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A Study On Clinical Outcome Of Ozone Disc Nucleolysis For Lumbar Disc Herniation In A Tertiary Care Medical College

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Abstract

Purpose of the study: All percutaneous minimally invasive disc treatments are typically indicated to contained disc herniations. Our study's aim is to evaluate prospectively the efficacy of ozone disc nucleolysis in the treatment of either contained or non contained lumbar disc herniations.

Methods: Fiftypatients, aged 25-50 years, with symptomatic herniated lumbar discs, without migration, sequestration, or severe degenerative disc changes, who failed conservative treatment, were included in our study. The patients underwent fluoroscopic-guided intradiscal oxygen-ozone mixture injection (10 ml) at a concentration of 27–33 µg/ml and periradicular injection of the same O2-O3 mixture, steroid, and local anesthetic. Clinical outcomes were evaluated, based on the Oswestry Disability Index and pain intensity scale results, obtained initially and at 2- and 6-month follow up.

Results Our initial results obtained at 2-month follow up were promising, indicating a significant decrease in pain disability and intensity in 78% (n=39) and 72% (n=36) of the patients respectively, and minimally increased to 82% (n=41) and 78% (39) at 6-month control. The mean preprocedural Oswestry disability index and pain intensity scores were 37 ± 12.1 and 2.45 ± 0.87, respectively, which were reduced to 17.56 ± 11.62 and 1.14 ± 0.86 at 6-month control.

Conclusion: Ozone disc nucleolysis is a safe cost-effective minimally invasive technique for treatment of contained and non contained lumbar disc herniations.

Keywords: Ozone, Lumbar disc herniation, Pain, Oswestry Disability Index

Introduction

Lumbar disc herniation is one of the most common causes of low back pain and/or radiculopathy. The pathogenesis of lumbo-radicular pain due to lumbar disc herniation is likely related to mechanical and or inflammatory factors[1]. The natural history of symptomatic disc herniation is favorable, with the majority (80–90%) of patients showing improvement with- in 6–12 weeks. However, relief of pain and disability during this period is essential[1]. The first-line treatment for pain management due to disc herniation is conservative. If conservative treatment, including rest, medications, and physical therapy, failed to relieve the pain, disc decompression is considered. The results of surgical treatment are suboptimal, and surgery harbors significant morbidity and potential complications [2].

Therefore, many alternatives minimally invasive disc decompression techniques have been developed over the last few decades to reduce the need for surgery. Nowadays, surgery is confined for treatment of patients with a progressive neurological deficit, cauda

equina syndrome, and severe intolerable pain. Minimally invasive techniques include percutaneous mechanical, laser or radiofrequency ablation disc decompression, and chemonucleolysis using gelified alcohol or oxygen-ozone mixture[3]. The oxygen-ozone chemonucleolysis is as effective as other percutaneous disc decompression techniques, which has a high therapeutic success rate (70–80%) with the lowest cost and complications[4].

Ozone has a powerful oxidizing effect on the proteoglycans of the nucleus pulpous, resulting in matrix dehydration, degeneration, and subsequent reduction of the herniating disc volume. Small-volume reduction can result in a significant drop in intradiscal pressure, thereby alleviating compression on the nerve roots and surrounding vessels with consequent reduction of venous stasis, nerve roots edema, and hypoxia. Also, it increases tissue oxygenation. Moreover, ozone has also a potent analgesic and anti-inflammatory actions through inhibition of synthesis and release of pro-inflammatory cytokines, prostaglandins E2, bradykinins, and stimulation of release of anti-inflammatory cytokines.

All percutaneous minimally invasive disc treatments are typically indicated for the treatment of contained disc herniations[3]. The aim of our prospective study is to evaluate the efficacy of oxygen-ozone nucleolysis in the management of pain and disability of either contained or non contained lumbar disc herniations.

Materials And Methods

This is a prospective clinical study of 6-month follow-up period, conducted on patients treated with oxygen-ozone chemonucleolysis, at Government Krishnagiri Medical College, Krishnagiri in department of orthopedics between December 2021 and April 2022. The study was performed in accordance with our institutional ethical guidelines with written informed consents were obtained from each participant prior to the treatment. All patients underwent a neurological evaluation with reviewing their magnetic resonance imaging (MRI) to confirm nerve roots or thecal compression. Out of all patients treated by O2-O3 chemonucleolysis.

Fifty patients, aged 25-50 years, with symptomatic herniated lumbar discs, without migration, sequestration, or severe degenerative disc changes, who failed conservative treatment, were included in our study. Inclusion criteria included patients with bulging, protruded, or extruded herniated lumbar discs, low back pain and/or radiculopathy, neuroradiological findings correlating with the clinical symptoms, and failure of conservative medical and/or physical therapies of at least 2-month duration. Exclusion criteria included patients with major or progressive neurological deficit, cauda equine syndrome, large migrated or sequestrated disc herniations, severe disc degeneration with height reduction of more than two thirds; structural spine abnormalities such as spinal stenosis or spondylolisthesis, failed back surgery, untreated spinal tumors or fractures.

Ozone Nucleolysis Technique:

The procedure, the benefits, and associated potential complications were explained to all patients. All patients underwent routine blood analysis and electrocardiogram before the procedure. All procedures were performed using digital angiography equipment, with the patient in prone position, lying on their abdomen. At first, the anteroposterior projection was obtained and alignment of the end plates of the concerned disc space was performed, through cranial and caudal angulations of the C-arm to clearly open the disc space. Then, the C- arm was rotated at an angle of 40°–45°, so that the facet joint superimposed on the posterior third of the disc space, can produce the so-called Scotty dog appearance. In the oblique projection, the needle was inserted just anterior and lateral to the superior articular process of the inferior vertebra at the direction of the X-ray beam.

Once the needle is inserted through the paravertebralmuscles for a short distance, C-arm was resumed to the lateral position and needle advancement continues until reaching a final position at the center of the concerned disc. Then, the anteroposterior projection was used to check the proper needleposition within the nucleus pulposus and can be corrected if needed.Under real-time fluoroscopic monitoring at lateral view projection, 10 ml of an oxygen-ozone mixture at a concentration of 27–33 μg/ml was obtained using a medical ozone generator and injected into the disc. In case of extruded disc herniation, more dose is required (up to 10 ml), as part of the injected mixture is leaked into

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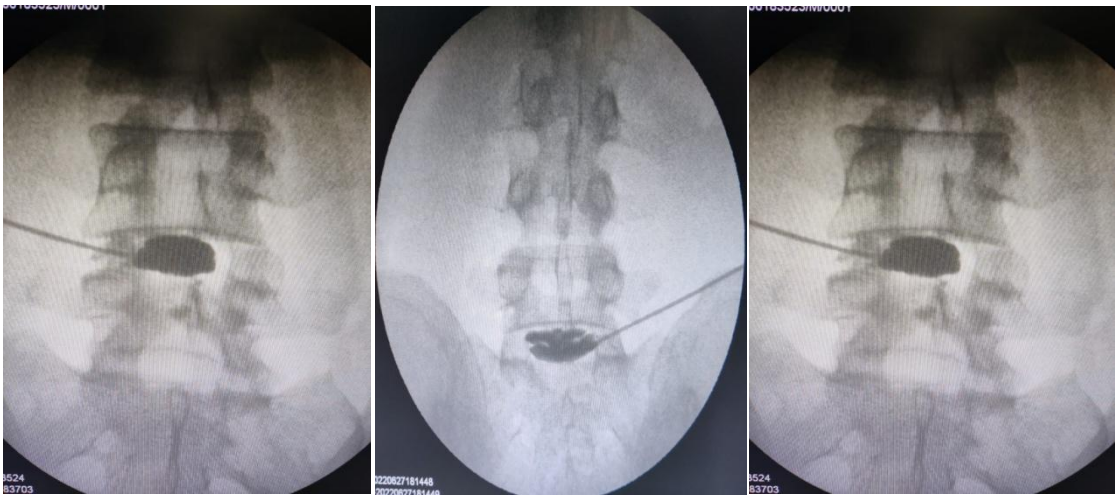
the epidural space. Then, the needle was withdrawn into the intervertebral foramen and 10 ml of the O2-O3 mixture was injected around the nerve root, followed by periganglionic injection of 1 ml of steroid (triamcinolone 40 mg) associated with 1 ml of local anesthetic (bupivacaine, 5 mg).

Picture 1: Ozone nucleolysis – procedure at different levels



Post-Procedure Care

The patients remained in prone for 30 min and then in supine decubitus for at least 2 h. Patients were instructed for relative bed rest for the first day after the procedure and homerest for at least the next 2 days. The patients were asked to limit physical work and avoid any lifting, prolonged seating, bending, or twisting the spine during the following after the procedure. Physical therapy was advised 1 month later with the emphasis on lumbar exercises. Heavy lifting is avoided on the next 6 months.

Outcome Evaluation

Our primary outcome was an assessment of pain disability using the Oswestry Disability Index (ODI) questionnaire. ODI is a percentage score (ranges from 0% = no disability to 100% = maximum disability, with a lower score that indicates less severe disability), Pain intensity as a secondary outcome was estimated using a simple descriptive (0–5) pain scale included in the ODI questionnaire. This score ranges from 0= no pain to 5 = worst possible pain.The ODI and painintensity values were recorded initially and at post procedure intervals of 2 and 6 months. A clinically significant outcome was defined as a reduction in the preoperative ODI values or pain intensity scores of at least 30% during follow-up, in accordance with literature recommendations. The outcome was graded according to the percentage of reduction into poor (0–29%), average or fair (30–49), good (50–74), and excellent outcome if the reduction was equal or more than 75%. Patients were considered to have a failure if graded as poor.

Data were collected and analyzed using SPSS Statistics Program, version 24. Repeated measures ANOVA test was used to compare the pre- and post-treatment ODI data.Analyses of the impact of patients' characteristics on the response were done using the chi-squared ($\chi 2$) test or Fisher's exact test, when necessary. $P < 0.05$ was considered statistically significant in all analyses.

Results

Patients' Demographics

Our study included 50 patients(25 males, 25females). All patients were injected on at one level (30 patients) or two levels (20 patients) with most commonly three lumbar levels. The included levels extended from L3 down to S1 with main distribution at L4-L5 and/or L5-S1 disc spaces (84%; 42 patients).

Our results were initially obtained at 2 months follow-up, and not before to avoid the effect of the peri-radicular corticosteroid, used after chemonucleolysis. The mean preprocedureODI score

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was 37 ± 12.1, which is reduced to 19.56 ± 12.32at the first two months and to 17.56 ± 11.62at six months. The mean reduction and percentages of improvement for ODI at the initial 2-monthwas17.44 and 47.13%, respectively, and was 19.44 and 52.54%, respectively, at 6-month(Table 1)

Table 1: Oswestry Disability Index

ODI	MEAN	SD
BEFORE TRT	37	12.1
AT 2 MONTHS	19.56	12.32
AT 6 MONTHS	17.56	11.62

The average pain intensity score was 2.45 ± 0.87 prior to the procedure, 1.39 ± 0.82 at 2 months and 1.14 ± 0.86 at 6 months. There were statistically significant differences in different ODI and pain scores obtained before and after the treatment. (Table 2)

Table 2: Pain intensity score

PIS	MEAN	SD
BEFORE TRT	2.45	0.87
AT 2 MONTHS	1.39	0.82
AT 6 MONTHS	1.14	0.86

The percentage of patients reporting significant improvement in disability symptoms, according to ODI scores was 78% (39 patients) at the time of 2-month follow-up and minimally increased to 72% (36 patients) at 6-month follow-up. Excellent and good outcomes were noted in 64% (32 patients), fair in 18% (9), and poor in 18% (9) of the patients at the last control. According to pain intensity score, significant decreases in pain intensity was found at 82% (41 patients) at the initial control and minimally increased to 78% (39 patients) at 6-month control, which was good to excellent in 76% (38) and fair at 10% (5) of the patients.

The statistical analyses of the impact of patients' characteristics on the outcome were studied. The percentage of success was higher with a statistically significant difference in patients with a short history of symptoms (less than 1 year), which was 83% compared to 65% in patients with a long history ($P < 0.05$). On the other hand, there was no significant difference between the responders and non-responders in terms of the age, gender, the degree of pretreatment disability, the type of the herniated disk, the injection level, the number of operated discs, and mildly or moderately degenerated discs.

Discussion

Oxygen-ozone disc chemonucleolysis is one of the minimally invasive disc treatments that is used to treat both contained and uncontained disc[5].Medical ozone is administered in the form of an O2-O3 mixture, at non-toxic concentrations, not exceeding 40 µg of O3 per ml of oxygen and prepared through conversion of pure oxygen (O2) into ozone (O3) using special medical generators, that can adjust ozone concentration as required [6].

In our study the procedure was performed under fluoroscopic guidance as a simple, rapid, and real-time control of the puncturing needle and gas distribution was allowed. The procedure can also be conducted under CT guidance with possible less X-ray exposure for the operator. The patients received single-session treatment of intradiscal ozone injection with concomitant periradicular infiltration of the oxygen-ozone mixture, steroid, and local anesthetic.

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In a previous study, Andreula et al. concluded that combined treatment of intradiscal ozone and periradicular injection of oxygen-ozone, steroid, and local anesthesia has a significant cumulative effect at 6-month follow-up, with a higher statistically significant success rate in 78.3% of the patients compared to a success rate of 70.3% in those treated with intradiscal injection of ozone alone [7]. Also, Gallucci et al. reported a success rate of 74% in a group of patients treated with combined intradiscal and transforaminal injections of oxygen-ozone, steroid, and local anesthesia versus a success rate of 47% in steroid and local anesthesia group, concluding that combined ozone and steroid treatment was more effective at 6-month control [8].

The injected O2-O3 mixture concentration was 27–33 μg ozone/ml of oxygen because such concentration was the best one that proved, by experimental studies, to dry out the nucleus pulposus proteoglycans and reduce the inflammation at disc/nerve root conflict[9]. The maximum ozone concentration applied safely for intradiscal and periganglionic injections is 40 μg/ml of oxygen.

On the basis of our results, the 6-months outcome was satisfactory and showed significant improvement of disability symptoms in 72% of the patients, mean reduction of ODI score of 19.44 points, and pain relief in 82% of the patients. There were no relevant complications during follow-up

period. Our clinical results were similar to those obtained from other similar studies [10,11], with a little difference in the included inclusion criteria or outcome measures. The meta-analysis of these studies reported ozone effectiveness in the range of 70 to 80%, a mean reduction of ODI score of 14.1points, and very rare incidence of complications, less than 0.1% [4]similar to our studies

Our results were also comparable to those obtained from other percutaneous disc decompression techniques as well as surgical treatments [12]. However, ozone disc chemonucleolysis has the advantage of being less invasive, as it uses smaller needles with very low complications rate (< 0.1%). In addition, it is a single-shot, 1-day hospitalization treatment with a lower cost compared to other alternative minimally invasive disc treatments.Also, the treatment can be administered more than one time, without preclusion of further surgical options[13].

In our patients, ozone disc chemodiscolysis was administered to both contained and uncontained herniations with no migrated or sequestrated fragments, and in the presence of mild to moderate degenerative disc changes. In addition, the concomitant periganglionic ozone infiltration in close proximity to the herniated disc material enhances the process of dehydration and volume reduction, while the anti-inflammatory properties of ozone and steroid act locally on the inflamed ganglion root and yield more clinical benefits and a good end result[14].

The main limitations of our study were a relatively small sample size and short follow-up period with lack of control group of patients. However, our study results are comparable to the results of larger series, longer-term follow-up, and controlled studies [4,5].

Conclusion:

Oxygen-ozone nucleolysis is a simple, cost-effective, and safe minimally invasive technique for the treatment of pain and disability due to contained and uncontained disc herniations, with a short recovery period. It can be considered as an intermediate treatment option between failed conservative treatment and surgery.

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