Effects of epidural injection of glucocorticoid and its combination with bupivacaine in palliating chronic low back pain due to discopathy

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Abstract: Chronic low back pain is defined as consistent or pendulous pain over 3 months. Epidural steroid injections (ESI) are common in treatment of chronic back pain. The present study was aimed to investigate the effects of epidural injection of glucocorticoid and bupivacaine compared to glucocorticoid alone in relieving chronic back pain due to discopathy. A randomized clinical trial was performed in the Shohada Medical Educational Center, Tabriz, Iran. Patients with chronic back pain who were candidates for epidural drug injection were recruited. They were divided into two groups of steroids or steroid and bupivacaine. Pain intensity, Oswestry Disability Index (ODI), Straight Leg Rising (SLR) test as well as clinical variables were evaluated before treatment and 3th month thereafter. Overall, 17 males and 23 females with a mean age ± SD of 47.54 ± 12.11 years were enrolled in two equal groups. No significant difference was observed between two groups in terms of gender and body mass index. In both groups, a significant relationship was observed for ODI (p =0.001), pain intensity (p =0.001), and SLR test (p=0.001) before and after treatment. However, the corresponding association was not observed for ODI, pain intensity and SLR test (p>0.05). Epidural steroid injections either alone or combined with Bupivacaine with no priority are effectively relief chronic low back pain due to discopathy.
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1. Introduction

Chronic LBP is the most common cause of disability in adults lower than 45 years. It is also the second leading cause of doctor visits and the fourth leading cause of hospitalization. There are many social and economic impacts of chronic LBP. Degenerative process in the lumbar spine is a common source of chronic LBP [1].

Incidence of LBP in lifetime is between 60 - 90 % and almost 15% of those referred to physicians are patients with LBP annually [2].The main characteristic of acute or chronic LBP is due to the pressure on the nerve root that is willing to distribute the dermatomes involved [3]. Acute low back pain is common because of the sciatic nerve [4]. Sciatica pain radiculopathy is caused by pressure on the posterior roots [5]. Pressure on the spinal cord or nerve roots in the spinal canal stenosis can cause lower back pain [6]. Process of degeneration changes in the lumbar region is gradually anatomical, biomechanical, radiological and clinical changes, and ultimately, is shown degenerative disease of lumbar discs [7].

History and physical examination in patients with chronic low back pain might be done to put the patient in one of following four groups: non-specific low back pain, low back pain due to radiculopathy or spinal stenosis, referral low back pain from nonspinal source and pain from other causes [8].

Positive SLR test can be suggested for lumbar disc herniation [9]. Routine laboratory examinations are not necessary in all patients with chronic low back pain [10]. Imaging techniques such as CT scan and MRI are recommended in patients whom do not improve symptoms during 6 weeks. MRI has the highest sensitivity in the diagnosis of lumbar disc herniation and it is selective for nerve root lesions [11].

Treatment goal for chronic low back pain in patients, viewpoint often is complete recovery and full return to previous levels of activity. It often has a large gap from the percentage of recovery is expected to have therapeutic value [12].

Epidural steroid injection has been recommended and approved as a non-surgical

treatment for radiculopathy pain of lumbar spine by the America Spine Society [13]. It has been reported for the first time in 1952 along with diagnostic and therapeutic benefits [14]. Anesthesiologists are required to master techniques for emergency occasions [15-19].

Due to some controversies in publications [25], the present study was conducted to compare the effects of epidural injection of glucocorticoid alone and its combination with bupivacaine in relieving chronic back pain.

2. Material and Methods

The study was designed as a double-blind randomized clinical trial and was conducted from Jan 2011 till Jul 2012. A written consent was obtained from all subjects. Examination and follow-up visits were free of charge. Participants and the individuals who evaluate and record the variables were not aware of any grouping. Setting was the Shohada Medical Educational Center affiliated to the Tabriz University of Medical Sciences, Tabriz, Iran. The study population was patients diagnosed with chronic back pain undergoing epidural injection of drugs. Routine conservative treatments were previously applied and have not responded. All 40 participants were divided into two equal groups based on random numbers table. Inclusion criteria included chronic back pain more than 3 months due to pure discogenic pain, disc herniation or degeneration signs on MRI, bulging or protrusion without motor involvement and deep tendon reflexes (DTR) and an indication for ESI. Exclusion criteria were previous surgery on the spine, Cuda-aquina symptoms, spinal stenosis, psychosomatic illness and drug addiction. All un-stability items were evaluated by a neurosurgeon. Patients were transferred to the operating room. After preparation in the sitting position, the physician injected into epidural space following local anesthesia using Touhy needle grades 19 to 20 (per patient) via the intermediate space of vertebrae L3-4 or L4-5. After aspiration and assurance of needle correctly located, the injection was performed in the epidural space. After the needle exiting, the area was dressed under sterilization condition, the patient was lie down in supine position, supervised for 30 minutes and vital signs were checked. If there are no changes in vital signs and stability, the patient was discharged. Before treatment (baseline) and the intervals of one week, two weeks, one month and three months after the injection the variables were evaluated and recorded.

Pain intensity classifications (no pain, low, medium, high), ODI at the baseline and at the end of the third month, SLR as positive (less than 60 °) and negative (greater than 60°) and clinical variables such as the ability to flexion, extension, lumbar bending and Torso rotation were checked baseline and the end of the third month. The time of return to normal activity, possible side effects, need to re-injection or receiving any other treatments were recorded till 6 months after injection.

Statistical analysis: Using SPSS statistical software version 16, data were analyzed as descriptive statistics (frequency, percentage, mean and standard deviation) and univariate analysis (Chi square, Fisher exact test). Probability values less than 0.05 were considered statistically significant.

3. Results

Overall, 40 patients including17 males and 23 females with a mean age ± SD of 47.54 ± 12.11 years were enrolled in two equal groups. No significant difference was observed between two groups in terms of gender and body mass index (Table1).

In both groups, a significant relationship was observed for ODI ($p = 0.001$), pain intensity ($p = 0.001$), and SLR test ($p=0.001$) before and after treatment. However, the corresponding association was not observed for ODI, pain intensity and SLR test ($p>0.05$), (Table 2). A comparison of pain between two groups before and after treatment and return to usual activity time at the baseline and after treatment have been illustrated in tables 3 and 4.

4. Discussion

Using Epidural steroid for an inhibitory effect on inflammation, inhibiting the transmission of nerve fibers C and reduce the capacity of permeability has reported to be useful [14]. The proper selection of patients, duration of symptoms and underlying pathophysiology are also important factors affecting treatment outcome. Patients without history of surgical treatment, nonsmokers and in patients less than 60 years old would have a better outcome [26].

ESI studies have conflicting results. In a meta-analysis, the results of 12 studies on the effect of ESI for chronic low back pain showed that 6 studies the benefit and 6 the harm of treatment [25]. Based on the results of another meta-analysis study, the final decision in this regard is not possible [27]. Others have recommended ESI only in acute back pain [28]. Runu and colleagues have implied ESI a safe and effective method [29].

Table 1. Intergroup comparison of tests for two groups (glucocorticoid, and glucocorticoid+Bupivacaine)

Test	*Test time*	*Test result*	*Frequency (G)*	*P value (G)*	*Frequency (G+P)*	*P value (G+P)*
SLR	Baseline	Normal	10	0.01	9	0.004
		Abnormal	10		11	
	3th month	Normal	17		19	
		Abnormal	3		1	
Flexion	Baseline	Normal	3	0.001	3	0.001
		Low Limitation	12		14	
		Moderate Limitation	1		1	
		Severe Limitation	4		2	
	3th month	Normal	16		17	
		Low Limitation	4		3	
		Moderate Limitation	0		0	
		Severe Limitation	0		0	
Extension	Baseline	Normal	5	0.002	2	0.001
		Low Limitation	12		15	
		Moderate Limitation	1		2	
		Severe Limitation	2		1	
	3th month	Normal	17		17	
		Low Limitation	3		3	
		Moderate Limitation	0		0	
		Severe Limitation	0		0	
Lumbar Bending	Baseline	Normal	10	0.008	6	0.005
		Low Limitation	8		11	
		Moderate Limitation	1		2	
		Severe Limitation	1		1	
	3th month	Normal	19		17	
		Low Limitation	1		3	
		Moderate Limitation	0		0	
		Severe Limitation	0		0	
Torso Rotation	Baseline	Normal	12	0.04	8	0.001
		Low Limitation	6		11	
		Moderate Limitation	1		0	
		Severe Limitation	1		1	
	3th month	Normal	19		17	
		Low Limitation	1		3	
		Moderate Limitation	0		0	
		Severe Limitation	0		0	

Table 2. Comparison between two groups of low back pain patients after treatment

Test	*G+B*	*G*	*P value*
SLR			0.29
Negative	19 (52.8)	17 (47.2)	
Positive	1 (25.0)	3 (75.0)	
Flexion			0.67
Normal	17 (51.5)	16 (48.5)	
Limitation	3 (42.9)	4 (57.1)	
Extension			1.0
Normal	17 (50.0)	17 (50.0)	
Limitation	3 (50.0)	3 (50.0)	
Lumbar bending			0.29
Normal	17 (47.2)	19 (52.8)	
Limitation	3 (75.0)	1 (25.0)	
Torso rotation			0.29
Normal	17 (47.2)	19 (52.8)	
Limitation	3 (75.0)	1 (25.0)	

However, Argoff and colleagues have suspected in the efficiency of ESI treatment for chronic low back pain [30]. In the present study, significant differences were observed before and after treatment confirming studies that have reported the efficacy of ESI treatment [24, 26,27]. In the present study, ESI was the most effective method in acute radiculopathy and no long-term benefits for chronic patients.

Table 3. Pain comparison between two groups of low back pain patients before and after treatment

Test	*G+B*	*G*	*P value*
Pain (base)			1
Low-moderate	14 (50)	14 (50)	
Severe	6 (50)	6 (50)	
Pain (1 w)			1
No	19 (50)	19 (50)	
Moderate-severe	1 (50)	1 (50)	
Pain (2 w)			0.3
Normal	0 (0)	1 (100)	
Low-moderate	20 (51.3)	19 (48.7)	
Pain (1 m)			0.04
Normal	1 (14.3)	6 (85.7)	
Low-moderate	19 (57.6)	14 (42.4)	
Pain (3th m)			1
Normal	14 (50)	14 (50)	
Low- moderate	6 (50)	6 (50)	

Table 4. Comparison of return to usual activity time between two groups

Group return to usual activity time	G	G+B	P value
1 week	2 (28.6)	5 (71.4)	0.5
2 week	6 (66.7)	3 (33.3)	
3 week	10 (50)	10 (50)	
4 week	2 (50)	2 (50)	

On the other hand, the majority of patients with acute LBP and legs pain did not respond to treatment better than chronic LBP without legs pain. Finally, researchers concluded that the results of ESI are not predictable [28]. The present study showed that although the initial state of each of the groups had significant improvement in pain but there were not significantly differences between two groups. This finding is consistent with previous reports [29]. Other studies in different countries, have confirmed the efficacy of ESI in treatment of LBP, but similar to our results, no significant differences have reported between two groups [23,30-34].

As conclusion, considering the fact that neurologic disorders and deficits are common [35-37], epidural steroid injections either alone or combined with Bupivacaine with no priority are effectively relief chronic low back pain due to discopathy.

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