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# OZONE DISCECTOMY VS INTERLAMINAR EPIDURAL STEROID INJECTION IN PROLAPSED LUMBAR INTERVERTEBRAL DISC: A RANDOMIZED CONTROLLED STUDY


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**ABSTRACT** Low back pain is a very frequent reason for medical consultations with lifetime prevalence as high as 84%. Ozone therapy has emerged as an alternative non-surgical intervention for intervertebral disc prolapse. A reduction in herniated disc volume is one of the therapeutic goal for intradiscal administration of ozone, as a reduction in disc size reduces nerve root compression and venous stasis and hence improves the microcirculation and supply of oxygen. A study was done at PMR Department, RIMS, Imphal to assess the effectiveness of intradiscal ozone and interlaminar epidural steroid injection in reducing pain and disability in prolapsed lumbar intervertebral disc. Eighty patients enrolled in the study were allocated to 2 groups (Group A and B). Group A (n=40) received intradiscal plus epidural ozone injection while Group B (n=40) received interlaminar epidural steroid injection. Visual Analogue Scale (VAS) and Oswestry Disability Index (ODI) were used as outcome measures. Group A showed significant improvement in pain from baseline to 6 months as shown by reduction in VAS score from 7.23±0.95 to 1.62±0.72 and 7.28±1.01 to 2.08±0.64 in Group B (p=0.000). Reduction in ODI from 68.70±8.33 (baseline) to 17.03±7.76 (6 months) in Group A was significantly (p=0.000) more than that of Group B, 73.80±7.68 (baseline) to 25.68±5.89 (6 months). The study concluded that intradiscal ozone injection is more effective than interlaminar epidural steroid injection in reducing pain and disability in prolapsed lumbar intervertebral disc at 6 months.


**KEYWORDS :** Ozone, lumbar, prolapsed disc, VAS, ODI

## Introduction

Low back pain is a very frequent reason for medical consultations with lifetime prevalence as high as 84%.[1] The 2010 Global Burden of Disease Study highlighted that low back pain is among the top 10 diseases and injuries that account for the highest number of Disability-Adjusted Life Years (DALYs) worldwide.[2]

The disc consists of a central avascular nucleus pulposus– a hydrophilic gel made of protein-polysaccharide, collagen fibres, sparse chondroid cells and water (88%), surrounded by concentric layers of fibrous tissue known as annulus fibrosus. Prolapsed intervertebral disc (PIVD) represents the tensile failure of the annulus fibrosus to contain the nucleus pulposus. The most common direction for a disc prolapse to occur is in the posterolateral, where the annulus fibrosus is thin and not supported by the anterior or posterior longitudinal ligament.[3] Prolapsed disc causes impairment by nerve root compression compelling the patient to seek medical advice for low backache.

Apart from conservative therapy, all other forms of treatment aim at decompressing the nerve root, which is considered as the cause of the patient's discomfort. These can be done by removing the disc either by surgery or by decompressing the disc by different interventions. Newer percutaneous techniques like chemonucleolysis, nucleo-discectomy, LASER discectomy and nucleoplasty have minimized invasive surgical techniques. Reducing disc size by mechanical aspiration of disc fragments or partially dissolving the herniation by drying reduces the conic pressure on the torn annulus and creates the space necessary for retropulsion whenever the fibres of annulus regain minimum capacity to contain the disc.[4]

The action of ozone is due to the active oxygen atom or the free radical liberated from breaking down of ozone molecule. As ozone is injected, the active oxygen atom attaches with proteoglycan bridges in the jellylike material of nucleus pulposus. They are broken down and they no longer capable of holding water. So, the disc shrinks leading to decompression of nerve roots. It is almost equivalent to surgical discectomy, so the procedure is called ozone discectomy. It has an anti-inflammatory action due to inhibition of formation of inflammatory substances and tissue oxygenation is also increased due to increased 2, 3 diphosphoglycerate level in the red blood cells. All these leads to decompression of nerve roots, decreased inflammation of nerve roots, and increased oxygenation to the diseased tissue for repair work.[5]

Ozone therapy has emerged as an alternative to surgery and has been proven to be safe with high success rates reported in various studies which vary from 65 to 80% of excellent or good results.[7]

Despite its widespread use, ozone therapy for PIVD remains unknown to most physicians. Ozone ($O_3$) is an allotropic form of oxygen, known for its ecological properties, industrial applications and therapeutic effects. However, its potential toxicity as an oxidising agent versus its reported clinical efficacy remains to be answered.

Epidural steroid injection is one of the standard treatment modality in intervertebral lumbar disc prolapse. The study was conducted with an aim to assess the efficacy between intradiscal ozone and epidural steroid in reducing pain and disability in prolapsed lumbar intervertebral disc.

## Materials and Methods

A randomized controlled study on 80 patients presenting with low back pain radiating to lower limb admitted in the Physical Medicine

and Rehabilitation ward, Regional Institute of Medical Sciences (RIMS), Imphal, India, was conducted from February 2016 to November 2016.

Approval from the Institutional Ethics Committee, RIMS, Imphal was taken before the start of the study and written informed consent was obtained from all the subjects.

Patients with back pain due to PIVD L3-L4, L4-L5 and L5-S1 confirmed by MRI (Grade II and III), age between 20-55 years, pain severity with minimum score of 5 based on 10 point scale VAS, ODI score more than 40, willingness to comply with treatment and follow-up assessments were included. However, patients with cauda equina syndrome, mental or physical condition that would invalidate evaluation results, prior lumbar surgery at any level, multiple level disc prolapse, pregnancy, systemic or local infection at the site, known allergy to corticosteroids, contrast dye or anesthetics, history of any malignancy (hematologic, non-hematologic), bleeding disorders, uncontrolled diabetes mellitus, uncontrolled hypertension, prior history of epidural steroid injection in the past 3 months and who refused to sign informed consent were excluded.

The intervertebral disc to be treated was decided by MRI finding in congruous with neurological deficit.

Considering 80% power, 5% error rate and 10% drop out rate a total sample size of 80 was fixed (40 in each group).

Patients enrolled in the study were assigned to two groups (Group A and B) by block randomization method. Group A consisted of 21 males and 19 females while Group B consisted of 15 males and 25 females [Table 1].

Group A received fluoroscopic guided intradiscal plus transforaminal epidural ozone while Group B received 2 doses of interlaminar epidural steroid injection two weeks apart with methylprednisolone 80 mg each.

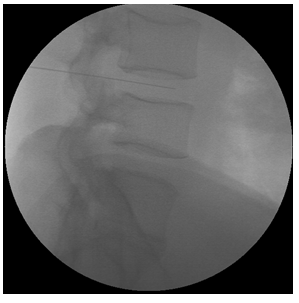

**Figure 1. Intradiscal needle placement**

An intravenous line and pulse oxymeter were secured and intravenous antibiotic coverage with piperacillin and tazobactum 4.5g was given just before the procedure after skin testing. The patient was placed prone with a pillow under lower abdomen. The area was prepared by antiseptics and draped in sterile manner. C-arm was first focused to obtain an antero-posterior view to localise the diseased disc. It was then cranially or caudally tilted to abolish any double end-plates thereby getting widest possible view of disc space. C-arm was then focused in such a way that facet joint came at the center of end plates. On the side of radiating pain, needle entry point was marked just lateral to the superior articular process exactly at the center of disc. Local 1% xylocaine without preservative was infiltrated to skin and subcutaneous tissue, then a 12 cm long, 22 G Chiba spinal needle was introduced into the diseased disc in an end-on view until a firm feeling of disc was felt. The position of needle tip was confirmed by lateral view. The needle was then advanced till it was at the centre of disc. The position of needle tip was confirmed by antero-posterior and lateral views. The ozone-oxygen ($O_2$-$O_3$) mixture gas collected from the ozone generator (Chemtronics, Made in India, Model No. MD/OG-60S) at 4 litre/min of oxygen, concentration of 40µg/ml ozone in a 10cc ozone resistant plastic syringe was injected into the disc over a period of 10 seconds. For transforaminal epidural ozone injection, the needle was advanced from the same needle entry point using an ipsilateral oblique view until the tip touched the lower edge of the Scottie dog eye, the junction of the transverse process and the superior articular process. The needle was then withdrawn for 2 to 3 mm and redirected inferiorly just under the lower edge of the transverse process for about 0.5 mm. Further advancement of the needle was done under AP and lateral views. The final needle tip position was kept at the posterior half of the neuroforamen just under the pedicle in the lateral view to minimize the potential injury to the vasculature, nerve root or dorsal root ganglion. In AP view, needle tip should not be medial to medial edge of pedicle to avoid penetrating dura mater. If the patient complained of pain or paresthesia, it was withdrawn and redirected superiorly. Once the needle was deemed at proper position, approximately 1 mL of the non-ionic water soluble contrast was injected under live fluoroscopic view. With satisfactory needle position, the contrast often outlined the exiting spinal nerve and fills the neuroforamen with epidural spreading or an epidurogram. Ten ml of ozone at concentration of 40µg/ml was given slowly. Then, the needle was removed and covered with a sterile pad. Patient was advised bed rest in supine position for 2 hours.

For interlaminar epidural steroid injection, a 24-gauge hypodermic needle was used to make a local anesthesia wheal over the desired interspace, and a 20-gauge, short, beveled spinal needle was introduced between the spinous processes. After penetrating the interspinous ligament, the stylet was removed and the needle connected to a 5cc, three-ringed glass syringe that was half filled with air. Using gentle pressure on the plunger of the syringe, the needle was slowly advanced towards the epidural space. The entry of the bevel into this space was signaled by a sudden absence of any resistance to injection of the air; as a result the syringe was usually emptied into the epidural space. Injection methylprednisolone 80 mg was given slowly. Then the needle was removed and covered with a sterile pad. Patient was advised bed rest in ipsilateral lateral position for half an hour. Second dose was given after one week. Follow-up assessments were done at 1 week, 3 months and 6 months.

### Statistical analysis

Data analysis was done using Statistical Package for Social Sciences (SPSS) version 21. Descriptive analysis including mean, percentage, standard deviation were used. Mann-Whitney U-test was used for significant test between group comparison of mean scores and Friedman test was used for within group comparison over time. Value of $p < 0.05$ was considered to be statistically significant.

### Results

**Table 1. Baseline characteristics of the patients**

| Characteristics | Group A n(SD/%) | Group B n(SD/%) | P value |
|---|---|---|---|
| Mean age (years) | 49.88 (6.14) | 53.53 (10.08) | 0.936 |
| Sex | | | |
| Male | 21 (52.5) | 15 (37.5) | 0.114 |
| Female | 19 (47.5) | 25 (62.5) | |
| Side of affection | | | |
| Right | 17 (42.5) | 24 (60) | 0.206 |
| Left | 23 (57.5) | 16 (40) | |
| Duration (months) | 10.13 (3.36) | 9.18 (2.74) | 0.078 |
| Level of prolapse | | | |
| L3-L4 | 10 (25) | 12 (30) | 0.002 |
| L4-L5 | 24 (60) | 23 (57.5) | |
| L5-S1 | 6 (15) | 5 (12.5) | |
| Grade | | | |
| 2 | 22 (55) | 19 (47.5) | 0.752 |
| 3 | 18 (45) | 21 (52.5) | |

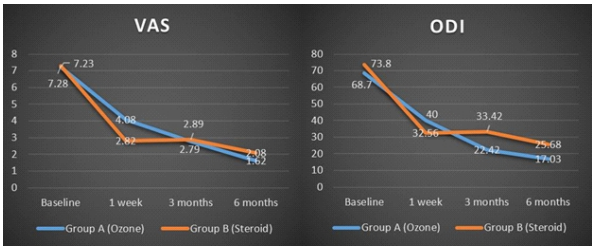


**Figure 2. Line chart showingthe improvement in VAS and ODI**

There were no significant differences in the baseline characteristics of the two groups and hence comparable.

Mean age of the patients in the Group A (Ozone) and Group B (Steroid) were 49.88±6.14 and 53.53±10.08 years respectively. Females constituted 55% (n=44) and PIVD L4-L5 was found in 58.8% (n=47) of the total patients. Reduction of pain intensity as measured by VAS showed significant reduction at the follow-up periods in both the groups. Group A showed better improvement in pain from baseline to 6 months as shown by reduction in VAS score from 7.23±0.95 to 1.62±0.72 and 7.28±1.01 to 2.08±0.64 in Group B (p=0.000) respectively [Figure 2].

Reduction in ODI from 68.70±8.33 to 17.03±7.76 in Group A was significantly more than that of Group B- 73.80±7.68 to 25.68±5.89 (p=0.000) [Figure 2].

Reduction in pain and improvement in functional score were significantly more in patients receiving epidural steroid at 1 week while those receiving intradiscal ozone showed significant improvement than epidural steroid at 6 months follow-up (p=0.000, Mann-Whitney U test) [Figure 2].

Three patients in Group A and two patients in Group B lost to follow-up. One patient each in the groups A and B underwent laminectomy and discectomy after 3 and 6 months follow-up respectively because of increasing pain with progressive neurological deficit.

There were no major complications following ozone injection. One patient had mild paralumbar muscle spasm, another complaint of nausea and headache and were managed conservatively.

## Discussion

Reduction in herniated disc volume is one of the therapeutic goal for intradiscal administration of medical ozone, as a reduction in disc size reduces nerve root compression. It also helps to reduce venous stasis caused by compression of vessels and hence improves the microcirculation and supply of oxygen. This reduces pain associated with neuronal hypoxia. Ozone has analgesic as well as anti-inflammatory effects as it inhibits synthesis of pro-inflammatory prostaglandins, release of bradykinins and algogenic compounds. Ozone also increases the release of antagonists to proinflammatory cytokines.[6]

Use of medical ozone for treatment of low back pain was advocated by Verga in the 1980s, treated about 8000 of disc herniation patients over 15 years, in whom pain relapsed occurred in less than 2%. Muto suggested intradiscal ozone injection for disc herniation in 1998 under CT guidance and Leonardi popularized fluoroscopy guided ozone injection into intervertebral disc.[7]

Viebahn[8] reported that the nontoxic concentration of ozone varies from one to 40 µg/ml of oxygen and concentration should not exceed 40 µg/ml. We used ozone in concentration of 40 µg/ml of oxygen to increase its tissue destruction property.

Ozone discectomy is mildly invasive entailing only a short hospital stay. By avoiding the spinal canal, it also eliminates the risk of post-operative scarring linked to surgery which is often responsible for pain recurrence. In the present study there is significant reduction in pain and disability due to lumbar intervertebral disc proplapse in both the groups receiving intradiscal plus transforaminal epidural ozone injection and interlaminar epidural steroid injection in the follow-up periods. Reduction in pain and improvement in functional activity of the patients were significantly more in patients receiving intradiscal ozone. Non-blinding of the study, small sample size and shorter follow-up are the main limitations of the study.

## Conclusion

Ozone discectomy is effective in reducing pain and functional disability in prolapsed lumbar intervertebral disc at 6 months. However, the long term benefit of intradiscal ozone is to be determined by studies with a larger sample size and longer follow-up period.

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