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# THE ROLE OF EPIDURAL STEROID INJECTIONS IN THE TREATMENT OF PAIN IN PATIENTS WITH DEGENERATIVE CHANGES IN THE LUMBAR SPINE

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**Abstract. The role of epidural steroid injections in the treatment of pain in patients with degenerative changes in the lumbar spine. Fishchenko Ia.V., Roy I.V., Kravchuk L.D.** *Epidural steroid injections (ESI) of the lumbar spine are a common interventional procedure that is used to alleviate radicular pain resulting from degenerative changes in the spine. Although several studies have compared epidural steroid injections with placebo with favorable outcomes, randomized controlled trials in this direction are needed. The purpose of the study was to evaluate the effectiveness of the use of epidural steroid injections in the treatment of pain in patients with degenerative lesions of the lumbar spine. During the study, 262 patients with degenerative lesions of the spine at one or two levels of the vertebral-motor segment (VMS) were selected. Epidurally transforaminally under fluoroscopic control all patients received steroid injections at the appropriate level (s) of VMS on the basis of the rehabilitation department of the Institute of Traumatology and Orthopedics of the National Academy of Medical Sciences of Ukraine during 2017-2019. Of the 262 patients who received epidural steroid injections, 204 were able to reduce pain and avoid surgery within one year. However, 58 patients experienced only slight pain relief and were recommended surgical treatment. In our study, patients with negative results were offered surgery after 1.98 ESI procedures with an interval of 3.7 months. In the group of operated patients, the preliminary use of steroid injections did not bring relief by the results of Oswestry Disability Index (ODI) and Visual Analog Scale (VAS), however, the condition of these patients improved significantly after surgery ($p<0.05$). The use of epidural injections is possible as a first-line therapy in patients with moderate functional limitations, which can subsequently be directed to surgery in the absence of a positive result.*

**Реферат. Роль эпидуральных стероидных инъекций в лечении болевого синдрома у пациентов с дегенеративными изменениями поясничного отдела позвоночника. Фищенко Я.В., Рой И.В., Кравчук Л.Д.** *Эпидуральные стероидные инъекции поясничного отдела – это обычная интервенционная процедура, которая применяется для облегчения корешковых болей, возникающих в результате дегенеративных изменений в позвоночнике. Хотя в нескольких исследованиях проведена сравнительная оценка эпидуральных стероидных инъекций с плацебо с благоприятными исходами, необходимы рандомизированные контролируемые исследования в этом направлении. Цель исследования – оценить эффективность применения эпидуральных инъекций стероидов в лечении болевого синдрома у пациентов с дегенеративным поражением поясничного отдела позвоночника. В ходе исследований было отобрано 262 пациента с дегенеративным поражением позвоночника на одном или двух уровнях позвоночно-двигательного сегмента. Все пациенты первично получали эпидурально трансфораминально под флюороскопическим контролем инъекции стероидов на соответствующем уровне (уровнях) позвоночно-двигательного сегмента на базе отделения реабилитации ГУ «Институт травматологии и ортопедии НАМН Украины» в течение 2017-2019 гг. Из 262 пациентов, получавших эпидурально инъекции стероидов, 204 удалось уменьшить болевой синдром и избежать операции в*

*течение одного года. Однако 58 пациентов испытали лишь незначительное облегчение боли и им было рекомендовано хирургическое лечение. В нашем исследовании пациентам с негативными результатами предлагали операцию после 1,98 процедур с интервалом в 3,7 месяца. В группе прооперированных пациентов предварительное применение инъекций стероидов не принесло облегчения состояния по результатам Oswestry Disability Index (ODI) и визуальной аналоговой шкалы боли (ВАШ), однако состояние этих пациентов значительно улучшилось после операции (p<0,05). Применение эпидуральных инъекций возможно в качестве терапии первой линии у пациентов с умеренными функциональными ограничениями, которые в последствии могут быть направлены на операцию при отсутствии положительного результата.*

Epidural steroid injections (ESI) of the lumbar spine are a conventional intervention procedure that is used to facilitate the radicular pain that arises as a result of degenerative changes in the spine. In some patients, the ESI improve symptoms and often is the best treatment method [2, 4, 8, 13]. Despite the large number of clinical studies that evaluate the ESI in the treatment of radicular pain, indications and duration of this treatment method remain not fully understood. Although in several studies, a comparable assessment of ESI with placebo with favorable consequences is carried out, randomized controlled research in this direction is required to finally determine the contingent of patients who are most likely to receive a positive effect from ESI [3, 5, 7, 9].

In one of the recent studies of Radcliff K. [6, 11], it was reported about the results of treatment of patients with spine problems (SPORT) in which there were no significant effects from ESI compared to surgical intervention, assuming that there are restrictions in indications for use of injections. In this study, we put forward the hypothesis that patients who receive the greatest potential benefits from the ESI are patients with slight or moderate functional limitations (according to the Oswestry Disability Index (ODI) questionnaire).

Carette et al. [4] reported unfavorable treatment results in 158 patients. They found that the benefits of the ESI were preserved within 3-6 weeks, but the positive effect disappeared in 3 months, while the frequency of subsequent operations on the spine did not decrease.

On the contrary, Vad et al. [12] in the randomized study, have shown a significant improvement in patients after ESI over a long period of observation (within 16 months). Consequently, it is important to correctly determine the role and indications to the ESI, and not to compare its priority and efficiency compared with surgical intervention.

The purpose of the study is to evaluate the effectiveness of epidural injections of steroids in the treatment of pain syndrome in patients with degenerative lesions of the lumbar spine.

We compared the results of treatment of patients who underwent only ESI with the results of patients who underwent ESI and and then were operated, in which even after injections moderate functional disorders by Oswestry Disability Index (ODI) preserved.

**MATERIALS AND METHODS OF RESEARCH**

In the period from 2013 to 2018, 262 patients with one-or two-level lesions of VMS at the lumbar level (hernia of intervertebral discs, spondylolistosis or stenosis of the vertebral canal) were examined. Patients with traumatic damage to the spine, including traumatic fracture or compression of the root as a result of neoplasms were excluded from our investigation. All patients under observation had only moderate functional disorders (visual analog pain scale (VAS) – 3.5-6.5; ODI – 15-35). All patients complained of the radicular pain that lasted for 12 weeks or more, or a neurogenic intermittent claudication, despite the use of conservative treatment.

Of 342 patients, initially included in the study, we excluded 54 patients with ODI indicators of more than 35 points and/or the presence of a neurological deficiency (for example, a significant pain syndrome with signs of compression neuropathy, myelopathy or progressive motor weakness) that required surgical intervention.

26 patients were excluded from the study, as the link with them after treatment was lost. All other 262 patients underwent ESI transforaminally under fluoroscopic control, with targeting at the affected nerve root, according to the patient's complaints and MRI results. After the procedure follow-up was carried out within 12 months. The research was conducted in accordance with the principles of bioethics set forth in the Helsinki Declaration "Ethical Principles of Medical Research with the Participation of People" and "General Declaration on Bioethics and Human Rights (UNESCO)."

*Technique of transforaminal ESI.* All procedures were performed by one specialist. For carrying out the procedure the patient was put on the table, the back was treated with a solution of betadine. Then, under fluoroscopic control, to the upper and frontal sides of the predicted hole, G22 needle was brought. As soon as the needle appeared in the correct plane of the tissue and the negative aspiration of blood and cerebrospinal fluid was confirmed, a 1 ml of contrast

medium was injected in order to indicate the appropriate propagation of the drug along the nerve root. Then a mixture of 2 ml of 1.0% lidocaine and 40 mg of triamcinolone was administered [11].

In order to assess the results of treatment, we used the questionnaire of Oswestry Disability Index, with further assessment of treatment. The evaluation of remote treatment results was carried out in 3, 6, 9 and 12 months after the procedure. If after 2 ESI procedures the symptoms were preserved or recurred, the patient was transferred to a group for surgical interventions. Patients with indications to surgery were recommended to consent, and they did. In the surgical group a decompression surgery of the affected nerve root was performed with execution or without spondylodesis of the vertebral segments. In the future, the results of the treatment between groups by clinical and demographic characterists at different stages of observation were compared.

To analyze the reliability of the differences in the average values of samples, which corresponded to the normal data distribution law, the Student T-criterion was used, and for samples that did not correspond to the normal data distribution law – the Wilcoxon nonparametric criterion. The selected level of reliability p corresponded to 95%, and the level of significance – p (5%). Mathematical calculations were made using "Excel" and "Statistica 6.0 programs". Statistical processing of research results was carried out using Statistica for Windows 13 (Statsoft Inc., No. JPZ804I382130ARCN10-J). Informativity of tests and indicators was recorded and carried out under standard measurement conditions [1].

**RESULTS AND DISCUSSION**

When comparing groups (patients with ESI only and those with ESI + surgery), it was found that patients of both groups were similar in gender, age, duration of symptoms before ESI, number of ESI procedures and the level of lesion of VMS (p=0.627; Table 1). T-criterion was used to determine the differences between the two groups. Between the two groups a reliable difference was not detected (p>0.05).

Of the 262 patients who underwent ESI, 204 (78%) experienced relief of pain during one year of follow-up. However, 58 patients (22%) underwent surgery on average in 3.7 months after the ESI.

*Table 1*

**Characteristics of groups of patients examined**

| | ESI group | ESI + surgery group (further) | p |
|---|---|---|---|
| Number of the examined | 204 | 58 | |
| Gender (m:f) | 75:129 | 24:34 | 0.627 |
| Age (years), M ± m | 56.78±15.26 | 57.28±14.14 | 0.812 |
| BMI, M ± m | 23.7±1.9 | 24.1±1.6 | 0.536 |
| Duration of pain (months.), M ± m | 7.22±4.22 | 6.51±3.28 | 0.113 |
| Number of ESI, M ± m | 1.98±1.18 | 1.60±1.44 | 0.075 |
| Time before surgery (months) | | 3.70±4.55 | |
| Level of lesion of L1-2 | 2 | 2 | 0.651 |
| L2-3 | 8 | 4 | |
| L3-4 | 19 | 8 | |
| L4-5 | 118 | 35 | |
| L5-S1 | 76 | 25 | |

**Notes:** ESI – epidural steroid injection; BMI: body mass index.

When comparing ODI and VAS outcome indicators, the examined of both groups were also homogeneous and did not have significant differences (in the first – 27.26 and 5.18, respectively, compared to the second – 30,05 and 5.85; (p=0.063)).

However, between the groups of ESI and ESI + surgery there was a significant difference in the results after the ESI procedures (p=0.316). Thus, in a group where only the ESI was performed, there was a constant decrease in ODI and VAS indicators during the year of the follow-up (p=0.779, Table 2), although the indicators had a tendency to increase until the final survey, but insignificantly. And in the ESI group + surgery the decrease in ODI or VAS indicators was not observed for several months (ODI 29.63±9.09 and VAS 5.00±2.16 respectively, in 3 months). According to the analysis of risk factors, there were no reliable differences between the selected indicators at the time of the latest examination (p=0.779).

*Table 2*

**Comparative assessment of results between groups (M±m)**

| | ESI group | Esi + surgery group | p |
|---|---|---|---|
| **Outcome ODI.** | **27.26±9.05** | **30.05±12.17** | **0.063** |
| **Outcome VAS** | **5.18±1.89** | **5.85±2.88** | **0.107** |
| **Intermediate ODI (3 months)** | **20.48±9.45** | **29.63±9.09** | ***<0.0001** |
| **Intermediate VAS (3 months.)** | **3.23±2.07** | **5.00±2.16** | ***<0.0001** |
| **Final ODI (1 year)** | **21.94±8.87** | **22.76±12.96** | **0.779** |
| **Final VAS (1 year)** | **3.73±2.03** | **4.40±2.96** | **0.316** |

**Notes:** ESI – epidural steroid injection, ODI: Oswestry Disability Index, VAS - visual analog pain scale; t-criterion was used to determine the differences between the two groups. Mid-term indicators of VAS and ODI significantly varied between the two groups (p<0.05).

The results of our own research have shown that the procedure of the ESI can significantly reduce pain syndrome for one year in most patients with moderate functional disorders in the history of lesions at the level of one or two VMS of the lumbar area. The same positive results of treatment have been received by Riew et al. [10] in a randomized clinical study in a group of patients, with selective blockades of the nerve root. The authors concluded that the selective blockade of the nerve root is indicated to patients with a radicalar pain with a lesion at the level of one or two VMS to consider the surgery option, which, in principle, confirms our research results. However, in a large prospective study of Radcliff K. et al. [6, 11] it was reported that patients with a discal hernia at the lumbar level who underwent ESI did not demonstrate improvements at both short-term and remote stages of observations (up to 4 years) compared with patients who did not undergo ESI.

Theoretically, ESI can interrupt the vicious circle of neuropathic pain, improving the natural course of degenerative disease and, consequently, allowing patients to avoid surgical interventions [6, 7, 9, 10, 11]. However, we found that a significant number of patients needed interventions, despite the use of ESI, even in a group with moderate functional disorders. Accordingly, our results showed moderate effectiveness of ESI as an alternative to surgical intervention. However, given the convenience and economical efficiency of ESI, the blockade may be a good variant of the first line therapy in patients with radicular pain. However, it is quite difficult to compare the effectiveness of ESI with that of the operation due to the lack of own remote treatment results in a group of patients with severe functional disorders.

In our study, most patients (78%) experienced relief of symptoms after ESI during one year of follow-up. However, we could not find significant differences at the level of affected segment, severity and duration of pain syndrome between the ESI group and the ESI + surgery group. All this means that the results of the ESI may not depend on the severity or duration of pain before surgery, the level of lesion, gender or age of the patient. It seems that in a significant number of patients with moderate functional disorders it is possible to

facilitate the symptoms of pain within one year, independently of the level of the affected segment and the duration of symptoms.

However, 22% of patients needed surgery, despite the use of ESI, which confirms a limited role of ESI. In our study, patients with negative results were operated after 1.98 of ESI procedures at an interval of 3.7 months. These observations confirm that several procedures of the ESI in a short time may affect the effectiveness of treatment. Thus, we can recommend a few courses of ESI in patients with moderate functional disorders before surgical treatment, which can expand the capabilities of treatment of this disease.

Our research also has a *number of limitations*. The observation period was limited by one year, which may reduce its value. In addition, VAS and ODI showed a tendency to increase at the time of the last follow-up, which may reduce the significance of the results.

To date, there is a problem of objectivization of pain syndromes against the background of degenerative diseases of the lumbar spine, all VAS and ODI criteria used are subjective scales. But, despite these restrictions, we believe that the results of our prospective cohort study complement the body of knowledge about the results of ESI application in patients with moderate functional disorders.

**CONCLUSION**

According to the results of research of 262 patients who underwent ESI, 204 (78%) patients experienced a relief of pain which lasted during one year of follow-up. However, 58 patients (22%) underwent surgery on an average in 3.7 months after epidural steroid injections. The obtained results allow us to conclude that the procedure of epidural steroid injections may be recommended as a first line therapy in patients with moderate functional disorders due to degenerative lesion at the level of one or two lumbar spine segments, taking into account small invasiveness and economic performance. With the progression of symptoms or deterioration of patients' state surgery is recommended.

Conflict of interest. The authors declare no conflict of interest.

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