

## COMMON CHARACTERISTICS OF PATIENTS TREATED WITH OZONE THERAPY THROUGH THE SKIN UNDER THE GUIDANCE OF CT SCAN FOR LUMBAR DISC HERNIATION TREATMENT

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### ABSTRACT

**Objectives:** To describe the common characteristics of patients undergoing intervention for lumbar disc herniation treatment using ozone therapy through the skin under the guidance of CT scan, to serve as a basis for intervention studies. **Methods:** The study describes the common characteristics and assesses pain scores of 147 patients with lumbar disc herniation (100 patients in the intervention group and 47 patients in the control group). **Results:** Lumbar disc herniation typically occurs in individuals over 30 years of age, with the majority being between the ages of >50 (49.7%) and 30-50 (44.2%). The average age of the study group was  $48.8 \pm 12.1$ , lower than the control group ( $57.4 \pm 14.8$ ), ( $p < 0.05$ ). Females had a higher incidence of lumbar disc herniation than males (1.5 times), but  $p > 0.05$ . Unilateral pain was predominant in both groups, mostly on the left side. The average VAS score before intervention in the study group was  $8.0 \pm 0.7$ , with no significant difference between the groups. Patients with pain symptoms before treatment had a high and severe level of pain, with no significant difference between the two groups. The average ODI score indicating functional disability of the study group was  $70.3 \pm 9$ ,  $p > 0.05$ . **Conclusion:** The study provides important information on the common characteristics of patients with lumbar disc herniation and pain symptoms. These results

serve as a basis for implementing intervention treatment for patients with lumbar disc herniation.

**Keywords:** Lumbar disc herniation; Electromagnetic; CT scan; pain score; Oswestry Disability Index; Interventional therapy

**Abbreviations:** EM: Electromagnetic; CT: Computed tomography; VAS: Visual Analog Scale; ODI: Oswestry Disability Index; LDH: Lumbar disc herniation; PT: Patients

### I. INTRODUCTION

Spinal pain caused by herniated discs (LDH) is a common condition affecting people of all ages, significantly affecting daily activities and reducing work productivity.

There are several treatment methods with different mechanisms of action depending on the severity of the herniation, clinical symptoms, and spinal degeneration. Non-surgical treatment such as medication, physical therapy, traditional medicine, and traction are preferred, but in cases of unresponsiveness, minimally invasive interventions through the skin, including corticosteroid injections around the root, thermal annuloplasty, laser or high-frequency waves to the herniated disc, or the use of nuclear decompression chemicals such as Ozone or Discogel are used. The general principle of minimally invasive interventions into the disc is to remove the condition of increased pressure inside the disc, helping the herniated part to shrink or disappear, thereby resolving nerve root compression

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conflicts and reducing inflammation caused by the herniation. Currently, minimally invasive skin-based interventions are strongly developing due to their good treatment effectiveness, low surgical rate, and low complication rate, especially the Ozone injection treatment method into the herniated disc under the guidance of computed tomography (CT) scan. Ozone treatment for LDH has been applied in Europe for the last 15 years with good results. A synthesis study of 117 other Ozone studies by Magalhaes showed high reliability and lower complication rates than other equivalent treatment methods. Moreover, recent studies have shown that combining Ozone injection into the disc with corticosteroid root canal irrigation produces better results than Ozone injection into the disc alone.

In Vietnam at present, there has been no study applying the Ozone injection method in treating LDH pathology as well as evaluating the effectiveness of treatment. To provide a basis for intervention research, we conducted this study with the aim of describing the general characteristics of patients in two groups: the intervention group treated for lumbar disc herniation with Ozone therapy via subcutaneous injection under the guidance of CT imaging, and the control group.

## II. SUBJECTS AND RESEARCH METHODS

### 2.1. Research subjects

Patients with mild or moderate LDH on corresponding MRI with clinical symptoms, may include signs of disc degeneration-spine, aged 18-70; patients who have undergone internal treatment or conservation treatment

for at least 1 month but have little or no response; VAS pain score > 6. Exclusion criteria are patients with congenital defects causing spinal stenosis, scoliosis; patients with coagulation disorders; pregnant or drug-allergic patients; patients with skin inflammation at the needle puncture site; patients with severe herniated disc with surgical indication or severe symptoms of root compression (muscle atrophy, numbness, paralysis of 2 lower limbs, circular muscle disorder, etc.); disc height reduction > 75% compared to normal disc; severe herniation, migration or rupture; history of spinal surgery due to herniated disc; back pain due to bone inflammation, tuberculosis, bone fracture, metastatic cancer, spinal cord tumors, etc.; incomplete information, patients unable to follow-up after treatment. Patients were randomly divided into 2 main groups: Control group and Intervention group; for each 2 intervention patients, 1 control patient was chosen.

### 2.2. Time and place of research

The study was conducted at Saint Paul Hospital. The research time was from September 2019 to September 2022.

### 2.3. Research methods

Using cross-sectional descriptive method, comparing the common characteristics of the 2 groups before intervention. During the study, we recruited 147 patients who agreed to participate in the study. 100 patients in the Intervention group will be treated with ozone injection for herniated disc, ozone and corticoid injection around the nerve root under the guidance of CT scan. The Control group of 47 patients will only be treated with corticoid injection around the nerve root and

the subdural space under the guidance of CT scan.

**2.4. Research indicators**

Age, gender, time of clinical symptoms progression. Time of lumbar back pain progression. Pain level: VAS pain score, the most common pain measurement scale. Patients rate their pain level from 0 to 10, with 0 indicating "no pain," 1-3 indicating mild pain, 4-6 indicating moderate pain, 7-8 indicating severe pain, and 9-10 indicating very severe pain (Ghai et al.). Pain level was assessed before, during and after treatment, as well as during long-term follow-up at 3 and 6 months. The Oswestry Disability Index (ODI) is used to evaluate the functional loss of the spine.

**2.5. Statistical methods and data processing**

Data is processed using SPSS 19.0 software. Descriptive statistics are used for variables related to clinical and technical characteristics. Paired t-tests are used to determine whether there is a statistically significant difference in pain severity and activity limitation between the two groups before and after treatment.

**2.6. Research ethics**

The study is for scientific purposes. Patients are fully informed and voluntarily agree to participate in the study. Patients who do not participate in the study are not treated differently during the treatment process. Patients may request to withdraw from the study at any time.

**III. RESEARCH RESULTS**

**Table 1.** Distribution characteristics of age between two study groups

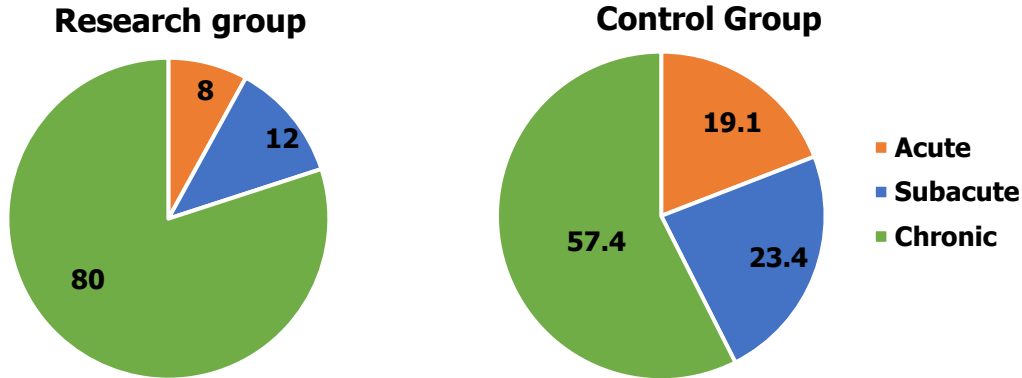
Variables	Study group	Control group	Overall
	n (%)	n (%)	n (%)
<=30*	7 (7)	2 (4,3)	9 (6,1)
30-50	50 (50)	15 (31,9)	65 (44,2)
>50*	43 (43)	30 (83,8)	73 (49,7)
p=0,06 (Chi-square test)			
Age±SD (years)	48,8 ± 12,1 (21-82)	57,4 ± 14,8 (24-83)	51,5 ± 13,6 (21-83)
p= 0,001 (Independent t-test)			
Total:	100 (100)	47 (100)	(100)

Age: disc herniation often occurs in people over 30 years old, mainly in the age group of over 50 years old (accounting for 49.7%) and 30-50 years old (44.2%),  $p > 0.05$ . The youngest age in the study was 21, the oldest was 83, and the mean age was  $48.8 \pm 12.1$ . The mean age of the study group was  $48.8 \pm 12.1$ , and that of the control group was  $57.4 \pm 14.8$ . The mean age of the study group was lower than that of the control group,  $p < 0.05$ .

**Table 2.** Distribution characteristics by gender of two study groups

Variables	Study group	Control group	Overall
	n (%)	n (%)	n (%)
Men	42 (42)	17 (36,2)	59 (40,1)
Women	58 (58)	30 (63,8)	88 (59,9)
Total	100 (100)	47 (100)	147 (100)
p=0,5 (Chi-square test)			

There were 88 cases (59.9%) of female and 59 cases (40.1%) of male, thus females had a 1.5 times higher incidence of lumbar disc herniation compared to males. However, the difference was not statistically significant with  $p > 0.05$ .



**Chart 1.** Distribution of time since onset of illness (%)

In both groups, the majority of patients had chronic illness (80% in the research group and 57.4% in the control group).

**Table 3.** Distribution of pain side by gender in the research groups

Pain side	Study group	Control group	Overall
	n (%)	n (%)	n (%)
Right	45 (45)	17 (36,2)	62 (42,2)
Left	50 (50)	25 (53,2)	75 (51,0)
Both	5 (5)	5 (10,6)	10 (6,8)
Total n (%)	100 (100)	47 (100)	147 (100)

$p = 0,34$  (Chi square test)

In both groups, unilateral pain was predominant, accounting for 95 patients (93.2%), mostly on the left side (51%). The difference in pain side between the two groups was not statistically significant with  $p > 0.05$ .

**Table 4.** VAS scores before treatment by gender and group

Index	Gender		Group		Overall (147)
	Men (42)	Women (58)	Research group (100)	Control Group (47)	
VAS pain score	8,1 ± 0,7	8,0 ± 0,6	8,1 ± 0,7	8,0 ± 0,7	8,1 ± 0,7
p	0,64 (Independent t-test)		0,69 (Independent t-test)		

The mean VAS score before intervention in the research group of 100 patients was  $8.0 \pm 0.7$ . The minimum score was 6 and the maximum was 9. There was no statistically significant difference in the mean VAS score before intervention between genders and between the two treatment groups with  $p > 0.05$ .

**Table 5.** Distribution of pain severity by VAS scores

Pain severity	Study group	Control group	Overall
	n (%)	n (%)	n (%)
Mild pain (6)	1 (1)	1 (2,1)	2 (1,4)
Moderate pain (7-8)	71 (71)	37 (78,7)	108 (73,5)
Severe pain (9-10)	28 (28)	9 (19,1)	37 (25,2)
Total	100 (100)	47 (100)	147 (100)

$p = 0,38$  (Fisher's Exact test)

Patients with pain symptoms before treatment mainly had moderate pain (73.5%) and severe pain (25.2%) based on the VAS pain scale. The distribution of pain severity before treatment between the two groups was not statistically significant with  $p > 0.05$ .

**Table 6.** Distribution of spinal dysfunction status by ODI% scale

ODI% score	Study group	Control group	Overall
	n (%)	n (%)	n (%)
Level 3 (severe dysfunction): ODI 41-60%	14 (14)	7 (14,9)	21 (14,3)
Level 4 (crippling dysfunction): ODI 61-80%	78 (78)	36 (76,6)	117 (77,6)
Level 5 (complete dysfunction): ODI >80%	8 (8)	4 (8,5)	12 (8,2)
Total:	100 (100)	58 (100)	100 (100)

$p = 0,98$  (Chi square test)

The average ODI score of 147 patients in the study group was  $70.3 \pm 9$ . Before treatment, most of the patients belonged to the severely disabled group, accounting for 117 patients (77.6%). There were 12 patients (8.2%) who completely lost their function. There was no significant difference in the ODI score between the two treatment groups before intervention with  $p > 0.05$ .

**IV. DISCUSSION**

Disc herniation is a common pathology at all ages, manifested clinically by back pain and symptoms of nerve compression. The diagnosis of disc herniation is based on clinical symptoms and imaging of the lumbar spine. There are many treatment methods for disc herniation, including conservative treatment, minimally invasive interventions, and surgery. All current treatment methods have good results, but there is no absolutely effective method. The choice of treatment depends on clinical symptoms, degree of disc herniation, complication rates, as well as the

financial ability of the patient and the availability of medical services.

The use of ozone in the treatment of lumbar disc herniation and back pain reduction under the guidance of CLVT is widely applied worldwide, but this method is still new in Vietnam and has not been clinically tested at any medical center or hospital. This necessitates research to evaluate the effectiveness of this method, the feasibility of the technique, and to provide additional data in selecting appropriate treatment protocols for patients.

In our study, 147 patients were divided into two groups, a study group of 100 patients treated for disc herniation and back pain reduction using ozone combined with corticosteroid, and a control group of 47 patients treated with corticosteroid alone. Of the total of 147 patients, 59 were male (40.1%) and 88 were female (59.9%). The male to female ratio was 1:1.5, but the difference was not statistically significant.

**Table 7.** Characteristics of age and gender in some previous studies

Authors	Number of patients	Male to female ratio	Average age
Bonneti	306	1,4 : 1	48
Galluci	159	1,2 : 1	40-41
Buric	108	1,1 : 1	46,7±15
Perri	517	1,6 : 1	43
Muto	93	1,2 : 1	38
Our study	147	1: 1,5	51,5 ±13,6

The male-to-female ratio in our study is also similar to some other studies by authors within and outside the country. Muto, Perri, Buric, Galluci, and Bonneti show a slight increase in male ratio compared to females, but it is not statistically significant (Table 4.1). A meta-analysis study by Migliorini in 2020 based on 22 studies with a total of 2050 patients shows that the male-to-female ratio is 57.3% to 42.7%, with a male-to-female ratio of 1.3:1.

The average age of the study patients is 51.5 ± 13.6, with the oldest being 83 years old and the youngest being 21 years old. Patients between 30 and 50 years old make up the majority, with 65% of the total patients. The average age of the study group is 48.8 ± 12.1, which is lower than the control group's age of 57.4 ± 14.8. Comparing with other studies in Table 4.1, the average age is similar. It can be observed that the average age in studies using Ozone therapy is relatively young, which can be explained by the age-related degeneration of the intervertebral discs and the spine. The intervertebral discs in young people have a high water content and gradually decrease with age, so young age is a prognostic factor for treatment. Saaksjarvi's study of the changes in intervertebral discs in 75 young people aged 20 and comparing with magnetic resonance imaging after 30 years found that about 71% had degeneration of the spine and intervertebral discs. Oder's study on factors

affecting Ozone therapy found that age was an important prognostic factor. In 612 patients treated, the VAS pain score improved significantly after 6 months in patients under 50 years old compared to those over 50 years old. Kim treated 3000 patients with disc herniation using chymopapain and found that the younger the age, the better the prognosis.

In our study, we found that the main disease progression time was subacute (1-3 months) and chronic (>3 months) in both groups. This result is also similar to other studies. Galluci's study on 159 patients found that the average disease progression time was 3.75 months. Bhatia's study on 39 patients found that the average disease duration was 22.9 ± 18.1 months. Migliorini's meta-analysis of 22 studies on Ozone treatment for spinal diseases with 2050 patients found that the average disease progression time was 10.7 ± 6.2 months.

For the ozone treatment indication by authors worldwide, all agreed on choosing BT when treating internal diseases but had little response to the treatment duration of 2-4 weeks corresponding to 1-2 internal treatment courses. Our study, with similar selection criteria, included BT with clinical symptoms that had minimal improvement after at least 4 weeks of internal treatment with drugs or other treatments such as traditional medicine and physical therapy. After a period of little improvement in



symptoms, BT went to see other specialized doctors to switch to more invasive treatments.

In our study, out of a total of 147 BT, the average VAS pain score before intervention was  $8.1 \pm 0.7$ , with the smallest score being 6 points and the largest being 9 points. Pain was mostly on one side (93.2%), with the left

side (51%) and right side (49%) having similar distributions. There was no difference between the two groups in terms of pain scores before treatment and pain distribution. This result is similar to that of author Ezeldin's study on 52 BT with an evenly distributed pain ratio on both sides of the spine.

**Table 8.** Pain severity according to VAS of some studies

<b>Authors</b>	<b>Number of patients</b>	<b>Average pain level according to VAS</b>
Oder	612	8,6
Hosseini	128	7,5 ±0.8
Hashemi	30	8,1 ±0.8
Elawamy	60	8,2 ±0.18
Our study	147	8,1 ±0.7

Similar to other authors around the world, the BT in our study were all BT who experienced a high level of pain on the VAS scale with an average score of  $\geq 6$  even after receiving internal treatment. The majority of BT experienced severe and intense pain. Upon analyzing the level of pain in detail, we noted that BT with severe pain with VAS scores of 7-8 accounted for 73.5% and those with intense pain with VAS scores of 9-10 accounted for 25.2%. The average spinal dysfunction score on the ODI scale for the 147 BT in the study was  $70.3 \pm 9$ , with the majority of BT falling into the category of severe spinal dysfunction (77.6%).

**Table 9.** Average spinal dysfunction score on the ODI scale (%)

<b>Authors</b>	<b>Number of patients</b>	<b>Average spine function loss according to ODI (%)</b>
Ezeldin	52	70
Gallucci	159	58,4
Oder	612	50
Hashemi	30	57
Hosseini	128	48,4
Our study	147	70,3

According to the table, when compared to other studies around the world, the ODI% score shows similarities.

**V. CONCLUSION**

This study reveals that lumbar disc herniation primarily affects individuals over 30 years old, with a higher incidence in females. Unilateral pain, mostly on the left side, is the predominant symptom. Patients with pain

before treatment experience severe levels of pain. The study group had a high level of functional disability. These findings provide valuable information for the implementation of intervention treatment for patients with lumbar disc herniation.

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