Journal of Experimental and Clinical Medicine
https://dergipark.org.tr/omujecm

Clinical Research

J. Exp. Clin. Med., 2018; 35(1): 7-13
doi: 10.5835/jecm.omu.35.01.002

Comparison of efficacy of epidural triamsinolone and betamethasone injection on blood glucose and pain in non-diabetic patients

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ARTICLE INFO

Article History
Received 12 / 03 / 2018
Accepted 22 / 05 / 2018
Online Published Date 25 / 10 / 2019

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Keywords:
Betamethasone
Blood glucose
Epidural steroid
Low back pain
Triamcinolone

ABSTRACT

The aim of this study is to compare the effects of two different steroid medication on pain and blood glucose for non-diabetic patients suffering from low back and leg pain for the purpose of providing epidural analgesia. ASA I-II classified non-diabetic 60 patients were involved into this study. In group 1, betamethasone 6 mgr+10 mgr bupivacaine and in group 2, triamcinolone 40 mgr+10 mgr bupivacaine were applied with epidural injection. VAS scores, blood glucose measures, and satisfaction scales were analysed. In the comparison of VAS values with initial VAS values of patients in group 1 and group 2, there was significant decrease for all time-points. VAS scores for the group 1 were found low, comparing to group 2, in the second, fourth and sixth hours after the injections, but it was found as high in the second week and first month. In the comparison of blood glucose values with its initial scores for group 1 patients, there was significant increase in the fourth hour. For group 2, significant difference was not observed. When the blood glucose values were compared between group 1 and 2 patients, there was significant increase for group 1 in the second and the fourth hour after injections. In the sense of patient satisfaction scale, significant difference cannot be observed between groups. Epidural betamethasone and triamcinolone were observed that both of them are effective for low back and leg pain. It was found that epidural betamethasone was more effective in the early period, and triamcinolone was more effective in the later period. Epidural betamethasone injection increased blood glucose levels in the early period. It was found that epidural triamcinolone injection did not cause any significant changes in blood glucose level. Triamcinolone not changing blood glucose levels can be regarded as an advantage of this treatment.

1. Introduction

Low back pain is one of the common causes of referral to physicians and its life-long incidence is 40-60% (Priffman et al., 2001; Tong et al., 2003; Lee et al., 2006). Spinal stenosis and lumbar intervertebral disc herniation are the most common causes of low back pain, leading to serious limitations in the social life of patients (Helliova et al., 1987; Bush et al., 1992; Botwin

et al., 2002; Vad et al., 2002; Karaeminoğulları et al., 2005; Jeong et al., 2007). The majority of the patients benefit from conservative treatments such as bed rest, oral medications, lifestyle changes, corset use, physical therapy and exercise. Epidural steroid injection is a low-risk treatment option that can be used in patients who do not benefit from conservative treatment. It has been suggested that the most important factor playing a role in the development of radicular symptoms is inflammation in nerve roots. Steroid administered to the epidural region exerts its effect by reducing inflammation. Epidural steroid application for low back pain was first described by Robecchi and Capra in 1952. Success rates of epidural steroid applications ranging from 20% to 100% have been reported (Lutz et al., 1998). Although initial success rates in acute and chronic pain were found to be equal, the 6-month success rate dropped to 34% in acute pain and to 12% in chronic pain. Studies have shown that epidural steroid and local anesthetic injections are effective and safe methods of reducing radicular pain in patients with lomber radiculopathy.

Steroid agents have been shown to increase blood glucose in non-diabetic and diabetic patients. Historically, steroid administration is under debate in patients with Type-I and Type-II diabetes. There are not enough prospective studies describing epidural steroid administration in diabetic and non-diabetic patients and the effect of various steroid-type drugs on blood glucose. In this study, we aimed to compare the effect of two different steroid preparations administered with epidural method on blood glucose levels and chronic low back and leg pain related to radiculopathy in non-diabetic adult patients aged 18-65 years.

2. Materials and methods

60 patients aged 18-65 years and ASA grade I-II, who applied to the Algology clinic of Ondokuz Mayıs University Medical Faculty for complaints of leg pain and low back pain for more than 6 weeks due to radiculopathy, who were not previously operated were included in the study. After receiving the approval of the Ondokuz Mayıs University Local Ethics Committee and written consent of patients, the patients were randomly assigned two groups. Patients with Type I-II diabetes and preoperative blood glucose levels outside 70-100 mg/dl, endocrine diseases, morbid obesity (BMI> 30), patients using drugs that affected sugar metabolism, patients with more than three failed epidural application attempts, patients with hemorrhagic disorder and receiving anticoagulant therapy, patients with infection in the treatment area and those who did not come to controls were excluded from the study. During the study, patients with blood glucose ≥ 160 were excluded from the study after initiating a GIK solution (5% dextrose + 8 ug insulin + 10 mEq potassium).

Patients were randomly divided into two groups.

Group 1; Betamethasone 6 mg + 0.5% 10 mg bupivacaine (reconstituted with saline as total 5 cc)

Group 2; Triamcinolone 40 mg + 0.5% 10 mg bupivacaine (reconstituted with saline as total 5 cc)

All patients were monitored on 3-lead ECG, pulse oximetry and non-invasive blood pressure measurements after being taken to the operation table after 8 hours fasting before the procedure. Patients were given 6 l/min oxygen with a mask. The vein was opened with 18-20 gauge cannula on the back of the hand. During the procedure, heart rate, mean arterial pressure and peripheral oxygen saturation were monitored.

Patients were lyed down on their side with the pain. Sterile treatment and covering of the intervention area was performed with antiseptic solution (10% povidone iodine). The reference anatomical points were determined so that the intervention could be made in the middle line and from the most appropriate intervertebral range (L2-3, L3-4 or L4-5). Local anesthesia was established with 2-3 mL of 2% prilocaine in the area of skin, subcutaneous and supraspinous ligament at the specified intervention point. An epidural injection was made with a median approach at the epidural distance from interlaminary distance with a 18 G (1.3 mm) Touhy needle (Perican, 88 mm) using the 'resistance loss' method with 3-5 ml sterile saline. Blood glucose levels of the patients were recorded before epidural injection, at 2nd, 4th, 6th, 48th hours, 2nd week, and 1st month after the injection, by measurements from the fingertip. Visual Analog Scale (VAS) scores were recorded before and after the injection at 2nd, 4th, 6th, 48th hours, 2nd week, and 1st month. Patients were followed-up regarding side effects and complications such as nausea-vomiting, itching, restlessness, tinnitus, numbness in the mouth, palpitations, metallic taste, dizziness, headache, hematoma at the injection site, infection, rash, weight gain, subarachnoid damage, arachnoiditis, paralysis, paraplegia, loss of strength, bladder dysfunction, meningitis, and flushing. Patients were also assessed at the end of the first month by a satisfaction scale. Satisfaction was assessed as follows: 0 = very bad, 1 = bad, 2 = good, 3 = very good, 4 = excellent. Satisfaction score of at least 2 was considered successful.

Statistical analysis

"SPSS for Windows 20.0" package program was used for statistical analysis. Shapiro Wilk test was used for checking normal distribution of continuous data. Student T test was used to compare groups. Anova test was used in the analysis of repeated measurements. Binary comparisons were made for repetitive measurement analysis in intra-group comparisons. Pearson Chi-Square independence test was used for the inter-group comparison of the data obtained by

census. Mann Whitney-U test was performed since VAS and SpO2 values did not fit normal distribution. Other continuous variables were expressed as Mean ± Standard Deviation as they were normally distributed. Significance level was accepted as $p < 0.05$.

3. Results

There was no significant difference between groups in terms of demographic characteristics and ASA classification (p>0.05) (Table 1).

Table 1. Demographic characteristics of groups and ASA Classification (Mean ± Standard Deviation).

Variable		Group 1	Group 2	P
Age		54.76±11.61	51.80±11.34	0.321
Gender	Female	12 (% 40)	15 (%50)	0.604
	Male	18 (% 60)	15 (%50)	
Weight		77.20±9.27	76.86±11.61	0.903
Height		168.13±8.61	168.33±8.82	0.930
ASA	ASA I	17 (%56.6)	16 (% 53.3)	1.000
	ASA II	13 (%43.4)	14 (% 46.7)	

There was no significant difference between the groups in terms of HR, MAP and SpO2 values. ($p > 0.05$).

When VAS scores of the patients were compared with the baseline VAS scores in Group 1 and Group 2, VAS scores were significantly lower at all time points ($p < 0.05$) (Table 2).

Table 2. Comparison of VAS scores with Baseline VAS Scores (Mean ± Standard Deviation).

VAS	Group 1	P	Group 2	P
Pre-Injection	7.33±0.75	-	7.26±0.90	-
2nd Hour	3.9±1.24	<0.001	5.40±1.27	<0.001
4th Hour	3.7±0.95	<0.001	5.16±1.11	<0.001
6th Hour	3.73±1.11	<0.001	4.96±1.21	<0.001
48th Hour	5.26±1.48	**<0.001**	4.83±1.17	<0.001
2nd Week	5.26±1.48	**<0.001**	4.7±0.98	<0.001
1st Month	5.3±1.31	**<0.001**	4.56±1	<0.001

The comparison of VAS scores between groups. is shown in Figure 1. Although the VAS scores of group 1 were lower than group 2 for post-injection hours 2, 4 and 6, VAS scores of group 2 were lower than group 1 on the 2nd week and 1st month after the injection ($p < 0.05$) (Fig. 1).

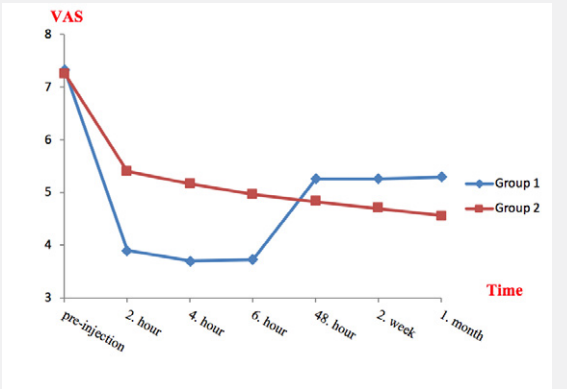

Fig. 1. VAS scores of Group 1 and Group 2

Comparison of blood glucose levels of patients in Group 1 and Group 2 with baseline blood glucose levels is shown in Table 3. Accordingly, only Group 1 had a statistically significant increase in blood glucose levels at 4 hours after injection ($p < 0.05$).

Table 3. Comparison of blood glucose levels in Group 1 and Group 2 with baseline blood glucose levels (Mean ± Standard Deviation).

Blood Glucose	Group 1	P	Group 2	P
Pre-Injection	94.60±7.44	-	93.60±10.56	-
2nd Hour	106.56±19.60	0.064	99.40±14.20	0.075
4th Hour	111.76±30.23	0.043	96.56±9.87	1.000
6th Hour	102±20.56	1.000	94.03±8.42	1.000
48th Hour	90.46±9.37	**0.054**	94±15.25	1.000
2nd Week	94.56±11.65	**1.000**	92.3±10.08	1.000
1st Month	94.53±6.61	**1.000**	92.13±7.97	1.000

When blood glucose levels were compared between groups, it was found that 2nd and 4th hour measurements were significantly higher in Group 1 in comparison with Group 2 ($p< 0.05$).

There was no significant difference between the groups in terms of patient satisfaction (Table 4) ($p > 0.05$).

Table 4. Comparison of patient satisfaction scale between groups.

	Group 1	Group 2
Bad (0-1)	%13.3(4)	%13.3(4)
Good (2)	%43.3(13)	%33.3(10)
Excellent (3-4)	%43.3(13)	%53.3(16)
P	0.704	

4. Discussion

In this study, we compared the effect of two different steroid preparations combined with local anesthesia administered by epidural method on blood glucose levels and chronic low back and leg pain related to radiculopathy in non-diabetic adult patients aged 18-65 years.

Injection of corticosteroids into the epidural space is a non-surgical interventional method that is used the treatment of pain. The use of this method in the treatment of low back and leg pain was first reported in 1925 by caudal procaine injection. In 1952, Robecci and Kapra reported the injection of hydrocortisone to the first sacral canal in patients with low back and leg pain, and Lievre reported lumbar epidural hydrocortisone injection for the treatment of low back pain in 1957 (Güldoğuş, 2007). Epidural steroids are used because of abnormal nociceptive formation around the lesion and secondary neuroradiculitis caused by inflammatory mediators (Güldoğuş, 2007). Corticosteroids inhibit prostaglandin synthesis, stabilize cellular membranes, and block the delivery of nociceptive C fibers. The point of effect of corticosteroids on eicosanoid synthesis is the step in which arachidonic acid forms from membrane phospholipids, and they exert their effect by inhibiting phospholipase A2 enzyme catalyzing this step (Saal and Saal, 1989; Güldoğuş, 2007). Epidural steroids can be applied in 3 different regions (cervical, thoracic and lumbar) by 2 different ways (interlaminar and transforaminal epidural) and caudally. In this study, steroid medication was administered to the lumbar epidural area via interlaminar way.

VAS is a simple, reliable, and quick method of measuring pain severity in the clinic. It is highly sensitive in evaluating efficacy of pharmacologic and nonpharmacologic treatments that reduce pain. Its correlation with verbal and numerical pain scales is good. Akbaş et al. (2009) examined 30 patients with radiculopathy for the efficacy of transforaminal epidural steroid injection. Patients were injected at the level of disc herniation, and pain severity was assessed with Verbal Numerical Rating Scale (VNRS) and satisfaction level was assessed with a 4-point scale at the end of the study. It was found that transforaminal epidural steroid injection significantly reduced pain for up to 3 months in the treatment of patients with radiculopathic pain (Akbaş et al., 2009). Interlaminar epidural injection method was chosen in our study because efficacy of epidural injection is not observed since there is no previous epidural injection; the transforaminal procedure is performed under fluoroscopy and includes radiation, is more difficult and may cause more neuronal damage. Our study suggests that betamethasone and triamcinolone cause a significant decrease in VAS values compared to pre-intervention values and may be administered epidurally in patients with chronic low back pain. In a study conducted by Gelalis et al. (2009), 40 patients with radiculopathy due to L4-L5 and L5-S1 disc herniation were treated with three epidural steroid injections consecutively every 24 hours via spinal catheter, and the other group was treated with three epidural steroid injections intermittently over 10 days via epidural needle. The VAS score of all patients decreased with respect to baseline at 1st month of follow-up and there was no significant difference between the two groups. VAS scores were found to be significantly lower in the group that was injected with epidural needle at 2nd month of follow-up (Gelalis et al., 2009). In a study by Ho-Joong Kim et al. (2012), the efficacy of transforaminal epidural steroid injection in lumbar disc herniation was examined. Fifteen patients with lateral herniation of the lumbar disc and 70 patients with interspinal lumbar disc herniation were included in the study. No difference was found between the two groups for VAS and Oswestry disability index (Kim et al., 2012). In the study of Benoist et al. (2012), the efficacy and safety of epidural steroid injection in the treatment of low back pain caused by radiculopathy was examined, and Cochrane performed a literature review. As a result, epidural steroid injections were generally well tolerated and most of the complications were due to technical problems (Benoist et al., 2012). No complications were observed in our study. In the study conducted by Ho-Jong Kim et al. (2013), the efficacy of two different methods for herniated lumbar disc-induced pain, epidural neuroplasty and transforaminal epidural steroid injection were compared. VAS and functional measurement index were assessed before treatment and at 2nd, 4th, and 8th weeks after treatment. VAS and functional measurement index decreased markedly after both treatments. As a result, they concluded that epidural neuroplasty and transforaminal epidural steroid injection were equally effective treatments for lumbar disc herniation (Kim et al., 2013a). In two different controlled studies conducted by Kraemer et al. (1997) on 182 patients, epidural perineural injection, conventional posterior epidural injection, and paravertebral local anesthetic were administered as control group in patients with lumbar radicular syndrome. Epidural perineural injections were found to be more effective than conventional posterior epidural injections. They reported that both groups administered with epidural injections had better results than the group receiving paravertebral local anesthetic injection. There were no serious complications or side effects in any group. Studies have shown that single shot epidural injection is effective in treating lumbar radiculopathy

(Kraemer et al., 1997). In a meta-analysis of 12 randomized clinical trials conducted by Koes et al. (1995), six of the studies showed that epidural steroids were more effective, while the other six reported that they were no better or worse than the reference treatment. In a meta-analysis of 11 placebo-controlled studies conducted by Watts and Silagy (1995), improvements were observed in both short-term (1-60 days) and long-term (12 weeks-1 year). In our study, the fact that betamethasone lowered VAS value more than triamcinolone in the early post-injection period can be attributed to the faster initiation of analgesic and antiinflammatory effect of betamethasone combined with local anesthetic than triamcinolone. On the other hand, in the late period, although the duration of action of betamethasone was longer, triamcinolone caused a further decrease in VAS values.

The effects of steroid agents on blood glucose are known; glucocorticoids stimulate gluconeogenesis to increase blood glucose, and the hypothalamo-hypophyseal axis is blocked by negative feed-back. Even et al. (2012) studied the effect of epidural steroid injection on blood glucose levels in diabetic patients. In diabetic patients, epidural steroid injection significantly increased blood glucose and these effects did not last longer than 2 days. In our study, the effect of betamethasone and triamcinolone on blood glucose was investigated. Betamethasone significantly increased blood glucose in the early period after epidural injection, and there was no significant difference in subsequent measurements. In triamcinolone treated patients, there was no change in blood glucose levels. In the study of Zufferey et al. (2011), the systemic effects of epidural injection of methylprednisolone on glucose tolerance in diabetic patients were investigated. The aim of the study was to investigate the effect of intra-articular or epidural 80 mg methylprednisolone acetate on glycemic profile in diabetic patients. In five patients treated with epidural injection, the glycemic profile did not change or the change was negligible, and blood glucose was increased by 3 mmol/lt for the next two days in the group given intraarticular steroids. Significant differences were observed in each individual treated with intraarticular injection. This is the first study to show that single dose epidural injection of depot methylprednisolone has no effect on glycemic control in diabetic patients. The absence of glycemic control changes was highly correlated with the low urinary excretion of the drug after epidural injection. In the study of Younes et al. (2007), systemic effects of epidural and intraarticular glucocorticoid injections were evaluated in diabetic and non-diabetic patients. Basal blood glucose increased significantly on day 1. In 12 patients, blood glucose levels significantly increased at day 7 compared to baseline levels. Plasma ACTH, cortisol and urinary cortisol increased markedly in the entire population on days 1 and 7. On day 21, these values were decreased in the epidural injection group whereas they were normal in the intraarticular group (Younes et al., 2007). In a prospective cohort study performed by Gonzales et al. (2009), lumbosacral or caudal epidural betamethasone was administered to 12 diabetic patients for neurogenic claudication or radicural pain. Fingertip blood glucose level was measured 2 times a day for 3 days before the injection, on the injection day, and for 3 days after the injection. A significant increase was found in blood glucose levels for the next 3 days after injection. It was found that this increase peaked on injection day and ended in about 2 days (Gonzales et al., 2009). In Kim et al.'s study (2013b), the effect of two different epidural steroid doses on blood glucose level and pain control in diabetic patients was examined. In one thousand diabetic patients, lumbar transforaminal, lumbar interlaminar, or caudal epidural thiramycinolone injection was performed at 20 mg and 40 mg doses for radiculopathy and spinal stenosis. On the next day after the injection, a significant increase in fasting blood glucose levels was found in the group administered with 40 mg dose, and a significant increase was found in postprandial blood glucose levels in both groups. High doses of triamcinolone increased fasting and postprandial blood glucose levels more, but there was no difference in pain control. Accordingly, 20 mg triamcinolone was found to be more recommendable than 40 mg in diabetic patients in terms of blood glucose and pain control. In our study, there was no change in blood glucose in non-diabetic patients who received triamcinolone. Our results suggest that triamcinolone may be more likely to be recommended in both diabetic and nondiabetic patients, as it causes less irregularity in blood glucose levels compared to betamethasone. In a study conducted by Moon et al. (2014), 29 diabetic and non-diabetic patients with sciatic or shoulder pain were treated with epidural or intra-articular glucocorticoid injection on the shoulder, and the changes in blood glucose and cortisol levels were examined. In patients, the fasting plasma glucose level was significantly increased the next day after injection but returned to the baseline value on the 7th day after injection. Cortisol levels decreased significantly on days 1 and 7 after injection compared to baseline. Moon et al. (2014) demonstrated the necessity of paying close attention to glucocorticoid injection treatment in diabetic patients, especially epidural injections, but they did not find any difference between the groups in terms of patient satisfaction, and both groups were evaluated with perfect scores. In the study conducted by Çetin et al. (2012), the efficacy and safety of transforaminal lumbar

epidural steroid injection in patients with radiculopathy due to lumbar disc herniation were investigated. In the patient satisfaction questionnaire, 63.9% of the patients stated their satisfaction as 'good or excellent (Çetin et al., 2012).

In conclusion, it was observed that triamcinolone and betamethasone combined with local anesthetic were effective on chronic low back and leg pain due to radiculopathy. Betamethasone was found to be more effective in the short term after injection, whereas triamcinolone was more effective in the long term. Triamcinolone did not cause changes in blood glucose levels after epidural injection. On the other hand, betamethasone significantly increased blood glucose levels in comparison with triamcinolone in the early period after epidural injection. Triamcinolone and betamethasone resulted in similar levels of patient satisfaction in the treatment of chronic low back and leg pain associated with radiculopathy. Triamcinolone not changing blood glucose levels can be regarded as an advantage of this treatment.

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