

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 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 providing heat or cool temperature, 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, more than 40 million Americans suffer from migraine disease and headache disorder. Headache disorders, including migraine, tension, and cluster headaches, are among the most prevalent neurological conditions in the United States. Women are twice as likely as men to experience migraine attacks.¹ 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. However, the total annual costs associated with migraine in the U.S. are now estimated to exceed \$22 billion, with nearly half attributed to lost productivity and workplace impairment.² Some of those costs include (but are not limited to):

Workplace Costs

- Migraine sufferers lose more than 157 million workdays annually in the United States.³

- Presenteeism—reduced productivity while at work due to symptoms—accounts for most work-related costs.⁴
- Individuals with migraine experience an average of 4.4 lost workdays and 11.4 days of impaired productivity per year.⁴

Medical Costs

- 3.5 million ED visits annually in the U.S. are due to migraine and other primary headaches.⁵
- Over two-thirds of migraine patients in the ED receive three or more interventions, reflecting high treatment burden.⁶
- 37% of ED visits for headache involve neuroimaging, often unnecessarily, increasing costs and radiation exposure.^{5,7}
- Many patients experience symptom recurrence within 72 hours, driving repeat ED visits and ongoing impairment.^{8,9}
- Patients with migraine are estimated to have significantly higher annual direct healthcare costs—ranging from \$6,575 to \$9,798—compared to demographically similar individuals without migraine.¹⁰

Social Costs

- Migraine attacks limit patients from performing their daily activities and negatively impact their physical, social, and psychological aspects of life. For example, over one-third of patients frequently concealed their migraines from family and friends, and nearly half did so at work.¹¹

The complexity of migraine treatment is compounded by underdiagnosis, suboptimal therapy, and poor patient satisfaction. About half of individuals with migraine do not seek medical care for their condition¹¹, with dissatisfaction regarding treatment efficacy being a significant contributing factor. This trend underscores the critical need for more effective, accessible, and patient-centered migraine therapies. Moreover, a survey by the National Headache Foundation revealed that 50% of migraine patients are extremely dissatisfied with their current preventive

treatments, citing ongoing frustration, stress, and anxiety.¹² These findings highlight the importance of improving treatment options and healthcare engagement strategies to better support individuals living with migraine.

Non-Pharmacological Treatment of Headaches

A myriad of treatments, largely pharmacological, are administered for headaches. While many patients experience relief through medication, a major complication is the development of “Medication Overuse Headache (MOH),” defined by the International Classification of Headache Disorders (ICHD) as headaches occurring on 15 or more days per month in patients with excessive use of acute medications for over 3 months. MOH affects approximately 50% of patients with chronic headaches.¹³

Chronic migraine, which impact approximately 1-5% of the population, are often difficult to manage and may persist despite typical pharmacologic interventions.¹⁴ Importantly, pharmacological treatments are not the only therapeutic option. Recent reviews of non-pharmacological, home-based, patient-administered therapies suggest these alternatives can be clinically effective and frequently more cost-efficient than traditional drug-based regimens.¹⁵

Numerous non-drug approaches have been studied for migraine prevention, including physical modalities such as chiropractic manipulation, acupuncture, transcutaneous electrical nerve stimulation (TENS), and physical therapy, as well as thermal therapies, biofeedback, relaxation techniques, and cognitive-behavioral therapy (CBT). Among these, CBT has shown potential for reducing migraine frequency when included in multicomponent behavioral interventions, though the strength of evidence is currently low due to methodological limitations. Biofeedback has also been evaluated, but current evidence is insufficient to draw firm conclusions about its effectiveness. Further high-quality research is needed to better establish the efficacy of these behavioral therapies.¹⁶

Non-pharmacologic remedies may also serve as first-line or adjunctive options for patients who prefer them due to medication side effects, contraindications, or limited treatment response. The primary goals of headache treatment remain:

- 1) to alleviate symptoms
- 2) to reduce frequency
- 3) to decrease severity

Secondary treatment goals include improving daily functioning and quality of life, minimizing reliance on pharmacotherapy, and empowering patients to actively manage their condition. These objectives are not restricted to medication-based interventions.¹⁷ The American Headache Society (AHS) and other leading organizations continue to support the integration of behavioral and physical therapies as essential components of migraine management.¹⁸ Common motivations for choosing non-drug approaches include:

- Alignment with personal values and philosophy^{19,20}
- Inadequate response or intolerance to pharmacological therapies²⁰
- Special population needs (e.g., pregnancy, breastfeeding, pediatric or geriatric patients)^{19,20}
- Stress sensitivity or comorbid conditions such as anxiety and depression^{19,20}
- History of medication overuse headache or chronic migraine²⁰
- Desire to avoid long-term medication use or polypharmacy²⁰
- Insurance restrictions or lack of access to preferred medications²⁰

Non-pharmacologic therapies—particularly those that are safe, cost-effective, and capable of being self-administered—remain vital elements in a patient-centered, comprehensive headache management plan. They are especially recommended for patients with frequent migraines or those seeking to minimize medication exposure.^{21,22,23,24}

Use of Thermal Therapy and Pressure for Headache Relief

While vasodilation of extracranial arteries was once considered a central mechanism in migraine pathophysiology, recent insights have shifted the focus to cortical and trigeminovascular processes. In particular, cortical spreading depression (CSD) - a wave of neuronal depolarization followed by suppression of brain activity - is now recognized as a primary mechanism underlying migraine with aura and a trigger for trigeminal nociceptive activation.^{25,26,27,28}

Recent neuroimaging and electrophysiological studies have confirmed real-time cortical changes during migraine attacks, highlighting the role of cortical excitability and central sensitization. Thermal therapy may impact these mechanisms through sensory input modulation, affecting pain perception by disrupting CSD propagation or influencing brainstem pain pathways.^{25,28}

Nonpharmacologic interventions such as cold application have been shown to activate inhibitory circuits via 'gate control' mechanisms, reducing transmission of pain signals centrally.

Contemporary studies support this shift. Sprouse-Blum et al. demonstrated that a frozen neck wrap targeting the carotid arteries significantly reduced migraine pain within 30 minutes, with benefits sustained even after removal of the device.²⁹ Hsu et al. reported that multiple cold-based interventions—such as cold caps, intraoral cooling, and cold wraps—achieved statistically significant short-term pain reduction compared to non-cold interventions.³⁰ Vanderpol et al. showed that intranasal evaporative cooling improved symptoms in 87% of treatments within 2 hours.³¹

These findings underscore the multi-mechanistic value of thermal therapy. While vasoconstriction may play a role when using cold therapy, emerging evidence highlights that peripheral inputs may also disrupt central migraine pathways. Cold thermal therapy may be especially effective when applied early in an attack, influencing the trigeminovascular system and possibly preventing the escalation of cortical and peripheral sensitization.^{30,31}

Both heat and cold therapies share the capacity to relieve muscle-related pain by reducing spasms and altering tissue metabolism. Heat application can relax tense musculature and increase circulation in targeted regions, while cold reduces nerve conduction velocity and inflammatory signaling.^{32,33,34} These effects can be tailored based on headache type and patient preference, providing a low-risk, self-directed alternative or adjunct to traditional pharmacological treatment.

Together with the evidence summarized in Table 1, these findings support the use of thermal and pressure-based interventions as part of a flexible, individualized approach to headache management.^{35,36,37}

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

Author	Apparatus & Study Design	N=Pts, Attacks Studied	Headache Type	Results	Conclusion
Sprouse-Blum et al. [29]	Adjustable neoprene neck wrap <ul style="list-style-type: none"> • Holds two freezable ice packs targeting the carotid arteries • Used in the treatment of migraine headaches • Data recorded using a one-page migraine pain diary • Pain measured with visual analog scale (VAS) • Time intervals for recording: onset, 15 minutes, 30 minutes, and one hour • Wrap worn for the first 30 minutes of each episode • Wrap removed after 30 minutes • Final pain score recorded 30 minutes later (at one hour) with wrap off 	55 x 2 attacks	Migraine with aura and migraine without aura	<ul style="list-style-type: none"> • Mean pain score at migraine onset: 2.83 ± 0.26 (frozen) vs. 2.61 ± 0.25 (non-frozen) • Max pain reduction at 30 min with frozen wrap: $31.8\% \pm 15.2\%$ • Pain reduction at 30 min without aura $39.3\% \pm 13.4\%$ • Pain reduction at 30 min with aura $11.2\% \pm 43.8\%$ • Pain improvement dropped to $27.3\% \pm 17.5\%$ at 1 hour after removing frozen wrap • Control group pain increased $31.5\% \pm 20.0\%$ at 30 min • Control group pain increased $35.4\% \pm 24.1\%$ at 1 hour 	These findings confirm the application of a frozen neck wrap at onset of migraine headache targeting the carotid arteries at the neck significantly reduced recorded pain in participants with migraine headaches ($P < .001$).
Hsu et al. [30]	Ice water application <ul style="list-style-type: none"> • Applied on the maxillary intraoral or dorsal surface of the tongue <ul style="list-style-type: none"> ◦ Duration: 40 minutes ◦ Used during migraine attacks • Headband with cold-gel or heat-gel packs <ul style="list-style-type: none"> ◦ Used for 3 respective headaches ◦ Maintained normal medication regimen • Dry oxygen gas or dry air therapy <ul style="list-style-type: none"> ◦ Flow rate: 15 L/min ◦ Duration: 15 minutes ◦ Used to cool nasal passages • Ice-packing wrap <ul style="list-style-type: none"> ◦ Applied on the neck ◦ Duration: 30 minutes ◦ Used during migraine attacks • Ice bag massage and hydrotherapy <ul style="list-style-type: none"> ◦ Ice bag massage on whole head: 5 minutes ◦ Hot bath for arms and feet: 20 minutes daily ◦ Frequency: 5 days a week for 6 weeks ◦ Combined with conventional medication • Cold-gel cap <ul style="list-style-type: none"> ◦ Duration: 25 minutes ◦ Used during migraine attacks 	224 x not reported	Migraine and episodic tension headaches	<ul style="list-style-type: none"> • 6 studies (4 RCTs, 2 non-RCTs) met inclusion criteria • Cold interventions used: <ul style="list-style-type: none"> ◦ Cold-gel headband ◦ Cold-gel cap ◦ Intraoral cooling ◦ Skin temperature biofeedback ◦ Cold wrap with massage • Short-term migraine relief (30 min post-intervention): <ul style="list-style-type: none"> ◦ Visual Analog Scale (VAS) pain score reduced ◦ SMD: -3.21 (95% CI $-5.94, -0.48$) • Long-term effects (24 h post-intervention): <ul style="list-style-type: none"> ◦ VAS pain score: SMD -0.44 (95% CI $-0.91, 0.03$) ◦ Nausea: SMD -0.56 (95% CI $-1.17, 0.04$) • Certainty of evidence (GRADE): very low to moderate • Insufficient results for nausea and vomiting in meta-analysis 	Cold intervention is an effective regimen to reduce migraine pain instantly. The long-term effect of cold interventions on migraine is not demonstrated.

Author	Apparatus & Study Design	N=Pts, Attacks Studied	Headache Type	Results	Conclusion
Vanderpol et. al. [31]	RhinoChill intranasal cooling system for the acute relief of migraine in an adult population <ul style="list-style-type: none"> • Short periods of intranasal cooling (maximum of 20 minutes) • Early stoppage if full pain relief achieved or at participant's request due to discomfort 	11 x 1 attacks 3 x 2 attacks 1 x 3 attacks	Episodic migraine with or without aura, or chronic migraine	<ul style="list-style-type: none"> • 40% (8 out of 20 treatments) resulted in full pain and symptoms relief immediately after treatment • 50% (10 treatments) resulted in partial pain relief (headache reduced from severe/moderate to mild) and partial symptom relief immediately after treatment • At 2 hours post-treatment: <ul style="list-style-type: none"> ○ 45% (9 treatments) provided full pain and symptom relief ○ 45% (9 treatments) resulted in partial relief of pain and symptoms • At 24 hours post-treatment: <ul style="list-style-type: none"> ○ 50% (10 treatments) resulted in pain and symptom freedom ○ 15% (3 treatments) provided partial pain relief • 87% (13 patients) experienced benefit within 2 hours that was sustained at 24 hours 	Intranasal evaporative cooling gave considerable benefit to patients with migraine, improving headache severity and migraine-associated symptoms. A further randomized, placebo controlled, double blinded, parallel clinical trial is required to further investigate the potential of this application.
Landy & Griffin [38]	Headband with pressure, heat and cold packs <ul style="list-style-type: none"> • Normal medication regimen • Use of headband on 3 consecutive headaches 	15 x 3 attacks	10 moderate to severe migraines 5 episodic tension headaches	<ul style="list-style-type: none"> • 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 [35]	Migra-lief apparatus soft-pack helmet with adjustable pressure, cooling compartment encircling head and neck, warming compartment to vertex <ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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 [39]	Cold Comfort commercial gel pack administered <ul style="list-style-type: none"> • 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)	<ul style="list-style-type: none"> • 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.

Author	Apparatus & Study Design	N=Pts, Attacks Studied	Headache Type	Results	Conclusion
Ucler et al. [34]	Gel Cold Cap covering head for 25 minutes <ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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 [33]	CHAMP Cold-Wrap within elastic bandage applied for 20-30 minutes of therapy <ul style="list-style-type: none"> • Plus usual abortive medication 	45 x at least 3 attacks	Migraine or migraine plus daily chronic headache	<ul style="list-style-type: none"> • 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 [36]	Pressure Headband with discs for temporal and occipital regions <ul style="list-style-type: none"> • Applied for 30 minutes with 30 additional minutes of observation without use of analgesic or vasoconstrictor agent 	23 x 3 attacks	Migraine	<ul style="list-style-type: none"> • 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.

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;⁴⁰ topical heat and ice have shown to be effective treatments of analgesic resistant headaches.^{40,41} Another common cause of headaches is sinusitis (acute or chronic). Application of heat is commonly prescribed in these cases to help relieve sinusitis symptoms.⁴² Conservative treatment, moreover, is particularly encouraged in children with sinusitis.⁴³

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.^{44,45} 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. However, there is ongoing debate about the optimal treatment pathway: some advocate for immediate medication withdrawal followed by preventive therapy, while others initiate preventive treatments before or instead of abrupt withdrawal. This variability underscores the need for personalized treatment plans and supports the use of modalities like thermal therapy as supportive, non-pharmacologic options during withdrawal or preventive efforts.¹³

The various apparatus used in the studies detailed in Table 1 demonstrate that pressure, cold, and heat can mitigate headache pain in many sufferers. However, these earlier devices were not able to consistently or simply maintain stable pressure and temperature, nor did they allow for user-directed modulation of therapy in real time to suit individual needs.

The Advantage of Patient-Administered Therapy

Physicians must consider numerous factors when managing patients with acute or chronic headache disorders. Headaches are often driven by hyperactivity within central and peripheral nociceptive pathways, dysfunction of pain modulatory systems, and activation of inflammatory or muscular mechanisms. Patient-administered, non-pharmacological therapies can influence these pathways through multiple mechanisms—offering both physiological

and psychological relief.

Thermal therapies—including hot compresses, cold packs, and contrast techniques—are widely used for symptomatic relief. Cold applications reduce nerve conduction and inflammation, while heat can relax tight muscle groups implicated in tension and cervicogenic headaches. Thermal interventions are generally considered non-invasive and safe, making them a practical option that individuals can use at the first sign of symptoms in everyday settings.

A retrospective study of 258 patients with migraines and mixed headache types found that nearly one-quarter of sufferers used multiple simultaneous self-relief maneuvers, including compression, massage, heat, and cold, often targeting regions such as the temple, neck, and vertex.

Efficacy was highest when patients combined two techniques (94% reported benefit), but even individual maneuvers like compression (85%), heat (77%), and cold (75%) yielded high satisfaction rates.³⁷

Beyond physiological mechanisms, patient-directed therapies confer psychological benefits - notably increased self-efficacy and a sense of control. This has been shown to improve adherence and reduce perceived disability. Involving patients in treatment selection and empowering them to intervene at home aligns with current evidence-based guidelines from the U.S. Headache Consortium, which recommends behavioral and physical therapies as either primary or adjunctive strategies.¹⁸

Given the low risk, cost-effectiveness, and convenience of self-administered thermal therapy systems, their role in modern headache care is increasingly justified. Compared to repeat physician visits, prescription costs, or emergency care, a portable and patient-controlled approach can reduce the burden on both individuals and the healthcare system.

Conclusion

Thermal therapy has evolved into a scientifically supported, low-risk treatment option for both acute and chronic headache conditions. No longer limited to the traditional vascular explanations, new understanding of migraine pathophysiology—including cortical spreading depression and trigeminovascular activation—further strengthens the rationale for interventions that influence peripheral and central pain mechanisms.

As a non-pharmacological therapy, thermal and pressure-based interventions offer a compelling option for patients seeking relief without medication-related side effects. These treatments are particularly beneficial for populations such as pregnant or nursing women, children, or those who are

refractory or sensitive to drug-based regimens.

A self-administered thermal therapy system—ideally one that allows user-directed modulation of temperature and pressure—can be implemented at the first sign of symptoms. By improving functional outcomes, decreasing frequency and severity, and reducing dependence on healthcare visits or prescriptions, these therapies provide both clinical value and economic efficiency. Their integration into standard headache care may reduce the personal and societal burden of a condition affecting tens of millions in the U.S. alone.

Emerging technologies—such as the FDA-cleared ThermaZone system—are specifically designed to address these limitations by delivering continuous, precisely controlled thermal therapy without the need for ice, water, or manual adjustment. While published studies evaluating ThermaZone’s efficacy in headache treatment are forthcoming, its engineering features suggest potential advantages over legacy apparatuses in achieving individualized and sustained symptom relief.

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