Complete Summary

GUIDELINE TITLE

(1) Assessment: prevention of post-lumbar puncture headaches. Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. (2) Addendum to assessment: prevention of post-lumbar puncture headaches. Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology.

BIBLIOGRAPHIC SOURCE(S)

Armon C, Evans RW. Addendum to assessment: prevention of post-lumbar puncture headaches: report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. Neurology 2005 Aug 23;65(4):510-2. [9 references] PubMed

Evans RW, Armon C, Frohman EM, Goodin DS. Assessment: prevention of post-lumbar puncture headaches: report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. Neurology 2000 Oct 10;55(7):909-14. [52 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis RECOMMENDATIONS

EVIDENCE SUPPORTING THE RECOMMENDATIONS

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS OUALIFYING STATEMENTS

IMPLEMENTATION OF THE GUIDELINE

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY

DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

Post-lumbar puncture headache

GUIDELINE CATEGORY

Prevention Technology Assessment

CLINICAL SPECIALTY

Anesthesiology Family Practice Internal Medicine Neurology Pediatrics

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

2000 Guideline

To identify risk factors that could be modified to reduce the frequency of postlumbar puncture headaches (PLPHAs) in patients undergoing diagnostic lumbar punctures

2005 Addendum

To classify the new literature and to affirm or modify the recommendations of the original assessment, as appropriate. A particular focus of this update was to identify any new evidence to support the use of the atraumatic or pencil-point needle over the use of the conventional "cutting" needle in performance of diagnostic lumbar punctures (LPs) to reduce post-lumbar puncture headaches.

TARGET POPULATION

Patients undergoing spinal anesthesia or diagnostic lumbar punctures

INTERVENTIONS AND PRACTICES CONSIDERED

Lumbar puncture, including the following procedural or practice variables:

- 1. Needle size
- 2. Direction of the bevel
- 3. Replacement of the stylet before withdrawing the needle
- 4. Needle design (Note: use of atraumatic spinal needle vs. cutting needle was a particular focus of the 2005 addendum)
- 5. Volume of spinal fluid removed
- 6. Duration of recumbency after the lumbar puncture
- 7. Increase hydration following the lumbar puncture

MAJOR OUTCOMES CONSIDERED

Frequency of post-lumbar puncture headaches in patients undergoing lumbar punctures

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

2000 Guideline

A literature search conducted by one of the authors served as the basis for this report. Appropriate literature was identified by MEDLINE searches back to 1966 using the following key words and phrases: post-lumbar puncture head-ache, prevention of post-lumbar puncture headache, complications of lumbar puncture, atraumatic and pencil point lumbar puncture needles, and Whitacre and Sprotte lumbar puncture needles. Additional articles were found through bibliographies of these articles and by checking pertinent textbooks. Articles deemed pivotal for making recommendations were reviewed by members of the Therapeutics and Technology Assessment (TTA) Subcommittee for the purpose of classification of the evidence as it pertained to the recommendations at hand. Some of the background literature was also reviewed independently by the Therapeutics and Technology Assessment Subcommittee members.

2005 Addendum

A MEDLINE search was conducted by one of the authors in June 2004, using the terms "post lumbar puncture headache" and "postdural puncture headache." Articles linked electronically to the original assessment were also considered. Abstracts of articles comparing needle types were reviewed. Full texts only of articles pertaining to diagnostic lumbar punctures (LPs) were retrieved for detailed analysis. Accompanying editorials and related letters to the editors were reviewed for relevant critique.

NUMBER OF SOURCE DOCUMENTS

2000 Guideline

Not stated

2005 Addendum

Five articles were identified initially, reporting on diagnostic lumbar punctures (LPs). Two additional case series 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

2000 Guideline

Quality of Evidence Ratings for Therapeutic Modalities

Class I. Evidence provided by one or more well-designed randomized controlled clinical trials.

Class II. Evidence provided by one or more well-designed clinical studies, such as case-control, cohort studies, etc.

Class III. Evidence provided by expert opinion, nonrandomized historical controls, or reports of one or more.

2005 Addendum

Classification of Evidence

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

- a. Primary outcome(s) is(are) clearly defined.
- b. Exclusion/inclusion criteria are 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 through D above OR a randomized, controlled trial in a representative population that lacks one criterion A through 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 assessment is independently assessed or independently derived by objective outcome measurement (objective outcome measurement is an outcome measure that is unlikely to be affected by an observer's (patient, treating physician, investigator) expectation or bias [e.g., blood tests, administrative outcome data]).

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

Note:

For the 2005 Addendum, in comparing atraumatic to cutting needle design, articles had to meet the following criteria, specified in the original assessment, to be considered class I evidence:

- 1. Prospective study design.
- 2. Randomization.
- 3. Double masking: neither patient nor evaluator of post-lumbar puncture headaches (PLPHA) aware of needle design used.
- 4. Equal needle diameter.
- 5. When using cutting needle, needle bevel parallel to dural fibers stated explicitly.
- 6. Stylet replaced before needle withdrawn documented explicitly.
- 7. Active ascertainment of occurrence of PLPHA by the investigators.

For the purposes of this update, any article failing in one of these areas was automatically classified as Class IV. The classification of the articles and the underlying justification are summarized in the annotated reference list and expanded selectively in the results section of the original guideline document.

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

2000 Guideline

Definitions for Strength of Recommendations

Type A. Strong positive recommendation based on Class I evidence, or based on overwhelming Class II evidence when circumstances preclude randomized clinical trials.

Type B. Positive recommendation based on Class II evidence.

Type C. Positive recommendation based on strong consensus of Class III evidence.

Type D. Negative recommendation based on inconclusive or conflicting Class II evidence.

Type E. Negative recommendation based on Class II or Class I evidence of ineffectiveness or lack of efficacy.

2005 Addendum

Classification of 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

2000 Guideline

Approved by the Therapeutics and Technology Assessment Subcommittee on May 2, 2000; by the Practice Committee on May 5, 2000; and by the American Academy of Neurology Board of Directors on June 9, 2000.

2005 Addendum

Approved by the Therapeutics and Technology Assessment Subcommittee on November 19, 2004; by the Practice Committee on April 13, 2005; and by the American Academy of Neurology Board of Directors on June 26, 2005.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

2000 Guideline

The quality of evidence ratings, I-III, and the strength of recommendations (Type A-Type E) are defined at the end of the "Major Recommendations" field.

- Class I and Class II data in the anesthesiology literature and either Class I or Class II data in the neurology series show that smaller needle size is associated with reduced frequency of post-lumbar puncture headache (PLPHA) (Type A). The actual choice of needle size will be influenced by balancing other considerations, such as ease of use, the need to measure pressures, and the flow rate, with the desire to prevent PLPHA.
- 2. Class I data in the anesthesiology literature show that, when using a cutting needle, ensuring that the bevel direction is parallel to the dural fibers reduces the frequency of PLPHA. (Type A).
- 3. Class I data using a noncutting needle show that replacement of the stylet before the needle is withdrawn is associated with lower frequency of PLPHA. (Type A).
- 4. For spinal anesthesia, Class I data show that non-cutting needles reduce the frequency of PLPHA (Type A). However, for diagnostic lumbar punctures (LPs), the data are inconclusive.
- 5. Class I and Class II data have not demonstrated that the duration of recumbency following a diagnostic lumbar puncture influences the occurrence of PLPHA.
- 6. There is no evidence that the use of increased fluids prevents PLPHA.

2005 Addendum

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. New conclusion: Most studies in the anesthesiology literature, across several needle sizes, and now also one study providing Class I evidence in a patient population undergoing diagnostic lumbar punctures with a 22-gauge needle support the use of an atraumatic spinal needle to reduce the frequency of PLPHA (Type A).

Reaffirmation of a previous conclusion: Class I and Class II data in the anesthesiology and the neurology literature show that smaller needle size is associated with reduced frequency of PLPHA (Type A).

Definitions:

2000 Guideline

Quality of Evidence Ratings for Therapeutic Modalities

Class I. Evidence provided by one or more well-designed randomized controlled clinical trials.

Class II. Evidence provided by one or more well-designed clinical studies, such as case-control, cohort studies, etc.

Class III. Evidence provided by expert opinion, nonrandomized historical controls, or reports of one or more.

Strength of Recommendations

Type A. Strong positive recommendation based on Class I evidence, or based on overwhelming Class II evidence when circumstances preclude randomized clinical trials.

Type B. Positive recommendation based on Class II evidence.

Type C. Positive recommendation based on strong consensus of Class III evidence.

Type D. Negative recommendation based on inconclusive or conflicting Class II evidence.

Type E. Negative recommendation based on Class II or Class I evidence of ineffectiveness or lack of efficacy.

2005 Addendum

Classification of Evidence

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

- a. Primary outcome(s) is/are clearly defined.
- b. Exclusion/inclusion criteria are 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 through D above OR a randomized, controlled trial in a representative population that lacks one criterion A through 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 assessment is independently assessed or independently derived by objective outcome measurement (objective outcome measurement is an outcome measure that is unlikely to be affected by an observer's (patient, treating

physician, investigator) expectation or bias [e.g., blood tests, administrative outcome data]).

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 recommendations are based on a review of the literature. The type of supporting evidence is identified and graded for each recommendation on the prevention of post-lumbar puncture headaches (see "Major Recommendations" field).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Reduction in the frequency of post-lumbar puncture headaches

Subgroups Most Likely to Benefit:

- Younger female patients with small body mass index (between the ages of 18-30)
- Patients with headaches before the lumbar puncture
- Patients with a history of post-lumbar puncture headaches

POTENTIAL HARMS

Replacement of the stylet before withdrawing the needle: Rarely, a nerve root can herniate through the dura due to aspiration by the needle during withdrawal. There is a single case report of transection and withdrawal of a nerve filament due to replacement of the stylet (into a hollow needle with an end-hole-side-hole needle) following a lumbar myelogram. Bacterial meningitis, a rare complication of diagnostic lumbar puncture, might theoretically be caused by reintroducing a stylet contaminated with respiratory droplets. The stylet should always be used on insertion through the skin and the subcutaneous tissue whether using a Quincke or atraumatic needle. Rarely, a needle without a stylet may implant a plug of skin which can grow into an intraspinal epidermoid tumor.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- The statement of this guideline 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.
- Post-lumbar puncture headache (PLPHA) has been defined in different ways. Definitions range from any headache after lumbar puncture to headache after lumbar puncture with definite characteristics -- in particular, a constant headache appearing or worsening significantly upon assuming the upright position and resolving or improving significantly upon lying down. Some of the definitions used do not permit excluding possible overlap between the PLPHA described and migraine without aura, at least in some of the patients. We elected to accept all definitions of PLPHA uncritically, but recommend that future studies of PLPHA adhere to rigorous definitions that will permit excluding other etiologies of headaches. Similarly, there is no uniform definition of "severe" PLPHA. Future studies should use established and well-defined criteria for PLPHA and its severity.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Personal Digital Assistant (PDA) Downloads

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

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Armon C, Evans RW. Addendum to assessment: prevention of post-lumbar puncture headaches: report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. Neurology 2005 Aug 23;65(4):510-2. [9 references] PubMed

Evans RW, Armon C, Frohman EM, Goodin DS. Assessment: prevention of post-lumbar puncture headaches: report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. Neurology 2000 Oct 10;55(7):909-14. [52 references]

ADAPTATION

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

DATE RELEASED

2000 Oct (revised 2005 Aug)

GUIDELINE DEVELOPER(S)

American Academy of Neurology - Medical Specialty Society

SOURCE(S) OF FUNDING

American Academy of Neurology

GUIDELINE COMMITTEE

Therapeutics and Technology Assessment Subcommittee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

2001 Guideline

Not stated

2005 Addendum

The authors report no conflicts of interest.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies of the original document and the addendum: Available from the American Academy of Neurology (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:

Addendum to assessment: prevention of post-lumbar puncture headaches. St. Paul (MN): American Academy of Neurology. 2005. 4 p. Available for personal digital assistant (PDA) download from the <u>American Academy of Neurology</u> (AAN) Web site.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on February 12, 2002. The information was verified by the guideline developer as of March 29, 2002. This summary was updated by ECRI on December 23, 2005.

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