Complete Summary

GUIDELINE TITLE

Practice parameter: immunotherapy for Guillain-Barre syndrome: report of the Quality Standards Subcommittee of the American Academy of Neurology.

BIBLIOGRAPHIC SOURCE(S)

Hughes RA, Wijdicks EF, Barohn R, Benson E, Cornblath DR, Hahn AF, Meythaler JM, Miller RG, Sladky JT, Stevens JC. Practice parameter: immunotherapy for Guillain-Barre syndrome: report of the Quality Standards Subcommittee of the American Academy of Neurology. Neurology 2003 Sep 23;61(6):736-40. [46 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Guillain-Barre syndrome

GUIDELINE CATEGORY

Management
Treatment

CLINICAL SPECIALTY

Neurology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To provide an evidence-based statement to guide physicians in the management of Guillain-Barre syndrome (GBS)

TARGET POPULATION

Adults and children with Guillain-Barre syndrome (GBS)

INTERVENTIONS AND PRACTICES CONSIDERED

Immunotherapy:

1. Plasma exchange (PE)
2. Intravenous immunoglobulin (IVIg)

Note: The guideline developers considered, but did not recommend the following treatments:

- Combination treatments
- Steroids

Note: The guideline developer considered the following treatment but found insufficient evidence to recommend its use:

- Immunoabsorption

MAJOR OUTCOMES CONSIDERED

- Recovery from Guillain-Barre syndrome (GBS), measured using a disability scale
- Cost-effectiveness
- Adverse effects, measured using relative risk

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

A search of MEDLINE from 1966 and of the Cochrane library was performed in March 2002. "Polyradiculoneuritis" was limited by "human" and cross-referenced with "therapy." The search results were reviewed for each question by at least two

members of the practice parameter group and supplemented from the reference lists in the articles retrieved and the personal reference lists of the members of the practice parameter group.

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

Class of Evidence for Therapy

Class I: High quality randomized controlled trials (RCTs).

Class II: Prospective matched group cohort studies or randomized controlled trials lacking adequate randomization concealment or blinding or potentially liable to attrition or outcome ascertainment bias.

Class III: Other studies such as natural history studies.

Class IV: Uncontrolled studies, case series, or expert opinion.

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

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Strength of Recommendations

A = established as effective, ineffective, or harmful or as useful/predictive or not useful/predictive.

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

C = possibly effective, ineffective, or harmful or as useful/predictive or not useful/predictive.

U = data inadequate or conflicting. Treatment, test or predictor unproven.

COST ANALYSIS

The costs in the United States related to Guillain-Barre syndrome (GBS) have been estimated as $110,000 for direct health care and $360,000 in lost productivity per patient.

In one study comparing plasma exchange (PE) with supportive therapy in Scandinavia, the cost of plasma exchange was more than offset by the savings in health care costs as a result of shorter hospital stay. Similar conclusions have been reached in the United Kingdom. For patients with moderately severe Guillain-Barre syndrome, one study calculated that four plasma exchanges are more cost-effective than two.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Draft guidelines were reviewed for accuracy, quality, and thoroughness by the American Academy of Neurology (AAN) members, topic experts, and pertinent physician organizations.

Final guidelines were approved by the Quality Standards Subcommittee on November 9, 2002, the Practice Committee on April 2, 2003, and the American Academy of Neurology Board of Directors June 20, 2003. They were published in *Neurology* 2003; 61:736-740.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Definitions of the ratings of recommendations (A, B, C, U) and the class of evidence for therapy (Class I-IV) are provided at the end of the "Major Recommendations" field.

Does initial immunotherapy hasten recovery?

Plasma exchange (PE)

1. PE is recommended in nonambulant patients within 4 weeks of onset (***Level A recommendation, Class II evidence***) and for ambulant patients within 2 weeks of onset (***Level B recommendation, limited Class II evidence***).

2. The effects of PE and intravenous immunoglobulin (IVIg) are equivalent (see below).
3. There is insufficient evidence to recommend the use of cerebrospinal fluid (CSF) filtration (***Level U recommendation, limited Class II evidence***).

Immunoabsorption

1. The evidence is insufficient to recommend the use of immunoabsorption (***Level U recommendation, Class IV evidence***).

Intravenous immunoglobulin (IVIg)

1. IVIg is recommended for patients with Guillain-Barre syndrome (GBS) who require aid to walk within 2 (***Level A recommendation***) or 4 weeks from the onset of neuropathic symptoms (***Level B recommendation derived from Class II evidence*** concerning PE started within the first 4 weeks and ***Class I evidence*** concerning the comparisons between PE and IVIg started within the first 2 weeks).
2. The effects of IVIg and PE are equivalent.

Combination treatments

1. Sequential treatment with PE followed by IVIg (***Level A recommendation, Class I evidence***) or immunoabsorption followed by IVIg (***Level U recommendation, Class IV evidence***) is not recommended.

Steroids

1. Corticosteroids are not recommended for the treatment of patients with GBS (***Level A recommendation, Class I evidence***).

<u>Are there special issues in the management of children with GBS?</u>

1. PE or IVIg are treatment options for children with severe GBS (***Level B recommendation derived from Class II evidence in adults***).

<u>Definitions</u>:

Class of Evidence for Therapy

Class I: High quality randomized controlled trials (RCTs).

Class II: Prospective matched group cohort studies or randomized controlled trials lacking adequate randomization concealment or blinding or potentially liable to attrition or outcome ascertainment bias.

Class III: Other studies such as natural history studies.

Class IV: Uncontrolled studies, case series or expert opinion.

Strength of the Recommendations

A = established as effective, ineffective, or harmful or as useful/predictive or not useful/predictive.

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

C = possibly effective, ineffective, or harmful or as useful/predictive or not useful/predictive.

U = data inadequate or conflicting. Treatment, test, or predictor 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").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- These guidelines may assist physicians in making appropriate clinical decisions regarding immunotherapy for patients with Guillain-Barre syndrome.
- Evidence suggests that plasma exchange (PE) hastens recovery in nonambulant patients with Guillain-Barre syndrome who seek treatment within 4 weeks of the onset of neuropathic symptoms. Plasma exchange also hastens recovery in ambulant patients who are examined within 2 weeks, but the evidence is limited to one trial.
- When started within 2 weeks from the onset, intravenous immunoglobulin (IVIg) has equivalent efficacy to plasma exchange in hastening recovery for patients with Guillain-Barre syndrome who require aid to walk.

POTENTIAL HARMS

Adverse events from therapy

In a Dutch trial, pneumonia, atelectasis, thrombosis, and hemodynamic difficulties occurred more often with plasma exchange (PE) than with intravenous immunoglobulin (IVIg). Sixteen out of 73 patients (22%) had multiple complications with plasma exchange compared with 5 of 74 (7%) with intravenous immunoglobulin. In the largest trial, adverse events occurred in 8 of 121 patients (7%) in the plasma exchange group (hypotension, septicemia,

pneumonia, malaise, abnormal clotting, and hypocalcaemia) and in 6 of 130 (5%) patients in the intravenous immunoglobulin group (vomiting, meningism, renal failure, myocardial infarction, and infusion site erythema).

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
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

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness
Timeliness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Hughes RA, Wijdicks EF, Barohn R, Benson E, Cornblath DR, Hahn AF, Meythaler JM, Miller RG, Sladky JT, Stevens JC. Practice parameter: immunotherapy for Guillain-Barre syndrome: report of the Quality Standards Subcommittee of the American Academy of Neurology. Neurology 2003 Sep 23;61(6):736-40. [46 references] PubMed

ADAPTATION

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

DATE RELEASED

2003 Sep 23

GUIDELINE DEVELOPER(S)

American Academy of Neurology - Medical Specialty Society

SOURCE(S) OF FUNDING

American Academy of Neurology (AAN)

GUIDELINE COMMITTEE

Quality Standards Subcommittee of the American Academy of Neurology

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Quality Standards Subcommittee Members: Gary Franklin, MD, MPH (Co-Chair); Catherine Zahn, MD (Co-Chair); Milton Alter, MD, PhD; Stephen Ashwal, MD; Richard M. Dubinsky, MD; Jacqueline French, MD; Michael Glantz, MD; Gary Gronseth, MD; Deborah Hirtz, MD; Robert G. Miller, MD; James Stevens, MD; and William J. Weiner, 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 is available:

- AAN guideline summary for clinicians: immunotherapy for Guillain-Barre syndrome. St. Paul (MN): American Academy of Neurology, 2003 Sep. Electronic copies: Available from the American Academy of Neurology (AAN) Web site. See the related QualityTool summary on the Health Care Innovations Exchange Web site.
- Practice parameter: immunotherapy for Guillain-Barre syndrome slide presentation. St. Paul (MN): American Academy of Neurology, 2003 Sep. Electronic copies: Available from the AAN Web site. See the related QualityTool summary on the Health Care Innovations Exchange Web site
- AAN guideline development process [online]. St. Paul (MN): American Academy of Neurology. Electronic copies: Available from the American Academy of Neurology Web site.

PATIENT RESOURCES

The following is available:

- AAN guideline summary for patients and their families: treatment for Guillain-Barre syndrome. St. Paul (MN): American Academy of Neurology, 2003 Sep. Electronic copies: Available from the American Academy of Neurology (AAN) Web site. See the related QualityTool summary on the Health Care Innovations Exchange Web site.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This summary was completed by ECRI on February 12, 2004.

COPYRIGHT STATEMENT

DISCLAIMER

NGC DISCLAIMER

The National Guideline Clearinghouse™ (NGC) does not develop, produce, approve, or endorse the guidelines represented on this site.

All guidelines summarized by NGC and hosted on our site are produced under the auspices of medical specialty societies, relevant professional associations, public or private organizations, other government agencies, health care organizations or plans, and similar entities.

Guidelines represented on the NGC Web site are submitted by guideline developers, and are screened solely to determine that they meet the NGC Inclusion Criteria which may be found at http://www.guideline.gov/about/inclusion.aspx .

NGC, AHRQ, and its contractor ECRI Institute make no warranties concerning the content or clinical efficacy or effectiveness of the clinical practice guidelines and related materials represented on this site. Moreover, the views and opinions of developers or authors of guidelines represented on this site do not necessarily state or reflect those of NGC, AHRQ, or its contractor ECRI Institute, and inclusion or hosting of guidelines in NGC may not be used for advertising or commercial endorsement purposes.

Readers with questions regarding guideline content are directed to contact the guideline developer.

Date Modified: 11/10/2008