The evidence base for deep vein stenting

Stephen Black

Consultant Vascular Surgeon
Guy's and St Thomas' Hospital
Reader in Venous Surgery
King's College London

KING'S College LONDON

Guy's and St Thomas' NHS Foundation Trust

NHS

KING'S HEALTH PARTNERS

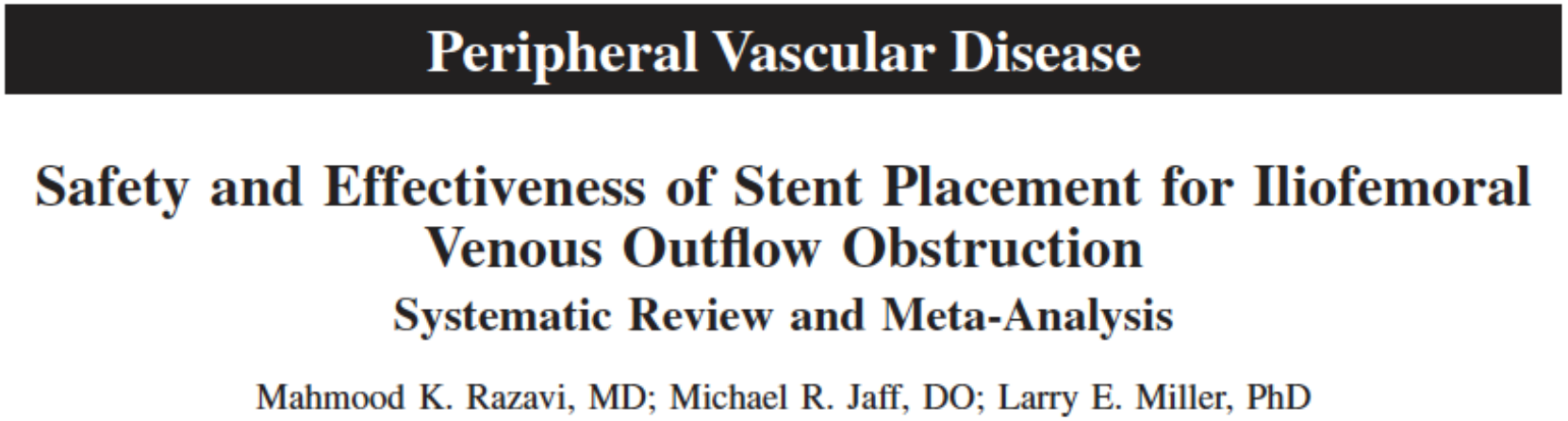
Pioneering better health for all

Venous Stenting is not new

1. **What data do we have?**
2. **What do we need?**

Venous Stenting is not New

What do we have?



Peripheral Vascular Disease

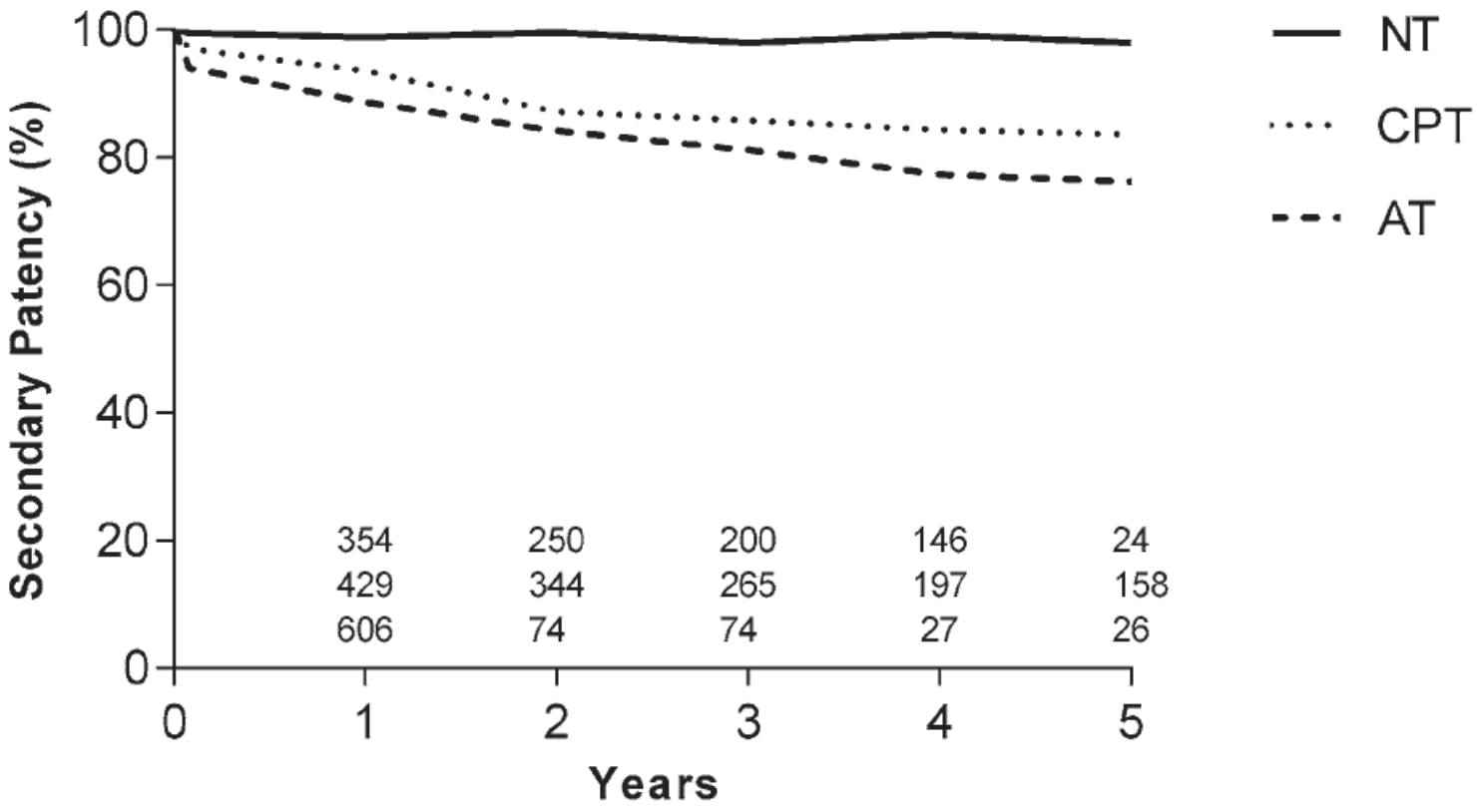
Safety and Effectiveness of Stent Placement for Iliofemoral Venous Outflow Obstruction

Systematic Review and Meta-Analysis

Mahmood K. Razavi, MD; Michael R. Jaff, DO; Larry E. Miller, PhD

- A meta- analysis of the available literature published in 2016
- 37 studies identified
- 2869 patients
- Patency rates were high 79 to 98%
- Inconsistent reporting of symptom relief

What do we have?



Guy's and St Thomas' NHS
NHS Foundation Trust

What do we have?

Variable	Nonthrombotic	Acute Thrombotic	Chronic Post-Thrombotic
No. of studies	8	19	18
No. of patients	1122	629	1118
Age, y*	41 (39–53)	54 (32–70)	43 (37–58)
Female sex	58% (324/556)	68% (233/342)	58% (280/480)
IVCS	100% (1109/1109)	81% (335/412)	65% (112/173)
Left limb	96% (547/571)	89% (396/444)	83% (292/351)
Coagulopathy	13% (29/220)	18% (25/140)	26% (212/812)
CEAP class			
C0–C2	14% (39/273)	...	2% (8/396)
C3	33% (91/273)	88% (45/51)	37% (147/396)
C4	11% (30/273)	12% (6/51)	26% (102/396)
C5	13% (36/273)	...	7% (29/396)
C6	28% (77/273)	...	28% (110/396)
Deep reflux	57% (147/260)	...	76% (144/190)
Edema	61% (352/576)	90% (101/112)	62% (327/530)
Pain	50% (130/260)	71% (74/104)	68% (283/414)
Ulcer	27% (156/569)	...	25% (135/545)

What do we have?

Randomized double-blinded study comparing medical treatment versus iliac vein stenting in chronic venous disease

Fabio H. Rossi, MD, PhD,[a] Antonio M. Kambara, MD,[a] Nilo M. Izukawa, MD,[a] Thiago O. Rodrigues, MD,[a] Cybelle B. Rossi, FACS,[a] Amanda G. Sousa, MD, PhD,[a] Patrick B. Metzger, MD, PhD,[a] *and* Patricia E. Thorpe, MD,[b] *São Paulo, Brazil; and Phoenix, Ariz*

- Randomized patients from C3 to C6
- VCCS dropped from a median of 18.5 to 11 ($p<0.001$)
- SF36 improved from 53.9 to 89 ($p<0.001$)
- No significant changes in either score in the medically managed arm

Guy's and St Thomas' NHS
NHS Foundation Trust

What do we have?

Eur J Vasc Endovasc Surg (2018) 56, 710—718

Two Year Outcome After Chronic Iliac Vein Occlusion Recanalisation Using the Vici Venous Stent®

Stephen Black [a,*], Adam Gwozdz [a], Narayan Karunanithy [b], Justinas Silickas [a], Karen Breen [c], Beverley Hunt [c], Alberto Smith [a], Ander Cohen [c], Prakash Saha [a]

[a] Academic Department of Vascular Surgery, Guy's and St. Thomas' NHS Trust, King's College London, London, UK
[b] Department of Interventional Radiology, Guy's and St. Thomas' NHS Trust, London, UK
[c] Thrombosis and Haemophilia Centre, Guy's and St. Thomas' NHS Trust, London, UK

- 88 patients with a minimum of 2 year follow up
- Only chronic occlusions
- Villalta improved from median 14 to 8 ($p<0.001$)
- Cumulative Patency 85% at two years

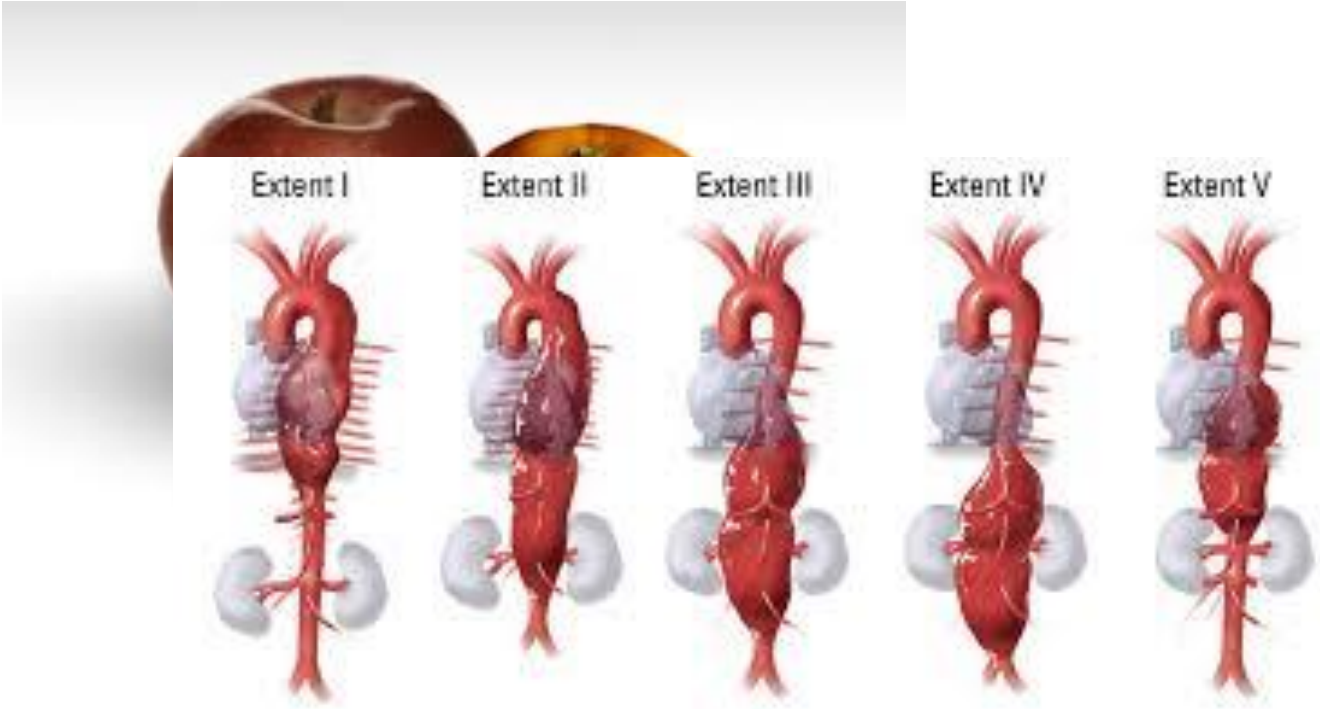
Guy's and St Thomas' NHS
NHS Foundation Trust

What do we have?

- A significant body of patients in a meta-analysis
- A single RCT
- Single centre Cohort

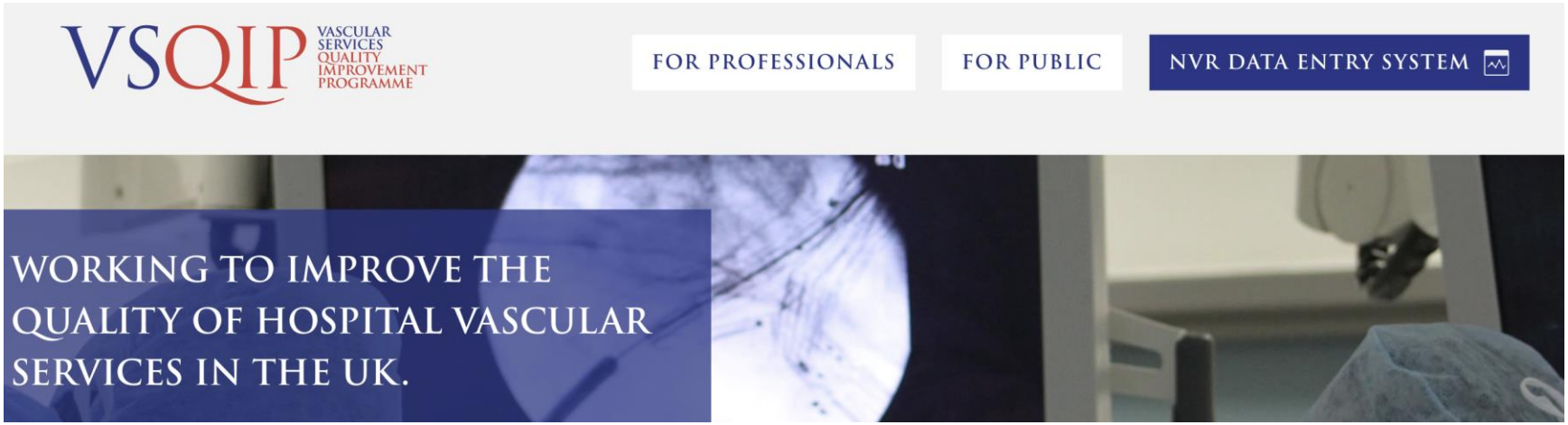
What do we need?

A standardized set of outcome measures that we all agree and publish too



What do we need?

Registries



Few implanted devices end up published or in registries

What do we need?

RCT

- Sample Sizing: Two-Arm Study (Fisher's Exact)
- Improvements in the literature are substantial up to 80%
- Assume an improvement of 25% in treatment arm and 5% in medical management
- 72 patients
- Problems – Ethics/Numbers/Inclusion and Exclusion Criteria/Experience
- Failure to recruit - ATTRACT
- Start with registry NVR

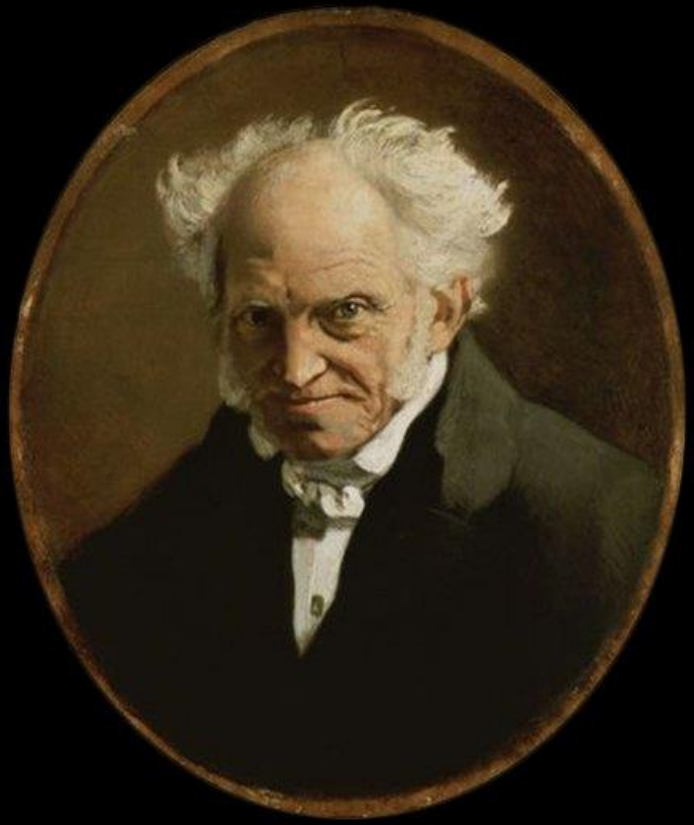
What do we need?

Abdominal aortic aneurysm: diagnosis and management

NICE guideline

Draft for consultation, May 2018

We need to learn the lessons that have been shown around us



All truth passes through three stages. First, it is ridiculed. Second, it is violently opposed. Third, it is accepted as being self-evident.

— *Arthur Schopenhauer*

AZ QUOTES

Conclusion

Venous stenting is not new but there are gaps in the evidence base

We need a standard agreed set of outcome measures to compare against

We need Registries, Real world practice and possibly RCT's, QOL, HE

We need to learn from the experience of Stroke, Coronaries and Arterial Disease


St Thomas'
Hospital