

Clinical Practice Guideline: **Acupuncture for the Treatment of Headaches**

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Product: **Specialty**

POLICY

American Specialty Health – Specialty (ASH) clinical committees have determined that acupuncture for the treatment of headaches including tension-type, migraine (with and without aura), and idiopathic chronic headache is established as clinically effective, is professionally recognized, is scientifically plausible, and has a favorable benefit:risk profile.

PROCESS AND DEFINITIONS

When developing, reviewing, and approving clinical policy, ASH peer-review committees consider whether the technique/procedure:

- Is established as clinically effective by:
 - Scientific information published in an acceptable peer-reviewed clinical science resource, and
 - The consensus opinion of the Evidence Evaluation Committee (EEC) when available;
- Is professionally recognized by:
 - Inclusion in the educational standards accepted by the majority of the professions' educational institutions,
 - Wide acceptance and use of the practice, and
 - Recommendations for use made by healthcare practitioners practicing in the relevant clinical area;
- Poses a health and safety risk; and
- Is plausible or implausible
 - A belief, theory, or mechanism of health and disease that can be explained within the existing framework of scientific methods, reasoning, and available knowledge is considered plausible.
 - A treatment intervention or diagnostic procedure that requires the existence of forces, mechanisms, or biological processes that are not known to exist within the current framework of scientific methods, reasoning, and available knowledge is considered implausible.

Substitution harm (indirect harm): Compromised clinical outcomes caused by:

- Utilizing a specific diagnostic or therapeutic procedure when the safety, clinical effectiveness, or diagnostic utility is either unknown or is known to be unsafe, ineffective, or of no diagnostic utility, *instead of* a diagnostic or therapeutic procedure known to be safe, be clinically effective, or to have diagnostic utility; or
- The utilization of a diagnostic or therapeutic procedure that is substantially less effective or safe than another procedure with established safety, and clinical effectiveness or utility.

Labeling effects (non-specific harm): The harm that results from identifying in a patient a condition or a finding that is not clinically valid.

Safe: The terms “safe” and “safety,” are used only with specific reference to the absence of direct harm. Direct harm would include any injury to a patient caused by the mechanical, thermal, biological, chemical, pharmacological, electrical, electromagnetic, or psycho-dynamic properties of a diagnostic or therapeutic procedure, and as such, the procedure would be considered unsafe.

Direct harm: Any injury to a patient caused by the mechanical, thermal, biological, chemical, pharmacological, electrical, electromagnetic, or psycho-dynamic properties of a diagnostic or therapeutic procedure.

Benefit versus risk profile: The relative effectiveness or utility of a therapeutic intervention or diagnostic procedure versus its potential for direct harm.

- Positive (benefits outweigh risks),
- Negative (risks outweigh benefits), or
- Equivocal (available information is inconclusive).

Acupuncture Safety

- Major adverse events associated with acupuncture are exceedingly rare.
- Minor adverse events (e.g. bruising, soreness at needle insertion point) associated with acupuncture were found to be common and transient.
- The incidence of adverse events of acupuncture is substantially lower than that of many drugs or other accepted invasive procedures.
- Proper acupuncture technique and patient selection is very important for acupuncture safety.

Description/Background

Nomenclature for headache subtypes, based on the International Classification of Headache Disorders-2 (ICHD-2) originated in 1988 by the International Headache Society (IHS), has become the standard for headache diagnosis and clinical research. The system identifies three major headache classifications: primary headaches, secondary headaches, and a third classification described as cranial neuralgias central and primary facial pain and other headaches.

The primary headaches include migraine, tension-type headache (TTH), cluster headache and other trigeminal autonomic cephalgias, and other primary headaches. Migraine headaches can be further categorized into many subtypes. Migraine subtypes include: migraine with aura, migraine without aura, menstrual migraine, complicated migraine, basilar migraine, chronic/transformed/refractory migraine, status migrainosus, retinal migraine, migraine variants, cyclic vomiting or childhood periodic syndromes, hemiplegic migraine or migrainous infarction, etc. TTH also consists of subtypes such as infrequent episodic TTH, frequent episodic TTH, chronic TTH (Headache Classification Subcommittee of the International Headache Society, 2004; Headache Classification Committee, 2006). Most people with chronic daily headaches (CDH) might have either chronic TTH or transformed migraine headaches which are considered as complications or natural progression from their previously existed infrequent episodic headaches. CDH also includes rare headache syndromes such as hemicrania continua, new daily persistent headache, and chronic disorders of short duration (Silberstein, 2005).

The secondary headaches include headaches attributed to head or neck trauma, cranial or cervical vascular disorders (e.g., venous thrombosis, arteritis, intracranial hemorrhage, unruptured vascular malformation), non-vascular intracranial disorders (e.g., high or low intracranial pressure, infection, sarcoidosis, inflammatory diseases, neoplasm), substance abuse or withdrawal, systemic infection, disorders of homeostasis (e.g., metabolic disorders, hypoxia, hypercapnia), disorders of facial or cranial structures (e.g., cranium, neck, eyes, ears, nose, sinuses, teeth, mouth or other), and psychiatric disorders (Headache Classification Subcommittee of the International Headache Society, 2004).

Evidence and Research

The efficacy of acupuncture is inherently difficult to evaluate but improved trial methods and outcome measures afford the ability to assess the efficacy of the therapy. Although a considerable amount of clinical trials have been conducted over the last decades and many of them indicated acupuncture was effective in management of headache, many of these studies had methodological issues and biased trial design. Even meta-analysis and systematic review face the challenge owing to heterogeneity in these study designs and variable qualities in their study conduction. These differences are reflected in their targeted population selection, sample size, study duration, treatment sessions, needling

1 techniques, acupoint selection, placebo controls, outcome measurements and follow-up
2 period.

3
4 Many randomized controlled trials (RCT) have been done evaluating the effect of
5 acupuncture in headache management. Most earlier published studies or review articles
6 included the patients with various headache types without further differentiation of the
7 subtypes of their headache using standard diagnosis guidelines. With increased numbers
8 of published RCTs and improved qualities of these trials in recent years, more review
9 articles are focused on addressing the collective outcome of acupuncture (traditional
10 needling procedure) in treatment of more specific types of primary headache, especially
11 for migraine prophylaxis and tension-type headache.

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13 A dedicated review article or RCT has not been published for cluster headaches or other
14 specific headache types probably due to small patient selections and the partial
15 overlapping mechanism with the two common types of headache syndrome mentioned
16 above. The patients with these rare headaches or mixed headache types, however, might
17 have been unintentionally enrolled in the studies for migraine or TTH due to less
18 restricted screening process. These patients could also have been included in the earlier
19 trials designed for idiopathic headaches or chronic headaches with less clear set of
20 inclusion and exclusion criteria in general (Melchart et al., 2001). The separate data set or
21 sub-analysis for these rare headache patients is not available for independent review and
22 validation.

23
24 Overall, the pooled effect size estimation of acupuncture in headache management is
25 mild compared to the placebo effect, and this conclusion is arguable depending on the
26 control group used in these studies. Most of the reviewers agree that there is a favorable
27 trend in proving that acupuncture intervention reduces the headache frequency, intensity,
28 and the need of rescue medication in patients who have migraines and tension headaches.
29 These improvements are statistically significant when compared to inactive controls (e.g.,
30 waiting lists) or groups using rescue medication only, but not when compared to sham
31 acupuncture. The long term effect of acupuncture in headache prophylaxis is promising,
32 but its relationship to total treatment sessions and duration are not yet well studied.

33
34 Although cross-study review and pooled meta-analysis are inherently difficult because of
35 the heterogeneity of the studies included, significant improvement in individual study is
36 also needed globally in order to demonstrate a consistent effect of acupuncture in
37 headache prophylaxis. To date, most RCTs included in the systemic reviews were done in
38 Europe and they had various shortcomings and weaknesses in trial design and
39 conduction. These shortcomings could introduce bias at baseline, undermine the
40 randomization and blinding process, inflate the placebo effect, reduce the study power,
41 and/or result in inconclusive and contradictory efficacy reports. The trial quality

assurance might be more in question for the studies conducted in China and Japan, which generally yield overwhelmingly positive results in favor of acupuncture therapy. Most of these studies were not included in the systematic review because of the language barrier. In summary, clinicians and researchers conducting acupuncture trials face major challenges that should be addressed further to ensure the quality of future studies in this area before a firm conclusion can be drawn for the consistent role of acupuncture as an effective and safe headache treatment.

By assessing the quantity and quality of the published and unpublished randomized controlled acupuncture studies, several evidence-based systematic reviews demonstrated a fair degree of consistency in these clinical trials that acupuncture, used as mono or adjunctive therapy, plays a role in headache prophylactic management, especially for headache patients who do not tolerate conventional pharmacological medications or who prefer alternative treatment. The following headache types are supported by the published RCTs and systemic reviews:

- Migraine with or without auras,
- Menstrual migraines,
- Migraines with complications,
- Recurrent migraine headaches,
- Transformed migraines,
- Episodic TTH,
- Chronic TTH,
- Mixed migraine and TTH,
- Idiopathic CDH.

Lee and Ernst (2011) published an overview of Cochrane Reviews of acupuncture and its effectiveness in reducing pain of many of the conditions. Eight reviews were included. Four reviews concluded that acupuncture was effective for migraines, neck disorders, tension-type headaches and peripheral joint osteoarthritis. Three reviews were inclusive for shoulder pain, lateral elbow pain and low back pain. Acupuncture was found not effective for rheumatoid arthritis. Schiapparelli et al. (2011) investigated acupuncture in the treatment of primary headache. They note that its effectiveness has been studied mainly for primary headaches, particularly for migraine and tension-type headache (TTH). They conclude that despite the complicated classification of headaches in TCM and the great diversity in treatments provided, acupuncture appears to be an effective option for patients with migraine or TTH. They also suggest it is cost-effective. A recent and rigorous review of the literature (Vickers et al., 2012) used individual patient data in a meta-analysis of the effectiveness of acupuncture for back and neck pain, osteoarthritis, chronic headache and shoulder pain. The analysis concluded that the positive effects of acupuncture for these conditions could not be attributed to placebo effects alone. This

review concluded that, “acupuncture is a reasonable referral option for patients with chronic pain.” The wording of this conclusion reflects the sensible supposition that for chronic musculoskeletal pain conditions beyond those that are specifically mentioned in this review, acupuncture is also a reasonable option. More recently, Plank et al. (2013) evaluated whether a standardized set of acupuncture points applied over a specific period of time could reduce frequency and intensity of migraine headache. Participants collected daily headache diaries and migraine quality-of-life measurements for 12 weeks before starting the acupuncture intervention. They then continued to record the frequency and intensity of their migraines during the intervention and for an additional 12 weeks beyond the intervention. When comparing pre- to post intervention measurements, migraine frequency and intensity demonstrated a significant decrease after acupuncture intervention that never returned to baseline pre-intervention levels. Results indicate that acupuncture decreases frequency and intensity of migraine headache with lasting effects.

Literature is very limited on cluster headache (CH) and acupuncture, however in 2014, Fofi et al. described four patients with CH that were treated with acupuncture treatment 2x/week for two weeks then once a week for eight weeks then once every other week for two more weeks. After using a specified protocol, each patient had an interruption of their cluster headache with acupuncture. Further research is needed to determine the role of acupuncture in treatment of CH.

Summary of Evidence

1. The evidence supports the use of acupuncture as either a mono or adjunctive prophylactic treatment for migraine headaches (with or without aura).
2. There is limited evidence to support the use of acupuncture as an abortive treatment for migraine headaches.
3. The evidence supports the use of acupuncture as either a mono or adjunctive prophylactic treatment for tension-type headaches.
4. There is insufficient evidence to support or refute the effectiveness of acupuncture in the management of cluster headaches.
5. There was no random controlled study that specifically enrolled the patients with cluster headache or other types of headaches besides the ones that might be categorized as “recurrent headache” or “chronic headache” nonspecifically.

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