

Prospective Evaluation

The Effect of Pre-Treatment Depression, Anxiety and Somatization Levels on Transforaminal Epidural Steroid Injection: A Prospective Observational Study

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Background: Results of the lumbar transforaminal epidural steroid injection (L-TFESI) used in the treatment of lumbar radiculopathy may be affected by the current psychiatric condition of the patient.

Objectives: The study aimed to assess the effects of pretreatment comorbid psychiatric conditions on patient outcomes in patients with lumbar disc herniation and radiculopathy.

Study Design: The study used a prospective-observational study design.

Setting: Research was conducted at a university hospital international pain management center.

Methods: In this observational study, 103 patients were included. All patients were evaluated with the Hospital Anxiety and Depression scale (HADS) for depression and anxiety levels and the Somatosensory Amplification Scale (SSAS) for somatization levels before the L-TFESI. The treatment results were evaluated with the Numeric Rating Scale (NRS) and the Oswestry Disability Index (ODI) at baseline, the third week, and the third month. Relative to baseline, a 50% reduction in the NRS was accepted as a successful treatment.

Results: HADS-depression, HADS-anxiety, and SSAS levels were similar between the patients with successful treatment outcome and the patients in whom treatment failed. However, there were negative correlations between percent reduction in the NRS and the HADS-depression levels at 3 weeks ($r = -0.182$, $P = .022$) and 3 months ($r = -0.204$, $P = .037$). Also, there were positive correlations between patients' pre-injection ODI scores and both the HADS-anxiety ($r = 0.271$, $P = .001$) and SSAS ($r = 0.201$, $P = .013$) scores.

Limitations: The study was limited by a relatively short-term follow-up period.

Conclusions: Although psychiatric conditions affected the pain and disability of patients before and after the L-TFESI, and may have an impact on patient-related outcomes, they should not be a reason to not treat patients or expect a lower chance of success.

Key words: Anxiety, depression, disc herniation, low-back pain, lumbar radiculopathy, patient-related outcomes, somatization, transforaminal epidural steroid injection

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Lumbar disc herniation is a disabling and painful disease that causes suffering that affects the daily lives of people of all ages; it is one of the most common causes of low back pain (LBP) (1,2). Pharmacological agents, chiropractic treatment, physical therapy, and interventional methods such as lumbar

epidural steroid injections are important steps in LBP treatment, especially since less than 3% of patients who apply for lumbar pain treatment are thought to require surgical intervention (3). Radicular pain is thought to be caused by inflammation of the spinal nerve roots near an intervertebral disc injury. In this context, lumbar transforaminal epidural steroid injection (L-TFESI) has been increasingly preferred by patients who cannot benefit from a conservative approach in the treatment of lumbosacral radiculopathic pain due to recent lumbar disc herniation (1,4).

The factors affecting negative responses to L-TFESI have been shown in various studies, but it has not yet been predicted which patient group will benefit from the treatment (5,6). There are numerous studies showing that comorbid psychological factors, such as depression, anxiety, and fear of pain, are associated with increased pain and disability in patients with LBP (7). It has been suggested that patients who have lumbar disc herniation have increased comorbid depression, anxiety, and somatization levels; it has also been found that comorbid psychological disabilities negatively affect functional impairment due to disc herniation (2,8). The results of the inverse relationship between depression and lumbar spinal surgery results have been shown previously (3). Previous studies have emphasized that the treatment of psychiatric disorders before surgery increases the success of pain reduction (9). Although the presence of comorbid psychiatric conditions has been investigated in patients undergoing surgical interventions, the effect on nonsurgical interventional treatments, such as L-TFESI, has not yet been fully elucidated.

The aim of this study was to evaluate the effect of the presence of comorbid psychiatric conditions such as depression, anxiety, and somatization on L-TFESI outcomes in patients with lumbar disc hernia and radiculopathy.

METHODS

Patient Selection

We evaluated patients who had LBP with leg pain and who were scheduled for L-TFESI injections in our pain medicine outpatient clinic between 2013 and 2015. Physical examination was also performed, and lumbar imaging was investigated for all evaluated patients. Inclusion criteria were as follows: (1) diagnosis of lumbar radiculopathy due to lumbar disc herniation, (2) history of being unresponsive to

conservative treatments, (3) duration of pain less than 3 months, and (4) patients were scheduled for L-TFESI for the first time. The exclusion criteria were as follows: (1) cases where fluoroscopy or epidural injection was contraindicated (coagulation disorders, pregnancy, etc.), (2) patients who underwent epidural injection in the last 6 months, (3) a history of lumbar spinal surgery, (4) inflammatory diseases (rheumatoid arthritis, spondyloarthropathy), spinal infection, or malignancy, (5) reluctance to participate in the study, (6) illiteracy, and (7) patients with psychotic disorders or intellectual disability. In addition, all patients were questioned about additional information, such as age, gender, and symptomatic side.

This study was designed as a prospective observational cohort design. Written and verbal informed consent were obtained from all patients who were scheduled for injection. The study was approved by the institutional review board of our university (approval date: September 6, 2014; project number: 09.2014.0089) and was carried out in compliance with the Helsinki Declaration. The trial was registered with ClinicalTrials.gov under number NCT03821350.

Outcome Measures

Pain Level and Pain-Related Disability

Patient-reported outcome (PRO) measures for pain and disability were recorded at baseline, at 3 weeks and at 3 months after fluoroscopically guided L-TFESI. Validated questionnaires were used to collect PROs; pain levels were measured using a 10-point Numeric Rating Scale (NRS) for LBP and disease-specific disabilities were evaluated using the Oswestry Disability Index (ODI). The ODI is a survey designed to investigate how lumbar and leg pain affects a patient's daily life. It consists of 10 questions interrogating the general life activities of the patient. The patient receives 0 to 5 points from each question. Higher scores indicate increased disability. Accordingly, the percentage of the patient's life activity being affected was calculated. The validity and reliability of the Turkish version of the ODI was performed by Yakut et al (10).

At follow-up, a reduction in the NRS score of 50% or more was accepted as a successful treatment, and the percentage reduction in the NRS was accepted as a primary outcome. The ODI score change was obtained by calculating the difference between the baseline ODI level and the 3-week and 3-month ODI levels at follow-up.

Depression, Anxiety and Somatization

Before the L-TFESI, all patients were assessed using the HADS for depression and anxiety symptoms and the SSAS for somatization levels. The evaluation of depression, anxiety, and somatization levels of the patients was done before the L-TFESI. The HADS is an easy-to-use questionnaire consisting of 14 questions that examine the symptoms of depression with 7 questions and the symptoms of anxiety with 7 questions. The validity and reliability of the Turkish versions was assessed by Aydemir et al (11). Total scores between 0 and 7 indicates that there is no abnormality, 8-10 is borderline, and 11 and above indicate anxiety or depression (12). The SSAS is a scale consisting of 10 items to be rated. The items include a series of disturbing bodily sensations that do not present a disease. Participants generally respond to questions based on their personal character. The scale is between 1 and 5 for each condition, with higher scores indicating greater symptom amplification. Amplification scores are obtained by totaling the points received (the total score ranges from 10 to 50). The validity and reliability of the Turkish version was performed by Gulec et al (13,14).

Interventional Technique

Transforaminal epidural steroid injection

Before the transforaminal epidural steroid injection (TFESI), the patient lies down in a prone position with a cushion under the abdomen. The skin is wiped 3 times with povidone iodine, and the area is allowed to air-dry for one minute. After the sterile drape is secured, the relevant right or left lumbar pedicle or foramen is positioned for the C-arm fluoroscopy. A 22-gauge, 8.9-centimeter spinal needle is directed under intermittent fluoroscopic guidance into the epidural area; then 1 to 2 mL of iohexol is administered to ensure that the needle tip is in the epidural area. Two mL of 40 mg/mL methyl prednisolone acetate, 1 mL of saline, and 1 mL of (0.5%) bupivacaine is injected after confirming that there is an epidural distribution and no vascular distribution. However, if 2 sides or 2 levels are to be treated during the same session, the above procedures are applied for each root, and each root is equally divided by mixing 2 mL of 40 mg/mL methyl prednisolone acetate, 1 mL of saline, and 1 mL of (0.5%) bupivacaine. The patient was observed for one hour in the recovery room after injection.

Statistical Analysis

Data was analyzed using SPSS Version 22.0 (IBM Corporation, Armonk, NY). The histogram, normality

plots, and the Shapiro-Wilk normality test were used for data distribution analysis. Descriptive statistical methods (mean, standard deviation, frequency) were used when study data was evaluated. The t test was used for comparison between 2 groups of normally distributed parameters, and the Mann-Whitney test was used for comparison between 2 groups of nonnormally distributed parameters. The Pearson correlation coefficient was preferred when data were distributed normally and the Spearman rank correlation coefficient was preferred when data were not distributed normally. A *P* value of < .05 was considered significant.

RESULTS

The study was conducted on 161 patients between the ages of 18 and 80 years, of whom 85 (53%) were women and 76 (47%) were men. No major complications such as nerve damage, unceasing hemorrhage, and infection were observed. At the third week of follow-up, 2 patients were excluded from the study because they had undergone surgery. In the third month of follow-up, 7 patients had undergone surgery, 2 patients had facet injections, and 3 patients had TFESI repeated. In addition, there were 6 patients who did not come to the third week follow-up and 43 patients who did not come to third month follow-up. Thus, 3 months of data were obtained from the records of 103 patients. The mean age of the cases was 48.93 ± 13.39 years. The demographic characteristics and clinical data of the patients are summarized in Table 1.

Relationship Between Comorbid Psychiatric Conditions and Pain and Disability

With a $\geq 50\%$ decrease (the difference between baseline and follow-up) in the NRS considered as a successful treatment, there was no significant difference between SSAS scores, depression, and anxiety states of patients who had successful and failed treatment outcomes ($P > .05$) (Table 2, Table 3). When the percent change rates in NRS scores during the first hour, the third week, and the third month were examined in relation to SSAS scores, there was no correlation between changes in NRS and SSAS scores. Additionally, the correlation of depression, anxiety, and SSAS scores with pain were examined. There was a negative correlation between depression levels and the percent reduction in NRS scores in the third week ($r = -0.182$, $P = .022$) and the third month ($r = -0.204$, $P = .037$). A similar relationship was not found between anxiety and somatization levels and NRS scores. Furthermore, there was no

Table 1. Demographic characteristics and clinical data of the patients.

		Min-Max	Overall Mean ± SD
Age		18-80	48.86 ± 13.38
BMI		18.22-40.82	28.10 ± 4.52
HADS- Depression level		1-19	7.29 ± 3.18
HADS- Anxiety level		1-21	8.26 ± 4.17
SSAS		10-46	29.25 ± 8.10
		n	%
Injection side	Right	58	36
	Left	64	39.7
	Bilateral	39	24.2
Injection level(s)	L3	1	0.6
	L4	15	9.3
	L5	62	38.5
	S1	58	36
	L3 and L4	3	1.9
	L4 and L5	9	5.6
	L5 and S1	12	7.4
	L2 and L3	1	0.6

BMI = Body Mass Index; HADS = Hospital Anxiety and Depression Scale; n = number of patients; SD = standard deviation; SSAS = Somatosensory Amplification Scale

Table 2. The relationship between depression and anxiety levels of patients with or without a successful treatment.

Treatment success*		Depression (Mean ± SD)	P-value
1 st hour	≥ 50%	7.28 ± 0.26	.262 ¹
	< 50%	8.62 ± 1.10	
3 rd week	≥ 50%	7.65 ± 0.33	.112 ¹
	< 50%	6.72 ± 0.38	
3 rd month	≥ 50%	7.48 ± 0.42	.359 ¹
	< 50%	6.87 ± 0.42	
		Anxiety	P-value
1 st hour	≥ 50%	8.21 ± 0.34	.779 ¹
	< 50%	8.38 ± 0.89	
3 rd week	≥ 50%	8.13 ± 0.42	.589 ¹
	< 50%	8.43 ± 0.54	
3 rd month	≥ 50%	7.88 ± 0.49	.988 ¹
	< 50%	7.91 ± 0.64	

¹Mann-Whitney U test

*≥ 50% reduction in the NRS score was considered as a successful treatment

NRS = numeric rating scale; SD = standard deviation

Table 3. The relationship between somatization levels of patients with or without a successful treatment.

Treatment success*		SSAS (Mean ± SD)	P-value
1 st hour	≥ 50%	29.09 ± 8.12	.220 ¹
	< 50%	32.75 ± 9.57	
3 rd week	≥ 50%	29.56 ± 8.01	.689 ¹
	< 50%	29.01 ± 8.30	
3 rd month	≥ 50%	27.80 ± 7.89	.083 ¹
	< 50%	30.48 ± 7.73	

¹Mann-Whitney U test

*≥ 50% reduction in the NRS score was considered as a successful treatment

SSAS = Somatosensory Amplification Scale

statistically significant relationship between baseline NRS score and psychiatric comorbidities ($P > .05$) (Table 4). When the relationship between changes in the ODI and psychiatric status levels was examined, a positive correlation was found between pre-injection ODI level and the HADS-anxiety ($r = 0.271$, $P = .001$) and SSAS scores ($r = -0.201$, $P = .013$). Similar findings were not observed between HADS-anxiety and follow-up ODI scores changes at 3 weeks and 3 months. No correlation was found between the depression levels of HADS and the ODI change at pre-treatment, 3 weeks, and 3 months ($P > .05$) (Table 5).

DISCUSSION

In the current study, we proposed to investigate the effect of pre-procedure psychiatric status on PROs. L-TFESI is a useful and usable method for patients with symptomatic lumbar disc herniation with back pain and radicular pain. When the effects of psychiatric comorbid conditions on the outcomes of the procedures were examined, it was observed that high depression levels increased postprocedure pain levels, and high anxiety and somatization levels caused increases in pre-injection disability scores. To the best of our knowledge, this is one of the first studies to investigate the effect of pre-treatment depression, anxiety, and somatization on the PROs of the L-TFESI.

The positive effect of the L-TFESI for lumbar radiculopathy treatment on radicular pain and functionality has also been demonstrated in previous studies (1,15). It is known that depression, anxiety, and fear of pain increase back pain and decrease functionality (7). In addition to this, depression and anxiety can lead to an increase in the sensations of pain and may result in less effective surgical outcomes (16,17). A study by

Suri et al (18) has shown that depression contributes to the recurrence of LBP and leg pain after discectomy. Although the effects of these comorbid psychiatric conditions on the results of surgical treatments have been investigated, they have not been studied in detail for nonsurgical interventional methods (3,19,20). Kim et al (3) found no significant difference in lumbar epidural steroid injection outcomes in patients with and without depression. Initial and 12th month pain of the patients, their disability levels, and quality-of-life scores were found to be worse in cases with patients suffering from depression. However, there was no difference between patients with and without depression in terms of PROs. This study showed that depression has a potentially negative effect on pain, disability, and health status, but no significant effect on the efficacy of the treatment (3). In our study, there was no significant effect on levels of anxiety and somatization at follow-up; however, a relationship between high levels of HADS-depression and changes in pain levels post procedure was observed. With this result, it can be seen that as the depression scores of the patients increased, the benefits of the treatment decreased. Although there was no significant difference between psychiatric comorbidity and treatment results, the negative correlation between the 2 parameters (changes in NRS scores and depression levels) can be attributed to various factors. First, the study was carried out with a small sample size. Second, our follow-up period was not long enough (3 months).

The catastrophic effect of pain on the presence of anxiety has been demonstrated in chronic pain treatment and in patients prior to surgery (9,21). It has been suggested that anxiety can cause patients to develop a careful focus on pain stimulation, and thus reflect the effect of anxiety on pain (22). On the other hand, some studies suggest that anxiety may have a pain-reducing effect through the endogenous opioid release (22). These studies have shown contradictory results of the effect of anxiety on pain and the functioning of the anxious patients. This results of our study shows that high anxiety scores according to HADS do not negatively affect the L-TFESI outcomes and that patients may benefit from this treatment. In a study conducted by Walega et al (23), anxiety levels were found to be low in patients with cervical and lumbar interlaminar epidural steroid injection; the study argued that the patients should not be treated for injection-related anxiety, especially if there is no preexisting anxiety disorder. However, patients' anxiety has a negative effect

Table 4. *The correlation of depression, anxiety, and somatization levels with the percent reduction in NRS.*

The NRS percent change		HADS-Depression	HADS-Anxiety	SSAS
Pre-injection NRS	r	0.130	0.145	0.113
	p	.096	.062	.158
1-hour	r	-0.066	-0.089	-0.020
	p	.403	.260	.807
3-week	r	-0.182	0.068	-0.035
	p	.022	.399	.670
3-month	r	-0.204	-0.053	0.033
	p	.037	.596	.745

NRS = numeric rating scale; SSAS = Somatosensory Amplification Scale

Table 5. *The correlation of depression, anxiety, and somatization levels with change in ODI score.*

The ODI change		HADS-Depression	HADS-Anxiety	SSAS
Pre-injection ODI	r	0.112	0.271	0.201
	p	.161	.001	.013
3-week ODI change	r	0.054	0.162	0.162
	p	.527	.054	.060
3-month	r	0.022	0.025	0.128
	p	.828	.806	.210

ODI = Oswestry Disability Index; SSAS = Somatosensory Amplification Scale

on pre-injection ODI scores. The patient's preprocedural disability may have a negative effect on anxiety, and this negative relationship may be eliminated by the improvement of disability after the TFESI.

The main effect of somatization has been shown for disability and chronicity (24). In our study, there was a relationship between somatization level and pre-injection disability level, but not between the pre- and post-injection pain levels. The main reason for this may be the high level of SSAS due to pessimism in patients with higher functional impairment before the procedure. However, after the injection, as the patients' pain decreased and their functionality increased, the relationship between somatization level and disability level was attenuated. The absence of a significant effect of the somatization level on the NRS score and the post-injection ODI score may be due to the fact that the patient group studied was a selected population and that patients who had had LBP for more than 3

months were not included. It would be more accurate to observe the effect of somatization with long-term follow-up (as in the 12-month follow-up).

Limitations and Strengths of the Study

The study has several limitations that should be noted. First, the patients were monitored for short follow-up periods (3 months). The effects of psychiatric conditions on treatment results may occur after longer periods of time. Second, minor complications during the procedure and patient satisfaction were not investigated. However, Walega et al (23) did not show an effect of anxiety levels on vasovagal symptoms and mobility of the patient during the procedure.

The main strength of the study is that this is one of the pioneer observational trials to investigate the effects of pretreatment depression, anxiety, and somatization levels on L-TFESI outcomes.

CONCLUSION

This study demonstrated the effectiveness of TFESI in the treatment of lumbar radiculopathy. Also, it showed that the decrease in pain with L-TFESI treatment was less in patients with high depression scores, and the level of pre-injection disability was higher in patients with higher anxiety and somatization scores. It should be taken into consideration that psychological conditions may also be influential in the PROs wherein the patients evaluate themselves. If these patients are also evaluated and treated for mood disorder prior to intervention, then TFESI approaches may be as effective in that found in patients without mood disorder.

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