J Minim Invasive Surg Sci. 2016 February; 5(1):e34136. doi: 10.17795/minsurgery-34136.

Published online 2016 February 27. **Research Article**

The Relation Between Injection Volumes and Efficacy of Epidural Steroid Injections in Treatment of Acute Low Back Pain

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Received 2015 October 28; **Revised** 2015 December 31; **Accepted** 2016 January 12.

Abstract

Background: Low back pain (LBP) is one of the most common complaints that is reported by all age groups.
Objective: This study was aimed to investigate the efficacy of epidural steroid injections (EPSI) related to different volume injections for treatment of acute low back pain with radiculopathy.
Patients and Methods: The study is consisted of seventy five patients who had acute discogenic pain. Three groups composed namely Group 1, Group 2 and Group 3. All patients were assigned to one of the groups randomly and recevied combination of triamcinolone (80 mg) and bupivacaine (12.5 mg) as a single epidural dose. Volume of 10 mL, 15 mL, and 20 mL epidural injections were used for Group 1, 2 and 3 respectively. The efficacy of treatment was assessed with visual analog scale; VAS (O = no pain, 10 = unbearable pain) straight leg elevation test; SLET (0° = worst, 85° = best), and oswestry disability index; ODI (0 to 20%: minimal disability, 80 to 100%: bed bound patients) before and 2 weeks after the epidural steroid injections (EPSI).
Results: Fifty seven 57 (76%) female and 18 (24%) male were entered to the study. Two weeks after the procedure, significant improvement was observed in each group regarding the results of VAS, SLET and ODI. Temporary radicular pain, not required treatment, was reported for 10 patients; 40% of group II and 18 patients; 72% of group III, but not reported in group I ($P < 0.001$).
Conclusions: Different volumes of EPSI in patients with acute low back pain associated with radiculopathy causes significant pain relief in all groups. There was no superiority between the groups. Temporary radicular pain we encountered can be explained by high volumes.

Keywords: Epidural Analgesia, Low Back Pain, Acute

1. Background

Low back pain (LBP) is one of the most common complaints that is reported by all age groups (1).

Epidural steroid injections (EPSI) are frequently utilized in treatment modalities in managing chronic low back and lower extremity pain due to disc herniation and radiculitis (2). Despite the extensive literature on the subject, controversy regarding their safety and efficacy continues (3).

Some studies suggest that there may be a relation between the efficacy of EPSI and the volume injected, but this relationship is not confirmed yet (4-6).

Transforaminal ESI techniques are more recent and were initially implemented for preoperative verification of root compression sites (7). Interspinous epidural injections are easy to perform, even in the practitioner's office, with a low risk of complications. Transforaminal injections are more technologically complex and require radioscopic or computerized tomography control (8), thus exposing the patients to radiation. The rates of complications were not different between interspinous and transforaminal approaches (9). Ninety-seven percent of academic institutions and 79 percent of private practices polled the loss of resistance technique as the primary means to identify the epidural space (10).

2. Objectives

We aimed to investigate the efficacy of epidural steroid injections (EPSI) related to different volume injections for treatment of acut low back pain with radiculopathy.

3. Materials and Methods

With the approval of local ethics committee of faculty and informed consent, 75 patients (25 - 60 years old),

ASA (American society of anaesthesiologist) with physical status I or II, were enrolled in this prospective and randomized study. These patients were admitted to the algology and orthopedic clinics of the authers' institution from September 2008 through May 2013. At admission, a precise locomotor system examination, four-view lumbosacral vertebrae radiograhys, lumbar magnetic resonance imaging (MRI) and routine blood exams were performed for each patient.

Criteria for inclusion in this trial were: (1) acute low back pain of less than three months duration not responding to other modalities of conservative management [NSAIDs, physiotherapy, bracing, etc.]; (2) unilateral radicular type of pain; (3) association with lumbar nevre root compression confirmed by MRI, which indicates disc herniation corresponding to the clinical symptoms of nevre root compression; (4) age older than 25 years; (5) an Oswestry daily activity score (11) more than 20 percent; (6) resistance to treatment.

Exclusion criteria were: (1) bilateral root impingement symptoms; (2) neurological deficits; (3) history of previous lumbar disc surgery; (4) known allergy to the drugs used in the study; (5) severe clinical ailments such as cardiac disease, glaucoma, and chronic renal failure. Many of our patients especially patients with cardiac disease and neurological deficits, were excluded from the study. Therefore the duration of the study lasted long. However, these patients were not recorded because the study excluded.

Consecutive sampling was our sampling method. Patients assigned to one of three groups randomly. The patients were randomly assigned according to a computer-generated random number list into three groups of 25 patients each receive either different volume of normal saline (0.9% NaCl). Patients were blinded (they didn't aware of their injection type). Groups had different volumes of normal saline (0.9% NaCl). All patients received 80 mg of triamcinolone acetonide [Kenacort ampule, Bristol-Myers Squibb] and 12.5 mg bupivacaine [MarcaineTM 0.5% Flakon, AstraZeneca] combination. Volume of 10 mL, 15 mL, and 20 mL epidural injections used for Group 1, 2 and 3 respectively. Systolic (SAP) and diastolic (DAP) arterial pressures, heart rate (HR) and SpO_2 were monitored. Normal saline solition was infused through an intravenous (i.v.) cannula (22 G) at 6 $mLkg^{-1}$. Patients were given a sitting position so that the lumbar lordosis flattened as much as possible. A 18 gauge Touhy needle used for epidural injection in the interspinous space of the involved segment (in case of multiple, injection was performed in the midline), "loss of resistance" technique is used. Suction in four directions applied to make sure that tip of the needle was not in the subdural space after that, needle was redirected to the side of the root compression and 4 ml of the prepared solution injection was made. Five minutes later and after making sure that there is no spinal block, rest of the solution was injected in a four quadrant. The epidural injection is carefully and aseptically transferred to the anesthesiologist who injects it slowly (approximately in 10 seconds) through the epidural needle. The procedure continued since 10 – 15 - 20 mL of epidural steroid injections was injected totally or since low back pain, radicular pain spraded to legs.

15 minutes after the procedure, the pin-prick testing in the lower extremities is used for testing the epidural analgesia. 10 to 20 minutes after local anesthesia during epidural block; adequate dosages of anesthesics exists in spinal nerve roots and rootlets. Diffusion to intradunal spinal roots at early stages of epidural anesthesia is important. Because of this, patients were kept lying for 30 minutes on the side relevant to the discal radiculalgia or in supine position. During and after two hours of the operation, patients were observed for EPSI. Patients arterial pressures (SAP, DAP), HR and SpO_2 were noted before the epidural analgesia was started, and at 5 and 10 min and then every 15 minutes during 2 hours. Also possible side effects including nausea, hypotension, accidental dural puncture, bradicardia and radicular pain during injection were noted. Any potential late complication was documented (epidural abscess, bacterial meningitis, etc.). All enrolled patients completed the study.

The efficiency of treatment was assessed using visual analog scale (VAS: 0= no pain, 10 = unbearable pain). The objective assessment was done by straight leg elevation test (SLET: 0° = worst, 85° = best), and the daily activities were evaluated [walking, sleeping, social activities, etc.] by the Oswestry disability index (ODI: 0 to 20 = minimal disability, more than 35 = severe disability, 80 to 100% = bed bound patients) before and 2 weeks after the EPSI.

3.1. Statistical Analysis

Data are given as the mean $\pm$ SD and median, as propriate. Statistical Package for the Social Sciences (SPSS) version 13.0 was used for statistical analysis of the data. P value of $<$ 0.05 was considered statistically significant. A power analysis was performed to determine the extent to which proposed sample size in designing stage of study. Power analysis was performed based on 3 $\pm$ 3.5 unit changes of VAS scores between pre and post treatment. To detect significant changes between pre and post treatment, minimum sample size was determined as 22 for each group ($\alpha = 0.05$, $1\text{-}\beta = 0.80$). Statistical analysis was performed with Kruskal-Wallis test for comparisons between the groups, One-way ANOVA and paired t-tests were used for intra-group comparisons.

4. Results

Fifty seven (76%) female and 18 (24%) male entered the study. Groups were similar regarding age, sex, mean duration of pain prior to EPSI (Table 1). L3-L4 was the most affected level in patients (Table 1).

In none of the patients we needed to change the position of the needle due to motor block from the first 4 mL of the injected solution which indicates the malposition of the needle. Two weeks after the procedure, significant improvement was observed in each group regarding the results of VAS, SLET and ODI. The mean VAS scores were 8.5 ± 0.5, 8.3 ± 0.7, 8.4 ± 1.1 before the EPSI and improved statistically significant to 3.1 ± 0.9, 2.7 ± 1.5, and 2.8 ± 1.4 for group I, II and III respectively ($P < 0.01$). Moreover, the degree of painful leg elevation was increased in SLET in all groups as well as better scores in Oswestry disability index ($P < 0.05$). The results were summarized in the Table 2. The intra- and intergroup differences in SAP, DAP, HR and SpO_2 of patients were not significant ($P > 0.05$).

No side effects (including nausea, hypotension, accidental dural puncture, bradicardia, etc.) were reported for groups during and two hours after EPSI. Temporary radicular pain, not required treatment, was reported for 10 patients; 40% of group II and 18 patients; 72% of group III, but not reported in group I ($P < 0.001$).

5. Discussion

The approach to nonoperative management of lumbar disk herniation is often multifactorial having many aspects of conservative treatments such as life style modification, bed rest, drug therapy with non-steroid anti-inflammatory drugs, muscle relaxant, systemic injection of corticosteroids, epidural injection, physiotherapy and three cyclic anti-depressants after initial evaluation (11).

To relieve symptoms of pain and to reverse inflammatory process around the spine that stimulates lumbar disk herniation pathology, corticosteroids used frequently. Corticosteroids can be administered orally, intramuscularly, and epidurally (12).

Epidural corticosteroid injections have been used frequently for patients with herniated disk with satisfying results (13).

The volume-anesthesia relationship for epidural anesthesia was firstly reported by Bromage (14). Bromage (14) reported that there is a linear volume-anesthesia relationship. So, doubling epidural volume results doubled spinal segment blocks. But other researchers found that out relationship is not linear and increased volumes result relatively small increases in the spread (15, 16). Also, Runu et al. (17) and Shahbandar and Press (18) reported that there is no relationship between volume and spread effect. Also it is claimed that very small injection volumes (1 or 2 mL) possible in case of corticosteroid alone is injected (4).

We examined the different epidural volumes of equal local anesthetic and steroid dose in each group to compare the clinical outcomes between the groups. It is possible that pre-injecting different saline volumes change the epidural pressure gradient and affect the spread of subsequent local anesthetic (19). If there is no clinical difference among the different volumes of EPSI as in our trial, the spread of different epidural volumes of saline may not affect the clinical results. May be therefore our clinical effects were similar between the groups during and two hours after EPSI.

Temporary radicular pain, not required treatment, was reported for 10 patients; 40% of group II and 18 patients; 72% of group III, but not reported in group I ($P < 0.001$). Our findings show that when salin, local anesthetic and steroid used at the same time, using lower levels of epidural volumes may yield better post-op results. Temporary radicular pain we encountered can be explained by high volumes. It is stated in recent anesthesia literature that epidural injection volumes of 20 mL or less is used mostly when a local anesthetic is included (4-6).

According to the results of our study, different volumes of EPSI in patients with acute lumbar disc herniation causes significant pain relief in all of the groups. There was no superiority between the groups.

In 40 percent of group II and 72 percent of group III patients complained of a temporary radicular pain when a large volume of saline is administered with a local anesthetic. The risk of temporary radicular pain of EPSI can be reduced by keeping injection rates slow and using lower volumes as much as possible to accomplish the desired analgesia.

Two major limitations of our study: (1) because the majority of our patients were patients from outside of the province, pain improvement was not evaluated after second weeks. There was no superiority between the different volumes of EPSI. Clinical outcomes were measured only during the injection and 2 weeks later but improvement could take longer than three weeks to manifest; (2) In the period we study, we do not have fluoroscopy. So because of this, it was not done for confirmation of the correct position of the space. However the rates of complications were not different between interspinous and transforaminal approaches (5).

5.1. Conclusions

Different volumes of EPSI in patients with acute low back pain associated with radiculopathy causes significant pain relief and does similar work to analgesic effects. But

Table 1. Demographic Datas and Mean Duration of Pain prior to EPSI of the Patients[a]

	Group 1 (n = 25)	Group 2 (n = 25)	Group 3 (n = 25)	P Value
Age, y	35.1 ± 4.8	35.2 ± 8.3	35.2 ± 5.6	NS
Gender				NS
Male	20	19	18	
Female	5	6	7	
Pain duration, w	3	3	4	NS
Disk Herniation Levels; L3-L4	14 (56)	15 (60)	12 (48)	NS
Disk Herniation Levels; L4-L5	5 (20)	5 (20)	6 (24)	NS
Disk Herniation Levels; L5-S1	6 (24)	5 (20)	7 (28)	NS

[a]Values are expressd as mean ± SD or n (%).

Table 2. Visual Analog Scale, Straight Leg Elevation Test, and Oswestry Disability Index Changes of the Groups During Follow-Up

Groups	Baseline	2 Weeks Later
VAS (0 - 10)		
Group 1	8.5 ± 0.5	3.1 ± 0.9[a]
Group 2	8.3 ± 0.7	2.7 ± 1.5[a]
Group 3	8.4 ± 1.1	2.8 ± 1.4[a]
SLET (0° - 85°)		
Group 1	35.5 ± (30 - 60)	75 (30 - 85)[b]
Group 2	30.4 ± (20 - 60)	80 (40 - 85)[b]
Group 3	32.6 ± (20 - 50)	78 (35 - 45)[b]
ODI (0 - 100)		
Group 1	51.3 ± 11.7	36 ± 13.2[b]
Group 2	62 ± 17.2	32 ± 10[b]
Group 3	55 ± 12.7	36 ± 13.2[b]

[a]P < 0.01 (significant differences within group).
[b]P < 0.05 (significant differences within group).

the risk of temporary radicular pain of EPSI can be reduced by keeping injection rates slow and using lower volumes as much as possible to accomplish the desired analgesia.

Footnotes

Authors' Contribution: Study concept and design: Lutfiye Pirbudak, Neslihan Uzture; acquisition of data: Lutfiye Pirbudak, Neslihan Uzture; analysis and interpretation of data: Mustafa Isik, Savas Guner; drafting of the manuscript: Lutfiye Pirbudak, Neslihan Uzture, Mustafa Isik, Savas Guner; critical revision of the manuscript for important intellectual content: Lutfiye Pirbudak; statistical analysis: Lutfiye Pirbudak; administrative, technical, and material support: Lutfiye Pirbudak; study supervision: Lutfiye Pirbudak.

Funding/Support: This study was founded by Gaziantep University.

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