

Pulsed radiofrequency ablation of dorsal root ganglions in the treatment of postsurgical radicular pain

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Introduction The incidence of radicular pain that arises without a surgically significant cause of compression is 4.8–10.2 % in the structure of the "failed back surgery syndrome". Pulsed radiofrequency treatment (PRF) is successfully used for several neuropathic pain syndromes, but its effectiveness for postoperative radicular pain has not been studied sufficiently. **Materials and methods** Prospective non-randomized open study was performed. A group of 56 patients with postoperative radicular pain syndrome was included. Twenty-two patients of the index group underwent PRF treatment of dorsal root ganglia (DRG) in combination with transforaminal epidural steroid injection (TFES) while 34 patients of the control group received only TFES. Outcome of a successful response was defined as a 50 % reduction in numeric rating scale (NRS-11) or 4-points pain reduction and/or a 20 % decrease in the Oswestry Disability Index (ODI), and/or an 8-point decrease in the sciatica bothersomeness index (SBI) from the baseline and the effect duration for six or more months. Dynamics of the decrease in the parameters studied was assessed and compared; a search for significant prognostic factors was carried out. **Results** Positive results of interventions, based on specified criteria, were obtained in 18 patients (81.82 %) in the index group and in 19 patients (55.88 %) in the control group (significant difference, $p = 0.045$). There was a significant decrease in all indices after the intervention, a decrease in SBI in the main group was significantly lower than in the control one, $p = 0.021$. There were no major complications and side effects. The presence of allodynia/hyperpathy was the main negative prognostic factor in the index and in control groups with OR 0.79 at 95 % CI (0.735–0.897) and OR 0.82 at 95 % CI (0.780–0.929), respectively. **Conclusion** The use of the PRF in combination with TFES is an effective method in comparison with TFES alone for treatment of postsurgical radicular pain syndrome.

Keywords: degenerative disc disease, radicular pain, pulsed radiofrequency treatment, epidural steroid injection, failed back surgery syndrome

INTRODUCTION

Radicular pain syndrome is the main target in surgical management of degenerative diseases (DD) of the spine. Persistent or resumed radicular pain after a successful operation without any obvious substratum for a repeated intervention is the basis of the so-called "failed back surgery syndrome" (FBSS). FBSS incidence is reported in the range of 10–40 %, depending on the choice of assessment methodology, initial pathology and type of surgical intervention [1–5]. Common approaches to the therapy of chronic radicular pain after surgery are absent. Most non-invasive methods have a weak evidence base and are supported by a limited number of low evidence studies [6, 7]. Interventional methods show significantly better results. Failure of surgical pain management is the criterion for diagnosing FBSS and indications for performing neuromodulation [8, 9, 10]. Currently, the works of level of evidence I to II have confirmed the effectiveness of epidural administration of

glucocorticosteroids and percutaneous adhesiolysis [11, 12]. Pulsed radiofrequency ablation (PRF) is a method of pain management which is based on the ultrastructural effect of high frequency current on myelin-free nerve fibers with the simulation of a pain impulse passage. Studies of different levels demonstrate the effectiveness of the method for treatment of pain syndrome of various etiologies, including radiculopathy [13–17]. However, the number of works devoted to the treatment of radicular pain after surgical treatment is small, the results are inconsistent. In most studies, patients without surgery in their history were jointly studied [18–22].

The purpose of our study was to evaluate the possibility of using PRF for treating spinal ganglia in combination with epidural steroid injection (ESI) for management of radicular pain syndrome after surgical interventions for degenerative disease in the lumbosacral spine.

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MATERIAL AND METHODS

A subgroup of patients was analyzed in this study that constituted part of the main study on the diagnosis and treatment of pain syndromes after surgical treatment of the lumbar spine DD, which was conducted in the period from 2012 to 2017. The main study examined and followed prospectively 310 patients. A subgroup of patients with postoperative radicular pain syndrome that met the selected criteria for compliance included 56 people. Twenty-two patients of the main group underwent PRF treatment of spinal ganglia in combination with ESI and 34 patients of the control group had ESI only from the transforaminal access. Patients with radicular pain syndrome were selected, primarily operated or re-operated on one or more levels for herniated intervertebral discs (HID) or degenerative spinal stenosis with discectomy/decompression or decompression with posterior interbody fusion and transpedicular fixation.

Inclusion criteria

1. Radical pain syndrome that persisted after the intervention or appeared within one year after it.

2. The level of pain syndrome of 4 or more points according to the scale of pain (NRS-11) and/or 8 points or more according to the index of anxiety caused by radiculopathy, and/or impairment of life activity of 20 % or more by the Oswestry Disability Index (ODI).

3. Absence of obvious compression factors proved by postoperative magnetic resonance imaging (MRI) and/or computer tomography (CT), as well as myelography for an incompletely removed intervertebral hernia or eliminated stenosis, incorrect position of transpedicular screws or migration of interbody implant. Epidural fibrosis was not referred to compression factors. Root compression was assessed according to C.S. Pfirmann et al. [23], spinal stenosis according to C. Schizas et al. [24], and foraminal stenosis according to S. Lee et al. [25]. Perforation of the medial wall of the arch pedicle was allowed and the protrusion of the screw into the canal had to be not more than 4 mm (based on the recommendations of the review by E.J. Woo and M.N. DiCuccio) [26].

4. Absent pain relief (minimum by 50 % or 4 points on the NRS-11 scale, 20 % ODI, and 8 SBI points) after intake of at least one drug from the group of antidepressants or anticonvulsants recommended for the treatment of neuropathic pain in adequate dosages for 1 month.

5. With a predominant pain in the lower limb above the knee, pain associated with movements, chronic back pain (a single test blocking of the intervertebral

joints and/or sacroiliac joints with a 0.2 % solution of ropivacaine under fluoroscopic control was performed in a number of patients to exclude other possible mechanisms of pain syndrome). When pain reduced by 50 % or more on the NRS-11 scale, patients were excluded from further analysis.

Exclusion criteria

Chronic back pain as a leading clinical syndrome, radiculopathy without pain syndrome, severe pain syndrome, severe neurological deficit, signs of an infectious process.

Outcome measures

The tools for assessing the preoperative state and outcome of the interventions were NRS-11 and SBI for determining the intensity of the pain syndrome and the ODI index for assessing disability. Patient's positive result was the main outcome studied. A positive result was a decrease of the NRS-11 index by 50 % or by 4 points, and / or a 20 % decrease in the ODI index, and /or a decrease in the SBI score by 8 points from the baseline, with the effect duration for 6 months or more. Patients were examined during one year with follow-ups at 6 and 12 months after the procedure. If other interventional procedures and / or an increase in the dose of analgesic drugs were established or contact with the patient was lost during the first 6 months, the result was considered negative. The evaluation of the main outcomes was carried out by telephone survey, by e-mail or at an outpatient visit after six and 12 months following the procedure.

Additional outcomes

The dynamics of the studied NRS-11, ODI and SBI was analyzed before and 6 months after the procedure. In order to find the factors of positive outcome of interventions, the following parameters were taken into account and analyzed: age, sex, amount and volume of operations for this pathology in patient's medical records, presence of allodynia or hyperpathy, presence of a neurological deficit, duration of pain before the intervention, the level and number of affected roots.

Description of medical intervention

All interventions were performed by one researcher in an operating room equipped with a mobile X-ray machine with a C-arm, with the patient in prone position, under local anesthesia and monitoring of vital functions. A puncture needle or ablation needle was installed and conducted into the zone between the tip of the upper articular process of the underlying vertebra and arch pedicle of the overlying vertebra under fluoroscopic control

in an oblique projection, (**Fig. 1**). In the lateral projection, the tip of the needle should be positioned in the posterosuperior quadrant of the intervertebral foramen (**Fig. 2**), in the frontal projection – not further than the medial pedicular line (**Fig. 3**). During the subsequent epidurography, the distribution of contrast was assessed; in the absence of adequate contrasting of the epidural space or with intravascular spreading, the needle position was changed (**Fig. 4**). Given the possible distribution such as cranial or caudal spread of contrast and preparations injected afterwards (**Fig. 4**), the transforaminal access was carried out at two levels in monoradicular syndrome, at the pathology level and below, and at three levels by the biradicular syndrome.

At L5-S1 level, the access to the S1 was realized through the first sacral orifice (**Fig. 5**); to perform the PRF of the S1 spinal ganglion – through hiatus

sacralis using the epidural electrode (**Fig. 6**) due to the anatomical features of the sacrum and the technical difficulty of reaching the spinal ganglion through the sacral orifice. In the index group, an electrode was installed in the needle for ablation and sensory and motor stimulation was produced with threshold values of 0.5 V and 1.0 V, respectively; to further verify the positioning near the target nerve, in the case of exceeding these stimulation thresholds, the position of the needle was adjusted. Pulsed radiofrequency ablation was carried out for 10 minutes with the following parameters: voltage – 65 V, pulse duration – 5 ms, frequency – 5 Hz, temperature limit – 42° C; at the end of the procedure, 5–8 ml of 0.2 % solution of ropivacaine and 1 ml of a suspension containing 40 mg of triamcinolone acetonide was injected epidurally. In the control group, only the epidural administration of these drugs was carried out.

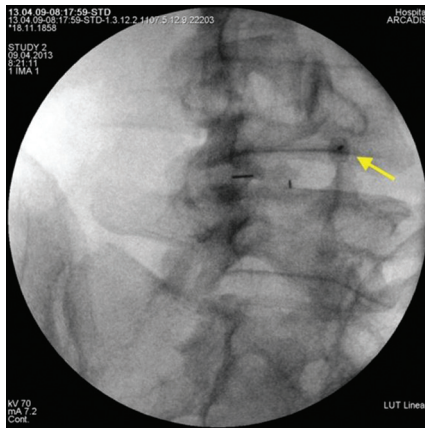


Fig. 1 Intraoperative X-ray of the lumbar spine in oblique projection. The puncture needle (marked with an arrow) is located in the area between the top of the L5 superior articular process and the L4 arch pedicle on the right

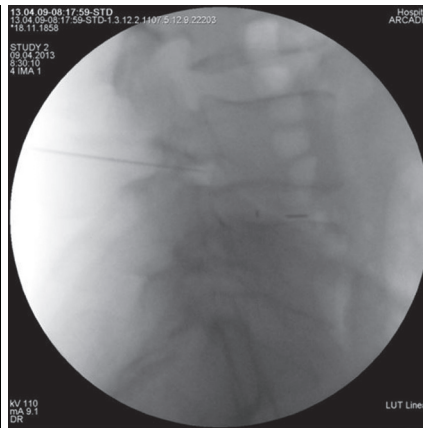


Fig. 2 Intraoperative X-ray of the lumbar spine in the lateral projection. The tip of the puncture needle is located in the upper external quadrant of the intervertebral foramen L4-L5

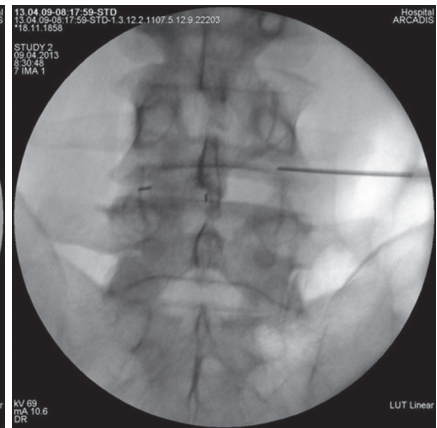


Fig. 3 Intraoperative X-ray of the lumbar spine in a straight projection. The tip of the puncture needle is located in the intervertebral foramen of L4-L5 on the right along the medial pedicular line

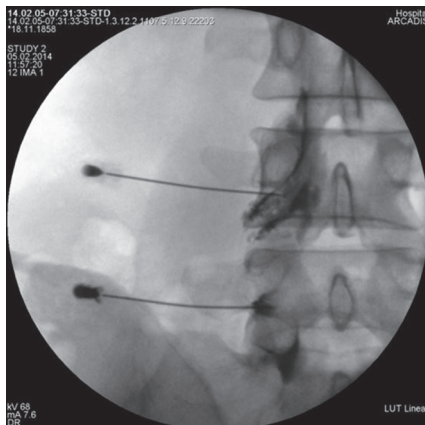


Fig. 4 Intraoperative X-ray of the lumbar spine in a straight projection. Epidurography and possible ways of contrast substance distribution

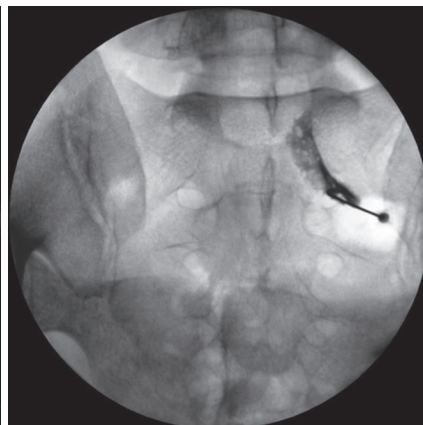


Fig. 5 Intraoperative X-ray of the lumbar spine in a straight projection. Puncture of the first sacral orifice and the spread of the contrast along the S1 root

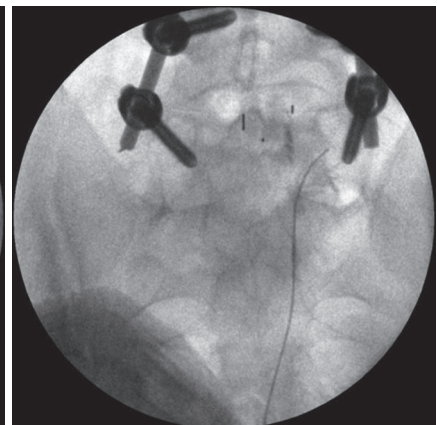


Fig. 6 Intraoperative X-ray of the lumbar spine in a straight projection. The epidural electrode is inserted through the hiatus sacralis and is located in the projection of the S1 spinal ganglion on the left

After the procedure, patients could continue taking pain killers. In the case of effective treatment, a stepwise reduction in the dose of anticonvulsants / antidepressants was recommended not earlier than 1 month after the intervention, by half of the dose administered once a week until complete withdrawal or until the onset of pain.

Statistical processing of the data

The verification of the correspondence between the empirical laws of distribution of the investigated parameters showed a significant difference of the majority of them from the theoretical law of normal distribution by the Shapiro-Wilk criterion ($p < 0.05$). In accordance with this, the median and interquartile interval were used [Me (25 %, 75 %)] for statistical description; statistical hypotheses were tested with non-parametric methods of analysis. Evaluation of the significance of the differences in quantitative and

qualitative parameters between the groups was carried out, respectively, according to the Mann-Whitney U and χ^2 Pearson criteria; with a small number of expected values in the conjugacy table the exact Fisher test was used. Significance of differences in quantitative and qualitative indicators before and after treatment within the groups was assessed according to the Wilcoxon T-test and the McNemar's test. To determine the statistical relationship between the indicators, a correlation analysis was performed using the rank correlation coefficient ρ Spearman. To identify predictors of the outcome, a binary logistic analysis was performed with the determination of the odds ratio (OR) with a confidence interval (CI) of 95 %.

Compliance with ethical standards

The study was approved by the ethics committee. All patients included in the study gave written informed consents.

RESULTS

Out of 310 patients with pain syndromes after operative treatment of the lumbar spine DD, 91 patients (29.36 %) continued with pain in the lower limb without any obvious compression substratum according to neuro-imaging findings. When performing the test ESI for differential diagnosis, pain relief was achieved in 26 patients (28.57 %). Correction of conservative treatment yielded a positive effect in 9 patients (9.89 %), as a result. The remaining 56 patients underwent interventions. They all were followed within a year after the procedure and were included in the final analysis.

Table 1 shows the patients with the characteristics found before the intervention. There were no significant differences between the groups. For both groups, a high percentage of patients with residual radiculopathy was noted after two or more interventions (46.63 % in total), and L5 was most commonly affected (58.93 %).

Positive results of interventions, based on specified criteria, were obtained in 18 patients (81.82 %) of the main group and 19 patients (55.88 %) in the control group; the differences were significant, $p = 0.045$.

A year after the intervention, a positive effect was maintained in 16 patients of the main group (72.73 %) and 15 patients (44.12 %) of the control group; the differences were significant, $p = 0.048$. In the control group, ten patients who had a sufficient but a short-term effect from ESI (at least 2 weeks) underwent PRF subsequently with a positive effect in 7 cases.

The dynamics of changes in the parameters analyzed is presented in Table 2. There was a significant decrease in all indices after the intervention. The differences in the NRS-11 and ODI before and after the intervention were not reliable by using the intergroup analysis. The median of the SBI index in the main group was significantly lower than in the control group, $p = 0.021$.

In both groups, no complications of interventions, no side effects from the administration of drugs were recorded.

The presence of allodynia and / or hyperpathy was the main risk factor for negative outcomes in both groups, with an OR of 0.79 at 95 % CI (0.735-0.897) in the index group and an OR of 0.82 at 95 % CI (0.780-0.929) in the control group.

Table 1

Characteristics of patients' groups before the study

Parameter	IG (n = 22)	CG (n = 34)	p*
Age, Me [25 %;75 %]	47.5[38; 60.5]	35[34.25; 60]	0.860
Males	14 (63.64 %)	14 (41.18 %)	0.171
Females	8 (36.36 %)	20 (58.82 %)	
Discectomy	2 (9.09 %)	2 (5.88 %)	0.103
Decompression	3 (13.64 %)	4 (11.76 %)	
Decompression+stabilization	9 (40.91 %)	16 (47.06 %)	
Decompression+stabilization of more than 3 segments	8 (36.36 %)	12 (35.29 %)	
Reoperation history	12 (54.55 %)	14 (41.18 %)	0.414
Allodynia/hyperpathy	5 (22.73 %)	9 (26.47 %)	0.752
L3 root	–	1 (2.94 %)	0.811
L4 root	3 (13.64 %)	3 (8.82 %)	
L5 root	13 (59.09 %)	20 (58.82 %)	
S1 root	6 (27.27 %)	10 (29.42 %)	
Biradicular symptoms	2 (0.09 %)	5 (1.47 %)	0.417

* – level of significance between the groups

Table 2

Changes in the medians of NRS-11, ODI and SBI after intervention

Score system	Group	Periods		p*
		Before treatment	After treatment	
NRS-11	IG	6 [4.25; 6]	4.5 [2; 6]	< 0.001
	CG	6 [5; 7]	4 [3; 7.75]	0.004
	p**	0.261	0.725	
ODI	IG	49.5 [36; 56.5]	28.5 [16.75; 47.75]	0.02
	CG	40.5 [33.25; 49]	33 [14.75; 48]	0.045
	p**	0.135	0.294	
SBI	IG	15 [13.25; 17.75]	5.5 [3.25; 11]	0.019
	CG	14 [11; 17]	12 [7; 15.75]	0.031
	p**	0.507	0.021	

* – level of significance within the group before and after treatment; ** – level of significance between the groups

DISCUSSION

According to the meta-analysis of the studies devoted to FBSS [27], the incidence of radicular pain syndrome without an obvious substratum of compression is 4.8-10.2 % among all postoperative problems. The frequency of epidural fibrosis, according to the same work, reaches 34 %, and if fibrosis is not considered as an independent compression factor, along with residual stenosis or hernia, the rate of radicular pain will be even higher. The relationship between the clinical outcomes of spinal interventions and the severity of epidural fibrosis according to MRI data has been currently not proven, neither is the importance of methods for its prevention [28-31], therefore, the severity of the scar process was not taken into account in the present study. The incidence of uncompressed radicular pain syndrome was 11.46 % among patients with various pain syndromes and /or pathological conditions after lumbar spine surgery. It should be noted that at the selection stage, 26 out of 91 patients were

excluded with pain in the lower extremity according to the results of positive ESI test or other potential generators of pseudo-radicular pain.

The effectiveness of epidural pain arrest by medication was confirmed by one randomized controlled trial [32]; a positive result in 59 % of patients with a 50 % reduction in the pain syndrome was preserved during the first year. Among the shortcomings of the study was the fact of a large number of repeated injections (an average of 4 per year), the use of the least suitable from the point of anatomy caudal access and the recognition of the positive result in case of the duration of the effect for at least 3 weeks. V. Wilde et al. [33] based on the analysis of five works concluded that there is insufficient evidence of the ESI efficacy in the treatment of postoperative pain syndrome. In our study, satisfactory results were achieved with ESI in 55.88 % of patients with a single injection in the control group, with a duration of the effect for 6 months, and

in 44.12 % the effect persisted throughout the year.

Positive differences can be associated with a transforaminal route of steroids which is much closer to the area of inflammation compared to the caudal route, thus a higher concentration of the drug is achieved. The significance of the administration way choice is indirectly confirmed by the analysis of the results of the application of percutaneous adhesiolysis - interventions with selective catheterization of the epidural space with a flexible X-ray-positive catheter and the introduction of a steroid through it in combination with hyaluronidase and hypertonic sodium chloride solution. The procedure showed a greater efficacy as compared with caudal arrest, but the result was more influenced by the positioning of the catheter in the ventral epidural space, rather than by the use of enzymes and aggressive solutions [34].

The effectiveness of PRF treatment for radicular pain in the pathology of the cervical spine was confirmed by a randomized study [35] with double-blinded control and placebo procedure. In many prospective studies [18, 21, 22] and retrospective [20, 36-39] studies, rather contradictory results were obtained: the number of patients with satisfactory outcomes did not exceed 50 %, there were no significant differences in the dynamics of parameters being studied as compared to the control group, or poorer outcomes were found in patients with FBSS. It should be noted that patients with various pathologies were included in all the studies mentioned, including surgically significant conditions such as hernias of ID and degenerative stenosis, for

which the ineffectiveness of conservative treatment is an expected clinical outcome. For the evaluation of the results, the pain scale and the Oswestry Index were traditionally used. The latter was developed, first of all, for measuring impairment in back pain, but not radiculopathy.

In a number of high-level studies comparing the results of surgery and therapy in the treatment of herniated ID, degenerative stenosis and spondylolisthesis [40], there were no significant differences in these parameters between the groups after treatment. Differences were found only for SBI index, specially designed to evaluate radiculopathy. In the pathogenesis of radiculopathy, inflammation is recognized as the leading component, and the use of corticosteroids is an obvious pathogenetic component of the treatment. The exclusion of steroid use when selecting patients for PRF or selection based on the inefficiency of ESI may affect the expected result. The combination of ESI and PRF was studied in the work of W. Koh et al. [22] and was found to be significantly more effective than the ESI alone.

Higher results (81.8 % of positive results within six months and the preservation of the effect during a year in 72.73 % of patients), obtained in our study, can be explained by its organization as the data were obtained by the literature search. Patients were included only after exclusion of the surgical substrate of radicular pain syndrome, with an additional exception of other mechanisms and sources of pain in controversial cases with the help of ESI test.

CONCLUSION

Based on the results of the study, it can be concluded that pulsed radiofrequency ablation and epidural injection of steroids are effective and safe methods for treatment of postoperative radicular pain syndrome, provided there are no surgically significant substrates of compression. The use of PRF

in combination with ESI is a more effective method in comparison with isolated ESI which is confirmed by significant differences in the number of patients with satisfactory results (81.82 % versus 55.88 %, $p = 0.045$), as well as a large decrease in the SBI index after the intervention ($p = 0.021$).

Limitations of the study

Main limitations of the study are a lack of randomization, a small number of cases, and an open design. Simultaneous use of PRF and ESI does not allow full appreciation of the role of pulsed ablation. The intake of medications permitted in this study reduces the "purity" of the experiment and requires the organization of higher-level studies, where the main problem will be the search for patients, given a relatively small number. Nevertheless, the efficacy of PRF treatment in combination with ESI, in the absence of significant complications and side effects demonstrated by the study, allows us to recommend this method for treatment of postoperative radicular pain syndrome.

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