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The Use of Interferential Current and Therapeutic Exercise in the Treatment of Acute Low Back Pain

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Clinical Scenario: In clinic, I see a large number of patients who have worker's compensation injuries. Many of those patients experienced an injury at work to their lower back, leaving them with pain, muscle guarding, and inflammation. After completing my initial evaluation, I am struggling to find treatment options that are appropriate for patients with acute, highly severe and irritable conditions. Beyond a basic exercise program that consists of gentle stretching and light strengthening, I usually use interferential current as an intervention to decrease their pain.

My Clinical Question: Does the literature support the use of interferential current to reduce acute low back pain following work injuries?

Clinical Question PICO:

Population: Men and women, age 18-70, with acute low back pain (injury no more than 21 days ago) due to work related activities
Intervention: Treatment including 15 minutes of interferential current and a basic lower extremity and trunk stretching and strengthening program.
Comparison: A basic stretching and strengthening program only.
Outcomes: Oswestry Disability Index, visual analog scale for pain

Overall Clinical Bottom Line: Based on the outcomes from Herman et al. and Hurley et al. electrotherapy consisting of TENS or IFC is not an effective modality to use in combination with exercise or manual therapy when treating patients with subacute low back pain. Both studies had weaknesses in methodological quality that would limit a clinician's ability to generalize the results to a larger population. Regardless, neither study found outcomes indicating a positive effect of electrotherapy in this population. Neither study answered my clinical question specifically, as the patients were far more subacute than the patients I treat. Also the exclusion criteria may have restricted the study populations in a way not to match my clinical case load. Future research with high methodological quality is needed to look at the effect of TENS use on pain and mobility in patients with acute low back pain, occurring in the past two to three weeks' time. Special notice should be made regarding blinding of patients and therapists if possible, as well as accounting for study losses over the treatment period.

Search Terms: interferential current, low back pain, physical therapy, electrical stimulation

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Article 1: Herman, et al. "A randomized controlled trial of transcutaneous electrical nerve stimulation (CODETRON) to determine its benefits in a rehabilitation program for acute occupational low back pain." Spine 1994; 19(5), 561-568.

Clinical Bottom Line: This article does not support the use of TENS treatment in conjunction with an exercise program for pain relief or reduction of disability in patients with acute low back pain. The results of this study do not indicate a significant or clinical difference between active TENS treatment with exercise and a placebo TENS treatment with exercise for this population over a four week period. The threats to internal and external validity also limit the strength of the results and our ability to generalize the results to a larger population of patients with work-related low back pain.

Article PICO:

Population: 58 subjects with work-related low back pain of 3-10 weeks duration.
Intervention: Active transcutaneous electrical nerve stimulation (TENS) plus exercise
Comparison: Placebo TENS plus exercise
Outcomes: Roland Morris Disability questionnaire, 100mm visual analog scale, upper and lower extremity strength

Blinding: Subjects and the principal investigator were blinded from group allocation, but the physical therapist administering the TENS was not blinded from treatment groups. It was impossible to blind the physical therapist providing treatment. This is not a threat to validity because these physical therapists did not take part in measuring outcomes.

Controls: The control group in this study received a placebo treatment to mimic TENS as well as the same exercise treatment used with the intervention group. This was an appropriate control, although I am unsure whether a subject would be unaware of the difference between active TENS and placebo.

Randomization: All subjects were randomly allocated to treatment groups by using random number tables. The principal investigator was unaware of allocation throughout the study. The groups were reported similar at baseline.

Study: This was a randomized, single blinded, placebo controlled study. Fifty-eight subjects were divided evenly into two treatment groups (n=29). Exclusion criteria included pregnancy, pathology of the spine, previous spinal injury, cardiac disease or pacemaker, concurrent intervention (PT or chiropractic), use of narcotic medication, psychiatric issues, and prior use of TENS. The intervention group received 30 minutes of active TENS treatment prior to exercise activities. During the first fifteen minutes, high frequency TENS with a "strong but comfortable tingling sensation" was used, and it was followed by fifteen minutes of pulsed TENS producing a strong sensation and muscle contraction. After the thirty minutes of TENS treatment, the exercise program consisted of stretching in the pool, mobility exercises for the spine and lower extremities, strengthening for the abdominals, back extensors, and extremities, and cardiovascular training on a cycle ergometer. The control group completed thirty minutes of placebo TENS. If the subjects asked about the absence of sensation from the TENS, they

were told the treatment had a subliminal effect. After the placebo TENS, the twenty-nine subjects in this group went through the same exercise program as the intervention group. Treatments were received for four weeks in both groups, although there was no mention of frequency of sessions during that time. All subjects in both groups were asked not to take pain medication for four hours prior to each appointment.

Outcome Measures: The outcome measures in this study that most closely match my clinical scenario are the Roland Morris Disability Questionnaire and the visual analog scale for pain. Both outcome measures were evaluated prior to the start of treatment and at a four week follow-up. The authors report that the Roland Morris Disability Questionnaire is reliable and capable of assessing change in patients with low back pain over time, but they do not cite a study that supports this. They determined the clinically important difference to be a two point change, but no other research was used to support their finding. The 100mm visual analog scale was measured three times each day (before TENS, after TENS, after exercise). The test-retest reliability for this instrument is r=.95. Again, the researchers determined that a clinically important change between groups would be 10mm, but did not mention how these differences were determined.

Study Losses: Fourteen subjects were lost in the intervention group, while only three subjects were lost in the control group. The study losses affect the results of the experiment and limit its validity.

Summary of Internal Validity: The internal validity of this study is fair. Randomization and the similarity of subjects at baseline strengthen the study's validity. Limitations include the method of blinding patients to placebo TENS (stating subliminal stimulation) and the large number of patients lost in the intervention group.

Evidence: The results of the Roland Morris Disability Questionnaire and Visual Analog Scale were measured before treatment and at a four week follow-up. The results are summarized in Tables 1 and 2.

Table 1: Roland Morris Disability Questionnaire

	Baseline ±SD	4 Week Follow-up ±SD	Change Score
Intervention	12.5 ±5.1	8.9±5.0*	-3.6
Control	14.3±5.2	9.9±6.4*	-4.4

* Asterisks indicate significant differences (p<.0001) within groups from baseline to four week follow-up

When looking at the change in the subjects' perception of disability over the four week study, one can see both groups had a similar decrease in score (Table 1). The authors did not report the standard deviation of the change scores, so I am unable to calculate statistics for these values. The authors report there is a statistical difference (p<.0001) between baseline and follow-up scores within each group, but there is not a statistically significant difference between treatment groups. The authors state the clinically importance difference between disability scores to be 2.0 points, and these results indicate that the clinically important difference was not met for these two groups.

Table 2: Visual Analog Scale

	Baseline ±SD	4 Week Follow-up ±SD	Change Score
Intervention	42.7±23.3	35.8±27.7**	-6.9
Control	47.9±21.3	35.9±27.0**	-12.0

**Asterisks indicate significant differences (p<.005) within each group from baseline to four week follow-up

The pain ratings based on a visual analog score show a greater decrease in pain for the control group compared to the intervention group from the beginning to the end of the four weeks of treatment (Table 2). The authors do report that patients in the TENS group experienced less pain immediately after each TENS treatment when compared to the control group, but this difference was not a clinically significant difference. Again, since the authors did not report a standard deviation for the change score, I cannot calculate statistics for these results. The authors report a significant difference from baseline to follow-up within groups (P=.005), but there was no significant difference between treatment groups. The authors determined the clinically importance difference between groups to be 10.0 point change in pain, and this clinically importance difference was not met.

Discussion: The results of this study do not support the hypothesis that treatment with TENS for acute low back pain results in significantly less disability or pain after four weeks of treatment. Also, the clinically important differences between groups for disability and pain were not met in this study. This indicates that change over the four week period were neither statistically or clinically significant.

Applicability of Study Results

Benefits v. Costs: This study does not support the benefits of TENS treatment for acute low back pain. There are small costs associated with TENS treatment which include purchase of the machines, electrodes, and other materials. Also, a small amount of money is reimbursed for this treatment by insurance companies. The TENS treatment added an additional thirty minutes of treatment time to the intervention group sessions, and this additional treatment time may not be beneficial according to the results from this study.

Feasibility of Treatment: Parts of this intervention protocol would be difficult to implement clinically. The specific exercises for this protocol were not described in the article, and my clinic does not have a pool for the aquatic portion of the program. No additional education would be necessary for the physical therapists to complete the program. The authors did not mention the frequency or duration of interventions other than it was a four week program. I am not sure how feasible it would be to implement the program depending on the number of days and hours of treatment per week. There was no pain inflicted on patients in either treatment group.

Summary of External Validity: The subjects in this study are not particularly similar to the patients in my clinical scenario. My patients' injuries are more acute in nature, usually occurring within the last week or two. The exclusion criteria of this study are not specific, and many patients from my clinical scenario

could have been excluded from this program due to "pathology of the spine." It is difficult for the results of this study to be generalized for the entire population due to a relatively small sample size from a single city in Canada and a large loss of participants from the intervention group. Also, the control group may be an issue as the procedure of the placebo TENS treatment may not have served as an adequate control group.

Article 2: Hurley, et al. "A randomized clinical trial of manipulative therapy and interferential therapy for acute low back pain." Spine 2004; 29(20), 2207-2216.

Clinical Bottom Line: This study does not support the use of interferential current for the treatment of acute low back pain. The results do not indicate a significant difference between interferential current and manual therapy and manual therapy alone when treating patients for this condition over an eight week period. The threats to internal and external validity also limit the strength of the results for this study. A particular concern is the population not matching the clinical scenario, and the lack of information about frequency and duration of treatment for this protocol.

Article PICO:

Population: 240 subjects (age 18-65 years) with low back pain of 4-12 weeks duration
Intervention: Interferential current (IFC) and manual therapy
Comparison: Manual therapy
Outcomes: Roland Morris Disability Questionnaire, McGill Pain Questionnaire, quality of life

Blinding: The principal investigator was blinded to group assignment, although there was no way to blind therapist or patient to the intervention received. Since the subjects knew their group and treatments received, it could have an impact on the study results.

Controls: Three different treatment groups were used in this study: manual therapy, IFC, and manual therapy with IFC combined. The group chosen as a comparison group for this paper received manual therapy only. This group was chosen to ensure that differences between groups could only be attributed to the treatments received.

Randomization: Subjects were randomly allocated into one of three treatment groups based on a random number table. The principal investigator was not aware of patient allocation during the study. The authors state patient characteristics for each group were "well balanced at baseline."

Study: This was a randomized, single blinded, controlled study. One hundred twenty patients were evenly divided into three groups (n=40). All patients were referred for low back pain with or without radicular pain into the extremities. Exclusion criteria included previous spinal surgery, recent motor vehicle accident, systemic disease, concurrent medical conditions, reflex or motor signs of spinal cord, or cauda equina compression, low back pain in the last six months, physical therapy in the last twelve months, psychiatric illness, pregnancy, lack of fluency speaking English, and a Roland Morris Disability score less than four (not significantly disabled). All the subjects in this study received a copy of *The Back*

Book for education and were asked not to seek any other form of treatment during the study. The eighty patients in the intervention group received manual therapy consisting of mobilization and/or manipulation of the lumbar spine as well as interferential therapy for thirty minutes. The control group received only manual therapy treatments of mobilization and manipulation. Patients were treated for 4-10 sessions over a period of eight weeks.

Outcome Measures: The outcome measures that best match my clinical scenario are the Roland Morris Disability Questionnaire and the McGill Pain Questionnaire. The outcome measures were completed at baseline, discharge from treatment, and at six and twelve month follow-ups. For the purposes of this paper, I will examine the outcomes at baseline and discharge as it most closely matches my clinical scenario. The authors state all outcome measures were valid and reliable, and specific values for these properties were cited in the footnotes by one other study. They do cite the minimal clinically important difference (MCID) for the Roland Disability Questionnaire to be a three point change. An MCID was not given for the McGill Pain Questionnaire.

Study Losses: Participants were lost in both of the treatment groups. The intervention group which received interferential and manual therapy lost a total of 29 subjects. The control group which received only manual therapy lost 28 total subjects. An intention to treat analysis was completed, and the authors determined each treatment group needed fifty subjects to account for the possible loss of subjects and still complete the experiment with meaningful results.

Summary of Internal Validity: The internal validity of this study was fair. The principal investigator was blinded and the subjects were randomly assigned to treatment groups, but the lack of blinding to patients could have affected their perception of treatment and their outcomes. There is no way to know if subjects in each group were similar at baseline, as the groups were described as "well balanced." They did use valid outcome measures and cited reliability and validity from another study to support this assertion.

Evidence:

Table 3: Roland Morris Disability Questionnaire Scores from Baseline to Discharge from Treatment

	Change Score (95% confidence interval)
Intervention	-4.65 (-5.8 to -3.5)
Control	-4.53 (-5.7 to -3.3)

In Table 3, the self-reported changes in disability scores based on the Roland Morris Disability Questionnaire are slightly greater for the intervention group compared to the control group. No standard deviations were presented for the change scores; therefore statistical calculations could not be completed. The authors report no statistically significant difference between the two treatment groups. Both groups met the authors stated MCID of three points change from baseline to discharge from therapy. This indicates within group improvements for both groups were clinically significant, although there was no difference between the group receiving manual therapy and IFC and the group receiving manual therapy alone. The 95% confidence intervals do not cross zero, indicating that the results could

not be reversed and patients in either group could not have an increase in disability over the treatment period.

Table 4: McGill Pain Questionnaire Scores from Baseline to Discharge from Treatment

	Change Score (95% confidence interval)
Intervention	-6.64 (-9.2 to -4.4)
Control	-5.12 (-7.7 to -2.5)

Table 4 presents the McGill Pain Questionnaire data for each group from baseline to discharge from therapy. Due to missing standard deviations of the change scores, statistical calculations could not be completed. Both groups appeared to have a similar decrease in overall disability scores over the treatment period. The authors report no statistically significant differences between the two groups. They also do not report an MCID for this outcome measure, making it impossible to determine if the decrease in pain was clinically significant for either group. The 95% confidence intervals both stay positive, which indicates that with these protocols patients likely would not have an increase in pain due to the treatments.

Discussion: This study does not support the hypothesis that use of IFC in conjunction with manual therapy is an effective treatment method to decrease disability and pain in patients with acute back pain. A clinically significant decrease in disability was seen within both treatment groups (more than three point change), but there was no difference between the two treatments themselves. No statistically or clinically significant changes were made in McGill Pain Questionnaire scores over the treatment period.

Applicability of Study Results

Benefits v. Costs: There are no extreme benefits or costs associated with this treatment protocol. Purchasing the IFC machines initially would be expensive, although most clinics have them already. Insurance reimburses well for manual therapy treatment and a small amount for IFC as well. Therapists can leave patients unattended on IFC, so this treatment is not a drain on productivity. Patients received anywhere from 4-10 treatments over eight weeks, so the amount of time in treatment could vary greatly between subjects.

Feasibility of Treatment: Implementation of this protocol is clinically feasible. Manual therapy is a common treatment method for low back pain, and all physical therapists should have an entry level education on this subject. The number and duration of sessions are similar to those allowed by insurance, although specific information about the number of appointments each week was not provided. Four to ten sessions over an eight week period is reasonable to fit into a patient's schedule. Patients may have felt mild discomfort with manual therapy procedures, although it should not be unbearable.

Summary of External Validity: The internal validity limits the external validity of this study. The treatment groups were larger, which allows for results to be generalized to a larger population. This

does not really matter, as the results did not indicate significant differences between the treatment groups. Again, the subjects in this study are more subacute when compared with my clinical scenario. Usually, we are using IFC on patients injured within the past 1-14 days, and these patients were injured a month or more in the past. The ages of the subjects in this population match the age range I am seeing clinically.

Synthesis/Discussion: The two studies used different treatment methods, but both found similar results. In the study by Herman et al., the results found no statistical or clinical difference between groups for disability or pain. Both groups experienced decreased disability and pain, but TENS therapy did not appear to work any better than exercise alone. Hurley et al. found a clinically important difference for both groups when looking at disability scores over eight weeks of treatment, although no statistical or clinical difference was noted in McGill Pain Scores. Again, both groups saw similar decreases in pain and disability scores, and IFC treatment did not improve their outcomes more than manual therapy alone.

Both studies had limitations in internal and external validity which impacted the applicability of their results. A large number of losses occurred in each study. Hurley et al. had study losses that were similar for both groups and accounted for these losses through an intention to treat analysis. The study by Herman et al. had a smaller sample size and a large loss of subjects in the intervention group that was not accounted for. One study examined the affect of TENS with exercises and stretching, while the other looked at the affect of IFC and manual therapy for treatment of low back pain. Although different interventions were used in each study, similar results were found. The studies did not support the use of electrotherapy to reduce pain or disability in patients with acute low back pain.

References:

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