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# Efficacy of Transforaminal Epidural Steroid Injection with Local Anesthetic and Ozone Versus Transforaminal Epidural Steroid Injection with Local Anesthetic in Patients with Lumbar Radiculopathy

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## ABSTRACT

***Objective:*** To compare the efficacy of Transforaminal Epidural Steroid Injection with local anesthetic versus Transforaminal Epidural Steroid Injection with local anesthetic and Ozone in patients with lumbar spine radiculopathy.

***Study Design:*** Quasi-experimental study.

***Place and Duration of Study:*** Pain Management Centre, Department of Anesthesia, Combined Military Hospital Rawalpindi, Pakistan from Oct 2022- Mar 2023.

***Methodology:*** A total of 412 patients who underwent interventional procedures for radiculopathy were included in the study. These patients were divided into two equal groups, group-A (n=206) received Transforaminal Epidural Steroid Injection (40mg Triamcinolone) with local anesthetic (20mg Lignocaine) and Ozone (30 µg/ml) and group-B (n=206) received Transforaminal Epidural Steroid Injection (40mg Triamcinolone) with local anesthetic (20mg Lignocaine). The effects of both the regimens to treat pain in lower back were observed in the groups. Patients were assessed for pain using the visual analogue scale (VAS), for disability using Oswestry Disability Index (ODI), at pre-injection, one month post injection and six-months post injection. Imaging device C -arm fluoroscope was used to carry out all the procedures under aseptic measures.

***Results:*** VAS at pre-procedure was 7.96 ± 0.587 and 8.15 ± 0.615 for group-A and B respectively ($p$= 0.005) and then at six months was 3.06 ± 0.898 for group-A and 3.45 ± 1.075 for group-B ($p$=0.001). Similarly, ODI at pre-procedure was 29.95 ± 4.032 and 30.06±3.761 for group-A and B respectively ($p$< 0.001) and then at six months was 13.83 ± 2.345 for group-A and 14.65± 2.336 for group-B ($p$=0.020) Both regimens were effective in the treatment of low back pain. The Transforaminal Epidural Steroid Injection with local anesthetic and Ozone was more effective in comparison to the Transforaminal Epidural Steroid Injection with local anesthetic in treating low back pain. Comparing both the groups the response rate was found to be highest in the group-A as compared with group-B for VAS and ODI at pre-procedure, one and six months.

***Conclusion:*** Lumbar Radiculopathy treated with Transforaminal Epidural Steroid Injection with local anesthetic and Ozone has more patient satisfaction and relief as compared to the Transforaminal Epidural Steroid Injection with local anesthetic only.

**Keywords:** Epidural Steroid Injection, Low Back Pain, Ozone, Radiculopathy

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## INTRODUCTION

Chronic low back pain (CLBP) is one of the most common complaints distressing the world. Disability imparted by low back pain is the most common cause worldwide causing a public and monetary strain on sufferers and their peers.[1] The European Guidelines for prevention of low back pain defines it as "pain and discomfort, localized below the costal margin and above the inferior gluteal folds, with or without leg pain".[2] Different strategies, modalities and interventions have been used from decades to treat this debilitating pathology. Non-pharmacological interventions and strategies include rest, massage, heat application, exercises, cognitive behavior therapies and reassurances. However, back pain restricting life activities are dealt with pharmacological and interventional therapies which include variety of analgesic, psychoactive drugs administered to body topically, parenterally, orally or intramuscularly. Novel therapies other than mentioned are Chemonucleolysis using Chymopapain, Collagenase, Chondroitinase, Matrix Metalloproteinases, and Ethanol gel, to reduce herniated disc size.[4] However, these therapies are still in experimental phase and have not been patented by drug regulatory authorities. Patients who don't respond to pharmacological therapies are often advised intervention to augment the on-going

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treatment. Minimally invasive approaches can be used to prevent or delay open surgery in such patients (LDH). Intra-discally applied laser decompression, thermal lesion with radiofrequency and chemonucleolysis with ozone are a few of the methods that have been developed to reduce disc volume.[4]

Transforaminal approach has become increasing popular among pain specialist recently as it involves anesthetizing the exiting nerve root from the inter vertebral foramen causing minimal scar and pain to the patient and offers an instantaneous relief at occasions.[4-6] Recent advances have revealed the anti-septic, anti-inflammatory and analgesic properties of the Ozone gas beside its ecological properties. Ozone naturally surrounds our planet and is an allotrope of oxygen. It is also being used a sole treatment for low back pain in many centers over the globe.[7]

The most frequent complaint of patients reporting to OPD at Pain Clinic CMH Rawalpindi is chronic low back pain. This study was conducted to determine the analgesic and anti-inflammatory properties of Ozone when added with admixture of local anesthetic and Steroid in treating low back pain patients. This study aims to provide best patient relief with minimally invasive interventions using the three afore mentioned drugs.

## METHODOLOGY

After obtaining a written informed consent and approval of the Ethical Committee Combined Military Hospital, Rawalpindi (No. 71/05/20) a quasi experimental study was conducted at the Department of Anaesthesia CMH Rawalpindi from October 2022 to March 2023.

For sample size calculation primary outcome of study was decided as reduction in pain at six months. Open Epi Version 3 open-source calculator was used to calculate the sample size. Difference between the means of VAS at six months after intervention was used from both groups as 3.6±2.4 and 4.1±1.6 respectively1. The total sample size of study was found as 412. The recruited patients were divided into two groups equally through consecutive sampling. 206 patients were placed in group-A and group-B as shown in figure.

**Inclusion Criteria:** Male and female patients aged 18-70 years having low back pain due to lumbar radiculopathy evident on clinical examination and imaging from at least 3 months, non-responsive to conventional treatments. Patients with no interventional pain treatment within the last 6 months, having a pain score greater than 6 on the visual analogue scale were included in the study.

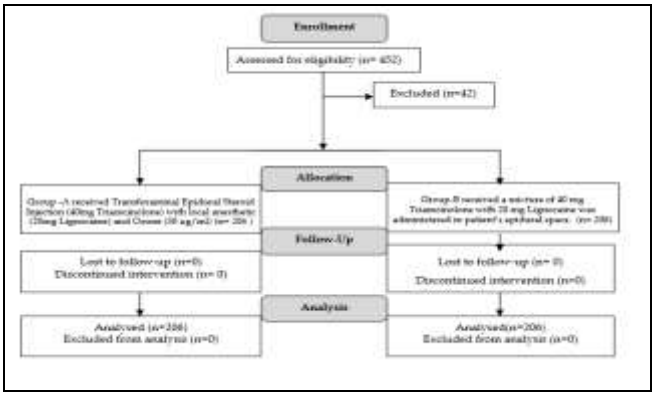


**Figure: Patient Flow Diagram**

**Exclusion Criteria:** Patients with systemic infection, uncontrolled systemic disease, bleeding disorder, history of lumbar surgery, pregnancy, or presence of any neuro motor degenerative disease were excluded.

The selected patients were at American Society of Anesthesiologist (ASA) physical status I and II. Patients were evaluated for pain and functionality at time of procedure, one month- and six-months post injection. Pain was assessed by Visual Analogue Scale (VAS) and functionality by Oswestry Disability Index (ODI). The Oswestry Disability Index (Oswestry Low Back Pain Disability Questionnaire) is an extremely important means to measure a patient's permanent functional disability. It includes following ten parameters of functionality i.e., pain intensity, personal care, lifting, walking, sitting, standing, sleeping, social life, travelling and employment. Each of these parameters have six probable answers with score range from 0-5. Added scores are then categorized into five subsets as shown in Table-I.

**Table- I: Treatment Choices as per Oswestry Disability Index**

| Scores | Disability Level | Treatment |
|---|---|---|
| 0-4 | No | Conservative |
| 5-14 | Mild | Conservative |
| 15-24 | Moderate | Detailed Investigations with pharmacological intervention. |
| 25-34 | Severe | Surgical intervention in addition to pharmacological treatment |
| 35-50 | Complete | Palliative |

Details of the procedure and possible hazards and failure of response were counselled in detail to the

patient. Those willing for the procedure were then taken to procedure room and prepared. The patients' vital signs were monitored by Nihon Kohden Cardiac Monitor (Life Scope 3500 Series) and imaging was accomplished with a C-arm fluoroscopy device (GE Brivo OEC 850). Each patient was placed in prone position and a soft polyester pillow was placed under the abdomen to flatten any curvature in spinal vertebrae. The injection site was cleaned with Povidone Iodine along with Chlorhexidine Spray for asepsis. A 22 gauge 10 cm Quinke spinal needle was placed through foramen in the epidural space using Omnipaque® (Iohexol) contrast with Fluoroscopy. Ozone was generated by using O3 Elite-Dual Machine®. In group-A 10 ml mixture of Ozone(O2-O3) containing 30 µg/mL O3 along with 20 mg Lignocaine and 40 mg Triamcinolone was administered to the patient's epidural space. In group-B, a mixture of 40 mg Triamcinolone with 20 mg Lignocaine was administered in patient's epidural space. After completing the procedure, patients were monitored for one hour in day care detention and then discharged following a recommendation of 3 days of rest and Cefixime 400 mg once daily for 5 days post procedure.

Data was analyzed using IBM Statistical Package for the social sciences (SPSS) version 23.0. Descriptive statistics were used to analyze quantitative and qualitative variables. Mean and standard deviation were calculated for quantitative variables i.e., age, weight, etc., Frequency and percentage were considered for qualitative variables i.e. gender. Groups were compared for Pain using VAS and functionality with ODI using Chi- square test. The $p$ value of ≤ 0.05 was considered statistically significant.

## RESULTS

Total 412 patients were included in this study. These patients were then divided into two equal groups A and B (n=206). Group-A comprised of those patients who would receive transforaminal epidural Steroid with local anesthetic and ozone and group-B comprised of those patients who would receive transforaminal epidural Steroid with local anesthetic. There were 109(52%) males and 97(48%) females in group-A, while 95(46%) males and 111(54%) were female in group-B respectively as shown in Table-II. Patients ASA Status was also noted in both the groups as shown in Table II. Mean age in group-A and group-B were 44.1±6.27 and 44.1±6.09 years respectively ($p$=0.371). Mean weight in group-A and group-B were 83.8±6.6 and 84.9±5.40Kg respectively. Mean height was also not significant as shown in Table-III. The response rate was found to be highest in the group-A as compared with group-B for VAS and ODI at pre-procedure, one and six months. VAS at pre-procedure was 7.96±0.587 and 8.15±0.615 for group-A and B respectively ($p$=0.005) and then at six months was 3.06±0.898 for group-A and 3.45±1.075 for group-B ($p$=0.001). Similarly, ODI at pre-procedure was 29.95±4.032 and 30.06±3.761 for group-A and B respectively ($p$< 0.001) and then at six months was 13.83±2.345 for group-A and 14.65±2.336 for group-B ($p$=0.020) as shown in Table-IV.

**Table-II Gender and American Society of Anesthesiologist (ASA) physical Status of the Patients (n=412)**

| Gender Distribution | Male Patients | Female Patients |
|---|---|---|
| Group-A (n=206) | 109(52%) | 97(48%) |
| Group-B (n=206) | 95(46%) | 111(54%) |
| American Society of Anesthesiologist (ASA) physical Status | I | II |
| Group-A (n=206) | 68(33%) | 138(67%) |
| Group-B (n=206) | 91(44%) | 115(56%) |

**Table-III Demographic and Clinical parameters of the Patients (n=412)**

| Parameter | Group-A(n=206) | Group-B (n=206) | $p$- value |
|---|---|---|---|
| Age (years) | 44.1±6.27 | 44.1±6.09 | 0.37 |
| Weight (kg) | 83.8±6.60 | 84.9±5.40 | < 0.001 |
| Height (m) | 1.72±0.07 | 1.72±0.06 | 0.02 |
| Duration of Pain (months) | 28.2±2.80 | 29.3±2.90 | < 0.001 |

**Table-IV: Pain and Disability Analysis of the Patients (n=412)**

| Outcomes | | Group-A (n=206) | Group-B (n=206) | $p$-value |
|---|---|---|---|---|
| Visual Analogue Scale (VAS) | Pre-Procedure | 7.96±0.58 | 8.15±0.61 | 0.005 |
| | 1st Month | 5.69±0.95 | 5.95±0.97 | 0.003 |
| | 6th Month | 3.06±0.89 | 3.45±1.07 | 0.001 |
| Oswestry Disability Index (ODI) | Pre-Procedure | 29.95±4.03 | 30.06±3.76 | < 0.001 |
| | 1st Month | 21.87±3.59 | 22.46±3.81 | 0.368 |
| | 6th Month | 13.83±2.34 | 14.65±2.33 | 0.020 |

## DISCUSSION

Lumbar Radiculopathy treated with Transforaminal Epidural Steroid Injection with local anesthetic and Ozone has more patient satisfaction and relief as compared to the Transforaminal Epidural Steroid Injection with local anesthetic only. Low back

pain is the most common presenting complaint at Pain Management Centre CMH Rawalpindi. Our study aimed to find the combined efficacy of ozone with Transforaminal Epidural Steroid Injection (TFESI) and local anesthetic. Various literatures conclude that addition of steroid to local anesthetic given in epidural space for low back pain has no superiority in reduction of ailment.[6]

Manchikanti *et al*., assessed the effectiveness of transforaminal epidural injections of local anesthetic with or without Steroids in handling chronic low back. The outcomes were assessed by Numeric Rating Scale and Oswestry Disability Index. Follow up results at 2 years after intervention revealed that Steroids along with local anesthetic or Steroids alone have no advantage in treating the condition.[8] In another study conducted by Spijker Huiges *et al*., segmental epidural Steroid was added to regular treatment. However, this intervention did not benefit the patient and had no clinically relevant effect on low back pain.[9]

Jamadar *et al*., showed in the study that Steroids alone are very beneficial in treatment of low back pain in young adults due to herniated disc. The study showed a success rate of 83.9%.[10] Zhang *et al*., declared in their study that injection of oxygen- ozone mixture in the epidural space should be used as a first line treatment on patients who fail to respond to usual conservative treatments as the mixture plays a role in pain relief.[11] Masini *et al*., found that targeted epidural endoscopy associated with injection of ozone and Steroids is a harmless and effective minimally invasive technique to be used in patients with refractory low back pain. Ozone when combined with Steroids provide a long-lasting pain relief window to the patients.[12] Schoenfeld *et al*., compared best treatment for lumbar radiculopathy and concluded that surgical intervention provides a prompt relief. However, the decision to undergo type of intervention is totally dependent on patient.[13]

Muto *et al*., used intradiscal and peri-radicular ozone infiltration and found cost effective and promising results in treating pain.[15] Similarly, Gallucci *et al*., found that Intraforaminal and intradiscal injections of a Steroid, an anesthetic, and ozone are more effective at 6 months as compared to injections of only a Steroid and an anesthetic in the same sites.[16] Fritz *et al*., showed in their study that diagnostic intervention injections must be performed under radiological guidance either with fluoroscope or Computerized Tomography or Magnetic Resonance Imaging.[17]

This study is novel and pioneer at our institution as it comprises of injecting ozone and TFESI with local anesthetic in epidural space. Patients evaluated that 6 months of follow up have more reduction in their pain scores and an improvement in their disability as shown in the results. Use of this intervention is recommended to be used on those patients who do not respond to conservative methods and are not yet ready for surgical intervention.[18]

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## CONCLUSION

Transforaminal Epidural Steroid Injection with local anesthetic and ozone mixture administered to the patient for treatment of low back pain due to radiculopathy is more superior in response and cure as compared with TFESI with local anesthetic only.

**Conflict of Interest:** None.

**Discolure:**

**Funding Source:** None.

**Authors Contribution**

The Following authors have made substantial contributions to the manuscript as under:

TM & MRI: Conception, study design, drafting the manuscript, approval of the final version to be published.

CRR & MI: Data acquisition, data analysis, data interpretation, critical review, approval of the final version to be published.

AA & AYZ: Conception, data acquisition, drafting the manuscript, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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