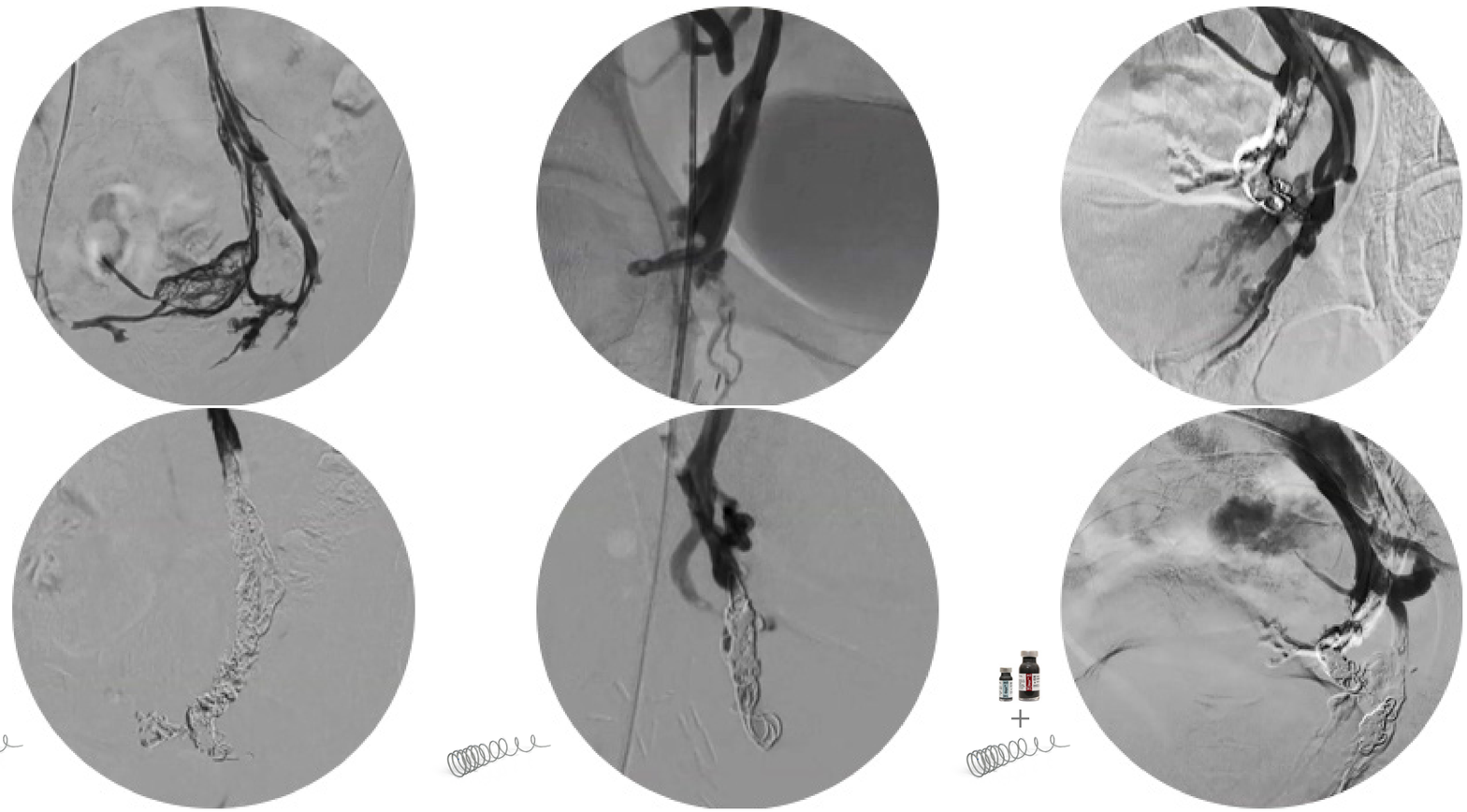
Case report

Left ovarian vein

Right ovarian vein

Left internal iliac vein

Before



After

Latest evidence in the treatment of PeVD with Onyx™

Objective

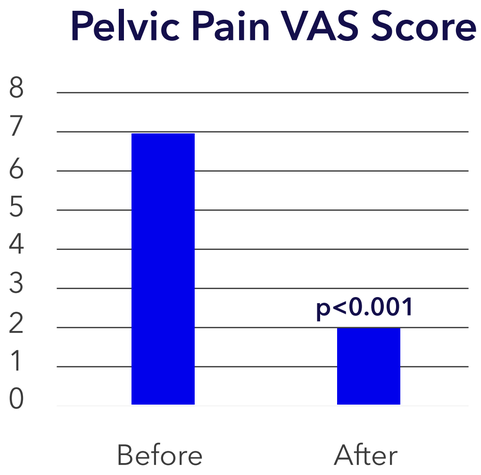
To evaluate clinical mid-term outcome of transcatheter embolization with Onyx™ in women with PeVD.

Results

92.4% patients achieved an improvement or disappearance of pain

80.9% Short-term success rate of embolization with Onyx™

95.8% patients achieved an improvement of QoL



Single center, retrospective study

327 consecutively-recruited patients with PeVD suspected pelvic congestion syndrome (PCS) or lower leg varices (LLV) >6 months

All patients underwent embolization with the **Onyx™ Liquid Embolic System**

Follow-up at 1, 6, and 12 months, and then annually for 5 years. Additional clinical data (pain relief and QoL) were collected via phone

Conclusions

Embolization of pelvic veins by using the Onyx™ technique and stent placement has been shown to be an **effective and safe technique, resulting in relevant clinical success with anoverall improvement of pain and QoL.**

Source: Sénéchal Q et al. "Endovascular Treatment of Pelvic Congestion Syndrome: Visual Analog Scale Follow-Up". Front. Cardiovasc. Med. 2021; 8 :751178

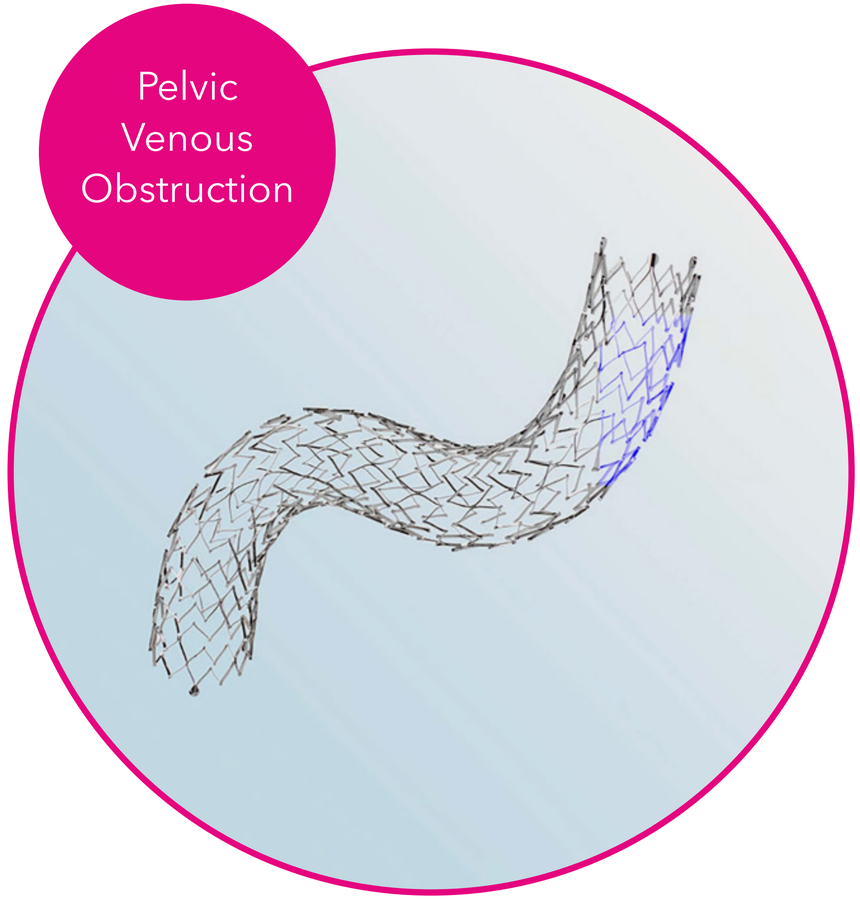
Venous Self-Expanding Stent System

Abre™

The Abre™ Venous Self-Expanding Stent system is designed for the unique challenges of venous disease. It offers easy deployment, to let physicians focus on their patient, and delivers demonstrated endurance, to give patients freedom of movement.[1,2]

The ABRE clinical study demonstrates the safety and effectiveness of the Abre™ Venous Stent.[1]

- 88% primary patency at 12 months*
- 98% freedom from MAEs at 30 days†
- 0% fracture rate at 50 years in bench testing[2]
- 0% fracture rate in clinical trial with 44% of stents extending below inguinal ligament into the CFV[1]



1. ABRE CSR v1.2 30/JUL/2020.
2. Test data on file at Medtronic. Report 10558227DOC_Rev A. Bench test results may not be indicative of clinical performance.
* Primary Patency was defined as meeting all of the following criteria at 12 months post-procedure: Freedom from occlusion or restenosis ≥ 50% of the stented segment of the target lesion and freedom from clinically driven target lesion revascularization.
† MAEs included all-cause death, clinically significant pulmonary embolism, procedural major bleeding complication, stent thrombosis, and stent migration. MAEs were adjudicated by a Clinical Events Committee, except stent thrombosis and stent migration, which were assessed by an imaging core laboratory.

Case study

incathlab

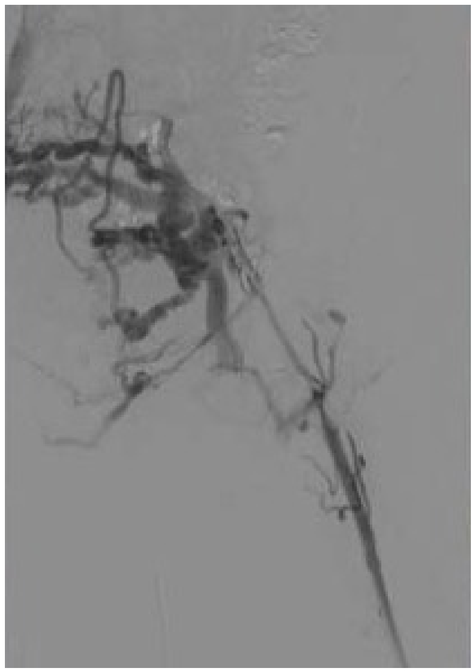
Recanalization of an ilio-femoral chronic venous obstruction

Abre™

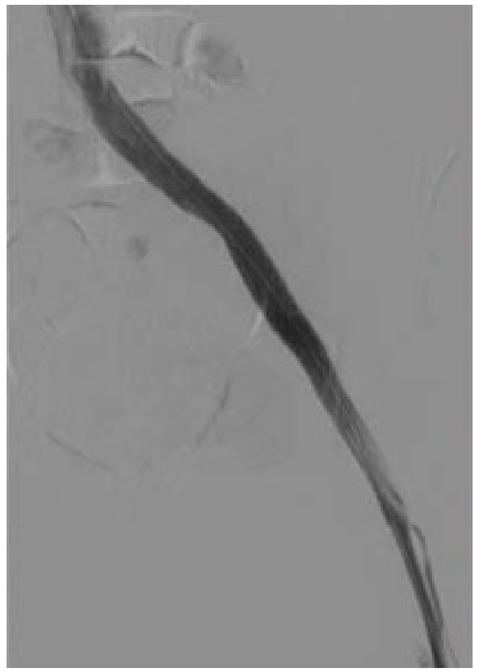
33-year-old woman with left ilio-femoral descending DVT for 2 years

- Pain, swelling, tension and venous claudication (Villalta score 14)
- Chronic obstruction of the left common iliac vein, external iliac vein
- Non obstructive synechiae at the common femoral vein
- No involvement of the femoral and deep femoral vein (good inflow)
- Abdominal collaterals
- Procedure performed under local anesthesia
- Two Abre™ Stents were deployed:
  - 14mm x 150mm
  - 12mm x 80mm

Before



After



Medtronic solutions for lower extremity varices

ClosureFast™

The ClosureFast™ Procedure, with its patented overlap design, is the only RFA procedure with published long-term clinical data demonstrating safety and efficacy, with a 91.9% closure rate at 5 years.[1–2]

1. Proebstle TM, Alm BJ, Göckeritz O, et al. Five-year results from the prospective European multicentre cohort study on radiofrequency segmental thermal ablation for incompetent great saphenous veins. Br J Surg. February 2015;102(3):212-218.
2. ClosureFast and ClosureFast RFS Patents. Available at www.medtronic.com/patents. Accessed March 9, 2021.

VenaSeal™

Reach new lengths and treat more diseased vein with VenaSeal™ Closure System. The VenaSeal™ Closure System delivers immediate and lasting vein closure with its proprietary medical adhesive formula, with a demonstrated 94.6% closure rate at 5 years.[3-7]

3. Morrison N, Gibson K, McEnroe S, et al. Randomized trial comparing cyanoacrylate embolization and radiofrequency ablation for incompetent great saphenous veins (VeClose). J Vasc Surg. April 2015;61(4):985-994.
4. Proebstle T, Alm J, Dimitri S, et al. Three-year follow-up results of the prospective European Multicenter Cohort Study on Cyanoacrylate Embolization for treatment of refluxing great saphenous veins. J Vasc Surg Venous Lymphat Disord. March 2021;9(2):329-334.
5. Gibson K, Ferris B. Cyanoacrylate closure of incompetent great, small and accessory saphenous veins without the use of post-procedure compression: Initial outcomes of a post-market evaluation of the VenaSeal System (the WAVES Study). Vascular. April 2017;25(2): 149-156.
6. Almeida JI, Javier JJ, Mackay EG, Bautista C, Cher DJ, Proebstle TM. Thirty-sixth month follow-up of first-in-human use of cyanoacrylate adhesive for treatment of saphenous vein incompetence. J Vasc Surg Venous Lymphat Disord. September 2017;5(5):658-666.
7. Morrison N, Gibson K, Vasquez M, Weiss R, Jones A. Five-year extension study of patients from a randomized clinical trial (VeClose) comparing cyanoacrylate closure versus radiofrequency ablation for the treatment of incompetent great saphenous veins. J Vasc Surg Venous Lymphat Disord. November 2020;8(6):978-989.

Redefining the management of Pelvic Venous Disorders

The new SVP classification encapsulates historical syndrome nomenclatures into one framework that supports the precise characterization of PeVD patients

The SVP classification was endorsed by the main Vascular Surgery and Interventional Radiology Societies and included in the 2022 CVI guidelines from ESVS

It enables a better targeted and more holistic treatment approach that may include embolization, stenting, and superficial procedures

Our comprehensive set of proven solutions addresses the varied therapeutic needs of PeVD patients, including embolization and venous stenting

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