

Visual Aids for Improving Patient Decision Making in Severe Symptomatic Carotid Stenosis

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Background: Because of the large amount of information to process and the limited time of a clinical consult, choosing between carotid endarterectomy (CEA) and carotid angioplasty with stenting (CAS) can be confusing for patients with severe symptomatic internal carotid stenosis (ICA). *Goal:* We aim to develop a visual aid tool to help clinicians and patients in the decision-making process of selecting between CEA and CAS. *Materials and Methods:* Based on pooled analysis from randomized controlled trials including patients with symptomatic and severe ICA (SSICA), we generated visual plots comparing CEA with CAS for 3 prespecified postprocedural time points: (1) any stroke or death at 4 months, and (2) any stroke or death in the first 30 days and ipsilateral stroke thereafter at 5 years and (3) at 10 years. *Results:* A total of 4574 participants (2393 assigned to CAS, and 2361 to CEA) were included in the analyses. For every 100 patients with SSICA, 6 would develop any stroke or death in the CEA group compared with 9 undergoing CAS at 4 months (hazard ratio [HR] 1.53; 95%CI 1.20-1.95). At 5 years, 7 patients in the CEA group would develop any periprocedural stroke or death and ipsilateral stroke thereafter versus 12 undergoing CAS (HR 1.72; 95%CI 1.24-2.39), compared with 10 patients in the CEA and 13 in the CAS groups at 10 years (HR 1.17; 95%CI 0.82-1.66). *Conclusion:* Visual aids presented in this study could potentially help patients with severe symptomatic internal carotid stenosis to better weigh the risks and benefits of CEA versus CAS as a function of time, allowing for the prioritization of personal preferences, and should be prospectively assessed. **Key Words:** Outcomes—visual aid tool—endarterectomy—stroke—carotid—angioplasty—stenting—decision making. © 2017 National Stroke Association. Published by Elsevier Inc. All rights reserved.

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Introduction

In addition to optimal medical therapy, currently available interventions for prevention of ischemic stroke in patients with symptomatic and severe internal carotid artery stenosis (SSICAS) comprise carotid endarterectomy (CEA) and carotid angioplasty with stenting (CAS).^{1,4} Differences between outcomes of both procedures are evident shortly after the intervention and become negligible years after.^{1,4} Whereas some patients prioritize short-term results (eg, older individuals with shorter life expectancy), others base their decisions on long-term outcomes. For instance, older individuals may base their decision on short-term results because of their presumably shorter life expectancy, whereas younger patients may consider long-term outcomes when choosing between different options. Therefore, patients with ischemic stroke and transient ischemic attack who are deemed candidates for either CEA or CAS need to be informed of current evidence in terms of possible benefits and harms of each option at different time points after the procedure. Furthermore, a single net benefit measure would be simpler for patients and for physicians who need to incorporate large amounts of data from a considerable number of clinical trials and meta-analyses.

Patients' informed decision making is usually challenging because of the complexity of information to be conveyed and presented by treating physicians. Visual aids have been shown to improve medical decision-making processes⁵ by facilitating the communication between health care providers and patients, when discussing treatment options and their expected outcomes. As a result, better delivery of medical information improved the consistency between chosen options and subjects' values.⁶

Graphical representations showing the entire population at risk of a given outcome have shown to be effective decision aids.⁷ Cates plots help to quantify risks and benefits of specific interventions in a standardized manner (<http://www.nntonline.net>). Indeed, these plots have been proposed as an aid for ischemic stroke patients with atrial fibrillation when choosing between novel oral anticoagulants and warfarin,⁸ and in patients with acute stroke when choosing between standard care and thrombectomy.⁹ In this study, we present visual aids comparing the risk of stroke and death associated with CEA and CAS at 4 months, 5 years, and 10 years after each procedure.

Materials and Methods

We searched MEDLINE, Embase, Stroke Trials Registry (<http://www.strokecenter.org/trials/>), and Cochrane Library databases for articles published before September 30, 2016, comparing CAS with CEA among patients with SSICAS. Studies qualified for inclusion if they met the following criteria: (1) randomized controlled trials,

or meta-analysis, or pooled analysis of randomized controlled trials; (2) including patients of any gender or age with SSICAS, (3) providing a clear definition of CAS or CEA, and (4) outcomes comprising at least stroke (any and ipsilateral ischemic) and death.

We generated modified Cates plots¹⁰ comparing outcomes of CAS with CEA for SSICAS at 3 prespecified postprocedural time points: (1) any stroke or death at 4 months³; (2) any stroke or death in the first 30 days, and ipsilateral stroke thereafter at 5 years; and (3) any stroke or death in the first 30 days and ipsilateral stroke thereafter at 10 years. We used these outcome measures because they comprise the complications that patients are usually more concerned about,¹¹ and because they represent the most consistently reported outcomes across studies^{1-4,12,13} and in the literature of visual aids used for cardiovascular diseases.¹⁴ As secondary analyses, we developed modified Cates plots for different age strata¹² and for the sex, contralateral occlusion, age, and restenosis (SCAR) rule.¹³ Subjects are considered SCAR positive if they fulfill any of the following criteria: male sex, age >75 years, and contralateral occlusion or restenosis.¹³

We obtained data from 2 pooled analyses,^{3,13} 2 randomized controlled trials,^{1,2} and a systematic review further validated in randomized controlled trials.¹² For the short-term outcome, we used results from a pooled analysis.^{3,13} We extracted data from the International Carotid Stenting Study trial for 5-year outcomes,¹ whereas we used data from the Carotid Revascularization Endarterectomy versus Stenting Trial for 10-year results.² For secondary analysis, we obtained data from the SCAR rule systematic review,¹³ whereas for the age strata analysis we selected data from a recent pooled analysis.¹²

A classical Cates plot includes a single figure showing different proportions of 4 categories of smiley faces to visually compare outcomes of 2 treatment options: (1) green faces for patients with good outcomes after both procedures; (2) red faces for patients with bad outcomes for both procedures; (3) yellow faces for patients for which a given treatment changes their category from a bad outcome to a good outcome compared with other treatment; and (4) crossed out green faces for patients for which treatment causes an adverse event and changes their category from a good outcome to a bad outcome.⁷ With the aim of further simplifying these plots, we decided to create 1 figure for each procedure at each time point and we reduced the number of smiley faces by including only 2 categories: (1) green faces: proportion of patients with good outcome (eg, free from stroke or death), and (2) red faces: proportion of patients with bad outcome (eg, with stroke or death).

The plots were modified after being created with the available online calculator (<http://www.nntonline.net>) by entering the event rate of the control group (CEA), and hazard ratio of the intervention with 95% confidence intervals (CI), obtained from each referenced paper.

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