



## EFFICACY OF OZONE NUCLEOLYSIS IN THE MANAGEMENT OF DISCOGENIC PAIN AND IMPROVEMENT OF FUNCTIONAL OUTCOME IN PATIENTS SUFFERING FROM LUMBAR AND LUMBOSACRAL DISC PROLAPSE: A PROSPECTIVE STUDY

### Orthopaedics

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### ABSTRACT

**BACKGROUND-** One of the most common symptoms in our day to day life is discogenic low back pain. For treatment of this pain many percutaneous minimally invasive therapeutic modalities have evolved. Intradiscal oxygen-ozone therapy is one of the modalities showing promising results. This study was undertaken to evaluate the therapeutic outcome of intradiscal oxygen-ozone therapy on patients with lumbar and lumbosacral disc prolapse attending PMR OPD RIMS IMPHAL.

**METHODS-** 50 patients complying selection criteria were included in the study with clinicoradiological diagnosis of lumbar or lumbosacral disc prolapse. These patients received oxygen-ozone mixture at a concentration of 30-40 mcg/ml in the disc, neural foramen, facet joint regions and therapeutic outcome was assessed at 4 weeks, 3 months and 6 months post procedure based on VISUAL ANALOGUE SCALE (VAS), OSWESTRY LOW BACK PAIN DISABILITY QUESTIONNAIRE (ODI) and MODIFIED MACNAB METHODE.

**RESULTS-** Pain intensity was significantly reduced following treatment from baseline mean VAS 8.46 $\pm$ 0.67 to 3.8 $\pm$ 1.29 at one month, at three months 3.1 $\pm$ 0.7 and at 6 months follow up 3.78 $\pm$ 1.13,  $p < 0.0001$ . Similarly the ODI and modified MacNab criteria showed a remarkable improvement in the functional status of the patients  $p < 0.05$ .

**CONCLUSION-** Oxygen-ozone treatment is highly effective in relieving discogenic pain and improving functional outcome in lumbar or lumbosacral disc related low back pain patients.

### KEYWORDS

#### INTRODUCTION

In today's world low back pain is one of the major cause of morbidity. There are various causes related to failure of various treatment modalities used for treating low back pain which includes-epidural fibrosis, arachnoidal adhesions, muscle or fascial fibrosis or mechanical instability. Due to its safety and efficacy ozone nucleolysis is becoming widely used intermediate procedure between surgery and conservative therapy to relieve pain, decompress nerve roots and to maintain structural integrity. The mechanism of action includes analgesic, anti-inflammatory and oxidant actions which work together to cause symptomatic and radiological improvements in prolapsed disc. When ozone is injected into prolapsed disc the active oxygen molecule liberated by breakdown of ozone binds to the proteoglycan bridges in nucleus palposus and break them causing a loss in their water holding capacity resulting in reduced volume of nucleus palposus causing a reduction in size of prolapsed disc portion and thus help in decompression of nerve roots. Anti-inflammatory action is produced by decreased concentration of inflammatory mediators and inflammatory cells<sup>1</sup>. Ozone also increases release of antagonists to pro-inflammatory cytokines (TGF-beta, IL-4, IL-10).<sup>2,3</sup>

#### METHODS

The prospective study included 50 patients of either gender of all ages from July 2018- December 2019 with clinic-radiological diagnosis of low back pain due to lumbar or lumbo-sacral disc prolapse attending PMR OPD RIMS IMPHAL.

#### INCLUSION CRITERIA

None of the patients had sensory or motor deficits, bladder and bowel involvement or trauma history, all of them were non responders to 3 months of conservative treatment. Dynamic x-ray of lumbosacral spine was done to exclude instability of spine, computed tomography was done to lumbar canal stenosis and magnetic resonance imaging was done to exclude any disc fragment as ozone nucleolysis is contraindicated in sequestered disc prolapse.

#### EXCLUSION CRITERIA

- 1) Glucose 6 phosphatase deficiency
- 2) Diabetes mellitus
- 3) Chronic hypertension
- 4) Bleeding disorder
- 5) On anticoagulant medication

- 6) Hyperthyroidism
- 7) Pregnancy
- 8) Untreated systemic infection

Pre-procedural severity of symptoms was assessed by self-reported questionnaire using VAS, ODI and modified MacNab's criteria.

#### PROCEDURE

The patient was made to lie prone in operating table and positioned in such a way that there is a break at lower lumbar region, procedure was done under local anesthesia Lidocaine 2% infiltrated at puncture site. Right or left side injection was planned based on side of radiation which was first in chronology on history or side with more severity of pain was chosen as site of injection.

The procedure was done under C-arm guidance which was adjusted in such a way that facet joints come at center of end plates and Scotty dog appearance is obtained. Quincke type spinal needle (BD, 18 gauge 9cm) was used and needle entry point was 8-10cm lateral to midline at disc level concerned and the needle entry point at disc level was anterior to the superior articular process at center of the disc. For injection oxygen-ozone mixture freshly prepared from ozone generator was collected in a BD polypropylene 10cc leuc lock with leuc mount syringe through Millipore bacterial filter, injection time was 15 seconds as ozone starts decaying after 20 seconds at rate of 2mcg/second<sup>4</sup>. 6 to 8 cc of oxygen-ozone mixture at 29-40 microgram/ml was injected into the disc and then needle was withdrawn and 15-20 cc of gas mixture was injected into neural foramen and root canal and then by further withdrawing the needle 8-10 cc of gas mixture was injected into facet joint region and paravertebral muscles.

Post procedure the patient was kept supine and advised to take bed rest for next 12 hours and discharged next day morning with advice to avoid strenuous activity for 3 days post procedure.

#### Follow-up

The follow up data was collected at 4 weeks, 3 months and 6 months post procedure and patients were evaluated using VAS, ODI and modified MacNab method at each visit. If 50% reduction in symptom repeat ozone injection after 4-6 weeks, if 70-80% improvement in symptom reduction only physiotherapy was advised and if only 10-

20% reduction in symptoms patient wasn't given any further ozone injection and was considered for surgical microscopic discectomy. All patients were advised to do MRI lumbar spine 6 months after procedure to document reduction in prolapsed disc size.

**RESULTS**

**Table 1- MacNab grading**

FOLLOW UP	EXCELLENT	GOOD	FAIR	POOR
1 MONTH	2(4%)	8(16%)	34(68%)	6 (12%)
3 MONTHS	2 (4%)	14(28%)	30 (60%)	4 (8%)
6 MONTHS	1 (2%)	38(76%)	9 (18%)	2( 4%)

**Table2- At 6 months follow-up MacNab grade (disc prolapse level wise)**

Prolapse level	excellent	good	Fair	Poor
L4-L5 & L5-S1 (15patients -30%)	0	8 (16%)	5(10%)	2(4%)
L4-L5 (33patients-66%)	1 (2%)	30 (60%)	2(4%)	0
L3-L4 & L4-L5 (2Patients-4%)	0	0	2 (4%)	0

**Table 3- Vas Score**

VAS Score	Minimum	Maximum	Mean	Median	Standard Deviation
Pre-procedure	7	9	8.46	9	.67
1 Month Followup	0	6	3.8	4	1.29
3 Months Follow Up	1	4	3.1	3	0.7
6 Months Follow Up	2	6	3.78	4	1.13

**Table 4- ODI Scores**

ODI Scores	Minimum	Maximum	Mean	Median	Standard Deviation
Pre-procedure	32	38	35.52	36	1.52
1 Month Follow Up	16	30	22.61	20	5.53
3 Months Follow Up	16	28	23.28	24	3.8
6 Months Follow Up	12	26	20.52	20	3.41

**Table 5- Age Related Outcome**

Age In Years	Excellent	Good	Fair	Poor
20-30(10)	1(2%)	9(18%)	0	0
31-40(17)	0	16 (32%)	1(2%)	0
41-50 (14)	0	12(24%)	1(2%)	1(2%)
51-60(8)	0	1(2%)	7(14%)	0
61-70(1)	0	0	0	1(2%)

In 50 patients age range was 22-62 (mean age 41.62 years) and pain reduced significantly following ozone therapy. Pain intensity was significantly reduced following treatment from baseline mean VAS 8.46±0.67 to 3.8±1.29 at one month, at three months 3.1±0.7 and at 6 months follow up 3.78±1.13, p value was < 0.0001 which was significant (wilcoxon signed rank test). Table-3

Reduction of ODI index from baseline to 1 month, 3 months and 6 months following treatment was 35.52±1.58 to 22.615.53,23.283.8 and 20.523.41 p value was <0.0001 which was significant (Wilcoxon signed rank test). Table-4

As per modified MacNab criteria results are as follows- at 1,3 and 6 months post procedure excellent 4%,4%,2%; good 16%,28%,76%; fair 68%,60%,18%;poor 12%,8%,4% respectively. Table-1

**DISCUSSION**

Disc bulge is a term used when more than 180° of the disc circumference is outside ring epiphysis boundary. Disc prolapse means nucleus palposus material coming out of annular confines. The herniated nucleus palposus acts as an antigen and inflammatory response is initiated around it.<sup>9-10</sup>

This prospective as well as retrospective study was undertaken in 50 patients suffering from low back pain and lumbar and lumbosacral prolapsed intervertebral disc on MRI with clinicoradiological correlation. Six to eight cc of oxygen-ozone mixture at 29-40

microgram/ml was injected into the disc and then needle was withdrawn and 15-20 cc of gas mixture was injected into neural foramen and root canal and then by further withdrawing the needle 8-10 cc of gas mixture was injected into facet joint region and paravertebral muscles.

Following ozone therapy pain intensity was significantly reduced following treatment from baseline mean VAS 8.46±0.67 to 3.8±1.29 at one month, at three months 3.1±0.7 and at 6 months follow up 3.78±1.13, p value was < 0.0001 which was significant(wilcoxon signed rank test). Table-3

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The two (4%) patients who didn't respond to treatment were subjected to surgical micro discectomy. Patients having L4-L5 prolapse were having superior results (Table-2) and also younger age group patients with shorter duration of back pain were showing better results (Table-5). Bonetti et al reported successful results in 74.4% patients after 6 months.<sup>5</sup>

**CONCLUSION**

Ozone nucleolysis provides better pain relief in patients with prolapsed lumbar or lumbosacral intervertebral disc and concordant low back pain with or without radiation who didn't respond to 3 months conservative treatment. The procedure has least complications and it is cost effective and can be repeated. Limitations of the study are lack of blinding and lack of control.

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