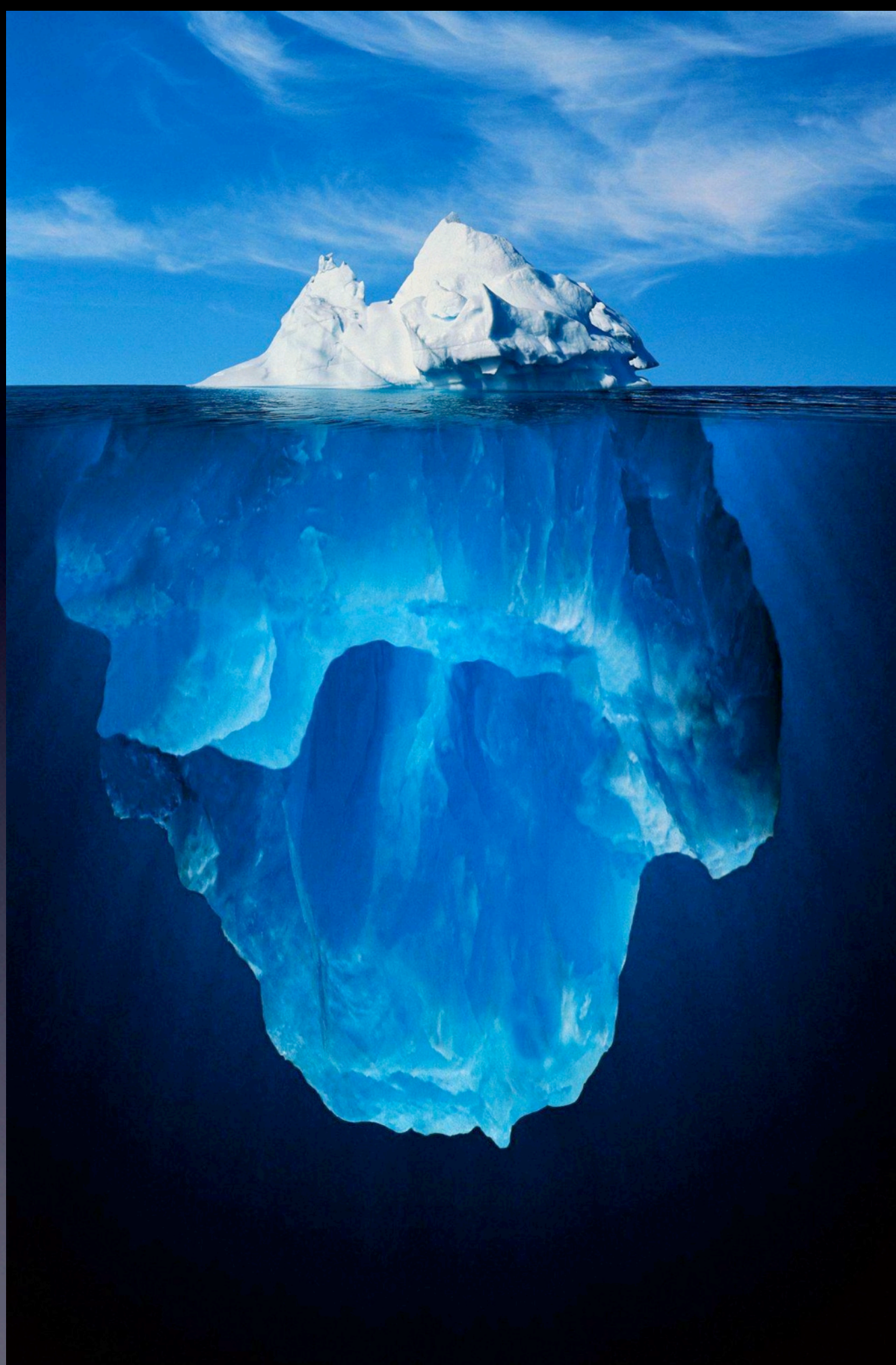


# Improving Long-Term Headache Control for ED patients with Chronic Headache

Jim Burke MD MS, University of Michigan Department of Neurology  
Will Meurer MD MS, University of Michigan Department of Emergency Medicine







# Evidence-based guideline update: Pharmacologic treatment for episodic migraine prevention in adults

Report of the Quality Standards Subcommittee of the American Academy of Neurology and the American Headache Society



S.D. Silberstein, MD,  
FACP

S. Holland, PhD

F. Freitag, DO

D.W. Dodick, MD

C. Argoff, MD

E. Ashman, MD

| Level A: Medications with established efficacy ( $\geq 2$ Class I trials) | Level B: Medications are probably effective (1 Class I or 2 Class II studies) | Level C: Medications are possibly effective (1 Class II study) |
|---|---|--|
| Antiepileptic drugs   | Antidepressants/SSRI/SSNRI/TCA  | ACE inhibitors<br>Lisinopril                                   |
| Divalproex sodium   | Amitriptyline   | Angiotensin receptor blockers                                  |
| Sodium valproate  | Venlafaxine   | Candesartan  |
| Topiramate  | $\beta$ -Blockers   | $\alpha$ -Agonists   |
| $\beta$ -Blockers   | Atenolol <sup>a</sup>   | Clonidine <sup>a</sup>   |
| Metoprolol  | Nadolol <sup>a</sup>  | Guanfacine <sup>a</sup>  |
| Propranolol   | Triptans (MRM <sup>b</sup> )  | Antiepileptic drugs  |
| Timolol <sup>a</sup>  | Naratriptan <sup>b</sup>  | Carbamazepine <sup>a</sup>                                     |
| Triptans (MRM <sup>b</sup> )  | Zolmitriptan <sup>b</sup>   | $\beta$ -Blockers  |
| Frovatriptan <sup>b</sup>   |   | Nebivolol  |
|   |   | Pindolol <sup>a</sup>  |
|   |   | Antihistamines   |
|   |   | Cyproheptadine   |

# Topiramate for the prophylaxis of episodic migraine in adults (Review)

Linde M, Mulleners WM, Chronicle EP, McCrory DC

| Study or subgroup     | Topiramate | Placebo    | Odds Ratio<br>M-<br>H,Random,95%<br>CI | Weight         | Odds Ratio<br>M-<br>H,Random,95%<br>CI |
|-----------------------|------------|------------|--|----------------|--|
|                       | n/N        | n/N        |  |                |  |
| Brandes 2004          | 59/120     | 26/114     |  | 16.9 %         | 3.27 [ 1.86, 5.76 ]                    |
| de Tommaso 2007       | 8/13       | 0/11       |  | 1.8 %          | 35.55 [ 1.72, 734.05 ]                 |
| Diener 2004           | 51/139     | 31/143     |  | 17.6 %         | 2.09 [ 1.24, 3.54 ]                    |
| Edwards 2000          | 7/15       | 1/15       |  | 3.0 %          | 12.25 [ 1.27, 118.36 ]                 |
| Gupta 2007            | 35/56      | 17/57      |  | 13.1 %         | 3.92 [ 1.79, 8.59 ]                    |
| Mei 2004              | 22/35      | 8/37       |  | 9.7 %          | 6.13 [ 2.17, 17.37 ]                   |
| Silberstein 2004      | 68/125     | 26/115     |  | 17.0 %         | 4.08 [ 2.33, 7.16 ]                    |
| Silberstein 2006      | 55/138     | 25/73      |  | 16.4 %         | 1.27 [ 0.70, 2.30 ]                    |
| Storey 2001           | 5/19       | 2/21       |  | 4.5 %          | 3.39 [ 0.57, 20.10 ]                   |
| <b>Total (95% CI)</b> | <b>660</b> | <b>586</b> |  | <b>100.0 %</b> | <b>3.18 [ 2.10, 4.82 ]</b>             |

Total events: 210 (Topiramate), 126 (Placebo)





*An initiative of the ABIM Foundation*

## American Academy of Neurology

### Five Things Physicians and Patients Should Question

3

**Don't use opioid or butalbital treatment for migraine except as a last resort.**

Opioid and butalbital treatment for migraine should be avoided because more effective, migraine-specific treatments are available. Frequent use of opioid and butalbital treatment can worsen headaches. Opioids should be reserved for those with medical conditions precluding the use of migraine-specific treatments or for those who fail these treatments.



# Why Focus on the ED?

- Severity Selection
- Only place to target the population in greatest need?
- Increased salience of prevention message
- It hasn't been focused on before



# Research Questions

1. Will headache prophylaxis, provided to the ED headache population at ED discharge effectively reducing headache frequency?
2. Will headache self-management programs, initiated in the ED, effectively reduce headache frequency?
3. Can ED-focused quality improvement initiatives change prescribing practices?



# Design

- Individual Level Factorial RCT — prophylaxis initiation, self-management and visit navigation
- Facility Level — cluster randomized trial



# Patient Selection

- **Inclusion**
  - Headache primary ED reason for visit
  - Prior ED visit for headache within prior 3 months OR MIDAS > 5
  - Ability to provide informed consent
- **Exclusion**
  - Age < 18
  - Prophylaxis contraindication
  - Red Flags/Abnormal neurological examination
  - Pregnancy



# Design

|                                       | Prophylaxis/<br>Topiramate | Placebo |
|---------------------------------------|----------------------------|---------|
| Self Management +<br>Visit Navigation | 25%                        | 12.5%   |
| Self Management                       | 12.5%                      | 12.5%   |
| Visit Navigation                      | 12.5%                      | 12.5%   |
| Usual Care                            | 12.5%                      | 0%      |



# Quality Improvement

- Facilities randomized to a multi-faceted quality improvement initiative vs. No intervention
- Practitioner education on medication overuse headache
- Development of site-specific headache discharge pathways
- Monthly feedback to practitioners on compliance with pathways



# Outcomes

- **Primary Outcome:** Change in MIDAS score from enrollment to 180 days
- **Secondary Outcomes:** ED Visits in 180 days, PCP visits, Active narcotic prescription? Active prophylactic prescription?
- **Safety:** Medication-related adverse effects





# Innovation

- Central Telemedicine Randomization
- Broad-based outcome ascertainment platform
- Potential for novel funding sources











## The Migraine Disability Assessment Test

The MIDAS (Migraine Disability Assessment) questionnaire was put together to help you measure the impact your headaches have on your life. The information on this questionnaire is also helpful for your primary care provider to determine the level of pain and disability caused by your headaches and to find the best treatment for you.

### INSTRUCTIONS

Please answer the following questions about ALL of the headaches you have had over the last 3 months. Select your answer in the box next to each question. Select zero if you did not have the activity in the last 3 months.

- \_\_\_\_\_ 1. On how many days in the last 3 months did you miss work or school because of your headaches?
- \_\_\_\_\_ 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? (Do not include days you counted in question 1 where you missed work or school.)
- \_\_\_\_\_ 3. On how many days in the last 3 months did you not do household work (such as housework, home repairs and maintenance, shopping, caring for children and relatives) because of your headaches?
- \_\_\_\_\_ 4. How many days in the last 3 months was your productivity in household work reduced by half or more because of your headaches? (Do not include days you counted in question 3 where you did not do household work.)
- \_\_\_\_\_ 5. On how many days in the last 3 months did you miss family, social or leisure activities because of your headaches?
- \_\_\_\_\_ Total (Questions 1-5)

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

**Scoring:** After you have filled out this questionnaire, add the total number of days from questions 1-5 (ignore A and B)

| MIDAS Grade | Definition              | MIDAS Score |
|-------------|-------------------------|-------------|
| I           | Little or no disability | 0-5         |
| II          | Mild disability         | 6-10        |
| III         | Moderate disability     | 11-20       |
| IV          | Severe disability       | 21+         |

**Please give the completed form to your clinician.**

This survey was developed by Richard B. Lipton, MD, Professor of Neurology, Albert Einstein College of Medicine, New York, NY, and Walter F. Stewart, MPH, PhD, Associate Professor of Epidemiology, Johns Hopkins University, Baltimore, MD.