Does Your Headache Treatment Plan Include Targeted Thermal Therapy?

Evidence for Thermal Therapy Application as Primary or Adjunctive Headache Relief

Targeted Thermal Therapy: A Drug-Free Alternative for Headache Relief

Physicians have many treatments available for the headache sufferer. Most treatment plans include medication and/or lifestyle modifications, but for multiple reasons, many patients need or desire a safe, self-administered, simple, drug-free alternative for their headache relief. Targeted thermal therapy can provide primary relief of symptoms, and also bridge the gap between the onset of headache and the relief provided by an individualized treatment plan. The variation in headache etiologies and patient symptoms demands a flexible treatment plan that allows the patient to quickly mitigate disabling headache pain. Thermal therapy, a validated treatment modality combining temperature and pressure, can help alleviate symptoms from a variety of headache types and augment the clinical treatment plan. Both physicians and patients should be aware of the evidence supporting this low-risk, drug-free option for headache relief.

Background and Impact of Headaches

According to the National Headache Foundation an estimated 45 million Americans suffer from recurrent headaches. While migraine headaches are the most common form of headache - affecting 6% of American men and 18% of American women for a total of almost 30 million people[1] - many people also suffer from tension, sinus, and cluster headaches. Because many headache sufferers experience crossover among headache types, it is often difficult to determine a proper form of treatment.

The direct and indirect costs of headaches are difficult to calculate because of the individuality of headache pain and suffering. One estimate of the total annual costs of migraine headaches, however, approaches $17 billion.[2] Some of those costs include (but are not limited to):

Workplace Costs

- 2-14 work days per year are lost on average per headache sufferer[3]
- 64-150 million work days are lost nationally[2]
- Reduced effectiveness when headache sufferers report to work

Medical Costs

- Hospitalization rates for migraine sufferers, also known as migraineurs, are twice that of a non-migraine control (6-11%)[3]
- Up to 48% of migraineurs resort to Emergency Room care in a 12 month period[3]
- 95% percent of migraine sufferers use at least over-the-counter (OTC) medications and up to 40% use prescription medications[3]
- The cost of treating migraineurs is 1.6 times that of treating a matched control of non-migraine sufferers;[4, 5] with nearly twice the medical claims, 2.5 times the pharmacy claims, and a 64% overall greater cost of care[5]

Social Costs

- 94% of headache sufferers report missing a social or family event due to headache[6]

The complexity of migraine treatment is reflected by the fact that patients are often poorly diagnosed and subjected to ineffective or inappropriate treatments;[7] half of all migraineurs stop seeking medical care due to dissatisfaction with their treatment regimen.[2]

Non-Pharmacological Treatment of Headaches

A myriad of treatments, largely pharmacological, are administered for headaches. A large population of patients experience significant results from these medications, but one of the complications of these treatments is "Medication Overuse Headache (MOH)," defined in the ICHD-II as headaches with a reliance on analgesics for 15 days per month for greater than 3 months.[8] MOH may account for nearly half of those diagnosed with chronic daily headaches.[9, 10] Chronic daily headaches, which afflict one out of 20 headache sufferers,[11] is a diagnosis given when headaches occur on 15 or more days per month. Pharmacological treatments are not the only option for headache sufferers. Several studies of non-pharmacological, home-based, patient-administered therapies suggest that natural treatments can be clinically effective and significantly less costly than their pharmacological counterparts.[3] Numerous non-pharmacologic treatments for headache have been

studied and reported. Some of these techniques include physical treatments such as chiropractic manipulation, acupuncture, transcutaneous electrical nerve stimulation (TENS), and physical therapy. Others, such as thermal therapies, EMG bio- feedback/relaxation therapy, and cognitive-behavioral therapy have also been successful for treating headache pain.[7, 12-17]

Additionally, non-pharmacologic remedies for headache may be safe and effective alternatives for those patients who prefer them.

The primary goal of headache treatment is three-fold:

(1) to alleviate symptoms

(2) to moderate frequency

(3) to reduce severity

The secondary goals for treatment may include reducing disability, improving quality of life, avoiding escalation of medication use, and educating and enabling patients to manage their condition.[2] The achievement of these goals is not limited to pharmacological remedies. The U.S. Headache Consortium recognizes that some patients prefer to seek non-pharmacological treatment in the primary management of their headaches before medication is employed.[18] Besides the detrimental effect of "medication overuse" defined above, additional reasons for this predilection include:

- Preferences, values, or philosophical orientations[18]
- Insufficient response to medications
- Pregnancy, nursing, or planning for pregnancy[18]
- Stress or deficient stress-coping skills[18]
- A history of medication overuse headache (MOH) resulting in chronic daily headaches
- Age, specifically youth
- Not enough prescription medication allowed by insurance company

Use of Thermal Therapy and Pressure for Headache Relief

The association of migraine headaches with the distension of extra-cranial arteries has been studied for over a century[19]. Localized pressure of the temporal and occipital blood vessels has proven effective in mitigating pain; this lends some credibility to the notion that dilated scalp vessels contribute to migraine pain as these vascular structures are pain sensitive.[20] Indeed, results from a study of the effectiveness of compression and cold applied in conjunction to the temporal artery and extra-cranial vasculature have proven this etiology.[19] High frequency ultrasound, moreover, showed that the lumen of the superficial temporal artery was wider during a painful migraine attack, further suggesting a vasodilatory response.[13]

In light of this knowledge, many researchers believe that the application of cold results in vasoconstriction and that this mechanism alone, or combined with pressure, may result in migraine relief.[19, 20] The "gate theory" provides another possible mechanism through which cold relieves migraine pain: the cold sensations may overwhelm and block the transmission of pain stimuli into the cerebral cortex.[12, 21] Additionally, cold reduces the release of histamines, vasoactive substances and enzymes that stimulate nerve endings, and the conduction velocity of peripheral nerves.[21] This reduction in the conduction velocity of peripheral nerves results in the pain signals moving more slowly throughout the nervous system. Body tissues generally respond to cold by decreasing the need for oxygen and reducing cell metabolism, thus reducing inflammation and resulting in pain relief.[22]

Heat, on the other hand, helps to reduce the pain from the cutaneous vasoconstriction, often observed (in areas except the superficial temporal artery, as previously noted) by thermography. When heat is applied to muscular masses, superficial vasodilation is accompanied by a reduction in the temperature of the deeper layers which may contribute to pain relief.[13] Heat also increases metabolic activity, which results in increased oxygen demand, removal of cell metabolites, and accelerated inflammation.[22] This effect results in localized reduction of muscle spasm.

The application of heat and/or cold share similarities in that they both decrease painful muscle spasms and result in pain relief but do so through opposite mechanisms. However, they can produce equally effective outcomes depending on the cause of pain.[22] Multiple studies have reported on the effect of pressure and/or heat and cold (Table 1) with a minimum of 50% to nearly 90% success as a primary or adjunctive therapy.

All of the studies demonstrated that the application of heat, cold, pressure, or a combination of two or three as a primary or adjunctive headache relief technique is safe, low risk, and has few to no contraindications.

While the majority of attacks evaluated in Table 1 used thermal therapy to treat migraine headaches, thermal therapy has been documented as treatment for other types of headaches as well. For example, tension headaches typically do not respond to analgesic therapy alone;[25] topical heat and ice have shown to be effective treatments of analgesic resistant headaches.[25, 26] Another common cause of headaches is sinusitis (acute or chronic). Application of heat is commonly prescribed in these cases to help relieve sinusitis symptoms.[27] Conservative treatment, moreover, is particularly encouraged in children with sinusitis.[28]

Thermal and/or pressure therapy has been shown to be an effective, safe, easy, patient-administered therapy for migraine, tension, cluster, sinus, and mixed type headaches. Additionally, the increasing problem of MOH is only remedied through complete drug withdrawal; often patients require pharmacological and non-pharmacological bridge support during the withdrawal period.[29, 30] Thermal and pressure therapy might be useful adjuncts for MOH treatment, and further, could be utilized as a prophylaxis to help break the MOH cycle.

The various apparatus used in the studies detailed in Table 1 prove the concept that pressure, cold, and heat mitigate headache pain in some sufferers. No apparatus, however, was able to consistently and simply maintain constant pressure and temperature, or allow for temperature modulation to suit individual patient needs.

The Advantage of Patient-Administered Therapy

Physicians have many considerations when treating a patient with acute or chronic headaches. Headaches generally involve the hyperactivity of central or peripheral neural nociceptive substrates, the dysfunction of central pain modulatory systems, and the feed-forward activation of peripheral inflammatory or muscular contractile mechanisms. Self-administered therapies can affect these neurologic pathways at multiple levels.[31] A combination of such therapies including biofeed- back, cognitive behavior therapy, guided imagery, hypnosis, meditation, relaxation training, yoga, and others provided some benefit to headache sufferers.[3, 31, 32] The control and monitoring of a variety of self-administered pain relieving maneuvers can, themselves, produce a physiologic benefit.[32] Therapies that relax muscles—including thermal therapies—can mitigate centrally mediated pain patterns.[31] Evidence supports the value of non-pharmacological approaches that promote relaxation and coping for headache disorders; some therapies produce comparable and durable results to pharmacological intervention.[14-16, 33, 34]

Zanchin and colleagues[13] studied 258 patients who used self- administered techniques to manage their headaches. The most prevalent modalities were the application of compression, cold, massage, and heat. The sample represented migraine patients with and without aura, episodic tension, and cluster type headaches. Of the 382 individual remedies studied, about a quarter of patients used two to five different remedies during an attack in multiple regions of the head (n=472) including the temple, forehead, neck/nape, and vertex.
Efficacy of the maneuvers was reported:

Maneuver Type	Efficacy (%)
Simultaneous application of 2 maneuvers	94
Compression	85
Heat application	77
Cold application	75
Massage	74

The U.S. Headache Consortium's Evidence-Based Guidelines for Migraine Headaches: Behavioral and Physical Treatments[18] agrees that the general practice principles to improve the quality of care in patients with chronic headaches include involving the patient in developing a management plan, encouraged by self-administered therapies. Multiple studies show that patient directed, non-pharmacological therapies can be effective in reducing the severity and duration of headaches; this result is likely caused by a combination of the therapy itself and the stress reduction that results when a patient feels in control of his or her care.[31, 32]

Furthermore, such interventions can promote regular, patient directed therapy, and pose minimal risks and side effects. The relative costs of prescribing a portable, self-administered thermal therapy system can be compelling when compared with the possibility of visits to the ER and increased use of OTC or prescription medications that contribute to the higher medical care costs associated with headache sufferers.[4, 5]

Conclusion

Thermal therapy has been studied scientifically and validated as a method for primary or adjunctive headache relief for patients who have had a complete evaluation and diagnosis by a physician. This therapy is administered easily and safely outside of the physicians' office and allows for patient directed modulation of the heating and cooling mechanism for maximum pain relief, without adverse side effects. Ideally the thermal therapy would be delivered through an integrated mechanism that allows for patient directed modulation of the heating and cooling affect. Thermal and pressure therapy mitigates pain for multiple types of headaches. This therapy is safe and effective for the many patients who prefer non-pharmacological treatment or desire adjunctive relief, including pregnant and nursing women, children, and those sensitive or refractory to medications. A low cost, self-administered, integrated thermal therapy system can help reduce the financial burden and disability associated with acute and chronic headaches with its low cost, self-administered system, restoring headache sufferers to function quicker and reducing the frequency of headaches in some of the nearly 45 million afflicted in the United States.

References

1. Silberstein, S.D. and R.B. Lipton, *Epidemiology of migraine.* Neuroepidemiology, 1993. 12(3): p. 179-94.
2. Aukerman, G., D. Knutson, and W.F. Miser, *Management of the acute migraine headache.* Am Fam Physician, 2002. 66(11): p. 2123-30.
3. Duke University, *Resource Utilization and Costs of Care for Treatment of Chronic Headache, in NTIS Technical Review 2.1*, C.f.C.H.P.R.A.f.H.C.P.a.R. (AHCPR), Editor. 1999, National Technical Information Service.
4. Joish, V.N., P.S. Cady, and J.W. Shaw, *Health care utilization by migraine patients: a 1998 Medicaid population study.* Clin Ther, 2000. 22(11): p. 1346-56.
5. Clouse, J.C. and J.T. Osterhaus, *Healthcare resource use and costs associated with migraine in a managed healthcare setting.* Ann Pharmacother, 1994. 28(5): p. 659-64.
6. Foundation, N.H. (2007) *Headache Causes Sufferers To Miss Out On Major Life Events*. National Headache Foundation Press Releases.
7. Landy, S., *Migraine throughout the life cycle: treatment through the ages.* Neurology, 2004. 62(5 Suppl 2): p. S2-8.
8. *IHS, INTERNATIONAL CLASSIFICATION of HEADACHE DISORDERS 2nd edition (1st revision) (ICHD-II).* 2003/5, International Headache Society.
9. Mathew, N.T., *Transformed migraine, analgesic rebound, and other chronic daily headaches.* Neurol Clin, 1997. 15(1): p. 167-186.
10. Mathew, N.T., E. Stubits, and M.P. Nigam, *Transformation of episodic migraine into daily headache: analysis of factors.* Headache, 1982. 22(2): p. 66-8.
11. Tepper, S.J. and D.E. Tepper, *Breaking the cycle of medication overuse headache*. Cleve Clin J Med, 2010. 77(4): p. 236-42.
12. Ucler, S., et al., *Cold Therapy in Migraine Patients: Open-label, Non-controlled, Pilot Study.* Evid Based Complement Alternat Med, 2006. 3(4): p. 489-93.
13. Zanchin, G., et al., *Self-administered pain-relieving manoeuvres in primary headaches.* Cephalalgia, 2001. 21(7): p. 718-26.
14. Astin, J.A., *Mind-body therapies for the management of pain.* Clin J Pain, 2004. 20(1): p. 27-32.
15. Symvoulakis, E.K., et al., *Headache: a 'suitable case' for behavioural treatment in primary care?* Br J Gen Pract, 2007. 57(536): p. 231-7.
16. Holroyd, K.A. and D.B. Penzien, *Pharmacological versus non-pharmacological prophylaxis of recurrent migraine headache:a meta-analytic review of clinical trials.* Pain, 1990. 42(1): p. 1-13.
17. Mathew, N.T., *Dynamic optimization of chronic migraine treatment: current and future options.* Neurology, 2009. 72(5 Suppl): p. S14-20.
18. Campbell, J., Penzien, DB, Wall, EM, *Evidence-Based Guidelines for Migraine Headache: Behavorial and Physical Treatments*, U.H. Consortium, Editor. 2000. p. 29.
19. Lance, J.W., *The controlled application of cold and heat by a new device (Migra-lief apparatus) in the treatment of headache.* Headache, 1988. 28(7): p. 458-61.
20. Vijayan, N., *Head band for migraine headache relief.* Headache, 1993. 33(1): p. 40-2.
21. Robbins, L.D., *Cryotherapy for headache.* Headache, 1989. 29(9): p. 598-600.
22. Tepperman, P.S. and M. Devlin, *Therapeutic heat and cold. A practitioner's guide.* Postgrad Med, 1983. 73(1): p. 69-76.
23. Landy, S.H. and B. Griffin, *Pressure, heat, and cold help relieve headache pain.* Arch Fam Med, 2000. 9(9): p. 792 3.
24. Diamond, S. and F.G. Freitag, *Cold as an adjunctive therapy for headache.* Postgrad Med, 1986. 79(1): p. 305-9.
25. Stevens, M.B., *Tension-type headaches.* Am Fam Physician, 1993. 47(4): p. 799-806.
26. Repschlaeger, B.J. and M.A. McPherson, *Classification, mechanisms, and management of headache*. Clin Pharm, 1984. 3(2): p. 139-52.
27. Fried, M.P.M. *Sinusitis: Nose and Paranasal Sinus Disorders.* Merck Manu- al Medical Library: Ear, Nose, Throat, and Dental Disorders 2008 Last full review/revision July 2008 7/15/2010]; Available from: http://www. merck.com/mmpe/print/sec08/ch091/ch091g.html.
28. Emhart, O., *[Sinusitis]*. Rev Chil Pediatr, 1989. 60(2): p. 112-7.
29. Obermann, M., T. Bartsch, and Z. Katsarava, *Medication overuse headache*. Expert Opin Drug Saf, 2006. 5(1): p. 49-56.
30. Rossi, P., et al., *A narrative review on the management of medication overuse headache: the steep road from experience to evidence.* J Headache Pain, 2009. 10(6): p. 407-17.
31. Sierpina, V., J. Astin, and J. Giordano, *Mind-body therapies for headache.* Am Fam Physician, 2007. 76(10): p. 1518-22.
32. Wahbeh, H., S.M. Elsas, and B.S. Oken, *Mind-body interventions: applications in neurology.* Neurology, 2008. 70(24): p. 2321-8.
33. Gauthier, J., G. Cote, and D. French, *The role of home practice in the thermal biofeedback treatment of migraine headache.* J Consult Clin Psy- chol, 1994. 62(1): p. 180-4.
34. McGrady, A.V., et al., *Psychophysiologic Therapy for Chronic Headache in Primary Care.* Prim Care Companion J Clin Psychiatry, 1999. 1(4): p. 96-102.

Table 1: Studies of Patient-Administered Thermal and/or Pressure Therapy for Headache

Author	Apparatus & Study Design	N=Pts, Attacks Studied	Headache Type	Results	Conclusion
Landy [23]	Headband with pressure, heat and cold packs • Normal medication regimen • Use of headband on 3 consecutive headaches	15 x 3 attacks	10 moderate to severe migraines 5 episodic tension headaches	• 87% "optimally effective" (p=.004) • 13% "moderately effective" • All patients preferred pressure • Heat and cold found equally effective • Heat found soothing for neck and shoulders • Duration of headache with headband: .67-2.83 hours; without headband: 2-8 hours	Simultaneous pressure, heat and cold help relieve headache and reduce headache duration. Self-administered and tailored to individual preferences for temperature and pressure. Low risk compared to medication.
Lance [19]	Migra-lief apparatus soft-pack helmet with adjustable pressure, cooling compartment encircling head and neck, warming compartment to vertex • Patients maintained apparatus for various durations • Patients kept a diary for recurrent headaches	28 x not reported	20 migraine 7 tension 1 cluster All patients lacked response to prophylactic and acute medications	• 75% reported reduction in severity • 50% reported reduction in duration • 3 patients ceased narcotic injections • 14 patients reduced required medication	Migra-lief apparatus provides safe and reliable adjunctive relief to other forms of therapy by inducing vasoconstriction (migraine) and/or vasodilation (tension), and counter-irritation.
Diamond & Freitag [24]	Cold Comfort commercial gel pack administered to the left calf • Crossover design with 2 of 4 attacks using cold packs adjunctive to standard abortive medication plus abortive med control and 2 of 4 attacks using medication only	90 x 4 attacks	30 acute migraine 30 cluster 30 mixed (migraine plus muscle contraction)	• 71% of all patients, 80% of migraineurs considered cold effective • 63% overall decrease in pain	Cold gel packs are a safe adjunctive treatment and offer symptomatic relief of headache and psychological alleviation of pain.
Ucler [12]	Gel Cold Cap covering head for 25 minutes • Cap used for 2 consecutive headaches • Monitoring for up to 3 hours • None using prophylactic therapy • Analgesics allowed, if needed, after 25 minutes of cold therapy	26 x 2 attacks	migraine with and without aura	• Visual Analog Score (VAS) measured headache severity • 50% had a clinical response in first use (>50% reduction in pre-headache severity, by VAS), 58% response in second use • All VAS scores improved significantly from baseline (p<.001) in both pain severity and duration with cold cap	Cold application alone may be effective in some patients with migraine by vasoconstriction and the gate theory.
Robbins [21]	CHAMP Cold-Wrap within elastic bandage applied for 20-30 minutes of therapy • Plus usual abortive medication	45 x at least 3 attacks	Migraine or migraine plus daily chronic headache	• 64% mildly to completely effective • 58% would use cold pack again • The stages of cryotherapy require that a minimum of 12 minutes of cold be applied for maximum efficacy	Contraindications to cryotherapy are scarce. It is likely that cold aids in the secondary headache generating mechanism of muscle contraction and vasodilation.
Vijayan [20]	Pressure Headband with discs for temporal and occipital regions • Applied for 30 minutes with 30 additional minutes of observation without use of analgesic or vasoconstrictor agent	23 x 3 attacks	Migraine	• 87% relief • 95% of those with relief experiencing > 50% relief • 67% of those with relief had > 80% relief	Pressure band is beneficial for temporary and partial control of pain in migraineurs, believed due, in part, to vasoconstriction of temporal and occipital vessels and manual compression, producing counter-irritation in the inflamed vascular and perivascular tissues.