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Outcome Measurements for Pain Relief in Elderly Patients with Spinal Stenosis Undergoing Epidural Steroid Injection: Is Conservative Approach an Option?

Ali Muhittin TASDOGAN[1], Ebru TARIKCI KILIC[2]

[1]Hasan Kalyoncu University, Faculty of Medicine, Department of Anesthesiology, Gaziantep, Turkey
[2]Umraniye Training and Research Hospital, Department of Anesthesiology and Perioperative Medicine, Istanbul, Turkey

Corresponding author: Ebru TARIKCI KILIC ✉ ebru.tarkc@yahoo.com

ABSTRACT

AIM: To evaluate the short-term outcomes of epidural steroid injections (ESIs) among elderly patients with lumbar spinal stenosis.

MATERIAL and METHODS: This was a retrospective study. The sample consisted of 44 patients aged 65 or older who underwent epidural steroid injections secondary to lumbar spinal stenosis between 2014 and 2016 at a single center. Data were collected using the Numeric Rating Scale (NRS), Oswestry Disability Index (ODI), and Istanbul Low Back Pain Disability Index (ILBPDI) before and at 3-month follow-up visit.

RESULTS: Participants had lower mean scale scores at all times after ESI administration than before. Four patients (9.1%) needed additional injections while two (4.5%) needed operation. No minor or major ESI-related complications were observed.

CONCLUSION: Epidural steroid injections are an effective nonsurgical option for pain relief and improvement of physical function in elderly patients. The NRS, ODI, and ILBPDI are reliable and valid scales that can be used to evaluate the outcomes of ESIs in a selected group of elderly patients.

KEYWORDS: Elderly, Epidural steroid injection, Lumbar spinal stenosis, Low back pain, Pain relief

INTRODUCTION

There is a substantial growth in the number of elderly in need of pain relief secondary to spinal stenosis. Lumbar spinal stenosis (LSS) is one of the leading causes of morbidity and disability among the elderly (20,22). Spondylosis, disc degeneration, scoliosis, facet arthropathy, and degenerative changes may lead to spinal stenosis, which is usually multifactorial and variable. Central canal, intervertebral foramen, and lateral recesses may also be affected. Symptoms frequently associated with poor patient health outcomes range from low back pain to several neurogenic changes for LSS, and symptoms worsen over time (8,10,14).

Less invasive, safer, and more cost-effective treatment options have become more popular in recent years because pain medications, anti-inflammatory agents, and surgeries pose numerous risks for elderly patients with comorbidity.

In the last decade, epidural steroid injections (ESIs) have been used as a conservative method to control spinal pain. ESIs can be performed via an interlaminar, transforaminal, or caudal route (21).

Local anesthetics or steroids introduce therapeutic agents with anti-inflammatory properties adjacent to intervertebral discs. Local anesthetics can suppress inflammation by inhibiting phagocytosis, and reducing phagocytic oxygen consumption and polymorphonuclear leukocyte lysosomal enzyme release. Anesthetic agents are also capable of improving neural blood flow and repairing dysfunction. Steroids with anti-inflammatory properties improve neural membranes by suppressing ectopic

Ali Muhittin TASDOGAN : 0000-0002-4017-9071 Ebru TARIKCI KILIC : 0000-0002-5377-1090

neural discharges, and also have a direct anesthetic effect on unmyelinated nociceptive C-fibers (15,17).

After degeneration, the nucleus pulposus of the intervertebral disc responds to highly sensitive proinflammatory cytokines, and therefore, local anesthetics and steroids provide a therapeutic benefit by bathing the posterolateral annular fibers, which are most susceptible to injury. Because of their anti-inflammatory effects, ESIs eliminate inflammatory mediators and inhibit neurotransmission of pain signals in C fibers (15,17).

ESIs should be performed in hospital-based surgery centers with ready access to intravenous fluids, cardiac, and pulse oximetry monitoring. ESIs can be performed with or without fluoroscopic guidance and frequently require support staff.

There is, however, little research on the effectiveness of ESIs on spinal stenosis pain relief. The aim of this study was, therefore, to assess the effectiveness of ESIs on pain relief in LSS patients who are too old to undergo surgery.

MATERIAL and METHODS

This retrospective study was designed and conducted between 2014 and 2016 in a pain department of a single center to determine the results of a three-month follow-up of ESIs. The study was approved by the local ethics committee of the hospital (23.06.19/233), and conducted according to the ethical principles outlined by the World Medical Association's Declaration of Helsinki. Written informed consent was obtained from participants prior to participation.

We calculated the sample size using power analysis (effect size of 0.05) on the first- and third week NRS scores reported by Ercalik et al. The result showed that a minimum sample size of 26 achieved 95% power to detect significant differences with a confidence interval of 95%. However, we recruited 18 more participants (n=44) than the minimum suggested by the power analysis (7).

The inclusion criteria were: 1) 65 years of age or older; 2) diagnosis of low back pain and unilateral lumbosacral radicular pain due to a herniated disc for at least six months; 3) an indication for ESIs for LSS-induced low back pain; 4) no major LSS-related neurological deficits; 5) no response to non-steroidal anti-inflammatory drugs and neuropathic pain medications for at least six months.

The exclusion criteria were: 1) younger than 65 years of age; 2) cauda equina syndrome; 3) progressive neurological or psychiatric disorders; 4) metastatic cancer; 5) allergy to medications used in the trial; 6) infection on the injection side; 7) coagulation abnormalities; and 8) inability to communicate in Turkish.

Either transforaminal or interlaminar ESIs (depending on the patient) were administered by a pain medicine expert. Participants' pain levels were evaluated using the Numeric Rating Scale (NRS), Oswestry Disability Index (ODI), and Istanbul Low Back Pain Disability Index (ILBPDI) before ESI administration and then two weeks, and first and three months after ESI administration.

The procedure was performed under aseptic conditions in a fluoroscopy room. Saline solution was intravenously administered, and vitals were monitored prior to ESI administration. The target pathological location of the spinal level was determined based on symptoms. Fluoroscopically guided epidural steroid injections were performed by a pain management specialist with more than 10 years of experience. Contrast was injected after the needle position (25-gauge spinal needle for transforaminal or interlaminar ESI) was confirmed. Dexamethasone (4mg/mL) diluted in 0.9% normal saline was administered after contrast injection. At the end of ESI administration, participants were transferred to a recovery room for hemodynamic monitoring. Participants with paresis, pain, and loss of leg function were offered to stay in the hospital for 48 hours. ESI was repeated in a period of two weeks in case of failure. The NRS, ODI, and ILBPDI were used for back and leg pain evaluation.

The NRS is a scale used to measure pain intensity in the range of 0 (no pain) to 100 (intolerable pain) (8).

The ODI is a 10-item scale for evaluating treatment outcomes. The scale items are scored on a scale of 0 to 5, with the total score ranging from 0 to 50. The items assess pain intensity, personal care, lifting, walking, sitting, standing, sleeping, social life, traveling, and changing degree of pain (8).

The ILBPDI is a scale used to assess patients' disability status. It consists of 18 items scored on a scale of 0 to 5, with the total score ranging from 0 to 90. Higher scores indicate more disability (8).

Statistical Analysis

Means and standard deviations were used for scale parameters while frequencies were used for nominal and ordinal parameters. The Kolmogorov–Smirnov test was used for normality testing. A paired-samples t-test was used for tests of significance in participants before and after ESI administration. Data were analyzed using the Statistical Package for Social Sciences (SPSS, v 17.0) at a significance level of 0.05. G Power 3.1.9.2 version was used for power analysis in the statistics method section.

RESULTS

Data were collected from 49 patients; however, five patients were excluded due to missing data. Table I shows the participants' demographic and procedural characteristics.

The mean age of participants was 78.50 ± 10.61 years. Of participants, 75.0% were women. The mean weight and symptom duration of participants was 74.16 ± 10.30 kg and 19.75 ± 5.23 months, respectively. Two participants (4.5%) were operated, eight (18.2%) were administered opioid treatment, and four (9.1%) needed additional injections within a month. Twelve participants (27.3%) had diabetes mellitus (DM), nineteen (43.2%) hypertension (HT), two (4.5%) heart failure (HF), one (2.3%) both DM and HF, four (9.1%) both DM and HT, and five (11.4%) both HT and HF (Table II).

Table I: Baseline Characteristics

Parameter	Value
Age, Mean ± SD	78.50 ± 10.61
Gender, n (%)	
Female	33 (75.0)
Male	11 (25.0)
Weight, Mean ± SD	74.16 ± 10.30
Symptom duration (month), Mean ± SD	19.75 ± 5.23
Operated patients, n (%)	2 (4.5)
Opioid, n (%)	8 (18.2)
Additional injection, n (%)	4 (9.1)

Table II: Comorbidities of the Patients

Comorbidity	n (%)
DM	12 (27.3)
HT	19 (43.2)
HF	2 (4.5)
DM + HF	1 (2.3)
DM + HT	4 (9.1)
HT + HF	5 (11.4)

DM: *Diabetes mellitus,* ***HT:*** *Hypertension,* ***HF:*** *Heart failure.*

Figure 1 shows the participants' mean NRS, ODI, and ILBPDI scores.

Participants' NRS, ODI and ILBPDI scores decreased linearly with time. Table III shows the discriminant analysis results for their initial, second-week, first-month, and third-month NRS, ODI, and ILBPDI scores. All participants were discharged on the same day. Their vital signs were stable with no major complications.

DISCUSSION

Pain associated with LSS is one of the main health concerns not only for elderly patients and their family members but also for physicians. Patients usually present with low back pain, neurogenic claudication, back stiffness, and spasms with a higher incidence in women than in men (4,12).

Table III: Discriminant Analysis Results for Initial, Second-Week, First-Month and Third-Month NRS, ODI and ILBPDI Scores

Median (range)	NRS	ODI	ILBPDI
Initial-2nd hour	0.000	0.000	0.000
Initial-1st month	0.000	0.000	0.000
Initial-3rd month	0.000	0.000	0.000
2nd week-1st month	0.000	0.000	0.000
2nd week-3rd month	0.000	0.000	0.000
1st month-3rd month	0.000	0.000	0.000

NRS: *Numeric pain rating scale,* ***ILBPDI:*** *Istanbul low back pain disability index,* ***ODI:*** *Oswestry disability index.*

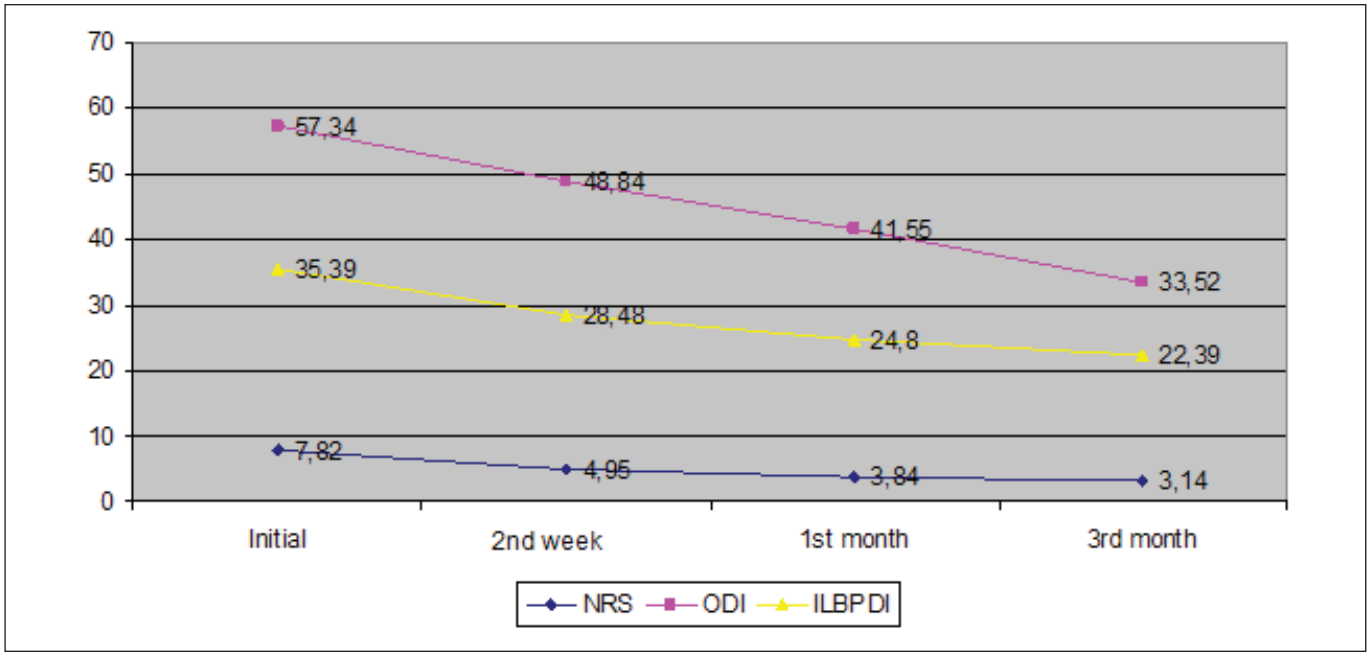

Figure 1: Baseline and post-treatment scores of NRS, ILBPDI, and ODI. **NRS:** Numeric pain rating scale, **ILBPDI:** Istanbul low back pain disability index, **ODI:** Oswestry disability index.

Pain relief is the primary outcome measure used in outpatient pain clinics to determine the effect of treatment on LSS-related pain. Although physical performance is one of the primary criteria for deciding on the treatment option, it is hard to measure.

Reliable and strongly recommended questionnaires were used to evaluate treatment outcomes in this study. Our participants' NRS, ODI, and ILBPDI scores showed that they had significantly lower levels of pain in posttreatment (second-week, first-month, and third-month) than in pretreatment (initial) (3,9).

The NRS is easier to understand and use to measure pain levels in elderly patients than other scales, such as the Visual Analogue Scale and Verbal Rating Scale.

The ODI is a valid and reliable scale used to measure physical disability. The ILPDI is a recent scale developed in Turkey to measure disability. We used both of them to measure the same component more accurately.

There are numerous studies on the effect of ESI on pain. Ercalik et al. conducted a prospective study on 82 patients who underwent ESI due to lumbar disc hernia. They used the NRS, ODI, and ILBPDI to assess pain and disability before ESI administration and then three weeks and three months after ESI administration. They reported that ESI was effective in relieving pain and that the scales had the highest sensitivity for detecting post-ESI changes (7). Lee et al. conducted a study on 172 patients older than 60 years and reported that ESI was effective in redundant nerve root syndrome (13).

Advanced age is one of the factors that determines the extent of an operation, secondary to the varying rates of morbidity and mortality related to complex lumbar surgeries in elderly patients. These issues should be considered in the context of the ever-enlarging geriatric population. Both risks and benefits of an operation should be carefully addressed, particularly in elderly patients with more complex issues that adversely affect health outcomes. Age, physiological status, and medical comorbidities should all be taken into account. The more invasive the operation, the higher the morbidity. Cheh et al. reported that decompression alone resulted in recurrent stenosis in elderly patients (1). Perioperative complications are expected to be more prevalent in octogenarians and nonagenarians than in the younger population, which has also been reported by Ciol et al. and Deyo et al. (2,6). Raffo and Lauerman reported 20 percent incidence of major complications (19). Recent research shows that blood loss or aggressive blood transfusion and prolonged hospital stay may also result in higher rates of complications positively correlated with existing comorbidities in elderly patients. The overall rate of minor and major complications increases with age.

Of clinical outcomes, performing activities of daily living is the most important issue. However, ESI is becoming more and more a standard treatment in elderly patients. Therefore, all patients with advanced age and multiple comorbidities are eligible for ESI on the condition that those factors have been shown to present a low risk.

The sample consisted of a high risk group (44 patients aged 65 or older) for lumbar surgeries with an American Society of Anesthesiologists (ASA) physical status of III, and two or more comorbidities. Only four participants (9.1%) needed a further operation. Our results also show that even high-risk patients with severe comorbidities can benefit from ESIs performed by experienced healthcare professionals in safe centers.

Manchikanti et al. investigated the effectiveness of lumbar interlaminar epidural injections with or without steroids on long-lasting pain relief and concluded that they were an effective management option for chronic function-limiting low back pain and lower extremity (16).

Zaina et al. compared different types of surgery and non-surgical interventions in adults with symptomatic LSS and concluded that the latter were an effective option especially in elderly patients (25).

Davis et al. conducted a two-year longitudinal follow-up study and found that transforaminal ESI resulted in a reduction in the incidence of pain in patients opting for surgery (5).

John and Hodgden reported that long-term pain relief was achieved by ESI (11).

Przkora et al. also recruited sixteen patients 68-83 years of age and found that participants had lower pain scores and higher quality of life scores one month after ESI administration (18).

The dose of corticosteroids is also controversial due to rare, but neurological deficits. Van Boxem et al. conducted a meta-analysis to identify the complications of corticosteroids and to determine the ideal dose. They recommend a minimum dose of corticosteroids for elderly patients with comorbidities (diabetes, renal failure, infectious diseases, etc.), but report no evidence of toxicity upon intra-arterial or epidural administration (24).

Studies have also looked into different doses of dexamethasone (7.5 to 15 mg) and reported that it has as many side effects as epidural corticosteroids. A recent clinical trial found that even 8 mg dexamethasone injection resulted in a reduction in cortisol levels (23).

We used dexamethasone because it is a promising alternative to ESIs. We administered a minimum dose of 4 mg, as recommended in the literature, and observed pain relief without side effects in a short period of time. However, dose comparative trials are warranted for long-term results.

This study has three limitations: First, it was a retrospective study with short-term results obtained in a single center. Second, the sample size was small and, no control group was used. Third, no radiological data were available. Future studies are, therefore, warranted.

CONCLUSION

Advanced age and comorbidity are risk factors for LSS-related complications. ESI is, therefore, an effective non-surgical pain relief treatment that can be used in a selected group of elderly patients.

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