THE ACUTE CARE APPROACH TO MIGRAINE TREATMENT:
STRATIFIED APPROACH TO OPIOID AND NON-OPIOID
PHARMACOLOGIC AGENTS

By

Tara Lynn Morris

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The members of the committee appointed to examine the College of Nursing and Washington State University requirements and manuscript of TARA L. MORRIS find it satisfactory and recommend that it be accepted.

Chair

Laura Hahn
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Acute Care Approach To Migraine Treatment: Stratified Approach To Opioid and Non-Opioid Pharmacologic Agents

By Tara Morris, BSN, RN, FNP Student

Abstract

As many as 30 million Americans suffer from migraines. Migraine is a highly disabling condition associated with a substantial economic burden (Diamond, 2007 p.1269). As noted by Hurtado, Vinson and Vandenberg, an estimated 1-2% of emergency department (ED) visits are due to migraine symptoms and ED providers use over 30 medications for the treatment of headaches. A review of the 1998 National Hospital Ambulatory Medical Care Survey demonstrated that the majority of patients treated for migraine headache in the ED in the US are treated with opioid agonists. Current guidelines suggest the use of non-opioid medications as the initial treatment for acute migraine (Moriarty-Sheehan, 2002). The purpose of this manuscript is to provide a detailed look into suggested guidelines for migraine therapy, involving opioid and non-opioid medication options and the use of a stratified treatment approach.
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The Acute Care Approach to Migraine Treatment: Stratified Approach With The Use Of Opioid and Non-Opioid Pharmacologic Agents

Introduction

“Migraine headache is a common and often disabling health problem. It has been estimated that 6% of men and 15-17% of women experience migraine worldwide (Colman 2004 p. 1695).” Migraine is characterized by episodic attacks that may be described as unilateral and pulsatile ranging in moderate to severe intensity, aggravated by physical activity. Associated signs and symptoms may include precluding aura, photophobia, phonophobia and nausea, with or without vomiting. In fact “emergency department (ED) patients report headache as one of their top 3 complaints, 5% of the time” (Hurtado 2007 p. 1135).

With the shortage of healthcare providers, emergency departments are becoming overwhelmed with primary care complaints. As a result, patient wait times have increased and patient satisfaction has decreased. In an effort to invert these relationships, hospitals are focusing on quicker turn around times.

In attempts to alleviate migraine symptoms, patients often times present to the ED having already tried a variety of pharmacologic therapy without relief. One of the more common methods for relief of migraine symptoms is the use of opioid analgesics. The use of opioid analgesics vs. non-opioid agents for the treatment of migraine has stimulated a controversial debate.

When treating migraine in the ED one must consider efficacy and speed. Previous algorithms have favored step-care in migraine management as the treatment of choice when introducing pharmacologic agents. The step-care approach offers treatment options in a ‘ladder’ fashion. There is no regard to patient severity of symptoms and medication is started from first-line options to second-line options and progress with each ‘failed’ rung. This system has proven to be more costly, and non-compliance is higher due to patient frustration. The step-care approach requires that patients try lower rung therapy first. If that fails, patients may step up to the next level with each succeeding migraine. This approach leads to
patient dissatisfaction and provider frustration. An example of step-care may be when a patient presents with migraine and therapy is first aimed at over-the-counter (OTC) analgesics, if this fails then a provider might suggest dihydroergotamine (DHE) or triptan medication. By this time these medications might prove to be ineffective, because the migraine is already well-established. With continued pain, opiates or higher level options may be suggested. Patients may get frustrated with this process, because it takes multiple patient visits, including co-pay and increased time to subdue headache. “The step-care approach aims to prevent the overtreatment of migraine and minimize treatment costs by restricting the use of the more expensive specific agents (Lucas 2006 p10).”

Recent studies have shown that the stratified approach, where acute treatment is based on patient disability, is more cost-effective and offers higher levels of success with regards to pain relief. Acute treatment is based on the degree of the patient’s disability. Patients with moderate to severe migraine are prescribed migraine-specific agents, such as the 5-HT agonists (triptans), while those with mild migraine are treated with simple analgesics. This treatment plan focuses on migraine specific treatment, when patients are experiencing disability caused by pain. As a result, the stratified care model in the ED offers specific options for treatment that are advantageous to the patient and to the ED process.

Levels of treatment offered in the stratified approach depend on severity of patients’ symptoms. The first level for treatment of mild to moderate pain includes simple non-specific analgesics, such as acetaminophen, aspirin and ibuprofen. These options may also include an anti-emetic for treatment of nausea with or without vomiting. For mild to moderate pain with poor response from non-specific therapy, treatment plans may include the use of triptans or dihydroergotamine (DHE). This modality may also be attempted for those with moderate to severe pain who have not yet attempted using these specific migraine agents. When migraine is moderate to severe and accompanied with nausea and vomiting, oral routes of administration should be avoided. The use of non-specific migraine agents such as opioids, non-steroidal anti-inflammatory drugs (NSAIDS) and combination drugs may also be introduced when migraine is rated in the moderate to severe category. It can be argued that rating pain from mild to severe
is subjective; Table I offers a detailed assessment tool in classifying migraine disability and treatment of migraine to the level of pain identified. Treatment plans for migraine patients have proven to be challenging due to the importance of individuation of therapies for specific patient responses.

**Purpose**

The purpose of this article is to review if the existing literature supports the use of stratified migraine treatment with the use of opioid and non-opioid pharmacologic agents as opposed to step-care migraine treatment. The literature supports the use of stratified migraine therapy because it more appropriately addresses specific patient needs. Using such literature support, the author will propose a stratified treatment plan based on current guideline recommendations for treatment of migraine, utilizing an algorithm which should provide adequate functionality in an ED setting. The author suggests that such a tool will benefit providers with a method which standardizes migraine treatment utilizing a stratified approach.

**Pathophysiology**

The cause of migraine headache is not clearly understood. Frazel notes that “Current theory proposes that migraine is a neurovascular disorder of the central nervous system that involves a cortical spreading depression phenomena and an activation of the trigeminal-vascular system (2004 p. 22)” Various clinical and experimental studies suggest that “the mechanism of the migraine headache pain has three components. The first component involves vasodilatation of intracranial blood vessels stimulating trigeminal nerve terminals to send pain impulses to the pain receptors in the brain stem, thalamic nuclei, and cortex. Trigeminal nerve excitation triggers the second component—a release of neuropeptides from nerve fibers involved in pain transmission, including substance P, neurokinin A, and calcitonin gene related peptide. The neuropeptides exacerbate vasodilatation, thereby escalating trigeminal nerve activation and intensifying headache pain. The third component involves recruitment and sensitization of second order sensory neurons of the trigeminal nuclei in the caudal brain stem and upper cervical spinal
tract. This central sensitization can produce symptoms of pain-associated phenomena known as 
hyperalgesia (lowered pain threshold) and cutaneous allodynia (pain resulting from an innocuous stimulus 
to normal skin or scalp (Frazel 2004 p. 23).” “The trigeminal nerve, in addition to supplying the major 
somatosensory innervations to the extracranial tissues of the anterior head and face, also has a much 
smaller intracranial component that provides sensory innervations to the cranial meninges. Thus, 
myelinated nerve fibers in the intracranial dura were assumed to have sensory function. This idea was 
strengthened by neurosurgical observations that direct stimulation of the meninges, particularly at 
vascular sites, could evoke painful, headache-like sensations (Strassman & Levy 2006 p. 1299).” See 
Figure 1.

The goal of migraine treatment continues to be avoidance of triggers, prophylactic avenues and pain 
relief from acute attacks. Headache is primarily a subjective symptom, which makes it difficult to study 
because no objective measures or standardizations are available and studies are relegated to humans.

Literature Review

Therapies for migraine treatment are broken down into prophylactic treatment and acute treatment based on the severity of symptoms. “Acute treatment is necessary for almost all patients, its aims being to reduce the severity of the pain and associated symptoms, and to lessen the impact of migraine on daily functioning (D’amico 2006 p. 117).” Peters and colleagues (2005) report that between 80%-99% of migraine patients rely on some acute medication for their attacks and only between 5%-11% of patients in population-based studies used prophylactic medications. Despite the majority of migraine patients relying on medication, only between 25% and 36% of migraine sufferers are satisfied with management of their migraine. This same study evaluated different treatment options and found that early stratified care yields the best results focusing on early triptan administration. “Patients with minimal or mild disability can be treated with non-specific drugs (NSAIDs, analgesics); Those with moderate to severe disability are given triptans as first-choice treatment. With stratified care, more disabled patients are
likely to receive migraine-specific treatment sooner than in step-care, reducing their suffering and minimizing risks of lapsing from care, self-medicating and overusing medications” (Peters 2005).

Colman, Rothney, Wright, Zilkalns and Rowe (2004) found that acute migraine management by ED providers did not follow current migraine treatment guidelines. This study used a retrospective chart review design evaluating 500 acute migraine headache patient charts from five Canadian ED’s. This study evaluated many different factors regarding treatment such as patient history, additional symptoms (nausea, vomiting, photophobia, meds prior to ED visit), and time of ED visit. This study found that time spent in the ED was significantly shorter for those who received narcotic analgesics, with meperidine being used 73% of the time, as a first-line agent compared with those who did not. Those who received first-line narcotics were significantly more likely to return to the same ED with a headache within 7 days of the original visit. This rebound effect may be caused by opiate overuse, dependence and/or tolerance. Patients who had taken anti-headache medications prior to ED presentation were two and half times more likely to receive narcotics. The utilization of first-line narcotic administration as a treatment modality appears to be primarily a treatment of convenience in an ED setting. But such ‘convenient’ treatment in reality becomes an inconvenience with added costs and provider effort as the patient returns within a short period for further treatment. “Acute migraine management in these ED’s does not meet current consensus guidelines. Factors associated with narcotic use are predictable, and a concerted effort to replace narcotics with more evidence-based first-line treatments is needed (Colman 2004)”.

Dodick et al. completed a study that analyzed data pooled from 10 randomized, double-blind, placebo-controlled, parallel-group studies evaluating the efficacy and tolerability of eletriptan in the acute treatment of migraine headaches. “A multivariable logistic regression analysis identified significant predictors of headache recurrence. This study found that female gender, age ≥ or equal to 35 years, and severe baseline headache pain are significant predictors of headache recurrence during a migraine attack (Dodick 2004 p. 184).”
Hurtado, Vinson and Vandenberg (2007) found that emergency providers report that a variety of factors influence their parenteral pharmacotherapy in the management of patients with migraine headache. A descriptive analysis done by Hurtado, Vinson and Vandenberg found that, “the majority of ED providers initial drug of choice was dopaminergic antiemetics 93% of the time and parenteral NSAIDs 22% of the time. If initial therapy failed, an opioid with a non-specific antiemetic was used 40% and 24% of the time respectively. Opioid use was influenced by patients’ failure to respond to ED and outpatient alternatives and the presence of contraindications and or intolerances to non-opioids (Hurtado 2006 p.1134).” This study consisted of 105 ED providers ranging from physician assistants, residents and attending physicians from 5 different emergency departments. The evaluation tool consisted of a 5-point Likert scale to evaluate medication choices and factors that influenced their treatment decision. Choice of therapy was influenced by medication availability and its anti-migraine properties. The most important factors that influenced initial choices of medications were the effectiveness of the medication as determine by the provider at aborting migraine headache and the availability of this medication in the ED (Hurtado 2007). The authors suggest that additional research be done to determine why providers choose one class of medication over another. The authors also question why providers are not using DHE or triptan therapy despite the fact that they are recommended as first-line therapy.

A review of Lucas (2006) found that early intervention with triptans is supported by our understanding of the pathophysiology of migraine. The early phase of migraine is characterized by the peripheral sensitization of trigeminovascular neurons and the development of headache pain. The progression of a migraine attack involves central sensitization of trigeminovascular neurons with associated increasing severity of headache pain. Triptans have been shown to be significantly more efficacious than placebo for treating migraine headache when taken during moderate-to-severe pain.

Diamond (2007) provides a literature review that details many treatment options available for acute and preventative treatment of migraine; focusing on the fact that treatment should be tailored to the specific needs of each patient. For the treatment of acute migraine, Diamond states “The primary goals of
acute therapies are to abort and reduce the severity and duration of attacks and to reduce the disability associated with an attack…medication should be prescribed on the basis of anticipated severity of attack, and the route of administration should be chosen according to individual patient needs (2007 p.1273).”

Recommendations for mild attack focus on over-the-counter (OTC) analgesics such as; NSAIDS, acetaminophen, as well as caffeine containing products. Moderate pain relief is best relieved by early use of triptans. When triptans are contraindicated or too expensive, higher doses of non-specific pain medications may be substituted. Pain medications that are non-specific to migraine may include narcotics, NSAIDS and or dopaminergic anti-emetics.

Frazel (2004) discussed the use of the U.S. Headache Consortium guidelines to provide a framework for optimizing migraine diagnosis and treatment. By using the stratified care model along with patient education, providers can offer individualized care to migraine patients. This article offered a 5-step schematic for optimal migraine management. Treatment plans ranged from mild to moderate migraine up to severe advanced migraine that failed to respond to other treatments.

Friedman, Corbo, Lipton, Bijur, Esses, Solorzano et. al. (2005) compared the use of aggressive IV metoclopramide therapy and standard dose of subcutaneous (SQ) sumatriptan. This study utilized 78 of 91 eligible patients. By using a randomized, double-blind, clinical trial with two intervention arms, Friedman et al. found that migraine patients experienced a comparable amount of pain relief at both 2 and 24 hours after treatment.

Goolsby (2003) discusses the use of clinical practice guidelines in the treatment of migraine headaches, whose review provides a detailed look into migraine diagnosis, acute therapy and preventative therapy. Acute therapy recommendations are aimed at the use of a step-approach with administration of NSAIDs, as first-line treatment. Second-line treatment involves the use of DHE, triptans and opiate combinations. Readers are advised to limit acute treatment of migraine to no more than twice a week due to increased incidence of headache. Moriarty-Sheehan (2002) describes the use of triptans in the
treatment of migraine. Although patient response to triptans varied, she discussed the provider role in helping to determine the most efficacious treatment course. "With stratified care, acute treatment is based on the degree of the patient's disability. Patients with moderate to severe migraine are prescribed migraine-specific agents, such as triptans, while those with mild migraine are treated with simple analgesics...triptans should be considered first-line agents for moderate to severe migraine to avoid wasting time and money on ineffective agents (2002 p. 357)."

Ko and Sahai-Srivastava (2008) suggested a long term treatment plan including 5 steps. Step 1 involves an accurate clinical diagnosis based on International Headache Society (IHS) criteria, step 2 requires a disability exam using the Migraine Disability Assessment Scale (MIDAS) Table 1. Step 3 is a stratified treatment plan for migraine. Treatment ranges from NSAID treatment for mild symptoms, triptan and ergots for moderate disability and parenteral or inhaled form of triptans for patients with severe headache and nausea. Step 4 is to individualize treatment for the patient and Step 5 is patient education focusing on avoiding triggers, keeping a headache diary and prophylaxis. This treatment option would best be used in the primary care setting or in a pain clinic for individual patients.

The article titled 'Opioid Therapy for Migraine" summarized the pros and cons in the use of opioid therapy. It surmised that this class of medications can be useful in treating acute pain, but the short-acting opioids are not typically appropriate for chronic long-term use. Apart from the article by Colman et al., other articles failed to directly compare ED provider migraine treatment to current guidelines. These studies did not evaluate the many different factors that guide provider treatment choices, such as hospital formulary, prior patient visits, pain contracts, prior attempt at first line treatment, allergies and cardiac history.

Theoretical Framework

Roy's Adaptation Model was used in the evaluation for this review. This model explains that humans are adaptive systems that cope with change through adaptation. Although evidence based practice has
provided a guideline for the treatment of migraine, independent providers have adapted the treatment of migraine to their environment and comfort level with certain medication regimens. Practice has been molded to fit provider needs and not necessarily individual patient needs. Patients have also adapted with living with migraine symptoms, dealing with pharmacological and non-pharmacological therapies and adapting to different provider treatment modalities. Patients have the freedom of choice to seek care from different providers until they find one that works best for their needs.

Discussion

This multifaceted issue of providing migraine patients with adequate pain relief has no easy answer. The many diversions center on the fact that pain is a very individualistic response. Providers have the autonomy to treat pain in many different ways, and migraine not truly understood can have several different etiologies. A literature review seems to support a stratified-care approach to migraine treatment. This treatment varies depending upon several key elements. These elements are based on a thorough history and physical exam. Upon assessment providers must determine a level of disability to institute pharmacologic treatment. Recommendations starting from OTC analgesics as first line therapy are often tried prior to emergency department assistance. Triptans are commonly used in the outpatient setting for migraine prophylaxis; however ineffective pain relief may force patients to require additional assistance. Patients seeking additional therapies are often forced to visit emergency departments because of higher level pharmacological access in the treatment of acute migraine pain.

In the acute care setting providers have a variety of pharmacological choices depending on pharmacy formulary. This formulary may steer providers’ treatment choices. Because of this, it may be suggested that acute care facilities offer a treatment guideline to providers that is specific to its formulary. The suggested treatment guideline in the form of an algorithm can assist providers in adequate stratified pharmacological treatment in migraine patients with pain ranging from mild to severe. This algorithm allows providers to follow the stratified approach in the treatment of migraines, while staying within
Implementation of an acute care migraine therapy guideline offers providers a consistent treatment plan for migraine patients. This treatment plan provides a collaborative approach in the use of pharmacological migraine therapies. Although this guideline will be specific to each institution, therapies will include: NSAIDS, triptans, DHE, anti-emetics and opiates. Factors to be considered are: patient age, patient weight, allergies, previous migraine history, previous migraine work-up, contraindications to treatment options, physical exam, and route of medication administration. It is suggested that continued research be done on the use of a stratified treatment plan for migraine therapy. In addition to a stratified treatment plan, further investigation is needed with the use of triptans, NSAIDS and opiates for migraine.
### Table 1  Migraine Disability Assessment Instrument

To determine the MIDAS Score, total the numbers given in answer to questions 1-5 and determine treatment needs from MIDAS stratification scale. Questions A and B are not used to calculate the MIDAS score but provide additional information that may be helpful in determining a treatment plan. Please note: MIDAS scores >20 are of limited benefit in headache evaluation.

1. On how many days in the last 3 months did you miss work or school because of your headaches? ____ days

2. How many days in the last 3 months was your productivity at work or school reduced by half or more because of your headaches? ____ days

3. On how many days in the last 3 months did you not do household work because of your headaches? ____ days

4. How many days in the last 3 months was your productivity in household work reduced by half or more because of your headaches? ____ days

5. On how many days in the last 3 months did you miss family, school or leisure activities because of your headaches? ____ days

**Total Score** ........................................................................................................... ____ TOTAL

a. On how many days in the last 3 months did you have a headache (If headache lasted more than 1 day, count each day) ____ days

b. On a scale of 0-10, on average how painful were these headaches? (Where 0=no pain at all, and 10=pain as bad as it can be) ____

### MIDAS score stratification scale:

- Grade I: Score 0-5 Low or no treatment needs
- Grade II: Score 6-10 Moderate treatment needs
- Grade III: Score 11-20 High treatment needs
- Grade IV: Score >21 Urgent treatment needs

Based on MIDAS grade and headache frequency, select treatment from the MIDAS algorithm, considering drug contraindications and warnings, the patient's prior experiences with the various treatments, and the therapies already tried for this particular episode.

#### MIDAS-based Treatment Algorithm

<table>
<thead>
<tr>
<th>Mild to moderate intermittent migraine (MIDAS Grade I-II)</th>
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<tr>
<td>Mild to moderate frequent migraine (MIDAS Grade I-II)</td>
<td>Prophylaxis</td>
</tr>
<tr>
<td>Mild to moderate migraine previously failed on NSAIDS or combination analgesics (MIDAS Grade I-II)</td>
<td>Triptans, Dihydroergotamine, Rescue Medication</td>
</tr>
<tr>
<td>Moderate to severe infrequent migraine (MIDAS Grade I-II)</td>
<td>Triptans, Dihydroergotamine, Rescue Medication</td>
</tr>
<tr>
<td>Moderate to severe infrequent migraine (MIDAS Grade III-IV)</td>
<td>Triptans, Dihydroergotamine, Rescue Medication</td>
</tr>
<tr>
<td>Moderate to severe frequent migraine (MIDAS Grade III-IV)</td>
<td>Prophylaxis</td>
</tr>
<tr>
<td>Very frequent headaches (MIDAS Grade IV)</td>
<td>Suspect chronic daily headache, diagnose and treat accordingly</td>
</tr>
</tbody>
</table>

www.pplusic.com-UW Health Adult Migraine Assessment & Treatment Guideline
Cross-section of the human brain showing some of the nerve connections that may be involved in migraine

www.drugdevelopment-technology.com
Yakima Valley Memorial Hospital Migraine Treatment Algorithm

Patient Weight: ________
Patient Allergies: ________________________________
Contraindications: Allergy  CAD  CVA  HTN  Pregnancy
Associated Signs and Symptoms: Nausea with vomiting Nausea without vomiting
                             Photophobia     Phonophobia
                             Aura             Neurological Deficit
Previous CT scan: yes/no

*Tier assignment is based on patient presentation, level of disability and physical exam.

Tier I
- Ibuprofen 800mg PO
- Zofran ODT 4mg PO
- Imitrex 50mg PO

Tier II
- Imitrex 6 mg SQ
- Ketorolac 60mg IM
- Promethazine 25mg IM or
- Vistaril 25mg IM
- Hydromorphone 1-2mg IM or
- Morphine 7.5-10mg IM

Tier III
- Consider IV fluid bolus 1 liter NS
- Ketorolac 30mg IV
- Prochlorperazine 10mg IV or
- Metoclopramide 10mg IV or
- Ondansetron 4mg IV
- Hydromorphone 1-2mg IV or
- Morphine 5-10mg IV

*Discharge patient home with escort, verbal and written instructions. Instruct patient to go home and rest in dark, quiet area. Follow up with primary care provider in 1-2 days or return to ED sooner if worse.

September, 2009-draft 1
References


Watson, J.. (2008, Sep.). Head pain strikes at will, but primary headaches are easily treated-and even prevented. Retrieved May 17, 2009 from CINAHL with full text database.