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RESEARCH ARTICLE
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A Prospective comparison between the effect of reflexology and steroid injection for relieving of pain in patient with chronic low back pain a clinical randomized trial study

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ABSTRACT

Introduction: Reflexology is one of the alternative therapies categorized under hand massage in the treatment of lower back pain. To affect bio-physiological changes in the body, it employs a particular technique of pressing or pushing the reflexology points on the palms and soles. Epidural injection of corticosteroids is one of the most used medical interventions in managing chronic back pain, However, controversy surrounds the appropriate uses of injection therapies.

Aim: In this study we compared reflexology and steroid for their ability to relieve pain in people suffering from chronic pain.

Method and Materials: The study included 60 patients with chronic low back pain. Divided into, reflexology, and corticosteroid injection groups. Reflexology interventions were carried out in intercourse sessions for two weeks, three days a week, for 40 minutes each day (20 minutes for each foot, and one session for injection of corticosteroid exactly in the caudal epidural area.

Result: The study showed significant differences between the two groups in terms of, improvement in pain after the first session, after 1 week, and after 3 months (P=0.0001, 0.0001, 0.013) respectively.

Conclusion: In conclusion, Reflexology therapy is an important and effective non-pharmacological method for chronic lower back pain treatment. And it has higher efficacy and lower side effects than caudal steroid injection.

Keywords: *reflexology, steroid, chronic pain, chronic low back pain.*

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INTRODUCTION

In the past, chronic pain has been regarded as among the most significant medical conditions and as the main global reason for human distress and incapacity. Chronic pains degrade human existence. Chronic pain, unlike acute pain, is long-term and causes suffering, and lowers the pain threshold. Chronic pain lasts three months or more. 10%–40% of people have chronic pain (1). Studies that look at how chronic pain affects people's life and health sometimes focus on particular illnesses, including back pain (2). Every year, low back discomfort causes disability in about 25% of adults (3). Approximately 10% of adults suffer from severe chronic pain, with CBP being the major cause. Such conditions reduce the quality of life and increase anxiety and depression (4).

Chronic back pain is the key factor influencing this demographic (CBP). Such situations lessen life's quality and exacerbate sadness and worry (4). Effective therapies for low back pain include anti-inflammatory drugs, muscle relaxants, opioids, and neuropathic pain medications. Transcutaneous electrical nerve stimulation, acupuncture, epidural steroid injections, and chiropractic adjustments are among the therapy options available to those with severe back pain (5). Complementary therapies are now widely used in palliative care or to treat a condition without addressing the underlying causes, in attempt to enhance a patient's psychological, physical, and emotional development and to increase the value of their life (6). A popular non-invasive supplementary and alternative therapy is reflexology. This style of foot massage involves applying pressure on reflex zones, usually those on the feet, which are thought to correspond to specific other body parts. Reflexologists assert that this pressure might affect the body's physiological reactions, which are meant to encourage recovery and the restoration of equilibrium. There are many applications for reflexology. They include psychological or energy-related variables, energy effects, calcium and uric acid crystal breakdown, improved blood flow, a calming impact on the nervous system, and energy effects (7). Reflexology also has an analgesic impact, which relieves pain by releasing endorphins into the body, aids in opening brain connections, and reduces stress levels (8). Furthermore, because pressure applied to a particular area of the skin activates nerve endings and communicates messages to the brain, it has an impact on the body's nervous system. Foot reflexology, on the other hand, activates the nerve's chemical system (9). Reflexologists contend that the foot and hand are the body's mirrors and also that they contain the body's map since each organ of the body reflects in the feet, hand, and ear. Because of this, certain reflected stimuli have an effect on connected organs and systems (10). Foot reflexology is a massage technique in which the fingers, particularly the thumbs, are used to apply the pressure to the reaction zones mostly on foot. These points are thought to be linked to all parts of the body, and pressing on them can change how the body behaves physiologically. (11). Reflexology is an easy, affordable, non-invasive technique that successfully controls the nervous system system's activity, regulates physiological reactions, reduces anxiety, and promotes relaxation (12).

Epidural steroid injection (ESI) is commonly used for treatment of LBP, although controversy surrounds the appropriate uses of injection therapies (13). The annulus' posterolateral perimeter is bathed in discogenic CLBP while corticosteroids are injected into anterior epidural space. This technique reduces hyperalgesia to improve pain and function and enables the patient to engage in a thorough physical therapy program to address biomechanical deficiencies. Before receiving epidural steroid injections, the target disc must be determined as the source of the discomfort (ESIs). To be effective, a therapeutic drug should enter the anterior epidural area and reach hypersensitive nerve terminals (14). Costs associated with chronic pain include medical expenses as well as indirect expenses such as lost productivity at work, tax revenue, legal services, and disability benefits.

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Therapy lost days of work, disability benefits, and legal costs associated with chronic pain total between US$550 and US$625 billion annually (15). In this study we compared reflexology and steroid for their ability to relieve pain in people suffering from chronic pain.

Aim

In this study we compared reflexology and steroid for their ability to relieve pain in people suffering from chronic pain.

PATIENTS AND METHODS

The study included 60 Patients of chronic low back pain divided into two groups: reflexology (30 patients) and corticosteroid injection (30 patients). A questionnaire was designed to collect information from the study groups at four different stages: before, after, one week, and three months after intervention. Interventions included two weeks of sex sessions, three days per week, and 40 minutes each day (20 minutes for every foot) for reflexology, as well as one session for corticosteroid injection in the epidural space, specifically in the caudal.

Inclusion criteria

This study required patients with good health feet that are free of injury or damage, as well as a willingness to participate.

Exclusion criteria

Participants were removed when they had previously decided to participate in another clinical study within the previous three months, had prior experience or knowledge of reflexology, were pregnant or breast - feeding, can use other forms of complementary treatment as during study, or had cardiovascular, deep vein thrombosis, or diseases such as urinary infection or kidney problems (with pain in the lower back). They also were barred from participating if the patients sustained bodily harm that rendered them unable to continue, or if they used new medical treatments (new pain-relieving medicines, physical therapy, or other means).

Reflexology method

Participants in the treatment group received precision reflexology, which included a series of pressure massages that allowed activation of the several reflex locations mostly on feet that are linked to organs throughout the body. The reflexology therapy included key points on the feet that represented the vertebral column of the spine and the around its muscular strength; such points are located around the inner side of the feets.

The people' feet were washed, dried, and placed in a cozy supine posture as part of the treatment (in the studied patients). The legs were again massaged from the ankle to the sole of the feet, and finally to the toes. Several times, these acts were performed. In addition, the ankle was repeatedly twisted to the left and right (while the heel was maintained by one hand). In order to get the foot ready for reflexology, these two treatments were relaxing methods. Initially, general reflexology was performed by massaging each specific foot reaction site (upper regions of the inner and outer soles on the right and left feet). The inner surface of the arched feet was then given a particular reflexology treatment for 5 to 10 minutes on each foot.

Caudal injection method

Caudal injections were carried out as an outpatient procedure, so patient can leave the hospital the same day. Normally, the entire process takes 15 to 30 minutes. Steroid injections were given into the lower epidural space (the sleeve-like area that surrounds your nerve roots).

Under fluoroscopic guidance, all patients got a caudal epidural injection. The patients were positioned prone on a fluoroscopy table. Following the standard sterile prep, drape, and local anesthetic, a 22-gauge spinal needle was pushed in a midline position through the sacrococcygeal ligament into the sacral epidural area. Fluoroscopic images of the anteroposterior and lateral sides indicated correct needle placement.

The epdural flow to the target level was then documented using Omnipaque 180 contrast. The needle was moved to achieve proper flow if the flow was intravascular or unilateral. After confirming good epidural spread, 80 mg of methylprednisolone and 6 cc of 0.5% lidocaine (Xylocaine®, preservative free) were injected. After that, the needle was removed, and the patient was examined for any adverse reactions. All injections were given by a single investigator (GEL). After one week, patients were re-evaluated. No further injections were provided if they experienced significant pain alleviation (> 80%). If they had some pain reduction, a repeat injection was administered at 2-week intervals. If patients did not get relief, no more epidural injections were provided.

RESULTS

Table 1 shows that among males, the study showed significant differences between the two groups in terms of, pain post-intervention (P=0.0001), where the mean value of the Caudal steroids injection group was higher (3.00±0.408) than the mean value of the Reflexology group (1.95±0.669). Also, significant differences were observed between the study groups regarding pain after 1 week of intervention (P=0.0001), where the mean value of the Reflexology group was higher (1.86±0.573) than the mean value of the Caudal steroids injection group (1.08±0.277). Additionally, significant differences were observed between the study groups regarding pain after 3 months of intervention (P=0.019), where the mean value of the Reflexology group was higher (1.76±0.831) than the mean value of the Caudal steroids injection group (1.15±0.376). However, no significant differences were observed between the study groups in terms of pain preintervention (P=0.218).

Among females, the study showed significant differences between the two groups in terms of pain post-intervention (P=0.0001), where the mean value of the Caudal steroids injection group was higher (3.29±0.470) than the mean value of the Reflexology group (1.56±0.527). However, no significant differences were observed between the two study groups in terms of pain pre-intervention, after 1 week, and after 3 months of intervention (P=0.071, 0.111, 0.387) respectively.

(Table 1)

TABLE 1 Comparison between the two study groups in terms of sex in the four study occasions

Sex		**Group**	**N**	**Mean**	**SD**	**t.**	**P-value**
Male	Pain pre-intervention	Reflexology group	21	4.48	0.750	1.256	0.218
		Caudal steroids injection group	13	4.15	0.689		
	Pain post-intervention	Reflexology group	21	1.95	0.669	-5.074-	0.0001
		Caudal steroids injection group	13	3.00	0.408		
	Pain after 1 week	Reflexology group	21	1.86	0.573	4.568	0.0001
		Caudal steroids injection group	13	1.08	0.277		
	Pain after 3 months	Reflexology group	21	1.76	0.831	2.476	0.019
Female	Pain pre-intervention	Reflexology group	9	4.11	0.601	-1.889-	0.071
		Caudal steroids injection group	17	4.59	0.618		
	Pain post-intervention	Reflexology group	9	1.56	0.527	-8.615-	0.0001
		Caudal steroids injection group	17	3.29	0.470		
	Pain after 1 week	Reflexology group	9	1.56	0.527	1.656	0.111
		Caudal steroids injection group	17	1.24	0.437		
		Reflexology group	9	1.33	0.500	0.882	0.387
	Pain after 3 months	Reflexology group	9	1.33	0.500	0.882	0.387
		Caudal steroids injection group	17	1.18	0.393		

In table 2 dizziness was found to be significantly associated with the Caudal steroids injection approach (P=0.024), where (20%) of the Caudal steroids injection group had dizziness compared to the Reflexology group which did not have such symptoms. (Table 2)

TABLE 2 Comparison of occurrence of post-intervention dizziness in the two study groups

		Group		Total	P-value*
		Reflexology group	Caudal steroids injection group		
Side effect post-intervention	No	30	24	54	0.024
		100.0%	80.0%	90.0%	
	Dizziness	0	6	6	
		0.0%	20.0%	10.0%	
Total		30	30	60	
		100.0%	100.0%	100.0%	

* Fisher's Exact Test

Table 3 shows that, among the Reflexology group, the mean value of the pain score preintervention was significantly higher than the mean value of the pain score at the time of intervention, 1 week after intervention, and 3 months after intervention with a mean difference of (2.533, 2.600, 2.733) respectively. While the mean value of the pain score at the time of intervention was significantly lower than the mean value of the pain score pre-intervention (2.533). Also, the mean value of the pain score after 1 week of intervention was significantly lower than the mean value of the pain score pre-intervention (-2.600). And the mean value of the pain score after 3 months of intervention was significantly lower than the mean value of the pain score pre-intervention (-2.733).

Among the Caudal steroids injection group, the mean value of the pain score pre-intervention was significantly higher than the mean value of the pain score at the time of intervention, 1 week after intervention, and 3 months after intervention with a mean difference of (1.233, 3.233, 3.233) respectively. While, the mean value of the pain score at the time of intervention was significantly lower than the mean value of the pain score pre-intervention (-1.233), and it was significantly higher than the mean value of the pain score after 1 week and 3 months of intervention (2.000, 2.000). Also, the mean value of the pain score after 1 week of intervention was significantly lower than the mean value of the pain score pre-intervention and at the time of intervention (-2.233, 2.000) respectively. And the mean value of the pain score after 3 months of intervention was significantly lower than the mean value of the pain score pre-intervention and at the time of intervention (-2.233, -2.000) respectively. (Table 3)

TABLE 3: Comparison between the two study groups according to pain score in the four study occasions

Group	(I) Pain	(J) Pain	Mean Difference (I-J)	P-value*
Reflexology group	1	2	2.533	0.0001
		3	2.600	0.0001
		4	2.733	0.0001
	2	1	-2.533-	0.0001
		3	0.067	0.161
		4	0.200	0.136
	3	1	-2.600-	0.0001
		2	-0.067-	0.161
		4	0.133	0.293
	4	1	-2.733-	0.0001
		2	-0.200-	0.136
		3	-0.133-	0.293
Caudal steroids injectiongroup	1	2	1.233	0.0001
		3	3.233	0.0001
		4	3.233	0.0001
	2	1	-1.233-	0.0001

		3	2.000	0.0001
		4	2.000	0.0001
	3	1	-3.233-	0.0001
		2	-2.000-	0.0001
		4	0.0001	1.000
	4	1	-3.233-	0.0001
		2	-2.000-	0.0001
		3	0.0001	1.000

* Post Hoc ANOVA Tests

In terms of blood pressure as shown in table 4, among the Reflexology group, the mean value of blood pressure pre-intervention was significantly higher than the mean value of blood pressure at the time of intervention, after 1 week, and after 3 months with a mean difference of (3.600, 3.233, 2.000) respectively. While the mean value of blood pressure at the time of intervention was significantly lower than the mean value of blood pressure pre-intervention and after 3 months (3.600, -1.600) respectively. Also, the mean value of blood pressure after 1 week was significantly lower than the mean value of blood pressure pre-intervention (-3.233). And the mean value of blood pressure after 3 months was significantly lower than the mean value of blood pressure preintervention (-2.000), while, the mean value of blood pressure after 3 months was significantly higher than the mean value of blood pressure at the time of intervention (1.600).

Moreover, among the Caudal steroids injection group, the mean value of blood pressure preintervention was significantly higher than the mean value of blood pressure after 3 months with a mean difference of (2.200). And the mean value of blood pressure after 3 months was significantly lower than the mean value of blood pressure pre-intervention (-2.200). (Table 4)

TABLE 4: Comparison between the two study groups according to blood pressure in the four study occasions

Group	**(I) Blood Pressure**	**(J) Blood Pressure**	**Mean Difference (I-J)**	**P-value***
Reflexology group	1	2	3.600	0.0001
		3	3.233	0.0001
		4	2.000	0.028
	2	1	-3.600-	0.0001
		3	-0.367-	0.574
		4	-1.600-	0.024
	3	1	-3.233-	0.0001
		2	0.367	0.574
		4	-1.233-	0.100
	4	1	-2.000-	0.028
		2	1.600	0.024
		3	1.233	0.100
Caudal steroids injection group	1	2	1.200	0.175
		3	1.867	0.117
		4	2.200	0.019
	2	1	-1.200-	0.175
		3	0.667	0.396
		4	1.000	0.058
	3	1	-1.867-	0.117
		2	-0.667-	0.396
		4	0.333	0.682
	4	1	-2.200-	0.019
		2	-1.000-	0.058
		3	-0.333-	0.682

* Post Hoc ANOVA Tests

Table 5 shows that, among the Reflexology group, the mean value of pulse rate preintervention was significantly higher than the mean value of pulse rate at the time of intervention, 1 week after intervention, and 3 months after intervention with a mean difference of (3.533, 5.633, 4.567) respectively. While the mean value of pulse rate at the time of intervention was significantly higher than the mean value of pulse rate after 1 week of intervention (2.100), and lower than the mean value of pulse rate pre-intervention (-3.533). Also, the mean value of pulse rate after 1 week of intervention was significantly lower than the mean value of pulse rate pre-intervention and at the time of intervention (-5.633, -2.100) respectively. And the mean value of pulse rate after 3 months of intervention was significantly lower than the mean value of pulse rate pre-intervention (-4.567).

Among the Caudal steroids injection group, the mean value of pulse rate pre-intervention was significantly lower than the mean value of pulse rate at the time of intervention (-5.333), and it was higher than the mean value of pulse rate after 1 week and 3 months of intervention with a mean difference of (3.000, 4.300) respectively. While, the mean value of pulse rate at the time of intervention was significantly higher than the mean value of pulse rate pre-intervention, after 1 week, and 3 months of intervention (5.333, 8.333, 9.633) respectively. Also, the mean value of pulse rate after 1 week of intervention was significantly lower than the mean value of pulse rate pre-intervention and at the time of intervention (-3.000, -8.000) respectively. And the mean value of pulse rate after 3 months of intervention was significantly lower than the mean value of pulse rate pre-intervention and at the time of intervention (-4.300, -9.633) respectively. (Table 5)

TABLE 5: Comparison between the two study groups according to pulse rate in the four study occasions

Group	**(I) Pulse Rate**	**(J) Pulse Rate**	**Mean Difference (I-J)**	**P-value**
Reflexology group	1	2	3.533	0.0001
		3	5.633	0.0001
		4	4.567	0.0001
	2	1	-3.533-	0.0001
		3	2.100	0.008
		4	1.033	0.327
	3	1	-5.633-	0.0001
		2	-2.100-	0.008
		4	-1.067-	0.224
	4	1	-4.567-	0.0001
		2	-1.033-	0.327
		3	1.067	0.224
Caudal steroids injection group	1	2	-5.333-	0.0001
		3	3.000	0.004
		4	4.300	0.006
	2	1	5.333	0.0001
		3	8.333	0.0001
		4	9.633	0.0001
	3	1	-3.000-	0.004
		2	-8.333-	0.0001
		4	1.300	0.159
	4	1	-4.300-	0.006
		2	-9.633-	0.0001

		3	-1.300-	0.159

* Post Hoc ANOVA Test

DISCUSSION

The present study found that there is a significant difference regarding reduction in the pain scores for patients treated with reflexology at the time of treatment, after one week, and after three months of therapy in comparison to caudal steroid injection. the line graph of the change in pain scores showed that the pain intensity scores dropped below two directly after reflexology while it needs about to one week to drop after steroid injection. Similar to our results regarding reflexology therapy, in research by Sirawal, the patients experienced less pain than the control group after one week of reflexology (16). Quinn et al. (2008) came to the conclusion from an international study that reflexology help in the treatment of low back pain; they discovered that the experimental group's pain intensity score dropped to an average degree at six, twelve, and eighteen weeks after therapy. However, although reporting an average decrease in the patients' persistent low back pain, they did not confirm the reflexology's obvious efficacy (17). Poole et al. (2001) examined the impact of reflexology on patients with chronic low back pain. They recommended reflexology as an additional treatment for the relief of low back pain (18). Evidently, these researchers do not view reflexology as the sole form of treatment but rather recommend it as a complement to other therapeutic techniques based on their findings. Reflexology's mechanics and functions are still shrouded in mystery. The gate control theory of pain, the nerve impulse theory, the increase in endorphin and encephalon secretion that lead to better pain control, the improvement of lymphatic flow and strengthening of the immune system, the optimization of nerves and blood flow, and the efflux of toxins from the body that eventually enhance the patient's treatment are some theories that have been put forth in this regard (19). Although the caudal steroid injection had reduced the pain significantly lower than the reflexology in this study, still the patients get benefits from the treatment. According to a large number of studies and the Kreiner and colleagues' guideline (20), steroid injection appear to be safe and highly successful in reducing the primary symptoms, particularly in short-term follow-ups, and in postponing surgery.

The amount of pain intensity reduction was significantly higher in male patients between reflexology and steroid injection groups at time of injection, one-week post injection, and at three months after injection while it was significant only at the time of injection in the caudal injection group. Regarding gender differences in non-pharmacological pain therapies, men reported less pain than women when asked to concentrate on the sensory components of pain, whereas women reported more suffering than men when asked to concentrate on the affective components of pain (21). Women reported a lower pain threshold and tolerance level than males in a study looking at the impact of acceptance-based coping instructions on cold-pressor discomfort, and the acceptance instructions only helped women (22)

Steroid therapy in this study associated with dizziness in 20% of the patients while no such symptoms were reported with reflexology. Lee et al., in their study regarding the evaluation of side effects of caudal steroid injection, found a transient increase in blood pressure in hypertensive patients after a steroid injection, a finding which is contrary to our results; The increase in blood pressure caused by a steroid injection in the study mentioned may be subjective or erroneous because numerous factors, like timing and technique of blood pressure monitoring or antihypertensive medications, impact blood pressure. however, both increase and decrease in blood pressure may cause dizziness.

CONCLUSION

In conclusion, Reflexology therapy is an important and effective non-pharmacological method for chronic lower back pain treatment. And it has higher efficacy and lower side effects than caudal steroid injection.

Ethical Approval

The ethical consideration of the study was examined by the ethical committee of the Tehran university of medical sciences, and ethical approval for the study was obtained (ethical code: IR.TUMS.SPH.REC.1401.193).

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Conflict of Interest

The authors of this study has no conflicts of interest to report that's

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