IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)
e-ISSN: 2279-0853, p-ISSN: 2279-0861.Volume 18, Issue 11 Ser.5 (November. 2019), PP 64-68
www.iosrjournals.org

Role of Oxygen-Ozone (O_2 –O_3) Therapy in Contained Lumbar Disc Prolapse: A Randomized Control Trial

Dr. Swapan Kumar Mishra[1], Dr. Tushar Kanti Saha[2]
[[1]Associate Professor, Department of Physical Medicine & Rehabilitation; [2]Associate Professor, Department of Community Medicine] North Bengal Medical College, Sushrutanagar, Darjeeling
Corresponding Author: Dr. Tushar Kanti Saha, C/O Satyarthi Mishra, Flat- B-10, ABAKASH, 121/24/F, Kalitala Road, North Purbachal, Kolkata – 700078

Abstract: *Low back pain is one of the common complaints among patients encountered in clinical practice. Contained lumbar disc prolapse is one of the primary causes. Invasive approach is best reserved only for those patients who show failure to respond to conservative treatment. Besides minimal invasive surgical lumbar discectomy, different minimally invasive procedures addressing Low Back Pain (LBP) & sciatica syndromes are available for relief of pain & other symptomatic improvements of which Intraforaminal or caudal epidural Injection of steroids is the most commonly used procedure. However, Intraspinal use of long acting steroid preparations has a swarm of adverse effects. Hence, a newer method termed as Ozone Chemodiscolysis or Chemonucleolysis is being applied and has gained much success. The purpose of our study is to compare the clinical effectiveness of Intradiscal (3-4ml) as well as Transforaminal /Intraforaminal (6-8 ml) Oxygen-Ozone mixture at a concentration of ozone 30ugm/ml in oxygen in one group (Group-A) versus the transformational / Intraforaminal injection of steroid (injection Methylprednisolone-40mg) with injection Hyaluronidase (1500 i.u.) & local anesthetics (Lignocaine 2%-2-3ml) in another group of patients (Group-B) among the selected patients (according to inclusion criteria) who are symptomatic with clinical features (LBP not responding to conservative treatment). Procedure was performed under fluoroscopic guidance at the Main Operation Theater (MOT) of the study institute. Whole procedure was done as a day care procedure & during post procedure period rest is advised for 2-4 hours at recovery room in supine position. During discharge, after 2-4 hours of the procedure, all patients were advised to take rest (particularly to avoid strenuous activity) for 4 days then to resume movement & activity gradually. A total of 3(three) follow-up visits (at 2nd week, at 3rd month & at 6th month) after the injection at the first visit was done in both the groups. Initial assessment & outcome measure at interval of 2 weeks & 3 months and at the final follow up at 6-months after the intervention were assessed by calculation of Oswestry Disability Index (ODI)[after application of Oswestry Low Back Pain Disability Questionnaire (OLBPDQ)], Ronald Morris Disability Score (RMDS) [after application of Ronald Morris Disability Questionnaire (RMDQ)] and Modified Macnab method. Analysis of the results revealed that at initial follow-up (2nd weeks) there was little difference in success among the two the procedure groups of patients but gradually at the end of the study, i.e. after 3 months (2nd Follow up) & after 6 months (3rd & final follow up) the difference in success is significant between two groups of patients. At final follow up(at 6th Month) it is noticed that 25 patients (56%) in Group-A, 35 patients (78%) in Group-B shows successful result. So it can be stated that the overall success rate of ozone – oxygen mixture therapy is around 80% and the failure rate is 20%. Thus, it can be concluded that Intradiscal & Intraforaminal Injection of Oxygen-Ozone mixture (Ozone Chemonucleolysis) alone is better procedure in management of pain in radiculopathy due to contained lumber disc prolapsed than Injection of Steroid (Methylprednisolone) with local anesthetics in terms of long term benefit (after 6 months). Moreover it is a low cost, highly effective & simple method*

Key Words: *Low Back Pain, contained disc Prolapse, Intraforaminal / Transforaminal steroids, Ozone Chemodiscolysis*

Date of Submission: 30-10-2019 Date of Acceptance: 15-11-2019

I. Introduction

Low Back Pain (LBP) & Sciatica with other nerve root pain (radiculopathy) affect most of the population at least once during lifetime [(1, 2)] In Western world, the incidence rate is 80% & 55% of them are associated with radiculopathy.[(3)] LBP is often caused by disc disease, though other factors are responsible for nerve root syndromes as well.

Cases of LBP where clinical symptoms fail to correlate with the radiological findings (CT/MRI) should be seriously evaluated.[(4)] Natural history of lumbar disc herniation is favourable & improvement of symptoms is a norm in majority by conservative management and 70-80% patient shows clinical, radiological as well as

anatomical resolution within 1 year of conservative treatment [2, 5-9] Therefore, invasive approach is best reserved only for those patients who show failure to respond to conservative treatment. Earlier, surgical lumber discectomy was a well-known invasive procedure in majority. But later surgery is less preferred due to discovery of many minimaly invasive procedures but the success rate in those procedures were not much satisfactory & pain relief occurs in no more than 80%–85% of patients [2,10] Around 15-20% of them show treatment failure after surgical discectomy with Failed Back Surgery Syndrome (FBSS) [18.19-26] FBSS also develops in 10-40% cases of surgical Lumbar Discectomy [2, 11]. Besides Minimal Invasive Surgical Lumbar Discectomy, different minimally invasive procedures in Low Back Pain (LBP) & Sciatica syndromes are available for relief of pain & other symptomatic improvements. Intraforaminal or caudal epidural Injection of steroid (Inj.triamcenolone /methyl-Prednisolone) with or without inj. hyaluronidase $\pm$ Inj. Anesthetics (Lignocaine 2% usually) is most commonly practised. [29]However, Intraspinal use of long acting steroid preparation may cause tubercular meningitis, adhesive arachnoiditis, aseptic meningitis, sclerosing spinal pachymeningitis & hypercortisolism. [29]. To treat the cases of lumbar disk herniation a newer method termed as Ozone Chemodiscolysis or Chemonucleolysis is being applied and has gained much success [13,18,27]

This procedure alleviates pain by means of percutaneous intradiscal Oxygen-Ozone (O_2-O_3) injection (Termed as "Ozone Chemonucleolysis") along with percutaneous Intraforaminal injection of (Periganglionic & Periradicular) Oxygen-Ozone mixture. Ozone (having the molecular weight 48 kDa) is an unstable allotropic compound produced from oxygen which was first discovered and named by German scientist Schorbein in 1840 and applied at Germany in medical science since 1940.

"Chemonucleolysis" or "Chemodiscolysis" is the digestion & degradation of nucleus pulposus by a chemical reaction that typically results from interaction with a percutaneously injected substance.The result of This treatment has been tested in large clinical studies and findings of which have shown positive outcomes in clinical, neurological and radiological as well as anatomical findings with LBP in 70%–80% of patients [2, 12-16].

II. Aims & Objectives

To evaluate & prospectively compare the clinical effectiveness of Intradiscal (3-4ml) as well as Transforaminalforaminal /Intraforaminal (6-8 ml) Oxygen-Ozone mixture at a concentration of ozone 30ugm/ml in oxygen in one group (Group-A) versus the Transformational / Intraforaminal injection of steroid (injection Methylprednisolone-40mg) with injection Hyaluronidase (1500 i.u.) & local anesthetics (Lignocaine 2%-2-3ml) in another group of patients (Group-B) among the selected patients (according to inclusion criteria) who are symptomatic with clinical features (LBP not responding to conservative treatment).

III. Materials & Methods

This Prospective, Randomized Controlled Double Blind Study was conducted at Pain Clinic, Department of Physical Medicine & Rehabilitation. Malda Medical College, Malda, From March 2012 to August 2013.

Approvals from the Institutional Ethical Committee & Informed consent from all patients were obtained prior to the study. All pre-procedure investigation relating to VCTC was done for all patients. 92 Patients, age ranging from 35 years to 55 years, female 48 & Male 44, were selected and subsequently they were randomly assigned in 2(two) groups (Group-A & Group-B) with 46 patients in each group. Patients in Group-A underwent Intradiscal (3-4ml) the mixture of Oxygen-Ozone in the concentration of 30 ugm/ml in this study. Patients in Group-B underwent Intraforaminal/transformational Injection of Steroid (injection methylprednisolone-40mg) with Injection Hyaluronidase (1500 i.u.)& Anesthetic (Inj. Lignocaine-2%-2-3ml). 3 Follow-up visits were arranged for all patients; the first two at 2 weeks & at 3 months respectively and the final assessment was made at 6 months after treatment.

Patients who are otherwise medically fit but having LBP with Oswestry Disability Index (ODI)$\geq$20%, Ronald Morris Disability Score (RMDS) > 6 and fulfilled the Neurological & Radiological (contained lumber disc herniation) criteria are included in the study. Patients with extruded hernia, free disc segments, hypoesthesia, significant paresthesia, conus cauda syndrome, hyperalgesic-paralysing sciatica with progressive neurological impairment and any degree of muscle weakness, bladder – bowel disturbance and also patients with pregnancy were excluded from the study. Allergy to proposed materials, patients with sacroiliitis & bony lesions (e.g. infective, inflammatory & neoplastic) and with hypertension, diabetes mellitus & coagulation disorder were also excluded from the study. Procedure was performed under fluoroscopic guidance at the Main Operation Theater (MOT) of the study institute. Mean surgical time was 25 minutes (15 to 35 minutes). Whole procedure was done as a day care procedure & during post procedure period rest is advised for 2-4 hours at recovery room in supine position. During discharge, after 2-4 hours of the procedure, all patients were advised to take rest (Particularly to avoid strenuous activity) for 4 days and to resume movement & activity gradually thereafter.

[Picture-1-8]

A total of 3(three) follow-up visits (at 2nd Week, at 3rd Month & at 6th month) after the injection at the first visit was made in both the groups. Initial assessment & Outcome measure at interval of 2 weeks & 3 months and at the final follow up at 6-month after the intervention were assessed by calculation of Oswestry Disability Index (ODI)[after application of Oswestry Low Back Pain Disability Questionnaire (OLBPDQ)], Ronald Morris Disability Score (RMDS) [after application of Ronald Morris Disability Questionnaire (RMDQ)] and Modified Macnab method.

[Table 1]

IV. Results

Assessment with all three outcome measurement tools Oswestry Disability Index (ODI), Ronald Morris Disability Score (RMDS), Modified Mac Nab Method (MMnM) showed that at initial follow-up (2nd weeks) there was little difference in success among the two procedure groups of patients but gradually at the end of the study, i.e. after 3 months (2nd Follow up) & after 6 months (3rd & final follow up) the difference in success is significant between two groups of patients. At final follow up (at 6th Month) it is noticed that 25 patients (56%) in Group-A, 35 patients (78%) in Group-B shows successful result. So it can be stated that the overall success rate of ozone – oxygen mixture therapy is around 80% and the failure rate is 20%.

[**Table 2-5]**

V. Discussion

Analysis of the results revealed that at initial follow-up (2nd weeks) there was little difference in success among the two the procedure groups of patients but gradually at the end of the study, i.e. after 3 months (2nd Follow up) & after 6 months (3rd & final follow up) the difference in success is significant between two groups of patients.

At final follow up (at 6th Month) it is noticed that 25 patients (56%) in Group-A, 35 patients (78%) in Group-B shows successful result.

So it can be stated that the overall success rate of ozone –oxygen mixture therapy is around 80% and the failure rate is 20%. Retrospective analysis of failure cases discloses the fact that those failures are mostly related to calcified herniated disc, patients having spinal canal stenosis & recurrent herniated disc with epidural fibrosis as found after detailed review of the MRI findings of those patients

VI. Conclusion

Intradiscal & Intraforaminal Injection of Oxygen-Ozone mixture (Ozone Chemonucleolysis) alone is a better procedure in management of pain in radiculopathy in contained lumber disc Prolapse than Injection Steroid (Methyl Prednisolone) with local anesthetics in this study as a long term benefit (after 6 months). Moreover it is a low cost with highly effective & simple method. The only potential limitation of this study is small number of patient taken in this study.

References

[1]. Deyo RA, Weinsteit JN. Low back pain. N Engl J med 2001; 344:363-370.
[2]. Gallucci M,Limbucci N, Jugaro L et. al. RSNA 2007;242:907-913.
[3]. Long MD. Dcision making in lumber disc disease. Clinical Neurosurg 1991; 39:36-51.
[4]. Muto M, De Maria G, Izzo R, Fucci G, Aprile I, Non Discal lumber radiculopathy combined diagnostic approach by CT and MRI. Rivista De Neuroradiologia 1997; 10:165-173.
[5]. Bozzao A, Gallucci M, Masciocchi C, Aprile I, Barile A, Passariello R. Lumbar disk herniation: MR imaging assessment of natural history in patients treated without surgery. Radiology 1992; 185:135–141.
[6]. Bush K, Cowan N, Katz DE, Gishen P. The natural history of sciatica associated with disc pathology: a prospective study with clinical and independent radiologic follow-up. Spine 1992; 17:1205–1212.
[7]. Delauche-Cavallier MC, Budet C, Laredo JD, et al. Lumbar disc herniation: computed tomography scan changes after conservative treatment of nerve root compression. Spine 1992; 17:927–933.
[8]. Gallucci M, Bozzao A, Orlandi B, Manetta R, Brughitta G, Lupattelli L. Does postcontrast MR enhancement in lumbar disk herniation have prognostic value? J Comput Assist Tomogr 1995; 19:34–38.
[9]. Splendiani A, Puglielli E, De Amicis R, Barile A, Masciocchi C, Gallucci M. Spontaneous resolution of lumbar disk herniation: predictive signs for prognostic evaluation. Neuroradiology 2004; 46:916–922.
[10]. Spaziante R. La terapia chirurgica nel conflitto disco-radicolare. Riv Neuroradiol 1997; 10:545–550.
[11]. Osborn AG. Nonneoplastic disorders of the spine and spinal cord. In: Diagnostic neuroradiology. St Louis, Mo: Mosby, 1994; 820–875.
[12]. D'Erme M, Scarchilli A, Artale AM, Pasquali Lasagni M. Ozonetherapy in lumbar sciatic pain [in Italian]. Radiol Med (Torino) 1998;95:21–24.
[13]. Andreula CF, Simonetti L, De Santis F, Agati R, Ricci R, Leonardi M. Minimally invasive oxygen-ozone therapy for lumbar disk herniation. AJNR Am J Neuroradiol 2003; 24:996–1000.
[14]. Muto M, Andreula C, Leonardi M. Treatment of herniated lumbar disc by intradiscal and intraforaminal oxygen-ozone (O2–O3) injection. J Neuroradiol 2004; 31:183–189.

[15]. Muto M, Avella F. Percutaneous treatment of herniated lumbar disc by intradiscal oxygen-ozone injection. Intervent Neuroradiol 1998; 4:279–286.
[16]. Paradiso R, Alexandre A. The different outcomes of patients with disc herniation treated either by microdiscectomy, or by intradiscal ozone injection. Acta Neurochir Suppl 2005; 92:139–142.
[17]. He Qing,Du Feng, Li Tao, Luo Hui, L. Xiao Fang L. Dong—Report on 602 Cases of percutaneous ozone puncture Chemonucleolysis treating lumber disc potrusion; rivista italiana di ossigeno-Ozonoterapia 4;145-148;2005.
[18]. Cosma F. Andreula, L Simonetti[a], Fde Santis, R Agati, R Ricci & M Leonardi[:] Minimally Invasive oxygen-Ozone therapy for lumber Disc Herniation: AJNR Am Neuroradiol 24; 996-1000 May 2003.
[19]. Crock HV. Observation on the management of failed spinal operations. *J Bone Joint Surg Br*1976; 58 :193 –199 .
[20]. Greenwood J, McGuire TH, Kimbell F. A study of the causes of failure in the herniated intervertebral disc operation: an analysis of 67 reoperated cases. *J Neurosurg*1952; 9: 15 –20[
[21]. Law JD, Lehman RW, Kirsc WM. Reoperation after lumbar intervertebral disc surgery. *J Neurosurg*1978; 48 :259 –263.
[22]. Matsui H, Terahata N, Tsuji H. Familial predisposition and clustering for juvenile lumbar disc herniation. *Spine*1992; 17: 1323 – 1328.
[23]. Pheasant HC. Sources of failure in laminectomies. *Orthop Clin North Am*1975; 6: 319 –329.
[24]. Spaziante R. La terapia chirurgica nel conflitto disco-radicolare. *Riv Neuroradiol*1997; 10: 545 –550.
[25]. Muto M, Avella F. Percutaneous treatment of herniated lumbardisc by intradiscal oxygen-ozone injection. *Intervent Neuroradiol*1998; 4: 279 –286.
[26]. Iliakis E. Ozone treatment in low back pain. *Orthopaedics*1995; 1: 29 –33
[27]. M.Muto, G. Ambrosanio et al; Low back pain & Sciatica: treatment with intradiscal-intraforaminal O_2-O_3 injection .Our experience: musculo-skeletal *Radiology: Radiol* (Med (2008)113:695-706.
[28]. G. K. Talu. MD, R, Derby. MD.AGRI; 20:2; 2008.
[29]. J.M. Cuckler. M.D. P.A. Bernini. M.D. S.W. Wiesel. M. D. et al: The Use of Epidural Steroid in Lumber Radicular Pain: The Journal of Bone &Joint Surgery: 67A:1: January 1985.

Picture 1-5: Procedure under Fluoroscopic Guidance

Picture-1 Picture-2 Picture-3 Picture-4 Picture-5

Picture 6-8: Fluoroscopic images

Picture-6 Picture-7 Picture-8

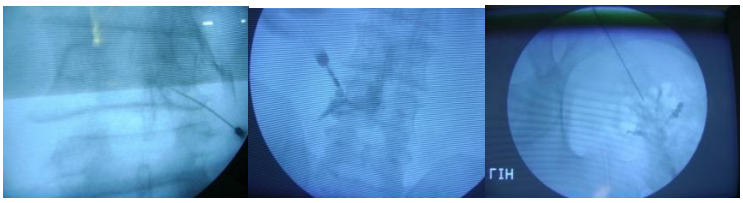

Table 1: Assessment tools & marker of success & failure

MARKER	***TOOL***	**ODI**	**RMDS**	**MODIFIED MACNAB**
SUCCESS		≤ 20	0-6	EXCELLENT / GOOD / FAIR
FAILURE		>20	>6	MEDIOCRE / NO RESULT /BAD

Table 2: OSWESTRY DISABILITY INDEX (ODI)

	GROUP-A (n) / %				**GROUP-B (N) / %**			
Minimum Disability (0-20%)	**Day-0**	**2nd Week**	**3-Month**	**6-Month**	**Day-0**	**2nd Week**	**3-Month**	**6-Month**
Moderate Disability (21-40%)	00 (0%)	32 (69.6%)	34 (73.9 %)	36 (78.3%)	00 (0%)	31 (67.5%)	30 (65.3%)	26 (56.5%)
Severea Disability (41-60%)	06 (13%)	06 (13%)	05 (10.9%)	07 (15.2%)	05 (10.9%)	06 (13%)	05 (10.9%)	09 (19.6%)
Crippled (61-80%)	16 (34.8%)	02 (4.3%)	03 (6.5 %)	02 (4.3%)	17 (37%)	03 (6.5%)	06 (13%)	05 (10.9%)
Bed Ridden /EXAGERATION (81-100%)	18 (39.1%)	03 (6.5%)	02 (4.3 %)	01 (2.2%)	19 (41.3%)	02 (4.3%)	03 (6.5%)	02 (4.3%)
TOTAL	06 (13%)	03 (6.5%)	01 (2.2 %)	00 (0%)	05 (10.8%)	04 (8.7%)	02 (4.3%)	04 (8.7%)

N=Number of Patients

Table 3: Ronald Morris Disability Score (RMDS)

	GROUP-A (n)				GROUP-B (N)			
	Day-0	**2nd Week**	**3-Month**	**6-Month**	**Day-0**	**2nd Week**	**3-Month**	**6-Month**
Score 0-6	00 (0%)	33 (71.8 %)	36 (78.3%)	34 (73.9 %)	00 (0%)	30 (65.2%)	29 (63%)	25 (54.4%)
Score-7-12	06 (13%)	04 (8.7%)	05 (10.9%)	09 (19.6%)	07 (15.2%)	04 (8.7%)	05 (10.9%)	10 (21.7%)
Score13-18	18 (39.2%)	07 (15.2%)	03 (6.5%)	02 (4.3%)	19 (41.3%)	05 (10.9%)	07 (15.2%)	06 (13%)
score 19-24	22 (47.8%)	02 (4.3%)	02 (4.3%)	01 (2.2%)	20 (43.5%)	07 (15.2%)	05 (10.9%)	05 (10.9%)
total	46 (100%)	46 (100 %)	46 (100%)	46 (100 %)	46 (100%)	46 (100 %)	46 (100 %)	46 (100%)

N=Number of Patients

Table 4: Modified mac nab Method

		GROUP-A (Nr)			GROUP-B (N)		
		2nd Week	**3-Month**	**6-Month**	**2nd Week**	**3-Month**	**6-Month**
Success	**Excellent**	09 (19.6%)	09 (19.6%)	10 (21.7%)	06 (13%)	05 (10.9%)	05 (10.9%)
	Good	11 (23.9%)	14 (30.4%)	18 (39.2%)	09 (19.6%)	11 (23.9%)	12 (26%)
	Fair	14 (30.4%)	14 (30.4%)	09 (19.6%)	10 (21.8%)	10 (21.7%)	09 (19.6%)
Failure	**Mediocre**	05 (10.9%)	05 (10.9%)	04 (8.7%)	12 (26%)	09 (19.6%)	08 (17.4%)
	No Response	04 (8.7%)	03 (6.5%)	03 (6.5%)	04 (8.7%)	10 (21.7%)	11 (23.9%)
	Bad	03 (6.5%)	01 (2.2%)	02 (4.3%)	05 (10.9%)	01 (2.2%)	01(2.2%)
TOTAL		46 (100%)	46 (100%)	46 (100%)	46 (100%)	46 (100%)	46 (100%)

N=Number of Patients

Table 5: Analysis of Result of All Methods Together:

	Group-A						Group-B					
	2nd week		**3 Month**		**6-Month**		**2nd week**		**3 Month**		**6-Month**	
	S*	**F****	**S***	**F****	**S***	**F****	**S***	**F****	**S***	**F****	**S***	**F****
ODI***	32 (69.6 %)	14(30.3 %)	35(76 %)	11(23.9 %)	36(78.3 %)	10(21.7 %)	31(67.4 %)	15(32.6 %)	28(60.8 %)	18(39.2 %)	24(53.2 %)	22(47.8 %)
RMDS***	33 (71.7 %)	13(28.3 %)	36 (78.3 %)	10(21.7 %)	34(73.9 %)	12(26.1 %)	30(65.2 %)	16(34.8 %)	29(63 %)	17(37 %)	25(54.3 %)	21(45.7 %)
MMNM***	34 (73.9 %)	12(26.1 %)	37 (80.4 %)	09(19.6 %)	38(82.6 %)	08(17.4 %)	26(56.5 %)	20(43.5 %)	27(58.7 %)	19(41.3 %)	26(56.5 %)	20(43.5 %)
AVERAGE	33 (71.7 %)	13 (28.3%)	36 (78.3 %)	10 (21.7%)	36 (78.3%)	10 (21.7%)	29 (63 %)	17 (37%)	28 (60.9%)	18 (39.1%)	25 (54.3%)	21 (45.7%)

*S= Success, **F= Failure, ***ODI = Oswestry Disability Index, **** RMDS = Ronald Morris Disability Score, *****MMnM = Modified Mac Nab Method

Dr. Swapan Kumar Mishra. "Role of Oxygen-Ozone (O2 –O3) Therapy in Contained Lumbar Disc Prolapse: A Randomized Control Trial." IOSR Journal of Dental and Medical Sciences (IOSR-JDMS), vol. 18, no. 11, 2019, pp 64-68.