J Nepal Health Res Counc 2023 Oct.-Dec.; 21(61):684-88

Clinical Outcome for Lumbar Disc Herniation Treatment with Intradiscal Oxygen-ozone Therapy

Rupesh Kumar Yadav,[1] Tshering Sherpa,[1] Pawan Kumar Hamal, [1] Nabin Pokhrel, [1] Jay Prakash Thakur, [1] Shirish Prasad Amatya,[2] Roshan Piya [2,3]

[1]Department of Anesthesiology, Critical Care and Pain Medicine, National Trauma Center, National Academy of Medical Sciences, Mahankal, Kathmandu, [2]Nepal Pain Care and Research Center, New Baneswor, Kathmandu, [3]Department of Anesthesiology, Patan Academy of Health Sciences, Lagankhel, Lalitpur.

ABSTRACT

Background: Low back pain due to disc herniation is a common problem causing frequent hospital visits and loss of working days with major socio-economic impact. Conservative treatments like analgesics, physiotherapy do not work in all patients. Surgical treatment has been main stay of treatment when indicated but is associated with anesthetic and surgical complications. Intradiscal oxygen-ozone chemonucleolysis is minimum invasive procedure done under local anesthesia and has promissing role in shrinking the bulged disc and reducing nerve root compression and related symptoms. This retrospective study was done to see how intradiscal oxygen-ozone chemonucleolysis reduces the pain severity in patient with discogenic low back pain.

Methods: Retrospective data were retrieved of those patients who underwent fluoroscopy guided intradiscal oxygen-ozone chemonucleolysis with 5-6 ml of an O2-O3 mixture (concentration of 30 microgram/ml) during the period of two years in Nepal pain care and research center. Numerical pain scale (NRS) at various follow ups were compared to preprocedural NRS.

Results: Preprocedural NRS was 8± 1. NRS at three hours, one week, one month, three months and six months were 2± 0.3 (73.44 percent reduction), 2.5± 2 (68.85 percent reduction), 2.3± 2 (72.13 percent reduction), 1.8± 1.7 (77.87 percent reduction) and 1.67± 1.4 (79.51 percent reduction) respectively.

Conclusions: Intradiscal oxygen-ozone chemonucleolysis can be useful modality of treatment for discogenic low back pain when failed to respond to the conservative management and in whom surgery is not indicated.

Keywords: Chemonucleolysis; disc prolapse; fluoroscopy; low back pain; ozone.

INTRODUCTION

Disc prolapse is one of the main causes of low back pain with radiation to lower limbs.[1] It affects up to about 80% of the world's population.[2] Low back pain is one of the leading causes of hospital visits and loss of working days, with major socio-economic impact. [3]

Medical treatment, physiotherapy, surgery, mini-invasive interventional treatments like nucleolysis (mechanical, laser, heat), epidural steroids, and oxygen-ozone (O2-O3) chemonucleolysis are common treatment modalities. [4]

Current research on oxygen-ozone therapy shows 65% to 80% of patients have reduced herniated disc symptoms and few complications.[3,5,6]

Ozone's free radicles bind and break down the proteo-glycan bridges in nucleus pulposus so that they are no longer capable of holding water. As a consequence, disc shrinks and mummifies resulting in decreased compression on nerve roots. All this leads to decompression of nerve roots, decreased inflammation of nerve roots and i ncreased oxygenation to the diseased tissue for repair work.[7-8]

METHODS

After receiving ethical approval from NHRC (Nepal Health Research Council), a retrospective observational study

Correspondence: Rupesh Kumar Yadav, National Trauma Center, National Academy of Medical Sciences, Mahankal Marg, Kathmandu, Nepal. Email: rupeshdoc905@gmail.com, Phone: +9779851244161.

was done. Patients who underwent intradiscal oxygen-ozone therapy for discogenic low back pain during the year 2022 and 2023 in Nepal Pain Care and Research Center was enrolled in this study. Inclusion criteria were patients who presented to the center with low back pain with or without radiculopathy, without neurological deficit, not responding to other conservative treatment, got ozone chemonucleolysis and completed follow ups.

Patients with active untreated systemic or local infection, taking any anticoagulants, having previous spine surgery, having severe neurological deficit, spine trauma, pregnancy, incomplete follow ups and patient who changed to other therapy such as surgery during follow up periods were excluded from the study.

Retrospective data retrieval was done of consented patients who met the inclusion criteria. Included patients had undergone the following procedural in sequence.

Patients had undergone clinical and radiological assessment to determine the exact level of disc prolapse or bulge. All patients had given informed consent for the procedure and future research use of the related data. Serology screening, complete blood count, prothrombin time and International normalized ratio, random blood sugar, erythrocyte sedimentation rate were done.

Numerical rating scale (NRS) of pain scoring and vitals were recorded before procedure.

The procedural room was sterile and equipped with necessary anesthetic equipment and emergency drugs. Peripheral venous access was obtained, prophylactic antibiotic was given 30 minutes before the procedure.

Standard monitoring of patients with electrocardiogram, oxygen-saturation, non- invasive blood pressure was done. The patients were positioned prone on the operating table with proper positional support and pressure points care.

Under C-arm guidance proper spine level for intervention was identified.

Local anesthesia (2% lignocaine) was used for skin and subcutaneous tissue at level of insertion for intervention. Intradiscal Ozone was injected by trained pain physician on desired level using 22 G, 150 mm long spinal needle with 5-6 ml of an O2-O3 mixture (concentration of 30 microgram/ml). The needle was withdrawn and transforaminal injection with 10 ml of ozone and another 10 ml of mixture of local anesthetic and steroid consisting (2ml of 2% lignocaine as local anesthetic with methylprednisolone 40 mg and 7 ml of normal saline) was injected.

After the procedure patients were kept in recovery room for observation. The patients were also placed in strict supine position for 3 hours. NRS score was assessed before discharge. Patients were also advised to have bed rest for next 12 hours at home. The patients were discharged on the same day and were advised to avoid any strenuous activity for 3 days.

Data was collected from records of the center by single investigator to prevent variation.

The SPSS (version 26.0, IBM, USA) were used for statistical analysis. The measurement data are expressed as mean ± standard deviation (mean ±SD). Students paired t-test significant was used to compared of NRS at different follow up visits.

RESULTS

During the allocated study period, total 24 cases of low back pain, had undergone ozone chemonucleolysis. Among them 21 patients were able to follow up and three patients did not follow up and could not be contacted. Of the 21 cases 15 completed the follow ups and had satisfactory decrease in pain whereas six patients did not have improvement in pain and needed surgical interventions. None of the cases encountered any kind of complications.

Table 1. Patient characteristics: variables are mean ± SD.

Number of patients		
Age (year)		41± 12
Sex	Male	15
	Female	9

Table 2. Patient periprocedural vitals: variables are mean ± SD.

Vitals	Blood pressure (MAP) mmHg	Heart rate (per minute)
Pre procedural	74± 7	95± 5
Post procedural	68± 2	84± 7

Table 3. Comparison of Numerical Pain Scale (NRS) between follow ups (mean ± SD). Numerical pain scale		
NRS* at different follow ups	NRS (mean±SD)	Percent decrease from pre-procedural NRS
Pre-procedure	8± 1	
At 3 hours	2± 0.3	73.44%
At 1 week	2.5± 2	68.85%
At 1 month	2.3± 2	72.13%
At 3 months	1.8± 1.7	77.87%
At 6 months	1.67±1.4	79.51%

In comparing the NRS score of 3 hours, 1 week, 1 month, 3 months and 6 months paired with pre-procedural NRS score, paired t-test was done using SPSS (version 26.0, IBM, USA). With 95% confidence interval, p value less than 0.005 was considered significant. Significant decrease in the NRS score was observed.

Table 4. Comparison between pre-procedural (NRS-0) with NRS at different follow ups.	
Paired t- test	P value
NRS-0 - NRS-3 hour	<0.001
NRS-0 - NRS-1week	<0.001
NRS-0 - NRS-1month	<0.001
NRS-0 - NRS-3month	<0.001
NRS-0 - NRS-6month	<0.001

DISCUSSION

Low back pain due to lumbosacral disc bulge or prolapse is common in population needing health care. Many treatment options have come forward over the period. Some methods became popular used during certain period and were phased out due to ineffectiveness or complications. Much remains to be done, but an easy method which is minimally invasive, rapidly effective, with fewer or no complications for solving back pain problems due to disc bulge or prolapse is evolving and showing good results. This treatment is useful in patients who have not responded to physical therapy, and conventional pain therapy and at the same time avoiding aggressive surgical measures and prolonged post-surgical hospital stay. The results of this intradiscal ozone therapy seems promising for many if not for all.

Ozone is an inorganic molecule. Ozone molecule is unstable and has short half-life. So, ozone is freshly prepared on site before injection. Ozone is prepared through conversion of pure oxygen (O2) into ozone (O3) using special medical generators, that can adjust ozone concentration as required.[5,9]

Ozone has properties of anti-inflammation, analgesic, immune-modulator and bactericidal activity.[10]

Ozone is an oxidizing agent when injected intradiscally releases active oxygen atom (singlet oxygen) which binds with the proteo-glycan bridges in nucleus pulposus and breaks them so that they are no longer capable of holding water. As a consequence, intervertebral disc shrinks and mummifies (decreased in size) so there is decreased compression of nerve roots. It is almost comparable to surgical discectomy and so the procedure is called ozone discectomy or ozonucleolysis. Ozone has some complications which are rare such as post-procedural muscle spasm (transient), post-procedural burning pain (transient) and discitis (very rare due to bactericidal effect of ozone) can occur.

Ozone with 29-40 mcg/ml concentrations is not harmful to tissue. We used 30mcg/ml of ozone for injection in this study. Procedural complications such as site infection, bleeding, nerve root injuries, discitis can occur but are rare due to sterile precautions, screening and fluoroscopic guidance.

In 15 patients whose data were used for analysis in this study, there was significant decrease in the NRS score in post-operative period, 1 week, 1 month, 3 months and 6 months follow up compared to the pre-procedural NRS score with p value <0.005.

There was 73% decrease in NRS post-procedural period, 68% decrease in 1 week, 72% decrease in 1 month, 77% decrease in 3 months and 79% decrease in 6 months.

Dall'olio et. al.[3] in 2014 studied effects of intradiscal ozone therapy along with transforaminal steroid injection in 13 patients with lumbosacral disc bulge or prolapse. Their results showed 100 percent resolution of motor weakness while 84.6 percent had complete pain relief without any complications.

Yadav K et al.[5] in 2016 conducted prospective study in 50 patients with lumbosacral disc prolapse with or without radicular pain and found that pain was significantly reduced following ozone therapy. The reduction of NRS score from baseline to one month following treatment was 8.46±0.67 to 3.8±1.29, at three months 3.1±0.7 and at six months follow up 3.78±1.13 (p value was < 0.0001)

which is significant. There were no complications such as allergy, stroke, systemic hypotension, bradycardia.

Rashid et al.[11] studied in 3871 patients during period of 2005 to 2015, patients with cervical disc herniation who got ozone therapy. Their result showed 60% of the patients (2322) showed complete recovery with disappearance of symptoms. 20% of the patients (774) complained of occasional episodic neck pain and arms pain with no limitation of occupational activity. 5% of the patients (193) showed some improvement. 5% of the patients (193) had insufficient or no improvement and went for surgery. 10% of the patients (387) never turned up after the first visit. No side effects were reported at short or long term follow up.

Alexandre A et al.[6] studied 6665 patients from 1994 to 2000 who underwent treatment of disc disease by intradiscal oxygen-ozone injection. Among the 6665 patients pain symptomatology was completely abolished in 80.9% (5392 patients), amelioration was obtained in 12.4% (827 patients) and the result was poor in 6.7% (446 patients). Total 3317 patients were randomly chosen by an external person for undergoing CT/MRI control imaging 7 months after the treatment. In 41% (1360 cases) we have observed a significant reduction in volume of the hernia. In in 37% (1227 cases) the hernia has been completely eliminated, while in 730 cases morphology was unmodified.

Gupta et al. [12] used intradiscal ozone for disc herniation and in result the mean pre-treatment NRS score was 7.40 ± 0.50, and at the end of follow up was 3.40 ± 1.25.

The results in our study were similar to that of previous studies where there was significant reduction in pain score (NRS) in follow ups as compared to the pre-procedural pain score.

Our study had some limitations as it's a retrospective study and number of patients enrolled were not large.

CONCLUSIONS

From this study we conclude that intradiscal injection of oxygen-ozone can be a useful modality of treatment for lumbar disc herniation failing to respond to conservative management.

CONFLICT OF INTEREST

The authors declare no conflict of interest

REFERENCES

1. Charan R, Runu R, Kumar A, Chauhan H. Ozone discolysis in lumbar disc prolapse. Int J Res Orthop. 2017 Jun 23;3(4):724. doi: https://doi.org/10.18203/issn.2455-4510.IntJResOrthop20172133

2. Smith A, Weigand J, Greenwood J, Tierney K. Safety and effectiveness of regional anesthesia compared with anesthetic techniques not using regional anesthesia on outcomes after free tissue flap surgery: a systematic review protocol. JBI Evidence Synthesis. 2022 Oct;20(10):2591–8. PMID: 36065948 doi: 10.11124/JBIES-21-00476

3. Dall'Olio M, Princiotta C, Cirillo L, Budai C, De Santis F, Bartolini S, et al. Oxygen-Ozone Therapy for Herniated Lumbar Disc in Patients with Subacute Partial Motor Weakness Due to Nerve Root Compression. Interv Neuroradiol. 2014 Sep;20(5):547–54. PMID: 25363257 PMCID: PMC4243224 doi: 10.15274/INR-2014-10078

4. Fonoff ET. Ozone Therapy as a Treatment for Low BackPain Secondary to Herniated Disc: A SystematicReview and Meta-analysis of RandomizedControlled Trials. Pain Phys. 2012 Mar 14;2;15(2;3): E115–29. PMID: 22430658

5. Yadav K, Bhaskar P, Jagetia A, Kaif M. Role of ozone nuleolysis in management of discogenic pain in lumbar and lumbosacral disc prolapse. Int Surg J. 2016;2092–7. doi:10.18203/2349-2902.ISJ20163580

6. Buric J, Rigobello L, Hooper D. Five- and Ten-Year Follow-up on Intradiscal Ozone Injection for Disc Herniation. Int J Spine Surg. 2014;8:17. PMID: 25694935

7. Bocci V, Luzzi E, Corradeschi F, Paulesu L, Di SA. Studies on the biological effects of ozone: 3. An attempt to define conditions for optimal induction of cytokines. Lymphokine Cytokine Res. 1993 Apr;12(2):121–6. PMID: 8324077

8. Smith L. Enzyme Dissolution of the Nucleus Pulposus in Humans. JAMA [Internet]. 1964 Jan 11 PMID: 14066733 doi: 10.1001/jama.1964.03060150061016

9. Travagli V, Bocci V, Borrelli E, Zanardi I. The

usefulness of ozone treatment in spinal pain. DDDT. 2015 May;2677. doi: 10.2147/DDDT.S74518

10. Grangeat AM, Erario MDLA. The Use of Medical Ozone in Chronic Intervertebral Disc Degeneration Can Be an Etiological and Conservative Treatment. IJMS. 2023 Mar 31;24(7):6538. PMID: 37047511 PMCID: PMC10095297 DOI: 10.3390/ijms24076538

11. Rashid U, Rauf F, Leonardi M. Ozonucleolysis in Cervical Radiculopathy. Neurol Res Surg. 2018 Dec 30;1(1):1–3. DOI:10.33425/2641-4333.1006

12. Gupta VS, Singh PK, Banode P, Khan S. Intradiscal Ozone Oxygen in Lumbar Disc Prolapse. Orthopaedic Journal of MP Chapter. 2016 Jun 30;22(1):15-9.doi: https://doi.org/10.5281/zenodo.3970819