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The efficacy of lumbar epidural steroid injections in "failed back surgery syndrome" and lumbar radiculopathy

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ABSTRACT

Aims: Lumbago is one of the common conditions in our present community. Definite periods of human's life people encountered in the form of usually regressing attacks that 10-15% of this important condition requires surgical therapy. Cause of wrong diagnosis and treatment Spinal surgery may not always give favourable result. Patients undergone one or more back surgery exist back and/or leg pain which does not improve, is called failed back surgery syndrome. Epidural steroid administration is one of the most invasive method which is used in back pain. Effects and application results are controversial. İn this study we aimed to compare the effects of steroid and local anesthetic solutions which administered by epidural way on pain controlling between the patients that have chronic back pain because of lomber radiculopathy, undergone surgery and not surgery.

Methods: It was evaluated retrospectively pain controlling effect of administered steroid and local anesthetics by interlaminal epidural way to ASA 1-2-3, between 18-80 aged 40 patient which undergone piror one or plural back surgery and have no surgery between May 2009-December 2009 apply with back pain complaint to İstanbul Training and Research Hospital Algology Department. Patient's visuel analog scala (VAS) and severity of back pains, before procedure, second week after procedure, fourth week after procedure, sixth week after procedure in either two groups out of ten points was estimated.

Results: Totally of 7 ml solution which contains 1 ml triamsinolon asetonid 40 mg/ml (Sinakort-A ampul, İ.E. Ulugay), 3 ml levobupivacaine 5 mg/ml (Chirocaine ampul, Abbott) and 3 ml serum phsiyologic (0.9% NaCl) administered by epidural way into either two group patients. There were no significant difference between two groups by mean of age, weight, height, BMI and back pain durations. Evaluating the groups into themselves, opioid requirements and VAS scores before injection was markedly higher than 2nd, 4th and 6th week scores in either two groups ($p<0.05$). There was no statistically significant difference when we compare into groups of 2nd, 4th and 6th week opioid requirements and VAS scores in either two groups. All patient manifested their pleasure and there was no complication occured.

Conclusion: Consequently; it was thought that epidural administration of steroid (triamsinolon), local anesthetics (levobupivacaine) and serum physiologic solution was effective especially on early back pain treatment, also safe method and beneficial to patient satisfaction in the patients who has failed back surgery and chronic back pain.

Keywords: Radicolopaty, pain, steroid

INTRODUCTION

It has been determined that 70-90% of individuals in contemporary society experience lower back pain at least once in their lives. While 75-85% of acute lower back pain cases can be self-resolving within 6-8 weeks without the need for any treatment, 38% of these cases may experience a second attack within a year, and new acute attacks can occur in 41% of subacute lower back pain cases and 81% of chronic lower back pain cases within the same year.[1]

The lack of a developed algorithmic, multidisciplinary approach in the diagnosis and treatment of back pain may be one of the main reasons for unsuccessful and incorrect treatments. Surgical treatment is required in only 10-15% of patients with disc herniation.[2] While the rate of disc herniation in patients with low back pain is given as 5%, one of the leading causes among back operations is lumbar disc herniation; This makes us think about the conditions

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under which disc surgery is actually indicated.[3,4] The presence of persistent back and/or leg pain in patients who have undergone one or more back surgeries is called failed back surgery syndrome (FBSS). It is one of the problems that spinal surgeons frequently encounter. The most common causes include misdiagnosis, operating at the wrong level, and inadequate surgery.[5] Regardless of the cause of low back pain, the treatment should be arranged in accordance with the algorithm and conservative treatment methods should be applied initially. First of all, the patient's symptoms are controlled and the dysfunctions caused by pain are tried to be reduced as much as possible.[6] Epidural steroid injection is one of the non-surgical treatment methods for neck and low back pain. Bed rest may be preferred for disc-related waist, leg, neck and arm pain that does not improve with conservative methods such as medication and physical therapy and does not have neurological deficit.[7]

This study aims to compare the effectiveness of epidurally administered steroids and local anesthetic solutions in controlling pain between patients who have undergone surgery for chronic back pain due to lumbar radiculopathy (FBSS) and those who have not undergone surgery.

METHODS

This study was produced from a thesis done in 2010 with the approval of the institution.All procedures were carried out in accordance with the ethical rules and the principles of the Declaration of Helsinki. This retrospective study included 40 consecutive patients aged 18-80, classified as ASA 1-2-3, who had previously undergone one or more back surgeries and had not undergone surgery, and who presented to the Algology outpatient clinic of a university hospital with complaints of back pain between May 2009 and December 2009. The participants were divided into two groups: the Failed Back Surgery Syndrome (FBSS) Group, consisting of 20 patients who had previously undergone one or more back surgeries but continued to experience back and/or leg pain, and the Chronic Back Pain (CBP) Group, consisting of 20 consecutive patients with back pain for at least 3 months, with radicular symptoms in the examination, unresponsive to medical treatment, and with magnetic resonance ımaging (MRI) findings consistent with their clinical symptoms.

Inclusion Criteria

Patients fasting for 8 hours before the procedure. Patients with recorded cardiac rhythm, pulse-oximeter, and non-invasive blood pressure measurements in the operating room. Patients with recorded VAS scores routinely taken in our clinic before the procedure, and complete VAS records at pre-procedure, post-procedure, and at the 2nd, 4th, and 6th weeks. Patients in whom a 22G intravenous cannula was inserted into the dorsum of the hand and 500 ml of 0.9% isotonic NaCl solution was administered for premedication before the operation. Patients who received a total of 3 mg of midazolam intravenously for premedication purposes before the operation. Patients included in the study received a combination of interlaminar epidural steroids and local anesthetic components: 1 ml of triamcinolone acetonide 40 mg/mL (Sinacort-A ampule, İ.E. Ulagay), 3 mL of levobupivacaine 5 mg/mL (Chirocaine ampule, Abbott), and 3 mL of physiological saline (0.9% NaCl).

VAS

A 10-point horizontal line was used to indicate pain intensity, with the left side of the line indicating no pain (0 points) and the right side indicating unbearable pain (10 points). Patients were asked to mark their pain level on this line. VAS values of 3 and below were considered to provide effective analgesia.

Exclusion Criteria

Patients who refused to participate in the study. Patients with bleeding diathesis, local infection, or allergy to the drugs used. Pregnant or lactating women. Patients using anticoagulant drugs or platelet aggregation inhibitors. Patients with a history of psychiatric illness. Patients with conditions that may interfere with the evaluation of treatment effectiveness, such as known allergy to steroids. Patients with clinically significant spinal stenosis that may cause neurological deficits. Patients with known systemic diseases (such as diabetes mellitus, chronic renal failure, chronic obstructive pulmonary disease, etc.) that may cause peripheral neuropathy. Patients who received psychological therapy within the last year or planned to receive therapy during the study. Patients who had undergone surgery in the last 6 months. Patients with malignant tumors. Patients with suspected somatic diseases.

Procedure

Visual analog scale (VAS) scores were routinely recorded before the procedure in our clinic. After premedication and a 10-minute wait, patients were placed in the lateral decubitus position with the side where radiculopathy complaints were prominent facing downward. After cleaning the skin with an appropriate antiseptic solution, infiltration anesthesia was applied by injecting 3 ml of 2% lidocaine subcutaneously from the level of the vertebra causing radicular pain. The epidural space was reached with an 18 G Toughy needle using a midline approach and loss of resistance. After confirming the absence of blood or cerebrospinal fluid, the prepared standard solution was injected into the epidural space. Patients were observed for 3 hours, and those without any complications were discharged.

All patients were called for follow-up visits at the 2nd, 4th, and 6th weeks after the injection. During the follow-ups, records were kept regarding VAS scores, opioid use, side effects, patient satisfaction, and recommendations to others.

Statistical Analysis

Statistical analyses were performed using the Statistical Package for the Social Sciences (SPSS) version 18.0 software program. Categorical variables were expressed as percentages, and continuous variables were expressed as mean±standard deviation. The chi-square test was used to compare categorical variables between groups, while independent samples t-test was used to compare continuous variables. Related sample one-way analysis of variance (ANOVA) was used for intra-

group comparisons, and chi-square test and Fisher's exact chi-square test were used for comparison of qualitative data. Benferroni correction was made for intra-group comparisons and the p significance value was taken as 0.008 and corrected to 0.05. Repeated-measures (ANOVA) was used to evaluate changes in VAS scores over time within each group. P-values less than 0.05 were considered statistically significant.

RESULTS

A total of 40 patients were included in the study, with 20 patients in each group. The demographic characteristics of the patients are presented in (Table 1). There were no statistically significant differences between the two groups in terms of age, sex, body-mass index (BMI), and duration of pain.

Table 1. Demographic data and pain characters

	FBSS group	CBP Group	p
Age, mean±SD	51.65±12.39	55±13.92	0.426
Sex, n (%)			
Male	8 (40)	6 (30)	
Famele	12 (60)	14 (70)	0.507
Height (cm), mean±SD	164.75±9.73	163.75±7.69	0.720
Weight (kg), mean±SD	63.8±12.34	68.85±8.74	0.144
BMI (kg/m^2), mean±SD	23.47±3.89	25.81±3.84	0.063
Back pain duration(month), mean±SD	6.25±7.12	9.55±9.37	0.218
Pain location			
Right leg, n(%)	6 (30)	3 (15)	
Left leg, n(%)	6 (30)	5 (25)	0.389
Both right and left leg, n(%)	8 (40)	12 (60)	
VAS			
Before drug administration, mean±SD	7.35±0.75	7.15±1.04	0.489
2nd week, mean±SD	2.7±2.25	2.7±2.01	1
4th week, mean±SD	3.75±2.17	3.1±1.65	0.294
6th week, mean±SD	4.2±2.02	3.65±1.69	0.356

FBSS: Failed back surgery syndrome, CBP: Chronic back pain, SD: Standard deviation, BMI: Body mass index, VAS: Visual analog scale

Between the two groups, there is no statistically significant difference in VAS values before injection, at 2nd, 4th, and 6th weeks (p>0.05). When evaluated within each group, pre-injection VAS values were significantly higher than the 2nd, 4th, and 6th week VAS values in both groups (p<0.001). In Group FBSS, the measured VAS values at the 2nd week were significantly lower than the 6th week VAS values (p=0.035). Other than this, there was no statistically significant difference in VAS values at 2nd, 4th, and 6th weeks in intra-group comparisons (FBSS group 2nd/4th week VAS: p=0.208, 4th/6th week VAS: p=0.423. CBP group 2nd/4th week VAS p=1, 2nd/6th week VAS p=0.321, 4th/6th week VAS p=0.365) (Table 2).

When evaluated within each group, pre-injection opioid requirements were significantly higher than the 2nd, 4th and 6th week VAS values in both groups (p<0.05) (Table 3). Other than this, there was no statistically significant difference in opioid requirements at 2nd (p=0.478), 4th (p=0.34), and 6th (p=0.759) weeks between the two groups (Table 4).

None of the patients who participated in the study experienced any of the possible side effects, including nausea, vomiting, tremors, hypotension, hypertension, allergy, bleeding, and urinary incontinence.

Table 2. VAS values of patients are updated according to the weeks within their group

Opioid requirements	FBSS Group		CBP Group	
	mean	P	mean	P
Before injection/2nd week	7.35±0.75/2.70±2.25	0.000	7.15±1.04/2.70±2.01	0.000
Before injection/4th week	7.35±0.75/3.75±2.17	0.000	7.15±1.04/3.10±1.65	0.000
Before injection/6th week	7.35±0.75/4.20±2.02	0.000	7.15±1.04/3.65±1.69	0.001
2nd week/4th week	2.70±2.25/3.75±2.17	0.208	2.70±2.01/3.10±1.65	1.000
2nd week/6th week	2.70±2.25/4.20±2.02	0.035	2.70±2.01/3.65±1.69	0.321
4th week/6th week	3.75±2.17/4.20±2.02	0.423	0.30±0.47/3.65±1.69	0.365

FBSS: Failed back surgery syndrome, CBP: Chronic back pain

Table 3. Distribution of patients' opioid needs within the groups based on days

Opioid requirements	FBSS Group		CBP Group	
	mean	P	mean	P
Before injection/2nd week	1±0/0.20±0.41	0.000	1±0/0.30±0.47	0.000
Before injection/4th week	1±0/0.45±0.51	0.001	0.30±0.47	0.000
Before injection/6th week	1±0/0.50±0.51	0.002	1±0/0.45±0.51	0.001
2nd week/4th week	0.20±0.41/0.45±0.51	0.338	0.30±0.47/0.30±0.47	1.000
2nd week/6th week	0.20±0.41/0.50±0.51	0.179	0.30±0.47/0.45±0.51	1.000
4th week/6th week	0.45±0.51/0.50±0.51	1.000	0.30±0.47/0.45±0.51	0.497

FBSS: Failed back surgery syndrome, CBP: Chronic back pain

Table 4. Distribution of patients' opioid needs by group

Opioid requirements	FBSS Group		CBP Group		
	mean	SS	mean	SS	P
Before injection	1	0.00	1	0.00	
2nd week	0.20	0.41	0.30	0.47	0.478
4th week	0.45	0.51	0.30	0.47	0.340
6th week	0.50	0.51	0.45	0.51	0.759

FBSS: Failed back surgery syndrome, CBP: Chronic back pain

DISCUSSION

When groups were evaluated internally, pre-injection VAS values were significantly higher than the 2nd, 4th, and 6th-week VAS values in both groups (p<0.001). Apart from this, there was no statistically significant difference in intra-group comparisons of VAS values at 2nd, 4th, and 6th weeks. When groups were evaluated internally, pre-injection opioid requirements were significantly higher than the 2nd, 4th, and 6th-week VAS values in both groups (p<0.05). There was no statistically significant difference in opioid requirements between the two groups at the 2nd (p=0.478), 4th (p=0.34), and 6th (p=0.759) weeks.

Epidural steroid injection (ESI) is used in the treatment of symptoms of lumbosacral radicular or axial pain caused by spinal stenosis or disc herniation.[8] Epidural steroid injection is used for secondary neuroradicularitis caused by abnormal nociceptive and inflammatory mediators around lumbosacral disc herniation.[9] Administered corticosteroids inhibit prostaglandin synthesis, stabilize membranes, block the transmission of nociceptive C fibers, suppress the immune response, increase neuronal blood flow, and accelerate the removal of inflammatory mediators from tissues.[10-13] The success rate of ESI in patients with low back pain lasting less

than 3 months has been shown to be between 83% and 100% in various studies.[14]

Although the success rates of ESI for acute and chronic back pain are initially similar, they decrease to 34% for acute pain and up to 12% for chronic pain at 6 months.[15] In our studies, we found a high success rate in the early period, consistent with the literature. ESI applications should be made at the level where the painful dermatome is closest to the root. The most commonly used steroids are methylprednisolone and triamcinolone. Local anesthetic is added to the combination to be injected, which prevents muscle spasm associated with back pain and also has an effect on root irritation by creating sympathetic blockage.[16] In addition, reflex sympathetic dystrophy that may occur can also be prevented. In our studies, we used a combination of triamcinolone, levobupivacaine, and saline. Studies show that the success rates of surgeries performed for lumbar discopathy exceed 80%. And, after discectomy, up to 70% of patients develop resistant back pain to varying degrees over the years.[17] As the number of surgeries performed increases, the success rate decreases to 5%.[18] Because the etiology of FBSS is very diverse, treatment should be directed towards the cause with a multidisciplinary approach. The success rate of surgical intervention for recurrence or residual disc herniation is close to the success rate of the initial surgery.[19] Back pain is one of the significant causes of workforce loss. According to studies conducted in the United States, the cost of a patient being treated lying down for chronic back pain is estimated to be $17,225 per year, while outpatient treatment is between $7,000 and $10,000. Guo et al.[20] found that in the United States, back pain caused 150 million workdays and a loss of $14 billion annually. They stated that even if improvement is achieved in 1% of these patients, millions of dollars in losses could be prevented. ESI application is both an effective and inexpensive treatment method from this perspective.

One of the biggest challenges faced by those dealing with spinal surgery is the treatment of patients with chronic back pain and/or leg pain. In this case, the most important and effective approach is to surgically remove pathologies that can be removed after examinations, and if there are no indications for decompression, to use other treatment methods.[5] At this stage, if short-term and rapid recovery is desired, epidural steroid application can be applied.[6] In the chronic period after spinal surgery, recurrence of disc herniation, scar tissue, pseudofusion, instability, spinal stenosis, and secondary gain should be investigated in patients complaining of pain.[5]

Adhesions in the epidural space can be seen due to various etiologies such as surgical disc herniation, disc fragmentation, infection, vertebral body fracture, arachnoiditis, mechanical instability, pseudomeningocele, and trauma. Studies have suggested that adhesions in the epidural region may prevent the steroid from reaching the target area, leading to inadequate pain control.[21] They added hyaluronidase to the solution prepared to eliminate these adhesions.[21,22] Although some studies show effectiveness, in some studies, no significant difference has been found. The sole cause of epidural adhesions is not surgical interventions. Epidural adhesions can also be observed in non-operated patients. In studies related to ESI, patients with back pain generally caused by the same etiology are preferred. In this thesis study, we aimed to compare the effectiveness of ESI application in patients with FBSS who underwent surgery and patients with CBP who did not undergo surgery.

When each group was evaluated internally, opioid requirements before injection were significantly higher than opioid requirements at 2nd, 4th and 6th weeks. This led us to the conclusion that ESI provided effective analgesia in both groups. There was no statistically significant difference in terms of opioid requirements at 2nd, 4th and 6th weeks both within groups and between groups.

Carette et al.[23] reported in their studies that they performed the 2nd injection to 49% of patients with back pain for 1 month to 1 year, the 3rd injection to 29%, and at the end of the 3rd month, there was no difference between the ESI group and the Placebo group, and 55% of patients were successfully treated. Buchner et al.[24] reported a success rate of 41.5% in their studies. In our study, we achieved a high success rate in the early period with ESI application in patients with chronic back pain lasting more than 3 months.

The effectiveness of steroids administered epidurally varies from 18% to 100% in various publications. Saal et al.[25] investigated the possible reasons for this and suggested factors such as the presence of serious pathology, failure to deliver the corticosteroid to the target area, decreased activity after the block, and non-injection factors such as not suppressing the pain generator as reasons for the failure of steroid injection.

Riew et al.[26] investigated the effectiveness of epidural corticosteroids in a randomized, prospective, controlled double-blind study. Patients were followed up at 2-4-8 weeks after injection and 1 year. Steroid and local anesthetic or local anesthetic alone were given to patients who had previously undergone surgery, and improvement in back and leg pain was less observed in patients who had undergone surgery compared to patients who had not undergone surgery. Both acute and chronic complaints regressed with ESI application. In patients treated with corticosteroids, surgery was not necessary in 71%, while in the local anesthetic group, it was not necessary in 33%.

In our study, there was no statistically significant difference in VAS values between the FBSS group, consisting of surgically treated patients, and the CBP group, consisting of patients with chronic back pain who did not undergo surgery. Although the average VAS values of Group FBSS at 4th and 6 weeks were slightly larger than those of group CBP, this is not statistically significant. No major complications have been reported in large series studies published. The most commonly observed complication is accidental puncture. In our study, we investigated possible complications and side effects, such as nausea, vomiting, tremors, hypotension, hypertension, allergy, bleeding, accidental puncture, and urinary incontinence with spinal block. We did not encounter any complications or side effects in our study.

We have some limitations in this study. First of all, the study is retrospective and single-center. Number of patients in our study Since it is a limited and single-center study, the

results cannot be generalized to a wider population. For this, prospective studies including more patients are needed.

CONCLUSION

It has been concluded that the application of epidural space to steroid (triamcinolone), local anesthetic (levubupivacaine), and saline solution is an effective, reliable method in the treatment of early-stage back pain, especially in patients who have undergone unsuccessful back surgery and in patients with chronic back pain. It has been found to be beneficial in terms of patient satisfaction.

ETHICAL DECLARATIONS

Ethics Committee Approval

This study was produced from a thesis done in 2010 with the approval of the institution.

Informed Consent

Because the study was designed retrospectively, no written informed consent form was obtained from patients.

Referee Evaluation Process

Externally peer-reviewed.

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

Financial Disclosure

The authors declared that this study has received no financial support.

Author Contributions

All of the authors declare that they have all participated in the design, execution, and analysis of the paper, and that they have approved the final version.

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