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Original Article

Outcome measurement in patients with low back pain undergoing epidural steroid injection

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ABSTRACT

Objectives: This study aims to evaluate the outcomes of epidural steroid injection (ESI) in patients with low back pain.

Patients and methods: This prospective study included a total of 82 patients (51 females; 31 males; mean age 50.8±14.2 years; range, 17 to 86 years) who underwent ESI due to lumbar disc hernia-induced radiculopathy between September 2014 and May 2015. The Numeric Rating Scale (NRS), Oswestry Disability Index (ODI), Istanbul Low Back Pain Disability Index (ILBPDI), and the Short Form-36 (SF-36) were administered to all patients before and three weeks and three months after ESI.

Results: The mean scores of all scales were significantly lower at three weeks and three months following ESI compared to the baseline scores. There were no significant differences between the mean scores at three weeks and three months. The NRS yielded the highest post-ESI change from baseline.

Conclusion: Our study results showed that all scales used in this study were effective tools for the evaluation of outcomes of EPI in patients with low back pain. Although the NRS yielded the highest sensitivity for detecting change, evaluating functional state and quality of life is essential for multivariate analyses.

Keywords: Epidural steroid injection, low back pain, physical function, quality of life.

Chronic low back pain (LBP) is the most common form of musculoskeletal disorders. A variety of methods ranging from conservative treatment to surgical intervention are available for LBP treatment. Although many studies have investigated the efficacy of each method, meta-analyses comparing the outcomes of these treatment modalities have provided no reliable data, since different scales have been used in these studies. In an attempt to describe a common language understood by users such as researchers, policymakers, healthcare professionals, and patients, the International Classification of Functioning, Disability, and Health (ICF) describes a globally agreed framework for the evaluation of patients.[1] This framework recommends the inclusion of body function and structure, activity and participation items in outcome measures for the purpose of standardization. Using these items facilitates high quality data collection and provides consistency and meaningful comparison across clinical trials.

To date, several studies have been conducted in LBP to form a standard set similar to the core set according to the ICF recommendations.[2,3] Apart from these efforts, some scales have been specifically recommended for the common use in LBP owing to their properties of universal utility for each of the components to be evaluated, validity in several languages, and favorable psychometric properties such as reliability and responsiveness.[4]

Epidural steroid injection (ESI) has been successfully used for the treatment of LBP caused by lumbar disc herniation.[5] Various scales have been used by studies aiming to evaluate the efficacy of ESI treatment for LBP. These may either be different scales rating the same or different domains.[6] Using core sets

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or strongly recommended outcome measures would provide more reliable data to compare ESI treatment method with the other treatment methods and to include it in meta-analyses.

In the present study, we aimed to evaluate the outcomes of ESI in patients with LBP and to provide an overview of the outcome measures previously recommended for the evaluation of LBP treatment.

PATIENTS AND METHODS

This prospective study was conducted at Marmara University, Medical Faculty, Physical Therapy and Rehabilitation Department, Section of Pain Medicine between September 2014 and May 2015 and included a total of 82 patients (51 females; 31 males; mean age 50.8±14.2 years; range, 17 to 86 years) who underwent ESI due to lumbar disc hernia-induced radiculopathy. *Inclusion criteria were as follows:* having a schedule for ESI for lumbar disc hernia-induced radiculopathy, being older than 18 years, having low back and/or leg pain unresponsive to conservative treatment, and being literate. *Exclusion criteria were as follows:* being pregnant or in lactation period, suffering from an illness with progressive neurological deficit, lumbar spinal stenosis, facet syndrome, spondylolisthesis-spondylolysis, or cauda equina syndrome, having a history of ESI within the last six months, and suffering from concurrent psychiatric disorders. A written informed consent was obtained from each patient. The study protocol was approved by the Marmara University School of Medicine Ethics Committee. The study was conducted in accordance with the principles of the Declaration of Helsinki.

Epidural steroid injection was administered by a pain medicine expert or fellow under the fluoroscopic guidance. Transforaminal or caudal epidural application technique was used depending on the suitability of each patient. The patients were evaluated using the following scales before and three weeks and three months after the injection: The Numeric Rating Scale (NRS), Oswestry Disability Index (ODI), Istanbul Low Back Pain Disability Index (ILBPDI), and the Short Form-36 (SF-36).

The NRS is used to measure and monitor pain intensity. Scores range from the absence of pain (0) to intolerable pain (10 or 100).

The ODI is composed of 10 items rating pain intensity, personal care, lifting, walking, sitting, standing, sleeping, social life, traveling, and changing the degree of pain, scoring between 0 and 5. The maximum possible score is 50, with the total score being multiplied by 2 to obtain a result in percentage. This form is used to assess treatment outcomes and compare different treatments in chronic LBP, and its validity and reliability in Turkish have been previously shown.[7]

The SF-36 is a generic, health-related scale which has been found to be valid and reliable in Turkish, commonly used to rate the quality of life (QoL). It is composed of eight subscales containing 36 items evaluating physical and mental health. These subscales are a physical functioning (PF), social functioning (SF), physical role functioning (PR), emotional role functioning (ER), bodily pain (BP), vitality (VT), general health (GH), and mental health (MH).[8]

The ILBPDI is a specific disability scale developed in Turkish to evaluate patients with chronic LBP. It contains 18 questions and each item is scored on a 6-point Likert (0-5) scale. The questions are answered based on the patients' daily activities during the past month. Global scores range from 0 to 90 and higher scores indicate greater disability.[9]

Statistical analysis

Statistical analysis was performed using the Number Cruncher Statistical System (NCSS) 2007 statistical software (NCSS LLC, Kaysville, UT, USA). Data were expressed in mean ± standard deviation (SD), median (min-max) or number and frequency. Normal distribution of quantitative variables was assessed by histogram, Q-Q graph, and Kolmogorov-Smirnov and Shapiro-Wilk tests. Since the variables were not normally distributed, the Friedman test was used for repeated comparisons and data were expressed in median with 95% confidence interval (CI). A p value of <0.05 was considered statistically significant. Wilcoxon signed rank test with the Bonferroni correction was used for pairwise comparisons and the level of statistical significance was set to 0.05/3. The ability of outcome scales

Table 1. Demographic characteristics

	n	%	Mean±SD
Age (year)			50.8±14.1
Gender			
Female	51	62.2	
Male	31	37.8	
Body mass index			28.3±4.61
Symptom duration (month)			18.9±25.1
Operated patients	24	29.3	

SD: Standard deviation.

Table 2. Baseline and post-treatment scores of NRS, ILBPDI, and ODI

	Baseline		3rd week		3rd month		
	Median	95% CI	Median	95% CI	Median	95% CI	*p*
NRS	7	7.00-7.93	3	3.20-4.51	5	3.88-5.3	0.0001**
ILBPDI	36	32.13-39.21	24	21.54-29.94	26	21.89-34.81	0.0001**
ODI	56	52.70-61.13	40	37.63-46.68	46	39.67-55.52	0.001*

NRS: Numeric Pain Rating Scale; ILBPDI: Istanbul Low Back Pain Disability Index; ODI: Oswestry Disability Index; CI: Confidence interval; * p<0.05 statistically significant; ** p<0.001; Friedman's test was applied.

Table 3. Pairwise comparisons of the time points of NRS, ILBPDI and ODI scores

	NRS	ILBPDI	ODI
Baseline/3rd week	0.0001*	0.0001*	0.0001*
Baseline/3rd month	0.0001*	0.002*	0.011*
3rd week/3rd month	0.287	0.281	0.201

NRS: Numeric Pain Rating Scale; ILBPDI: Istanbul Low Back Pain Disability Index; ODI: Oswestry Disability Index; * p<0.016 statistically significant; Wilcoxon signed-rank test with Bonferroni correction was applied.

to rate treatment responsiveness was evaluated by calculating the effect size (change in all patients), standardized mean response (effect size in a group with improvement), and Guyatt's Responsiveness Index (effect size in a group without improvement). An effect size higher than 50% was considered moderate sensitivity and higher than 80% high sensitivity.[10] The internal consistency of ODI and ILBPDI were evaluated using the Cronbach's alpha coefficient and >0.70 was considered statistically significant for reliability. The post-hoc power was calculated using the website http://istatistikakademisi.com/orneklem-buyuklugu.html to identify the power of the study. Based on the results which were found statistically significant, the effect sizes were calculated from 0.41 to 1.26 and the power ranging from 0.74 to 0.99 was found using an alpha of 0.05 and a sample size of 82.

RESULTS

Demographic characteristics of the study population are shown in Table 1.

The mean NRS scores at three weeks and three months were significantly lower compared to the baseline scores (p=0.0001); however, there was no significant difference between the mean NRS scores at three weeks and three months (p=0.549).

The Cronbach's alpha coefficient values of the ODI and ILBPDI were 0.84 and 0.95, respectively. The mean ODI and ILBPDI scores at three weeks and three months were significantly lower compared to the baseline scores, although there was no significant difference between the mean scores at three weeks and three months (Tables 2 and 3).

Despite the presence of an increase in all parameters of the SF-36, these changes were significant for only BP, PF, and SF subscales at three weeks and three months. There was, however, no significant difference between the mean scores at three weeks and three months (Tables 4 and 5).

Table 4. Baseline and post-treatment scores of SF-36 subscales

	Baseline		3rd week		3rd month		
SF-36	Median	95% CI	Median	95% CI	Median	95% CI	*p*
PF	30	29.85-39.21	45	40.79-50.53	40	29.93-47.35	0.021*
SF	50	48.81-59.52	62.5	56.02-67.4	62.5	50.29-64.29	0.036*
PR	0	8.8-21.2	13.63	22.34-40.99	0	16.19-45.93	0.163
ER	33.33	20.61-34.5	33.33	32.15-50.24	33.33	27.57-57.28	0.061
MH	52	48.78-57.46	60	52.68-62.73	56	43.5-49.05	0.158
VT	40	36.83-46.5	50	41.62-52.05	40	36.54-53.46	0.066
BP	30	24.52-33.56	45	45.12-56.21	45	35.14-52.74	0.002*
GH	35	31.37-40.76	40	36.94-46.96	45	34.9-50.86	0.485

SF-36: Short Form 36; CI: Confidence interval; PF: Physical functioning; SF: Social functioning; PR: Physical role functioning; ER: Emotional role functioning; MH: Mental health; VT: Vitality; BP: Bodily pain; GH: General health; * p<0.05 statistically significant; Friedman's test was applied.

Table 5. Pairwise comparisons of the time points of SF-36 subscale scores

	PF	SF	BP
Baseline/3rd week	**0.001***	**0.006***	**0.0001***
Baseline/3rd month	0.103	0.052	**0.001***
3rd week/3rd month	0.051	0.100	0.709

SF-36: Short Form 36; PF: Physical functioning; SF: Social functioning; BP: Bodily pain; * p<0.016 statistically significant; Wilcoxon signed-rank test with Bonferroni correction was applied.

Among all outcome measures, the NRS yielded the highest post-ESI change from baseline. In the patients in whom an improvement was observed, the ILBPDI and ODI showed a moderate and high sensitivity, respectively, while in those without improvement, the ILBPDI yielded a high sensitivity and ODI yielded a low sensitivity. In the SF-36 QoL scale, the highest sensitivity was observed in the pain variable in those with improvement and in the RF in those without improvement. Outcome measures are summarized in Table 6.

DISCUSSION

In this study, we used the questionnaires strongly recommended for each domain to assess the treatment outcomes of patients undergoing ESI for LDH-induced LBP. Scale sets formed in previous studies were not used, since the validity and reliability of these scales were not shown in the Turkish population. Based on the literature data, different pain rating scales such as pain relief scale, VAS, and NRS can be used for rating pain in studies of ESI.[11-15] In this study, NRS was used, since it is an easy-to-perform and more strongly recommended rating scale[4] and significant improvements were shown both at three weeks and three months, consistent with the literature data.[16-18]

Although various scales can be used for measuring physical disability, ODI is the most widely used scale in the ESI studies.[14,15] Its validity and reliability have been also shown in many languages, and it is recommended for the standardization of LBP studies. In the present study, we utilized the ODI together with ILPDI, a recently developed scale in Turkey, which was considered to be able to measure the same component to a more specific extent.[9] These scales were found to have a good level of reliability. The results of both scales indicated a significant improvement in disability. In the literature, domains can be assessed by different scales similar to one another, which have been developed to fulfill the same goal. In the present study, we also used two different scales to rate disability, which yielded similar results. However, a database analysis by Morris et al.,[19] in which more than one studies were collectively analyzed, showed that the scales were not compatible with one another, recommending not to include studies using different scales. Hence, in the ESI studies, the use of the same scale, but not similar scales, or their collective use, would yield more reliable results in meta-analyses.

Furthermore, the effects of LBP treatments on QoL have been extensively studied. However, only few studies have investigated changes in QoL after ESI in detail.[6] The QoL is an important component which needs to be measured in outcome measures. Although

Table 6. Responsiveness of outcome measures to treatment

	Effect size	Standardized mean responsiveness	Guyatt's responsiveness index
Numeric Pain Rating Scale	1.17*	2.05*	1.06*
Istanbul Low Back Pain Disability Index	0.65*	0.77**	0.87*
Oswestry Disability Index	0.70*	0.89*	0.37
Short Form 36-physical functioning	0.45	0.59**	0.22
Short Form 36-social functioning	0.40	0.36	0.50**
Short Form 36-physical role functioning	0.40	0.56**	0.87*
Short Form 36-emotional role functioning	0.31	0.47	0.58**
Short Form 36-mental health	0.31	0.41	0.47
Short Form 36-vitality	0.22	0.28	0.14
Short Form 36-bodily pain	0.90*	0.99*	0.23
Short Form 36-general health	0.12	0.09	0.32

* High sensitivity; ** Moderate sensitivity.

there are some other recommended scales, this study employed the SF-36 as the QoL scale with proven validity and reliability in Turkish.

In addition, the efficacy results of this study are consistent with the results reported in the literature.[5,20] Since this study did not primarily aim to evaluate treatment efficacy, a control group was not included; therefore, the results do not necessarily suggest the efficacy of ESI. However, this study is still valuable, since it included an analysis of QoL and showed the utilization of the outcome measures recommended for all other LBP studies in this patient group.

Responsiveness is one of the primary psychometric properties which needs to be addressed by every outcome measure tool. By calculating the responsiveness levels of the outcome measures, this study also aimed to evaluate the ability of the recommended outcome measures to rate the change elicited by ESI treatment. The most impressive responsiveness scores were achieved by the NRS pain scale. The high sensitivity of the pain parameter of NRS for rapid relief of pain by ESI indicated the importance of the NRS scale in rating treatment outcomes. Although it was found similarly high in the patients with improvement in disability scores, a more sensitive responsiveness was revealed in the ILBPDI compared to the ODI in the patients without improvement. This finding suggests that both scales used for rating disability can be used in this patient population. Consistent with our study, another study reported that the ODI had a high sensitivity in the group with treatment-induced changes and lower sensitivity in the group without treatment-induced changes.[21] Although the ODI is the common disability scale recommended for use for standardization in LBP studies, this study is clinically important, as it showed that the ILBPDI, a newly developed scale for the Turkish population, offer a higher sensitivity for the assessment of the response to ESI in patients with LBP. The SF-36, on the other hand, yielded a lower sensitivity in general. Similar to this study, a recent study showed that the EQ-5D Health-Related Quality of Life Scale had a lower sensitivity than the ODI for the evaluation of treatment response in patients with LBP undergoing ESI treatment. This finding suggests that either improvement, unlike pain and disability, cannot be reflected the QoL with adequate sensitivity, or SF-36 and EQ-5D Health-Related Quality of Life Scale are generic scales not specific to LBP. Furthermore, it also indicates the necessity of a QoL scale specific for LBP.

This study also has some limitations. First, although the sample size was found to be appropriate with the poc-hoc power analysis, larger sample size may yield more meaningful results about the outcome measurements' ability to detect changes produce by ESI. Second, a control group was not included to this study. However, since the aim of this study was not to evaluate ESI efficacy, inclusion of the control group was not required.

In conclusion, this study used all scales recommended for establishing a common language for measuring the outcomes of ESI and yielded results consistent with the literature. Although the pain scale yielded the highest sensitivity for detecting change after ESI, evaluating other components, as well, is essential for multivariate analysis. In addition, ESI needs to take its true place in LBP treatment guidelines with a high level of evidence with the help of efficacy data which would be provided by future studies using these scales or scale sets to be formed in the future.

Declaration of conflicting interests

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