Complete Summary

GUIDELINE TITLE

Inpatient treatment of headache: an evidence-based assessment.

BIBLIOGRAPHIC SOURCE(S)

Freitag FG, Lake A 3rd, Lipton R, Cady R, Diamond S, Silberstein S. Inpatient treatment of headache: an evidence-based assessment. Headache 2004 Apr;44(4):342-60. [83 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

** 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.

On July 19, 2006, the FDA notified healthcare professionals and consumers of new safety information regarding taking medications used to treat migraine headaches (triptans) together with certain types of antidepressant and mood disorder medications, selective serotonin reuptake inhibitors (SSRIs) and selective serotonin/norepinephrine reuptake inhibitors (SNRIs). A life-threatening condition called serotonin syndrome may occur when triptans are used together with a SSRI or a SNRI. See the FDA Web site for more information.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Chronic headache (CH) including:

- Chronic daily headache (CDH)
- Chronic migraine (CM) or transformed migraine (TM)
- Chronic tension-type headache (CTTH)
- Hemicrania continua
- New daily persistent headache
- Medication overuse headache (MOH)
- Chronic cluster headache (CCH)

GUIDELINE CATEGORY

Management
Treatment

CLINICAL SPECIALTY

Anesthesiology
Emergency Medicine
Family Practice
Internal Medicine
Neurology
Pharmacology
Physical Medicine and Rehabilitation
Psychiatry
Psychology

INTENDED USERS

Advanced Practice Nurses
Dentists
Health Plans
Hospitals
Managed Care Organizations
Nurses
Occupational Therapists
Physical Therapists
Physician Assistants
Physicians
Psychologists/Non-physician Behavioral Health Clinicians
Substance Use Disorders Treatment Providers
Utilization Management

GUIDELINE OBJECTIVE(S)

- To evaluate inpatient treatment of headache in the United States

- To review the epidemiology and economic impact of chronic headache (CH), criteria for inpatient treatment, components of inpatient care, and outcomes of treatment, and provide a consensus statement and recommendations for further research to address the role of inpatient treatment of headache

TARGET POPULATION

Patients with chronic headache (CH)

INTERVENTIONS AND PRACTICES CONSIDERED

Inpatient Treatment/Management

1. Inpatient vs. outpatient treatment (admission criteria)
2. Intravenous dihydroergotamine (DHE)
3. Intravenous histamine
4. Treatment of withdrawal symptoms in patients with medication overuse headache
    - Clonidine (opiate withdrawal)
    - Phenobarbital (short-acting barbiturate withdrawal)
5. Antidopaminergic agents
6. Muscle relaxants
7. Nonopioid analgesic agents
8. Valproic acid
9. Patient education
10. Use of prophylactic medication (e.g., monoamine oxidase inhibitors, selective serotonin reuptake inhibitors)

Treatment Modalities in a Multidisciplinary Inpatient Headache Treatment Program

1. Detoxification
2. Pharmacologic therapy
3. Nursing intervention
4. Physical therapy
5. Dietary management and education
6. Stress management
7. Exercise programs
8. Biofeedback and relaxation therapy
9. Cognitive-behavioral treatment
10. Group psychotherapy
11. Individual and family psychotherapy
12. Family groups
13. Interactions between patients
14. Lifestyle management
15. Discharge planning

MAJOR OUTCOMES CONSIDERED

- Length of hospitalization
- Headache recurrence

- Patient satisfaction
- Analgesic intake
- Work absenteeism
- Work efficiency
- Pain measurement
- Frequency and duration of headache
- Number of emergency department (ED) visits
- Sleep
- Side effects of medication

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
Searches of Unpublished Data

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Committee)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Meta-Analysis of Observational Trials
Systematic Review with Evidence Tables

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

A meeting organized under the auspices of the United States Headache Guidelines Consortium was held on April 9, 1999, in New York City to evaluate inpatient treatment of headache in the United States. Current treatment criteria for inpatient care, survey data of the potential role of treatment, and outcomes data were presented and discussed. From this meeting emerged a mission statement. "There are patients with frequent, intractable headache who do not benefit from traditional outpatient care. Based upon a review of the existing data, many individuals appear to benefit from advanced and intense levels of care, including inpatient treatment."

Each of the authors was part of the writing committee each with specific areas that they were responsible for conducting the literature reviews and submitting a portion of the original document for editing and review. Dr. Freitag coordinated this process and assembled the first draft of the article for circulation and review among the authors and chairpersons. In the absence of class I evidence, consensus expert opinion was fundamental to the process.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

The guideline developers reviewed the direct costs of headache care. In one study, patients in primary care cost 87% more to care for than similarly matched patients without headache. A review in 2000 showed that hospitalizations for migraine have a mean length of stay of 5.1 days and a mean cost of $6908. These migraine-specific costs are only a portion of the overall direct medical costs of caring for patients with migraine. Migraine-associated comorbidities also add to medical care costs. Migraineurs generated twice the psychiatric claims as matched controls, with a monthly medical claim of $186 versus $112. Overall, the direct medical costs attributable to migraine are small relative to the indirect costs. Effects of comorbid illness were demonstrated in a study by Villareal who compared patients from a major headache center who were hospitalized for headache treatment with those who were not hospitalized; those who required hospital treatment had significantly higher levels of anxiety, depression (as measured both by the Beck Depression Inventory and the Zung Self-rating Scale), more severe pain, and a higher frequency of analgesic use.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not applicable

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Inpatient Treatment

Admission Criteria

Inpatient headache treatment occurs in 2 different hospital environments: community/regional hospitals and specialty headache treatment units. A recent survey was conducted in 174 physicians with an interest in headache selected from the membership of the American Headache Society (American Association for the Study of Headache at the time of the study). Over 50% used inpatient hospitalization on at least some occasions for detoxification from opioids, barbiturates, or prescription analgesics in patients with headache.

A second survey (see table 3 of the original guideline document) was undertaken of a selection of physicians with a special interest in headache. This included 5 physicians, who had dedicated inpatient treatment programs of varying size and complexity, as well as 10 community-based physicians and 6 university-based physicians, who did not have inpatient programs. Of these 21 physicians, 19 had criteria they used for admitting patients, or were interested in obtaining criteria. One of the 2 physicians not interested in criteria was a community-based physician who no longer even attempted the process because of the high managed care penetration in his area; the second was a university-based physician who did not believe in treatment guidelines in general. Attempts were also made to obtain specific criteria from insurance industry utilization review organizations for inpatient hospitalization of headache. This data was available from only 7 insurance companies.

Though this survey relied upon a convenience sample, clinicians and the insurance industry had a surprisingly convergence of interests and criteria given the high profile of cost containment. Criteria from inpatient programs substantially overlapped in their admission criteria guidelines, as did the criteria of community- and university-based physicians who did not have inpatient programs.

Previously, there had been 2 sets of published criteria for admission to headache treatment centers (see tables below entitled "Admission Criteria of Michigan Headache and Neurological Institute for Inpatient Headache Treatment Program at Chelsea Hospital" and "Admission Criteria of the National Headache Foundation for Treatment of Headache"). The historic background of these criteria has certainly contributed to the criteria found in the survey and utilized today.

Table: Admission Criteria of Michigan Headache and Neurological Institute for Inpatient Headache Treatment Program at Chelsea Hospital

• Presence of moderate to severe intractable headache that fails to respond to appropriate and aggressive outpatient or emergency department measures and requires repetitive sustained parenteral treatment (e.g., dihydroergotamine [DHE])
• Presence of continuing nausea, vomiting, or diarrhea

- Need to detoxify and treat toxicity, dependency, or rebound phenomena and/or monitor protectively against withdrawal symptoms, including seizures, in cases in which this cannot be achieved effectively or safely on an outpatient basis
- Presence of dehydration, electrolyte imbalance, and prostration that requires monitoring and intravenous (IV) fluids
- Presence of unstable vital signs
- Presence of repeated previous emergency department treatments
- Likely presence of serious disease (e.g., subarachnoid hemorrhage, intracranial infection, cerebral ischemia, severe hypertension)
- Need to rapidly develop both immediate pain reduction and an effective pharmacologic prophylaxis in order to sustain improvement achieved by parenteral therapy (aggressive daily drug manipulation, requiring careful monitoring and drug level evaluation)
- Need to urgently address other comorbid conditions contributing to or accompanying the headache, including medical and/or psychological illness
- Presence of concurrent medical and/or psychological illnesses requiring careful monitoring in high-risk situations

Table: Admission Criteria of the National Headache Foundation for the Treatment of Headache

- Severe dehydration, for which inpatient parenteral therapy may be necessary
- Diagnostic suspicion (confirmed by appropriate diagnostic testing) of organic etiology, such as an infectious disorder involving the central nervous system (e.g., brain abscess, meningitis), acute vascular compromise (e.g., aneurysm, subarachnoid hemorrhage), structural disorder with accompanying symptoms (e.g., brain tumor)
- Prolonged unrelenting headache with associated symptoms such as nausea and vomiting, which, if allowed to continue, would pose a further threat to the patient's welfare
- Status migraine or dependence on analgesics, ergots, opiates, barbiturates, or tranquilizers
- Pain that is accompanied by serious adverse reactions or complications from therapy - continued use of such therapy aggravates or induces further illness
- Pain that occurs in the presence of significant medical disease, but appropriate treatment of headache symptoms aggravates or induces further illness
- Failed outpatient detoxification, for which inpatient pain and psychiatric management may be necessary
- Intractable and chronic cluster headache, for which inpatient administration of histamine or DHE may be necessary
- Treatment requiring copharmacy with drugs that may cause a drug interaction, thus necessitating careful observation (e.g., monoamine oxidase inhibitors and beta-blockers)

Treatment

Inpatient care differs depending on the type of facility and the nature of the headache. Although community-based inpatient treatment, regional or university centers, and dedicated headache inpatient treatment centers may all share the common elements of IV protocols and 24-hour nursing care, significant differences exist in the level and sophistication of other aspects of medical management, the diversity and coordination of multidisciplinary services, and the intractability of the patient population. Other factors that influence both the need for hospitalization and the type of care rendered include: medical stability of the patient, presence of coexisting medical illness, medication overuse headache (MOH) or drug dependency issues, psychological and psychiatric comorbidities, and need for patient monitoring during administration of medical therapies.

The Consortium does not know if one specific treatment environment for inpatient care is more successful than another. Efforts to compare one treatment setting with another must include a careful comparison of patient populations. The patient population in published outcome studies of specialized headache treatment centers predominantly includes patients who have failed other treatments, which in many cases have included more limited previous inpatient protocols. Evidence exists that patients with MOH, using small amounts of agents, treated on an outpatient basis, may have outcomes as good as those with inpatient care - no clear guidelines exist for the patient with MOH. Dedicated inpatient programs, however, suggest that patients with highly complex headache problems associated with significant MOH and medical and psychological comorbidities are more likely to need treatment in multidisciplinary treatment environments (see table below).

Table: Typical Treatment Modalities in a Multidisciplinary Inpatient Headache Treatment Program

- Detoxification
- Pharmacologic therapy
- Nursing intervention
- Physical therapy
- Dietary management and education
- Stress management
- Exercise programs
- Biofeedback and relaxation therapy
- Cognitive-behavioral treatment
- Group psychotherapy
- Individual and family psychotherapy
- Family groups
- Interactions between patients
- Lifestyle management
- Discharge planning

It may be necessary to hospitalize a patient when severe headache is associated with significant changes in vital signs or clinical condition, such as repetitive vomiting. Repetitive IV DHE used >2 days has been recognized by the American Academy of Neurology in their practice parameter as necessitating inpatient monitoring.

Overuse of acute treatments for migraine and its associated pain (e.g., analgesics, alone or combined with caffeine; sympathomimetics; barbiturates; opiates; triptans; ergots) is a major problem. The International Headache Society (IHS) guidelines for drug dependency headache were revised in late 2004. The new terminology is medication-overuse headache (MOH).

Treatment of MOH is crucial, since preventive therapy often does not work. It may take as long as 12 weeks to reverse the effects of medication overuse. Failure to achieve successful detoxification as an outpatient occurs in over 50% of patients due to increased pain during the initial period of withdrawal, and acute withdrawal symptoms in cases of high levels of analgesic use, including butalbital and opioid use, can occur. Even when withdrawal could be managed safely in an outpatient setting, patients have a fear of pain, which interferes with successful withdrawal. Techniques, such as the use of clonidine for opiate withdrawal, may be of benefit in the outpatient arena. Phenobarbital can be used for withdrawal of short-acting barbiturates. This requires at least a short-term hospital stay for observation and dose titration.

Management of the patient with MOH requires acute and preventive therapies for the underlying headache, as well as symptom management related to the withdrawal of the agent producing rebound. The IV use of diverse agents including antidopaminergics, muscle relaxants, nonopioid analgesics, and valproic acid may be required to provide interim control of headaches while initiating treatment with preventive medications.

Significant complications of withdrawal of opiates, benzodiazepines, and barbiturates may occur. Observation of patient with close medical monitoring may be required in the first several days of withdrawal of these agents.

Some patients with chronic cluster headaches (CCHs) do not respond to standard methods of treatment. Adjunctive therapies such as IV DHE or IV histamine, which are rendered on an ongoing basis over the course of days to a week, have proven effective in leading to improved treatment outcomes.

Rapid transitions in medical therapies are sometimes initiated to reduce the length of hospitalization and to gain control of the patient's headaches. One example is the patient who needs to undergo a rapid transition from selective serotonin reuptake inhibitor antidepressants to monoamine oxidase inhibitor types, or the reverse. Product labeling specifies that in almost all of these cases, a drug-free interval of 10 to 14 days is required before starting the new agent. This is not a practical solution for patients who suffer profound disabling headaches, and a more rapid transition with a shorter evaluation period should be initiated. Generally, this type of transition has proven safe for most patients, although on occasion this type of therapy may be potentially dangerous. Warning signs include the serotonin syndrome with elevated temperature, agitation, and other serotonergic indications. If left untreated, a potentially morbid situation could occur. Careful observation of these patients during this transition period is essential.

Chronic pain, including headache, may be significantly aggravated by psychological problems. Long-term follow-up research has found that patients with multiple psychiatric diagnoses have a more negative long-term prognosis

than patients with little or no psychiatric disturbance. Accurate diagnosis by qualified psychologists and psychiatrists is essential if development of a long-term treatment program is indicated. Treatment for the patient with CH attempts to identify specific components of suffering and pain behaviors. Specific psychological intervention occurs on 2 levels. Group therapy sessions, such as assertiveness training, are conducted with a focus on problems common to patients with headache. If indicated, individual psychological counseling is also initiated during the first few days of hospitalization, and continued, as necessary, during and after hospitalization. Intractable headache has a significant impact on family functioning, and both individual family and family group intervention is often an important part of the program. Patients with refractory headache usually have psychological issues affecting their ability to respond to treatment. In many patients, the headache process is obscured by personality characteristics, coexisting depression, or other major psychiatric conditions including personality disorders. After an initial assessment and basic psychological intervention, it is imperative to establish a pain management program to help these patients deal with the varied aspects of their condition.

Education of the patient with headache provided by physicians, psychologists, pharmacists, and dieticians, is essential in enhancing the patient's understanding of the headache problem and ensuring a successful treatment program. Family members also are encouraged to be involved in the program.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is not specifically stated.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate utilization of advanced and intense levels of care, including inpatient treatment, for patients with frequent, intractable headache

POTENTIAL HARMS

- Significant complications of withdrawal of opiates, benzodiazepines, and barbiturates may occur. Observation of patient with close medical monitoring may be required in the first several days of withdrawal of these agents.
- Rapid transitions in medical therapies are sometimes initiated to reduce the length of hospitalization and to gain control of the patient's headaches. One example is the patient who needs to undergo a rapid transition from selective serotonin reuptake inhibitor antidepressants to monoamine oxidase inhibitor types, or the reverse. Product labeling specifies that in almost all of these

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QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

None of the studies reported to date provide class I evidence for efficacy, either as an inpatient or an outpatient. Recommendations are made to assess headache treatment of patients with high-frequency headaches to garner better scientific evidence for differing treatment approaches.

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

Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Freitag FG, Lake A 3rd, Lipton R, Cady R, Diamond S, Silberstein S. Inpatient treatment of headache: an evidence-based assessment. Headache 2004 Apr;44(4):342-60. [83 references] PubMed

ADAPTATION

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

DATE RELEASED

2004 Apr

GUIDELINE DEVELOPER(S)

US Headache Guidelines Consortium - Private Nonprofit Research Organization

SOURCE(S) OF FUNDING

US Headache Guidelines Consortium

GUIDELINE COMMITTEE

Not stated

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Committee Members: Seymour Diamond, MD (*Chairperson*); Stephen Silberstein, MD (*Chairperson*); Frederick Freitag, DO; Al Lake, III, PhD; Richard Lipton, MD; Roger Cady, MD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

A conflict of interest for hospitalization of patients with headache may exist for the following authors of this article: Frederick G Freitag, DO; Al Lake, III, PhD; and Seymour Diamond, MD, since all currently are affiliated with a dedicated inpatient treatment program for headache. Dr. Stephen Silberstein has written several articles on inpatient treatment of headache and formerly ran an inpatient program. Of the participants in the conference leading to this article, the following attendees hospitalized patients, maintained an inpatient program at the time, or had been previously affiliated with an inpatient treatment program: R. Michael Gallagher, DO; Ninan Matthew, MD; Joel Saper, MD; and Alan Rapoport, MD.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Not available at this time.

Print copies: Available from Dr. Frederick Freitag, DO, Diamond Headache Clinic, Suite 500, 467 West Deming Place, Chicago, IL 60614.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on January 21, 2005. The information was verified by the guideline developer on January 26, 2005. This summary was updated by ECRI on August 29, 2006, following the U.S. Food and Drug Administration advisory on Triptans, SSRIs, and SNRIs.

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