

Intradiscal Ozone injection for Disc Pathology – A Prospective case series.

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Abstract:

Introduction: Interventions for lumbar disc herniations vary from conservative to minimally invasive surgeries to open laminectomy and discectomy. Use of intradiscal ozone has been used extensively in Europe and analysis of a single surgeon consecutive cases are presented here.

Material and methods: Patients with contained disc on MRI and failed conservative trial were included in the study. Patients with cauda equina syndrome, pregnant women, spinal tumors or infections were excluded. A total of 93 patients were injected with intradiscal ozone. There were 34 females and 59 males with average age of 54±13.2 years (range 32 to 78). 51 patients had two level lesions while 24

had three level lesions, only 18 had single level disc. 11 patients had both sensorimotor deficits while 6 had only sensory and 2 had only motor deficit, remaining patients had no neurological deficit. 11 of these patients had previous open laminectomies done (failed back). Greenough and Fraser score was used to study the outcome.

Results: The mean follow up was 27.86±3.25 months. The preoperative Greenough and Fraser score improved from mean 24.33±5.94 (12 to 45) to postoperative (final follow up) mean of 68.36±6.24 (50 to 75) (p <0.001). 20 patients had good result while 66 had excellent results according to Greenough and Fraser score. Four patients did not follow up. Three patients had to undergo surgery in form of microdiscectomy. Nine out of 13 patients with motor deficit had significant recovery (grade 4 power) while only 3 out of 17 having sensory symptoms continued to have sensory symptoms. Five patients in this series had post operative headaches and were treated conservatively. There were no cases of infection.

Conclusion: This study reports successful treatment of contained lumbar disc herniation using intradiscal ozone; however a comparative and controlled trial will be essential to firmly establish this modality.

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Introduction:

Lumbar disc herniation is commonest cause of lumboradicular pain and lumbar surgery. Lumbar herniations are shown to resolve by themselves given adequate time and conservative treatments would succeed if patient can tolerate the symptoms till auto healing.¹⁻³ Modalities like conservative trials, epidural nerve blocks are used in these patients with rationale to tide over the acute phase by providing short term relief and allow the lesion to heal.^{1,4} Standard discectomy was used previously and now micro discectomy and endoscopic techniques have been developed for treatment of lumbar disc herniation. The success rate of these procedure has been reported to vary between 56% to 93% with approximately 10-12% requiring revision surgeries.⁵⁻⁹ This is found to be irrespective of micro or macro discectomies¹⁰, however recurrence of pain is more with macro discectomies and recurrence of herniation is more common with micro discectomies.^{10,11} Intradiscal use of ozone has been shown to be effective in lumbar disc herniation with good success rate.^{12,13} Even with use in vast number of patients, there still exists skepticism and doubt with respect to this modality.¹⁴ Recent metaanalysis¹⁵ has found Intradiscal ozone to be effective and safe procedure, yet most of the reports are limited to Europe, with no studies reported from our country. We report our results of prospective study of 93 patients treated with Intradiscal ozone.

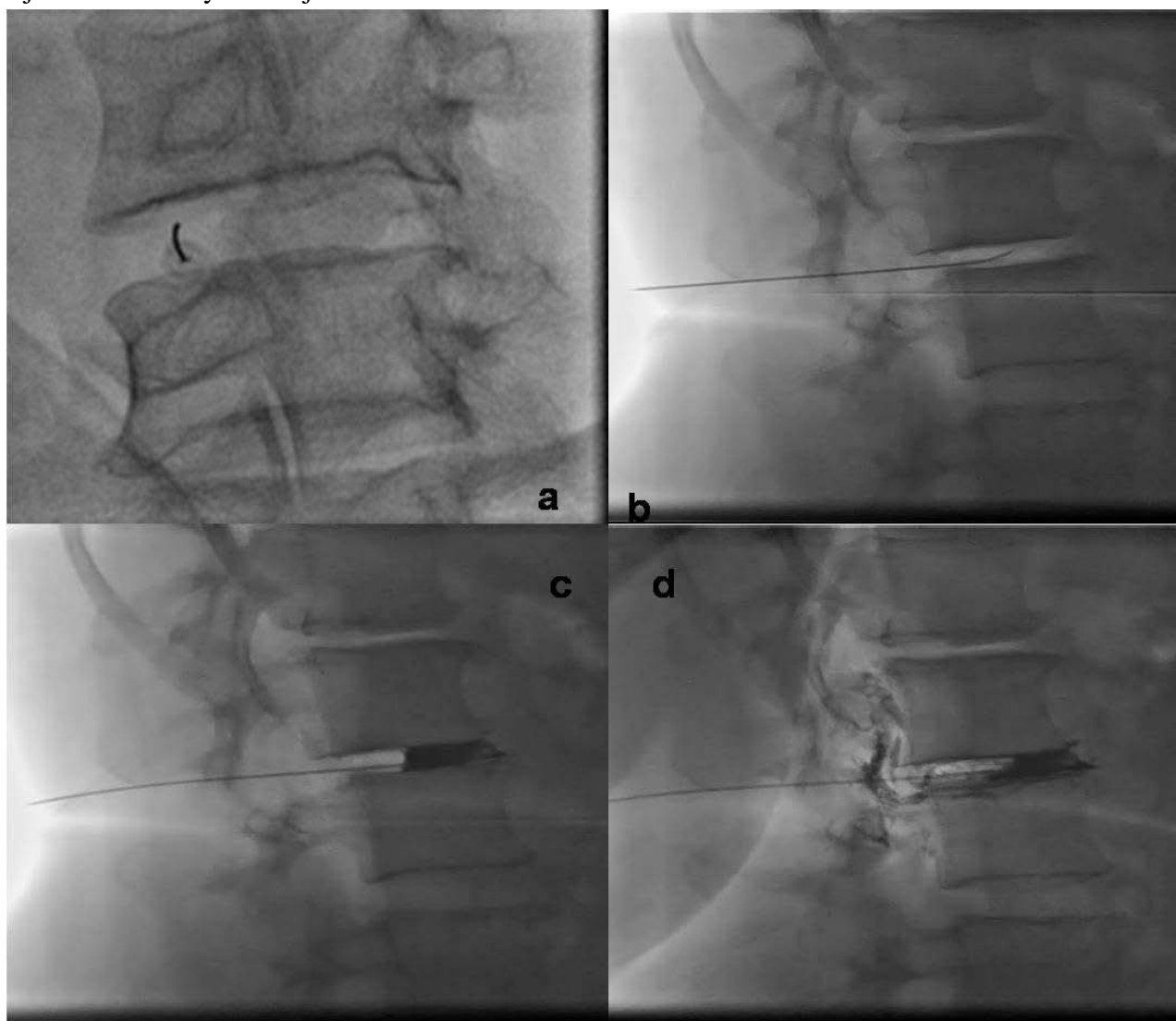
Material and methods: A prospective study was set up from 2006 to 2008, and included patients treated with intra discal ozone therapy for lumbar disc pathology. Patients were selected with strict inclusion and exclusion criteria. All patients with symptoms since at least three months with fair trial of conservative treatment like rest, medications like anti-inflammatory, analgesics and muscle relaxant for not less than three weeks and a course of ambulatory treatment including bracing, medications and physiotherapy for not less than six weeks to three months. Only patients with MRI evidence of contained disc were included in the study. Patients with severe neurological deficit involving bladder and bowel, pregnant women, patients with spinal cord tumors and infection were excluded from the study. Also patients with MRI evidence of extruded disc or free disc fragments in spinal canal were excluded. These inclusion exclusion criteria are in good agreement with recently published guidelines for percutaneous disc procedures.¹⁶ The nature of this procedure was well explained to all patients and a written informed consent was taken from every patient. Data of 93 consecutive patients treated by Intradiscal ozone with at least 2 years follow up are analysed and presented here. There were 34 females and 59 males with average age of 54±13.2 years (range 32 to 78). All patients had symptoms of prolapsed intervertebral disc with diagnosis confirmed on MRI scans. 51 patients had two level lesions while 24 had three level lesions, only 18 had single level disc. 11 patients had both sensorimotor deficits

while 6 had only sensory and 2 had only motor deficit, remaining patients had no neurological deficit and main complain was pain not responding to adequate conservative management. 11 of these patients had previous open laminectomies done (failed back).

Procedure of injection: This procedure was done as outpatient procedure (OPD) in cardiac

cath-lab for better imaging. All patients were given local anesthesia and also sedation to avoid pain during the procedure. The patient was made to lie prone with pillow under the abdomen to correct lumbar lordosis. The skin was prepared like any surgical procedure and patient was thoroughly draped.

Figure 1. **a**- insertion of the needle in oblique view. **b**-needle tip in the center of the disc. **c**- injection of the dye. **d**- Injection of intradiscal ozone



Oblique view of the involved disc space is taken and fixed on the screen on the image intensifier. The lumbar disc area is approached at the base of superior facet of inferior vertebra in oblique view with 15 cm long 22 no. spinal needle [Fig 1 a]. Needle is bent 2mm from the tip for 10 degrees. This aids in directing the needle into the disc space and is advanced towards disc space at approximately 50-60° angle. The angle is facilitated to accuracy by oblique views on image. When the annulus is reached, the surgeon should obtain a gritty feel of annulus. Then the needle is advanced up to the center of disc and the position is verified by Anterior posterior and lateral imaging [Fig 1b]. The tip of the needle should be in line of spinous process and medial to the most medial aspect of pedicle. Discography is carried out using water soluble contrast like conray-60 which confirms the needle position [Fig 1c]. When the disc is pathological, the dye spreads all along upto the canal and when disc is normal, the dye remains in center, thus confirming the abnormal to normal disc. Once confirmed 5-7cc of 27-40mcg of oxygen – ozone gas is injected into the disc space. Distraction of the space and whitish visualization of gas on the screen confirms the presence of gas in the disc space [Fig 1 d]. Once all the offending discs are injected, epidural injection is given with 2ml Depo-medrol and 7to 8cc of epidural ozone and 10 cc of saline. Needle is then removed and dressing done. The procedure lasts for approximately 20 to 30 mins and patient is discharged within 2 hours. Follow up was

carried out at one, three and six months and yearly thereafter. Detailed clinical examination was carried out at each follow up and functional scoring was done using Greenough and Fraser score.¹⁷ According to the scale patients were graded into four categories; excellent (score ≥ 65), good (score 50-64), fair (score 30-49) and poor (score 0-29). Comparison between preoperative total score and grades was done using paired t test and Fischer's exact test respectively.

Results:

The mean follow up was 27.86 ± 3.25 months. The preoperative Greenough and Fraser score improved from mean 24.33 ± 5.94 (12 to 45) to postoperative (final follow up) mean of 68.36 ± 6.24 (50 to 75) ($p < 0.001$). 20 patients had good result while 66 had excellent results according to Greenough and Fraser score. Four patients were lost to follow up. Three patients had to undergo surgery in form of microdiscectomy as they had persistent symptoms. 9 out of 13 patients with motor deficit had significant recovery (\geq grade 4 power) while only 3 out of 17 having sensory symptoms continued to have sensory symptoms. For purpose of this study repeat MRI was done after 6 months in two patients. It showed resolution of the disc bulge [Fig 2]. Four patients did require a second injection (after a mean period of 4 weeks) and had good outcome. Five patients in this series had post operative headaches and were treated conservatively. There were no cases of infection in our series.

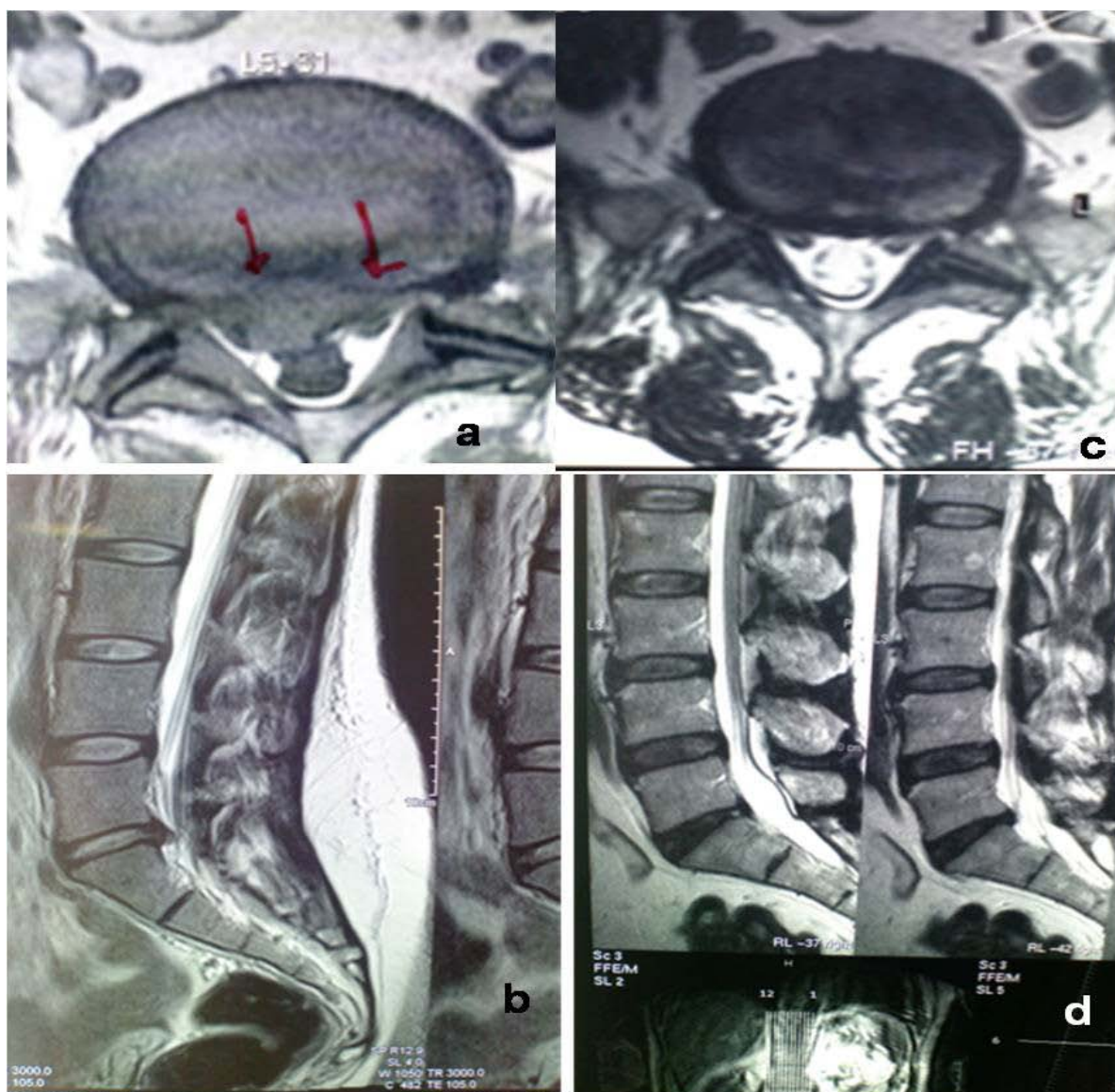


Figure 2. a and b- preoperative MRI of the patient with L4 and L5 prolapsed intervertebral disc. c-d post operative MRI axial and sagittal cuts showing resorption of the disc.

Discussion:

Injection therapy like chemoneucleolysis using chymopapain, laser discectomies and epidural steroids are minimally invasive options that have shown proven effectiveness and are considered as intermediate step between conservative and surgical treatment of lumbar disc herniation.¹⁸ Present study uses

percutaneous injection of Intradiscal oxygen-ozone mixture for treatment of lumbar disc herniation.

Medical use of ozone has been studied extensively and various applications are in field of asepsis, dental surgery and immunomodulation.¹⁹⁻²¹ Use of intra discal ozone for herniated lumbar disc was used first by

Jucopilo et al in 1995.¹⁹ Ozone is hypothesized to act in variety of ways to benefit patients of herniated disc. Two most important pathological components of disc herniation are mechanical compression and inflammation. Intradiscal ozone dissolves in interstitial fluid leading to generation of peroxide and hydroxyl ions. These highly reactive ions act on the collagen and proteoglycan of the nucleus pulposus causing its breakdown. Resorption of these hydrolytic products and water causes progressive shrinkage of the disc, thus relieving the mechanical compression and pressure on the nerves.^{19,22-24} This decrease in mechanical compression will also relieve compression on the local vasculature and improve microcirculation, thus reducing the heightened pain perception of the hypoxic nerves.²⁵ Along with this the analgesic and anti-inflammatory properties of ozone also play a major role.^{19,26,27} This further decreases the edema and improves circulation. Bocci suggested a two phase mechanism of action of Intradiscal Ozone.¹⁹ The initial rapid phase of pain and symptomatic relief was secondary to the decrease in mechanical compression and anti-inflammatory action as listed above. This is followed by second stage in which he postulated release of TGF β 1 and FGF β causing reorganization and fibrosis of nucleus pulposus.¹⁹ Effectiveness of Intradiscal ozone is reported both in published and unpublished literature with acceptable results.^{13,14,19, 22,28-37} Andreula et al treated 300 patients with intradiscal ozone and reported 70.3% good to excellent results.²² Buric et al reported 80% success rate in their series of 30 patients.³⁶ In a

large series by Muto et al where 2200 patients were subjected to intradiscal ozone, 80% success rate was reported.³¹ Another recent publication by Muto et al involving 2900 patients reported 75-80% success rate in cases with soft disc.²⁹ In present series, 70.96% patient had excellent results with only 4.3% requiring a surgical intervention. Low incidence of poor results may be due to the rigid criteria for selecting patients for this procedure. Muto et al commented cause of failure to be calcified disc and canal stenosis.³¹ Similarly even we found that the patients who required surgery had hard calcified discs at surgery. Wu et al in their study of comparison of percutaneous ozone-collagenase and lumbar surgery reported former to be an alternative for surgery in non contained disc herniations.³² Keeping these studies in mind sequestered disc cases were not included in this series. This also may be a reason for higher success rate reported in our series

Most common complications are post operative headaches and transient aggravation in patient's symptoms.¹⁹ Five patients in this series had post operative headaches and responded well to conservative treatment. None of the patients reported transient increase in symptoms requiring intervention. Infection post Intradiscal ozone should be very rare as ozone itself has antibacterial properties¹⁹, however a possibility of contamination of the gas by air or compromise of sterility cannot be ruled out.

This study has few limitations. Although this is a prospective series, lack of control or

comparison group is an important limitation. Another limitation is recoding of data and scores which is performed by either one of the authors and no inter-observer study was done. Thus in conclusion this study reports successful treatment of contained lumbar disc herniation using intradiscal ozone; however a comparative and controlled trial will be essential to firmly establish this point.

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