PEDIATRIC AND ADOLESCENT HEADACHES

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Disclosure

- I have no relevant financial relationships with the manufacturers(s) of any commercial products(s) and/or provider of commercial services discussed in this CME activity
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OUTLINE:

- APPROACH TO PEDIATRIC HEADACHE HISTORY TAKING
- INITIAL EVALUATION
- RED FLAGS FOR SECONDARY HEADACHE PATHOLOGY IN CHILDREN AND ADOLESCENTS
- INTRACRANIAL NEOPLASMS
- NEUROIMAGING
- PEDIATRIC HEADACHE FEATURES NOT RED FLAGS FOR SECONDARY PATHOLOGY
- PRIMARY HEADACHE DISORDERS AFFECTING CHILDREN AND ADOLESCENTS
- TREATMENT OF PEDIATRIC AND ADOLESCENT MIGRAINE
- CONCLUSION

APPROACH TO PEDIATRIC HEADACHE HISTORY TAKING

- Step 1: Assign seats
- Step 2: Set expectations at the outset
- Step 3: “Good headache histories are taken, not given.”
  - Very Young Children less than 6 years old
    - information from parent/guardian
    - Have children draw a picture of themselves and how they feel
  - Preadolescent School aged children
    - Time is a challenging concept – details on duration and frequency may be obtained from parents, calendars, diaries
    - Medication names/dosages
  - Adolescents
    - Can usually give complete history with minimal parental assistance
    - May ask parent to step out for a confidential discussion on alcohol, drug use

INITIAL EVALUATION: PRIMARY vs. SECONDARY HEADACHES

- As in adults, childhood and adolescent headaches can be divided into primary and secondary headaches. This is well delineated in the International Classification of Headache Disorders, Third Edition, beta version (ICHD-3 beta)

- Primary headaches are headaches that represent a disease state in themselves

- Secondary headaches are headaches directly caused by or exacerbated by an identifiable or presumed etiology.

INITIAL EVALUATION:

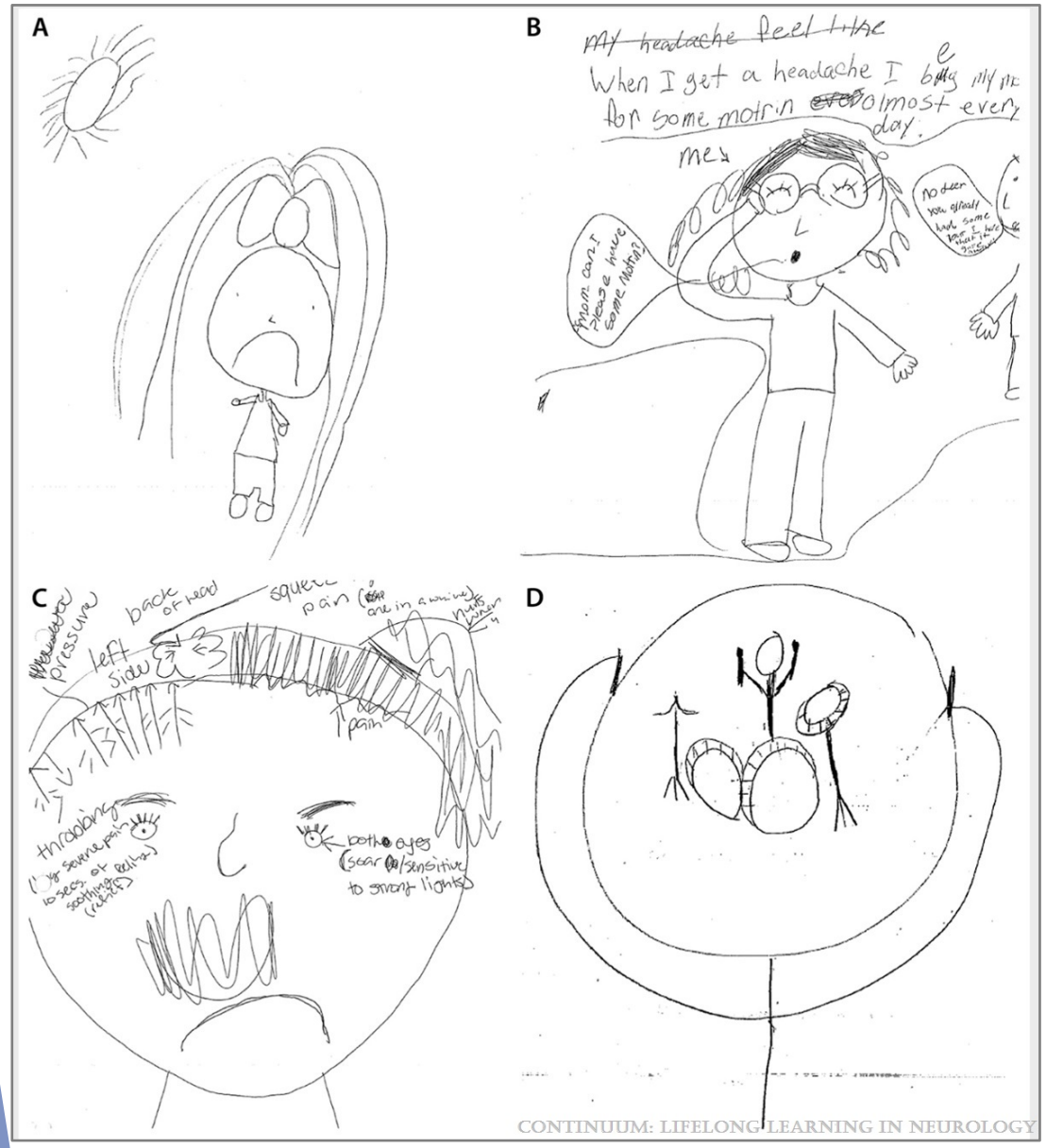
A detailed history of headache:

- characteristics and timing of the headaches.
- events preceding the start or exacerbation of headaches,
- triggering and premonitory factors,
- patterns of headaches,
- family history,
- response to treatment.

Included in this evaluation can be the use of:

- drawings for younger children who have difficulty describing their headaches,
- calendars and diaries,
- disability assessments,
- tabulation of the frequency of acute treatments used
- documentation of lifestyle habits.

Figure 1



Headache symptoms as drawn by children and adolescents

A) A 4-year-old girl's drawing demonstrating photophobia;

B) A 7-year-old girl's drawing demonstrating medication overuse;

C) A 12-year-old girl's drawing of multiple headache features;

D) A 16-year-old boy's drawing demonstrating phonophobia.

Pediatric Headache

Hershey, Andrew D.

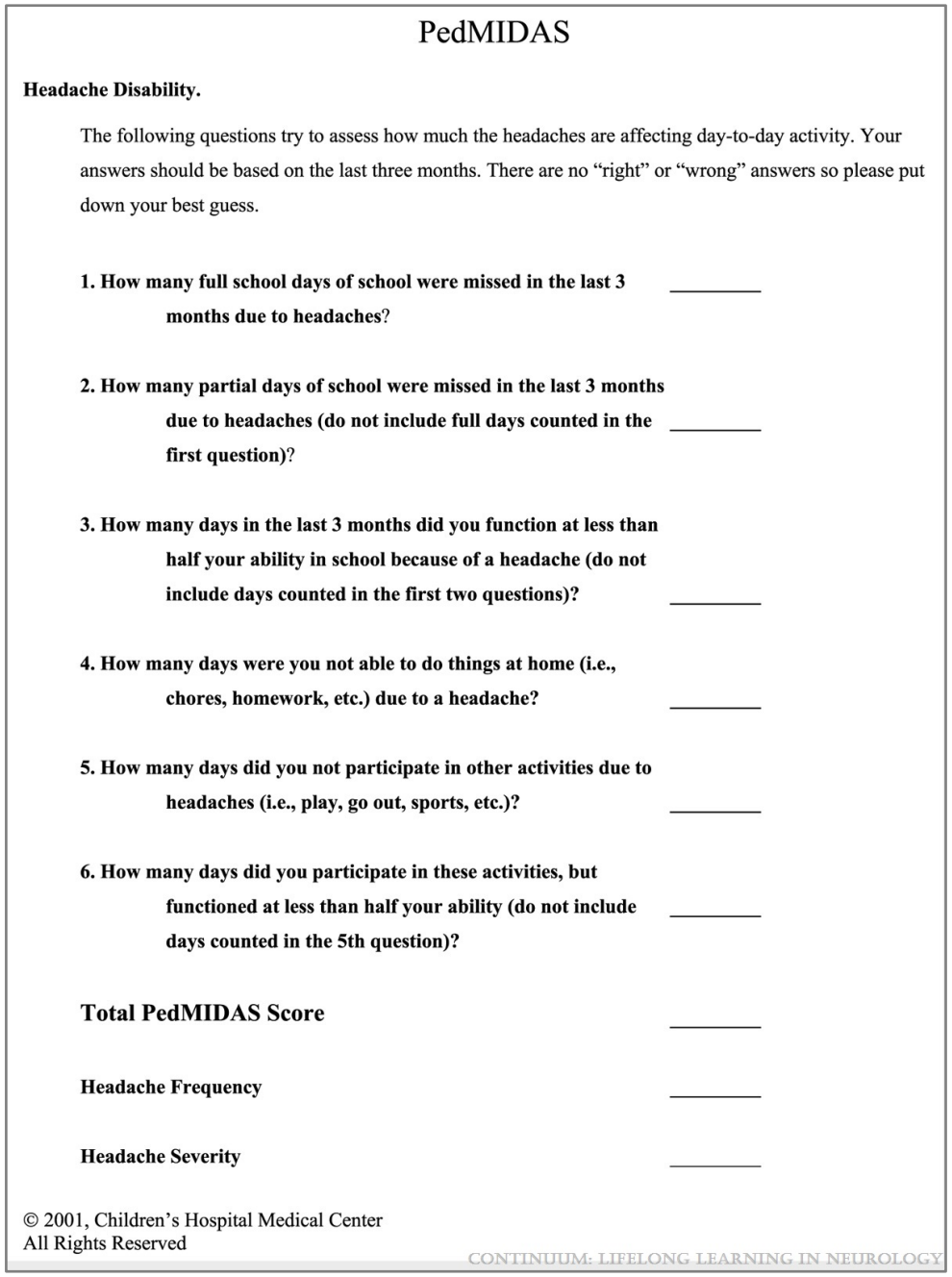
CONTINUUM: Lifelong Learning in Neurology21(4, Headache):1132-1145, August 2015.

doi: 10.1212/CON.0000000000000197

DISABILITY ASSESSMENT:

- The assessment of impact and disability caused by the headaches is a subjective but important tool.
- This can include both disease-specific and nonspecific features.
- For children and adolescents, disease nonspecific disability has been demonstrated using the Pediatric Quality of Life Inventory (PedsQL).
- For migraine and other primary headaches, disease-specific features may be the associated symptoms (eg, vomiting) or characteristics of the aura. Additionally, disease-specific components of migraine may impact functioning socially, at school, and at home.
- The Pediatric Migraine Disability Assessment (PedMIDAS) was developed as a modification of the Migraine Disability Assessment (MIDAS) to assess migraine- related disability in children and adolescents.
- It is not intended to be an exact measure, but has been demonstrated to correlate well with the overall impact of migraine and is a useful tool to follow treatment response.

Pediatric Migraine Disability Assessment (PedMIDAS).



PedMIDAS

Headache Disability.

The following questions try to assess how much the headaches are affecting day-to-day activity. Your answers should be based on the last three months. There are no "right" or "wrong" answers so please put down your best guess.

1. How many full school days of school were missed in the last 3 months due to headaches? _____

2. How many partial days of school were missed in the last 3 months due to headaches (do not include full days counted in the first question)? _____

3. How many days in the last 3 months did you function at less than half your ability in school because of a headache (do not include days counted in the first two questions)? _____

4. How many days were you not able to do things at home (i.e., chores, homework, etc.) due to a headache? _____

5. How many days did you not participate in other activities due to headaches (i.e., play, go out, sports, etc.)? _____

6. How many days did you participate in these activities, but functioned at less than half your ability (do not include days counted in the 5th question)? _____

Total PedMIDAS Score _____

Headache Frequency _____

Headache Severity _____

Figure 2

Hershey, Andrew D.

CONTINUUM: Lifelong Learning in Neurology21(4, Headache):1132-1145, August 2015.

doi: 10.1212/CON.0000000000000197

INTRACRANIAL NEOPLASM

- 2nd most common malignancy in childhood and the most common solid tumor in children.
- Headache is the most common presenting symptom and can occur in isolation, but it is often accompanied by vomiting, unsteadiness, or focal weakness.
- The prevalence of brain tumor in patients with a normal examination and headache history of > 6 months is 0.01% to 0.4%.
- Patients with headaches < 6 months and either sleep-related headache, vomiting, confusion, absence of visual aura, absence of family history of migraine, or an abnormal neurologic examination have a brain tumor prevalence of 4%.
- Initial symptoms are nonspecific, so either the persistence of the symptoms or additional localizing symptoms should prompt further evaluation;
- The most sensitive indicator is an abnormal neurologic examination or the development of neurologic symptoms such as seizures.
- A delay in diagnosis does not appear to change the long-term morbidity or mortality.

NEUROIMAGING:

One aspect of secondary headache evaluation is the role of neuroimaging. Several key components of guidelines (from AAN, CNS, AHS) that indicate the need for neuroimaging include:

- neurologic symptoms,
- any abnormality on the neurologic examination,
- an exclusively occipital location to the headaches.
- lack of family history
- frequent early morning headaches that awaken the child from sleep or result in vomiting, suggestive of a pressure effect;
- not meeting ICHD-3 beta criteria;
- recent onset of headaches without a history of headaches;
- a recent change in the headaches, suggestive of a new type of headache;
- children aged 6 or younger who may have difficulty describing their headaches.
- brain MRI is the preferred modality choice in children and adolescents.
- neurophysiologic testing (EEG) and blood chemistry testing – not useful

RED FLAGS FOR SECONDARY HEADACHE PATHOLOGY IN CHILDREN AND ADOLESCENTS

- Persistent headaches of less than 6-months' duration that do not respond to medical treatment
- Headache associated with abnormal neurologic findings, especially if accompanied by papilledema, nystagmus, or gait or motor abnormalities
- Persistent headaches associated with a negative family history of migraine
- Persistent headaches associated with substantial episodes of confusion, disorientation, or emesis
- Headaches that repeatedly awaken a child from sleep or occur immediately on awakening
- Family and medical history of disorders that predispose to CNS lesions and clinical laboratory findings that suggest CNS involvement

Reprinted with permission from Medina J, Pinter J, Zurakowski D, et al. Children with headache: clinical predictors of surgical space-occupying lesions and the role of neuroimaging. Radiology 1997;202:819.

CONTINUUM: LIFELONG LEARNING IN NEUROLOGY

NEUROIMAGING OF HEADACHES

Mechtler, Laszlo L.

CONTINUUM: Lifelong Learning in Neurology14(4, Neuroimaging):94-117, August 2008.

doi: 10.1212/01.CON.0000333202.83097.bc

PEDIATRIC HEADACHE FEATURES NOT RED FLAGS FOR SECONDARY PATHOLOGY

- Occipital Headache Location
- Headaches Accompanied by Nasal Congestion, Itchy Eyes, or Ear Pressure
- The list of cranial autonomic symptoms recognized in the International Classification of Headache Disorders, Third Edition (ICHD-3) is as follows:
  - Conjunctival injection and/or lacrimation
  - Nasal congestion and/or rhinorrhea
  - Eyelid edema
  - Forehead and facial sweating
  - Forehead and facial flushing
  - Sensation of fullness in the ear
  - Miosis and/or ptosis

PRIMARY HEADACHE DISORDERS AFFECTING CHILDREN AND ADOLESCENTS

- Tension-Type headaches
- Trigeminal-Autonomic Cephalalgias (TAC)
- Post-Traumatic headaches
- Primary stabbing headaches
- Migraine

TENSION-TYPE HEADACHES:

Diagnostic criteria:

A. At least 10 episodes of headache occurring on 1-14 days per month on average for >3 months (≥12 and <180 days per year) and fulfilling criteria B-D

B. Lasting from 30 min to 7 days

C. At least two of the following four characteristics:

1. bilateral location
2. pressing or tightening (non-pulsating) quality
3. mild or moderate intensity
4. not aggravated by routine physical activity such as walking or climbing stairs

D. Both of the following:

1. no nausea or vomiting
2. no more than one of photophobia or phonophobia

E. Not better accounted for by another ICHD-3 diagnosis.

Trigeminal-Autonomic Cephalalgias (TAC)

Trigeminal autonomic cephalalgias

- **3.1 Cluster headache**
  - 3.1.1 Episodic cluster headache
  - 3.1.2 Chronic cluster headache
- **3.2 Paroxysmal hemicrania**
  - 3.2.1 Episodic paroxysmal hemicrania
  - 3.2.2 Chronic paroxysmal hemicrania
- **3.3 Short-lasting unilateral neuralgiform headache attacks**
  - 3.3.1 Short-lasting unilateral neuralgiform headache attacks with conjunctival injection and tearing (SUNCT)
    - 3.3.1.1 Episodic SUNCT
    - 3.3.1.2 Chronic SUNCT
  - 3.3.2 Short-lasting unilateral neuralgiform headache attacks with cranial autonomic symptoms (SUNA)
    - 3.3.2.1 Episodic SUNA
    - 3.3.2.2 Chronic SUNA
- **3.4 Hemicrania continua**
- **3.5 Probable trigeminal autonomic cephalalgia**
  - 3.5.1 Probable cluster headache
  - 3.5.2 Probable paroxysmal hemicrania
  - 3.5.3 Probable short-lasting unilateral neuralgiform headache attacks
  - 3.5.4 Probable hemicrania continua

Posttraumatic Headache

- According to the ICHD-3, posttraumatic headache must begin within 7 days of head trauma to be attributed to that injury
- The topic of concussion and its management is a burgeoning and important area of research and is beyond the scope of this presentation.
- In brief, the phenotype of posttraumatic headache in children and adolescents can be featureful (ie, migrainous) or featureless (ie, similar to tension-type headache).
- In the absence of randomized trials guiding posttraumatic headache treatment in this age group, treating the headache based on the underlying phenotype seems reasonable.

Primary Stabbing Headache

- Brief attacks of sharp pain.
- The pain is typically described as a stab or series of stabs. It can be quite severe. Some children will be brought to their knees by the pain.
- Duration is typically just a few seconds, although some children may experience attacks lasting several minutes.
- Location can change from attack to attack or be fixed.
- The complete absence of cranial autonomic symptoms is important in distinguishing primary stabbing headache from trigeminal autonomic cephalalgias.
- Migratory location is also a helpful feature in distinguishing primary stabbing headache from a trigeminal autonomic cephalalgia.
- Usually, attacks are rare and short enough that they do not require any specific treatment. Reassurance about the benign nature of the headaches is typically all that families need.
- However, preventive treatment may be considered in cases where the attacks are frequent and distressing.
  - Indomethacin is useful for some adult patients.
  - Some patients will respond to nightly melatonin.

How Common is Migraine?

36 million Americans are affected by migraine

18% women and **6%** of men in the US have migraine

1 in every 4 American households
includes an individual affected by migraine

American Migraine Prevalence and Prevention (AMPP) Study

Identifying Migraine

The 3 Question ID Migraine Screen (a validated screen) for migraine

1. Has a headache limited your activities for a day or more in the last three months?

2. Are you nauseated or sick to your stomach when you have a headache?

3. Does light bother you when you have a headache?

Lipton R. et al, Neurology, 2003

PHENOTYPIC FEATURES OF MIGRAINE THAT DIFFER IN CHILDREN AND ADOLESCENTS VERSUS ADULTS

- PREMONITORY PHASE OF PEDIATRIC AND ADOLESCENT MIGRAINE
  - Fatigue, irritability/mood change, neck stiffness, and facial changes
- ICTAL PHASE OF PEDIATRIC AND ADOLESCENT MIGRAINE
  - Migraine duration in children can be shorter, particularly in children younger than 7 years of age.
  - In the ICHD-3, the lower margin of duration for untreated or unsuccessfully treated attacks in children is 2 hours versus 4 hours in adults.
  - The majority (more than 80%) of children and adolescents report bilateral migraine headache. This is the phenotype through late adolescence.
- POSTDROME PHASE OF PEDIATRIC AND ADOLESCENT MIGRAINE
  - thirst, somnolence, visual disturbances, and food cravings
  - In the vast majority of patients, postdrome symptoms resolved within 12 hours.

Calcitonin gene-related peptide (CGRP) levels are elevated in pediatric migraine attacks just as they are in adult migraine attacks

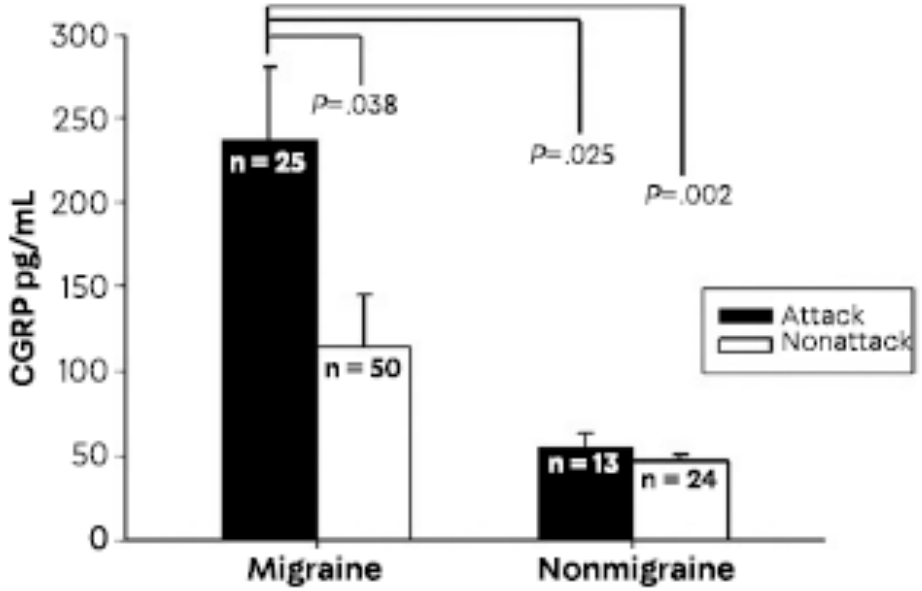


FIGURE 8-3

Calcitonin gene-related peptide (CGRP) levels in children with migraine versus children with nonmigraine headache both during headache and when without headache.

Reprinted with permission from Fan PC, et al, Cephalalgia.[28]

EPISODIC SYNDROMES THAT MAY BE ASSOCIATED WITH MIGRAINE.

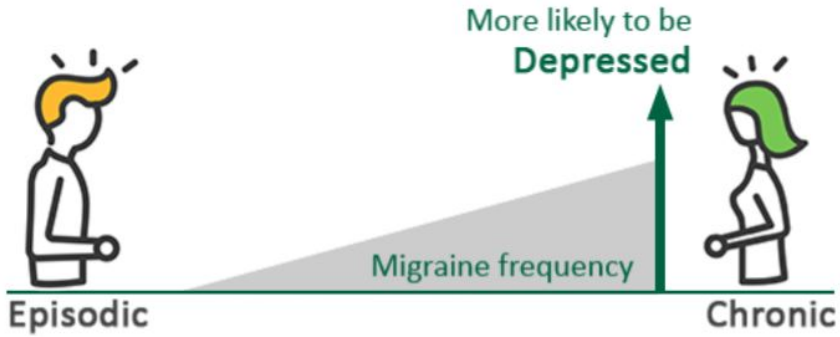
- INFANT COLIC
- BENIGN PAROXYSMAL TORTICOLLIS
- BENIGN PAROXYSMAL VERTIGO
- CYCLIC VOMITING SYNDROME
- ABDOMINAL MIGRAINE

Migraine & Psychiatric Comorbidities

- Depression
- Anxiety Disorders
- Bipolar Disorder
- Post Traumatic Stress Disorder
- History of Abuse
- Stress
- Sleep

DEPRESSION

Migraine frequency is associated with higher rates of depression



American Migraine Prevalence and Prevention (AMPP) Study
Taiwanese National Health Insurance Research Database (NHIRD) Study

DEPRESSION

Let's Look at the Data

UK Study: Using the Primary Care Evaluation of Mental Disorders (PRIME-MD)

47% of migraineurs had depression vs. 17% of non-migraineurs

Detroit Area Study of Headache telephone survey/household interview

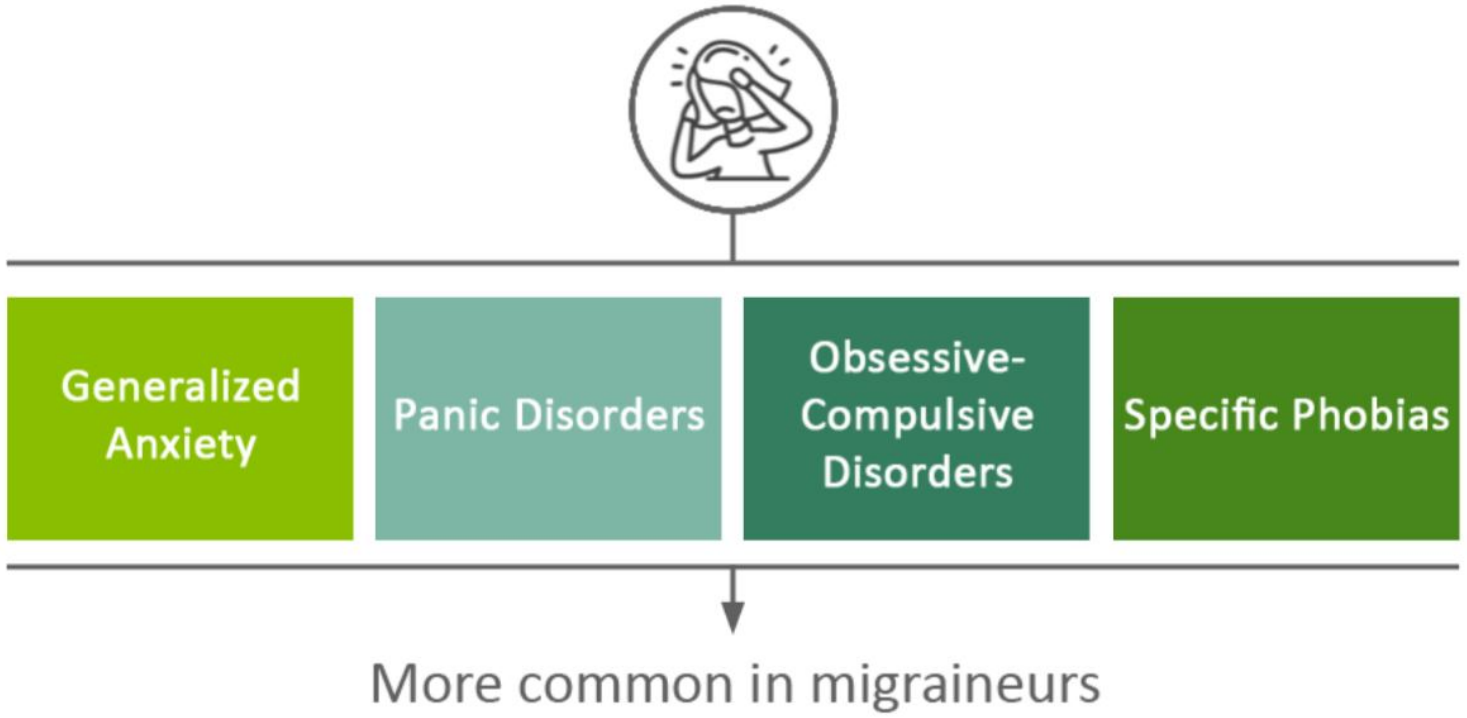
40.7% with migraine vs. 16% without migraine had depression

3rd study by Zwart et al. using the Hospital Anxiety and Depression Scale (HADS)

Migraineurs were 2.7x more likely to be depressed than people without migraines.

Lipton RB. Neurology. 2000
Breslau N et al. Neurology. 2000
Zwart JA et al. Eur J Neurol. 2003

ANXIETY DISORDERS



Breslau N et al. Psychiatry Res. 1991

ANXIETY DISORDERS

Let's Look at the Data

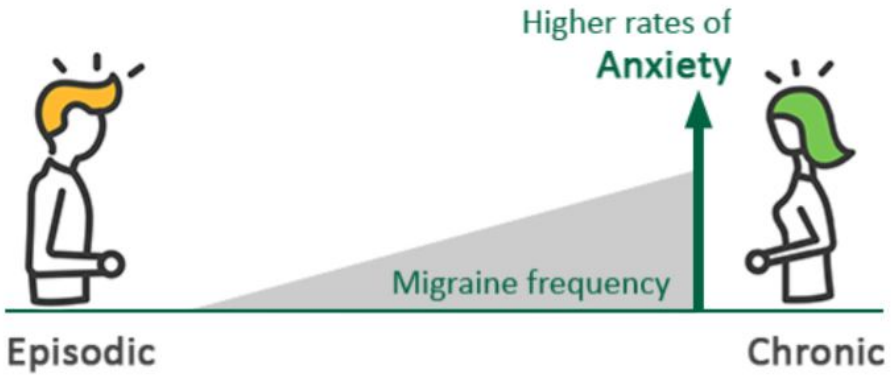
ANXIETY → **2 times** more common in migraineurs than depression

51-58% of migraineurs

Zwart JA et al. Eur J Neurol. 2003
Saunders K et al. Neurology. 2008
Breslau N. Cephalgia. 1998

ANXIETY DISORDERS

Migraine frequency is associated with higher rates of anxiety



American Migraine Prevalence and Prevention (AMPP) Study
International Burden of Migraine Study (IBMS)

BIPOLAR DISORDER

Bipolar disorder (BD) patients

Migraine prevalence is up to **39%**

Migraineurs

3x More likely to have BD

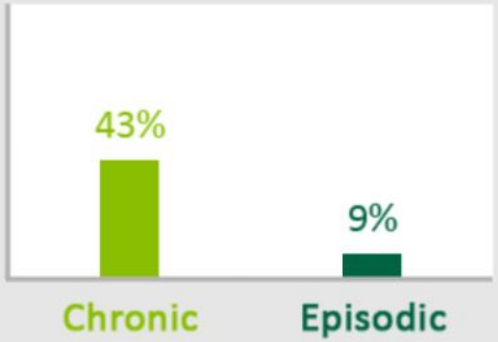
esp. for migraineurs with aura

Low NC et al. Headache. 2003
McIntyre RS et al. Headache. 2006
Breslau N et al. Psychiatry Res. 1991
Merikangas KR et al. J Psychiatr Res. 1993
Merikangas KR et al. Arch Gen Psychiatry. 1990

POST TRAUMATIC STRESS DISORDER

PTSD has been found to be in 25% of patients in a headache clinic being treated for chronic migraine or medication overuse headache compared to the general population (between 1-12%)

PTSD may occur at higher rates in chronic migraine (43%) compared to episodic migraine (9%).



Peterlin BL et al. Headache. 2008
Kessler RC. J Clin Psychiatry. 2000

ABUSE AND MIGRAINE

Childhood trauma (abuse or neglect) was reported by **58%**

Emotional abuse + neglect most common	38%
Physical abuse	21%
Sexual abuse	25%
Physical neglect	22%

Abuse during adulthood was reported in over **33%**

Physical abuse	20%
Sexual abuse	22%

Tietjen G et al. Headache. 2010
Tietjen G et al. Neurology. 2007

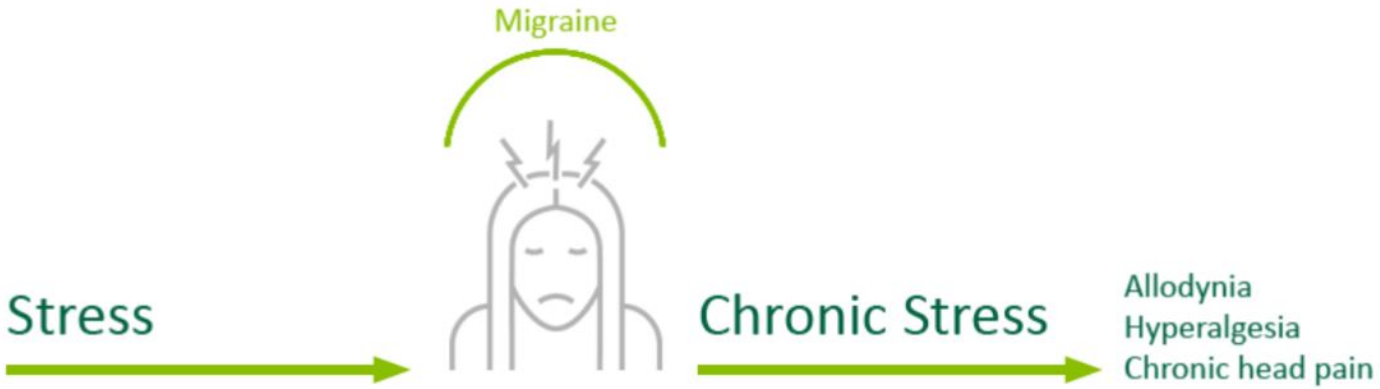
STRESS

- Hormonal changes
  - Nocturnal peak in prolactin
  - Delayed nocturnal peak in melatonin
  - Increased amount of cortisol
  - Menstrual Cycle
- Medication overuse can also affect allostasis

Borsook D et al. Neuron. 2012

STRESS

Stressful Life Events and Migraine



In a Taiwainese study:

Physical abuse and parental divorce were more common in families of adolescents with chronic daily headache

Borsook D et al. Neuron. 2012
Juand KD et al. Cephalgia. 2004

SLEEP DISORDERS

In psychiatric illness, there is evidence that sleep disturbances have a detrimental effect on the course of the psychiatric disorders and contribute to impaired function

Studies have found the following associations

Poor sleep quality and daytime sleepiness

- Out of 61 new patients only 38.6% reported sleeping the recommended duration
- Half of patients with suspected migraine screen positive for insomnia

Restless Leg Syndrome

- Lifetime prevalence 17.3% vs. 5.6%

Parasomnias

- Sleep walking, nightmares, sleep vocalizations, teeth grindings

Rhode AM et al. Cephalalgia. 2007
Cevoli S et al. Neurol Sci. 2012

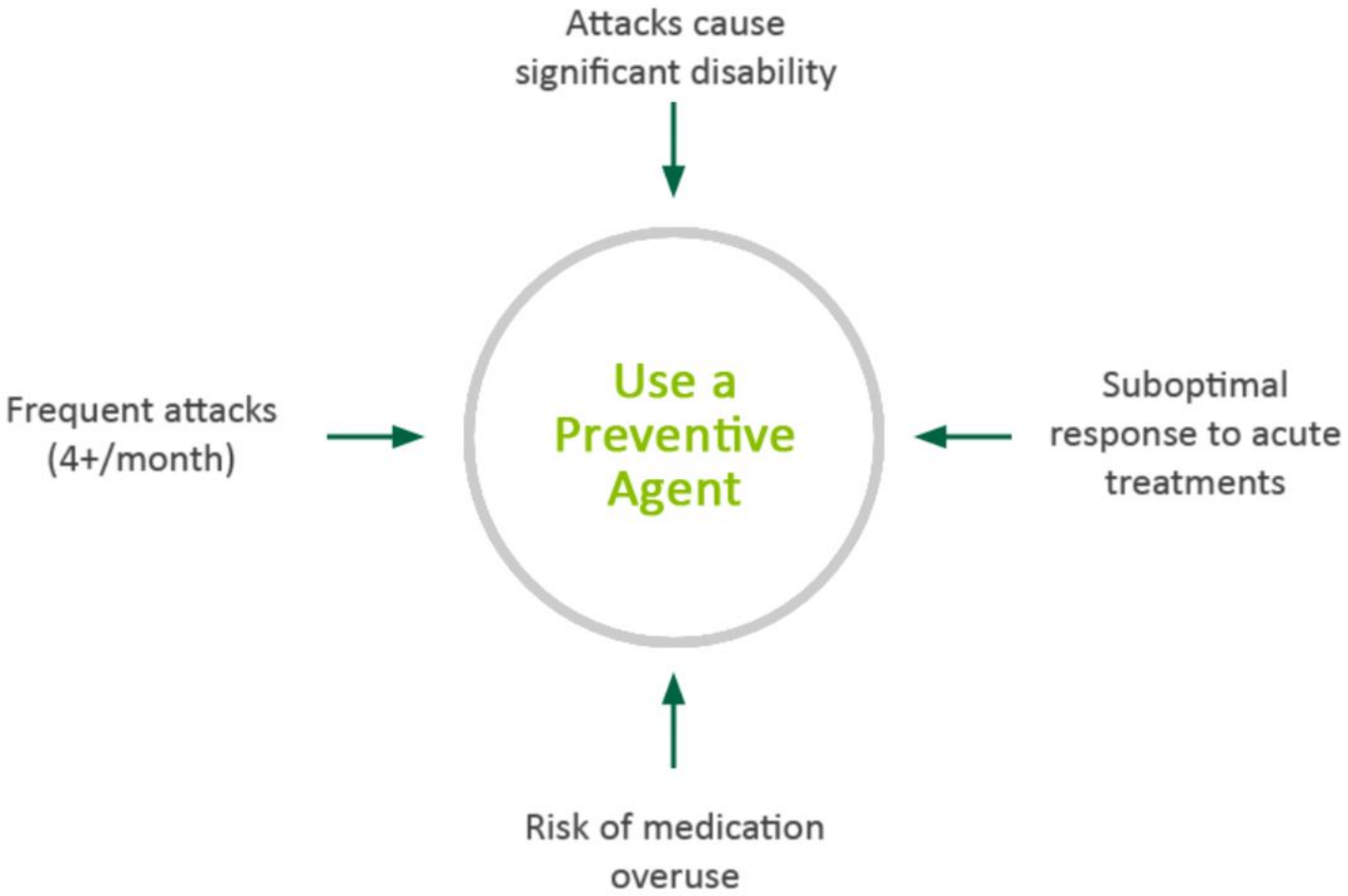
Screening Tools

CONDITIONS	SCREENING TOOLS	
Mood Disorders	BDI	Beck Depression Inventory
	PHQ-9	9-item Patient Health Questionnaire
	HADS	Hospital Anxiety and Depression Scale
	NIH PROMIS	National Institutes of Health Patient-Reported Outcomes Measurement Information System – Depression Short Form
Anxiety	GAD-7	7-item Generalized Anxiety Disorder
	BAI	Beck Anxiety Inventory
	PCL-5	Post-Traumatic Stress Disorder Checklist – 5
	NIH PROMIS	National Institutes of Health Patient-Reported Outcomes Measurement Information System – Anxiety Short Form
Sleep Disorders	ISI	Insomnia Severity Index (ISI)
		Berlin Sleep Apnea Questionnaire

TREATMENT OF PEDIATRIC AND ADOLESCENT MIGRAINE

- Pharmacologic Preventive Treatment
- Lifestyle Aspects of Migraine Prevention
- Behavioral Preventive Treatments for Pediatric and Adolescent Migraine
- Acute Migraine Treatment in Children and Adolescents

When to Use a Preventive Agent



Pharmacologic Preventive Treatment

- The CHAMP trial published in 2017 has helped to reframe the approach to migraine prevention in children and adolescents
- NIH-funded multisite trial designed to identify a first-line preventive for pediatric migraine prevention in children and adolescents ages 8 to 17 years, participants could have episodic or chronic migraine
- The three treatment arms of the CHAMP trial were amitriptyline (goal dose of 1 mg/kg), topiramate (2 mg/kg), and placebo.
- In all three treatment arms, approximately 60% of the participants met the primary end point of a 50% or more reduction in headache days 24 weeks after starting preventive therapy
- Topiramate currently remains FDA-labeled for migraine prevention in adolescents 12 to 17 years of age, and no preventive therapies labeled for children younger than age 12 exist.

High placebo response rate seen in the CHAMP trial:

- Lifestyle migraine management advice on sleep, exercise, hydration/eating, and caffeine. This advice was reinforced at monthly study visits.

- All participants received evidence-based optimal acute therapy, specifically nonsteroidal anti-inflammatory drugs (NSAIDs) and triptans, dosed appropriately and with use frequency guidance so as to avoid medication overuse.

Lifestyle Aspects of Migraine Prevention

- Maintaining regularity and homeostasis

American Academy of Sleep Medicine Recommendations for Sleep in Children and Adolescents[a]

Age of Children/Adolescents	Recommended Hours of Sleep
3–5 years of age	10–13 hours of sleep per 24 hours (including naps)
6–12 years of age	9–12 hours of sleep per 24 hours
13–18 years of age	8–10 hours of sleep per 24 hours

[a] Data from Paruthi S, et al, J Clin Sleep Med.[48]

Lifestyle Aspects of Migraine Prevention

- HYDRATION
  - Headachereliefguide.com
- CAFFEINE
- AVOIDING MEAL SKIPPING
- EXERCISE

Behavioral Preventive Treatments for Pediatric and Adolescent Migraine

- Cognitive Behavioral Therapy
  - incorporates identification and modification of thinking patterns and behaviors to improve perception of pain
- Biofeedback
  - Subconsciously controlled body functions (skin temperature, heart rate) are monitored with a technical device and patients learn to control them
- Relaxation Techniques
  - Mindfullness Stress Reduction Therapy
  - Aerobic exercise
  - Acupuncture

NEUTRACEUTICALS

- The evidence for the use of nutraceuticals is low or conflicting.
- For migraine prevention, Level B evidence, at best, exists for the use of feverfew, magnesium, and riboflavin (vitamin B2) in adults.
- Level C evidence exists for coenzyme Q10 (CoQ10)
- Level U evidence for melatonin.
- The evidence level for IV magnesium for acute migraine treatment is B.
- Recent AAN guidelines, concluded that relaxation training, thermal biofeedback combined with relaxation training, EMG biofeedback, and cognitive-behavioral therapy all have Grade A evidence for episodic migraine prevention.

Acute Migraine Treatment in Children and Adolescents

- ACETAMINOPHEN
- NONSTEROIDAL ANTI-INFLAMMATORY DRUGS
  - Ibuprofen
  - Naproxen
  - Ketorolac
- TRIPTANS
  - almotriptan (oral),
  - zolmitriptan (nasal spray),
  - rizatriptan (melt),
  - sumatriptan/naproxen (oral)

- Counseling to ensure the patient does not develop medication-overuse headache

Acute Migraine Treatment in the Emergency and the Inpatient setting:

- **Sumatriptan 4 mg to 6 mg subcutaneously**
- **Antiemetics plus dihydroergotamine (0.5 mg to 1 mg IV, repeat in 1 hour)**
- **Neuroleptics**
  Chlorpromazine (0.1 mg/kg) 12.5 mg to 37.5 mg IV/IM
  Prochlorperazine 5 mg to 10 mg IM, 25 mg per rectum
  Haloperidol 5 mg IV in 500 mg normal saline over 20 to 30 minutes
- **Ketorolac 30 mg to 60 mg IM; may treat cutaneous allodynia if not complicated by opioid use**
- **Magnesium 1 g to 2 g IV; limited evidence; may treat photophobia/phonophobia**
- **Valproate 300 mg to 500 mg IV; open-label trials**
- **Corticosteroids (eg, dexamethasone 10 mg to 24 mg IV)**
- **Metoclopramide 20 mg IV; may repeat**

Data from Acute Migraine Treatment.[31] *www.americanheadachesociety.org/assets/1/7/NAP_for_Web_-_Acute_Treatment_of_Migraine.pdf.* CONTINUUM: LIFELONG LEARNING IN NEUROLOGY

Rizzoli, Paul B. CONTINUUM: Lifelong Learning in Neurology18(4, Headache):764-782, August 2012. doi: 10.1212/01.CON.0000418641.45522.3b

Medication-overuse headache (MOH)

Diagnostic criteria

- Headache occurring on 15 days per month in a patient with a pre-existing headache disorder
- Regular overuse for >3 months of one or more drugs that can be taken for acute and/or symptomatic treatment of headache
- Not better accounted for by another ICHD-3 diagnosis

Medication-overuse headache (MOH)

Fear of future headaches

Ergotamine-, triptan- or opioid
Requires intake on 10+ days/ month for 3+ months

Simple analgesics
Require 15+ days, 2-3 treatment days/week

Butalbital-APAP-Caffeine
Known by the brand name-fioricet
Not recommended first line treatment

CONCLUSION

- Headache is common in children and adolescents.
- Most children who come to see the neurologist for headaches will have a primary headache disorder, with migraine being most common in this setting.
- For acute migraine treatment, acetaminophen and NSAIDs have been studied in children age 4 and older and have been found to be effective.
- Triptans are also effective in children and adolescents. Four triptans are now FDA-labeled for acute migraine treatment in adolescents, and rizatriptan is labeled for use in children age 6 and older.
- For preventive migraine treatment, the recent CHAMP trial indicates that approximately 60% of children and adolescents with migraine will improve with a three-pronged treatment approach that includes:
  - lifestyle management counseling
  - evidence-based optimally dosed acute therapy, specifically NSAIDs and triptans
  - a daily preventive treatment that has some evidence for efficacy and a side effect profile that is similar to that of placebo

References:

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