Evaluation study

THE TREATMENT WITH OXYGEN-OZONE THERAPY OF FIRST-DEGREE SPONDYLOLISTHESIS SECONDARY TO SPONDYLOLYSIS. OBSERVATIONAL STUDY ON 168 PATIENTS

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ABSTRACT

In recent years several studies have demonstrated the utility of oxygen-ozone therapy in the treatment of herniated discs with the result of herniated discs reduced in size. In this study the authors evaluate the therapeutic results obtained in the treatment of 168 patients suffering from non-discogenic low back pain caused by pathology of the posterior vertebral compartment afflicted by spondylolisthesis secondary to spondidolysis. The patients recruited into the study were evaluated in the short, medium and long term (one week, three months and six months) and were clinically assessed using a modified version of McNab's method.

KEYWORDS: *oxygen, ozone, ozone therapy, spondylolysis, spondylolisthesis*

INTRODUCTION

Oxygen-ozone therapy for the treatment of herniated discs was introduced for the first time in 1985. Over the years, numerous case studies have been presented in the literature reporting positive results ranging from 75% to almost 90% in the treatment of low back pain complicated or not by sciatica due to disc-radicular impingement caused by disc herniation (1-22).

Low back pain and lumbosciatica are highly disabling pathologies, increasingly widespread in every social category and at an increasingly earlier age. They arise acutely following efforts or unusual movements or slowly, often with progressive aggravation. They can have numerous etiologies related to spinal pathology: disc disease, facet joint disease, spondylolysis olisthesis, spinal canal stenosis, radicular cysts, meningiomas, primary or metastatic tumor pathology, etc. (23-29). It is therefore essential to come to a precise diagnosis formulated after a careful objective examination and supported by suitable instrumental tests, such as – in addition to standard radiographs of the spine – Computerized Axial Tomography (CT) and/or Nuclear Magnetic Resonance (MRI) (11, 13).

We have been carrying out oxygen-ozone therapy in our clinics for over twenty-five years for the treatment of low back pain and lumbosciatica due to disc-radicular conflict.

Received: 4 April 2023
Accepted: 10 May 2023

In this article, we report the results obtained in the selected treatment of patients with low back pain and/or sciatica not due to herniated and/or disc protrusions.

In particular, we focused our attention on cases of 1st degree spondylolisthesis secondary to spondylolysis, possibly responsible for the described symptomatology (27).

The treated patients were clinically evaluated in the short term (one week), medium term (three months) and long term (6 months).

Spondylolysis - spondylolisthesis

Spondylolysis (a term coined by Kilian in 1854) is a bony defect of the neural arch that consists of a forward shift of one vertebral body on another.

Spondylolistheses are classified according to the Meyerding classification in relation to the degree of slippage of the vertebral body above compared to the one below (Fig. 1).

MEYERDING'S CLASSIFICATION

The degree of forward shift of one vertebral body on another is measured as a percentage according to Meyerding's classification:

Grade I 0-33%

Grade II 34-66%

Grade III 67-99%

Grade IV 100% and spondyloptosis

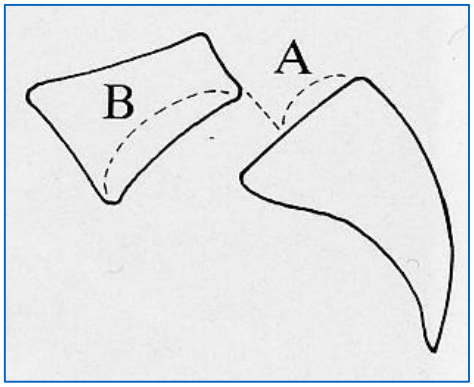


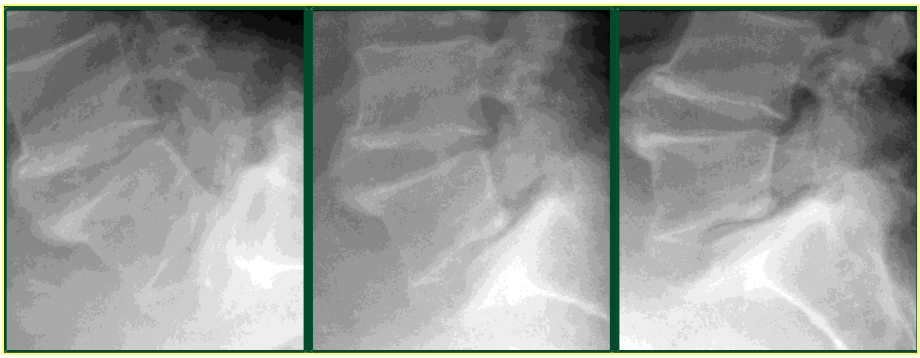
Fig. 1. *Schematic representation of L5 listhesis on S1 first degree of Meyerding.*

In the majority of cases, first degree spondylolisthesis is asymptomatic and is often an occasional finding, however it can manifest itself with low back pain complicated or not by sciatica, in a small percentage of patients.

The majority of patients with symptomatic first degree spondylolisthesis and spondylolysis do not require surgery and the proposed therapeutic approach is often physiokinesitherapy. However, when the symptoms are not resolved with physical therapy, they may require vertebral surgery stabilization.

MATERIALS AND METHODS

In light of the therapeutic success found with oxygen-ozone therapy in the treatment of disc-radicular conflicts due to disc herniation, it was intended to evaluate the effectiveness of this therapy in patients suffering from 1st degree spondylolisthesis (antelisthesis less than 33%), bilateral isthmic lysis (Fig. 2 A-C) and associated disc disease (herniated disc or protrusion).



A (flexion) **B (indifferent)** **C (extension)**

Fig. 2. *Meyerding's first degree spondylolisthesis radiographic control of the degree of stability in flexion- extension. A) flexion, B) indifferent, C) extension.*

In our sample, 169 patients (93 females and 75 males, aged between 24- and 69-years-old median age 43.6) were included. Inclusion criteria were: presence of listhesis, isthmic lysis and associated disc disease, symptoms characterized by low back pain complicated or not by sciatica. In total, we enrolled 106 cases of listhesis L5 on SI and 62 cases L4 on L5; 119 protrusions in the bilateral median-paramedian area and 49 contained lateralized disc herniations.

In all cases the pathology was documented with standard radiograms completed with dynamic-morfal tests. In all patients, the diagnosis of the pathology of the posterior compartment to be treated was confirmed with Magnetic Resonance Imaging (MRI), all MRI investigations were carried out with Siemens Magnetom AERA 1.5 T equipment, SYNGO MR D13 software, using standard sequences and then completing the examination using Fat/Sat sequences without administration of contrast medium (Table I).

Table I. *MRI scan protocol.*

T2 SAG	(Thickness 3 mm, Gap 20%, TR 3500, TE 100, Fov 300 mm, Matrix 384 Pd HF)
T1 SAG	(Thickness 3 mm, Gap 20%, TR 550, TE 9.7, Fov 300 mm, Matrix 384 Pd HF)
T2 AX	(Thickness 3 mm, Gap 10%, TR 4280, TE 100, Fov 220 mm, Matrix 384 Pd AP)
T2 SAG pair	(Thickness 3 mm, Gap 20%, TR 3900, TE 100, Fov 300 mm, Matrix 384 Pd HF)
T1 COR	(Thickness 3 mm, Gap 15%, TR 420, TE 9.1, Fov 300 mm, Matrix 384 Pd RL)
T1 FS SAG	(Thickness 3 mm, Gap 20%, TR 2500, TE 39, Fov 300 mm, Matrix 384 Pd HF, Fat/Sat)
T1 FS AX	(Thickness 3 mm, Gap 20%, TR 3500, TE 39, Fov 220 mm, Matrix 384 Pd AP, Fat/Sat)

The infiltrative treatment was performed using Hitachi model Supria 16/32 Computed Tomography (CT) equipment. All patients were treated by CT-guided bilateral periganglionic infiltration of O_2-O_3 and O_2-O_3 injection into the lysis points in the neural arch.

To produce the oxygen-ozone mixture, a “Maxi Ozon Active International produced by Medica S.r.l. CE” generator device was used, equipped with a digital photometer for the regulation of ozone concentrations, with check valves for the collection of the gaseous mixture in absolute sterility.

Infiltration technique

After receiving written informed consent from the patients, the injection level was established based on neuroradiological findings and clinical symptoms. The level was confirmed by preliminary CT scans with patient in a prone position to determine the point of needle entry (Fig. 3).

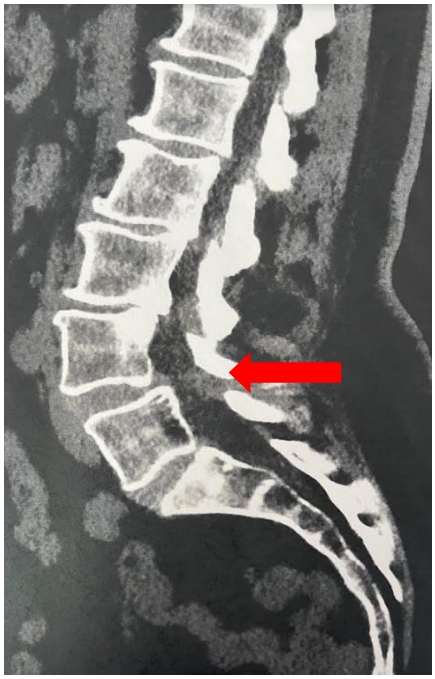


Fig. 3. *CT study preliminary to the treatment documenting first degree Meyerding's listhesis of L4 on L5 (arrow).*

The skin was disinfected using a polyvinylpyrrolidone iodine solution after local anesthetic with ethyl chloride spray. CT-guided puncture was then performed using needles with a caliber 22 G. CT guidance also served to check the correct position of the needle (Fig. 4).

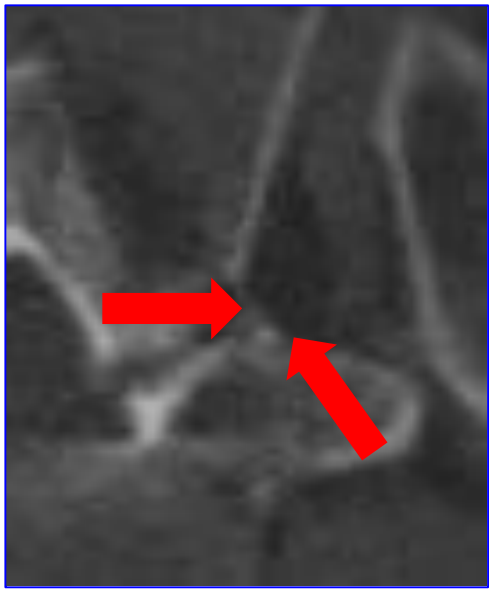
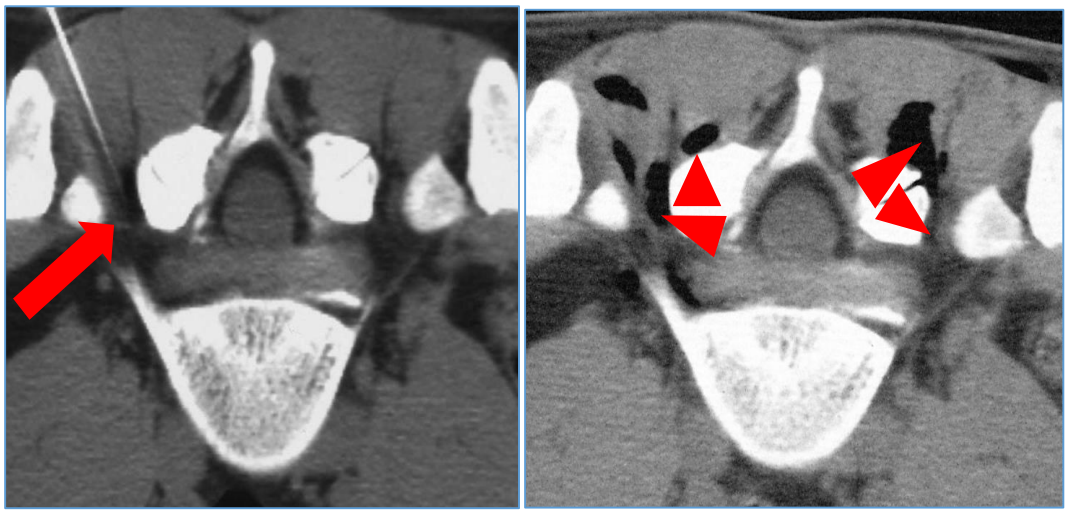


Fig. 4. *CT scan with bone algorithms: verification of the correct positioning of the needle at the lysis point (arrows).*

An aseptic technique was used to fill a 10 ml polyethylene syringe with a gas mixture of oxygen-ozone 3 ml at a concentration of 25 µg/ml and was injected using a microporous filter to minimize the risk of contamination. Further CT scans were done after infiltration to confirm the correct distribution of the gas mixture in the treatment site (Fig. 5 A-B).



A **B**

Fig. 5. ***A****) correct positioning of the needle at the level of the periganglionic region (arrow);* ***B****) CT control of the distribution of the oxygen-ozone gas mixture at the level of the foraminal region (arrowheads) and in correspondence with the articular masses (arrowheads).*

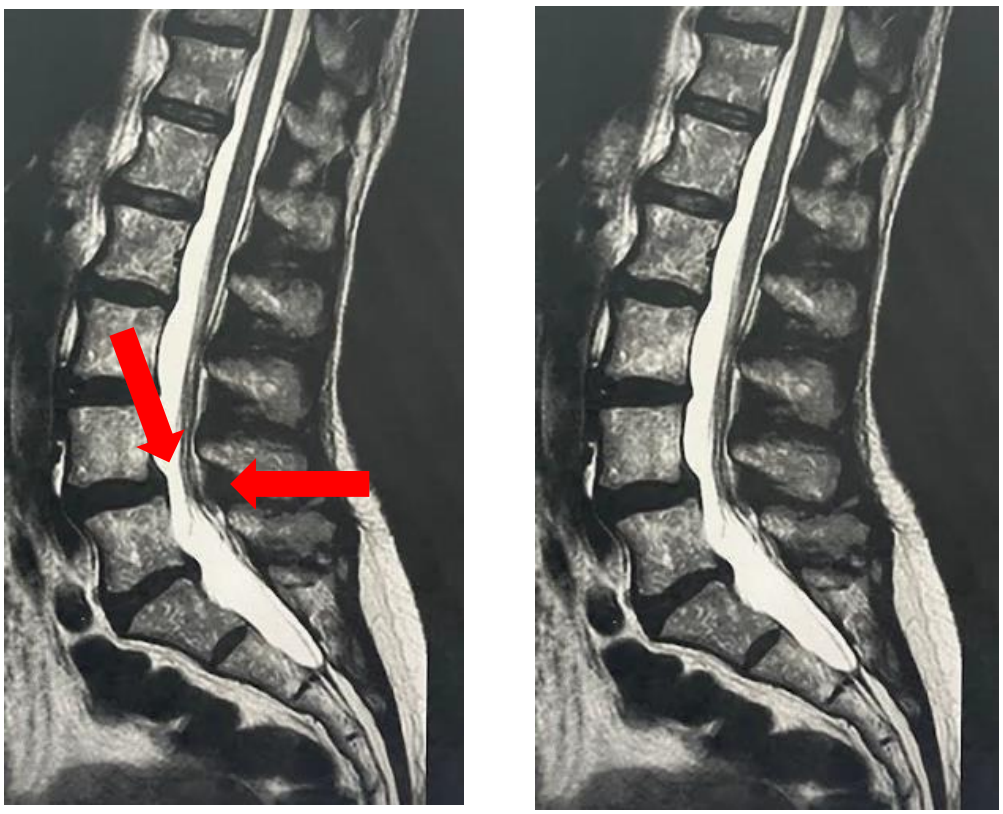
Patient was then kept under observation for around 30 min and subsequently discharged. Clinical outcome was assessed in all patients by short (one week), medium (3 months) and long-term (6 months) follow-up using a modified version of McNab's method:

a) excellent: resolution of pain and return to normal activity carried out prior to pain onset;
b) good or satisfactory: more than 50% reduction of pain;
c) poor: partial reduction of pain below 70%.

DISCUSSION

In this study we propose the treatment of the posterior compartment with injections of a gaseous mixture of oxygen and ozone, carried out through targeted infiltrations.

All treated patients with spondylolysis and spondylolisthesis were evaluated in a short-term (one week), medium (three months) and long-term (six months) period using the modified McNab's method as an evaluation tool. In 114 patients (114/168, equal to 67.9%), a total resolution of the painful symptoms was obtained, in 21 (12.5%) we obtained a result considered satisfactory by the patient, while in 33 patients no therapeutic benefit was obtained. At the subsequent three-month check-up (medium term), 106 (63%) reported that the benefit of the treatment had remained constant while 44 (26.2%) were in patients for whom the situation had not substantially changed with the therapy. In the long term (clinical follow-up at 6 months), 98 patients (58.3%) continued to report an excellent clinical result obtained with the therapy, while 16 (9.5%) reported a satisfactory result, while 54 (32.2%) were patients who had not experienced substantial benefits (Fig. 6 A-B).



A B

Fig 6. ***A****) Sagittal MRI before treatment documenting first degree Meyerding listhesis of L4 on L5 (arrows).* ***B****) MRI check at six months, from the iconographic point of view there are no substantial changes in the picture compared to a clear clinical benefit obtained with the therapy performed.*

In particular, control CT in patients who, in addition to listhesis, had a herniated disc (49 patients, 29.1%) documented complete dehydration of the hernia (in 29 out of 49, 59.1%), obviously without any modification in the degree of listhesis (Fig. 7 A-B).

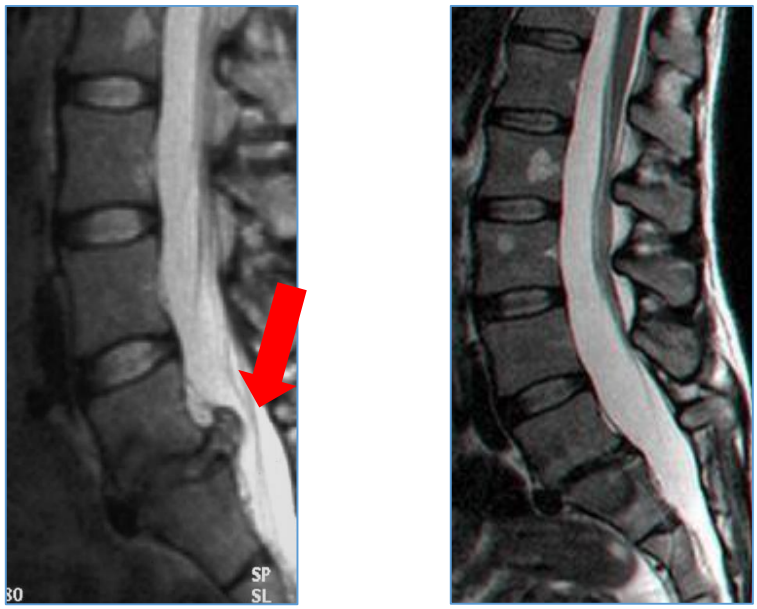


Fig. 7. *Large right paramedian herniated (arrow) disc treated by oxygen-ozone therapy in patients with spondylolysis and spondylolisthesis. Complete dehydration after treatment.*

In the 54 patients re-evaluated in the long term (6 months) we requested a neurosurgical evaluation of the situation and in 11 cases (6,5%) the neurosurgeon opted for spinal stabilization surgery, while in the remaining 43 the patient continued exclusively a physiokinesitherapy rehabilitation program.

At the six-month clinical follow-up, the therapy therefore proved to be effective from an exclusively analgesic point of view in 98 patients (58.3%) (Table II).

Table II. *O_2-O_3 treatment in 168 patients.*

Outcome	excellent	good	poor
At 1 week	114 (67.9%)	21 (12,5%)	33 (19.6%)
At 3 months	106 (63,0%)	18 (10.8%)	44 (26,2%)
At 6 months	98 (58,3%)	16 (9.5%)	54 (32.2%)

Based on the acquired experience, we therefore believe that this therapeutic option can be offered to patients with Meyerding's first degree listhesis. We also consider that, to achieve a satisfactory clinical result, a multidisciplinary therapeutic approach to this problem is indispensable and that the support of your physiatrist colleague is fundamental to plan a subsequent postural re-education intervention aimed at maintaining the acquired therapeutic result over time.

On the other hand, in cases where the therapeutic result has been poor or unsatisfactory, in addition to the intervention of the physiatrist colleague, a neurosurgical re-evaluation of the situation is essential to decide whether or not spinal stabilization surgery is essential.

CONCLUSIONS

In recent years, several studies have demonstrated the utility of oxygen-ozone therapy in the treatment of herniated discs (1-22). In light of the well-known mechanisms of action of the oxygen-ozone mixture (7-10), in this study we evaluated the therapeutic results obtained in the treatment of 168 patients suffering from non-discogenic low back pain caused by pathology of the posterior vertebral compartment afflicted by spondylolisthesis secondary to spondylolysis (28).

In most cases, good patient selection allows for striking clinical results; in reference to our case series, we found optimal therapeutic results in a percentage of approximately 58.3% and satisfactory in 9.5% of the cases treated considering the various pathologies.

We believe, in this regard, that the administration of deep paravertebral CT-guided oxygen-ozone therapy has precise control of needle tract, permitting the curative properties of the gas mixture, which improves local circulation and allows eutrophication in proximity of the compression of the nerve root during the experience of muscle spasms. It normalizes the level of cytokines and prostaglandins, acting as an anti-inflammatory and a pain reliever; it also increases the production of superoxide dismutase (SOD) with minimization of oxidizing reagents (ROS). Finally, the close proximity to the herniated material which causes accelerated dehydration or destruction of a non-vascularized tissue justify the satisfactory end result (7-10, 14, 17, 21-23).

The rapid resolution of pain with no complications, the ease of performing the method and the complete control of infiltration thanks to the use of CT scan allow today to propose CT-guided oxygen-ozone therapy as a viable therapeutic alternative to other infiltrative or surgical treatment, also underlining how this type of therapy does not present contraindications that can hinder the success of the procedure itself.

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