# Oxygen-Ozone Chemonucleolysis for Herniated Disc with Sciatica. A Comparison of Treatments in Patients with Subacute and Chronic Symptoms

M. LEONARDI, L. ALBINI RICCIOLI, S. BATTAGLIA, F. DE SANTIS, P. CENNI, L. RAFFI, L. SIMONETTI

*Neuroradiology Service, Bellaria Hospital, Bologna*

**Key words:** chemonucleolysis, lumbar herniated disc, sciatica

**SUMMARY -** This study compares the results obtained after $O_2$-$O_3$ chemonucleolysis in patients treated early and patients with long-standing symptoms. Because very few patients are referred in the acute stage, we considered patients treated early all those with symptoms of less than six months duration. Patients were divided into two groups: *Group A*: 37 patients with symptoms lasting less than six months; *Group B*: 52 patients with long-standing symptoms lasting from more than six months up to 20 years. Intradiscal and periganglionic injection was administered by extraspinal lateral approach using a 22 G × 17.78 cm spinal needle. Results were assessed by a modified version of the Oswestry questionnaire to make the evaluation as objective as possible. The questionnaire was administered to patients before chemonucleolysis and one, six and 18$^{th}$ months after treatment.

## Background

Our team has gained 18 years' experience in the percutaneous treatment of herniated lumbar disc in more than 4000 patients. The techniques adopted have changed over the years for a number of reasons.

From 1987 to 1993 we treated lumbar herniated disc by papain injection obtaining satisfactory results [3,4]. However, the lack of a CE mark led us to suspend the use of this product. We subsequently treated roughly 200 patients by nucleotomy according to Onik6 but the results were somewhat disappointing. A number of other techniques have also been used.

Since 1997 we have performed intradiscal injection of an oxygen-ozone ($O_2$-$O_3$) mixture [2,7,8]. The positive outcome obtained in 70% of our patients using a low cost technique virtually free of contraindications and side effects lent support to the continued use of the treatment.

We have often been criticised for not having undertaken a randomized trial comparing oxygen-ozone administration with commonly prescribed medical treatments and the supposedly gold standard of surgery. There are no randomized studies on the efficacy of any of the percutaneous techniques proposed and our own attempts to perform such studies have encountered major difficulties.

Firstly, patients are not referred to us in the acute stage, but only after failure of other physical or medical treatments. Secondly, our patients do not agree to be enrolled in a randomized study comparing oxygen-ozone chemonucleolysis with commonly administered drug treatments because they have already experienced medical management failure.

In practical terms, our chemonucleolysis procedures are comparable with drug treatments but a comparative study of patients treated with oxygen-ozone only in the acute stage has hitherto been impossible.

In addition, the pathophysiology of low back pain and sciatica is complex since disc herniation is only part of the cause and not necessarily the most important factor. It is also difficult to pinpoint the exact time of disease onset.

This hinders the possibility of randomized studies but also accounts for the many therapeutic techniques available and their ongoing development.

Despite the lack of randomized studies, the large number of patients treated to date is in itself evidence of the efficacy of $O_2$-$O_3$ chemonucleolysis.

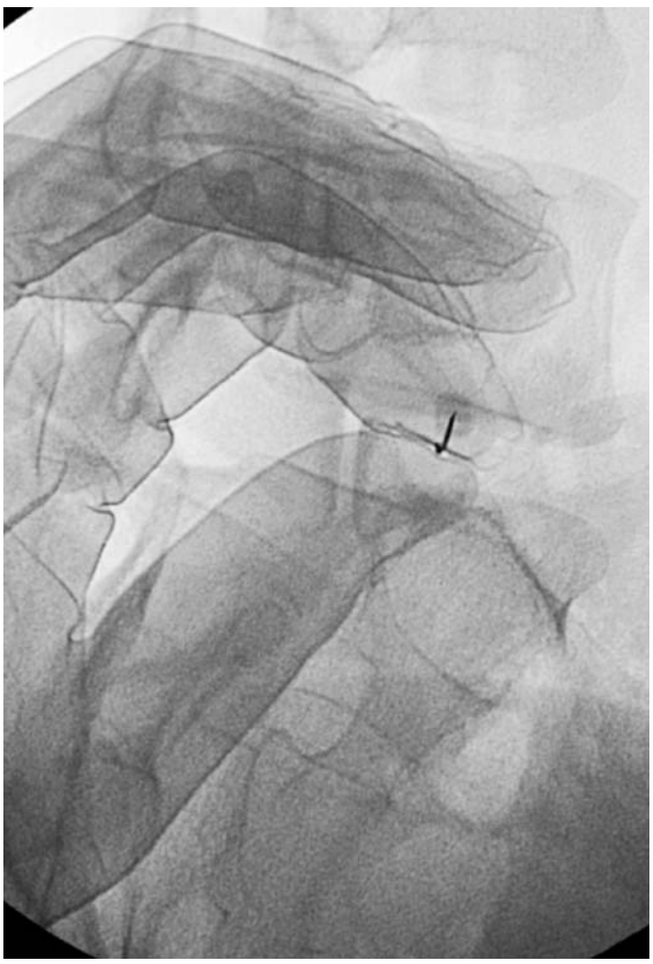

Figure 1

## Introduction

This study compares the results obtained after $O_2$-$O_3$ chemonucleolysis in patients treated early and patients with long-standing symptoms. Because very few patients are referred in the acute stage, we considered patients treated early all those with symptoms of less than six months duration.

## Materials and Methods

From 1st January to 30th June 2004 we treated 89 patients with single herniated disc by $O_2$-$O_3$ chemonucleolysis in a single session. Results were assessed 18 months after treatment.

Patients were divided into two groups: *Group A*: 37 patients with symptoms lasting less than six months; *Group B*: 52 patients with long-standing symptoms lasting from more than six months up to 20 years. *Group A* comprised nine men and 11 women with an average age of 57 years. *Group B* comprised 19 men and 16 women with an average age of 49 years. Before referral to us all patients had received drug treatments of varying duration generally proportional to the duration of low back pain. The technique used has been described in previous articles [2,8]: patients received intradiscal (4 ml) and periganglionic (10 ml) injection of an oxygen-ozone mixture with an ozone concentration of 27 μg/ml, followed by periganglionic injection of corticosteroid (1 ml Depo-Medrone 40 mg) and anaesthetic (2 ml Bupivacain 0.5%) at the same session.

Intradiscal and periganglionic injection was administered by extraspinal lateral approach using a 22 G × 17.78 cm spinal needle. No premedication or anaesthesia was given. The procedure was carried out in the day hospital. Needles were positioned over the site of injection using fluoroscopic guidance5 (figures 1, 2).

Results were assessed by a modified version of the Oswestry questionnaire to make the evaluation as objective as possible. The questionnaire was

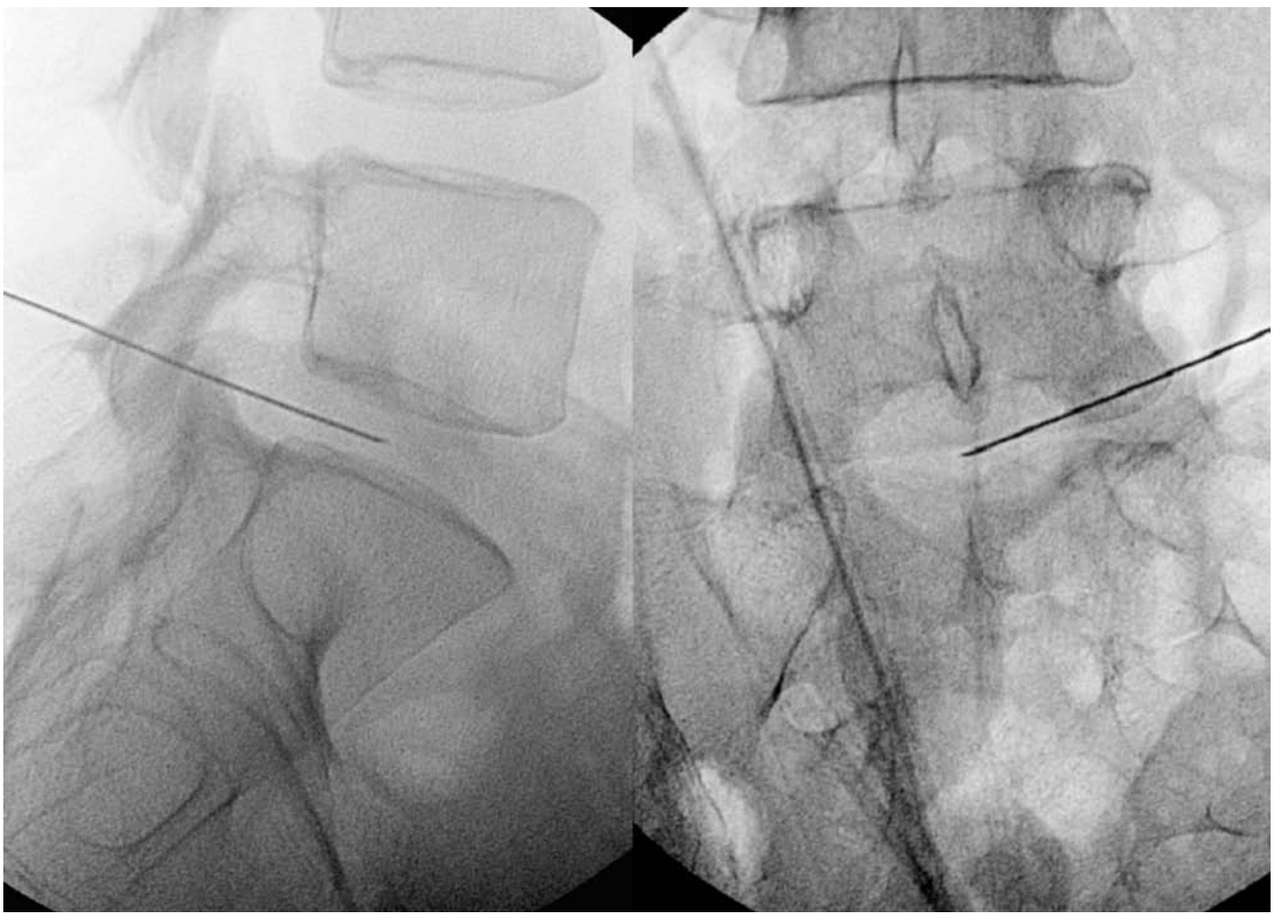

Figure 2

administered to patients before chemonucleolysis and one, six and 18th months after treatment.

## Results

For simplicity treatment outcome was classified as positive, negative or null. A positive outcome was considered a complete or almost complete resolution of symptoms without the need for further treatment. Any mild recurrence on pain was controlled by traditional medical management with NSAIDs. Negative or null outcome was failure to relieve pain after treatment.

Treatment outcome was positive in 56 patients (62.9%) and negative or null in the remaining 33 (37.1%).

*Group A* patients obtained a positive outcome in 20 cases (54%). The initial symptoms in this group yielded an average Oswestry score of 19.5, whereas the final average score after treatment was 9.75.

*Group B* patients obtained a positive outcome in 35 cases (67.3%). The initial symptoms in this group yielded an average Oswestry score of 18, whereas the final average score after treatment was 7.17. 25 of the 33 patients with a negative or null outcome after treatment underwent surgery for microdiscectomy. In all cases $O_2$-$O_3$ chemonucleolysis had no effect on the surgical procedure.

No complications related to $O_2$-$O_3$ chemonucleolysis treatment were encountered in any patient. Some patients not included in this cohort were unsatisfied with the treatment outcome and underwent repeat $O_2$-$O_3$ chemonucleolysis. The results obtained in these cases will be the object of a further study.

## Discussion

A positive treatment outcome was obtained at 18 months after $O_2$-$O_3$ chemonucleolysis in 62.9% of patients in both groups. This is a satisfactory result for a mildly invasive procedure virtually free

from risks and complications. In addition $O_2$-$O_3$ chemonucleolysis is a low cost technique and can be repeated if necessary. It is difficult to account for the different outcome obtained in the two groups of patients treated in this study. As a whole, the patients with more recent onset of symptoms presented a more severe clinical status and were older on average. This could explain the lower percentage of positive results in *Group A* with respect to *Group B*.

In our experience, it is useful to administer $O_2$-$O_3$ chemonucleolysis to treat low back pain and herniated disc before resorting to surgery. Our study demonstrated that the likelihood of a positive treatment outcome is irrespective of elderly patient age and chronic symptoms.

A comparison of $O_2$-$O_3$ chemonucleolysis and commonly administered drug treatments (steroids, NSAIDs) in acute lumbar disc disease is currently precluded by the difficulty in recruiting patients in the acute stage who have not already tried medical management.

## References

1 Andreula CF, Muto M, Leonardi M: Interventional spinal procedures. European Journal of Radiology 50: 112-119, 2004.
2 Andreula CF, Simonetti L, de Santis F et Al: Minimally invasive oxygen-ozone therapy for lumbar disk herniation. Am J Neuroradiol 24: 996-1000, 2003.
3 De Nardi E, Ceccotto C, Pomelli L et Al: La chemonucleolisi nell'ernia discale lombare, 1° parte: analisi clinica dei risultati. Rivista di Neuroradiologia 1: 53-61, 1988.
4 Fabris G, Lavaroni A, Zappoli F et Al: La chemonucleolisi nell'ernia discale lombare. Rivista di Neuroradiologia 2: 93-102, 1989.
5 Leonardi M: Disc Punture under Fluoroscopic Guidance. Rivista Italiana di Ossigeno-Ozonoterapia 1: 73-78, 2002.
6 Leonardi M, Fabris G, Lavaroni A: Percutaneous discectomy and chemonucleolysis. In: Valavanis A (ed): Medical Radiology: Interventional Neuroradiology. Editor. Springer Verlag, Heidelberg 1993: 173-190.
7 Muto M, Andreula CF, Leonardi M: Intradiscal oxygen-ozone in the treatment of herniated lumbar disc. In: Image-guided spine interventions. John M.Mathis (editor). Springer-Verlag 2004.
8 Muto M, Andreula CF, Leonardi M: Treatment of herniated lumbar disc by intradiscal and intraforaminal oxygen-ozone ($O_2$-$O_3$) injection. Journal of Neuroradiology 31: 183-189, 2004.

Prof. Marco Leonardi
Neuroradiology Department
Bellaria Hospital
Via Altura, 3
40139 Bologna - Italy
Tel.. +39 051 6225520 - Mobile: +39 348 8714153
Fax: +39 051 6225785
E mail: marco.leonardi@ausl.bologna.it