Disclosures

Susan Hutchinson, MD
Advisory Board & Consultant: Alder, Allergan, Amgen, Biohaven, electroCore, Lilly, Novartis, Promius, Supernus, Teva, Theranica
Speaker’s Bureau: Allergan, Amgen, electroCore, Lilly, Novartis, Promius, Supernus, Teva

Linda Davis, MD
Advisory Board & Consultant: Amgen, Lilly, Teva
Speaker’s Bureau & Stock Shareholder: Lilly

Statement of Commercial Support
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Special Populations and Migraine
Pre-Pregnancy

Meet Beth

• 28-year-old female planning on stopping her oral contraceptive and trying to get pregnant

• Has frequent episodic migraine and takes Sumatriptan 100 mg tablet with Naproxen OTC for acute migraine. Is on Topiramate 100 mg hs for prevention

• She states, “I am worried my migraines will get worse when I go off my birth control pill. What options do I have?”
Pre-pregnancy Treatment Options

- Sumatriptan 100 mg continue but stop the Naproxen
- Stop the Topiramate since it’s not advised for pregnancy (risk of cleft palate)
- B-2 and Magnesium OK for prevention
- Emphasize non-pharmacologic treatment including exercise, adequate hydration, sleep, yoga
- Acupuncture, PT, CBT, stress-reduction measures
- Reassure her that most women improve with migraine during pregnancy

Pregnancy
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Pregnancy – Acute Treatment

- Acetaminophen
- Caffeine in moderate
- Hydration, Rest
- Doxylamine 10 mg/Pyridoxine 10 mg for nausea (FDA approved for pregnant women); max 4 tablets per day
- Metoclopramide considered safe in pregnancy*
- Triptans weigh risks vs benefits (observational studies - no adverse outcomes or fetal malformation 1st trimester. 2nd and 3rd trimester is associated with increased risk of uterine atony and increased blood loss during labor and delivery)
- Acupuncture, Non-invasive stimulators


Ondansetron and Pregnancy

- Formerly thought to be safe
- One study showed an association with cleft palate
- Two studies show an association with heart defects
- At higher dosages, may increase risk of QT interval prolongation


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Pregnancy – Preventive Options

- Propranolol and Labetalol – generally considered safe
- Nonpharmacologic options 1st (relaxation training, thermal biofeedback, electromyographic biofeedback, cognitive behavior therapy)
- NO: Valproic acid (teratogenic), topiramate, NSAID's
- TCA's, SSNRI's, SSRI's-weigh risk vs benefit
- Occipital nerve blocks with Bupivacaine or Lidocaine
- B-2 and Riboflavin (approx. 200 mg twice a day for each)
- Onabotulinum Toxin A in select cases if benefits outweigh risks
- If in doubt: refer to high risk OB provider

Breast-feeding
Breast-feeding

- Acetaminophen
- Ibuprofen
- Metoclopramide
- Droperidol
- Prochlorperazine
- Diphenhydramine
- Sumatriptan
- Non-invasive stimulators
- Avoid aspirin (excreted into breast milk; peaks at 3 hrs)

Pump and Dump Concept

- BF mom can take her acute Rx (triptan) then pump and discard breast milk for 2-3 hours to allow concentration in breast milk to decrease
- No known negative effects on infants from maternal triptan ingestion
- Consider being more conservative if infant born premature and in first few months after birth; as infant matures, the ability to clear out drug from kidney and liver increases
### Resources for Pregnancy and Breast-feeding

- Hales Medications and Mother’s Milk. Updated regularly. Most recent edition 2019
- User friendly (put in name of medication-all current information that is known comes up)

### Pediatric Migraine
Epidemiology and Key Features

- Boys and girls equal prevalence
- Pediatric (<12 years old) – migraines come on fast, resolve quicker than adults, more often associated with nausea/vomiting
- Cyclical vomiting syndrome, abdominal migraine often lead to costly GI work-ups
- Key: Look for family history and complete resolution in between attacks

Recurrent GI Disturbances

- Recurrent episodic attacks of abdominal pain and/or discomfort, nausea and/or vomiting, occur infrequently, may be associated with migraine
- At least 5 distinctive episodes, normal GI exam and evaluation, not attributed to another disorder
- ICHD 1.6.1
### Cyclical Vomiting Syndrome

- Recurrent episodes nausea/vomiting
- Complete resolution between attacks
- Nausea and vomiting 4+ times per hour and lasting >1 hour or more
- GI work-up negative for underlying GI disorder
- ICHD 1.6.1.1

### Abdominal Migraine

- Recurrent episodes mod-severe midline abdominal pain lasting 2-72 hours
- Complete resolution between attacks
- GI work-up negative
- ICHD 1.6.1.2
Benign Paroxysmal Vertigo of Childhood

- At least 5 episodes of severe vertigo lasting minutes to hours
- One or more of the following: Nystagmus, ataxia, vomiting, pallor, fearfulness
- Resolve spontaneously
- Normal audiogram, neurological exam, and vestibular function between attacks
- ICHD 1.6.2

Acute Treatment
Pediatric Migraine

- Anti-nausea Rx (Ondansetron 4 mg every 8 hours; oral or ODT formulation)
- Acute treatment: acetaminophen vs nsaidshow ibuprofen best results
- Rizatriptan oral/MLT* 5 mg (wt <88 lbs); 10 mg (wt>88 lbs)
- Caffeine in moderation; Hydration
- Rest, avoid TV/computer screen

*MLT = orally disintegration formulation
Preventive Treatment
Pediatric Migraine

- Prevention: Limited data/conflicting results
  - Propranolol
  - Topiramate
  - Cyproheptadine
  - Amitriptyline
  - Valproic acid
  - Levetiracetam


Adolescents and Migraine
### Acute Treatment Options

- NSAID's
- Anti-emetics (Ondansetron oral or ODT 4-8 mg)
- Triptans (FDA approved for ages 12-17 include Almotriptan, Rizatriptan, Sumatriptan/Naproxen combination, Zolmitriptan nasal spray)
- Non-oral triptans (nasal sprays, injectables)
- Caffeine in moderation
- Non-pharmacologic treatment

### Preventive Treatment Options

- Life-style (adequate sleep, healthy diet, stress-reduction, adequate hydration, caffeine in moderation)
- Screen for alcohol, substance abuse, depression, anxiety, issues at school/home
- Cognitive behavioral therapy (CBT)
- For females, screen for menstrual migraine and consider short-term targeted prevention during vulnerable time of cycle
### Preventive Prescription Options

- Amitriptyline, Nortriptyline-start low, increase gradually
- Escitalopram, Fluoxetine
- Propranolol
- Topiramate, Divalproex sodium
- Cyproheptadine
- Non-invasive stimulators

### Elderly and Cardiovascular Risk Patients
Migraine and Aging

- Prevalence of migraine decreases with age in men and women after age 55
- If women had a strong hormonal trigger for migraines when younger more likely to improve with menopause than women with no hormonal trigger
- About 2/3 women experience improvement in migraine if spontaneous menopause; only 1/3 improve if surgical menopause occurs

Giant Cell Arteritis

- Occurs in patients 50 years and older
- ESR at least 50 mm/hr
- CRP may be helpful
- Headache-constant or intermittent
- Intermittent visual symptoms, tender scalp muscles may be present
- Prednisone 60-80 mg/day to prevent blindness
- Arrange for temporal artery biopsy

ESR = Erythrocyte Sedimentation Rate
CRP = C-Reactive Protein Test
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Special Considerations in Aging Patients

- Triptans and Ergots are vasoconstrictive and contraindicated in patients who have cardiac disease and/or peripheral vascular disease
- Triptans and Ergots should be used with caution in patients with cardiac and stroke risk factors
- Better acute options include NSAID’s if no contraindication to taking an NSAID
- Oral CGRP antagonists and Lasmiditan may be good options for acute migraine once available

Migraine Prevention in Elderly and Those With CV Risk Factors

- Pick a preventive that may address an underlying condition (e.g. anti-hypertensive)
- Anti-CGRP mAB’s
- Oral CGRP antagonists once available and approved-may include Rimegepant and Atogepant
- Non-invasive stimulators
- Non-pharmacologic (yoga, etc.)
Menstrual Migraine

Migraine Prevalence: US Female Population

Menstrual Migraine

- Goal is to initiate therapy before the anticipated onset to decrease severity and disability
- Frovatriptan, naratriptan, zolmitriptan
- Continuous OCPs (caution in migraine with aura), hormonal IUD


Migraine and Menarche

- Beginning with puberty, migraine is more common in girls than boys
- Menstrually-associated migraine begins at menarche in 33% of women
- 60-70% of female sufferers experience migraine in association with menses

Silberstein SD. Neurology. 1991; 41:786-793.
Menstrual migraine is migraine that occurs in the perimenstrual window of -2 to +3 of the menstrual cycle and occurs at least 66% of the time in a patient; i.e. the migraine begins sometime in that time frame.

Day 1 is first day of bleeding; there is no Day 0.

Prospective diary recommended but not mandatory to make the diagnosis.

### ICHD-3 Classification

- **A1.1 Migraine without aura**
  - A1.1.1 Pure menstrual migraine
  - A1.1.2 Menstrual-related migraine
  - A1.1.3 Non-menstrual migraine (attacks in menstruating women fulfilling criteria for 1.1 Migraine without aura and not fulfilling criteria for A1.1.1 or A1.1.2)
ICHD Classification

- A1.2 Migraine with aura
  - A1.2.0.1 Pure menstrual migraine
  - A1.2.0.2 Menstrual-related migraine
  - A1.2.0.3 Non-menstrual migraine with aura (attacks in menstruating women fulfilling criteria for 1.2 and not fulfilling criteria for A1.2.0.1 or A1.2.0.2)

Estrogen Withdrawal Headache

- ICHD-3 8.3.3 defined as headache or migraine developing within 5 days after 3 or more weeks of exogenous estrogens is interrupted (for example during placebo week of oral contraceptive pills) and headache/migraine resolves within 3 days in absence of further exogenous estrogen
- [ICHD 8.3 headache attributed to substance withdrawal]
Menstrual Migraine Subtypes

• Menstrually-related Migraines (MRM): perimenstrual exacerbation of migraines in women who have migraines at other times of month; 50-60% of female migraineurs

• Pure Menstrual Migraines (PMM): women who have migraines only in association with their menses; 7-14% of female migraineurs

• Hormonal prophylaxis more likely to be effective for pure menstrual migraine

Diagnostic Tool

• A headache calendar or diary is THE MOST IMPORTANT TOOL to diagnose menstrual migraine and then to classify as pure menstrual migraine (PMM) vs menstrual related migraine (MRM)

• The patient MUST mark down the first and last day of menses on the calendar as well as all headache days.

• Day 1 of cycle = first day of bleeding
Why So Important To Differentiate PMM vs MRM?

- For women with PMM (pure menstrual migraine) her treatment can be targeted to her vulnerable time of the cycle.
- For women with MRM (menstrual related migraine) her treatment will need to be expanded to looking at all her triggers and risk factors and a broader preventive approach.

Hormone Levels During Menstrual Cycle

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Hormone Influence

- Drop in estrogen is a strong migraine trigger
- Late luteal injections of estradiol postponed migraine occurrence
- Late luteal injections of progesterone postponed bleeding but not migraines

Estradiol-Treated Cycle

<table>
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<tr>
<th>Days From Onset of Menstruation</th>
<th>Plasma Estradiol (ng/100 ml)</th>
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<tbody>
<tr>
<td>-6</td>
<td>2</td>
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<tr>
<td>-5</td>
<td>10</td>
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<tr>
<td>5</td>
<td>110</td>
</tr>
<tr>
<td>6</td>
<td>120</td>
</tr>
</tbody>
</table>

Estradiol valerate 10 mg

Migraine-unilateral, duration 8 hours. Nausea.

Migraine-unilateral, duration 12 hours. Nausea.

Case Study - Beth

- Beth is a 29-year-old female with a 5-year history of migraine headaches. She describes her headaches as 3-4 days in duration with menses, typically starting 1 day before the onset of menses. She experiences photosensitivity; nausea and a throbbing sensation with her menstrual related migraines. She does not experience aura. She estimates a migraine with menses >90% of the time.

PMM vs MRM

- Beth has an occasional 1-2 headache days outside the menstrual window. Triggers include lack of sleep, stress, skipped meals and travel. She can often take naproxen 500 mg for those non-menstrual headaches. For her menstrual headaches, she needs her triptan.

- Occasionally these “other headaches” are associated with nausea and photosensitivity. She has MRM without aura (ICDH-3 A1.1.2).
Treatment Approaches

- NSAID’s
- Magnesium
- Hormonal
- Triptans including non-oral and short-term preventive during vulnerable time
- Standard migraine preventives
- Rescue options if severe

Short-Term Prevention: Naproxen Sodium

- Naproxen sodium 550 mg BID vs placebo (n=35)
  - Day -7 to Day +6 (start of menses = Day 1) for 3 cycles
  - Significantly reduced headache intensity, duration, number of headache days compared to baseline, p<.05
  - Naproxen was only superior to placebo at 3 months of treatment, p<.05
  - 33% were headache free (none with placebo)

Short-Term Prevention: Magnesium

- Magnesium (Mg) is postulated to affect pain threshold
- Magnesium pyrrolidone carboxylic acid 360 mg/day or placebo from Day 15 to start of menses for 2 cycles (n=20)
- Mg treatment
  - Reduced number of headache days (P<.01)
  - Reduced Total Pain Index (P<.005)


Hormonal Treatment Options

- Add-back estrogen-perimenstrually: e.g. estradiol patch .1 mg the week of menses
- Continuous OCP's-monophasic
- Continuous contraceptive ring (NuvaRing)
### Short-Term Prevention: Percutaneous Estradiol Gel

- **Study 1. de Lignieres et al, 1986**
  - Double-blind placebo-controlled crossover design (n=20)
  - Day -2 from onset of menses to Day +5
  - 1.5 mg estradiol in 2.5 gram gel applied to ≥ 400 cm²
  - Reduced migraine frequency, duration, and severity, p<.01

- **Study 2. Dennerstein et al, 1988**
  - Double-blind placebo-controlled crossover design with 1.5 mg estradiol in 2.5 gram gel vs placebo (n=22)
  - 7 days encompassing menstruation
  - Significant reduction in occurrence of moderate or severe migraine

- No long-term safety data from either study

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### Short-term Prevention With Estradiol Gel Timing Matters

- Estradiol gel or placebo on tenth day following the first day of peak fertility and continued daily until, and including, day +2
- Percutaneous estradiol was associated with a 22% reduction in migraine days, p=0.04
- The migraines were less severe and had less nausea
- **However,** there was a 40% increase in migraine in the 5 days following Rx!
- Benefit during treatment was offset by deferred estrogen withdrawal, triggering post-dosing migraine immediately after the gel was stopped

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Short-Term Prevention: Transdermal Estrogen

- Dose matters
  - No benefit observed in placebo-controlled trial with 50 µg 17-beta-estradiol\(^1\)
  - Reduced frequency (ns) and use of rescue medication (P<.05) with 100 µg dose compared with 25 µg dose\(^2\)
  - No long-term safety data from these studies

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Migraine as Risk Factor for Stroke

- Migraine is an independent risk factor for stroke in women <45 years old
- 2-fold increase in ischemic stroke compared to women without migraine
- This increase primarily driven by the subgroup of women who have migraine with aura
- Approximately 1.5 increased risk hemorrhagic stroke in women with migraine
- Other risk factors such as smoking amplify this risk

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Risk of Stroke with Use of Estrogen Containing Contraception in Women with Migraine

• Risk for both ischemic and hemorrhagic stroke higher in high dose (>50 mcg) ethinyl estradiol dose than lower dose (<50 mcg)
• OR ischemic stroke 50 mcg EE 2.9-4.8, OR 1.6-2.7 30-40 mcg EE, OR 1.7 20 mcg EE, OR .9-1 progestin only pills (data from 3 studies)
• Ischemic stroke risk higher in women with aura (OR 6.1) using combined oral contraception vs women without aura (OR 1.8) who used CHC’s within 90 days prior to the first diagnosis of stroke

Absolute Risk of Stroke

• 3.56 per 100,000 women reproductive age in UK population-based study
• 21.7 per 100,000 women annual stroke incidence in women with migraine with aura who use CHC’s
• Increased risk of stroke in pregnancy in women with migraine (OR 7.9-30.7)
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Estrogen Controversy

• To date, there is no consensus on guidelines for prescribing combined oral contraceptives in women who have migraine with aura. The International Headache Society advises that low-dose estrogen may be prescribed in women who have simple visual aura. The American College of Obstetricians and Gynecologists recommends using progestin-only intrauterine or barrier contraception. Meanwhile, the World Health Organization states that estrgen-containing contraception is an absolute contraindication in all women who have migraines with aura.


Clinical Practice

• Low dose estrogen dose CHC’s are appropriate in the majority of women with migraine without aura who do not smoke

• CHC’s may be an option for women with migraine with aura if the benefits outweigh the risks (individualized approach)

• Use of the vaginal ring contraceptive decreased aura frequency in women with migraine with aura in one study

### Contraceptive Options: The Younger Woman With Migraine Without Aura

- Regular menses
- Low-dose, monophasic
- Dose of ethinyl estradiol 10-35 mcg
- Oral or vaginal ring delivery

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### Contraceptive Options: The Younger Woman With Migraine With Aura

- Progesterone only oral contraceptive
- IUD (Progesterone; copper)
- Progesterone implant
- Progesterone Injection
- Low dose estrogen containing contraception if non-smoker and benefits>risks

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**Triptans**

- Acute or short-term preventive
- None are FDA approved for short-term prevention of menstrual migraine
- Frovatriptan 2.5 mg and Naratriptan 2.5 mg are most suited due to long half-life and low chance of medication overuse
- Can be dosed once daily or twice daily for 5-7 days beginning 1-2 days prior to expected onset of menstrual migraine

**Mini-Prophylaxis of MRM**

- Begin treatment 3-5 days prior to flow and as many as 3-7 days after onset of flow
- Naratriptan:
  - 1 mg BID taken 6 days perimenstrually reduced frequency of MAM
  - At least 50% of patients had no MRM
  - Superior to placebo

---

Mini-Prophylaxis of MRM

• Frovatriptan given for 6 days (treatment began 2 days before anticipated start of MRM) was effective in reducing the incidence of MRM. >50% who used frovatriptan 2.5 mg BID had no MRM during the 6-day perimenstrual period. (67% incidence for placebo; 41% incidence MRM for frovatriptan)


Standard Preventives

• Anti-depressants (SSRI's, SNRI's, TCA's)
• Anti-epileptics (AED's)
• Anti-hypertensives (Beta-blockers, Calcium channel blockers, ACE inhibitors, ARB’s)
• Devices (Cefaly, SpringTMS, GammaCore, Nerivio)
• Onabotulinum Toxin A (Botox)
• Anti-CGRP monoclonal Antibodies
### Evidence Based Guidelines – Preventives

<table>
<thead>
<tr>
<th>Level A Established (&gt; 2 Class I Trials)</th>
<th>Level B Probable (1 class I or 2 class II)</th>
<th>Level C Possible (1 Class II)</th>
<th>Level U Inadequate or conflicting data</th>
<th>Other Probably or possibly ineffective</th>
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<td>Divalproex sodium/sodium valproate</td>
<td>Amitriptyline</td>
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*Menstrual migraine short-term prophylaxis
Onabotulinumtoxin A – chronic migraine

### Evidence Based Guidelines

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*Safety concerns


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<th>Rescue Options – Menstrual Migraine</th>
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<tbody>
<tr>
<td>• Sumatriptan injectable (3, 4, 6 mg)</td>
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<td>• Sumatriptan or Zolmitriptan nasal delivery</td>
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<tr>
<td>• Ketorolac 60 mg IM injectable</td>
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<td>• Anti-emetic suppository</td>
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<td>• Occipital Nerve Block</td>
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<tr>
<td>• Sphenopalatine Ganglion Nerve Block (SPG)</td>
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<tr>
<td>• Infusion Center IV orders (Ketorolac 30 mg, Ondansetron 4 mg, Magnesium 1-2 gram)</td>
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<thead>
<tr>
<th>Headache Diary</th>
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<tbody>
<tr>
<td>• Advise all women with migraine to record menses in their headache diary to better understand headache pattern</td>
</tr>
<tr>
<td>• Review headache diary at visits</td>
</tr>
<tr>
<td>• Watch for changing pattern of headache anytime Rx hormones are changed or when a women’s own hormonal milieu is changing</td>
</tr>
</tbody>
</table>
Resources

Patient Resources

• American Migraine Foundation
• Migraine Again
• Migraine World Summit
• Migraine.com
• Miles for Migraine Events
• National Headache Foundation
Provider Resources

• American Headache Society
• Headache Cooperative of the Pacific
• National Headache Foundation
• Primary Care Network
• Mentoring opportunities with Drs. Hutchinson and Dr. Davis
  • drhutchinson@ocmigraine.org
  • drdavis.kolvita@yahoo.com

Summary

• The diagnosis and treatment of migraine can be managed successfully in the busy primary care setting
• A knowledge of new and emerging acute and preventive migraine treatment options is vital for successful migraine management
• Target specific migraine treatment offers hope to give our patients their life back….
Clinical Updates in Migraine: Dawn of a New Day

Making a Difference... One Patient at a Time

Clinical Updates in Migraine: Dawn of a New Day

Thank You!

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