Bare vs Covered Stents for Central Veins: What to Use?

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The Palo Alto Medical Foundation

and

Sutter Health

Disclosures – Bart Dolmatch, MD FSIR

Consultancies

- Becton Dickinson and Co.
- Merit Medical Systems Inc.
- Venova Medical Inc.
- Boston Scientific Inc (CEC)

Options and Royalties

- Merit Medical Systems Inc.
- Venova Medical Inc.
- Alio Ai

The IMPORTANT Disclosure: Stent placement and covered stent placement for TCVO is mostly done off-label.

Wallstent: The ONLY Stent FDA-cleared for use in the Thoracic Central Veins in the US

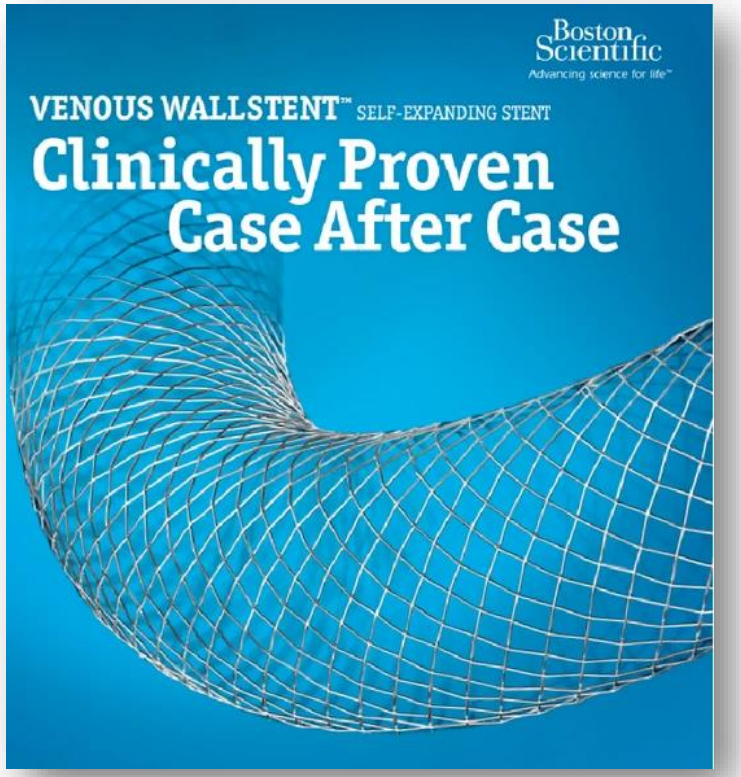
54 pts

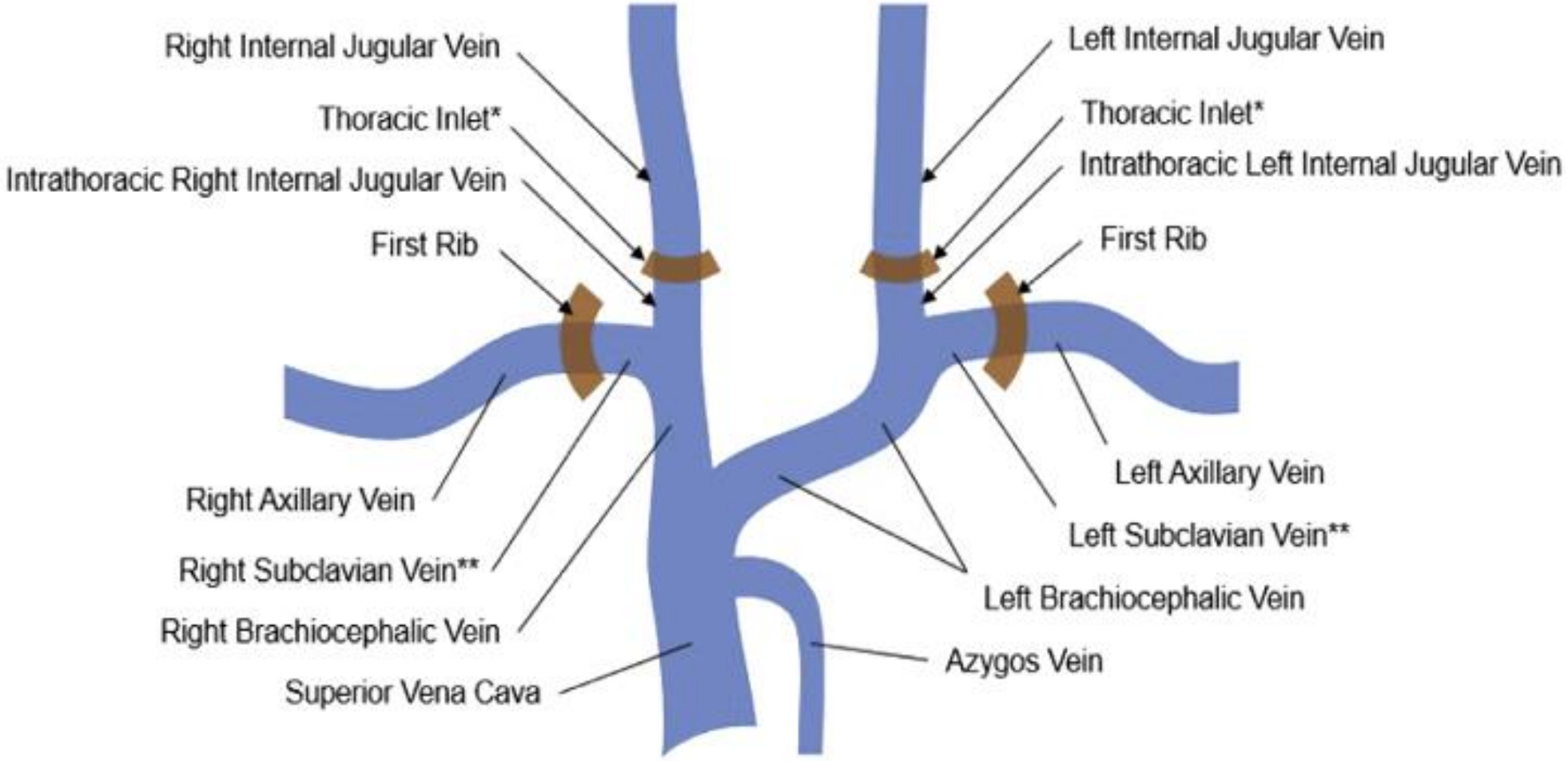
42 pts in US Multicenter Registry (12 sites)

12 pts from single site retrospective data

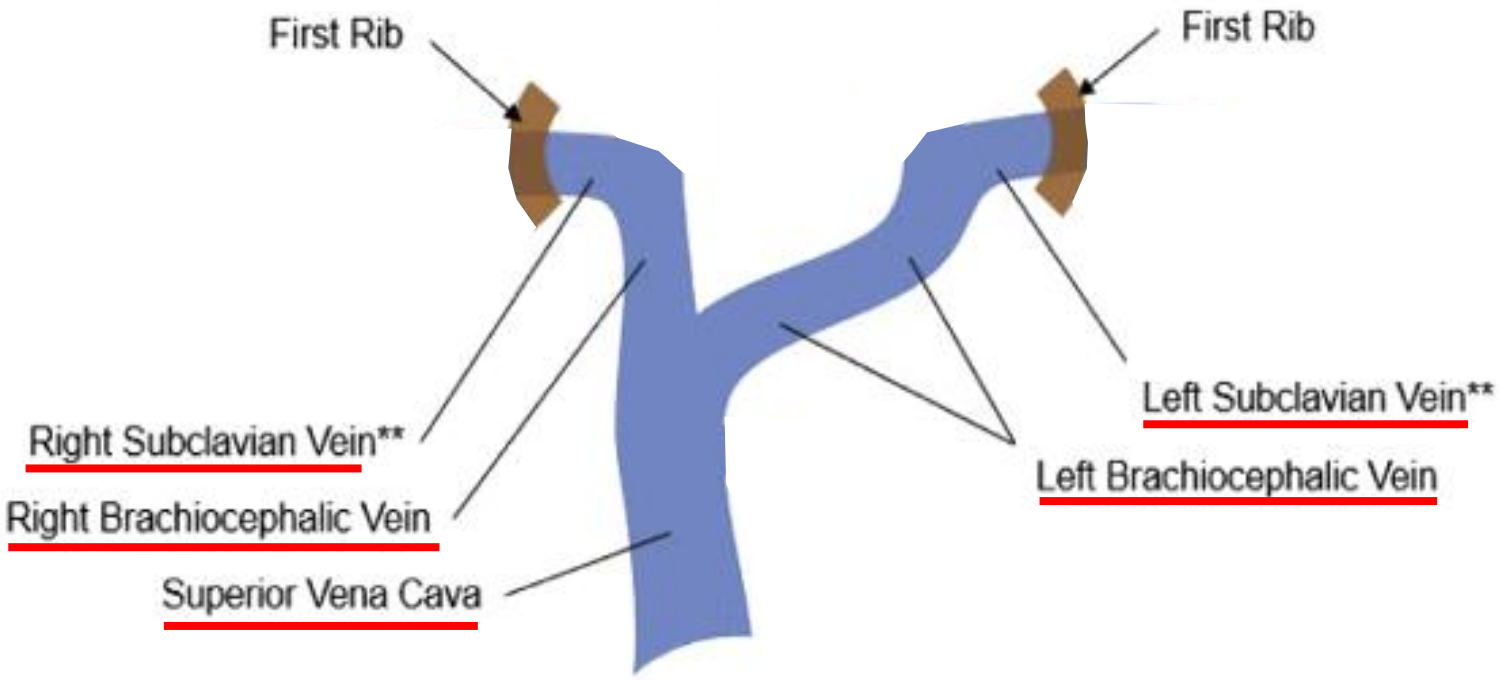
24.4% 6-mo Primary Patency

40.5% Recurrent Arm-Face Edema



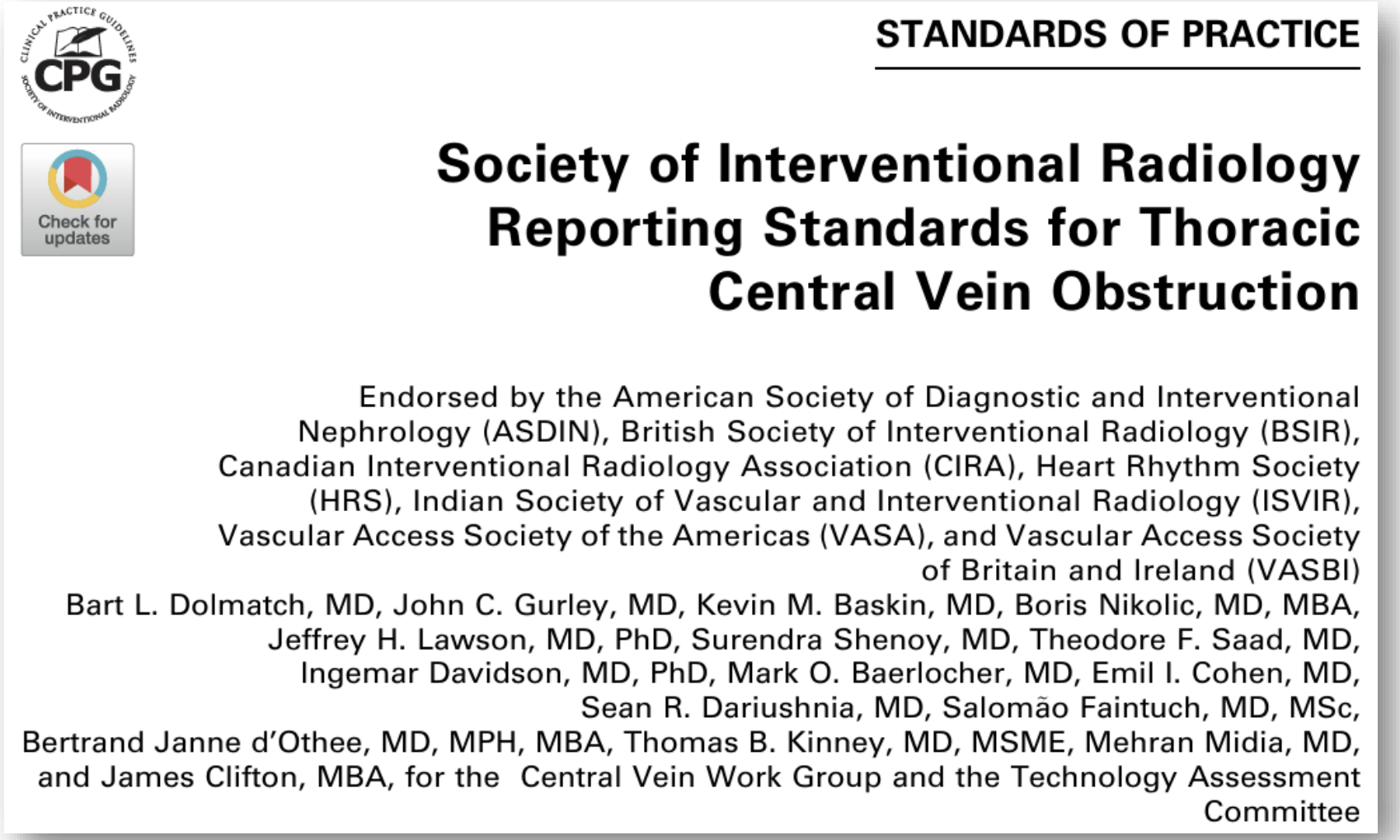


Dolmatch BL, et al. Society of Interventional Radiology Reporting Standards for Thoracic Central Vein Obstruction. J Vasc Interv Radiol 2018; 29:454–460.



**The SCV begins at the lateral border of the first rib.

Dolmatch BL, et al. Society of Interventional Radiology Reporting Standards for Thoracic Central Vein Obstruction. J Vasc Interv Radiol 2018; 29:454–460.



STANDARDS OF PRACTICE

Society of Interventional Radiology Reporting Standards for Thoracic Central Vein Obstruction

Endorsed by the American Society of Diagnostic and Interventional Nephrology (ASDIN), British Society of Interventional Radiology (BSIR), Canadian Interventional Radiology Association (CIRA), Heart Rhythm Society (HRS), Indian Society of Vascular and Interventional Radiology (ISVIR), Vascular Access Society of the Americas (VASA), and Vascular Access Society of Britain and Ireland (VASBI)

Bart L. Dolmatch, MD, John C. Gurley, MD, Kevin M. Baskin, MD, Boris Nikolic, MD, MBA, Jeffrey H. Lawson, MD, PhD, Surendra Shenoy, MD, Theodore F. Saad, MD, Ingemar Davidson, MD, PhD, Mark O. Baerlocher, MD, Emil I. Cohen, MD, Sean R. Dariushnia, MD, Salomão Faintuch, MD, MSc, Bertrand Janne d'Othee, MD, MPH, MBA, Thomas B. Kinney, MD, MSME, Mehran Midia, MD, and James Clifton, MBA, for the Central Vein Work Group and the Technology Assessment Committee

Dolmatch BL, et al. Society of Interventional Radiology Reporting Standards for Thoracic Central Vein Obstruction. J Vasc Interv Radiol 2018; 29:454–460.

Performance Status Due to TCVO

0. Asymptomatic: No change in performance

I. Symptomatic: No change in performance

II. Symptomatic : Impaired; some restriction in physical exercise, self-care and/or performance of some daily activities but not disabled

III. Symptomatic : Disabled; cannot exercise, and capable of only limited self-care and daily activities

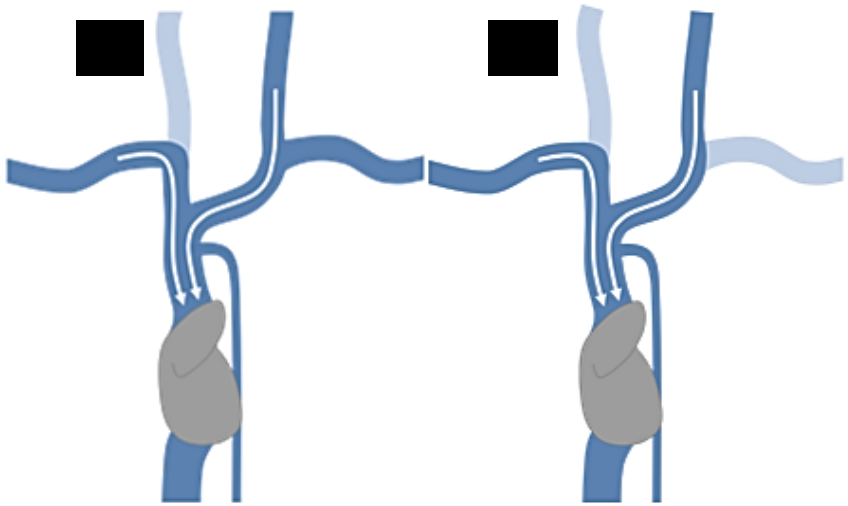
IV. Symptomatic: Incapacitated; incapable of self-care and daily activities

CLASSIFICATION OF CENTRAL VEIN OBSTRUCTION

Based on obstructed segments, residual patent segments, and clinical significance

TYPE 1

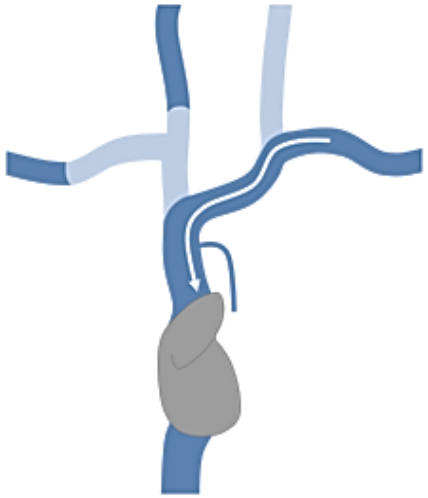
OBSTRUCTED SEGMENTS:
Single internal jugular or subclavian (1A) or
Contralateral internal jugular + subclavian (1B)



PATENT SEGMENTS:
In-line flow to right atrium is maintained via both brachiocephalic segments and the SVC

TYPE 2

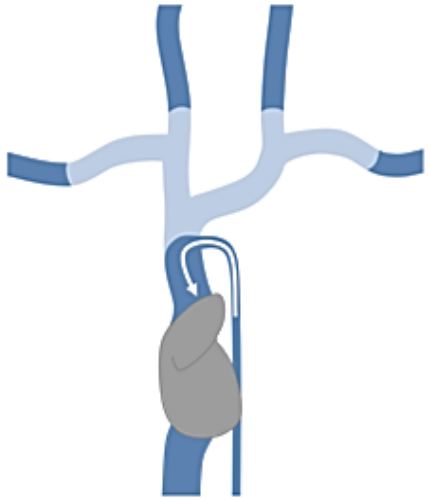
Unilateral brachiocephalic



Flow via one patent brachiocephalic

TYPE 3

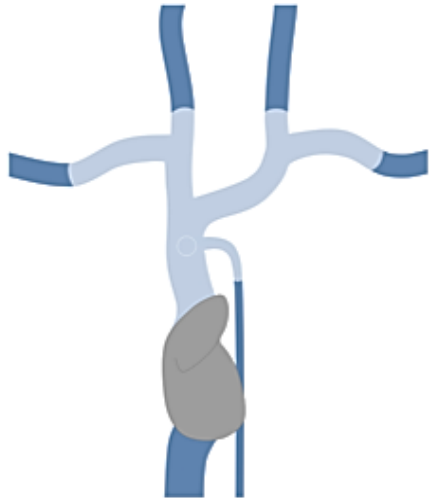
Bilateral brachiocephalic



Flow to RA via SVC is collateral-dependent

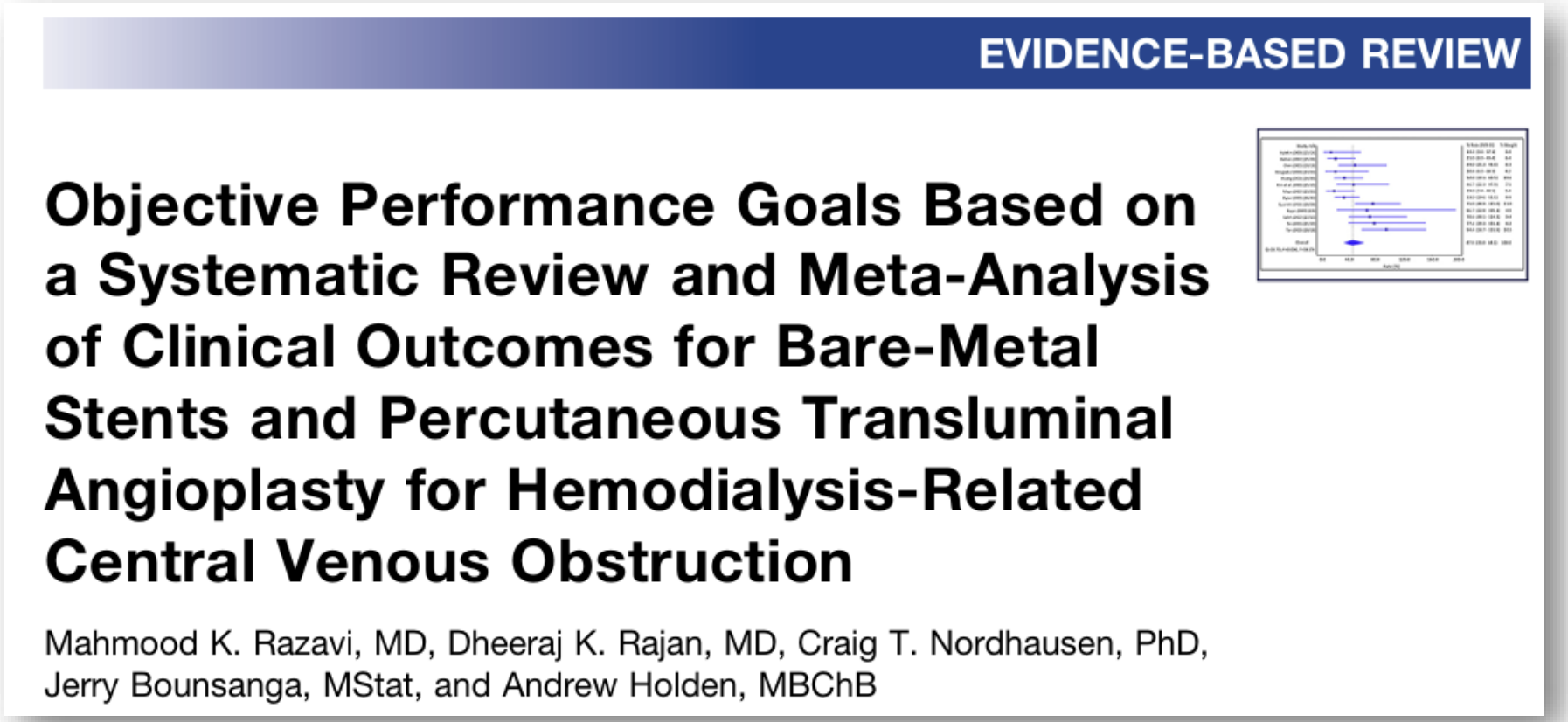
TYPE 4

SVC occlusion at RA junction



No remaining flow from SVC to RA

Meta-Analysis: What Do We "Know" About PTA and Bare Stent Placement for Hemodialysis-Related TCVO?



Razavi M, et al. J Vasc Intervent Radiol. 2023; 34:1664-1673.e3

Meta-analysis based on heterogeneous small studies

Only 17 of 66 clinical series met criteria for analysis (over 21-years)

8 of the 17 studies had <20 patients.

12 studies were retrospective from single centers.

Target lesions were heterogeneous

- 7 stenosis trials
- 3 occlusion trials
- 7 mixed stenosis/occlusion trials

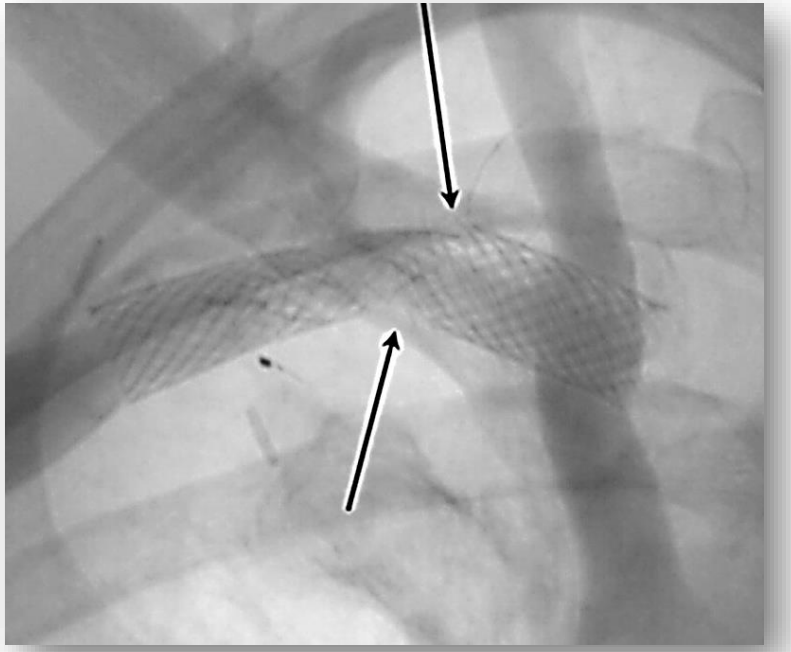
Location of TCVO was often unclear (some included axillary vein!)

Severity of symptoms usually not reported at treatment or follow-up.

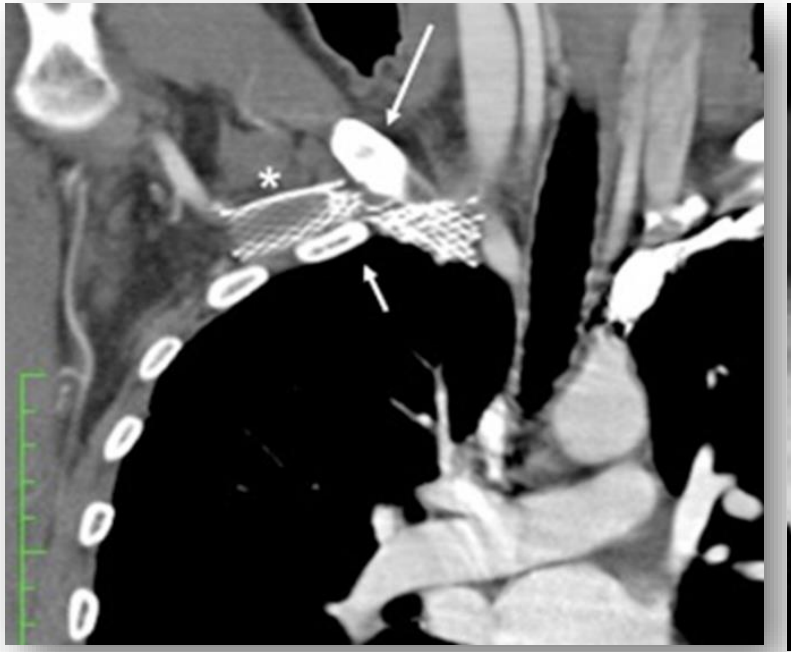
Different stents were used, including the Wallstent (used in most of the early studies)

Different end points: venographic recurrence in some, clinical outcome in others.

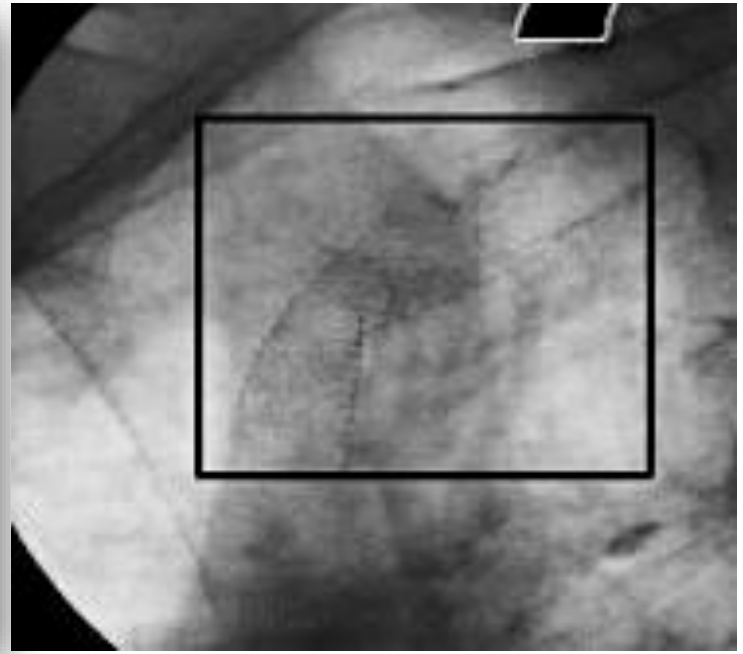
Bare stents in TCVO are prone to fracture



Mallios A, et al. J Vasc Surg
2013;58; 1440-1441



Molinelli L et al.
European J Vasc Endovasc Surg
2017; 55292



Wada, M. Cardiovasc Revasc Med.
2007;8(2):103-106

Safety of PTA and Bare Stents for TCVO?

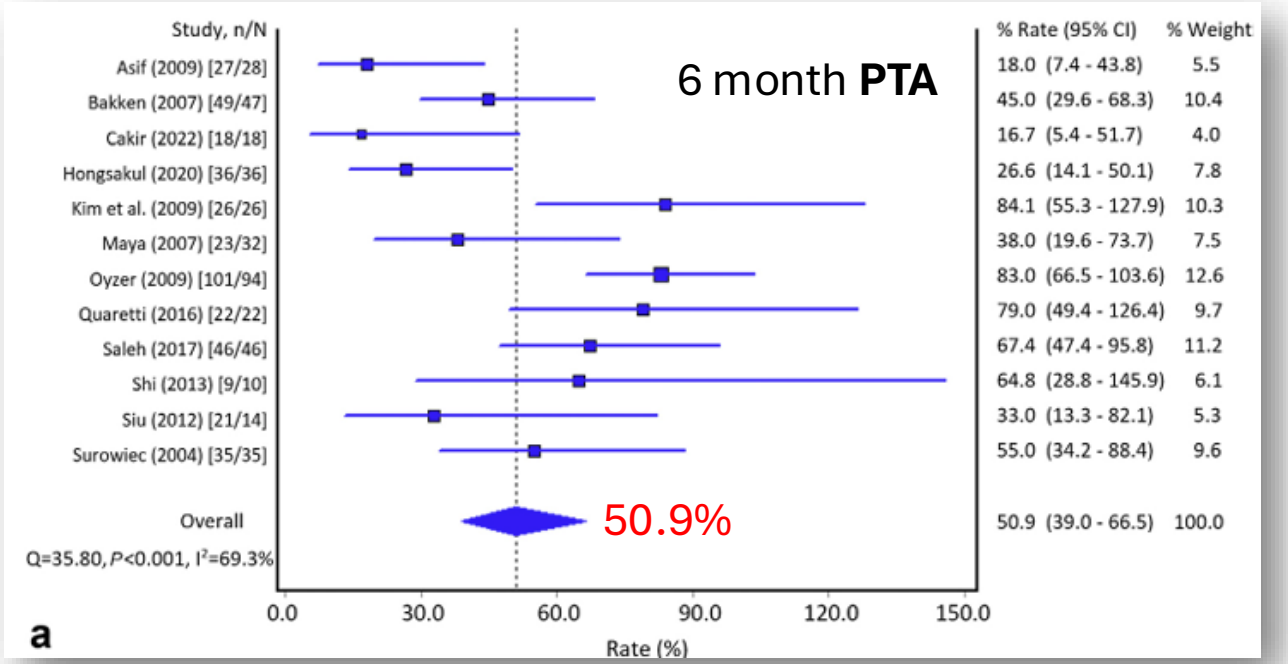
SAE rate [Serious Adverse Event rate]

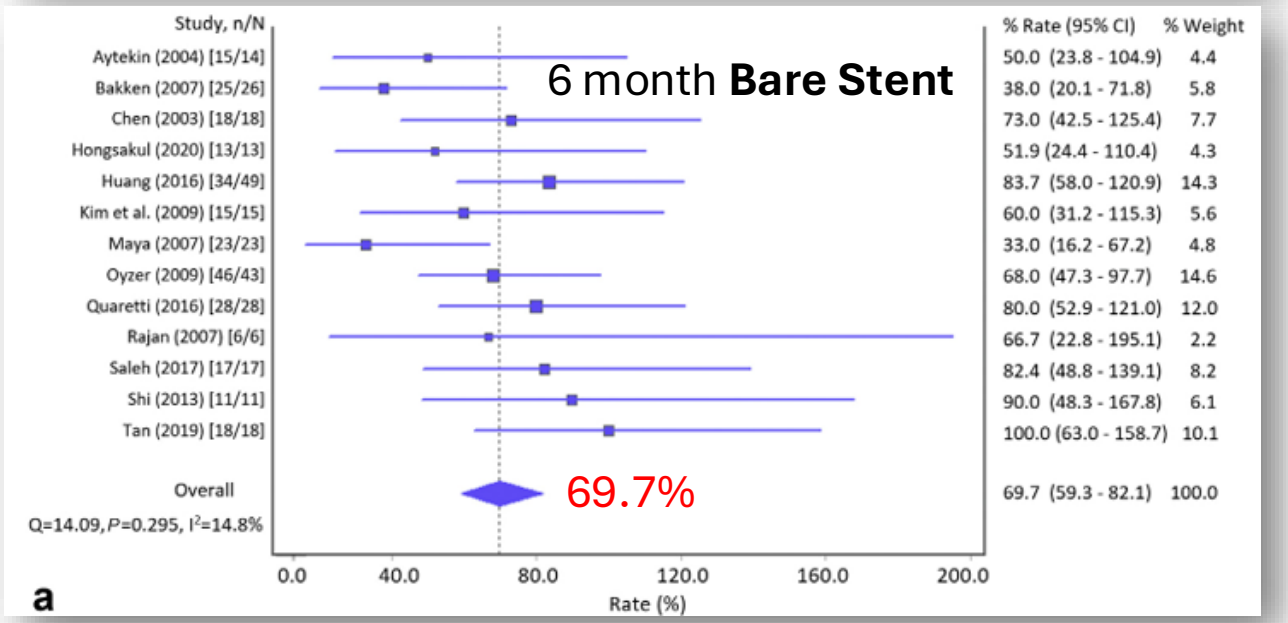
The SAE rate for **PTA** was **3.8%** (95% CI, 1.4%–10.1%)

The SAE rate for **stent placement** was **8.1%** (95% CI, 4.8%–13.6%)

PTA had a significantly lower SAE than the stent placement (p = .022)

Let’s look at 6-month primary patency for stents compared to PTA.





6-month primary patency PTA and bare stents

"The estimated primary patency rates for stent placement were significantly higher than those for PTA at 6 months (P = .002)"

Razavi M, et al. J Vasc Intervent Radiol. 2023; 34:1664-1673.e3

How about TLPP for TCVO covered stents?
Reported primary patency rates (6 months) : 60-100%

Author	Indication	Device (N)	Technical Success Rate	6 month TLPP primary patency
Anaya-Ayala 2011 (r)	CVS/CVO	Viabahn (24) Fluency (1)	100%	-
Boutrous 2019 (r)	CVS/CVO	Viabahn (29)	100%	92.9%
Chen 2020 (r)	CVS/CVO	Gore Excluder Limb (60)	100%	90.7%
Jones 2011 (r)	CVS/CVO	Viabahn (42)	100%	81%
Moawad 2024 (r)	CVO	Viabahn (20)	85%	94%
Vestandig 2013 (r)	CVS	Viabahn (30) Fluency Plus (27)	100%	60%
Ma 2021 (r)	CVS/CVO	Fluency Plus (16)	100%	86.7%
Gilbert 2021 (p)	CVS/CVO	Wrapsody (11)	100%	100%

PRESENTED AT SIR MEETING MARCH 2026

Initial six-month clinical outcomes of patients from the thoracic central venous cohort of the WRAP Global registry

Prof. Dheeraj Rajan, MD, FSIR, FACR
University of Toronto

University Medical Imaging Toronto

University Health Network
Toronto General Hospital Toronto Western Hospital Princess Margaret Hospital

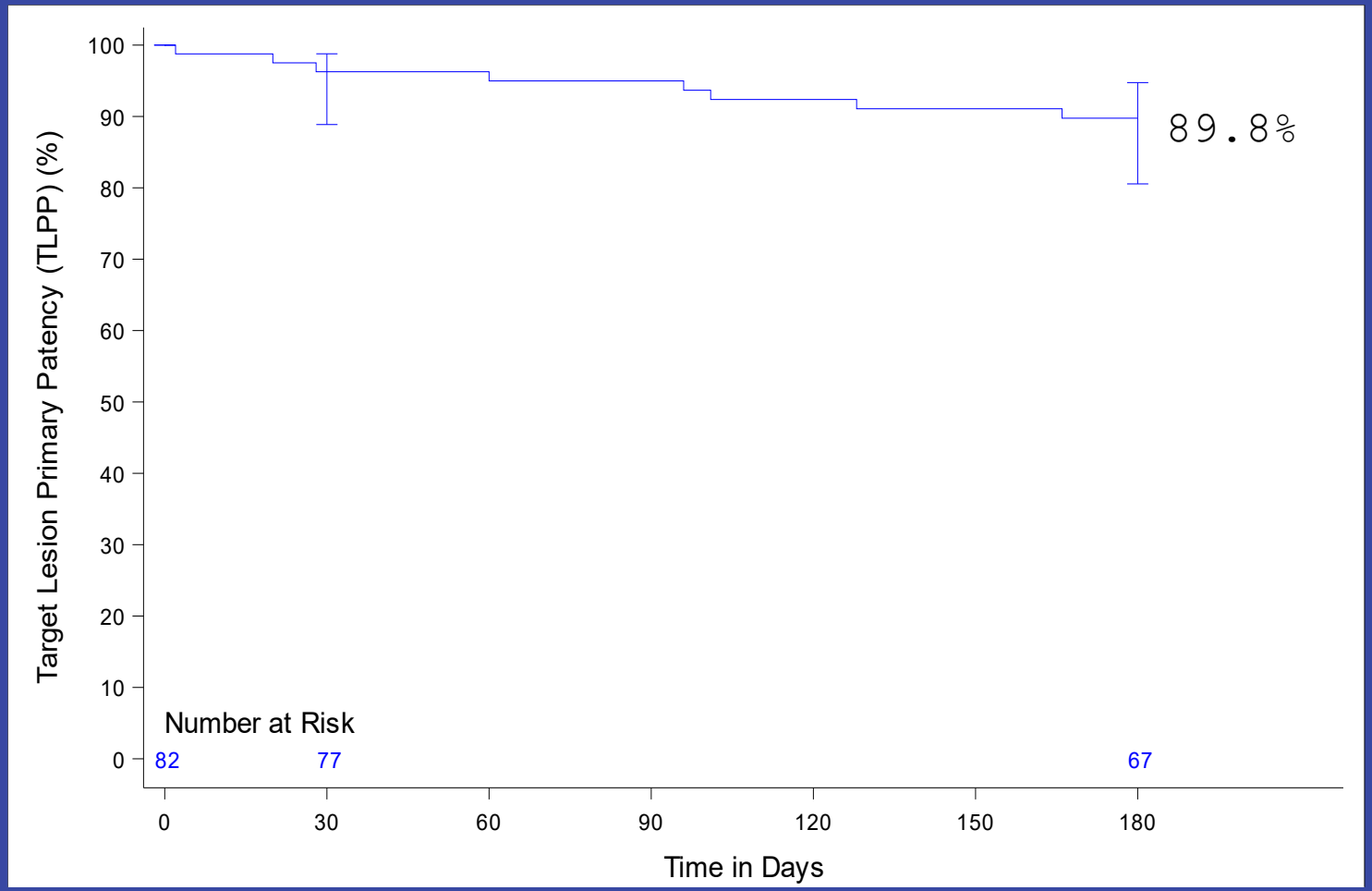
Population

- 496 patients enrolled in the WRAP Global Registry
  - 41 centers
  - Prospective patient follow up
- 143 patients had the Wrapsody CIE devices placed centrally
  - Of this group 82 assessable at 6 months for safety
  - At 6 months patency available in 75 patients
    - Loss to follow-up, access abandonment and death

30-Day Safety Endpoint

	Patients (N=82)
Freedom from localized or systemic safety events (Intention to Treat Population), n/N (%)	79 / 81 (97.5)
Freedom from localized or systemic safety events (Per Protocol Population), n/N (%)	77 / 78 (98.7%)

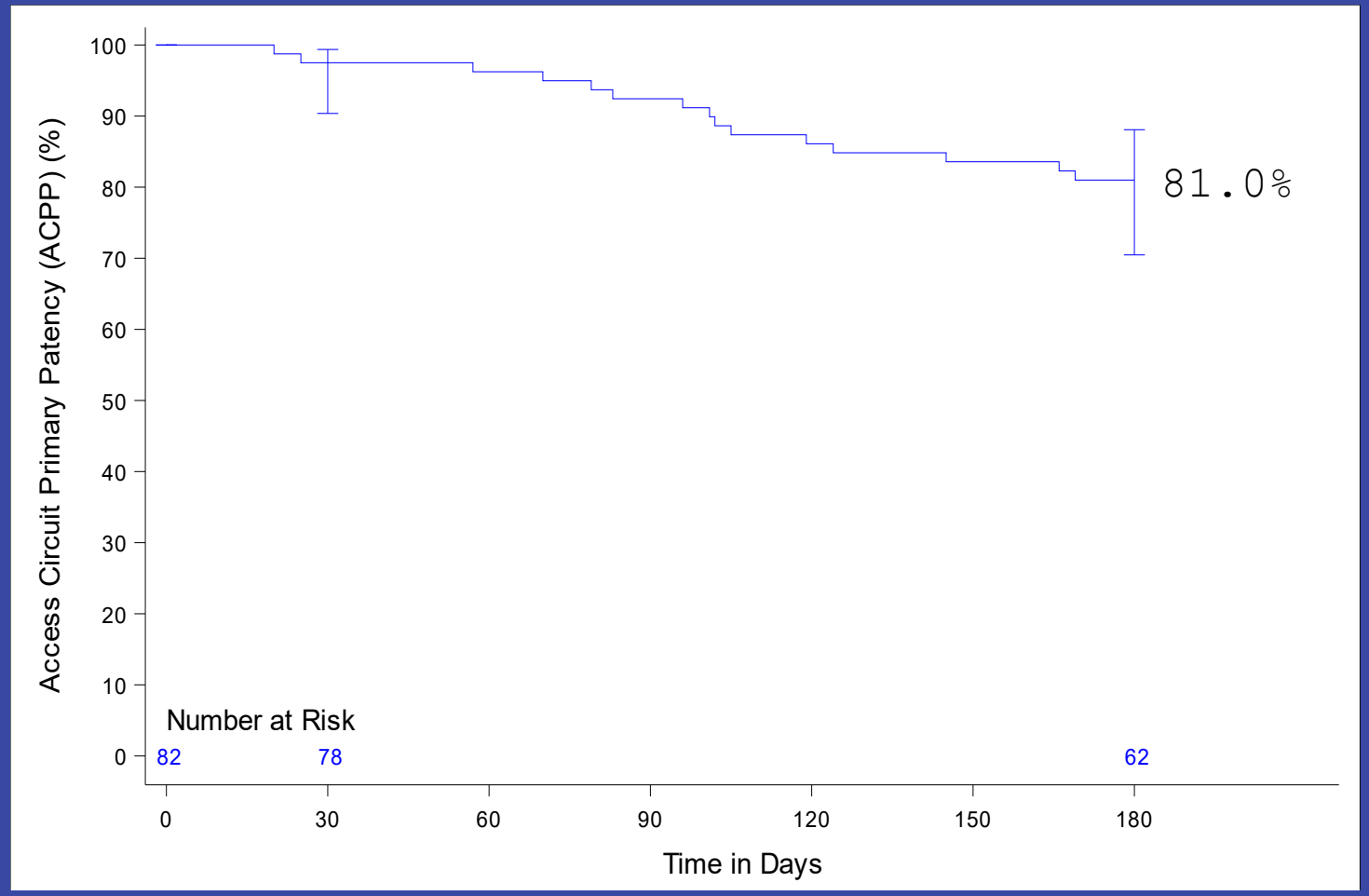
Target Lesion Primary Patency



University Medical Imaging Toronto

University Health Network
Toronto General Hospital Toronto Western Hospital Princess Margaret Hospital

Access Circuit Primary Patency

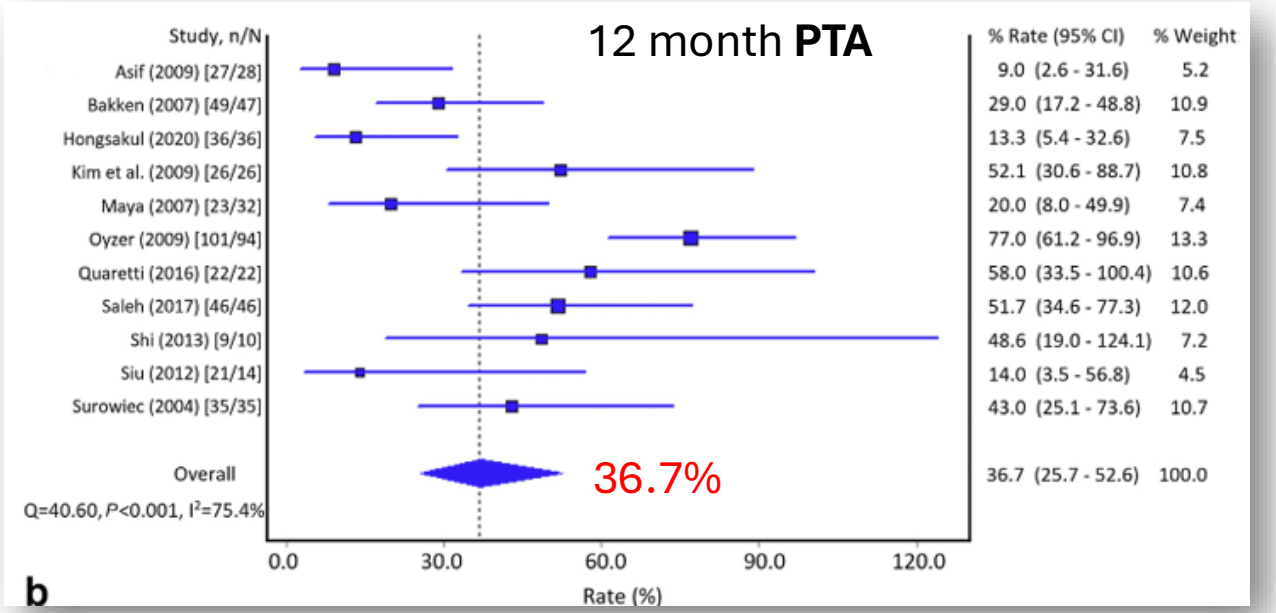


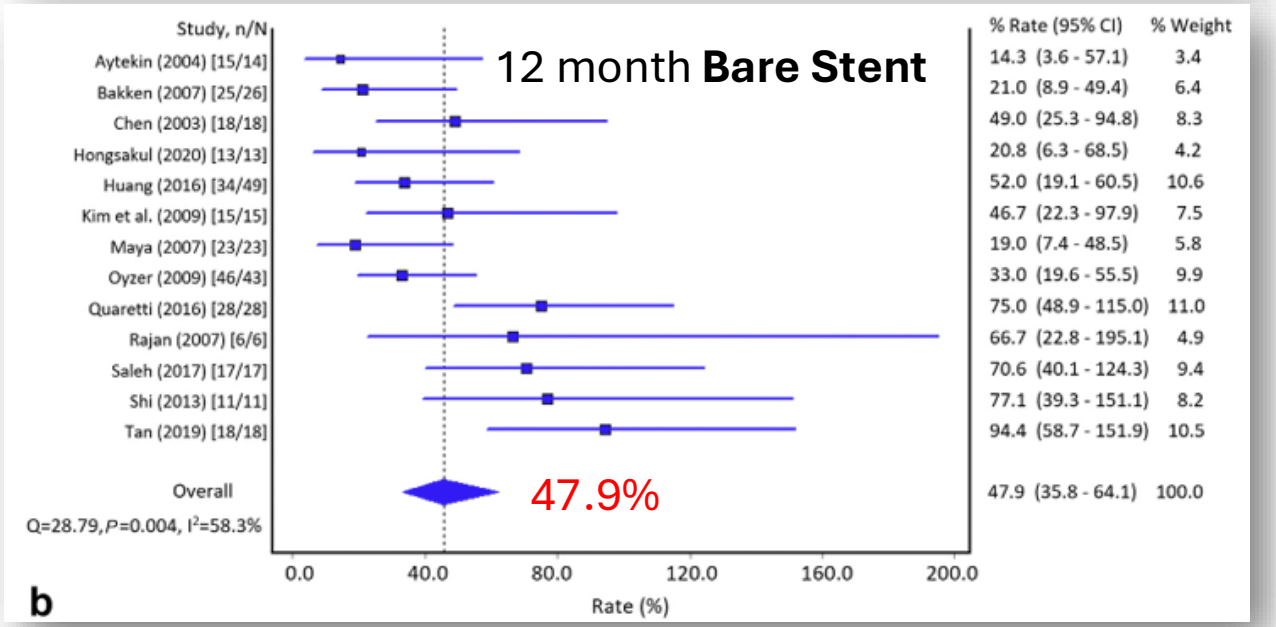
University Medical Imaging Toronto

University Health Network
Toronto General Hospital Toronto Western Hospital Princess Margaret Hospital

OK, that’s 6-month data – not very long follow up.

Let’s look at 12-month TCVO primary patency.

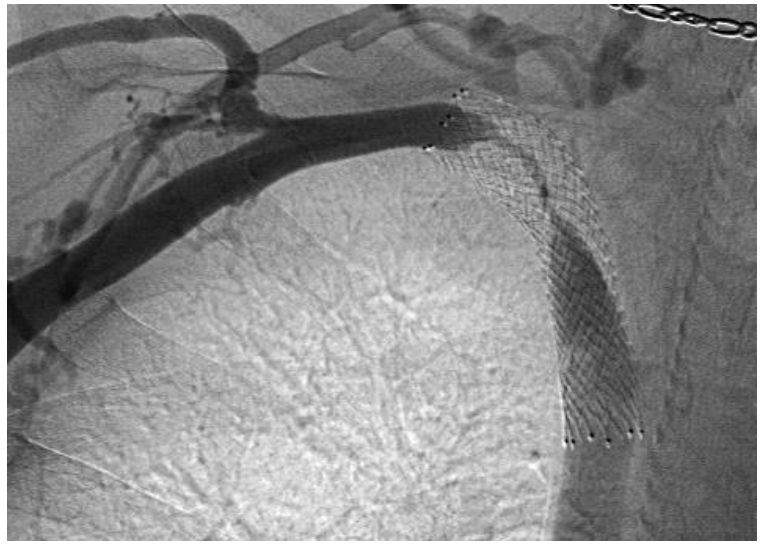




Razavi M, et al. J Vasc Intervent Radiol. 2023; 34:1664-1673.e3

12-month primary patency PTA and bare stents

"no significant differences were observed at 12 months between primary patency rates for PTA and stent placement"



A recent publication of Covered Stents for TCVO (2024) with long term follow up



www.nature.com/scientificreports

scientific reports

Check for updates

OPEN

Clinical outcomes and predictive factors of stent grafts treatment for symptomatic central venous obstruction in end stage kidney disease patients with arteriovenous access

Yamin Liu, Yufei Wang, Xinfang Wang, Beihao Zhang, Xiaoqing Lu, Xianhui Liang & Pei Wang✉

Subclavian vein 17 (28.8%)
Brachiocephalic vein 34 (57.6%)
Vena cava 8 (13.6%)

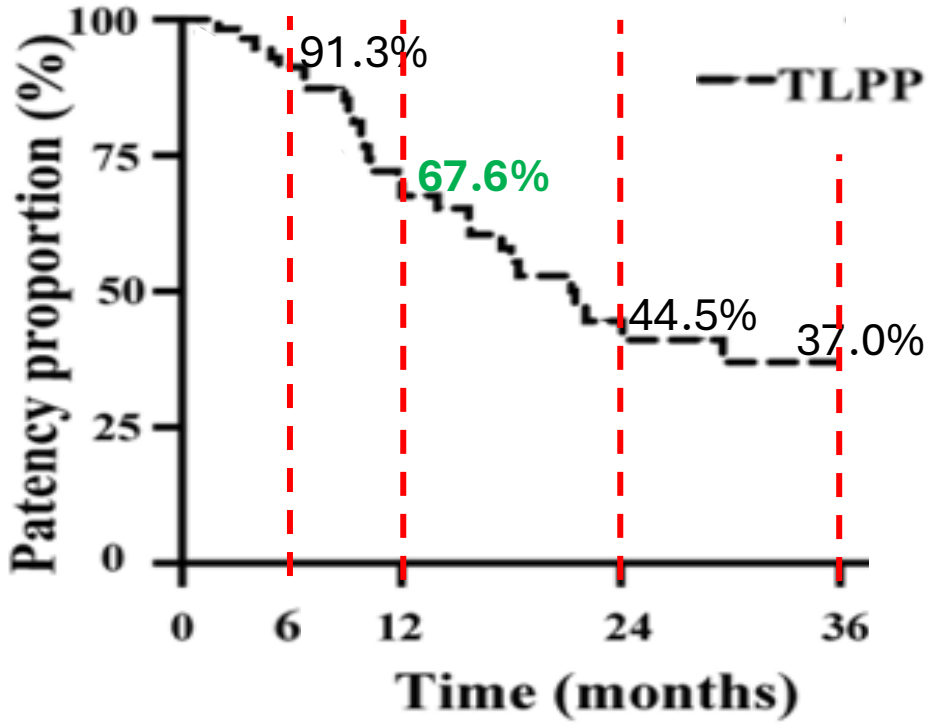
Stenosis 30 (50.8%)
Occlusion 29 (49.2%)

Viabahn™ 43 (72.9%)
Excluder™ 15 (25.4%) (EVAR limb)
Fluency™ Plus 1 (1.7%)

Across costoclavicular joint, case (%)
Yes 34 (57.6%)
No 25 (42.4%)

Liu, Y. *et al.* *Sci Rep* **14**, 12709 (2024).

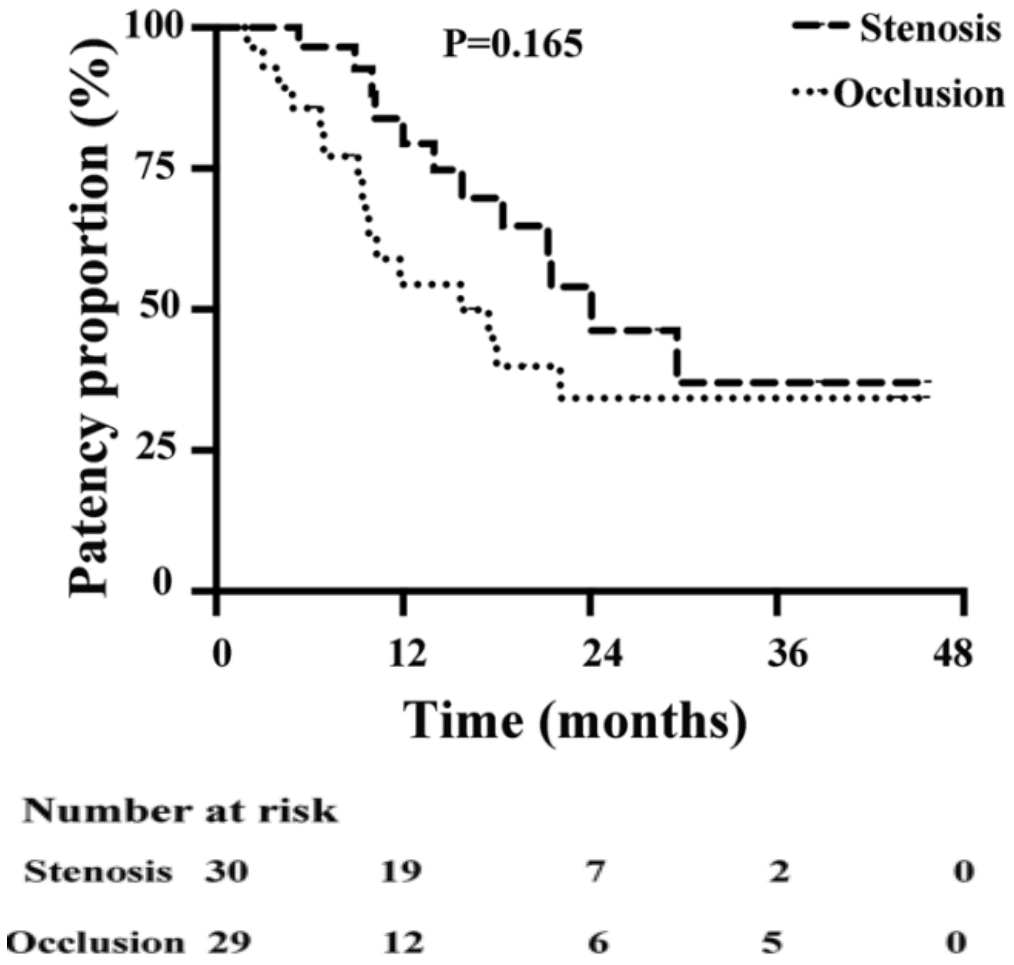
TLPP for 59 patients with TCVO treated with CS



Number at risk			
TLPP 59	31	13	7
ACPP 59	25	10	5

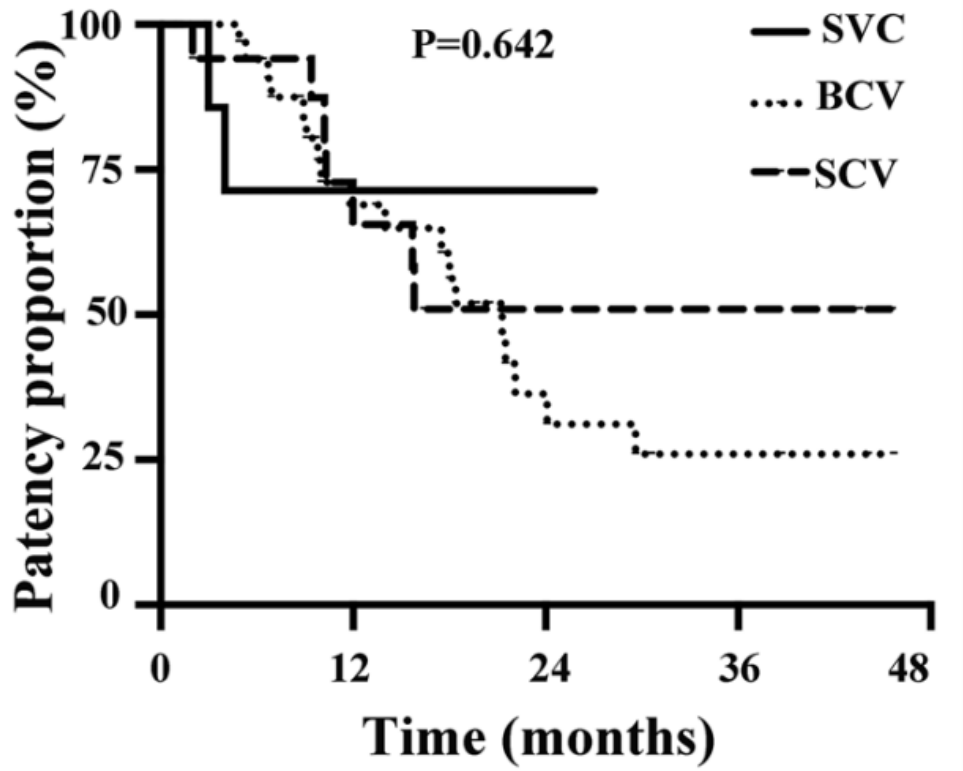
Liu, Y. *et al.* *Sci Rep* **14**, 12709 (2024).

Stenosis or Occlusion – not statistically different



Liu, Y. *et al.* *Sci Rep* **14**, 12709 (2024).

SVC or BCV or SCV – not statistically different

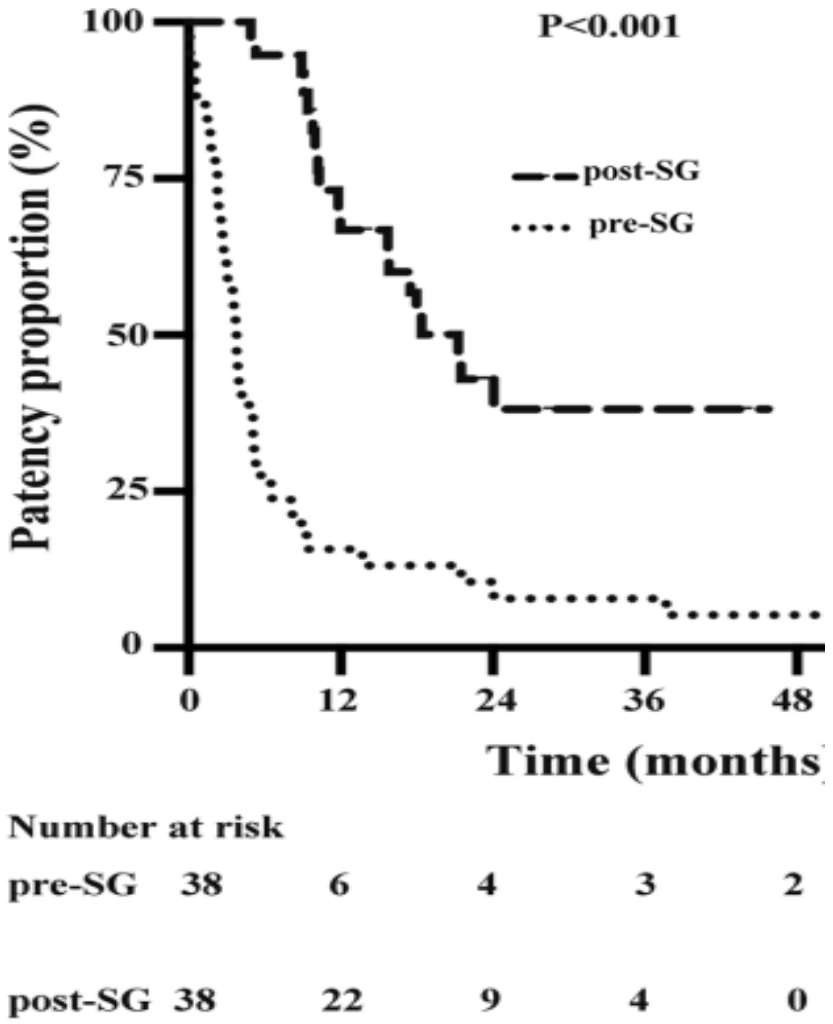


Number at risk					
SVC	8	3	1	0	
BCV	34	18	7	4	0
SCV	17	10	5	3	0

Liu, Y. *et al.* *Sci Rep* **14**, 12709 (2024).

TLPP for 38 patients as their own control (Prior PTA, subsequent SG)

TLPP post-SG placement compared to proximate PTA pre-SG (P<0.001)



Liu, Y. *et al.* *Sci Rep* **14**, 12709 (2024).



ATTENTION: Off-label use in the US

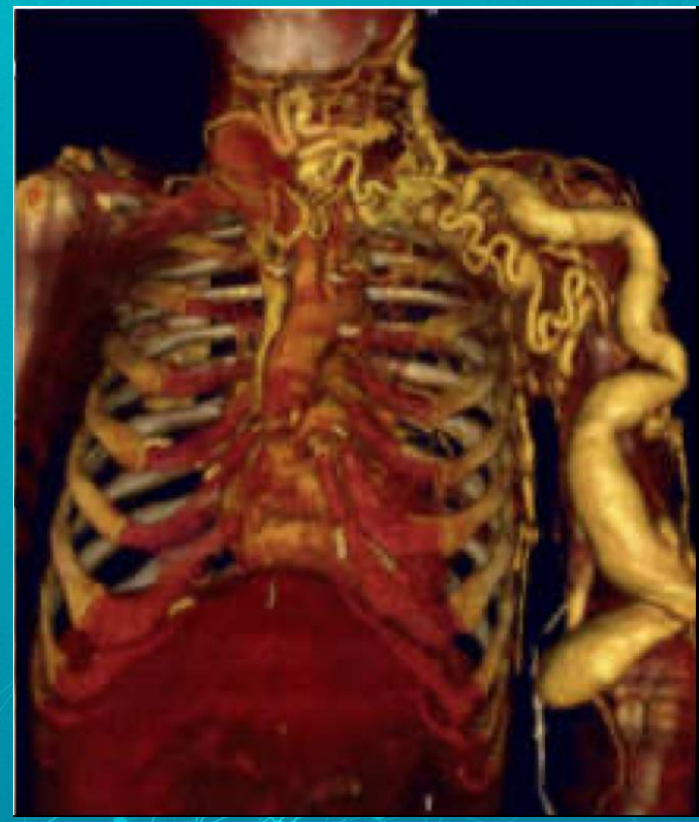
WRAPSODY ® ENDOPROSTHESIS IN CENTRAL VENOUS OCCLUSION



Leonardo Cortizo
(for the SAVE Group)

Vascular and Endovascular Surgeon, Salvador, Bahia, Brazil

- Vascular Surgery Brazilian Society Member - SBACV
- Vascular Access Society – VAS Member
- SAVE Team Member
- IVA Vascular Clinic Director



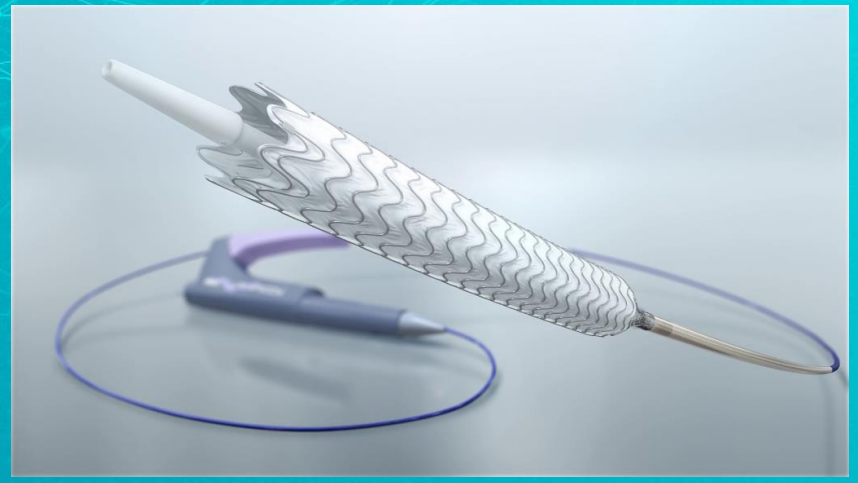


Table X. Descriptive analysis of the sample

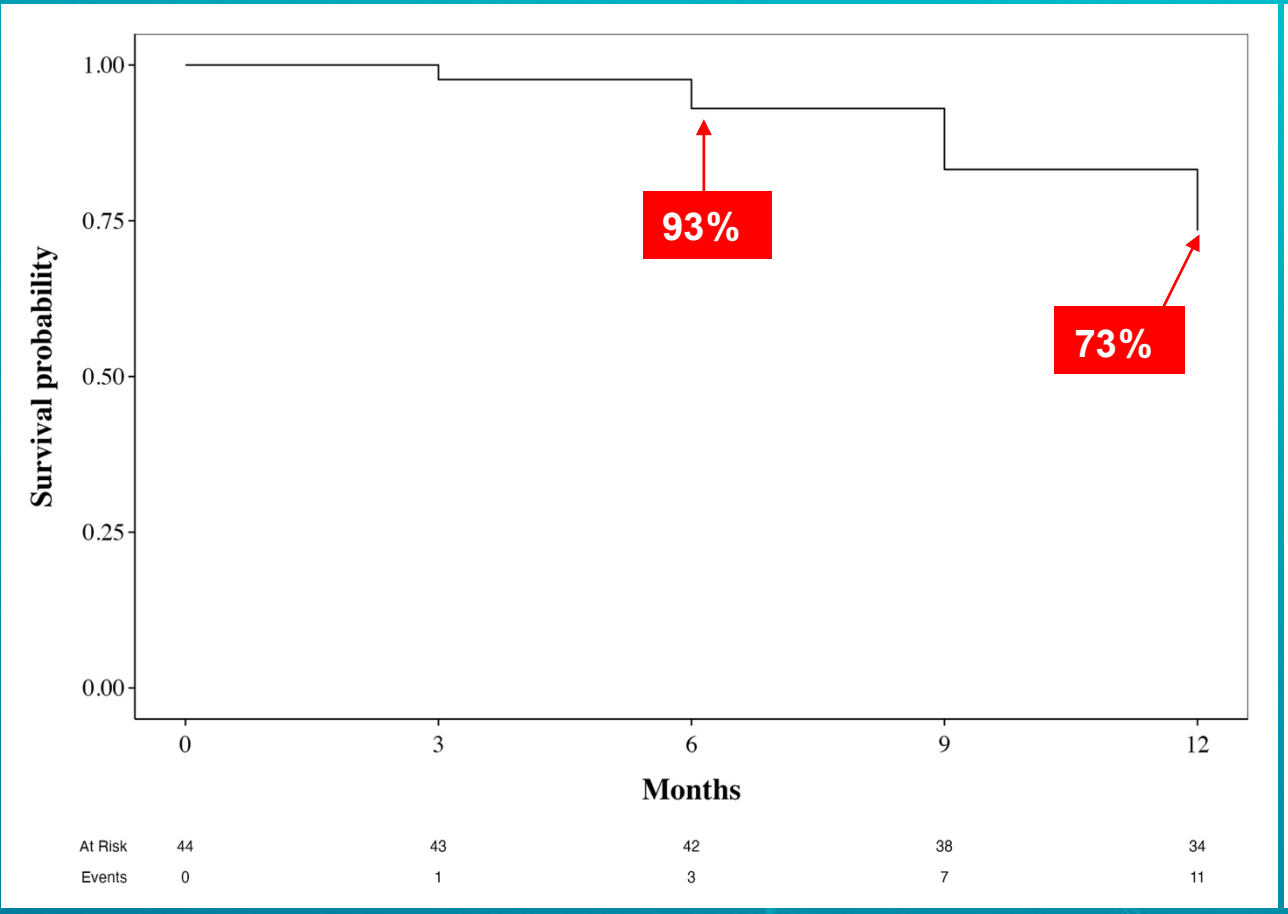
Characteristic	N = 44[1]
Age	
< 65 years old	26 (59.1%)
>= 65 years old	18 (40.9%)
Gender	
Female	20 (45.5%)
Male	24 (54.5%)
Hypertension	36 (81.8%)
Diabetes	21 (47.7%)
Coronary artery disease	9 (20.5%)
Tobacco smoking	3 (6.8%)
Stroke	4 (9.1%)
Other	5 (11.4%)

Table X. Clinical characteristics of the sample

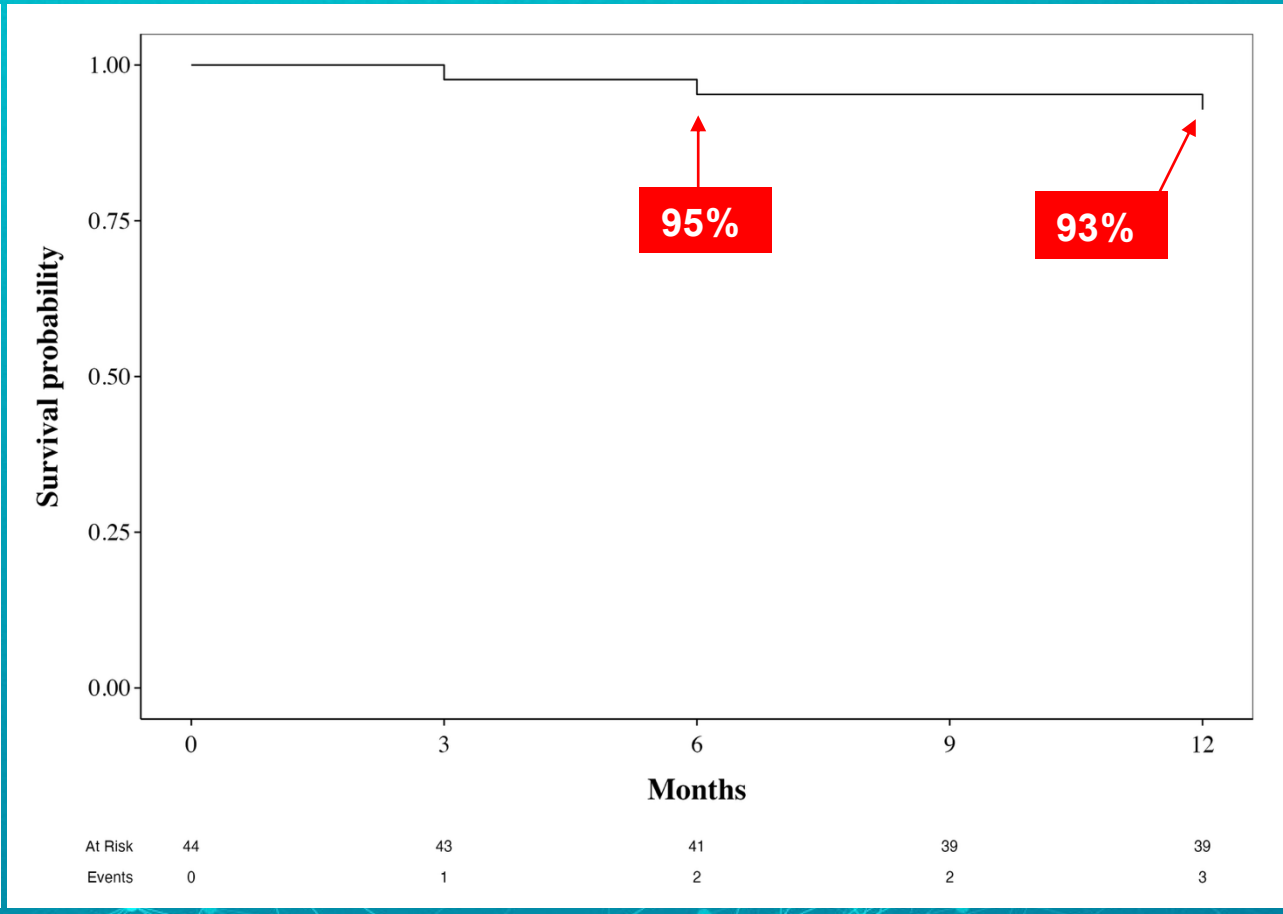
Characteristic	N = 44[1]
Balloon diameter (pre)	
< 10	2 (4.5%)
10	7 (15.9%)
12	23 (52.3%)
14	9 (20.5%)
16	3 (6.8%)
Stent diameter	
10	1 (2.3%)
12	6 (13.6%)
14	17 (38.6%)
16	20 (45.5%)
Stent length	
30mm	1 (2.3%)
40mm	8 (18.2%)
50mm	4 (9.1%)
60mm	13 (29.5%)
70mm	2 (4.5%)
80mm	16 (36.4%)
Stent crosses costoclavicular space	26 (59.1%)
Angioplasty access	
FAV	9 (20.5%)
Femoral vein	35 (79.5%)

RESULTS

Target Lesion Primary Patency

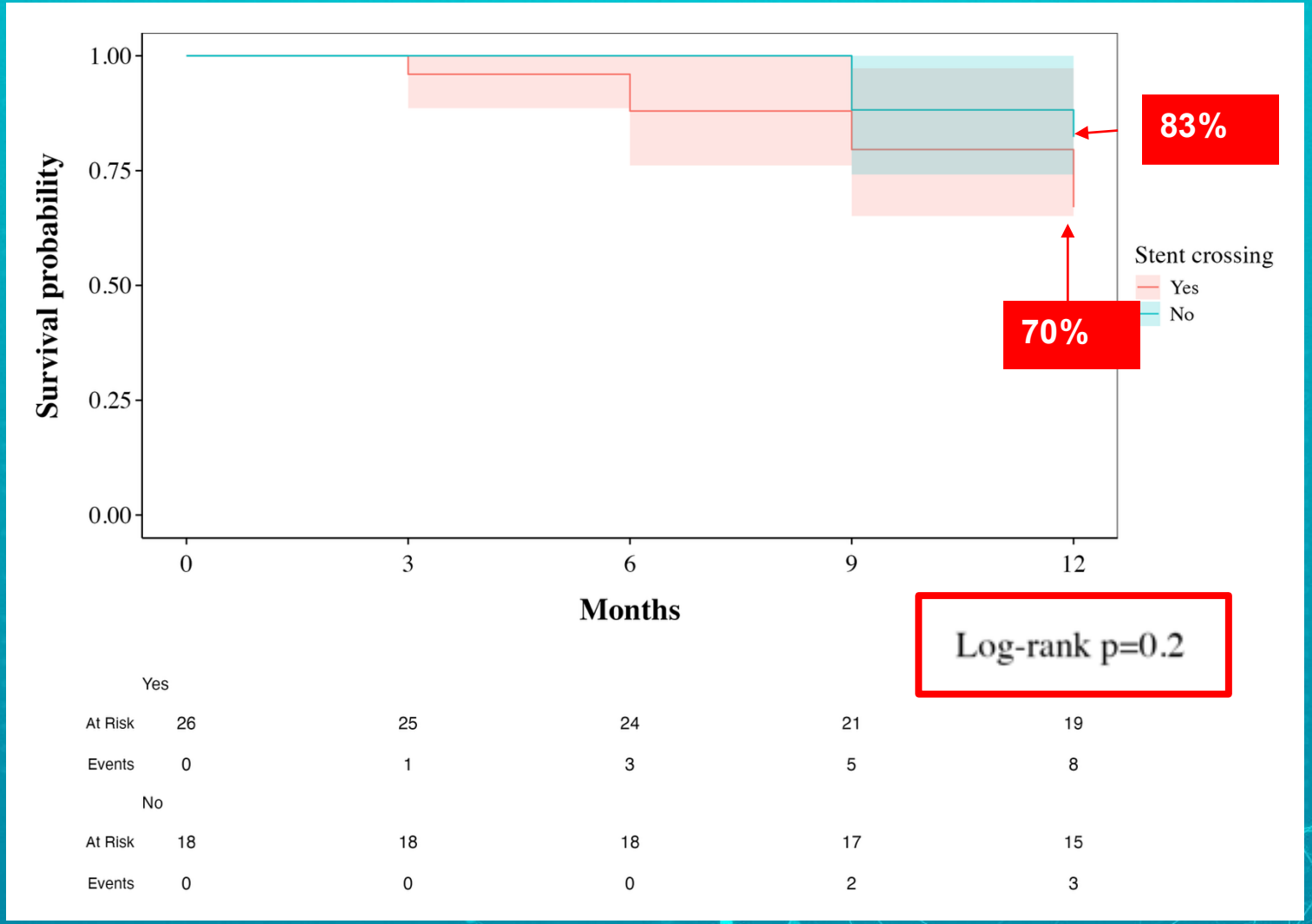


Target Lesion Secondary Patency



RESULTS

TLPP: Wrapsody across costoclavicular space



Summary

TCVO data is weak and heterogeneous for PTA and Bare Stents

- PTA appears safer than bare stents (more SAE's with bare stents, fractures)
- 6 months: Bare stent primary patency was statistically better than PTA
- 12 months: Bare stents not statistically better than PTA

Clinical studies suggest comparable or better 6-month and 12-month primary patency using covered stents compared to bare stents.

Early recent Covered Stent data

- 6 months: Covered stents seem comparable or better than bare stent data.
- 12 months: Better primary patency with covered stents than PTA or bare stents

Bare stent or Covered Stent for TCVO?

Covered stent data is encouraging. Based on prior and ongoing studies, many practitioners are using covered stents for TCVO when anatomically appropriate.

Beside the Wallstent, no bare or covered stents are FDA cleared for TCVO. More data will be forthcoming from the Global WRAP and US WAVE Post-approval registries.

Are there any indications for bare stents treating TCVO in hemodialysis patients?

Few! Perhaps right BCV and SVC obstructions (my opinion)

