http://www.cjmb.org

Open Access Original Article

Crescent Journal of Medical and Biological Sciences
Vol. 5, No. 1, January 2018, 57–61
eISSN 2148-9696

Comparison of Epidural Methylprednisolone, Bupivacaine and Normal Saline Injection in Chronic Low Back Pain Due to Discal Hernia

Naghi Abedini[1], Hojjat Pourfathi[1], Maghsoud Eskandari[1], Masoud Parish[1*]

Abstract

Objective: Low back pain is the most common skeletal-muscular complaints, requiring medical care, causing many complications and social and economic damages to society as the fifth most common reason for a physician visit especially among men. The purpose of this study was to compare epidural injection of methylprednisolone, bupivacaine, normal saline in chronic low back pain due to discal hernia.

Material and Methods: In a randomized, single-blind, clinical trial conducted on patients with chronic low back pain, the impact of epidural injection of methylprednisolone, bupivacaine, normal saline in chronic low back pain due to disc herniation in three groups was randomly studied. Method of epidural injection in all groups was similar. In the first group, 80 mg of methylprednisolone in 10 cc volume, in the second group, local anesthesia drug, 10 mL of bupivacaine 0.5 %, and in the third group, 10 mL of normal saline solution (equal injected volumes) were prepared. During the injection, the patient was monitored in terms of pain, hemodynamics, consciousness, arterial oxygen saturation.

Results: Three months after treatment, the severity of pain in methylprednisolone group was less, the rate of disability in normal saline group was significantly high ($P<0.001$) and also disability reduction rate in methylprednisolone group was significantly high ($P<0.001$). In our study, the average time to return to daily activities in normal saline patients was significantly more ($P=0.005$).

Conclusion: Epidural methylprednisolone and bupivacaine injection were more effective than placebo (normal saline) injection in these patients.

Keywords: Backache, Epidural methylprednisolone, Bupivacaine, Normal saline injection.

Introduction

Low back pain is one of the most common skeletal-muscular diseases with high economic burden on different societies, especially in industrial and developed countries, involving approximately 90% of people at least once in their lifetime (1-3). It may be mentioned that back pain is the most common disease in human after common cold, and is the second common reason of patients for a physician visit (2).

In Iran, 6 out of 19 adults suffer from low back pain annually. In the third decade of life, 26% and in the sixth decade of life, 23% of patients are afflicted. Adams also maintains that discopathy is developed in the third and fourth decades of life (4). In some researches, prevalence age is stated to be 31 to 40 (5). However lumbar disc may develop at any age and can be found among all people but it occurs in the fourth and fifth decades of men's lives (6). Low back pain treatment methods include drug and non-drug treatment. Medical treatment includes using painkillers, anti–inflammatory drugs, muscle relaxants and so on and non-drug treatments include surgery and non-surgical options (7) and in the case of low back pain maintenance treatment failure, interventional treatment such as drug injection in epidural space and surgery can be conducted indeed (7). Any injection inside the epidural space can have therapeutic effects on chronic low back pain caused by discal hernia. Since low back pain is developed from the inflammation of epidural space and nerve roots, steroid can be useful. Corticosteroids influence inhibition of pro-inflammatory mediator synthesis which decreases inflammation. It also has reversible anesthetic impact (4,8,9). Anesthesia by bupivacaine can cause short-term and long-term analgesia and anti-inflammatory impacts reducing the pain (9,10). Due to few studies on saline injection, this study provides more evidence and results concerning saline injection impact and compares it with

Received 20 January 2016, **Accepted** 3 March 2017, **Available online** 19 March 2017

[1] Department of Anesthesiology, Faculty of Medicine, Tabriz University of Medical Sciences, Tabriz, Iran.
***Corresponding Author:** Masoud Parish, Tel: +989141145030, Email: Masoudparish@yahoo.com

other drugs.

Materials and Methods

This study is a randomized single-blind clinical identifier: IRCT2015122025702N1 registered in the Iranian Registry of Clinical Trials (http://www.irct.ir).

In this trial, we examined the impact of epidural injection of methylprednisolone, bupivacaine and normal saline in chronic low back pain due to discal hernia.

Sampling Method

Patients with chronic back pain who referred Shohada Medical Research and Training Center of Tabriz University of Medical Sciences for medical treatment by epidural injection method were enrolled in the study. The patients were randomly selected by anesthesiologist from different groups and epidural injection was conducted. A doctor recorded necessary data during the study. Intensity of pain was considered as a primary outcome.

According to the previous study and various statistical results for pain relief from 38% to 80%, $\alpha = 0.05$ and $\beta = 0.2$ is considered 80%, p0 equals to 0.40 and p1 equals to 0.80, and the sample size for 3 groups is 84.

Informed consent was obtained from all patients who did not have indications for surgery, and then they were randomly assigned to 3 groups to be studied. The process of randomization was conducted using online software (http://www.graphpad.com/quickcalcs/randomize1.cfm).

After approval of the Ethics Committee of Tabriz University of Medical Sciences (approval number 93/3-9/6), the patients suffering from chronic low back pain were sent to the Pain Clinic of Shohada Medical and Training Center in order to be treated by epidural injection method and examined in 3 groups during the study.

Inclusion Criteria

All patients over the age of 18 years suffering from pain who were visited at the clinic (direct attending or neurosurgeons' referrals) with initial diagnosis of radicular chronic low back pain due to discal hernia (bulging, protrusion, etc) and radiological evidence or CT-scan, the onset of back pain during the last 6 weeks and absence of response to systematic pharmacotherapy were included in the study and the patients with exclusion criteria were excluded.

Exclusion Criteria

- Cardiovascular diseases
- History of psychotic drugs use and psychotic diseases
- Addiction to narcotic drugs
- Patients with spinal canal stenosis
- Any type of hemorrhagic background
- Prohibition of spinal anesthesia
- Unwillingness to participate in the study
- Indications for surgery of lumbar disc
- Disc surgery background

Low back pain due to sacroiliac joint problems and in case of lack of indication for surgery such as the following subjects:

- Severe pain that does not respond to nonsurgical treatment (physical therapy and rehabilitation) at least for 3 to 6 months.
- Myasthenia or numbing progress or deterioration in nerve bar or muscle.
- Urinary symptoms such as urinary retention or numbing and paresthesia in genital area.

These 3 groups were distinguished according to proprietary code so that neither the participants in study nor assessors and recorders of variables were informed of actual grouping. Medicines were prepared and coded in similar syringes by non-involved persons and were given to the researcher. Method of epidural injection in all groups was similar and after preparation in surgery room, through establishing an intravenous line, prehydration and hemodynamic monitoring at sitting position, depending on the patient's condition segment involvement determined by CT-scan or magnetic resonance imaging (MRI), local anesthesia with 1% lidocaine solution with 18-20 G Touhy needle by loss of resistance method was entered the epidural space (L3-L4) and after aspiration, and contrast agent injection in the spot, and fluoroscopy, and being sure that needle is placed in proper place, injection was done For the first group, 80 mg of methylprednisolone, for the second group, 10 cc of bupivacaine 0.5% (50 mg), and for the third group, normal saline solution (equal injection volumes) were prepared.

During the injection, the patient was monitored in terms of pain, hemodynamics, consciousness, and arterial oxygen saturation. After the needle had been injected, the patient was monitored in supine position for half an hour and the vital signs were controlled. In the case of not having changes in the vital signs and good general condition, sensory-motor and autonomic symptoms recovery, the patient would be discharged.

Patients were asked in term of intensity of pain (without pain 0, little 1-3, average 3-6, high 7-10) based on visual analogue scale (VAS) and Oswestry Disability Index Questionnaire taught before. These questions were recorded 1 week, 2 weeks, 1 month and 2 months and 3 months after injection. Clinical examination findings included complete explanation regarding how these tests were performed and their scores at the end of the third month.

After oral medication and injection the patients did not receive painkillers, but for ethical consideration to control possible pain, the patients were switched to other treatment modalities and were mentioned in the study. Pain reduction duration and range of motion needed to be re-blocked or other modalities in determined intervals were recorded. The study method is single blind and the person who did the injection was aware of the injected medicine type (due to equal volumes of injected medicine). The operator

of epidural injection method and data recording were different and in all the steps of questionnaire completion; the recorder was unaware of the type of injected medicine. The examined variables included age, sex, stature, body mass index (BMI), duration of suffering from back pain, pain intensity before injection, pain intensity after epidural injection during the examining time and clinical findings including reflection ability, extension, bending sideways and rotational movement of waist, returning time to normal daily activities after epidural injection, any possible adverse side effects (bleeding, infection of the injected spot and laceration) which were excluded from study and duration of analgesia after epidural injection with a 3-month follow-up.

Statistical Analysis

Data were analyzed and examined using descriptive statistical methods (mean ± standard deviation, frequency/percent). analysis of variance (ANOVA) with repeated measure and the chi-square test were used in SPSS version 15.0. In this study, $P \leq 0.05$ was considered statistically significant.

Results

Forty-one patients (11 patients from methylprednisolone group, 16 patients from bupivacaine group, and 14 patients from normal saline group) were males and 43 patients (17 patients from methylprednisolone group, 12 patients from bupivacaine group, and 14 patients from normal saline group) were females and there was not any significant difference among the 3 groups ($P = 0.404$). The patients' mean age was 42.0 ± 12.2 in methylprednisolone group, 45.6 ± 11.6 in bupivacaine group and 42.6 ± 12.2 in normal saline group. In terms of age, there was not any significant difference among patients in the 3 groups ($P = 0.503$; Table 1).

The patients' pain score before study in epidural methylprednisolone, bupivacaine, and normal saline group was 6.5±0.8, 6.9±1.1 and 6.6±0.8 that reduced to 1.9±0.8, 2.1±0.7 and 2.5±1.2 respectively, after 1 month of treatment, and reduced to 1.6±0.6, 2.0±0.7 and 2.0±0.7 after 3 months of treatment. The average pain score of patients was significantly low ($P = 0.022$) 3 months after treatment in methylprednisolone group (Table 2).

Table 1. Demographic profile of the groups and their comparison based on ANOVA (n = 84)

Variables		*P* Value
Age (y), Mean ± SD		0.503
Methylprednisolone group (A)	42.0 ± 12.2	
Bupivacaine group (B)	45.6 ± 11.6	
Normal Saline group (C)	42.6 ± 12.2	
BMI, Mean ± SD		0.01
Methylprednisolone group (A)	24.2 ± 4.8	
Bupivacaine group (B)	26.6 ± 2.6	
Normal Saline group (C)	26.5 ± 1.7	
Sex, No. (%)		0.404
Male		
Methylprednisolone group (A)	11 (39.3)	
Bupivacaine group (B)	16 (57.1)	
Normal Saline group (C)	14 (50.0)	
Female		
Methylprednisolone group (A)	17 (60.7)	
Bupivacaine group (B)	12 (42.9)	
Normal Saline group (C)	14 (50.0)	

P value <0.05 is significant.

In our study, the average time of returning to daily activities in saline patients was significantly more ($P = 0.005$).

Patients' disability levels decreased in 3 groups after 3 months of treatment, but in methylprednisolone group was significantly more ($P < 0.001$), and there was not significant difference in sideways bending level between groups ($P > 0.05$; Table 3).

There was not significant difference in range of flexion, extension and rotation in 3 groups before and after injection ($P > 0.05$; Figure 1).

Discussion

Results demonstrated that epidural methylprednisolone and bupivacaine injection is more effective than normal saline injection in these patients. Some studies stated that epidural steroid injection was effective in the reduction of pain up to 65% in the patients. However, other studies did not show enough evidence. It gives a general idea that all patients need maintenance treatment period in the sensible period of time in order to reduce symptoms before surgery (11). However, for maintenance treatment

Table 2. The mean score of patients' pain based on ANOVA (n = 84)

	Mean ± SD			*P* Value
	Methylprednisolone Group (A)	Bupivacaine Group (B)	Normal Saline Group (C)	
Before injection	6.5 ± 0.8	6.9 ± 1.1	6.6 ± 0.8	0.180
A week after injection	6.2±1.2	6.9±1.1	6.6 ± 0.8	0.036
Two weeks after injections	3.7±1.8	5.9±1.5	5.2±1.2	>0.001
Three weeks after injection	2.8±1.6	3.3±1.6	3.1±1.4	0.597
One month after injection	1.9±0.1	2.1±0.7	2.5±1.3	0.130
Three month after injection	1.6±0.6	2.0±0.7	2.0±0.7	0.022

P value <0.05 is significant.

Table 3. Assessing disability and sideways bending level of patients before, 1 week, and 3 months after treatment in 3 groups based on ANOVA (n = 84)

	Mean ± SD			*P* value
	Methylprednisolone Group (A)	Bupivacaine Group (B)	Normal Saline Group (C)	
Disability level				
Before injection	37.4 ± 13.3	23.9 ± 6.3	28.1 ± 10.8	0.001<
1 week after injection	34.2 ± 10.8	24.7 ± 4.5	29.8 ± 8.4	0.001<
3 months after injection	6.2 ± 1.9	5.2 ± 2.1	7.8 ± 1.8	0.001<
Sideways bending level				
Before injection	2.2 ± 0.5	2.1 ± 0.5	2.1 ± 0.5	0.677
1 week after injection	2.2 ± 0.5	2.1 ± 0.5	2.1 ± 0.5	0.837
3 months after injection	1.0 ± 0.2	1.2 ± 0.5	1.2 ± 0.4	0.118

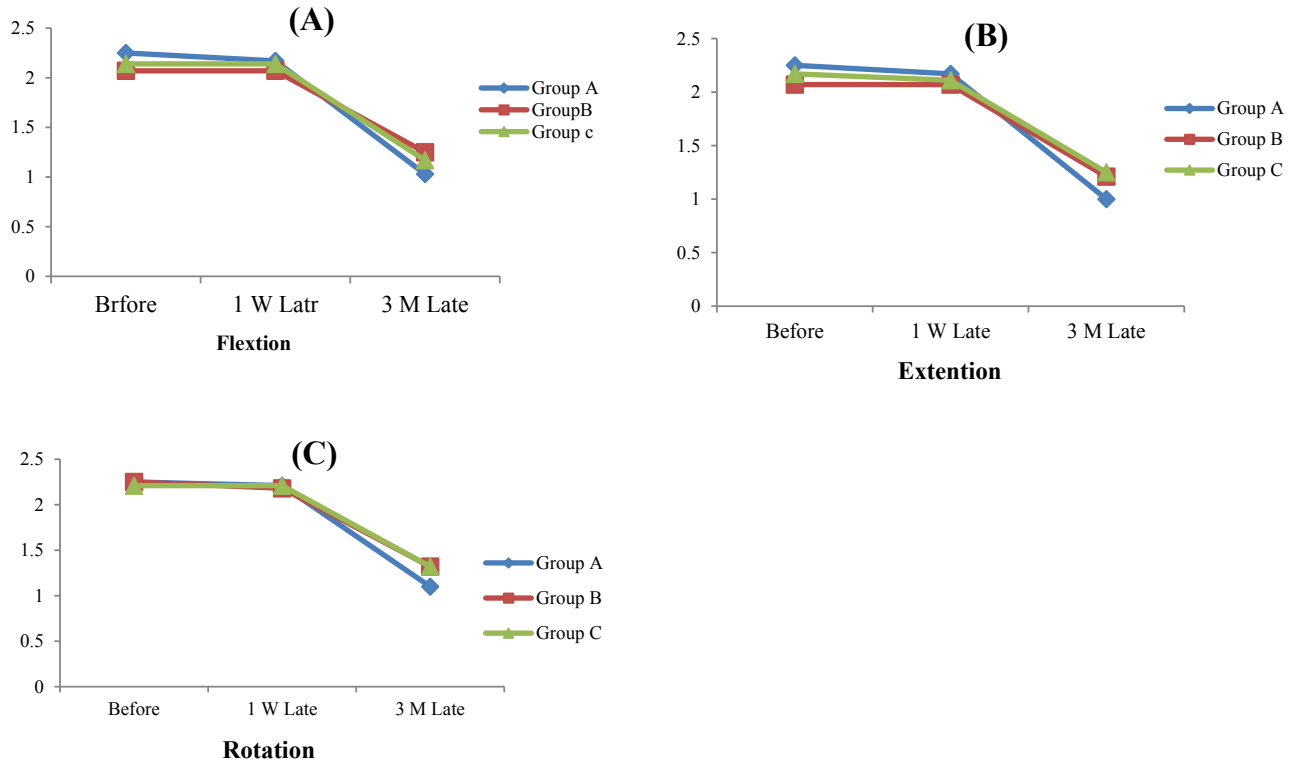

Figure 1. Variation Range of Flexion (A), Extension (B) and Rotation (C) in 3 Groups Before and After Injection.

indications, there is no consensus and also according to review study, there is still many controversies concerning epidural injection spot (root) (10).

Koes et al in a meta-analysis concluded the results of 12 studies regarding the impact of epidural-steroid in chronic low back pain, of which 6 studies supported this treatment and 6 studies opposed it (12).

Another meta-analysis of the results of 13 studies highlighted that making definite decision is not possible (10).

Murakibhavi et al in an RTC study, through comparing local anesthesia injection and steroid with an epidural method in hernia discal and spinal stenosis, showed that general success level ranged from 63% to 80 % with more success in recovery of pain in hernia discal in long term (13).

Gaurav et al in a systematic review in regard to impact of caudal injection with local anesthesia and steroid concluded that strong evidence shows that caudal injection is not effective for long-term soothing of low back pain (for any reason) and it is recommended that local anesthesia injection and steroid be compared to the control group (14).

In our study, the level of patients' pain in 3 months after treatment in methylprednisolone group was low and level of disability in three months after treatment in normal saline was significantly high ($P<0.001$) and reduction level of disability in methylprednisolone group was

significantly high ($P < 0.001$).

Runu et al in a study showed that epidural steroid injection is a safe and effective way for back pain treatment and in this program, analgesia period makes patients to be active for physical therapy, helping them to recover sooner (15).

Manchikanti et al in a 2-year follow–up study of caudal injection with local anesthesia and local anesthesia along with steroid in patients with spinal stenosis, the reduction of pain was significant and 38% improvement was observed in patients receiving local anesthesia and 44% in patients receiving local anesthesia along with steroid at the end of two years (16).

In our study, 30 minutes after injection, the average pain intensity significantly decreased and reached to the 30% of the initial amount. However, the average pain intensity that gradually increased after 30 days of injection reached 70 % of the initial intensity. These changes indicate that injecting epidural medicines such as methylprednisolone, and bupivacaine is effective in reducing the initial pain and their effects gradually decrease. In other study, injection of epidural medicine with a 2-day interval by combining 2 mL of prednisolone acetate 50 mg or 2 mL of saline in patients with sciatica pain was performed and it is concluded that effectiveness of saline isotonic and injected steroid in the epidural space was similar (17) .

Conclusion

Epidural methylprednisolone and bupivacaine injection was more effective than placebo (normal saline) injection in these patients with low back pain and can be used by the anesthesiologists.

Conflict of Interests

The authors declare that they have no competing interests.

Ethical Issues

Ethics Committee of Tabriz University of Medical Sciences approved the study (No. 93.3-9.6).

Financial Support

This work was supported by the financial helps of Tabriz University of Medical Sciences.

References

1. Richardson SM, Hoyland JA. Stem cell regeneration of degenerated intervertebral discs: Current status. Curr Pain Headache Rep. 2008;12(2):83-88. doi:10.1007/s11916-008-0016-3
2. Furlan AD, Imamura M, Dryden T, Irvin E. Massage for low back pain: an updated systematic review within the framework of the Cochrane Back Review Group. Spine (Phila Pa 1976). 2009;34(16):1669-1684. doi:10.1097/BRS.0b013e3181ad7bd6
3. Henchoz Y, Kai-Lik So A. Exercise and nonspecific low back pain: a literature review. Joint Bone Spine. 2008;75(5):533-539. doi:10.1016/j.jbspin.2008.03.003
4. Schwarzer AC, Aprill CN, Derby R, Fortin J, Kine G, Bogduk N. The prevalence and clinical features of internal disc disruption in patients with chronic low back pain. Spine (Phila Pa 1976). 1995;20(17):1878-1883.
5. Kosarian H, Habibollah Zadeh C, Goldsmith Marandi, the "Statistical analysis disc at a hospital in Tehran in 1369 -70." Medical journal grace: Issue quarter. 1990;20(3-4):15-13.
6. Maroon JC, Kopitnik TA, Schulhof LA, Abla A, Wilberger JE. Diagnosis and microsurgical approach to far-lateral disc herniation in the lumbar spine. J Neurosurg. 1990;72(3):378-382. doi:10.3171/jns.1990.72.3.0378
7. Benyamin RM, Manchikanti L, Parr AT, et al. The effectiveness of lumbar interlaminar epidural injections in managing chronic low back and lower extremity pain. Pain Physician. 2012;15(4):E363-404.
8. Schwarzer AC, Aprill CN, Bogduk N. The sacroiliac joint in chronic low back pain. Spine (Phila Pa 1976). 1995;20(1):31-37.
9. Vad VB, Bhat AL, Lutz GE, Cammisa F. Transforaminal epidural steroid injections in lumbosacral radiculopathy: a prospective randomized study. Spine (Phila Pa 1976). 2002;27(1):11-16.
10. Cassuto J, Sinclair R, Bonderovic M. Anti-inflammatory properties of local anesthetics and their present and potential clinical implications. Acta Anaesthesiol Scand. 2006;50(3):265-282. doi:10.1111/j.1399-6576.2006.00936.x
11. Benyamin RM, Manchikanti L, Parr AT, et al. The effectiveness of lumbar interlaminar epidural injections in managing chronic low back and lower extremity pain. Pain Physician. 2012;15(4):E363-404.
12. Koes BW, Scholten RJ, Mens JM, Bouter LM. Efficacy of epidural steroid injections for low-back pain and sciatica: a systematic review of randomized clinical trials. Pain. 1995;63(3):279-288.
13. Murakibhavi VG, Khemka AG. Caudal epidural steroid injection: a randomized controlled trial. Evid Based Spine Care J. 2011;2(4):19-26. doi:10.1055/s-0031-1274753
14. Friedman JH, Dighe G. Systematic review of caudal epidural injections in the management of chronic back pain. R I Med J (2013). 2013;96(1):12-16.
15. Runu R, Sinha NK, Pai R, Shankar PR, Vijayabhaskar P. Our experience with epidural steroid injections in management of low backpain and sciatica. Kathmandu Univ Med J (KUMJ). 2005;3(4):349-354.
16. Manchikanti L, Cash KA, McManus CD, Pampati V, Fellows B. Results of 2-year follow-up of a randomized, double-blind, controlled trial of fluoroscopic caudal epidural injections in central spinal stenosis. Pain Physician. 2012;15(5):371-384.
17. Valat JP, Giraudeau B, Rozenberg S, et al. Epidural corticosteroid injections for sciatica: a randomised, double blind, controlled clinical trial. Ann Rheum Dis. 2003;62(7):639-643