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**Authors' Affiliation:**

<sup>1</sup>Euro Pain Clinics, Nahrábach 94/3, 085 01 Bardejov, Slovak Republic

<sup>2</sup>Institute of Measurement Science, Slovak Academy of Sciences, Dúbravská cesta 9, 841 04 Bratislava, Slovak Republic

<sup>3</sup>Clinic of Anaesthesiology and Intensive Care Medicine, East Slovak Institute of Cardiovascular Disease, Ondavská 8, 040 11 Košice, Slovak Republic

<sup>4</sup>EuroPainClinics, Poliklinika Terasa, Toryská 1, 040 11 Košice, Slovak Republic

<sup>5</sup>Europainclinics, Kominárska 21/5, 831 04 Bratislava – Nové mesto, Slovak Republic

<sup>6</sup>EuroPainClinics, Starochodovská 1750/91, 149 00 Prague 4, Czech Republic

<sup>7</sup>Department of Medical and Clinical Biochemistry, Faculty of Medicine, Pavol Jozef Šafárik University in Košice, Tr. SNP 1, 040 11, Košice, Slovak Republic

**\*Corresponding author**

Department of Medical and Clinical Biochemistry, Faculty of Medicine, Pavol Jozef Šafárik University in Košice, Tr. SNP 1, 040 11, Košice, Slovak Republic

Email: janka.vaskova@upjs.sk

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## Comparing the effectiveness of treatment with radio frequency denervation, cryoablation and endoscopic debridement of the facet joints

Rapčanová Simona<sup>1</sup>, Rapčan Róbert<sup>1</sup>, Witkovsky Viktor<sup>2</sup>, Kočan Ladislav<sup>3,4</sup>, Poliak Ľubomír<sup>5</sup>, Lenčes Peter<sup>5</sup>, Mláka Juraj<sup>4</sup>, Griger Martin<sup>5</sup>, Burianek Miroslav<sup>6</sup>, Vašková Janka<sup>7\*</sup>

**ABSTRACT**

**Background:** One of the main causes of chronic lower back pain is lumbar facet syndrome (LFS). It develops due to the damage of the facet joints and subsequent irritation of the adjacent sensory nerves. The diagnosis of LFS is based on comprehensive clinical examinations of the patient, evaluation of imaging diagnostic studies and nerve blockades under X-ray guidance. **Methods:** In a prospective observational multicenter clinical trial NCT04684303, we compared the clinical outcomes of three groups of patients who underwent denervation procedures of the zygapophyseal joints with either cryoablation therapy (n=48), radio frequency denervation (n=18) or endoscopic facet debridement (n=21). **Results:** Evaluation of changes in pain perception and quality of life were made by comparing the quality of life scale (EQ-VAS), and the numerical pain scale, which showed a statistically significant improvement ( $p<0.001$ ) in 3 months follow up after procedure. **Conclusion:** Study showed an equivalent effectiveness of endoscopic facet joint debridement compared to radio frequency denervation and cryoablation of the dorsal nerve branch, with persistent outcome.

**Keywords:** cryoablation, endoscopic facet debridement, facet joint, lower back pain, lumbar facet syndrome

**1. INTRODUCTION**

Lumbar facet joint syndrome is a common cause of vertebral algic syndrome (15-45%). It usually occurs in the older population of patients, with a long history of chronic lower back pain with radiation of dull to burning pain to the lower back with frequent spread of this pain to the lower limbs (Perolat et al., 2018). In the general population, it is connected with a number of co-

morbidities such as depression, immobilization and in ability to work, all of which have a negative impact on health costs (Meloncelli et al., 2020). The most common cause of facet joint pain is osteo arthritis, which can be diagnosed using X-ray, CT or MRI imaging methods. Ganglions and synovial cysts of the facet joints could cause compressive symptoms of the nearby structures, most often radiculopathy, lower back pain and sensory or motor deficits (Anaya et al., 2021).

Currently, the most effective diagnostic technique for lumbar facet joint syndrome is a test blockade of the medial nerve branch of the posterior branch of the spinal nerve, which gives sensory innervation to the facet joints. Sensory innervations of the lumbar facet joints are by way of the medial branches of the posterior branches of the L1-L5 spinal roots. Each medial nerve branch innervates the joints above and below its course, with the exception of the L5 root, which has a medial branch only for the L5-S1 facet joint (Venglarčík et al., 2017). The nerve block is performed twice (to rule out a placebo effect after the first block) under radiographic or ultrasound guidance at a time interval of most commonly 14 to 28 days.

Commonly mentioned techniques are radio frequency denervation, cryoneurolysis and endoscopic debridement of the facet joint (Perolar et al., 2018). Radio frequency involves the precise placement of radio frequency electrodes under X-ray or USG guidance, which deliver a sinusoidal current (400-500 kHz). The areas through which the current passes are subject to ion exchange, which leads to tissue heating through particle friction. The purpose is to expose nerve cells to temperatures  $> 45^{\circ}\text{C}$ , causing irreversible cell denaturation (Saravanakumar and Harvey, 2008). Cryoneurolysis is the application of cold to a nerve to cause its denaturation. The physical principles rely on the Joule Thompson effect based on the rapid decompression of a gas (either  $\text{N}_2\text{O}$  or  $\text{CO}_2$ ) at the end of a probe, which is capable of delivering extremely low temperatures down to  $-89^{\circ}\text{C}$  (Smiley and Mc Guire, 2018). Endoscopic debridement of the facet joints is the removal of capsular tissue of the facet joint with disturbance of the peripheral sensory nerve endings innervating the corresponding joint (Haufe and Mork, 2010).

The aim of prospective observational multicenter study is to describe the clinical outcomes after three different denervation procedures of the zygapophyseal (facet) joints.

## 2. MATERIALS AND METHODS

This prospective observational clinical study was proven by the Ethics Committee of the University of Pavol Jozef Šafárik in Košice (approval number 26N/2020) and the Regional Ethics Committee (approval number 03595/2020/OZ-31), registered on Clinicaltrials.gov with registration ID NCT04684303. All participants signed informed consent. Patients with diagnosed facet joint symptomatology (diagnosed by clinical examination and two positive test nerve blocks) who were referred for radio frequency thermo ablation, cryoablative facet joint denervation, and endoscopic facet joint capsule debridement were approached to enrol in the study. Patients were admitted from one of three pain clinics in Bratislava, Bardejov and Košice in the Slovak Republic between January 2021 & February 2022.

The inclusion criteria were age between 20 and 80 years, a positive patient history of chronic low back pain for at least 6 months with back and leg pain (visual analogue scale,  $\text{VAS} \geq 5$ ) and signed informed consent to participate in the clinical study. The exclusion criteria were a history of other spinal disorders (compression fracture, spondylitis, tumor). After approaching eligible patients and obtaining written informed consent, participants were assigned a generated unique identification number (ID) under which the patient figured throughout the clinical study. The values obtained from the patient questionnaires were entered into an encrypted database by the attending physician or nurse. After meeting the entry criteria, patients were diversified into three groups depending on the procedure they underwent, namely: Radio frequency (RF) facet joint denervation, cryoablative facet joint denervation (Cryo), or endoscopic debridement and endoscopic facet joint denervation (ED). Outcome assessment of individual scores was analyzed before and in 3 months follow-up after procedure.

In percutaneous radio frequency (RF) thermal denervation of the facet joint, the tip of the RF needle is inserted parallel to the course of the medial branch, in cryoablation, the probe points directly with the tip on the course of the medial branch. The procedures were performed under strict aseptic conditions in local anaesthesia under C-arm X-ray guidance. During the procedure, typical projections were used to verify the position of the RF needle/Cryo probe relative to the bony structure of the spine according to the Spine Intervention Society recommendations (poster anterior, lateral, oblique, and pillar projections). Using an RF generator, a specific electric current was applied to generate heat from  $80$  to  $90^{\circ}\text{C}$  at 90 second intervals. The electric current was directed along the uninsulated tip and produced a lesion of the sensory nerve. The cry generator acted on the nerve by the principle of low temperature action, by lowering the temperature of the electrode to  $-89^{\circ}\text{C}$  for 120 seconds in two cycles.

Endoscopic debridement of the capsule of the facet joints included the removal of the capsular tissue of the facet joint with the disturbance of the peripheral sensory nerves innervating the corresponding joint. All procedures were performed under the combination of local anesthesia and sedation under direct visual control. All procedures were done as outpatient surgeries, with the

patient leaving the clinic directly after the procedure. All the procedures are considered as equal. Neither of the procedures is considered according to EBM as superior, better or more profitable from a medical or ethical point of view compared to the other procedures. After completion of the first preoperative examination protocol, this protocol was sent to the study coordinator as well as to the researcher in charge of data processing of the study. Pre intervention baseline Euro QoL-5 (EQ-5D) and VAS pain scores were obtained.

The EQ 5D is a standardized questionnaire instrument developed by Euro QoL group as a measure of health related quality of life that can be used for a wide range of health conditions and their treatment. The questionnaire covers five dimensions: Mobility, self care, everyday activities, pain/discomfort and anxiety/depression. Individual parameters can be scored numerically from 1 to 5, with level 1 indicating the least severe (optimal) condition and level 5 indicating the most severe (critical) condition. VAS is a measurement score that indicates pain severity status. The VAS score consists of a 10-point pain scale, where a value of 0 represents "no pain sensation" and a value of 10 represents "maximum pain sensation". Descriptive statistical methods (mean, median, maximum, minimum, and standard deviations (SD) were used to evaluate the VAS scores. The probability distribution characteristics of the observed VAS scores were plotted using box plots. The analysis of variance was used to evaluate the statistical significance of changes in each treatment group in a simple sorting model. P values of less than 0.05 were considered significant. Statistics calculations were performed using the statistical software package Graph Pad Prism8.

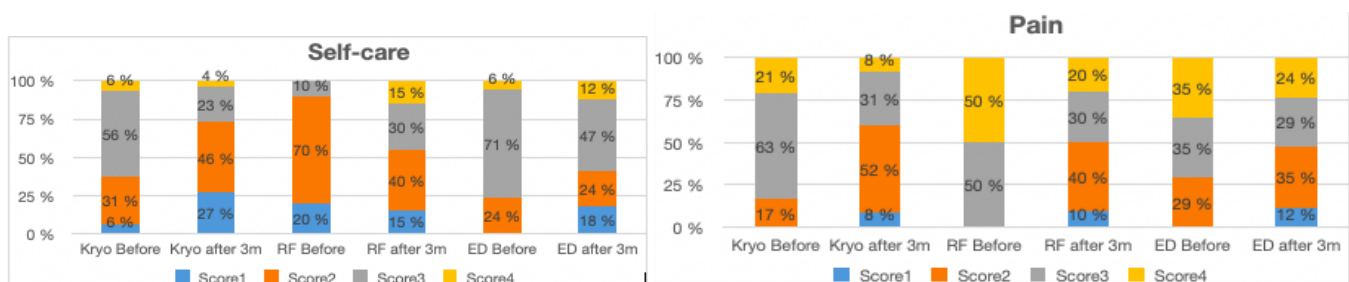
### 3. RESULTS

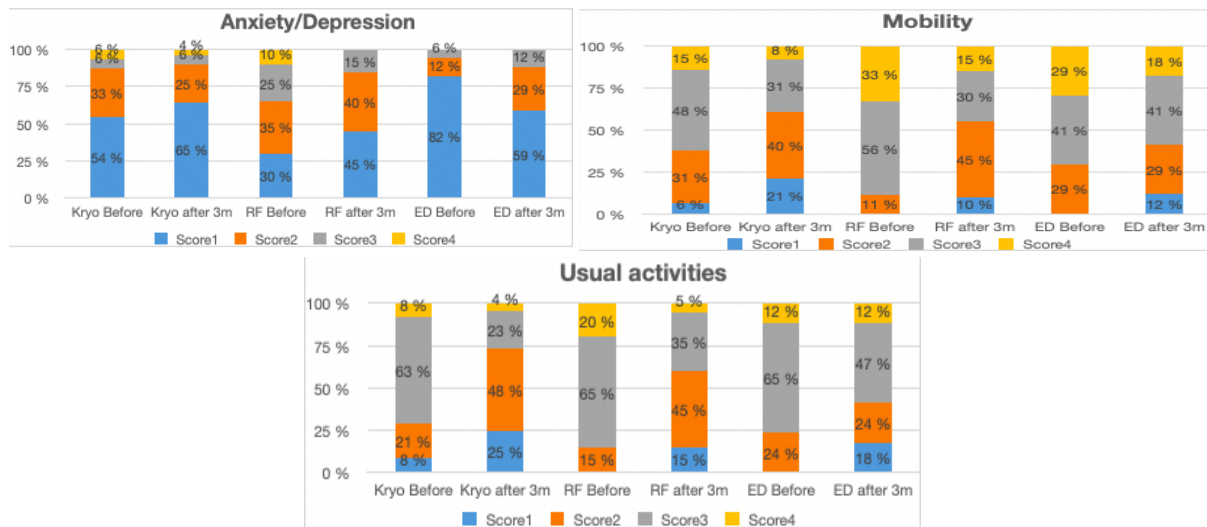
From all the approached patients, 87 fulfilled the selection criteria and were divided into groups according to the procedure performed: RF (n=18), Cryo (n=48) and ED (n=21). The baseline characteristics are summarized in Table 1.

**Table 1** Characteristics of the patients in groups based on the performed interventional procedure.

	Performed procedure		
	RF	Cryo	ED
N of patients before treatment	18	48	21
N of patients after the 3-month follow-up	18	48	21
Age spectrum	50-74	34-82	39-77
Average age	65	56	57
Sex M/F	10/8	20/28	3/17

Three months after the procedure, all patients showed improvement in the EQ-5D dimensions of mobility, habitual activities, and pain, which can be seen in the graphs (Figure 1). In the self care dimension, there was a worsening of the condition between the RF Before and RF After 3m groups. Similarly, there was a worsening in the anxiety/depression dimension between the ED before and ED after 3m groups. The level of discomfort in each dimension is denoted as Score 1 - Score 5. None of the patients reported the worst possible condition (Score 5) in any of the studied parameters. However, when summarizing the change (before vs. 3 months post intervention) of all EQ-5D test dimensions, we observed a significant improvement in quality of life in all three groups with  $p < 0.0001$ .



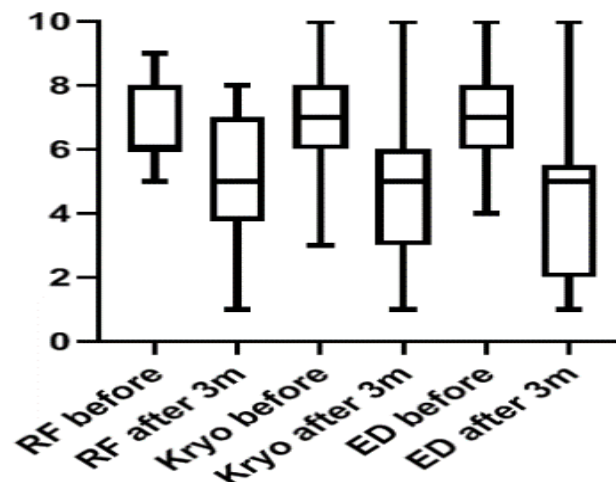


**Figure 1** Distribution of patient answers in percentages before and after procedure in EQ-5D assessed dimensions.

After all three interventional procedures, we observed a statistically significant betterment in the VAS parameter (Table 2), with a p value=0.0445 in group RF and  $p<0.001$  in groups Cryo and ED (Figure 2). When comparing the different methods, we observed the lowest difference of improvement in status in the RF before vs. RF after 3m group (1.5) compared to the Cryo before vs. Cryo after 3m (2.313) and ED before vs. ED after 3m (2.524) groups.

**Table 2** Descriptive statistics of the individual groups before the procedure and 3 months post procedure in assessment of VAS parameter.

Descriptive	RF before	RF after	Cryo before	Cryo after	ED before	ED after
N	18	18	48	48	21	21
Minimum	5	1	3	1	4	1
25% Percentile	6	3.750	6	3	6	2
Median	6	5	7	5	7	5
75% Percentile	8	7	8	6	8	5.5
Maximum	9	8	10	10	10	10
Mean	6.611	5.111	7.021	4.708	7.095	4.571
SD	1.243	2.055	1.591	1.845	1.700	2.541
Lower 95% CI	5.993	4.089	6.559	4.173	6.321	3.415
Upper 95% CI	7.229	6.133	7.483	5.244	7.869	5.728



**Figure 2** Evaluation of VAS scores in patients indicates a significant decrease of pain in all three groups 3 months after the procedure

#### 4. DISCUSSION

Back pain is frequent health complications affecting adults in the current population, with 10-20% of adults suffering from chronic low back pain. Facet joint degeneration as a source of chronic pain is often referred to as "facet joint syndrome" and arises as a result of osteoarthritic changes (Kim et al., 2015). Endoscopic modes enable the visualizing the facet joint and dorsal medial nerve branch, allowing for a more precise performance of the medical intervention. Furthermore, this procedure is associated with only a low percentage of minor complications (Walter et al., 2020).

This prospective, observational clinical study is designed to initially assess the change in clinical status 3 months after undergoing one of the interventional pain management procedures for the patients diagnosed with facet joint syndrome. We compared three groups of patients who underwent radio frequency thermo ablation, cryoablative facet joint denervation, or endoscopic facet joint capsule debridement after meeting the inclusion criteria. The current study describes an initial cohort of  $n=87$  patients, which will be further expanded over the course of the study to an estimated number of  $n=150$  participants (50 participants for each of the three groups). At the clinical change follow-up after three months, the follow-up sample of patients from the Cryo group showed improvement in all EQ-5D parameters. In the self care dimension, we observed deterioration in the RF group. Similarly, deterioration occurred in the ED group in the anxiety/depression dimension. This worsening may be due to both extraneous subjective factors that were not taken into account in the evaluation of the outcome questionnaire, as well as the small sample size of patients compared to the Cryo group. However, when all parameters of the EQ-5D test were evaluated together, we observed a significant improvement in the quality of life in all three groups.

When evaluating the VAS questionnaire, we observed a significant improvement with a  $p<0.001$  value for the groups that underwent the facet joint cryodenervation procedure and endoscopic facet joint debridement. The group that underwent radio frequency facet joint denervation demonstrated a statistically significant improvement with  $p=0.0445$ , with the mean absolute difference being the lowest using this technique. The choice of nerve ablation technique may have an impact on the final clinical outcome, as all the methods have a different mechanisms nerve damage mechanism. The return of pain after nerve ablation is due to nerve regeneration after peripheral nerve damage over a period of weeks or months (Ehler et al., 2008). As this study reports changes in clinical status three months after the procedure, the results provide only partial information on predictors of success. Other studies report a statistically significant improvement at a one-year follow-up (Manchikanti et al., 2015; Lee et al., 2017). However, to date, there have been no published studies comparing these three treatments. In order to obtain higher statistical significance, a larger sample of patients who have been followed longitudinally needs to be included in each study arm. It will be possible to analyses such results after further follow-up examinations, which are planned after 6, 12 and 24 months.

#### 5. CONCLUSION

Statistically significant reductions in pain were noted in the EQ-5D scale and VAS at 3 months in all three study groups. Further follow-up examinations are planned at 6, 12 and 24 months.

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#### Ethical approval

The study was approved by the Ethic Committee of Faculty of Medicine Pavol Jozef Šafárik University in Košice under number 26N/20202 and Regional Ethics Committee under number 03595/2020/OZ-31.

#### Funding

This study has not received any external funding.

#### Conflict of interest

The authors declare that there is no conflict of interests

#### Data and materials availability

All data associated with this study are present in the paper.



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