On Which Criteria Do You Select Your Stent for Ilio-femoral Venous Obstruction?

North American Point of View

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CONTROVERSIES & UPDATES IN VASCULAR SURGERY

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MAYO CLINIC

Conflict of Interest

None

Venous Thromboembolism

- Incidence: 1 per 1000 in the US, increases with age
- ~ 201,000 first life-time cases diagnosed annually
- 7 day mortality is 25%

Iliofemoral Venous Thrombosis

- **Incidence:**

  1 in 10,000 of the population/year

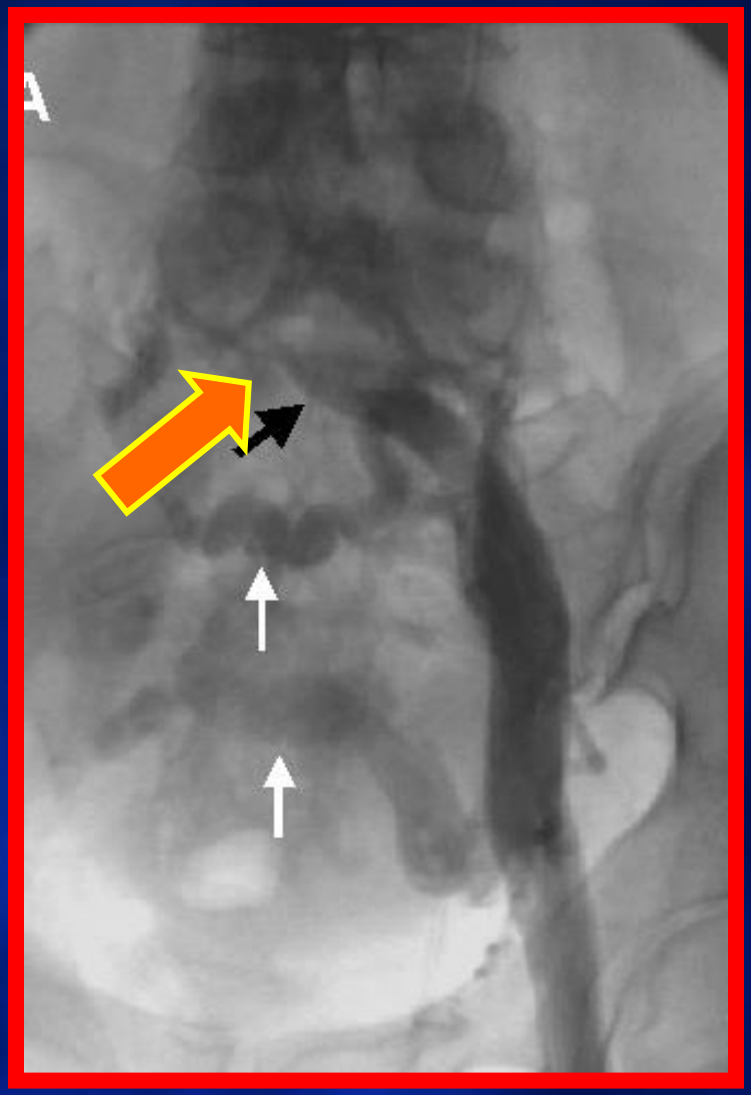
- **Post-thrombotic syndrome:**

  25% of patients, even with anticoagulation and compression stockings

Criteria for Stents in Iliofemoral Venous Obstruction

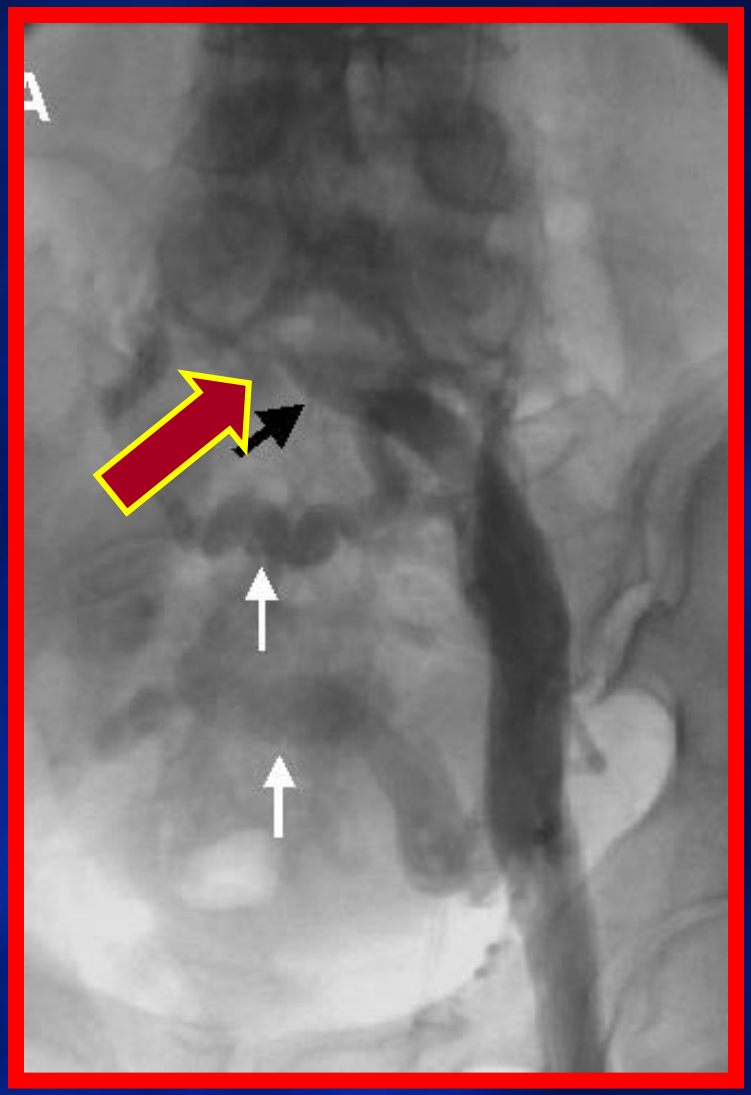
- Etiology
- Clinical presentation
- Anatomy
- Risks/benefits of endovascular intervention

Etiology



- Acute iliofemoral deep vein thrombosis
  - With or without May-Thurner Syndrome
  - Stent thrombosis

Etiology



- Acute iliofemoral deep vein thrombosis
  - With or without May-Thurner Syndrome
  - Stent thrombosis
- Chronic obstruction
  - Non-thrombotic iliac vein stenosis or occlusion (May-Thurner Syndrome)
  - Chronic post-thrombotic occlusion
  - Chronic occlusion of iliac or ilio-femoral stent

Clinical Presentation

- Acute
  - Pain
  - Leg swelling
  - Phlegmasia alba/coerulea dolens

Clinical Presentation

- Acute
  - Pain
  - Leg swelling
  - Phlegmasia alba/coerulea dolens
- Chronic
  - Pain
  - Swelling
  - Venous claudication
  - Abdominal wall, lower extremity and suprapubic varicosity
  - Skin changes, venous ulcerations
  - Symptoms of pelvic venous congestion

Anatomy

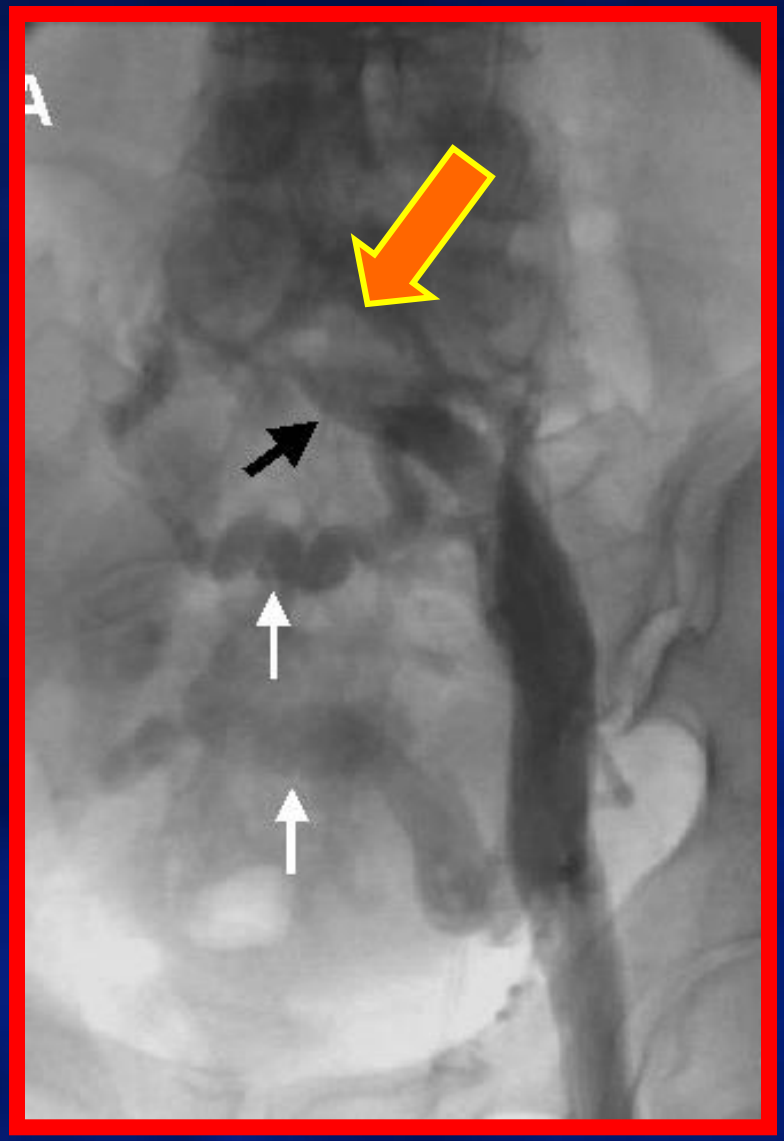
- Inflow
- Outflow
- Obstruction
  - can be crossed
  - can be dilated

Anatomy

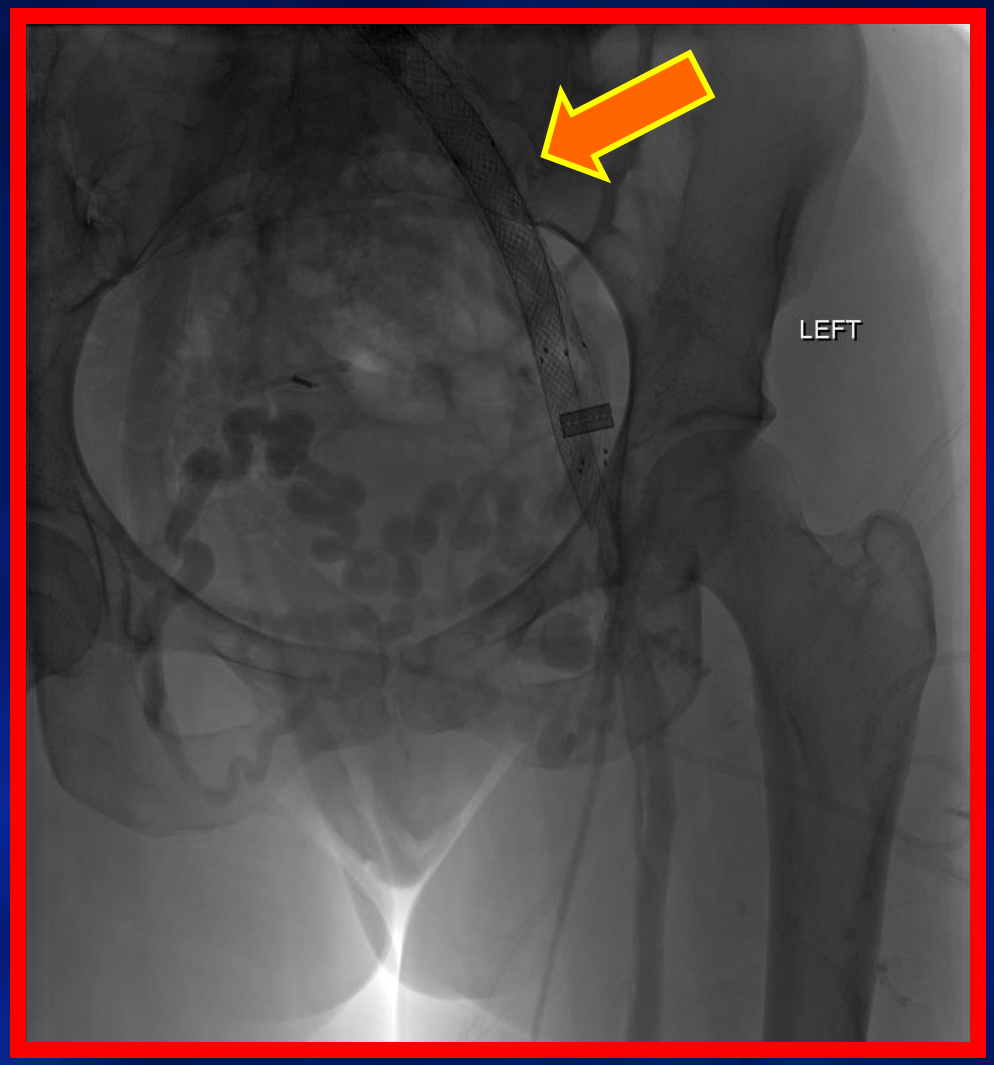
Anatomy

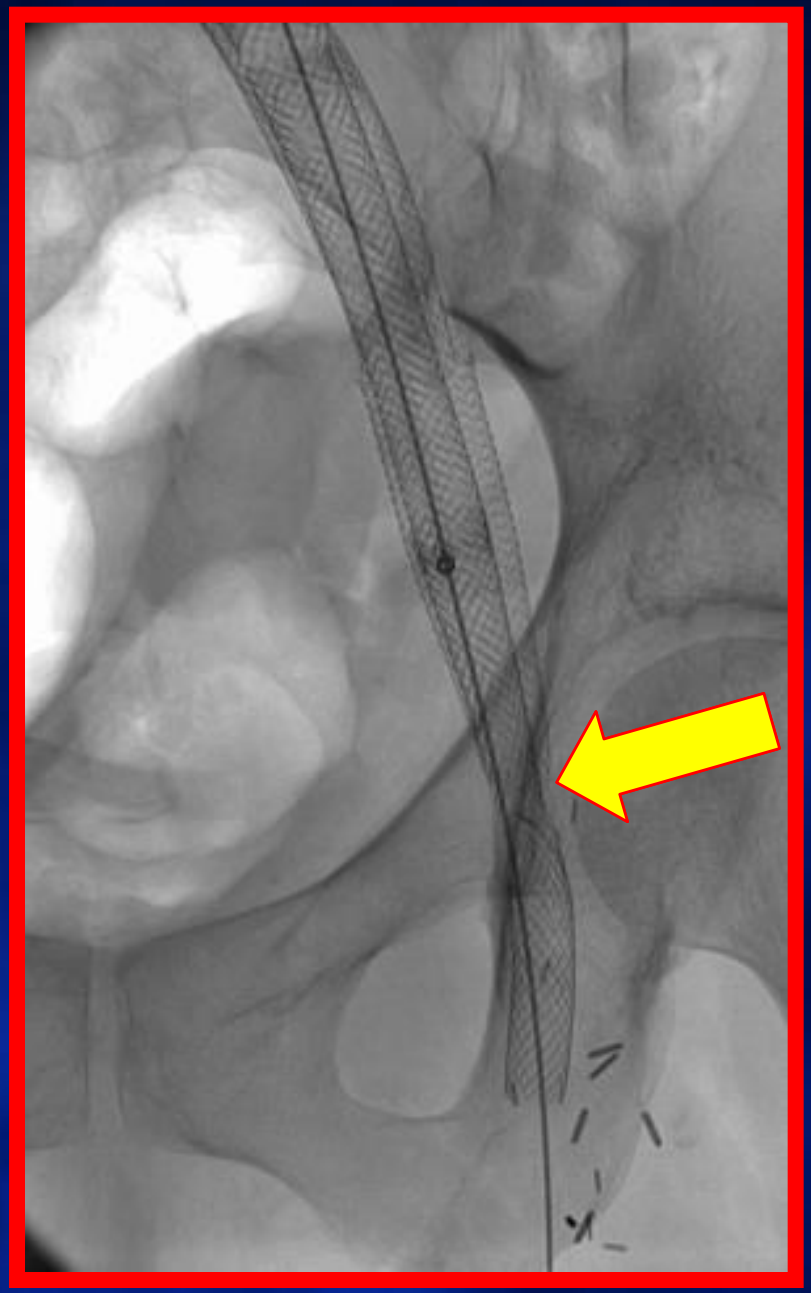
Anatomy

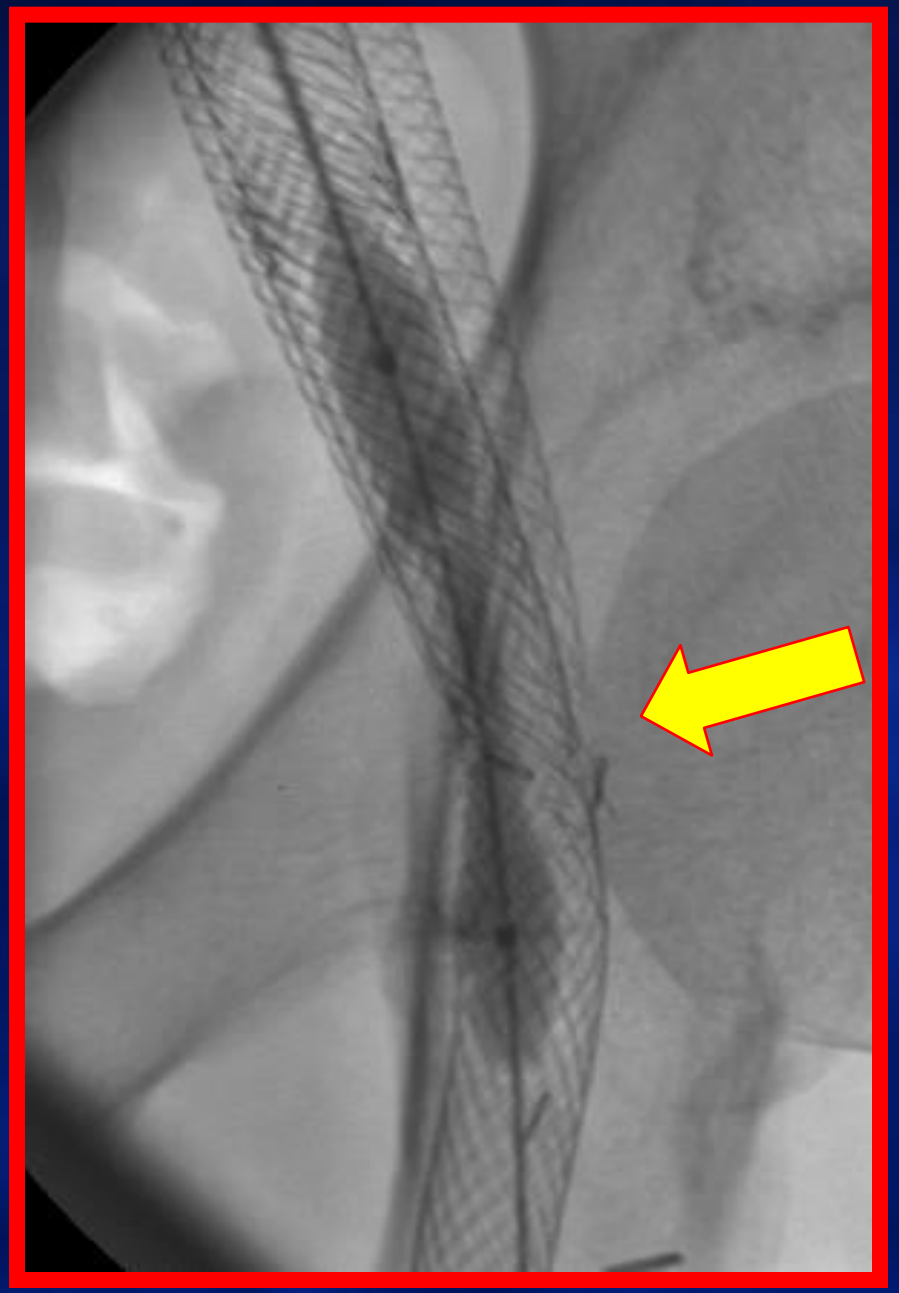
Anatomy



Anatomy







Patient Selection for Stenting

- Good inflow to common femoral vein or
  - Endophlebectomy with patch angioplasty
  - Stenting of the profunda femoris vein

Increased Risks of Intervention

- Chronic renal failure
- Underlying thrombophilia
- Sedentary or bedridden patient
- High cardiac and pulmonary risk
- Retroperitoneal fibrosis
- Previous radiation
- Previous stenting

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 R...lts—We searched MEDLINE and EMBASE for studies evaluating safety or effectiveness of stent placement in patie... ...femoral venous outflow obstruction. Data were extracted by disease pathogenesis: nonthrombotic, acute throm... ...post-thrombotic. Main outcomes included technical success, periprocedural complications, symptom relief at ... ...ary/secondary patency through 5 years. A total of 37 studies reporting 45 treatment effects ... patients (nonthrombotic, 1... success rates were compar... among groups for major ... mortality, and from 1.0% ... year, primary and seconda... and 94% for chronic post-...

Conclusions—Stent placeme... complication rates regar...

CIRCINTERVENTION...

37 studies, 2869 patients

(nonthrombotic, 1122; acute thrombotic, 629; and chronic post-thrombotic, 1118)

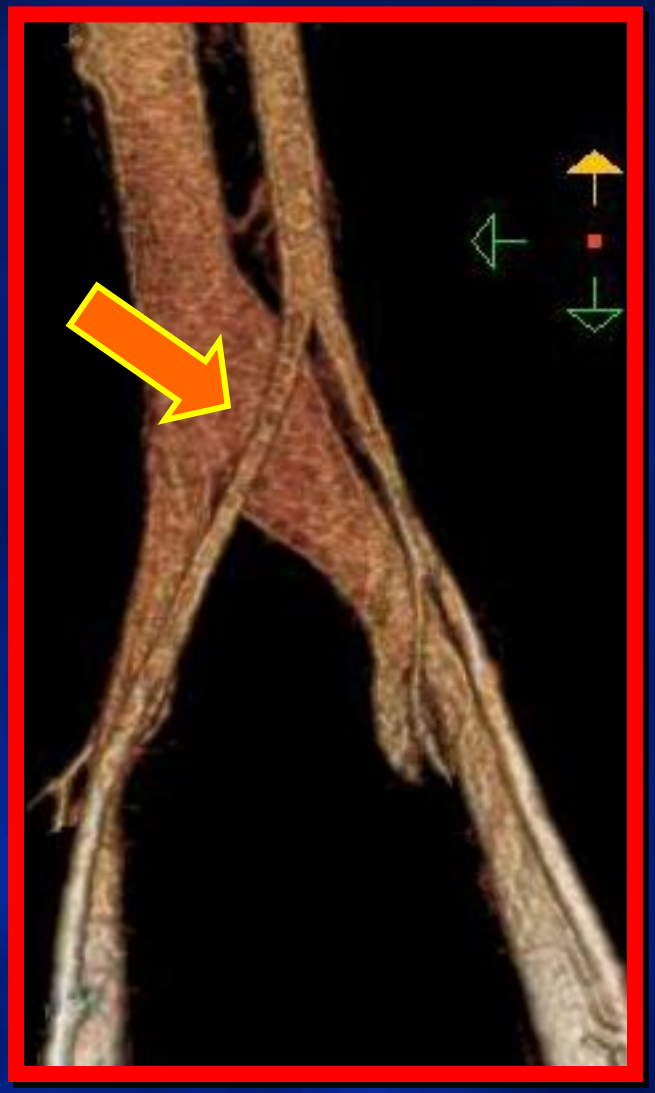
Technical success rates: 94% - 96%

- **Periprocedural mortality: 0.1% - 0.7%**
- **Early thrombosis: 1.0% to 6.8%**
- **Major bleeding: 0.3% - 1.1%**
- **Pulmonary embolism: 0.2% - 0.9%**

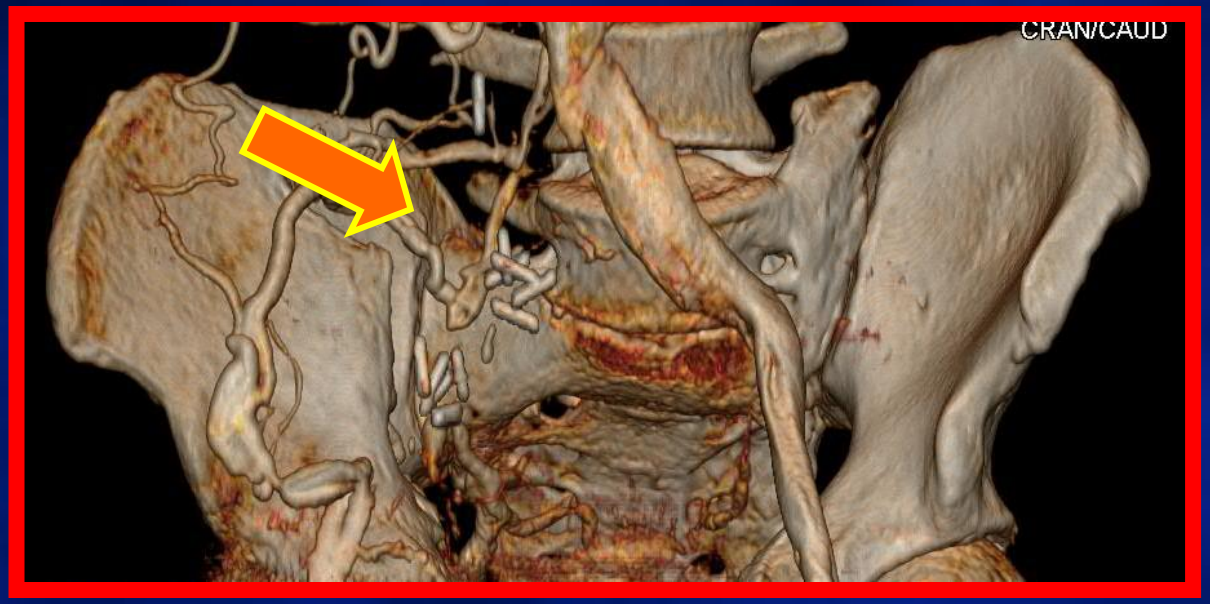
Preoperative Diagnostic Evaluation

- Duplex scanning
- Magnetic resonance venography
- Computed tomographic venography
- Direct contrast venography with venous pressure measurements
- Intravascular Ultrasound (IVUS)

MRV



CTV



May – Thurner Syndrome

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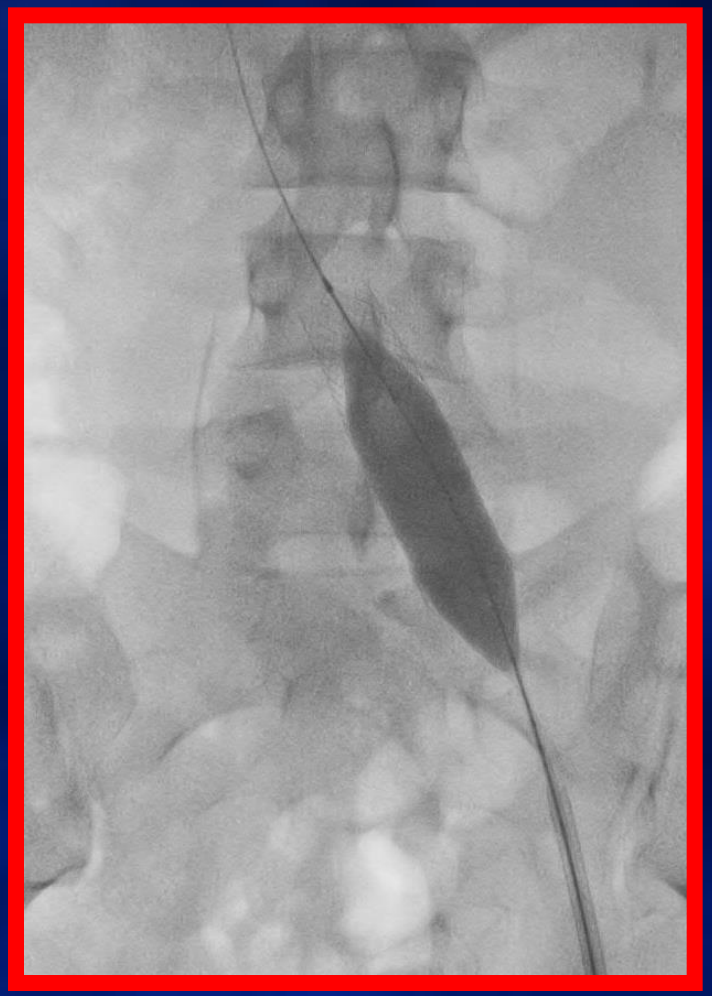
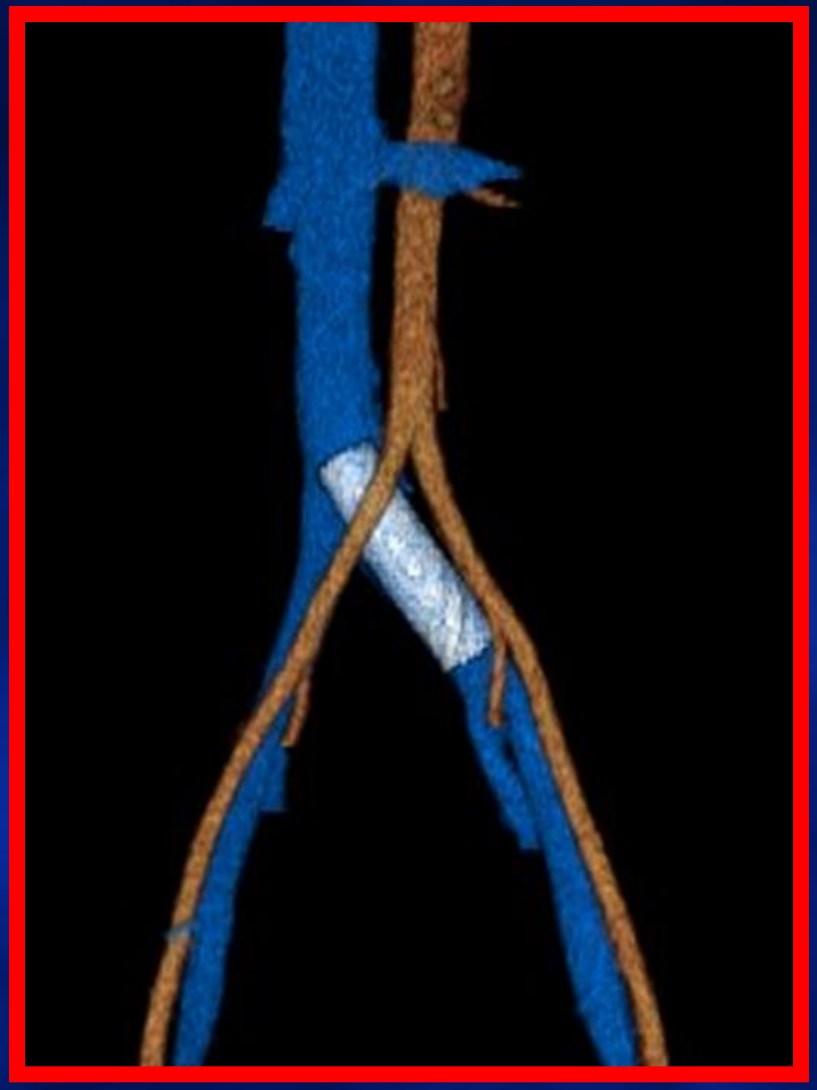
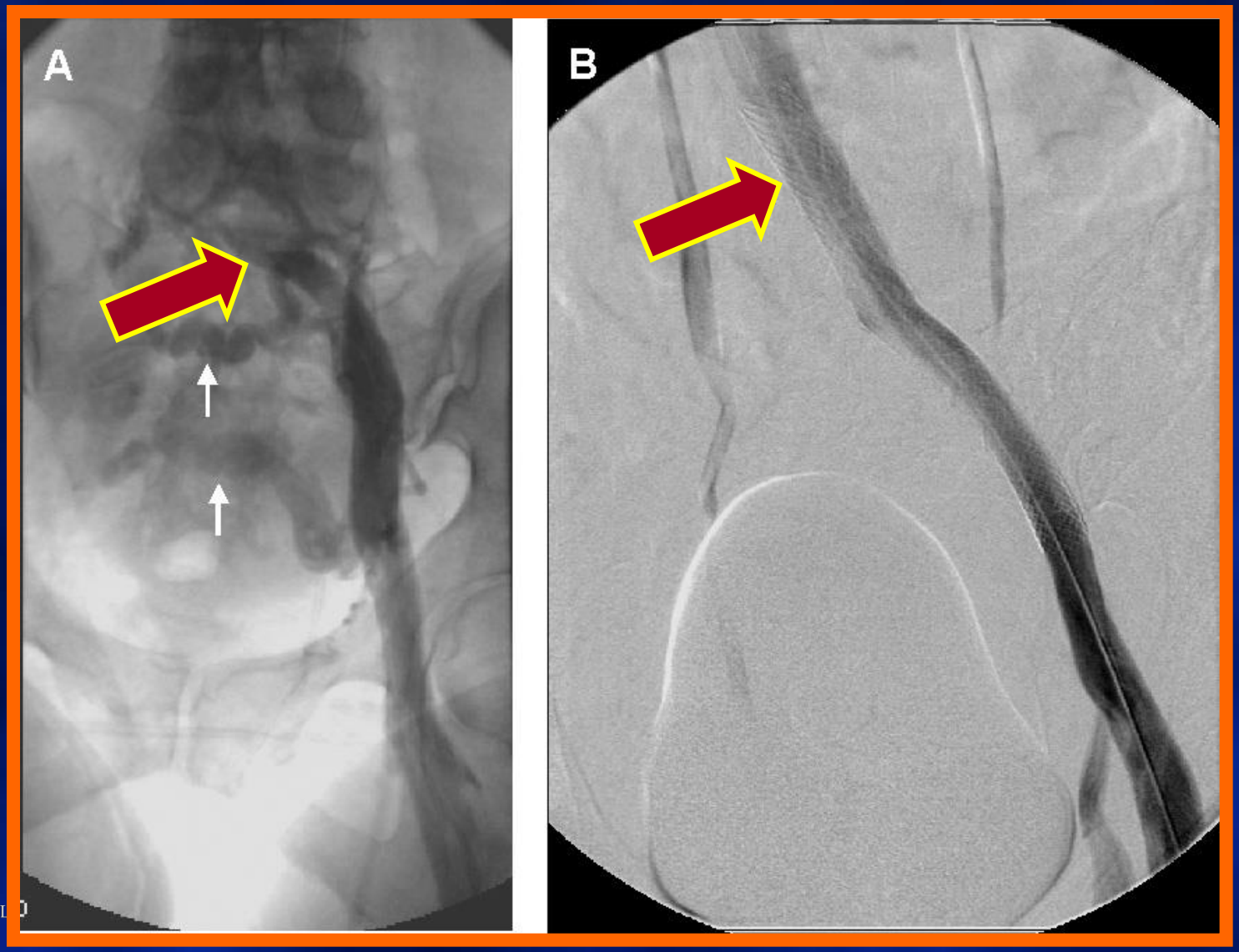


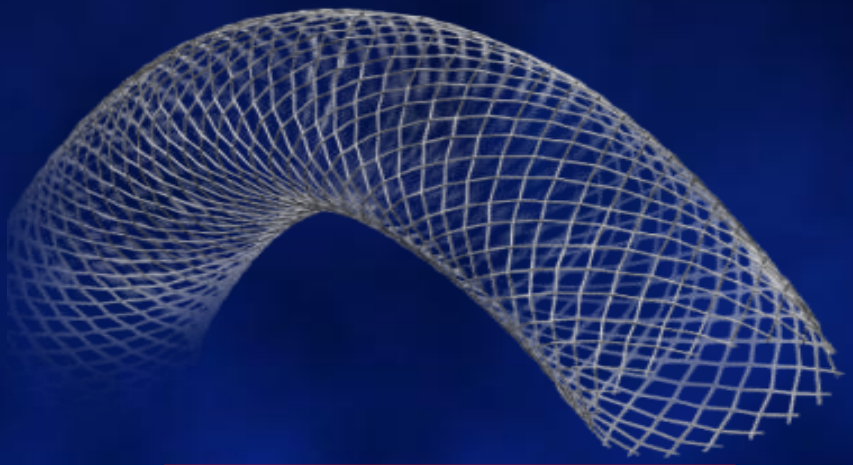
May – Thurner Syndrome



Stents

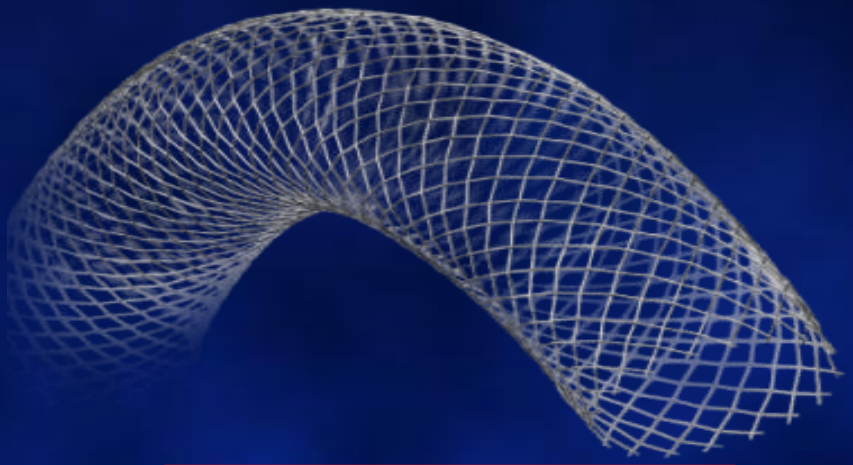


Current Commercially Available Stents



Wallstent
Boston Scientific
Marlborough, MA

Current Commercially Available Stents



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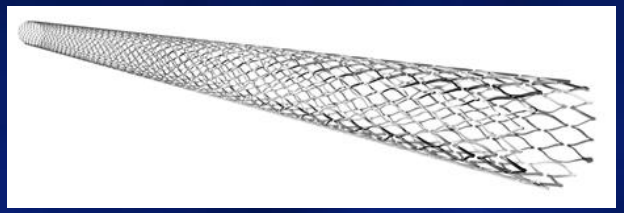
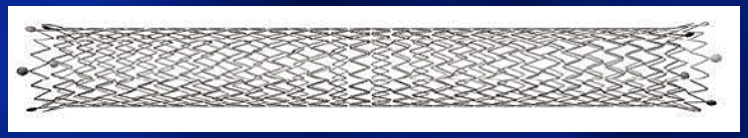
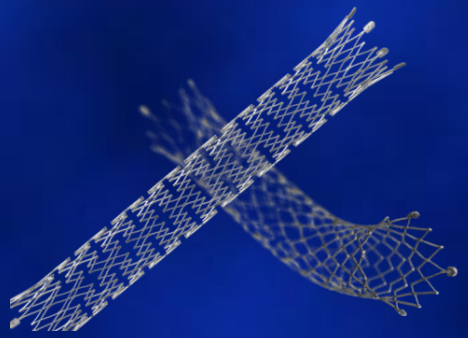


Protégé
ev3, Plymouth, MN

Gianturco Z-Stent
Wilson-Cook Medical
Winston-Salem, NC

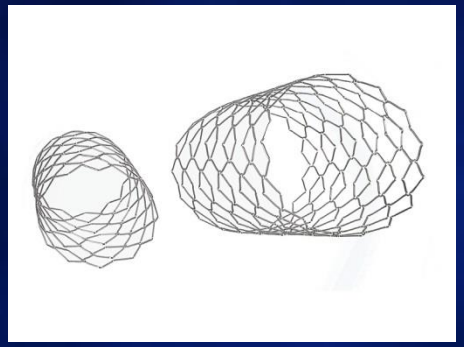


Smart
Cordis Endovascular
Warren, NJ



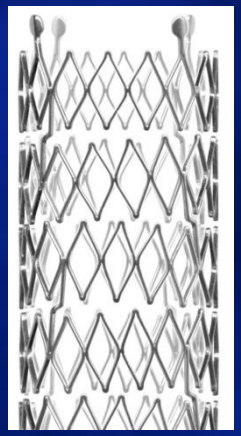
Luminexx
Angiomed/Bard
Karlsruhe, Germany

Stents in Europe



AndraStent
Reutlingen, Germany

Sinus-XL



Sinus Venous stent

Optimed, Ettlingen, Germany

Two ongoing iliofemoral stent RCTs

To assess safety and efficacy

VICI™ Venous Stent System
VENITI INC., St. Louis, MO

Zilver Vena stent
Cook Inc., Bloomington, IN

- **The Veniti VIRTUS study**

  Symptomatic patients with non-malignant iliofemoral venous obstruction

- **Zilver Vena VIVO Study**

  Symptomatic patients with iliofemoral venous obstruction

Results from United States
Single center

Author, year	Study period	Stented segment	No of patients/ limbs	Type of stents	Technical success (%)	Follow-up (month) (range)	Year	PP (%)	PAP (%)	SP (%)
Neglén, 2007	1997-2005	Iliofemoral and caval	870/982	Wallstent Other nitinol stents	--	22 (1-107)	6* 6†	79 57	100 80	100 86
Titus, 2011	2005-2009	Iliofemoral	36/40	--	--	10.5 (0-38)	0.5 1 2	88 78 78	93 83 83	100 95 95
Kurklinsky, 2012	2003-2008	Iliofemoral	87/91	Wallstent Other nitinol stents	100	11.3 (0.8-72)	1 3	81 71	94 90	95 95

*: non-thrombotic disease; †:thrombotic disease

Results from European Countries
Single center

Author, year, country	Study period	Stented segment	No of patients/ limbs	Type of stents	Technical success (%)	Follow-up (month) (range)	Year	PP (%)	PAP (%)	SP (%)
Oguzkurt, 2008 Turkey	2003-2006	Iliofemoral	36/36	Wallstent Protégé	94	18 (3-48)	1 4	85 80	-- --	94 82
Hartung, 2009 France	1996-2008	Iliocaval	89/89	Wallstent	98	38 (1-144)	1 3 10	89 83 83	94 89 89	96 93 93
Rosales, 2010 Norway	2000-2009	Femoroiliocaval	34	Wallstent	94	33 (1-196)	2	67	76	90
de Graaf, 2015 The Netherlans	2009-2014	Biiliocaval	40/40	Sinus XL Sinus venous Zilver Vena Andrastent	100	15 (0.2-56)	1 3	79 70		908 2 73 78
de Wolf, 2015 Germany	2012-2014	Iliofemoral	75/75	Sinus venous	100	5.4 (1-18)	0.25 0.5 1	99 96 92	99 99 99	100 100 100

PP, primary patency; ***PAP,*** primary assistant patency; ***SP,*** secondary patency

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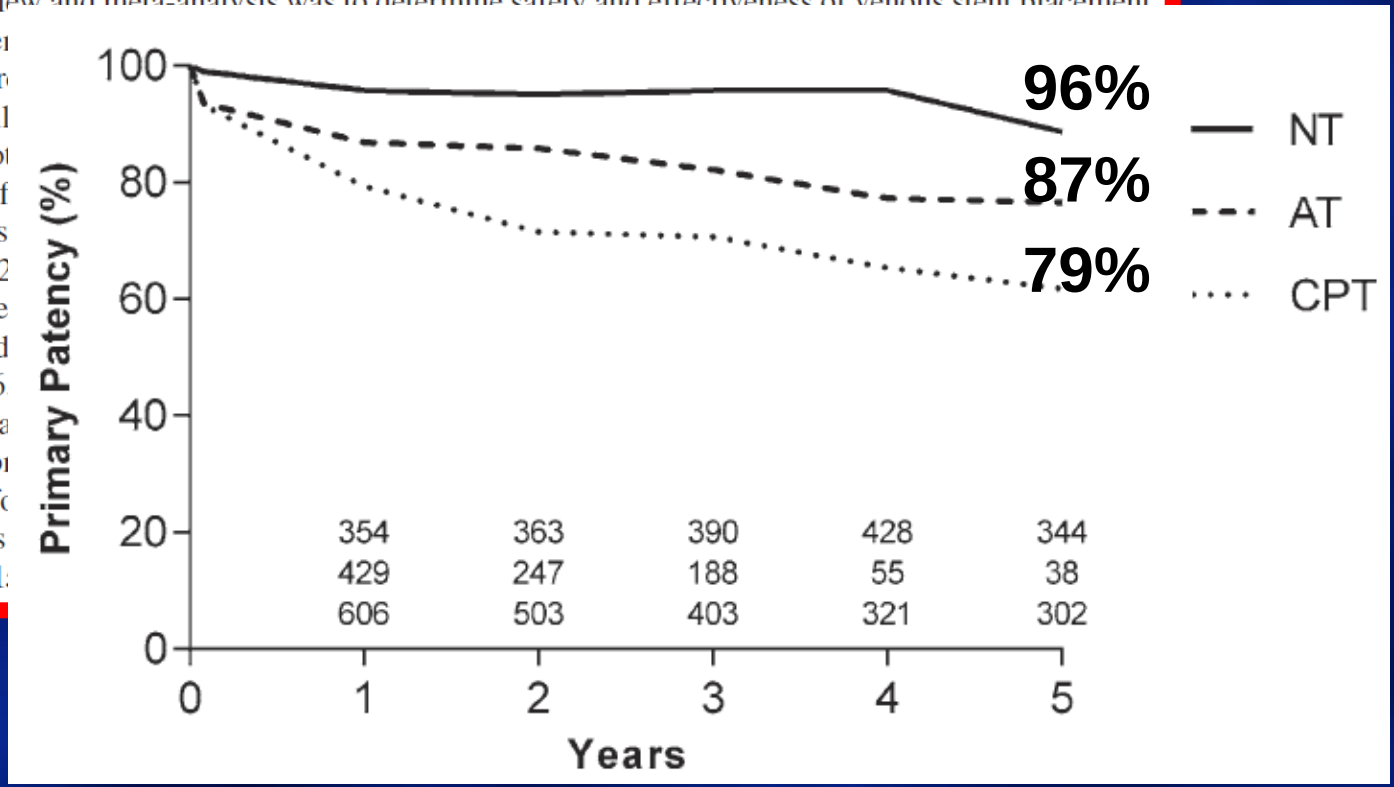
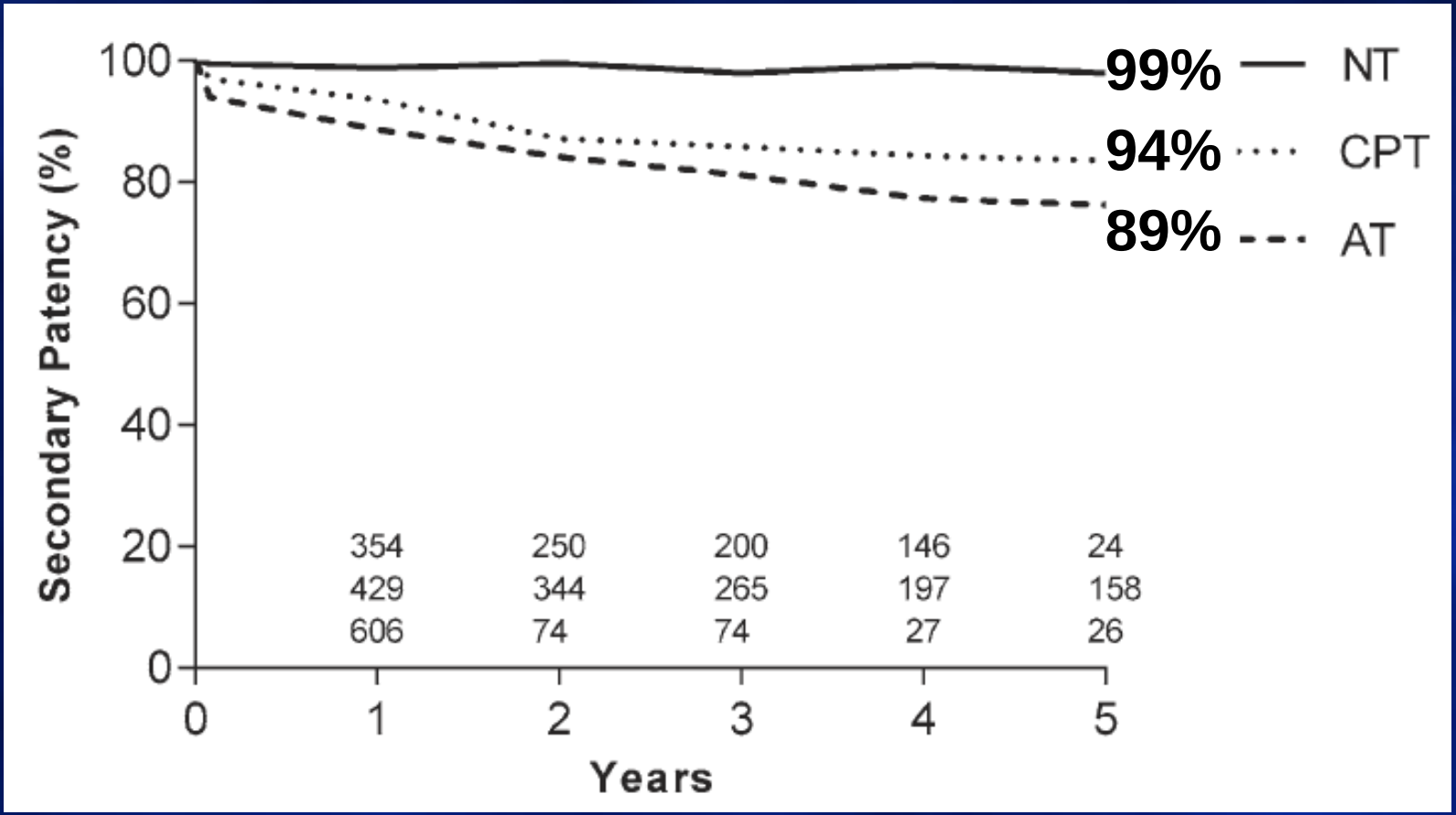
Conclusions—Stent placement f complication rates regardless **CIRCINTERVENTIONS.11**



Secondary Patency at 5 Years



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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.**)

Stent placement for iliofemoral venous outflow obstruction results in high technical success and acceptable complication rates regardless of cause of obstruction.

Reinterventions for nonocclusive iliofemoral venous stent malfunctions

Seshadri Raju, MD,[a,b] Paul Tackett Jr, BS,[a,b] and Peter Neglen, MD, PhD,[a,b]
Jackson and Flowood, Miss

Background: Percutaneous iliofemoral venous stenting has been shown to be effective, safe, and durable in both nonthrombotic iliac vein lesion (NIVL) and postthrombotic disease. A small fraction of stented limbs require reintervention to correct stent malfunction. This manuscript examines the reasons for reintervention, types of procedures performed, and outcome.

Methods: Femoro-ilio-caval stenting was performed in 1085 limbs over a 10 year period from 1997 to 2007 (NIVL/postthrombotic limb ratio 1:1). Reinterventio

Results: Median time of reintervention afte
was stent
after initial s
combination of
only a single reinter
categorized into four typ
correct inflow problems; (3)
lesions encountered were differ
had a greater incidence of patholog
of uncertain aetiology that occurred b
restenosis (ISR) occurred in both subse
flow channel lined by thrombus within
independently, was resistant to dilatati
and swelling at 18 months following int
dermatitis/ulcer was 90% at 12 month

Conclusion: Venous stenting for chroni
limbs requiring reinterventions. Reint
inflow, outflow and/or the stent. Reint
durable fashion. (J Vasc Surg 2009;49

- 1085 limbs
- Reinterventions : 137 limbs (13%) for non-occlusive stent malfunction
  - Median time : 15 months
  - Indications
    - Stent abnormalities: 31%
    - Recurrent symptoms: 69%
  - Reinterventions
    - Single: 77%
    - Multiple: 23%

Eur J Vasc Endovasc Surg (2016) 51, 100–120

REVIEW

Editor's Choice — A Systematic Review of Endovenous Stenting in Chronic Venous Disease Secondary to Iliac Vein Obstruction

M.J. Seager, A. Busuttil, B. Dharmarajah, A.H. Davies *

Department of Surgery and Cancer, Imperial College London, Charing Cross Hospital, London, UK

WHAT THIS PAPER ADDS

This review demonstrates that quality of evidence behind the use of deep venous stenting to treat obstructive chronic venous disease is weak. However, the consistent effects and marked changes to disease course mean that it should be considered as an acceptable treatm
vascular teams are aware of this, and it will serv

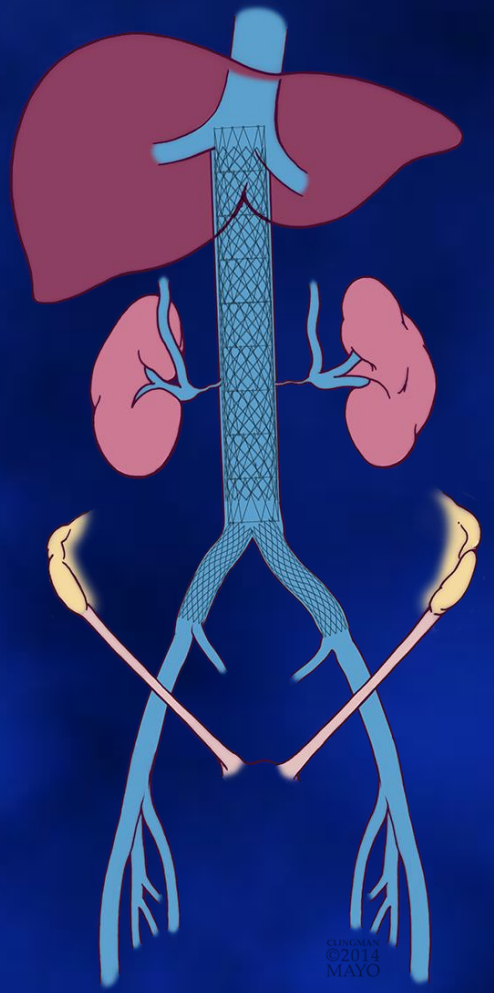
Objectives: Deep endovenous stenting to relie
non-thrombotic iliac vein obstruction is becom
reported systematic reviews on the topic are la
analysis of the available data, reported to the
Analyses guideline.
Methods: MEDLINE, EMBASE, and the Cochra
references were searched.
Results: Sixteen studies were included (14 be
case series) e
thrombotic limbs a
were significant improve
of life. Persistent ulcer healing
management. Primary and secondar
major complication rate ranged from 0 to
of the evidence for five outcomes to be "Very
Conclusions: The quality of evidence to suppo
currently weak. The treatment does however app
a treatment option while the evidence base is imp

16 studies, 2,586 post-thrombotic or nonthrombotic limbs (2,373 patients) were included.

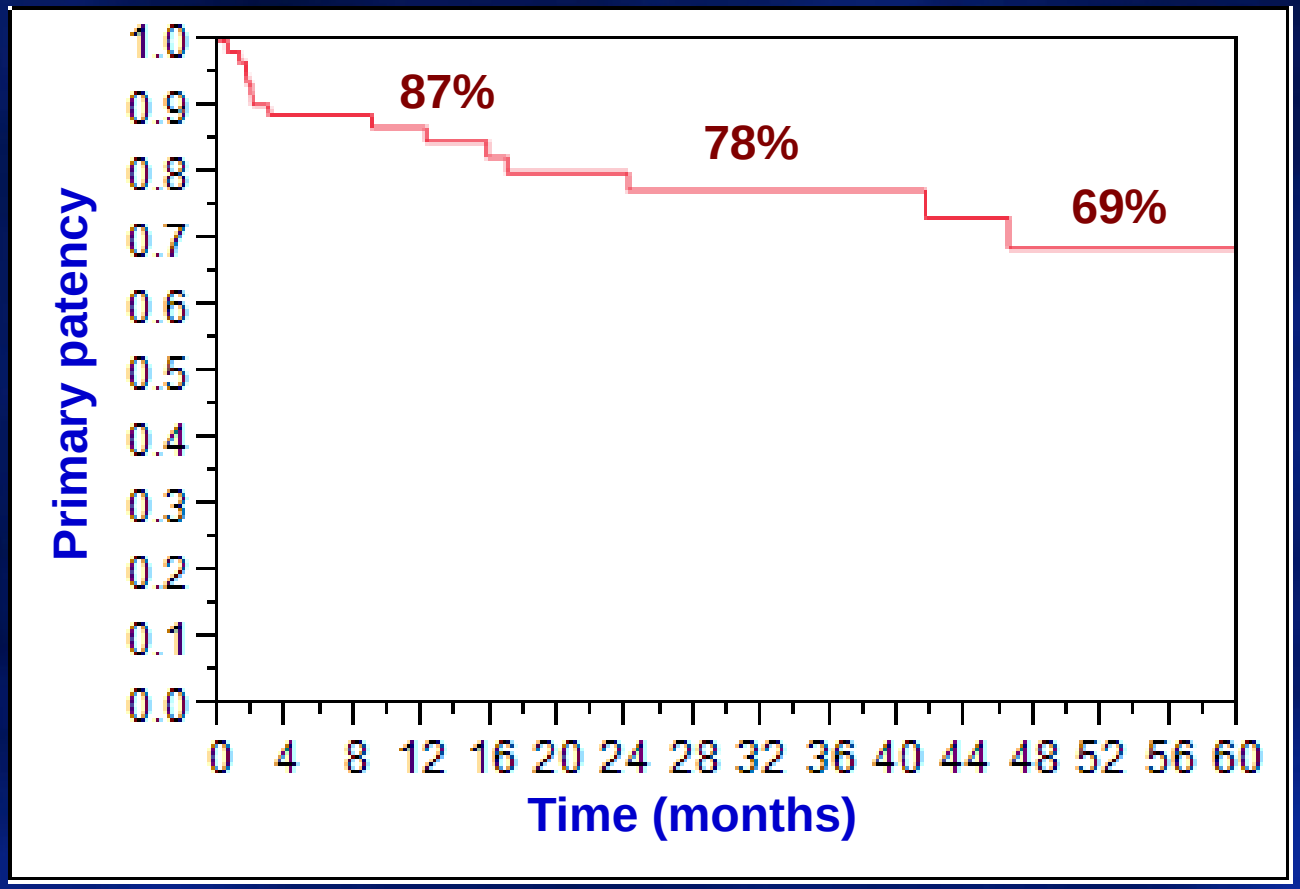
- **Persistent ulcer healing rates: 56% - 100%**
- **Primary patency: 32% - 98.7%**
- **Secondary patency: 66% - 96%**
- **Major complication rate: 0 - 8.7%**

The quality of evidence to support iliac vein stenting is weak

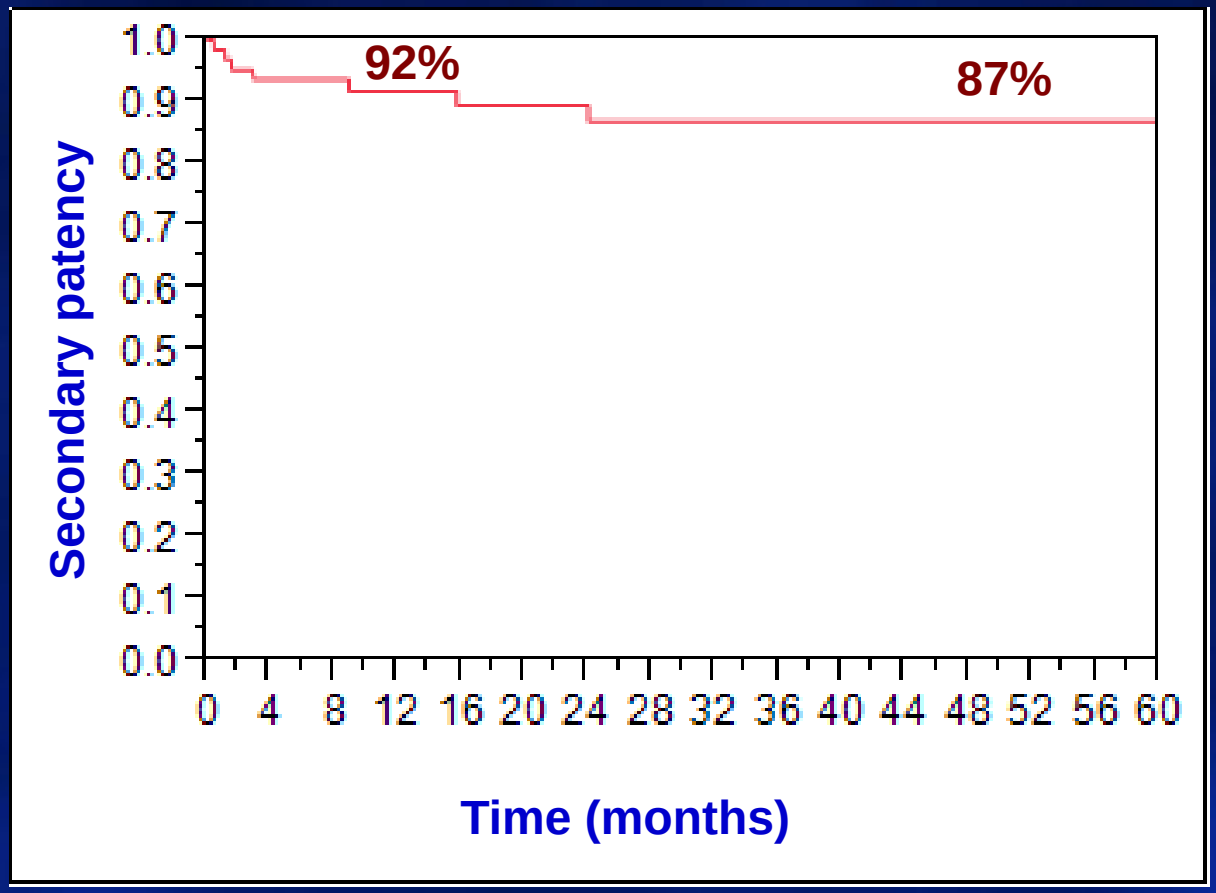
Mayo Clinic Experience with Stenting in 66 Complex Iliocaval Obstructions



Primary Patency



Secondary Patency



Guidelines 4.17.0 and 4.18.0 of the American Venous Forum on Endovascular Reconstruction for Primary and Post-thrombotic Iliac Vein Obstruction

Guideline No.		*GRADE of recommendation*	*Level of evidence*
4.17.1 4.18.1	We recommend endovenous stenting as the current "method-of-choice, " for treatment of symptomatic primary and post-thrombotic iliac vein obstruction	1	B

THANK YOU!