The effect of intradiscal injection of percutaneous radiopaque gel ethanol on pain in patients with lumbar disc herniation: Our clinical experience

Lomber disk hernisi olan hastalarda intradiskal perkütan radyoopak jel etanol enjeksiyonunun ağrı üzerine etkisi: Klinik deneyimimiz

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ABSTRACT

Introduction: Lumbar disc herniation (LDH); It is an important disease that is common in society and can cause socioeconomic problems. There are many treatment algorithms for LDH, including medical and surgical. Our aim in this study; To evaluate the clinical results of patients with LDH who did not benefit from conservative treatment after percutaneous intradiscal radiopaque gel ethanol (RGE) procedure in the light of the literature.

Methods: A total of 44 levels of percutaneous intradiscal RGE were applied to 41 patients, 14 men and 27 women, hospitalized with the diagnosis of LDH. patients; Demographic characteristics, treatments they received, lumbar magnetic resonance imaging (MRI) taken 6 months later, visual analog scores (VAS) before and 6 months after percutaneous intradiscal RGE procedure, complications, side effects and patient satisfaction after the procedure were evaluated.

Results: The VAS values of the patients were 8 before the procedure and 4.2 6 months after the procedure. A 47.5% reduction in pain was observed and these data were evaluated as statistically significant. When patients were asked about their satisfaction with the procedure after the percutaneous RGE procedure; 4 patients answered "poor", 13 patients "moderate", 13 patients "good" and 11 patients "excellent". The rate of those who were satisfied with the procedure was 90.2%, and these data were not considered statistically significant.

Conclusion: As a result; Percutaneous intradiscal RGE procedure, in patients with a diagnosis of LDH and who did not benefit from conservative treatment; It can be a minimally invasive technique that reduces pain.

Key words: Lumbar disc herniation, Percutaneous intradiscal injection, Radiopaque gel ethanol, Visuel analog scale

ÖZET

Giriş: Lomber disk hernisi (LDH); Toplumda sık görülen ve sosyoekonomik sorunlara neden olabilen önemli bir hastalıktır. LDH için tıbbi ve cerrahi dahil olmak üzere birçok tedavi algoritması vardır. Bu çalışmadaki amacımız; konservatif tedaviden fayda görmeyen LDH'li hastaların Perkütan intradiskal radyoopak jel etanol (RGE) işlemi sonrası klinik sonuçlarını literatür ışığında değerlendirmektir.

Yöntemler: LDH tanısı ile yatırılan 14'ü erkek, 27'si kadın olmak üzere 41 hastaya toplam 44 seviyede perkütan intradiskal RGE uygulandı. Hastalar; demografik özellikler, aldıkları tedaviler, 6 ay sonra çekilen lomber manyetik rezonans görüntüleme (MRG), perkütan intradiskal RGE işlemi öncesi ve 6 ay sonraki görsel analog skorlamalar(VAS), komplikasyonlar, yan etkiler ve işlem sonrası hasta memnuniyeti açısından değerlendirildi.

Bulgular: Hastaların VAS değerleri işlem öncesi 8, işlemden 6 ay sonra 4.2 olarak saptandı. Ağrıda %47.5'lik bir azalma olduğu izlendi ve bu veriler istatistiksel olarak anlamlı olarak değerlendirildi. Perkütan RGE işlemi sonrası hastalara işlemden memnuniyetleri sorulduğunda; 4 hasta "kötü", 13 hasta "orta", 13 hasta "iyi" ve 11 hasta "mükemmel" yanıtını vermiştir. İşlemden memnun olanların oranı %90,2 olup bu veriler istatistiksel olarak anlamlı kabul edilmedi.

Sonuç: Sonuç olarak; Perkütan intradiskal RGE işlemi, LDH tanısı olan ve konservatif tedaviden fayda görmeyen hastalarda; ağrıları azalmasını sağlayan minimal invaziv bir teknik olabilir.

Anahtar Kelimeler: Lomber disk herniasyonu, Perkütan intradiskal enjeksiyon, Radyoopak jel etanol, Görsel analog skala

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Eskisehir Med. J. 2022; 3(2):130-137.
Received date:10.01.2022 Accepted date:06.04.2022
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INTRODUCTION

Approximately 13-40% of the general population experience sciatica episodes at least once in any period of their lives due to nerve root irritation due to lumbar disc herniation (LDH). Since sciatica causes loss of work force as well as lowering the living standards, it is very important to be treated effectively. Today, the treatment goal of sciatica is; It is the alleviation of all symptoms in the short-medium periods and the reduction of functional disability in the long term (1, 2).

Today, there is a treatment algorithm for sciatica, which is caused by nerve root irritation as a result of LDH and does not cause motor deficit. These are respectively; Medical and physical therapy, followed by minimally invasive techniques such as spinal infiltration of corticosteroids and surgical treatment if the symptoms do not regress despite these treatments. Percutaneous intradiscal procedures such as nucleolysis and nucleotomy are performed in certain specialist centers in patients who do not benefit from conservative treatment. These techniques; Since it is less aggressive than lumbar microdiscectomy surgery, it has been recommended to evaluate sciatalgia within the treatment algorithm (3, 4).

Nucleolysis; It is defined as the injection of compounds in the middle of the intervertebral disc in order to eliminate all or a part of LDH. Nucleotomy; It is defined as the creation of small cavities within the disc by physical means such as intradiscal needle aspiration and laser or radiofrequency vaporization. Although these percutaneous techniques are based on the same mechanism of action as the volume reduction or elimination of LDH, they allow compression of LDH and limitation of nerve root irritation as a result of induction of annulus fibrosis by diffusion (5, 6).

In the 1970s, chemopapain was the first substance used in disc nucleolysis. It was the only percutaneous technique that could be validated with a sufficient number of controlled studies (7). Although chemopapain is not used much today, it is still considered as a reference technique. However, different treatment options are increasing day by day (8, 9). Radiculitis risk in nucleolysis is a situation that can be encountered in relation to epidural leakage of the injected product (10). In one study, various cases of radiculitis were reported during intradiscal injection of rectified volatile material (10).

In order to limit the risk of diffusion to the outside of the disc; A viscous gel containing radiopaque tungsten in ethylcellulose and 95% ethanol has been developed. This gel; For the treatment of sciatica caused by LDH, percutaneous intradiscal applied radiopaque gel is used as ethanol (RGE). Percutaneous intradiscal RGE has two different mechanisms of action, mechanical and chemical, in the treatment of LDH: 1) It increases the amount of water in the degenerated and dehydrated disc due to the hydrophilic nature of ethylcellulose, 2) The rectified volatile material causes local necrosis in the disc hernia (11). In addition, this gel can be radiographically visualized since the tungsten in its content is radiopaque. This allows the operator to see both a possible leak and the amount injected fluoroscopically. The safe use of tungsten in vertebroplasty cases has also been reported (12).

Our aim in this study; To evaluate the clinical results of patients diagnosed with lumbar disc herniation, who did not benefit from conservative treatment and who underwent percutaneous intradiscal RGE procedure in the light of the literature.

METHODS

This study was carried out retrospectively after obtaining the necessary ethics committee approval with the decision number of 08/04/2014 and 07-07 from the Clinical Research Ethics Committee of Fırat University Medical Faculty Hospital. Our study was conducted over a period of 1 year, and a total of 44 levels of percutaneous intradiscal RGE procedure was applied to

41 patients diagnosed with lumbar disc hernia who had lower back pain for more than 3 months but did not have neurological deficits and did not benefit from conservative treatment.

Patients; demographic data, history, characteristics of pain, additional diseases, allergy status, operations, medications used, physical examinations, radiological findings and post-procedures were evaluated.

Diagnosis; It was made by anamnesis, physical examination, and radiological imaging methods (MRI). Infectious, inflammatory, tumoral and metabolic causes, fractures, abdominal or reflective pains that could be the source of low back pain were excluded, and percutaneous RGE was not applied to these patients. Pregnant women, patients with extruded and sequestered disc hernias, and patients with severe depression were not included in this study. Noyear limit was imposed for the patients included in the study.

Cases; demographic characteristics, previous treatments, control lumbar magnetic resonance imaging (MR) at the earliest 6 months later, visuel analog scale (VAS) values before and 6 months after percutaneous intradiscal RGE, complications, side effects and patient satisfaction after the procedure evaluated aspects.

Percutaneous Intradiscal RGE Procedure

Ethics committee approval was obtained for this procedure. The patients were premedicated with 5 mg midazolam + 0.25 mg atropine 45 minutes before the procedure. Patients were taken to the operation room and placed in the prone position and monitored. Later, the area to be treated was covered with sterile covers after staining with povidone iodine. When starting the procedure, patients were administered sedoanalgesia with midazolam and fentanyl, and additional doses were given if needed. Then, local anesthesia was applied to the area to be treated. The intervertebral disc center was reached with a thinner 22-gauge needle inside an 18-gauge guiding needle, accompanied by fluoroscopy using anterior-posterior and lateral approaches in the painful body part. Then, after removing the inner fine needle, a total of 0.8 mL-1 mL of gel was slowly injected into the intradiscal space, in accordance with RGE's recommendations for use, giving 0.1 mL every 30 seconds. When the injection was complete, the inner shaft guide of the needle was put back in place and the needle was left in position for at least 2 minutes to limit the risk of leakage at the time of removal. At the end of the procedure, patients were given 0.1 mg of flumanezil as a benzodiazepine antidote, and they were awakened and taken to the service beds for follow-up. Patients were followed for 3 hours after the procedure for the disappearance of sedoanalgesia effects. Patients were discharged from the hospital after waiting for at least one day with a prescription for the use of weekly anti-inflammatory and analgesics.

Demographic characteristics of the patients, occupations, duration and characteristics of pain, the effect of pain on work efficiency, sports activities, trauma histories, and previously applied treatment methods were recorded. The patients were evaluated twice, before the RGE procedure and at least 6 months after the end of the treatment.

Pain assessment; Since the description is very subjective and contains personal definitions, 2 different tests were used in order to verify the effectiveness of the procedure more clearly.

Visual Analogue Scale (VAS)

It is one of the most widely used methods in determining the degree of pain. It provides information about the measurement of the effective component as well as the severity of the pain. The VAS consists of a 10 cm long line drawn on the horizontal or vertical axis. At one end of this line is the word "no pain" and at the other the word "worst pain possible". Patients were asked to mark the place on this line corresponding to

the severity of their pain. These values were noted before the procedure and 6 months after the procedure.

Patient Satisfaction Scale

It is a scale consisting of 4 different responses prepared to be 1: poor, 2: moderate, 3: good, 4: perfect and we use to evaluate the satisfaction of the patients after the procedure.

Statistical Analysis

When the patients were evaluated according to confidence level: 95%, margin of error: 5, population proportion: 50 data, the power analysis was determined as 38 and our study was conducted with 41 patients. SPSS (Statistical Package for Social Sciences for Windows 22.0) program was used for the statistical analysis of the study. While evaluating the data, besides descriptive statistical methods (mean, standard deviation), comparisons of parameters showing normal distribution for quantitative data between groups were evaluated with analysis of variance (ANOVA) and then osthoc Tukey HSD test was used. Repeated measurements within the group were evaluated using the Wilcoxon sign test. Paired simple t test was used for related variables. The results were evaluated at 95% confidence interval and p <0.05 significance level.

RESULTS

When the demographic characteristics of the patients in our study are examined; 14 of the patients were male (34.1%), 27 of them were female (65.9%). The average year of men was 51.2 and the average year of women was 47.7. When the patients were asked about their complaints, it was learned that 10 patients had right leg pain, 9 patients had left leg pain, 9 patients had mid-waist pain, and 13 patients had diffuse pain (Figure 1).

When systemic diseases of the patients in addition to lumbar disc herniation are questioned; It was learned that 9 patients had cardiac diseases, 3 patients had respiratory diseases, 1 patient had malignancy, 3 patients had endocrine diseases, 4 patients had endocrine and cardiac diseases, 3 patients had cardiac and respiratory diseases and 18 patients had no additional disease.

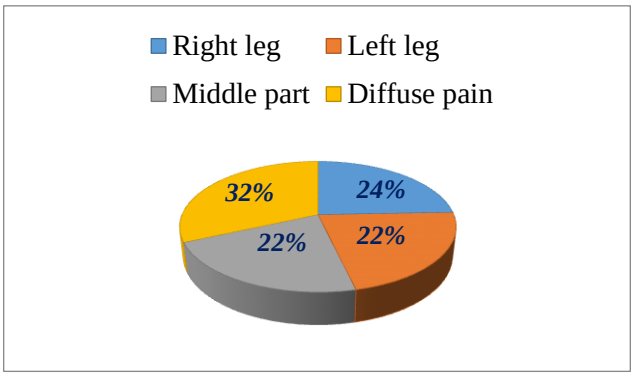

Figure 1. Distribution percentages of pain localizations in patients with lumbar disc herniation

Levels of the procedure applied to the patients: L1-L2 in 2 patients, L3-L4 in 3 patients, L4-L5 in 19 patients, L5-S1 in 10 patients, L4-L5 in 1 patient, L3-L4 in 1 patient, L3-L4 and L5-S1 in 1 patient. , 3 patients were determined as L4-L5 and L5-S1 (Figure 2). No side effects or complications were observed in any patient during and after the procedure.

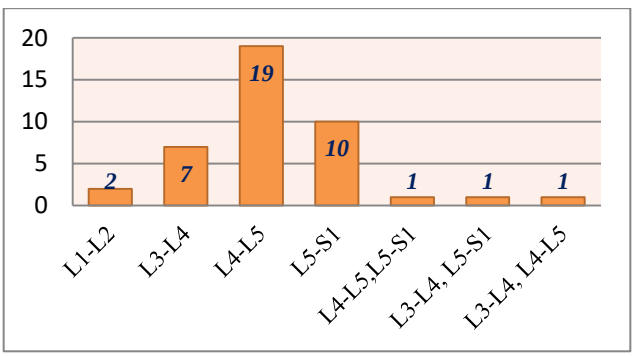

Figure 2. Distribution of patients according to lumbar disc herniations levels

When evaluated according to the MRI findings of the patients and whether they have previously received treatment for lumbar disc herniation; Diffuse bulging

was detected in 19 patients and protrusion in 22 patients. It was learned that 15 of the 41 patients received only medication (non-steroid anti-inflammatory, myorelaxan, steroid, etc.) 20 of them received transforaminal steroid treatment and 6 of them did not receive any treatment because they did not want to receive medical treatment.

Comparing the VAS value evaluated before the RGE procedure and the VAS values evaluated 6 months after the RGE procedure in the patients, the average score was calculated as 8 ± 0,9 before the procedure and 4.2 ± 2,0 after 6 months after the procedure. There was a 47.5% reduction in pain, and these data were interpreted as statistically significant (p <0.05) (Figure 3).

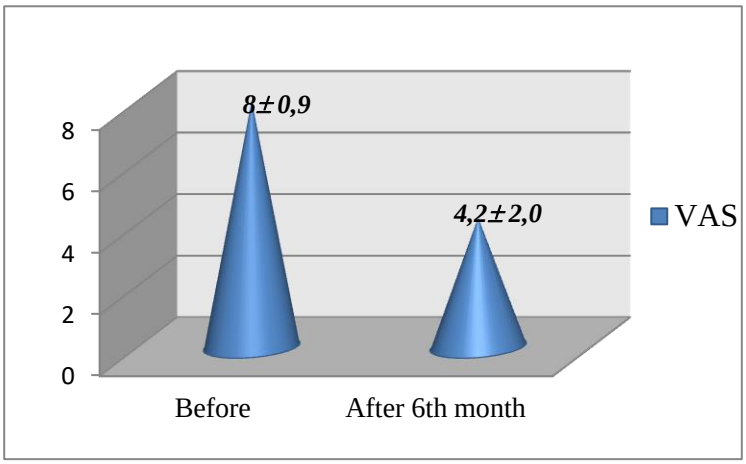

Figure 3. Comparison and statistical analysis of the VAS scores of the patients before and after the procedure at the 6th month

When the patients were asked about their satisfaction with the procedure after percutaneous intradiscal RGE; 4 patients answered "poor", 13 patients "moderate", 13 patients "good" and 11 patients "excellent". Distribution analysis of the satisfaction values of the patients according to year groups was also performed. Accordingly, under the year of 50; 2 patients replied "poor", 8 patients "moderate", 3 patients "good", 7 patients answered "excellent". Over the year of 50; 2 patients answered "poor", 5 patients answered "fair", 10 patients answered "good", 4 patients answered "excellent". In total, only 4 of the patients answered "poor" and this rate corresponds to only 9.8%. The remaining 90.2% stated that they were satisfied with the transaction. However, when theyear groups and patient satisfaction scale were evaluated, no statistically significant difference was found (p> 0.05). (Table 4).

The satisfaction of the patients with respect to their pathology in lumbar MRI was determined as follows; in patients with diffuse bulging findings; 2 patients answered "poor", 8 patients answered "moderate", 6 patients answered "good", 3 patients answered "excellent". In patients with protrusion findings; 2 patients replied "poor", 5 patients "moderate", 7 patients "good", 8 patients answered "excellent". When the patients' lumbar MRI pathologies and satisfaction scale were evaluated, no statistically significant difference was found. (p> 0.05) (Table 1).

Table 1. Distribution of patient satisfaction scores according to year and MR images after percutaneous intradiscal RGE procedure

Satisfaction	Year		MRI	
	Under 50 year	Over 50 year	Diffuse Bulging	Protrusion
Poor	2	2	2	2
Moderate	8	5	8	5
Good	3	10	6	7
Excellent	7	4	3	8
Total	**20**	**21**	**19**	**22**
p	*0,32****		*0,41****	

*p <0,05 significant

When the patients were called for VAS evaluations 6 months later, it was learned that 1 patient who was not satisfied with the percutaneous RGE treatment received surgical treatment. All patients were asked to have a control MRI to analyze the possible radiological changes that the RGE procedure might cause, but 11 patients agreed to have an MRI. As a result of lumbar

MRI comparisons; While 7 patients (63.6%) with protrusion showed improvement in the control MRI findings, no change was observed in the images of 3 patients. In addition, it was observed that there was no difference in MRI findings of 1 patient known to have diffuse bulging. Although a 63.6% improvement was observed in patients who had radiologically underwent lumbar MRI, this result was not statistically significant.

DISCUSSION

Nervous system lesion or dysfunction causing neuropathic pain may be due to mechanical or metabolic trauma, incision, ischemia, infiltration, or their combination in the neuron cell body in the peripheral or central nervous system (13).

Chronic discogenic low back pain is a common type of neuropathic pain with a prevalence of 35-75% in the population and can cause serious personal and social costs. Therefore, in recent years, determination of risk factors, recognition of the characteristics of chronic diseases, medical developments in diagnosis and treatment have gained importance (14).

Multidisciplinary approaches are very important in the treatment of low back pain. Methods used in treatment; It can be classified as medical therapy, physical therapy, percutaneous invasive methods and surgery (15). In the last 10 years, interest in the use of percutaneous minimally invasive techniques in the treatment of chronic low back pain has been increasing. This increased attention may be related to potential complications associated with surgical procedures. Percutaneous procedures shorten the length of hospital stay and prevent the formation of surgical scar tissue that can cause recurrence of pain (16).

In this study, we evaluated the effects and results of intradiscal RGE procedure, which is a percutaneous invasive intervention technique, in the treatment of low back pain in the light of the literature.

Lumbar disc herniation is more common in men, but the vast majority are between theyears of 30-55 (17). In our study, the averageyear of patients who underwent RGE was 51.2 for men and 47.7 for women, which is similar to the literature.

In a study, improvement was found in physical examination findings and VAS scores in 25 patients who received conservative and medical treatment at the first control compared to before treatment, but no improvement was found in lumbar MRI results. While a statistically significant improvement was observed in VAS scores at the end of the treatment of 25 patients who received conservative and medical treatment, the change in MRI findings was not found to be significant (18). Sharps et al. (19) reported nucleoplasty in 45 patients with lumbar radiculopathy and found a significant improvement in VAS scores after the procedure. Sinan et al. (20) conducted nucleoplasty in 83 patients with lumbar radiculopathy in their study and found a significant decrease in the 12 th month VAS scores of the patients.

In our study, the mean VAS score of the patients was found to be 8 before the procedure and 4.2 after 6 months post-procedure. According to these results, a 47.5% reduction in pain was found in parallel with the studies reported in the literature. These data were considered statistically significant.

In a study conducted in 2010 (21), the effectiveness of nucleolysis using RGE in the treatment of cervical disc herniation was investigated in a small group of patients with cervical discogenic or radicular pain. The results were satisfactory in 89.5% of the patients, and no side effects were observed before or after.

The number of those who expressed this process as "poor" according to the "patient satisfaction scale" in our study was 4, and this rate was only 9.8% of all patients. 90.2% of the patients stated that they were satisfied with this procedure. These data are similar to the studies reported in the literature.

Zhu et al. (22) reported that there was a significant improvement in pain scores in 54% after the nucleoplasty performed in 42 patients with chronic low back pain and radicular pain and protrusion detected on MRI.

According to our study, when the satisfaction data of 41 patients with lumbar MRI pathologies and satisfaction data with theyear groups under 50 and over 50 years of year were evaluated, although a satisfaction rate of 90.2% was reported, these results were both there were no statistically significant difference for the groups.

Lo Giudice et al. (23) reported a case of bilateral vision loss and retinal hemorrhage that developed after intradiscal ozone procedure due to disc herniation. Ginanneschi et al. (24) reported a case of ventral and dorsal root injury that developed in a patient in whom 10 microgram / ml intradiscal ozone was administered due to chronic low back pain complaint. In another study (25), no allergic reaction or infection was observed during or after percutaneous RGE injection between the disc.

In our study, no infection, allergic reaction or any complication was observed in 41 patients who underwent percutaneous intradiscal RGE during and within 6 months after the procedure.

Bellini et al. (26) in 2015, they reported percutaneous intradiscal RGE to a total of 80 patients, 73 of whom had lumbar disc herniation and 7 of which were diagnosed with cervical disc hernia, who did not benefit from 4-6 weeks of conservative treatment, and they checked the patients' VAS and Oswestry Disability Index (ODI). 62 (85%) of 73 lumbar disc herniated patients and 6 (83%) of 7 cervical disc herniated patients reported significant improvement in symptoms with a decrease of at least 4 points in VAS values and at least 40% in ODI values. In 19 patients, there were leakage in the surrounding tissues, but no clinical adverse effects were observed.

In our study, similar to this article, percutaneous intradiscal RGE procedure; We observed that it is effective in reducing symptoms, and the possibility of side effects and complications is very low.

We can list the limitations of our study as follows: 1) This procedure was performed in patients with diffuse bulging and protruding disc herniation. Since extruded and sequestered disc herniation were not included in the study, their effectiveness on them is unknown. 2) Since this procedure is performed only on lumbar disc herniations, its effect on cervical and thoracic disc hernias are also unknown. 3) In this study, patients were followed for 6 months. Therefore, unknown long-term results of RGE injection is another limiting factor of our study.

CONCLUSION

As a result; Percutaneous intradiscal injection of RGE may be an effective and safe minimally invasive treatment in reducing pain caused by disc pathologies. In order to better understand the efficacy of this treatment, there is a need for large series of clinical studies on this subject.

Conflict of Interest: Authors declared no conflict of interest.

Financial Disclosure: Any company or institution has not financially contributed to the study.

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Cite as: Gurbuz O, Surme MB. The effect of intradiscal injection of percutaneous radiopaque gel ethanol on pain in patients with lumbar disc herniation: Our clinical experience.. Eskisehir Med J. 2022;3(2):130-137.