

## Original Research Article

# Ozone discolysis in lumbar disc prolapse

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**Received:** 03 May 2017

Revised: 15 May 2017

**Accepted:** 18 May 2017

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### ABSTRACT

**Background:** Treatment of low back ache due to prolapsed intervertebral disc is still controversial. Several conservative modalities are available with varied results. Surgical discectomy may lead to failed back syndrome due to change in vertebral column anatomy and its mechanics. To prevent it, conservative means are better and Ozone discolysis is one of the nonsurgical methods. The indications and effectiveness of this condition is not well defined. The present study was done to correlate the clinical outcome of this technique.

**Methods:** This was a prospective study conducted on 67 patients presenting with symptoms of back pain with arid without radicular symptoms. X ray and MRI were done in all cases. Then intradiscal ozone gas was given at one level from a specialized machine under C arm guidance. For evaluation Oswestry disability index and Macnab scoring system was used. Post injection patients were evaluated at 2, 6 weeks and 6 months.

**Results:** Sixty seven patients with mean age of 47.7 years were followed up for 7.8 months. Low back pain was the commonest symptom and SLR was positive in 5.36%. The modified Macnab scoring with good and fair score improved from 16% to 89% and Oswestry disability index with minimal and moderate disability improved from 41% to 91% at end of 6 months. Seven patients had relapse of pain due to repeat disc prolapse.

**Conclusions:** Ozone discloses is better modality of treatment for low back pain with disc bulge and early disc prolapsed.

**Keywords:** Low back pain, Prolapsed intervertebral disc, Ozone discolysis, Modified Macnab scoring, Oswestry disability index

### INTRODUCTION

Treatment of symptomatic lumbar disc prolapsed is still controversial.<sup>1</sup> There are various modalities like analgesics, muscle relaxants, physical therapy, chiropractic manipulations and surgical interventions. None of the procedures are fully satisfactory.<sup>2</sup> Pain following surgical intervention leading to failed back syndrome is reported in more than 10% of cases.<sup>3</sup> Hence these cases require thorough analysis before surgical intervention.<sup>4</sup> Before surgical removal of disc all means of conservative therapy should be exhausted. Epidural

steroids and chymopapain intradiscal injections are reported with poor results and complications.<sup>5,6</sup> Ozone is a newer modality known to reduce the discogenic pressure and hence reduces the radiculitis.<sup>7</sup> Hence we conducted a study on the efficacy of ozone discolysis in the cases of discogenic low back pain without neurological deficit.

### METHODS

This was a prospective non randomized study on 75 patients in a tertiary care teaching hospital from May

2013 to April 2015. The patients of 30 to 60 years reporting to orthopaedic OPD with low back pain with or without radicular symptoms not responding to conservative treatment for at least 3 months were included in the study.

**Table 1: Modified Macnab score.**

<b>Excellent</b>	No pain, no restriction of mobility, return to normal work and level of activity
<b>Good</b>	Occasional non-radicular pain, relief of presenting symptoms, able to return to modified work.
<b>Fair</b>	Some improved functional capacity, still handicapped and/or unemployed
<b>Poor</b>	Continued objective symptoms of root involvement, additional operative intervention needed at index level irrespective of length of postop follow up.

**Table 2: Oswestry disability scores.**

<b>0%-20%</b>	Minimal disability: The patient can cope with most living activities. Usually no treatment is indicated apart from advice on lifting sitting and exercise
<b>21%-40%</b>	Moderate disability: The patient experiences more pain and difficulty with sitting, lifting and standing. Travel and social life are more difficult and they may be disabled from work. Personal care, sexual activity and sleeping are not grossly affected and the patient can usually be managed by conservative means
<b>41%-60%</b>	Severe disability: Pain remains the main problem in this group but activities of daily living are affected. These patients require a detailed investigation.
<b>61%-80%</b>	Crippled: Back pain impinges on all aspects of the patient's life. Positive intervention is required.
<b>81%-100%</b>	These patients are either bed-bound or exaggerating their symptoms.

Exclusion criteria were chronic radicular pain, calcified or migrated herniated disc, neurological deficit due to disc prolapsed, previous lumbar spine surgery, other spinal pathology. Patients on oral anticoagulants were excluded from the present study. Informed consent regarding the effectiveness of Ozone usage in low back pain and chances of failure was discussed with the patients.

Thorough history was taken and clinical examination was done in all patients. Pain status was recorded as per visual pain analogue. Any motor or sensory deficit was recorded as per medical research council. All the patients were subjected for X- ray of lumbosacral spine as the duration

of pain was more than 3 months. MRI was suggested in all cases to determine the exact level of disc bulge or prolapse.

Under sterile OT conditions the patients were positioned prone on the operating table. Under C arm guidance proper level was defined and Ozone injection was given by trained anesthetists. Levels injected were L3-L4 (17), L4-L5 (28) and L5-S1 (22). The post injection patients were kept in post op room for observation. Then the patients were taught for back extension exercises and postural training was given. The patients were discharged on the same day. Tools: visual pain analogue, modified Macnab scores (Table 1) and Oswestry disability index (ODI) were used to assess the outcome of the procedure (Table 2).<sup>9</sup> The scoring was done by single author to prevent inter observer variation. The follow up was done at 2, 6 weeks and 6 months.

#### Statistical analysis

The pre injection and post injection scores were analyzed by paired t test using SPSS 10.0 version. The value was significant when  $p < 0.05$ .

#### RESULTS

Sixty seven patients (39 males and 28 females) were observed for an average duration of 7.8 months (3 months to 14 months). The mean age of patients was 47.73 years (30-61 years). The mean duration of symptoms was 10.8 months (3months to 7 years). The commonest complaint was low back pain (83%) other was radicular pain (15%) and stenotic features (2%). On examination, SLR was positive in 8 patients (5.36%). X ray of LS spine was done in all cases. The X-ray showed degenerative changes (8 cases), L5 sacralization (2 cases), L5 wedging (2 cases), L4-L5 spondylosis (4 cases), spina bifida occulta (2 cases) and normal in 49 cases. MRI was done in all cases showed disc bulge at various level in 61 cases (91%) and prolapsed disc in 38 cases (56.71%). The level of disc bulge and prolapsed is shown in Table 3. Multiple level disc bulges was seen in 14 cases (20.89%).

**Table 3: Level of disc bulge and prolapse.**

Level	Bulge	Prolaps	Injection Given
<b>L3-L4</b>	19	4	17
<b>L4-L5</b>	33	23	28
<b>L5-S1</b>	15	11	22
<b>Total</b>	67	38	67

Seventy five patients were selected for study. Seven patients were excluded since they did not give consent for injection. Sixty seven patients were given single intradiscal ozone injection. In case of multilevel disc bulge or prolapse only the symptomatic level was injected.

There was significant improvement in pain and ODI at the end of 2 weeks and 6 months. In 7 patients (10.44%) the pain relapsed due to disc prolapsed at same level in 3 patients (4.47%) and at different level 4 patients (5.97%). These patients were subjected rest and discectomy.

**Table 4: No. of cases.**

	Pre Inj	2 weeks	6 weeks	6 months
<b>VAS (Mean)</b>	6	1.33	2	1.2
<b>Modified Macnab</b>	11 (16%)	34 (51%)	57 (83%)	60 (89%)
<b>ODI</b>	31 (41%)	53 (79%)	59 (88%)	61 (91%)
<b>Mean ODI</b>	68.75	37.44	22.62	23.2

Analyzing the ODI at 2 weeks 38% patients improved. The change was significant compared to pre injection status at 2 weeks (p value 0.0154) and at 6 weeks (p value 0.0112). The improvement was not significant at 6 months compared to 6 weeks (0.8305).

## DISCUSSION

The treatment of low back pain (LBP) is controversial. Multiple treatments are being advised to the patient with variable results.<sup>2</sup> Rest is usually sufficient for cases having mild pain with occasional use of analgesics. Deyo et al found two days of bed rest as adequate duration on long term follow up.<sup>10</sup> Analgesics has no role in LBP except having short duration of pain relief with high chances of abuse potential. There are other modes of treatment like transcutaneous electrical nerve stimulation (TENS), ultrasound therapy, short wave diathermy and spinal manipulation. The scientific efficacy of these modalities is not proved.<sup>1</sup> Discectomy is indicated in cases with large disc prolapsed not responding to conservative treatment, acute neurological deficit and in cases with worsening neurological deficit. After discectomy persistent low back pain was found to be inversely proportional to the degree of disc prolapsed.<sup>11</sup> Failed back syndrome is a known complication with incidence up to 10%.<sup>3</sup> The etiology of failed back surgery can be poor patient selection, incorrect diagnosis, poor surgical technique and/or recurrent pathology.<sup>4,12</sup> Recurrent disc herniation is reported in 3 - 7% cases.<sup>3</sup> Hence before operating a patient with low back pain all means of conservative treatment should be tried to prevent failed back syndrome.

Intradiscal chymopapain injection and epidural steroid injections are conservative means of treatment for PIVD. Chymopapain use is obsolete due to multiple complications.<sup>13,14</sup> Percutaneous injections of epidural steroid are a documented procedure for sciatic symptoms without neurological deficit. The risks involved are allergic reactions, epidural abscess. Epidural hematoma,

dural puncture and vasovagal reactions are reported in individual cases. Due to longer stay of the methyl prednisolone the inflammatory response is controlled. It has no role in reduction of discal pressure and disc size. Hence the chances of recurrence of pain are Medical ozone is being used in lumbar disc prolapse in Europe since 1996.<sup>6</sup> On intradiscal injection of ozone free oxygen radicals are released which leads to degeneration of matrix and the disc is replaced by fibrous tissue. The effective disc volume is reduced and the pressure over the nerve root is reduced. Simultaneously due to its analgesic and anti-inflammatory activity the discogenic pain is reduced.<sup>7</sup> In a randomized controlled trial, Gallucci et al. showed that intraforaminal and intradiscal injections of a steroid, anesthetic and ozone are more effective at six months than injection of only a steroid and anesthetic at the same sites.<sup>17</sup> Moto et al. showed that between 1996 and 2003 of 2200 patients with low back pain or sciatica due to LBP. CT guided intradiscal oxygen ozone injection achieved an 80% success in 1750 patients at 6 months follow up. Success rate dropped to 75% in 1400 patients followed up to 18 months. Reduction in size of herniated disc was seen in 63% of followed up patients. Failure was mostly due to calcific herniated disc, spinal canal stenosis, recurrent disc herniation and multilevel degenerative disease.

In our study on 67 patients we found that 88 percent of patient had good relief at 6 weeks. The pain level decreased and the functional capacity increased gradually. There was not much improvement between 6 weeks and 6 months. The initial pain relief may be due to analgesic anti inflammatory effect of ozone since analgesic was not prescribed routinely. Postural training and back exercises helped in maintaining the good functional capacity. Relapse in seven patients was due separate disc prolapse. After initial rest they underwent discectomy.

## CONCLUSION

Ozone discolysis is better modality of treatment for low back pain with disc bulge and early disc prolapse. It helps in early rehabilitation and maintenance of vertebral mechanics by retaining the disc.

*Funding: No funding sources*

*Conflict of interest: None declared*

*Ethical approval: The study was approved by the institutional ethics committee*

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**Cite this article as:** Charan R, Runu R, Kumar A, Chauhan H. Ozone discolysis in lumbar disc prolapse. *Int J Res Orthop* 2017;3:724-7.