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Research Article

Intradiscal injection of oxygen-ozone and intraforaminal steroid for the treatment of prolapsed intervertebral disc: 4 years follow up

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ABSTRACT

Background: Intradiscal injection of Oxygen-Ozone (O_2-O_3) and intraforaminal steroid is a minimaliy invasive procedure for treatment of low back pain due to prolapsed intervertebral disc. About 9 out of 10 adults experience at least one episode of low back pain at some point in their lifetime. It has been studied that intradiscal and intraforaminal injection of mixture of O_2-O_3 and steroid produces good outcome than steroid only in such patients. The aim of the study was to evaluate long term therapeutic outcome of Intradiscal injection of Oxygen-Ozone (O_2-O_3) and intraforaminal steroid in Indian population.
Methods: There were 98 patients who were treated with intradiscal injection of O2-O3 and intraforaminal steroid 4 years' back. All of them had clinical signs of lumbar nerve root compression along with CT and/or MR evidence of contained disk herniation. Eighty two patients were available for follow- up at 4 years. Retrospective study was carried out in those patients. All patients received about 3.5 to 4.0 ml of intradiscal O2- O3 mixture at concentration of 20-24- microgram/ml and intraforaminal injection of 40 mg of inj. Trimnicelone along with 2ml of local anesthetic. Clinical outcome after the injection was assessed by Modified MacNab method and the success of treatment was assessed by means of a visual analog pain scale and the Oswestry Disability Index.
Results: A significant reduction in the VAS was observed after 6 weeks and 6 months (from 8.6 to 5.4 and 6.0; $p<0.001$) in all patients; an excellent therapy response (VAS below 3.0) was achieved at 4 years. A significant improvement in ODI was registered in all patients (36 to 14.8; $p < 0.001$). Patients below 50 years had significantly better values in the VAS and the ODI score 4 years after treatment. Final VAS and ODI scores for patients with a single diseased segment were 4.2 and 28.0. The total effective rate according to Modified MacNab method (excellent and good /fair) was 93.9% at end of 6 months, 97.55% at 1 year and 4 years it was 97.55%. No patient was operated for spine surgery.
Conclusions: Intradiscal injection of O2-O3 and intraforaminal steroid is highly effective in relieving lower back pain in patients with lumbar disc herniation not responding to conservative therapy. There was significant clinical outcome even after 4 years.

Keywords: Oxygen-ozone therapy, Prolapsed intervertebral disc, Low back pain, Ozone nucleolysis

INTRODUCTION

There are number of studies which have shown prevalence rate of low back pain (LBP) to be approximately 22% to 65% in one year and lifetime prevalence to be in the range of 29% to 70%. In 60% to 75% patients suffering from LBP, causative factors are muscle pain or ligament injuries. In 5% to 15% of patients LBP is associated with degenerative joints and disc disease.[1] The short term success rate after surgery for disc herniation is approximately 95-98% which decreases to 88% in long term.[2] These findings have led to research

into newer minimal invasive techniques to improve clinical results.[3] Ozone nucleolysis is currently available such technique which has shown promise for the relief of herniated disc related back pain. Number of studies has been published in the literature on the O_2-O_3 treatment of disc herniation with satisfactory results in selected cases.[4] At present, intradiscal and paravertebral injections through the posterior-lateral route are conventionally used in the treatment of lumbar disc herniation. For patients with minimal or inclusive disc herniation, the efficacy of ozone treatment is very significant. This method may be considered an option to treat lumbar disc herniation-related low back pain that has failed to respond to conservative treatment, representing an alternative to surgery. Experimental studies have shown that an oxygen-ozone gas mixture at the concentrations used for intradiscal treatment have the same effect as steroids on inhibiting cytokine production and hence the pain induced by the same.[5] We undertook retrospective study of clinical data of our clinical experience of intradiscal injection of mixture of O2-O3 and intraforaminal steroid for patients with LBP.

METHODS

From May 2010 to April 2011, we performed intradiscal injection of O2-O3 and intraforaminal steroid injection in 98 patients with low back pain due to lumbar disk herniation. We performed retrospective study of these patients. We gathered data from medical record section. We could contact 82 of them out of which there was drop-out of 16 patients during follow up.

Patients were selected on the basis of clinical, neurological and neuroradiological criteria.

Clinical criterion was low back pain resistant to conservative management (drugs, physiotherapy and others) lasting at least 3 months.

Neurologic criterion was low back pain with positive signs of nerve root involvement, with or without paraesthesia or hypaesthesia, with appropriate dermatome distribution.

Neuroradiologic criteria were CT and/or MR evidence of contained disk herniation, co-relating with the patient's clinical symptoms, with or without disk degeneration.

Exclusion criteria for oxygen-ozone therapy were

1. Positive red flag,
2. Bleeding disorder,
3. Pregnancy,
4. Hyperparathyroidism,
5. G6pd deficiency & CT/MR evidence of a herniated disc fragment with symptoms of motor and/or sphincter disturbance, Calcified disc, other spinal pathologies such as tumors, severe stenosis, and previous spinal surgeries and patient refusal.

Procedure

The patient was taken to the operation room and positioned prone with pillow underneath lower abdomen. The area was prepared with antiseptic lotion and draped in sterile linen. The target disc was identified. After local anaesthesia and needle tip position confirmation, 22G needle was advanced with posterior paramedian approach towards the disc at an angle of 45 to 60 degree under fluoroscope or CT guidance. Before injection, it was confirmed that needle tip is into nucleus pulposus with AP and Lat views under fluoroscope to avoid injection in outer annulus. About 3.5 to 4.0 ml of O3 O2 mixture at concentration of 20-24 microgram/ml (safe therapeutic limits) obtained with help of ozone generator was injected into the disc. The side of injection was chosen on the basis of main location of symptoms. Fluoroscope was positioned in exact AP view and then fluoroscope was tilted cranially or caudally to abolish any double endplates for getting widest possible view of the disc. After that fluoroscope was rotated in axial plain so that ipsilateral facet joint divided width of vertebral body into two. The needle entered with end on view (tunnel trajectory) into disc just lateral to superior articular process. Tip of needle was confirmed at the centre of the disc in AP and lateral views (Figure 1, 2). Then needle was withdrawn and positioned so that intraforaminal injection of 40 mg of inj. Trimnicelone along with 2ml of local anesthetic is performed. All patients were admitted for 24 hours for observation and discharged afterward.

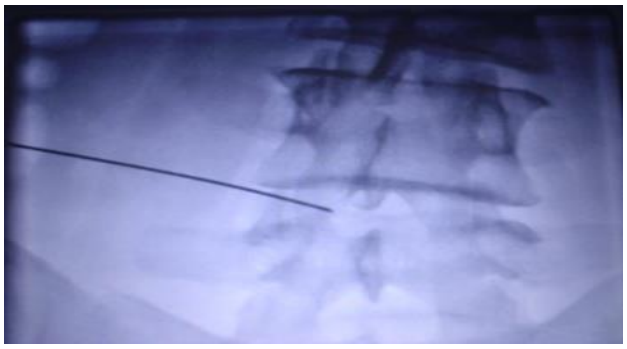

Figure 1: AP view.

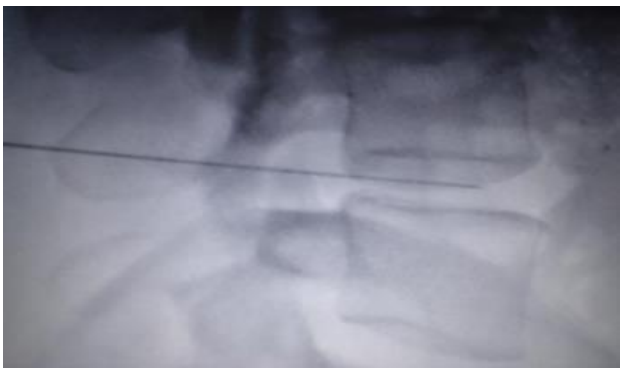

Figure 2: LAT view.

There are many and different protocols to analyse in an objective way the clinical results in patients with low back pain (16-18). We evaluated our results according to a modified mac nab method.

Table 1: Modified mac nab method

Success	Failure
Excellent	Poor
Disappearance of symptoms	Insufficient
Improvement of symptoms	Periodic administration of drugs
Complete recovery in working and sport activities	Limitations of physical activity
Good No improvement Occasional episodes of low back pain or sciatica No limitations of occupational activities	No improvement
Fair Improvement of symptoms Limitation of heavy physical activity	Worsening of clinical situation Surgery required

RESULTS

Patients' range of age was 38-67yrs. Mean age was 55 years. There were more men than women (male: female ratio of 73: 27).

All these patients received single sitting of intradiscal injection of O2-O3 and intraforaminal steroid injection. Only one patient required repeat treatment after 6 weeks.

There were 9 patients who had undergone spine surgery at another level.

Table 2: Modified McNab evaluation.

	Excellent	Good	Poor
6 Months	59 (71.95%)	18(21.95%)	5 (6.09%)
1 Year	62 (75.60%)	18 (21.95%)	2 (2.43%)
4 Years	65 (9.26%)	15 (18.29%)	2 (2.43%)

According to the modified MacNab criteria, outcomes were classified as excellent, good, and poor. The therapeutic outcomes were: excellent efficacy in 59cases (71.95%), good/fair in 18 (21.95%) and poor in 5 (6.09%), and the total effective rate (excellent and good/fair) was 93.9% at end of 6 months, 97.55% at 1 year and 4 years it was 97.55% (Table 1).

Table 3: Changes in VAS over time.

	Mean	S.D.	Obs	Total
Baseline	8.6	1.34	82	705.2
6 months	2.7	1.42	82	221.4
1 Year	2.6	1.90	82	213.2
4 Years	2.5	1.1	82	205.0

Table 4: Changes in ODI over time.

	Mean	S. D.	Obs	Total
Baseline	36	2.8	82	2952
6 months	27	2.7	82	2214
1Year	14.7	6.1	82	1205.4
4 Years	14.8	5.6	82	1213.6

A significant reduction in the VAS (table 2) was observed from baseline to 6 months (from 8.6 ±1.34 to 2.7 ±1.42,) & 1 and 4 years after treatment 2.6 ±1.9 & 2.5 ±1.1 $p< 0.001$. An excellent therapy response (VAS below 3.0) was achieved by all patients.

A significant improvement in ODI (table 3) was registered in all patients after 6 months (36±2.8, 27±2.7). It was 14.7 ±6.1 & 14.8 ±5.6, $p < 0.001$, after 1 & 4 years respectively.

In this study, there were no major intraoperative or postoperative neurological or infectious complications. There was only one episode of bradycardia noted in one patient which responded to inj. atropine.

DISCUSSION

For disc herniations the use of open surgical approaches is reduced since new method allowing shrinkage of the disc and improvement of the radicular function is gaining interest. Studies on the spontaneous disappearance of disc fragments have demonstrated autoimmune responses with a chronic inflammatory reaction. Also radicular pain has been shown to be mostly due to biochemical mechanisms. Researchers in different fields surprisingly noticed that a brief, calculated, oxidative stress by ozone administration may correct a persistent imbalance due to excessive, chronic oxidative injury. Oxygen-ozone gas injection in painful patients has a dramatic effect on clinical symptoms.

After O_2-O_3 mixture is injected in the disc, it acts on the nucleus pulposus of the disc resulting in release of water molecules subsequently leading to shrinkage of the disc which was compressing on the nerve roots. There is further cell degeneration of the matrix of nucleus pulposus which is then replaced by fibrous tissue in about next 4-5 weeks. As the disc shrinks and mummifies, there is reduction in the venous stasis caused by the disc compression of the surrounding vessels resulting in improved local microcirculation. Also there is increased oxygenation to the diseased tissue due to increased 2, 3

diphosphoglycerate level in the red blood cells.[10-13] The indicated level of evidence is II-3 for ozone therapy applied intradiscally on long-term relief in low back pain secondary to disc herniation. Based on Guyatt et al, grading the strength of recommendations and quality of evidence in clinical guidelines, the recommendation are 1C for ozone therapy applied intradiscally.[21] Periganglionic administration of steroids is supposed to be acting on the spinal ganglion which causes and transmits pain.

Based on this theory we conducted retrospective analysis of patients treated with ozone therapy. Patients were followed up for 4 years using VAS, McNab method and ODI. A significant improvement was observed in functional status of patients and severity of pain. Oder et al studied effect of intradiscal injection of Oxygen-Ozone and periradicular steroid therapy for discogenic LBP with or without radicular symptoms. They divided patients into five groups (disc bulging, disc herniation, postoperative patients, osteochondrosis, others) and subjected to CT guided nucleolysis with ozone and to periradicular infiltration with steroids and local anesthesia. There was significant reduction in VAS after 6 months in patients suffering from disc herniation from the five groups. There was also significant reduction in ODI in the herniation group. They observed functional and sustained analgesic effect in patients not responding to conservative therapy. This therapy was more effective in patients below 50 years.[16]

Andreula C.F. et al compared 300 patients (group A) which received intradiscal injection of Oxygen-Ozone and periganglionic steroid therapy for discogenic LBP with or without radicular symptoms to other 300 patients (group B) who received in addition periganglionic steroid and anesthetic.[8] Clinical outcome was assessed 6 months after the therapy. They observed excellent or good outcome in 70.3% patients in group A and 78.3% patients in group B. The difference in outcome was statistically significant. The study concluded that intradiscal and periganglionic injection of Oxygen-Ozone and periganglionic steroid therapy exerts cumulative effect for pain caused by disc herniation.

Muto et al published 3 studies between 1998 and 2008 using intradiscal injection of an oxygen-ozone mixture under CT guidance to treat approximately 3,700 patients and reported an 80% success rate at short-term follow-up (6 months) and a 75% success rate at long term follow-up (18 months), with no major or minor side effects.[17] There are very few studies published regarding long term therapeutic effect of intradiscal ozone. J Buric et al studied five and ten year follow-up on 108 patients treated with intradiscal injection of 5-10 ml of ozone.18 They observed average reduction of 56% in herniation volume in 79% patients. There were 19 patients who underwent spine surgery. At 5 years 82% of the patients that avoided surgery were improved and at 10 years 88% were improved. They concluded that benefit was sustained till 10 years in 75% patients. Though these studies have not studied MRI changes, only 9 patients underwent spine surgery at another level at 4 years. There were no complications as observed in other studies19, 20. In our experience excellent was 93.9% at end of 6 months, 97.55% at 1 year and 4 years it was 97.55%. Probably our success rate was high due to selection of patients. We had excluded patients suffering from calcified disc, lumber canal stenosis and previous spine surgery. In other observational study 89.7% patients had good outcome where failure of ozone therapy was related to patients with some amount of lumber stenosis, recurrent herniated disc.[22]

The main difficulty encountered in this study is one that universally applies to any retrospective analysis – a lack of accurate information though clinical outcome was documented adequately.

CONCLUSION

In our experience, intradiscal O2-O3 treatment of herniated lumbar disc has revolutionized the percutaneous approach to nerve root disease making it safer and easier to repeat than treatments currently in use. In addition, periganglionic steroid is helpful in treating pain factor. The technique is also reliable and compatible with other percutaneous procedures.

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