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The Influence of Epidural Steroids Injections with Transforaminal and Interlaminal Approaches on Quality of Sleeping, Anxiety, and Depression in Patients With Chronic Lumbal Radicular Pain – Prospective, Randomized Research

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ABSTRACT

Chronic lumbar radicular pain is connected with the anxiety, depression and sleep disorders. The aims of this study are to compare the effect of pain on sleep quality, anxiety and depression in patients receiving interlaminar and transforaminal epidural steroids injections. The study is an original scientific-research work, a prospective randomized controlled clinical trial that included 70 patients with lumbar radicular pain at the Clinical Hospital Centre Osijek. The selected patients were divided into two groups considering the approach of administration of epidural steroids, the interlaminar (IL) and transforaminal group (TF). The anxiety, depression and sleep disorders were evaluated with questionnaires "Hospital Anxiety and Depression Scale (HADS)" and "Questions for assessing sleep in chronic pain". In the end 64 patients completed the study, 41 women (64.1%) and 23 men (35.9%). Significantly lower values were recorded during the assessment of the sleep quality in the group with the interlaminar injection of steroids (ANOVA, p = 0.030), compared to the group with the transforaminal injection of steroids (ANOVA, p = 0.002), but there is no difference between the groups. In both groups, there is an improvement in anxiety and depression, but only in the sixth measurement a significantly lower evaluation value of the HADS questionnaire was obtained in transforaminal (TF) group (Mann Whitney test, p = 0.025). Within the TF group, the values of anxiety (Friedman's test, p <0.001) and depression (Friedman's test, p = 0.007) are significantly reduced. In patients who received epidural steroids injection with a transforaminal approach, lower levels of depression and anxiety were observed as there was a greater reduction in pain, compared to an interlaminar group. Sleep quality was higher in patients who received steroids via transforaminal compared to the interlaminar approach.

Keywords: *Lumbar radicular pain, epidural steroids injections, interlaminar approach, transforaminal approach, anxiety, depression, sleep quality*

Introduction

Poor sleep quality is highly prevalent in patients with lower back pain (LBP) and is associated with high levels of pain, psychological distress, and physical disability [1]. Lumbar radicular pain (LRP) is caused by irritation, inflammation, pressure or injury of the lumbar segment spinal nerves. The pain propagates along the lower extremity on the same side as spinal nerve injury and has the characteristic of a sharp, piercing sensation or electric shock. By definition, radicular pain affects the area outside the spine. Patients with lower back pain may experience pain in the vertebra and along the lower extremities, but pain along the legs is more intense in patients with LRP. Several recent studies have concluded that epidural application of steroids is an effective method for pain treatment in patients with acute lumbar radiculopathy[2]. Patients requiring such treatment usually have an inadequate analgesia after performing physical therapy and other forms of rehabilitation[3]. Data on the epidural application of steroids in most studies include a classical interlaminar approach[4]. By contrast, the pathology of the nerve root and the intervertebral disc is located in the anterior epidural space. The transforaminal approach for epidural

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steroids injection results in the disposal of steroids in the anterior epidural space, very close to the pathology site and therefore a lower dose of steroid is required[4,5]. Although the prevailing view is that epidural application of steroid is not effective in treating chronic LRP, clinical practice denies it every day. By duration, pain can be acute and chronic. Chronic pain has no protective role; it is long lasting, exhausting and becomes a chronic pain syndrome. Chronic pain is a personal experience, accompanied by a series of psychological and emotional reactions that significantly change the quality of the patient's life. Pain has a direct effect on sleep quality, and numerous studies have shown that pain has a significant impact on the development of anxiety and depression.

Hypothesis and aim of the study

Previous studies have shown the efficacy of epidural application of steroids in the treatment of the acute, but also and chronic radicular pain. The transforaminal approach for epidural steroids injections has yielded better results, although numerous studies have proven successful pain reduction by the interlaminar approach.

It is well known that pain is a direct trigger for anxiety and depression, as well for sleep disorders. After all the above we can make a hypothesis that epidural applications of steroids with an interlaminar or transforaminal approach will decrease the intensity of pain, which will result in a decreasing degree of anxiety and depression and improving the quality of sleep for the patients with chronic lumbosacral radicular pain.

Aims of this study:

1. Compare the effect of pain on sleep quality in patients receiving interlaminar and transforaminal steroid injections in chronic lumbar radicular pain
2. Compare the effect of pain on anxiety and depression in patients receiving interlaminar and transforaminal steroid injections in chronic lumbar radicular pain

Materials and methods

The study was carried out as an original scientific research work, as a prospective randomized controlled clinical trial. The Ethics Committee of the Osijek Clinical Hospital Center and the Faculty of Medicine at the Josip Juraj Strossmayer University in Osijek approved research conducting. Patients with radicular pain were selected in the Pain Clinic, Department of Anesthesiology and Intensive Care of the Clinical Hospital Center Osijek. Selected patients were divided into two groups considering the approach of administration of epidural steroids, the interlaminar (IL) and transforaminal group (TF).

The selection was made by random selection, "pulling out of the hat". Basal evaluation has been done just before randomization and the first epidural steroid injection (ESI). The first checkup was done just before the second epidural steroid injection, the second checkup was performed before the third epidural steroids injection. The third checkup has been performed two weeks after the third epidural steroids injection. The fourth and fifth checkup was performed after 12 and 24 weeks after the first basal assessment. Randomization was continued until a total of 64 patients, or respectively 32 patients per each group, did not complete the tracking via all six visits to the doctor in both groups. Patients who have fallen out from monitoring for any reason are not involved in data processing. All patients had magnetic resonance imaging (MR) of the lumbosacral segment of the spine and electromyoneurography of lower extremities (EMNG). ESI was performed at the level of the spine with overlapping of MR and EMNG verified pathology site and the patient radicular pain dermal distribution. In cases with several pathological levels as a possible cause of radicular pain, ESI has been applied at the level that has been most pathologically altered (EMNG and MR verified).

To include patients in the study, they had to meet the inclusive criteria:

- Age between 18 and 80 years
- The intensity of pain along the leg assessed by a visual-analog scale (VAS 0-10) equal to or greater than five before the first epidural steroids injection
- The intensity of pain along the leg stronger than the lower back pain
- Patients with lumbar radicular pain that in the last 6 months did not have a satisfactory response to conventional treatment (pharmacotherapy and physical therapy)
- Spinal stenosis or compression of the lateral lumbar stenosis duct documented by MR images, which could potentially explain the clinical patient's signs and symptoms of radicular pain
- The absence of significant motor deficiency or fecal/urine incontinence

Excluding criteria, for patients were the same for both groups (they have not been included or they have been excluded from the study if they have one exclusion criteria):

- Age younger than 18 years or older than 80 years
- The intensity of pain along the leg assessed by a visual-analog scale (VAS 0-10) equal or less than four
- The intensity of the low back pain stronger than pain along the leg
- Symptoms of lumbar radicular pain shorter than 6 months
- Pregnant and lactating women or women in the generative age without adequate contraception
- Patients with bilateral radicular pain
- Patients with progressive neurological deficit
- Patients with previous lumbar spine surgery
- Patients with coagulation disorder, including those receiving anticoagulant medications
- Patients with previous allergic reactions to local anesthetics, steroids, contrasts or opiates

- Patients who received epidural steroids injection in a period of a year ago
- Patients with a history of addiction to opioids or patients currently on long-acting opioids

After careful selection of patients who met the inclusion criteria of the study, an interview was conducted with patients, in which the researcher explained to them the nature, the course, treatment options, the possible risks of the treatment, the goal of the treatment, and the possible outcome of the treatment of their lumbar radicular pain. After agreeing to participate in the research, the patients signed an informed consent for performing the procedure and consent for the collecting and statically processing of data for scientific purposes, with the protection of patients identity. All collected materials were encrypted for the anonymity of patients.

Patients who entered the study were not subjected to aggressive tests or therapeutic interventions outside of the usual procedures for treating such patients.

After signing informed consent, the patients filled the questionnaire for receiving basic information about the patient. This questionnaire represents a patient's history and patients completed it before the first injection of steroids. During controls, patients only filled new changes. Patients also completed questionnaires assessing the effect of pain on sleep quality, anxiety, and depression. These questionnaires are:

- Questions for assessing sleep in chronic pain
- Hospital Anxiety and Depression Scale (HADS)

By reading a scale (0 to 100) about sleep estimation in chronic pain, higher values indicated better sleep quality, and lower values indicated poor sleep quality. HADS is a questionnaire consisting of 14 questions - seven related to depression and seven to anxiety. Four responses are possible, and the scoring scale is ranging from 0 to 3. The total points for each part are from 0 to 21. It is assumed that the normal state is 0 to 7 points, the border disease state is from 8 to 10 points, and a disease state is from 11 to 21 points. Patients received a series of three steroid injections into the lumbar epidural space by the interlaminar or transforaminal approach, within 2 weeks intervals. Patients did not receive anticonvulsive or antidepressive therapy during follow-up. For mitigation of penetrating pain, patients received one or two Tramadol 50 mg pills as needed (max. 400 mg / 24 hours). Researchers monitored and reevaluated patients on each visit before ESI application, and three and six months after first steroid injection. Patients reported adverse reactions on each control, which was recorded in a special paper form for each patient.

Statistics

Numerical data are described by the basic measures of medium and dispersion. The normality of distribution of observed numeric variables was tested by Kolmogorov-Smirnov test. The category variables are described in absolute and relative frequencies. Testing of differences was done for groups of respondents in six measurements. To study the differences between the two independent groups within each measurement, Student's T-test and Mann-Whitney test were used, depending on the normality of the distribution. The differences between categorical variables were tested by the $\chi 2$ test (Fisher's exact test). To investigate the differences between the six measurements of individual parameters, ANOVA was used for repeated measurements and Friedman's test, a nonparametric test of variance analysis for dependent measurements. We used originally written database programs and statistical package Stat Soft, Inc. (2005). Statistica (data analysis software system), version 7.1. www.statsoft.com.

To evaluate the importance of the results obtained, the level of importance $\alpha = 0.05$ was chosen.

During this clinical research, ethical principles were respected in accordance with well-known and established fundamental principles of ethics and human rights protection valid in the field of medical sciences.

Results

In our research, we included 70 patients by random selection, and 64 of them completed the study. By gender, 41 were women (64.1%) and 23 men (35.9%). Six patients did not complete the monitoring. Three patients left each group after the first, second or third ESI and they did not enter in the statistical analysis. Patients in both groups, transforaminal and interlaminar, had a significant reduction in pain intensity after the receiving epidural steroids injection procedure during the control visits.[6]

Significantly lower values were recorded during the assessment of the sleep quality in the group with the interlaminar injection of steroids (ANOVA, $p = 0.030$), compared to the group with the transforaminal injection of steroids (ANOVA, $p = 0.002$), but there is no difference between groups (Figure 2).

Mood disorders (depression, anxiety) were followed with the HADS questionnaire in order to obtain the overall impression of pain and its impact on the general condition of the patients. It consists of 14 questions; seven refer to depression and seven to anxiety. Four responses are possible, and the scoring scale is ranging from 0 to 3. The

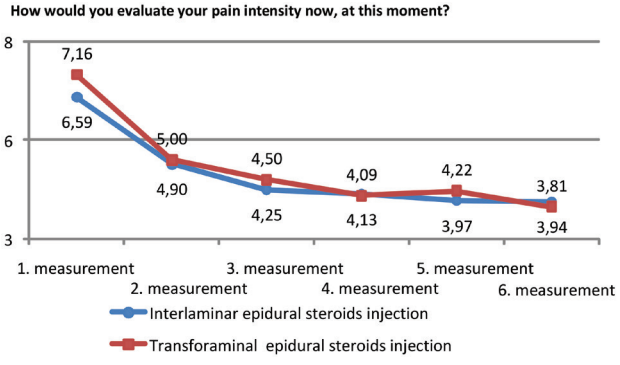

Fig.1. Evaluation of pain intensity after epidural steroid administration by transforaminal or interlaminar approach.6

TABLE 1
AVERAGE VALUES OF HADS ESTIMATES OF ANXIETY AND DEPRESSION

HADS questionnaire	Epidural steroids injection		Total	p†
	Interlaminar	Transforaminal		
	Sv (±SD)*	Sv (±SD)*	Sv (±SD)*	
ANXIETY				
measurement	12,03 (3,82)	11,25 (4,4)	11,64 (4,11)	0,531
measurement	11,09 (4,89)	10,28 (4,5)	10,69 (4,7)	0,467
measurement	11,28 (5,46)	9,81 (4,7)	10,55 (5,11)	0,233
measurement	10,47 (5,26)	9,75 (4,4)	10,11 (4,84)	0,666
measurement	10,66 (5,28)	9,22 (4,7)	9,94 (5,01)	0,148
measurement	11 (5,17)	9,09 (4,8)	10,05 (5,04)	0,071
DEPRESSION				
measurement	10,63 (3,94)	10,56 (4,37)	10,59 (4,13)	0,930
measurement	10,56 (4,26)	9,69 (4,62)	10,13 (4,43)	0,599
measurement	10,25 (4,11)	9,75 (4,46)	10 (4,27)	0,666
measurement	9,72 (4)	9,03 (4,71)	9,38 (4,35)	0,576
measurement	10,03 (3,95)	8,69 (4,88)	9,36 (4,45)	0,240
measurement	10,44 (3,74)	8,44 (4,93)	9,44 (4,46)	0,025

* Mean value (standard deviation); †Mann-Whitney test

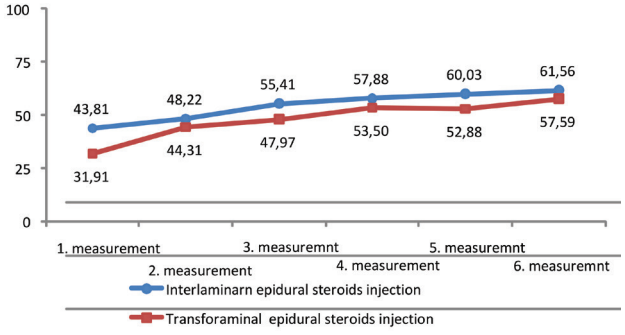

Fig.2. Evaluation of sleep quality in chronic pain by groups and measurements.

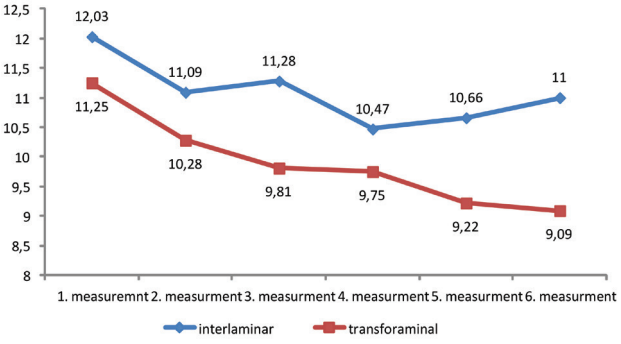

Fig.3. HADS anxiety assessment by measurements and groups.

total points for each part are from 0 to 21. It is assumed that the normal state is 0 to 7 points, the border disease state is from 8 to 10 points, and a disease state is from 11 to 21 points. The only psychiatrist sets the final diagnosis of the depressive or anxiolytic condition, after completing the clinical evaluation.

In both groups, there is an improvement in anxiety and depression, but only in the sixth measurement a significantly lower evaluation value of the HADS questionnaire was obtained in transforaminal (TF) group (Mann Whitney test, $p = 0.025$) (Table 1). Within the TF group, the values of anxiety (Friedman's test, $p < 0.001$) and depression (Friedman's test, $p = 0.007$) are significantly reduced (Table 1, Figure 3 and 4).

Discussion

In patients with chronic pain, the usual problems are insomnia and depression[7]. A group of authors from Turkey compared sleep quality in 200 patients with low back pain (LBP) versus 200 healthy individuals. In patients with LBP, the mean Pittsburgh Sleep Quality Index (PSQI) was 8.1 +/- 4.3 versus 4.6 +/- 3.4 in healthy individuals in the control group. ($p < 0.001$). This study showed that sleep quality was significantly impaired in patients with LBP compared to a healthy control group[8]. Bahouq et al., in their study conducted in 2013, found that the prevalence of insomnia in patients with lower back pain was 64%[9]. Before first epidural steroids injection, over 50% of pa-

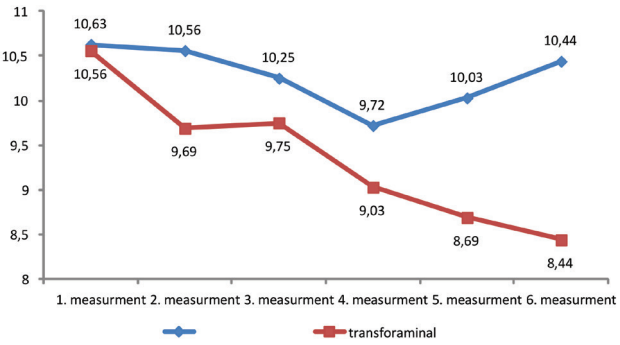

Fig. 4. HADS depression assessment by measurements and groups.

tients in this study had a moderate or strong adverse effect of pain on sleep quality. This is not surprising because sleep disorders and chronic pain are associated in the way that pain leads to sleep disorders, and sleep disorders increase the perception of pain.

A group of German authors made a meta-analysis of 34 studies. The perception of pain in patients with lower back pain is significantly associated with depression and fear[10]. Inadequately diagnosed and insufficiently treated sleep disorders, with emotional, cognitive and behavioral maladaptive processes in patients with chronic pain, can lead to the development of chronic sleep disorders, which then contribute to mentioned maladaptive emotional, cognitive and behavioral responses [11.] The insomnia will also significantly enhance the impact of pain on daily functioning, particularly when it comes in pair with a major depressive disorder[7].

In our study, the patients in both groups in the first control had a severe state of anxiety. At the sixth control, patients in the IL group on average stayed in an illness state of anxiety, and in the TF group, the condition improved so that the patient's average was in the border state of anxiety. In the assessment of depression, both groups were in a state of illness, and at the end of monitoring after six months, they were in a border state.

A group of authors from Turkeystudied the effect of transforaminal use of steroids on functional status, psychological status and sleep quality in patients with a herniated disc of the lumbar spine. The results showed an 83% reduction in pain intensity, a 71% increase in functional status, and a 69% improvement in sleep quality 2 weeks after the procedure. After 12 months, slight decrease in improvement appear, so that the reduction of pain intensity at the end was 73%, 65% increase in functional status and improvement in sleep quality by 62%[12]. In our study, in both groups of patients (interlaminar and transforaminal ESI), the proportion of patients with anxiety (65.6% and 53.1%) is higher than the proportion of anxiety in the general population (18%), which is consistent with other studies. Shilabant and al. compared the interaction of pain intensities, sleep disorders and emotions in patients with non-specific pain in the lumbar spine (NSLBP) in 555 patients and 112 healthy subjects. Patients with NSLBP had a greater incidence of sleep disorder, anxiety disorders and depression than healthy subjects. More than half of the patients with NSLBP (278-50.1%) experienced anxiety symptoms, 379 (68.3%) had depression, and 161 (29.0%) had a sleep disorder. In a group of 112 healthy subjects, 18 (16.1%) had anxiety symptoms, 13 (11.6%) had depression and 14 (12.5%) had sleep disorders. Patients with NSLBP had statistically significantly more symptoms of anxiety, depression and sleep disorders ($p < 0.01$)[13]. Simultaneously with the treatment of pain, it is of great importance to treat anxiety and depression due to the strong interaction of pain with anxiety and depression, as vice versa. Depression and pain significantly affect chronic pain, but also the quality of life of patients. Hiyama et al. have studied the effect of depression and neuropathic pain on the quality of life in patients with Low Back Pain (LBP). The incidence of neuropathic pain was higher in patients with depression than in patients who did not have depression. Patients with depression had a higher intensity of pain (NRS) and poor quality of life (QQL) [14].

Among the group of patients suffering from a major depression, 69% of them complain of physical symptoms, among which the most common are a headache, arthritis, chest pain, joint pain, muscle pain, digestive disorders, cardiac palpitations, fatigue, fluid interference, and libido interference. Non-inclusion of physical symptoms in the therapeutic goal is the most common cause of depression relapse, and 76% of patients have experienced relapse within 10 months[15,16].

In primary health care system patients appear with painful physical symptoms (a headache, abdominal pain, muscular pain) in 80% of all cases, and pain symptoms are clinically significant in 92% of primary depressive patients[17]. Of the total number of patients with severe depression disorder, 65% have painful symptoms, while in 35% there are no painful symptoms. The success of recognizing depression when only affective symptoms are present is 90%, while with the presence and physical symptoms success is reduced to 50%[18]. In the co-morbidity of chronic pain (musculoskeletal pain) and depression as well as anxiety, disabling effect is higher and the quality of life is worse[19]. Although it is understandable that depression and painful conditions occur often together, and their treatment is more expensive and harder than each condition individually, their interaction is incomprehensible. Large studies have shown that the symptoms of depression are the precursor of future episodes of arthritis, neck pain and musculoskeletal symptoms compared to those patients without depressive symptoms[20]. Other studies have shown that low back pain is twice as likely in depressed individuals as compared to individuals without depression[21]. Patients with multiple painful symptoms such as back pain, headache, abdominal pain, chest pain, and facial pain have a 3-5 times greater chance of developing depression than painless patients and painful symptoms associated with at least double increase in the risk of coexisting depression[21]. In addition, patients with

chronic pain have three times higher possibility to meet the criteria than those patients who do not have chronic pain[22].

The relationship between depression and pain becomes stronger if the strength of these two conditions increases. For example, an increase of pain intensity will increase the symptoms of depression and the depression will deteriorate. In the same way, if the symptoms of depression increase, the patients will more regret on pain, often go to the visits to the doctor due to back pain. It will lead to greater number of diagnostic procedures, increase in medications using, and the cost of such treatment will be far greater in comparison with those who do not have depression[24,25,26]. Depression in patients with lower back pain is associated with poor treatment outcomes. Social support is a factor that can be affected and so mitigate the symptoms of depression could improve the outcome of the treatment of patients with low back pain. More social support is associated with a better recovery of symptoms of depression.

It follows that in the treatment of pain in the lumbar spine, multidisciplinary approach, which include social support to patients, is extremely important[27]. The presence of pain negatively affects the recognition and treatment of depression. Depression is often unrecognizable and therefore it is not treated. It is not yet quite clear the mechanism of why patients with depression and pain have a weaker response to the usual treatment of depression in comparison with patients suffering from depression without pain. Depression also increases the overall cost of health care for patients with pain, lead to a weaker response to pain management, decrease patient's satisfaction and result in more common additional episodes of pain in the future[28]. The combination of depression and pain is associated with a worse clinical picture in comparison with a present of only one clinical entity. It is vital to treat depression and pain at the same time to get optimal treatment outcomes.

Conclusion

In patients who received epidural steroids injection with a transforaminal approach, lower levels of depression and anxiety were observed as there was a greater reduction in chronic pain, compared to an interlaminar group. Sleep quality was higher in patients who received steroids via transforaminal compared to the interlaminar approach.

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UTJECAJ EPIDURALNIH INJEKCIJA STEROIDA S TRANSFORAMINALNIM I INTERLAMINALNIM PRISTUPIMA NA KVALITETU SPAVANJA, ANKSIOZNOST I DEPRESIJU KOD PACIJENATA S KRONIČNOM LUMBALNOM RADIKULARNOM BOLI

S A Ž E T A K

Bol u lumbalnom dijelu kralježnice je povezana sa anksioznošću, depresijom i poremećajem spavanja. Ciljevi ovoga istraživanja su usporediti utjecaj boli kod bolesnika sa boli u lumbalnom dijelu kralježnice na kvalitetu spavanja, te anksioznost i depresiju kod interlaminarne i transforaminalne primjene steroida. Provedena je prospektivna randomizirana studija u KBC Osijek. U studiju je uključeno 70 bolesnika koji su podjeljeni u dvije grupe slučajnim odabirom obzirom na način primjene epiduralnih steroida. Kvaliteta spavanja, anksioznost i depresija su evaluirani »Upitnikom za procjenu spavanja kod kronične boli« i »Bolničkom skalom anksioznosti i depresije (HADS)«. Istraživanje je završilo 64 ispitanika od kojih je 41 bila žena (64.1%) i 23 (35.9%) muškaraca. Značajno su niže vrijednosti u procjeni kvalitete spavanja u grupi s interlaminarnim injiciranjem steroida (ANOVA, p=0,030), u odnosu na grupu s transforaminalnim injiciranjem steroida (ANOVA, p=0,002), no nema razlike među skupinama. U obje skupine dolazi do poboljšanja po pitanju anksioznosti i depresije, no samo su kod šestog mjerenja značajno niže vrijednosti procjene HADS upitnikom kod ispitanika iz TF skupine (Mann Whitney test, p=0,025). Unutar TF skupine značajno se smanjuju vrijednosti kod anksioznosti (Friedmanov test,p<0,001) i kod depresije (Friedmanov test, p=0,007). Kod bolesnika koji su steroide primili transforaminalnim u odnosu na interlaminarni pristup zabilježene su niže razine depresije i anksioznosti jer je bilo veće smanjenje boli. Kvaliteta spavanja bila je veća kod bolesnika koji su steroide primili transforaminalnim u odnosu na interlaminarni pristup.