



INTERFERENTIAL STIMULATION FOR THE TREATMENT OF MUSCULOSKELETAL PAIN

INTRODUCTION

The California Technology Assessment Forum has been asked to review the scientific literature on the safety and efficacy of Interferential Stimulation for the treatment of musculoskeletal pain.

BACKGROUND

Acute or chronic musculoskeletal pain is common, frequently under-reported and inadequately treated. Its evaluation and treatment is often frustrating for both the patient and the clinician. Patients with chronic pain may become isolated from friends and family, lose their jobs and develop depression. Despite its prevalence, pain is often poorly understood and inconsistently managed by health care providers (Devereaux, 2003).

Treatment of pain may consist of pharmacologic and/or non-pharmacologic approaches. Pharmacologic treatments generally include non-steroidal anti-inflammatory drugs (NSAIDS) and opioid or non-opioid analgesics and antidepressants. Non-pharmacologic techniques such as acupuncture, massage and relaxation may also be helpful to the patient with acute or chronic pain. Corticosteroid injections can provide short-term relief but do not improve functional status or reduce the need for surgery. Spinal manipulation and physical therapy are alternative treatments for symptomatic relief among patients with subacute low back pain, but the effects are limited (Andersson et al., 1999).

Interferential Stimulation

Interferential stimulation (IFS), also known as interferential therapy (IFT), is a type of electrical stimulation that uses paired electrodes of two independent circuits carrying medium-frequency alternating currents. The electrodes are aligned on the skin so that the current flowing between each pair intersects at the underlying target, thus maximizing the current permeating the tissues while reducing to a minimum unwanted stimulation of cutaneous nerves. IFS resembles transcutaneous electrical nerve stimulation (TENS) therapy, another noninvasive treatment for pain that involves application of electrical current at the affected site, though IFS produces less impedance in the tissue and its intensity is perceived as more comfortable to patients than that produced by low frequency stimulators such as a TENS machine (Hurley et al., 2004).

IFT has been used to treat back pain, injury or inflammation of soft tissues, to promote healing after knee surgery, to treat psoriasis and resistant constipation in children (Chase et al., 2005; Philipp et al., 2000). IFT has also been proposed as a means of accelerating healing of bone fractures (Fourie and Bowerbank, 1997). The underlying theory of IFT is that the low-frequency electrical current causes inhibition or habituation of the nervous system and to activate endogenous analgesic mechanisms (Johnson and Tabasam, 2002). Some research suggests that IFT has a vasodilatory effect on peripheral blood flow, perhaps from loss of sympathetic tone within the smooth muscle wall of blood vessels (Noble et al., 2000). There are no standardized protocols for the use of IFT; the therapy may vary according to the frequency of stimulation, the pulse duration, treatment time and electrode-placement technique. To apply IFS, the patient's skin is cleaned and two to four electrodes are fixed to the skin with tape or suction cups. The electrodes are oriented so that the currents intersect within the target structure and the intensity of the current is increased gradually. Most therapists select interferential currents in the range of 5 to 150 Hz, with intensities ranging from 1 milliamp (mA) to 30 mA. This intensity is often adjusted repeatedly during therapy. Initially, the current is turned up to the point at which the patient experiences a "buzzing" or "tingling" sensation that is comfortable and not too strong. This sensation fades within a few minutes and the interferential current intensity is increased until the sensation returns to a comfortable level. IFS can be done in a medical setting or at home with a portable unit. Most treatment sessions last for 15 to 30 minutes, with a total of 3 to 12 sessions in a few days or a few weeks. There are few contraindications, though it is recommended not to treat patients with acute inflammation, fever, thrombosis or pregnancy (Goats, 1990).

TA Criterion 1: The technology must have the appropriate regulatory approval.

Numerous Interferential stimulators (too many manufacturers to note here) have received FDA 510(k) clearance. These devices are considered Class II devices and there are >50 devices approved through the FDA 510(k) process.

TA Criterion 1 is met.

TA Criterion 2: The scientific evidence must permit conclusions concerning the effectiveness of the technology regarding health outcomes.

The Medline database, Cochrane clinical trials database, Cochrane reviews database and the Database of Abstracts of Reviews of Effects (DARE) were searched using the key words "interferential stimulation", "interferential therapy", "direct current stimulation", "inflammation" and "chronic pain". The search was performed for the period from January

1970 through August 2005. The bibliographies of systematic reviews and key articles were manually searched for additional references. Further references were obtained when relevant from experts in the field, manufacturers and professional societies. The abstracts of citations were reviewed for relevance and all relevant articles were reviewed in full.

The published peer reviewed literature examining the use of IFS therapy in the treatment of pain consists of seven randomized clinical trials that have evaluated the effectiveness of IFS for the treatment of back pain, jaw pain, soft tissue shoulder pain, cervical neck pain and post-operative knee pain (Taylor et al., 1987; van der Heijden et al., 1999; Werners et al., 1999; Hurley et al., 2001; Hou et al., 2002; Jarit et al., 2003; Hurley et al., 2004). In addition, there are numerous non-randomized trials and case reports that will not be reviewed in this assessment. Outcomes assessed in these trials include pain intensity and unpleasantness as measured by visual analogue scale (VAS), pain rulers and pain diagrams, days of reduced activities, medication use, the Oswestry and other disability scales and functional and range of motion indices. Follow-up in most of the trials is generally short.

The seven studies above of IFS therapy met criteria for detailed review. Although all of these studies involved randomization of patients to treatment groups, two were not placebo-controlled, three were not double-blinded and only two involved randomization of large numbers of patients. Another significant shortcoming of the reviewed studies is that only one trial (Jarit et al., 2003) involved a large number of treatment sessions.

In sum, because of the heterogeneity of indications, the variation in technique and the overall small numbers of patients studied, it is impossible to reach definitive conclusions concerning the effectiveness of IFS regarding health outcomes.

Levels of Evidence: 1, 5

TA Criterion 2 is not met.

TA Criterion 3: The technology must improve the net health outcomes.

Patient Benefits

In a randomized, single-blind, placebo-controlled study, 40 patients with temporomandibular joint pain or myofascial pain syndrome received a short series of treatments with either active or placebo IFS (Taylor et al., 1987). The principal outcomes were pain assessed by a questionnaire and range of motion. After three treatment sessions,

lasting approximately 20 minutes each, there was no statistically significant difference in outcomes between the treatment and placebo groups.

Van der Heijden et al. (1999) report on a randomized, double-blinded, placebo-controlled, two-by-two factorial design trial of IFT and ultrasound (US) for treatment of soft shoulder tissue disorders. The primary goal of the study was to assess whether IFT or US add to the effect of exercise for shoulder disorders (i.e. pain in the deltoid region or restricted range of motion or both). They randomized 180 patients, with soft tissue shoulder disorders in 17 primary care physiotherapy practices, to undergo therapy in one of the following groups in addition to a program of exercise therapy: 1) active IFT plus US; 2) active IFT plus dummy US; 3) dummy IFT plus active US; 4) a placebo group consisting of dummy IFT plus dummy US; or 5) exercise only. Principal outcome measures included recovery, functional status, pain, clinical status and range of motion at six weeks after the therapy had been completed and at intervals up to one year. Most patients improved in all treatment groups; they found no significant differences in outcomes between the groups at all time intervals. The authors concluded that neither US nor IFT are effective as adjuvants to exercise therapy for soft tissue shoulder disorders.

In a study of IFS for low back pain, Werner et al. (1999) randomized 152 patients with low back pain either to treatment with IFT or motorized lumbar traction. There was no control or placebo group and patients may have sought treatment in other settings or used analgesics during the study. The authors note that reviews of traction for back pain do not provide evidence that traction is effective. Outcomes were based on the results of the Oswestry Disability Index and a pain visual analog scale. Both groups recorded improvements over a three-month period; there were no significant differences between the two groups in pain or disability. These results may reflect spontaneous improvements or a placebo effect rather than true treatment effects since this study did not involve an untreated control group or placebo treatments.

Hurley et al. (2001) report on a randomized, single-blind study of IFT for acute low back pain. They randomly assigned 60 patients with lower back pain (LBP) for one to three months into one of three groups: 1) IFT of the painful area plus "The Back Book", an evidence based patient education book; 2) IFT of the spinal nerve root plus The Back Book; and 3) a control group who received only The Back Book. Those assigned to active treatment groups received two to three treatments per week of 30 minutes duration for variable periods of time. The principal outcome measures were based on results of the Pain Rating Index (PRI) and the Roland-Morris Disability Questionnaire. Of note, subjects received treatment until "the relevant therapist considered maximal benefit had been achieved and were discharged after completion of the outcome measure questionnaires". The authors report that all three groups had significant improvements in pain, functional disability and overall health measures at discharge (an expected finding in light of the study design) and there were no significant between-group differences

in these outcomes. At three months post discharge, PRI scores and disability actually increased in the IFT "painful area" group (group #1) while subjects in groups #2 and #3 maintained the reduction in pain and improvement in disability at three months, though the IFT nerve root group had a greater reduction in disability scores than the control group. The authors conclude that IFT electrode placement may be important when treating subjects with LBP. Since all groups received The Back Book and outcomes for groups # 2 and #3 were substantially similar, it is not possible to conclude from this study that IFT is an effective treatment for acute LBP.

Hou and colleagues (2002) report on a randomized clinical trial of 119 patients with "palpably active myofascial trigger points" treated with a variety and combination of therapies including hot packs, "stretch and spray", ischemic compression, myofascial release and IFT. The IFT group received treatment with hot packs plus active range of motion and myofascial release techniques, in addition to 20 minutes of IFT. Several of the combination treatment groups reported improvement in pain, however interpretation of data is limited due to the complex intervention that combined different treatment modalities and because there was no control or placebo group.

Jarit and colleagues (2003) report on a randomized, double-blinded, placebo-controlled trial of home-based IFT after knee surgery. They randomized 87 post-operative patients to receive either IFT or a placebo. A representative of the company that supplied the IFT machines instructed patients on the use of the units. They were told to use the unit three times daily, for 28 minutes each session, for seven to nine weeks. The IFT group was instructed to increase the setting as high as possible without pain or muscle contraction while the placebo group was instructed to turn the unit to a standard setting and to "not be alarmed" if no sensation was felt. The three surgical groups included patients who underwent ACL reconstruction (n=28), meniscectomy (n=34) and knee chondroplasty (n=25). To participate, the subjects needed to be cleared by their surgeon; no other specific inclusion or exclusion criteria is listed. The method of randomization is not described. Subjects were not asked if they were able to ascertain whether they received IFT or placebo. The authors report that subjects in all three groups who received active IFT showed statistically significant improvements in all outcome measures, specifically pain, edema and range of motion. Strikingly, they report significant differences at 24 hours in pain and edema. Although these results suggest that IFT may be helpful in post-operative recovery from knee surgery, there are several methodological issues that are problematic. First, the fact that a non-blinded company representative participated in the study and instructed active and placebo patients on use of the IFT units may have introduced bias. Second, there is no description of the randomization process. Third, there is inadequate description of how the outcomes were obtained and a question of whether physician blinding could have been compromised since the authors state that physicians checked the IFT unit to "check for compliance". Finally, the statistical analysis used was not appropriate and may have overestimated some of the differences reported in the study.

Hurley and colleagues (2004) report on a multi-center randomized trial of manipulative therapy (MT) and IFT for acute low back pain. They recruited 240 patients with LBP of between 4 and 12 weeks duration and randomly allocated them to one of three groups: 1) MT; 2) IFT; or 3) a combined treatment of both IFT and MT. In addition, all subjects received a copy of The Back Book. The therapists were not blinded to the protocol content. Outcomes included the Roland Morris Disability Questionnaire, a pain visual analog scale, QOL and other patient centered measures. They found significant improvements at 6 and 12 months from baseline in virtually all measures (except SF-36 General Health) for all three groups. Subjects in all groups experienced clinically meaningful improvements at discharge; these remained largely unchanged at subsequent follow-up. The absence of a control or placebo group in this study make it difficult to conclude whether patient improvement on these mainly subjective measures was a result of the active treatment or can be reasonably explained by the natural history of acute LBP that tends to improve with time combined with the placebo affect of the IFT and MT.

Several randomized trials have examined the efficacy of IFT to relieve experimentally induced pain in healthy subjects. The results are mixed. For example, Johnson and Tabasam (2002) found that IFT improved experimentally induced ischemic pain in healthy subjects significantly more than sham or no treatment, while Johnson and Tabasam (2003b) and Minder et al. (2002) found that IFT had no beneficial effect on cold induced pain or on delayed onset muscle soreness in healthy adult volunteers.

Patient Risks

There are no significant adverse events from IFT reported in the literature. Lambert et al. (2000) report on the transfer of micro-organisms from the skin of one subject to another through the use of IFT machine electrodes. They suggest that suction cups and sponges be disinfected with 70% isopropyl alcohol after the treatment of each patient to mitigate the chances of disease transmission.

TA Criterion 3 is not met.

TA Criterion 4: The technology must be as beneficial as any established alternatives.

Alternatives to IFT for the treatment of musculoskeletal pain include pharmacotherapy such as analgesics (acetaminophen, opioids), NSAIDS and muscle relaxants; physical therapy; and non-traditional therapies such as massage and acupuncture. One recent review found support for the use of massage for persistent low back pain and that acupuncture was not effective (Cherkin et al., 2001). Injection of soft tissue pain points combined with physical therapy can be helpful in selected patients (Blomberg et al., 1993) and exercise programs can reduce pain and improve function in patients with chronic low back pain (Frost et al., 1998). The acute therapy of neck pain includes

posture modification and physical therapy exercises. The benefits of a cervical collar for immobilization are unclear. Unfortunately, few treatments for musculoskeletal pain have been scientifically validated in randomized clinical trials.

TENS is an alternative non-invasive electrotherapeutic modality used in the treatment of musculoskeletal pain, among other conditions. Like IFT, TENS units stimulate peripheral nerves via skin surface electrodes and can be self-administered. Several types of TENS applications, differing in frequency, amplitude, pulse width and waveform, are used in clinical practice. IFT differs from TENS in that it delivers two out of phase electric currents that theoretically allow deeper penetration of energy into the tissue with less discomfort. The published literature on the efficacy of TENS for musculoskeletal pain is inconclusive. There are no published randomized clinical trials that compare TENS to IFT in the treatment of musculoskeletal pain.

In summary, validated treatments for musculoskeletal pain include medication as necessary, such as acetaminophen, nonsteroidal anti-inflammatory agents, muscle relaxants or opioids; discourage bed rest, consider spinal manipulation for pain relief and refer for exercise therapy (Koes, 2001). To date, IFS has not been shown to be as beneficial as the alternatives for the treatment of musculoskeletal pain.

TA Criterion 4 is not met.

TA Criterion 5: The improvement must be attainable outside the investigational settings.

IFS is not technically difficult to administer and devices are sold directly to the public by numerous manufacturers. However, since IFT has not been found to be effective under investigational settings, its use cannot be endorsed outside of these settings.

TA Criterion 5 is not met.

CONCLUSION

The evaluation and treatment of acute or chronic musculoskeletal pain is often frustrating for both patient and the health care system. There may be serious medical and social co-morbidities for patients suffering from chronic pain such as isolation from friends and family, loss of employment and often depression. Despite its prevalence, pain is often poorly understood and inconsistently managed. IFS has been proposed as a treatment for musculoskeletal

pain either alone or in conjunction with other therapies. It is generally a safe technique with only minor and transient discomfort reported in the literature and no known serious adverse effects.

The published peer reviewed literature examining the use of IFS therapy in the treatment of pain consists of seven randomized clinical trials that have evaluated its effectiveness for the treatment of back pain, jaw pain, soft tissue shoulder pain, cervical neck pain and post-operative knee pain (Taylor et al., 1987; van der Heijden et al., 1999; Werners et al., 1999; Hurley et al., 2001; Hou et al., 2002; Jarit et al., 2003; Hurley et al., 2004) and numerous non-randomized and experimental trials. Of these, two reached negative conclusions (Taylor et al., 1987; van der Heijden et al., 1999) and findings from the others are impossible to interpret due to the fact that two were not placebo-controlled, three were not double-blinded and only two involved randomization of large numbers of patients. Only one of these trials (Jarit et al., 2003) conclusively demonstrated that IFT was superior to placebo and this trial had serious methodological shortcomings discussed above.

The lack of a placebo arm in several of these trials is especially problematic in studies of pain where the natural history of the disorder generally favors resolution or diminishment of the pain. In acute LBP, for example, 90% of patients recover spontaneously within four weeks and only 5% remain disabled longer than three months (Papageorgiou et al., 1991). In light of this fact, it is difficult to reach conclusions about the efficacy of IFT for treatment of acute back pain in which patients in all arms of the trial demonstrated improvement (Hurley et al., 2001; Hurley et al., 2004).

The varied and inconsistent use of IFT in the literature and in practice, contribute to the difficulty in reaching conclusions regarding its effectiveness. Several experts point out that IFT is used inconsistently by therapists who generally administer it on a trial and error basis (Hurley et al., 2001).

In sum, it is not possible to conclude from the published literature that IFT is superior to placebo for the treatment of musculoskeletal pain.

RECOMMENDATION

It is recommended that Interferential Stimulation does not meet California Technology Assessment Forum TA Criteria 2-5 for the treatment of musculoskeletal pain.

The CTAF panel voted unanimously to accept the recommendation as written.

October 19, 2005

RECOMMENDATIONS OF OTHERS

Blue Cross Blue Shield Association (BCBSA)

The BCBSA Technology Evaluation Center has not conducted a formal review of this technology.

Centers for Medicare and Medicaid Services (CMS)

CMS language addresses the use of TENS but is not specific to IFS or IFT.

California Orthopaedic Association (COA)

The COA does not have an opinion regarding this technology and was not able to participate in the meeting.

Association of California Neurologists (CAN)

The ACN does not have an opinion regarding this technology and was not able to participate in the meeting.

California Society of Anesthesiologists (CSA)

The CSA has been invited to provide an opinion regarding this technology and to participate in the meeting.

American Academy of Pain Medicine (AAPM)

The AAPM does not have a formal opinion of the use of this technology. Individual members have mixed opinion regarding its use. A representative of the AAPM was not able to participate in the meeting.

California Society of Physical Medicine and Rehabilitation (CSPMR)

The CAPMR does not have a formal opinion regarding this technology and did not participate in the meeting.

American Orthopaedic Foot and Ankle Society (AOFAS)

The AOFAS has been invited to provide an opinion regarding this technology and to participate in the meeting.

ABBREVIATIONS USED IN THIS ASSESSMENT:

ACL: Anterior Cruciate Ligament

IFS: Interferential Stimulation

IFT: Interferential Therapy

LBP: Lower Back Pain

mA: Milliamp

MT: Manipulative Therapy

NSAIDS: Non-Steroidal Anti-Inflammatory Drugs

PRI: Pain Rating Index

QOL: Quality of Life

TENS: Transcutaneous Electrical Nerve Stimulation

US: Ultrasound

VAS: Visual Analogue Scales

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