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Treatment of Contained Herniated Lumbar Discs With Ozone and Corticosteroid: A Pilot Clinical Study

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Abstract

Purpose: The primary objective of this pilot study was to compare pain and function scores from patients before and after an ozone injection in combination with steroids and bupivacaine to treat herniated discs. A secondary objective was to correct some of the methodological weaknesses of some previously published ozone studies.
Methods: Fifty patients were enrolled; 1-3 mL of 2 wt% ozone in 98 wt% oxygen was delivered into the nucleus pulposus, and 7-9 mL into the adjacent paravertebral tissues. The oxygen/ozone treatment was followed by a periganglionic injection of corticosteroid and bupivacaine. All patients were evaluated 1 month after the treatment to quantify improvement in pain and function, and to monitor for potential adverse events.
Results: Forty-four patients had intradiscal injections and were included in the analysis. After 1 treatment, 75.0% showed significant improvement in pain based on the visual analog scale (improvement >1.8), 72.7% showed significant improvement in function based on the Oswestry disability index (improvement >15%), and 79.5% showed improvement based on the modified MacNab criteria. There were no adverse events associated with the treatment.
Conclusions: Patients showed significant improvement in pain and function after receiving ozone injections in combination with steroids and bupivacaine for the treatment of herniated discs. Because of the lack of a control group and short follow-up times, conclusions about the safety and efficacy of ozone injections for the treatment of herniated discs are not warranted. However, the results provide sufficient evidence that the risk and expense of an additional randomized controlled study is merited.

Résumé

Objet : Cette étude pilote avait pour principal objectif de comparer les notes des patients à l'évaluation de la douleur et de la capacité fonctionnelle avant et après le traitement de hernies discales par injection d'ozone en association avec des stéroïdes et de la bupivacaïne. Elle avait également comme objectif secondaire de corriger une partie des faiblesses méthodologiques que présentaient certaines études sur l'ozone précédemment publiées.
Méthodes : Cinquante patients ont participé à l'étude. Une dose de 1 à 3 mL d'un mélange à 2 % en poids d'ozone et à 98 % en poids d'oxygène a été injectée dans le noyau pulpeux, et de 7 à 9 mL, dans les tissus paravertébraux adjacents des patients. Le traitement par oxygène et ozone a été suivi d'une injection périganglionnaire de corticostéroïdes et de bupivacaïne. Tous les patients ont été évalués un mois après le traitement, afin de quantifier l'amélioration observée au chapitre de la douleur et de la capacité fonctionnelle et d'effectuer le suivi d'éventuels événements indésirables.
Résultats : Quarante-quatre patients ont reçu des injections intradiscales et ont été pris en compte dans l'analyse. Après un traitement, l'échelle visuelle analogue a révélé une amélioration considérable de la douleur chez 75,0 % des patients (amélioration supérieure à 1,8), le questionnaire d'Oswestry une amélioration considérable de la capacité fonctionnelle chez 72,7 % des patients (amélioration supérieure à 15 %) et les critères modifiés de MacNab une amélioration chez 79,5 % des patients. Aucun événement indésirable n'a été associé au traitement.
Conclusions : Les patients ont fait état d'une amélioration notable de la douleur et de la capacité fonctionnelle à la suite du traitement des hernies discales par injection d'ozone en association avec des stéroïdes et de la bupivacaïne. En l'absence d'un groupe témoin et en raison

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d'une période de suivi courte, nous ne sommes pas en mesure de formuler des conclusions au sujet de la sécurité et de l'efficacité des injections d'ozone pour le traitement des hernies discales. Les résultats permettent toutefois de justifier la tenue d'une autre étude clinique aléatoire en dépit des risques et des frais qui y sont associés.

Key Words: Herniated disc; Ozone; Corticosteroid; Lumbar disc; Clinical study

The mechanism of disc-related pain in the lumbar region is not fully understood, but is likely due to mechanical and/or inflammatory factors. The incidence of lumbar disc herniations in the American population is estimated to be 1%-2% for which approximately 200,000 lumbar discectomies are performed annually [1]. Since 1934, the accepted rationale for surgical treatment of disc herniations has been that lumbar back pain is a result of mechanical nerve compression and that surgical removal decreases mechanical compression, which relieves the pain [2,3].

Many common minimally invasive treatments such as percutaneous lumbar discectomy [4], laser discectomy [5], percutaneous plasma disc decompression (nucleoplasty) [6], rely on the removal of disc material to reduce pressure on the ganglion nerve root. Others such as intradiscal electrothermal therapy (IDET) [7] and percutaneous intradiscal radiofrequency thermocoagulation (PIRT) [8] rely on fibrosis of the disc to diminish nerve root compression. The needles used by these devices to perform these procedures range in size from 8-17 gauge, and are sometimes difficult to deliver safely into the disc.

The safety and efficacy of oxygen/ozone injections through a 20-22 gauge needle has been reported in the literature and is summarized by a meta-analysis [9], which quantifies the safety and effectiveness of ozone injections in herniated discs on pain and function. The primary objective of this pilot study was to compare pain and function scores from patients before and after an ozone plus steroid and bupivacaine injection to treat herniated discs. A secondary objective was to correct some of the methodological weaknesses of some previously published ozone studies. Specifically, Johnson [10] pointed out a lack of rigorous patient follow up and possible unintentional variation of ozone dose generation and delivery due to ozone generator inconsistencies. This clinical investigation was designed to specifically address these concerns through rigorous dose control and independently audited patient follow-up with well-validated back pain outcome scales.

Methods

Study Design

This prospective pilot study was designed as a single-center, single-arm clinical study. All patients were treated by Dr. Muto at A. Cardarelli Hospital in Naples, Italy, from October 2005 to March 2006. Institutional Review Board approval for this study, as well as registration of the study in a publicly available database, was not performed, or required, because the procedure being studied is regularly performed at the institution by Dr. Muto and was not considered experimental. The only difference between this study and the standard treatment was that we monitored the ozone concentration that was injected and performed patient follow-ups in which the patient's progress was recorded. Informed consent was obtained from each patient prior to his or her treatment. All other applicable guidelines of the Declaration of Helsinki [11] were followed in this study. Dr. Muto did not receive any additional compensation for the study. The study sponsor's only involvement was obtaining, tracking, and analysing patient outcome. No significant changes were made to the study design after study initiation.

Patient Selection

Fifty patients who met the exclusion/inclusion criteria described in Table 1 were enrolled for this study.

Table 1
Inclusion and exclusion criteria

Inclusion criteria
• 18–75 years of age
• Single herniated disc between L1 and S1 evident on diagnostic imaging (CT and/or MR)
• Lower back pain and/or mild sciatica exacerbated by sitting and/or standing with recumbent relief based on patient questioning.
• Low back pain with or without radicular symptoms that did not improve after conservative therapy for at least 3 months
• Able and willing to return for the 1-month follow-up evaluation
Exclusion criteria
• Previous spine surgery evident on CT/MR
• Abnormal neurological exam indicative of cord compression or cauda equina syndrome evident on baseline neurological exam
• Structural deformities (eg, spondylolisthesis, vertebral canal stenosis, spinal fracture, scoliosis, disc herniations >4 mm, sequestered herniation) evident on CT/MR
• Extruded/free disc fragment evident on CT/MR
• Calcified disc fragment evident on CT/MR
• Disc height loss >75% evident on CT/MR
• Infection as evidenced by patient clinical evaluation, history, and blood test
• Uncontrolled/acute illness
• Women who are known or suspected to be pregnant
• Worker's compensation, injury litigation, disability remuneration
• Participation in another clinical investigation or course of care that may confound the outcome of this study.
• Patients whose L5-S1 disc is not accessible. Disc accessibility may not be evident until the procedure is underway.
• Platelet count >50,000, INR <1.4, PTT <1.3, WBCC >12,000

CT = computed tomography; INR = international normalized ratio; MR = magnetic resonance; PTT = partial thromboplastin time; WBCC = white blood cell count.