Clinical Practice Guideline: **Acupuncture Point Injection Therapy (APIT)**

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GUIDELINES

American Specialty Health – Specialty (ASH) clinical committees have determined that acupuncture point injection therapy (APIT) is not medically necessary for any indications. Based on the available literature, it has been determined that APIT is no more effective than acupuncture. Acupuncture, for the purposes of this policy, refers to solid needles without injection. Additionally, the safety profile of APIT has not been established.

DESCRIPTION/BACKGROUND

Acupuncture point injection therapy (APIT) is a procedure in which pharmaceuticals, vitamins, herbal extracts, or other liquid agents are injected—using a syringe and needle—into intramuscular, intradermal, or subcutaneous tissue at a site corresponding to the location of an acupuncture point. It emerged in China during the 1950's as an amalgamation of traditional Chinese medicine (TCM) and modern biomedicine. According to Sha et al. (2016), adherents hypothesize that the injected fluid enhances the effect of acupuncture by creating an additional synergistic effect thought to have longer and more sustainable effects than needling alone. There are several agents that are commonly used for injections. These include saline, pharmaceutical agents (e.g., botulinum, cortisone, and lidocaine), biological agents (e.g., herbal extracts and vitamins) and homeopathic remedies. The purpose of this policy is to provide a scientific overview and assessment of the current evidence base for the safety and effectiveness of APIT.

Within the United States, the professional requirements for performing APIT and the agents approved for injection vary widely by state.

EVIDENCE REVIEW

Most of the evidence from randomized controlled trials (RCTs) is equivocal because of underpowered RCTs and subjective outcomes.

One study conducted by Xu in 2005 for premenstrual syndrome demonstrated injections of huangqi (astragalus root) at acupuncture points ST 36 & SP 6 along with acupuncture was more effective than drug therapy. Another study conducted by Zhou et al. (2007) for trigeminal neuralgia found injections of vitamin B12 at acupuncture point ST 7 more effective than drug therapy (Tegretol). Wade et al. (2016) completed an RCT of acupuncture point injection treatment for primary dysmenorrhea. The investigators

attempted to determine if injection of vitamin K3 in an acupuncture point is optimal for the treatment of primary dysmenorrhea, when compared to 2 other injection treatments (saline acupuncture point injection and vitamin K3 deep muscle injection). Patients in each group received 3 injections at a single treatment visit. Patients in all 3 groups experienced pain relief from the injection treatments. The authors concluded that acupuncture point injection of vitamin K3 relieved menstrual pain rapidly and may be a useful treatment.

Hou et al. (2015) studied acupoint injection of onabotulinumtoxin A (BoNTA) for migraines. The purpose of this study was to evaluate and compare the effectiveness of fixed (muscle)-site and acupoint-site injections of BoNTA for migraine therapy in a randomized, double-blinded, placebo-controlled clinical trial extending over four months. Subjects with both episodic and chronic migraines respectively received a placebo (n = 19) or BoNTA (2.5 U each site, 25 U per subject) injection at fixed-sites (n= 41) including occipitofrontalis, corrugator supercilii, temporalis and trapezius, or at acupoint-sites (n = 42) including Yintang (EX-HN3), Taiyang (EX-HN5), Baihui (GV20), Shuaigu (GB8), Fengchi (GB20) and Tianzhu (BL10). BoNTA injections at fixed-sites and acupoint-sites significantly reduced the migraine attack frequency, intensity, duration, and associated symptoms for four months compared with placebo ($p < 0.01$). The efficacy of BoNTA for migraines in the acupoint-site group (93% improvement) was more significant than that in the fixed-site group (85% improvement) ($p < 0.01$). BoNTA administration for migraines is effective, and at acupoint-sites shows more efficacy than at fixed-sites. Further blinded studies are necessary to establish the efficacy of a low dose toxin (25 U) introduced with this methodology in chronic and episodic migraines.

The four systematic reviews evaluated varied greatly in their rigor and methodology. Two showed minimal evidence in support of injection therapy (Bernstein, 2001; Lee et al., 2005). One showed no evidence of further therapeutic effect from regular needling (Cummings and White, 2001) and one demonstrated neither strong evidence for nor against injection therapy (Staal et al., 2009). Staal et al. concluded that the effectiveness of injection therapy for low back pain is still debatable and there is insufficient evidence to support its use for low back pain. They suggest however, that there may be a sub-group of patients who may benefit from it.

Bernstein (2001) proclaimed support for APIT, though the study was flawed. While it did assess the included studies per evidence-based medical guidelines, there were at least 15 disparate surgical and injection interventions included without any aggregation of the data. Only two interventions were relevant with minimal evidence: (1) local glycosaminoglycan injection for lateral epicondylitis and (2) nonspecific injections for painful shoulder showed limited (level 3) evidence supporting efficacy.

Lee et al. (2005) did not follow standards of systematic reviews by including 10 studies (out of 15) based on animal research with minimal assessment of the remaining clinical trials. Only 2 studies, 1 each for rheumatoid arthritis and osteoarthritis, were RCTs and those were underpowered, with 1 only using self-reported subjective measures as outcomes.

Wang et al. (2015) performed a systematic review of the effectiveness of APIT with Vitamin B12 for patients with incomplete recovery from Bell's Palsy. The investigators found that APIT with B12 was superior to acupuncture alone. The results suggested that 29% of Bell's Palsy patients who received APIT with B12 were more likely to achieve complete recovery than those with acupuncture alone. The main outcome measure was a favorable improvement of at least 2 points in the House-Brackmann scale (or an equivalent score using an alternate scoring system). Among the 5 studies evaluated in the review, the sample sizes were small ranging between 30 and 38. The authors reported that due to the methodological issues and insufficient sample sizes for the studies included, their results were unreliable, and further research is called for with more rigorous study designs.

Du and Liu (2021) evaluated the effects of injecting acupuncture points with mecobalamin on the motor function of 60 participants who had suffered from cerebrovascular accidents. The control group was treated with conventional stroke therapies. Injections were administered once a day for fourteen days. Acupoint therapy was found to improve neurological deficits and motor function in the lower extremities, activities of daily living and quality of life more than conventional treatment.

Zhai et al. (2022) randomly divided 40 participants with diabetic neuropathy into two groups of 20 each. One group received intramuscular mecobalamin injections into muscles surrounding the hip and the second group was given acupuncture injections of mecobalamin at Zusanli (stomach 36) acupuncture points bilaterally. Outcomes were measured by the Toronto Clinical Neuropathy Score and diffusion tensor imaging (MRI-DTI) at baseline and 2 weeks after treatments. The neuropathy scores in both groups decreased and the difference in reduction between the two groups was not significant. The MRI-DTI parameters showed that acupuncture injection with mecobalamin had greater therapeutic effects on the neuropathy than the intramuscular injections.

A number of more recent systematic reviews and one meta-analysis demonstrate better adherence to methodological quality, yet they all similarly conclude that although individual studies may seem promising, a reliable conclusion about the effectiveness of APIT may not be drawn at this time. Further research of better quality must occur first. (Wang et al., 2015; Cho et al., 2018; Huang et al., 2019; Xie et al., 2020; Yang et al., 2020).

Xue et al. (2023) studied 90 patients undergoing laparoscopic sleeve gastrectomy with general anesthesia. Two-thirds of the patients were assigned to receive anisodamine

injections at the ST 36 acupuncture point, while the remaining third served as the control group. Nausea and vomiting were monitored post-operatively on days 1-3 and at 3 months. Additional outcomes such as recovery from anesthesia, gastrointestinal function, sleep quality, anxiety, and depression, as well as other complications were measured. In the treatment group, 42% of patients experienced vomiting, while in the control group, 72.4% did. The treatment group required less antiemetic medication and had a longer delay in needing the first dose as compared to the control group. Neither the incidence of nausea nor the other recovery indicators were different between the treatment and control group.

Cheng et al. (2024) also studied the effect of acupuncture point injections at Stomach 36 given after induction of general anesthesia on post-operative recovery quality of 141 participants undergoing laparoscopic sleeve gastrectomy. Participants were divided into three groups – injection with normal saline, injection of anisodamine, or control group. The Quality of Recovery (QoR-40) tool was used before surgery and on post-op days 1,3, and 7. Injection of anisodamine at St 36 was shown to assist in recovery after surgery by aiding with return of digestive functioning and reducing pain and nausea.

Jeong et al. (2024) performed a literature review of acupuncture injection with bee venom for treating shoulder pain. Conditions included post-stroke, rotator cuff syndrome, brachial plexus palsy and adhesive capsulitis. Twenty-three studies were selected for review (15 cases studies and 8 RCTs) with a total of 452 participants. Outcome measures included pain level by VAS score or pressure algometer, physical exam findings, x-ray results, and levels of interleukin 1B and 10 and TNF-alpha. Bee venom acupuncture was shown to improve pain, inflammation, and function. One study reported adverse effects including mild local pain, redness, swelling, and numbness. More severe adverse events reported included chest pain and hyperventilation. The authors noted that the lack of reporting of adverse events from all but one study makes safety assessments difficult. Overall, the authors noted that the majority of the studies had low level evidence and poor design; higher quality studies and standardized treatment protocols were recommended.

Ai et al. (2024) performed a systematic review and meta-analysis including 12 studies and 965 participants to evaluate effectiveness of acupoint injection of metoclopramide as an antiemetic therapy for people undergoing chemotherapy. Acupoint injection was shown to reduce vomiting when used at the Zusanli point and outperformed intravenous/intramuscular injection.

Fu et al. (2025) studied nine-three participants undergoing laparoscopic cholecystectomy. Participants were randomly assigned to groups - a control, and TAP (transversus abdominus plain) blocks under direct vision with or without acupuncture injection. Pain levels were significantly lower in the acupoint group compared with the control and the TAP block without acupoint injection group. Post-operative passing of gas was much earlier in the acupoint injection group.

Lin et al. (2025) performed a systematic review to evaluate the best acupuncture therapy for peripheral neuropathy in patients with diabetes. The review included 62 randomized controlled studies with 5,942 participants. Electroacupuncture was the most effective at improving motor nerve conduction velocity. Acupuncture injection combined with Traditional Chinese Medicine herbal therapies was the second most effective treatment. Acupuncture injection therapy was the most effective for improving sensory nerve conduction velocity; second was acupuncture injection with Traditional Chinese Medicine herbal therapies. The acupuncture injections were done with vitamin B12. All therapies tested were more effective than medically administered mecobalamine alone.

To investigate methods of treating postoperative ileus, Zhang et al. (2025) reviewed 24 meta-analyses. Treatment methods included Zusanli point injection which were shown to significantly improve postoperative ileus with low quality evidence. Injectable substances included vitamin B1, metoclopramide, normal saline, and astragalus.

In a randomized controlled study, Li et al. (2025) evaluated treatments for postoperative catheter-related bladder discomfort. Ninety patients who were status-post elective gynecological surgery were randomly divided into three equal groups. Group A received acupuncture point injections of saline solution at ST 36, SP 6, CV 3, and CV4. Group B received intravenous tramadol, and Group C was given intravenous normal saline. Outcome measures included discomfort on the visual analog scale at time 0, 0.5, 1, 2, and 6 hours after treatment. Acupuncture injection was more effective than tramadol, demonstrated a more rapid onset of treatment effects and did not demonstrate the gastrointestinal side effects common with tramadol administration.

Acupuncture-related therapies for chronic pelvic inflammatory disease were evaluated in a network meta-analysis by Zheng et al. (2025). Eighty-four randomized, controlled studies were included with 8,147 participants. Acupuncture injections (4 studies, 2 with astragulus and 2 unstated) were best for C-reactive protein regulation and TNF-alpha regulation.

SAFETY

Acupuncture point injection therapy (APIT) has greater safety concerns than acupuncture. These concerns include inappropriate injection agent selection, allergic or other adverse reactions to the injected substance, and improper injection site and/or technique. The literature includes harmful effects from injection therapy such as an outbreak of methicillin-resistant Staphylococcus aureus (MRSA) (Murray et al., 2008), sciatic nerve injury causing drop foot (Sobel et al., 1997), and respiratory depression and hemiplegia due to pneumocephalus (Nelson and Hoffman, 1998). In 2015, an outbreak of thirty-three cases of extrapulmonary tuberculosis infection in China was traced to APIT (Jia et al., 2015).

In their qualitative review, Sha et al. (2016) noted an increase in reports of adverse effects during their review period between 2010 and 2015. The safety of APIT has not been established; however, APIT inherently poses more risk for adverse events than acupuncture. APIT, while considerably riskier than acupuncture, seems to be relatively safe with the application of appropriate aseptic procedure to avoid infection and needle insertion safety guidelines to avoid organ puncture.

PRACTITIONER SCOPE AND TRAINING

Practitioners should practice only in the areas in which they are competent based on their education, training and experience. Levels of education, experience, and proficiency may vary among individual practitioners. It is ethically and legally incumbent on a practitioner to determine where they have the knowledge and skills necessary to perform such services and whether the services are within their scope of practice.

It is best practice for the practitioner to appropriately render services to a patient only if they are trained to competency, equally skilled, and adequately competent to deliver a service compared to others trained to perform the same procedure. If the service would be most competently delivered by another health care practitioner who has more skill and training, it would be best practice to refer the patient to the more expert practitioner.

Best practice can be defined as a clinical, scientific, or professional technique, method, or process that is typically evidence-based and consensus driven and is recognized by a majority of professionals in a particular field as more effective at delivering a particular outcome than any other practice (Joint Commission International Accreditation Standards for Hospitals, 2020).

Depending on the practitioner's scope of practice, training, and experience, a patient's condition and/or symptoms during examination or the course of treatment may indicate the need for referral to another practitioner or even emergency care. In such cases it is essential for the practitioner to refer the patient for appropriate co-management (e.g., to their primary care physician) or if immediate emergency care is warranted, to contact 911 as appropriate. See the *Managing Medical Emergencies (CPG 159 – S) clinical practice guideline for information.*

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