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Piezoelectric Stimulation For Back And Neck Pain: A Randomized Controlled Trial

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ABSTRACT

Background: Many uses for piezoelectric stimulation of acupuncture points, including pain management, have been described. No randomized trials have tested this modality.

Objective: To study the stimulation of acupoints with piezoelectricity to treat acute back and neck pain in a clinical study.

Design, Setting, and Patients A randomized controlled trial in 2000 and 2001 conducted among 18 patients in a family practice setting in New Jersey who presented to their primary care physician with acute back or neck pain.

Intervention All patients received ibuprofen, methocarbamol, and acetaminophen plus oxycodone. Intervention patients received piezoelectric treatment at each of the 5 visits. For neck pain, each patient received 10 stimulations bilaterally at SI 4 and BL 58 for a total of 40 stimulations. In addition, each patient received 2-10 local stimulations on Ah Shi (tender) points in the local area of pain. For back pain, each patient received 5 stimulations bilaterally on GB 34 and GB 39, and 10 stimulations bilaterally on BL 60 for a total of 40 stimulations.

Main Outcome Measures Outcomes were assessed on the following measures: (1) descriptive pain scale (none, a little, some, a lot, or complete relief); (2) percentage pain scale ("What percent relief have you had?") (3) visual analog scale (VAS) (pain severity from 1-100). Additionally, pain medication consumption was measured.

Results The time required for both groups to reach "a lot" or "complete" relief was 11.67 days for the control group and 8.78 days for the treatment group. The treatment group reached this level of relief 2.89 days (24.8%) faster than the control group did. Calculated also was the time to "at least 50% relief." This was 8.83 days for the control group and 6.89 days for the treatment group. The degree of relief was similar for each group at this point (66.67% for controls and 68.89% for the treatment group). However, the treatment group achieved this level of relief 1.94 days (22%) faster than the control group did. The change in VAS scores from day 1 to 21 of the protocol was not appreciably different between groups (control: VAS scores decreased over 21 days an average of 36.25 points per patient; intervention: VAS scores decreased 38.75 points per patient). Pill counts revealed reductions in the consumption of pills per initial VAS point in the treatment group of 11% for ibuprofen, 28% for methocarbamol, and 29% for acetaminophen/oxycodone.

Conclusions The use of a piezoelectric device for acute back or neck pain shortened the time to recovery by 2-3 days, lowered final VAS scores by 20%, and reduced the use of medication, including muscle relaxers and narcotics. No adverse effects were noted. These findings need to be verified in a larger and more varied study population.

KEY WORDS

Piezoelectric, Acupoints, Back Pain, Neck Pain, Pain Management

INTRODUCTION

Piezoelectric stimulators in common use are hand-held devices that use a piezoelectric crystal to produce a high-voltage spark with minimal current. This appears to "activate" the acupoint or group of points and produce effects similar to more traditional methods of acupoint activation. A negative charge is produced at the tip of the device, but the precise effect within adjacent tissue

is not well understood.

Many uses for piezoelectric stimulation of acupuncture points, including pain management, have been described. Prior publications have dealt primarily with case reports and theories that attempt to explain the mechanism by which piezoelectric devices produce their effects.[1-3] The unique treatment method used here was previously reported.[3]

A study of the stimulation of acupoints with piezoelectricity to treat acute back and neck pain is discussed herein. This is the first reported randomized controlled clinical trial using a piezoelectric device.

METHODS

Randomization and Exclusion Criteria

All study subjects were private patients in a family practice setting in New Jersey who presented to their primary care physician with acute back or neck pain. Eighteen adults (age range, 22-76 years) seen in 2000 and 2001 agreed to be randomized into 1 of 2 groups: medication alone or medication plus piezoelectric treatments. The study protocol and consent forms were approved by the local institutional review board (IRB).

Patient consent was obtained, and patients were randomized into the study by placing equal numbers of color-coded cards into a box and blindly withdrawing 1 card on the 1st day of treatment. All patients were seen 5 times over 3 weeks (days 1, 4, 14, and 21) except for 2 patients who had complete resolution of symptoms in less than 21 days. Patients with fractures, bone infection, bone tumor, or spinal disease requiring surgery were excluded in an effort to limit the study population to patients with primarily soft tissue injury.

Study Completion

Three patients did not complete the study: 1 patient had osteoporosis and a severe spondylolisthesis that required surgery, 1 patient had spinal stenosis and lumbar disk disease for which surgery was recommended, and 1 patient could not take the study medications due to adverse effects.

Nine patients completed the study in the medication plus piezoelectric stimulation group (treatment group); 6 patients completed the study in the medication-only group (control group).

Medications

All patients in both groups were given the same 3 prescriptions:
1) ibuprofen, 600 mg orally tid; #40; 1 refill;
2) methocarbamol, 750 mg 1 or 2 orally 3 times daily as needed for muscle spasm; #40; 1 refill;
3) acetaminophen, 325 mg plus oxycodone, 5 mg 1 or 2 orally 4 times daily as needed for pain, #30; 1 refill.

Patients were required to bring their medication bottles at each visit and the number of pills remaining were counted and recorded by the physician or staff.

The pill counts were recorded on a questionnaire at each visit along with the patient's responses to a variety of standard pain scales. These methodologies were adapted from pill studies.[4]

The questionnaire included:

1. Descriptive pain scale: Patients were asked to compare their current pain to their original pain by selecting one of the following categories of improvement: none, a little, some, a lot, or complete relief.
2. Percentage pain scale: Patients were asked to compare their current pain to their original pain by answering the question: "What percent relief have you had?"

3. Visual analog scale (VAS): Patients were asked to mark the severity of their pain on a VAS from 1 to 100.

Piezoelectric Treatments
Patients in the piezoelectric treatment group completed the same questionnaire and received the same medications. In addition, they also received treatments with a Piezoelectric stimulator and grounding pole. The grounding pole is held in the ipsilateral hand for leg point stimulation or in the ipsilateral antecubital fossa for hand stimulation. Patients received piezoelectric treatment at each of the 5 visits.

For neck pain, each patient received 10 stimulations bilaterally at SI 4 and BL 58 for a total of 40 stimulations. In addition, each patient received 2-10 local stimulations on Ah Shi (tender) points in the local area of pain.

Table 1. Time to Relief of Pain

	No. of Days			
Outcome	Control Group (n=6)	Intervention Group (n=9)	Between-Group Difference	Reduction in Recovery Time, %
Time to "a lot or complete relief"	11.67	8.78	2.89	24.8
Time to "50% relief"	8.83	6.89	1.94	22

Table 2. Change in Visual Analog Scale (VAS) Scores

	Initial VAS Score	Final VAS Score	Difference	Reduction in Final Scores, %
Control group (n=6)	54	24	30	63
Intervention group (n=9)	70	17.5	52.5	75

For back pain, each patient received 5 stimulations bilaterally on GB 34 and GB 39, and 10 stimulations bilaterally on BL 60 for a total of 40 stimulations. In addition, each patient received 2-10 stimulations on Ah Shi points in the local area of pain.

Statistics

Using the questionnaire described above, several end points were measured:

- the time to achieve "a lot or complete relief" (descriptive pain scale)
- the time required to achieve 50% relief (percentage pain scale)
- the percentage reduction between initial and final VAS scores
- he number of pills consumed per initial VAS point for each group (VAS scores and pill counts).

This last measurement allows for a global assessment and comparison of the consumption of each type of medication adjusted for the severity of the initial pain in each group.

The Mann-Whitney U test and the unpaired t test were applied to the data for responders (patients achieving relief within the 21 days of the study), and for the patient population as a whole. Due to the relatively small number of patients in this study, statistically significant P values were not obtained by either method. However, for the percentage pain scale (time to 50% relief), a value approaching significance was present for responders: P=.07. Data analyses were performed using Graph-Pad Instat by Graphpad Software (http://www.graphpad.com).

RESULTS

Descriptive Pain Scale (Table 1)

The time required for both groups to reach "a lot" or "complete" relief was calculated. This was 11.67 days for the control group and 8.78 days for the treatment group. Thus, the treatment group reached this level of relief 2.89 days (24.8%) faster than the control group did (Table 1).

Percentage Pain Scale (Table 1)

Calculated also was the time to "at least 50% relief." This was 8.83 days for the control group and 6.89 days for the treatment group. The degree of relief was similar for each group at this point (66.67% for controls and 68.89% for the treatment group). However, the treatment group achieved this level of relief 1.94 days (22%) faster than the control group did (Table 2).

VAS Scores

The Total Group (15 Patients)

The change in VAS scores from day 1 to day 21 of the protocol was not appreciably different between groups for the study group as a whole. In the control group, VAS scores decreased over 21 days an average of 36.25 points per patient (63%). In the treatment group, VAS scores decreased 38.75 points per patient (63.4%).

Responders (12 patients) (Table 2)

However, there were differences between the groups when the scores of non-responders were removed from the data. The non-responders were patients who did not achieve the treatment goals described above, i.e., "a lot" or "complete" relief, or at least 50% relief within the 21 days. These were patients with prolonged or refractory pain regardless of the treatment method. One control and 2 treatment patients were considered non-responders. When data from the remaining 12 patients (5 controls and 7 treatment patients) were analyzed a difference was noted. For responders in the control group the VAS scores decreased from initial values of 54 points per patient to a final value of 24 points per patient. This represents a decline in VAS scores of 30 points (63%). Values for the treatment group decreased from an initial value of 70 points per patient to a final value of 17.50 points per patient. This was a total drop of 52.5 points or 75%. Thus, the percentage decrease in VAS scores from day 1 to day 21 for responders in the treatment group was 20% greater than responders in the control group.

Medication Consumption (Table 3)

In addition, total medication consumption was lower for the treatment group when compared to the average initial VAS score for each group. Comparing the average number of pills consumed per patient to the average initial VAS scores for each group allowed a comparison of medication consumption relative to the severity of the initial pain for each group. The average initial VAS score for the control group was 57.5. The average pill consumption per patient for the control group was 44.80 for ibuprofen, 46.60 for methocarbamol, and 9.5 for acetaminophen/oxycodone. Thus, the ratio of pills consumed over the 21 days per initial VAS point was 0.649 for ibuprofen, 0.675 for methocarbamol, and 0.165 for acetaminophen/oxycodone.

The average initial VAS score for the treatment group was 61.11. The total pill consumption per patient for the treatment group was 35.22 for ibuprofen, 29.78 for methocarbamol, and 7.22 for acetaminophen/oxycodone. Thus, the ratio of pills consumed over the 21 days per initial VAS

point was 0.576 for ibuprofen, 0.487 for methocarbamol, and 0.118 for acetaminophen/oxycodone. This represents reductions in the consumption of pills per initial VAS point in the treatment group of 11% for ibuprofen, 28% for methocarbamol, and 29% for acetaminophen/oxycodone.

DISCUSSION

This was a limited study of a very powerful technique. It was limited primarily by the difficulty in obtaining larger numbers of patients for study within the context of a single family practice. This was especially true as patients became familiar with the value of the technique. As time went on, fewer patients were willing to be randomized into the study. Patients who had experienced these results on themselves or their family members frequently did not want to take a chance that they would be randomized into the control group. The power of the technique is also evident in that positive effects were demonstrated despite the relatively small number of patients. Clearly, these findings are tantalizing and suggest the need for further research.

Table 3. Change in Medication Consumption

	Control Group (n=6)	Intervention Group (n=9)	Difference (Control-Intervention)	Reduction in Consumption, %
Average initial VAS score	57.5	61.11	3.61	
Average pill consumption				
Ibuprofen	44.8	35.22	-9.58	21.38
Methocarbamol	46.6	29.78	-16.82	36.09
Acetaminophen/oxycodone	9.5	7.22	-2.28	24
Pills per initial VAS point				
Ibuprofen	0.649	0.576	-0.073	11.23
Methocarbamol	0.675	0.487	-0.188	27.85
Acetaminophen/oxycodone	0.165	0.118	-0.047	28.47

Abbreviation: VAS, visual analog scale.

Unfortunately, we do not have a clear understanding of this piezoelectric phenomenon. However, we have some inferences. In a recent article, Dolson described the piezoelectric properties of various tissues:

> "Connective tissue literally interconnects all aspects of the body energetically...Collagen, the most common component of connective tissue, is piezoelectric and serves as a biological transducer converting mechanical information into electrical information, and vice versa. The mucopolysaccharide portion of connective tissue serves as a biological effector. It is intimately associated with collagen electrically and functions to regulate many biological processes." "....The cytoskeleton, which is formed largely of the piezoelectric materials actin and myosin, likely functions in a similar way to the piezoelectric collagen of the body, energetically regulating the microcosm of the cell."[5]

In another recent article, Niemtzow et al described the physical properties of the piezoelectric device:

> "The negative voltage output of the crystal is carried to the insulated tip of the device by means of a wire.... The output of a typical piezoelectric stimulator is in the range of about 6000 V. The current is extremely low... The output of the piezoelectric stimulator is difficult to measure and is best achieved by an oscilloscope; its wave pattern is similar to an electrical spark emission. The emission is chaotic and brief, covering a wide frequency spectrum with overlying harmonics. This is contrasted to the typical square wave pattern that acupuncturists typically employ in treating ear and body points."[2]

The obvious conclusion is that the "chaotic and brief" spark of the piezoelectric device somehow influences or changes the piezoelectric property of connective tissue. This is a logical conclusion, but not a known fact. Even if this hypothesis is true, the precise nature of this bioelectric phenomenon is not well understood. In addition, we do not know the relationship of piezoelectric stimulation to needle acupuncture or the other forms of electrical therapy (TENS, PENS, magnets, pellets, polarized ion generators, Genesen point stimulators, etc) as described by Kobrin.1 More primary research is needed so that the basic science of these techniques is understood, and clinicians are able to distinguish between them for different clinical purposes.

The technique described in this study is simple, direct, and relatively easy to learn. It requires only a few minutes of treatment time. It is also relatively innocuous. The device is so simplistic that most versions are sold over-the-counter. However, the device used in this study is produced for medical purposes and is presumably more precisely constructed and calibrated. Over the past 7 years, I have administered hundreds of treatments with this device, not only for various musculoskeletal complaints but also for a variety of medical problems. There have been no reported adverse effects. Theoretically, piezoelectric treatment of back and neck pain could be administered by anyone who learns to locate 5 acupoints and operate the device. This raises the possibility that patients could be taught to treat themselves at more frequent intervals. But, more importantly, it raises the possibility of designing a larger study with true double-blind technique.

It is important to note that even though patients can purchase these devices over-the-counter, the US Food and Drug Administration still lists the device as experimental. Therefore, if it is used by medical personnel, a waiver for use of an experimental device is required. The rudiments of the waiver I use in clinical practice were incorporated into the consent form approved by the IRB for this study. I also refrain from using the device on pregnant patients, in patients with implanted electrical devices such as pacemakers or nerve stimulators, or directly over surgically implanted orthopedic hardware. Other authors advise not stimulating over the heart, carotid bodies, or head.[2]

CONCLUSION

In this study, the use of a piezoelectric device for acute back or neck pain shortened the time to recovery by 2-3 days, lowered final VAS scores by 20%, and reduced the use of prescription medication including muscle relaxers and narcotics. Relative to initial VAS scores the use of anti-inflammatories was decreased by 11%, muscle relaxers by 28%, and codeine derivatives by 29%. These results suggest that the stimulation of acupuncture command points with a piezoelectric device in this manner is effective at relieving both muscle spasm and pain. The procedure takes only 1-2 minutes to complete and no adverse effects have been noted.

These results also suggest the need for more extensive research with proper funding to help understand the electrophysiology of piezoelectric therapy and its relationship to other "electrical" therapies, and delineate clinical uses for the device.

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