Original Article

Intradiscal ozone neucleolysis with periradicular steroid to reduce pain of disc herniation

Asmita Karnalkar[1*], Pratap Karnalkar[2]

[1]Associate Professor, Department of Anaesthesia, BKL Walawalkar Rural Medical College, Maharashtra, INDIA.
Email: asmitak55@ymail.com

Abstract

Introduction: Ozone nucleolysis (ONL) is a minimaliy invasive procedure for treatment of with low back pain caused by disc herniation and nerve root compression. ONL with periradicular steroid infiltration has been shown to effectively reduce pain and disability in such patients. **Aim** of study was to evaluate clinical outcome of the ozone nucleolysis combined with periradicular steroid at different follow up period. **Method**: Retrospective study was carried out in 38 patients complying with selection criteria. All of them had clinical signs of nerve root compression along with CT and/or MR evidence of contained disk herniation. They were treated with ozone nucleolysis followed by periradicular steroid infiltration. Visual analogue scale was assessed after 6 weeks, 6 months and 18months. Also patients were asked to describe There clinical outcome since the injection. **Result:** A significant reduction in the VAS was registered after 6 weeks and 18 months (from 8.8 to 5.4 and 2.7; $p<0.001$); an excellent therapy response (VAS below 3.0) was achieved by all patients. All patients had resolution of motor weakness. Patients below 45 years had significantly better values in the VAS. Twelve patients required second session of ozone nucleolysis. No patient was operated for spine surgery for the same level of treatment. There were no spine related or ozone related complications. **Conclusion:** ONL with periradicular steroid was safe and highly effective in relieving lower back pain as well as motor weakness in patients with disc herniation not responding to conservative therapy and have not fulfilled the indication for surgical treatment. This was a retrospective study and randomized trials are needed.

Keywords: ozone neucleolysis, disc herniation.

[*]**Address for Correspondence:**
Dr. Asmita Karnalkar, Associate Professor, Department of Anaesthesia, BKL Walawalkar Rural Medical College, Maharashtra, INDIA.
Email: asmitak55@ymail.com

Received Date: 12/10/2015 Revised Date: 25/11/2015 Accepted Date: 20/12/2015

Access this article online

Quick Response Code:

Website: www.statperson.com

DOI: 24 December 2015

INTRODUCTION

In about 60%-80% of low back pain patients, it is difficult to diagnose specific cause. In many the cause of pain is supposed to be degenerative nature or related to disc lesion. Nucleus pulposus herniation is one of the most important disc pathology. There are various therapeutic modalities for management of disc herniation. The short term success rate after surgery for disc herniation is around 95-98%. This decreases to 88% in long term[1]. Conservative care must be exhausted before subjecting patients to surgery. Ozone nucleolysis (ONL) is currently available such technique which has shown promise for the relief of herniated disc related back pain. Intradiscal injection of ozone gas was first described in 1980s for patients with disc herniation. Number of studies have been published in the literature on the O_2-O_3 treatment of disc herniation with satisfactory results in selected cases[2,3]. At present, intradiscal and paravertebral injections through the posterior-lateral route are conventionally used in the treatment of lumbar and cervical disc herniation. 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. It is being performed widely in European countries. Experimental studies on rabbits 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[4]. There is evidence of dose related response of ozone on collagen fibrils and nucleus cells. The action of ozone of long duration compared with steroid injection. Ozone blocks inflammatory reaction in intraforaminal space with long term pain relief. There are very few randomized control trials comparing ONL with other treatment at present. They have shown success rate in the range of 65%-85% and complications as low as 0.1%. Two meta-analysis have concluded that ONL is both safe

How to site this article: Asmita Karnalkar, Pratap Karnalkar. Intradiscal ozone neucleolysis with periradicular steroid to reduce pain of disc herniation. *International Journal of Recent Trends in Science and Technology.* December 2015; 17(2): 145-148. http://www.statperson.com (accessed 26 December 2015).

and effective in patients with disc herniation.[24] We undertook retrospective study to evaluate clinical outcome of patients with LBP due to disc herniation treated with the ozone nucleolysis combined with periradicular steroid at different follow up period

MATERIALS AND METHODS

From May 2010 to April 2013, we performed O2-O3 chemonucleolysis procedures with periganglionic steroid injection in 50 patients with low back pain due to lumbar disk herniation at Karnalkar orthopedic hospital. We performed retrospective study of these patients who had maintained follow up at 6weeks, 6 months and 18months. We gathered data from medical records which included patient history, demographic and clinical data. There was drop out of 12 patients. All 38 patients had undergone clinical and radiological assessment before undergoing the procedure. 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 criteria 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, in line with the patient's clinical symptoms without disk degeneration. Exclusion criteria for oxygen-ozone therapy were positive red flag, bleeding disorder, pregnancy, hyperparathyroidism, G6PD deficiency and CT/MR evidence of a herniated disc fragment with symptoms of sphincter disturbance. In these cases, the patients underwent surgical treatment.

Procedure

The patient was taken to the operation room. Patient was positioned prone with pillow underneath lower abdomen. Patients received premedication – injection midazolam after securing intravenous access. The area was prepared with anti-septic 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. When needle entered into the disc a specific resistance was felt. Before injection, it was confirmed that needle tip was into nucleus pulposus with AP and Lat views under fluoroscope to avoid injection in outer annulus. (Fig 1 and fig 2) About 3.5 to 4.0 ml of O3 O2 mixture at concentration of 20-4- 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. The needle was then extracted from the disc and positioned so that periradicular injection of 40 mg. Trimnicelone with local anesthetic was deposited. After this procedure patients remained in lateral position for 15-20 minutes. All patients were discharged after 24 hours of observation.

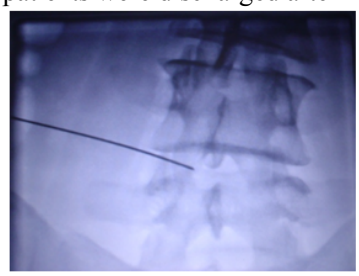

Figure 1: AP View

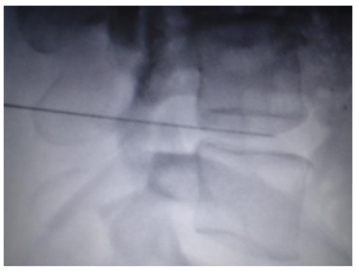

Figure 2: Lateral View

All patients were reassessed after the procedure, 6 weeks, 6 months and 18 months later. Patients were asked to describe their clinical outcome since the procedure by asking following questions- Have you had any recurrence of pain since the initial injection? Have you used pain killers for the same problem: never, occasionally, frequently or daily? How will you describe present clinical status compared to that before receiving injection: worse, same, better or much better?

RESULTS

Patients range of age was 38-67(average 45 yrs). There were more men than women (male: female ratio of 45: 55). A significant reduction in the VAS was registered after 6weeks and 6 months (from 8.8+-1.35 to 3.6 +-1.46 $p<0.001$) and 6,18 months after treatment 2.8+-1.88 and 2.7+-1.02; an excellent therapy response (VAS below 3.0) was achieved by all patients as shown in table 1. It was observed that 12 patients required second session of ONL which was performed at 6 weeks.

Table 1: Changes in VAS over time

	Mean	S.D.	Obs	Total
Baseline	8.8	1.35	38	334.4
6 Weeks	3.6	1.46	38	136.8
6 Months	2.8	1.88	38	106.4
18 Months	2.7	1.02	38	102.6

Six patients did not recover motor weakness completely at 6 weeks and all patients recovered at 18 months as presented in table 2.

Table 2: Outcome of recovery of Motor weakness

Time interval after treatment	Complete recovery of motor weakness	Partial recovery of motor weakness	No recovery of motor weakness
6 Weeks	32/38	6/38	0/38
6 Months	36/38	2/38	0/38
18 Months	38/38	0/38	0/38

On interviewing the patients who felt "same" were 15%, "better" were 50% and those who felt much better were

"35%"at 6 months. At 18 months number of patients who felt "better" was increased to 75% while 25% patients felt "much better". Patients who took medication occasionally were 85% and those who never took medication for the same complain were 15% after 18 months since injection. After 18 months twenty four (63.1%) patients reported of no recurrence of similar pain or motor weakness after the injection but 5% patients experienced symptoms of disc herniation at different level. In conclusion after the 2 sessions of treatment 100% patients had complete remission of motor weakness, pain resolution and excellent therapy response was observed in all patients at 18 months.

Table 3: Shows summary of these observations at 18 months

Level of disc herniation	Remission of neurologic deficit	Remission of pain	No. of ONL sessions	No. of patients
L3-L4	+	+	1	28
L4-L5	+	+	1	2
L5-S1	+	+	2	8

In this study, there were no ozone related or procedure related major complications.

DISCUSSION

Ozone chemonucleolysis has been reported to be successful in treating low back pain pain with or without cruralgia but without acute motor deficit caused by disc herniation persisting for atleast 3 months[7-10]. For disc herniations the use of open surgical approaches is reduced since new method allowing shrinkage of the disc and improvement of the pain is gaining interest. Studies on the spontaneous disappearance of disc fragments have demonstrated autoimmune responses with a chronic inflammatory reaction. In clinical practice surgical management of patients with partial motor weakness is invasive approach. The pain and motor weakness makes patients incapacitating. After O2-O3 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[11-13]. Also there is increased oxygenation to the diseased tissue due to increased [2,3] diphosphoglycerate level in the red blood cells[5,17-19]. The nerve root injury may be caused by partial demyelination that increases mechanosensitivity of nerve root making it more susceptible to mechanical pressure. This in turn seems to trigger hyperexcitability and nerve impulses which causes neuropathic paresthesia and pain[14]. In patients with disc herniation periganglionic steroid infiltration results in relief of periganglionic inflammation by enhancing recovery of the normal gaglionic myelin sheath and thus improving nerve function at the disease site. Patients receiving epidural steroid injections take an average of 2.5 injections per year[15]. The clinical benefit results in transient improvement in leg pain.[16] 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*[23], grading the strength of recommendations and quality of evidence in clinical guidelines, the recomendation is 1C for ozone therapy applied intradiscally. Based on these findings we conducted retrospective study to establish effectiveness of ONL and periradicular steroid infiltration in this category of patients with disc herniation. Andreula *et al* reported a success rate of 78.3% in patients treated with ONL and periganglionic steroid injection compared with 70.3% in those treated with ONL alone.[6] There were 235 patients and only 2 complications occurred in the form of impaired sensation in the lower limb on the treated side which resolved after 2 hours. 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.[20] In terms of pain relief, in the present study significant reduction was observed at 6 months. There were 12 patients who required second session of treatment at 6 weeks and excellent outcome with complete resolution of pain in all patients. The success rate being high in this study could be attributed to selection of patients. We did not include patients suffering from lumber canal stenosis, previous spine surgery and calcified disc. In other study 89.7% patients had good outcome where failure was related to some amount of lumber stenosis and recurrent herniated disc[21]. The recovery of motor weakness in all patients in this study could be attributed to antiinflamatory action of periganglionic steroid injection. This finding correlates with study done by Massimo D *et al* where they treated 13 patients with low back pain associated with cruralgia and subacute partial motor weakness caused by nerve root compression unresponsive to medical treatment. They had promising outcome with moderate pain reduction and 100% resolution of motor weakness.[22] After 2 sessions of ONL all 13 patients had complete recovery of motor weakness and 84.6% patients had complete remission of pain. It has been studied from CT/MRI scans that the disc volume is not the most important but just one of the factors that influence the symptoms[24]. The reduction in

herniation volume does not always correlate with improvement in pain, motor or sensation disturbances. Asymptomatic patients may have positive C T scans findings for disc herniation. So we have not studied CT/ MRI of these patients in this study. This retrospective study has obvious drawbacks that there is lack of control group and there may be lack of accurate information. Still we have tried to document clinical outcome adequately. This study does support the safety of this treatment. Since there is lack of control group in this study we have conducted a literature review on the clinical outcome of ONL, steroid injections and surgery. The results were equivocal. Also it is challenging to design randomized trial comparing surgical and non surgical treatment. Patients in this study appear to be suited to balance the risk and benefit of the treatment options. According to this study patients have benefited from the treatment with excellent clinical outcome.

CONCLUSION

Minimally invasive treatment for disc herniation by intradiscal ONL with periganglionic steroid infiltration is a valuable and competitive technique that provides excellent results without complications. It is also effective in patients with partial motor weakness unresponsive to medical management. It can be included into the treatment modality as an intermediate modality before passing to surgery.

REFERENCES

1. Osborn AG- Nonneoplastic disorder of spine and spinal cord in diagnostic neuroradiology, St. Louis, Mosby 1994; 820-875.
2. Alexander A , Coro L- intrdiscal inj. Of O2-O3 mixture for treatment of cervical disc herniation-Acta Neurochir Suppl 2005; 92:79-82
3. Buric J,Molino L R- Ozone chemonucleolysis in non contained lumbar disc herniation- Acta Neurochir Suppl 2005; 92: 92-97
4. IkiakisS E. Ozone treatment in low bak pain. Orthopaedics 1995(1)29-33
5. Vaillant JD, Fraga A, *et al*. ozone oxidative postconditioning decreases proinflamatory cytokine levels and oxidative stress in rats. Eur J Pharmacol 2013;14:318-24
6. Andreula CF, Simonetti I. Minimally invasive ozone therapy for disc herniation. American J of Neuroradiol 2003;24:996-1000
7. Muto M, Andreula C, Treatment of herniated lumbar disc by intradiscal and intraforaminal ozone inj. J.NeuroRadiology 2004, 31(3) 183-189
8. Muto M *et al*-Low back pain and sciatica treatment with intradiscal transforaminal O2-O3 injection are experience-Radio med. 2008,113(5)695-706
9. Andreula C. *et al*. Lumbar Herniated disk and degenerative changes. Interventional spinal treatment with chemiodiscolysis with nucleoptesis with O_3 and periganglliar infiltration in 150 cases. Rivista di Neuroradiologia 2002; 14: 81-88.
10. Gallucci M, limbucci N .Sciatica treatment with intradiscal and intraforaminal inj. Of steroid and O2-O3 vs. steroid only-Radio 2007,242(3)907-13
11. Jim Steppan *et al*, A meta- analysis of effectiveness and safety of ozone treatment for herniated lumbar disc, Journal of Vascular and interven. Radio. 2010; 21(4)534-538
12. Rilling S, Veibahn R; (book) Use of ozone in medicine, New York,1987
13. Bocei V Biological and clinical Effects of O3- Br J. Biomed. Sc. 56;1990:270-279
14. Olmarker K, Larsson k. Tumor necrosis factor and nucleus pulposus induced nerve root injury. Spine1998;7;83-90
15. Gestern P, Smuck M. Plasma disc decompression compared to TFEI for DH.J.Neurosurg Spine 2010;12:357-371
16. Fridely j, Chan L.Increases in lumbosacral injections in medicare population. Spine2007;32:1754-60
17. Bonetti M, Fontara A- intraforaminal O2-O3 vs. periradicular steroid in LBP:randomized control study, AJNR-2005;26:996-1000.
18. T Lehnert, M S Heri- result of combined intradiscal and periganglionic injection of medical ozone and periganglionic steroid for treatment of lumbar disc herniation, Journal of Vascular and interven. Radio. 2010; 21(2) S70
19. D K Baheti, S Bakshi: Interventional Pain Management – A Practical Approach, first edition 2009:308-13
20. Muto M, Andreula C, Treatment of herniated lumbar disc by intradiscal and intraforaminal ozone inj. J.NeuroRadiology 2004, 31(3) 183-189
21. Vanderlinden R, Subarticular entrapment of the dorsal root ganglia as a cause of sciatic pain. Spine 1984;9:19-22
22. Massimo D, Ciro P. *et al*.Oxygen-Ozone therapy for herniated lumbar disc with subacute partial motor weakness. International Neuroradiology 2014 ,20:547-554
23. Guyatt G, Gutterman D, Baumann MH, Addrizzo-Harris D, Hylek EM, Phillips Grading strength of recommendations and quality of evidence in clinical guidelines: Report from an American College of Chest Physicians task force. Chest 2006;
24. Fraser RD, Sandhu A. MRI findings 10 years after treatment for disc herniation. Spine 1995;20:710-14 Francisco N. De Oliveira Magalhaes, MD, Luciana Dotta, MD, Andre Sasse, PhD, Manoel J. Teixeira, MD, PhD, and Erich T. Fonoff, MD, PhD Ozone Therapy as a Treatment for Low Back Pain Secondary to Herniated Disc: A Systematic Review and Meta-analysis of Randomized Controlled Trials Pain Physician 2012; 15:E115-E129

Source of Support: None Declared
Conflict of Interest: None Declared