Complete Summary

GUIDELINE TITLE

Treatment of primary headache: episodic tension-type headache. Standards of care for headache diagnosis and treatment.

BIBLIOGRAPHIC SOURCE(S)

Ruoff G, Urban G. Treatment of primary headache: episodic tension-type headache. In: Standards of care for headache diagnosis and treatment. Chicago (IL): National Headache Foundation; 2004. p. 53-8. [6 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 information has been released.

- June 15, 2005, COX-2 Selective (includes Bextra, Celebrex, and Vioxx) and Non-Selective Non-Steroidal Anti-Inflammatory Drugs (NSAIDs): Labeling revised to include a boxed warning and a Medication Guide, highlighting the potential for increased risk of cardiovascular (CV) events and life-threatening gastrointestinal (GI) bleeding.
- April 7, 2005, Bextra (valdecoxib), Cox-2 inhibitors, Celebrex (celecoxib), Non-steroidal anti-inflammatory drugs (NSAIDS) (prescription and OTC, including ibuprofen and naproxen: Bextra (valdecoxib) withdrawn from the market and labels for other Cox-2 inhibitors and NSAIDS revised to include a boxed warning and a Medication Guide, highlighting the potential for increased risk of cardiovascular (CV) events and life-threatening gastrointestinal (GI) bleeding.

Additional Notice

- 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).

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SCOPE

DISEASE/CONDITION(S)

Episodic tension-type headache (TTH)

GUIDELINE CATEGORY

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 design a treatment plan, combining nonpharmacologic with pharmacologic approaches as necessary to:
    - Minimize symptomatology
    - Reduce disability
    - Improve quality of life
- To make practicing physicians aware of the existence of tension-type headache (TTH), as well as general treatment strategies for it, including both drug and nondrug approaches

TARGET POPULATION

Patients with episodic tension-type headache (TTH)

INTERVENTIONS AND PRACTICES CONSIDERED

Drug Treatment

Simple Over-the-Counter Analgesics

1. Aspirin
2. Acetaminophen
3. Nonsteroidal anti-inflammatory drugs (NSAIDs)
    - Acetylsalicylic acid
    - Ibuprofen
    - Naproxen sodium

Over-the-Counter Combination Analgesics

1. Aspirin/caffeine
2. Acetaminophen/caffeine
3. Aspirin/acetaminophen/caffeine

Prescription Medications

1. NSAIDs
    - Celecoxib
    - Diclofenac
    - Diflunisal
    - Etodolac
    - Fenoprofen
    - Flurbiprofen
    - Ibuprofen
    - Indomethacin
    - Ketoprofen
    - Ketorolac
    - Meclofenamate
    - Mefenamic acid
    - Meloxicam
    - Nabumetone
    - Naproxen
    - Naproxen sodium
    - Rofecoxib
    - Salsalate
    - Tolmetin
    - Valdecoxib
2. Muscle relaxants, alone or combination
    - Baclofen
    - Carisoprodol
    - Carisoprodol/aspirin
    - Chlorzoxazone
    - Cyclobenzaprine
    - Metaxalone
    - Methocarbamol

    - Orphenadrine citrate
    - Orphenadrine citrate/aspirin/caffeine
    - Tizanidine
3. Barbiturate-containing analgesics
    - Butalbital/aspirin/caffeine
    - Butalbital/acetaminophen/caffeine
    - Butalbital/acetaminophen
4. Other
    - Isometheptene mucate/dichloralphenazone/acetaminophen

Nondrug Treatments

1. Relaxation techniques
2. Proper sleep and diet habits
3. Exercise
4. Avoidance of behaviors or situations that may trigger an attack
5. Biofeedback
6. Physical interventions
    - Acupuncture and acupressure
    - Heat or cold applications

MAJOR OUTCOMES CONSIDERED

Not stated

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

Episodic Tension-Type Headache (TTH)

Drug Treatment

Once a more serious underlying condition has been ruled out, the goal of TTH therapy is acute intervention with the simplest, most effective, and best-tolerated agent (see figure 5.1 of the original guideline document). Selection of an appropriate therapeutic approach is based on a thorough history, including the patient's response to previous treatments and an assessment of the impact of the

attacks on the patient's quality of life. Physicians should specifically inquire about over-the-counter (OTC) medications, as few patients recognize how differences in this class of analgesics can affect subsequent treatment (see table 5.1 of the original guideline document for guidelines for use of selected abortive therapies in the treatment of TTH).

Simple OTC Analgesics

Unless the patient has already tried simple analgesics without success, treatment of TTH should begin with a nonprescription aspirin, acetaminophen, or nonsteroidal anti-inflammatory drug (NSAID) such as ibuprofen, naproxen sodium, or ketoprofen. In general, recommend a relatively high dose and stress the importance of early intervention to maximize effectiveness.

OTC Combination Analgesics

If simple analgesics fail, consider recommending a nonprescription medication that contains aspirin and/or acetaminophen with the addition of caffeine. Caffeine is an adjunct that provides mild vasoconstrictive, psychomimetic, and pain-enhancing action as well as a gastrokinetic effect.

Prescription Medications

If OTC analgesics are unsuccessful, prescription medications are the next appropriate step, including NSAIDs and barbiturate-containing medications (see table below). Keep in mind that the response to NSAIDs is highly individual, and failure of one agent should not preclude the use of another for future attacks. Further, prescribe barbiturate-containing products only with extreme caution, as they have a strong tendency to induce analgesic rebound, which often leads to their overuse.

Prescription NSAIDs and Barbiturate-Containing Analgesics	
NSAIDs	**Barbiturate-Containing Analgesics**
• Celecoxib • Diclofenac • Etodolac • Fenoprofen • Flurbiprofen • Indomethacin • Ibuprofen • Ketoprofen • Ketorolac • Mefenamic acid • Meloxicam • Nabumetone • Naproxen • Naproxen sodium • Rofecoxib* • Salsalate • Valdecoxib**	• Butalbital/aspirin/caffeine • Butalbital/acetaminophen/caffeine • Butalbital/acetaminophen

*On September 30, 2004, Vioxx (rofecoxib) was withdrawn from the U.S. and worldwide market due to safety concerns of an increased risk of cardiovascular events. See the U.S. Food and Drug Administration (FDA) Web site for more information.

**Subsequently, on April 7, 2005, after concluding that the overall risk versus benefit profile is unfavorable, the FDA requested that Pfizer, Inc voluntarily withdraw Bextra (valdecoxib) from the market. The FDA also asked manufacturers of all marketed prescription nonsteroidal anti-inflammatory drugs (NSAIDs), including Celebrex (celecoxib), a COX-2 selective NSAID, to revise the labeling (package insert) for their products to include a boxed warning and a Medication Guide. Finally, FDA asked manufacturers of non-prescription (over the counter [OTC]) NSAIDs to revise their labeling to include more specific information about the potential gastrointestinal (GI) and cardiovascular (CV) risks, and information to assist consumers in the safe use of the drug. See the FDA Web site for more information.

Additional Prescribing Considerations

Preventive therapy is not required unless the number of TTH attacks exceeds 15 per month. Muscle relaxants with or without analgesics may be used effectively, if the attacks are associated with the pericranial muscles (see table below). In rare cases, depression, anxiety, or both may be associated with TTH and should be treated as appropriate.

Muscle Relaxants with/without Analgesics
• Baclofen • Carisoprodol • Carisoprodol/aspirin • Chlorzoxazone • Cyclobenzaprine • Metaxalone • Methocarbamol • Orphenadrine • Orphenadrine/aspirin/caffeine • Tizanidine • Isometheptene/dichloralphenazone/acetaminophen

Safety Issues

Physicians should be aware of, and should thoroughly explain to the patient, any potential side effects associated with treatments for TTH. For example, prolonged use or abuse of analgesics may lead to gastrointestinal irritation, impair platelet function, and cause renal or hepatic complications. Barbiturate-containing analgesics may cause drowsiness, analgesic rebound headache, and habituation.

Patients should always be reminded to follow precisely the recommended usage for any acute headache medication. For example, patients who medicate their attacks on a daily or near-daily basis may be susceptible to the rebound phenomenon. Although the medication initially relieves the pain, response may

gradually decrease over time, prompting the gradual use of additional medication. As this cycle continues - and worsens - the patient may ultimately develop chronic TTH or daily headache. Reminding patients to limit their use of acute medications to a single dose (with one repeat dose if pain persists) may help to avoid a serious problem before it begins.

Nondrug Treatments

Nondrug treatments can be an effective approach to TTH treatment, especially when used in conjunction with medication. Strategies include relaxation techniques, proper sleep and diet habits, exercise, and avoidance of behaviors or situations that may trigger an attack. Biofeedback has been used successfully in practice, but clinical studies on its effectiveness have been inconclusive. Physical interventions, such as acupuncture and acupressure, as well as simple heat or cold applications may also be useful.

CLINICAL ALGORITHM(S)

A clinical algorithm is provided for the pharmacologic approach to tension-type headache (TTH)

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 treatment of episodic tension-type headache (TTH)

POTENTIAL HARMS

- Prolonged use or abuse of analgesics may lead to gastrointestinal irritation, impair platelet function, and cause renal or hepatic complications.
- Barbiturate-containing analgesics may cause drowsiness, analgesic rebound headache, and habituation.
- Patients who medicate their attacks on a daily or near-daily basis may be susceptible to the rebound phenomenon. Although the medication initially relieves the pain, response may gradually decrease over time, prompting the gradual use of additional medication. As this cycle continues - and worsens - the patient may ultimately develop chronic TTH or daily headache.

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
Clinical Algorithm
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

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Ruoff G, Urban G. Treatment of primary headache: episodic tension-type headache. In: Standards of care for headache diagnosis and treatment. Chicago (IL): National Headache Foundation; 2004. p. 53-8. [6 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: Gary Ruoff, MD, and George Urban, 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 June 16, 2005, following the U.S. Food and Drug Administration advisory on COX-2 selective and non-selective non-steroidal anti-inflammatory drugs (NSAIDs). This summary was updated by ECRI Institute on May 8, 2007, following the U.S. Food and Drug Administration advisory on Zanaflex (tizanidine hydrochloride).

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