

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

Christopher L. Henry, MD,<sup>a</sup> Spencer K. Hansen, MD,<sup>b</sup> Cara E. Gable,<sup>c</sup> Bradley R. Grimsley, MD, FACS,<sup>a</sup> and Dennis R. Gable, MD, DFSVS, FACS, RVT,<sup>b</sup> Dallas, Plano, and College Station, Tex

## ABSTRACT

Transcatheter arterial revascularization (TCAR) with flow reversal offers a less invasive option for carotid revascularization in high-risk surgical patients. TCAR has been shown to have similar complication rates for stroke and mortality compared with carotid endarterectomy and lower complication rates compared with transfemoral carotid artery stenting. A relative contraindication for carotid stenting includes heavily calcified lesions. Intravascular lithotripsy has been approved for use in other vascular beds for endovascular treatment of heavily calcified lesions. In the present report, we have demonstrated the application of intravascular lithotripsy for heavily calcified carotid lesions, enabling treatment with TCAR for those who otherwise might be at high risk of transfemoral carotid artery stenting or carotid endarterectomy. (*J Vasc Surg Cases and Innovative Techniques* 2021;7:68-73.)

**Keywords:** Carotid; Carotid stenting; Intravascular lithotripsy; TCAR; Transcatheter

Carotid artery stenosis (CAS) is responsible for  $\leq 30\%$  of ischemic strokes.<sup>1</sup> Traditional treatment options have included carotid endarterectomy (CEA) and transfemoral carotid artery stenting (TF-CAS). TF-CAS has many theoretical benefits; however, TF-CAS has failed to become popular in the treatment of asymptomatic or symptomatic patients with CAS. The CREST (carotid revascularization endarterectomy vs stenting) trial<sup>2</sup> found that at 4 years, these two procedures had statistically similar rates of stroke, myocardial infarction, and death. Even with the evolution of distal embolic protection devices, the rate of perioperative stroke has not improved significantly, and CEA has remained the primary intervention for patients with carotid artery disease.

Transcatheter arterial revascularization (TCAR) with flow reversal offers another option for treating CAS in high-risk patients.<sup>3</sup> TCAR has resulted in composite rates of stroke, death, and myocardial infarction similar to those with open CEA despite the older and substantially higher

risk patients.<sup>4</sup> Compared with TF-CAS, TCAR has resulted in significantly lower in-hospital transient ischemic attack, stroke, and death rates.<sup>5</sup> A relative contraindication for TCAR includes heavily and/or circumferentially calcified lesions. In the peripheral and coronary circulation, intravascular lithotripsy (IVL) has been approved for use in the treatment of heavily calcified lesions. IVL generates a sonic pressure wave that interacts with calcium, creating shear stress that fractures the calcium within the atherosclerotic plaque but without rupturing the plaque or associated vessel.<sup>6</sup> This increases vessel compliance, restores vessel mobility, and improves the therapeutic effectiveness of angioplasty and stenting. In the present study, the use of IVL was applied to heavily calcified carotid lesions undergoing TCAR in patients at high risk for endarterectomy.

## METHODS

Two patients with an off-label/off-indication (instructions for use) were treated with predilation of a highly calcified internal carotid artery lesion during TCAR using IVL. The main objective of treatment was procedural success plus the absence of stroke in the immediate and 30-day postoperative periods. The goals of treatment included an improvement in target lesion stenosis using the North American Symptomatic Carotid Endarterectomy Trial (NASCET) criteria and nonsignificant residual stenosis on follow-up imaging. The institutional review board approved the present study (approval no. 014-209). The patients were selected at the discretion of the operating surgeon. Both patients had met the high-risk criteria for TCAR. Patient 1 had had a contralateral internal carotid artery occlusion and patient 2 had a history of head and neck radiation with contralateral laryngeal nerve palsy. Both patients had asymptomatic stenosis of  $\geq 70\%$  using the NASCET criteria. Preoperative imaging studies with computed tomography angiography

---

From the Department of Vascular Surgery, Baylor Scott & White Heart and Vascular Hospital, Dallas<sup>a</sup>; the Department of Vascular and Endovascular Surgery, Baylor Scott & White Heart Hospital Plano, Plano<sup>b</sup>; and the College of Veterinary Medicine and Biomedical Sciences, Texas A&M University, College Station.<sup>c</sup>

Author conflict of interest: B.R.G. has been paid by Silk Road for speaking engagements. C.L.H., S.K.H., C.E.G., and D.R.G. have no conflicts of interest.

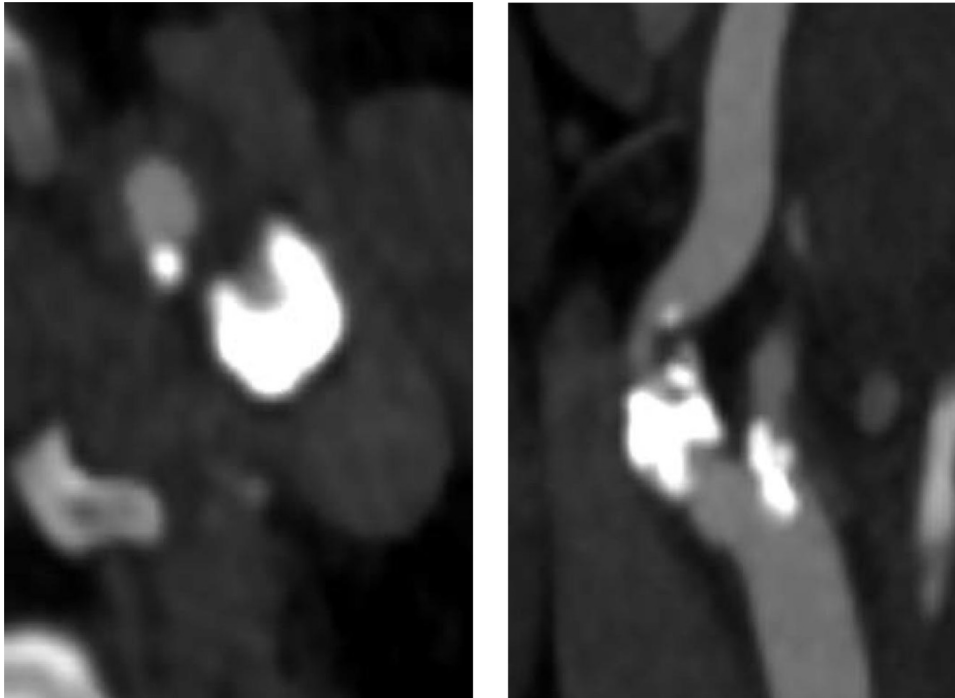
Correspondence: Dennis R. Gable, MD, DFSVS, FACS, RVT, Department of Vascular and Endovascular Surgery, Baylor Scott & White Heart Hospital Plano, 4716 Alliance Blvd, Ste 200, Plano, TX 75093 (e-mail: [dennis.gable@bswhealth.org](mailto:dennis.gable@bswhealth.org)).

The editors and reviewers of this article have no relevant financial relationships to disclose per the Journal policy that requires reviewers to decline review of any manuscript for which they may have a conflict of interest.

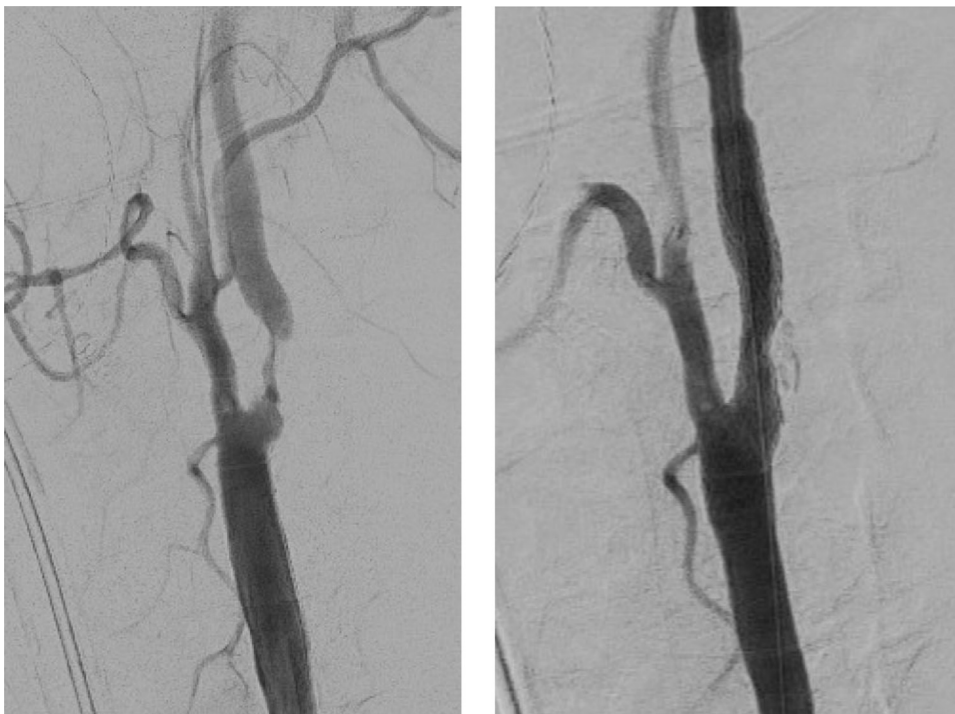
2468-4287

© 2020 The Authors. Published by Elsevier Inc. on behalf of Society for Vascular Surgery. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

<https://doi.org/10.1016/j.jvscit.2020.10.018>



**Fig 1.** Preoperative computed tomography angiogram of patient 1.

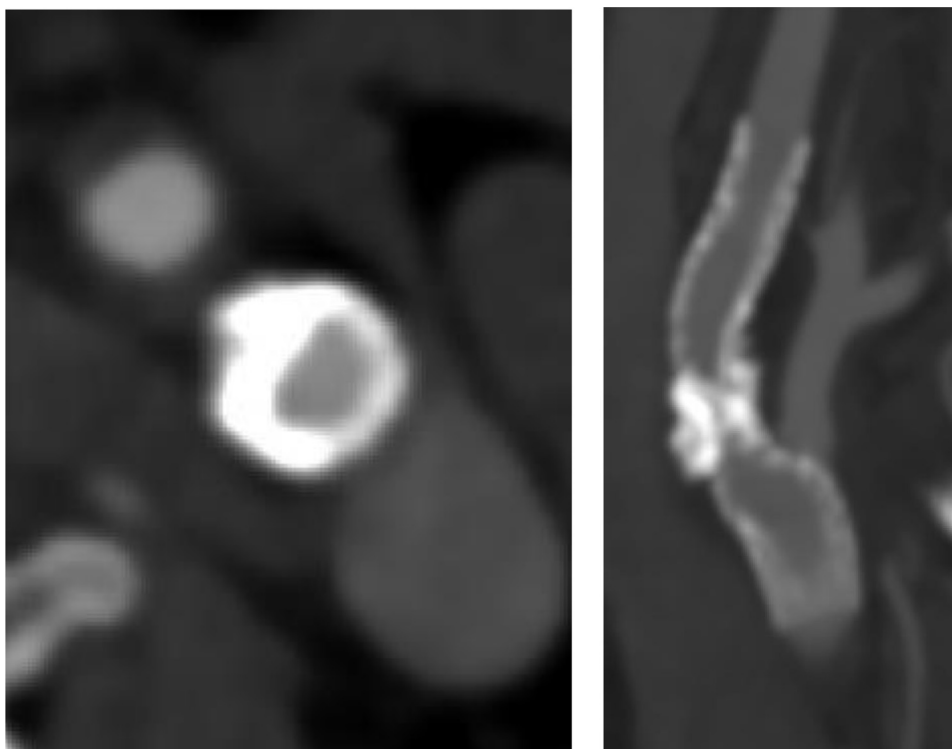


**Fig 2.** Intraoperative imaging studies before and after intervention of patient 1.

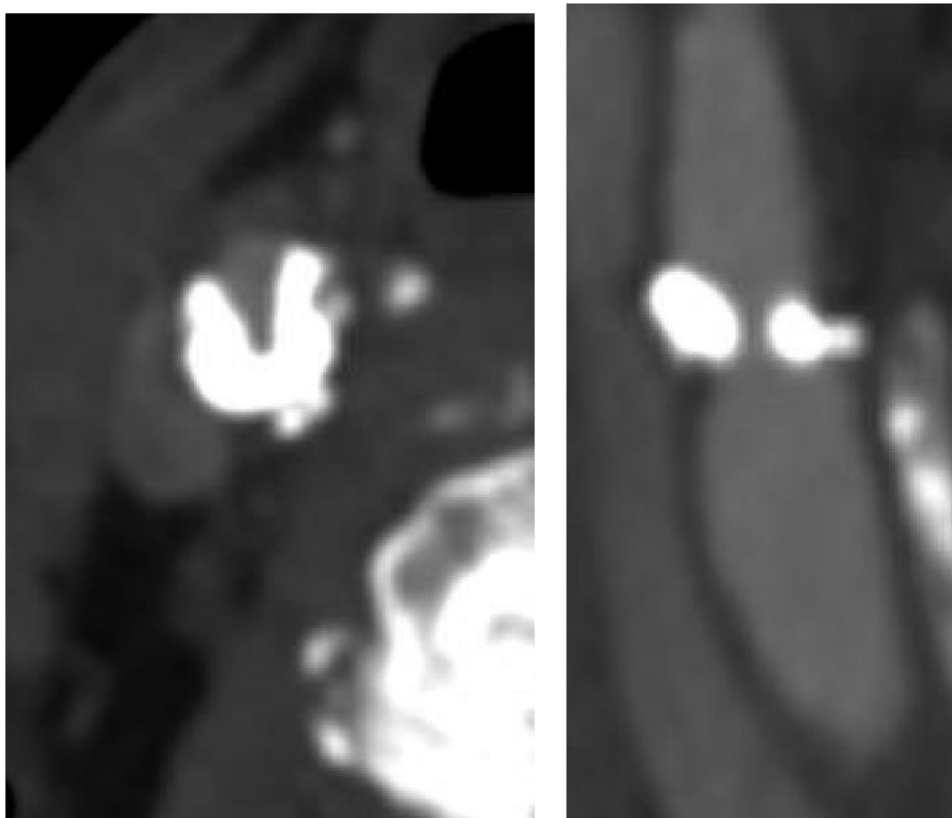
(CTA) of the neck and carotid duplex ultrasonography were obtained. Surgery was performed by vascular surgeons with experience with TCAR and IVL.

The Shockwave peripheral IVL system (Shockwave Medical, Fremont, Calif) consists of a generator,

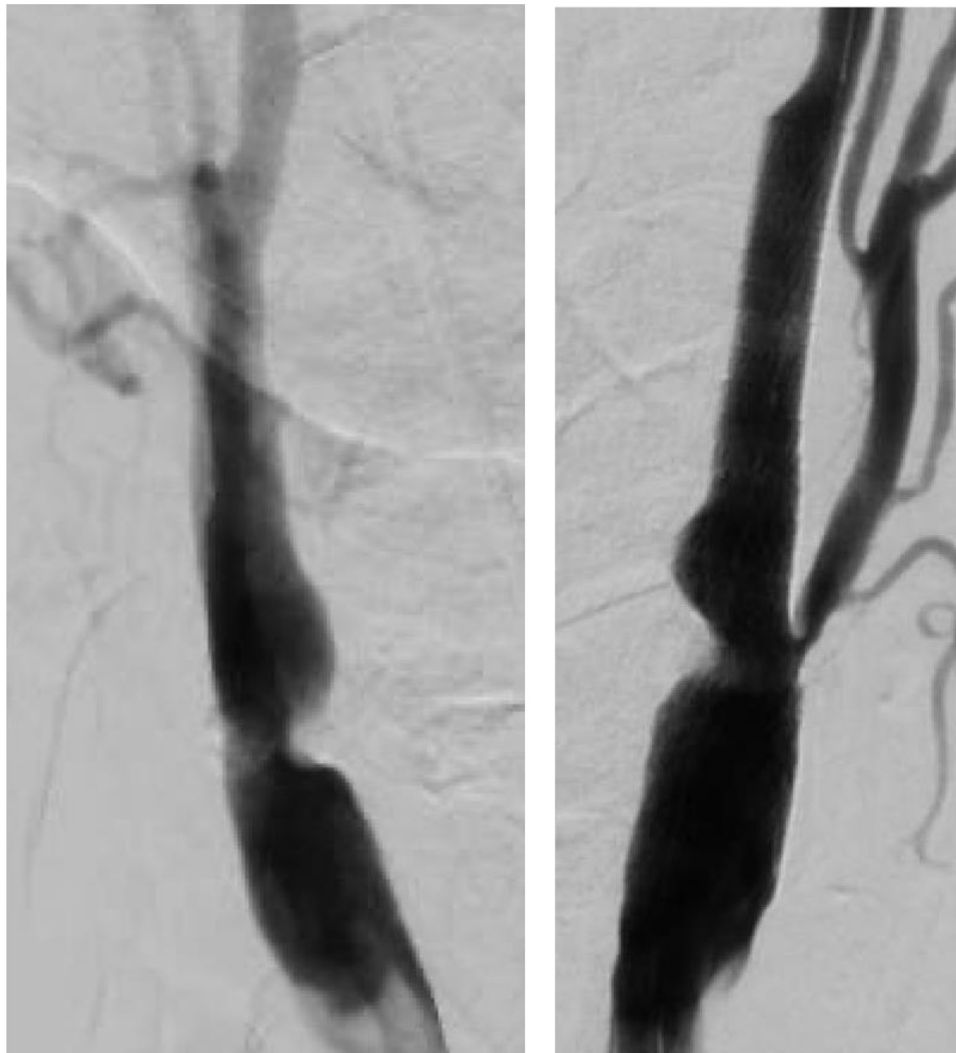
connector cable, and a disposable catheter that contains lithotripsy emitters in an integrated balloon to create a field effect via sonic pressure waves. The peripheral IVL system has been approved for lithotripsy-enhanced, low-pressure balloon dilation of calcified, stenotic



**Fig 3.** Postoperative computed tomography angiogram of patient 1.



**Fig 4.** Preoperative computed tomography angiogram of patient 2.



**Fig 5.** Intraoperative imaging studies before and after intervention of patient 2.

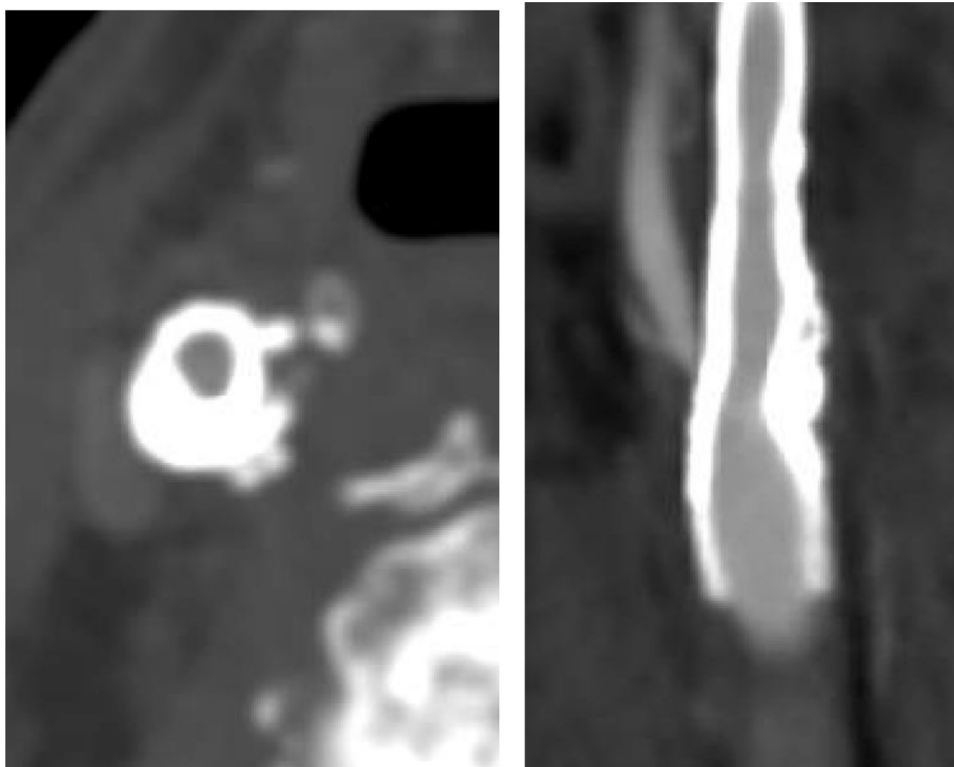
peripheral and coronary arteries. It is available in eight diameters, from 3.5 mm to 7.0 mm in 0.5-mm increments, all 60 mm in length.<sup>6</sup>

The technical aspects and details of the TCAR procedure have been well described.<sup>3,7</sup> The technical aspects of IVL in the peripheral and coronary circulation have also been described.<sup>6,8,9</sup> Both patients had undergone surgery under general anesthesia with electroencephalographic monitoring. A transverse incision was made at the base of the neck, between the sternal and clavicular heads of the sternocleidomastoid, and the proximal common carotid artery (CCA) was exposed. The CCA was accessed using the ENROUTE TCAR (Silk Road Medical, Sunnyvale, Calif) with the provided micropuncture needle, wire, and sheath. An angiogram was performed to identify the lesion. The common femoral vein was accessed with the provided 8F sheath. Reversal of flow from the CCA to the common femoral vein was initiated. The CCA was clamped proximally to complete the reversal of flow. The target lesion was crossed with a

long (300-cm) 0.014-in. wire. The kit-provided 0.014-in. wire length will not accommodate the lithotripsy balloon without loss of wire control, given a shaft length of 135 cm on the lithotripsy balloon. The lesion was predilated with a lithotripsy balloon and inflated to 4 to 6 atm and activated to deliver 30 pulses within 30 seconds before balloon deflation. This can be repeated for a maximum of 300 pulses, with deflation required for 10 seconds between each cycle. The balloon was then removed and the ENROUTE stent deployed across the lesion. Postdilation can then be performed. Procedural success was defined as a reduction of the stenosis to <50% with the absence of stroke or death.

## RESULTS

**Patient 1.** Patient 1 was a 73-year-old man with diabetes, hypertension, and hyperlipidemia. His preoperative medications included amlodipine, aspirin, clopidogrel, and atorvastatin. The lesion was asymptomatic and had been found on routine screening. The



**Fig 6.** Postoperative computed tomography scan of patient 2.

preoperative imaging study included CTA of the neck with right internal carotid artery (ICA) occlusion and left-sided ICA stenosis of 80% to 99% using the NASCET criteria (Fig 1). Carotid duplex ultrasonography confirmed a right ICA occlusion and >70% left ICA stenosis. Predilation of the lesion was performed with a 5-mm × 60-mm lithotripsy balloon and delivery of a total of 120 pulses. The lesion was treated with an 8-mm × 40-mm ENROUTE stent (Silk Road Medical). The stent was postdilated with a 5.5-mm × 30-mm Viatrac balloon (Abbott Vascular, Santa Clara, Calif). The flow reversal time was 15 minutes. The post-treatment angiogram demonstrated <50% stenosis (Fig 2). No complications were noted in the immediate postoperative period or at the 30-day follow-up examination. Postoperative CTA revealed a residual 47% stenosis using the NASCET criteria (Fig 3).

**Patient 2.** The second patient was an 81-year-old man with hypertension, emphysema, hyperlipidemia, previous cancer of the tongue treated with radiation therapy, and a resultant left recurrent laryngeal nerve palsy. The patient was receiving β-blocker therapy, aspirin, and clopidogrel. The patient was evaluated by the otorhinolaryngology team before the procedure.

Preoperative imaging studies included CTA of the neck, which revealed an 80% stenosis of the right ICA using the NASCET criteria (Fig 4). TCAR was indicated secondary to the patient's previous neck radiotherapy and

contralateral recurrent laryngeal nerve palsy. The lesion was predilated using a 5-mm × 60-mm lithotripsy balloon, with a total of 120 pulses. A second dilation was performed with a 5.5-mm × 20-mm Viatrac balloon (Abbott Vascular). A 10-mm × 40-mm ENROUTE (Silk Road Medical) and a 10-mm × 30-mm XACT stent (Abbott Vascular) were used. The lesion was postdilated with a 6-mm × 30-mm Viatrac balloon. The flow reversal time was 32 minutes. Post-treatment angiography demonstrated <50% stenosis (Fig 5). The patient was free of complications in the immediate postoperative period and at the 30-day follow-up examination. The follow-up CTA of the neck revealed a 37% ICA stenosis (Fig 6).

## DISCUSSION

Treating CAS with TCAR and IVL represents a treatment modality for highly calcified or circumferentially calcified carotid artery lesions in patients who would otherwise be poor candidates for carotid stenting. IVL has been shown to be a feasible, safe, and effective method for treating calcified lesions in various vascular beds.<sup>6,8,9</sup> The Disrupt PAD II trial (shockwave lithoplasty DISRUPT trial for PAD [peripheral arterial disease]) demonstrated good long-term results with IVL peripherally and a low incidence of complications.<sup>6</sup> Given that complications would be much less tolerable in the carotid artery, the safety record with IVL is encouraging. The aim of the

present study was to prove the technical feasibility of combining these two relatively new technologies.

## CONCLUSIONS

The present study has shown that adding IVL to TCAR is possible and appears to be safe and feasible, at least for our two patients treated with this modality. This combined modality could provide an option for patients who otherwise would be at high risk for CAS alone or CEA because of highly calcified or circumferential calcifications of the carotid circulation. It would be of value to investigate the short- and long-term outcomes of this technique in a randomized, controlled trial with a larger patient cohort to provide additional statistically relevant information.

## REFERENCES

1. O'Brien M, Chandra A. Carotid revascularization: risks and benefits. *Vasc Health Risk Manag* 2014;10:403-16.
2. Stenting versus endarterectomy for treatment of carotid-artery stenosis. *N Engl J Med* 2010;363:11-23.
3. Pinter L, Ribo M, Loh C, Lane B, Roberts T, Chou TM, et al. Safety and feasibility of a novel transcervical access neuroprotection system for carotid artery stenting in the PROOF study. *J Vasc Surg* 2011;54:1317-23.
4. Wang SK, Fajardo A, Sawchuk AP, Lemmon GW, Dalsing MC, Gupta AK, et al. Outcomes associated with a transcarotid artery revascularization-centered protocol in high-risk carotid revascularizations using the ENROUTE neuroprotection system. *J Vasc Surg* 2019;69:807-13.
5. Malas MB, Dakour-Aridi H, Wang GJ, Kashyap VS, Motaganahalli RL, Eldrup-Jorgensen J, et al. Transcarotid artery revascularization versus transfemoral carotid artery stenting in the Society for Vascular Surgery Vascular Quality Initiative. *J Vasc Surg* 2019;69:92-103.e2.
6. Brodmann M, Werner M, Holden A, Tepe G, Scheinert D, Schwindt A, et al. Primary outcomes and mechanism of action of intravascular lithotripsy in calcified, femoropopliteal lesions: results of Disrupt PAD II. *Catheter Cardiovasc Interv* 2019;93:335-42.
7. Kwolek CJ, Jaff MR, Leal JI, Hopkins LN, Shah RM, Hanover TM, et al. Results of the ROADSTER multicenter trial of transcarotid stenting with dynamic flow reversal. *J Vasc Surg* 2015;62:1227-34.
8. Di Mario C, Goodwin M, Ristalli F, Ravani M, Meucci F, Stolcova M, et al. A prospective registry of intravascular lithotripsy-enabled vascular access for transfemoral transcatheter aortic valve replacement. *JACC Cardiovasc Interv* 2019;12:502-4.
9. Brodmann M, Holden A, Zeller T. Safety and feasibility of intravascular lithotripsy for treatment of below-the-knee arterial stenoses. *J Endovasc Ther* 2018;25:499-503.

Submitted Aug 9, 2020; accepted Oct 30, 2020.