Microembolization During Complex Endovascular Procedures Is Causing More Damage Than We Think To The Already Compromised Pedal Runoff and Is Paclitaxel A Causal Agent

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Peter A. Schneider Disclosures

Consulting:

Surmodics, Medtronic, Boston Scientific, Phillips, Cagent, Acotec, Abbott, Endologix, Shockwave, Silk Road, Healthcare Inroads, Inari, BD

Role of Microembolization in Lower Extremity Procedures

- Embolization is common during lower extremity interventions.
  - We do not yet know the consequences.
- Personal clinical experience.
  - Clinically apparent ischemia during a procedure caused by non-target lesion occlusion.
- Data from studies of distal filters and perfusion assessment tools.
- Unexplained events possibly related to microvascular occlusion:
  - Slowly healing/non-healed wounds despite patent target lesion
  - Loss of wound blush
  - Worsening runoff over serial interventions
  - Unplanned amputation

Carotid Lesions: A Paradigm for Embolization

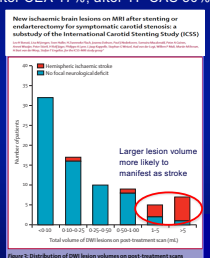
Reference	Protection	N	Debris retrieved	Comment
Piazza et al.	Distal filter	278	74%	Gross and microscopic
Ledwoch et al.	Distal filter	944	89%	Gross and microscopic
Leckie et al.	TCAR	750	47%	Gross only

Leckie et al. Vascular 2023;31:1173

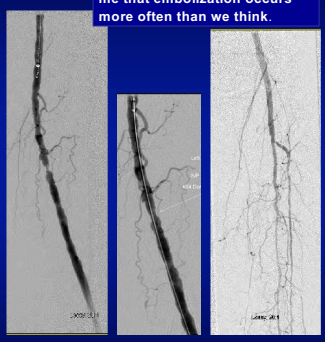
New DW-MRI Lesions in 50-87% of patients after TF-CAS

Leal et al.
Eur J Vasc Endovasc Surg 2010;39:661

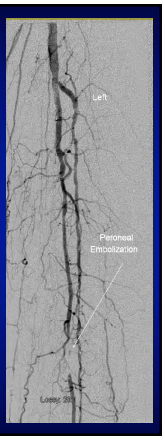
New DW-MRI Lesions in ICSS RCT: After CEA 17%, after TF-CAS 50%

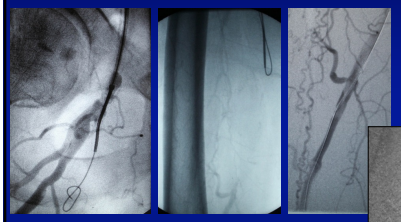


Bonati et al. Lancet Neurology 2010;1016:1474

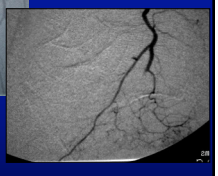


This is the case that convinced me that embolization occurs more often than we think.





Lower Extremity Embolization



As we go after more complex lesions…

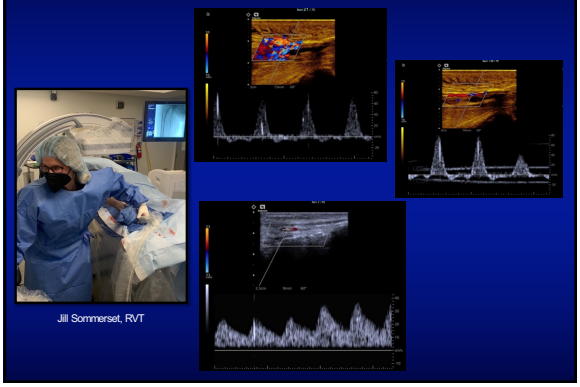
Factors Associated with Clinically Apparent Embolization

Variable	RR	95% CI Lower	95% CI Upper	*P* value
Age	0.97	0.95	0.98	<.0001
Indication: CLI vs claudication	2.61	1.58	4.32	<.001
No. of treated arteries	1.21	1.03	1.44	.025
Total occlusion length	1.02	1.01	1.02	.001
Urgency				
Urgent vs elective	1.07	0.63	1.81	.81
Emergent vs elective	3.54	1.37	9.16	.009
Stent[a] vs balloon[b] and atherectomy[c]	0.36	0.17	0.73	.005
Balloon vs balloon and atherectomy	0.234	0.13	0.41	<.0001
Atherectomy vs balloon and atherectomy	0.36	0.05	2.61	.31
Balloon and stent vs balloon and atherectomy	0.29	0.17	0.49	<.0001
Stent and atherectomy vs balloon and atherectomy	0.93	0.48	1.83	.84

Ochoa-Chaar et al. J Vasc Surg 2017;66:143

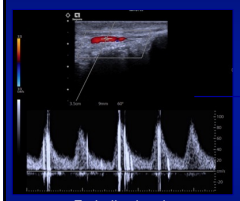
- Age
- CLTI
- Occlusion length
- Number of treated arteries
- Emergency
- Atherectomy

Embolization Detected Intraoperatively by Pedal Artery Duplex

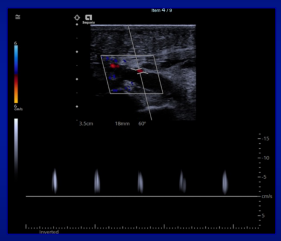


Jill Sommerset, RVT

Flow in the Lateral Plantar Artery

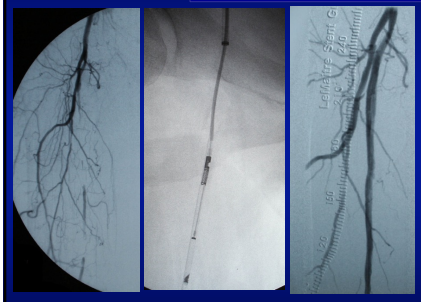


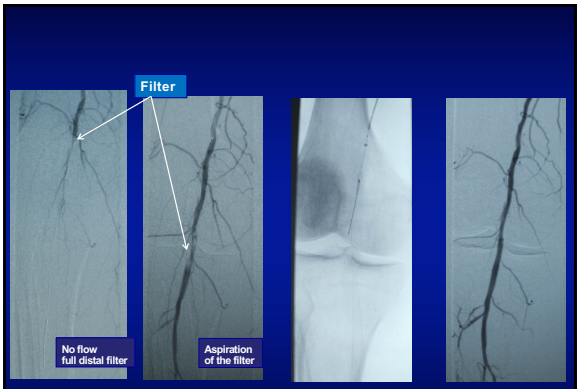
Embolic signals



Flow nearly undetectable after numerous embolic signals

This is the case that convinced me to use a filter when performing atherectomy.





Directional atherectomy before paclitaxel coated balloon angioplasty in complex femoropopliteal disease: The VIVA REALITY study

- 13 centers
- 102 patients
- High complexity disease

Debris Captured →

Distal embolization →

TABLE 2 Baseline lesion characteristics and procedure outcomes

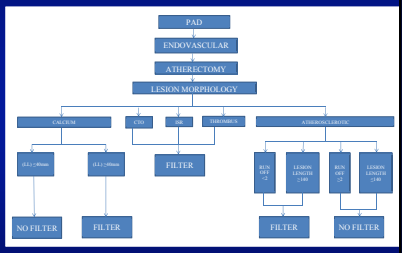
	Treated subjects (n = 102)
Lesion characteristics	
Lesion length (mm)	179 ± 81 (99)
Lesion length ≥ 150 mm	55.6 (55/99)
Calcium PACSS score	
Grade 0	1.0 (1/102)
Grade 1	2.9 (3/102)
Grade 2	0.0 (0/102)
Grade 3	18.6 (19/102)
Grade 4	67.6 (69/102)
Distal protection used	97.1 (99/102)
Debris captured in distal protection device	93.9 (93/99)
Procedure-related complication	
Perforations	3.1 (3/98)
Perforations requiring stenting	100.0 (3/3)
Dissections ≥ grade C[b]	14.3 (14/98)
Dissections requiring stenting	35.7 (5/14)
Distal embolization	12.8 (11/86)
Distal embolization requiring aspiration only	45.5 (5/11)
Distal embolization requiring stenting	9.1 (1/11)

Rocha-Singh et al. Catheter Cardiovasc Interv 2021;98:549

Algorithm for Distal Filter with Atherectomy

508 patients
331 (65%) had
macro-embolic debris

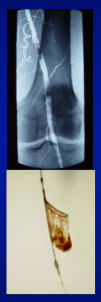
Calcified lesion >4cm
Standard lesion >14cm
Less than 0-1 vessel runoff



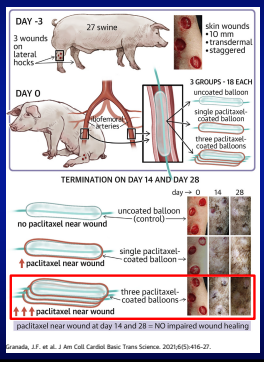
Krishnan et al. J Am Coll Cardiol Intv 2017;10:403

Lower Extremity Embolic Protection Device

Author	N	Indication	Debris	Predictors	Comment
Schneider et al IJET, 2012	68	Selective	79%	Atherectomy TASC D	Filter occlusion 15% Emboshield
Muller-Hulsbeck et al JEVT, 2009	30	Primary	92%	Atherectomy	Filterwire
Allie et al TCT, 2008	115	Selective	70%	Atherectomy Occlusion	>2mm in 24%
Shammas et al JEVT, 2008	40	Primary	55%	Atherectomy PTA/stent	>2mm in 90% >2mm 28%
Karnabatidis JEVT, 2006	48	Primary	58%	Occlusion Long lesion	>3mm in 12%



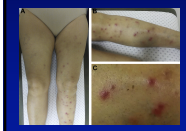
FDA-Mandated Pre-clinical Protocol

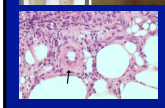


Granada, J.F. et al. J Am Coll Cardiol Basic Trans Science. 2021;6(5):416-27.

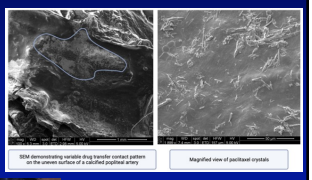
Healing not impaired
in distal extremity wounds in presence of intentional paclitaxel overdose.

Particulate Embolization After DCB

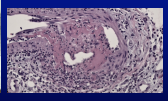




Thomas et al. J Vasc Surg 2014;59:520



Courtesy: Trisha Roy, MD



Hawkins et al. J Am Acad Derm 2022;23:1

Slow Flow After DCB

	Slow Flow (n=7:8%)	No Slow flow (n=81)	P Value
Freedom from Restenosis	71%	91%	0.09
Freedom from TLR	71%	97%	<0.01
Amputation free survival	71%	95%	0.02

Shirai et al. Heart Vessels 2021;36:1818

Possibly due to
diffuse microembolization

The no-flow phenomenon following drug-coated balloon angioplasty in a patient with chronic limb-threatening ischemia and a history of below-knee amputation

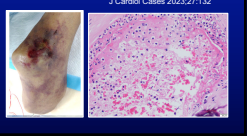
Mitsuo Sobajima (MD, PhD) *, Teruhiko Imamura (MD, PhD, FJCC), Atsuko Fukuo (MD), Yohei Ueno (MD, PhD), Hiroshi Onoda (MD, PhD), Hiroshi Ueno (MD, PhD), Koichiro Kinugawa (MD, PhD, FJCC)

J Cardiol Cases 2023;27:132

Slow-flow phenomena following lower limb paclitaxel- and sirolimus-coated balloon angioplasty in the setting of chronic limb threatening ischaemia—a case series

Tjun Y. Tang*^, Muhammad S. B. Sulaiman^, Shereen X. Y. Soon^, Cheryl J. Q. Yap^, Ankur Patel^, Yen T. Chong*^

Quant Imaging Med Surg 2022;12:2058



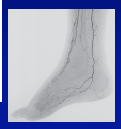
Small Artery Disease Is Common

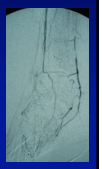
TABLE III.—*Prevalence of lesions and lesion severity across arterial districts in 1915 limbs.*

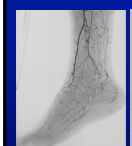
Parameter	Stenosis	Occlusion	Any disease
Dorsalis pedis*	262 (15.3%)	381 (22.3%)	643 (37.6%)
Lateral plantar*	329 (19.2%)	663 (38.8%)	992 (58.0%)
Medial plantar*	269 (15.7%)	567 (33.2%)	836 (48.9%)
Small foot arteries**	271 (16.5%)	143 (8.7%)	414 (25.2%)

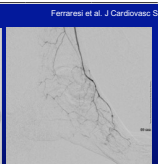
Data are presented as number of cases (percentage).
*Base, N=1711 legs with the study of big foot arteries; **base, N=1640 legs with the study of small foot arteries.

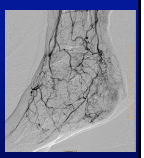
Ferraresi et al. J Cardiovasc Surg 2018;59:655











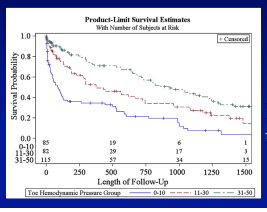
Severity of Runoff Disease Has Changed

Kim and Schneider. J Endovasc Ther 2020

AFS lower with decreased toe pressure

Toe pressure <10mm Hg:
1-year AFS 35%

31% underwent intervention but did not achieve hemodynamic improvement



TP <10mmHg

Table IV. Kaplan-Meier amputation-free survival (AFS) by revised toe hemodynamic pressure group (N = 282 limbs)

Toe pressure <50mm Hg	*6 months*	*1 year*	*2 years*	*3 years*
Overall	0.64 (0.031)	0.54 (0.032)	0.41 (0.033)	0.28 (0.032)
TP 31-50 mm Hg (group 0, n = 115)	0.82 (0.040)	0.71 (0.048)	0.58 (0.053)	0.44 (0.056)
TP 11-30 mm Hg (group 1, n = 82)	0.69 (0.054)	0.53 (0.060)	0.38 (0.060)	0.27 (0.057)
TP 0-10 mm Hg (group 2, n = 85)	0.36 (0.055)	0.35 (0.055)	0.21 (0.050)	0.08 (0.036)

Vallabhaneni et al. J Vasc Surg 2016;63:105

Microembolization during complex revascularization is causing more runoff damage than we think

- Serial procedures over months to years
- Treating more complex lesions
- In patients with more severely compromised runoff

↓

- Further damage to already diseased microcirculation
- More patients with no improvement in perfusion after revascularization
- More patients with unexplained treatment failure, slowly healing or nonhealed wounds

Microembolization During Complex Lower Extremity Revascularization is Causing More Damage Than We Think

Conclusion

- Embolization is clinically apparent in about 5% (when we look).
- Angiography is not sensitive enough but the more we look, the more we find.

- Combination of more aggressive endovascular approach to more extensive occlusive disease morphology and repeated procedures in patients with poor runoff integrity, will likely have negative consequences.

- We do not know whether there are long-term consequences to microembolization-but we may be accelerating the deterioration of the runoff bed. We need more information about the effect on outcomes.

Microembolization During Complex Endovascular Procedures Is Causing More Damage Than We Think To The Already Compromised Pedal Runoff and Is Paclitaxel A Causal Agent

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