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Medical Policy Manual

Topic: Interferential Current Stimulation

Date of Origin: February 4, 2004

Section: Durable Medical Equipment

Last Reviewed Date: February 2014

Policy No: 83.07

Effective Date: May 1, 2014

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Interferential current stimulation (IFS) is a type of electrical stimulation. It is believed that IFS permeates the tissues more effectively and with less unwanted stimulation of cutaneous nerves, making it more comfortable than transcutaneous electrical stimulation (TENS). Interferential current stimulation has been investigated primarily as a technique to reduce pain but has also been proposed to increase function of patients with osteoarthritis and to treat other conditions such as dyspepsia, irritable bowel syndrome, and constipation.

IFS uses paired electrodes of 2 independent circuits carrying high-frequency (4,000 Hz) and medium-frequency (150 Hz) alternating currents. These superficial electrodes are aligned on the skin around the affected area. There are no standardized protocols for the use of interferential therapy; the therapy may vary according to the frequency of stimulation, pulse duration, treatment time, and electrode-placement technique.

Regulatory Status

A number of interferential stimulator devices have received 510(k) marketing clearance from the U.S. Food and Drug Administration (FDA), including the Medstar™ 100 (MedNet Services) and the RS-4i® (RS Medical).

MEDICAL POLICY CRITERIA

I. Interferential current stimulation is considered **not medically necessary** for the treatment of pain.

II. Interferential current stimulation is considered **investigational** for the treatment of all other indications.

SCIENTIFIC EVIDENCE

The principal outcomes associated with treatment of a condition due to any cause may include: relief of pain, improved functional level, return to work, and improved overall health. Relief of pain is a subjective outcome that is typically associated with a placebo effect. Therefore, data from adequately powered, blinded, randomized controlled trials (RCTs) are required to control for the placebo effect, determine its magnitude, and determine whether any treatment effect from an electrical stimulation device provides a significant advantage over the placebo.

Treatment with an electrical stimulation device must also be evaluated in general groups of patients against the existing standard of care for the condition being treated. For example, in patients with pain symptoms, treatment with an electrical stimulation device should be compared to one or more forms of conservative therapy.

Literature Appraisal

Musculoskeletal Pain, Range of Motion, and Function

Several systematic reviews and clinical trials have been published on the use of interferential current stimulation for the treatment of pain. The focus of this review is on evidence from randomized controlled trials.

Systematic Reviews and Meta-Analysis

- In 2010, Fuentes and colleagues published a systematic review and meta-analysis of studies evaluating the effectiveness of interferential stimulation for treating pain.[1] A total of 20 studies met the following inclusion criteria: randomized controlled trial; included adults diagnosed with a painful musculoskeletal condition; compared IFS (alone or as a co-intervention) to placebo, no treatment or an alternative intervention; and assessed pain on a numeric scale. Fourteen of the trials reported data that could be included in a pooled analysis. Interferential stimulation as a stand-alone intervention was not found to be more effective than placebo or an alternative intervention. For example, a pooled analysis of two studies comparing IFC alone and placebo did not find a statistically significant difference in pain intensity at discharge. In addition, a pooled analysis of 2 studies comparing IFC alone and an alternative intervention (e.g., traction or massage) did not find a significant difference in pain intensity at discharge. Moreover, a pooled analysis of 5 studies comparing IFC as a co-intervention to a placebo group did not find any between group differences either. These results do not support the use of interferential stimulation for the treatment of pain.

- Poitras and Brosseau conducted a Cochrane-structured systematic review of management of back pain with therapeutic modalities including transcutaneous electrical nerve stimulation and interferential stimulation published in 2008; however, the authors found no eligible studies on which

to base recommendations for IFS.[2]

Randomized Controlled Trials (RCTs)

Several RCTs have been conducted on the use of IFS versus placebo or conservative care for the treatment of pain. The studies detailed below compare IFS to placebo.

- Taylor and colleagues randomized 40 patients with temporomandibular joint syndrome or myofascial pain syndrome to undergo either active or placebo interferential stimulation.[3] The principal outcomes were pain assessed by a questionnaire and range of motion (ROM). There was no statistically significant difference in the outcomes between the two groups. However, these results should be interpreted with caution as the small sample size may have limited the ability of the researchers to find differences between groups where there were any.

- van der Heijden and colleagues randomized 180 patients with soft tissue shoulder disorders to undergo therapy in one of the following groups in addition to a program of exercise therapy: 1) IFS plus ultrasound; 2) active interferential therapy plus dummy ultrasound; 3) dummy IFS plus active ultrasound; 4) dummy IFS plus dummy ultrasound (i.e., the placebo group); or 5) no adjuvant therapy.[4] Principal outcome measures included recovery, functional status, chief complaint, pain, clinical status, and range of motion at 6 weeks after the therapy had been completed and at intervals up to 1 year. The authors reported that neither interferential therapy nor ultrasound proved to be effective as adjuvants to exercise therapy.

- In a randomized controlled trial by Defrin and colleagues, 62 patients with osteoarthritic knee pain were randomized to one of four active treatment groups or two control groups (sham or non-treated).[5] Acute pre- versus post-treatment reductions in pain were found in all active groups but not in either control group. Stimulation resulted in a modest pre-treatment elevation of pain threshold over the 4 weeks of the study. However, the small sample size in this study restricts the ability to rule out chance as an explanatory factor. Additional evidence is needed to establish the acute and long-term effects of IFS.

- A randomized double-blinded trial compared IFS or horizontal therapy (HT) with sham stimulation in 105 older women with chronic low back pain due to multiple vertebral fractures.[6] All participants received a full therapeutic exercise program and blinded evaluation revealed no differences between the groups following 2 weeks of active or sham stimulation. However, at 4 weeks following treatment, analgesic consumption had decreased by 47%, 57%, and 31%, in the IFS, HT, and control groups, respectively. Subsequent analysis showed that significantly more patients improved in the HT group versus the sham group, but that no treatment benefit was observed in IFS over sham. The results of this study do not support the conclusion that IFS provides treatment benefits over sham treatment.

- In 2012, Atamaz and colleagues conducted a double-blind RCT comparing the efficacy of IFS, transcutaneous electrical stimulation (TENS), and shortwave diathermy in 203 patients with knee osteoarthritis.[7] Patients were randomized to one of 6 groups, 3 with active treatment and 3 with sham treatment. The primary outcome was knee pain as measured by a 0 to 100 visual analog scale (VAS). Other outcomes included range of motion, time to walk 15 meters, paracetamol intake, the Nottingham Health Profile (NHP) and the Western Ontario and McMaster University Osteoarthritis Index (WOMAC). At the 1-, 3-, and 6-month follow-ups, there was not a statistically significant difference among the 6 groups in the VAS pain score, the WOMAC pain score or the NHP pain score. Moreover, the WOMAC function score, time to walk 15 meters, and the NHP physical

mobility score did not differ significantly among groups at any of the follow-up assessments. At the 1-month follow-up, paracetamol intake was significantly lower in the IFS group than the TENS group.

- In a 2011 study, Gundog and colleagues randomly assigned 60 patients with knee osteoarthritis to 1 of 4 groups; 3 IFS groups at frequencies of 40 Hz, 100 Hz, and 180 Hz, or sham IFC.[8] IFC or sham IFC treatments were performed 5 times a week for 3 weeks. During the sham treatment, placement of the pads was the same and duration was the same, but no electrical stimulation was applied. The primary outcome was pain intensity assessed by the Western Ontario and McMaster University Osteoarthritis Index (WOMAC). Mean WOMAC scores one month after treatment were 7.2 in the 40 Hz group, 6.7 in the 100 Hz group, 7.8 in the 180 Hz group, and 16.1 in the sham IFC group. However, interpretation of these findings is restricted by the small sample size, which limits the ability to rule out the role of chance as an explanation of study findings. In addition, the number of patients assigned to each group and patient follow-up rates were not reported. Because high loss to follow-up can be associated with treatment type (and thus bias results toward a specific treatment group), the lack of this information restricts overall interpretation of results.

Several other randomized controlled trials have been conducted which compare interferential stimulation to a component of conservative care. None of these studies included a placebo comparison group.

- In 2013, Lara-Paloma and colleagues published data from a single-blind RCT in patients with chronic low-back pain that compared massage with IFS (n=31) to superficial massage (n=30).[9] The superficial massage intervention involved gentle techniques using light pressure in the lumbar area. In contrast, in the treatment group, providers could use deeper massage and dorsal-lumbar as well as lumbar areas were massaged. Patients received 20 sessions over 10 weeks; outcomes were assessed by blinded personnel at baseline and immediately after the final session. Sixty of 61 participants completed the study. The primary outcome was change in the score on the Roland Morris Disability Questionnaire (RMDQ, range 0: no disability to 24: severe disability). Baseline scores on the RMDQ were 10.33 (standard deviation [SD]: 3) in the massage with IFS group and 11.13 (SD: 2.9) in the control group. Post-treatment, scores were 7.96 (SD: 3.3) and 10.97 (SD: 3.1), respectively. Authors reported a statistically significant improvement in the reduction of RMDQ scores in the treatment group; however, this difference did not meet the pre-defined minimal difference of 2.5 points. A number of secondary outcomes were also assessed and findings were mixed. As with the primary outcome, the absolute change in scores in the intervention group on secondary outcomes tended to be small. For example, on a 10-point visual analogue scale, the mean score in the intervention group was 6.67 (SD: 1.67) at baseline and 5.01 (SD: 1.89) at follow-up. This change in the VAS score did not reach the pre-defined threshold for clinical significance of 2.0 points. A limitation in the study design was that the potential impact of IFS could not be isolated because a combination intervention was used. Beneficial effects in the treatment group may have been due to use of deeper or more extensive massage rather than the addition of IFS.

- In 2011, Facci and colleagues published an RCT that compared IFS (n=50) and TENS (n=50) to a no-treatment control group (n=40) in patients with chronic low-back pain.[10] Patients were assessed by a blinded evaluator before and after completing ten 30-minute treatment sessions over 2 weeks. Patients in the control group were reassessed after 2 weeks. A total of 137 of 150 (91%) patients completed the intervention; analysis was intention to treat. The mean pain intensity, as measured by a 10-point VAS, decreased 4.48 cm in the IFS group, 3.91 cm in the TENS group, and 0.85 cm in the control group. There was not a statistically significant difference in pain reduction in the active treatment groups. Both groups experienced significantly greater pain reduction than the control group. Since a sham treatment was not used, a placebo effect cannot be ruled out when comparing

active to control treatments. Moreover, findings from this trial do not demonstrate equivalence between IFS and TENS; studies with larger numbers of patients that are designed as equivalence or non-inferiority trials would be needed before drawing this conclusion.

- Werners and colleagues reported on the results of a study that randomized 152 patients with low back pain to either treatment with IFS or traction.[11] Outcomes were based on the results of the Oswestry Disability Index and a pain visual analogue scale. The authors recorded improvements in both groups over a 3-month period; no statistically significant difference in outcomes was noted between the groups.

- Hurley and colleagues randomly assigned 60 patients with back pain to one of three groups: 1) IFS of the painful area; 2) IFS of the spinal nerve; and 3) a control group that received no IFS.[12] All patients received educational materials. Those assigned to active treatment groups received 2–3 treatments per week for variable periods of time. The principal outcome measures were based on results of pain-rating index and the Roland-Morris Disability Questionnaire. Placement of the IFS electrodes over the spinal nerve, as compared to the painful area, resulted in a significantly larger reduction in disability scores.

- In a randomized trial, Hou and colleagues studied a various combination of therapies in a group of 119 patients with myofascial disease and active trigger points, including hot packs, "stretch and spray," ischemic compression, myofascial release, and IFS.[13] Conclusions regarding IFS treatment cannot be reached due to the use of other physical modalities in conjunction with IFS treatment.

- In 2011, Facci and colleagues published an RCT that compared IFS (n=50) or transcutaneous electrical stimulation (TENS) (n=50) to a no-treatment control group (n=40) in patients with chronic low-back pain.[10] Patients were assessed by a blinded evaluator before and after completing ten 30-minute treatment sessions over 2 weeks. A total of 137 of 150 (91%) patients completed the intervention; analysis was intention to treat. The mean pain reduction as measured by a 10-point VAS was significantly greater for the active treatment versus control groups (4.48 cm in the IFC group, 3.91 cm in the TENS group, and 0.85 cm in the control group). However, study duration (2 weeks) precludes any conclusions about long-term effectiveness.

Conclusion

The single meta-analysis of randomized controlled trials did not find a significant benefit of IFS over control for treating pain. In addition, the majority of randomized studies have reported no significant difference between IFS treatment groups compared to placebo or other co-intervention. Studies which have reported some benefit of IFC treatment for pain have been limited by small sample size, limited follow-up, and lack of placebo control group. Overall, the current body of evidence suggests that IFS is not efficacious for improving pain, function and/or range of motion for patients with musculoskeletal conditions.

Gastrointestinal Disorders

Constipation

Several RCTs evaluating IFS for treating children with constipation and/or other lower gastrointestinal symptoms were identified. The RCTs had small sample sizes and did not consistently find a benefit of interferential stimulation. For example, in 2012, Kajbafzadeh and colleagues randomized 30 children with intractable constipation to receive IFS or sham stimulation.[14] Children ranged in age from 3 to 12 years-old, and all had failed 6 months of conventional therapy e.g., dietary changes and laxatives.

Patients received fifteen 20-minute sessions, 3 times a week over 5 weeks. Over 6 months, the mean frequency of defecation increased from 2.5 times per week to 4.7 times per week in the treatment group and from 2.8 times per week to 2.9 times per week in the control group. The mean pain during defecation score decreased from 0.35 to 0.20 in the treatment group and from 0.29 to 0.22 in the control group. The authors reported that there was a statistically significant difference between groups in constipation symptoms.

Another RCT was published by Clarke and colleagues in 2009 which included 33 children with slow transit constipation (mean age, 12 years) who were randomized to receive IFS or sham treatment.[15] They received twelve 20-minute sessions over 4 weeks. The primary outcome was health-related quality of life and the main instrument used was the Pediatric Quality of Life Inventory (PedsQL). The authors only reported within-group changes; they did not compare the treatment and control groups. There was not a statistically significant change in QOL, as perceived by the parent in either the active or sham treatment group. The mean parentally perceived QOL scores changed from 70.3 to 70.1 in the active treatment group and from 69.8 to 70.2 in the control group. There was also no significant difference in QOL, as perceived by the child after sham treatment. The score on the PedQL group as perceived by the child, did increase significantly in the active treatment group (mean of 72.9 pre-treatment and 81.1 post-treatment, p=0.005).

Irritable Bowel Disease

In 2012, Coban and colleagues published a study which randomized 67 adults with irritable bowel syndrome to active or placebo interferential current simulation (IFS).[16] Patients with functional dyspepsia were excluded. Patients received a total of four 15-minute sessions over 4 weeks. Fifty-eight of 67 (87%) patients completed the study. One month after treatment, primary outcomes measures did not differ significantly between the treatment and control groups. Treatment response was defined as more than a 50% improvement in symptoms. For the symptom of abdominal discomfort, for example, the response rate was 68% in the treatment group and 44% in the control group. For bloating and discomfort, the response rate was 48% in the treatment group and 46% in the placebo group. Using a visual analogue scale (VAS) measure, 72% of the treatment group and 69% of the control group reported improvement in abdominal discomfort.

Dyspepsia

One RCT, by Koklu and colleagues, was identified that evaluated interferential current stimulation for treating dyspepsia.[17] The study randomized patients to active IFS (n=25) or sham treatment (n=25); patients were unaware of treatment allocation. There were 12 treatment sessions over 4 weeks; each session lasted 15 minutes. A total of 44 of 50 (88%) randomized patients completed the therapy session and follow-up questionnaires at 2 and 4 weeks. The authors did not specify primary outcome variables; they measured the frequency of 10 gastrointestinal symptoms. In an intention-to-treat (ITT) analysis at 4 weeks, IFS was superior to placebo for the symptoms of early satiation and heartburn, but not for the other 8 symptoms. For example, before treatment, 16 of 25 (64%) patients in each group reported experiencing heartburn. At 4 weeks, 9 patients (36%) in the treatment group and 13 patients (52%) in the sham group reported heartburn; p=0.02. Among symptoms that did not differ at follow-up between groups, 24 of 25 patients (96%) in each group reported epigastric discomfort before treatment. In the ITT analysis at 4 weeks, 5 of 25 patients (20%) in the treatment group and 6 of 25 (24%) patients in the placebo group reported epigastric discomfort.

Conclusion

Interferential current stimulation has been tested for a variety of gastrointestinal (GI) conditions, with a

small number of trials completed for each condition. The results of these trials are mixed, with some reporting benefit and others reporting no benefit. This body of evidence is inconclusive to determine whether IFS is an efficacious treatment for GI conditions.

Clinical Practice Guidelines

Several clinical practice guidelines specifically address the use of interferential therapy. However, no guidelines were identified which recommend the use of this therapy for the treatment of pain. In addition, no clinical guidelines were identified that discussed interferential current stimulation for the treatment of gastrointestinal disorders.

American College of Physicians and the American Pain Society

Clinical practice guidelines from the American College of Physicians and the American Pain Society published in 2007 concluded that there was insufficient evidence to recommend interferential stimulation for the treatment of low back pain.[18]

American College of Occupational and Environmental Medicine (ACOEM)

In 2011, the ACOEM guideline for low back disorders recommended indicated there was insufficient evidence regarding the use of interferential stimulation (IFS) for acute back pain with or without radiculopathy.[19] The ACOEM recommended against use of IFS for chronic back pain or spinal fractures or spinal stenosis. In addition, the 2009 ACOEM recommend the use of IFS in early management of persistent non-specific low back pain.[20]

Summary

The body of high-quality evidence on interferential current stimulation (IFS) treatment of pain reported no significant difference between IFS treatment groups compared to placebo or other co-interventions. Studies which have reported some benefit of IFC treatment for pain have been limited by small sample size, limited follow-up, and lack of placebo control groups. Overall, the evidence suggests that IFS is not efficacious for improving pain, function and/or range of motion for patients with musculoskeletal conditions; therefore, IFS is considered not medically necessary for the treatment of pain.

The limited evidence on interferential current stimulation (IFS) treatment of a variety of gastrointestinal (GI) conditions report mixed results, with some studies reporting benefit and others reporting no benefit. This body of evidence is inconclusive, so it is not possible to determine whether IFS is an efficacious treatment for GI conditions. Therefore, IFS is considered investigational as a treatment of all GI conditions, including but not limited to constipation, irritable bowel disease and dyspepsia.

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Pulsed Electrical Stimulation for the Treatment of Arthritis, DME, Policy No. 83.10

Transcutaneous Electrical Modulation Pain Reprocessing, Medicine, Policy No. 143

Percutaneous Neuromodulation Therapy (PNT), Surgery, Policy No. 44

Spinal Cord Stimulation for Treatment of Pain, Surgery, Policy No. 45

Occipital Nerve Stimulation, Surgery, Policy No. 174

CODES	NUMBER	DESCRIPTION
CPT	None	
HCPCS	A9900	Miscellaneous DME supply, accessory, and/or service component of another HCPCS code
	E1399	Durable medical equipment, miscellaneous
	S8130	Interferential current stimulator, 2 channel
	S8131	Interferential current stimulator, 4 channel