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ORIGINAL ARTICLE

Outcome of Intradiscal Ozone Injection in Management of Lumbar Disc Herniation

Ahmed Ibrahim Akar, Lotfy Mohamed Aly Shwitter, Mohammad Wageh Mohammad Al-Sisi
Orthopedic Surgery, Faculty of Medicine, Al-Azhar University, Cairo, Egypt.

Correspondence to *Mohammad Wageh Mohammad Al-Sisi, Orthopedic Surgery, Faculty of Medicine, Al-Azhar University, Cairo, Egypt.*
E-mail: mohammadmedicine2018@gmail.com

Background Lumbar disc herniation (LDH) is a common disease. Its main symptoms are low back pain (LBP) as well as sciatica, which can lead to disability. This study aims to assess the outcome of intradiscal ozone injection in pain and disability management from lumbar disc herniation.

Subjects and Methods This was a prospective, single-arm, non-randomized clinical trial, conducted at the orthopedic surgery department at Al-Hussein University Hospital and Syed Jalal University Hospital. The study was conducted on patients receiving ozone chemonucleolysis treatment in herniated lumbar discs. The follow-up duration was 6 months. The Oswestry Disability Index (ODI) questionnaire and Visual analogue scales were used to assess pain impairment and physical performance as the main outcome (VAS).
IBM SPSS 25 Windows software was used to conduct the statistical analysis.

Results The number of included patients was 30, with 12 females and 18 males. The mean age was 40.23±5.67. The majority of included patients had neither hypertension nor diabetes (N=28). Regarding the ODI, the analysis revealed a significant mean decrease from the baseline of 23.47 and a standard error of 2.37. As for the VAS, there was also a significant mean decrease of 3.5 and a standard error of 0.29 (p<0.001).

Conclusions The study showed significant ODI and VAS score reductions. Therefore, intradiscal ozone injection showed significant improvements in pain disability and physical performance in LDH.

Keywords Intradiscal injection, Lumbar disc herniation, Ozone injection.

INTRODUCTION

Lumbar disc herniation (LDH) is a common disease [1], and disc herniation happens when there is a partial or complete protrusion of the nucleus pulposus through the annulus fibrous [2]. Disc herniation is most commonly due to aging and its degenerative process that leads to less hydrated and weakened nucleus pulposus, while trauma is 2nd the most common cause [2]. Other causes may also lead to disc herniation, such as connective tissue disorders [2]. LDH is characterized by back and leg pain [1].

Low back pain (LBP) as well as sciatica, which are LDH's main symptoms, can lead to disability; therefore, they hugely affect the patient's working hours [3,4]. LBP is a major, worldwide, burdensome health problem, as it is highly costly due to its treatment and patients' requirement for sick leave from work [5]. LDH results from various alterations in the intervertebral disc, which eventually lead to a local increase in inflammatory chemokines and mechanical compression [6]. LDH leads to mechanical stress on the nearby nerve root resulting in a chemical reaction with inflammatory cytokines' release in the adjacent tissues. Consequently, the nerve root becomes oversensitive to the mechanical compression itself [7].

LDH treatment follows the step-by-step treatment principle [8]. Fortunately, the majority of LDH's symptomatic presentations are short-term and resolve in six to eight weeks [6]. Thus, the initial management is usually conservative [6], mainly including bed

rest, manual, drug, and physical therapies, patients' education, and nerve block. In case of presented red flag symptoms [6], ineffective conservative treatment, or more serious symptoms, minimally invasive treatment or open surgery should be taken into consideration [8]. There has been an increase in minimally invasive methodology use, in spinal surgery, during the previous two decades, while surgery is the last option for LDH [6].

A minimally invasive approach may be needed to avoid or postpone open surgery in those not responding to the standard conservative management. Methods like thermal lesion with radiofrequency intradiscally applied laser decompression, and ozone chemonucleolysis is targeted to reduce the disc volume. Despite intradiscal ozone chemonucleolysis showing comparable clinical results to the other minimally invasive methods, it has additional advantages of low side effects and cost ratio [9,10]. Ozone is a strong oxidizer that results in interstitial fluid dissolving, following applying it to the nucleus, and decreases the disc's ability to preserve water through cleavage of the proteoglycan molecules as well as negatively charged sulfate side chains' neutralization. Therefore, it leads to a herniation volume [11,12].

This study aims to assess the outcome of intradiscal ozone injection in managing pain and disability due to lumbar disc herniation.

SUBJECTS AND METHODS

This was a prospective, single-arm, non-randomized clinical trial. The study was conducted at the orthopedic surgery department at Al-Hussein University Hospital and Syed Jalal University Hospital, with a follow-up period of 6 months.

Participants

The study was performed on patients receiving ozone chemonucleolysis treatment with the following eligibility criteria.

Inclusion criteria

Individuals with Radiculopathy, bulging, protruded, or extruded herniated lumbar discs, low back pain, and concurrent failure of conservative medicinal and/or physical therapy lasting at least two months.

Exclusion criteria

Patients with significant progressive neurological deficit or cauda equina syndrome, migrated or sequestrated (free) disc fragments, asymptomatic disc herniation, severe disc degeneration with severe disc collapse (more than 70% height reduction), Spondylolisthesis or significant spinal stenosis, additional spinal conditions like spinal tumours or fractures at the same level to be treated, a history of unsuccessful back surgery, active infections or bacteremia at the time of the procedure, and other.

Methods of participants' selection and follow-up

We assessed patients between 20 to 60 years, both clinically and through Magnetic resonance imaging (MRI), for enrolling patients with pain and disability analysis, using Oswestry Disability Index (ODI) questionnaire [13]. The patients' selection for ozone chemonucleolysis scheduling was based on their clinical history and the physical examination with concomitant MRI. Regarding the follow-up, all patients underwent a clinical follow-up at 2 and 6 months following treatment. The imaging follow-up was not needed, as the study's main objective was to evaluate the efficacy and clinical response of ozone nucleolysis, apart from imaging the discs' morphological changes of the discs that could occur following the treatment.

Injection technique

The position of the patients was the prone one. The lumbar lordosis was flattened by placing a pillow under the abdomen under fluoroscopy guidance. The needle was inserted at an angle of 25 degrees to the horizontal, about 10cm from the mid-line. The lateral view was continued after the 22 G, 15–20cm Chiba needle had been introduced into the muscle, and the needle was then injected into the nucleus pulposus. 10 ml of O_2O_3 was injected intradiscally during the procedure (Figures 1,2).

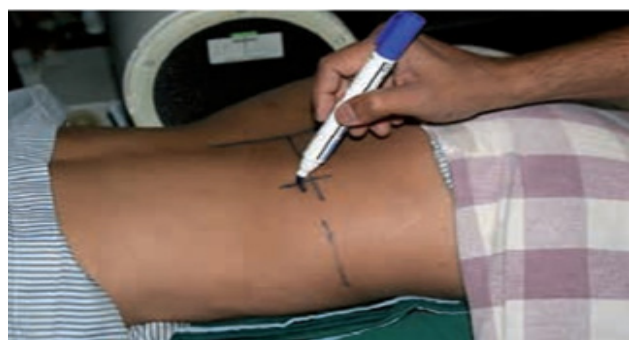

Figure 1: The point of entry is marked with a cross on the skin from 9 to 10cm from midline.

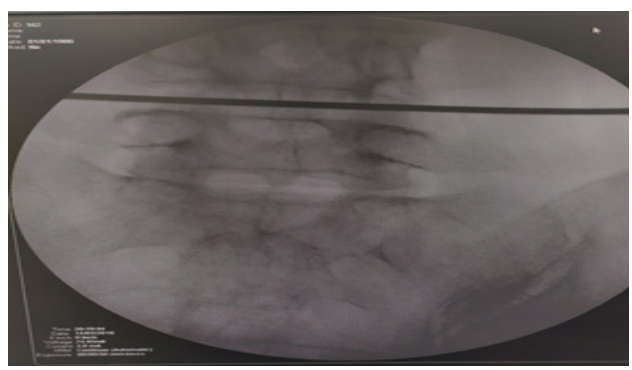

Figure 2: A confirmatory C-arm image showing the path to the disc space.

Study's outcomes and measurements

The Oswestry Disability Index (ODI) questionnaire 13 and Visual analogue scales were used to assess pain disability and physical performance as the primary outcomes (VAS). ODI is a percentage score that ranges from 0%, which indicates no disability, to 100%, which indicates the greatest level of disability. A questionnaire with 10 items-one for pain and the other nine for how much pain affects daily activities-is used to determine the score. The VAS, on the other hand, is a straight 10cm line with labels that serve as anchors for the scale. Although there are horizontal and vertical presentations, horizontal ones are more prevalent. Patients were instructed to mark the line at a location that best represented the intensity of their pain. The anchors were 'pain as awful as it possibly be' and 'no pain' (labels differ among studies). The total score has a range of 0 to 100 millimetres because the scores are expressed in millimetres. Last but not least, the ODI questionnaire's pain intensity scale ranged from 0 (no pain) to 10 (worst possible agony).

The ODI and pain intensity scores were measured at the beginning of the procedure and two and six months thereafter. A drop in the preoperative ODI values or pain intensity scores of at least 30% over the course of follow-up was recommended by the literature as a clinically significant outcome [14]. The outcome will be rated as bad (0–29%), average or fair (30–49), good (50–74) or exceptional (if the decrease is equal to or greater than 75%) depending on the percentage of the reduction. If a patient receives a bad grade, they will be considered to have failed. The recommended cut points for the pain VAS were no discomfort (0–4mm), mild pain (5–44mm), moderate pain (45–74mm), and severe pain (>74mm) (75–100mm).

Statistical analysis

A student t-test was employed to compare continuous values, and continuous data were given as mean standard deviation. The frequency of dichotomous data was given (percentage). A *p*-value less than 0.05 is considered significant. The statistical analysis was carried out using Windows-based IBM SPSS 25 software.

RESULTS

The number of patients was 30, with 12 females and 18 males. The mean age was 40.23±5.67. Only one patient had diabetes, and one had hypertension. The majority of the patients' affected level was L4-5 (70%) while in four patients (13.3%), it was L3-4, and in another four patients, it was L5-S1. Only one patient had a level of L2-3. The mean ODI before the procedure was 50.53±10.87. While the mean VAS before surgery was 7.5±1.14 (Table 1).

The postinjection mean was 27.07±7.09, with a significant mean decrease from the baseline of 23.47 and a standard error of 2.37 (p<0.001). The postinjection mean was 4±1.14, with a significant mean decrease of 3.5 and a standard error of 0.29 (p<0.001) (Table 2).

Table 1: Characteristics of the patient

	Mean
Age	40.23±5.67
Sex	
Female	12 (40%)
Male	18 (60%)
Comorbidity	
Diabetes	1 (3.3%)
Hypertension	1 (3.3%)
No	28 (93.3%)
Level	
L2-3	1 (3.3%)
L3-4	4 (13.3%)
L4-5	21 (70%)
L5-S1	4 (13.3%)
ODI_pre	50.53±10.87
ODI_post	27.07±7.09
VAS_pre	7.50±1.14
VAS_post	4.00±1.14

Table 2: Comparison between before and after the procedure

	Preinjection	Postinjection	Mean difference	Standard error	*p* value
ODI	50.53±10.87	27.07±7.09	23.47	2.37	<0.001
VAS	7.5±1.14	4±1.14	3.5	0.29	<0.001

DISCUSSION

In The results showed that the ODI scores decreased by 53.8%, which indicates a good outcome. Also, there was a reduction of 53.3% in the VAS score. All in all, reflecting the significant role of intradiscal ozone injection in LDH, in terms of pain disability and physical performance management.

Intradiscal ozone therapy was found to improve patients' bulging and protrusion outcomes (single level), as it reduced the pain by 4.87±0.21 at 6 months, and 5.22±0.20 at 2 years [15] Similar to this study's results, Ezeldin *et al*., [16] found a decrease in the ODI and pain scores, concluding that ozone nucleolysis is safe and cost-effective in contained and uncontained LDH treatment.

Adding periforaminal steroids as well as local anesthesia to intradiscal ozone injection was recommended [7]. However, contrary to the literature, Ercalik *et al*., recently found no additional benefit of adding steroids, suggesting that sole intradiscal ozone therapy was adequate for improving LBP and leg pain induced by LDH. Still, more trials regarding additional factors are needed [17].

In a study investigating prior spinal surgery's effect on treatment with intradiscal O_2–O_3, in LBP caused by LDH, the results indicated that the group of patients who underwent surgery had significantly greater VAS and ODI scores than the group of patients without surgery, but statistically significant reductions were found in the scores with both groups. Overall, concluding that intradiscal injection was effective for them both; however, it showed greater success in patients with no prior surgery [18].

Intradiscal ozone administration's efficacy in LBP induced by LDH is believed to be accomplished through decreasing mechanical compression as well as through acting on biochemical cycles. These factors include inflammatory prostaglandin cascade interruption via ozone, preventing tissue hypoxia through increased O_2 concentration, repair of the damaged disc via fibroblastic cells' activation, and above all, decreasing disc volume through water retention prevention as well as mechanical pressure reduction [7].

Regarding the optimal dose, in a randomized study, of 60 patients, evaluating pain improvement using two O_3–O_2 intradiscal injections doses (10 ml, 40 µg/ml, and 10 mL, 30 µg/ml), there were no significant variations between the different doses [19].

CONCLUSION

In line with the literature, intradiscal ozone injection in LDH had significant enhancements in pain disability and physical performance, as the study showed significant ODI and VAS scores reductions. However, regarding the non-randomized nature of this study, future randomized controlled trials on large sample sizes, and with longer follow-up durations are recommended to support this conclusion and provide more solid evidence, and also to assess whether intradiscal ozone injection is sufficient, or adding periforaminal steroids or local anesthetics provide more significant improvements.

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CONFLICTS OF INTEREST

There are no conflicts of interest.

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