

## Original Article

# Safety Evaluation of Primary Carotid Stenting: Transcranial Doppler and MRI

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**ABSTRACT: Background and Purpose:** Cerebral emboli are generated by every step of standard carotid angioplasty and stenting. Primary carotid stenting (PCS) is a technique in which the use of balloon angioplasty (BA) is minimized to decrease the embolic load. The primary aim of this study is to establish the number of emboli generated by each step of primary stenting and determine the relationship to new diffusion (DWI) lesions on subsequent magnetic resonance imaging (MRI). **Methods:** Eighty-five patients with severe, symptomatic carotid stenosis were prospectively recruited and underwent carotid stenting. Intraoperative transcranial Doppler was performed in 77 patients. The number and size of microemboli for each of seven procedural steps were recorded. Correlation was made with the number and location of new DWI lesions. **Results:** PCS was performed in 73 patients. BA was required in 12 patients. The mean number of microemboli was 114, and most microemboli were generated by stent deployment, followed by BA. Balloon techniques generated significantly more emboli than primary stenting ( $p = 0.017$ ). There was a significant relationship between total microemboli and new DWI lesions ( $p = 0.009$ ), and between new DWI lesions in multiple territories and the severity of pretreatment stenosis ( $p = 0.002$ ). **Conclusions:** During PCS, more emboli are generated by stent deployment than during any other stage of the procedure. When BA is necessary, more malignant emboli are generated but total emboli are unchanged and there is no difference in new diffusion lesions on MRI. PCS is safe and is not inferior to historical controls for the generation of new DWI lesions.

**RÉSUMÉ :** Évaluation de l'innocuité de la pose d'endoprothèses carotidiennes en première intention, par échographie Doppler transcrânienne et IRM. **Contexte et buts :** Il peut se produire des embolies cérébrales à chacune des étapes de l'angioplastie carotidienne classique et de la pose d'endoprothèses. La pose d'endoprothèses carotidiennes en première intention est une technique durant laquelle le recours à l'angioplastie par ballonnet est réduit au minimum afin de diminuer la charge de caillots. L'étude ici présentée avait pour buts principaux de déterminer le nombre d'embolies formés à chacune des étapes de la pose d'endoprothèses, et d'établir une relation avec la présence de nouvelles lésions de diffusion, observées ultérieurement à l'imagerie par résonance magnétique (IRM). **Méthode :** Il s'agit d'une étude prospective à laquelle ont participé 85 patients atteints d'une sténose carotidienne symptomatique grave, et chez qui on a procédé à la pose d'endoprothèses carotidiennes. Une échographie Doppler transcrânienne a été effectuée en cours d'intervention chez 77 d'entre eux. Ont été consignés le nombre et la taille des microembolies qui se sont formés à chacune des sept étapes de l'intervention, après quoi une corrélation a été établie entre le nombre de nouvelles lésions de diffusion et leur siège. **Résultats :** Une pose d'endoprothèses carotidiennes en première intention a été effectuée chez 73 patients, tandis qu'une angioplastie par ballonnet a dû être pratiquée chez 12 patients. Le nombre moyen de microembolies s'élevait à 114; leur formation s'explique, pour la plupart, par l'expansion de l'endoprothèse, puis par l'angioplastie par ballonnet. Les techniques effectuées par ballonnet produisent significativement plus d'embolies que la pose d'endoprothèses ( $p = 0,017$ ) en première intention. En outre, une relation significative a été établie entre le nombre total de microembolies et les nouvelles lésions de diffusion ( $p = 0,009$ ), ainsi qu'entre la formation de nouvelles lésions de diffusion dans différents territoires et le degré de gravité de la sténose avant le traitement ( $p = 0,002$ ). **Conclusion :** Durant la pose d'endoprothèses carotidiennes en première intention, il se forme plus d'embolies au moment de l'expansion des endoprothèses qu'à toute autre étape de l'intervention. Par ailleurs, quand l'angioplastie par ballonnet s'impose, il se forme plus d'embolies dangereux, mais le nombre total d'embolies ne change pas et il n'y a pas de différence quant aux nouvelles lésions de diffusion à l'IRM. Enfin, la pose d'endoprothèses carotidiennes en première intention est une intervention sûre et elle se révèle non inférieure aux données recueillies chez les témoins historiques relativement à la formation de nouvelles lésions de diffusion.

**Keywords:** Carotid artery disease; Interventional neuroradiology; Stroke; Transcranial Doppler

(Received 2 July 2022; final revisions submitted 6 October 2022; date of acceptance 10 October 2022; First Published online 17 October 2022)

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**Cite this article:** Pelz DM, Lownie SP, Iftikhar UF, Munoz C, Lopez-Ojeda P, and Azarpazhooh R. (2023) Safety Evaluation of Primary Carotid Stenting: Transcranial Doppler and MRI. *The Canadian Journal of Neurological Sciences* 50: 651–655, <https://doi.org/10.1017/cjn.2022.304>

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## Introduction

Primary carotid stenting (PCS) is a technique designed to reduce the complexity, cost, and possibly the risk of carotid angioplasty and stenting (CAS) in patients with severe, symptomatic carotid stenosis.<sup>1,2,3,4</sup> At our center, stenting is performed without the deliberate use of angioplasty balloons or embolic protection devices (EPDs). This technique relies on the chronic outward force of self-expanding stents (SEs) to gradually expand the vessel caliber. The goal is not to immediately produce a normal diameter artery but to eliminate the embolic potential of atherosclerotic plaque and to provide adequate cerebral hemispheric blood flow. In patients with appropriate plaque characteristics on CT angiography (CTA) (i.e. predominantly non-calcified plaque), satisfactory long-term morphological results are achievable.<sup>5</sup> The number of steps is reduced, fewer costly devices are used, and the avoidance of balloons eliminates significant intra- and post-procedural hemodynamic instability.<sup>6</sup> In our experience, PCS alone is effective in over 80% of patients referred for CAS.<sup>1</sup>

Every step during CAS with balloon angioplasty (BA) protocols generates embolic debris, with the most emboli produced by stent deployment, BA, and EPD placement.<sup>7,8</sup> The primary aim of this study was to establish the number of micro-embolic signals (MES) on transcranial Doppler (TCD) generated by each step of PCS and to determine the relationship of MES to new DWI lesions on post-procedural magnetic resonance imaging (MRI). The secondary aim was to compare the number of MES and new DWI lesions in the PCS patients to historical controls of standard carotid stenting techniques with BA and EPD use, and the small number of patients in whom BA was deemed to be necessary in our series.

## Methods

This is a prospective, single-arm, cohort study, approved by the Health Sciences Research Ethics Board (HSREB) of Western University, London, Ontario, Canada. Eighty-five patients with symptomatic, severe (>70% NASCET) carotid stenosis and able to give informed consent were recruited. Subjects who were unable to undergo an MRI scan or those without an adequate window for TCD monitoring were excluded. Patients with unfavorable plaque morphology on preoperative CTA (thick, circumferential calcification, and little soft plaque) were excluded. The primary authors encountered the cases consecutively, but recruitment was delayed by the COVID-19 pandemic and other logistical factors.

Carotid stenting was performed with intention to use PCS alone for 78 vessels in 76 patients (2 patients had bilateral stenoses). PCS is routinely performed under conscious sedation provided by an anesthesiologist. Patients are placed on dual-antiplatelet medications (ASA and clopidogrel) for at least 48 h. prior to the procedure. Common femoral or radial artery access is used in all patients with systemic heparinization initiated after access is obtained. Activated clotting time is maintained at 2–3 times baseline level. The target common carotid artery is accessed using a 6Fr Envoy guide catheter (Cook, Bloomington, IN), and digital subtraction angiograms (DSAs) are obtained. Under Roadmap guidance, the carotid stenosis is crossed with a 0.014 Transend micro-guide wire (Stryker Neurovascular, Fremont CA), followed by advancement of a SES (Precise PRO RX, 8 mm × 4 cm, Cordis, Fremont CA). No EPD is utilized. Pre-stent BA is performed with a small diameter balloon if there is resistance to stent advancement (2 of 78 vessels). Post-stent BA is performed if the post-deployment DSA shows an unacceptable residual stenosis (21

of 78 vessels). Femoral closure devices (AngioSeal, St Jude Medical, St Paul, MN) are used in most patients. Compression bands are used following transradial procedures. Subjects are monitored overnight in a neuro-observation unit and usually discharged next day after duplex carotid ultrasound. Patients remain on clopidogrel for at least 1–6 months, and ASA indefinitely. Follow-up ultrasounds are performed at 1, 6, and 12 months post-procedure, and then annually.

In nine patients, CAS with BA was performed at the discretion of the operator. This was usually due to a real or anticipated unacceptable morphologic result with PCS alone (>30–40% residual stenosis by NASCET criteria). In these patients, the protocol was identical, with the addition of initial EPD (FilterwireEZ, Boston Scientific, Marlborough, MA) deployment, and balloon (Sterling, Boston Scientific) angioplasty pre- ± post-stent deployment.

TCD was performed throughout the procedure in all patients using a transcranial power M-Mode Doppler machine (ST3; Spencer Technologies, Seattle WA). A high-power (2 MHz) ultrasound probe was fixed to a head frame (Marc 600; Spencer Technologies) for monitoring of the ipsilateral proximal middle cerebral artery at 45–65 mm depth. The interventionalist informed the TCD operator continuously about the progress of the stenting procedure, which was divided into the following seven steps: crossing the arch with the guiding catheter; catheterizing the common carotid artery; crossing the stenosis with the guide wire; crossing the stenosis with the stent; deploying the stent; removing the guide wire; and retrieving the guide catheter. The times of every step, contrast injections, and any unexpected events were recorded. The number and size of TCD emboli (MES) for each step were manually counted, measured, and registered offline by two readers (CM and RA). Signals detected during contrast injections were excluded. Embolus analysis was performed on both the spectrogram and the power M-mode to improve reliability. Embolus signals on the spectrogram were identified visually as unidirectional, short-lasting (<300 ms) signals with an amplitude of >73dB above background and a typical chirping sound. The sizes of the emboli were calculated using the relative energy index of microemboli (REIM) signals, as previously described.<sup>7,8</sup> An embolus with REIM >1.0 was considered to be malignant. Malignant emboli are those with a diameter >500 μm, large enough to occlude small penetrating arteries.

Every patient was assessed for the development of any new or worsening neurological deficit in the first 24 hours post-stenting by the neurointerventional team comprised of neurologists, neurosurgeons, and neuroradiologists. Duplex carotid ultrasound was performed before discharge in all patients. All patients had undergone MRI examinations with DWI within 30 days prior to CAS. Post-procedure MRI with DWI was performed within 24–48 hours in all patients and analyzed by independent neuroradiologists (DP, MS, SP, and MM) who were blinded to the TCD data. The number and location of DWI lesions on the post-stent MRI were compared to the preoperative study. DWI lesions were classified as single or multiple, but the total number was not recorded.

All statistical analysis was done on SPSS Statistics for Windows, version 27 (SPSS Inc., Chicago, Ill). At first, a descriptive analysis was done for all the variables in the dataset and the distribution of continuous variables was checked. The number and intensity of TCD emboli and the number of DWI lesions were analyzed and compared to study variables. Correlation analysis was done to find any relationship between continuous variables, while relationship between categorical variables was assessed through chi-square and

Fisher's exact tests. Most of the continuous variables followed non-normal distribution, so we used nonparametric tests for further analysis. The Mann-Whitney *U* test was used to assess any difference between number and intensity of TCD emboli in those patients who underwent PCS compared to those who underwent CAS with BA. Similarly relationships of total and malignant MES to pretreatment NASCET stenosis, and the difference between pre- and posttreatment NASCET stenosis were determined and compared those who had new DWI changes and to those who did not have new DWI changes. Negative binomial regression was done to assess the relationship of TCD emboli count and size of TCD emboli with the type of procedure and level of pre- and posttreatment NASCET stenosis. Logistic regression analysis was done to find association of new DWI lesions with other study covariates. Results were expressed as absolute numbers, percentages, mean with standard deviation, median with interquartile range, odds ratio with 95% confidence interval, and effect size. A two-tailed *p*-value of 0.05 was considered as significant for all the tests.

## Results

A total of 85 patients were recruited for the study. The mean age was 67.8 years. There were 64 males (75.2%) and 21 (24.7%) females. All patients were symptomatic and had severe (>70%) internal carotid artery stenoses by NASCET criteria. Co-morbidities between those patients who underwent PCS alone and those who required BA were similar. Two patients had bilateral stenting procedures performed on the same date and were considered as single patients.

TCD data were not available in 8 procedures, leaving 79 procedures (in 77 patients) for analysis. Seventy-six patients underwent PCS (two bilaterally), without deliberate use of angioplasty balloons unless required for initial passage of the SES through the stenosis or failure of adequate stent expansion. BA was required in three of these patients. Nine patients underwent CAS with BA and EPD use due to real or anticipated unacceptable morphologic results. In the group of 12 BA patients, 7 required pre only, 2 required post only, and in 3 patients, both pre- and post-stent BA were required.

The mean clinical follow-up is 4 years, 3 months (median 3.5 years). Clinically, one patient in the PCS group (1.3%) and one patient in the CAS with BA group (11%) experienced a transient ischemic attack (TIA) within 48 hours of the procedure. One patient in the CAS with BA group experienced post-procedural hypotension (11%). Another patient in the CAS with BA group sustained a NSTEMI at 2 weeks post-procedure and died 27 days post-procedure. Another patient in the CAS with BA died of cardiac failure 5 weeks post-procedure. No other 30-day clinical complications were observed. The 30-day major stroke and death rate differed significantly between PCS and CAS, favoring PCS ( $p = 0.01$ ).

With regard to delayed stent concerns, eight patients in the PCS group (10.6%) restenosed and required delayed angioplasty, while three in the BA group (25%) also required delayed angioplasty for restenosis. The time intervals ranged from 2.5 months out to 6 years post-procedure. The recurrent stenoses were severe or approaching 70% by NASCET criteria. One of these had suffered an infarct 5 months after the initial procedure. The other 10 patients were asymptomatic. Three stents (two post-PCS and one post-BA) were found occluded (4.1%) during follow-up. Two were asymptomatic, but one at 9 months post-procedure suffered a fatal infarct. Two others in the PCS group developed

**Table 1:** Descriptive analysis of total and malignant MES at the most relevant stages of PCS and CAS

Stage of procedure	MES	Mean ( $\pm$ SD)	Median (Q1, Q3)	Range
Stent deployment ( $n = 79$ )	Total MES	57.7 ( $\pm$ 37.2)	65 (23, 83)	154
	Malignant MES	15.5 ( $\pm$ 14.2)	13 (5, 22)	64
EPD deployment ( $n = 5$ )	Total MES	22.8 ( $\pm$ 27.5)	13 (7, 43)	71
	Malignant MES	11.2 ( $\pm$ 19.0)	3 (0.5, 26)	45
Balloon inflation ( $n = 7$ )	Total MES	22.8 ( $\pm$ 29.0)	20 (3, 23)	83
	Malignant MES	8.7 ( $\pm$ 8.2)	9 (0, 17)	19

**Table 2:** Mean proportion of MES and benign/malignant proportions at the most relevant stages of PCS and CAS

Stage of procedure	Mean proportion of MES out of total MES ( $\pm$ SD)	Benign MES proportion	Malignant MES proportion
Arch/CCA ( $n = 79$ )	23% ( $\pm$ 17.68%)	54.1%	46.1%
Stent deployment ( $n = 79$ )	53.5% ( $\pm$ 27.04%)	73.1%	26.9%
EPD deployment ( $n = 5$ )	14.8% ( $\pm$ 11.16%)	51.7%	49.1%
Balloon inflation ( $n = 7$ )	22.5% ( $\pm$ 29.63%)	61.9%	38.1%

thrombus within the stent. One resolved with anticoagulation, but one experienced TIAs at 1 and 2 months post-procedure, and a new ipsilateral stroke at 3 months. He later died of an unrelated medullary infarct at 13 months.

The results of the TCD examinations are shown in Tables 1, 2, and 3. The average number of MES generated per procedure is 114. The average number of malignant emboli was 44. Overall, 61.4% of MES are nonmalignant and 38.6% are malignant. The mean proportion of MES generated during each stage out of total MES is given in the tables. The most MES are generated by stent deployment (mean = 57.7, mean proportion = 53.5%). For CAS with BA, additional total MES are generated with balloon inflation (mean = 22.8, mean proportion = 22.5%) and EPD deployment (mean = 11.2, mean proportion = 14.8%) (Tables 1 and 2). Malignant emboli account for 46.1% of MES for aortic arch catheterization, 26.9% for stent deployment, 38.1% for balloon inflation, and 49.1% for EPD deployment (Table 2). There is no significant association between overall MES count and: PCS; CAS with BA; level of pretreatment and posttreatment stenosis on negative binomial regression. Similarly, no association is found between overall malignant MES and: PCS; CAS with BA; level of pretreatment and posttreatment stenosis. However, there are significant differences in the total and malignant MES generated during different stages of PCS and CAS with BA (Table 3). Comparing PCS and CAS with BA, more total/malignant MES are generated during aortic arch/common carotid artery catheterization in CAS with BA. The total number of MES generated during stent deployment is greater with PCS, and overall malignant MES generation is greater in CAS with BA. There is no other significant difference in MES generation during the remaining stages of PCS and CAS with BA (Table 3).

**Table 3:** Significant differences between PCS and CAS for generation of MES

Stage of Procedure	PCS (n = 70) CAS (n = 9)		p-Value
	Mean Rank	Mean Rank	
Total MES in arch/CCA	37.9	56.4	0.02
Malignant MES in arch/CCA	37.4	59.9	0.006
Total MES for stent deployment	42.1	22.9	0.018
Malignant MES for stent deployment	37.8	57.1	0.017

**Table 4:** Relationships of new DWI lesions and study covariates

Covariates	Mann-Whitney U test Mean rank		Fisher exact test statistics	p-Value
	No new DWI lesions	New DWI lesions		
Pre-stent NASCET stenosis	48.44	32.15	–	0.002*
Post-treatment stenosis	44.84	36.43	–	0.109
Pre-/post-stent stenosis change	43.51	38.01	–	0.295
Benign MES	33.40	44.17	–	0.034*
Malignant MES	33.63	39.38	–	0.125
Total MES	32.19	45.51	–	0.009*
Balloon angioplasty	–	–	1.01	0.537
EPD use	–	–	0.40	0.459

\*Significant at 5% level of significance.

Of the 12 patients who required BA, those who underwent pre-stent BA averaged 59 malignant and 99 total MES; those who underwent post-stent BA averaged 59 malignant and 156 total MES; and those who underwent both pre- and post-BA averaged 39 malignant and 107 total MES.

Table 4 summarizes the relationship of new DWI lesions with other study covariates between PCS and CAS with BA. Overall, new DWI changes were seen in 37 patients (45%). Thirty of 37 patients (81%) had lesions in the same territory as the stented artery. Seven of 37 patients (19%) had lesions in a different territory, and 9 of 37 patients (24%) had DWI lesions in multiple territories. In 16 of the 37 patients (43%), multiple DWI lesions were in the same territory, 10 of which (63%) were on the same side as the stented artery. There were statistically significant differences between: new DWI lesions and pretreatment NASCET stenosis ( $p = 0.002$ ); benign MES ( $p = 0.034$ ) and total number of MES ( $p = 0.009$ ). There are no statistically significant differences for new DWI lesions between PCS and CAS with BA and EPD use.

In the 12 patients who underwent BA, 5 of the 7 patients who underwent pre-stent BA (71%) had new DWI lesions; neither of the 2 post-stent BA patients had new DWI lesions, and 1 of the 3 pre- and post-stent BA patients (33%) had new DWI lesions.

## Discussion

CAS with BA is now widely regarded as an alternative intervention for carotid bifurcation atherosclerotic disease.<sup>9</sup> It has, however, been shown to result in higher post-procedural stroke rates than

carotid endarterectomy (CEA),<sup>9,10,11</sup> despite the routine use of EPDs designed to capture embolic debris generated by the endovascular maneuvers. Each step of CAS with BA generates emboli as detected by intraprocedural TCD analysis.<sup>7,12</sup> Most embolic debris results from stent deployment, BA, and EPD placement.<sup>7,12,13</sup> Despite the use of EPDs, new ischemic lesions on post-procedural DWI are seen in up to 80% of patients undergoing CAS, although most are asymptomatic.<sup>7,14</sup> Although credited with reducing the incidence of strokes during CAS, many authors have reported complications from EPD use and some have questioned their overall utility.<sup>15,16,17</sup>

In 2013, a report from the Calgary group<sup>7</sup> used procedural TCD and post-procedural DWI to investigate the relationship of MES to DWI lesions using CAS with BA. They found a median MES signal count of 212 (108 benign and 80 malignant) and new DWI lesions in 80% of patients (70% ipsilateral). The highest number of malignant MES was observed during stent and EPD deployment, and there was a significant relationship between malignant emboli and new DWI lesions.

Others have investigated the safety of CAS with BA and EPDs using intraprocedural TCD monitoring. The mean total number of MES generated per procedure has ranged from 116 to 276 despite the use of EPDs.<sup>7,12,13,14,18,19,20,21,22</sup> In all studies, the most MES were generated by stent deployment, followed by BA and EPD deployment, similar to our experience. In one study, more MES were generated in patients with EPD use than in a comparison group without EPD use.<sup>18</sup> Our average number of 114 MES (70 benign and 44 malignant) per procedure compares favorably with these historical controls. There were significantly more malignant MES in our small series of CAS with BA patients than with PCS, although total MES were not significantly different.

We observed new DWI lesions in 36 patients, 44.5% of PCS and 54.5% of CAS with BA patients, a nonsignificant difference. We found a correlation between the total number of MES and new DWI lesions, similar to the Calgary experience. Despite the prevalence of new DWI lesions, only one patient experienced a TIA and none of the patients suffered an acute stroke. The number of new DWI lesions reported following CAS ranges from 15 to 80%.<sup>7,13,14,22</sup> Many series have included asymptomatic patients with stenoses less than 70% by NASCET criteria. Considering that all of our patients were symptomatic with severe ipsilateral stenoses, our figures are quite acceptable.

Our 30-day stroke and death rate of 1.2% compares favorably to other large series with short-term stroke and death rates of 4–6%.<sup>9,23</sup>

PCS may not be appropriate for all patients. We selected our patients based on CTA plaque morphology,<sup>5</sup> particularly those with low calcification scores and visible soft plaque. Circumferential calcification has been identified as a risk factor for distal embolic complications in CAS.<sup>24</sup> These patients are more suited to CEA. PCS has been shown to reduce the incidence of hemodynamic instability,<sup>6</sup> and avoidance of aggressive BA, particularly post-stent dilatation, may also lessen the incidence of neurological events up to 30 days post-procedure.<sup>25</sup> Several studies have advocated the safety and utility of CAS without BA,<sup>26,27</sup> and unprotected CAS with BA.<sup>3,4,17,27</sup>

There are limitations to our study, a small series of patients from a single center. Selection of patients for PCS was made primarily by CTA plaque morphology, introducing possible selection bias. Although an attempt was made to recruit patients consecutively, logistical challenges of the COVID-19 pandemic resulted in significant disruptions and delays. Multiple operators with

different levels of experience performed the PCS and CAS procedures. There was a large difference in the numbers of PCS (75) and CAS with BA (12) procedures, making direct comparisons between groups in our series of limited validity. TCD data were unavailable in 4 of 12 (33%) of BA cases, compared to lack of TCD data in only 4 of 75 (5%) PCS cases, also introducing potential bias. We used a stent with an open-cell design, and delayed embolization through the stent struts can occur.<sup>28,29</sup> DWI lesions occurring more than 24–48 hours after the procedure may be missed. The avoidance of BA in PCS may lead to a higher rate of restenosis than the 4–10% at 1 year using CAS with BA.<sup>30,31</sup> There is however no association between restenosis and stroke for CAS with BA.<sup>30</sup> Our rate of delayed stent occlusion in the PCS group (2.7%) is similar to that reported with CAS and BA (3%),<sup>32</sup> and only one patient became symptomatic.

## Conclusion

We believe that PCS is a safe and effective method to treat severe, symptomatic carotid stenosis in selected patients, based on preoperative plaque morphology on CTA. It generates fewer MES on intraprocedural TCD and an acceptable number of new DWI lesions on post-procedural MRI compared to historical controls of CAS using BA and EPDs. In patients with appropriate plaque characteristics on preoperative CTA, PCS can be considered a safe, faster, and less costly alternative to CAS with BA.

**Acknowledgments.** Solo K, Pandey S, Sharma M, Lee DH, Boulton M, Mayich M, Kiwan R, Salehi F, Johnson P, and Shariatzadeh A for TCD and carotid intervention performance, data collection, and analysis.

**Conflicts of Interest.** The authors declare no conflicts of interest.

**Disclosures.** None.

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