

## Clinical outcome of patients after endoscopic discectomy performed by two specialists

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**ABSTRACT**

**Background:** Endoscopic lumbar discectomy (ELD) is a percutaneous minimally invasive procedure used in the treatment of lumbar disc herniation. The study (NCT02742311 ClinicalTrials.gov) compares clinical outcomes after the interventional pain physician (IPP) and spine surgeon (SPS) provided transformational discectomy. **Methods:** Subjects were followed for 12 months via planned examinations by pain physicians. Leg pain and back pain intensity was assessed by an 11-point numerical rating scale (NRS). Patient's functional disability was assessed by the Oswestry Disability Index (ODI). Re-operations between both physicians were calculated by relative risk (RR). **Results:** Study subjects showed a significant decrease in ODI scores in both groups ( $p < 0.001$ ). The mean ODI in the IPP-group was  $41.1 \pm 16.4$  and in the SPS-group  $38.9 \pm 16.3$  preoperatively. Postoperatively it was  $16.3 \pm 11.5$  in the IPP-group and  $15.9 \pm 14.3$  in the SPS-group. Significantly lower pain scores for leg pain ( $p < 0.001$ ) and back pain ( $p < 0.001$ ) were also recorded at the 12-month follow-up. RR for re-herniation was 1.19 with 95% CI (0.33 to 4.26,  $p > 0.05$ ). **Conclusion:** We did not discover any significant difference between groups in the clinical outcomes during the 12-months evaluation. There was no significant difference in re-herniation rate in groups. Overall percentage of disc re-herniation was 5.26%.

**Keywords:** Back pain, disc herniation, endoscopic discectomy, functional disability, leg pain

**1. INTRODUCTION**

Back pain with or without radiation to the lower extremities was for a long time treated by neurologists, physio-rehabilitation specialists and spinal surgeons. The establishment of pain medicine as a separate specialization has introduced new approaches in the treatment of back pain, especially since the moment when diagnostic and therapeutic minimally invasive procedures started to be routinely used in pain medicine (Manchikanti et al., 2010). Intervertebral disc herniation, defined as the displacement of disc material (nucleus pulposus or annulus fibrosus) beyond the intervertebral disc space, has been the interest of solely spinal surgeons regarding its treatment (Gadjradj et

al., 2017).

In recent years, interventional pain management clinics have become more common, where, as a complex approach to the treatment of back pain, interventional pain management physicians perform percutaneous endoscopic surgeries on the intervertebral disc (Mlaka et al., 2020). Based on the routine of the pain management specialist in performing various minimally invasive procedures on spinal structures, a skillful management of percutaneous endoscopic discectomy is a logical consequence. Moreover, there should be no concern that the interventional pain physician will not be able to handle possible post-operative complications. They perform number of different interventions, with a similar portfolio of post-operative risks and they are fully capable of managing all complications, except for an epidural hematoma. The risk of epidural bleeding is, however, in the case of percutaneous endoscopic interventions minimal, comparable to other anesthesiology and pain procedures, such as epidural injections, epidural catheter techniques or intrathecal injections (Passia and Genevay, 2017; Wulf, 1996).

In the case that this clinical scenario occurs, a neurosurgical intervention is in place. It is ideal when the pain physician works along with a spinal surgeon. The fact that a pain specialist deals with the patient in a complex way regarding the diagnostics and treatment, increases the probability of a good quality indication for a minimally invasive procedure. A high surgical competence is logically expected, as pain specialists perform a relatively high amount of the same procedure, as their surgical portfolio is very narrow. Repeating the same procedure regularly and frequently in long time interval is the basic principle of the excellent mastery of a surgical technique (Elrod and Fortenberry, 2017).

## 2. MATERIALS AND METHODS

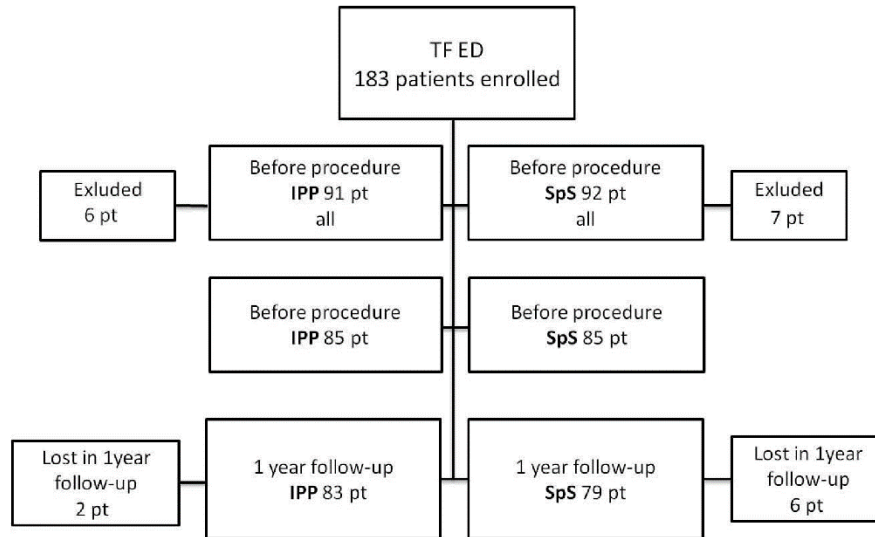
### **Ethical considerations**

A multicenter prospective comparative study design was used. The study underwent in accordance with ethical principles of the Declaration of Helsinki and was approved by the Medical Faculty, PavolJozefŠafárik University in Košice Ethical committee (no. 9N-2015) and with ClinicalTrials.gov identifier number NCT02742311 (registered 19.04.2016). Written informed consent was obtained from all participants. Patients with acute radicular low back pain caused by a herniated intervertebral disc or disc sequester were considered to undergo an endoscopic discectomy procedure performed via the transformational approach. After written informed consent was obtained, participants obtained a unique clinical trial identification number (ID), which was generated by computer software before the procedure. Study outcome measurements were obtained by an independent research team from the Medical Faculty, PavolJozefŠafárik University in Košice. Study continuance was maintained by an independent clinical study coordinator from the East Slovak Institute of Cardiovascular Diseases in Košice and the report was prepared in accordance with the Consolidated Standards of Reporting Trials (The “CONSORT statement”). All data are assembled in a protected and encrypted database accessible only to the study coordinator including statisticians from an independent statistical institution and local study site coordinators.

### **Patients**

From January 2016 to July 2021, we enrolled 183 patients accepted for Endoscopic Lumbar Discectomy (ELD). Patients were classified by the American Society of Anesthesiology physical status (ASA) with classes I, II, III and were aged between 18-80 years. Approved clinical investigation and recruitment took place in pain clinics in Bratislava, Bardejov and Košice in the Slovak Republic. Criteria for inclusion were as follows: age of 18 years or older, written informed consent, magnetic resonance imaging evidence of intervertebral disc herniation or sequestration, permanent pain radiating to the lower limbs despite previous periradicular therapy or similar intervention combined with conservative treatment (Rehabilitation, pharmacological treatment).

Exclusion criteria were as follows: bleeding diathesis, problems with urination or defecation, presence of infection, neoplasm, possible pregnancy and patient disapproval. All eligible patients were approached and the procedure was performed by a spine surgeon or interventional pain physician. Each patient included in the study obtained a unique clinical trial ID number. The operator performing ELD divided participants into two groups: Interventional Pain Physician (IPP-group) or Spine Surgeon (SPS-group) (Figure 1 and Table 1).



**Figure 1** Flow chart of the patient selection, enrolment and follow-up.

Primary outcomes were pain intensity spreading in the back and legs expressed by numerical rating scale (NRS) (0-10) and also evaluation of the Oswestry Disability Index (ODI) with grading scale from (0%-100%) focused on disability of patients caused by low back pain. 0% –20% describes minimal disability and value 81%–100% are bed-bound patients or patients who have an exaggeration of their symptoms. We also examined the Patient Status Score (PSS) with its grading scale from 0-4, where 0 means the patient is without pain, has a normal life, normal job, is able to exercise; 4 means the patient needs help to take care of themselves and is bed-ridden. Then the Patient Self-Content Score (PSCS) is graded on a scale from 0 to 10, where the patient describes how self-content they feel after the epiduroscopy procedure (0 being the worst and 10 being the best).

**Table 1** Characteristic of patients included

Characteristic	IPP group	SPS group
Gender	M 38pt / F 45pt	M 42pt / F37pt
Age	(min 18 - max 78) med 46	(min 23 - max 76) med 43
ASA	(min 1 - max 3) med 2	(min 1 - max 3) med 2
Height (m)	(min 1.56 - max 1.92) med 1.77	(min 1.62 - max 1.89) med 1.78
Weight (kg)	(min 48 - max 140) med 78.5	(min 49 - max 122) med 80
BMI kg/m <sup>2</sup>	(min 18.14 - max 49.02) med 26.2	(min 16.96 - max 36.57) med 26.73
Level of operation		
L1-L2	0	1
L2-L3	1	1
L3-L4	7	5
L4-L5	42	56
L5-S1	33	16

The second examination was performed 12 months after the procedure during an appointment in one of the included centers. Severity of pain by numerical rating scale and neurological state was examined. The second examination was performed 12 months after the procedure during an appointment in one of the included centers. Severity of pain by numerical rating scale and neurological state was examined.

**Surgery and anesthesia**

Percutaneous endoscopic procedures of the lumbar spine are performed via the transforminal, translaminar or interlaminar approach. Most surgeons perform the procedure using local anesthesia with light sedation. The patient’s consciousness and ability to communicate is the best neuro-monitoring and the risk of damaging nervous structures is reduced. During the transforminal approach, a safe entrance to the foramen is important, as well as the correct placement of the endoscope in the proximity of the herniated fragment. Our clinics prefer entering the foramen through delicate drilling of a part of the superior articular process with a series of manual drills (MaxMore Spine). The correct establishment of the skin entry point for the endoscope can be calculated geometrically or anatomically. In the case of extraforaminal, foraminal and Para central herniation, geometrical calculations are used, by measuring the distance from the anterior edge of an intervertebral disc to the skin or more precisely, the center of the disc to the skin. Anatomical calculations use the anatomical position of the facet joints and spinal prominences. The incision for the entry of instruments is around the size of 8-10mm on the skin. The approach for creating the working channel is strictly with dilators, without damaging the muscular and bony structures. Not only are specific instruments needed for working in the spinal canal, a specific type of coagulation with a 4MHz frequency is also necessary. This frequency enables the ablation of tissues and coagulation of vessels with a minimal risk of damage to the nerve structures.

The PELD procedure was done under local anesthesia with sedation of the patient in the prone position on a radiolucent table. The patients communicated with the surgeon during the entire procedure. The entry point was generally 10–15 cm from the midline. After infiltration of the entry point with local anesthetics, an 18-gauge spinal needle was loaded under fluoroscopic guidance to reach the superior articular process. The following steps were performed: 1) A guide wire was brought in through the spinal needle; 2) The spinal needle was removed; 3) A small 8 mm incision was made in the skin at the entry site; 4) A series of three dilators were used 5) Manual drills from 4mm up to 8 or 9 mm diameter were used to remove part of the superior articular process 6) After the last drill was removed, a working channel was inserted through the guide-wire and dilator and 7) The endoscope was inserted through the working channel to the epidural space close to the herniation.

**Statistical Methods**

Descriptive statistics (mean, median, maximum, minimum and SD) were used to evaluate the results. The distributional form for score and time data was determined by box plots indicating minimal value, lower quartile, median, upper quartile and maximal value. Normality of data distribution and homogeneity of variances were estimated by the Shapiro-Wilk and Levene tests. The statistical significance of changes within each treatment group was assessed by a Student's t-test. Differences between continuous variables were analyzed by a Kruskal–Wallis one-way test. Statistical analysis was performed with SPSS Version 11.0 statistic software package. Comparing the occurrence of complications between two groups (exposed group treated by an interventional pain physician and control group treated by a spine surgeon) was expressed by a calculation of the relative risk (RR), its standard error, 95% confidence interval and statistical significance. In all statistical calculations, P values of < 0.05 were considered significant.

**3. RESULTS**

79 patients in the SPS group and 83 patients in the IPP group were included in the statistical processing (Figure 1). Several parameters were evaluated between groups (Table 2). Prior to discectomy, patient quality of life was assessed with an ODI questionnaire and subsequent calculation of the ODI index. No statistically significant difference was found between both groups. The second questionnaire evaluating the quality of life was the PS questionnaire, evaluating the quality of life from 1-4. There was also no significant difference found before surgery between both groups.

**Table 2** Comparison between the groups of patients with discectomy provided by interventional pain physician (IPP) and spine surgeon (SPS) before and 12 months after procedure

Parameters	Time interval	IPP		SpS			
		Mean	S.E.M	Mean	S.E.M	CI 95%	p-value
ODI	Before procedure	41.06	1.976	38.93	1.925	-3.326 – 7.581	0.442
	12 months follow-up	16.29	1.391	15.94	1.685	-0.283 – 0.973	0.279
NPS - back pain	before procedure	4.13	0.372	5.64	0.364	-2.537 – -0.480	0.004
	12 months follow-up	2.42	0.227	2.04	0.234	-0.267 – 1.024	0.248
NPS - leg pain	before procedure	7.07	0.276	7.32	0.243	-0.981 – 0.493	0.513

	12 months follow-up	2.28	0.217	1.93	0.231	-0.283 – 0.973	0.279
PSS	before procedure	2.93	0.997	2.97	0.968	-0.230 – 0.310	0.748
	12 months follow-up	1.22	0.124	1.21	0.120	-0.350 – 0.332	0.958
PSCS	12 months follow-up	7.33	0.337	7.49	0.317	-0.761 – 1.067	0.742
EuroQol	before procedure	48.03	1.851	48.24	2.204	-5.506 – 5.920	0.943
	12 months follow-up	70.07	2.360	70.42	2.642	-6.680 – 7.369	0.344

*EuroQOL - Quality of life grading scale, IPP – Interventional Pain Physician – group, NPS – Numerical Pain Scale, ODI – Oswestry Disability Index, PSCS - Patient Self-Content Score, PSS – Patient Status Score, SPS – Spine Surgeon – group*

The third questionnaire evaluating the quality of life from 0-100 was the Euro QOL questionnaire, where the statistical significance of the difference between the groups before the operation was also not found. The perception of back pain intensity was significantly different between the IPP and SPS groups before the procedure but not for the lower limbs. By comparing the results between the groups after 12 months, we did not find any statistically significant difference in the monitored parameters of NRS lower limb and back pain. No difference was found between the groups after 12 months in the quality of life observed on the base of PSS, ODI and Quality of life questionnaires.

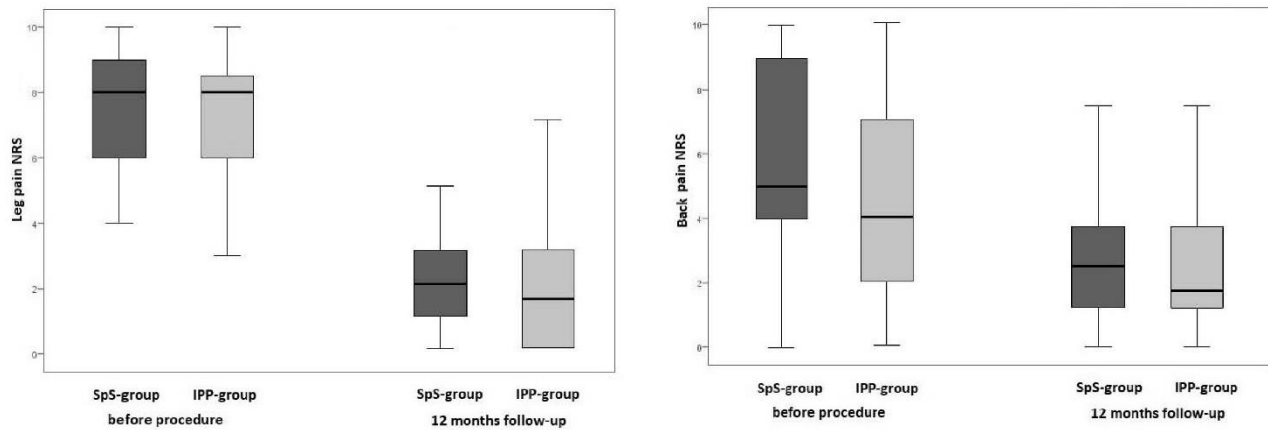
**Table 3** Evaluation of differences inside the groups of patients with discectomy provided by interventional pain physician (IPP) and spine surgeon (SPS) before and 12 months after procedure

Parameters	Groups	Before procedure		12 months follow-up			
		(min – max) med	SD	(min – max) med	SD	CI 95%	p-value
ODI	IPP	(6 – 86) 38	16.416	(2 – 42) 18	11.552	20.453 – 29.084	< 0.001
	SpS	(8 – 78) 38	16.331	(0 – 60) 12	14.298	18.828 – 27.144	< 0.001
NPS - back pain	IPP	(0 – 10) 8	2.955	(0 – 9) 2	1.982	2.716 – 4.229	< 0.001
	SpS	(0 – 10) 8	2.291	(0 – 9) 2	1.806	4.167 – 5.427	< 0.001
NPS - leg pain	IPP	(0 – 10) 8	2.223	(0 – 9) 2	1.960	4.379 – 5.677	< 0.001
	SpS	(0 – 10) 8	2.290	(0 – 8) 2	1.806	4.167 – 5.427	< 0.001
PSS	IPP	(1 – 4) 2	0.889	(0 – 3) 1	1.027	1.329 – 1.976	< 0.001
	SpS	(1 – 4) 3	0.822	(0 – 4) 1	1.020	1.459 – 2.069	< 0.001
PSCS	IPP	–	–	(10 – 0) 8	2.736	–	–
	SpS	–	–	(10 – 0) 9	2.691	–	–
EuroQol	IPP	(20 – 90) 45	15.37	(10 – 100) 70	19.60	-29.97 – -16.11	< 0.001
	SpS	(0 – 90) 45	18.70	(10 – 75) 75	22.42	-28.98 – -15.38	< 0.001

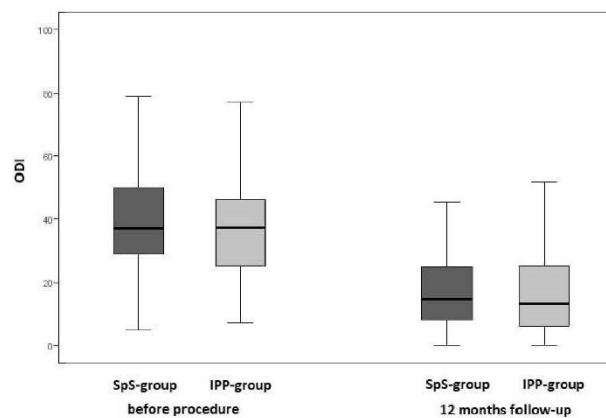
*Euro QOL - Quality of life grading scale, IPP – Interventional Pain Physician – group, NPS – Numerical Pain Scale, ODI – Oswestry Disability Index, PSCS - Patient Self-Content Score, PSS – Patient Status Score, SpS – Spine Surgeon – group*

Comparison of parameters within the groups themselves before the operation and 12 months after the operation showed a significant improvement in the reduction of back pain, painful limbs as well as significant changes in the evaluated questionnaires (Table 3). Before surgery, the median values in the SPS group of NRS lower limb pain and NRS back pain were 8. In the IPP group, we recorded the median values of NRS lower limb pain before surgery and the median values of NRS back pain 8. After 12 months, the median values in both groups and for both parameters dropped to 2. Box plots of comparable measurements NRS of back and leg pain (Figure 2) represented median, the box 25th to 75th percentile and the whiskers the range of the data with a significant difference before performance and after performance in both groups.

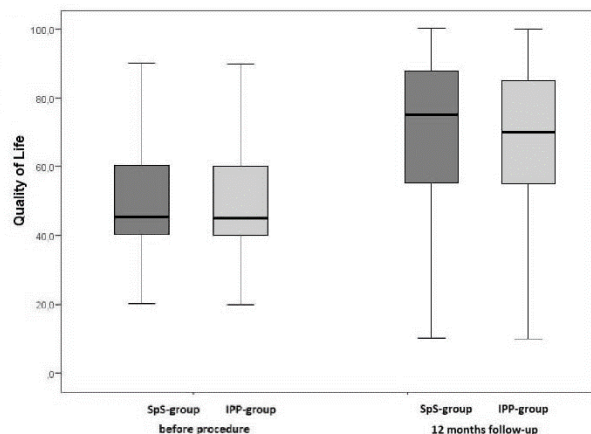
Patient satisfaction with performance was median 8 in the SPS group and 9 in the IPP group on a scale (0-10). There was a statistically significant improvement in quality of life in all three questionnaires monitoring quality of life 12 months after ODI, PS, and Quality of life (Figure 3, 4).



**Figure 2** Evaluation and comparison of the leg pain and back pain between the groups of patients with discectomy provided by interventional pain physician (IPP) and spine surgeon (SPS) before and 12 months after procedure



**Figure 3** Evaluation and comparison of the Oswestry Disability Index (ODI) between the groups of patients with discectomy provided by interventional pain physician (IPP) and spine surgeon (SPS) before and 12 months after procedure



**Figure 4** Evaluation and comparison of the Quality of Life between the groups of patients with discectomy provided by interventional pain physician (IPP) and spine surgeon (SPS) before and 12 months after procedure

The incidence of possible postoperative complications expressed in Table 4 was comparable between SPS and IPP groups. By comparing the Risk Ratio of re-operation between the surgeon and the interventional pain physician, we did not find any statistically significant difference.



**Table 4** Comparison of the incidence of complications after discectomy between the groups of patients with interventional pain physician (IPP) and spine surgeon (SPS) provided intervention. RR – risk ratio

Complications	IPP	SpS	RR	p-value	CI%
Nerve root injury	0	0	0.9524	0.9805	0.0191 – 47.4290
New level herniation	3	4	0.7139	0,6520	0.1650 – 3.0890
New level operation	2	2	0.9518	0.9601	0.1374 – 6.5945
Surgical errors	0	0	0.9524	0.9805	0.0191– 47.4290
Dural puncture	0	1	0.3175	0.4803	0.0131 – 7.6797
Hematoma	0	0	0.9524	0.9805	0.0191 – 47.4290
Wound complications	0	0	0.9524	0.9805	0.0191 – 47.4290
Re-herniations	5	4	1.1898	0.7899	0.3314 – 4.2715
Reoperations	5	4	1.1898	0.7899	0.3314 – 4.2715

#### 4. DISCUSSION

A microdiscectomy has been considered for years to be the gold standard for the treatment of a symptomatic herniated disc (Seigeret al., 2017). Despite the efforts of minimal invasiveness and reduction of the surgical incision size, even this technique is linked to side effects in the long-term. Any open spine surgery requires muscle damage, laminectomies, nerve retraction and removal of the yellow ligament. This can cause instability and scarring of the epidural space, appearing clinically symptomatic in 10% or more patients (Jamison et al., 2014; Rapčan et al., 2018). Lately, percutaneous endoscopic lumbar discectomy (PELD) is being performed as an alternative to classic open discectomy with clinical results that are comparable to those of open discectomy (Ahn et al., 2015; Gibson et al., 2017). With PELD, muscles are unimpaired and the possibility of postoperative epidural scar formation and instability might be minimized (Mlaka et al., 2020). Even if many studies have shown the effectiveness of PELD with good clinical outcomes, the percutaneous approach bear challenges to surgeons and the PELD learning curve is usually perceived to be steep (Ahn et al., 2015; Sharif and Afsar, 2018). There certainly are differences between transforaminal and interlaminar, if appropriate, the translaminar approach, with concern to the learning curve (Zelenkov et al., 2020).

Relatively recently, interventional pain physicians have included PELD in their portfolio of procedures, which often provokes negative reactions in spine surgeons, who historically have the ownership of surgical procedures on spinal structures. This historical fact develops in parallel with the development of medicine. The trend towards minimal invasiveness through percutaneous techniques is notable in numerous medical fields, not only in pain medicine, but also cardiology, interventional radiology and various others. In the last few decenniums, we have encountered the situation where two various specialists from two various medical fields perform a competitive medical procedure, the result of which is supposed to be the correction of a function of the same organ. As example of this are cardio logical interventions focused on replacing the aortal and mitral valves performed by two different specialists, a cardiologist and a cardiac surgeon (Adler et al., 2012).

Some further examples are endoscopic procedures performed by gastroenterologists and abdominal surgeons (Provenzale et al., 2003) and neurosurgical procedures performed by neurosurgeons and interventional pain management specialists (Mlaka et al., 2020) or even interventional radiologists. Similar difficulties at the beginning of the establishment of a procedure for specialists from other medical fields bring about the discussion on the issues of competence and quality of performance. It is, therefore, necessary to prove the quality of work and defend the competence of another specialist.

The goal is to achieve a rational compromise, answer constructive questions on the technical limitations, new advantages as well as relevant risks and the management of complications, where the result should be for the highest possible benefit to the patient with minimal risks. Nowadays, the cooperation between interventional cardiologists and cardiac surgeons is obvious, similarly as is coiling in intracranial aneurysms managed by interventional radiologists with the back-up of a neurosurgeon (Shao et al., 2019). It is also clear that interventional cardiologists and radiologists require quality clinical training to maintain the competence for performing interventional procedures (Elrod and Fortenberry, 2017).

Interventional pain physicians standardly perform a wide range of minimally invasive procedures on spinal structures. Their daily routine involves transforaminal injection techniques, median branch blockades, discographies, radiofrequency denervation techniques, catheter techniques in the epidural space (Patel et al., 2015). Routine use of injection techniques under X-ray guidance leads to the high competence in radiological navigation on the spinal structures. Interventional pain specialization programs are most effectively performed in health institutions known as “Centers of excellence”, similarly as in all other fast-developing progressive specializations. They also have an ability to provide higher quality of care through the utilization of innovative tools,

technologies and techniques improving outcomes (Elrod and Fortenberry, 2017). It seems only logical that percutaneous endoscopic techniques on intervertebral discs especially via the transforaminal approach are easily adopted by interventional pain physicians, as they perform numerous interventions in the anatomical space (Patel et al., 2015).

In our study, we compared two specialists, a spine surgeon with 20 years of experience in percutaneous endoscopies and interventional pain physicians with the same experience in spinal interventions. Prior to the start of the study, the interventional pain physician completed a formal cadaver course in endoscopies, followed by 50 procedures under the supervision of an endoscopic specialist. After 50 supervised procedures, he performed approximately 300 additional procedures alone. The whole learning curve lasted about 24 months. The study showed equally good clinical results of transforaminal endoscopy as well as the same incidence of complications when comparing the two specialists. This confirms the fact, that a percutaneous endoscopic procedure is quickly adopted by the interventional pain physicians, due to their long-term preparation with similar minimally invasive procedures.

Interventional pain management specialists work with the patient from the beginning of their clinical symptoms and often manage the diagnostics and treatment rationally with a goal, if possible, to avoid surgery. The mentality of a pain physician includes minimal invasiveness and the effort to improve the patient's clinical condition and reduce the risks of permanent consequences. Unfortunately, in spine surgery, it is a relatively common phenomenon to indicate surgery according to MRI findings, without a clear correlation with the patient's clinical condition (Epstein and Hood, 2011).

Studies showed that MRI findings without an appropriate indication do not improve the outcomes and seem to have a strong iatrogenic effect in acute lower back pain, regardless of whether the patient has acute radiculopathy (Webster et al., 2013). It also occurs that the indicated surgery is unnecessarily robust, with excessive damage to the surrounding structures and the development of FBSS (Rapčan et al., 2018). Patients with diagnosed sciatica and correlating MRI findings of spinal cord compression are indicated by pain specialists for PELD after a thorough clinical examination and clinical reaction to conservative therapy.

Surgery is preceded by epidural application of corticosteroids under fluoroscopic guidance. The patient is followed for the next two weeks, under which their condition may improve with conservative therapy and can, therefore avoid surgery (Benzakour et al., 2019). Endoscopic discectomies are indicated by interventional pain physicians in persisting clinical signs of spinal cord compression or the deterioration of the patient's clinical condition.

## 5. CONCLUSION

According to our results, preoperative equality of patients, post operative clinical outcome and rate of complications did not show any difference between both specialists. The main advantage for proper learning and mastering the procedure for an IPP is extensive training in invasive spinal pain relief procedures. An IPP accomplishes up to 50 epidural transforaminal injections with X-ray navigation assistance during one week on average. Therefore, performing endoscopic discectomies is a suitable method for both specialists, spinal surgeon and invasive pain physician. Good cooperation between the interventional pain management specialists and the spine surgeons should lead to a significant improvement in clinical outcomes in the treatment of back pain globally. The interventional pain physicians can focus in detail on the patient up to the percutaneous endoscopic procedure, which they have an opportunity to perform frequently and in numbers that guarantee the excellence of the surgical technique. At the same time, they can properly indicate patients for surgical procedures for the spine surgeon in cases of spinal stenosis, significant instabilities of the spine and certain other advanced degenerative changes. Complications such as re-herniation, disc tears, discitis and damage to the neural root are easily managed by the interventional pain physician. The trend of minimal invasiveness and focus on the accurate performance of the surgical procedure is the golden standard in every medical field. PELD in the hands of interventional pain physicians has great potential to raise the standard in the treatment of back pain, without increasing the risks of post-operative complications. At the same time, it increases the availability of the procedure in indicated patients and shortens waiting times, which are usually quite long for busy spine surgeons. Extending the waiting times for nerve decompression can significantly increase the risk of permanent nerve root damage. PELD in the hands of interventional pain physicians give spine surgeons more room for surgical solutions to complicated spinal syndromes that require open surgical solutions.

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**Author contribution**

RR, LK contributed to the conception and study design. Data collection by RR, LK, MB, SR, JM, MM, MG, HK, were performed. Analysis and evaluation of data were performed by RR, LK, JV, HK, SR, JM, MM and MG. The first draft of the manuscript was written by LK, RR, SR, JV and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

**Ethical approval**

The study was approved by the Medical Faculty, Pavol Jozef Šafárik University in Košice Ethical committee (no. 9N-2015).

**Informed consent**

Written and oral informed consent was obtained from all individual participants included in the study. Additional informed consent was obtained from all individual participants for whom identifying information is included in this manuscript.

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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 sets collected during this study are available upon reasonable request from the corresponding author.

**REFERENCES AND NOTES**

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