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RĪGAS STRADIŅA UNIVERSITĀTE

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ULTRASOUND VERSUS FLUOROSCOPIC-CONTROLLED ANALGESIC EPIDURAL BLOCKADE IN PATIENTS WITH DEGENERATIVE DISEASES OF THE SPINE

Summary of the Doctoral Thesis
for obtaining the degree of a Doctor of Medicine
Speciality – Anesthesiology and Reanimatology

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The study was carried out in Pauls Stradins Clinical University Hospital Anesthesiology and Reanimatology Clinic and Riga 2nd Hospital

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1. INTRODUCTION

Back pain with or without pain in the lower extremities is one of the most common problems among the chronic pain disorders with significant influence on economic, public life and health [1, 2]. The study on habits of the Latvian citizens affecting the health conducted by the Health Economical Centre in 2010 shows that one of the most common health problems found in the Latvian citizens is pain. In men, the most common pain localization is back — 29.8%, and in women back pain is the second most common pain after headache — found in 38.6% [3]. Also in European countries one of five people suffers from chronic back pain [4].

Effective treatment of back pain is provided by combined therapy. At the initial period of the treatment non-invasive methods (physiotherapy, psychotherapy, medications etc.) are used, and if the selected therapy does not work invasive methods (injections, blockades etc.) are used [5, 6]. The American Society of Anesthesiologist and the American Society of Regional Anesthesia recommend using multimodal invasive therapy in the treatment of chronic pain [7].

Injection of steroids in the epidural space of the spinal canal has been used for treatment of back pain already for 50 years [8]. Because the steroids injected epidurally blocks the inflammatory mediators in the zone of neural roots and hence also pain, the term “epidural blockades” (EB) is used frequently instead of the “epidural steroid injections” [9]. Currently the guidelines of the American Society of Anesthesiologist (ASA) for therapy of chronic pain published in 2010 recommend performing injections of the epidural steroids under fluoroscopic guidance to confirm the correct needle position and avoid the dramatic complications [7]. This method allows a specialist to visualize the needle direction at the intervertebral level and

distribution of the contrast media in the epidural space during the blockade that increases the accuracy of the needle placement and delivery of the injected drug in the pathologic place [10, 11].

Fluoroscopy is useful method for needle visualization in patients with signs of anatomical changes of the spine that may interfere with the injection technique (for example, degenerative changes and adiposities) [12]. The only exceptions for the (injection) blockade without visualization are young patients without adiposities, as well as patients with no previous back surgery. However, it was found in the study on the technical aspects of epidural blockades that only 30% of lumbar epidural injections were done under fluoroscopic guidance in public clinics and 77% in the private medical institutions [13]. The possible explanation of this situation is lack of fluoroscopic equipment and radiation risk or allergy to the contrast media.

Ultrasound is used mostly in the world as a visualization method for epidural anesthesia [14, 15]. Currently available data show that ultrasonoscopy can be considered as a new technology also for treatment of pain [16]. Pre-procedural ultrasonoscopic examination of the spine allows determining the level of vertebral pathology where the puncture should be done and the optimal puncture place [17, 18]. The main limitation of this procedure is that operator does not visualize a needle during the procedure and therefore it can be difficult to move the needle through the interlaminar space. However, the ultrasound method may be an attractive alternative for the interlaminar lumbar injection of the epidural steroids under fluoroscopic guidance if the patient is allergic to contrast media or the fluoroscopy is not available. Contrary to fluoroscopy it does not need the rooms protected against radiation, protective measures and additional maintenance costs. Patients and medical personnel are not exposed to gamma radiation, as well as the waiting time for the procedure for patient decreases significantly.

There are no randomized studies in the word in which ultrasound would be used as an alternative to fluoroscopic guidance during the epidural steroid injections.

This study was designed to compare the quality, accuracy, technical difficulties of the epidural blockades, as well as its analgesic effects and functional improvement performing interlaminar epidural injections after ultrasound spine visualization by comparing with the injections under fluoroscopic guidance in patients with lower back pain due to degenerative spine diseases.

Aim of the work

To compare the diagnostic significance of ultrasonoscopic and fluoroscopic visualization methods for epidural analgesic blockades in patients with back pain and degenerative vertebral diseases.

Objectives of the work

1. To compare the efficiency and quality of ultrasound assisted and fluoroscopic controlled epidural blockades depending on patient demographic and clinical parameters when determining their effect on relieving pain and functional disability.
2. To compare technical difficulties and performance characteristics of epidural blockades under ultrasonoscopic and fluoroscopic visualization by determining the procedural parameters (duration of procedure, number of needle puncture and changes of needle direction).
3. Evaluate the adverse reactions and complications of epidural blockades done by using both methods.

Hypotheses of the work

1. Ultrasonoscopy is effective control method for ensuring technical quality of epidural blockades in the cases of back pain and degenerative diseases of the spine.
2. It is possible to achieve an equivalent analgesic effect of blockade after ultrasound spine visualization comparing with the effect of blockades done under fluoroscopic guidance ("gold" standard in pain medicine).
3. Blockades done after ultrasound spine visualization do not cause any serious adverse reactions or delayed complications.

Scientific and practical novelty of the work

This is the first study at Latvian level on the possibilities of visualization of epidural blockades and detailed analysis of the methods. The results of the efficiency, quality, technical difficulties and possible complications are compared with the results of epidural blockades done under fluoroscopic guidance ("gold" standard in pain medicine).

The results of the promotion work allow to develop ultrasound use for epidural blockade in conditions when fluoroscopy availability is limited or any allergic reaction to radiologic contrast media is found in the patient, as well as if this visualization method must not be used in pregnant women or other patient groups to avoid the radiation.

Amount and structure of the promotion work

The promotion work is written in Latvian. Sections of the promotion work: introduction, literature review, materials and methods, results, discussion, conclusions and bibliography. The work consists of 143 pages in total, including 22 tables, 38 pictures and four attachments. The reference list consists of 293 references.

2. MATERIALS AND METHODS

2.1. General characteristics of the study

The research work was worked out during the period from January, 2010 till September, 2012.

The promotion work is done after receiving of the permission of the Central Medical Ethical Committee (14.01.2010.). The study was conducted in the Pauls Stradins' Clinical University Hospital and Riga 2nd Hospital.

137 patients with lower back pain and radicular pain were included in the prospective, randomized study; according to the protocol epidural injection of the steroids were indicated to them.

The patients were initially referred to the day hospital of the pain clinic by other specialists (neurologists, neurosurgeons, traumatologists, rheumatologists, rehabilitologists) who were introduced to selection criteria. All patients have had unsuccessful previous conservative therapy, including use of several pharmacological analgesics, physical therapy and other non-spinal injections but have not had any epidural injections of steroids or surgery on vertebral lumbar part in the last 6 months. Careful and thorough standard assessment was done for each participant of the study and the collected parameters: clinical anamnesis, data of physical examination, results of computed tomography (CT) or magnetic resonance imaging (MRI).

Before the therapy, the patients were introduced to the points of the Numerical Rating Scale (NRS) for pain, questions of the Oswestry Functional Disability Index and technique of the epidural steroid procedure, as well as informed about the possible adverse reactions and complications. All patients were introduced to the study protocol and were signed a written consent.

During the study all its participants continued to receive other therapy, for example, physical therapy and initially prescribed pharmacological

analgesics but no new analgesics were used and no additional peripheral injections, central injections or operations were done.

Inclusion criteria:

1. Lumbar or lumbosacral back pain, unilateral or bilateral radicular pain with/without radiculopathy
2. Chronic back pain limiting the movement function (longer that 3 months)
3. Pain severity according to the NRS at least 5 points
4. Multiple degenerative changes in the lumbar spine confirmed by computed tomography (CT) or magnetic resonance imaging (MRI): spondylosis, spondyloarthrosis, stenosis of the spinal canal, foraminal stenosis, disc protrusion, herniation, scoliosis, spondylolisthesis
5. Ineffective (longer than 3 months) previous conservative therapy

Exclusion criteria:

1. Patients with the previous vertebral surgery in the lumbar part
2. Epidural blockades within the last 6 months
3. Previous allergy to the administered medications and contrast media
4. Patients with severe coagulation disorders
5. Infection at the puncture site
6. Specific back pain (diagnosis of cancer, current psychiatric co-morbidity etc.)
7. Severe neurological deficiency (paresis, paralysis etc.)

2.2. Characteristics of the patient groups

Male and female patients aged 47 to 94 years (median 70 years) were included in the study. From 137 patients fifteen were excluded from the study due to different reasons, two patients did not agree to take part in the study and 120 patients continue the study.

Patients were randomized in two groups with approximately equal number in each group depending on the used control visualization method of the blockade (fluoroscopy (FS) or ultrasonoscopy)):

Fluoroscopic group (FS) — patients in which analgesic epidural blockades were done under fluoroscopic guidance.

Ultrasonoscopic group (US) — patients in which analgesic epidural blockades were done after visualization of the spine and injection site by ultrasonoscopy.

All patients received interlaminar median and paramedian epidural injection between L_4—L_5 and L_5—S_1 or at higher level of the lumbar spine based on the clinical and radiological signs of the disease.

Injection site (intervertebral level, median, paramedian at the left or right side) was determined following the clinical testing and the results of diagnostic CT or MRI. Blockade was done 3 times with the interval of 2—3 weeks.

All blockades were performed by the author of the work personally after learning the use of fluoroscopic and ultrasonoscopic control techniques.

Allowed doses of the drugs were used during the procedures and allowed types of administration were used according to the terms for the Medical Technologies registered in Latvia.

Data were collected by two study-independent nurses. One observer recorded procedural parameters, whereas the second nurse (which was not involved in the procedure) continued to monitor the patients and collect the data

after each procedure, 1 and 3 months after the procedure (by phone during the survey).

Patients of both groups were placed on the operating table in prone position with a pillow under their hips. The lying position is the most convenient both for a patient and pain specialist because then the patient's free movements are limited and there will not be any deviation of the epidural space during the procedure. This position provides the ability to identify the midline, as well as prevents spinal rotation characteristic for the side or sitting position and so complicating identification of the epidural space.

The nurse ensured intravenous approach before each blockade and the patient follow-up — non-invasive measurement of blood pressure, electro-cardiogram (ECG), as well as indirect measurement method of blood oxygen saturation or pulsoxymetry (SpO_2) — provided in the standards of the society Association of Anesthesiologists and Reanimatologists of Latvia was followed. Appropriate monitoring and prevention of the complications was done after the procedure in the day hospital.

Fluoroscopy was used in the FS group for localization of the intervertebral space and injection site, at every correction of the needle position, as well as during the phase of contrast injection. During the study, fluoroscopy was used in the US group only for confirmation of distribution of the contrast media in the epidural space and only after already performed introduction of the epidural needle in the epidural space after ultrasonoscopic spine visualization.

2.2.1. Technique of the fluoroscopy procedure

When the patient is placed in the optimal lying position with a pillow under his hips, an antiseptic is applied to the skin using the iodine-based

antiseptic solution and alcohol solution. The doctor then localizes intervertebral spaces using irregular fluoroscopic photographing of the lumbar spine.

Fluoroscopic projection

The fluoroscopic projections are developed depending on the direction (course) of the X-rays. Movement of the X-rays from back to front forms an AP projection. Movement of the X-rays from one side to another forms a side projection referred as LL (from the lateral surface to the lateral surface) projection.

Technical parameters:

- Film dimensions: 20 x 40 cm, in the longitudinal size
- Distance of the film focus: 115—150 cm
- Focus: large
- With grid
- Expositional parameters: 90kV, automatic exposition, central field of the exponometer

Visualization of the vertebral structures and puncture site

AP projection is used where the end plates of the lumbar vertebrae are seen like linear or oval forms. Space between the upper and lower vertebral arcs is regarded as an intervertebral space and entrance in the epidural space. The upper part of the sacrum and lumbosacral transition appears on the screen regarded as a L_5—S_1 space. Counting upwards, the next space is regarded as a L_4—L_5 space and so on. Using a sterile tool, the physician marks a median and paramedian injection site and does the infiltration anesthesia of the skin, subcutaneous tissues, supraspinal ligament and interspinal ligament with local anesthetics (1% lidocaine solution).

Evaluation of the visualization quality

While looking in the monitor, the specialist evaluated the intervertebral spaces and entrance in the epidural space.

Injection technique

Epidural needle of size No. 18 is introduced directly into the mid-plane (median approach) or 2—3 cm paramediany (paramedian approach) in the pre-anesthetized site through the supraspinal ligament, in the intraspinal ligament. Needle stylet then is removed and 10 ml syringe is attached with a well-sliding plunger filled with air to perform the resistance losing maneuver. In this case the risk associated with the accidental dislocation of the needle out of the epidural space during replacement of the syringe.

The investigator holds the needle camera tightly with the left thumb and forefinger. The left hand is firmly supported against the patient's back to avoid uncontrolled movement of the needle if the patient unexpectedly moves. The syringe with the needle is slowly driven forward with the left hand and the plunger is pushed simultaneously with the right thumb. As soon as the needle slope passes through the yellow ligament and enters the epidural space, sudden resistance release of the injection occurs and the plunger loses the resistance to forward motion. Air test is performed by injecting 2 ml of air with a sterile syringe and well-sliding plunger to make sure that the needle is in the epidural space. Strength required for the injection should not exceed that needed for overcoming of the resistance. Noticeable pain or sudden increase in resistance during the injection suggests an incorrect position of the needle, and the injection must be stopped immediately and the needle localization must be redirected.

Injection of the contrast

When the resistance loss has occurred, 1 ml of contrast media Omnipaque 300 is injected using an alternating fluoroscopic filming to make sure that the needle is in the epidural space and exclude intravascular, intrathecal and/or soft tissue infiltration. For confirmation that the contrast has reached the epidural space, all images were acquired in the AP projection. The

LL side projection was used only in the cases when it was difficult to determine distribution of the contrast media.

Injection of the steroids

When the needle position is confirmed, the syringe containing solution for injection (1 ml methylprednisolone acetate, 80 mg, 4 ml saline with 1% of lidocaine) provided for injection in the epidural space (total volume 5 ml) is carefully attached to the needle. Gentle aspiration is done to make sure that no cerebrospinal fluid or blood appears.

2.2.2. Technique of the ultrasonoscopic-assisted procedure

Patients randomized in the US group were placed on the procedure table in the lying position with a pillow under their hips and the ultrasound imaging of the lumbar spine was done visualizing the intervertebral spaces and marking the injection site on the skin with a waterproof marker.

Axis of the ultrasonoscope probe

- Longitudinal — inclined toward the vertebral midline
- Transversal — orientation is perpendicular to the vertebral midline

Technical parameters:

- Frequency 2—5 MHz
- Initial depth settings 7—8 cm
- Enhancement —50%

Visualization of the vertebral structures and puncture site

Paramedian approach

Using vertebral visualization by ultrasound, intervertebral space, midline, epidural space and distance from the skin to the epidural space is identified. Non-sterile probe is placed to the vertebral lumbar part, 2—3 cm laterally and inclined toward the midline, and placing the probe longitudinally it

is drifted inclined down in the direction of legs up to the horizontal hyperechogenic line.

Hyperechogenic line is a sacrum from the upper border of which the number of spaces is counted. The first space between the line of the sacral upper border and "Saw-tooth" (line of the L_5 arc) is the L_5—S_1 intervertebral space. Attribute of the L_5—S_1 space is that it is narrower that other spaces of the vertebral lumbar part and it can facilitate their identification. Other spaces are easily identifiable with an oblique longitudinal view guiding the probe in the head direction counting from the lumbosacral junction (L_5—L_4; L_4—L_3 etc.).

Ultrasound allows identifying not only intervertebral spaces but also epidural space, spinal canal and posterior part of the vertebral body. Epidural space is a hypoechogenic space between the yellow ligament and posterior dura mater of the spinal cord. Epidural space is not frequently seen as a separate structure but these structures (yellow ligament, posterior dura mater of the spinal cord together with the epidural space) appear as an unified whole and are referred as a “posterior complex”. Anterior dura mater of the spinal cord and the posterior wall of the vertebral body form the “anterior complex”. If the anterior complex is viewable, it means that the beam has penetrated the spinal canal and the operator can be sure that the intervertebral space is identified. Lateral and articular processes are the additional useful landmarks in complicated cases because they are found in approximately the same transversal plane as the intervertebral space. A hypoechogenic longitudinal structure visualized between the posterior and anterior complexes is a structure of the spinal canal.

Median approach

When the paramedian approach has been visualized and the intervertebral space required for injection has been selected the probe was rotated to 90 degrees in the transversal orientation perpendicularly to the spine

and the same structures were identified and the midline injection site was marked.

Assessment of the visualization quality

Specialist evaluates the quality of the vertebral structures when viewing at the ultrasonoscope screen.

Measurements

As soon as the view of intervertebral spaces is acquired, depth from the skin surface to the posterior complex is determined using the electronic meter built in the ultrasonoscope.

Marking the puncture site and determination of the needle slope

When the best acoustical window is found showing the best view (epidural space), midpoints were marked on the skin in each side from the probe both in transversal and longitudinal plane. The puncture site is in the point where the lines connecting two vertical midpoints with the line connecting two horizontal midpoints intercross. It is possible to evaluate the slope degree of the needle needed during the puncture by changing the probe angle to precisely insert it in the intervertebral space, as well as to obtain the optimal transversal view.

Injection technique

After determination of the puncture site, the ultrasound probe is taken off and placed aside and gel is removed from the skin. Puncture place then prepared applying the antiseptic to the skin using the iodine-based antiseptic solution and alcohol solution. Injection of the local anesthetics is done to infiltrate the injection site.

Epidurals needle of size No. 18 was introduced using the puncture site determined by ultrasound and taking into account the angle of the needle direction and depth to the epidural space determined before the procedure during the scanning technique.

Injection of the contrast

During the study, 1 ml of the contrast media Omnipaque 300 is injected to make sure of localization of the needle in the epidural space puncture of which has been done after ultrasonoscopic visualization in the certain puncture site and to exclude intravascular, intrathecal and/or soft tissue infiltration when the resistance loss has occurred and then fluoroscopic filming is done only for documentation the needle position in the ultrasonoscopically pre-determined site. All images were acquired in the AP, and the LL side projection was used only in the cases when it was difficult to determine distribution of the contrast media.

Injection of the steroids

After following all safety measures, the provided solution (1 ml methylprednisolone acetate, 80 mg, 4 ml saline with 1% of lidocaine) is injected in the epidural space.

If the cerebrospinal solution is aspired or intravascular, intrathecal and/or soft tissue infiltration is found, epidural injection is repeated in other intervertebral space. Injection speed was about 1 ml/s.

2.3. Data collecting and analysis

Patient demographic and physical data (age, gender, body mass index (BMI)) and clinical characteristics (types of the morphological changes in vertebral lumbar part, number of the morphologic changes, duration of the back pain, intensity of the pain and level of the functional disability) were collected during the study. Procedural parameters (needle approach, quality of the visualization, duration of the procedure, number of the needle punctures, number of the change in needle direction) were monitored during the procedure. Complications were monitored during the procedure and 24 hours after it.

Patient and procedural data

Body mass index

Body mass index (BMI) is a numerical value calculated considering person's height and weight. BMI is used for evaluation the possible weight problems. Reliability of BMI and correlation with the direct measurements of fat amount is showed.

Formula for calculating BMI: weight (kg)/(height (m))^2

Interpretation: standard categories for adults: BMI below 18.5 kg/m^2 shows a reduced body weight; from 19 to 25 — normal; from 25.1 to 30 — overweight; 30.1—35 — corpulent; 35—40 — clinical adiposities; > 40 — pathologic adiposities [19].

Patient clinical characteristics

Types of the morphological changes in lumbar spine — type of changes in the lumbar spine found by CT or MRI (spondylosis, spondylo-arthrosis, central stenosis of the spinal canal, disc protrusion, disc herniation, scoliosis, spondylolisthesis, hyperlordosis).

Number of the morphological changes (MC) — number of changes in the lumbar spine found by CT or MRI.

Duration of the back pain (months) — period from the onset of back pain till the first consultation.

Numerical Analogue or Rating Scale (NRS) — the subject marks the pain intensity on the 11-points numerical scale where the number 0 to 10 corresponds to the pain intensity; 0—there is no pain, 10 points — the most intense, unbearable pain, respectively. The pain is considered as mild if it is 3 and less points, 4—6 points correspond to moderate pain and 7 and more — to severe pain [20].

NRS measurements were done before the therapy (NRS 0), after the first (NRS 1), the second (NRS 2), the third (NRS 3) blockade, one (NRS 4) and

three (NRS 5) months after therapeutic course (phone survey or during the repeated visit).

Decrease in the pain intensity for ≥ 50% comparing with the baseline (NRS 0) is considered as significant reduction of the pain intensity [21].

Oswestry Functional Disability Index (ODI) — questionnaire for evaluation of the functional disability developed due to the back pain and the life quality. It consists of 10 questions about the patient daily activities and their influence to his/her social life. Each answer to the question is evaluated with points (0 to 5) depending on the severity of functional disability. Total number of the points are multiplied by two and expressed in percentages; the maximal possible percentage is 100%. Finally, the patient condition is evaluated beginning with the minimal degree to extreme degree.

Expression of the percentages in degrees:

- Minimal degree (0%—20%) — the patient suffers from back pain but can deal with most of his/her life activities
- Moderate degree (21%—40%) — the patient suffers more from pain when sitting, standing up and standing, the pain complicates traveling and social life, as well as his/her ability to work
- Medium degree (41%—60%) — back pain significantly affects the daily activities
- Severe degree (61%—80%) — back pain affects all aspects of the patient life
- Extreme degree (81%—100%) — the patient does not go out of his/her house due to the back pain

The patient completes the questionnaire individually — before the therapy (ODI 0), one (ODI 1) and three (ODI 3) months after the therapy course (phone survey or during the repeated visit).

Level of the ODI decrease for ≥ 50% comparing with the baseline (ODI 0) is considered as significant [21].

Procedural parameters

Approach (needle position vs. spine) — selection of the injection site against the vertebral midline (median, paramedian).

Indicators of the visualization quality:

1. Fluoroscopy group: the image was considered as good if the borders of the interlayer space were sharps and with clear separation (good visualization). The image was considered as poor if there were vague and unclear borders (poor visualization).

2. Ultrasonoscopy group*:* the image was considered as good if the posterior complex, spinal canal and anterior complex can be visualized (good visualization). The image was considered as poor if only the posterior complex is seen in it (poor visualization).

Duration of the procedure (sec) — total amount of time required for determination of the bone landmarks and performing the injection of epidural steroids (duration of visualization + duration of the injection):

1. Duration of visualization (sec) — time required for creating the further puncture landmarks.

- In the FS group, it was defined as the time period when the operator localizes the intervertebral space by using the alternating irregular fluoroscopic photographing of the lumbar spine, and it ends with the marking of the injection site.
- In the US group it was defined as the time period when the probe was attached to the patient's back when operator localizes the intervertebral space and does all measurements, and it ends with the marking of the injection site by marker.

2. Duration of injection (sec) **—** is the time required for injection the steroids in the epidural space. It is defined as the time period between the first inserting of the epidural needle in the patient's spine, drug administration and needle removal from the patient's spine

Number of the needle punctures — attempts to insert the needle required for the successful reaching of the epidural space:

- at one level (one intervertebral space)
- at several levels (above or below the selected adjacent intervertebral space)

Number of changes of needle direction — after penetration of the skin, each shifting of the needle (change of angle) required for successful puncture of the epidural space before complete removal of the needle from the patient's skin.

In case the repeated punctures are required during one blockade, all indicators of the parameters are added together. Assessment of the blockade quality was done during each blockade (blockade 1, 2, 3).

Complications

The following complaints were listed:

1. During the procedure — complications observed directly during the procedure:

- dizziness
- nausea, sweating
- puncture of the blood vessel
- puncture of the spinal space
- tenderness at the injection site

2. Complications observed 24 h after the procedure:

- aggravated pain
- facial flushing

The measurements were done after each procedure.

2.4. Statistical methods used in the study

In this study, the software package *SPSS "Statistical Package for the Social Sciences", version 19.0 for Windows,* was used for statistical analysis of data and presentation of the research results.

The primary data used in the research was *quantitative* (weight, height, age, duration of symptoms, NRS and ODI category before treatment, number morphological changes) and *qualitative* (gender, ODI degree), as well as patients' demographic and clinical indicators, procedural settings (needle position vs. spine, visualization, duration of visualization, duration of injection, duration of procedure *per se*, number of needle punctures, changes of needle directions at different phases of the research), and the indicators of the treatment results (NRS, ODI).

The secondary (computational) indicators were the averaged ones, obtained as average (mean) arithmetic indexes of the primary data (number of morphological changes per patient, average data within three blockades, duration of visualization, duration of injection, duration of procedure *per se*, number of needle punctures, changes of needle directions). In some cases, the standardization of qualitative indictors was applied — for better understanding and further interpretation. The Standard Indicators were distributed according to the normal rule, with zero average and unit variance. This way, it is convenient while proceeding with comparative analysis and standard assessment of various indicators, or the same indicators — within various groups of respondents.

The proof of hypotheses was performed using such statistical criteria as: *Chi-Square Tests* (χ^2) — non-parametric test allowing evaluation of the correlation (the difference level) between two quantitative features, as well as

the magnitude of the same feature, but at different research stages. At the same time, the *Cramer's V Criteria* allows to evaluate the intensity of this correlation.

The *One-Sample Kolmogorov-Smirnov Test* is a non-parametric statistical test intended to estimate whether the distribution of the analyzed indicators is significantly different from the normal ones.

The *Mann-Whitney U-test* allows comparing the level of an indicator in the groups under research; the *Wilcoxon test* allows comparing the magnitude of the indicators at different stages.

For research purposes, the *Pearson and Spearman Correlation Coefficients* were applied to study the correlation relationship between indicators. *The Pearson Correlation Coefficient* was used in case the distribution of indicators was not significantly different from the normal one. *The Spearman Correlation Coefficient* allows estimating the magnitude and significance of relation between two indicators, which are not subject to normal distribution, or between indicators measured by ordinal scale.

For all statistical criteria used in this research, the acceptable error borderline related to the distribution of the observable result including all population, was the *p-level* (the level of statistical significance), which equals 0.05. With $0.05 < p < 0.1$, correlations are considered at the level of statistical tendency.

In order to separate homogenous patient groups on the basis of their clinical indicators, procedural indicators, and indicators, characterizing the treatment efficiency, the two-step cluster analysis was used in this research.

3. RESULTS

3.1. Characteristics of the patient demographic, physical and clinical data

112 patients from the 137 previously selected completed the study successfully. Totally 25 patients withdraw from the study. Seventeen patients were excluded before the randomization; in three patients acute disc herniation was diagnosed, in two — osteoporotic vertebral fracture and three patients have done the blockade outside the protocol. And finally, fifty-six patients in each group completed the study and they data were analyzed. Procedures were done in 90% cases between L_5—S_1 vertebrae and in 10% cases — between L_4—L_5 vertebrae and the mean interval between the procedures was 3 (2—5) weeks.

The Table 3.1. represents **average (mean) indicators and mean square deviations** of initial characteristics of patients from the researched groups. The average age of the study patients was 69 years. Mostly women were included in both groups. There were only 29% of men in the US group and only 14% — in the FS group. According to the χ square criteria, these differences between both study groups are not statistically significant.

Table 3.1.

Patients' initial characteristics

Indicators	FS (n = 56)	US (n = 56)	P
Age (years)	69.23 ± 10.27	69.14 ± 10.19	0.650
Gender (F/M)	48/8 (86%/14%)	44/12 (79%/29%)	0.230
Weight (kg)	86.50 ± 14,04	86.18 ± 16.61	0.912
Height (cm)	165.52 ± 7.71	166.30 ± 7.91	0.596
Body Mass Index (kg/m^2)	31.73 ± 5.72	31.2 ± 5.96	0.963

Patient age, weight, height and body mass index (BMI) are expressed as an average ± SD

The level of statistical significance in all cases exceeded 0.05 allowing to conclude that based on initial characteristics of patients there were no statistically significant distinctions between the groups.

Table 3.2 illustrates the **types of morphological changes in the lumbar spine** of patients of the studied groups. The most common changes in the groups were spondylosis and spondyloarthrosis and the less common — disc herniation, scoliosis and hyperlordosis, and there were not any statistically significant differences between the groups.

Table 3.2

Types of morphological changes per patients' groups

Types of changes	FS (n = 56)	US (n = 56)	P
Spondylosis	55(98%)	56(100%)	1.000
Spondylarthrosis	53(95%)	55(98%)	0.618
Central spinal stenosis	32(57%)	32(57%)	1.000
Foraminal spinal stenosis	38(68%)	31(55%)	0.244
Disc protrusion	43(77%)	48(86%)	0.333
Disc herniation	9(16%)	7(13%)	0.788
Scoliosis	8(14%)	10(18%)	0.798
Spondylolisthesis	25(45%)	30(54%)	0.450
Hyperlordosis	2(4%)	6(11%)	0.271

Number of patients, n (%) per the studied group (FS, US)

Number of the spinal changes per one patient was calculated regarding to the number of the vertebral morphological changes found in the patients. The mean sign value in the FS group is 4.74 ± 1.15, in the US group — 4.91 ± 1.10. Distribution of the sign in both groups significantly differed from the normal distribution. According to the Mann-Whitney criteria, no statistically significant differences between groups were detected (p = 0.559) (Fig. 3.1).

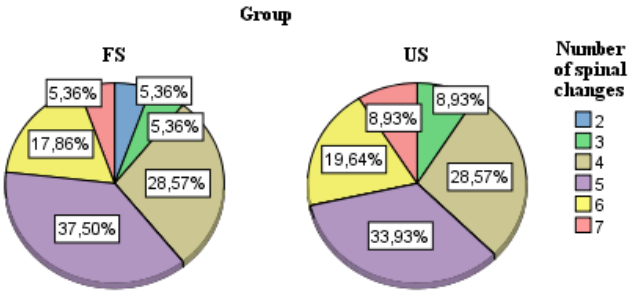

Fig. 3.1. **Number of the spinal morphological changes per one patient in the FS and US group**

Sign of the duration of back pain varied in the range from 3 to 240 months. Amplitude of the variations is 237 (i.e. 240—3) months, however in a half of patients of the FS group this sign value did not exceed 36 months and in the US group — 30.5 months. The mean sign value for the FS group was 58 months and for the US group — 59.32 ($p = 0.437$).

Average intensity of the back pain before the procedure (NRS 0) was similar, without any differences: 7.52 ± 0.99 in the FS group and 7.32 ± 1.35 in the US group ($p = 0.287$). In both groups pain intensity after each blockade changed alike comparing with the NRS level before initiation of the therapy. NRS 4 changes a month after the therapy course was an average of 54% (FS) and 52% (US) and after three months (NRS 5) — 47.5% (FS) and 43% (US).

Statistically significant decrease in **the pain intensity (≥ 50%)** was observed after the 1st blockade in the FS group for 25% and in the US group for 32% of patients ($p = 0.531$); after the 2nd blockade the pain decreased in the FS group for 50% and in the US group for 52% of patients ($p = 1.000$); after the 3rd blockade the pain decreased in the FS group for 71% and in the US group for 64% of patients ($p = 0,544$). One and three months after the therapy course the pain decreased significantly in the FS group for 73% and in the US group for

68% of patients (p = 0,679) and in the FS group for 55% and in the US for 55% of patients (p = 1,000), respectively (table 3.3).

Table 3.3

Dynamics of the indicators of the numerical analogues scale (NRS) at different study phases

Research phase	FS (n = 56) Mean ± SD	US (n = 56) Mean ± SD	P
NRS 0	7.52 ± 0.99	7.32 ± 1.35	0.287
After the 1st blockade	4.98 ± 1.48	4.82 ± 1.67	0.693
Changes of NRS 1 ≥ 50%	14(25%)	18(32%)	0.531
After the 2nd blockade	4.38 ± 1.53	3.75 ± 1.77	0.064
Changes of NRS 2 ≥ 50%	28(50%)	29(52%)	1.000
After the 3rd blockade	3.45 ± 1.75	3.32 ± 1.74	0.783
Changes of NRS 3 ≥ 50%	40(71%)	36(64%)	0.544
One months after the therapy course	3.52 ± 2.02	3.45 ± 1.91	0.699
Changes of NRS 4 ≥ 50%	41(73%)	38(68%)	0.679
Three months after the therapy course	3.98 ± 2.34	4.09 ± 2.01	0.789
Changes of NRS 5 ≥ 50%	31(55%)	31(55%)	1.000

NRS (numerical value in the 11-point scale), NRS 0 — before initiation the therapy, NRS 1— after the first blockade, NRS 2 — after the second blockade, NRS 3 — after the third blockade, NRS 4 — month after the therapy course, NRS 5 — three months after the therapy course; Number of patients n (%) regarding to the studied group (FS, US); the mean ± SD

Indicators of the Oswestry functional disability index are summarized in the Table 3.4.

Table 3.4

Indicators of the Oswestry functional disability index at the study stages

Research phase	FS (n = 56) Mean ± SD	US (n = 56) Mean ± SD	P
Before initiation of the therapy ODI 0	55.41 ± 11.02	54.68 ± 1.09	0.815
One month after the therapy course	30.80 ± 14.53	29.98 ± 14.02	0.501

Research phase	FS (n = 56)	US (n = 56)	P
Changes of ODI 1 ≥ 50%	30(54%)	33(59%)	0.703
Three months after the therapy course	33.05 ± 15.47	32.25 ± 15.48	0.784
Changes of ODI 3 ≥ 50%	24(43%)	26(46%)	0.849

ODI (numerical value in 100-point scale), ODI 0 — before initiation of the therapy, ODI 1 — one month after the therapy course, ODI 3 — three months after the therapy course; number of patients n (%) regarding to the studied group (FS, US); the mean ± SD

Level of the statistical significance of **the mean ODI values in the FS and US groups** was higher that 0.05 in all cases indicating the lack of the statistically significant difference in the comparable groups (table 3.5). **ODI changes** a month after initiation of the therapy course (ODI 1) was an average of 45.5% in the FS group, and 30 patients (54%) have at least for 50% less comparing with the ODI 0 before initiation of the therapy. In the US group, changes were an average of 47.2%, and 33 patients (59%) — at least 50%. According to the χ square criteria, these differences are not statistically significant ($p = 0.703$). Three months after the therapy course (ODI 3) number of patients with ODI changes for at least 50% in the comparable groups is 24 (43%) and 26 (46%) but these differences also are not statistically significant ($p = 0.849$).

Before the initiation of the procedure (ODI 0), the greatest number of patients met medium and severe degree of functional disability without any statistically significant difference between the groups ($p = 0.131$). One month after the therapy course (ODI 1) in both patient groups already minimal and moderate degree of functional disability prevailed ($p = 0.992$); three month after the therapy course (ODI 3) most of the patients still had minimal moderate degree of functional disability ($p = 1.000$) and no statistically significant differences in the groups were found. (Fig. 3.2, 3.3, 3.4)

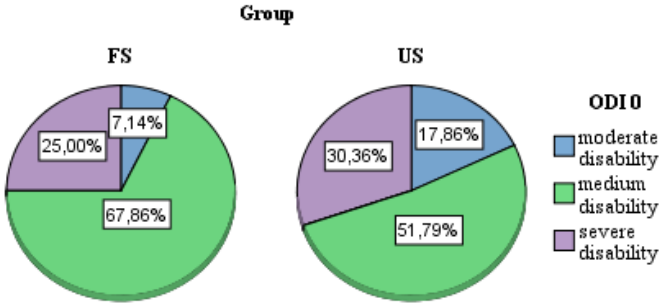

Fig. 3.2 **Degrees of the Oswestry Functional Disability Index in the groups before initiation of the therapy**

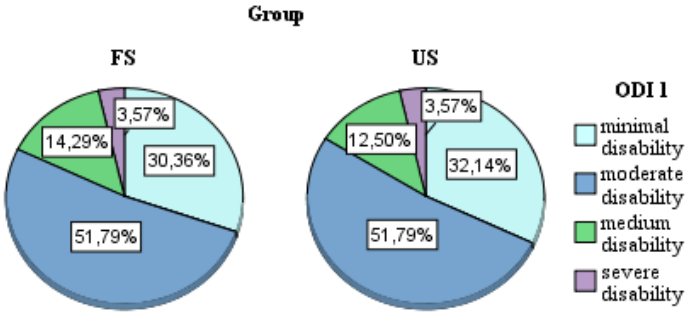

Fig. 3.3. **Degrees of the Oswestry Functional Disability Index in the groups one and three months after the third blockade**

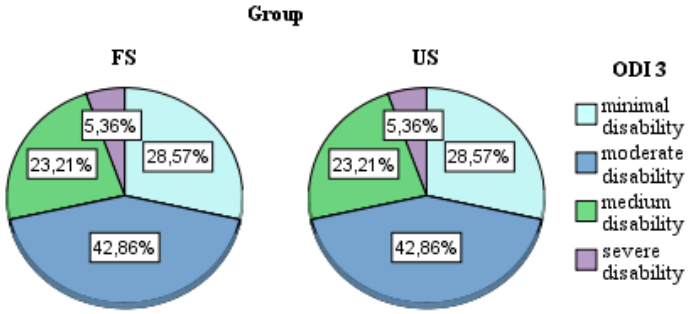

Fig. 3.4. **Degrees of the Oswestry Functional Disability Index in the groups three months after the therapy course**

3.2. Procedural parameters

No statistically significant differences were observed in the studied groups regarding such parameters as **visualization of the vertebral structures** (p = 0.352). In most cases the injections were done paramediany against the vertebral midline for treatment of unilateral pain (needle position vs. spine) (Table 3.5).

Table 3.5

Procedural Indicators

Indicators	FS (n=56)	US (n=56)	P
Visualization (poor/good)	24/32 (43%/57%)	27/29 (48%/52%)	0.352
Needle position vs. spine (median/paramedian)	18/38 (32%/68%)	16/40 (29%/71%)	0.895

Number of patients n (%)

Number of the needle punctures at the study stages are given in the Table 3.6

Table 3.6

Number of the needle punctures at different study stages

Research phase	FS (n = 56)	US (n = 56)	P
	0/1	0/1	
1st blockade	48/8 (82%/18%)	51/5 (91%/9%)	0.133
2nd blockade	52/4 (93%/7%)	52/4(93%/7%)	1.000
3rd blockade	53/3 (95%/5%)	53/3 (95%/5%)	1.000

0 — attempts to insert the needle (number of needle punctures) at one level followed by successful puncture of the epidural space, 1— attempts to insert the needle at more than one level followed by successful puncture of the epidural space; Number of patients n (%)

There are no statistically significant differences between **the number of the needle puncture** at one level. During the 1st blockade, one attempt of needle insertion at one level was required in the FS group for 48 (82%) patients

and for 51 (91%) patient in the US group (p = 0.133). During the second blockade, puncture of the epidural space after one attempt of needle insertion was similar in the FS and US groups — 52 (93%) for patients of both groups (p = 1.000). During the third blockade, successful puncture of the epidural space at one level was similar in both groups — 53 (95%), (p = 1.000).

The mean values of the procedural parameters are given in the Table 3.7.

Table 3.7

The mean values of the procedural parameters

Procedural indicators	FS (n=56)	US (n=56)	P
	Mean ± SD	Mean ± SD	
Duration of procedure (sec)	370.63±222.24	323.85±114.71	0.644
Duration of visualization (sec)	127.92±60.77	141.27±47.57	0.026
Duration of injection (sec)	242.70±183.71	182.10±84.63	0.033
Number of needle punctures	0 [0—1]	0 [0—1]	0.338
Changes of needle direction	5.5 [4—8]	5 [3—6]	0.097

Average ± SD, median [quartile values]

The mean value of **procedural parameters** of three blockades in the groups significantly differed from the normal distribution. Comparative analysis allows determining the statistically significant differences in the duration of visualization and injection in the FS and US groups. In the US group, the mean duration of visualization was greater than the mean duration of visualization in the FS group (p = 0.026). In a half of the patients in the FS group the duration of visualization did not exceed 111 sec whereas the duration of injection was little greater in a half of the patients for 181 sec. Conversely, in a half of the patients in the US group the duration of visualization was grater — 133 sec but the duration of injection was lesser for 147 sec. **The mean value of the total procedural duration for three blockades** in the groups did not differ statistically significantly (p = 0.644). In the FS group, the duration of procedure for a half of the patients did not exceed 288 sec, whereas in the US group — 283 sec. Quadrille amplitude of the duration of procedure in the FS group was

90 sec, in the US group — 147 sec but these differences are not statistically significant (Tab. 3.7).

3.3. Interaction of the procedural parameters

Using the two factors dispersion analysis, the interaction between the factor of **visualization quality (poor/good)** and **duration of procedure** was determined in both patient groups. Moreover, the statistically significant interaction between factors of group and visualization was found during this process (p = 0.003). **Visualization quality** affected the duration of procedure in the FS group and no significant differences in the duration of procedure were detected in the FS and US group in case of **good visualization**, whereas in case of **poor visualization** the duration of procedure were greater in the FS group and these differences were statistically significant (Fig. 3.5).

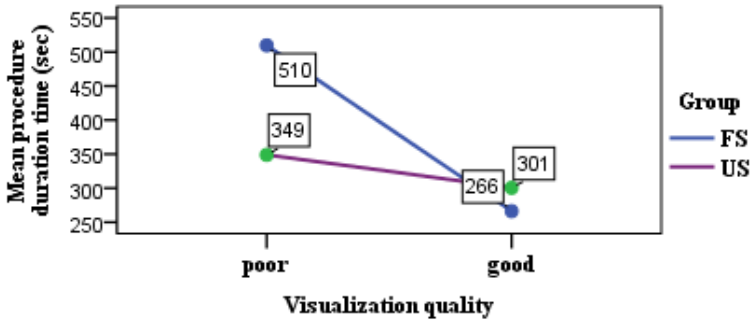

Fig. 3.5. **Influence of the visualization quality on the mean *duration of procedure* in the groups**

3.4. Interaction of the patient data and procedural parameters

Data of the correlation analysis between the patient parameters and procedural parameters are given in the Table 3.8.

Table 3.8

Correlation analysis of the patient clinically demographic indicators and procedural parameters in the groups

Patients' indicators / Procedural indicators	Age		Duration of symptoms		Number of morphological changes	
	FS	US	FS	US	FS	US
Duration of visualization	0.346**	0.115	0.253	0.071	0.249	0.132
Duration of injection	0.287*	0.333*	0.298*	0.122	0.086	0.306*
Duration of procedure	0.367**	0.221	0.298*	0.139	0.173	0.331*
Number of needle punctures	0.455**	0.215	0.325*	0.146	0.452**	0.269*
Changes of needle direction	0.564**	0.295*	0.362**	0.012	0.428**	0.273*

* — correlations with level of significance $p < 0.05$ (significant correlations)
** — correlations with level of significance $p < 0.01$ (highly significant correlations)

Correlation analysis allows detecting the relationships:

1. There is a direct significant relationship between the variable **"Age"** and all **procedural parameters** in the FS group — the older is the patient the longer is the time of procedure and number of change the needle punctures and direction. Direct significant relationships in the US group are observed only between the age and the duration of injection, between the age and the number of change the needle direction — the older is the patient the longer is the time of injection and greater number of change the needle direction;

2. The variable **"Duration of pain"** is associated with almost all **procedural parameters**, except the duration of visualization in the FS group — the longer is the patient pain the longer is the time of procedure,

as well as the number of change the needle punctures and direction is greater. In the US group, no statistically significant relationship between the duration of pain and procedural parameters was observed;

3. The variable **"Number of the spinal morphological changes"** is associated with such procedural parameters as the **change of needle punctures** and **needle direction** in the FS group — the greater in the number of patient vertebral changes the greater in the number of needle manipulations. In the US group, statistically significant relationships were observed also between the duration of injection and the duration of procedure.

3.5. Analysis of the patient subgroups

Depending on the **indicators of procedural parameters,** the two stage cluster analysis allowed grouping the patients in two homogenous subgroups. The **worse procedural parameters** are characteristic for the **first subgroup (PR_P)** with 33 patients (29.5%) from both groups because they had the greatest time of procedure and the greatest number of needle manipulations. 79 patients (70.5%) from both groups were included in the **second subgroup (PR_G)** with **good procedural parameters,** and they had the shorter time of visualization and injection but the number of needle punctures were 0 or one accurate attempt in one space during all three blockades (Table 3.9).

In the FS group, also 18 patients (32%) should be included in the first subgroup with poor procedural parameters and in the US group — 15 patients (27%). 38 patients (68%) in the FS group and 41 patients (73%) in the US group correspond to the second subgroup. According to the Chi-Square Test, these differences are not statistically significant ($p = 0.339$).

The mean values of the procedural parameters in the isolated subgroups of the FS and US groups are given in the Table 3.9.

Table 3.9

The mean values of the procedural parameters in the isolated subgroups

Parameters of procedure	PR_P (n=33)	PR_G (n=79)
	Mean ± SD	Mean ± SD
Duration of visualization (sec)	179.34±67.52	115.91±34.53
Duration of injection (sec)	333.69±212.61	161.73±59.90
Duration of procedure (sec)	513.84±243.79	277.65±62.13
Number of needle punctures	0.30±0.19	0
Changes of needle direction	2.69±0.75	1.44±0.72

In the PR_P — subgroup with poor procedural parameters, in the PR_G — subgroup with good procedural parameters; Average ± SD

The mean values of the patient clinically demographic indicators in the isolated subgroups of the FS and US groups are given in the Table 3.10.

Table 3.10

Patient clinically demographic indicators regarding the procedural parameters in the isolated subgroups

Group	Indicator	PR_P (n = 33)	PR_G (n = 79)	P
		Mean ± SD	Mean ± SD	
FS	Age (years)	76.28 ± 5.76	65.89 ± 10.29	0.001
	Persistence of symptoms	93.50 ± 85.51	41.18 ± 43.08	0.030
	Number of morphological changes	5.28 ± 0.96	4.47 ± 1.16	0.019
US	Age (years)	72.20 ± 9.59	68.02 ± 10.28	0.118
	Persistence of symptoms	72.93 ± 68.82	54.34 ± 67.03	0.197
	Number of morphological changes	5.20 ± 1.21	4.80 ± 1.05	0.282

In the PR_P — subgroup with poor procedural parameters, in the PR_G — subgroup with good procedural parameters; Average ± SD

Analysis of the changes in pain intensity depending on the NRS indicators allowed grouping the patients in two homogenous subgroups. 59 patients (52.7%) having better indicators of decrease in the pain intensity were included in the first isolated subgroup (NRS G) because NRS decrease for an average of 42% after the first blockade and reached 69.5% after the third blockade, but three months after the therapy course the level of the pain decreasing was still for 64.5% lower comparing with the baseline. In the second subgroup (NRS P) where 53 patients (47.3%) were included there were the worse indicators of decrease in the pain intensity because the NRS changes after the first blockade was only 26%, whereas after the third one — 37.4%, but after three months only 23.75% from the baseline level (Fig. 3.6).

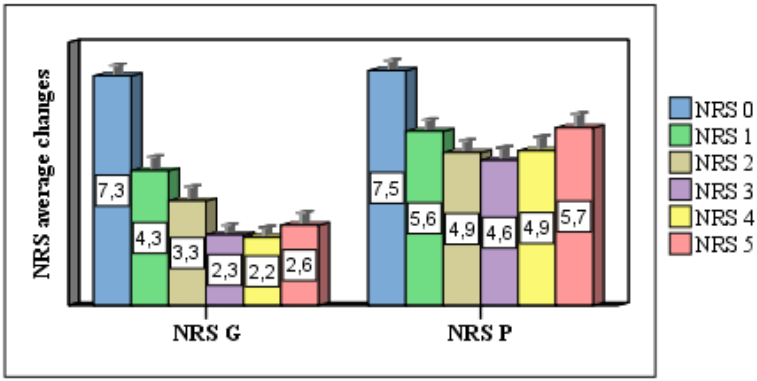

Fig. 3.6. **Indicators of the pain intensity for patients in the isolated subgroups at different study stages**

NRS 0 — before initiation of the therapy, NRS 1 — after the first blockade, NRS 2 — after the second blockade, NRS 3 — after the third blockade, NRS 4 — one month after the therapy course, NRS 5 — three months after the therapy course, in the NRS G — subgroup with the maximal changes in NRS values, NRS P — subgroup with the minimal changes in NRS values

In the FS group, 29 patients (53.6%) belonged to the first of the isolated subgroups (NRS G), whereas in the US group — 30 patients (53.6%). 27 patients (48.2%) belong to the second subgroup (NRS P) in the FS group and in the US group — 26 patients (46.4%), and these differences are not statistically significant (p = 0.850).

The mean values of the patient clinically demographic indicators regarding to the changes in pain intensity in the subgroups of the FS and US groups are given in the Table 3.11.

Table 3.11

Patient clinically demographic indicators in the subgroups isolated depending on the changes in pain intensity

Group	Indicators	NRS_G	NRS_P	P
		Mean ± SD	Mean ± SD	
FS	Age (years)	66.83±10.45	71.81±9.60	0.091
	Persistence of symptoms	40.31±46.37	77.00±75.28	0.040
	Number of morphological changes	4.48±1.24	5.00±1.00	0.106
US	Age (years)	68.37±10.78	70.04±9.59	0.537
	Persistence of symptoms	53.00±66.74	66.62±68.72	0.419
	Number of morphological changes	4.80±1.16	5.04±1.04	0.413

In the NRS_G — subgroup with the maximal changes of NRS values, in the NRS_P — subgroup with the minimal changes of NRS values, average ± SD

In the FS group, statistically significant dependence of the analgesic efficiency of treatment on such patient parameters as the duration of pain ($p < 0.05$) and age (at the level of statistical trend) was observed. In the US group, no statistically significant dependence on the patient characteristics was found.

Analysis of the ODI changes allowed isolating two homogenous subgroups. Moreover, ODI 3 changes three months after the therapy course have a greater discriminate ability. In the first of the isolated subgroups (ODI_G) these changes were an average of 61% comparing with the baseline ODI 0 value measured before initiation of the therapy, while in the second subgroup (ODI_P) this value were 21% of the baseline indicator. In the subgroups isolated one month after the therapy, ODI changes were 61% and 32%, respectively. Moreover, in the first subgroup no significant differences of ODI were observed one (ODI 1) and three (ODI 3) months after the therapy course, while in the second subgroup the mean ODI values three months after the therapy course were greater that one month after the therapy course, and these differences are statistically significant ($p < 0.001$) (Fig. 3.7).

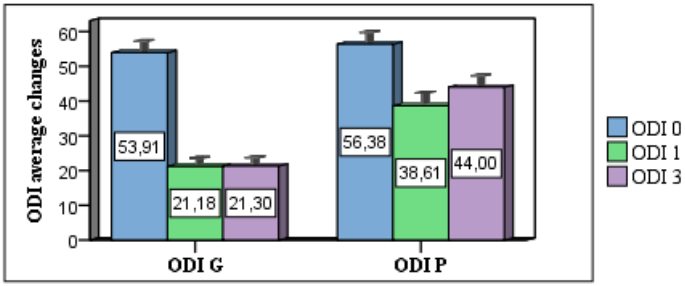

Fig. 3.7. **The mean values of the Oswestry Functional Disability Index regarding the ODI changes in the isolated subgroups at different study stages**
ODI 0 — before initiation of the therapy, ODI 1one month after the therapy course, ODI 3 — three months after the therapy course; in the ODI_G — subgroup with the maximal changes of the ODI values, in the ODI_P — subgroup with the minimal changes of the ODI values

In the FS group, 27 patients (48%) belonged to the first group of the isolated subgroups, in the US group — 29 patients (52%). 27 (48%) patients belong to the second subgroup in the FS group, in the US group — 27 patients (48%) and these changes are not statistically significant ($p = 0.425$).

3.6. Complications

Frequency of the complications during the procedure and within 24 hours after the procedure in both patients groups is given in the Table 3.12.

Table 3.12

Complications	FS (n=56)						US (n=56)					
	During the procedure			24 hrs after the procedure			During the procedure			24 hrs after the procedure		
	1bl.	2bl.	3bl.	1bl.	2bl.	3bl.	1bl.	2bl.	3bl.	1bl.	2bl.	3bl.
Vasovagal (sweating, nausea)	1	1	0	0	0	0	2	0	0	0	0	0
Aggravated pain	0	0	0	0	0	0	0	0	0	1	0	0
Pain at injection site	1	2	0	0	0	0	1	1	1	0	0	0
Puncture of blood vessels	0	0	2	0	0	0	1	1	1	0	0	0
Face flushing	0	0	0	1	0	0	0	0	0	1	1	0
Puncture of spinal space	0	1	0	0	0	0	0	0	0	0	0	0

No serious complications were observed during the study. Frequency of vasovagal complications, aggravated pain, pain at injection site, puncture of blood vessels and facial flushing was similar in both groups. Intrathecal injection of the contrast media was observed in one patient in the FS group, in all other cases, distribution of the contrast media in the epidural space was approved.

4. DISCUSSION

The purpose of the work was to show that when doing epidural blockades in patients with degenerative spine diseases after ultrasonoscopic visualization of the spine, the technical and outcome indicators of the procedure are equal to those for blockades done under fluoroscopic guidance.

During the study, data on the duration of the patient disease, spinal degenerative changes (types of the morphological changes), degrees of the pain and functional disability, as well as on the parameters of procedural performance. Considering the patient clinically demographic parameters and procedural parameters and using the two-stage cluster analysis, patient subgroups were created that allowed more detailed comparison of quality and efficiency.

Clinical characteristics of the patients selected for this study and procedural parameters ply important role in determination the procedural efficiency and technical quality described in several studies. It is shown that the procedural efficiency can be determined from such clinical characteristics as intensity of the back pain and decrease in the degree of functional disability. Range of the duration of back pain and clarification of the types of morphological changes of the lumbar spine provided an opportunity to further examine the efficiency of epidural blockades using two types of visualization methods.

According to tasks of the work, demographic, clinical and procedural parameter data of 112 back pain patients are obtained and statistically processed during the study. For the first time in Latvia EB are done after ultrasonoscopic spine visualization.

Patient demographic, clinical and procedural parameters were analyzed and compared both in the overall study population and in the isolated subgroups. The average age in the overall study population was 69 years. When

analyzing gender in the groups, it is seen that groups dominated by women (women 82%, men 23% of all patients) with the body mass index corresponding to the category "corpulent" (31 kg/m^2) dominate. These observations partially confirm reports in the previous publications saying that women suffer more from pain and degenerative changes in the spine is the most common pathology after the 60-year age [3]. The fact that overweight patients prevail in the study groups can be explained by that overweight people prevail in the Latvian population because it is known that inactivity and weight gain contribute to pain.

Adiposities can decrease the image quality during the spinal sonoscopy because the additional layer of fatty tissues can decrease ultrasound transmission resulting in scattering of the ultrasound beam in the tissues and increasing the total scanning time. The mean BMI in studies usually 18.5 (1.2) kg/m^2. The age may also play its role because the mean visibility of the neuroaxial structures in the study with younger volunteers were involved was significantly greater comparing in the recent study involving older people (the average age 66.3 (21.7) years) [22]. Currently, there are not any objective data on age-related differences in the visibility of neuroaxial structures in the spinal sonoscopy.

The average duration of back pain in the groups was 58 months corresponding to the chronic stage of disease. We followed-up the patients for 3 months because it is concluded in many literature sources that epidural blockades were effective in the case of chronic lumbar and lower extremities' pain syndrome at the mean follow-up time (2 weeks to 3 months), but there are little information on pain relieve of long-term pain [23]. Our study shows the analgesic efficiency and improvement of the functional status in both (US and FS) groups within one month. Regarding degenerative lumbar changes resulting in inflammation of the neural roots at several vertebral levels, we have found

that only half of the patients have an improvement after the injection lasting for 3 months.

The aforementioned fact was recognized by *Briggs et al.,* who observed the blockade efficiency when treating pain in adult (60 years old and older) patients with diagnosed degenerative lumbar stenosis. Generally, the pain indicators improved significantly in this study after one month. The author concluded that injectable analgesics do not have a lasting effect; however they provide certain pain relieving even after 3 months [24]. According to our data, the pain decrease and Oswestry Functional Disability Index in the groups does not differ at study stage.

Currently, there is no consensus on the issue of the minimal and maximal number of epidural injections per year or volume of the injectable anti-inflammatory drugs [25]. Proposed maximal number of the injections usually is three and the volume of 5—10 ml was recommended at the lumbar level to lave the damaged neural root near the pathologic level, as well as also the surrounding neural roots affected by inflammation [26]. In our study, 3 blockades were done in order to achieve an optimal therapeutic effect and not to provoke adverse reactions of steroids. Volume of the injected diluted medication was 5 ml that was chosen as the optimal according to the literature data at the lumbar level using interlaminar injection in order to achieve several pathologic levels and anterior epidural space.

It is proposed currently in the recommendations on lumbar epidural blockade to insert the needle under fluoroscopic guidance, and visualization should be used in the case of transforaminal epidural blockades to minimize as much as possible the risk of damage of the medulla, *Adamkiewicz*'s artery or neural roots [27]. Level of steroid injection in our study was in between L_4—L_5 vertebrae and L_5—S_1 vertebrae that coincide with the study of *Manchikanti et al.* [28] who pointed out that the pathologic level most frequently is localized

between the mentioned spaces. Doing the injections at those levels, we avoid the risk of puncturing the *Adamkiewicz*'s artery localized at the level of L_1—L_2.

Unilateral and bilateral back pain symptoms depend on the vertebral segment and side involved in the pathologic process. In the group of fluoroscopically controlled injections, we have used median approach for bilateral distributed back pain, however in the case of unilateral back pain paramedian approach was used as described in the previous studies [26]. In ultrasonoscopic group, transversal medial spine visualization was used in the case of bilateral pain and paramedian oblique visualization — in the case of unilateral pain [29].

In our study, the total time of procedure in the groups did not differ because the injection time was longer than in the FS group. Performing the EB in the FS group, we have used a tunnel vision method during the blockade by moving the needle parallel to the X-ray beam direction that increased the injection time and balanced the total time of procedure, respectively, in both groups [30]. Association between the quality of visualization of the vertebral structures and successfulness of the injection was also detected. In the case of poor visualization of the vertebral structures, duration of the procedure increases statistically significantly only in the FS group ($p = 0.003$), whereas in the US group poor visualization does not lengthen the duration of the procedural parameters. It means that fluoroscopic control with suspected technical difficulties of the blockade performance must not been necessarily chosen for patients with severe spine problems, but the patients can be send to the blockade under ultrasonoscopic guidance.

Chin et al., when investigating patient with complicated anatomical landmarks and body mass index greater than 35 kg/m^2 selected for spinal anesthesia, reported successful inserting of the needle in the spinal space after the first attempt in 65% of patients using ultrasound-assisted method and the first needle passage in 27% of patients [31]. In our study, the first insertion of

the needle was successful in 73% (FS) and 80% (US) of patients and the first needle passing was successful 18% (FS) and 27% (US) of patients, respectively, without any significant differences between the groups.

Grau et al. studied the total number of attempts to insert a needle in the patient spine by determining the success of neuroaxial punctures after spine examination by ultrasound in young patients with abnormal vertebral anatomy or after vertebral surgery [32]. The authors found that the mean number of repeated needle insertion was 1.5 ± 0.9, whereas in older corpulent patients the number of repeated attempts to insert the needle was greater [31]. In our study patients with degenerative changes of the spine and overweight, the number of repeated attempts to insert the needle was not greater in the case of partially blind ultrasound-assisted epidural injections comparing with the group where needle fluoroscopic visualization in real time was done.

In older patients, the most common degenerative vertebral changes are spondylosis, spondyloarthrosis and stenosis of the spinal canal provoking pain and functional disability and resulting in reduced of life quality [33].

Lumbar injections are usually used in treatment of lumbar pain with or without radiculopathy, as well as pain caused by degenerative spine disease, including lumbar spinal stenosis. In our study, these changes were found in 60 to 100% of patients, although there are cases described in literature when the mentioned changes were detected also in asymptomatic patients [8]. Correlation analysis was done to found the dependence of procedural parameters on patient clinically-demographic indicators in the group using the following values: age, pain duration, number of morphological spinal changes, duration of visualization, duration of injection, duration of procedure, number of needle puncture, number of change the needle direction. According to the data obtained in the correlation analysis, a true that the older is the patient the longer in the time of injection and greater the number of needle direction change. Procedural parameters are affected also the number of morphological spinal

changes; the greater number of morphological spinal changes the longer is the procedure the greater is the number of needle punctures and change of direction. Procedural parameters depend on age, pain duration and number of morphological spinal changes also in the FS group.

Generally, such interrelated parameters as duration of visualization, duration of injection, duration of procedure, number of attempts of the needle punctures or insertion, number of change in the needle direction are characteristic for the analgesic EB procedure. When analyzing procedures, patients with greater values of these parameters are divided into a separate subgroup. We group the patients in two homogenous subgroups depending in the procedural parameters, pain intensity and indicators of functional disability. The first subgroup is characterized by worse procedural parameters because longer procedural duration and greater number of needle manipulation, worse indicators of pain release are observed in them since NRS indicators has decreased only by 24% after three months and ODI changes — only by 21% three months after the therapy course. On turn, patient with good procedural parameters from both groups were included in the second subgroup, and for them shorter procedural time was characteristic for them and the number of needle puncture was in one level in all three blockades. In these patients, NRS decrease by an average of 65% three months after the therapy course, and changes of the functional disability three months after the therapy course was an average of 61% comparing with the baseline value measured before initiation of the therapy. Both in FS and US group an equal number of patients are included and these differences are not statistically significant ($p > 0.05$). In FS group, the statistically significant dependence from such patient parameters as pain duration and age ($p < 0.05$) was detected. In the US group, no statistically significant relationship of the treatment efficiency and patient clinically demographic characteristics was found.

In the US group, comparing with the FS group no statistically significant difference between the patient clinical characteristics and procedural parameters was found ($p = 0.235$); regarding to the changes in the number of spinal morphological changes and degrees of the Oswestry Functional Disability Index, and indicators of the procedural parameters in the isolated subgroups. It means that EB with pre-injection ultrasonoscopic visualization of the spine can by done in patients with medium or severe degree of functional disability and several types of the vertebral changes without worsening the procedural parameters (procedural duration, number of the needle punctures and change of the direction).

All types of epidural steroid injections can cause complications and negative effects. In our study, we have not detected any serious complications corresponding to the previous results [34].

Abbasi et al. summarized the literature about complications after interlaminar epidural injections and concluded that the indicators vary from 0% to 16.8%. The authors also concluded that the complication risk is lower for higher-experienced specialists when performing the patient's pre-injection spine visualization by fluoroscopy [35].

Mild complications, such as vasovagal episodes, pain at the injection site and aggravated symptoms are generally observed in 5 patients in the FS group and in 6 patients in the US group, and they disappear within 24 hours.

Botwin et al. [36], when investigating fluoroscopic interlaminar cervical EB, reported pain aggravating at the cervical part in 6.7% of cases, transitory headache in 4.6% disappearing within 24 hours; they observed vasovagal reactions in 1.7% and in 1.5% — patient's facial flush. After studying literature overviews and complications associated with EB, *Abbasi et al.* [35] reported facial flush (9.2%) and vasovagal episodes (0% to 4%). Incidence of the facial flush varies from 0.13% to 28% [37] with disappearing of the symptoms within 48 hours.

We observed episodes of puncture the blood vessel during the procedure in 2 patients in the FS group and in 3 patients in the US group. Intravasal puncture is the most commonly reported complication during transforaminal EB (7.9%) comparing with other epidural injections varying at about 0.5% in the lumbar part, 3.1% in the sacral and 4% — in the thoracic part [36], however *Manchikanti et al.* [37] reported intravenous needle positioning in 14% of patients in his previous studies.

Puncture of the spinal space after interlaminar epidural procedures was observed generally in 0.5% to 1% off patients [36]. Puncture of the spinal space in our study occurred in one patient of the FS group with very severe vertebral deformation and poor visualization of the vertebral structures.

Complications are reported more frequently in women than in men and mostly at about the age of 70 years [38].

This study showed that ultrasound-assisted interlaminar epidural blockades are accurate, ensure analgesic effect and improvement of functional disability in patients with lumbar pain caused by degenerative spine diseases and such injections are comparable with fluoroscopically controlled injections.

5. CONCLUSIONS

1. When performing epidural steroid blockade after ultrasonoscopic visualization of the injection site, analgesic effect and decrease in the functional disability index is comparable with the effect achieved after use of traditional fluoroscopically controlled blockades.
2. It is possible to do the epidural blockades after ultrasonoscopic spine visualization as quickly as fluoroscopically controlled blockades but with less needle direction changes.

3. Ultrasonoscopy is an effective control method for epidural blockade in the patients with degenerative spinal diseases. Patients with good demographic and clinical indicators, as well as procedural parameters have better treatment efficiency in both groups.
4. Ultrasound assisted epidural blockades is a safe method after which no serious adverse reactions and delayed complications were observed.

6. PRACTICAL RECOMMENDATIONS

Considering the data obtained in the study, we can recommend for practicing the following:

1. To continue to develop the pre-puncture ultrasonoscopic method for spine visualization when performing the epidural blockades;
2. To use ultrasonoscopic spine visualization method if the patient is allergic to contrast media or fluoroscopy is not available;
3. To use ultrasonoscopic spine visualization method in patients with vertebral degenerative diseases, as well as in patients with predictable difficulties of the puncture before epidural and spinal anesthesia.

7. PUBLICATIONS RELATED TO THE SUBJECT OF THE THESIS

Scientific publications

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