Original Article

Efficacy of intraoperative epidural dexamethasone and bupivacaine in reduction of pain and disability following lumbar discectomy

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Abstract

Background: In lumbar disc herniation, although surgery can provide relief from pain in the low back and lower extremities, many drugs can provide more relief; thus, the aim was the evaluation of epidural dexamethasone and bupivacaine efficacy in lumbar disc herniation surgery. **Methods:** A total of 42 cases were evaluated in a triple-blind randomized clinical trial study. Patients were divided into intervention and control groups based on permuted block randomization. The patient's condition was assessed based on the Visual Analogue Scale (VAS) at 3, 6, 12, and 24 h and 1, 3, and 6 months after surgery. In addition, the patient's disability was assessed by Oswestry disability index (ODI) at 1 and 6 months after surgery. **Results:** Of the 42 evaluated cases, age (44.0 ± 12.4, $P = 0.4$) and hospitalization duration (1.9 ± 0.3 days, $P = 0.02$) had statistically significant difference between two groups. The severity of low back pain before surgery was 2.9 ± 1.9 ($P = 0.74$), and 3 hours after surgery was 4.9 ± 1.9 in the control group and 2.8 ± 1.3 in the intervention group ($P = 0.03$), and there was a statistically significant difference between the two groups. In addition, based on the repeated measure test, there was no significant difference between the two groups. ODI value was before surgery 31.7 ± 8.3 ($P = 0.77$), 5.2 ± 2.4 ($P = 0.9$) at 1 month after surgery, and 4.5 ± 1.8 ($P = 0.6$) at 6 months after surgery, and there was no statistically significant difference between the two groups. **Conclusion:** Dexamethasone and bupivacaine can be effective in post-operation pain control, although this difference between the two groups was not statistically significant.

Keywords: Bupivacaine, dexamethasone, discectomy

Introduction

Low back and radicular pain in candidate cases for discectomy are common clinical manifestations of lumbar disc herniation.[1] Discectomy is one of the most common surgeries performed on the spine. In addition, cases under lumbar discectomy experience recurrent and/or persistent lower extremities or back pain following surgery.[2,3]

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However, basic and clinical aspects of pain modulation and transmission have increased dramatically, and postoperative pains are insufficiently treated. This condition and this pain delay physical therapy and mobilization, increase hospitalization, and change patient perspective conditions.[4] Increased postoperative pain has been related to complications, including myocardial ischemia, pulmonary embolism, deep venous thrombosis, decreased pulmonary function, postoperative chronic pain, and infections.[5] Some studies have examined novel and additional postoperative analgesics, including intraoperative local anesthetics and/or corticosteroids.[1]

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For many years, epidural steroids have been administered as an additional drug in lumbar disc surgery. Novel approaches in this condition are an effort to decrease the late formation of scars and early postoperative inflammation to reduce postoperative pain.[6] Ranguis *et al.*[7] in a systematic review of 12 clinical trials examined subjects during 1992–2008 for reduction of postoperative pain of discectomy. Also, a study on 112 neurosurgeons in 2009 observed that 61% do not administer epidural steroids in lumbar discectomy.[8] This indicates that the clinical effects of intraoperative steroids in lumbar discectomy are still controversial. Based on the importance of pain reduction in a candidate for discectomy, the aim of the study was the evaluation of epidural dexamethasone and bupivacaine in discectomy for postoperative pain control, as a clinical trial study.

Materials and Methods

Study oversight

The protocol was approved by relevant ethics committees and institutional review boards. Written informed consent was obtained from each patient before the study. This study was performed to evaluate dexamethasone and bupivacaine efficacy on postoperative pain of discectomy. In this study, patients with disc herniation presenting in Vliasr Hospital in Arak and satisfying the inclusion criteria were considered as the study group.

Study participants

In total, 42 patients with unilateral lumbar disc herniation presenting to Valiasr Hospital in Arak who were candidates for unilateral laminectomy surgery were considered as the study group. These patients were divided into intervention (N = 21) and control (N = 21) groups.

Study design and procedures

This study is a triple-blind (patients, surgeon, and postoperative clinical evaluator) randomized clinical trial study to evaluate the effects of dexamethasone and bupivacaine to reduce low back and leg pain and other postoperative symptoms associated with lumbar disc herniation.

We selected 42 patients for one-sided discectomy referring to Valiasr Hospital in Arak. By block random sampling, we divided the patients into two equal groups of control and intervention. Patients with complaints of radicular and low back pain were carefully examined and after matching the patients with MRI images and spinal X-rays were candidates for discectomy in the study.

Inclusion criteria were selected patients in the range of 17–75 years who were candidates for unilateral laminotomy and discectomy with a diagnosis of unilateral lobar disc herniation. Exclusion criteria consisted of multilevel disc herniation, spinal instability, patients with couda equina syndrome, and any pathology of the spine, including kyphosis and scoliosis, modal changes, or current or previous infection.

Sufficient information about the study was given to the patients; then, the forms related to Visual Analogue Scale (VAS) and Oswestry Disability Index (ODI) were delivered to the patients. Preoperative procedures were performed uniformly for patients. Patients were operated by a midline incision and unilateral laminotomy and discectomy. All surgical procedures for patients were performed in exactly the same way by a surgeon. At the end of the surgery, after discectomy and release of nerve root and checking foramina, patients were divided into two groups of intervention and control. For the intervention group, 2 cc of dexamethasone (8 mg) and bupivacaine (4 cc of 0.5% solution) impregnated gelfoam (2 × 1) was applied at the entrance of irritated nerve root foramina. In addition, for the control group, only 6 cc of normal saline impregnated gelfoam was used at the injured nerve root foramina.

Outcomes

In follow-up, we used VAS and ODI indices. The ODI consists of 10 questions that describe the severity of pain and limitations experienced by the patient in the positions of sleeping, sitting, standing, walking, resting, intercourse, activities, body moving, and personal activities determined based on the 0–5 Likert numbers. If the patient has no pain and limitations related to the mentioned activity, the score is 0. If severe pain causes inability to perform the mentioned activity, the score is 5. In total, the patient's disability score is numerically between 0 and 50, and a higher score means the severity of the patient's disability is higher. In addition, VAS as patients pain intensity scale is a numerical index from 0 to 10. This questionnaire was completed once before surgery, four times after surgery at intervals of 3, 6, 12, and 24 h after surgery, and twice at 1 and 6 months after surgery.

In addition, the total dose of opioids received by the patients in the hospital was also recorded. Morphine intake for patients with moderate to high pain intensity (VAS above 4) was injected intramuscularly. Patients get out of bed at the earliest opportunity and begin to walk, and were discharged 24–48 h after surgery.

Statistical analysis

After collecting the data, the information was analyzed by SPSS software (version 23) with Chi-square (Qualitative data) and Independent Sample T-test (Quantitative data). In addition, we used the repeated measure test for analytic evaluation of patients at follow-up.

Ethical considerations

1. The principles of confidentiality were observed at all stages of the study.
2. At all stages, researchers complied with the provisions of the Declaration of Helsinki.
3. No additional costs were imposed on patients.

4. In the process of treatment, no changes were made and routine treatment was performed on patients.

(Ethical Code: IR.ARAKMU.REC.1399.185, IRCT Code: IRCT20201003048906N1)

Results

Basic and clinical characteristics

In the 42 evaluated cases, the age was 44.0 ± 12.4 years, 40.7 ± 11.2 and 46.6 ± 13.0 years in the intervention and control groups, respectively (P = 0.4). Hospitalization duration was 1.9 ± 0.3 days, 1.8 ± 0.3 and 2.1 ± 0.3 days in the intervention and control groups, respectively (P = 0.02), and there was a statistically significant difference between the two groups. Regarding imaging, L3-L4, L4-L5, and L5-S1 levels were found in 1, 20, and 21 patients, respectively (P = 0.2) [Table 1].

Visual analog scale

Lower extremity pain intensity scores before surgery (P = 0.87), 3 h (P = 0.5), 24 h (P = 0.7), 2 weeks (P = 0.4), 1 month (P = 1.0), 3 months (P = 1.0), and 6 months (P = 0.3) after surgery did not have statistically significant difference between the two groups, but this index at 6 (P = 0.04) and 12 (P = 0.03) h after surgery had significant difference [Table 2]. Based on the repeated measure test, there was no statistically significant difference between the two groups (P = 0.21) [Figure 1].

Low back pain severity scores before surgery (P = 0.74), 6 h (P = 0.5), 12 h (P = 0.6), 24 h (P = 0.7), 2 weeks (P = 0.6), 1 month (P = 0.8), 3 months (P = 0.6), and 6 months (P = 0.6) after surgery were not statistically significant different between the two groups. However, this index 3 h after surgery showed a statistically significant difference between the two groups (P = 0.03). Based on the duplicate data test, there was no statistically significant difference between the two groups [Table 3]. Based on the repeated measure test, there was no statistically significant difference between the two groups (P = 0.41) [Figure 1].

Oswestry disability index

ODI before surgery (P = 0.77) and 1 (P = 0.9) and 6 months (P = 0.6) after surgery did not have statistically significant differences between the two groups [Table 4]. Based on the repeated measure test, there was no statistically significant difference between the two groups test of two (P = 0.70) [Figure 1].

Analgesics

Also, analgesics consumption in the intervention group was 2.3 ± 2.5 and in the control group was 3.5 ± 3.5 mg (P = 0.2), and there was no statistically significant difference between the two groups [Table 5].

Discussion

In candidate cases for discectomy, low back and radicular pain are common clinical manifestations of lumbar disc herniation.[1]

Table 1: Basic and clinical data of evaluated cases

Variables	Groups			Statistical Value
	Intervention	Control	Total	
Age				0.4[1]
Mean	42.3	45.6	44.0	
SD	11.9	13.0	12.4	
Hospitalization duration				0.02[1]
Mean	1.8	2.1	1.9	
SD	0.3	0.3	0.3	
Disc Level				0.2[2]
L3-L4	0	1	1	
L4-L5	8	12	20	
L5-S1	13	8	21	

[1]Independent Sample *t*-test. [2]Chi-square

Table 2: Lower extremities pain (VAS) in the follow-up of evaluated cases

VAS	Groups			Independent sample *t*-test	Repeated measure test
	Intervention	Control	Total		
Preoperational	7.5±1.7	7.3±1.9	7.4±1.8	0.87	0.21
3 Hours	1.5±1.4	2.4±1.7	2.0±1.6	0.09	
6 Hours	1.3±1.0	2.0±1.2	1.6±1.1	0.04	
12 Hours	0.9±0.9	1.5±0.9	1.2±0.9	0.03	
24 Hours	1.2±0.8	1.4±1.1	1.3±0.9	0.6	
2 Weeks	1.1±0.9	1.4±0.8	1.3±0.9	0.4	
1 Month	1.2±0.8	1.2±0.9	1.2±0.8	1.0	
3 Months	0.9±0.7	0.9±0.8	0.9±0.8	1.0	
6 Months	1.0±0.7	0.7±0.8	0.8±0.7	0.3	

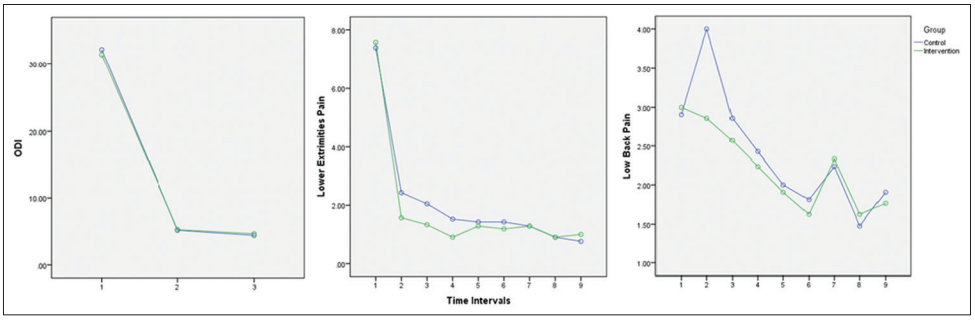

Figure 1: ODI, lower extremities, and low back pain in follow-up of evaluated cases

Table 3: Low back pain (VAS) in the follow-up of evaluated cases

VAS	Groups			Independent Sample *t*-test	Repeated Measure test
	Intervention	Control	Total		
Preoperational	3.0±2.0	2.9±1.8	2.9±1.9	0.74	0.41
3 Hours	2.8±1.3	4.0±1.9	3.4±1.7	0.03	
6 Hours	2.5±1.1	2.8±1.9	2.7±1.5	0.5	
12 Hours	2.2±0.9	2.4±1.3	2.3±1.1	0.6	
24 Hours	1.9±0.9	2.0±1.1	1.9±1.0	0.7	
2 Weeks	1.6±1.2	1.8±1.2	1.7±1.2	0.6	
1 Month	2.3±1.5	2.2±1.1	2.2±1.3	0.8	
3 Months	1.6±0.8	1.4±1.1	1.5±0.9	0.6	
6 Months	1.7±0.8	1.9±1.1	1.8±0.9	0.6	

Table 4: ODI condition in the follow-up of evaluated cases

ODI	Groups			Independent sample *t*-test	Repeated measure test
	Intervention	Control	Total		
Preoperational	31.3±7.4	32.1±9.3	31.7±8.3	0.77	0.70
1 Month	5.2±2.5	5.2±2.3	5.2±2.4	0.9	
6 Months	4.7±1.8	4.4±1.9	4.5±1.8	0.6	

Table 5: Amount of analgesics consumed

Analgesics	Groups			Independent Sample *t*-test
	Intervention	Control	Total	
Mean±SD	2.3±2.5	3.5±3.5	2.9±3.1	0.2

Cases under lumbar discectomy experience recurrent and/or persistent lower extremities or back pain following surgery.[2,3] Novel methods for reducing postoperative pain are an effort to decrease the late formation of scars and early postoperative inflammation.[6] In the present study, it was observed that lower limb pain before discectomy was 7.4 ± 1.8 (P = 0.87), and 6 and 12 hours after surgery had a statistically significant difference in the two groups. Also, the severity of low back pain before surgery was 2.9 ± 1.9 (P = 0.74), and 3 hours after surgery, there was a statistically significant difference between the two groups (P = 0.03). In addition, based on the repeated measure test, there was no significant difference between the two groups. Samoladas *et al.*[9] evaluated epidural steroids in analgesia of discectomy and stated that none of the patients in the intervention group and 12 patients in the control group needed more analgesics (P = 0.01). Three hours after surgery, VAS was significantly lower in the intervention group compared to the control group (P < 0.05). Cai *et al.*[6] observed that epidural steroids were associated with reduction of three indices included as lower extremities and low back pain, morphine use, and hospitalization, which these studies were consistent with the present study.

Aminmansour *et al.*[3] reported that the lower extremity pain was lower in the dexamethasone group, although this difference was not statistically significant. However, we observed a statistically significant difference. Mirzai *et al.*[10] found that epidural methylprednisolone reduced low back pain and reduced opium use in discectomy candidates. Modi *et al.*[11] observed that epidural methylprednisolone reduced low back pain of the intervention group within 1 month after surgery in the intervention group. Debi *et al.*[12] observed that epidural methylprednisolone reduced back and lower limb pain in patients after unilateral lumbar disc surgery. Tavakol *et al.*[13] commented that dexamethasone can reduce VAS after discectomy. Ranguis *et al.*[7] in a systematic review of 12 clinical trials examined subjects during 1992–2008 for reduction of postoperative pain of discectomy. Also, a study on 112 neurosurgeons in 2009 observed that 61% do not administer epidural steroids in lumbar discectomy.[8] This indicates that the clinical effects of intraoperative steroids in lumbar discectomy are still controversial. However, **based on most of the discussed studies, equal to our results, steroid administration can reduce early postoperative pain and introduce better conditions for these patients.**

Conclusion

Dexamethasone and bupivacaine combination can be effective in improving the pain score of patients after discectomy, which can be associated with reducing lower extremities and low back pain and lower analgesics administration after surgery; however, this difference was not statistically significant in all times interval.

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Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

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