Original Article

Efficacy of intradiscal ozone gas therapy combined with physical therapy in contained lumber disc prolapse

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Abstract

Percutaneous intra-discal ozone therapy has promising results in contained lumber disc prolapse but the effectiveness of this treatment has been tested in large clinical studies show a positive outcome in 70%–80% of patients. To increase success rate of ozone discectomy and prevention of disc surgery, intradiscal ozone therapy combined with physical therapy may bring new options for the management of low back pain (LBP) due to lumber disc prolpase. This prospective experimental study was done from August 2014 to Octber 2014 at the Popular Medical College Hospital, Dhanmondi, Dhaka, Bangladesh with the intention to assess the efficacy of percutaneous intra-discal ozone therapy combined with physical therapy in acute and chronic low back pain due to contained prolapsed intervertebral lumber disc (PLID). Seven (7) ml of oxygen-ozone mixture at a concentration of 30 mc/ml was injected in the disc by ozone resistant syringe over a period of 15-20 seconds. All patients got physiotherapy for 30 minutes, two times/day, up to two weeks and strictly maintained activities of daily living (ADL). The main outcome variable was VAS(Visual Analogue Scale) & ODI (Oswestry Disability Index). 100% patient experienced radiation of pain in the leg before ozone gas & physical therapy and 90% had relieved radiation till 4th week. The reduction of VAS score from baseline to four weeks following treatment was 8.0±1.63 to 0.30±0.95. Reduction of Oswestry Disability Index (ODI) from baseline to four weeks following treatment was 37.7±6.5 to 15.8±1.0. Percutaneous intra-discal ozone therapy in combination with physical therapy is an effective treatment for management of low back pain (LBP) due to contained lumber disc prolpase.

Key words: Lumber disc prolapse, ozone, physical therapy

Introduction

The sciatalgia is one of the main reasons for medical consultation worldwide. One of the most common causes of sciatalgia is the intervertebral disc prolapse. Chemonucleolysis using chymopapain was the first intradiscal therapy done in human in 1963.[1] Subsequently some other percutaneous therapeutic options evolved. Many common minimally invasive treatments such as percutaneous lumbar discectomy[1], laser discectomy[2], percutaneous plasma disc decompression (i.e. nucleoplasty)[3], intradiscal electrothermal therapy[4] and percutaneous intradiscal radiofrequency thermocoagulation[5] rely upon the removal of disc material to reduce pressure on the nerve root. The proposed mechanism of action for each of these procedures is that a small change in volume produces a large change in pressure.[6] Oxygen/ozone treatment is a minimally invasive injection for the treatment of disc herniations that is widely practised in Europe and Asia.[6] Intradiscal injection of ozone was first reported in the 1990s by Muto and Avella[7]. Ozone nucleolysis by intradiscal injection under CT guidance was first suggested by Muto et al in 1998. Intradiscal oxygen/ozone (O2/O3) gas therapy is a good alternative to surgical treatment for lumbar disc herniation for patients with a successful percentage of 70-80% without complications.[8]

The intervertebral discs occupy one third of the height of the spinal column and consist of an outer annulus fibrosus and inner nucleus pulposus. The nucleus pulposus is sandwiched inferiorly and superiorly by cartilage endplates. In childhood the annulus fibrosus is separated from the nucleus pulposus by a transitional zone. In the growing phase during skeletal maturation the boundary between annulus and nucleus becomes less obvious. The nucleus pulposus is a ball of transparent jelly which consists of collagenous fibres, cells

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and mucopolysaccharides. Disc prolapse results from herniation of soft disc material from the nucleus pulposus through a tear in the annular ligament. Pain and inflammation develop from the pressure of the herniated material on the posterior longitudinal ligament and the dura mater, which may ultimately affect the nerve roots. About 90% of patients respond to medical treatment including analgesics and physiotherapy. The remaining 10% require decompression of nerve roots either by surgery or some percutaneous intradiscal procedure. The action of ozone is due to the active oxygen atom released by the breakdown of the ozone molecule. This active oxygen atom or singlet oxygen is attached to the proteoglycan bridges of the nucleus pulposus. Due to this reaction proteoglycans in the nucleus pulposus is no longer able to hold water and there is shrinkage or mummification of the disc leading to decompression of nerve roots.[9] Besides, analgesic and anti-inflammatory effects of ozone may counteract disc induced pain. [10]

Based on this theory of ozone nucleolysis we conducted this study to evaluate the effects of percutaneous intra-discal oxygen/ozon therapy in combination with physical therapy in acute and chronic low back pain due to contained prolapsed intervertebral lumbar disc (PLID) with a view to relieve pain and reduce disability. To our knowledge/review no such experimental study has been undertaken among the Bangladesh population.

Methods

This prospective experimental study was carried out between August 2014 and October 2014 with a follow-up period fixed at intervals of one day, one week, two weeks & four weeks at the Popular Medical College Hospital, Dhanmondi, Dhaka, Bangladesh. Ten consecutive adult patients with low back pain due to lumber disc prolapse were included in this study. Clinical diagnosis was established by physical examination and was supported by magnetic resonance imaging (MRI).

All patients were referred or self-directed after failure to respond to conservative therapy or refusal or non-feasibility of surgical intervention. So we included all the patients available during the recruitment period of three months. The inclusion criteria were: age- 20-70 years, acute (<12 week) or chronic (>12 week) low back pain with radiation to one or both side, previous history of taking any conservative treatment, patient having MRI images with contained lumber disc prolapse, patients who agreed to be admitted in hospital for one week after procedure for physiotherapy and learning ADL. The exclusion criteria were: age less than 20 and more than 70, progressive neurological deficit, uncontrolled diabetes, uncontrolled hypertension, pregnancy, past medical history of carcinoma, tuberculosis, osteoporosis, major trauma, uncontained lumbar disc prolapse, presence of bleeding disorder, local infection and previous treatment with surgery or ozone therapy. Informed consent was obtained from all the patients.

The procedure was performed under fluoroscopic guidance by C-arm. The C-arm was first focused to an antero-posterior view for identification of the diseased disc centralization). Then the C-arm was angled cranially or caudally to olish any double end-plates and to achieve the widest possible view of the disc space (penalization). Then the C-arm was rotated obliquely so that the image of the facet joint appeared at the centre of the end plates. At this stage needle entry point was just lateral to the superior articular process, which corresponds to the centre of the disc. The needle puncture site was identified and marked on the skin. After antiseptic dressing and draping, the proposed site was infiltrated with local anaesthetic agent. A 23 gauge 12 cm long needle was introduced through paravertebral approach into the affected disc using the tunnel view under fluoroscopic guidance. The position of the needle was confirmed by AP and lateral view of the spine and 7 ml of oxygen-ozone mixture at a concentration of 30 mc/ml was injected in the disc by ozone resistant syringe over a period of 15-20 seconds (Figure- 1). At the end of the procedure, patients were advised to rest in supine position for at least two hours. There were no complications such as systemic hypotension, bradycardia, vagal shock, meningeal irritation or neurological deficit observed in this series. All patients were admitted in hospital received physiotherapy (transcutaneous electric nerve stimulation - TENS over lumbar spine for 15 minutes and intermittent pelvic traction considering 1/4th to 1/5th of body weight for 15 minutes) twelve hourly and strictly maintained ADL, discharged after 7 days and were advised to gradually resume motor activity with continuation of outdoor physical therapy once a day for two weeks. All patients underwent follow-up examination at second day, one week, second weeks and four weeks after the procedure. Pain intensity was assessed by 0-10 points visual analog scale (VAS) and Oswestry Disability Index (ODI)[11] was used to assess functional impairment. Consecutive sampling technique was adopted and total 10 samples were taken. Data was collected by trained personal from a preformed questionnaire. Data was processed, edited and analyzed by SPSS windows version 20. A p value of < 0.05 was considered statistically significant at 95% confidence Interval.

Results

Among the study population (n=10), the mean age was 42.00±14.01 (standard deviation) and the age range was 22

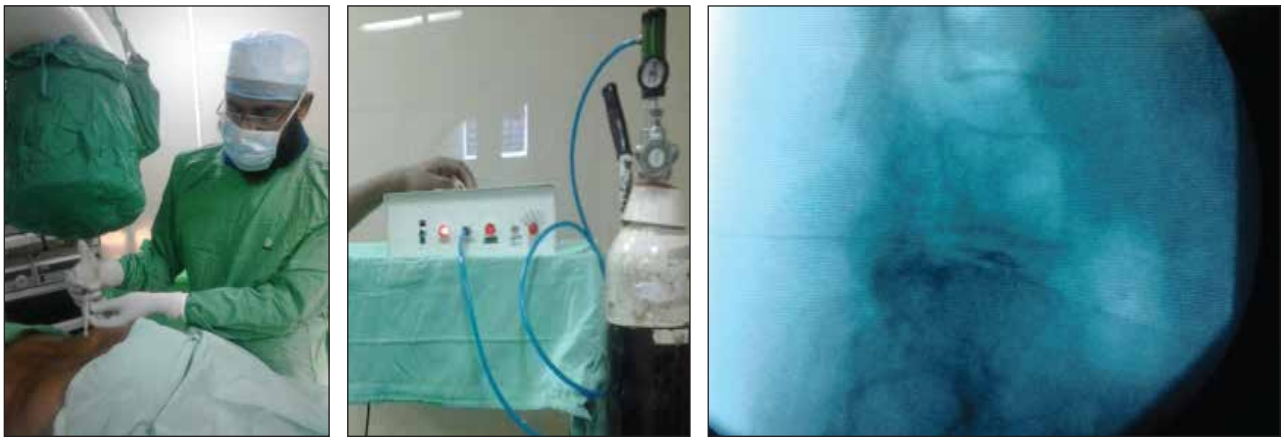

Figure- 1 : *Ozone gas therapy & fluroscopic view during the procedure*

years to 68 years. 40% was male, 60% was female and male: female ratio was 2:3, 50% was housewife, 20% was businessmen, 10% was student, 10% was labour and 10% was sedentary worker in private job. Among them, 40% was using high commode and 60% was using low commode. 60% had within 12 (twelve) weeks, 40% had more than 12 weeks of pain, 50% had left sided radiation, 30% had right sided radiation and 20% had bilateral radiation. The mean duration of pain was 17.90±15.89 weeks. Regarding imaging, Magnetic Resonance Imaging (MRI) showed 80% had disc prolapsed at L4/5 level and 20% had at L5/S1 level. In all MRI showed contained, central & paracentral disc prolapse with compression of exiting nerve root at the same level. Regarding treatment history, 60% patients had previous experiences some physiotherapy like deep heat modalities, pelvic traction, exercises with medicine and 40% had only medicine.

All the patients experienced radiation in the leg before ozone & physical therapy and 90% got relief from radiation of pain after one day and radiation did not recur till last follow up (4 weeks). Around 90% patient had moderate (grade-3) tenderness and 10% had severe (grade-4) tenderness over lumbar spine before therapy Within 4 weeks of therapy, 60% had no tenderness and 40% had mild (grade-1-2) tenderness. Before ozone & physical therapy, muscle power (MP) of extensor hallucis longus (EHL) was 4/5 in 80% patients and 20% had 5/5. After one day & one week of ozone & physical therapy, no further improvement was seen in MP of EHL but after two weeks, 60% enjoyed MP of EHL 4/5 and 40% enjoyed 5/5; after four weeks, 40% enjoyed MP of EHL 4/5 and 60% enjoyed 5/5. (Table-I)

Table- I: Comparison of variables before and after ozone therapy (n=10)

Variables	Before ozone therapy	After 1 day	After1 wk	After 2 wk	After 4 wk
Radiation					
Present	10 (100%)	1(10.0%)	0(10%)	0(10%)	1(10%)
Absent	0(0.0%)	9 (90.0%)	10(100.0%)	10(100.0%)	9(90.0%)
Tenderness over lumbar spine					
No tenderness	No tenderness	No tenderness	No tenderness	No tenderness	No tenderness
Mild (1-2)	Mild (1-2)	Mild (1-2)	Mild (1-2)	Mild (1-2)	Mild (1-2)
Moderate(3)	Moderate(3)	Moderate(3)	Moderate(3)	Moderate(3)	Moderate(3)
Severe(4)	Severe(4)	Severe(4)	Severe(4)	Severe(4)	Severe(4)
MP of EHL					
4/5	8(80.0%)	8(80.0%)	8(80.0%)	6(60.0%)	4(40.0%)
5/5	2(20.0%)	2(20.0%)	2(20.0%)	4(40.0%)	6(60.0%)

MP-Muscle Power, EHL-Extensor hallucis Longus

Before ozone & physical therapy, 50% had straight leg raising test (SLR) of 20^0-30^0, 30% had SLR of 51^0-60^0, 10% had SLR of 31^0-40^0, 10% had SLR of 41^0-50^0 whereas after ozon & physical therapy, 90% had 71^0-80^0 and 10% had 81^0-90^0. The increase of SLR score from baseline at 1st day, one week, two weeks & four weeks following treatment was 38.1±15.6 to 66.2±10.3, 73.5±7.9, 77.6±5.0 and 76.4±3.9 respectably and P value was <0.001 which was statistically significant. (Table-II)

Among the study population, before ozone and physical therpay, 0% had visual analogue scale (VAS) score 8-10, 30% had VAS score 4-7 and mean±SD was 8.0±1.63. After one day of procedure, 20% had VAS score 4-7, 80% had 1-3 and mean±SD was 3.4±1.71. After one week of ozone and physical therapy, 10% had VAS 4-7, 90% had 1-3 and mean±SD was 2.90±1.9. After two weeks, 50% had VAS 1-3, 50% had no pain and mean±SD was 1.30±1.42. After four weeks, 10% had VAS 1-3, 90% had no pain and mean±SD was 0.30±0.95. Before ozone procedure, Oswestry Disability Index (ODI) [11] was 37.7±6.5. After one day of procedure, mean±SD was 28.4±3.5, after one week of ozon and physical therapy, mean±SD was 22.9±2.4, after two weeks, mean±SD was 19.0±1.4, and after four weeks, mean±SD was 15.8±1.0 and P value was <0.001 which was statistically significant. (table-III)

Table-II: Comparison of SLR before and after ozone therapy(n=10)

SLR (degree)	Before ozone therapy	After 1 day	After1 wk	After 2 wk	After 4 wk
20-30	5(50.0%)	0	0	0	0
31-40	1(10.0%)	0	0	0	0
41-50	1(10.0%)	0	0	0	0
51- 60	3(30.0%)	5(50.0%)	0	0	0
61-70		1(10.0%)	4(40.0%)	0	0
71-80		4(40.0%)	5(50.0%)	9(90.0%)	9(90.0%)
81-90		0	1(10.0%)	1(10.0%)	1(10.0%)
Mean ±SD	38.1±15.6	66.2±10.3	73.5±7.9	77.6±5.0	76.4±3.9
P value		<0.001*	<0.001*	<0.001*	<0.001

*SLR- Straight Leg Raising Test, *= significant, Data were analyzed by paired student t test

Table-3: Comparison of variables before and after ozone therapy(n=10)

Variables	Before ozone therapy	After 1 day	After 1wk	After 2 wk	After 4
VAS					
Mean ±SD	8.0±1.63	3.4±1.71	2.90±1.9	1.30±1.42	0.30±0.95
ODI					
Mean ±SD	37.7±6.5	28.4±3.5	22.9±2.4	19.0±1.4	15.8±1.0
P value		<0.001*	<0.001*	<0.001*	<0.001

*VAS-Visual Analogue Scale, ODI- Oswestry Disability Index, *= significant,
Data were analyzed by paired student t test

The reduction of ODI score from baseline with in four weeks was 37.7±6.5 to 15.8±1.0. The reduction of VAS score from baseline with in four weeks was 8.0±1.63 to 0.30±0.95. The p value was <0.001 which was statistically significant.

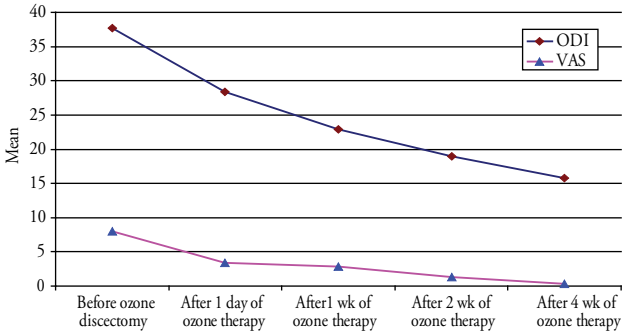

Figure-1: *Improvement of Pain and Functional outcome measured by VAS & ODI*

Discussion

The present study observed the mean age was 42.00±14.01 years ranging from 22 years to 68 years. 40% was male, 60% was female and male: female ratio was 2:3. G das et Al[12] found that Patients range of age was 21-65 (average 46.04) years which was closely resembles the present study. 50% were housewife, 20% was businessmen, 10% was student, 10% was labour and 10% was sedentary worker in private job. Among them, 40% was using high commode and 60% was using low commode. Most of the female were housewife and they had to do work in kitchen room with repeated squatting and also history of using low commode specially after low back pain.

Among the study population, 60% had pain within 12 (twelve) weeks and 40% had within 48 (fourty eight) weeks; 50% had left sided radiation, 30% had right sided radiation and 20% had bilateral radiation of pain towards lower limbs. The mean duration of pain was 17.90±15.89 weeks. Though most of the study population had pain less than 12 weeks, mean duration was high due to few patients with long duration of pain was included. Among the chronic LBP, 10% had acute on chronic low back pain, 30% had lumber canal stenosis due to disc prolapse. Whether it was acute or chronic, all were included in this study due to discogenic pain. Regarding imaging, Magnetic Resonance Imaging (MRI) showed 80% had disc prolapsed at L4/5 level and 20% had at L5/S1 level. In all MRI showed contained, central & para-central disc prolapse with compression of exiting nerve root at the same level. Most of the study showed effectiveness of ozone on prolapsed disc, few on sequestrated non-contained disc. Regarding treatment history, 60% patients had previous experiences some physiotherapy like deep heat modalities eg. Short Wave Diathermy or Ultrasound Therapy, pelvic traction, exercises with medicine and 40% had only medicine. It is very natural, with pain no patients will wait without treatment and we enrolled all patients irrespective of previous treatment except surgery.

All the patients (100%) experienced radiation in the leg before ozone and physical therapy and 90% had relieved radiation after one day and radiation will not recur in last follow up (4 week). This was probably due to analgesic effect of ozone as for volume shrinkage, it will take time. 90% patient had moderate (grade-3) tenderness and 10% had severe (grade-4) tenderness over lumbar spine before procedure and within 4 week; 60% had no tenderness and 40% had mild (grade1-2) tenderness.

Before ozone & physical therapy, 80% had muscle power of extensor hallucis longus (EHL)-4/5 and 20% had 5/5. After ozone & physical therapy, 60% enjoyed muscle power of EHL 5/5 and 40% enjoyed 4/5. Before ozone & physical therapy, 50% had SLR of 20^0-30^0, 30% had SLR of 510-60^0, 10% had SLR of 31^0-40^0, 10% had SLR of 41^0-50^0 and after ozone & physical therapy, 90% had 71^0-80^0 and 10% had 81^0-90^0. The increase of SLR score from baseline to four weeks following treatment was 38.1±15.6 to 76.4±3.9. Bonetti et Al also reported excellent results in 74.4% patients after six months.[13] Possibly, four weeks was not enough for recovery of EHL strength and there was a good chance of recovery of EHL in next few months as pain, tenderness, SLR-all modalities of LBP was improved and due to hospital admission and learning activities of daily living (ADL) or recurrence of disc prolapse.

Around 70% had visual analogue scale (VAS) score of 8-10 and 30% had VAS score of 4-7. After ozone & physical treatment, 90% patient enjoyed VAS score 0 after 4 weeks and only 10% patient had VAS-2. The reduction of VAS score from baseline with in four weeks following treatment was 8.0±1.63 to 0.30±0.95. G das et Al[12] found that the reduction of VAS score from baseline to three weeks following treatment was 7.58 ±86 to 2.75 ±1.42 which was similar to present study.

Oswestry disability index (ODI) showed a significant improvement in functional status of the patients. Reduction of ODI from baseline with in four weeks following treatment was 37.7±6.5 to 15.8±1.0. G das et Al[12] found that reduction of oswestry disability index from baseline to

three weeks following treatment was 27.26 ± 2.89 to 14.49±5.69 which was also similar to present study. Regarding physical findings, most of the parameters of LBP were recovered whereas mean ODI decline to 15.8±1.0 after four weeks indicate that patients need endurance and fitness training for further improvement of ODI scores. Besides, ODI score of 15.8±1.0 was explained as minimum disability.

Seven ml of oxygen-ozone mixture at a concentration of 30 mc/ml were injected into the disc. The mean concentration of ozone was 30.2 mc/ml in this series, which is absolutely safe for the patient. Viebahn reported that the nontoxic concentration of ozone varies from one to 40 microgram per milliliter of oxygen and concentration should not exceed 40 mc/ml.[13] The dose of ozone is crucial and must not exceed the capacity of antioxidant enzyme and glutathione to prevent accumulation of the superoxide anion and hydrogen peroxide, which can cause cell membrane degradation.[14,15] Ozone not only attenuates nerve root compression by reducing the size of the disc, it also helps to reduce venous stasis caused by compression of vessels and hence improves the microcirculation and supply of oxygen. This reduces pain associated with neuronal hypoxia. Ozone has analgesic as well as anti-inflammatory effects[16] as it inhibits synthesis of proinflammatory prostaglandins, release of bradykinins and algogenic compounds. Ozone increases the release of antagonists to proinflammatory cytokines.[16]

Ozone nucleolysis provides excellent pain relief within one day in most herniated disc patients who failed to respond to conservative therapy. The limitations of this study are lack of control and lack of blinding, very few number of patients and lack of MRI follow up due to high expense. Further study is necessary to evaluate the long-term outcome of ozone nucleolysis therapy. However, Percutaneous intra-discal ozon therapy in combination with physical therapy is an alternative options for interventional physiatrist.

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