Epidural injection of Methylprednisolone and Bupivacaine on Management of Chronic low back Pain

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ABSTRACT
Lumbar pain is the most common skeletal and muscular complaint requiring medical care, which causes many complications and economic and social damages to the society and the fifth reason for visiting medical centers, especially for men. The aim of this study was to compare the effect of epidural injection of methylprednisolone, Bupivacaine and normal saline in chronic lumbar pain due to discal herniation. In a single-blind randomized-clinical trial performed in the Department of Anesthesia of Tabriz University of Medical Sciences on patients with chronic lumbar pain, the effect of epidural injections of methylprednisolone, Bupivacaine and normal saline in treatment of chronic lumbar pain due to discal herniation were studied. In this study, 84 patients with lumbar pain were treated and the effect of epidural injections of methylprednisolone, Bupivacaine and normal saline in treatment of chronic lumbar pain due to discal herniation were studied. The mean ages of patients in the methylprednisolone group, Bupivacaine group and normal saline group were 42.3 ± 12.20, 45.57 ± 11.59 and 42.64 ± 12.21 years respectively (P=0.503). In this study, the mean times to return to daily activities in patients in methylprednisolone group, Bupivacaine group and normal saline group were 56.00 ± 14.88, 55.11 ± 11.16 and 73.71 ± 35.13 hours respectively and the mean time to return to daily activities in patients in normal saline group was significantly higher (P=0.005). In this study, evaluating the therapeutic outcomes of epidural injection of methylprednisolone, Bupivacaine and normal saline were studied in patients with chronic lumbar pain due to discal herniation and the results show that epidural injections of methylprednisolone and Bupivacaine are more effective than placebo injection (normal saline) in these patients.
Introduction

Lumbar pain is the most common skeletal and muscular complaint requiring medical care, which causes many complications and economic and social damages to the society and the fifth reason for visiting medical centers, especially for men. Its common cause has been picking up heavy objects. Over 80% of people experience lumber pain throughout their lives, associated with lower extremity pain in 30% of cases. Its annual incidence rate is 15-45% (1). Lumber pain can be originated from different lumbar structures. Pathophysiology of spinal pain has always been a subject of research and discussion. In addition to the mechanical components, nerve root inflammation is an important factor in the root pathophysiology of disk-related pain (2). Although most lumbar pains are self-improvement, they may limit the performance if sustainable and associated with radicular pain. It can be determined as the certain cause in most patients with hip pain (3). The pain of the lumbar roots is often described in the form of a sharp, trenchant and diffusive pain, that prickles from waist to limb(s) in the path of a nerve root. Radicular pain is caused by inflammation or injury of the nerve root. The clinical appearance of nerve root inflammation includes some or all of the following: radicular pain, Hyperesthesia, Dermatomes, weakness of muscle groups that take their nerves from the nerve root involved, loss of deep tendon reflexes, and positive SLR test (3). Studies using fluoroscopy and diagnostic contrast material injection methods for differentiating the source of lumbar pain, reported that 39% lumbar pains are due to disc internal damage and 13-19% caused by sacroiliac joints dysfunction and 13-17% induced by painful fasciitis joints (4-7). Specific treatment should be taken based on the underlying cause of lumbar pain. Non-surgical treatments of radicular lumbar pain include the use of NSAIDs, Pain relievers and oral or injective steroids, Physiotherapy and drug injection into the epidural. In case of failure of maintenance treatment for lumbar pain, interventional treatments, such as drug injection into the epidural space and finally, surgery are performed (8). The first recorded and documented operation of drug injection in the epidural space by caudal injection was carried out in 1901 with cocaine injections to treat lumbar pain and sciatic pain. From 1920 to 1940, epidural injections were performed using high volumes of normal saline and local anesthetics. Injection of corticosteroids into the epidural space for the treatment of radicular lumbar pain for the first time was recorded in 1952 (9). Epidural block is performed by caudal, lumbar interlaminar and transforaminal (10).

So, based on the above-mentioned controversies, in this study, we are about to examine the effect of epidural injection of local anesthetics (Bupivacaine) and steroids (methylprednisolone) and normal saline alone in patients with lumbar pain who have no indication for surgery. There are ongoing studies suggesting that the injection of normal saline, as a drug in epidural infusion to control chronic lumbar pain, can be effective as well as the other drugs due to its lower side effects than other medications. It is important that any epidural injection may have therapeutic effects on chronic lumbar pains resulting from discal herniation; and due to less studies on the injection of normal saline, this study can provide further results and evidences for the effectiveness of injecting normal saline and comparison with other medicines.

Materials and Methods

In a Single-blind clinical - randomized trial on patients with chronic lumbar pain in Tabriz, the effects of epidural injections of
methylprednisolone, Bupivacaine and normal saline were examined in chronic lumbar pain due to discal herniation.

The study population included the patients with chronic lumbar pain referred to Shohada medical and educational center of Tabriz University of Medical Sciences for treatment by epidural injection. Patients were randomly assigned to different groups selected by the anesthesia expert and epidural injections were performed. Patients with chronic lumbar pain referring to the pain clinic of Shohada Hospital of Tabriz for treatment by epidural injection were examined in three groups during the study.

**Ethical Considerations**

After conversations with the patients providing them detailed description on the intended actions and explaining that this method is completely safe and widely used on a daily basis, written consent was taken from all patients. All information was kept confidential.

**Statistical analysis**

The collected data were analyzed by SPSS-17 statistical software. The collected data were expressed as percentage and mean ± SD. Continuous (quantitative) variables were compared by Independent samples and Paired t test. Categorical (qualitative) variables were compared by contingency tables and Chi-square test or Fisher's exact test. P-value ≤0.05 was considered statistically significant.

**Results and Discussion**

In this study, 84 patients with lumbar pain were treated and the effect of epidural injections of methylprednisolone, Bupivacaine and normal saline on chronic lumbar pain due to discal herniation was examined and the following results were obtained:

41 patients (11 in group A, 16 in group B and 14 in group C) were male and 43 patients (17 in group A, 12 in group B and 14 in Group C) were female (P=0.404).

The mean age of patients was 42.12±03.20 years in group A, 45.11±57.59 years in group B and 42.12±64.21 years in group C (P=0.503).

The mean height of patients was 168.7±96.37cm in group A, 167.4±25.70cm in group B and 170.5±6.41cm in group C (P=0.113).

The mean time to return to daily activities was 56.14±00.88 hours in group A, 55.11±11.16 hours in group B and 73.35±71.13 hours in group C (P=0.005).

Pain is a most common complaint in a variety of diseases. Although its nature, location and cause is different in every case, it is the basic complaint of about half of patients who visit the doctor (1). Since ancient times, many efforts have been done to reduce, control or eliminate pain. The current treatment strategies to control pain around the surgery time are mainly based on treatment with analgesic medications, opioids and NSAIDS drugs.

In this study, evaluating the treatment results, the efficiency of epidural injection of methylprednisolone, Bupivacaine and normal saline in chronic lumbar pain due to discal herniation in patients was examined and the results indicate that epidural injections of methylprednisolone and Bupivacaine is more effective than placebo injections (normal saline) in these patients.
Some studies have reported that epidural steroid injection was effective in reducing pain by 65%. However, in other studies, no sufficient evidences were obtained for this finding. Meanwhile, there is a general idea that all patients need a maintenance treatment in a reasonable period of time before surgery to reduce their symptoms (10).

However, there is no consensus for the indications of maintenance treatment; and as well, based on the reviewed studies, there are still many controversies on the location (route) of epidural injection (10-11).

Koes et al., in a meta-analysis, concluded the results of 12 studies on the effect of epidural steroid injections in chronic lumbar pain where 6 were in favor of the treatment and 6 to the detriment of it (12).

In a meta-analysis by the Rozenberg et al., of the results of 13 studies, they concluded that definitive decision in this regard is not possible (13).

Murakbhavi et al., in an RCT study comparing epidural injection of local anesthetic and steroid in discal herniation and spinal stenosis, the overall success rate ranged from 63% to 80% with higher success rate in long-term improving of pain for discal herniation cases (14).

Gaurav D. et al., in a systematic-review study on the effect of caudal injection with local anesthetic and steroid concluded that there is no strong evidence of effectiveness of Caudal injection on long-term relieving of exclusive lower lumbar pain and local anesthetic and steroid injection is better to be compared with the control group (15).

Runu et al., showed in a study that epidural steroid injection is a safe and effective method in treatment of lumbar pain and in this program, the painless period leads to patient's active participation in physical therapy which helps to gain a faster recovery (16).

Fig.1 Disability distribution of patients in three groups of patients
Manchikanti et al., in the two-year follow-up of patients with spinal stenosis by caudal injection in two groups with local anesthetic alone and local anesthetic with steroid, showed that a significant reduction of pain and improved functional status was observed in 38% of patients receiving local anesthetic alone and 44% of patients receiving local anesthetic with steroid at the end of the two-year follow-up period (17).

In this study, disability rate in patients in three months after treatment had declined in all three groups, but the rate of decline in the methylprednisolone group was significantly higher (P<0.001). In a study, 30 min after injection, the mean pain intensity significantly decreased to about 30% of the baseline pain rate. However, the mean pain intensity increased gradually so that after 30 days of administration, it reached to 70% of the baseline.

These changes indicate that epidural injection of triamcinolone, lidocaine and normal saline was well effective in reducing the initial pain, but their effect declined gradually. In another study, epidural injection was applied in patients with sciatic pain every 2 days combining 2 ml of prednisolone acetate (50 mg) or 2 ml of normal saline and concluded that isotonic saline and steroid injection in the epidural space had similar efficacy (13).

In this study, the mean time to return to daily activities in patients with methylprednisolone group, group B and group C was 56.14±00.88, 55.11±11.16, and 73.71±35.13 hours respectively, and the mean time to return to daily activities in patients in group C was significantly higher (P=0.005).

Recommendations

According to the obtained results, conduction of further studies with large sample sizes is recommended.

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