# Complete Summary

## GUIDELINE TITLE

Carotid endarterectomy — an evidence-based review. Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology.

## BIBLIOGRAPHIC SOURCE(S)

Chaturvedi S, Bruno A, Feasby T, Holloway R, Benavente O, Cohen SN, Cote R, Hess D, Saver J, Spence JD, Stern B, Wilterdink J. Carotid endarterectomy--an evidence-based review: report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. Neurology 2005 Sep 27;65(6):794-801. [27 references] PubMed

## GUIDELINE STATUS

This is the current release of the guideline.

## COMPLETE SUMMARY CONTENT

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## SCOPE

### DISEASE/CONDITION(S)

- Carotid artery stenosis
- Stroke

### GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
Prevention
Risk Assessment

## CLINICAL SPECIALTY

Neurological Surgery
Neurology

## INTENDED USERS

Physicians

## GUIDELINE OBJECTIVE(S)

To assess the efficacy of carotid endarterectomy for stroke prevention in asymptomatic and symptomatic patients with internal carotid artery stenosis

## TARGET POPULATION

Asymptomatic and symptomatic patients with internal carotid artery stenosis

**Note**: Patients are considered symptomatic if they have had a recent (preceding 6 months) carotid distribution transient ischemic attack or nondisabling stroke

## INTERVENTIONS AND PRACTICES CONSIDERED

1. Carotid endarterectomy
2. Perioperative aspirin therapy
3. Combined carotid endarterectomy and coronary artery bypass surgery (considered but not recommended)

## MAJOR OUTCOMES CONSIDERED

The guideline authors selected 9 important clinical questions for which study outcomes were available:

1. Does carotid endarterectomy (CE) benefit symptomatic patients?
2. Does CE benefit asymptomatic patients?
3. Is emergent CE beneficial in patients with progressing stroke of <24 hours?
4. What are the most important clinical variables that impact the risk/benefit ratio?
5. What are the most important radiologic factors that impact the risk/benefit ratio?
6. What is the ideal dose of aspirin preoperatively in patients undergoing CE?
7. What is the evidence/practice gap? Can trial results be achieved in practice?
8. What are the data regarding CE concurrent with or prior to coronary artery bypass graft?
9. How long should one wait after a stroke to perform CE?

# METHODOLOGY

## METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

## DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

A literature search was performed using Ovid Medline for relevant articles published from 1990 to 2001 using the following key words: carotid endarterectomy, carotid stenosis, carotid artery diseases, clinical trials. Further details of the search process can be found in appendix E-1 of the original guideline document (go to the *Neurology* Web site at www.neurology.org). Standard search procedures were used and subheadings were applied as appropriate. Two committee members also reviewed the Cochrane Library statements on carotid endarterectomy (CE) for symptomatic and asymptomatic stenosis in August 2004 to confirm that relevant citations from 2002 to 2004 were identified.

The initial search was done in July 2001 and identified 1,462 citations. This list was refined further by reviewing these citation abstracts with exclusion of the following types of articles: case reports, letters to the editor, review articles without primary data, studies addressing carotid endarterectomy technical issues, case series from a single surgeon, and non-English articles. Case series from a single institution were not excluded. This reduced the articles to 186 and each of these articles was reviewed independently by two committee members. The committee also stipulated that if a pooled analysis of the major symptomatic carotid endarterectomy studies or if the results of the Asymptomatic Carotid Surgery Trial were published prior to the completion of the committee's manuscript, these would subsequently be reviewed. For some of the clinical questions, additional screening criteria were used before the study was selected for full abstraction. The number needed to treat and harm were evaluated in studies as described in the table below:

| | Formula |
|---|---|
| No. needed to treat (NNT) | 100/absolute risk reduction |
| No. needed to harm (NNH) | 100/absolute risk increase |

## NUMBER OF SOURCE DOCUMENTS

After exclusions, a total of 186 articles were reviewed.

## METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

## RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

**Class I**: Prospective, randomized, controlled clinical trial (RCT) with masked outcome assessment, in a representative population. The following are required:

a. Primary outcome(s) clearly defined.
b. Exclusion/inclusion criteria clearly defined.
c. Adequate accounting for drop-outs and cross-overs with numbers sufficiently low to have minimal potential for bias.

d. Relevant baseline characteristics are presented and substantially equivalent among treatment groups or there is appropriate statistical adjustment for differences.

**Class II**: Prospective matched group cohort study in a representative population with masked outcome assessment that meets a-d above OR a RCT in a representative population that lacks one criterion a-d.

**Class III**: All other controlled trials (including well-defined natural history controls or patients serving as own controls) in a representative population, where outcome is independently assessed, or independently derived by objective outcome measurement.

**Class IV**: Evidence from uncontrolled studies, case series, case reports, or expert opinion.

## METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

## DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

## METHODS USED TO FORMULATE THE RECOMMENDATIONS

Other

## DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Recommendations were generated based on the application of levels of evidence to the abstracted articles using the American Academy of Neurology schemes.

## RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

**A** = Established as effective, ineffective, or harmful for the given condition in the specified population. (Level A rating requires at least two consistent Class I studies.)

**B** = Probably effective, ineffective, or harmful for the given condition in the specified population. (Level B rating requires at least one Class I study or at least two consistent Class II studies.)

**C** = Possibly effective, ineffective, or harmful for the given condition in the specified population. (Level C rating requires at least one Class II study or two consistent Class III studies.)

**U** = Data inadequate or conflicting; given current knowledge, treatment is unproven.

## COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

## METHOD OF GUIDELINE VALIDATION

Internal Peer Review

## DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

This guideline was approved by the Therapeutics and Technology Assessment Subcommittee on November 19, 2004; by the Practice Committee on April 13, 2005; and by the Board of Directors on June 26, 2005.

# RECOMMENDATIONS

## MAJOR RECOMMENDATIONS

Definitions of the classification of the recommendations (A, B, C, U) and classification of the evidence (Class I through Class IV) are provided at the end of the "Major Recommendations" field.

1. Carotid endarterectomy (CE) is established as effective for recently symptomatic (within previous 6 months) patients with 70 to 99% internal carotid artery (ICA) angiographic stenosis (**Level A**). CE should not be considered for symptomatic patients with less than 50% stenosis (**Level A**). CE may be considered for patients with 50 to 69% symptomatic stenosis (**Level B**) but the clinician should consider additional clinical and angiographic variables (**Level C**, see below). It is recommended that the patient have at least a 5-year life expectancy and that the perioperative stroke/death rate should be <6% for symptomatic patients (**Level A**). Medical management is preferred to CE for symptomatic patients with <50% stenosis (**Level A**).
2. It is reasonable to consider CE for patients between the ages of 40 and 75 years and with asymptomatic stenosis of 60 to 99% if the patient has an expected 5-year life expectancy and if the surgical stroke or death frequency can be reliably documented to be <3% (**Level A**). The 5-year life expectancy is important since perioperative strokes pose an up front risk to the patient and the benefit from CE emerges only after a number of years.
3. No recommendation can be provided regarding the value of emergent CE in patients with a progressing neurologic deficit (**Level U**).
4. Clinicians should consider patient variables in CE decision making. Women with 50 to 69% symptomatic stenosis did not show clear benefit in previous trials. In addition, patients with hemispheric transient ischemic attack (TIA)/stroke had greater benefit from CE than patients with retinal ischemic events (**Level C**). Clinicians should also consider several radiologic factors in decision making about CE. For example, contralateral occlusion erases the small benefit of CE in asymptomatic patients whereas in symptomatic patients, it is associated with increased operative risk but persistent benefit (**Level C**). CE for patients with angiographic near-occlusion in symptomatic patients is associated with a trend toward benefit at 2 years but not

associated with a clear long-term benefit (**Level C**). Patients operated on within 2 weeks of their last TIA or mild stroke derive greater benefit from CE (**Level C**).

5. Symptomatic and asymptomatic patients undergoing CE should be given aspirin (81 or 325 mg/day) prior to surgery and for at least 3 months following surgery to reduce the combined endpoint of stroke, myocardial infarction, and death (**Level A**). Although data are not available, it is recommended that aspirin (81 or 325 mg/day) be continued indefinitely provided that contraindications are absent. Aspirin at 650 or 1,300 mg/day is less effective in the perioperative period. The data are insufficient to recommend the use of other antiplatelet agents in the perioperative setting.
6. At this time the available data are insufficient to declare either CE before or simultaneous with coronary artery bypass graft (CABG) as superior in patients with concomitant carotid and coronary artery occlusive disease (**Level U**).
7. For patients with severe stenosis and a recent TIA or nondisabling stroke, CE should be performed without delay, preferably within 2 weeks of the patient's last symptomatic event (**Level C**). There is insufficient evidence to support or refute the performance of CE within 4 to 6 weeks of a recent moderate to severe stroke (**Level U**).

**Definitions**:

**Classification of Evidence**

**Class I**: Prospective, randomized, controlled clinical trial (RCT) with masked outcome assessment, in a representative population. The following are required:

a. Primary outcome(s) clearly defined.
b. Exclusion/inclusion criteria clearly defined.
c. Adequate accounting for dropouts and crossovers with numbers sufficiently low to have minimal potential for bias.
d. Relevant baseline characteristics are presented and substantially equivalent among treatment groups or there is appropriate statistical adjustment for differences.

**Class II**: Prospective matched group cohort study in a representative population with masked outcome assessment that meets a-d above OR a RCT in a representative population that lacks one criterion a-d.

**Class III**: All other controlled trials (including well-defined natural history controls or patients serving as own controls) in a representative population, where outcome is independently assessed, or independently derived by objective outcome measurement.

**Class IV**: Evidence from uncontrolled studies, case series, case reports, or expert opinion.

**Classification of Recommendation**

**A** = Established as effective, ineffective, or harmful for the given condition in the specified population. (Level A rating requires at least two consistent Class I studies.)

**B** = Probably effective, ineffective, or harmful for the given condition in the specified population. (Level B rating requires at least one Class I study or at least two consistent Class II studies.)

**C** = Possibly effective, ineffective, or harmful for the given condition in the specified population. (Level C rating requires at least one Class II study or two consistent Class III studies.)

**U** = Data inadequate or conflicting; given current knowledge, treatment is unproven.

### CLINICAL ALGORITHM(S)

None provided

## EVIDENCE SUPPORTING THE RECOMMENDATIONS

### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations" field).

## BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

### POTENTIAL BENEFITS

Improved clinical decision making regarding carotid endarterectomy

### POTENTIAL HARMS

Perioperative and postoperative complications, including stroke, myocardial infarction, and death

## QUALIFYING STATEMENTS

### QUALIFYING STATEMENTS

This statement is provided as an educational service of the American Academy of Neurology. It is based on an assessment of current scientific and clinical information. It is not intended to include all possible proper methods of care for a particular neurologic problem or all legitimate criteria for choosing to use a specific procedure. Neither is it intended to exclude any reasonable alternative methodologies. The American Academy of Neurology recognizes that specific patient care decisions are the prerogative of the patient and the physician caring for the patient, based on all of the circumstances involved.

## IMPLEMENTATION OF THE GUIDELINE

### DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

### IMPLEMENTATION TOOLS

Patient Resources
Personal Digital Assistant (PDA) Downloads
Quick Reference Guides/Physician Guides
Slide Presentation

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

## INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

### IOM CARE NEED

Living with Illness
Staying Healthy

### IOM DOMAIN

Effectiveness
Patient-centeredness
Timeliness

## IDENTIFYING INFORMATION AND AVAILABILITY

### BIBLIOGRAPHIC SOURCE(S)

Chaturvedi S, Bruno A, Feasby T, Holloway R, Benavente O, Cohen SN, Cote R, Hess D, Saver J, Spence JD, Stern B, Wilterdink J. Carotid endarterectomy--an evidence-based review: report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. Neurology 2005 Sep 27;65(6):794-801. [27 references] PubMed

### ADAPTATION

Not applicable: The guideline was not adapted from another source.

### DATE RELEASED

2005 Sep

### GUIDELINE DEVELOPER(S)

American Academy of Neurology - Medical Specialty Society

## SOURCE(S) OF FUNDING

American Academy of Neurology (AAN)

## GUIDELINE COMMITTEE

Therapeutics and Technology Assessment Subcommittee

## COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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## FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

The authors report no conflicts of interest.

## GUIDELINE STATUS

This is the current release of the guideline.

## GUIDELINE AVAILABILITY

Electronic copies: A list of American Academy of Neurology (AAN) guidelines, along with a link to a Portable Document Format (PDF) file for this guideline, is available at the AAN Web site.

Print copies: Available from the AAN Member Services Center, (800) 879-1960, or from AAN, 1080 Montreal Avenue, St. Paul, MN 55116.

## AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- AAN guideline development process [online]. St. Paul (MN): American Academy of Neurology. Available from the American Academy of Neurology Web site.
- Assessment: carotid endarterectomy--an evidence-based review. AAN evidence-based guideline summary for clinicians. St. Paul (MN): American

Academy of Neurology. 2 p. Available in Portable Document Format (PDF) from the AAN Web site.
- Carotid endarterectomy: an evidence-based review. St. Paul (MN): American Academy of Neurology. 2005. 12 p. Available for personal digital assistant (PDA) download from the AAN Web site.
- Assessment: carotid endarterectomy--an evidence-based review. Slide presentation. St. Paul (MN): American Academy of Neurology. Available as a PowerPoint file from the AAN Web site.

### PATIENT RESOURCES

The following is available:

- Carotid endarterectomy to prevent stroke in patients with or without symptoms. AAN guideline summary for patients and their families. St. Paul (MN): American Academy of Neurology (AAN). 2 p.

Electronic copies: Available in Portable Document Format (PDF) from the AAN Web site.

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### NGC STATUS

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