Clinical Practice Guideline: **Intradermal Needles and Ear Tacks**

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GUIDELINES

American Specialty Health – Specialty (ASH) considers the use of intradermal needles (i.e., acupuncture devices that puncture and remain in the patient's skin upon the patient leaving the office) such as needle implants or ear tacks not medically necessary due to risk of direct harm.

Due to the potential for direct harm from this procedure, including infection and injury, practitioners are strongly recommended to use the safer alternative of ear seeds, press balls, as well as other acupressure devices that do not puncture the skin. For more information, see the ASH *Techniques and Procedures Not Widely Supported as Evidence Based (CPG 133 – S)* clinical practice guideline.

Patients must be informed verbally and in writing of the nature of any procedure or treatment technique that is considered experimental/investigational or unproven, poses a significant health and safety risk, and/or is scientifically implausible. If the patient decides to receive such services, they must sign a *Member Billing Acknowledgment Form (*for Medicare use *Advance Beneficiary Notice of Non-Coverage form*) indicating they understand they are assuming financial responsibility for any service-related fees. Further, the patient must sign an attestation indicating that they understand what is known and unknown about, and the possible risks associated with such techniques prior to receiving these services. All procedures, including those considered here, must be documented in the medical record. Finally, prior to using experimental/investigational or unproven procedures, those that pose a significant health and safety risk, and/or those considered scientifically implausible, it is incumbent on the practitioner to confirm that their professional liability insurance covers the use of these techniques or procedures in the event of an adverse outcome.

DESCRIPTION/BACKGROUND

Intradermal needles are typically short, sterile needles made of stainless steel that are inserted just under the skin. There are two common types of intradermal needles. One has about a 3mm needle and a flat wire head resembling a tiny thumbtack. These small tack-shaped needles are generally applied to acupuncture points on the ear but can be placed on other body areas as well. The other type of needle is about a centimeter long and has a small head resembling a grain of wheat. These needles are inserted horizontally under the skin on various body areas. Once embedded, the handle or exposed part of the needle is

covered with an adhesive (e.g., medical tape) to protect against infection and hold the needle in place. Typically, intradermal needles are only left in place for a few days.

Intradermal needles are intended to provide continuous stimulation of acupuncture points by remaining embedded in the skin. They are typically used to treat certain chronic and/or painful diseases in which patients may benefit from prolonged needle retention. Examples of conditions in which intradermal needles may have traditionally been used include headache, stomachache, asthma, insomnia, and dysmenorrhea. Embedded intradermal needles have also been used to treat patients seeking assistance in tobacco cessation or weight loss.

EVIDENCE REVIEW

In one controlled, double-blind study, Kotani et al. (2001) concluded that postoperative pain, analgesic requirements, and opioid-related side effects after both upper and lower abdominal surgery were reduced with preoperative insertion of intradermal needles at acupuncture points 2.5cm from the spinal vertebrae (along the urinary bladder meridian in acupuncture).

Another study by Kotani, Kushikata, Suzuki et al. (2001) tested the hypothesis that insertion of intradermal needles into painful abdominal scars reduces scar pain. Data suggest the insertion of intradermal needles into painful points is an effective treatment for intractable abdominal scar pain.

Acupuncture's usefulness in obesity management has not yet been fully evaluated. In their review Lacey et al. (2003) surveyed and critically evaluated the available descriptive and controlled trials of acupuncture for enhancing weight loss. The underlying principles of acupuncture point stimulation are described, with an emphasis on auricular (ear) acupuncture, the method most often chosen for obesity studies. The difficulties of selecting suitable placebo controls are highlighted. To date, most trials have been descriptive in nature, of short duration (less than or equal to 12 weeks) and designed using nonstandard treatment protocols. Sacks (1975) performed a retrospective review of patients treated for drug addiction, obesity, alcoholism, and excessive smoking. The studies used ear tacks and body points for various lengths of time in 1,030 cases of obesity. Success rates were noted as 25% excellent success (weight loss of 8–10 lb/month), 50% good success (control of eating habits and half of their individual goal being met), while 20% were "not influenced at all."

Further careful study of acupuncture's potential usefulness as an adjunct in weight management is recommended.

Since acupuncture provides analgesia, it might be expected to reduce the need for conventional anesthetic drugs during general anesthesia. Akca and Sessler (2002) discuss

4 double-blind, placebo-controlled studies evaluating acupuncture's ability to reduce analgesic or anesthetic requirement. Three studies (Greif et al., 2002; Morioka et al., 2002; Taguchi et al., 2002) examined whether transcutaneous electrical stimulation of some acupuncture points reduces anesthetic requirement. None of these 3 studies showed that the stimulation of the acupuncture points produces clinically important reductions in anesthetic requirement. In contrast, Kotani et al. (2001) tested the hypothesis that preoperative insertion of intradermal needles in the bladder meridian reduces postoperative pain and opioid requirement and showed that at least some acupuncture techniques provide substantial postoperative analgesia and significantly reduce opioid requirements. Usichenkco (2005) showed that auricular acupuncture with press needles retained in the ear for three days helped reduce the analgesic needs of patients after total hip arthroplasty. Deng et al. (2008) sought to determine whether intradermal acupuncture reduced pain or analgesic use in patients with cancer after thoracotomy compared with a sham acupuncture technique (control). Results demonstrated no statistically significant differences between groups for chronic pain assessments at 60 and 90 days, in-patient pain, and medication use in the hospital and after discharge.

One RCT ($n = 90$) evaluating the effectiveness of auricular acupuncture for reducing cancer pain found a positive effect for acupuncture using steel ear implants at acupuncture points where an electrodermal signal was detected (Alimi et al., 2003).

Jing et al. (2021) reported on a 45-study, 3,058-patient meta-analysis of intradermal acupuncture for insomnia. Intradermal acupuncture was compared to acupuncture, no acupuncture, and control groups with and without acupuncture. Scores on the Pittsburgh Sleep Quality Index improved when intradermal acupuncture was used. However, the level of evidence was rated very low to low due to risk of bias and lack of conformity between studies.

Garner et al. (2018) examined the use of auricular acupuncture applying a standard protocol for chronic pain and insomnia. The aims of this research were to assess the feasibility and credibility of auricular acupuncture, to evaluate its effects on pain severity and interference scores, and to assess its effects on insomnia severity over an 8-day period. Forty-five participants were randomized to either an auricular acupuncture group (AAG) or a usual care group (CG) on study day 4. A standard auricular acupuncture protocol was administered, with penetrating semi-permanent acupuncture needles in place for up to 4 days. The main outcome measures were feasibility of conducting the study, credibility of auricular acupuncture as a treatment modality, Brief Pain Inventory pain severity and interference scores, and Insomnia Severity Index (ISI) scores. There was high interest in the study and the retention was 96%. Credibility of auricular acupuncture as a treatment was high in both groups, which may have biased the results. The use of auricular acupuncture led to significant within- and between-group reduced pain severity and interference scores, compared to the CG. Both groups showed within-group decreased ISI

scores. However, the AAG showed significant between-group reduced ISI severity scores compared to the CG. Authors concluded that this treatment may be an option for treating military beneficiaries who have chronic pain and insomnia. Study limitations require further research to substantiate results.

Luo et al. (2020) evaluated the effect of hand-ear acupuncture on chronic low-back pain (cLBP). All 152 participants with cLBP were randomly assigned to hand-ear acupuncture (n = 54), standard acupuncture (n = 50), or usual care groups (n = 48). Eighteen treatments were provided over 7 weeks. Back-related dysfunction and symptom severity were assessed by the Roland-Morris Disability Questionnaire (RMDQ) and the Visual Analogue Scale (VAS), which were collected at baseline, 2 months, and 6 months post treatment. Authors concluded that both hand-ear acupuncture and standard acupuncture modes have beneficial and persistent effectiveness against cLBP compared with the usual care. Furthermore, hand-ear acupuncture was significantly more effective than the standardized acupuncture, especially in the long term.

In a randomized, controlled trial, Usichenko et al. (2022), participants undergoing elective c-section deliveries were equally randomized to an acupuncture group or placebo group of 60 patients each. All participants received spinal anesthesia. Another 60 patients received standard care with post-operative analgesia. The treatment group received auricular and body acupuncture with indwelling intradermal needles remaining in place for three days after the procedure. Patients in the placebo group received non-penetrating placebo needles. Patients in the active treatment group demonstrated lower mean pain intensities, more rapid mobilization, and earlier urinary catheter removal than the standard and placebo groups. Adverse events reported for the acupuncture group were fatigue, nausea and vomiting, bradycardia all at comparable rates to the placebo acupuncture and standard care groups. Two patients from the acupuncture group reported unpleasant sensations at the acupuncture needle sites.

A review was performed of battlefield acupuncture including 5 trials and 344 participants who received semi-permanent intradermal ear needle treatments (Yang et al., 2022). The treatments showed no significant efficacy for reducing pain levels when compared to no intervention, usual care, and sham. Adverse events were few and all were mild and transitory. The studies were said to be of poor methodological quality and the authors recommended randomized controlled trials in the future.

Adverse effects from the use of intradermal needles have also been observed. Yamashita et al. (2001) reviewed Japanese literature and noted 124 cases of adverse events with acupuncture; Forty-eight cases were caused by needle breakage including 26 cases of intentionally embedded needles.

Ou et al. (2023), conducted a systematic review and network meta-analysis including 3,046 participants and 32 RCTs investigating acupuncture for cancer-related insomnia. Acupuncture and moxibustion were more effective than sham, Western treatments, and routine care. The most effective therapies were acupuncture and moxibustion together, acupuncture with electric stimulation, auricular acupuncture, intradermal needling along with routine care, and intradermal needling alone. No serious acupuncture or moxa-related events were reported in the studies. A few cases of non-serious acupuncture side effects (hematomas and local pain) were recorded. The incidence of adverse events was much higher in the groups receiving medication than the acupuncture-moxa groups.

A systematic review and meta-analysis of acupuncture-related migraine therapies by Song et al. (2022) included 39 studies of 4,379 patients and 13 different acupuncture therapies. For reduction of pain scores, acupoint injection and needle implantation were the most effective methods. Embedded needling was the second most effective therapy for reducing migraine days with electroacupuncture coming in first. Embedded needling was best for reducing the duration of the migraine. One study of embedded needling reported the retention time of 24 hours. The one study with implanted needle did not record the retention time. There were no reported adverse events in the embedded or implanted needling groups.

Wu et al. (2024) conducted a multicenter randomized controlled trial with 120 participants to see the efficacy of intradermal acupuncture against major depressive disorder. Participants were divided at random into one group taking selective serotonin reuptake inhibitor (SSRI) medication, a second group with SSRI and intradermal acupuncture, and a third group with SSRI and sham intradermal acupuncture. Both acupuncture groups received 10 treatments over 6 weeks at the same point locations and then were followed another 4 weeks later. The true intradermal needle group showed a more significant reduction in the Hamilton Depression rating scale, and in symptoms including somnolence, palpitations, and nausea. MRI studies also showed enhanced functional connectivity in the brain after intradermal acupuncture. No serious adverse events occurred.

Zhang et al. (2024) completed a placebo-controlled, randomized trial of 96 patients who received either indwelling intradermal needle acupuncture or sham acupuncture with a placebo needle. The objectives were to evaluate the effectiveness and safety of auricular on post-operative pain management acupuncture (measured by VAS and pain medication usage), nausea, and inflammation levels (measured by C-reactive protein, erythrocyte sedimentation rate, and white blood cell count) after total knee arthroplasty. The VAS, serum C-reactive protein, nausea, and analgesic injections were all lower in the needle acupuncture group than the sham group. Other outcomes were not different between the two groups.

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