



Complete Summary

GUIDELINE TITLE

Treatment of primary headache: cluster headache. Standards of care for headache diagnosis and treatment.

BIBLIOGRAPHIC SOURCE(S)

Biondi D, Mendes P. Treatment of primary headache: cluster headache. In: Standards of care for headache diagnosis and treatment. Chicago (IL): National Headache Foundation; 2004. p. 59-72. [38 references]

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.

- [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.
- [April 11, 2007, Zanaflex \(tizanidine hydrochloride\)](#): Changes to the product labeling for Zanaflex, a drug used to treat spasticity, to warn against its hypotensive and sedative effects when administered with fluvoxamine or ciprofloxacin (CYP1A2 inhibitors).
- [July 19, 2006, Triptans](#): Healthcare professionals and consumers of new safety information regarding taking triptans together with selective serotonin reuptake inhibitors (SSRIs) and selective serotonin/norepinephrine reuptake inhibitors (SNRIs).

COMPLETE SUMMARY CONTENT

**** REGULATORY ALERT ****

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis

RECOMMENDATIONS

EVIDENCE SUPPORTING THE RECOMMENDATIONS

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

CONTRAINDICATIONS
QUALIFYING STATEMENTS
IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT
CATEGORIES
IDENTIFYING INFORMATION AND AVAILABILITY
DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

Cluster headache

GUIDELINE CATEGORY

Prevention
Treatment

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Neurology

INTENDED USERS

Health Care Providers
Physicians

GUIDELINE OBJECTIVE(S)

- To improve the medical treatment of headache
- To help physicians and other health care professionals to:
 - Minimize symptomatology
 - Reduce disability
 - Improve quality of life

TARGET POPULATION

Patients with cluster headache

INTERVENTIONS AND PRACTICES CONSIDERED

Acute Drug Treatment

1. Oxygen
2. Sumatriptan succinate subcutaneous (SQ) injection
3. Sumatriptan nasal spray
4. Zolmitriptan

5. Dihydroergotamine (DHE) intramuscular (IM), subcutaneous, or intravenous (IV) injection
6. Dihydroergotamine mesylate intranasal spray
7. Ergotamine tartrate sublingual
8. Intranasal lidocaine
9. Topical intranasal cocaine
10. Capsaicin
11. Butorphanol
12. Olanzapine

Preventive Drug Treatment

Transitional Prophylaxis or Rapid Suppression of Attacks

1. Corticosteroids
 - Prednisone
 - Dexamethasone
2. Ergotamine derivatives
 - Ergotamine tartrate
 - Ergotamine
 - Dihydroergotamine (DHE)
 - Bellergal-S® or Bellergal® plain (ergotamine, phenobarbital, and belladonna combination)
3. Occipital nerve blockade
 - Local anesthetic (i.e., lidocaine) and steroid (i.e. Kenalog-40®)

Maintenance Therapy

1. Verapamil
2. Methysergide maleate (not currently available in the U.S.)
3. Lithium carbonate
4. Divalproex sodium
5. Valproic acid
6. Topiramate
7. Melatonin
8. Other agents (considered, but not recommended as routine treatment)
 - Clonidine
 - Diltiazem
 - Flunarizine
 - Somatostatin
 - Indomethacin
 - Pizotifen
 - Phenelzine
 - Naratriptan
 - Gabapentin
 - Methylphenidate
 - Mirtazapine
 - Tizanidine
 - Baclofen

Treatment of Refractive Cluster Headaches

1. Intravenous histamine desensitization
2. Surgery
 - Radiofrequency thermal neurolysis of the trigeminal nerve
 - Glycerol injection
 - Gamma knife radiosurgery

Nondrug Treatment

1. Avoiding afternoon naps or other significant changes in sleeping habits
2. Avoiding alcohol use, particularly during cluster period
3. Avoiding prolonged exposure to chemical agents
4. Avoiding excessive bursts of anger or extreme emotion
5. Avoiding prolonged physical exertion
6. Avoiding extreme changes in altitude

Monitoring of Drug Therapy

1. Liver function tests
2. Serum lithium concentrations
3. Serum valproic acid levels
4. Electrocardiography
5. Magnetic resonance imaging (MRI)
6. Kidney function tests
7. Thyroid function tests

MAJOR OUTCOMES CONSIDERED

- Complete relief of pain
- Incidence of adverse events
- Duration of headache relief
- Patient compliance
- Remission rate
- Recurrence rate

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

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

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

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

The guidelines presented in this monograph represent the consensus of an advisory panel of practitioners chosen by the National Headache Foundation (NHF) for their expertise. In addition to incorporating the US Headache Consortium's recommendations, their conclusions reflect clinical experience and the most recent medical literature.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

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

METHOD OF GUIDELINE VALIDATION

Not stated

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not applicable

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Cluster Headache

Acute Drug Treatment

The goal of treatment for acute cluster is to decrease the pain, severity, and duration of each attack. Early intervention is critical, since a single cluster headache can be as short as 15 minutes. Because of the brief nature of cluster headaches, consider a non-oral route of administration when treating these headaches (see table 6.1 of the original guideline document).

Oxygen

Oxygen inhalation is the standard recommended therapy for cluster headaches. Treatment is initiated with 100% oxygen by non-rebreathing facial mask. Flow rate is set at 7 to 10 liters per minute and treatment should continue for 15 minutes. Although up to 70% of patients experience relief within 5 minutes, some patients report that oxygen suppresses rather than aborts the attack and that pain may return. Oxygen seems to be most successful when administered at the maximum pain intensity. There are no side effects with this treatment.

Sumatriptan

Sumatriptan, 6 mg administered subcutaneously (SQ), is an effective acute treatment for episodic and chronic cluster headaches, but it is most useful for patients who report 1 or 2 cluster attacks per day. Cluster attacks usually respond within 10 minutes. There is no evidence of tachyphylaxis, rebound syndromes, or drug dependency with the use of subcutaneous sumatriptan for cluster headaches. Cluster patients may find that their attacks can be aborted with sumatriptan SQ at smaller doses, such as 2 to 3 mg.

Intranasal sumatriptan 20 mg is not as effective as the subcutaneous injection. In a trial comparing subcutaneous versus intranasal sumatriptan in cluster patients, injection resulted in 87% of patients experienced complete relief of pain within 15 minutes after injection compared with only 13.4% with sumatriptan nasal spray. Sumatriptan is contraindicated in patients with ischemic heart disease, uncontrolled hypertension, peripheral vascular disease, and concurrent use of another 5-HT₁ agonist or ergot derivative medication.

Zolmitriptan

In a single open-label trial, oral zolmitriptan 10 mg demonstrated efficacy for cluster attacks; however, the adverse profile was significant. No data are available at this time with the nasal spray formulation.

Dihydroergotamine (DHE)

DHE administered by nasal spray or injection can decrease the intensity of individual attacks and may also completely abort the pain. Intravenous injection gives quicker relief, usually within 10 minutes, when compared with intramuscular or SQ injection. DHE dosage is 0.5 to 1 mg whether given intravenously, intramuscularly, or subcutaneously. Treatment can be repeated every 1 hour as needed up to a total of 3 mg per day. The total intranasal dose is 2 mg for a single treatment.

Nasal Lidocaine

Nasal lidocaine 4% topical solution can be applied in the form of nose drops or spray for acute treatment of a cluster attack. Patients should apply 15 drops in the nostril on the affected side at the onset of the headache, with the head turned to the ipsilateral side and tilted backwards. If necessary, this application can be repeated in 15 minutes. Lidocaine can be used up to 4 times per day but only twice per headache. The most common side effects of lidocaine include lightheadedness and a feeling of nervousness.

Topical Intranasal Cocaine

Topical intranasal cocaine has been used as a local anesthetic for treatment of cluster headaches, but because of its addictive potential, it is rarely used.

Capsaicin

Capsaicin acts by depleting substance P stores in neurons, and it can therefore desensitize sensory neurons. When a 0.025% capsaicin cream is applied intranasally twice a day via a cotton-tipped applicator in the nostril ipsilateral to the cluster headache, patients may experience less frequent and less intense attacks.

Narcotic and Nonparenteral Analgesics

Due to their slow onset of action, oral narcotics and other nonparenteral analgesics play little role in the treatment of cluster headaches. However, there may be a role for butorphanol, an opioid analgesic that can be administered by a nasal spray. Since butorphanol has no known cardiovascular risks, it is an alternative for patients who cannot use vasoconstrictive medications and for whom oxygen has failed. Given the high frequency of attacks in some cluster patients, opioid analgesics, if used, require close supervision.

Olanzapine

Olanzapine is an atypical neuroleptic that has been reported to be as effective in treating both chronic and episodic acute cluster attacks. In a report, the starting dose was 5 mg, with an increase up to 10 mg if no pain relief was found at the lower dose.

Preventive Drug Treatment

Effective preventive treatment is an important component of managing cluster headache (refer to Table 6.2 of the original guideline document). The 2 main goals of preventive treatment for cluster are to rapidly suppress individual attacks and to maintain that remission throughout the patient's typical cluster period. It is necessary to start prophylactic pharmacotherapy early in the cluster period. Daily prophylaxis should be continued until the patient is headache-free for at least 14 days. When indicated, a slow taper of preventive medications is recommended. Prophylactic drugs are restarted at the beginning of the next cluster cycle.

Transitional Prophylaxis or Rapid Suppression of Attacks

Corticosteroids

Prednisone and dexamethasone are rapidly acting transitional or suppressive prophylactic drugs that are used at the onset of a cluster period for up to 3 weeks while a maintenance prophylactic agent is initiated and allowed to take effect. Total relief from attacks is seen in up to 50% of patients. Prednisone is usually initiated at a dose of 40 to 60 mg per day for 3 days, followed by a 5 to 10 mg dosage reduction every 2 to 3 days until discontinued. Dexamethasone 4 mg twice a day for 2 weeks, then 4 mg per day for 1 week, is also effective. When corticosteroids are tapered, however, the cluster attacks tend to recur, so maintenance preventive therapy should be started at the time that corticosteroids are begun. During the steroid taper, recurrence of the cluster attacks often occurs when a physiologic level of the steroid is achieved (i.e., daily prednisone dose of 20 mg per day or equivalent). Corticosteroids are most often used in episodic cluster patients to break the cluster cycle. Potential side effects include insomnia, restlessness, personality changes, hyponatremia, edema, hyperglycemia, osteoporosis, myopathy, and gastric ulcers. Aseptic necrosis of the hip or shoulder has also been reported. The use of long-term corticosteroids is discouraged in patients with chronic cluster headaches because the incidence of side effects increases with prolonged use.

Ergotamine Derivatives

Ergotamine derivatives are effective for quick suppression of cluster attacks when administered on a daily schedule for a short period. Ergotamine tartrate is available as a tablet, a suppository, and, in some countries, an inhalant. Oral or sublingual ergotamine may be taken 30 to 60 minutes before an expected attack. This form of treatment is particularly suitable for patients with clusters that occur soon after initiating sleep. For those with short cluster periods, patients may take ergotamine tartrate 3 to 4 mg daily in divided doses for periods of up to 3 weeks. Some patients also respond to rectally administered ergotamine. For DHE-45®, the maximum daily dose is 3 mg, usually given in divided doses. Even though this class of drugs may be given daily for 2 to 3 weeks, rebound headaches do not occur in this group of patients. Bellergal-S® or Bellergal® plain (ergotamine, phenobarbital, and belladonna combination) can be given 1 tablet 2 to 4 times a day for 2 weeks. Patients cannot use triptans while on this therapy.

Occipital Nerve Blockade

Occipital nerve blocks with local anesthetic and steroid injected around the nerve ipsilateral to the side of cluster pain have been used with some success. One study found that the duration of headache relief ranged from 5 to 73 days, with many patients requiring more than 1 injection. Occipital nerve blocks can be helpful until maintenance therapy becomes effective. One cubic centimeter of a mixture of lidocaine and Kenalog-40® at a 1:9 dilution has been used in some headache centers.

Maintenance Therapy

Verapamil

Verapamil is the first-line prophylactic drug for both episodic and chronic clusters. Slow-release verapamil is effective as well and improves patient compliance. Treatment can be started as verapamil 80 mg 3 times a day or 240 mg daily sustained-release. Doses range between 120 and 480 mg a day. Higher doses can be used, but it is advisable to obtain electrocardiograms with each increase above 480 mg per day. When combination therapy with lithium is used, there may be an increased sensitivity to lithium. Serious side effects are rare, but constipation is common. Other side effects include dizziness, nausea, edema, bradycardia, fatigue, and hypotension.

Methysergide Maleate

Although methysergide maleate is currently unavailable in the United States, it is hoped that it may come back to the market for physicians to use for headache treatment. Methysergide, an ergot derivative, is effective in 65 to 69% of cases of episodic cluster headaches, but it is not commonly used because of its association with potentially serious, systemic fibrotic reactions. Response rates are lower in chronic cluster patients than in episodic cluster patients. Other side effects are nausea, lightheadedness, leg cramps, diarrhea, and epigastric pain. These usually abate after several days. Methysergide is used more often for episodic clusters because the cycles are usually less than 4 months long. When treating chronic cluster patients with methysergide, provisions should be made for a 1-month drug holiday for every 6 months of treatment in order to minimize the risk of retroperitoneal, pleural, pulmonary, and cardiac valvular fibrosis, although these complications are rare (1/1,500). A chest x-ray, an echocardiogram, and magnetic resonance imaging (MRI) of the abdomen must be performed during the drug-free holidays. Treatment consists of a dose of 2 to 6 mg per day, starting at 2 mg (1 tablet) per day and increasing over a few days to a maximum dose of 8 mg per day. Doses up to 12 mg per day have been used when tolerated. The concurrent use of triptans and methysergide is contraindicated. Other contraindications include pregnancy, coronary artery disease, collagen vascular disease, phlebitis, hypertension, peripheral vascular disease, and compromised liver or renal function.

Lithium Carbonate

Lithium carbonate is effective against episodic and chronic cluster headaches. Of cluster headache patients, 78% of patients with chronic clusters and 63% of patients with episodic clusters respond to lithium. It is effective at rather low serum concentrations (0.3 to 0.8 micromole/L). The usual daily dose ranges from 600 to 900 mg in divided doses. Because of its long half-life (24 hours), a steady state is generally reached within 1 week after initiation of treatment. With prolonged use, some patients can become resistant to lithium efficacy. Side effects might include tremor, polyuria, and diarrhea. Renal and thyroid function should be checked before and during the treatment, since nephrotoxicity and hypothyroidism can occur with long-term use. Lithium blood levels should be checked after the first week of treatment and periodically thereafter. Since sodium depletion can result in high lithium levels and neurotoxicity, concomitant use of sodium-depleting diuretics should be avoided. Caution should also be exercised when nonsteroidal anti-inflammatory drugs (NSAIDs) are prescribed along with lithium because of possible nephrotoxicity.

Valproic Acid

Valproic acid has shown up to a 73% favorable response with doses ranging from 600 to 2,000 mg per day. Nine of 15 patients had complete suppression of attacks and 2 had a marked improvement. Patients can experience good outcomes within 1 to 4 days after initiation of treatment. Treatment is usually started in divided doses of 250 mg twice a day, followed by 250 mg increments as needed and tolerated. Serum valproic acid levels can be used as a guide for dosing since side effects and risk of toxicity increase when supratherapeutic blood levels are maintained. Extended-release valproic acid can also be used, thereby improving compliance by means of once-a-day dosing. Side effects include tremor, alopecia, weight gain, and drowsiness. The monitoring of complete blood counts and liver function tests are needed, since valproic acid can cause platelet dysfunction, thrombocytopenia, and pancreatitis.

Topiramate

Patients with both episodic and chronic cluster headaches have benefited from prophylactic treatment with topiramate. An open-label study showed remission of cluster headaches within 1 to 3 weeks after initiation of treatment in 9 patients. Response was seen at doses ranging between 50 and 125 mg per day in twice daily dosing. Treatment should be started at 25 mg at night and increased by 25 mg every 5 days as tolerated. Dosages as high as 200 mg may be needed in some patients. Side effects include paresthesias, somnolence, cognitive symptoms, weight loss, ataxia, and light-headedness. Topiramate is contraindicated in patients with renal calculi.

Melatonin

Studies have suggested that serum melatonin levels are decreased in patients with cluster headache, especially during a cluster period. Cluster headache cycle suppression with 10 mg oral melatonin was achieved within 3 to 5 days in 50% of patients in a double-blind, placebo-controlled trial with 10 patients.

Other Agents

Many other agents have been reported in small trials or case reports as having shown efficacy in treating patients with cluster headaches. These include clonidine, diltiazem, flunarizine, somatostatin, indomethacin, pizotifen, phenelzine, naratriptan, gabapentin, methylphenidate, mirtazapine, tizanidine, and baclofen. Before these drugs can be recommended as routine treatment for cluster headache patients, further studies should be conducted. It is reasonable for patients in whom all standard medical treatments have failed to try these agents before being referred for surgery.

Treatment for Refractive Cluster Headache

Intravenous Histamine Desensitization

Intravenous histamine has been found to be an effective treatment for patients with cluster headache that has become refractive to medical therapy. Patients

treated with histamine infusions repetitively over a course of about 10 days appear to have restitution of response to standard medical therapies. Because of the prolonged nature of intravenous therapy, it is not recommended for patients who have other medical options available. Since the course of histamine infusions can be repeated if cluster headaches recur and since this therapy is well tolerated by most patients, it may be considered as an alternative to surgery.

Surgery

About 10% of patients with cluster headaches are nonresponsive to pharmacologic prophylaxis or have significant contraindications to effective prophylactic agents or acute treatment. When patients have exhausted all acute medications or have medical conditions that preclude medical options, surgical treatment should be considered. In addition, to be eligible for surgery, patients must have strictly unilateral headache and a stable personality profile with no addictive potential. A variety of surgical procedures can be tried. Surgical techniques are based on ablation of components of the sensory trigeminal nerve and the cranial parasympathetic system or nervus intermedius. Methods include radiofrequency trigeminal rhizolysis, glycerol injection into the trigeminal cistern, and gamma knife radiosurgery.

Radiofrequency Thermal Neurolysis of the Trigeminal Nerve

Radiofrequency thermal neurolysis of the trigeminal nerve is a potential treatment choice. Results vary, but 50 to 73.3% of 30 patients described 50 to 90% relief from their cluster headaches. Complications include keratitis, corneal anesthesia in the ipsilateral eye, hyperacusis, ice-pick pain, jaw deviation, anesthesia dolorosa (<4% of cases), transient diplopia, and recurrent sty. Repeat neurolysis may be necessary if pain recurs.

Glycerol Injection

Glycerol injection into the trigeminal cistern has been used for intractable cluster headache patients. It can afford significant pain relief and less risk to the cornea.

Gamma Knife Radiosurgery

Gamma knife radiosurgery has also shown some efficacy for treatment of intractable, medically unresponsive cluster patients. The results were observed immediately or within 1 week after the procedure. Although the overall efficacy, safety, and durability of this procedure are still unknown, it should be considered an alternative for some patients because it is noninvasive and does not permanently destroy nerve structure.

Nondrug Treatment

The intensity of cluster headache pain and the anticipation of future attacks can cause increased anxiety for many patients. When counseling these patients, it is important to set appropriate treatment expectations at the outset. Clinicians should try to alleviate any unnecessary fears by assuring patients that most attacks can be prevented with prophylactic treatment and that breakthrough

attacks can be managed with pharmacologic treatments. In addition, there are specific nondrug treatments that patients can employ to optimize management of cluster headaches (see table below).

Nondrug Treatment Strategies
Patients should avoid the following: <ul style="list-style-type: none">• Afternoon naps or other significant changes in their sleeping habits• Alcohol, especially during the cluster period• Prolonged exposure to chemical agents such as cleaning solvents, gasoline, and oil-based paint• Excessive bursts of anger or extreme emotion• Prolonged physical exertion• Extreme changes in altitude

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.

In addition to incorporating the US Headache Consortium's recommendations, the conclusions reflect clinical experience and the most recent medical literature.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate prevention and treatment of cluster headache

POTENTIAL HARMS

- The most common side effects of lidocaine include lightheadedness and a feeling of nervousness.
- Topical intranasal cocaine is rarely used because of its addictive potential.
- Potential side effects of corticosteroids include insomnia, restlessness, personality changes, hyponatremia, edema, hyperglycemia, osteoporosis, myopathy, and gastric ulcers. Aseptic necrosis of the hip or shoulder has also been reported. The use of long-term corticosteroids is discouraged in patients with chronic cluster headaches because the incidence of side effects increases with prolonged use.
- Verapamil is the first-line prophylactic drug for both episodic and chronic clusters. When combination therapy with lithium is used, there may be an increased sensitivity to lithium. Serious side effects of verapamil are rare, but

constipation is common. Other side effects include dizziness, nausea, edema, bradycardia, fatigue, and hypotension.

- Methysergide, an ergot derivative, is effective in 65 to 69% of cases of episodic cluster headaches, but it is not commonly used because of its association with potentially serious, systemic fibrotic reactions. Other side effects are nausea, lightheadedness, leg cramps, diarrhea, and epigastric pain. These usually abate after several days.
- Side effects of lithium carbonate might include tremor, polyuria, and diarrhea. Renal and thyroid function should be checked before and during the treatment, since nephrotoxicity and hypothyroidism can occur with long-term use. Lithium blood levels should be checked after the first week of treatment and periodically thereafter. Since sodium depletion can result in high lithium levels and neurotoxicity, concomitant use of sodium-depleting diuretics should be avoided. Caution should also be exercised when nonsteroidal anti-inflammatory drugs (NSAIDs) are prescribed along with lithium because of possible nephrotoxicity.
- Serum valproic acid levels can be used as a guide for dosing since side effects and risk of toxicity increase when supratherapeutic blood levels are maintained. Side effects include tremor, alopecia, weight gain, and drowsiness. The monitoring of complete blood counts and liver function tests are needed, since valproic acid can cause platelet dysfunction, thrombocytopenia, and pancreatitis.
- Side effects of topiramate include paresthesias, somnolence, cognitive symptoms, weight loss, ataxia, and light-headedness. Topiramate may rarely cause renal stones, angle closure glaucoma, and metabolic acidosis; monitor accordingly.
- Divalproex sodium side effects may include hepatic dysfunction (especially in children), gastrointestinal (GI) upset, tremor, sedation, nausea, weight gain, alopecia, pancreatitis, and bone marrow suppression; polypharmacy (especially barbiturates and anticonvulsants) might increase the incidence of hepatic complications.
- Complications of radiofrequency thermal neurolysis of the trigeminal nerve include keratitis, corneal anesthesia in the ipsilateral eye, hyperacusis, ice-pick pain, jaw deviation, anesthesia dolorosa (<4% of cases), transient diplopia, and recurrent sty. Repeat neurolysis may be necessary if pain recurs.

CONTRAINDICATIONS

CONTRAINDICATIONS

- Sumatriptan is contraindicated in patients with ischemic heart disease, uncontrolled hypertension, peripheral vascular disease, and concurrent use of another 5-HT₁ agonist or ergot derivative medication.
- The concurrent use of triptans and methysergide is contraindicated. Other contraindications include pregnancy, coronary artery disease, collagen vascular disease, phlebitis, hypertension, peripheral vascular disease, and compromised liver or renal function.
- Topiramate is contraindicated in patients with renal calculi.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

Drug therapy is constantly evolving as new research, clinical trials, case reports, and opinions are published. Many of the drugs recommended in these guidelines are not approved by the US Food and Drug Administration (FDA) for treatment of headache, nor are they necessarily the same as those therapies recommended by the manufacturer for labeled indications. Their use in headache, however, may be supported by the scientific literature and by the authors' clinical experiences. While efforts have been made to ensure accuracy, the authors and publisher do not assume responsibility for the consistent updating of available information for these guidelines, nor for any errors or omissions, nor for any consequences thereof. The onus is on the practitioner to evaluate recommendations in light of the clinical condition of the patient and recent medical literature. The authors advise the practitioner to consult other sources, especially the manufacturers' warnings and precautions, before prescribing any drug with which they are unfamiliar. Practitioners are also advised that while these guidelines will address the needs of many patients, there will be circumstances calling for exceptions to these recommendations.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Chart Documentation/Checklists/Forms
Foreign Language Translations
Patient Resources
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
Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Biondi D, Mendes P. Treatment of primary headache: cluster headache. In: Standards of care for headache diagnosis and treatment. Chicago (IL): National Headache Foundation; 2004. p. 59-72. [38 references]

ADAPTATION

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

DATE RELEASED

2004

GUIDELINE DEVELOPER(S)

National Headache Foundation - Private Nonprofit Organization

SOURCE(S) OF FUNDING

National Headache Foundation

GUIDELINE COMMITTEE

Not stated

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Authors: David Biondi, DO, and Paula Mendes, MD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: None available

Print copies: Available from the National Headache Foundation, 820 N. Orleans, Suite 218, Chicago, IL 60610; Phone: (888) NHF-5552; Web address: www.headaches.org

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- The complete headache chart. Chicago (IL): National Headache Foundation (NHF); 2 p. Electronic copies available in Portable Document Format (PDF) from the [National Headache Foundation Web site](#)
- National Headache Foundation fact sheet. Chicago (IL): National Headache Foundation (NHF); 2004 Oct. 2 p. Electronic copies available in Portable Document Format (PDF) from the [National Headache Foundation Web site](#).

Print copies: Available from the National Headache Foundation, 820 N. Orleans, Suite 218, Chicago, IL 60610; Phone: (888) NHF-5552; Web address: www.headaches.org

PATIENT RESOURCES

The National Headache Foundation (NHF) has created a variety of educational resources for patients, including informative brochures, a patient diary for migraines, Power Point presentations, and patient guides; many of these resources are available in both Spanish and English. Some of these items are available as print copies for purchase through the [NHF online store](#). Electronic versions of other resources are available through the consumer education section of the [NHF Web site](#).

Print copies: Available from the National Headache Foundation, 820 N. Orleans, Suite 218, Chicago, IL 60610; Phone: (888) NHF-5552; Web address: www.headaches.org.

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 NGC summary was completed by ECRI on April 11, 2005. The information was verified by the guideline developer on April 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. This summary was updated by ECRI Institute on May 8, 2007, following the U.S. Food and Drug Administration advisory on Zanaflex (tizanidine hydrochloride). This summary was updated by ECRI Institute on November 9, 2007, following the U.S. Food and Drug Administration advisory on Antidepressant drugs.

COPYRIGHT STATEMENT

These guidelines are for reference purposes only and are not to be mass produced. This information is copyrighted by the National Headache Foundation, 2005.

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.

© 1998-2008 National Guideline Clearinghouse

Date Modified: 10/6/2008

