

From the Society for Vascular Surgery

## Decision aids for patients with carotid stenosis

Brianna M. Krafcik, MD, MS,<sup>a</sup> Isabel A. Jarmel, BS,<sup>b</sup> Jocelyn M. Beach, MD,<sup>a,b</sup> Bjoern D. Suckow, MD,<sup>a,b</sup> Jennifer A. Stableford, MD,<sup>a,b</sup> David H. Stone, MD,<sup>a,b</sup> Philip P. Goodney, MD,<sup>a,b</sup> and Jesse A. Columbo, MD, MS,<sup>a,b</sup> *Lebanon and Hanover, NH*

### ABSTRACT

**Background:** Shared decision-making tools have been underused by clinicians in real-world practice. Changes to the National Coverage Determination by Medicare for carotid stenting greatly expand the coverage for patients, but simultaneously require a shared decision-making interaction that involves the use of a validated tool. Accordingly, our objective was to evaluate the currently available decision aids for carotid stenosis.

**Methods:** We conducted a review of the literature for published work on decision aids for the treatment of carotid disease.

**Results:** Four publications met inclusion criteria. We found the format of the decision aid impacted patient comprehension and decision making, although patient characteristics also played a role in the therapeutic decisions made. Notably, none of the available decision aids included the widely adopted transcatheter aortic valve replacement as an option.

**Conclusions:** Further work is needed in the development of a widespread validated decision aid instrument for patients with carotid stenosis. (*J Vasc Surg* 2023;■:1-4.)

**Keywords:** Carotid disease; Carotid artery stenosis; Patient preferences; Shared decision-making; Decision aid

The recent highly debated changes to the National Coverage Determination (NCD) by Medicare for carotid stenting greatly expands coverage to beneficiaries by including standard risk patients, not requiring clinical trial participation, and removing facility standards.<sup>1</sup> These changes fundamentally alter how carotid stenting is delivered in the United States. However, these modifications include a new requirement that clinicians and patients engage in a shared decision-making interaction guided by a validated decision tool.<sup>1</sup> Unfortunately, the use of such instruments in vascular surgery, cardiology, and interventional radiology remains uncommon in real-world practice.<sup>2-4</sup> Therefore, our objective was to summarize the currently available decision aids for patients with carotid disease to determine the feasibility of meeting the NCD's requirement.

### METHODS

**Study identification.** We reviewed the Cochrane collaboration for all studies examining the use of decision aids for patients with carotid artery stenosis from 2010 to 2022. We next performed a MEDLINE search for studies containing the terms "patient preference" OR "decision aid" OR "shared decision making" AND "carotid stenosis" OR "carotid artery disease" from 2010 to 2022. Next, we conducted a search within the CINAHL database using the same search terms. We included studies of patients with a diagnosis of carotid disease as well as studies that used simulated patients with no known carotid disease. We excluded publications involving nonatherosclerotic carotid disease or patients <18 years old. We also excluded studies that did not measure outcomes related to the decision aids or that only described a study protocol.

**Study outcomes assessed.** Our objective was to understand the currently available decision aids for patients with carotid disease. Our secondary outcome was to determine patient preference in the content and format of the information presented.

### RESULTS

**Included studies.** Our database search identified 427 publications. Upon review of the titles and abstracts, 394 did not specifically study carotid disease and/or patient decision-making, 16 involved patients <18 years old, and 9 studies involved nonhuman subjects. Eight articles underwent full-text review. Of these, four were excluded: one described a protocol for a future study of

From the Section of Vascular Surgery, Dartmouth-Hitchcock Medical Center, Lebanon<sup>a</sup>, and the Geisel School of Medicine at Dartmouth, Hanover.<sup>b</sup>

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Correspondence: Brianna M. Krafcik, MD, MS, Section of Vascular Surgery, Heart and Vascular Center, Dartmouth-Hitchcock Medical Center, 1 Medical Center Dr, Lebanon, NH 03766 (e-mail: [Brianna.M.Krafcik@hitchcock.org](mailto:Brianna.M.Krafcik@hitchcock.org)).

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**Table.** Summary of included studies describing variables studied, outcomes, patient population, and information presentation format

Author	Study population	No. of patients	Management options studied	Decision aid presentation format	Outcomes measured
Jayasooriya, 2011 <sup>2</sup>	Vascular surgery patients eligible for carotid screening without known carotid disease, asked to imagine asymptomatic, unilateral 70% carotid stenosis	102	BMT, CEA + BMT, or TF-CAS + BMT	Information booklet	Therapeutic decision
Silver, 2012 <sup>1</sup>	Neurology patients without known carotid disease	409	BMT or BMT + CEA	Video	Therapeutic decision
Scalia, 2021 <sup>5</sup>	Patients carotid disease status unknown, identified by survey technology company	407	BMT, TF-CAS, or CEA	Online graphical display	Understanding of risk information, format preference
Scalia, 2019 <sup>4</sup>	Vascular surgery patients with carotid disease	27	BMT, TF-CAS, or CEA	Information booklet	Preferred format for time-dependent risk

*BMT, Best medical therapy; CEA, carotid endarterectomy; TF-CAS, transfemoral carotid stenting.*

carotid decision aids, one was a summary of available online information resources for patients (not specifically decision aids), one described the creation of a visual aid without further testing, and one presented amalgamated results for decision aids for a variety of vascular procedures without a subgroup analysis of carotid interventions. Ultimately, four studies were included in our final review.

We stratified publications by the outcome(s) measured: therapeutic decision, understanding of risk information, and patient format preference. Presentation of the material included information booklets, videos, and online graphical displays. The number of included patients varied between 27 and 409. The populations studied included vascular surgery patients with or without carotid disease, neurology patients without carotid disease, and, in one case, the carotid disease status was not known as patients were identified by an online survey technology company. All included individuals with carotid stenosis were asymptomatic (Table).

**Outcome: Therapeutic decision.** Two studies examined the patients' therapeutic decision as their primary outcome (carotid intervention vs best medical therapy [BMT]).<sup>5,6</sup> One of these two publications examined both decision aid information format and patient characteristics as exposures.<sup>5</sup> Patients shown risk information in a qualitative format were 3.3 times as likely (95% confidence interval [CI], 1.7-3.2;  $P < .001$ ) to choose carotid intervention compared with when the risk information was presented as a 1-year absolute risk reduction.<sup>5</sup>

Similarly, when presented with the information as a relative risk reduction at 5 years, patients were 3.1 times as likely 95% CI, 1.6-5.9;  $P < .001$ ) to opt for carotid intervention compared with the 1-year absolute risk reduction format.<sup>5</sup>

Only one study considered the type of revascularization patients selected. It found that 52% of participants opted for a procedure after viewing the decision aid; 30% chose carotid endarterectomy and 22% preferred transfemoral carotid stenting.<sup>6</sup>

Two of the publications evaluated patient characteristics and therapeutic choice.<sup>5,6</sup> Patient factors associated with selecting carotid intervention over BMT after viewing a decision aid include age, gender, education, and smoking status.<sup>5,6</sup> In one publication considering age, a younger age was associated with a higher likelihood of selecting intervention (odds ratio, 1.4; 95% CI, 1-2.1;  $P = .07$ ) for age <55 years old as compared with patients >55 years old.<sup>5</sup> Similarly, in a second publication, patients selecting carotid endarterectomy and transfemoral carotid stenting were, on average, 5 and 8 years younger, respectively, than those choosing BMT.<sup>6</sup> Males in both of these studies were more likely to opt for intervention as compared with females, with an odds ratio of 1.4 (95% CI, 1.0-2.1;  $P = .08$ ).<sup>5</sup> In the publication by Jayasooriya et al,<sup>6</sup> 60% of female participants opted for BMT as compared with 43% of males. Patients with education beyond high school were 1.5 times as likely to select carotid intervention as compared with those with a high school education or less.<sup>5</sup> Patients actively smoking were more likely to select carotid intervention,

with approximately 10% more smokers selecting intervention than nonsmokers or former smokers.<sup>6</sup>

**Outcome: Patient format preference.** Two of the publications included in this review considered patient preference of visual format as an outcome.<sup>7,8</sup> Both publications found that formats other than icon arrays were generally preferred by patients.<sup>7,8</sup> Icon arrays can communicate risks to patients with lower numeracy skills by portraying the risk of a particular outcome using a graphical representation of stick figures, circles, or other icons to symbolize affected individuals.<sup>9</sup> However, in one study, 66% of patients preferred bar graphs over icon arrays, because they were reported to be less complicated and easier to read and understand.<sup>7</sup> Similarly, in a second study, patients preferred pie charts over icon arrays; they were found to be easier to understand and to better depict the risks associated with carotid disease over time.<sup>8</sup> Patients in general found icon arrays to be confusing and difficult to read.<sup>7,8</sup> Nevertheless, a minority of participants found icon arrays to be informative and visually appealing, allowing for a more clear understanding of the number of patients expected to suffer no event when compared with alternative presentation methods.<sup>7,8</sup>

## DISCUSSION

We identified four publications describing decision aids for patients with carotid artery stenosis. These studies document that patient characteristics and the format of information presentation have an impact on patients' understanding of carotid disease and therapeutic decision-making. Furthermore, although certain patients may be predisposed to opt for a procedure regardless of any outside influences, decision aids outlining the risks and benefits of carotid intervention can impact patient understanding and their ultimate therapeutic decision. Notably, all of these studies antedated the widespread adoption of transcatheter artery revascularization, which is now offered at >600 centers with >30,000 procedures entered into the Vascular Quality Initiative registry and, as such, do not incorporate it as a treatment option.<sup>10</sup> Therefore, the currently available decision aids do not adequately summarize the available treatment options and remain ill-equipped to meet the requirements set forth by the Medicare NCD of a shared decision-making conversation using a validated decision aid tool.

Across medical specialties, patients who use decision aids with their provider are more knowledgeable about their clinical condition and report higher satisfaction with the decision-making process.<sup>11,12</sup> In addition, decision aids assist patients in understanding the likely outcomes of each treatment option and manage expectations with less decisional conflict.<sup>13,14</sup> Despite these benefits, decision aids are underused clinically, even with the development of aids that can be

employed in ≤5 minutes.<sup>2,15-17</sup> As such, there is a gap in the incorporation of these potentially valuable tools into vascular practice and a need for the creation and dissemination of a validated instrument for many vascular conditions, including carotid stenosis.

The creation of a clinically relevant, validated decision aid for carotid disease requires multiple iterative phases evaluating content and format, as well as usability, acceptability, appropriateness, and feasibility.<sup>18,19</sup> Input from patients with carotid disease is critical in the development and testing of the instrument. The decision aid must be validated in various geographic and sociodemographic regions to ensure universal applicability. Furthermore, effective decision aids must address the needs of patients with limited health literacy skills and be tested in these groups.<sup>20</sup>

The proven patient benefits of decision aid usage combined with the emphasis on these instruments by Medicare has some important implications. First, the available decision aids for carotid stenosis do not incorporate the range of available options to patients and, therefore, do not meet the requirements of the recently approved Medicare NCD on carotid stenting adequately. However, the available literature provides a foundation from which a more comprehensive decision aid can be built and subsequently validated for contemporary patients with carotid stenosis.

## CONCLUSIONS

The format of decision aids for carotid disease impacts patient understanding and decision-making, although patient characteristics also play a role in choice of therapy. To best inform patients with carotid stenosis and meet the requirements of the NCD, dedicated work is needed to design a decision aid that can appropriately guide shared decision-making interactions for patients with carotid stenosis. This task is complex but achievable and will require thoughtful development and validation.

## DISCLOSURES

None.

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