

Clinical Practice Guideline: **Acupuncture for the Treatment of Fibromyalgia Syndrome**

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Product: **Specialty**

POLICY

American Specialty Health – Specialty (ASH) clinical committees have determined that acupuncture for the treatment of fibromyalgia syndrome (FMS) is professionally recognized, scientifically plausible, and may have a favorable benefit:risk profile. The literature is insufficient to conclude acupuncture is either clinically effective or ineffective for the treatment of FMS. ASH clinical committees have determined that acupuncture for the treatment of certain symptoms associated with FMS (e.g., neuromusculoskeletal pain, fatigue, and anxiety) is professionally recognized and, based on the evidence for acupuncture treatment of FMS associated symptoms, a trial of acupuncture treatment for these symptoms may be clinically appropriate.

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 patient selection and acupuncture technique are very important for acupuncture safety.

Description/Background

Fibromyalgia syndrome (FMS) is a common chronic pain disorder of unknown etiology characterized by widespread musculoskeletal pain, fatigue, difficulty with memory,

morning stiffness, and multiple tender points. According to the criteria for fibromyalgia developed by the American College of Rheumatology (ACR), a diagnosis of FMS traditionally requires both a history of chronic widespread pain and the presence of at least 11 of 18 possible tender points on examination. Other common symptoms include disturbances in bowel function, weakness, depressive episodes, and anxiety crises (Spaeth, 2009).

In 2010, the American College of Rheumatology (ACR) “provisionally” approved another method of clinical diagnosis and severity classification for FMS. According to the 2010 ACR criteria, the most important diagnostic variables are the Widespread Pain Index (WPI) and categorical scales for cognitive symptoms, unrefreshed sleep, fatigue, and number of somatic symptoms. The categorical scales were added together to create a symptom severity scale (SS). The SS and WPI were combined to form the following recommended criteria to define fibromyalgia: (WPI >7 AND SS >5) OR (WPI 3–6 AND SS >9). In addition, the patient must have had the symptoms at a similar level for 3 or more months and not have a condition that would otherwise explain the pain.

Evidence and Research

According to a 2013 Cochran review, the authors concluded “There is low to moderate-level evidence that compared with no treatment and standard therapy, acupuncture improves pain and stiffness in people with fibromyalgia.” This review of the research also noted, “There is moderate-level evidence that the effect of acupuncture does not differ from sham acupuncture in reducing pain or fatigue, or improving sleep or global well-being.” The authors added that electro-acupuncture is probably more effective than manual acupuncture to reduce pain and stiffness as well as improve sleep, fatigue, and global well-being. The effects last up to a month, and were not maintained at follow-up, six month’s post treatment. The level of evidence and its clinical implications are weakened due to the small sample size, scarcity of studies for each comparison, and lack of an ideal sham acupuncture. The authors concluded that while larger scale studies are needed, acupuncture appears safe and those suffering from fibromyalgia may consider using electro-acupuncture alone or with exercise and medication. For patients with a contra-indication to electro-acupuncture, it may be reasonable to provide a short trial of standard acupuncture to determine if the patient responds favorably.

The evidence of acupuncture as a treatment for fibromyalgia has inconsistencies and contradictions, due in part to insufficient numbers of well-designed randomized controlled trials (RCTs). Although three (3) systematic reviews have been published looking at acupuncture in FMS, their results and conclusions need to be interpreted with caution. Berman’s review is the highest-quality systematic review on FMS, however, it was published in 1999 and it includes only one high-quality RCT (Berman et al., 1999). Although Mayhew set out to update Berman’s review in 2007, Mayhew’s is not as comprehensive or rigorous as Berman’s and the results of the two cannot be compared

(Mayhew et al., 2007). In addition, in reviews published by Erntz group, the presentation of the studies and conclusions appear to be biased against acupuncture.

Out of five (5) RCTs cited in this review and used to draw the final conclusions, three (3) were positive (Deluze et al., 1992; Guo et al., 2005; Martin et al., 2006) and two (2) (Sprott et al., 1998; Assefi et al., 2005) were negative. Although Assefi's is a large, well-designed study, the Sprott study cited is a three (3) arm-study with only 30 subjects total. Of the positive studies, Deluze and Martin are, according to Mayhew, two (2) of the most rigorous studies. It is interesting to note that the results of the 2006 Martin study indicates the benefit of acupuncture in FMS may lie primarily in its ability to change other significant patient-centered domains (i.e., energy, sleep, well-being, or other physical symptoms, relationships, and spirituality), whether or not the main outcome or "chief complaint" also changes. In this study, while differences in pain trended closely toward statistical significance, all symptom subscales were improved with acupuncture, but only fatigue and anxiety were statistically significant on their own. The authors concluded, "the benefits of acupuncture were additive to the benefits obtained with the Fibromyalgia Treatment Program (education, counseling, and group discussion about symptom management)."

Martin-Sanchez' review focused on pain intensity only and provides no information about any other relevant outcomes for FMS patients. In the only additional study included in the meta-analysis published in 2009 (Martin-Sanchez et al., 2009), Harris and colleagues (Harris et al., 2005) concluded, "a subset of individuals obtained improvements in clinical pain, fatigue, and function from acupuncture, although efficacy was not related to needle placement or stimulation."

Taken together, the Mayhew and Martin-Sanchez reviews include results of four (4) additional studies with approximately 294 patients. Although this would seem to be a sufficiently large cohort when pooled together, it is important to keep in mind that the studies are highly heterogeneous in the selection of active points, type of stimulation used, and selection of controls. In addition, each study focuses on slightly different outcomes, highlighting the challenges and methodological inconsistencies in conducting systematic reviews of acupuncture and reporting conclusive data from these studies. These reviews indicate that acupuncture has not demonstrated efficacy above and beyond acupuncture-like sham controls. However, looking at the Berman and Mayhew reviews in conjunction with three (3) well designed studies (Harris et al., 2005; Martin et al., 2006; Targino et al., 2008), acupuncture may have a role in improving the quality of life in people with FMS, but more research is needed. It is possible that acupuncture has not significantly or conclusively outperformed sham acupuncture in studies of FMS, because although effective in treating peripheral pain conditions, acupuncture may not be an effective intervention in treating central pain conditions such as FMS.

It is also possible that acupuncture treatments have been designed for FMS with a poor understanding of how to treat ‘central pain conditions,’ and have instead focused on the treatment of FMS as a peripheral pain syndrome. Although acupuncture and sham may seem to have a similar clinical effect in FMS and can be argued that the therapeutic effect of both may be due to only non-specific factors (i.e., attention and expectancy), sham acupuncture has shown larger effect sizes compared to conventional placebos and no treatment (Park et al., 2008), indicating that sham acupuncture treatments are actually not inert. In a recent study of FMS patients (Harris et al., 2009), acupuncture and invasive sham acupuncture elicited a similar amount of pain relief; however, their effects on opioid receptors were markedly different. The study noted sham acupuncture evoked the release of endogenous opioids, a mechanism involved in the “placebo effect,” whereas acupuncture increased the opioid receptor binding strength, suggesting that although the clinical effects of acupuncture and sham acupuncture may be similar, their underlying mechanisms are not.

Conclusions

1. The evidence of acupuncture effectiveness in treating pain in fibromyalgia patients is inconclusive.
2. The evidence of acupuncture effectiveness in treating other domains outside of pain in fibromyalgia patients is inconclusive.

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