

**FULL PAPER**

# Investigating the effect of methylprednisolone pulse on treatment of back pain

Masoud Hatefi<sup>a</sup>  | Khalil Komlakh<sup>b,\*</sup> <sup>a</sup>Associate Professor of Neurology, School of Medicine, Emam Khomeini Hospital, Ilam University of Medical sciences, Ilam, Iran<sup>b</sup>Assistant Professor of Neurosurgery, Department of Neurosurgery, School of Medicine, Imam Hossein Hospital, Shahid Beheshti University of Medical Sciences, Tehran, Iran

Pain is a common problem afflicting humanity. Back pain is a musculoskeletal disorder with a high prevalence; this pain may occur to anyone at least once during their lifetime. The present study was performed to investigate the effect of methylprednisolone pulse on the pain status of patients suffering from back pain in Ilam city. This double-blind study in 2021 in Ilam city with experimental and control. The patients with vertebral disc herniation diagnoses suffering from diffuse pain with the right leg were assigned into experimental and control groups. A methylprednisolone 500 mg IV would be administered to the patient as pulse inside DW 500 cc serum. The extent of pain was compared before and after the intervention at one, two, three, and seven days later. Placebo was applied for the control group patients. The data were analyzed by SPSS 16 and based on descriptive and analytical tests. Results showed no statistically significant difference between the demographic characteristics and pain of patients receiving methylprednisolone and patients in the control group ( $p < 0.05$ ). Also, the mean (SD) pain score in the experimental group was 6.59(0.88) before the intervention and 1.76(0.69) in the week after the intervention, which was statistically significant ( $P = 0.000$ ). While, the changes in the control group's score before intervention were 6.82(0.71), and after the intervention were 6.77(1.12) ( $P > 0.05$ ). Considering the effect of methylprednisolone on mitigating the pain of patients suffering from back pain, it is suggested to use injective methylprednisolone to reduce the pain of patients suffering from back pain.

**\*Corresponding Author:**

Khalil Komlakh

Email: [khalil.komlakh@yahoo.com](mailto:khalil.komlakh@yahoo.com)

Tel.: +98 21 22 43 97 70

**KEYWORDS**

Methylprednisolone; back pain; drug therapy.

**Introduction**

Pain is a common problem afflicting humanity [1]. Pain causes the development of numerous problems and constraints for the patient, including reduction of quality of life, psychological health, life expectancy, daily activities, spiritual health plus related factors [2-5], and the development of depression, disability, and stress [6,7]. Back pain is a musculoskeletal disorder with a high prevalence; this pain may occur to anyone at

least once during their lifetime [8]. Today, with changes that have occurred in the lifestyle of people, different groups may experience this pain. This disease may respond to ergonomic-mechanical, individual, and social factors [9]. Back pain is a common cause of visits and medical interventions. Chronic back pain has considerable effects on functional status, constraining occupational activity, and certain socioeconomic consequences [10,11]. From among skeletal disorders, the damage related to back pain

claims the most significant share, and in addition to healthcare aspects, it has also attracted the public attention economically [12]. The causes of this disease are numerous, and its precise identification is sometimes difficult. Back pain is considered a significant health problem that is common in all countries, especially industrial ones. Musculoskeletal disorders are typically associated with pain and permanent disorders in muscles, joints, nerves, and tendons. The effects of back pain may go beyond pain, which can be very serious and profound, causing incurrance of indirect costs, diminished capacity of individual ability, and increased risk of suffering from other medical conditions [13-15].

In pain etiology, various factors are involved, and one of the standard features is neck movements; as these movements increase, so does the pain in that region [16]. Radiculopathy refers to nerve root disorders that may develop in response to structural injuries such as disk, tumor, trauma, vascular disorders, or infection such as viruses [17]. The radicular back pain is a kind of neuralgia that develops following sensory root stimulation or the dorsal root ganglion of a spinal nerve. Radicular back pains occur because of the generation of abnormal impulses in the dorsal root ganglion and its transfer through the peripheral nerve axon [18,19].

Different studies have been performed to treat back pain, and various therapeutic protocols have been criticized and examined. These methods include nonpharmacological methods such as educational intervention [20], exercise interventions [21,22], and pharmacotherapy [23]. There are different drugs for mitigating pain in patients suffering from radicular pain, including methylprednisolone. Prescription of this drug can help treat spinal nerve injury given its anti-inflammatory properties, immunosuppression, and improving neurological recovery [24].

## Objectives

Identification of pain mitigation methods and especially attempts in choosing the best pain alleviation method in neurosurgery patients is one of the essential duties of neurosurgeons. This can be effectuated only through clinical research and performing interventional studies in this regard. Accordingly, the present study was performed to investigate the effect of methylprednisolone pulse on the pain status of patients suffering from back pain in Ilam city.

## Methods

### *Study design*

This study is a clinical trial (IRCT20211116053077N1) conducted as double-blind in 2021 in Ilam city with pretest and posttest groups plus a control group. The patients with vertebral disc herniation diagnosis suffering from diffuse pain with right leg were assigned into test and control groups. A methylprednisolone 500 mg IV would be administered to the patient as pulse inside DW 500 cc serum. The extent of pain was compared before and after the intervention at one, two, three, and seven days later. Placebo was applied for the control group patients.

### *Study population*

The statistical population in this study consisted of patients referring to hospitals, clinics, and practice offices of physicians in Ilam where the radicular pain. The sample size consisted of 94 patients; 12 of them were excluded after the intervention. Eventually, the data were analyzed by 42 patients in the experimental group and 40 patients in the control group. Patients were divided into experimental and control groups using the random allocation method.

### Inclusion and exclusion criteria

#### Inclusion criteria

Informed consent for participation in the study, their age was older than 20 years, at least three months past the disease, definite diagnosis of the disease by a neurosurgeon, at least one month of unsuccessful treatment, living in Ilam province, and patients suffering from diffuse pain to the right leg were the inclusion criteria.

#### Exclusion criteria

The exclusion criteria were the history of consuming medications other than the intervention drugs, history of any other disease affecting pain, and requiring surgery for radicular pain treatment. Furthermore, patients with underlying problems, spondylolisthesis, spinal tumors, and congenital lesions were also excluded.

#### Ethical approval

Receiving ethics code in the research with the code IR.MEDILAM.REC.1400.118, voluntary participation or lack of participation in the study, freeness of all visits, medications, and costs related to the interventions, Patients' free will to participate or not to participate in

the study, the confidentiality of patient information, follow all Helsinki guidelines and the Belmont Declaration, explaining the objectives of pharmacological intervention with an understandable language for patients.

#### Study tools

Demographic characteristics form and pain scale were used. VAS pain scale was applied to determine the severity of patients' pain. According to the patient's report, this scale is a 10 cm graduated ruler used here to score the most severe pain and zero scores [25].

#### Statistical analysis

The data were analyzed by SPSS 16 and based on descriptive and analytical tests.

### Results

82 patients were enrolled in the experimental group with 42 patients and the control group with 40 patients. Also, patients' mean (SD) age was 44.25(5.24) years. According to the findings of Table 1, no statistically significant difference was observed between the demographic characteristics of patients receiving methylprednisolone and patients in the control group( $p < 0.05$ ).

**TABLE 1** Comparison of demographic characteristics of patients under study

pain	Experimental Group		Control Group	P
	N (%)		N (%)	
<b>Gender</b>	Male	23(54.8)	25(62.5)	0.48
	Female	19(45.2)	15(37.5)	
<b>Marital status</b>	Married	29(69)	28(70)	0.92
	Single	13(31)	12(30)	
<b>economic situation</b>	Weak	19(45.2)	10(25)	0.11
	medium	18(42.9)	24(60)	
	Excellent	5(11.9)	6(15)	
<b>Age, M(SD)</b>		51.87(18.46)	51.52(9.40)	0.91

Table 2 compares patients' pain scores in the two groups. According to the findings, the Mean (SD) pain score in the experimental group was 6.59(0.88) before the intervention and 1.76(0.69) in the week after the

intervention, which was statistically significant( $P < 0.001$ ). Also, the changes in the control group's score before intervention were 6.82(0.71) and after the intervention was 6.77(1.12) ( $P > 0.05$ ).

**TABLE 2** Comparison of pain scores of patients receiving methylprednisolone with patients in the Control group before and after the intervention

pain	Experimental Group	Control Group	P, F
	Mean $\pm$ SD	Mean $\pm$ SD	
Pain pre intervention	6.59 $\pm$ 0.88	6.82 $\pm$ 0.71	P=0.2, F=2.38
pain after 1 days	4.88 $\pm$ 1.08	6.72 $\pm$ 0.59	P=0.000, F=9.34
pain after 2 days	3.83 $\pm$ 0.62	6.45 $\pm$ 0.95	P=0.000, F=11.43
pain after 3 days	2.50 $\pm$ 0.63	6.35 $\pm$ 1.23	P=0.000, F=14.04
pain after 7 days	1.76 $\pm$ 0.69	6.77 $\pm$ 1.12	P=0.000, F=4.66

## Discussion

This study was conducted to explore the effect of methylprednisolone on pain mitigation among patients suffering from radicular back pain. The group of patients suffering from back pain claims a considerable percentage; in the meta-analysis by [Azizpour *et al.*], it was found that the prevalence of back pain in 20 papers with the total sample size of 5670 subjects was 51%, mainly afflicting 15-50-year-old age group [26] as the most considerable prevalence. As a result, this group of patients requires special attention.

In this study, the treatment with of methylprednisolone drug could lead to a reduction of patient back pain. In a retrospective study by [Dobohue *et al.*] to compare methylprednisolone and dexamethasone drugs on pain mitigation, it was found that although both drugs could reduce the patient's pain But the difference was not statistically significant. Further, methylprednisolone two months following the intervention had caused 65% pain reduction for patients, which was 75% for dexamethasone [27]. In the study by [Li *et al.*], to explore the effect of methylprednisolone on neuropathic pain, they found that methylprednisolone could improve QOL and mitigate pain. In that study, the extent of pain reduction was reported about 50% or more [28].

The findings of other studies have also concurred with the present study results. The meta-analysis by [Liu *et al.*] showed that using

methylprednisolone at 6 and 24 h post-injection could alleviate patients' pain. Further, injection of this drug contributed to reduced nausea and vomiting for the researched patients [29]. Also, in the study by [Lunn *et al.*] on patients with total knee arthroplasty, again methylprednisolone led to reduced pain and fatigue and improved sleep quality [30]. The results of the mentioned studies [29,30] have been in line with the present study's findings regarding the effect of methylprednisolone on pain alleviation of patients.

## Conclusion

Considering the effect of methylprednisolone on mitigating the pain of patients suffering from back pain, it is suggested to use injective methylprednisolone for reducing the pain of patients suffering from back pain.

## Authors' Contribution

MH, KK did study conception, data analysis, and manuscript writing. MH, KK did data collection and manuscript writing. MH, KK did data collection and manuscript writing. Both authors (MH, KK) contributed to all stages of the article.

## Conflict of Interest

The authors declare no conflict of interest.

## Ethical approval

The Ethics Committee of the Ilam University of Medical Sciences approved (IR.MEDILAM.REC.1400. 118).

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## Orcid:

Masoud Hatefi: <https://orcid.org/0000-0002-1529-2419>

Khalil Komlakh: <https://orcid.org/0000-0002-8291-5540>

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