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COMPARATIVE STUDY ON OUTCOME ASSESSMENT IN MANAGEMENT OF LOW BACK PAIN WITH RADICULAR SYMPTOMS BETWEEN DIFFERENT INTERVENTIONAL APPROACHES

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ABSTRACT

BACKGROUND: Low back pain associated with lumbar disc herniation is appears to be the commonest symptom in the PMR OPD practice. Patients refractory to conservative treatments are the valid candidate for minimally invasive interventions after considering their other co-morbidities. Though Intraforaminal or caudal epidural Injection of steroid is practiced most commonly, but Ozone Chemodiscolysis or Chemonucleolysis has been suggested as an alternative due to its long term potential analgesic and anti-inflammatory effect without significant adverse effects.

OBJECTIVE: To assess prospectively and then compare the clinical effectiveness of Transformational / Intraforaminal injection of steroid with that of Intradiscal and Transforaminal /Intraforaminal use of O2-O3 mixture.

METHOD: This Prospective Study included 118 Patients, female 68 & Male 50, randomly assigned in 2(two) groups (Group-A & Group-B) with 59 patients in each group. Group-A received Intraforaminal/transformational Injection of methylprednisolone-40mg/ml along with Injection Hyaluronidase (1500 i.u.) & Anesthetic (Inj. Lignocaine-2%-2-3ml) whereas patients in Group-B received Intradiscal (3-4ml) mixture of Oxygen-Ozone at a concentration of 30 ugm/ml. Procedures were performed under fluoroscopic guidance. Assessment & Outcome measures at 2nd weeks, 3rd months and at the 3rd or final follow up at 6th month after the intervention were assessed by Oswestry Disability Index (ODI), Ronald Morris Disability Score (RMDS) and Modified Macnab method (MMNM).

RESULTS: All three measurement tools e.g. ODI, RMDS, MMNM showed statistically insignificant ($p>0.05$) difference in success between the two groups in first follow up. But Chi-square test has shown that the difference in success was statistically significant after 3rd month during 2nd Follow up ($p=0.03$ for ODI, $p=0.01$ for MMNM) & after 6th month during final follow up ($p=0.01$ for ODI, $p=0.00$ for MMNM), which indicates a statistically significant better outcome of patients in Group B compared to the patients of Group A.

CONCLUSION: Ozone Chemonucleolysis is a better procedure in management of pain in Radiculopathy in contained lumber disc prolapse than Steroid injection with added long term benefits without much adverse effects.

KEYWORDS : Ozone-oxygen Therapy, Low Back Pain, Interventional Study

INTRODUCTION:

Low Back Pain (LBP) with Radiculopathy, also termed as Sciatica Syndrome, is the most common pain presenting symptom in PMR Practice and with the experience of at least once in lifetime.[1, 2] Though several factors are responsible for such nerve root syndromes but commonly caused with disc disease. [1] Lumbar disc herniation and its symptoms has favourable outcome in majority cases with conservative management only. Study revealed that 70-80% patient shows clinical, radiological and anatomical resolution within 1 year with conservative treatment. [2] Therefore invasive management for LBP is reserved only for them, who failed to respond to conservative care. Surgical lumber discectomy considered to be the primary invasive procedure in most cases during earlier days. But subsequently with the advent of minimal invasive procedures surgery is less preferred, mostly due to the fact that 15-20% shows treatment failure after surgical discectomy and they presents with Failed Back Surgery Syndrome (FBSS)[2,3].

Other than Minimal Invasive Surgical Lumbar Discectomy a few minimally invasive procedures also able to relief the pain & other symptom in LBP with Sciatica Syndrome, and amongst them Intraforaminal or caudal epidural Injection of steroid (Inj.triamcenolone /methyl-Prednisolone) with or without inj. Hyaluronidase $\pm$ Inj. Anaesthetics (Lignocaine 2% usually) is most commonly practiced. [4] . But the fact is that, such Intraspinal use of long acting steroid is responsible for precipitation of tubercular meningitis, adhesive arachnoiditis, aseptic meningitis, sclerosing spinal pachymeningitis & hypercortisolism.[4]. Moreover diabetic individuals are not considered to be suitable for use of Intraspinal steroid.

Therefore to overcome all these limitations and also to offer relief from pain and other related symptoms in cases with lumbar disk herniation, method like Oxygen-Ozone Chemodiscolysis or Chemonucleolysis is considered as a better option and that gets much success in current day's pain practice. [3,5,6] Here pain is relieved by percutaneous Intradiscal Oxygen-Ozone (O_2-O_3) injection (Termed as "Ozone Chemonucleolysis") along with percutaneous Intraforaminal injection of (Periganglionic & Periarticular) 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 and "Chemonucleolysis" or" Chemodiscolysis" is a process by which there is digestion & degradation of nucleus pulposus by

means of a chemical reaction which typically results from interaction with a substance introduced in to the intervertebral disc percutaneously. The results of such procedures were tested in several large clinical trials with findings of them found to be positive both clinically and Neuro-radiologically in patients with LBP in 70%–80% situations [2,7].

AIMS & OBJECTIVES:

Our main objective of this study is to assess prospectively and then compare the clinical effectiveness of commonly practiced Transformational / Intraforaminal injection of steroid (injection Methylprednisolone-40mg with injection Hyaluronidase (1500 i.u.) & Lignocaine 2%-2-3ml) with the Intradiscal (3-4ml) and Transforaminal /Intraforaminal (6-8 ml) Oxygen-Ozone mixture (concentration of ozone 30ugm/ml in oxygen).

MATERIALS & METHODS:

This Prospective Study was conducted at Pain Clinic, Department of Physical Medicine & Rehabilitation. Malda Medical College from January 2013 to December 2013. After receiving necessary approval from the Institutional Ethical Committee, Informed consent was taken from all patients prior to the study. All pre-procedure investigation relating to VCTC was done for all patients.

During inclusion of the patients for the study, only those patients were considered, who presents with LBP with Oswestry Disability Index (ODI)≥30%, Ronald Morris Disability Score (RMDS) > 6 and those who fulfilled the Neurological & Radiological (contained lumber disc herniation) criteria.But all those patients having extruded hernia, free disc segments, hypoesthesia, significant paresthesia, conus cauda syndrome, hyperalgesic-paralysing sciatica, or having any neurological impairment and any degree of muscle weakness, or those who has disturbance in Bladder & Bowel Function or with pregnancy and finally shows allergy to proposed materials used for the intervention were excluded from the study. Along with this patients with sacroiliitis & bony lesions (e.g. infective, inflammatory & neoplastic) and patients with co-morbidities like hypertension, diabetes mellitus & coagulation disorder were also been excluded from the study. In this study total 118 Patients, age ranging from 32 years to 52 years, female 68 & Male 50, were finally approved to be included for the study then all of them were randomly assigned in 2(two) groups (Group-A & Group-B) with 59 patients in each group. Patients under Group-A of Study received the commonly practiced Intraforaminal/transformational Injection of methylprednisol one-40mg/ml along with Injection Hyaluronidase (1500 i.u.) & Anesthetic (Inj. Lignocaine-2%-2-3ml) where as patients in Group-B received Intradiscal (3-4ml) mixture of Oxygen-Ozone at a concentration of 30 ugm/ml. In both situations fluoroscopic guidance was used. Mean surgical time was 27 minutes (18 to 33 minutes). Both were done as day care procedure & at the end of the procedure an average 3 hours of rest at recovery room were provided under supine position to all patients. During discharge after rest all patients were advised to avoid strenuous activity for next 5 days followed by they were allowed to resume movement & other normal activities gradually subject to no problem occurred meanwhile.

[Picture-1-5-Described the details of the procedure-See Below]

Picture 1-5: Procedure under Fluoroscopic Guidance For assessment of outcome, a total of 3(three) follow-up visits (at 3rd Week, at 4th Month & at 8th month) after the injection procedure day was done for both the groups. Assessment & Outcome measures at 3rd weeks, 4th months and final follow up at the 8th month after the intervention were assessed by Oswestry Disability Index (ODI) by use of Oswestry Low Back Pain Disability Questionnaire (OLBPDQ), Ronald Morris Disability Score (RMDS) by use of Ronald Morris Disability Questionnaire (RMDQ) and Modified Macnab method (MMNM).

[Table 1-(Below) shows the list of assessment Tools used with methods to measure success & failure of procedure in study]

MARKER	TOOL	ODI	RMDS	MODIFIED MACNAB
Success		< 30	0-6	Excellent / Good / Fair
Failure		>30	>6	Mediocre / No Result /bad

RESULTS:

Assessment of outcome was measured by the use of all three measurement tools e.g. Oswestry Disability Index (ODI), Ronald Morris Disability Score (RMDS), Modified Mac Nab Method (MMNM) and chi-square test showed that at initial follow-up on 2nd weeks after the procedures, there was little difference in success between the two groups of patients which was statistically insignificant (p>0.05) but gradually at the end of the study, i.e. after 3rd months during 2nd Follow up (p=0.03 for ODI, p=0.01 for MMNM) & after 6th months during 3rd & final follow up it was observed that the improvement of patients in Group B was statistically significant compared to Group A(p=0.01 for ODI, p=0.00 for MMNM in final follow up).

[Table 2-5 (Below) describes different assessment results of the study]

Table 2-Distribution of Study Subjects according to Modified Mac Nab Method N=Number of Patients

		GROUP-A (n)			GROUP-B (N)		
		3rd Week	4-Month	8-Month	3rd Week	4-Month	8-Month
Success	Excellent	09(15.25%)	10(16.95)	10(16.95)	12(20.34%)	15(25.42%)	18(30.51%)
	Good	11(18.64%)	12(20.34%)	13(22.03)	15(25.42%)	20(33.90%)	25(42.37%)
	Fair	20(33.90%)	15(25.42%)	16(27.12%)	20(33.90%)	15(25.42%)	13(22.03)
Failure	Mediocre	10(16.95)	10(16.95)	09(15.25%)	08(13.56%)	05(8.47%)	01(1.69%)
	No Response	05(8.47%)	06(10.17%)	05(8.47%)	02(3.39%)	02(3.39%)	01(1.69%)
	Bad	04(6.78%	06(10.17%)	06(10.17%)	02(3.39%)	02(3.39%)	01(1.69%)
Total		59(100%)	59(100%)	59(100%)	59(100%)	59(100%)	59(100%)

Table 3- Study objects has been distributed as per Ronald Morris Disability Score (RMDS) N=Number of Patients

	GROUP-A (n)				GROUP-B (N)			
	Day-0	3rd Week	4-Month	8-Month	Day-0	3rd Week	4-Month	8-Month
Score 0-6	00(0%)	43(72.88)	46(77.97%)	42(71.19%)	00(0%)	47(79.66%)	47(79.66%)	49(83.05%)
Score-7-12	11(18.64%)	08(13.56%)	06(10.17%)	10(16.95)	12(20.34%)	04(6.78%)	06(10.17%)	06(10.17%)
Score13-18	28(47.46%)	05(8.47%)	04(6.78%)	04(6.78%)	30(50.85%)	02(3.39%)	04(6.78%)	02(3.39%)
Score 19-24	20(33.90%)	03(5.08%)	03(5.08%)	03(5.08%)	17(28.81%)	06(10.17%)	02(3.39%)	02(3.39%)
total	59(100%)	59(100%)	59(100%)	59(100%)	59(100%)	59(100%)	59(100%)	59(100%)

Table 4- Distribution of Study records on Oswestry Disability Index (ODI)

	GROUP-A (n) / %				GROUP-B (N) / %			
	Day-0	3rd Week	4-Month	8-Month	Day-0	3rd Week	4-Month	8-Month
Minimum Disability (0-20%)	01(1.69%)	44(74.58%)	35(59.32%)	33(55.9%)	02(3.39%)	44(74.58%)	47(79.66%)	48(81.36%)
Moderate Disability (21-40%)	11(18.64%)	05(8.47%)	12(20.34%)	14(23.73%)	13(22.03%)	07(11.86%)	06(10.17%)	07(11.86%)
Severe Disability (41-60%)	18(30.50%)	03(5.08%)	08(13.56%)	07(11.86%)	27(45.76%)	03(5.08%)	03(5.08%)	02(3.39%)
Crippled (61-80%)	20(33.90%)	03(5.08%)	02(3.39%)	03(5.08%)	13(22.03)	03(5.08%)	02(3.39%)	01(1.69%)
Bed Ridden / Exaggeration (81-100%)	09(15.25%)	04(6.78%)	02(3.39%)	02(3.39%)	04(6.78%	02(3.39%)	01(1.69%)	01(1.69%)
TOTAL	59(100%)	59(100%)	59(100%)	59(100%)	59(100%)	59(100%)	59(100%)	59(100%)

N=Number of Patients

Table 5-Description of result in Chi-Square Test analyzing all methods together:

Method Of Assessment	Out Come	3rd Weeks		X^2 Value, P-value	4 Months		X^2 Value, P-value	8 Months		X^2 Value, P-value
		GROUP -A NUMBER (%)	GROUP B NUMBER (%)		GROUP A NUMBER (%)	GROUP B NUMBER (%)		GROUP-A NUMBER (%)	GROUP B NUMBER (%)	
ODI	SUCCESS	44 (74.58%)	44 (74.58%)	0, 1.0	35 (59.32%)	**47 (79.66%)**	**4.84, 0.03***	33 (55.93%)	**48 (81.36%)**	**7.72, 0.01***
	FAILURE	15 (25.42%)	15 (25.42%)		24 (40.68%)	12 (20.34%)		26 (44.07%)	11 (18.64%)	
	TOTAL	59	59		59	59		59	59	
RMDS	SUCCESS	43 (72.88%)	47 (79.66%)	0.42, 0.52	46 (77.97%)	47 (79.66%)	0, 1.0	42 (71.18%)	49 (83.05%)	1.73, 0.19
	FAILURE	16 (27.12%)	12 (20.34%)		13 (22.03%)	12 (20.34%)		17 (28.81%)	10 (16.95%)	
	TOTAL	59	59		59	59		59	59	
MMNM	SUCCESS	40 (67.80%)	47 (79.66%)	1.58, 0.21	37 (62.71%)	**50 (84.74%)**	**6.30, 0.01***	39 (66.10%)	**56 (94.92%)**	**13.83, 0.00***
	FAILURE	19 (32.20%)	12 (20.34%)		22 (37.29%)	09 (15.25%)		20 (33.90%)	03 (5.08%)	
	TOTAL	59	59		59	59		59	59	

ODI = Oswestry Disability Index, * RMDS = Ronald Morris Disability Score, *****MMNM = Modified Mac Nab Method,

DISCUSSION:

All the percutaneous Intradiscal minimally procedures were only indicated in selected LBP patients when conservative managements fail to provide satisfactory improvements. Among them Intraforaminal or caudal epidural Injection of steroid (Inj. triamcinolone/methyl-Prednisolone) is most commonly practiced [8-10], but the benefits appear to be short lived[11,12]. As a result O_2 -O_3 gas mixture was introduced in managing these patients (Ozone Chemodiscolysis or Chemonucleolysis). The O_2-O_3 gas mixture injected proximal to the root ganglion is thought to normalize the levels of cytokines and prostaglandins, increase superoxide dismutase levels, minimize reactive oxidant species, and improve local Periganglionic circulation with a eutrophic effect on the nerve root resulting in both short and long term benefits in radiating LBP patients. [8,13]

Till date very few studies were done to compare the efficacy of these two procedures and in some of them outcomes were contradictory. Gallucci et al. in 2007 concluded that Ozone Chemonucleolysis has better long term beneficial effects.[2] Bonetti et al. in 2005 also suggested administration of ozone as the first choice to replace epidural steroid to avoid surgery.[14]

In our study, it has been revealed that at initial follow-up on 3rd weeks after the procedure, the difference in success between the two groups of patients are less but gradually towards the end of the study, i.e. during 2nd and 3rd (Final) follow up, the difference in success is significant between two groups of patients. Chi-square test has shown that the difference in success between the two groups of patients was statistically insignificant ($p>0.05$) in 3rd week, but after 4th month during 2nd Follow up ($p=0.03$ for ODI, $p=0.01$ for MMNM) & after 8th month during 3rd & final follow up ($p=0.01$ for ODI, $p=0.00$ for MMNM) it has been observed that the better outcome of patients in Group B is statistically significant compared to Group A. Effectiveness of Percutaneous ozone nucleolysis for lumbar disc herniation is also supported by some recent studies by Bhatia A et.al.2019, Ezeldin M et.al.2018, Bonetti M et.al.2016, Giurazza F et.al.2017.[15-18]

From our study, it can be clearly stated that the overall success rate of ozone –oxygen mixture therapy in Group B was definitely better and long lasting compared to the intervention with steroid in Group A patients. The only potential limitation of this study is small number of patients taken in this study.

CONCLUSION:

It can be concluded from our study that, the Intradiscal & Intraforaminal Injection of Oxygen-Ozone mixture (Ozone Chemonucleolysis) alone is a better procedure in long term management of Radicular pain in contained lumber disc Prolapse than Injection Steroid (Methyl Prednisolone) with local anesthetics. Moreover it is a low cost with highly effective & simple method without significant adverse effects.

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