

## **A RAND NOTE**

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## Derivation of Clinical Indications for Carotid Endarterectomy by an Expert Panel

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**Abstract:** We used a two-round consensus panel method to derive and rate the appropriateness of comprehensive sets of detailed clinical indications for performing carotid endarterectomy. Before meeting, nine nationally influential physicians rated 675 indications; after review and discussion, they rated 864. The method did not force unanimity; our purposes were not only to encourage agreement but also to uncover areas of disagreement concerning the procedure's appropriate use. The panelists agreed on the level of appropriateness for 54 per cent of the final 864 indications and disagreed on 18 per

cent. Ratings were reliably reproduced six to eight months after the completion of the process. The physicians' indications and ratings were consistent with those in the literature, and statistical analysis demonstrated that they followed logical clinical rationale. We conclude that consensus methods that do not force agreement can be used with panels of physicians to produce detailed, reliable, and valid indications. They can also identify medically controversial reasons for using a procedure that can serve as a starting point for a research agenda. (*Am J Public Health* 1987; 77:187-190.)

### Introduction

Formal consensus methods are being used increasingly to solve problems in health and medicine.<sup>1</sup> One use of these methods is to define levels of agreement on medically controversial issues and to provide practitioners and policy makers with recommendations for clinical action. Perhaps their most active proponents are the National Institutes of Health (NIH) which have organized over 40 Consensus Development Conferences since 1977 to address a wide range of concerns from the use of coronary artery bypass graft surgery to the definition of obesity.<sup>2</sup>

Despite their widespread use, many consensus processes, including those of the NIH, have been criticized for being "bland," for reflecting the lowest common denominator of a debate,<sup>3</sup> and for producing vague recommendations.<sup>1</sup> Often, too, the clinical merit of the recommendations has gone unexamined.

In this paper, we report a consensus process in which a panel of physicians produced and rated the appropriateness of a highly detailed set of possible indications for performing carotid endarterectomy, an operation about which there has been some controversy.<sup>4</sup>

### Methods

#### Consensus Panel Selection

The consensus process relied on a panel of nine physicians. The panelists were recommended by eminent researchers and practitioners. In selecting panelists, we attempted to keep a geographic balance, and also chose panelists to represent a range of medical specialties and, within them, diverse perspectives on the management of cerebrovascular disease. Panelists were selected purely on the basis of peer recommendations, not as organizational

representatives. Only one of those invited declined to participate, due to a schedule conflict.

#### Indications and Ratings

We compiled 675 possible indications for carotid endarterectomy based on a review of the literature and interviews with physicians. Our aim was to make the indications sufficiently detailed so that all patients within a given category would be reasonably homogeneous and performing endarterectomy would be equally appropriate (or inappropriate) for all. We also attempted to create a comprehensive list including all possible indications that might arise in clinical practice.

Each indication stated the patient's clinical presentation, the results of carotid arteriography, the patient's surgical risk, and, for asymptomatic patients, degree of stroke risk. There were 11 possible clinical presentations; six involved transient ischemic attacks (TIAs), two stroke, two asymptomatic patients, and one dementia (Appendix A).

We instructed the panelists who convened in 1984 to rate the appropriateness of each of the 675 indications using their own best clinical judgment and considering an average group of patients presenting to an average US physician who performed the procedure during 1981. The year 1981 was chosen because of the needs of the Rand-UCLA Health Services Utilization Study, a study of geographic variations in the use of common medical procedures.<sup>5</sup> "Appropriate" was defined to mean that the expected health benefit exceeded the expected negative consequences by a sufficiently wide margin that the procedure was worth doing, and "inappropriate" meant the opposite. Extremely appropriate indications were rated 9, extremely inappropriate indications as 1, and those neither clearly appropriate nor clearly inappropriate as 5. Three separate sets of ratings were developed for patients with high (class IV), elevated (class II or III), and low (class I) surgical risk.<sup>7</sup> Appendix B shows, as an example, a portion of the rating sheet for patients who presented with a single episode carotid TIA or amaurosis fugax.

The ratings were confidential, took place in two rounds, and were organized according to a modified Delphi format.<sup>5</sup> The first round (675 indications) was conducted by mail, and the second (864 indications) during a one and one-half day meeting. Two hundred forty-six of the final indications were unchanged from the initial round, and 598 indications were modified; the clinical presentation categories remained the same.

From the Departments of Economics and System Sciences, Rand Corporation, (Drs. Brook, Chassin, and Park); Fink and Kosecoff, (Drs. Fink and Kosecoff), all in Santa Monica, CA; Department of Medicine (Dr. Solomon) and Departments of Medicine and Public Health, Center for the Health Sciences, University of California at Los Angeles, (Drs. Brook, Fink, and Kosecoff); VA-Robert Wood Johnson Clinical Scholars Program, VA Medical Center, West Los Angeles (Dr. Merrick). Address reprint requests to: Nancy Merrick, MD, Prospective Payment Assessment Commission (ProPAC), 300 7th Street, SW, Washington, DC 20024. This paper, submitted to the *Journal* February 27, 1986, was revised and accepted for publication July 7, 1986.

**Agreement and Disagreement and Categories of Rated Indications**

We defined agreement among panelists on a given indication as resulting when, after discarding one extreme high and one extreme low rating, the remaining seven ratings all fell within any three-point range.<sup>5</sup> Disagreement meant that after discarding one extreme high and one extreme low rating, at least one of the remaining seven ratings fell in the lowest 3-point region (1 to 3) and at least one fell in the highest (7 to 9). We categorized indications as clearly appropriate (a median rating of 7 to 9 without disagreement), clearly inappropriate (a rating of 1 to 3 without disagreement), or equivocal; an indication was equivocal if the panelists considered the benefits and risks of doing carotid endarterectomy to be about the same (a median rating of 4 to 6), or if they disagreed on the proper rating.

**Reliability**

A reliable measure avoids random error and provides consistent information. To assess the reliability of the panelists' ratings, we studied their stability when repeated six months following completion of the panel process. We asked the panelists to rerate 132 indications: all 66 for the clinical presentation "Multiple TIAs, failure of medical treatment," 33 randomly selected from 50 chosen by the panelists as the most frequently used, and 33 from the remainder. To test the relationship between the two sets of ratings, we computed Spearman rank correlation coefficients.

**Validity**

A valid measure avoids systematic error and provides unbiased information. To assess the validity of the panelists' ratings, we compared them to data from the literature on carotid endarterectomy and to a clinically logical order.

*Comparing Ratings to the Literature*—We reviewed more than 130 articles from the carotid endarterectomy literature published from 1977 through 1981<sup>8</sup> and counted the number of recommendations for and against operation within each of the 11 clinical presentations. We used a simple count as opposed to a more sophisticated analysis, which could have been based on the strength of the research design from which the recommendations emanated, because of the lack of experimental trials in the carotid literature. Next, we rank-ordered presentations so that the top ranked had the largest per cent of recommendations for surgery. The panelists' ratings were also placed in a similar rank order. We computed the average median rating assigned to 16 indications that were rated for each clinical presentation. The 16 chosen indications specified: a) low or elevated surgical risk; b) an operable stenosis of 50 to 99 per cent; c) and/or a multicentric or large ulcerative lesion. Top rank was assigned to the clinical presentation with the highest median. We compared the two sets of ranks with a Spearman rank correlation coefficient.

*Comparing Ratings to a Logical Order*—We studied how information concerning clinical presentation, arteriography result, and surgical risk influenced panel median ratings to assure that it did so in a logical way. Specifically, we studied how six variables influenced panel median ratings: 1) clinical presentation; 2) surgical risk; 3) ulcerative lesion on angiography; 4) diameter stenosis of the operated artery; 5) diameter stenosis of the opposite artery; and 6) side of surgery relative to symptoms. Each variable was further divided into subcategories. For example, "surgical risk" was subcategorized as low, elevated, or high. Using multiple regression analysis, we then analyzed the extent to which each subcategory influenced the median ratings to assure that logical relationships existed in the way in which they did so.

**TABLE 1—Per Cent of Indications for Carotid Endarterectomy on which Panelists Agreed and Disagreed during a Two-Round Consensus Process**

	Agreement <sup>a</sup>		Disagreement <sup>b</sup>	
	Per Cent	Standard Error	Per Cent	Standard Error
Initial Round N = 675	55.6	1.9	21.6	1.6
Second Round N = 864	53.8	1.7	18.1	1.3

a) Agreement: After discarding one extreme high and low rating, the remaining seven ratings fall within any three-point range.

b) Disagreement: After discarding one extreme high and low rating at least one of the remaining seven ratings fell into the lowest and at least one in the highest three-point region.

Did high surgical risk or low-grade stenosis (1 to 49 per cent) result in ratings consistently lower than for low surgical risk or high-grade stenosis (70 to 99 per cent), as one would logically expect?

**Results**

**Ratings**

The panel's ratings for the 864 indications were skewed toward the lower end of the nine-point scale with an average median rating of 2.7. The low average rating does not necessarily suggest that carotid endarterectomy is performed inappropriately, however, because the procedure may be used in practice almost exclusively for highly appropriate indications. In fact, the average median appropriateness rating for the indications selected by the panel as the 50 most frequent reasons for performing carotid endarterectomy was 7.5.

**Agreement and Disagreement**

According to our definition, panelists agreed on the final ratings for 54 per cent of the indications and disagreed on 18 per cent (Table 1). The majority (67 per cent) of indications were found to be inappropriate (a probable reflection of our attempt to exhaustively list all possible indications for the surgery), just under 10 per cent were clearly appropriate, and 23 per cent were equivocal.

**Reliability**

Seven of the nine panelists returned the reliability assessment materials in the six to eight months following the panel meeting. For each of the seven, the original and the later repeated ratings were highly correlated, with correlation coefficients ranging from 0.75 to 0.96.

**Validity**

*The Panel's Ratings and the Literature*—Specific recommendations for using carotid endarterectomy were found in 46 articles (Table 2). From the counts for and against using the operation, we found that carotid TIAs and post-arterothrombotic stroke were well-accepted clinical settings for use of carotid endarterectomy. There were 20 endorsements of the procedure's use in treating these two clinical conditions and none against. Performing the procedure was more controversial for asymptomatic patients, and it was generally not recommended for patients with vertebrobasilar TIAs or a stroke-in-evolution. The pattern of ratings assigned by the panelists and the rank ordering of indications were nearly identical to the endorsement patterns found in the literature.

*Comparing Panelists' Ratings to a Logical Order*—The results of multiple regression analysis suggest that panel

**TABLE 2—Clinical Indications for Carotid Endarterectomy: A Comparison of Panelists' Ratings and Published Recommendations (1977 through 1981)**

Endarterectomy should be performed if the patient has the presentation	Articles <sup>a</sup>			Panel	
	Number			Rating <sup>c</sup>	Order
	Yes	No	Rank <sup>b</sup>		
Carotid Transient Ischemic Attack(s)	14	0	1	7.5	1
Completed Mild Stroke	6	0	2	7.2	2
Asymptomatic	15	4 <sup>d</sup>	3	5.0	3
Asymptomatic, other surgery planned	14	4 <sup>d</sup>	4	4.1	5
Stroke-in-evolution	3	4	5	4.3	4
Vertebrobasilar TIAs	0	8 <sup>d</sup>	6	3.1	6

a) 88 articles were reviewed; 46 had recommendations for or against carotid endarterectomy.

b) Based on per cent of articles endorsing each general clinical presentation.

c) Average median of panel's ratings across 16 identical indications: 1 = very appropriate; 5 = equivocal; 9 = very inappropriate.

d) Either no, or "medical therapy should be tried first."

**TABLE 3—Results of Multiple Linear Regression Analysis Applied to Panel's Median Appropriateness Ratings for Indications for Performing Carotid on Patients with Carotid Transient Ischemic Attacks**

Parameter	Parameter Coefficient
Intercept <sup>a</sup>	10.4
Clinical Presentation	
Multiple carotid TIAs, medical therapy failed	+0.1
Multiple carotid TIAs, medical therapy never tried	-0.3
Single episode	-0.7
Multiple carotid TIAs, medical therapy successful	-1.5
Surgical Risk	
Elevated	-1.1
High	-3.0
Ulcerative Lesion	
Large	-0.1
Small	-3.6
None described	-2.0
Side of Surgery	
Contralateral	-1.5
Stenosis of the operated carotid	
50-69%	-2.1
1-49%	-3.5
100%	-3.8
Stenosis of the opposite carotid	
Not occluded	+0.4
1-49%	-1.2
50-99%	-1.4
Adjusted R2 = 0.78.	

a) 10.4 is the score predicted for a patient with Crescendo TIAs, low surgical risk, multicentric ulcerative lesion, and 70-99 per cent stenosis of the operated carotid on the side consistent with symptoms and 100 per cent occlusion contralaterally.

ratings are logical and conform to clinical wisdom (Table 3). For each clinical parameter studied, categories associated with greater risk of developing a stroke without surgery are also associated with higher appropriateness ratings.

For example, after controlling for all other factors, the panelists assigned higher ratings to patients with 70-99 per cent stenosis of the carotid artery compared to those with a 1-49 per cent stenosis (3.5 points). Only one slightly illogical relationship was noted and remains unexplained: median ratings for indications specifying small ulcerative lesions were 1.6 points lower than those where no ulceration was present; our literature review, in contrast, suggests that ratings should be similar.<sup>8</sup> Seventy-eight per cent of the

variance in the median panel ratings for these carotid TIA indications was explained by the analysis.

**Discussion**

Despite the almost complete absence of relevant experimental data and the controversial status of treatment of cerebrovascular disease by carotid endarterectomy, the panel reached surprising agreement—and low disagreement—regarding the appropriate use of carotid endarterectomy. Further, the panelists' ratings proved to be highly reproducible six months following the panel meeting, suggesting that the group consensus produced stable, reasoned responses as opposed to arbitrary or compromised ratings. The ratings also mirrored the literature and manifested inherently logical reasoning.

Our process was different from that of others. We did not require unanimity or some specified level of agreement. Instead, we accepted disagreement and equivocal results. By doing so, we found that physicians could rate large numbers of indications as to their medical appropriateness. The specificity and comprehensiveness of the indications were much greater than those reported in the past.

The cost of the consensus process was considerable: about \$75,000 in 1984. This figure includes expenses for preparing the literature review, conducting the panel, and analyzing and interpreting the appropriateness ratings. If a similar process were performed for the 50 to 100 procedures that make up the bulk of medical practice, then a total expenditure of about \$3.75 million to \$7.5 million would be required. Such amounts, although large, are small compared to the amounts spent on performing such procedures. Con-

**APPENDIX A**

**Clinical Presentation Categories for 864 Rated Indications for Carotid Endarterectomy**

Category	Number of Indications
1. Carotid transient ischemic attack (TIA) and/or amaurosis fugax—single attack	66
2. Carotid TIAs and/or amaurosis fugax—multiple episodes, never tried on medical therapy	66
3. Carotid TIAs and/or amaurosis fugax—multiple episodes with at least one recurrence since initiation of medical therapy	66
4. Carotid TIAs and/or amaurosis fugax—multiple episodes; no recurrence since initiation of medical therapy (at least 3 months of therapy)	66
5. Vertebrobasilar TIA(s)	66
6. Post-atherothrombotic stroke	66
7. Stroke-in-evolution	66
8. Crescendo carotid TIAs	66
9. Asymptomatic	90
9A. Asymptomatic, normal stroke risk	
9B. Asymptomatic, high stroke risk	
10. Asymptomatic, patient to undergo other surgery <sup>a</sup>	180
10A1. Intra-abdominal or intra-thoracic surgery, normal stroke risk <sup>b</sup>	
10A2. Intra-abdominal or intra-thoracic surgery, high stroke risk <sup>c</sup>	
10B1. Coronary artery bypass surgery, normal stroke risk <sup>b</sup>	
10B2. Coronary artery bypass surgery, high stroke risk <sup>c</sup>	
11. Dementia of vascular origin	66
TOTAL	864

a) Implies that carotid endarterectomy is planned prophylactically prior to a patient's undergoing other non-carotid surgery.

b) Normal stroke risk: Risk of stroke is less than 10 per cent within eight years based on Framingham Study data.<sup>6</sup>

c) High stroke risk: Risk of stroke is 10 per cent or greater within eight years based on Framingham Study data.<sup>6</sup>

**APPENDIX B**  
**Form Used for Initial Ratings**

**CLINICAL PRESENTATION:**

1. CAROTID TIA and/or AMAUROSIS FUGAX - Single Episode

	Low Surgical Risk	Elevated Surgical Risk	High Surgical Risk
<b>APPROPRIATENESS OF OPERATING IPSILATERALLY IF ANGIOGRAPHY SHOWS:</b>			
Ipsi: Degree of stenosis of ipsilateral artery Contra: Degree of stenosis of contralateral artery			
1. Ipsi: Occluded Contra: None or 1-49%	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9
2. Ipsi: Occluded Contra: 50-99%	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9
3. Ipsi: 50-99% Contra: None, 1-49%, or 50-99%	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9
4. Ipsi: 50-99% Contra: Occluded	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9
5. Ipsi: 1-49% Contra: None or 1-49%	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9
6. Ipsi: 1-49% Contra: 50-99%	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9
7. Ipsi: 1-49% Contra: Occluded	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9
8. Ipsi: 1-49% with large ulcerative lesion Contra: None, 1-49% or 50-99%	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9
9. Ipsi: 1-49% w/multicentric ulcerative lesion Contra: None, 1-49%, or 50-99%	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9

sensus recommendations are clearly not a substitute for experimentally derived information; however, they provide useful guidance when experimental results are lacking.

It should be noted that the ratings reflect the panel's judgment of the appropriateness of performing carotid endarterectomy in 1981 and are not intended as recommendations for clinical management of individual patients.

The large number of indications of low appropriateness is likely an artifact of the consensus process in which panelists were asked to rate every potential use of carotid endarterectomy; in practice, most of these indications may be infrequently used. The large number of indications with equivocal ratings, however, probably reflects accurately the lack of experimentally derived data about the risks and benefits of performing carotid endarterectomy. These medically controversial areas, we believe, are important to identify and are candidates for new research on the procedure's efficacy and use.

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