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Application of epidural steroid injection for the treatment of lumbar disc herniation in Vietnam

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ABSTRACT: Epidural steroid injections (ESIs) have been mentioned by international medical literature as an option for treatment and pain relief for patients with lumbar disc herniation (LDH). Several studies worldwide have recognized the efficacy of treating LDH with ESIs to be between 72-86%. Our study aimed to elucidate the ESIs technique's effectiveness, advantages, and disadvantages. A 30-day pre-post study in 100 LDH patients underwent the ESIs technique. Patients meeting the criteria received physical examinations and magnetic resonance imaging (MRI) scans before undergoing the method. The Visual Analog Scale (VAS) was applied to assess the patient's hospitalization condition after ESIs 1 day, 7 days, and 30 days. After 1 day of ESIs, 85% of patients responded well (10% excellent and 75% moderate), and this prevalence increased up to 95% after 7 days and 30 of follow-up. The ESIs safety assessment after 1 day of treatment recorded that 2% of patients had complications and 24% had medication side effects. After 7 days, 4% of patients had epigastric pain and no more complications. Treatment outcomes of ESIs were effective and high

Keywords: Epidural steroid injections; lumbar disc herniation; low back pain; treatment outcomes

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1.0 INTRODUCTION

safety in patients with LDH.

Lumbar disc herniation (LDH) commonly affects the lumbar spine (Kim et al., 2011). LDH might cause various sequelae, reducing patients' quality of life and leading to severe complications: muscle atrophy, urinary disorders, and long-term disability (Bui, 2013). In the United States, according to statistics in 2014, disc herniation created a massive financial burden of treatment, up to 90 million US dollars annually (Ghai et al., 2015). The rate of developing the disease is reportedly from 5 to 20 cases in every 1000 adults annually (Al Qaraghli & De Jesus, 2022). The study by Tran and colleagues showed about

30% of the Vietnamese population suffered from sciatica, among whom 95% were caused by LDH (<u>Tran & Le, 2018</u>).

Epidural steroid injections (ESIs) have been mentioned by international medical literature as an option for treatment and pain relief for patients with low back pain (LBP) caused by disc herniation (Bui, 2013). ESIs were gradually cementing their position as a noncomplicated, effective, minimally invasive form of symptomatic treatment of disc herniation (Baral et al., 2011). Several studies worldwide have recognized the

efficacy of treating LDH with ESIs to be between 72-86% (Baral et al., 2011; Ghai et al., 2015; Leung et al., 2015; Taskaynatan et al., 2015). However, few studies have assessed the efficacy and safety of treating LDH using ESIs in Vietnam. Therefore, it is necessary to analyze clinical characteristics, risk factors, and magnetic resonance imaging (MRI) results and elucidate the ESIs technique's effectiveness, advantages, and disadvantages for the Asia population in general and the Vietnamese population in specific.

2.0 MATERIALS AND METHODS

2.1 Research objects

We performed a pre-post study with 30 days of followup on LDH patients treated with the ESIs technique at the Can Tho University of Medicine and Pharmacy Hospital between 2018-2019.

Inclusion criteria: All consented patients diagnosed with LDH and at least 4 weeks of unsuccessful pharmacological management (anti-inflammatory drugs, pain relievers, muscle relaxants). The diagnosis of LDH must be based on clinical criteria and lumbar MRI results. Clinical criteria included one of the following three symptoms: sciatica, mechanical low back pain, and positive Lasègue sign. Lumbar MRI results should record one of the following images (Moeller et al., 2016): prolapsed disc, extruded disc, and sequestrated disc.

Exclusion criteria: (1) Local or systemic infection; (2) Lidocaine, Depo-Medrol sensitivity; (3) Tuberculosis; (4) Malignancies, with or without surgical management; (5) Cauda equina syndrome; (6) Neurological comorbidities; (7) Other comorbidities; (8) Severe heart failure; (9) Uncontrolled hypertension; (10) Non-compliance.

2.2. Sample size

The sample size was decided based on this formula:

$$n=Z_{1-\alpha/2}^2\frac{p(1-P)}{d^2}$$

Following the study of Babita Ghai (2015), the rate of successful treatment of LDH patients using the ESIs technique was 86% (Ghai et al., 2015) (p=0.86). We calculated n = 94 with a confidence level 95% (Z1- α /2 = 1,96) error margin 7% (d=0.07). In actuality, 100 cases were recruited and analyzed.

2.3. Research content

Patients meeting the criteria received history and physical examinations, MRI scans, and ESIs treatment,

with a follow-up meeting to assess treatment efficacy after 30 days.

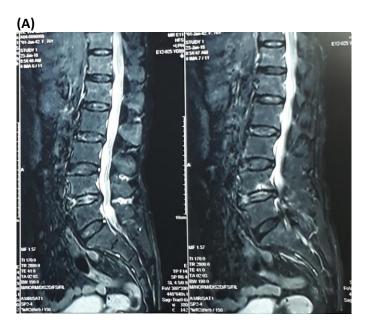
2.3.1 Clinical, paraclinical characteristics and risk factors of LDH patients

History and physical examinations recorded general and clinical characteristics with a questionnaire by specialized internal medicine physicians. Recorded characteristics included: (1) Age (under or over 40 years of age); (2) Gender; (3) Occupation (High risk professions were farmers, porters, free workers, office workers, accountants; low risk professions were housekeepers, vendors); (4) Body mass index (BMI; classified according to the criteria of WHO applied for Asia-Pacific region (WHO, 2004)); (5) Smoking habit (defined as minimum 10 cigarettes/day, continuous within a minimum of 2 years; no smoking habit was defined as an absolute lack or cessation of smoking habit longer than 2 months); (6) Pain rating according to visual analogue scales (VAS) (Hawker et al., 2011), (LBP, sciatica, pain relief postures); (7) Onset time (1-12 months, 13-24 months, 25-36 months, >36 months); (8) Onset circumstance (bending over or rotating the body, lifting heavy objects, climbing stairs, no specific circumstance); (9) Sensory disorders (Reduced or loss of superficial and deep sensations, or paresthesia at the calves, soles of feet, groin area); (10) Reflex disorder (Reduced or loss of patellar reflex or Achilles reflex); (11) Muscle atrophy (Found at the calves or thighs through circumference measurement and bilateral comparison).

Paraclinical characteristics were assessed with lumbar MRI results done with a 1.5T MRI machine (Sagittal T1W TSE, Sagittal T2W TSE, Axial T2W TSE). A qualified physician analyzed the results. Characteristics for analysis included: (1) Herniated disc quantity (analyzed on the sagittal plane, distinguished between single and multistage herniation); (2) Herniation location (L1-L2; L2-L3; L3-L4; L4-L5; L5-S1); (3) Herniation direction (analyzed on the axial plane, included lateral herniation, central herniation, conjugate hole, and extra conjugate hole herniation); (4) Herniation degree (distinguished into 3 stages: mild degree when less than 50% of the herniated disc nucleus protruded into the posterior longitudinal ligament, moderate degree when protrusion reached over 50% with attachment to the nucleus, severe degree when protrusion reached over 50% and separated from the nucleus; (5) Herniation stage (included: protrusion, extrusion, sequestration) (Moeller et al., 2016) (Figure 1).

2.3.2 Treatment efficacy assessment of the ESIs technique

This study employed only one treatment regimen: A single dose of 02 vials of Depo-Medrol 40mg and 3ml Bupivacaine and Natriclorid 0.9% totalled 10ml (Nguyen, 2003), combined with treating comorbidities (osteoporosis, hypertension, gastritis). In this study, the interlaminar ESI technique was performed by anesthesiologists and neurologists.



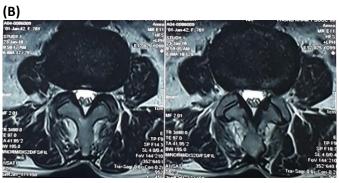


Figure 1. (A) L4-L5 posterior central herniation with **(B)** bilateral L4, L5 nerve root compression.

Treatment efficacy assessment was based on the VAS for quantifying pain relief before and after ESIs at 1 day, 7 days, and 30 days (Nguyen et al., 2015). The improvement after treatment was considered excellent when a patient reported total pain relief, moderate when the VAS showed a reduction, and unsatisfactory when the VAS did not decrease. Patients responded to treatment with an excellent or moderate degree of improvement.

Safety assessment of ESIs included safety of the technique and safety of medications. Safety of the technique was assessed at the point of conducting the procedure, considered excellent when medications were delivered into the epidural space without complications and unsatisfactory when medications were not delivered into the epidural space or complications occurred (shock; injection site infection; medications delivered meningitis; into subarachnoid space; injection site bleeding; falling blood pressure). Safety of medications was assessed through the side effects of medications at the point of conducting the procedure: epigastric pain, nausea, flatulence, and other effects recorded by thorough physical examination of each patient. The reprocess is illustrated in Figure 2.

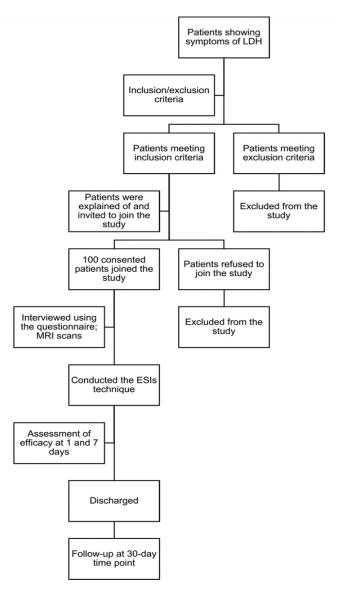


Figure 2. Flowchart of the research process.

2.4 Statistical analysis

Collected data were subjected to screening before input to ensure completeness of data. The SPSS 18.0 program was used for data analysis, calculating rates and frequencies, comparing rates (Chi-square test), calculating odds ratio with 95% confidence interval and significance of p-value at < 0.05, assessing the difference between values at the point of admission, 1 day, 7 days and 30 days after treatment.

2.5 Research ethics

Our research followed the criteria of medical ethics and was accepted by Can Tho University of Medicine and Pharmacy with Decision no. 149/QD-DHYDCT on February 18th, 2019.

3.0 RESULTS

3.1 Clinical, paraclinical characteristics and risk factors of LDH patients

The general characteristics of the study objects are described in **Table 1**. There were 90% of the patients ≥ 40, females accounted for 71%, and the high-risk occupational group accounted for 55%. There were 33% of patients smoking, 50% with a normal BMI, 42% were overweight, and 2% were obese.

Table 1. General characteristics and risk factors of research objects.

Characteristic		No. (patients)	Rate (%)
Λαο	<40	10	10
Age	≥40	90	90
Cov	Male	29	29
Sex	Female	71	71
Ossumational	High-risk	55	55
Occupational	Low-risk	45	45
	Underweight	6	6
BMI	Normal range	50	50
DIVII	Overweight	42	42
	Obese	2	2
Smoking	Yes	33	33
SHOKING	No	67	67

The clinical characteristics of the patients are detailed in **Table 2**. There were 100% of the patients with LBP and sciatica; severe pain accounted for 56%, and 14% for very severe. Patients with onset time <12 months accounted for 39%, and onset circumstances by bending or turning were 45%. Of about 98% of patients with foot paresthesia, 34% showed a reduced or loss of superficial and deep sensations, patellar reflex decreased by 40%,

and Achilles reflex decreased by 50%, muscle atrophy accounted for 18%.

Table 2. Clinical characteristics of research objects

Characteristic		No.	Rate
Characteristic		(patients)	(%)
	LBP	100	100
Pain	Sciatica	100	100
	Pain relief postures	61	61
	None	0	0
	Mild	0	0
Sex	Moderate	30	30
	Severe	56	56
	Very severe	14	14
	1-12 months	39	39
Onset time	13-24 months	21	21
Onset time	25-36 months	31	31
	>36 months	9	9
	Blending or rotating	45	45
Onset	Lifting heavy objects	23	23
circumstance	Climbing stairs	10	10
circumstance	No specific circumstance	22	22
Reduced or loss	Yes	34	34
of superficial and deep sensations	No	66	66
Foot paraethosia	Yes	98	98
Foot paresthesia	No	2	2
	Patellar reflex	40	40
Reflex disorder	Achilles reflex	50	50
	No	10	10
Musclo atrophy	Yes	18	18
Muscle atrophy	No	82	82

Table 3 describes the patient's MRI imaging characteristics. 67% of patients had multistage herniation, 89% at L4-L5, and 62% at L5-S1. Patients with center herniation accounted for 37%, and lateral herniation accounted for 35%. Moderate herniation degree accounted for 62%, and mild for 28%. Extrusion stage herniation accounted for 60%, and sequestration accounted for 3%.

3.2 Treatment efficacy assessment of the ESIs technique

The relief in the patient's pain level according to the VAS is detailed in **Table 4**. There were 16% very severe and 56% severe pain since hospitalization. After 1 day, 7 days, and 30 days of treatment with the ESIs technique, there was no very severe pain left. The prevalence of patients with severe, moderate, and mild pain gradually decreased over the treatment period.

Table 3. MRI imaging characteristics of research objects.

Chavastavistis		No.	Rate
Characteristic		(patients)	(%)
Herniated disc	Single-stage	33	33
quantity	Multistage	67	67
	L1-L2	5	5
Herniation	L2-L3	11	11
location	L3-L4	33	33
iocation	L4-L5	89	89
	L5-S1	62	62
	Lateral herniation	35	35
	Central herniation	37	37
Herniation	Bilateral herniation	15	15
direction	Conjugate hole herniation	13	13
	Extra conjugate hole herniation	0	0
	Mild	28	28
Herniation	Moderate	62	62
degree	Severe	10	10
	Protrusion	37	37
Herniation	Extrusion	60	60
stage	Sequestration	3	3

The treatment efficacy assessment is described in **Table 5**. After 1 day, 85% of patients reposed well with the ESIs technique. After 7 days and 30 days of treatment, this prevalence increased to 95% (p < 0.001).

Table 6 shows the safety assessment of the ESIs technique after treatment. 98% of the patients had no complications due to the procedure. After receiving the ESIs technique 1 and 7 days, variable side effects showed that 10% of patients had epigastric pain, 4% nausea, and flatulence.

4.0 DISCUSSION

4.1 Principal findings

In our study, the most common symptom was LBP and sciatica (100%), the second common symptom was foot paresthesia (98%), and Achilles reflex reduction was followed by the third most common symptom (50%) (Table 2). The LDH morphological via MRI in the longitudinal image recorded the most herniation location was at L4-L5 (89%), followed by L5-S1 (62%), and L3-L4 (33%) (Table 3).

Table 4. Relief in pain level according to the VAS

Pain grading	Hospitalized	1 day after treatment	7 days after treatment	30 days after treatment
raili graullig	(%)	(%)	(%)	(%)
None	0	10	60	70
Mild	0	55	23	20
Moderate	28	25	15	80
Severe	56	15	2	2
Very severe	16	0	0	0
Total	100	100	100	100

Table 5. Treatment efficacy evaluation.

Treatment response	After 1 day (%)	After 7 days (%)	After 30 days (%)	Р
Excellent	10	60	70	
Moderate	75	35	25	<0.001
Unsatisfactory	15	5	5	
Total	100	100	100	

Table 6. Safety assessment of the ESIs technique.

Characteristic		After 1 day (%)	After 7 days (%)
Tachnique complications	No complications	98	100
Technique complications	Unsatisfactory	2	0
	Epigastric pain	10	4
Medications side-effect	Nausea	4	0
	Flatulence	4	0
	Dyspepsia	6	0

The cross-sectional images showed a large group of patients had central herniation (37%), followed by lateral herniation (35%). There were no cases of extra conjugate hole herniation (Table 3).

After 1 day of receiving the ESIs technique, 85% of patients responded well (10% excellent and 75% moderate) (Table 5). After 7 days and 30 of follow-up, 95% of the patients responded well (Table 5). The technique is very safe; our study recorded that after 1 day of treatment, 2% of patients had hypotension completely resolved after 30 minutes of intervention. Medication side effects were recorded as mild and could not lead to mortality (10% abdominal pain, 4% nausea, 4% flatulence, and 6% dyspepsia) (Table 6). After 7 days of follow-up, 100% of patients showed no complications, and 96% had no side effects (4% of patients with mild abdominal pain) (Table 6).

4.2 Strengths and weaknesses of the study

Our study had a sample collection process strictly attached to selection and exclusion criteria. A highly qualified physician did the sample collection process and MRI image reading. All study participants volunteered and benefited from the study. The sample size is calculated, so all data in the study are specific to the population in Vietnam (n>94; we have 100 patients). Reputable sources referenced the design and content of the research. Our study results clearly showed the difference between high-risk and low-risk groups. The high-risk age group (≥40 years old) accounted for 90%, 9 times higher than the low-risk age group (<40 years old), and the high-risk occupation group is also recorded as having a higher prevalence than the low-risk age group (<40 years old). A higher rate (55%) than in the low-risk group (45%) (Table 1). Our study recorded the most characteristic symptoms and MRI images in patients with LDH among the Vietnamese population (100% with LBP and sciatica, 89% herniated at L4-L5). The ESIs technique's treatment outcome was defined as effective and safe. Therefore, the ESIs technique has clinical and practical value in treating patients with LDH.

However, the study was conducted in the hospital (the main goal was to evaluate treatment outcomes), which caused the inability to collect the control group. Therefore, we could not evaluate the LDH occurrence in the Vietnamese population and the correlation of risk factors between the LDH and control group. In this initial study, we did not clearly describe the type of back pain (axial LBP or radicular symptom). Therefore, our study could not assess the performant of the ESI technique between LBP and radiculopathy. The VAS limitation in

patients' self-reported could lead to bias. However, this scale was commonly used in measuring pain relief after the intervention in many studies, and the outcome is still accepted. In addition, our study could not evaluate the recurrence rate in treated patients. Our study design evaluated treatment outcomes after 30 days, but recurrence occurs over a more extended period.

4.3 Possible explanations and comparisons with other studies

Our study subjects age had 90% in the high-risk group (≥ 40 years old) (Table 1); the result was similar to some studies reported on study subjects with age ≥ 40 years (Duong, 2015; Duong & Tran, 2013; Motiei-Langroudi et al., 2014; Tran & Le, 2018). In our study, 71% were females (Table 1), different from some studies which recorded 1/1.14; 1/1.65 (Duong & Tran, 2013; Ghai et al., 2015). This characteristic is not specific to LDH.

LBP and sciatica were the most common symptom (100%) (Table 2). The prevalence of patients with LBP and sciatica was 100%, 88.57%, and 93%, respectively (Lewis et al., 1987; Nguyen, 2014; Tran & Le, 2018). The onset time was mainly less than 12 months (39%) (Table 2), which was different from some studies with the onset time recorded as 91.67%, 65.2%, 56.66%, 42.85% (Duong, 2015; Nguyen, 2014; Tran & Le, 2018). The difference could be due to the patient's current knowledge; our study was conducted in 2019, and others were conducted in 2014, 2015, and 2018 respectively. Therefore, the patient knew to buy pain relievers and only hospitalization when it worsened. The onset circumstances by blending or rotating accounted for the highest prevalence (45%), which was similar to the Tran and colleagues (48.1%; Tran & Le, 2018) and Nguyen and team (51.43%; Nguyen, 2014) Sensory disorder (98% foot numbness, 34% sensation reduced) and reflex disorder (40% patellar reflex reduction, 50% Achilles reflex reduction) (Table 2) were similar to some studies such as 100% sensory disorder, and 58.5% reflex disorders (Tran & Le, 2018), 65.11% sensory disorder and 43.33% reflex disorders (Duong, 2015), and 72% sensory disorder (Lewis et al., 1987). Muscle atrophy in our study (18%) was lower than as reported by Nguyen and the team's study (48.7%) (Nguyen, 2014) (Table 2). The difference was because of the difference in hospitalization onset. Nguyen and colleagues' study had the prevalence of hospitalization patients less than 12 months was 42.85%. Therefore, a large group of patients with late hospitalization made the muscle atrophy worse.

The longitudinal MRI images showed herniated disc quantity (67% multistage) and herniation location (89% L4-L5) (Table 3) were similar to studies such as Tran & Le (75% multistage, 73.6% L4-L5; Tran & Le, 2018), Duong and colleagues (multistage 87.22%, 47.97% L4-L5; Duong, 2015), Motiei-Langroudi and team (L4-L5 57.8%) (Motiei-Langroudi et al., 2014;). The cross-sectional MRI images showed herniation direction was 35% in 1 lateral, 37% in central, and the herniation stage was 60% in extrusion and 37% in protrusion (Table 3). This prevalence was different in comparison with other studies such as Tran and team (57.5% central, 47.2% 1 lateral, 36.6% extrusion, 70.8% protrusion; Tran & Le, Nguyen and team (87.9% 1 lateral, 54.6% 2018), extrusions, 33.3% sequestration; Nguyen, 2014), Wilberger & Pang (13.8% cental and 76.8% 1 lateral; Wilberger & Pang, 1983), Motiei-Langroudi and colleagues (54.8% protrusion; Motiei-Langroudi et al., 2014) and, Lewis and team (40% protrusion, 24% extrusion; Lewis et al., 1987). This difference was because of the distinctive living habits and occupations between populations. In addition, this difference might be due to the subjectivity of the researcher's filmreading process.

In our study, 85% of patients responded well to the ESIs technique after 1 day and increased to 95% after 7 days and 30 days followed up **(Table 5)**. This prevalence was similar to some of the same designed studies. In Nepal, the success rate of 62 patients with LDH treated with epidural steroid injections was up to 81%. (Baral et al., 2011). In Turkey, over 80 LDH patients treated with epidural steroid injections had a response rate of 72% (Taskaynatan et al., 2015). A study reported on 232 patients with LDH treated with epidural steroid injections recorded an excellent treatment outcome with an immediate response prevalence of 80.2% (186/232) (Leung et al., 2015).

Our study recorded 98% of patients without complications (Table 6), similar to a previous study that recorded 100% without complications after injection (Nguyen et al., 2015). Another study showed that 6% of patients had local pain at the injection location, and 5% had vasoconstrictor reactions (Baral et al., 2011). Medication side effects were uncommon (10% epigastric pain, 4% nausea, 4% flatulence, and 6% dyspepsia) (Table 6). Medication side effects were different between studies. A study in 2015 recorded 1.6% of patients with nausea, headache, injection site transient straining to urinate, hiccups, hyperglycemia, and tinnitus (Taskaynatan et al., 2015). Medication side-effects may be due to the differences in the natural disposition of populations. Overall, there was a similarity between our study and others in that most of the complications were mild and could not lead to mortality.

5.0 CONCLUSIONS

Treatment outcomes of the ESIs technique are defined for effectiveness and high safety. The study found a minimal number of patients had complications of hypotension, so it is necessary to monitor for timely treatment immediately after injection. Furthermore, a multicenter national study with a larger sample size and longer follow-up period is needed to document more specific treatment outcomes for Vietnamese and Asian populations.

Author Contributions: MVL, TN and TTTT conceived and designed the experiments; MVL performed the experiments; MVL, TN and TTTT analyzed the data; MVL contributed reagents/materials/analysis tools; BLTT and NMT wrote the paper.

Conflicts of Interest: The authors declare no conflict of interest.

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