Complete Summary

GUIDELINE TITLE

Practice parameter: the care of the patient with amyotrophic lateral sclerosis (an evidence-based review). Report of the Quality Standards Subcommittee of the American Academy of Neurology: ALS Practice Parameters Task Force.

BIBLIOGRAPHIC SOURCE(S)

Miller RG, Rosenberg JA, Gelinas DF, Mitsumoto H, Newman D, Sufit R, Borasio GD, Bradley WG, Bromberg MB, Brooks BR, Kasarskis EJ, Munsat TL, Oppenheimer EA. Practice parameter: the care of the patient with amyotrophic lateral sclerosis (an evidence-based review): report of the Quality Standards Subcommittee of the American Academy of Neurology: ALS Practice Parameters Task Force. Neurology 1999 Apr 22;52(7):1311-23. [112 references] PubMed

Practice parameter: the care of the patient with amyotrophic lateral sclerosis (an evidence-based review). Muscle Nerve 1999 Aug;22(8):1104-18. [112 references]

GUIDELINE STATUS

This is the current release of the guideline.

According to the guideline developer, this guideline has been reviewed and is still considered to be current as of October 2005. This review involved new literature searches of electronic databases followed by expert committee review of new evidence that has emerged since the original publication date.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- May 2, 2007, Antidepressant drugs: Update to the existing black box warning on the prescribing information on all antidepressant medications to include warnings about the increased risks of suicidal thinking and behavior in young adults ages 18 to 24 years old during the first one to two months of treatment.

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

Amyotrophic lateral sclerosis (ALS; also known as Lou Gehrig's disease)

GUIDELINE CATEGORY

Management
Risk Assessment

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Neurology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To develop practice parameters to improve the care and quality of life of people with amyotrophic lateral sclerosis (ALS) by providing a rational basis for managing the disease

TARGET POPULATION

Patients with amyotrophic lateral sclerosis

INTERVENTIONS AND PRACTICES CONSIDERED

Communicating the diagnosis

1. Communication of the diagnosis to the patient in an appropriate manner, utilizing specific techniques

Management of sialorrhea

1. Pharmacologic interventions, such as glycopyrrolate (Robinul), benztropine (Cogentin), transdermal hyoscine (Scopolamine), atropine, trihexyphenidyl hydrochloride (Artane), or amitriptyline (Elavil)
2. Treatment of thick mucus production associated with sialorrhea with propranolol (Inderal) or metoprolol (Toprol)
3. Clearing secretions, especially during acute infection with manually-assisted coughing and mechanical insufflation-exsufflation (In-Exsufflator cough machine)

Note: External beam radiation and surgical interventions were considered but not recommended.

Management of pseudobulbar affect (emotional lability)

1. Pharmacologic interventions, such as amitriptyline and fluvoxamine (as an alternate choice)

Nutritional Management

1. Identification of dysphagia through history and symptom assessment (for example, Colorado Dysphagia Disability inventory, bulbar question in the ALS Functional Rating Scale, or other instruments)
2. Monitoring of forced vital capacity (FVC) or vital capacity (VC)
3. Percutaneous endoscopic gastrostomy placement

Respiratory Management

1. Serial measurements of pulmonary function to detect hypoventilation
2. Noninvasive or invasive ventilation
3. Supplemental oxygen
4. Treatment with a sedative hypnotic (diazepam [Valium]) or opioid (morphine) to relieve dyspnea and anxiety
5. Respecting patient autonomy in refusing or withdrawing ventilatory support

Palliative care

1. Non-narcotic analgesics, anti-inflammatory drugs, antispasticity agents, and opioids (morphine) for pain management
2. Supplemental oxygen
3. Chlorpromazine (Thorazine) and acupuncture as adjunctive treatments for dyspnea
4. Referral to hospice
5. Advance directives

MAJOR OUTCOMES CONSIDERED

- Severity of sialorrhea (drooling)
- Body weight
- Scores on dysphagia assessment instrument, such as Colorado Dysphagia Disability Inventory or bulbar questions in the Amyotrophic Lateral Sclerosis Functional Rating Scale

- Level of forced vital capacity or vital capacity
- Quality of life
- Degree of symptom (pain, anxiety, dyspnea, etc.) control
- Prolongation of survival
- Patient satisfaction

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The authors searched OVID MEDLINE (1966 to date), OVID Excerpta Medica (EMBASE; 1974 to date), Cumulative Index to Nursing and Allied Health Literature (CINAHL; 1982 to date), OVID Current Contents (weeks 27 to 46, 1997), OVID BIOETHICS-LINE (1973 to date), and OVID International Pharmaceutical Abstracts (IPAB; 1970 to date). The search included studies on humans only and all languages. In the first search, ALS, Lou Gehrig´s disease, and motor neuron disease were searched for relevant subtopics. The second search on respiratory issues included neuromuscular diseases such as Duchenne muscular dystrophy, postpoliomyelitis, and spinal muscular atrophy. A third search regarding relating the diagnosis, palliative care, and advance directives included all neurologic diseases as well as acquired immunodeficiency syndrome (AIDS) and cancer.

The search yielded approximately 5,350 references with abstracts. After reviewing these abstracts, 750 articles containing the highest level of evidence were obtained (symptomatic management subcommittee reviewed 150 papers; palliative care, 190; nutrition, 230; and respiratory, 180). The strength of evidence in each paper was ranked using the definitions in table 2 of the guideline document and reproduced in "Rating Scheme for the Strength of the Evidence" in this summary.

NUMBER OF SOURCE DOCUMENTS

5,350

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

Definitions of classification of evidence

Class I: Evidence provided by one or more well-designed, randomized, controlled clinical trials
Class II: Evidence provided by one or more well-designed, observational clinical

studies with concurrent controls (e.g., case control and cohort studies)
Class III: Evidence provided by expert opinion, case series, case reports, and studies with historical controls

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Based on the strength of evidence, management recommendations were developed as guidelines or options using the definitions shown in the Major Recommendations field and in table 3 of the guideline document. Evidence tables containing the extracted data are placed in a registry (National Auxiliary Publications Service [NAPS]) and are available on request. Position statements or guidelines from national societies on issues such as communicating the diagnosis, advance directives, and respecting patient autonomy were included as broad expert opinion, which in some cases was elevated to guideline status. However, evidence of therapeutic intervention from diseases other than amyotrophic lateral sclerosis was downgraded to class III. Invasive therapy for symptom management (e.g., surgery or irradiation for sialorrhea) was not recommended unless there was evidence from amyotrophic lateral sclerosis.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Classification of Management Recommendations:

Standard A principle for patient management that reflects a high degree of certainty based on class I evidence, or very strong evidence from class II studies when circumstances preclude randomized trials

Guideline Recommendations for patient management reflecting moderate clinical certainty (usually class II evidence or strong consensus of class III evidence)

Option A strategy for patient management for which the evidence (class III) is inconclusive or when there is some conflicting evidence or opinion

COST ANALYSIS

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

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Numerous individuals, American Academy of Neurology (AAN) Sections, and organizations reviewed drafts of the guideline, including the Amytrophic Lateral Sclerosis (ALS) Association, the Muscular Dystrophy Association, the American Academy of Neurology Ethics and Humanities Subcommittee, and the Motor Neuron Disease Research Steering Committee of the World Federation of Neurology.

The guidelines were approved by the American Academy of Neurology (AAN) Quality Standards Subcommittee on October 17, 1998, by the Practice Committee on January 23, 1999, and by the Executive Board of the American Academy of Neurology on February 27, 1999.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Each clinical recommendation is rated based on the strength of the evidence. Definitions of the strength of the management recommendations (standard, guideline, option) and quality of the evidence (Class I-Class III) are presented at the end of the Major Recommendations field.

Principles of Amyotrophic Lateral Sclerosis (ALS) Management

1. High priority should be placed on patient self-determination or autonomy as an underlying assumption in the therapeutic relationship. Delivery of both information and care must take into consideration the cultural and psychosocial context of the patient and the family.
2. Patients and families need information that is timed appropriately for decision making, and delivered well in advance of major management crossroads, especially for respiratory care. Moreover, decision making is a dynamic process that may be subject to change as the disease becomes more severe.
3. The physician, in conjunction with other health care professionals, should address the full continuum of care for the patient with amyotrophic lateral sclerosis, and nurture the therapeutic relationship from diagnosis through palliative care for the terminal phase of the disease.
4. Discussions regarding advance directives should be introduced by the physician and reevaluated at intervals of no more than 6 months. Similarly, helping patients understand the issues to be faced in the terminal phase of the disease must be accomplished in a timely and empathic fashion.

Recommendations for Breaking the News

Clinical Recommendations

The following recommendations for communicating the diagnosis are based on the literature review and broad expert consensus (position statements, etc.):

1. The physician should give the diagnosis to the patient and discuss its implications. Respect the cultural and social background of the patient in the

communication process by asking whether the patient wishes to receive information or prefers that the information be communicated to a family member. **(Guideline)**
2. The diagnosis should always be given in person and never by telephone. **(Guideline)**
3. Provide printed materials about the disease and about support and advocacy organizations **(Guideline)**, and a letter or audiotape summarizing what the physician has discussed. **(Option)**
4. Avoid the following: withholding the diagnosis, providing insufficient information, delivering information callously, or taking away or not providing hope. **(Guideline)**

Recommendations for Symptom Management (Sialorrhea and Pseudobulbar Affect)

Clinical Recommendations for Sialorrhea

1. Treat sialorrhea with glycopyrrolate (see Figure 1 in the original guideline document for algorithm), benztropine, transdermal hyoscine, atropine, trihexyphenidyl hydrochloride, or amitriptyline. **(Option)**
2. Treat thick mucus production associated with sialorrhea with propranolol or metoprolol. **(Option)**
3. Consider manually assisted coughing and mechanical insufflation–exsufflation for clearing secretions, especially during acute infection. **(Option)**

Clinical Recommendations for Pseudobulbar Affect (Emotional Lability)

1. Treat pseudobulbar affect with amitriptyline. **(Option)**
2. Consider fluvoxamine as an alternate choice. **(Option)**

Recommendations for Nutrition Management

Patients with dysphagia are at risk for suboptimal caloric and fluid intake, and a worsening of muscle atrophy, weakness, and fatigue. Common symptoms include jaw weakness and fatigue, drooling, choking on fluid and food, and slow eating. Barium swallow may assist in developing strategies to maintain oral intake. The presence of laryngeal penetration on video fluoroscopy in the setting of dysphagia indicates a high risk for subsequent pneumonia. However, the variance among experienced speech pathologists in interpreting video fluoroscopy is large.

As dysphagia progresses, percutaneous endoscopic gastrostomy should be considered as an alternative or supplemental route for oral nutrition (see Figure 2 in the original guideline document for an algorithm for nutrition management).

Clinical Recommendations

1. Percutaneous endoscopic gastrostomy is indicated for patients with amyotrophic lateral sclerosis who have symptomatic dysphagia and should be considered soon after symptom onset. **(Guideline)**

2. For optimal safety and efficacy, percutaneous endoscopic gastrostomy should be offered and placed when the patient´s vital capacity is more than 50% of predicted. **(Guideline)**

Recommendations for Respiratory Management

Respiratory care presents the greatest challenge for the amyotrophic lateral sclerosis patients and the clinician. Deciding when to initiate noninvasive mechanical ventilation is critical because of the risk of either sudden death or ventilator dependence without proper advance planning. An early understanding of the patient's preferences will help ensure careful and timely planning (see Figure 3 in the original guideline document for an algorithm for respiratory management).

Clinical Recommendations

1. Be vigilant for symptoms indicating hypoventilation. Serial measures of pulmonary function (especially vital capacity) are recommended to guide management and to determine prognosis with the understanding that no single test can detect hypoventilation reliably. **(Guideline)**
2. Offer noninvasive ventilatory support as an effective initial therapy for symptomatic chronic hypoventilation and to prolong survival in patients with amyotrophic lateral sclerosis. **(Guideline)**
3. When long-term survival is the goal, offer invasive ventilation and fully inform patient and family of burdens and benefits. **(Guideline)**
4. In accordance with the principle of patient autonomy, physicians should respect the right of the patient with amyotrophic lateral sclerosis to refuse or withdraw any treatment, including mechanical ventilation. **(Guideline)**
5. When withdrawing ventilation, use adequate opiates and anxiolytics to relieve dyspnea and anxiety. **(Guideline)**

Bioethics statement: It is a strong consensus of both the Amyotrophic Lateral Sclerosis Task Force and the Quality Standards Subcommittee of the American Academy of Neurology that during withdrawal of ventilation, paralyzing drugs should not be used.

Recommendations for Palliative Care

Ethical considerations

<u>Shared decision making</u>. The physician and the patient should share in decision making, understanding that cultural and religious values will have an impact on decisions. The physician should explain the risks and benefits of treatments at each visit in an unbiased way, and understand that the patient´s choices could change as the disease progresses.

<u>Goals of palliative care</u>. As amyotrophic lateral sclerosis progresses, the goal of patient care changes from maximizing function to providing effective and compassionate palliative care. One approach to provide adequate relief from two of the most prevalent and unpleasant symptoms in the terminal phase—dyspnea and anxiety—is as follows:

- Treatment of reversible causes of dyspnea if present (e.g., bronchospasm, pneumonia)
- Treatment of intermittent dyspnea
    a. Relief of anxiety (0.5 to 2 mg lorazepam sublingually)
    b. Inhaled opiates (e.g., 5 mg morphine)
    c. A total of 5 to 10 mg IV midazolam (slowly) for severe dyspnea
- Treatment of constant dyspnea
    a. Opiates (e.g., morphine, start with 2.5 mg IV/subcutaneously/transdermally, or oral equivalent every 4 hours)
    b. For severe dyspnea, continuous IV morphine infusion
    c. Add 2.5 to 5 mg diazepam or midazolam for nocturnal symptom control
    d. For terminal restlessness, chlorpromazine (25 mg every 4 to 12 hours rectally or 12.5 mg every 4 to 12 hours IV)
- Treatment of hypoxia with oxygen only

Continued communication with the paralyzed patient is often difficult and must be given high priority. Psychological and spiritual guidance should be offered.

Clinical Recommendations for Pain Management

1. Utilize non-narcotic analgesics, anti-inflammatory drugs, and antispasticity agents for initial treatment of pain in patients with amyotrophic lateral sclerosis. **(Option)**
2. Administer opioids liberally, following the World Health Organization guidelines, when non-narcotic analgesics fail. **(Guideline)**

Clinical Recommendations for Treating Dyspnea in Terminal Stages of Amyotrophic Lateral Sclerosis

1. Use opioids, alone or with supplemental oxygen, to treat dyspnea at rest in patients with amyotrophic lateral sclerosis, despite the risk of respiratory depression with higher doses. **(Guideline)**
2. Consider chlorpromazine (Thorazine) and acupuncture as possible adjuncts. **(Option)**

Clinical Recommendations for hospice care:

1. Consider referral to hospice in the terminal phase of amyotrophic lateral sclerosis. **(Option)**

Recommendations for advance directives:

1. Initiate a discussion of advance directives well in advance of the terminal phase and reevaluate at least every 6 months. **(Option)**

<u>Definitions</u>:

Classification of Management Recommendations

Standard: A principle for patient management that reflects a high degree of certainty based on class I evidence, or very strong evidence from class II studies when circumstances preclude randomized trials.

Guideline: Recommendations for patient management reflecting moderate clinical certainty (usually class II evidence or strong consensus of class III evidence)

Option: A strategy for patient management for which the evidence (class III) is inconclusive or when there is some conflicting evidence or opinion.

Classification of Evidence

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

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Class III: Evidence provided by expert opinion, case series, case reports, and studies with historical controls

CLINICAL ALGORITHM(S)

Algorithms are provided for sialorrhea (drooling) management; nutrition management; and, respiratory management.

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

Improved care and the quality of life of people with amyotrophic lateral sclerosis by providing a rational basis for managing the disease.

POTENTIAL HARMS

Percutaneous endoscopic gastrostomy placement

Complications of percutaneous endoscopic gastrostomy placement include transient laryngeal spasm (7.2%), localized infections (6.6%), gastric hemorrhage (1 to 4%), failure to place percutaneous endoscopic gastrostomy due to technical difficulties (1 to 9%), and death due to respiratory arrest).

Oxygen

Extreme caution is indicated when administering oxygen to nonterminal patients to avoid inducing hypoventilatory respiratory failure in hypercapnic patients.

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

Clinical Algorithm
Quick Reference Guides/Physician Guides

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

End of Life Care
Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Miller RG, Rosenberg JA, Gelinas DF, Mitsumoto H, Newman D, Sufit R, Borasio GD, Bradley WG, Bromberg MB, Brooks BR, Kasarskis EJ, Munsat TL, Oppenheimer EA. Practice parameter: the care of the patient with amyotrophic lateral sclerosis (an evidence-based review): report of the Quality Standards Subcommittee of the American Academy of Neurology: ALS Practice Parameters Task Force. Neurology 1999 Apr 22;52(7):1311-23. [112 references] PubMed

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ADAPTATION

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

DATE RELEASED

1999 Apr (reviewed 2005 Oct)

GUIDELINE DEVELOPER(S)

American Academy of Neurology - Medical Specialty Society

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GUIDELINE COMMITTEE

Quality Standards Subcommittee

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

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According to the guideline developer, this guideline has been reviewed and is still considered to be current as of October 2005. This review involved new literature searches of electronic databases followed by expert committee review of new evidence that has emerged since the original publication date.

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:

- American Academy of Neurology (AAN) guideline summary for clinicians: manage ALS from the beginning: care makes a difference. St. Paul (MN): American Academy of Neurology, 1999 Apr. 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 statement definitions. St. Paul (MN): American Academy of Neurology.
- Practice statement development. St. Paul (MN): American Academy of Neurology.

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 Institute on November 2, 2007, following the U.S. Food and Drug Administration advisory on Antidepressant drugs.

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