

10:30 - 11:45 am

Improving Outcomes in Episodic Migraine

SPEAKERS
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primed

Presenter Disclosure Information

The following relationships exist related to this presentation:

- ▶ D. Michael Ready, MD: No financial relationships to disclose
- ► Anne H. Calhoun, MD: Speakers Bureau for Depomed, Inc.; Merck & Co, Inc.; and Teva Pharmaceuticals. Researcher for DuraMed Inc.; Scion Neuro Stim, LLC; and Autonomic Technologies. Consultant for Depomed, Inc.; and Teva Pharmaceuticals.

Off-Label/Investigational Discussion

► In accordance with pmiCME policy, faculty have been asked to disclose discussion of unlabeled or unapproved use(s) of drugs or devices during the course of their presentations.

Drug List

- · Almotriptan (Axert)
- · Diclofenac (Cambia)
- · Dihydroergotamine (Migranal nasal spray, generic DHE)
- Eletriptan (Relpax)
- · Ergotamine tartrate (Ergomar, generic)
- Frovatriptan (Frova)
- Naratriptan (Amerge, generic)
- · Rizatriptan (Maxalt, generic)
- Sumatriptan (Imitrex, generic)Sumatriptan (Imitrex Nasal Spray)
- Surnatriptan (Imittee Nasai Spray)
 Sumatriptan (Imittee STATdose, Sumavel DosePro, Alsuma, generic)
- Sumatriptan plus naproxen (Treximet)
- Sumatriptan plus naproxen (Trexinet)
 Sumatriptan iontophoretic transdermal system (Zecuity)
- Zolmitriptan (Zomig)
- Zolmitriptan (Zomig Nasal Spray)

Improving Outcomes in Episodic Migraine

Learning Objectives

- Employ key elements associated with assessment techniques to recognize primary headache syndromes in the presenting patient
- Correctly apply criteria for the clinical and differential diagnosis of episodic migraine
- Develop strategies for the optimal treatment of episodic migraine for improved quality of life in headache patients
- Summarize pharmacologic profiles, including safety and efficacy of current treatment options to develop an individualized management plan

Epidemiology

- Migraine affects approximately 36 million Americans
- Clear gender differences: affects more women than men
- Returning armed forces 38% females, 58% males, 20% Chronic Daily Headache
- Episodic migraine (EM); <15 days/month
 - 18% women vs 6% men
- Chronic migraine (CM); >15 days/month
 - Overall prevalence of CM: 1% to 3%
 - Three times more common in women than in men
- · Prevalence peaks during mid life

Lipton RB, et al. Neurology. 2007;68:343-349.; Bigal ME, et al. 2008;71(8):559-566.; Buse DC, et al Headache. 2013;53(8):1278-1299.; Natoli JL, et al. Cephalgia. 2010;30(5):599-609.

Migraine Consequences

- Economic burden in United States: >\$18B in 20041
- A leading cause of outpatient and emergency department (ED) visits²
 - Fourth leading cause of ED visits (adults) 2.8% of all visits³
- Important public health problem especially among reproductive-aged women²
- Significant effect on physical, social, and occupational functioning
- Quality of life (QoL) significantly more impaired in patients with CM vs EM⁴

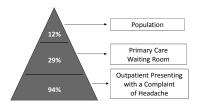
¹Hawkins K, et al. *Headache*. 2008;48(4):553-563.; ²Burch RC, et al. *Headache*. 2015;55(1):21-34.; ³Pitts SR, et al. *www.cdc.gov/nchs/data/nhsr/nhsr*007.pdf. ⁴Caunet L, et al. *Clin Neurosci*. 2008;62(6);738-740.

Quality of Life Issues

- Migraine has a negative impact on overall quality of life and is associated with:
 - Decreased productivity
 - Missed time from work, school, and other activities
 - Medical comorbidities

Bamford CC, Tepper SJ. Tech Reg Anesth Pain Manag. 2009;13(1):20-27.; Bigal ME, et al. Headache. 2009;49 Suppl 1:S21-S33.; Cutrer FM. Semin Neurol. 2010;30(2):120-130.; Diamond S, et al. Headache. 2007;47(3):355-363.; Headache Classification Committee of the International Headache Society. Cephalalgia. 2004;24(Suppl 1):629-808.

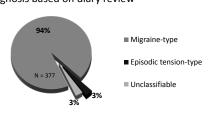
The Prevalence of Migraine in Primary Care



Lipton RB, et al. Neurology. 2007;68: 343-349.; Couch J, et al. Headache. 2003;43:570-571.; Tenner SI. et al. Headache. 2004:44:856-864.

Migraine – The Most Common Headache in Clinical Practice

- · Headache patients presenting in primary care
- IHS diagnosis based on diary review



IHS=International Headache Society
Tepper SJ, et al. Headache. 2004;44:856-864.

Role of Primary Care in Migraine

- >37% of women of reproductive age in a physician's waiting room have migraine
- People with episodic tension headache rarely seek medical advice
- Other primary headache disorders infrequently appear in a primary care office
- Chronic condition they will need a lifetime of care, they will need a good PCP
 - Only 520 certified headache specialists in the US

PCP=primary care physician
Couch JC, et al. Headache, 2003;43:570-571.

Diagnostic Challenges in Differentiating Episodic and Chronic Migraine

Case Study: Newly Diagnosed Migraine

Mary is a 34-year-old Caucasian female, married mother of 2 children under the age of 10

Headache history

- History of frequent headaches since the birth of her children
- Has had some relief with OTC remedies
- Reports having "several" headaches

Physical history

- In general good health
- Gastroesophageal reflux disease (GERD)
- Afebrile; vital signs within normal limits
- No current medications with the exception of OTC pain medications

OTC=over the counter Couch JC, et al. *Headache*. 2003;43:570-571.

Social history

- · Sleeps poorly
- Job stress; trying to work and manage kids and house responsibilities

Case Study: Newly Diagnosed Migraine

Mary is a 34-year-old Caucasian female, married mother of 2 children under the age of 10

Current complaint today

- Severe headache 1 week "Worse than usual
- Pain diffuse, 10/10 intensity, maximum intensity <1 min, photo/
- Attacks spontaneous and precipitated by cough and orgasm

Couch JC, et al. Headache, 2003;43:570-571.

Take a History!

- Where is the pain?
- Dull, throbbing, shooting, burning?
- Effect of physical exertion?
- Nausea or vomiting?
- Sensitive to light, sound, odors?
- Neck pain? Muscle tension?
- Autonomic features?
- Physical changes?
- Neurologic symptoms?
- Past headache history?

Diagnosis of Episodic Migraine (Without Aura)

- · At least 5 attacks
- Headache attacks lasting 4-72 hours
- · Headache with at least 2 of the following:
 - Unilateral location
 - Pulsating quality
- Moderate-to-severe pain
- Aggravation or avoidance of physical activity
- · During headache at least one of the following:
 - Nausea and/or vomiting
- Photophobia and phonophobia
- Not better accounted for by another ICHD-3 diagnosis

The International Classification of Headache Disorders. 3rd ed. (beta version) *Cephalalgia*. 2013:33(9):644-645.

Diagnosis of Migraine With Aura

- A. ≥2 attacks fulfilling criteria B and C
- ≥1 of the following fully reversible aura symptoms:
 - Visual Sensory
- Speech and/or language Motor
- 5. Brainstem
- C. ≥2 of the following 4 characteristics:
- 21 aura symptom spreads gradually over ≥5 minutes and/or ≥2 symptoms occur in succession Each individual aura symptom lasts 5-60 minutes ≥1 aura symptom is unilateral

- The aura is accompanied, or followed within 60 minutes, by headache
- · Not better accounted for by another ICHD-3 diagnosis, and transient ischemic attack has been excluded

The International Classification of Headache Disorders. 3^{rd} ed. (beta version) *Cephalalgia*. 2013;33(9):645-646.

Profiling Headache Pattern Recognition

Primary Headaches

- Migraine
- Tension-type
- Cluster
- Miscellaneous headaches unassociated with structural lesions

Secondary Headaches

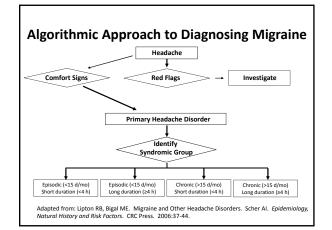
- · Post-traumatic
- Vascular disorders CVA, aneurysm
- · Nonvascular intracranial disorder
 - Neoplasm, meningitis, low or high CSF pressures
- · Substances/withdrawal
- · Systemic infection or metabolic d/o
- · Cranial, extracerebral lesions

CSF=cerebral spinal fluid; CVA=cerebrovascular accident International Classification of Headache Disorders: 2nd ed. *Cephalalgia*. 2004;24(Suppl 1):31-32.

Remember 2SNOOP4 Red Flags

- SYSTEMIC SYMPTOMS (fever, weight loss) or SECONDARY RISK FACTORS (HIV, systemic cancer)
- NEUROLOGIC SYMPTOMS or abnormal signs (confusion, impaired alertness or consciousness)
- ONSET: sudden, abrupt, or split-second (thunderclap)
- OLDER: new onset and progressive headache, especially in middle age >50 years (giant cell arteritis)
- PREVIOUS HEADACHE HISTORY: first headache or different (change in frequency, severity, or clinical features), POSITIONAL, PAPILLEDEMA, or PRECIPITANTS (cough, Valsalva)

Silberstein SD, Lipton RB. In: Silberstein, SD et al, eds. Wolff's Headache and Other Head Pain. 8th ed. New York: Oxford University Press;2008:315-377; Dodick D. N Engl J Med. 2006;354:158-165; Bigal ME, et al. J Headache Pain. 2007;8:263-272.



PIN the Diagnosis: ID™ Migraine

- · Strongest predictors of migraine diagnosis
 - <u>P</u>hotophobia
 - Does light bother you when you have a headache?
 - Incapacity
 - · Has a headache limited your activities for a day or more in the last 3 months?
 - <u>N</u>ausea
 - Are you nauseated or sick to your stomach when you have a headache?
- 2 out of 3 symptoms: 93% • 3 out of 3 symptoms: 98%

Lipton RB, et al. Neurology. 2003;61:375-382.

A New Migraine Paradigm

- Migraine can become a serious chronic disease
- Chronic migraine is a complication of episodic migraine
 - Poor acute treatment outcome¹
 - Medication overuse
- Treatment needs are attack-specific, not patient-specific
 - -50% of attacks do not have optimal outcomes today

¹Lipton RB, et al. Suboptimal treatment of episodic migraine may mean progression to chronic migraine. Poster presented at the IHC 2013, June 26, 2013; Abstract LB02,

Staging Migraine

- Developed by Lipton, Cady, Farmer, and Bigal
- First doctor/patient book
- · Based on frequency not severity of headache (HA)

www.managingmigraine.org

Staging of Migraine

- · Stage 1 Infrequent Episodic - One or less migraines/month
- Stage 2 Frequent Episodic - 1 to 6 days of headache per month
- Stage 3 Transforming Migraine - 7 to 14 days of headache
- Stage 4 Chronic Migraine
- · Education plus effective acute treatment
- · Education plus effective acute treatment with back up; medications limits; preventive measures
- Education; preventive pharmacology; acute pharmacology with back up
- · Education; preventive pharmacology; judicious acute pharmacology with back up and rescue; behavioral interventions

Risk Factors for Progression

Modifiable

Not Modifiable

- · Attack frequency
- Age
- Poorly treated acute HA Female sex
- Obesity
- Low education or
- Snoring/OSA
- socioeconomic status
- Stressful life events
- · Genetic factors
- Medication overuse
- · Head injury
- Caffeine overuse

Ashina S. et al. Curr Treat Options Neurol. 2008:10:36-43.

- · Accurate diagnosis is key
- Consider attack-based management strategies to improve patient outcomes

Summary

- Assess and prepare for the spectrum of acute treatment need
- Successful acute treatment may prevent chronification of migraine

Improving Outcomes in Episodic Migraine

Objectives

- Review current and novel formulations for acute migraine treatment
 - Efficacy
 - Safety
 - Side effects
- · Identify common barriers to effective treatment of episodic migraine
- Devise an optimal treatment strategy based on patient's clinical presentation

- · 46-year-old teacher with severe headaches 6 days a month
 - Misses 1-3 days of work/month
 - Three ER visits last year for headache
- Pain is throbbing, bilateral, with photo/ phonophobia and frequent vomiting Precipitated by weather change, stress,
- and allergies
- · Acute medications:
 - ASA/APAP/caffeine (~30/month)
 - Antihistamine/decongestant (~10/month)
- · Dad had "sinus headaches"
- · Neuro exam and lab normal

- States that she can't take triptans
 - Rizatriptan caused chest tightness and facial tingling
- Vomited after diclofenac potassium powder
- Dihydroergotamine mesylate, USP made nausea worse
- Wants an opiate for rescue so she won't have to go to ER
- Migraine-associated nausea

Goals of Acute Migraine Treatment

- Consistently and rapidly resolve attacks without recurrence
- 2. Restore the patient's ability to function
- 3. Minimize the use of back-up and rescue medications
- 4. Optimize self-care and reduce subsequent use of resources
- 5. Be cost-effective
- 6. Have minimal or no adverse events

Evidence-Based Guidelines for Migraine Headache in the Primary Care Setting: Pharmacological Management of Acute Attacks

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Evidence-Based Guidelines for Migraine Headache in the Primary Care Setting: Pharmacological

Should Patients Try Non-Prescription Options First?

- With infrequent, non-disabling, mild migraines, it is reasonable to try aspirin, an NSAID, or a combination product containing acetaminophen, aspirin, and caffeine
- All are available without prescription or as generics
- Caveats:
 - Inadequate initial treatment can allow an attack to progress to central sensitization
 - Overuse of these medications can lead to medication overuse headache and promote the transformation to chronic migraine

Ineffective Acute Treatment Can Lead to Chronic Migraine

- A longitudinal study of 5,681 episodic migraineurs (EM) found that 3.1% progressed to chronic migraine (CM) over the course of a year
- Progression was inversely related to the treatment efficacy employed
 - 1.9% of the maximum treatment efficacy group
 - 2.7% of the moderate treatment efficacy group
 - 4.4% of the poor treatment efficacy group
- 6.8% of the very poor treatment efficacy group
- Improving acute treatment outcomes might prevent new-onset CM

Lipton RB, et al. Neurology. 2015;84(7):688-695.

FDA-Approved Acute Abortive Treatments for Migraine

- Dihydroergotamine, ergotamine tartrate
- Triptans
 - Almotriptan
 - Eletriptan
 - Frovatriptan
 - Naratriptan
 - Rizatriptan
 - Sumatriptan [oral, nasal spray, injectable, transcutaneous patch]
- Zolmitriptan [oral and nasal spray]
- Diclofenac oral solution

Marmura MJ, et al. Headache. 2015;55(1):3-20.

Formulation of Triptan: Speed of Onset

- Injectable
 - Subcutaneous administration and absorption
- · Nasal spray
 - Absorption via nasopharyngeal mucosa
- Suppository
- Oral fast-onset
- · Transdermal patch
- Oral slow-onset triptan



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Evidence-Based Guidelines for Migraine Headache in the Primary Care Setting: Pharmacological

Persistent Frequent Nausea Can Lead to Chronic Migraine

- Migraineurs with persistent frequent nausea or no/low frequency nausea were identified from the AMPP study
- There were 3,182 migraineurs with 3 years' data of headache symptoms and nausea frequency
 - Frequent nausea was found in 43.7% of respondents, and 3.4% progressed to CM
 - No/low frequency nausea was seen in 27.6% of the EM group, and 1.5% progressed to CM
- Persistent frequent nausea doubled the risk of progression to CM after adjusting for socio-demographic variables

Reed ML, et al. Headache, 2015;55(1):76-87.

Goals of Acute Migraine Treatment

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Evidence-Based Guidelines for Migraine Headache in the Primary Care Setting: Pharmacological Management of Acute Attacks

Opioids Are Associated With Increased Migraine Disability

- Data from the AMPP study were used to categorize 5,796 migraineurs into 4 groups based on reported opioid use:
 - Nonusers (70.3%)
 - Previous users (13.8%)

 - Current opioid users (15.9%)
 16.6% met DSM4 criteria for probable dependence
 83.4% did not
- Both headache-related disability and headache frequency increased across groups (from non-users to current)
- · The prevalence of depression and anxiety was highest among current users with probable dependence
- Headache-related emergency department/urgent care, primary care, and specialty care visits were higher for all opioid-use groups compared to nonusers

Buse DC. et al. Headache. 2012:52(1):18-36.

Goals of Acute Migraine Treatment

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Evidence-Based Guidelines for Migraine Headache in the Primary Care Setting: Pharmacological Management of Acute Attacks

Trigger Management

- · Identifying common triggers: emotional stress, sleep disturbances, dietary factors
 - Migraine with aura: common triggers are sleep, stress
 - Migraine without aura: common triggers are environmental factors
- Research suggest "learning to cope" with triggers (graduated exposure to selected triggers to promote desensitization) may reduce migraines and medication consumption

Mollaoglu M. J Health Psychol. 2013;18(7):984-994.; Martin PR, et al. Behav Res Ther. 2014;61:1-11.

Inadequate Acute Treatment Can Result in ER Visits

- Migraine is the 6th leading cause of ER visits in the US
 - Up to 4% of all ER visits are for headache
 - About 2.8 million ER visits each vear
- Migraineurs are 4x more likely to visit the ER than non-migraineurs
 - 10x more likely if they use opioids
 - 25x more likely if they are opioid-dependent
- Estimated annual US healthcare costs (2010) for migraine:
 - Outpatient visits: \$3.2 billion
 - ER visits: \$700 million
 - Inpatient hospitalizations: \$375 million

Buse DC, et al. *Headache*. 2012;52:18-36.; Insinga RP, et al. *Cephalalgia*. 2011;31:1570-1575.

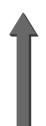
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Evidence-Based Guidelines for Migraine Headache in the Primary Care Setting: Pharmacological

Cost of Acute Migraine Treatment

- Inadequate treatment
 - ER visits
 - Lost work
- Non-generic formulations
- Generic triptans and ergotamines
- OTCs



Goals of Acute Migraine Treatment

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Evidence-Based Guidelines for Migraine Headache in the Primary Care Setting: Pharmacological Management of Acute Attacks

Oral Therapies

- Nontriptan
 - NSAIDS
 - Diclofenac potassium solution*
 - Combinations
 - Acetaminophen/aspirin/caffeine
 - Analgesics
 - Neuroleptics
- Triptans
- Ergotamines
- Opioids
- Corticosteroids

* FDA approved Matchar DB, et al. Evidence-based guidelines for migraine headache. AAN. US Headache

Triptans

- Sumatriptan*
 - Oral 25, 50, 100 mg
 - Nasal 5, 20 mgAuto-injector 4 or 6 mg
 - Needle-free
 injector 4 or 6 mg
 - Iontophoretic patch 6.5 mg
- Zolmitriptan*
- Oral 2.5, 5 mg ODT 2.5, 5 mg
- Nasal 5 mg Naratriptan* - Oral - 1, 2.5 mg
- Rizatriptan*
 - Oral 5, 10 mg - ODT - 5, 10 mg
- Almotriptan
 Oral 6.25, 12.5 mg
- Frovatriptan - Oral - 2.5 mg
- Eletriptan
 Oral 20, 40 mg
- Sumatriptan/naproxen
- Oral 85 mg/500 mg

*Available as generic ODT=orally disintegrating tablet Needle-free 4 mg and lontophoretic patch are newest additions to triptan class

Adverse Events With Triptans

- · Common AEs of triptans
 - Tingling/numbness/warmth/pressure/tightness of scalp, face, head,
 - chest or upper body
 - Dizziness/lightheadedness/drowsiness
 - Nausea or vomiting
- · Specific AEs with nasal spray
 - Burning, pain, or soreness in the nose
 - Change in the sense of taste
- · Specific AEs with injection
 - Burning, pain, or redness at injection site
 - Bleeding or bruising at injection site
- · Specific AEs with patch
 - Burning, pain, itching, or redness at the patch site

See Package Insert on specific drugs for complete descriptions of adverse events

Adverse Events With DHE

- Serious cardiac events, including fatalities, have occurred following injection but are extremely rare
- More common AEs include
 - ParesthesiaHypertension
- HeadacheFlushing
 - Dizziness Diarrhea
 - Anxiety Rash
 - Dyspnea Increased sweating

- Muscle cramps

DHE= Dihydroergotamine
See Package Insert on specific drugs for complete descriptions of adverse events

Adverse Events With Diclofenac Potassium Oral Solution

- In clinical trials, the most common adverse events were nausea (3%) and dizziness (1%)
- Efficacy is similar to triptans with a low rate of adverse events
- Efficacy may be significantly reduced if not taken on an empty stomach

CAMBIA [package insert]. Newark, CA: Depomed Inc; 2010

Novel Delivery Formulations for Acute Treatment

Transdermal Drug Delivery

- Sumatriptan iontophoretic transdermal system
- Single-use, battery-powered patch using electrical potential to advance medication through the skin
 - Bypasses stomach
 - Automatically powers off when dosing completed
- Appropriate candidates
 - Patients with significant AEs from triptans
 - Flushing, fatigue, gastrointestinal effects
 - AEs associated with vasoconstrictive properties of triptans.
 Patients with significant pauses who are unable to
 - Patients with significant nausea who are unable to swallow medications
 - Patients with difficulty absorbing oral medications

AE=adverse event Vikelis M, et al. Neuropsychiatr Dis Treat. 2012;8:429-434.

Intranasal/Inhaled Delivery

- Nasal anatomy
- Current intranasal formulations: sumatriptan, zolmitriptan, dihydroergotamine (DHE) (limited to acute management)
 - Intrinsic intranasal bioavailability: sumatriptan (max of 10%),¹ zolmitriptan (29%)²
- Formulations currently under investigation
 - Inhaled preparation DHE mesylate rejected by FDA in June 2014: ongoing concerns regarding "specifications around content uniformity and the improved canister filling process and on standards for device actuation." Approval delayed as of September 2015
 - AVP-85- sumatriptan powder (22 mg) delivered intranasal using novel breath powered delivery technology

¹Fuseau E, et al. Clin Pharmacokinet. 2004;41(11):801-811. ²Kagedal M, et al. Am J Drug Delivery. 2005:3(2)133-140.

Value of Different Triptan Formulations

- Oral
 - Convenience, portability
 - Variety of molecules (7) to choose from
- Parenteral (effective with nausea and vomiting)
 - Injection (needle or air-injection systems)
 - Fast-onset
 - Nasal
 - Avoids injection pain
 - Fast-onset
 - Patch
 - Avoids injection pain
 - Reduced triptan sensations
 - Bypasses the GI track

Preventive Nonpharmacologic Interventions

- Behavioral therapies
 - Sleep hygiene
 - Relaxation, biofeedback, cognitive behavioral therapy (CBT) reduce risk of transforming EM to CM
- Dietary considerations/GI issues
 - Food triggers, specific food allergies, obesity, and comorbid GI illness all appear to influence clinical expression of migraine. No clear direct evidence
- Fasting, skipping meals
- Patient emnowerment and education
- Exercise
 - Recent good quality studies provide evidence supporting effectiveness of exercise in prophylaxis of migraine
 - Monitor intensity, frequency, duration to optimize outcomes
 - Isometric neck exercise helpful if migraine + neck pain

Finkel AG, et al. Curr Pain Headache Rep. 2013;17(11):373.; Pistola F, et al. Curr Pain Headache Rep. 2013;17(1):304.; Mauskop A. Continuum (Minneap Minn). 2012;18(4):796-806.; Koseoglu E, et al. J Sports Med Phys Fitness. 2014 Jun 12.

 What are good options for our patient?

But first – is she strictly episodic?

- She reports 6 severe migraines a month with missed work
- Are the other days perfect or just "not bad"?

Are Our "Episodic" Migraineurs Strictly Episodic?

- Published studies of triptans have shown somewhat disappointing 2-hour pain-free and 2- to 24-hour sustained pain-free rates
- A major study design flaw may have contributed
 - Many subjects are not truly episodic—they discount days with mild headache and ignore days with migraine-related neck pain
- Subjects with 2-7 migraine attacks monthly and <15 headache and/or neck pain days per month were instructed to treat ≤30 minutes following onset of mild headache or neck discomfort on the first day of discomfort

Calhoun AH, Ford S. Postgrad Med. 2014;126:86-90.

Back To Our Case Study

- What are good options for our patient?
- Aggressive prevention of her specific triggers (allergies)
- Migraine preventive medication to reduce frequency
- Effective acute therapy
- Rescue option

- States that she can't take triptans
 - Rizatriptan caused chest tightness and facial tingling
- · Vomited after diclofenac potassium powder
- Dihydroergotamine mesylate, USP made nausea worse
- Wants an opiate for rescue so she won't have to go to ER
- Migraine-associated nausea

Summary

- Current FDA-approved acute migraine therapies are all efficacious, but individual responses may differ
- For best results, patients should treat episodic attacks early in the mild pain stage with appropriate acute therapy
 - Side effects with the treatment must be absent/minimal if patients are to treat early in the mild stage
- Be sure they're truly episodic
- Parenteral formulations may be included for attacks that are accompanied by nausea, have rapid onset, or awaken the patient from sleep