Iontophoresis: as a new treatment modality in the management of acute soft tissue injuries in the emergency department

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***Background*: Iontophoresis utilizes a transcutaneous process to deliver charged medication to a localized area of injury via an electrical current to remedy pain symptoms. Although this practice is largely used in the physical and occupational therapy settings, there is little evidence showing its use and efficacy in the emergency department as a therapeutic modality.**

***Methods*: Through the voluntary enrollment of 39-participants, 21 in the treatment group and 18 serving as controls, subjects were treated via iontophoresis using lidocaine-HCl and dexamethasone or oral NSAID therapy alone. Measurements of pain were numerated in person on the visual-analogue scale (VAS) using a 0-10 range immediately prior to treatment, 30 minutes after treatment, and via phone at 24 and 72-hours after treatment for both groups.**

***Results*: At the initiation of treatment, average pain scores for the treatment and control groups were 7.29 and 6.50, respectively. Greater reduction in pain was seen in the iontophoresis group compared to the control group; 62% pain reduction in the iontophoresis group and only 8% reduction in the control group at 30-minutes post-treatment ($p<0.001$). Similar results were seen at 24 and 72-hours with reductions of 71% and 73% in the experimental group at the respective times versus 18% and 40% reduction in the control group. Further, participants in the control group consumed over 4-times as many oral NSAIDs 24-hours after visiting the emergency department and almost 5-times more oral NSAIDs at 72-hours. At 24-hours the treatment group utilized, on average, less than 1-tablet while the control group had used over 3. At 72-hours, the control group averaged over 6-tablets compared to the less than 2-tablets, on average, for the treatment group.**

***Conclusions*: These results are promising in using iontophoresis as an effective treatment modality in the management of acute soft tissue injuries in the emergency department. They not only show greater pain reduction, but iontophoresis reduced the number of oral NSAIDs required for pain relief, lowering the complications associated with these medications.**

iontophoresis | emergency department | dexamethasone | lidocaine | NSAID

Iontophoresis is the transcutaneous delivery of charged medication to a local area of injury via a small electrical current. Since inception over 30 years ago, iontophoresis has been used as a treatment modality in many healthcare arenas and has become a standard of care in both physical and occupational therapy. While many medications can be delivered via iontophoresis, steroids and anesthetics are the primary medications used in the healthcare setting. These drugs are commonly used in the acute care phase of an injury; in particular, dexamethasone has been shown to be effective within the first 72-hours of injury (1). Although iontophoresis is effective in treating soft tissue injuries it has not yet been embraced as a common treatment modality in the emergency department (ED) setting (2). Potential reasons for this include lack of knowledge or appropriate equipment, associated costs, and concerns over duration of treatment in the ED setting.

Expanding the scope of iontophoresis to the ED could prove to be a cost effective and time efficient treatment modality. The current ED standard of care for treating acute soft tissue injuries is immobilization and use of non-steroidal anti-inflammatory drugs (NSAIDs). This pilot study will compare the use of iontophoresis to the use of ibuprofen in an acute care setting. With increasing concerns regarding the complications from the use of NSAIDs, such as renal failure, acute gastrointestinal hemorrhage, and cardiovascular complications to name a few, ongoing efforts to evaluate safer and more effective methods of pain management are imperative. Since iontophoresis has been primarily limited to the physical and occupational therapy settings, iontophoresis as an alternative to the use of oral pain medication could prove to be beneficial and safer than oral NSAIDs for the treatment of these injuries in the ED. This pilot study evaluates the effectiveness and practicality of iontophoresis as a trigger modality in the management of acute soft tissue injuries in the ED setting versus the use of typical oral anti-inflammatory therapy.

Materials and Methods

Study Design. This IRB approved study utilized a randomized control design to assess a pain management modality in patients who present to the ED with acute soft tissue injuries. The treated group received treatment via iontophoresis while the control group received oral NSAID therapy with ibuprofen. Randomization was conducted based on odd or even days of the month. NSAID therapy with ibuprofen was chosen as the control because it is arguably the most commonly used medication for acute soft tissue injuries in the ED setting. Subjects presenting to the ED with acute soft tissue injuries were placed in one of the two study groups provided they did not meet exclusion criteria and were willing to participate in this study. The exclusion criteria included those who were mentally incompetent, less than 13 years of age, women who were pregnant, subjects with injuries occurring greater than 72-hours prior to ED admission, those with a pacemaker implant, subjects who currently had a fracture, or those who had compromised skin integrity. Consent forms were provided to the subjects and were signed prior to inclusion in

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the study. Consent was provided by a parent or legal guardian forthose participants under the age of 18. Any subjects with potential fractures underwent imaging studies prior to enrollment in the study and were only enrolled if a fracture could be ruled out. Additionally, participants were screened for all pertinent past medical history and presence of any contraindications or allergies via interview prior to treatment.

Iontophoresis. This was performed on the treated group using a 4-milliamp (mA) current in a two-part procedure. The initial iontophoresis procedure involved the placement of 2-milliliters (ml) of a 4% lidocaine-HCl, a positively-charged solution, on the active positively-charged iontophoresis pad and was placed directly over the area of most intense pain as described by the subject. A second pad, the return pad, which is negatively charged, was placed 4 to 6 inches both ipsilateral and proximal to the active positively-charged pad. Using the 4-mA current, iontophoresis was set for 10-minutes for a total of 40-mA minutes. This was followed by a similar procedure for dexamethasone treatment using a 0.4% dexamethasone-sodium sulfate solution. The dexamethasone procedure was sent at the same 4-mA run over 20-minutes for a total of 80-mA minutes. The polarity of the electrodes was reversed for the dexamethasone treatment as dexamethasone is a negatively charged medication, and thus placed on a negatively charged pad and delivered toward the positive electrode. The control group received one 800-mg dose of ibuprofen upon initial contact (or appropriate dose based on weight).

Patient Care. Subjects in both groups received similar supportive management for acute soft tissue injuries including ice, immobilization/splinting, wrapping, and crutches as needed. Patient demographics are noted in Table 1. All participants who were discharged from the ED in both study groups were provided twenty 800-mg ibuprofen tablets and directed to take this medication up to three times per day as needed for pain relief.

Table 1. Pain site and participant demographics

	Knee	Back	Upper Extrem	Ankle	Age (avg)	M	F
Treated	5	6	4	3	37	9	12
Control	4	3	11	3	26	11	7

Statistical Analysis. The data collected for the study consisted of pain scale readings using the visual-analogue scale (VAS), the most commonly used scale in the ED setting, with a 0-10 range and number of NSAIDs used as measured by the number of ibuprofen tablets taken. Pain assessment was made at four different intervals starting prior to initiation of treatment, then at 30-minutes, 24-hours, and 72-hours post-treatment. The total number of NSAID doses was recorded at both the 24 and 72-hour time intervals. To assess the data, an independent t-test was used to differentiate and verify values at each specific time interval, and also to analyze the pain scores over the entire 72-hour period.

Results

A total of 39 subjects were enrolled in the experiment; 18 in the control group and 21 in the treated group. Patient demographics are noted in Table 1. Average pain scores showed a statistically significant difference ($p<0.01$) in pain reduction of the treated group at 30-minutes, 24-hours, and at the 72-hour intervals. Table 2 shows the average pain scores at the corresponding time intervals for both groups. Pain values at the initiation of this study, 0-minutes, showed comparable values for both the treated and control group (7.29 and 6.50, respectively).

Table 2 demonstrates the percentage of reduction in pain in the treated group versus the control group. At 30 minutes there was a 62% pain reduction in the treated group compared to 8% reduction in the NSAID group ($p<0.001$). Similar results were observed at 24 and 72-hours showing pain reductions of 71% and 73%

Table 2. Average pain score with treatment[1] vs. control

	Time 0 min	30 min	24 hrs	72 hrs
Treated	7.29±1.87*	2.76±2.84	2.14±2.03	1.95±2.11
Control	6.50±1.89	6.00±2.03	5.33±2.45	3,89±2.14
p-value	0.20	<0.001	<0.001	<0.001

*mean±SD
[1]Treatment = Iontophoresis, 4 mA two part procedure

in the treated group at the respective times versus 18% and 40% reduction in the control study group.

In addition to the pain reduction, ibuprofen tablet use was also analyzed in this study (Table 3). Differences in the amount of NSAID taken at 24 and 72-hours were significantly different in the control versus treated group. Table 3 shows on average at 24-hours that 0.76 ibuprofen tablets were taken by the treated group versus 3.22 tablets used in the control group (<0.001). At 72-hours the treated group used an average of 1.38 tablets versus 6.61 tablets by the control group ($p<0.001$). Table 3 further illustrates nearly a 5 fold increase in NSAID utilization by the control group compared to the treated group ($p< 0.001$) over the 72-hour period.

Table 3. Ibuprofen (800 mg) usage by treated subjects vs controls

	Time post discharge 24 hrs	72 hrs
Treated	0.76±1.41*	1.38±2.43
Control	3.22±1.26	6.61±3.24
p-value	<0.001	<0.001

*mean±SD
[1]Treatment = Iontophoresis, 4 mA two part procedure

The average number of ibuprofen tablets consumed was significantly different at each time interval ($p<0.001$), as well as over the entire study period ($p<0.001$). At 24-hours the control group took more than 4 times (average of 3.22 doses) the amount of 800 mg ibuprofen doses as the treated group (average of 0.76 doses). After a 72-hour period, the control group took nearly 5 times (average of 6.61 doses) as many of the 800 mg ibuprofen as the treated group (average of 1.38 doses).

Discussion

In this pilot study, iontophoresis proved to be a statistically and clinically more effective treatment modality in the management of acute soft tissue injuries in the ED as compared to oral NSAID (ibuprofen tablets) therapy alone. The efficacy of iontophoresis was demonstrated by increased pain relief experienced by subjects enrolled in the treated group as compared to the control group. The treated group also utilized less total doses of ibuprofen over time in relation to the control group. Comparatively, the control group used on average 5 times as many ibuprofen tablets with limited pain control. By a single 30-minute treatment in the ED with iontophoresis, acute soft tissue injury subjects were effectively treated for a period of up to 72-hours post-treatment with less overall NSAID use. Subjects, therefore, could be discharged without additional medications, minimizing the potential side effects commonly seen with widespread NSAID therapy. The only reported side effects known in the use of iontophoresis is mild redness at the site of pad placement (3). In this study, no adverse effects from iontophoresis were reported.

Iontophoresis, aside from improved subject comfort, can be managed efficiently in the emergency department setting for acute soft tissue injuries. Using in department equipment, the treatment can be completed in 30-minutes and with almost immediate pain control. This gives subjects significant improvement in functional ability and mobilization of these injuries allowing for an overall better outcome and earlier recovery.

Iontophoresis is also a cost effective management option. The cost of a permanent in-hospital electricity transmitting device ranges between $300 and $500 with disposable pads for these transmitters and the medication costing between $10 and $20. These devices are handheld requiring little maintenance except battery replacement, and the low cost of the pads create a cost-effective means of pain-relief. Recent technologies have created advancements in iontophoresis allowing for disposable and cost-effective means of medication delivery. All-in-one units including a medication chamber, dispersive electrode, and delivery device are also available. These units can be used for both short and longer treatments with 40-mA/min dose taking 75-minutes while an 80-mA/min takes 150-minutes (4). The cost of these disposable units range between $10 and $30.

The use of NSAIDs alone is associated with a significant risk of complications such as peptic ulcer disease, gastroesophageal reflux disease, bleeding complications, renal insufficiency, and renal failure (5-8). The use of COX-2 inhibitors has not been shown to minimize these risks and has in fact, led to the additional risk of myocardial infarction and stroke (9). Currently, the cost of complications from the use of NSAIDs ranges in the hundreds of millions of dollars per year in the United States alone (10). Minimizing the complications from these outpatient medications alone would show iontophoresis to be a cost effective alternative to management of soft tissue injuries. In addition to these complications, there are also many subjects with contraindications to NSAIDs and/or narcotics making iontophoresis an excellent alternative for this population.

Study Limitations. This study involved comparing iontophoresis treatment with medications to a control NSAID group. Ibuprofen was chosen because it is the currently accepted standard of care for soft tissue injuries. Further studies should look at comparing iontophoresis using saline versus dexamethasone and lidocaine to assess the iontophoresis procedure itself and its ability to manage pain for these soft tissue injuries. Any placebo effect though from the iontophoresis procedure should have clearly dissipated by the 72-hour time frame but this cannot be conclusively determined in this pilot study.

Future studies in evaluating a new disposable device that allows the subject to leave with the iontophoresis patch in place could further decrease the ED length of stay while still obtaining the benefits from iontophoresis in the acute care setting. Studies can also evaluate various other medications that could be used in the acute care setting. Differing levels of electrical stimulation may provide additional benefits in the ED environment as well.

Summary. In this study, iontophoresis proved to be an effective and efficient treatment modality in the management of acute soft tissue injuries presenting to the emergency department. Subjects in the treated group using iontophoresis had significantly better pain control at 30-minutes, 24-hours, and 72-hours post-treatment compared to standard management of oral NSAID treatment for similar soft tissue injuries. In addition to improved pain control, the subjects in the iontophoresis group took significantly less oral ibuprofen then the control group up to 72-hours after arriving to the emergency department. Iontophoresis may prove to significantly improve the functional ability and pain management of subjects presenting to the ED with acute soft tissue injuries. By significantly reducing the reliance on outpatient medications, iontophoresis may also be found to be a much safer and cost-effective outpatient treatment option as well.

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