

VEITH SYMPOSIUM
Connecting The Vascular Community

Value of Lithotripsy for TCAR or CAS in Heavily Calcified Lesions



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Disclosures

- Silk Road Medical (TCAR)
 - National PI: ROADSTER-3
 - Site PI: ROADSTER and ROADSTER-2
 - Physician Education/Training/Certification
- Medtronic
 - Physician/Trainee Education
- Adiant/CyndRx/Endospan/Endoron/Nectero
 - Clinical Events Committee/Data Safety Monitoring Board
- UpToDate (royalties for topics)
 - Author, carotid and aortic aneurysm
- Intersocietal Accreditation Commission (IAC)
 - Member, Carotid Stenting Board
- Will discuss "off label" devices/techniques
- Opinions are my own and do not represent official societal/committee endorsements

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Intravascular Lithotripsy (IVL)

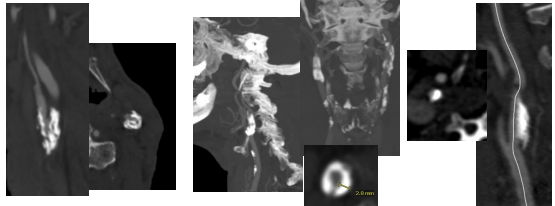



- Intravascular lithotripsy (i.e. Shockwave)
 - Use in PAD 2016
 - Use in coronary 2021
 - Not currently indicated for carotid artery

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Carotid Lesion Calcification

Severe calcium burden is exclusion criterion for all carotid stent trials

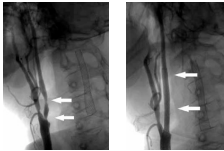


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Intravascular Lithotripsy (IVL) for Carotid Lesions

Critical calcified carotid stenosis treated with shockwave lithoplasty
Letter to the Editor
Arch Med Sci Atheroscler Dis 2018; 3: e164-e165

- Prior XRT for tongue CA
- Contralateral TF-CAS
- TF-CAS w/distal EPD
 - SpiderRx
 - 4 mm x 15 mm IVL



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Intravascular Lithotripsy (IVL) for Carotid Lesions

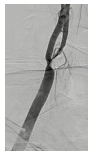
Intravascular Lithotripsy for Treatment of Calcified Lesions During Carotid Artery Stenting

Journal of Endovascular Therapy 2021; Vol. 28(1) 93-99

- 19 patients at 8 sites
 - 17 de-novo, 2 ISR
 - **IVL at physician discretion**
- Wide range of EPD/stents
- 100% success
- 1 stroke (17d): "TF-CAS; arch manipulation"
- 1 restenosis >70% (12 mo)
- f/u 6 months

Shockwave balloon diameters, mm	4.64±1.13 (3-6)
Shockwave balloon lengths, mm	12-30-60
Energy pulses	67.2±61.4 (10-180)
MLD before IVL, mm (n=11)	2.69±1.05
MLD after IVL, mm (n=11)	2.24±1.21
Postdilation balloon diameter, mm	4.53±0.67
Postdilation balloon pressure, atm	10±3.7
Postdilation duration, s	16.3±43.7

Abbreviations: IVL, intravascular lithotripsy; MLD, minimum lumen diameter.




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Intravascular Lithotripsy (IVL) in TCAR

The utilization of intravascular lithotripsy to facilitate transcarotid artery revascularization

The Journal of Cardiovascular Surgery 2020 December 61(6):759-62

- 93M, high function, symptomatic
 - Circumferentially calcified
 - Severe arch disease
 - Innominate stent
- 5 x 60 IVL; 8 x 30 mm stent; 6 x 20
- Golfing 2 weeks
- f/u 6 months

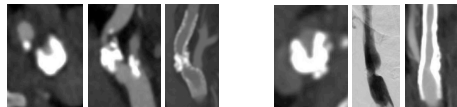


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Intravascular Lithotripsy (IVL) in TCAR

Intravascular lithotripsy during transcarotid arterial revascularization for highly calcified lesions in high-risk patients

J Vasc Surg Cases and Innovative Techniques 2021;7:68-73



73M, asymp, contralateral occlusion

- 5 x 60 IVL; 8 x 40 stent; 5-5 x 30
- 30d: 48% by CTA

81M, asymp, XRT, contralateral RLN palsy

- 5 x 60 IVL; 5-5 x 20; 10 x 40 and 10 x 30 stents; 6 x 30
- 30d: 37% by CTA

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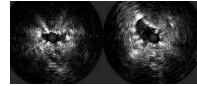
Intravascular Lithotripsy (IVL) in TCAR

Intravascular Lithotripsy Assisted Carotid Stent Expansion

Journal of Endovascular Therapy 2024, Vol. 31(1):479-484

82F, recurrent stenosis prior TCAR (8 months)

- TF-CAS, distal EPD, IVUS
- 5 x 60 IVL; IVUS: significant stenosis
- 18 atm angioplasty
- 30% residual stenosis, f/u 15 months



60F, heavily calcified CCA orifice/ICA lesion

- Contralateral occlusion, needs CABG
- TF-CAS, distal EPD, CCA stent
- 5 x 60 IVL; 10 x 31 stent
- <30%, f/u 2 months

86F, symptomatic, heavily calcified

- TCAR, 4 x 40 IVL; 7 x 30 stent
- Significant bradycardia
- f/u 2 months (PSV 645 cm/s)

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Intravascular Lithotripsy (IVL) in TCAR

Multi-center experience with intravascular lithotripsy for treatment of severe calcification during transcarotid artery revascularization for high-risk patients


J Vasc Surg 2024;80:757-63

- 9 institutions; 2018-22; 58 patients w/22 (38%) symptomatic
- TCAR w/IVL; Technical success 100%
- 4 (6.8%) w/30d stroke-TIA: 1 stroke/1 TIA in-hospital; 2 TIA post-discharge
- Mean f/u of 132 days; 5% recurrent stenosis

Conclusions: IVL sufficiently remodels calcified carotid arteries to facilitate TCAR effectively in patients with traditionally prohibitive calcific disease. One patient (1.7%) suffered a stroke within 30 days, although four patients (6.8%) sustained any new neurological event (stroke/TIA). These results raise concerns about the risks of TCAR+IVL and whether it is an appropriate strategy for patients who could potentially undergo CEA. *J Vasc Surg* 2024;80:757-63.

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IVL Technique in TCAR/CAS



Not all lesions are amenable to IVL!!!

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IVL Considerations in TCAR/CAS

Shockwave S⁴

DIAMETER (mm)	LENGTH (cm)
2.5	40
3.0	40
3.5	40
4.0	40

Shockwave M⁵

DIAMETER (mm)	BALLOON LENGTH (cm)
3.0	60
4.0	60
4.5	60
5.0	60
5.5	60
6.0	60
6.5	60
7.0	60
8.0	60

- Choose appropriate IVL diameter/length
- Sequence of intervention:
 - IVL catheter
 - "standard" angioplasty
 - Stent placement
 - =/- post-stent intervention
- Anticipate bradycardia/hypotension

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Use of IVL as Adjunct During TCAR/CAS

- Severe calcification represents a unique challenge in endovascular revascularization procedures
- Intravascular lithotripsy has demonstrated to be a safe and effective procedure in the periphery and coronary arteries
- Initial experience w/IVL in carotid interventions has shown feasibility in challenging subgroup of patients, but with increased rates of neurologic events.
- Successful carotid revascularization mandates durable "long-term" outcomes
- A CAS specific IVL catheter should be prospectively evaluated for long-term safety and efficacy.

Thank you!

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