

### Selected Papers from the Editorial Board

### An International, Expert-Based Delphi Consensus Document on Controversial Issues about TransCarotid Artery Revascularization (TCAR)

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**Background:** Transcarotid artery revascularization (TCAR) has emerged as an alternative therapeutic modality to carotid endarterectomy (CEA) and transfemoral carotid artery stenting (TFCAS) for the management of patients with carotid artery stenosis. However, certain issues regarding the indications and contraindications of TCAR remain unanswered or unresolved. The aim of this international, expert-based Delphi consensus document was to attempt to provide some guidance on these topics.

**Methods:** A 3-round Delphi consensus process was performed, including 29 experts. The aim of round 1 was to investigate the differing views and opinions of the participants. Round 2 was carried out after the results from the literature on each topic were provided to the participants. During round 3, the participants had the opportunity to finalize their vote.

**Results:** Most participants agreed that TCAR can or can probably or possibly be performed within 14 days of a cerebrovascular event, but it is best to avoid it in the first 48 hr. It was felt

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Conflicts of Interest: Ali F. AbuRahma was the Chairman of the 2022 SVS Guidelines for the management of patients with extracranial cerebrovascular disease. Clark J. Zeebregts has received consulting, research support, honoraria, and travel support from W.L. Gore  $\mathcal{C}$  Associates, LeMaitre Vascular, Atrium Maquet Getinge Group, Artivion, Terumo (Vaskutek and Bolton) and Cook Medical. Peter A. Schneider is a consultant for Silk Road Medical, Surmodics, Boston Scientific, Philips, Medtronic, Endologix, Acotec, Healthcare Inroads and Cagent. Isabelle Van Herzeele has participated in studies sponsored by Silk Road Medical. Caitlin W. Hicks has been a consultant for Silk Road Medical and a national Co-PI on ROADSTER 3. Jeffrey Jim is a consultant for Silk Road Medical, Adient, Endospan and Medtronic. He is the director of the TEST DRIVE training program and a national Co-PI for ROADSTER 3.

that TCAR cannot or should not replace TFCAS or CEA, as each procedure has specific indications and contraindications. Symptomatic patients >80 years should probably be treated with TCAR rather than with TFCAS. TCAR can or can probably be used for the treatment of restenosis following CEA or TFCAS. Finally, there is a need for a randomized controlled trial (RCT) to provide better evidence for the unresolved issues.

**Conclusions:** This Delphi consensus document attempted to assist the decision-making of physicians or interventionalists or vascular surgeons involved in the management of carotid stenosis patients. Furthermore, areas requiring additional research were identified. Future studies and RCTs should provide more evidence to address the unanswered questions regarding TCAR.

#### **INTRODUCTION**

In February 2015, Silk Road Medical Inc. announced that the Enroute transcarotid neuroprotection system (NPS) had received U.S. Food and Drug Administration (FDA) approval.<sup>1,2</sup> The Enroute NPS had been approved for patients at high risk for adverse events with carotid endarterectomy (CEA) due to anatomical or physiological criteria, who were either symptomatic with  $\geq$ 50% stenosis or asymptomatic with  $\geq$ 80% stenosis of the common or internal carotid artery confirmed by ultrasound or angiography.<sup>1,2</sup> The approval was

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<sup>20</sup>Smith Center for Outcomes Research, Division of Cardiology, Department of Medicine, Beth Israel Deaconess Medical Center, Boston, MA. provided by the FDA without supporting evidence from a randomized controlled trial (RCT).

Despite the lack of level 1 evidence, Transcarotid artery revascularization (TCAR) procedures have been rapidly adopted in the United States, with the number of centers performing TCAR rising quickly from 29 to >600.<sup>1</sup> In 2022, the FDA expanded the indications for TCAR to include patients at standard surgical risk for adverse events from CEA, with either symptomatic or asymptomatic  $\geq$ 70% internal or common carotid artery stenosis confirmed by ultrasound.<sup>3</sup>

The 2022 Society for Vascular Surgery (SVS) guidelines for the management of patients with

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extracranial cerebrovascular disease provided specific recommendations, indications, and relative contraindications for the use of TCAR in patients with symptomatic and asymptomatic carotid stenosis (Table I).<sup>4</sup> However, despite this guidance, several unanswered issues remain regarding the use and applications of TCAR.

The aim of the present international, expertbased Delphi consensus document was to address these issues in order to provide answers to everyday clinical questions and assist the decision-making of clinicians, interventionalists, and surgeons involved in the management of patients with symptomatic and asymptomatic carotid stenosis.

#### **MATERIALS AND METHODS**

An international, expert-based Delphi consensus document was prepared in accordance with the Conducting and Reporting Delphi Studies (CREDES) checklist.<sup>5</sup> A total of 29 experts from the United States (n = 18), Italy (n = 4), the Netherlands (n = 2), Belgium (n = 1), Spain (n = 1), Portugal (n = 1), Poland (n = 1), and Greece (n = 1) were invited to participate. All participants had at least 10 years of relevant clinical experience in the management of patients with carotid artery stenosis and proof of academic expertize, as documented by relevant publications.

Following a search of the literature (PubMed or MedLine, Scopus, and EMBASE) and after receiving feedback from the Delphi consensus participants, a questionnaire consisting of 6 unresolved issues was composed (Table II). A total of three rounds were undertaken. All 29 participants provided an answer to each of the 6 topics during each round. All responses were in a prespecified seven-answer format (yesprobably, yes-possibly, yes-uncertain or unknown or unproven or no opinion-possibly, no-probably, and no-no). The aim of round 1 was to collect the participants' opinion for each of the identified unresolved topics. During round 2, clarifications in certain areas were provided and the participants were asked to vote again after being provided with a list of relevant publications and articles from the literature supporting or refuting each question. Consensus was reached when >70% of the participants agreed on a response showing preference for a specific approach (e.g., "yes" or "probably yes", or "no" or "probably no"). All information was collected anonymously. In order to avoid any potential bias, no Delphi consensus participant was identified or was made aware of the identity of the comments by the rest of the participants. Only the Delphi consensus coordinator (K.I.P.) was aware of each participant's comments and vote.

The response "uncertain or unknown or unproven or no opinion" included one or more of the following.

- a. The evidence supporting or refuting a particular question is inadequate, controversial, or conflicting, and/or
- b. The Delphi consensus participant does not think that either a positive or a negative response is possible to answer a specific question and/or
- c. The Delphi consensus participant does not feel that one of the available answers can fully cover the topic.

The first draft of the Delphi consensus document was prepared by the Delphi consensus coordinator and was sent to all participants for their feedback. During this phase, all participants were asked to verify or finalize their vote for each topic (round 3). The manuscript was revised twice based on the comments and suggestions of the Delphi participants. All participants approved the final manuscript and provided their consent to proceed with its publication. Any potential conflict of interest of each participant was declared and is listed at the end of this manuscript.

#### RESULTS

Consensus was reached in some topics but not in others. Most of the participants (n = 27 of 29; 93%) modified their response in at least one topic from round 1 to round 2 or from round 2 to round 3 (e.g., from "possibly yes" to "probably yes").

Most participants (21 of 29; 72%) concurred that TCAR is probably safe to be performed within 14 days of a recent transient ischemic attack (TIA) or minor stroke episode after excluding the first 48 hr. Similarly, 24 of 29 (82.5%) voted that TCAR should not or should probably not replace CEA. Twenty-two of the 29 members of the panel (76%) agreed that patients >80 years should or should probably be treated with TCAR instead of transfemoral carotid artery stenting (TFCAS). Most experts (24 of 29; 82.5%) concurred that there is (probably) a need for an RCT comparing TCAR versus CEA and/or TCAR versus TFCAS. Finally, nearly all panelists (28 of 29; 96.5%) thought that TCAR can be used or can probably be used for the management of restenosis following CEA or TFCAS. Consensus could not be reached on whether TCAR procedures should replace TFCAS.

SVS recommendations for TCAR	<ul> <li>Neurologically asymptomatic patients with ≥70% stenosis should be considered for CEA, TCAR, or TFCAS for reduction of long-term risk of stroke, provided the patient has a 3- to 5- year life expectancy.</li> <li>TCAR is preferred over CEA and TFCAS in symptomatic patients with ≥50% stenosis and lesion above C2</li> <li>TCAR is preferred over transfemoral CAS but not CEA in symptomatic patients with ≥50% stenosis</li> </ul>
Contraindications for TCAR	<ul> <li>TCAR is preferred over CEA and TFCAS in high surgical risk (both anatomically and physiologically)</li> <li>Heavily calcified carotid lesion</li> <li>Lesion within 5 cm of clavicle</li> <li>Common carotid artery diameter &lt;6 mm</li> <li>Neck irradiation</li> <li>Tracheal stoma</li> <li>Hostile neck (due to obesity, immobility, kyphosis, radical neck dissection, and laryngectomy, etc.)</li> </ul>

**Table I.** Indications, recommendations, and contraindications for TCAR according to the 2022 SVS guidelines for the management of patients with carotid stenosis<sup>4</sup>

SVS, Society for Vascular Surgery; TCAR, TransCarotid Artery Revascularization; CEA, carotid endarterectomy; TFCAS, transfemoral carotid artery stenting.

Ten of the 29 Delphi consensus participants (34.5%) declared a possible conflict of interest relevant to this study (see conflicts of interest section at the end of the manuscript). A sensitivity analysis was performed, excluding participants who had a conflict of interest to investigate whether this would influence the results. The only topic that was affected by, excluding participants with a possible conflict of interest was whether or not it is safe to perform TCAR within 14 days of a recent TIA or minor stroke; consensus could no longer be reached with 12 of 19 (63.2%) participants now supporting that it is safe or it is probably safe for TCAR to be performed within 14 days of a recent TIA or minor stroke. Consensus on all other topics was still achieved as with all 29 participants.

#### DISCUSSION

The responses of the 29 Delphi consensus participants to each topic are presented, analyzed, and discussed below.

#### Is TCAR Safe to be Performed within 14 days of a Recent TIA or Minor Stroke with Stroke or Death Rates Similar to CEA?

A retrospective analysis of the SVS Vascular Quality Initiative (VQI) registry included all TCAR procedures performed since the initiation of the TCAR Surveillance Project (September 2016) until November 2019.<sup>6</sup> The VQI TCAR Surveillance Project is an FDA-approved registry sponsored by the SVS Patient Safety Organization to monitor the safety and effectiveness of TCAR in patients with symptomatic and asymptomatic carotid stenosis at high risk for CEA. The Centers for Medicaid and Medicare Services (CMS) provides reimbursement to hospitals and physicians who participate in the registry in compliance with the study protocol. The procedures were divided into 'urgent' (0-2 days from the most recent symptoms), 'early' (3-14 days after the most recent symptoms), and 'late' (15-180 days after the most recent symptoms).<sup>6</sup> The risk of stroke was considerably higher with urgent compared with early and late interventions (5.6% vs. 2.5% vs. 2.0%, respectively; P = 0.03), as was the risk of (TIA; 3.5% vs. 1.1% vs. 0.8%, respectively; P = 0.02), stroke or TIA (8.3%) vs. 3.6% vs. 2.7%, respectively; *P* = 0.004), and the composite end-point of stroke or death (6.5% vs. 2.9% vs. 2.3%, respectively; P = 0.02).<sup>6</sup> After adjusting for potential confounders, urgent intervention resulted in a nearly 3-fold increased risk of stroke (OR: 2.8; 95% CI: 1.3–6.2; *P* = 0.01) and stroke or death (OR: 2.9; 95% CI: 1.3–6.4; P = 0.01), and a nearly 2.5-fold increased risk of stroke or death or myocardial infarction (MI) (OR: 2.4; 95% CI: 1.1-5.1; P = 0.02) compared with late intervention.<sup>6</sup> In contrast, no differences were found between early and late intervention in the risk of stroke or death (OR: 1.2; 95% CI: 0.7–2.1; *P* = 0.48) and stroke or **Table II.** Unresolved questions or issues regarding the use of TCAR comprising the Delphi consensus questionnaire

- 1. Is TCAR safe to be performed within 14 days of a recent TIA/minor stroke with stroke or death rates similar to CEA?
- 2. Should TCAR procedures replace TFCAS?
- 3. Should TCAR procedures replace CEA?
- 4. Should patients >80 years be treated with TCAR rather than with transfemoral CAS?
- 5. Is there a need for a randomized controlled trial comparing TCAR vs. CEA or TCAR vs. transfemoral CAS?
- 6. Can TCAR be used for the management of restenosis following CEA or TFCAS?

death or MI (MI; OR: 1.1; 95% CI: 0.7–1.8; P = 0.67).<sup>6</sup> It was concluded that TCAR was safest when performed after the first 48 hours after symptoms.<sup>6</sup>

A retrospective study compared the 30-day outcomes of symptomatic patients in the SVS VQI registry who had undergone TCAR and CEA between January 2016 and February 2020 within 14 days of a stroke or TIA.<sup>7</sup> Overall, 13,429 patients undergoing CEA and 1,281 patients undergoing TCAR within 14 days of a neurologic event were considered for inclusion in the study.<sup>7</sup> After 1:1 propensity matching, 728 pairs were included for analysis. The primary composite outcome of stroke, death, or MI occurred more frequently in the TCAR group (4.7% vs. 2.6%, respectively; P =0.04). This was driven by a higher rate of postoperative ipsilateral stroke in patients undergoing TCAR (3.8% vs. 1.8%, respectively, P = 0.005), with no differences between the 2 procedures in terms of death (0.7% vs. 0.8%, respectively; P =0.8) or MI (0.8% vs. 1%, respectively; P = 0.7).<sup>7</sup> Importantly, performing TCAR within 48 hours of a stroke was associated with a >5-fold increased risk for postoperative stroke or TIA (OR: 5.4; 95% CI: 1.8–16; P < 0.001).

Another retrospective cohort study compared perioperative outcomes after TCAR, TFCAS, and CEA among patients in the SVS VQI database undergoing urgent, early, and delayed revascularization for symptomatic carotid artery stenosis (n =18,643 patients).<sup>8</sup> Overall, 2006 (10.8%) underwent 'urgent' (0-2 days from latest symptoms) revascularization (144 TCAR [7.2%]; 750 TFCAS [37.4%]; 1,112 CEAs [55.4%]), 7,423 (39.8%) underwent 'early' (3–14 days from latest symptoms) revascularization procedures (928 TCAR [12.5%]; 1,369 TFCAS [18.4%]; 5,126 CEAs [69.1%]), and 9,214 (49.4%) underwent 'late' (15-180 days from latest symptoms) revascularization (1,536 TCAR [16.7%]; 1,618 TFCAS [17.6%]; 6,060 CEAs [65.8%]).<sup>8</sup> For urgent revascularization procedures, the rates of in-hospital stroke or death were lower for CEA compared with TCAR and TFCAS (4.0% vs. 6.5% vs. 6.9%, respectively; P = 0.02) due to

the increased odds of death among patients undergoing urgent TFCAS and TCAR compared with CEA (3.8% vs. 1.4% vs. 0.9%, respectively; P < 0.001).<sup>8</sup> However, after adjusting for potential confounders, there was no difference between TCAR and CEA in in-hospital stroke or death rates (OR: 1.9; 95% CI: 0.9–4.0; P = 0.10).<sup>8</sup> In contrast, urgent TFCAS was associated with higher in-hospital stroke or death rates compared with urgent CEA (OR: 1.7; 95% CI: 1.0–2.9; P = 0.03). The rates of in-hospital TIA were also higher for TCAR versus CEA and TFCAS (3.5% vs. 0.6% vs. 0.4%, respectively; P =0.01).<sup>8</sup>

For patients undergoing early revascularization, in-hospital stroke or death rates were lower for CEA compared with TCAR and TFCAS (2.5% vs. 2.9% vs. 3.8%, respectively; P = 0.05).<sup>8</sup> Furthermore, compared with TCAR and TFCAS, CEA was associated with lower in-hospital TIA (1.1% vs. 1.4% vs. 0.6%, respectively; P = 0.01), death (1.0% vs. 1.3% vs. 0.6%, respectively; P = 0.03),stroke or TIA (3.6% vs. 4.2% vs. 2.7%, respectively; P = 0.02), and stroke or death or MI (3.2% vs. 4.5%) vs. 3.0%, respectively; P = 0.04).<sup>8</sup> Despite that, on adjusted analysis, TCAR and CEA had comparable odds of all complications, whereas TFCAS was associated with increased odds of in-hospital stroke or death (OR: 1.6; 95% CI: 1.1-2.4; P = 0.01) due to increased odds of death compared with CEA (OR: 2.4; 95% CI: 1.3–4.6; P = 0.01) but not compared with TCAR (OR: 1.4; 95% CI: 0.9-2.1; P = 0.15).<sup>8</sup>

In agreement with the results from the literature, in round 3 most of the Delphi consensus participants (21 or 29; 72%) voted that it is probably or possibly safe to perform TCAR with results similar to CEA within 14 days of a recent cerebrovascular event but only after excluding the first 48 hours (Table III).

## Should TCAR Procedures Replace TFCAS?

A retrospective study compared outcomes after TCAR (n = 5,251) versus TFCAS (n = 6,640) using prospectively collected data from the SVS VQI

Response	lst round Nr (%)	2nd round Nr (%)	3rd round Nr (%)	Excluding participants with COI
Yes (excluding the first 48 hr)	9 (31%)	9 (31%)	12 (41%)	6 (32%)
Probably yes	6 (20.5%)	9 (31%)	9 (31%)	6 (32%)
Possibly yes	5 (17.5%)	3 (10%)	2 (7%)	1 (5%)
Uncertain or unknown or unproven or no opinion	6 (20.5%)	5 (17.5%)	4 (14%)	4 (21%)
Possibly no	1 (3.5%)	1 (3.5%)	1 (3.5%)	1 (5%)
Probably no	2 (7%)	2 (7%)	_	_
No			1 (3.5%)	1 (5%)
Total	29 (100%)	29 (100%)	29 (100%)	19 (100%)

**Table III.** Is TCAR safe to be performed within 14 days of a recent TIA or minor stroke with stroke or death rates similar to CEA?

Bold values indicate >70% of the panel, there is consensus agreement.

carotid artery stent (CAS) registry from September 2016 to April 2019.9 After propensity scorematched analysis, 3,286 pairs of patients undergoing TCAR or TFCAS were identified.<sup>9</sup> In-hospital risk of stroke or death was considerably lower with TCAR compared with TFCAS (1.6% vs. 3.1%, respectively; absolute difference: -1.52% [95% CI: from -2.29% to -0.75%]; relative risk [RR]: 0.51; 95% CI: 0.37–0.72; *P* < 0.001). TCAR was associated with significantly lower risks of both stroke (1.3% vs. 2.4%, respectively: absolute difference: -1.10% [95% CI: -1.79 to -0.41%]; RR: 0.54; 95% CI: 0.38–0.79; P = 0.001) and death (0.4%) vs. 1.0%, respectively; absolute difference: -0.55%; 95% CI: -0.98% to -0.11%; RR: 0.44 [95% CI: 0.23–0.82]; P = 0.008).<sup>9</sup> At 30 days, TCAR was associated with significantly lower risk of stroke or death (1.9% vs. 3.7%, respectively; absolute difference: -1.73% [95% CI: -2.57% to -0.90%]; RR: 0.53; 95% CI: 0.39-0.72; P < 0.001) as well as the individual end points of stroke (1.3% vs. 2.5%; absolute difference: -1.19% [95% CI: -1.89% to -0.49%]; RR: 0.53; 95% CI: 0.37-0.76; *P* < 0.001) and death (0.8% vs. 1.5%; absolute difference: -0.70% [95% CI: -1.24% to -0.16%]; RR: 0.52; 95% CI: 0.32–0.84; *P* = 0.007). Finally, at 1 year, TCAR was associated with a significantly lower risk of ipsilateral stroke or death compared with TFCAS (5.1% vs. 9.6%, respectively; HR: 0.52; 95% CI: 0.41–0.66; P < 0.001).<sup>9</sup> By avoiding the aortic arch and utilization of neuroprotection (flow reversal) prior to crossing the stenosis, TCAR achieves significantly lower stroke and stroke or death rates compared with TFCAS.<sup>9</sup>

Another study used data from the SVS VQI from January 2017 to April 2020 to compare in-hospital outcomes following TCAR (n = 4,224) versus TFCAS (n = 5,644) among symptomatic and asymptomatic patients stratified by arch type (type I, type

II, and type III) and degree of calcification (none,  $\leq$ 50% and >50% calcification).<sup>10</sup> This analysis demonstrated that symptomatic patients with severe (>50%) calcification undergoing TCAR had lower rates of death (0.9% vs. 2.8%, respectively; P = 0.013), stroke or death (2.7% vs. 5.8%, respectively; P = 0.006), stroke or death or MI (3.3% vs. 6.5%, respectively; P = 0.007), and postoperative complications (6.0% vs. 12.4%, respectively; P <0.001) compared with TFCAS.<sup>10</sup> Stroke or death rates with TCAR compared with TFCAS were also reduced for asymptomatic patients with severe (>50%) calcification (1.5% vs. 3.1%, respectively; P = 0.029).<sup>10</sup> TCAR results were similar regardless of aortic arch anatomy, while stroke or death rates increased with TFCAS with complex aortic arch anatomy (type I: 4.2% vs. type II: 5.2%). It was concluded that these results suggest that TCAR should be preferred in patients with anatomy considered high risk for TFCAS.<sup>10</sup> The better results for TCAR compared with TFCAS have also been supported in other studies.<sup>11–14</sup> A drawback of TCAR is that it is not as cost-effective as TFCAS.<sup>15</sup>

The 2022 SVS guidelines for the management of patients with extracranial cerebrovascular disease identified specific 'high-risk' patient subgroups (based on specific anatomical or physiological criteria) for each carotid revascularization procedure (Table I).<sup>4</sup> Such 'high-risk' criteria for TCAR included heavily calcified carotid lesions, lesions within 5 cm of the clavicle, common carotid artery diameter <6 mm, tracheal stoma, hostile neck owing to obesity, immobility, or kyphosis etc.<sup>4</sup> In contrast, high-risk criteria for TFCAS included tortuous common or internal carotid artery, type 3 or tortuous aortic arch, heavy atherosclerotic burden of aortic, complex bifurcation stenosis >15 mm in length etc.<sup>4</sup> For neurologically asymptomatic patients with  $\geq$ 70% stenosis, the SVS

guidelines recommended CEA, TCAR, or TFCAS based on the presence or absence of these highrisk criteria for each procedure.<sup>4</sup> TCAR was recommended over CEA and TFCAS in symptomatic patients with  $\geq$ 50% stenosis and lesion above C2. In contrast, TFCAS was preferred in symptomatic patients with  $\geq$ 50% stenosis and tracheal stoma and patients where local tissues are scarred and fibrotic from prior ipsilateral surgery or external beam radiotherapy.<sup>4</sup>

A clinical equipoise was achieved on the topic "should TCAR procedures replace TFCAS?" Most of the Delphi consensus participants (27 of 29; 93%) voted that although TCAR should be preferred over TFCAS in most patients, both procedures have a role in the management of carotid patients. More specifically, 48.5% of the panel (14 of 29 participants) voted that TCAR should probably or possibly replace TFCAS in most (but not all) circumstances, while another 44.5% of the group (13 of 29 participants) voted that both procedures have or probably or possibly have a role in the management of carotid patients (Table IV).

#### **Should TCAR Procedures Replace CEA?**

Another controversial topic is whether TCAR should replace CEA as the treatment-of-choice for patients with symptomatic and/or asymptomatic carotid stenosis. A retrospective propensity matched cohort study using data from the SVS VQI registry from August 2016 to August 2019 compared outcomes after TCAR versus CEA.<sup>16</sup> The primary outcome was a composite end point of 30-day stroke or death or MI or 1-year ipsilateral stroke. After 1:3 matching, 2,962 patients undergoing TCAR were compared with 8,886 individuals undergoing CEA. There was no difference in the risk of the primary composite end point between patients undergoing TCAR versus CEA (3.0% vs. 2.6%, respectively; absolute difference: 0.40%; [95% CI: from -0.43% to 1.24%]; RR: 1.14; 95% CI: 0.87–1.50; P = 0.34).<sup>16</sup> Nevertheless, 1-year ipsilateral stroke rates were higher after TCAR than after CEA (absolute difference: 0.52% [95% CI: 0.03 to 1.08]; RR: 1.49; 95% CI: 1.05–2.11; P = 0.02).<sup>16</sup>

Another retrospective study compared outcomes of all VQI patients undergoing carotid revascularization between 2015 and 2020.<sup>17</sup> Patients were stratified by whether they met the CMS high-risk criteria.<sup>17</sup> Among high-risk patients, the incidence of perioperative stroke was 2.7% for CEA, 3.4% for TFCAS, and 2.4% for TCAR (P < 0.001), while among standard-risk patients, perioperative stroke rates were 1.7%, 2.7% and 1.8%, respectively (P < 0.001).<sup>17</sup> After adjusting for baseline demographic and clinical characteristics, the odds of perioperative stroke were lower for TCAR versus CEA in high-risk patients (adjusted OR: 0.82; 95% CI: 0.68–0.99) and similar in standard-risk patients (adjusted OR: 1.05; 95% CI: 0.84–1.31).<sup>17</sup>

The similar outcomes for TCAR compared with CEA were verified in a multi-institutional (n = 4) analysis of outcomes after TCAR versus a matched control group undergoing CEA.<sup>18</sup> After propensity matching by baseline characteristics, including age, gender, symptom status and diabetes, 30-day stroke (1.0% vs. 0.3%, for TCAR vs. CEA, respectively; P = 0.62), and 30-day death rates (0.3% vs. 0.7%, for TCAR vs. CEA, respectively; p = nonsignificant), as well as 1-year stroke (2.8% vs. 2.2%, respectively; P = 0.79) and 1-year death rates (1.8% vs. 4.5%, respectively; P = 0.09) were similar between the 2 procedures.<sup>18</sup> It was concluded that patients undergoing TCAR achieve broadly similar outcomes with those undergoing CEA (even those with high-risk comorbidities), while mitigating cranial nerve injury.<sup>18</sup>

A comparison of in-hospital outcomes of patients undergoing TCAR (n = 1, 182) and CEA (n = 10, 797)from January 2016 to March 2018 using the SVS VQI TCAR Surveillance Project Registry and the SVS VQI CEA database further demonstrated similar outcomes between the 2 procedures.<sup>19</sup> Although patients undergoing TCAR were older (median age: 74 vs. 71 years, respectively; P < 0.001), more likely to be symptomatic (32% vs. 27%, respectively; P < 0.001), and had more medical comorbidities, including coronary artery disease (55% vs. 28%; P < 0.001), chronic obstructive pulmonary disease (29% vs. 23%; P < 0.001), chronic kidney disease (39% vs. 34%; P = 0.001), and chronic heart failure (20% vs. 11%; P < 0.001), TCAR had similar rates of in-hospital stroke or death (1.6% vs. 1.4%, respectively; P = 0.33), and stroke or death or MI (2.5% vs. 1.9%; P = 0.16) compared with CEA.<sup>19</sup> However, patients undergoing TCAR were less likely to suffer cranial nerve injuries (0.6% vs. 1.8%; P < 0.001) and were less likely to have a postoperative length of stay >1 day (27% vs. 30%; P =0.046).<sup>19</sup> The lower incidence of cranial nerve injury (0.4% vs. 2.7%, respectively; RR: 0.14; 95% CI: 0.08–0.23; *P* < 0.001) and the lower rate of having a postoperative length of stay >1 day (26.4% vs. 30.1%, respectively; RR: 0.88; 95% CI; 0.82-0.94; P < 0.001) for patients undergoing TCAR versus CEA, with no difference in terms of in-hospital stroke and death rates between the 2 procedures (1.6% vs. 1.6%, respectively; RR: 1.01; 95% CI: 0.77–1.33; *P* = 0.945), was verified in the SVS VQI TCAR Surveillance Project.<sup>20</sup>

Response	lst round Nr (%)	2nd round Nr (%)	3rd round Nr (%)	Excluding participants with COI
Yes	2 (7%)	2 (7%)	2 (7%)	_
Probably yes (in most circumstances)	11 (37.5%)	13 (45%)	13 (45%)	10 (52%)
Possibly yes	1 (3.5%)	_	1 (3.5%)	_
Uncertain or unknown or unproven or no opinion	2 (7%)	_	_	_
Possibly no	2 (7%)	2 (7%)	2 (7%)	1 (5%)
Probably no (both have a role)	4 (14%)	4 (14%)	3 (10.5%)	2 (10%)
No (both have a role)	7 (24%)	8 (27%)	8 (27%)	6 (33%)
Total	29 (100%)	29 (100%)	29 (100%)	19 (100%)

Table IV. Should TCAR procedures replace transfemoral CAS?

A systematic review and meta-analysis including 6 studies (n = 14,200 patients) did not demonstrate any difference between the 2 procedures in reducing stroke or death or MI rates (OR: 0.85; 95% CI: 0.67–1.07; P = not significant), stroke (OR: 1.03; 95% CI: 0.77–1.37; P = not significant) or death (OR: 1.14; 95% CI: 0.67–1.94; P = not significant).<sup>21</sup> Nevertheless, TCAR was associated with a lower incidence of MI (P = 0.004), cranial nerve injury (P < 0.00001) and a shorter procedural time (P < 0.00001) compared with CEA.<sup>21</sup>

Although most studies indicate that outcomes after TCAR are comparable with CEA, TCAR is not as cost-effective as CEA.<sup>22</sup> The increased cost and the lack of availability of TCAR in many places outside the United States are probably 2 of the reasons why most Delphi consensus participants (24 of 29; 82.5%) voted that TCAR procedures should not or should probably not replace CEA (Table V).

## Should Patients >80 years be Treated with TCAR rather than with TFCAS?

The carotid revascularization endarterectomy versus stenting trial (CREST) subgroup analysis by age demonstrated inferior outcomes with TFCAS with increasing age.<sup>23</sup> The efficacy of TFCAS and CEA was approximately equal at the age of 70 for the primary end point (any stroke, MI, or death within the periprocedural period plus postprocedural ipsilateral stroke), while it was at 64 years for stroke only.<sup>23</sup> For TFCAS, the primary end point increased with TFCAS by 1.77 times (95% CI: 1.38–2.28; P < 0.0001) for each 10-year difference in age, whereas strokes increased by 1.76 times (95% CI: 1.35–2.31; P < 0.0001). In contrast, there was no evidence of a difference in risk with age for those treated with CEA.<sup>23</sup>

A recent study compared perioperative outcomes after CEA, TFCAS, and TCAR among octogenarian

patients, stratified by symptom status and degree of stenosis using data from all patients in the VQI aged >80 years with 50-99% carotid stenosis (49.8% symptomatic) who had undergone CEA (n = 20,912; 73.2%), TFCAS (n = 3,628; 12.7%), or TCAR (n = 4,031; 14.1%) between 2005 and 2020.<sup>24</sup> Perioperative stroke or death occurred more frequently following TFCAS compared with TCAR and CEA (6.6% vs. 3.1% vs. 2.5%, respectively; P < 0.001).<sup>24</sup> After adjusting for baseline differences between groups, TFCAS was associated with a >3-fold higher risk of stroke or death compared with CEA (adjusted OR: 3.35; 95% CI: 2.65–4.23; P < 0.001), whereas TCAR was associated with a nearly 1.5-fold higher risk of stroke or death (adjusted OR: 1.49; 95% CI: 1.18–1.87; P < 0.05). The risk of perioperative stroke or death remained higher for TFCAS compared with CEA regardless of symptom status and degree of stenosis (P < 0.05 for all associations).<sup>24</sup> In contrast, the risk of stroke or death was higher for TCAR versus CEA for asymptomatic patients (adjusted OR: 2.04; 95% CI: 1.41–2.94; P < 0.05) and those with highgrade stenosis (adjusted OR: 1.49; 95% CI: 1.11-2.05; P < 0.05) but similar for patients with symptomatic and moderate-grade stenosis (P > 0.05 for both).<sup>24</sup>

Another study compared outcomes after TCAR versus CEA and TFCAS in patients who are 60–69, 70–79, and 80–90 years old using the VQI from September 2016 to December 2019.<sup>25</sup> Overall, 33,115 patients undergoing CEA (80%), TFCAS (11%), or TCAR (9%) were identified (35% in their 60s, 44% in their 70s, and 21% in their 80s).<sup>25</sup> Among octogenarians, the adjusted hazards ratio [aHR] for TCAR relative to CEA was similar for both 30-day stroke death (aHR: 1.12; 95% CI: 0.59–2.13; P = not significant) and 1-year stroke or death (aHR: 1.28; 95% CI: 0.85–1.94; P = not significant). In contrast, TFCAS in octogenarians had

Table V.	Should	TCAR	procedures	replace	CEA?
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Response	1st round Nr (%)	2nd round Nr (%)	3rd round Nr (%)	Excluding parti-cipants with COI
Yes	_	_	1 (3.5%)	_
Probably yes	2 (7%)	2 (7%)	1 (3.5%)	_
Possibly yes	_	1 (3.5%)	_ ` ` ` `	_
Uncertain or unknown or unproven or no opinion	3 (10%)	2 (7%)	2 (7%)	2 (10.5%)
Possibly no	2 (7%)	1 (3.5%)	1 (3.5%)	_
Probably no	7 (24%)	6 (20.5%)	8 (27%)	4 (21%)
No	15 (52%)	17 (58.5%)	16 (55.5%)	13 (68.5%)
Total	29 (100%)	29 (100%)	29 (100%)	19 (100%)

Bold values indicate >70% of the panel, there is consensus agreement.

higher HR for both 30-day stroke and death (aHR: 1.78; 95% CI 1.10–2.89; P < 0.05) and 1-year stroke or death (aHR: 1.85; 95% CI: 1.35–2.54; P < 0.01) compared with CEA.<sup>25</sup> It was concluded that TCAR may serve as a promising less invasive treatment for carotid disease in older patients who are deemed at high anatomic, surgical, or clinical risk for CEA.<sup>25</sup>

A third study compared the association between age and outcomes after TCAR (n = 3,152), TFCAS (n = 10,381), and CEA (n = 61,650) in all patients undergoing carotid procedures in the SVS VQI registry between 2015 and November 2018.<sup>26</sup> Patients were divided into three different age groups, namely  $\leq$ 70, 71–79 and  $\geq$  80 years.<sup>26</sup> The rate of in-hospital stroke or death after TCAR was 1.4% in patients  $\leq$ 70 years, 1.9% in individuals 71–79 years, and 1.5% in patients >80 years (P = 0.55).<sup>26</sup> The results of TCAR and CEA did not differ among the different age groups and no interaction was noted between treatment and age in predicting in-hospital stroke or death (P = 0.80). In patients  $\geq 80$  years and compared with TFCAS, TCAR was associated with a 72% reduction in stroke risk (4.7% vs. 1%, respectively; OR: 0.28; 95% CI: 0.12–0.65; P < 0.01), a 65% reduction in risk of stroke or death (4.6% vs. 1.5%, respectively; OR: 0.35; 95% CI: 0.20-0.62; P < 0.001), and a 76% reduction in the risk of stroke or death or MI (5.3% vs. 2.5%, respectively; OR: 0.24; 95% CI: 0.12–0.47; P < 0.001).<sup>26</sup> Compared with TCAR, the odds of stroke or death after TFCAS doubled at 77 years (OR: 2.0; 95% CI: 1.4–3.0; P < 0.01) and tripled at 90 years (OR: 3.0; 95% CI: 1.6-5.8; P < 0.01).<sup>26</sup>

The majority of the Delphi consensus participants (25 of 29; 86%) concurred that patients >80 years should or should probably or should possibly be treated with TCAR rather than with TFCAS (Table VI).

#### Is There a Need for an RCT Comparing TCAR versus CEA or TCAR versus TFCAS?

One subject of criticism regarding TCAR is that its efficacy has never been tested against CEA or TFCAS within the context of an RCT.<sup>1,2</sup> It was thus supported that the absence of level I evidence underscores the importance of high-quality registry-based analyses to document TCAR's real-world outcomes and durability.<sup>1</sup>

The majority of participants in this Delphi consensus document (24 of 29; 83%) voted that TCAR should or should probably be compared with CEA and TFCAS within the context of an RCT (Table VII).

### Can TCAR be Used for the Management of Restenosis Following CEA or TFCAS?

When asked about the management of patients presenting with restenosis after previous CEA or TFCAS, vascular surgeons and physicians often face a dilemma regarding the treatment-of-choice (i.e., conservative treatment vs. re-do CEA or redo TFCAS). TCAR has been evaluated for the treatment of restenosis following previous CEA or TFCAS.<sup>27–29</sup> A recent study retrospectively analyzed all patients in the VQI database who underwent TCAR (n = 1,676; 37.9%), re-do CEA (*n* = 963; 21.8%), or TFCAS (*n* = 1,786; 40.4%) for restenosis after previous CEA between September 2016 and April 2020.<sup>27</sup> When compared with CEA, TCAR was associated with lower risks of in-hospital stroke or death (OR: 0.41; 95% CI: 0.24–0.70; P = 0.021), stroke (OR: 0.46; 95% CI: 0.23–0.93; P = 0.03), MI (OR: 0.32; 95% CI: 0.14–0.73; *P* = 0.007), stroke or TIA (OR: 0.42; 95% CI: 0.24–0.74; *P* = 0.002), and stroke or death or MI (OR: 0.41; 95% CI: 0.24–0.70; P = 0.001).<sup>27</sup> Furthermore, TCAR was also associated with a lower

Response	lst round Nr (%)	2nd round Nr (%)	3rd round Nr (%)	Excluding parti-cipants with COI
Yes	9 (31%)	11 (37.5%)	13 (45%)	6 (31.5%)
Probably yes	7 (24%)	9 (31%)	9 (31%)	8 (43%)
Possibly yes	7 (24%)	4 (14%)	3 (10%)	3 (15.5%)
Uncertain or unknown or unproven or no opinion	4 (14%)	2 (7%)	1 (3.5%)	1 (5%)
Possibly no	_	_	_	_
Probably no	_	2 (7%)	2 (7%)	1 (5%)
No	2 (7%)	1 (3.5%)	1 (3.5%)	_
Total	29 (100%)	29 (100%)	29 (100%)	19 (100%)

Table VI.	Should	patients >	80 years	be treated	l with I	ГCAR ra	ather tha	an with	transfemoral	CAS?
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Tab	le VII.	Is t	here a	a need	for a	RCT	comparing	TCAR	versus	CEA	or TCAR	versus	transfemora	l CAS?
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Response	lst round Nr (%)	2nd round Nr (%)	3rd round Nr (%)	Excluding parti-cipants with COI
Yes	13 (45%)	18 (62.0%)	19 (65.0%)	14 (74.5%)
Probably yes	8 (27%)	5 (17.5%)	5 (17.5%)	3 (15.5%)
Possibly yes	4 (14%)	3 (10.5%)	3 (10.5%)	1 (5%)
Uncertain or unknown or unproven or no opinion	_	_	_	_
Possibly no	2 (7%)	_	_	_
Probably no	2 (7%)	3 (10%)	2 (7%)	1 (5%)
No	_	_	_	_
Total	29 (100%)	29 (100%)	29 (100%)	19 (100%)

risk of stroke or TIA when compared with TFCAS (0.37; 95% CI: 0.18–0.74; P = 0.005).<sup>27</sup>

Another study compared outcomes of TFCAS (n = 1,834) and TCAR (n = 1,674) in patients with restenosis after prior ipsilateral CEA using the VQI database between January 2016 and August 2020.<sup>28</sup> Patients undergoing TCAR had lower 30-day stroke or death (1.6% vs. 2.7%; P = 0.025), stroke or death or TIA (1.8% vs. 3.3%; P = 0.004) and stroke or death or MI rates (2.1% vs. 3.2%; P = 0.048) compared with patients undergoing TFCAS. These lower rates were primarily driven by lower rates of stroke (1.3% vs. 2.3%; P = 0.031) and TIA (0.2% vs. 0.7%; P = 0.031).<sup>28</sup>

In accordance with the results from the literature,<sup>27–29</sup> the vast majority of the Delphi consensus participants (28 of 29; 96.5%) voted that TCAR can or can probably be used for the management of restenosis following previous CEA or TFCAS (Table VIII).

Most participants did not think that TCAR should replace TFCAS completely, despite the better results reported for TCAR.<sup>9–14</sup> Both procedures have specific indications and contraindications, and therefore, both procedures have a role in the management of carotid patients. The recent SVS guidelines provided recommendations and indications for each procedure (i.e., CEA, TFCAS, and TCAR) and identified specific patient subgroups who may be better candidates for a specific procedure.<sup>4</sup> These patient subgroups may need to be revised in the future depending on technological advances in TCAR, refinement of the available techniques, and increased expertise.

TCAR is not applicable to a substantial number of patients with short clavicle-to-carotid bifurcation distance, excessive calcification, or tortuosity of the internal carotid artery or in the presence of a tracheal stoma.<sup>30,31</sup> Symptomatic elderly patients (>80 years) are a special group of carotid patients, as the results of TFCAS in this age group are inferior compared with those of younger patients.<sup>23,25,26</sup> In contrast, TCAR has demonstrated comparable outcomes with increasing age, and therefore seems like a promising alternative to CEA for this group of patients. However, further research in the area is required before any final conclusions can be reached.

This study has some limitations. Although the Delphi consensus participants were highly experienced and provided their expert opinion based both on their personal expertise and the available literature, it could be argued that their responses are subjective and not based on level I evidence. Selection of different experts to participate in a similar consensus could lead to different results or conclusions to be reached. Nevertheless, given the lack of RCTs, such an

Response	lst round Nr (%)	2nd round Nr (%)	3rd round Nr (%)	Excluding parti-cipants with COI
Yes	15 (51.5%)	19 (65.5%)	19 (65.5%)	13 (68.5%)
Probably yes	9 (31%)	8 (27.5%)	9 (31%)	5 (26.5%)
Possibly yes	4 (14%)	2 (7%)	1 (3.5%)	1 (5%)
Uncertain or unknown or unproven or no opinion	1 (3.5%)	_	_	_ ` `
Possibly no	_	_	-	_
Probably no	_	_	-	_
No	_	_	_	_
Total	29 (100%)	29 (100%)	29 (100%)	19 (100%)

Table VIII.	Can TCAR	be used for the	he management	of restenosis foll	lowing CEA	or transfemoral CAS?

expert-based Delphi consensus panel may provide clinicians with some help and guidance in the optimal management of patients with symptomatic and asymptomatic carotid stenosis. Finally, there was no adjudication by a neurologist. This consensus document was the result of input from experienced vascular surgeons who provide conservative or medical, interventional, and surgical therapies for patients with carotid disease and does not include input from other specialties. However, all participants are knowledgeable and experienced in managing carotid disease with operative and nonoperative therapies.

#### CONCLUSIONS

The present international, expert-based Delphi consensus document attempted to provide some preliminary guidance to unanswered or unresolved issues concerning the use and indications of TCAR in the management of patients with symptomatic and asymptomatic carotid stenosis. The aim was to help the decision-making of physicians, vascular surgeons, and interventionalists involved in the management of carotid patients. Further research and at least one RCT are necessary in order to provide more definitive answers to the unresolved issues regarding TCAR identified in this Delphi consensus document.

# CREDIT AUTHORSHIP CONTRIBUTION STATEMENT

Kosmas I. Paraskevas: Writing – review & editing, Writing – original draft, Visualization, Supervision, Investigation, Formal analysis, Data curation, Conceptualization. Ali F. AbuRahma: Writing – review & editing, Validation. Christopher J. Abularrage: Writing – review & editing, Validation. Daniel G. Clair: Writing – review & editing, Validation. Jens Eldrup-Jorgensen: Writing – review & editing, Investigation. Vikram S. Kashyap: Writing – review & editing, Investigation. Alan **Dardik:** Writing – review & editing, Investigation. Gert J. de Borst: Writing – review & editing, Investigation. Meghan Dermody: Writing – review & editing, Investigation. Gianluca Faggioli: Writing - review & editing, Investigation. Caitlin W. Hicks: Writing – review & editing, Investigation. Christopher J. Kwolek: Writing – review & editing, Investigation. Sean P. Lyden: Writing - review & editing, Investigation. Armando Mansilha: Writing – review & editing, Investigation. Isabelle Van Herzeele: Writing – review & editing, Investigation. Piotr Myrcha: Writing – review & editing, Investigation. Jose Ignacio Leal Lorenzo: Writing – review & editing, Investigation. Jeffrey Jim: Writing – review & editing, Investigation. Rodolfo Pini: Writing - review & editing, Investigation. Eric A. Secemsky: Writing – review & editing, Investigation. Francesco Spinelli: Writing – review & editing, Investigation. Laura **Capoccia:** Writing – review & editing, Investigation. David H. Stone: Writing – review & editing, Investigation. Michael C. Stoner: Writing - review & editing, Investigation. Clark J. Zeebregts: Writing – review & editing, Investigation. **Brajesh** K. Lal: Writing – review & editing, Investigation. Peter A. Schneider: Writing – review & editing, Investigation. Mahmoud B. Malas: Writing – review & editing, Investigation. Marc L. Schermer**horn:** Writing – review & editing, Investigation.

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