

Integrative Approaches to Headache Management

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This discussion is based on a plenary presentation from our 20th Annual Clinical Meeting in October 2009.

Whether through a literature review or a refractory headache patient asking for additional options, we are often reminded of the need for improved headache management. In many cases, the lack of satisfaction does not stem from a missing treatment, but rather the need for a global perspective on the individual burden of headache, which can point to the most appropriate treatment approach. This perspective, known as the integrative approach, underscores the importance of proper diagnosis, education, and reassurance, as well as appropriate and individualized pharmacologic and interventional care. In addition, incorporating self-management skills and evidence-based integrative and behavioral approaches round out treatment offerings to optimize care. Overall, this approach can be a transformative experience for the patient and the clinician.

Headache Burden and Complementary and Alternative Medicine (CAM) Use

Those suffering from headaches deal with extensive sequelae from the primary diagnosis as well as from comorbidities that create a significant personal, social, and societal burden. Migraine has been declared one of the top 10 disabling medical conditions, with sufferers experiencing more pain and restrictions in their daily activities than people diagnosed with osteoarthritis, diabetes, and depression (1,2). In addition, those dealing with migraine are more likely to be diagnosed with mood, sleep, movement, and pain disorders, such as depression, anxiety, insomnia, restless legs syndrome, fibromyalgia, and myofascial pain syndrome (3-7).

One comorbidity that may be overlooked is myofascial pain syndrome, which is often diagnosed with

characteristic trigger points (TrPs). Active TrPs in the upper trapezius, sternocleidomastoid, and temporalis muscles are associated with chronic tension type headache (CTTH) as well as with greater headache intensity and duration (8). In another study, TrPs were noted in 93.9% of migraineurs versus 29% of controls ($p < 0.0001$) with the number of TrPs being significantly associated with the duration and frequency of migraine attacks (9). Other studies in both CTTH and migraine populations have noted pressure pain sensitivity of the trapezius, temporal, and suboccipital muscles as well as their association with development of peripheral sensitization/hyperalgesia (10).

Based on the lack of satisfaction, large number of comorbidities, and the effect on quality of life (QOL), it is not surprising that the most common reason (47.7%) for attempted use of CAM among headache sufferers was “potentially beneficial for headache.” A similar percentage (30% to 40%) found the therapies helpful. Unfortunately, these therapies are often isolated from conventional care or even each other, with 60% of CAM users not informing their medical doctors of CAM use (11).

The Integrative Team and Patient Flow

An integrative team best addresses the divergent needs of the headache patient. In the case of the Scripps Clinic, an integrative approach requires the neurological expertise of the Donald J. Dalessio Headache Center; physical therapists trained in postural, manual, and craniosacral therapy; and the Scripps Center for Integrative Medicine with its team of integrative physicians, nurse practitioners, nurses, acupuncturists, dieticians, pharmacists, psychologists, and biofeedback therapists (Figure 1).

The initial neurological evaluation includes diagnosis, discussion, and reassurance, with the incorporation of medical, interventional, and preventive approaches. Focus is placed on early incorporation of preventive and abortive treatments to avoid progression of headache into

a chronic daily phenomenon. Often a discussion of common triggers is important to help individualize self-management, pharmacologic, and nonpharmacologic therapies.

Subsequently, the patient undergoes an integrative medicine consultation that continues the discussion of trigger management, and develops an integrative plan using in-house therapies, such as acupuncture, biofeedback, hypnosis, healing touch, diet and dietary supplement counseling, and yoga, to provide an individualized menu of treatment options (Figure 2).

When outside services, such as chiropractic manipulation or additional psychobehavioral services, are deemed medically appropriate, referrals are made to specific practitioners in the community. The patient is followed by the neurology and integrative medicine specialists at both centers on a regular basis to determine the benefit of current therapies as well as the need for the introduction or tapering of therapies. At all stages, the clinician not only attempts to integrate appropriate therapies with patients, but also strives to integrate patients with their treatment plan. By incorporating patient preferences, motivations, and individual needs throughout the treatment process, the greatest likelihood of understanding, compliance, and self-empowerment are obtained.

Figure 1. The Scripps Clinic Integrative Headache Care Team



From left to right: Brenda Rodi, FNP; Robin Beltran, PhD, biofeedback specialist; Margie Moore, RN, Lac, acupuncturist; Michael K. Sullivan, physical therapist; Andrea Ogden, RD, registered dietitian; Steven Poceta, MD, neurologist; Christy Jackson, MD, neurologist; Josh Eha, Lac, acupuncturist; Emily Engel, MD, neurologist; Robert Bonakdar, MD, integrative medicine specialist; Deborah Stapel, NP; Sarah LaBarbera, BCIA-C, biofeedback specialist; Nancy Anderson, LAC, acupuncturist; Cathy Garvey, RD, registered dietitian. (Not Pictured: Sherrie Gould, NP-C; James Mattioda PhD, RPH; Karen Sothers, MEd [Yoga therapist])

Figure 2. Integrative Options for Headache Management



Pharmacologic and Interventional Options

In addition to improving QOL, early evaluation and medical treatment is important for several reasons. Appropriate preventative and abortive medication use can help avoid central sensitization, avoid medication overuse

headache, and help retain the efficacy of prophylactic medications (12,13).

Pharmacologic treatments for acute headache typically fall into the following categories: simple and combination analgesics, nonsteroidal anti-inflammatory drugs (NSAIDs), ergots, selective 5HT1 agonists, antiemetics, tranquilizers, corticosteroids, anxiolytics and narcotics. The incorporation of these treatments needs to be individualized, taking into consideration key factors including frequency of headache and medication use, timing of headache (e.g., early in the morning, menstrual migraine), severity of associated symptoms such as nausea, and need for repeated treatment.

New acute treatments, which currently include a combination of sumatriptan and naproxen to help reduce need for second dosing of rescue

medications, sumatriptan air injector, and DHE inhalation apparatus, are important to keep in mind to help optimize and individualize acute treatment choices.

Preventive treatment needs to be considered early in treatment. This is especially true if headache-related disability is >3 days/month, when symptomatic treatments are contraindicated, ineffective, or leading to overuse. Also, if there are any profound bouts of disability, including prolonged auras, neurological deficits, or migrainous infarcts, prevention should be immediately considered. Preventive treatments fall into the categories of b-blocker, calcium channel blockers, tricyclics, antidepressants, and certain neurological medications used in other settings, such as anticonvulsants, which may have benefit in the setting of headache. Similar to acute treatments, preventive treatments need to be individualized based on level on comorbid insomnia, anxiety, depression, and vasospasm, as examples. Patients may have varying levels of side effects (e.g., sedation, fatigue, weight change) which may alter available treatment options.

In addition to acute and preventive medications, injection and interventional therapies performed by trained specialists may be required in certain refractory cases such as with cervicogenic headache, occipital migraines, or headache associated with significant myofascial spasm. These procedures may include treatment of dysfunction at the level of the joint, nerve, or soft tissue, and include radiofrequency or chemical treatments such as injections with a continuum of agents based on severity (e.g., sterile water, anesthetic, corticosteroid, and botulinum toxin).

Nonpharmacologic Interventions

In conjunction with discussion of pharmacologic and interventional options, it is equally important to introduce nonpharmacologic interventions, which represent a diverse group of therapies (Figure 2). In 2000, the US Headache Consortium, a multidisciplinary group representing both primary care and specialty clinicians, concluded that nonpharmacologic treatments were well suited for patients who have: a preference for nonpharmacologic treatment; poor tolerance of, contraindications to, or insufficient response to pharmacologic treatment; planned to become or currently are pregnant or nursing; a history of long-term, frequent, or excessive analgesic or acute medications; and exhibited significant stress or deficient stress-coping skills (14).

Trigger Management

One of the most important aspects of nonpharmacologic management is trigger management. Since the vast majority of headache sufferers report some type of trigger for their migraine, an overview of triggers can be used to identify therapies that the patient is most motivated to pursue. One of the most commonly identified triggers is diet. We look closely at nutrition, in order to get rid of trigger foods, and fortify potential areas of deficiencies. Our end goal is not only to reduce headache, but to create an appropriate, health-promoting, anti-inflammatory diet.

When discussing trigger foods we often discuss “Aware of the A’s” as a quick reference for trigger food avoidance, which includes allergenic foods, such as gluten; additives, such as those found in processed or packaged foods; artificial ingredients, such as sweeteners; aged foods, such as cheese, wine, sauerkraut, or cured meats; and alcohol. Other important aspects of diet management include getting appropriate protein intake and avoiding excess pro-inflammatory fat. One study demonstrated that a reduction in dietary fat, and preferably a transition from saturated and trans fats to mono- and polyunsaturated fats (from 60 g/day to 30 g/day), demonstrated a reduction in the frequency, intensity, and duration of migraines, in addition to medication use (15).

Dietary Supplements for Headache

After discussing dietary triggers and transitioning to a more optimal diet, supplements can address areas of nutritional deficiency and/or suboptimal energy metabolism. If you consider migraine headache as a partially a mitochondrial disorder, several supplements—including magnesium, riboflavin, and CoQ10—may be depleted in the migraine state and replacement can provide symptomatic benefit. Additionally, recent research suggests that the efficacy of supplements—B vitamins in particular—may be determined by genetic factors that influence cofactor and energy metabolism, including methylenetetrahydrofolate reductase (MTHFR) enzyme dysfunction and non-H mitochondrial DNA haplotypes (16,17). Several of the more common supplements used in headache management are reviewed below.

Magnesium is important for many enzymatic conversions and may cause increased inflammatory burden when deficient in the diet. Unfortunately, most people do not get enough magnesium, since 68% of US adults consume

less than the recommended daily allowance (RDA) and 19% consume less than 50% of the RDA. Importantly, those who consumed less than the RDA of magnesium were 1.48 to 1.75 times more likely to have elevated C-reactive protein (CRP), which is linked to a number of inflammatory conditions (18).

Treatment appears safe in most groups. In a study of 118 children with migraine, it was demonstrated that 9 mg/kg magnesium oxide daily was more effective than placebo in reducing headache frequency and severity (19). Absorption and gastrointestinal effects are variable, and different formulations (i.e., oxide, sulfate, chelated forms) may need to be attempted. Of note, vitamin D can be predictive of optimal magnesium absorption, so checking and correcting vitamin D deficiency should also be a part of the headache and dietary supplement evaluation (20).

Riboflavin (vitamin B2) has also been shown to be effective in reducing headache days, although it may not significantly change the intensity or duration of episodes (21-23). Side effects are rare but, like with magnesium, may include diarrhea.

Coenzyme Q10 (CoQ10) may also be deficient in headache sufferers (as found in 1/3 of adolescent migraine sufferers) and appears safe and effective in the pediatric population. Replacement of 1 to 3 mg/kg per day in the adolescent population or 300 mg in the adult population appears to decrease headache frequency and disability (24,25).

Butterbur (*Petasites hybridus* root) was originally used for allergic disorders, so conceptually it may be effective in stabilizing the spreading inflammatory phenomenon seen in migraine. The recommended dosage that has been successful in decreasing migraine in adults is 150 mg/day, and in children 25 to 50 mg twice daily (31,32). Most of the trials use the Petadolex® formulation, which is typically well tolerated, other than mild gastrointestinal adverse events.

Research on **feverfew** (*Tanacetum parthenium*) has been very mixed, and may be based on the formulation utilized (26-29). New formulations, such as a sublingually administered feverfew and ginger may be effective for acute treatment of migraine when administered during the mild pain phase (30).

A green-bordered poster with white text. At the top, it says "Call for 2010 Poster Proposals!". Below this is a photograph of a person standing next to a large poster board displaying data. Under the photo, the text reads: "Display your data to our unique, integrative audience at the 21st Annual Clinical Meeting of the American Academy of Pain Management, September 21-24, 2010, Caesars Palace, Las Vegas, Nevada". Below that, it says "Submission deadline: June 1, 2010". At the bottom, it says "Visit the Academy's website (www.aapainmanage.org) for more information and the Poster Proposal Form".

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When recommending any dietary supplement, several key points need to be emphasized. In most cases, these supplements need to have 3 to 4 months of compliance for appropriate benefit evaluation, especially when trying to improve deficiency or cellular energy production. On a practical basis, it is important to educate the patient on why he or she is taking it, where to get it, what brand to buy, how to use it, and potential side effects.

Clear directions on finding and using supplements can help decrease the confusion that can often occur when attempting to identify a supplement on the shelf, a phenomenon we call the *Supplement Stare Syndrome*, which happens to both clinicians and patients. One approach that has worked at the Scripps Clinic is incorporating a dietary supplement pharmacy, staffed by a pharmacist trained in prescription and dietary supplement therapies. This approach, or a system in which clinicians collaborate with a community pharmacist or dietary supplement expert, helps to ensure that the patient is educated on the different formulations, and has the best chance of incorporating what is recommended.

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Patients with nausea: No dose adjustment against nausea is necessary in patients with Grade 1 nausea. The safety and efficacy of FENTORA when used in patients with nausea were similar to those in patients who did not have nausea.

Opening the Blister Package

1. Patients should be instructed not to open the blister until ready to administer FENTORA.
2. A single blister unit should be separated from the blister pack by tearing and tearing apart the perforations.
3. The blister unit should then be bent along the lines to remove the tablet.
4. The blister backing should then be peeled back to expose the tablet. Patients should NOT attempt to push the tablet through the blister as this may cause damage to the tablet.
5. The tablet should not be stored since it has been removed from the blister package as the tablet may be compromised and, more importantly, because this increases the risk of accidental exposure to the tablet.

Tablet Administration: Once the tablet is removed from the blister unit, the patient should immediately place the tablet in the mouth. The tablet is not to be placed in the mouth, between the upper front and back teeth. Patients should not attempt to split the tablet. The FENTORA tablet should not be crushed, chewed or swallowed, as this will result in lower plasma concentrations than when taken as directed. The FENTORA tablet should be taken with water and a full glass of water. After 20 minutes of removal from the FENTORA blister pack, the tablet should be swallowed with a glass of water. It is recommended that patients observe sides of the mouth when administering through the sides of FENTORA.

SAFETY AND HANDLING

FENTORA is highly and potentially weakly, acid-resistant blister packages. The amount of fentanyl contained in FENTORA can be fatal to a child. Patients and their caregivers must be instructed to keep FENTORA out of the reach of children. (See **DOSED WARNING, WARNINGS, PRECAUTIONS, and MEDICATION GUIDE**) Store at 20-25°C (68-77°F) with excursions permitted between 15° and 30°C (59° to 86°F) and only to use. (See USP Controlled Room Temperature.) FENTORA should be protected from bright light. Do not use if the blister package has been tampered with.

DISPOSAL OF FENTORA

Patients and members of their household must be advised to dispose of any tablets remaining from a prescription as soon as they are no longer needed. Information is available in Information for Patients and Caregivers and in the Medication Guide. If additional assistance is needed, refer to the Lexicomp.com (1-800-368-6989) website for more. To dispose of unused FENTORA, remove FENTORA tablets from blister packages and flush down the toilet. Do not flush FENTORA blister packages or tablets down the toilet. If you need additional assistance with disposal of FENTORA, call Cephalon, Inc., at 1-800-686-6874.

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Each carton contains 1 blister pack with 4 white tablets in each pack. The blisters are clear, resistant, and made of polyethylene and are protected from moisture. Each tablet is imprinted on one side with 222, and the other side of each tablet is imprinted with a unique identifier by the embossing on the tablet. The storage strength of each tablet is marked on the blister, the blister package and the carton. See blister package and carton for product information. **Note:** Carton/blister package colors are a secondary aid in product identification. Please be sure to confirm the printed color before dispensing.

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therapies includes their ability to increase self-efficacy in dealing with the burden of headache (39).

For example, we use various individualized biofeedback methods—whether thermogenic, muscular tension (sEMG), or heart rate variability—in most patients with headache, and find it extremely helpful in improving self-management. Our protocol is to have the patient meet with the biofeedback therapist once a week for 4 weeks with daily homework throughout the period to reinforce techniques. Most patients will graduate after this period, although some patients may need more sessions to fully incorporate techniques. By gaining more awareness and insight into their condition and the treatment they are utilizing, patients often gain greater confidence and ability in recognizing and self-managing symptoms and triggers on a long-term basis.

Movement Therapies

Movement-based therapies have great promise in the setting of headache, especially when associated with muscle tension, poor posture, and cervicgia. Unfortunately, reviews and trials are inconsistent and point to the fact that many headache sufferers suffer from tissue hyperalgesia and need very individualized and graded therapies to meet their needs. For example, physical therapies appear to be most beneficial for CTTH when patients have a high frequency of headache episodes. Also, physical therapies for migraine seem to be most effective when combined with treatments such as biofeedback, relaxation training, and exercise, lending more weight to the concept of an integrative approach (40). When examining the incorporation of movement and physical therapies, including exercise, stretching, massage, manual therapy, manipulation, and craniosacral therapy, it is important to start slow and utilize therapists experienced with headache.

Fortunately, it does not take much to gain benefit through movement. A study involving 284 office workers with chronic headache or neck pain, demonstrated that an educational and physical program involving simple relaxation exercises and stretches was effective in reducing headache frequency, neck and shoulder pain, and medication use after 6 months (41). We need more research on several of these therapies and who benefits most, but we often start with stretching or recommend yoga therapy, which has been shown in a preliminary trial to be beneficial for migraine without aura (42). We have several yoga therapists in our clinic that can demonstrate

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Mind-body Therapies

Mind-body therapies are an excellent choice for the most commonly identified headache trigger (stress) as well as other common comorbidities such as muscle tension, insomnia, and mood disorders that may often be difficult to resolve. Mind-body therapies, including biofeedback, guided imagery, cognitive behavioral therapy, meditation, music therapy, relaxation training, and stress management, have been long proven safe and effective in the setting of headache (33,34). Several meta-analyses have shown that the improvement ranges from 30% to 50% versus control for both migraine and tension-type headache (35,36). There also appears to be a synergistic impact when these therapies are used with medications with responder rate increasing to over 60% as compared to 30% to 40% with monotherapy (37,38). In addition to gains in common headache comorbidities such as anxiety and depression, one of the most underappreciated benefits of mind-body

which postures and breathing techniques can be helpful for headache with the goal of transitioning to use in the home and office setting.

Energetic Treatment

Because headaches and chronic pain affect patients on many levels, including physical, emotional, and spiritual, energetic therapies may be especially useful in certain cases. Preliminary evidence points to the benefit of healing touch among other energy treatments in the setting of headache (43). The energetic treatment with the most evidence is probably acupuncture. This treatment, which is a component of Traditional Chinese Medicine, has been used for several thousand years in the prevention and treatment of multiple conditions, including pain.

The recent Cochrane review of 22 trials (n=4419) (44) demonstrated that acupuncture appears to be effective for prevention of migraine headaches, and may be slightly better than pharmacotherapy with a strength of evidence of A, based on consistent and good-quality patient-oriented evidence. Interestingly, acupuncture appears to be based on a potent unspecific needling effect, thus making it difficult to differentiate from sham acupuncture in trials (45). Interestingly, in 4 trials comparing acupuncture with proven prophylactic pharmacologic treatment with beta blockers, calcium channel blockers, or valproic acid, acupuncture demonstrated slightly better outcomes at 2, 4, and 6 months after randomization, with fewer adverse effects reported (44).

Patient-centered Treatments

When considering integrative therapies, it is important to not only consider the evidence for a treatment, but also to what degree the patient is integrated into the treatment. In many cases, a treatment that theoretically is a perfect fit may not match a patient's preference, understanding, or belief system. This may be true of both pharmacologic and nonpharmacologic options and points to the importance of an open, nonjudgmental discussion regarding goals for therapy, so that the most appropriate and patient-friendly options can be incorporated. Research has suggested that in clinical trials patient preference can often be a strong indicator of treatment outcomes, including level of compliance, follow-up, and benefit. Thus, the treatment(s) initiated is suggested to blend available evidence and patient preference to best ensure safety, compliance, potential benefit, and ongoing clinician-patient dialogue.

Putting it all Together

When examining how to combine treatments effectively, research demonstrates that simple integration can be both clinically and financially effective. A study that looked at a low-cost group program, which included supervised exercise, stress management and relaxation, massage, and dietary education, resulted in an improvement in the overall frequency, severity, and duration of headaches at 6-week and 3-month follow-up (46). In addition, improvements were made in patients' functional status, QOL, health status, pain-related disability, depression. Many education and self-management techniques can be replicated in a clinic setting to provide more integrative options at a low cost to improve patients' headaches, increase their QOL, and most importantly, empower them to manage their pain on their own.

Conclusions and Next Steps

Headache disorders are often precipitated and exacerbated by a complex set of factors which can create significant multisystem dysfunction. Similarly, treatments often need to provide multipronged support to enable both pain reduction as well as management of significant comorbidities affecting sleep, mood, physical conditioning and social functioning. In many ways, an integrative model, which follows the principles discussed, provides a comprehensive, whole person approach to headache management while empowering the patient to increase awareness and self-management approaches. Such a model also has promise to provide both a more cost-effective and patient-friendly approach to headache management. The clinician plays a key role in openly discussing and providing guidance in the appropriate incorporation of integrative options to optimize care. ■



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