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Chronic Lumbosacral Painful Unilateral Radiculopathy: Dorsal Root Ganglion Pulsed Radiofrequency *vs.* Transforaminal Epidural Steroid Injection: A Prospective Randomized Study

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Abstract

Background: Pulsed Radiofrequency (PRF) procedures are a minimally invasive and target-selective modality procedure. PRF procedure becoming an increasingly used treatment for chronic radicular pain and competitive with Transforaminal Epidural Steroid Injection (TFESI).

Methods: A prospective randomized, blind study was performed to evaluate the therapeutic effect of lumbar Dorsal Root Ganglion (DRG) PRF treatment and lumbar TFESI and to compare efficacy of these two techniques, on the patient with chronic unilateral lumbosacral radicular pain with radiculopathy. The study included a total of 72 patients, of whom 35 were randomized to PRF group, 35 patients - to TFESI group, and 2 patients received placebo. The outcome of the treatment either by PRF or TFESI was evaluated by Global Perceiving Effect (GPE) and decrease in NRS and ODQ at day 30, 60 and 180. After 30th day follow-up, patients with GPE Likert scores ≤ 5 had received the second, identical procedure.

Results: GPE increased with time for both PRF and TFESI groups, reached at day 180 follow-up 6.2 for PRF and 6.3 for TFESI. Statistical comparison of improvements, caused by PRF and TFESI does not revealed significant difference in the treatment outcomes, i.e. generally values of GPE, decrease of NRS and decrease of ODQ was similar for PRF and TFESI treatments during entire follow up period. The only exception was decrease in ODQ scale at the day 30 that was higher for PRF treatment (P-value 0.02).

Alongside, in PRF group there was only 9% of patients with less than 20% improvement in disability, as compared with 29% in TFESI group. But at the day 180, the proportion of patient with pain reduction more than 60% in TFESI group exceeded one for PRF group.

Conclusion: The effectiveness of DRG PRF and TFESI by evaluation of three assessment's tools: GPE, NRS and ODQ demonstrates the efficiency of the PRF in short-term response (30 days follow-up) due to the notably higher decrease in ODQ scores in PRF than into the TFESI group, despite of similar GPE and NRS scores in both groups. TFESI procedure is more effective in long-term perspective, proved by slightly higher proportion of patients with pain reduction.

Keywords: Pulsed radiofrequency; Chronic lumbosacral radiculopathy; Dorsal root ganglion; Epidural steroid injection

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Background

Pulsed Radiofrequency (PRF) is neural tissue preserving alternative to spinal nerve ablation procedure, previously used to treat chronic pain conditions characterized by resistance and/or increasing tolerance to opioid analgesics and epidural steroid injections [1,2]. Chronic pain localization, ranged from most to least frequent, is lower and upper back is approximately 24% according to patient self-assessment [3-6].

Standardized PRF procedure has demonstrated clinical effectiveness, significantly reducing pain of different etiology and localization, such as herniated disk/failed back surgery syndrome induced low back and leg pain, chronic lumbar radicular pain and this type of pain with neuropathic futures etc. [7-11].

In approximately 45% of the cases of low back pain has originates from the degenerative intervertebral disc. PRF treatment in the nucleus would change the conductivity of nerve endings that have been sprouting into the nucleus because of disc degeneration. The application of the electric field of PRF in the disc may also induce healing processes involving the activation of the immune system, thus reducing the inflammation process of chronic pain. The effectiveness of PRF applied to the Dorsal Rot Ganglion (DRG) has been employed for pain relief in patients with cervicobrachial pain, thoracic radiculopathy, and chronic lumbar radicular pain [7,12,13].

Transforaminal Epidural Steroid Injection (TFESI) is a classical, minimally invasive treatment for radicular pain with a definite short-term efficacy. Injections are widely adopted to alleviate and control radicular pain in accord with current guidelines. The relief of pain or functional recovery outcome is higher at 2 weeks than 2 months. Although the efficacy term is controversial due to drug metabolism [14]. Repeated steroid injections may have adverse effects [15,16].

Objectives

This study was performed to compare the effectiveness of Pulsed Radiofrequency (PRF) administered to a targeted Dorsal Root Ganglion (DRG) and TFESI for the treatment of radicular pain and radiculopathy.

Methods

Target population: Patients aged 18 to 65 years who suffer from chronic unilateral lumbosacral radicular pain with radiculopathy (Numeric Analog (Rating) Scale (NRS) >5) with no significant motor deficit (muscle strength >3, Medical Research Council (MRC) Scale for Muscle Strength) and who does not respond to conservative therapy. The diagnosis of Chronic Lumbosacral Radicular Pain with radiculopathy (CLRP) was based on a medical history, clinical examination and Standardized Evaluation of Pain (StEP scale). Patient selection also was based on Computer Tomography (CT) or Magnetic Resonance Imaging (MRI) findings within the last 6 months. The results of the radiological study had to be consistent with the clinical symptoms.

For each patient participating this study, inclusions criteria, the nature and importance of the study and the course of all invasive procedures, with possible complications and side effects were explained. The study included a total of 72 patients, of whom 35 were randomized to PRF group, 35 patients- to TFESI group, and 2 patients received placebo. Considering the multisegmental innervation of the affected area, each procedure is performed at 1 or 2 levels, depending on anatomical changes and dermatomal irradiation. Prior the procedures, the patients were requested to estimate their pain level by Numeric Analog Scale (NRS) and fill the Oswestry Low Back Pain Disability Questionnaire (ODQ).

Patients, randomized to PRF group received DRG PRF stimulation procedure on the one or two level/s, depending on dermatomal contribution of pain, using Neurotherm (NT) 1100 generator, 10 or 15 cm, 20-gauge Radiofrequency (RF) needle with 5 mm active tip, under X-ray control. PRF procedure is performed with the following parameters: 42 volt, 7 min, 5 pulses per min, 5 millisecond one pulse length. Correct needle position was validated by sensor and motor neurostimulation. RF needle was considered as properly positioned, when sensor stimulation was positive at voltages till to 0.5 V, but motor stimulation- at voltages till to 1 V (or doubled sensor stimulation). During the PRF procedure, the device volume was muted to prevent the patient from recognizing which of the 3 procedures he is undergoing.

Patients, randomized to TFESI group received TFESI with Triamcinolone 40 mg - 1 ml, Bupivacaine 0.5% - 1 ml and saline 0.9% - 1 ml. The dose of Triamcinolone was total 40 mg/3 ml per procedure. If patients received TFESI on two levels volume of each injection was 1.5 ml. The injection was performed at the levels of intervertebral disc herniation's using standard technique, 10 cm or 15 cm, 20G Tuohy needle, under X-ray control and contrast fluid, in order to see medications spreading in to the anterior epidural space.

During the placebo procedure, puncture, sensory and motor stimulation were performed without actual application of PRF or drug administration. After any procedure, each patient was observed before discharge from 30 min up to 1 h. Skin anesthesia was performed with Lidocaine 2% - 1 ml.

During follow-up, the Globally Perceived Effect (GPE) of the treatment was evaluated using 7 level Likert scale. Patient's pain level and general disability were evaluated using NRS and ODQ scores. The follow-up sessions were assigned at 30+2, 60 ± 2 and 180 ± 2 day after procedure. All patients were evaluated by a pain specialist who had not performed the procedures and did not know what procedure had been completed previously. If at the day 30 of follow-up the GPE of a patient was less than 50% from the baseline (5 and less by Likert scale), the patient received second procedure, identical to the first one.

Exclusion Criteria was: Strong or progressive motor deficit (muscle strength <3 according to Medical Research Council (London, 1976)), patients with coagulation disorders, spinal canal stenosis with intermittent claudication, severe psychopathy or psychiatric illness in patients history, allergies to local anesthetics or contrast agents, chronic heart failure III-IV after NYHA, chronic renal disease with glomerular filtration rate less than 30 ml/min, chronic liver failure (stages II-III), pregnancy, malignant or benign spinal tumor or metastases, infection and previous spine surgery in patients history.

Observations, obtained for PRF and TFESI groups were compared, mainly using Student t-test for age and ODQ scores data and non-parametric Mann-Whitney rank test for GPE and NRS data. Significance level α=0.05 was applied through the whole study.

At the 30 day of follow-up, both placebo patients demonstrated GPE less than 25% and were excluded from further study due to ethical reasons in according with initial research design.

Results

The experimental pool included 38 females and 32 males, their average age, initial pain level (NRS scores) and disability level (ODQ scores) are summarized in the (Table 1). Statistical comparison of male and female patients using Student test for age (P=0.33) and ODQ scores (P=0.31), and Mann-Whitney test for NRS scores (P=0.79) did not indicated any difference between male and female groups. Therefore, no stratification by patient sex was applied.

In turn, characterizes randomized experimental PRF and

Tables 1: Characterization of the patient pool prior treatment.

	Patient number	Age, full years	Pain level, NRS scores	Disability level, ODQ scores
Females	38	50 ± 9	7.6 ± 1.0	28 ± 5
Males	32	52 ± 8	7.7 ± 0.9	27 ± 4
Total	70	51 ± 9	7.6 ± 1.0	27 ± 4

Tables 2: Characterization of the experimental group's prior treatment.

	Patient number	Age, full years	Pain level, NRS scores	Disability level, ODQ scores
PRF group	35	51 ± 9	7.2 ± 0.8	27 ± 4
TFESI group	35	51 ± 8	8.0 ± 1.0	28 ± 4
Total	70	51 ± 9	7.6 ± 1.0	27 ± 4

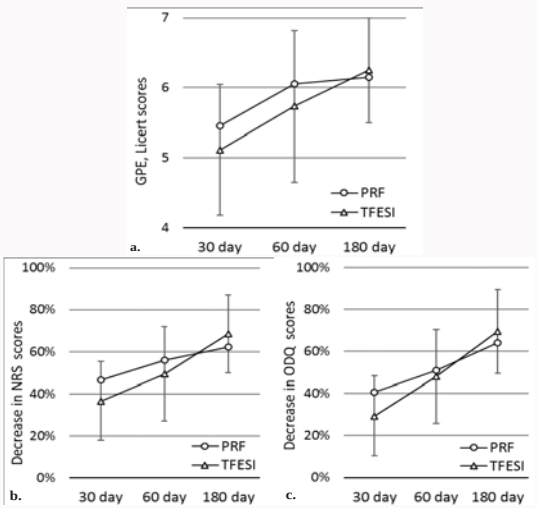

Figure 1: Changes in average indicators - GPE **(a)**, measured by Likert scale, reduction in pain level, measured by NRS scores and reduction in disability, measured by ODQ scores - for patient groups, treated with PRF **(b)** and TFESI **(c)**.

TFESI groups' prior procedure (Table 2). There was no difference in average age and ODQ scores between groups (Student test, P=0.95 and P=0.22, correspondingly), but NRS scores were higher for TFESI group (8.0 for TFESI against 7.2 for PRF, Mann-Whitney test P=0.00026). To avoid possible influence of between-group's difference, the improvement in both patient's pain and disability levels was evaluated as changes (decrease) in NRS and ODQ scores in respect to prior procedure values. The GPE, expressed using Likert scale, was evaluated in absolute values.

After 30th day follow-up, 17 patients (49%) in PRF group and 20 patients (57%) in TFESI group had GPE less than 50% (Likert scores ≤ 5) and had received the second, identical procedure. The difference was evaluated using Z-test for proportions, resulting P-value (P=0.47) suggests that there is no difference between groups in number of patients, having insufficient result after the first procedure. Hereby, using data for both groups, one could estimate that about 53% of patients would require second procedure.

During entire follow up period, 2 patients (6%) in PRF group and 7 patients (20%) in TFESI group started use of additional medication. Although number of such patients in TFESI group wars more than three times higher, this difference could be explained merely by chance (Exact Fisher test, P=0.12).

Table 3 -results of patient follow-up in both experimental groups

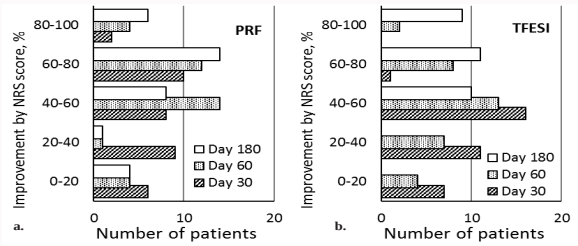

Figure 2: Distribution of the pain level improvement, measured by changes in NRS scores during follow-up in patients treated with PRF **(a)** and TFESI **(b)**.

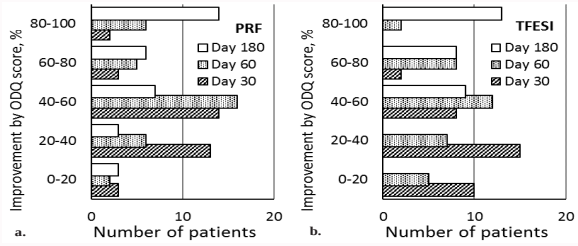

Figure 3: Distribution of the disability level improvement, measured by changes in ODQ scores during follow-up in patients treated with PRF and **(a)** TFESI **(b)**.

at 30, 60 and 180 days after procedure. The outcome of the treatment was evaluated for each group as average GPE scores, average decrease of NRS scores and average decrease of ODQ scores. Groups were compared using Mann-Whitney test for GPE and NRS and Student test for ODQ values, the corresponding P-values are presented in the Table 3, too.

Improvement, observed for both treatments demonstrated tendency to grow with time: average GPE increased from 5.5 at day 30 to 6.2 at day 180 for PRF and from 5.1 to 6.3 for TFESI (Figure 1a). Similarly, reduction in pain level and disability was observed. Average decrease of NRS scores gradually changed from 3.3 at day 30 to 4.5 at day 180 for PRF and from 2.9 to 5.5 for TFESI. This corresponds to the lowering of the initial NRS score and patient pain level by 46% to 62% for PRF and to 37% to 69% for TFSI (Figure 1b). Disability level scores decreased by 10.8 at the day 30, reduction reached 17.1 at the day 180 for PRF, figures for TFESI was 8.2 and 19.4. This decrement corresponds to lowering of the patients' disability (as measured by ODQ scores) by 41% to 64% for PRF and 29% to 69% for TFESI (Figure 1c). From the other hand, statistical comparison of the PRF and TFESI does not revealed significant difference in the treatment outcomes, i.e. generally values of GPE, decrease of NRS and decrease of ODQ was similar for both treatments at any follow-up day. The only exception is the values of ODQ decrease at the day 30, which is higher for PRF treatment, the corresponding P-value generated by Student test 0.02. Still, comparison of three parameters at three follow-up sessions required nine simultaneous tests at significance level 0.05, that gives nearly 36% probability to get at least one false-positive test result with P<α even for actually identical groups. In other words, present research results do not provide any reasons to claim either method to be more effective.

Summarizes results of improvement analysis for individual patients, indicating number of patients, that reported certain level of improvement during follow-up visit, alongside the data are visualized at (Figure 2 and 3) (Table 4). The findings are in line with

Tables 3: Treatment outcome for PRF and TFESI procedures over 180-days follow-up period.

GPE, average Likert scores	PRF	TFESI	P-value, Mann-Witney
30 days	5.5 ± 1.1	5.1 ± 0.9	7.2 ± 0.8
60 days	6.1 ± 1.0	5.7 ± 1.1	8.0 ± 1.0
180 days	6.2 ± 1.1	6.3 ± 0.8	7.6 ± 1.0
Pain reduction, average decrease in NRS scores	PRF	TFESI	P-value, Mann-Witney
30 days	3.3 ± 1.7	2.9 ± 1.5	0.45
60 days	4.0 ± 1.6	4.0 ± 1.8	0.9
180 days	4.5 ± 1.9	5.5 ± 1.5	0.083
Disability reduction, average decrease in ODQ scores	PRF	TFESI	P-value, Student
30 days	10.8 ± 4.3	8.2 ± 5.3	0.025
60 days	13.6 ± 4.5	13.4 ± 6.2	0.89
180 days	17.1 ± 7.3	19.4 ± 5.6	0.17

Tables 4: Distribution of treatment outcomes for individual patient after PRF and TFESI procedures over 180-days follow-up period.

	Pain level (NRS scores) reduction					
Improvement,	**Day 30**		**Day 60**		**Day 180**	
%	PRF	TFESI	PRF	TFESI	PRF	TFESI
0-20	17%	20%	11%	12%	12%	
20-40	26%	31%	3%	21%	3%	
40-60	23%	46%	40%	38%	24%	33%
60-80	29%	3%	34%	24%	42%	37%
80-100	6%		11%	6%	18%	30%
	Disability level (ODQ scores) reduction					
Improvement,	**Day 30**		**Day 60**		**Day 180**	
%	PRF	TFESI	PRF	TFESI	PRF	TFESI
0-20	9%	29%	6%	15%	9%	
20-40	37%	43%	17%	21%	9%	
40-60	40%	23%	46%	35%	21%	30%
60-80	9%	6%	14%	24%	18%	27%
80-100	6%		17%	6%	42%	43%

observations, made for average improvement values.

At the day 30, patients, treated with RPF demonstrated better outcomes: 35% of patients had more than 60% improvement in pain level, to be compared with 3% for TFESI treatment; in addition, there were no patient with improvement over 80% in TFESI group. Proportion of patient with less than 20% improvement in disability was 9% for PRF and 29% for TFESI. At the day 60, outcomes of both methods become closer: The pain level reduction over 60% was observed in 45% of patients, treated with PRF and in 30% of patients with TFESI, the proportion of patient with low improvement in disability after TFESI decreased nearly twice-up to 15%.

Finally, at the day 180, the proportion of patient with pain reduction more than 60% in TFESI group exceeded one for PRF group (67% *vs.* 60%). There were no patients in TFESI group with improvement less than 40% both for NRS and ODQ scores, while in the PRF group there were 15% of patients with less than 40% reduction in NRS scores and 16% of patients with less than 40% reduction in ODQ scores. There were no adverse effects observed after treatment with any modality.

Discussion

In this study, both the short and long-term effects of DRG PRF and TFESI to treat unilateral chronic lumbosacral painful radiculopathy were evaluated and the results were compared.

From previous research it is known that radiofrequency methods have been used over the last 30 years to treat pain syndromes caused by various pathologies, including back pain due to facet joint dysfunction, radicular pain, discogenic and sacroiliac joint pain, cervicogenic headache, medulla spinalis injuries, and intercostal neuralgia [1].

Our results showed that all indicators, - GPE, NRS and ODQ measured by us demonstrates similar tendency: The improvement and decrease of pains which is better at day 30 for the PRF treatment, but at the long time scale (day 180) the outcome of TFESI treatment exceeds one for PRF. This could suggest that PRF treatment provides better improvement in short term, while TFESI procedure is more effective in long-term perspective. Also, other scientists tried to compare the above-mentioned methods.

So, Lee et al. [15] in a prospective randomized trial also compared the effectiveness of PRF and TFESI for the treatment of radicular pain for forty-four patients with disc herniation's in the neck and lumbar part of the spine for a two year-long period. Trial patients' age varied with a range of 20-70 years and 38 patients were divided into two groups: PRF (n=19) and TFESI (n=19). After the procedure, patients were examined in 2, 7, 8 and 12 months, which was comparatively close to our examination time. Similar to our study, ODQ index was analyzed; however, our study differed with additionally detected NRS. The results showed no statistically significant difference between the PRF and TFESI groups. Thus, we suppose that probably even despite the different pathogenetic mechanisms in suppression of pain, the final result is similar in successful cases of treatment with both, - PRF and TFESI. This is our suggestion is directly supported by those scientists who have combined therapies of pains.

So, in search for depression in lumbar radicular pain Koh at al. [17] in a randomized, double-blinded, active-comparator controlled study determined the effects of combining PRF treatment and TFESI to treat sixty-two patients with chronic LRP caused by lumbar spinal stenosis. The PRF group received 3 cycles of PRF treatment, after a local anesthetic with the steroid was injected. The trial patients were divided into two groups (PRF group =31; control group =31). The study's outcome describes the use of the NRS, ODQ and GPE scale, as our trial does. The age of the patients included in the study was similar to ours >20 years. Pain intensity >4 on NRS like including criteria was the same. The results showed that the number of patients with successful treatment was higher in the PRF group. The conclusion was that PRF could be combined with TFESI to achieve best treatment effect compared to TFESI alone. This combination would increase the treatment response to the TFESI. Authors didn't observe significant differences in terms of the mean NRS, ODQ between the PRF and control groups. No serious adverse events and other complications were noted [17].

We agree that probably only one trial can't be the basis for this treatment combination to be recommended as a first-line treatment for patients with LRP with radiculopathy and as this trial's LRP caused

lumbar stenosis, the future studies are requested about PRF treatment. One of the latest and most unique studies compared PRF and local anesthetics epidural administration. De et al. [18] in a prospective, triple-blind, randomized, active control trial compared PRF of DRG and Transforaminal Epidural Local Anesthetic Injection (TFLAI) in patients with chronic LRP Patients aged a little bit younger than ours and with LRP after unsuccessful treatment by medication for >3 months received a selective diagnostic nerve root block with 1 mL 2% lidocaine. 50 patients with a positive response were then divided into PRF and LA groups, each with 25 people. The PRF group received 3 cycles of PRF and the TFELAI group received 1 mL 0.5% bupivacaine. Both groups were observed after 2 weeks, 2 months, 3 months and 6 months, which is also similar to our trial. The described study outcome didn't show a significant difference between the TFLAI and PRF groups in all baseline variables. However, reductions in VAS and ODQ scores were statistically significant at all time intervals (2-6 months) in both groups. Authors concluded that TFLAI with PRF of the DRG resulted in significant pain relief and functional improvement compared to the TFLAI patients' group [18].

Our results demonstrated that there were no significant differences between DRG PRF and TFESI, what coexists to other colleague's research. So, there were no significant differences between the PRF group and the TFESI group in terms of age and sex were mentioned [17]. However, we observed that the ODQ index 30 days after treatment was lower in the PRF group compared to the TFESI group. Moreover, on day 30, 57% of our patients from the TFESI group and 49% from the PRF group received an additional procedure. On average, the NRS scale 30 days after therapy decreased by 3.3 points using PRF and by 2.9 points after TFESI. Considering these facts, we could suppose that DRG PRF treatment has a more expressed short-term effect. In turn, after 60 days the NRS in both groups was the same – 4. Commonly, we agree that PRF treatment has progressively gained a place in the management of chronic pain syndromes [11]. However, long-lasting effects seems to be better after 180-day follow-up in the TFESI group because here the patients had a better outcome (5.5) based on the NRS scale than the PRF group [18,19]. This allows us to conclude that PRF has no longer effect than that of TFESI. There is strong evidence that lumbar TFESI is an effective treatment for radicular pain with or without radiculopathy due to disc herniation. TFESI is a popular treatment not only among our pain physicians, but worldwide.

We also completely agree with the De et al. [18], that PRF of the DRG is one of the most widely used modalities for management of LRP for those not responding to conventional treatment. PRF of the DRG involves a simple procedure, is low cost, and has a low complication rate. Also, our trial didn't show significant neurological complications after PRF management, as in the study by Cahana et al. [20].

Our results prove that PRF is good treatment method for many patients who suffer from chronic unilateral lumbosacral radicular pain with radiculopathy because the effects of PRF can persist for at least 6 months after the procedure without any complications [21]. However, not ignorable are data of other colleagues, who reported lack of sufficient evidence of DRG PRF in LRP, since only observational studies were reported.

Abejon et al. [22] and also Simpoulos et al. [23] reported significant data about improvement in patients with LRP, who received DRG PRF. Most of these studies alike use NRS and GPE for outcome quality of life and pain relief to report improvement.

In four other prospective studies, PRF also was found to be effective in the treatment of patients with LRP [10,19,24,25]. Chang et al. [26] in retrospective conducted study with chronic lumbosacral radicular pain after postlumbar surgery syndrome, who received PRF therapy, also had successful result.

There have not been many trials where PRF of DRG treatment was compared with other modalities in patients with LRP. Koh et al. [17] who compared PRF of the DRG with TFESI and TFESI group alone concluded that treatment method combinations significantly decrease NRS score and increase GPE, much more than patients receiving TFESI alone at 2 and 3 months, respectively.

Conclusion

The effectiveness of DRG PRF and TFESI by evaluation of three assessment's tools: GPE, NRS and ODQ demonstrates the efficiency of the PRF in short-term response (30 days follow-up) due to the notably higher decrease in ODQ scores in PRF than into the TFESI group, despite of similar GPE and NRS scores in both groups.

TFESI procedure is more effective in long-term perspective, proved by slightly higher proportion of patients with pain reduction more than 60% and lower proportion of patients with improvement less than 40% both for NRS and ODQ scores at the day 180.

Ethical Approval

The local Ethics Committee of Riga Stradins University approved this research.

Informed Consent

The patient provided informed consent for the publication of this report.

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