COMPARATIVE STUDY OF OXYGEN OZONE THERAPY, PERCUTANEOUS RADIOFREQUENCY THERMOCOAGULATION AND THEIR COMBINED EFFECTS FOR THE TREATMENT OF LUMBAR DISC HERNIATION

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Submitted on : -15-06-2014 **Resubmitted on :-13-07-2014** **Accepted on:-14-08-2014**

ABSTRACT

Aim: To compare the efficacy of Oxygen-ozone therapy, Percutaneous radiofrequency thermo coagulation and their combined effects for the treatment of lumbar disc herniation. **Methods:** Ninety adult patients with low back pain secondary to contained lumbar disc herniation were randomly assigned into three groups. Ozone group (Group-O) received Intradiscal oxygen-ozone therapy (4 to 7 mL of oxygen ozone mixture); PIRFT group (Group-R) received percutaneous Intradiscal radiofrequency thermo coagulation at 80°C for 360 s and the third group(Group O +R) received the combination of the above two. Outcome **Measures:** Primary outcome measures included a visual analog scale (VAS) for pain and the Oswestry disability index (ODI). Secondary outcome measures included pain relief, reduction of analgesic consumption, and patient's satisfaction. Clinical assessment of these outcome measures was performed at 2 weeks, 1 month, 3 months, 6 months, and 1 year after the procedure. **Results:** VAS scores and ODI were significantly decreased by all the three groups when compared with their baseline values at all points of follow-up; however, Ozone-PIRFT group produced a significant reduction in the VAS scores and ODI when compared to ozone and PIRFT group at 2 weeks, 1 month, 3 months, 6 months, and 1 year follow-up. Ozone-PIRFT group also resulted in a significant change in all secondary measures at all points of follow-up, as compared with the ozone and PIRFT group. **Conclusion:** Intradiscal Ozone-PIRFT is more efficacious than ozone and PIRFT alone in reducing pain scores, analgesic consumption, improving functional outcome, and satisfaction of patients with contained lumbar disc herniation.

Key Words: low back pain, lumbar disc herniation, ozone, percutaneous intradiscal radiofrequency thermo coagulation

INTRODUCTION

Noninvasive procedures, minimally invasive percutaneous injections and surgery are the treatments available in the management of lumbar disc herniation. Noninvasive treatments are plainly the first choice in most cases but when patients fail to respond, minimally invasive percutaneous injections or surgery might be considered.[1]

Minimally invasive treatments are aimed to offer good clinical results combined with a well-tolerated, low-cost procedure. In recent years, these procedures were further boosted by a growing number of reports of 15–25% treatment failure rate after surgical discectomy, with failed back surgery syndrome in 15% of cases.[2-9]

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Intradiscal Oxygen-ozone therapy is one of the different minimally invasive treatments currently available for discogenic radiculopathy (low back pain with radiation to legs) owing to its better success rate, less invasiveness, few chances of recurrences and remarkably few side effects.[10-14] A reduction in herniated disk volume is the therapeutic aim of intradiscal administration of medical ozone, as disk shrinkage may reduce nerve root compression.[15] Other reasons for using medical ozone to treat disk herniation are its analgesic and anti-inflammatory effects.[16,17]

Percutaneous Intradiscal radiofrequency thermo coagulation (PIRFT) is an another minimally invasive option that utilizes heat produced by radiofrequency for the treatment of discogenic pain. We hypothesized that the combination of oxygen-ozone\ therapy with PIRFT should be more efficacious than oxygen-ozone therapy or PIRFT alone in improving the outcome in low back pain patients secondary to contained lumbar dis herniation.

The study was designed to compare the efficacy of oxygen-ozone therapy, PIRFT and their combined effects for the treatment of contained lumbar disc herniation.

MATERIAL AND METHODS

Ninety adult patients of both sexes undergoing lumbar discectomy for various indications were randomly and equally placed into three groups using intradiscal oxygen-ozone therapy (Group O), Intradiscal radiofrequency thermo coagulation therapy (Group R) and combination of the above two therapies (Group O+R). The ethics committee of our institution approved the study and an informed consent was obtained from the patient.

Selection criteria were the following. Inclusion criteria were lumbar radicular pain resistant to conservative management (physical therapy, strengthening, conditioning exercises, and education followed by periganglionic administration of steroid and lignocaine2% at herniated disc levels) for ≥ 3 months with MRI evidence of contained disc herniation in line with the patient's clinical symptoms and motivated patient with no psychological issues. Exclusion criteria included infection, spinal tumor or fracture, spondylolisthesis, more than 2 symptomatic levels, severe motor deficit, sphincter disturbance, disc extrusion, or sequestration or spinal stenosis on MRI, history of open disc surgery at suspected levels and history of uncontrolled medical diseases. Patient's characteristics are mentioned in table 1.

Randomization

Patients meeting the above-described criteria were randomly allocated into three groups by a research nurse with the help of a computer generated table of random numbers; the treatment allocation was sealed in an envelope. This envelope was opened by a staff nurse before the procedure; subsequently, the radiofrequency generator technician was instructed whether or not to apply current during PIRFT. During PIRFT, radiofrequency generator display console was turned away from the operating table so that no visual or auditory signals could be conveyed to the patient or the treating physician. At the end of PIRFT, when the radiofrequency cannula tip temperature decreased to 40°C, the radiofrequency generator technician informed the operator to remove the radiofrequency cannula. Thus, both the treating physician and patient remained blinded to the treatment allocation. The ozone group received intradiscal oxygen-ozone therapy alone, while ozone-PIRFT group received a combination of oxygen-ozone therapy with PIRFT. In ozone group, the radiofrequency cannula was placed inside the disc, but no current was applied by the radiofrequency generator technician. Oxygen-ozone injection was performed on the symptomatic side, while PIRFT was performed on the contralateral side. In cases with bilateral symptoms, oxygen ozone injection was done on the right side and PIRFT was performed on the left side to maintain procedural uniformity. The disc level to be treated was chosen on the basis of findings of neurological examination and correspondence between imaging and clinical findings.

Procedural Technique

All patients were admitted the morning of the procedure with 4 h of fasting; their coagulation profiles were confirmed to be normal. The procedure was performed under strict aseptic conditions, mild sedation (Midazolam 1-2 mg) and local anaesthesia; vital parameters including pulse rate, ECG, non-invasive blood pressure, and oxygen saturation were monitored during the procedure. Cefazolin 1 g was administered 30 min before the procedure. All the procedures were performed by two specialist pain physicians. Procedure was performed under fluoroscopic guidance with the patient lying in the prone position. A 22 G 15 cm spinal needle for oxygen-ozone injection on one side and 20 G 15 cm radiofrequency cannula (BMC, Montreal, QC) with 10-mm active tip for PIRFT on the other side were placed inside the disc using posterolateral oblique approach. Needle placement in the center of disc was confirmed using antero-posterior (Figure-1) and lateral fluoroscopic views. Confirmation of correct position of the radiofrequency needle was accomplished by stimulation at 2 and 50 Hz, which is not expected to give a response at less than 2 V. Thereafter, discography was performed with 0.5 mL non-ionic contrast material to evaluate annular integrity. Annular integrity was confirmed by observing that the contrast did not pass into the epidural space. Patients having annular tear with contrast spreading into the epidural space were terminated from the study. Discography was performed solely to evaluate annular integrity, and not to determine whether or not there was a concordant pain (Figure-2). After discography, 2 mL of 2% lidocaine was injected and PIRFT was performed at 80°C for 360 s. The tip temperature was monitored until it decreased to 40°C, then the cannula was withdrawn. After PIRFT, oxygen-ozone injection was performed with 4 to 7 mL of freshly prepared oxygen/ ozone mixture at an ozone concentration of around 30 mcg/mL..

Outcome MeasuresPrimary outcome measures included visual analog scale (VAS, 0 to 100 mm; 0 = no pain and 100 = worst imaginable pain) for pain, and Oswestry disability index (ODI) 18 for measuring functional outcome. Secondary outcome measures included percent of pain relief, reduction

of analgesic consumption and patient's satisfaction (very satisfied, satisfied, or unsatisfied). Reduction of 50% or more of the analgesic dose was considered to be significant; daily dosage of analgesics used by a patient was documented before the procedure. Patients who reported being very satisfied or satisfied were counted as satisfied patients. Clinical assessment of patients for these outcome measures was done before the procedure (baseline assessment), at 2 weeks, 1 month, 3 months, 6 months, and 1 year after the procedure by an independent investigator unaware of patient randomization.Statistical AnalysisThe method of analysis was decided prospectively and incorporated

the intention-to-treat principle. Demographic data were analysed with Students t-test for continuous variables, and chi-square test for categorical variables. The VAS pain scores and ODI were analysed with ANOVA; proportion of patients with more than 50% pain relief, proportion of patients with reduced analgesic consumption, and proportion of satisfied patients were analysed with Fisher's exact test. P < 0.05 was considered as significant.

At the end of procedure, patients were advised to rest in supine decubitus position for 2 hours. All patients were discharged on the same day of procedure. The practitioner must realize, and point out to the patient, that recovery would be gradual. Each patient was told that during the first 7 days after the procedure, he might experience a significant increase in pain and significant pain relief may take 8-12 weeks. On discharge, patients were instructed to gradually resume motor activity. All patients underwent follow-up examinations 2 weeks, 1, 3 and 6 months and 1 year after treatment.

RESULT

There were no significant differences among the groups with regard to demographic parameters and disc levels treated (P > 0.05) (Table-1). There were no complications associated with the procedure during the follow-up period. VAS scores and ODI were significantly decreased by all three groups Group O,Group R and Group O+R, when compared with their baseline values in the same group at all points of follow-up (Table-2). However, ozone-PIRFT produced a significant reduction in the VAS scores, and ODI when compared with ozone and PIRFT at 2 weeks (P=.033 for VAS and P=.048 for ODI); 1 month (P = 0.005 for VAS and P=.045 for ODI); 3 months (P = 0.001 for VAS and P=.049); 6 months (P = 0.042 for VAS and P=.018 for ODI);1 year(P=.027 for VAS and P=.022 for ODI). Ozone- PIRFT also resulted in a significant change in all secondary measures at all points of follow-up as compared with the ozone and PIRFT groups(P< .05) (Table 3).

DISCUSSION

The appropriate treatment of lumbar sciatica and disc herniation is a challenge, particularly because the concept of a disc hernia represents only a simplification of the problem. So many largely unknown or poorly understood factors are involved in the patho-physiology of this disease that the right treatment is very difficult to pinpoint; this is the main reason so many treatments are continuously proposed. In addition, many specialists are convinced that conservative treatment offers the same level of results, if checked at a late follow-up, with surgery being undertaken less frequently. In this setting, attention has focused on minimally invasive treatments. Minimally invasive procedures are usually a day care procedure and general anesthesia is not usually required. They are gaining popularity in different countries due to low cost, less hospital stay, less post-procedural discomfort & morbidity and very few side effects.

Ozone is one of the minimally invasive treatments which can improve the clinical outcomes of lumbar disc herniation. A reduction in herniated disc volume is one of the therapeutic motives for intradiscal administration of medical ozone, as a reduction in disc size may reduce nerve root compression.[14] Disc shrinkage may also help to reduce venous stasis caused by disc compression of vessels, thereby improving local microcirculation and increasing the supply of oxygen. This effect has a positive effect on pain as the nerve roots are sensitive to hypoxia. Another reason for using medical ozone to treat disc herniation is its analgesic and anti-inflammatory effects [17], which may counteract disc-induced pain.[19,20] This may be due to inhibition of synthesis of proinflammatory prostaglandins or release of bradykinin or release of algogenic compounds; increase release of antagonists or soluble receptors that are able to neutralize proinflammatory

Table-1 : Patient Demographics and Clinical Data

Groups	Ozone	PIRFT	OZ + PIRFT
Age (Yrs.)	43.5±9.9	441±9.1	45.1±9.4
Wt. (kg)	56.2±9.6	56.2±9.2	55.7±9.7
Sex (M/F)	18/12	17/15	19/11
Disc levels treated			
L4-5	7 (23%)	9 (30%)	6 (20%)
L5S1	10 (33%)	12 (40%)	11 (27%)
L3-4 & L4-5	4 (14%)	4 (14%)	6 (20%)
L4-5 & L5-S1	10 (30%)	5 (16%)	7 (23%)

Data are presented as \either mean values±SD or by absolute numbers

Table-2 : Primary Outcome Measures : VAS Scores and ODI Data are presented as or Mean Values±SD

	VAS Score			ODI		
Group Period of follow up	Ozon	PIRF	OZ + PIRFT	Ozon	PIRF	OZ + PIRFT
Baseline	72.7±10.1	72.±9.6	70.1±9.9	45.5±8.8	46±8.4	47.9±8.9
2 weeks	63.2±10.6	60±9.2	55.9±11.9	36.5±10.9	35.2±10.3	30.2±9.6
1mt	40.9±10.8	41.5±10.1	33.2±11.3	33.3±12.8	34.5±11.5	27.6±9.2
3mt	42.6±13.3	40.6±12.2	30.3v12.3	28.8±11.6	27.2±10.6	22.4±8.6
6mt	35.8±14.7	34±13.7	27.6±10.3	25.2±11.1	26.6±10.3	19.8±8.2
1 yr	33.1±12.9	32.0±12.1	25.2±11.2	25.5±11.3	24.2±11.1	18.6±7.2

P < 0.05 during comparison of different values with baseline in the same group.

P < 0.05 during intergroup comparison of ozone vs. ozone-PIRFT.

VAS, visual analog scale; ODI, Oswestry disability index;

Table-1 : Secondary Outcome Measures : Patients with > 50% Pain Relief, Reduced Analgesic Consumption and Number of Satisfied Patients

	>50% Pain Relief			Reduced Analgesic consumption			Number of satisfied Patients		
Group Period of follow up	Ozone	PIRFT	OZ + PIRFT	Ozone	PIRFT	OZ + PIRFT	Ozone	PIRFT	OZ + PIRFT
2 weeks	16	18	25	15	17	24	17	17	25
1mt	17	19	26	16	18	25	18	19	26
3mt	19	20	27	18	19	26	20	19	27
6mt	21	20	28	20	21	28	22	20	28
1 yr	24	22	29	21	23	29	23	21	29

Data are presented as absolute number

***P<0.05 during intergroup comparison of ozone vs. ozone-PIRFT group.**

cytokines like interleukin (IL)-1, IL-2, IL-8, IL-12, IL-15, and tumor necrosis factor; and increase release of immunosuppressor cytokines like transforming growth factor-ß1 and IL-10.[17,21]

The dose of ozone administered is crucial (27-40 µg.ml-1).[22] We had used ozone at a concentration of 27 µg.ml-1 because empirical studies performed in vivo on rabbits and in vitro on resected human disc specimens had demonstrated that for intradiscal administration the optimal concentration of ozone per milliliter of oxygen is 27 µg. At this concentration, ozone has a direct effect on the proteoglycans composing the disc's nucleus pulposus, resulting in its release of water molecules and subsequent cell degeneration of the matrix, which is replaced by fibrous tissues in the space of 5 weeks and the formation of new blood cells. Together, these events result in a reduction in disc volume.[16]

Oxygen –ozone mixture was administered within 20 seconds because of the unstable condition of medical ozone, which starts

decaying after about 20 seconds. Periganglionic administration of steroid was given because literature reports on their efficacy to treat disc-induced pain.[23-26]

While needle with the syringe was taken out from the disc, some amount of oxygen-ozone mixture was also injected into the paraspinal muscle and para-radicular soft tissue to reduce nerve root inflammation and increased oxygenation of the paraspinal muscles.

PIRFT is thought to decrease discogenic pain by two different mechanisms: thermal modification of collagen fiber[27] and destruction of disc nociceptors.[28] In addition, the high water content of the disc, the insulating vertebral end plates, and the lack of circulation combine to facilitate disc heating.[29] Breakage of heat-sensitive hydrogen bonds of the collagen fibers causes collagen contraction. The tightening of annular tissue may enhance the structural integrity of degenerated disc and repair the annular fissures. The process of disc restructuring may take several months to reach its full extent. PIRFT may also cause destruction of sensitized nociceptors in the annular wall. Denervation by thermal energy is used widely for peripheral and central nervous system lesioning and may contribute to partial initial pain relief following the PIRFT procedure.

The available evidence does not support the efficacy of PIRFT for the treatment of discogenic low back pain. Barendse et al[30] randomized, in a prospective double-blind study, 28 patients in two groups. The first group received RF lesioning of the intervertebral disc at 70°C for 90 s, whereas patients in the second group, as a control, had a pro0 s be placed without RF. After 8 weeks, no statistical differences could be appreciated between the two groups, and the authors concluded that there is a lack of efficacy of intradiscal (nuclear) RF for the treatment for discogenic pain. Similar conclusions were reached by Ercelen et al.[31] after conducting a randomized controlled trial comparing percutaneous intradiscal RF thermo coagulation for 120 vs. 360sec.

Patients often have an increase in symptoms the first day or two following an PIRFT procedure. The symptoms are usually easily controlled with mild anti-inflammatory pain medications. The healing process reaches its peak 4 months after the procedure. During that period, the patient must limit physical activity and follow a carefully structured rehabilitation program.

In the present study, we hypothesized that a reduction of intradiscal volume by oxygen ozone therapy in combination with ablation of annular nociceptive fibres by PIRFT would improve the outcome as compared with oxygen ozone therapy alone in selected subjects. We observed that addition of PIRFT to oxygen ozone therapy resulted in significant improvement in VAS scores, analgesic consumption, patient satisfaction, and ODI as compared with oxygen ozone therapy alone in subjects with contained disc herniation. Efficacy reported for other minimally invasive percutaneous techniques for the treatment of LBP range from 60% to 80%. These include intradiscal electrothermal therapy (IDET),32 percutaneous laser disc decompression, 33 nucleoplasty,34 automated percutaneous discectomy,35 and oxygen-ozone therapy. We achieved more than 50% pain relief at 1 year follow-up in 97% patients in the ozone-PIRFT group. The reason of patients who did not get a good effect in either of groups was analyzed: some patients had a longer history (5–6 years with the atrophy of muscle of leg); others did not follow the doctor's advice after the treatment and continued to do the heavy work and rest were presented with a very high disc protrusion.

CONCLUSION

Combined intradiscal oxygen-ozone mixture with percutaneous radiofrequency thermo coagulation has a cumulative effect that enhances the overall outcome of treatment for lumbar disc herniation. Thus it can be considered as better option the treatment of lumbar disc herniation that has failed to respond to conservative management.

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