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The Effect Length of Rest Has On Self-Rated Pain Relief In Patients Following A Lumbar Epidural Steroid Injection

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ABSTRACT: A lumbar epidural steroid injection is aimed at decreasing inflammation in the low back and causing a residual decrease in low back and radicular pain. There is currently no community standard regarding the amount of bed rest and activity following a lumbar epidural steroid injection (LESI). The aim of this research was to determine if there is a relationship between length of rest and self-rated pain relief, disability and side effects following interlaminar LESIs in a given clinic population. A total of 110 subjects were recruited with an age range between 23 and 85. Mean age of the control group was 50.9 and experimental group mean age was 52.2. No statistical difference in pain relief, level of disability or side effects was found at the two week follow up survey. This research has the potential to influence how patients are cared for after a LESI and provide evidenced based care.

KEYWORDS: Lumbar epidural steroid injection, Length of rest, Pain relief, Activity

BACKGROUND

Low back pain is the fifth most common reason for all physician visits in the United States (U.S.). Approximately one quarter of U.S. adults reported having low back pain in the last year and more than 85% of patients who present to primary care have low back pain that can not reliably be attributed to a specific disease or spinal abnormality- nonspecific low back pain (Chou et al., 2007). Since its introduction as a treatment option in 1952, lumbar epidural steroid injections (LESI) have been conducted as one of the main treatment methods for low back and radicular pain, also called sciatica, which is pain that radiates from the site of a pinched nerve in the low back to the area of the body aligned with that nerve, such as the back of the leg or into the foot (Lee, Moon, & Lee, 2009). For managing low back pain, LESIs are one of the most commonly performed interventions in the U.S. (Manchikanti et al., 2011). It was found that interlaminar LESIs were effective for axial low back pain in four-fifths of patients (Lee et al., 2010).

LESI: What it is and how it works.

A LESI is a procedure in which the radiologist inserts a needle into the epidural space in the lower back under fluoroscopic guidance and a steroid is delivered. At the study site, a steroid solution (Celestone Soluspan) along with a local anesthetic (Lidocaine) are used. The steroid decreases the inflammation within the lumbar and sacral nerves and may provide pain relief for a period of time. Steroids inhibit the inflammatory response caused by chemical and mechanical sources of pain. Inflammation is reduced by the corticosteroids which inhibit either the synthesis or release of a number of pro-inflammatory mediators (Lee et al., 2010). Theoretically, LESIs place a higher concentration of steroid at the site of pathologically indicated pain compared with a systematic oral therapy approach which would likely also have more systematic side effects

(Friedrich & Harrast, 2010). The pain relief is not immediate and it may take up to two weeks to feel the full effects of the medication. The medication will not change the disc in any way but is intended to reduce inflammation around the disc, reducing pain which can be very beneficial for a patient during an acute episode of back and or leg pain.

Current aftercare practice

Patients undergoing a LESI at the Minnesota Diagnostic Center (MDC), imaging center for the Noran Neurological Clinic (NNC), currently complete 15 minutes of flat rest on the fluoroscopy table followed by 45 minutes of flat rest in the nursing area after the injection and are instructed to rest for the remainder of the day. The patient stays on the fluoroscopy table at a slight angle for 15 minutes to monitor that the Lidocaine has not gone into the subarachnoid space. If it has, the table can be adjusted to a greater angle to ensure patient safety. The current practice at the MDC requires patients to be in the clinic for at least two hours (including early arrival and bed rest) and have someone to drive them home.

An examination of this protocol needed to be implemented in order to determine its effectiveness because the MDC is currently the only clinic to practice one hour bed rest in the Twin Cities. There are several clinics in the Twin Cities that perform LESIs and they each have protocols following the injection. Phone interviews were conducted to technologists at six local facilities and it was found that the majority of facilities practice rest after the LESI ranging from 15-30 minutes, with one facility requiring no bed rest. At these facilities, patients resume normal activity following the LESI and a driver is usually required. When these facilities were contacted to explain their rationale for current aftercare protocols, the determining factor was how the patient was responding to the Lidocaine. If they were able to walk with no weakness, they were able to go after their allotted time while some facilities required the radiologist to assess the

patient before leaving. All of the facilities have been following their current protocols for at least five plus years or as long as they have been doing LESIs. There has been no published data pertaining to an increase in side effects following shorter bed rest and the other local facilities have not found an increase in adverse reactions or side effects with their required length of rest.

There is currently no community norm or standard of care in the radiology field for aftercare of patients receiving LESIs. Since there is no published data pertaining to the area, this study will begin to provide the baseline knowledge to the radiology field on the effect that rest either has or does not have following LESIs. It will also allow facilities performing these injections to base practice on current evidence rather than physician preferences and provide patients with evidence based care, promoting best patient care. In the future, this evidence has the potential to reduce health care cost and better utilize health care resources. The aim of this research was to determine if there was a relationship between length of rest and self-rated pain relief and Oswestry Disability Index (ODI) following interlaminar LESIs in a given clinic population.

Research questions

There were two research questions for this study: 1. Is there a difference between a subjects self reported pain and ODI before and two weeks post LESI after completing one hour of flat rest in the clinic (15 minutes on the fluoroscopy table and 45 minutes in the nursing area) and resting for the remainder of the day compared with completing 15 minutes of flat rest on the fluoroscopy table and 15 minutes of flat rest in the nursing area and resuming activity as normal? 2. What side effects (headache, facial flushing, increased low back pain, trouble sleeping, or sweating) were experienced by the subject following the LESI? The purpose of this study was to evaluate if

length of rest had an effect on a subject's self-rated pain relief, disabilities related to back pain, and side effects experienced following a LESI.

It was hypothesized that among patients receiving LESIs, those who completed 30 minutes of flat rest and resumed normal activity would have an equal amount of perceived benefit (pain relief) from the LESI compared with those that did one hour of flat rest and rested for the remainder of the day.

REVIEW OF LITERATURE

The research for this article was done with literature from 2000 to 2011 using CINAHL, Medline, and PubMed. Keywords for the searches of the literature included "Pain," "Lumbar," "Epidural," "Steroid," "Injection," "Back," "Activity," "Bed rest," "Benefits," and "Complications." Literature related specifically to bed rest and activity recommended after any type of LESI was non-existent. Studies that examined the effect length of bed rest had on the prevention of a spinal headache following a cervical or lumbar puncture were found along with the benefits, complications, and risks associated with LESIs. The final review of publications were scholarly, peer-reviewed journal articles in English that specifically discussed the benefits and complications of epidural steroid injections along with the effect activity has on cervical and lumbar punctures.

Potential benefits

Epidural steroid injections are commonly administered to relieve pain and improve mobility without surgery. LESIs are used to effectively treat lumbar spinal stenosis, herniated lumbar intervertebral disc disease, and lumbar degenerative disc disease (Yoo et al., 2009). Benefits of the epidural steroid injections include relief of radicular pain, improved quality of life, reduction of analgesic consumption, improved maintenance of work status and elimination of the need for

surgery in many patients. Acute lower back pain often starts with a traumatic event and many of the injuries can heal over time (Snarr, 2007). However, the issue for most patients is controlling the pain and maintaining function until healing can occur. Generally, up to three epidural steroid injections per year are performed if clinically indicated but it is believed that their effectiveness decrease over time.

Potential complications

Potential complications related to the procedure itself also need to be considered when planning an epidural steroid injection. Complications include infection, steroidal side effects, inadvertent dural puncture, epidural hematoma and nerve injury (Snarr, 2007). The most common technical complication (as high as seven percent) of epidural steroid injections is inadvertent dural puncture, which can lead to a post dural puncture headache with a distinguishing postural feature of the headache (Snarr, 2007). The epidural hematoma is an extremely rare complication, occurring approximately 1:200,000 neuraxial injections, which can lead to nerve ischemia (Snarr, 2007).

The Mayo Clinic Proceedings published a study on epidural injections. According to their research, epidural abscess is a rarely reported complication of epidural corticosteroid injection for treatment of radicular back pain (Hooten, Kinney, & Huntoon, 2004). The incidence remains undetermined but as the annual number of injections increase, specialists and physicians must become aware of the potential infectious complications of this procedure. Of those cases that developed a bacterial infection, diabetes mellitus is identified as the single most common risk factor and *S. aureus* was the principal organism in 73% of the patients. Recommendations were given to use chlorhexidine instead of povidone-iodine whenever a corticosteroid injection is to be administered because it has been proven superior.

Activity following cervical or lumbar puncture

Headache is a frequent problem following either a lumbar or cervical puncture. No evidence was found that longer bed rest after cervical or lumbar puncture was more beneficial than immediate mobilization in reducing the incidence of headache after diagnostic puncture, myelography, or spinal anesthesia (Thoennissen et al., 2001).

DEFINITION OF TERMS

In this study, an interlaminar LESI was performed anywhere between levels L1-S1 under fluoroscopic guidance and the number of injections in the last six months were recorded. Pain was defined as any low back pain which may or may not radiate into the buttocks, legs, and feet, potentially causing numbness and tingling and pain was measured by the Wong-Baker FACES Pain Rating Scale. Back related functional disability level was measured by the ODI, which is a nine-item scale ranging from zero to 100 percent with a high score indicating a high degree of restriction. The ODI remains a valid and vigorous measurement of condition-specific disability (Fairbank & Pynsent, 2000).

Expected adverse side effects of the lumbar epidural steroid injection were headache, facial flushing, increased low back pain, trouble sleeping, or sweating. During the flat bed rest, subjects laid flat on their stomach, side or back with one pillow under the head. Rest was defined as avoiding vigorous activities that were known to cause low back irritation and pain for at least 24 hours following the injection.

METHODS

Study design

A quasi-experimental design was used with a control and experimental group completing a pre and post surveys. The control group completed the current practice of the MDC which is 15

minutes of flat rest on the fluoroscopy table followed by 45 minutes of flat rest in the nursing area and were advised to rest for the remainder of the day. The experimental group completed 15 minutes of flat rest on the fluoroscopy table, 15 minutes of flat rest in the nursing area, and resumed normal activity for the remainder of the day. Prior to the LESI, both groups were informed that they may be kept longer if they experienced residual numbness from the Lidocaine that affected their walking or balance. Both groups received aftercare instructions and were required to have a driver.

Subjects were assigned to the control or experimental group based on a weekly rotation. For example, weeks one, three, and five were in the control group and weeks two, four, and six were in the experimental group. For the patients that had repeat LESIs, they remained in their original group. For subjects who had a LESI at our facility within six months prior to the study beginning, they were placed in the control group due to the radiologist wishing to maintain consistency for the patient. If a patient refused to participate in the study, he or she followed the current protocol of the MDC. When the primary radiologist or the primary investigator at the MDC was gone, the study was suspended until he or she returned to maintain consistency and eliminate any further variables.

Setting and participants

Subjects 18 years of age or older undergoing LESIs at the MDC in Minneapolis who were capable of signing their own consent were recruited for this study. Subjects were not offered inducements for participation. A professional medical interpreter was present if needed.

Subjects were enrolled in the study with no discrimination of age, race, gender, or number of previous LESIs. The following demographic data was compiled for research purposes with attention to HIPPA and privacy regulations: subject's gender, age, date of injection, date of

survey completion, and the number of LESIs they have had within the last year. Each subject was assigned a research number in order to track their response and ensure confidentiality. Confidentiality was maintained by tracking the subjects using their assigned research study number only and no data was collected that would personally identify the subject. This was clearly explained to the subject and they were encouraged to contact their ordering physician directly to discuss the results of the LESI and any future treatment options or concerns.

Intervention

First, standard procedure for the clinic was followed. This included having the subject change, obtaining a blood pressure, heart rate, and a history of their symptoms. The blood pressure and heart rate data along with the history of their symptoms was kept confidential in the medical record and not included in the study data. Then the LESI procedure was explained, risks described and consent for procedure was obtained.

Following that, all patients were informed a research study was being performed to evaluate the relationship between rest and pain relief following a LESI. If interested, they would complete bed rest in the clinic following their injection and fill out a survey while in the clinic and another survey would be mailed two weeks after. Patients were not told if they were in the control or experimental group. If the subject agreed, the study was explained further and the consent form was read. All questions were answered that the subject had and consent was obtained.

After consent was obtained, both groups were asked by the primary investigator, a radiology nurse, to fill out the pre-injection survey to rate their pain level base and disability. Due to the fact that the radiologist, nurse, and technologist were all aware of which group the subject was in, the study was single blind.

After the procedure was complete and the bed rest was done, each patient received written aftercare instructions. The only difference in the written aftercare instructions received were that the control group was told to “continue to rest for the remainder of the day” and the experimental group was told to “resume normal activity.” The subjects were informed that they would receive a survey two weeks post LESI by mail in a self-addressed, stamped envelope so they could report their pain and disability level along with any side effects (Figure I). The survey and cover letter were translated in Hmong, Somali, and Spanish by Garden & Associates, Inc, Translators and Interpreters. A cover letter was also attached to the survey to briefly explain the study again and what was needed from the subject. If the subject did not respond, one more survey was mailed one week later. If the subject did not respond again, they were removed from the study. Subjects were encouraged to call the radiology nurse anytime if they experienced complications or had any questions.

Measures

The Wong-Baker FACES Pain Rating Scale was used for assessing pain level and the ODI was used to assess disability level. The ODI has emerged as one of the most commonly recommended condition specific outcome measures for spinal disorders (Fairbank & Pynsent, 2000). Version 2.0 of the ODI was used with section eight omitted due to the possibility that subjects may feel a question on their sex life was inappropriate.

Data analysis

The t-test (two-tailed) was used to determine whether the two groups differed at baseline and follow-up for numerical variables. The Chi-square test was used to determine differences between the baseline groups for categorical variables (gender, previous LESI). Baseline and post treatment results were compared using the paired sample t-test. Differences were considered

significant if the *P* value was less than .05. All statistical analyses were performed using SPSS 15.0 (SPSS Inc, Chicago IL).

Ethical considerations

This study was approved by the Institutional Review Board of St. Catherine University. It was also approved by the NNC in conjunction with Dr. Anthony Cook, radiologist, and the director of the MDC. Written consent was obtained from the participants to participate in the study.

FINDINGS

Overall, 66% (73/110) of participants completed the initial survey and the two-week follow up survey, 70% (42) in the control group and 62% (31) in the experimental group.

Demographic Characteristics

The study includes 38% male in the control group and 48% male for the experimental group. The mean age was 50.9 in the control group and 52.2 in the experimental group. The days between initial survey completion and follow up survey completion for the control group was 22.2 and the experimental group was 23.6.

As for subjects who had previous LESIs within the last six months, the control group mean was 42.8% and the experimental group was 9.7% ($p = 0.003$). The only significant difference (p value < 0.05) found in the demographic characteristics was the mean value of LESIs subjects in the control group had within the last six months versus the experimental group. Over 30% more control group subjects had a LESI within the last six months compared to the experimental group (Table I).

Primary outcomes

Both groups had significantly less pain at the two-week follow-up period as measured by the FACES pain scale. There were no differences between the two group means at baseline or

follow-up (Table II). At baseline, the control group had a mean FACES score of 6.4 and the experimental group had a mean score of 6.7. At the two week follow up, the control groups mean score was 4.0 and the experimental groups mean score was 3.7.

Both groups had significantly less disability at the two-week follow-up period as measured by the ODI. There were no differences between the two group means at baseline or follow-up (Table III). At baseline, the control group had a mean ODI score of 0.404 and the experimental group had a mean ODI score of 0.366. At the two week follow up, the control groups mean score was 0.232 and the experimental groups mean score was 0.305.

Secondary outcome

Side effects were measured at the two-week follow-up period only. Participants could select multiple side effects including headache, facial flushing, increased lower back pain, trouble sleeping, sweating or other. The number of side effects for the control group mean was 1.9 and the experimental group mean was 1.68 and there was no differences between the two group means at follow-up (Table IV). The number of times a subject reported a side effect was also calculated in each group. The types of side effects reported in the control group were: headache (15), facial flushing (17), increased low back pain (12), trouble sleeping (17), sweating (10), other (8) and 8 subjects reported no side effects. The experimental group reported the following: headache (9), facial flushing (10), increased low back pain (10), trouble sleeping (12), sweating (8), other (3) and 11 subjects reported no side effects.

DISCUSSION

The purpose of this study was to evaluate if length of rest had an effect on a subject's self-rated pain relief and disabilities related to back pain following a LESI. The research questions were as follows: 1. Is there a difference between a subjects self reported pain and ODI before and two

weeks post LESI after completing one hour of flat rest in the clinic (15 minutes on the fluoroscopy table and 45 minutes in the nursing area) and resting for the remainder of the day compared with completing 15 minutes of flat rest on the fluoroscopy table and 15 minutes of flat rest in the nursing area and resuming activity as normal? 2. What side effects (headache, facial flushing, increased low back pain, trouble sleeping, or sweating) were experienced by the subject following the LESI?

The literature identified potential benefits and complications pertaining to LESIs along with how bed rest and activity had an impact on patients following a lumbar or cervical puncture. However, there was no literature found regarding the best aftercare practice for patients following a LESI to achieve maximum results. Findings from this study will help inform a community norm.

The results of this study indicate that pain, disability, and side effects are much the same regardless of the amount of rest immediately following a LESI which was also the hypothesized result. Both groups showed significant improvement in pain and disability at the two-week follow-up period, which was expected.

The finding of a significant difference between the experimental and control groups in terms of history of a previous LESI within the last six months was expected because if the subject had a previous LESI specifically within the previous six months, they were placed in the control group deliberately in order to follow MDCs current protocol and provide consistent care for the subject. It was possible for a subject in the experimental group to have had a previous injection because subjects were always placed in the same group if they had a repeat LESI within the time frame of the study. Pertaining to the rest of the baseline demographics, there was no

statistical difference found which was expected as well. Since the group selection was rotated on a weekly basis, it was not expected to find any difference in the characteristics.

Subjects from both experimental and control groups experienced a significant amount of pain relief which was expected because that is the intended purpose of the LESI procedure. However, there was no statistical difference in pain relief found between the control and experimental group. Specifically pertaining to the FACES pain scale, it was found that activity following the LESI did not have an effect on pain relief.

Subjects from both experimental and control groups experienced a significant decrease in disability. Between the control and experimental groups, there was no statistical difference related to their ODI scores. In regards to the ODI, it was found that activity following the LESI did not have an effect on the disability score by subjects.

There was no statistical difference in the number and type of side effects reported between the two groups. Activity after the LESI procedure did not affect the number or type of side effects reported by subjects.

Future practice implications

As a result of these findings, length of rest and activity following a LESI did not have an effect on the subject's self-rated pain relief and disabilities related to back pain. This research can be used to influence the standard of care for patients receiving a LESI at the MDC and hopefully across the radiology community. As a result, receiving a LESI could become more convenient for patients.

Limitations

The study was limited to subjects from one privately owned neurological clinic in the Midwest. In order to get a broader client base, the study could be repeated using several clinics at a variety

of locations. The control group had significantly more LESIs in the previous year and as a result, their prior knowledge or experience with LESIs could have affected their perception of procedural pain. This study also had limited power and is at risk for type II error due to the small sample size.

Another limitation was the 34% non-response rate. Since the surveys were sent out via mail, in order for the subject to respond, he or she needed to fill out the survey and then send back with the provided self-addressed, stamped envelope via mail. Participants may have chosen not to respond for a number of reasons, one of which may have been the time needed to fill out the survey.

Implications for nursing practice

This study will help influence and form a clinical norm for care after a LESI, provide patients with evidence based care, and promote the profession of nursing at the MDC as one that has patient-centered care at its focus which is followed through with by completing research. There is also the potential to make receiving LESIs more convenient for patients, with less time in the clinic and a quicker in clinic recovery time which could translate to less time off of work and less inconvenience. The best interest of the patient is at hand with the end goal of creating a standard of care that would be most beneficial to the patient. Implications for future research include repeating the study with a larger sample size and possibly adding another follow up survey at a month or longer to see what the long term relief of pain is for subjects. It would also be helpful to make the follow-up survey more convenient for subject completion, possibly adding an online completion option.

CONCLUSIONS

As shown by the results, there was no difference in pain relief found using the FACES pain scale and the ODI pertaining to bed rest and activity following a LESI. It was also found that between the control and experimental subjects, there was no statistical difference in number of side effects. In conclusion, subjects who completed one hour of flat rest and rested for the remainder of the day following a LESI had no statistical difference in pain relief, disability score, or side effects experienced as compared with subjects who completed 30 minutes of flat rest and resumed normal activity. This study concludes that activity and flat rest do not have an impact on the subject's self-rated pain relief, disability score, or number of side effects at the two week follow-up.

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Figure II. Two week post injection survey

Date:

Epidural Steroid Injection Follow-Up Survey

1. In the **past week**, what has been your **average level** of pain in the low back, buttocks, and or legs using the **FACES Pain Scale** below (please check the box that applies).

0 1 2 3 4 5 6 7 8 9 10

<u>Tell Us If You Have Pain</u>		
10 9		Worst Possible Pain
8 7		Very Severe Pain
6 5		Severe Pain
4 3		Moderate Pain
2 1		Mild Pain
0		No Pain

2. Did you have any of the following side effects after your lumbar epidural steroid injection? (please check boxes that apply)

- Headache Facial Flushing Increased Low Back Pain
- Trouble Sleeping Sweating Other (please specify)

3. Please fill out the following Oswestry Disability Questionnaire relating to your **average level** of ability **within the last week**.

Figure II. Two week post injection survey (continued)

Oswestry Disability Questionnaire

This questionnaire has been designed to give us information as to how your back or leg pain is affecting your ability to manage in everyday life. Please answer by checking **one box in each section** for the statement which best applies to you. We realize you may consider that two or more statements in any one section apply but please just shade out the spot that indicates the statement **which most clearly describes your problem**.

Section 1: Pain Intensity

- I have no pain at the moment
- The pain is very mild at the moment
- The pain is moderate at the moment
- The pain is fairly severe at the moment
- The pain is very severe at the moment
- The pain is the worst imaginable at the moment

Section 2: Personal Care (eg. washing, dressing)

- I can look after myself normally without causing extra pain
- I can look after myself normally but it causes extra pain
- It is painful to look after myself and I am slow and careful
- I need some help but can manage most of my personal care
- I need help every day in most aspects of self-care
- I do not get dressed, wash with difficulty and stay in bed

Section 3: Lifting

- I can lift heavy weights without extra pain
- I can lift heavy weights but it gives me extra pain
- Pain prevents me lifting heavy weights off the floor but I can manage if they are conveniently placed (eg. on a table)
- Pain prevents me lifting heavy weights but I can manage light to medium weights if they are conveniently positioned
- I can only lift very light weights
- I cannot lift or carry anything

Section 4: Walking*

- Pain does not prevent me walking any distance
- Pain prevents me from walking more than 1 mile
- Pain prevents me from walking more than ½ mile
- Pain prevents me from walking more than 100 yards
- I can only walk using a stick or crutches
- I am in bed most of the time treatment

Section 5: Sitting

- I can sit in any chair as long as I like
- I can only sit in my favorite chair as long as I like
- Pain prevents me sitting more than one hour
- Pain prevents me from sitting more than 30 minutes
- Pain prevents me from sitting more than 10 minutes
- Pain prevents me from sitting at all

Section 6: Standing

- I can stand as long as I want without extra pain
- I can stand as long as I want but it gives me extra pain
- Pain prevents me from standing for more than 1 hour
- Pain prevents me from standing for more than 30 min
- Pain prevents me from standing for more than 10 min
- Pain prevents me from standing at all

Section 7: Sleeping

- My sleep is never disturbed by pain
- My sleep is occasionally disturbed by pain
- Because of pain I have less than 6 hours sleep
- Because of pain I have less than 4 hours sleep
- Because of pain I have less than 2 hours sleep
- Pain prevents me from sleeping at all

Section 9: Social Life

- My social life is normal and gives me no extra pain
- My social life is normal but increases the degree of pain
- Pain has no significant effect on my social life apart from limiting my more energetic interests (e.g. sport)
- Pain has restricted my social life and I do not go out as often
- Pain has restricted my social life to my home
- I have no social life because of pain

Section 10: Travelling

- I can travel anywhere without pain
- I can travel anywhere but it gives me extra pain
- Pain is bad but I manage journeys over two hours
- Pain restricts me to journeys of less than one hour
- Pain restricts me to short necessary journeys under 30 minutes
- Pain prevents me from travelling except to receive

**** Please call with any questions or concerns you have- 612-879-1528. ****

(For internal use only: Research # _____ FACES score: _____ Oswestry score: _____)

Table I. Baseline demographic characteristics

	Control (N=42)	Experimental (N=31)	
	<i>Mean (SD) or %</i>	<i>Mean (SD) or %</i>	<i>P value</i>
Male	38%	48%	0.379
Age	50.9 (14.0)	52.2 (12.7)	0.674
Days between pre and post	22.2 (11.9)	23.6 (11.7)	0.605
LESI within last six months	42.8%	9.7%	0.003*

*Significant difference between groups ($P < .05$)

Table II. FACES pain scale score

	Control (N=42)	Experimental (N=31)	
	<i>Mean (SD)</i>	<i>Mean (SD)</i>	<i>P value</i>
Baseline	6.4 (1.9)	6.7 (2.1)	0.414
Follow-up 2 weeks	4.0* (2.1)	3.7* (2.3)	0.507

*Significant difference from baseline ($P < .05$)

Table III. Oswestry disability index score

	Control (N=42)	Experimental (N=31)	
	<i>Mean (SD)</i>	<i>Mean (SD)</i>	<i>P value</i>
Baseline	.404 (.156)	.366 (.158)	0.311
Follow-up 2 weeks	.232* (.174)	.305* (.190)	0.663

*Significant difference from baseline ($P < .05$)

Table IV. Number of side effects

	Control (N=42)	Experimental (N=31)	
	<i>Mean (SD) or %</i>	<i>Mean (SD) or %</i>	<i>P value</i>
Follow-up 2 weeks	1.90 (1.48)	1.68 (1.56)	0.528