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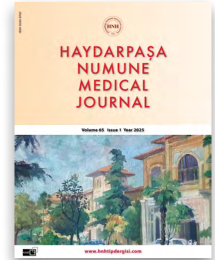

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ORIGINAL ARTICLE

Comparison of the Effects of Paravertebral Ozone, Local Anesthetic, and Normal Saline Injection on Pain, Disability, and Quality of Life in Chronic Low Back Pain: A Retrospective Clinical Study

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Abstract

Introduction: The aim of this study is to compare the effects of paravertebral ozone, local anesthetic (LA), and normal saline (NS) injections on pain, disability, and quality of life (QoL) in patients with chronic low back pain (CLBP).

Methods: Patients who underwent lumbar paravertebral ozone (Group 1), LA (Group 2), and NS (Group 3) injections due to CLBP between March and September 2023 were retrospectively screened. Patients with a history of surgery, injection, or physical therapy for the lumbar region in the last 6 months, as well as those with radicular spread or neurological deficits, were excluded from the study. Pain levels were assessed with the Numeric Rating Scale (NRS) for rest, movement, and night pain, disability levels with the Istanbul Low Back Pain Disability Index (ILBPDI), and QoL with the Nottingham Health Profile (NHP). Pre-treatment and post-treatment 3rd-month results were compared.

Results: In Group 1 (n=15), significant improvement was observed in NRS, ILBPDI, and NHP scores before and after treatment compared to baseline. In Group 2 (n=15), significant improvement was observed in NRS and ILBPDI, and in Group 3 (n=15), significant improvement was observed only in rest NRS scores ($p<0.05$). Group 1 showed significant improvement compared to Group 3 in all evaluation parameters ($p<0.05$). In Group 2, a more significant improvement was observed only in ILBPDI scores compared to Group 3 ($p<0.05$). Significant improvement was found in night NRS and NHP evaluations in Group 1 compared to Group 2 ($p<0.05$). No significant difference was observed in other pairwise comparisons ($p>0.05$).

Discussion and Conclusion: Lumbar paravertebral ozone is an effective treatment for pain, QoL, and disability in CLBP. Paravertebral ozone injection is a preferable treatment due to its advantages over LA and NS.

Keywords: Chronic low back pain; intramuscular injection; local anesthesia; normal saline; ozone; paravertebral.

Chronic low back pain (CLBP) can be defined as pain between the distal rib and the inferior gluteal fold lasting for more than 3 months [1]. A worldwide review found a midpoint prevalence of 18.3%, with a positive correlation shown between the human development index and low back pain [2]. Seventy percent of the general adult population suffers from low back pain at least once in their lifetime [3]. One of the most important goals of clinical trials

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is to find low-cost and effective treatments for low back pain, which poses a major burden on the health system worldwide [4,5].

Drug therapy, primarily non-steroidal anti-inflammatory drugs (NSAIDs), is recommended in the treatment of CLBP. Treatments involving injection or radiofrequency are also defined in the guidelines. In cases of disc herniation, widespread degenerative changes, or instability, surgical treatments may be considered [4]. Exercise therapy is also an effective treatment for both pain and disability [6]. Complementary and alternative medicine (CAM) methods are also effective options in the treatment of CLBP [7].

Ozone is a molecule consisting of 3 oxygen atoms and is a colorless gas. It is thought that subcutaneous and intramuscular applications to the lumbar region in low back pain help eliminate proinflammatory substances and reduce peripheral sensitivity through an immune regulatory effect [8]. However, ozone therapy is not widely accepted as a treatment option for CLBP and remains an empirical treatment [9]. Local anesthesia (LA) is also frequently used for myofascial pain [10]. LA injection is recommended with a low level of evidence in the presence of trigger points in CLBP [11]. Normal saline (NS) injection, 0.9% NaCl serum, may also be used as a treatment due to its low cost, good safety profile, and proven efficacy in myofascial pain [10,12].

The aim of this study was to investigate the effects of intramuscular ozone, LA, and NS injections on pain, disability, and quality of life (QoL) in the treatment of CLBP.

Materials and Methods

Study Design

The study was planned as a retrospective controlled study. It was conducted between March 2023 and September 2023 at the Physical Medicine and Rehabilitation (PM&R) Clinic. Ethical approval was obtained from the Clinical Research Ethics Committee of University of Health Sciences Şişli Etfal Training and Research Hospital (15.11.2022/Approval No: 3723). Informed consent was obtained from the patients. The study was conducted in accordance with the principles of the Declaration of Helsinki.

Participants

Patients who applied to the PM&R Clinic for low back pain lasting 3 months or longer were retrospectively screened through the hospital system. Patients aged 18 years and older who received local injections to the paravertebral muscles were included in the study. Patients with a history of injections, physical therapy, or surgery to the lumbar region in the last 6 months, those with low back pain with radicular spread and neurological deficits, and those with a history of malignancy were excluded.

Interventions

The patients were divided into 3 groups. Group 1 consisted of patients who received paravertebral ozone, Group 2 consisted of patients who received paravertebral LA, and Group 3 consisted of patients who received paravertebral NS injections. The injection protocol was applied to the lumbar paravertebral muscles intramuscularly at 4 points bilaterally in all 3 patient groups, completed in 2 sessions, 1 week apart. Ozone treatment in Group 1 was applied as 20 cc of a total of 15 µg/ml doses per session. In Group 2, LA injection was applied as a total of 8 cc of a 1/1 ratio of 2% prilocaine and 0.9% NaCl serum mixture. In Group 3, 0.9% NaCl serum was injected as 8 cc. All injections were performed by the same physician working in the injection clinic. Additionally, home exercises were demonstrated to all patients, and they were advised to do them at least 3 times a week.

Clinical Assessments

In the outpatient injection clinic of PM&R, some forms are routinely filled out to evaluate the results of the treatment for all patients who undergo the procedure. Data recorded in the hospital system before and after treatment were used for this study. Before treatment, pain levels were assessed with the Numerical Rating Scale (NRS) for rest, movement, and night pain. Low back pain disability was assessed with the Istanbul Low Back Pain Disability Index (ILBPDI). The ILBPDI is a scale consisting of 18 questions and scored between 0–90. As the score increases, the person's disability due to low back pain increases [13]. The Nottingham Health Profile (NHP) was used for QoL assessments. The NHP consists of two sections: the first section includes pain, emotional reactions, sleep, social isolation, physical activity, and energy subsections. These subheadings are assessed between 0–600 points, with each section worth 100 points. Calculations can be made without the second section. As the score increases, the QoL decreases [14]. Pre-treatment evaluations were compared with the evaluations performed at the routine control 3 months after treatment.

Statistical Analysis

Numerical variables in the descriptive data are given as percentage, mean, and standard deviation (for normally distributed data). Differences between groups in categorical variables were evaluated with the Chi-square test. Statistical significance between independent groups was evaluated with ANOVA and Kruskal-Wallis tests. Post-hoc analysis (Tukey, DSCF, respectively) was applied to data that revealed statistically significant differences in parameters evaluated with ANOVA and Kruskal-Wallis tests. P-values of post-hoc analyzed data are given with Bonferroni correction. In dependent groups, the Paired T-test was used for normally distributed data, and the Wilcoxon test was used for data that were not normally distributed. The statistical analysis of the study was performed using "The jamovi project (2024)" jamovi (Version 2.5) (Computer Software) (retrieved from https://www.jamovi.org).

Results

A total of 53 patients' data were obtained from hospital records. Five patients were excluded due to the presence of exclusion criteria, and three patients' data were missing. The study was completed with 45 patients, 15 in each group (Fig. 1). The mean age of Group 1 was 40.07±9.85 years, the mean age of Group 2 was 42.33±14.17 years, and the mean age of Group 3 was 42.40±11.01 years. The pain duration of Group 1 was 12.27±6.36 months, the pain duration of Group 2 was 15.73±14.94 months, and the pain duration of Group 3 was 14.04±7.71 months. There were no significant differences between the groups in terms of age, gender, and pain duration (p>0.05). Initial resting NRS, movement NRS, nighttime NRS, ILBPDI scores, and NHP scores were similar between the groups (Table 1).

In within-group evaluations, significant improvement was observed in all evaluations, including resting NRS, movement NRS, night NRS, ILBPDI scores, and NHP scores before and 3 months after treatment in Group 1 (p<0.05). In Group 2, post-treatment evaluations

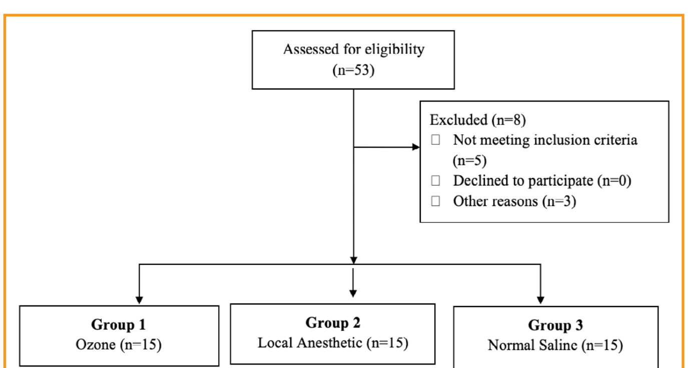

Figure 1. Flow diagram of the study. Adapted from the CONSORT 2010 Statement (www.consort-statement.org).

showed significant regression in resting NRS, night NRS, and ILBPDI (p<0.05). However, no significant change was found in NHP values (p>0.05). In Group 3, pre- and post-treatment evaluations revealed significant regression only in resting NRS values (p<0.05), while no significant change was observed in other assessment parameters (p>0.05) (Table 2).

When the changes in resting NRS and movement NRS were compared between the groups, a significant difference was found (p=0.034, p<0.001, respectively). Pairwise comparisons revealed a significant difference between Group 1 and Group 3 (p=0.031, p<0.001, respectively), while no significant difference was found between other pairwise comparisons (p>0.05). When the groups were compared in terms of night NRS, a significant difference was found (p<0.001). A significant difference was observed between Group 1 and the other groups (p=0.009, p=0.002, respectively), but no significant difference was found between Group 2 and Group 3 (p=0.834). When the changes in ILBPDI were compared between the groups, no significant difference was found between Group 1 and Group 2 (p=0.629), while the change in Group 3 was significantly lower than in Group 1 and Group 2 (p=0.001, p=0.014, respectively). When the changes in NHP were compared between the groups, a significant difference was found (p<0.001). A significant difference was observed between Group 1 and the other groups (p<0.001), but no significant difference was observed between Group 2 and Group 3 (p=0.695) (Table 2).

Table 1. Demographic variables of patients and pre-treatment assessments

	Group 1 (n=15)	Group 2 (n=15)	Group 3 (n=15)	p
Age (year)	40.07±9.85	42.33±14.17	42.40±11.01	0.828†
Gender (n, %)				
Female	12 (80)	11 (73.3)	12 (80)	0.879ǂ
Male	3 (20)	4 (26.7)	3 (20)	
Pain duration (month)	12.27±6.36	15.73±14.97	14.07±7.71	0.832*
Rest NRS	6.20±1.37	6.47±1.55	6.00±1.20	0.653†
Movement NRS	6.87±1.06	7.40±1.64	6.27±1.28	0.082†
Night NRS	5.67±1.45	5.60±1.80	5.60±1.12	0.989†
ILBPDI	47.93±17.42	42.13±23.39	47.47±15.57	0.656†
NHP	48.13±10.17	55.40±7.60	53.33±11.71	0.109†

†: ANOVA; ǂ: Chi-Square test; *: Kruskal Wallis Test. NRS: Numeric rating scale; ILBPDI: Istanbul low back pain disability index; NHP: Nottingham health profile.

Table 2. Pre-treatment and post-treatment changes within and between groups

	Group 1 (n=15)	Group 2 (n=15)	Group 3 (n=15)	p
Rest NRS				
Pre-treatment	6.20±1.37	6.47±1.55	6.00±1.20	0.034†
3rd month	3.51±1.30	4.93±1.89	4.93±1.33	
Mean change	- (2.67±1.54)	- (1.53±1.60)	- (1.07±1.83)	
p	<0.001ᵖ	0.005ʷ	0.041ᵖ	
Movement NRS				
Pre-treatment	6.87±1.06	7.40±1.64	6.27±1.28	<0.001†
3rd month	3.80±1.52	5.40±1.72	5.67±1.45	
Mean change	- (3.07±1.62)	- (2.00±1.46)	- (0.60±1.92)	
p	<0.001ᵖ	<0.001ᵖ	0.246ᵖ	
Night NRS				
Pre-treatment	5.67±1.45	5.60±1.80	5.60±1.12	<0.001†
3rd month	2.87±1.51	4.60±2.20	4.93±1.10	
Mean change	- (2.80±1.78)	- (1.00±1.41)	- (0.67±1.54)	
p	<0.001ᵖ	0.021ʷ	0.116ᵖ	
ILBPDI				
Pre-treatment	47.93±17.42	42.13±23.39	47.47±15.57	<0.001†
3rd month	25.93±13.48	24.60±13.23	44.20±15.17	
Mean change	-(22.00±12.25)	- (17.53±14.58)	- (3.27±12.81)	
p	<0.001ᵖ	<0.001ᵖ	0.340ᵖ	
NHP				
Pre-treatment	48.13±10.17	55.40±7.60	53.33±11.71	<0.001*
3rd month	32.40±7.35	52.33±8.97	49.27±11.22	
Mean change	-(15.73±6.05)	-(3.07±8.00)	-(4.07±7.79)	
p	<0.001ᵖ	0.160ᵖ	0.063ᵖ	

†: ANOVA; *: Kruskal Wallis Test; ᵖ: Paired T-test; ʷ: Wilcoxon test. NRS: Numeric rating scale; ILBPDI: Istanbul low back pain disability index; NHP: Nottingham health profile.

Discussion

This study aimed to compare different types of paravertebral injections commonly used in the treatment of low back pain. Local injections are emerging as a significant treatment modality, particularly for patients who cannot receive systemic medication. The paravertebral ozone injection resulted in a decrease in NRS scores, a reduction in disability, and a significant improvement in quality of life compared to pre-treatment levels. The present study also examined the effects of paravertebral LA injection on both NRS scores and disability. The results demonstrated a decrease in NRS scores and an improvement in disability; however, these improvements did not reach statistical significance. Conversely, the paravertebral saline injection showed a reduction in resting NRS scores, but no significant impact on pain intensity was observed. Furthermore, paravertebral ozone injections demonstrated significant improvements in resting and movement NRS values in comparison with the saline group, and statistically significant improvements in nighttime NRS and NHP values when compared with both the LA and saline groups. In light of these findings, paravertebral ozone injection emerges as a potential therapeutic modality for CLBP.

Intramuscular ozone injection can be used in cases related to low back and neck pain [15,16]. A systematic review published in 2018 stated that further studies are needed due to the small number and low quality of studies on the effect of ozone therapy on low back pain and disc herniation [17]. However, studies on this treatment have been increasing in recent years. A study published after this review showed that paravertebral ozone injection may be beneficial in lumbar disc herniation, radicular pain, or mechanical low back pain [18]. A recently published study showed that paravertebral ozone injection reduced pain levels and improved Oswestry Disability Index (ODI) scores [15]. A study comparing paravertebral ozone injection with epidural steroid-hyaluronidase injection in patients with lumbar stenosis showed that both treatments were effective for pain relief, with paravertebral ozone being even more effective [19]. Another retrospective comparative study showed that adding paravertebral ozone injection to physiotherapy had a more significant positive effect on Visual Analog Scale (VAS) and ODI scores compared to physiotherapy alone [20]. Despite these positive results, the fact that the studies were retrospective observational studies or lacked control groups limits the reliability of the findings. Current evidence suggests that the benefits of ozone therapy in the general approach to low back pain are limited [21]. In our study, significant differences were found in the paravertebral ozone injection group compared to the other treatment groups, supporting the findings in the literature.

LA can be applied alone or mixed with different injectates such as NS and steroids for pain control. LA injections, especially in low doses, can be applied in the treatment of trigger points that cause myofascial pain [10]. It is known that treatments such as local anesthetic injection or dry needling can be used for trigger point injection in individuals with subacute low back pain or CLBP who do not respond to medical treatment. However, it is recommended to apply it alongside an active exercise program [11]. Percutaneous procedures are not recommended for non-specific low back pain [22]. A recent meta-analysis reported that interventional applications, including intramuscular LA injection, did not significantly reduce pain, or reduced it only minimally, compared to sham treatment applications in non-cancer chronic spine pain [23]. In fact, this finding is similar to the results of our study. In our study, the results in the LA group were similar to those in the NS group, except for the ILBPDI score. This suggests the applicability of NS injection in patients who cannot receive LA injection due to allergies or other reasons.

In a study comparing the effects of NS and lidocaine+steroid trigger point injections on pain in patients with myofascial pain, it was determined that the effect of NS on pain was similar to that of the other group [12]. Another study showed that NS injection was effective for pain in myofascial pain and could be applied because it did not cause major side effects [24].

It must be acknowledged that there are certain limitations associated with our study. The present study adopts a retrospective design, and the relatively small number of patients is one limitation. Despite the recommendation of exercise therapy for all patients following injections, the retrospective design of the study precluded the assessment of exercise adherence. The limited number of patients and the possibility of a Type 2 error should be considered for data sets exhibiting no significant difference. Conducting prospective studies with a larger cohort would provide more robust evidence. Furthermore, while all patients were classified as CLBP cases, the absence of a comparison between different etiologies necessitates analogous studies in specific low back pain cases. Nevertheless, the significant differences between the treatment groups, the relatively low costs, the demonstrated effectiveness of the treatments, and the comparison of injections containing three different treatments are features that render our study robust.

Conclusion

CLBP paravertebral injection is a feasible and cost-effective treatment. Paravertebral intramuscular ozone, LA, and NS (only rest NRS) injections showed significant changes after treatment in the respective groups. Lumbar paravertebral ozone injection may provide more favorable results than LA and NS on pain and QoL, as well as more favorable results than NS on disability.

Ethics Committee Approval: The study was approved by University of Health Sciences Şişli Etfal Training and Research Hospital Clinical Research Ethics Committee (No: 3723, Date: 15.11.2022).

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