Complete Summary

GUIDELINE TITLE

Assessment: transcranial Doppler ultrasonography: report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology.

BIBLIOGRAPHIC SOURCE(S)

Sloan MA, Alexandrov AV, Tegeler CH, Spencer MP, Caplan LR, Feldmann E, Wechsler LR, Newell DW, Gomez CR, Babikian VL, Lefkowitz D, Goldman RS, Armon C, Hsu CY, Goodin DS. Assessment: transcranial Doppler ultrasonography: report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. Neurology 2004 May 11;62(9):1468-81. [149 references] PubMed

COMPLETE SUMMARY CONTENT

SCOPE
METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
QUALIFYING STATEMENTS
IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES
IDENTIFYING INFORMATION AND AVAILABILITY

SCOPE

DISEASE/CONDITION(S)

- Stroke in children with sickle cell disease
- Right-to-left cardiac shunts
- Intracranial steno-occlusive disease
- Occlusion of the middle cerebral artery, intracranial artery, vertebral artery, basilar artery (acute cerebral infarction)
- Extracranial internal carotid artery (ICA) stenosis
- Cerebral microembolization
- Reocclusion or recanalization during central thrombolysis
- Vasospasm after spontaneous subarachnoid hemorrhage
- Vasospasm after traumatic subarachnoid hemorrhage
- Cerebral circulatory arrest and brain death
- Intracerebral hemorrhage
- Stroke following coronary artery bypass surgery
- Stroke following carotid endarterectomy

GUIDELINE CATEGORY

Diagnosis
Technology Assessment

CLINICAL SPECIALTY

Neurology
Radiology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To determine if transcranial Doppler ultrasonography (TCD) provides useful information in specific clinical settings
- To determine if using this information improves clinical decision making, as reflected by improved patient outcomes
- To determine if TCD is preferable to other diagnostic tests in these clinical situations

TARGET POPULATION

Patients (adults and children) with cerebrovascular disease or stroke and those who are in various clinical settings that place them at risk of cerebrovascular disease or stroke

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis

1. Transcranial Doppler ultrasonography (TCD)
2. Transcranial color-coded sonography (TCCS)

Procedures using TCD and/or TCCS

1. Vasomotor reactivity testing
2. Detection of cerebral microembolic signals
3. Carotid endarterectomy (CEA)
4. Coronary artery bypass graft (CABG) surgery
5. Cerebral thrombolysis monitoring

Reference Standards

1. Conventional and digital subtraction angiography (DSA)
2. Magnetic resonance angiography (MRA)
3. Computed tomographic angiography (CTA)
4. Contrast-enhanced transesophageal echocardiography (TEE)

MAJOR OUTCOMES CONSIDERED

- Sensitivity and specificity of diagnostic tests
- Positive predictive and negative predictive values

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The subcommittee reviewed summary statements and other articles, based on selection of relevant publications cited in these new articles and additional Medline search through June 2003.

NUMBER OF SOURCE DOCUMENTS

Not stated

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

Rating of Diagnostic Article

Class I: Evidence provided by prospective study in broad spectrum of persons with suspected condition, using a "gold standard" to define cases, where test is applied in blinded evaluation, and enabling assessment of appropriate tests of diagnostic accuracy.

Class II: Evidence provided by prospective study in narrow spectrum of persons with suspected condition or well-designed retrospective study of broad spectrum of persons with suspected condition (by "gold standard") compared with broad spectrum of controls where test is applied in blinded evaluation and enabling assessment of appropriate tests of diagnostic accuracy.

Class III: Evidence provided by retrospective study where either persons with established condition or controls are of narrow spectrum and where test is applied in blinded evaluation.

Class IV: Any design where test is not applied in blinded fashion or evidence provided by expert opinion or descriptive case series.

Rating of Prognostic Article

Class I: Evidence provided by prospective study in broad spectrum of persons who may be at risk of outcome (target disease, work status). Study measures predictive ability using independent gold standard to define cases. Predictor is measured in evaluation masked to clinical presentation. Outcome is measured in evaluation masked to presence of predictor.

Class II: Evidence provided by prospective study of narrow spectrum of persons who may be at risk for having the condition, retrospective study of broad spectrum of persons with condition compared with broad spectrum of controls. Study measures prognostic accuracy of risk factor using acceptable independent gold standard to define cases. Risk factor is measured in evaluation masked to the outcome.

Class III: Evidence provided by retrospective study where persons with condition or controls are of narrow spectrum. Study measures predictive ability using independent gold standard to define cases. Risk factor measured in evaluation masked to outcome.

Class IV: Any design where predictor is not applied in masked evaluation or evidence by expert opinion, case series.

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Summary statements and other selected articles were reviewed using the American Academy of Neurology rating system (refer to the "Rating Scheme for the Strength of the Evidence" and "Rating Scheme for the Strength of the Recommendations" fields in this summary). When data were inconclusive, a U rating was given. Articles reviewed and cited within the original guideline document reflect a mixture of diagnostic, therapeutic, or prognostic information used as the reference standard in individual studies. Sensitivity and specificity reflect the ability of a diagnostic test to detect disease. For the purposes of this review, ratings of sensitivity and specificity were operationally defined as excellent ($\geq$90%), good (80 to 89%), fair (60 to 79%), and poor (<60%). The subcommittee reviewed the sensitivity and specificity of transcranial Doppler ultrasonography (TCD) (please refer to table 2 of the original guideline document) and transcranial color-coded sonography (TCCS) (please refer to table 3 of the original guideline document) for various disease states.

The clinical utility of a diagnostic test may be operationally defined as the value of the test result to the clinician caring for the individual patient. In this sense, value to the clinician refers to the ability of a diagnostic test to detect the disease process of interest, influence patient care, or provide prognostic information when compared with an appropriate reference standard or in a well-designed clinical trial. The subcommittee summarized the clinical utility (see table below) of

TCD/TCCS and focused on the clinical indications for which conclusions can be drawn.

Table: Definitions for Clinical Utility

1. Able to provide information and clinical utility established
2. Able to provide information and clinical utility, compared with other diagnostic tools, remains to be determined
3. Able to provide information, but clinical utility remains to be determined
4. Able to provide information, but other diagnostic tests are preferable in most cases

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Other

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

When formulating the recommendations the guideline developers considered the magnitude of the effect (benefit or harm of therapy, accuracy of tests, yield of studies) and the relative value of various outcomes. Under most circumstances, there is a direct link between the level of evidence used to formulate conclusions and the strength of the recommendation. This linkage is illustrated in Appendix 9 of the 2004 AAN Guideline Process Manual (see Companion Documents field). Thus, an "established as" (two class I) conclusion supports a "should be done" (level A) recommendation; a "probably effective" (two class II) conclusion supports a "should be considered" (level B) recommendation; a "possibly effective" (two class III) conclusion supports a "may be considered" recommendation. In those circumstances where the evidence indicates that the intervention is not effective or useful, wording was modified. For example, if multiple adequately powered class I studies demonstrated that an intervention is not effective, the recommendation read, "should not be done."

There are important exceptions to the rule of having a direct linkage between the level of evidence and the strength of recommendations. Some situations where it may be necessary to break this linkage are listed below:

- A statistically significant but marginally important benefit of the intervention is observed
- The intervention is exorbitantly costly
- Superior and established alternative interventions are available
- There are competing outcomes (both beneficial and harmful) that cannot be reconciled

Under such circumstances the guideline developers may have downgraded the level of the recommendation.

Edlund W, Gronseth G, So Y, Franklin G. Clinical practice guideline process manual. St. Paul (MN): American Academy of Neurology (AAN); 2004. 49 p.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Rating of Recommendations

A = established as useful/predictive or not useful/predictive for the given condition in the specified population.

B = probably useful/predictive or not useful/predictive for the given condition in the specified populations.

C = possibly useful/predictive or not useful/predictive for the given condition in the specified population.

D = data inadequate or conflicting. Given current knowledge, test/predictor unproven.

U = data inconclusive.

Translation of Evidence to Recommendations

Level A rating requires $\geq$1 convincing Class I or $\geq$2 consistent, convincing Class II studies.

Level B rating requires $\geq$1 convincing Class II or $\geq$3 consistent Class III studies.

Level C rating requires $\geq$2 convincing and consistent Class III studies.

COST ANALYSIS

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

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Guidelines were approved by the Therapeutics and Technology Assessment Subcommittee on August 8, 2003, the Practice Committee on November 8, 2003, and the Board of Directors on January 18, 2004.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Definitions of the strength 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. Settings in which transcranial Doppler ultrasonography (TCD) is able to provide information and in which its clinical utility is established.
    a. Screening of children aged 2 to 16 years with sickle cell disease for assessing stroke risk (Type A, Class I), although the optimal frequency of testing is unknown (Type U).
    b. Detection and monitoring of angiographic vasospasm (VSP) spontaneous subarachnoid hemorrhage (sSaH) (Type A, Class I-II). More data are needed to show if its use affects clinical outcomes (Type U).
2. Settings in which TCD is able to provide information, but in which its clinical utility, compared with other diagnostic tools, remains to be determined.
    a. Intracranial steno-occlusive disease. TCD is probably useful (Type B, Class II to III) for the evaluation of occlusive lesions of intracranial arteries in the basal cisterns (especially the internal carotid artery [ICA] siphon and middle cerebral artery [MCA]). The relative value of TCD compared with magnetic resonance angiography (MRA) or computed tomography angiography (CTA) remains to be determined (Type U). Data are insufficient to recommend replacement of conventional angiography with TCD (Type U).
    b. Cerebral circulatory arrest (adjunctive test in the determination of brain death). If needed, TCD can be used as a confirmatory test, in support of a clinical diagnosis of brain death (Type A, Class II).
3. Settings in which TCD is able to provide information, but in which its clinical utility remains to be determined.
    a. Cerebral thrombolysis. TCD is probably useful for monitoring thrombolysis of acute MCA occlusions (Type B, Class II to III). More data are needed to assess the frequency of monitoring for clot dissolution and enhanced recanalization and to influence therapy (Type U).
    b. Cerebral microembolism detection. TCD monitoring is probably useful for the detection of cerebral microembolic signals in a variety of cardiovascular/cerebrovascular disorders/procedures (Type B, Class II to IV). Data do not support the use of this TCD technique for diagnosis or monitoring response to antithrombotic therapy in ischemic cerebrovascular disease (Type U).
    c. Carotid endarterectomy (CEA). TCD monitoring is probably useful to detect hemodynamic and embolic events that may result in perioperative stroke during and after CEA in settings where monitoring is felt to be necessary (Type B, Class II to III).
    d. Coronary artery bypass graft (CABG) surgery. TCD monitoring is probably useful (Type B, Class II to III) during CABG for detection of cerebral microemboli. TCD is possibly useful to document changes in flow velocities and carbon dioxide (CO_2) reactivity during CABG surgery (Type C, Class III). Data are insufficient regarding the clinical impact of this information (Type U).
    e. Vasomotor reactivity (VMR) testing. TCD is probably useful (Type B, Class II to III) for the detection of impaired cerebral hemodynamics in patients with severe (>70%) asymptomatic extracranial ICA stenosis, symptomatic or asymptomatic extracranial ICA occlusion,

and cerebral small-artery disease. Whether these techniques should be used to influence therapy and improve patient outcomes remains to be determined (Type U).

f. VSP after traumatic subarachnoid hemorrhage (tSAH). TCD is probably useful for the detection of VSP following tSAH (Type B, Class III), but data are needed to show its accuracy and clinical impact in this setting (Type U).

g. Transcranial color-coded sonography (TCCS). TCCS is possibly useful (Type C, Class III) for the evaluation and monitoring of space-occupying ischemic middle cerebral artery (MCA) infarctions. More data are needed to show if it has value vs. computed tomography (CT) and magnetic resonance imaging (MRI) scanning and if its use affects clinical outcomes (Type U).

4. Settings in which TCD is able to provide information, but in which other diagnostic tests are typically preferable.

   a. Right-to-left cardiac shunts. Whereas TCD is useful for detection of right-to-left cardiac and extracardiac shunts (Type A, Class II), transesophageal echocardiography (TEE) is superior, as it can provide direct information regarding the anatomic site and nature of the shunt.

   b. Extracranial ICA stenosis. TCD is possibly useful for the evaluation of severe extracranial ICA stenosis or occlusion (Type C, Class II to III), but, in general, carotid duplex and magnetic resonance angiography (MRA) are the diagnostic tests of choice.

   c. Contrast-enhanced TCCS. (Contrast-enhanced) TCCS may provide information in patients with ischemic cerebrovascular disease and aneurismal subarachnoid hemorrhage (aSAH) (Type B, Class II to IV). Its clinical utility vs. CT scanning, conventional angiography, or nonimaging TCD is unclear (Type U).

Definitions:

Rating of Recommendations

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C = possibly useful/predictive or not useful/predictive for the given condition in the specified population.

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Level A rating requires $\geq$1 convincing Class I or $\geq$2 consistent, convincing Class II studies.

Level B rating requires ≥1 convincing Class II or ≥3 consistent Class III studies.

Level C rating requires ≥2 convincing and consistent Class III studies.

Rating of Diagnostic Article

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Class III: Evidence provided by retrospective study where either persons with established condition or controls are of narrow spectrum and where test is applied in blinded evaluation.

Class IV: Any design where test is not applied in blinded fashion or evidence provided by expert opinion or descriptive case series.

Rating of Prognostic Article

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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").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

The chief advantages of TCD are as follows: It can be performed at the bedside and repeated as needed or applied for continuous monitoring; it is frequently less expensive than other techniques; and dye contrast agents are not used.

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

This statement is provided as an educational service of the American Academy of Neurology (AAN). 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 neurology problem or all legitimate criteria for choosing to use a specific procedure. Neither is it intended to exclude any reasonable alternative methodologies. The AAN recognizes that specific 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.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Sloan MA, Alexandrov AV, Tegeler CH, Spencer MP, Caplan LR, Feldmann E, Wechsler LR, Newell DW, Gomez CR, Babikian VL, Lefkowitz D, Goldman RS, Armon C, Hsu CY, Goodin DS. Assessment: transcranial Doppler ultrasonography: report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. Neurology 2004 May 11;62(9):1468-81. [149 references] PubMed

ADAPTATION

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

DATE RELEASED

2004 May 11

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 of the American Academy of Neurology

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

American Academy of Neurology (AAN) Therapeutics and Technology Assessment Subcommittee Members: Douglas S. Goodin, MD (chair); Yuen T. So, MD, PhD (vice-chair); Carmel Armon, MD, MHS; Richard M. Dubinsky, MD; Mark Hallett, MD; David Hammond, MD; Chung Y. Hsu, MD, PhD; Andres M. Kanner, MD; David Lefkowitz, MD; Janis Miyasaki, MD; Michael A. Sloan, MD, MS; James C. Stevens, MD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

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 are available:

- AAN guideline development process [online]. St. Paul (MN): American Academy of Neurology (AAN). Available from the AAN Web site.
- Assessment of transcranial Doppler ultrasonography. AAN guideline summary for clinicians. St. Paul (MN): American Academy of Neurology. 2. p. Available in Portable Document Format (PDF) from the AAN Web site.
- Edlund W, Gronseth G, So Y, Franklin G. Clinical practice guideline process manual. St. Paul (MN): American Academy of Neurology (AAN); 2004. 49 p. Electronic copies available in Portable Document Format (PDF) from the AAN Web site.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on August 17, 2004. The information was verified by the guideline developer on September 9, 2004.

COPYRIGHT STATEMENT

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