Chemiodiscolysis CT-guided: critical review of indications according to our experience

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Aims and objectives

About 80% of adults suffer from low back or leg pain during their lifetime. In primary care, 4% of patients with this condition have a lumbar disk herniation, with L5 and S1 nerve roots involved in approximately 95% of cases. However the herniated portion of the disk tends to regress with time, after conservative therapy, with partial or complete resolution in two thirds of cases after 11 months. Oxygen-ozone(O2-O3) discolysis is a good alternative to surgical treatment for lumbar disk herniation for patients failing to respond to conservative treatment, with a successful percentage of 70-80% without complications. The basic principle of action of intradiscal injection of oxygen-ozone(O2-O3) mixture, is the reduction of proteoglicans, consequent dehydration and shrinkage of the disk. M. Muto et al and Gallucci et al in their experience of sciatica treatment due to discovertebral pathology report results of pain reduction, respectively in 18 and 6 months of follow-up between 74 and 75%. However, no study has been published on the possible relationship between the various types of discovertebral pathology and response to oxygen-ozone therapy. Therefore in our prospective analysis we aim to evaluate the different responses to the treatment of different discovertebral pathologies.
Methods and materials

We evaluated 257 patients underwent to chemiodiscolysis in the period between June 2011 and September 2014 (163 men, 94 women; age range 22-92 years), (L3-L4, 12 patients; L4-L5, 23 patients; L5-S1, 222 patients) after preliminary clinical evaluation, performed by one experienced neuroradiologist with 35 years experience. The procedures were performed by two neuroradiologists (respectively 35 and 5 years experience). Prospective trial was approved by the Medical Ethical Committee of our institution. All participants gave written informed consent prior to enrollment. Inclusion criteria comprised lumbar disk pathologies documented on CT and MR images, pain for at least 8 weeks with no or poor clinical improvement after conservative therapy, and initial mean VAS greater than 3. Exclusion criteria comprised pregnancy, referred allergy to proposed drugs and syndromes that are able to mimic the symptoms of a lumbar disk herniation as facet syndrome, sacroileitis, bone lesions, or previous spine surgery. Thereafter, patients were undergone follow-up clinical examination performed at sixth month after oxygen-ozone(O2-O3) discolysis. The outcome was measured the day of the procedure and subsequent follow up at sixth month, using a visual analog scale (VAS), ranging from 0 to 10 with cut-off 3. The questionnaire was administered by the same neuroradiologist.

MR imaging and Injection technique—Each participant underwent MRI exams of the lumbar spine in our radiology department (using GE Healthcare - Signa EXCITE 1.5T MRI scanner with a phased-array spine coil) before oxygen-ozone(O2-O3) discolysis. Sagittal FSE-T2 and T2 Fat-weighted images were acquired with the following parameters: 4000/108/4 (TR/TE/NEX), while for sagittal SE-T1 weighted images 500/20/2(TR/TE/NEX). Both T1 and T2 weighted images were acquired using the same values of matrix (256 x 192), slice thickness 5 mm, spacing 1 mm and a field of view (FOV) of 26 cm. Axial T2 weighted images were acquired parallel to the disk space with a field of view(FOV) of 17 cm. According to the recommendations of the combined task forces of the North American Spine Society, the American Society of Spine Radiology and the ASNR, on FSE-T2, FSE-T2 fat and SE-T1-weighted images, the type of herniated disk was classified as protrusion, extrusion and bulging. Disk degeneration and dehydration was assessed on the MR T2-weighted sagittal images by using a five-point scale according to the method of Pfirrmann et al(Figure 1). All procedures were performed by two neuroradiologists (respectively 35 and 5 years experience), under CT guidance (Somatom Plus 4; Siemens Medical Systems, Erlangen, Germany) and with the patient in the prone position. Before every procedure, the patients received premedication with intravenously administered 1 g of cefuroxima (CUROXIM; GlaxoSmithKline) and 50 mg of ranitidine (Zantac: GlaxoSmithKline). The O2-O3 gas mixture was achieved by using an ozone generator (OZO2 Futura; Alnitec, Cremosano, Italy). After local anesthesia using 6mg of mepivacain( about 2-3 mL of MEPICAIN 2%; Monico SPA, Venice, Italy), the
spinal needle (9 or 13 cm 22 gauge) was advanced to the intraforaminal space with an angle between 45° and 60°. Intradiscal and intraforaminal injections were administered with a paravertebral approach in 59 patients and an interlaminar approach in 9 patients. Before injection inside the disk, a CT scan was used to confirm that the needle tip was inside the nucleus pulposus. After injection a CT scan was acquired to evaluate O2-O3 distribution which was considered satisfactory when the gas was homogeneously distributed inside the nucleus pulposus with diffusion in the epidural and periganglionic space. After this last evaluation, the needle was removed and the procedure was concluded. Overall, the average injected volume of O2-O3 in patients was 8-10 mL (28 µg/ml concentration). Every patient additionally received 4 mg of betamethasone in the periganglionic area (Figure 2).

**Statistical analysis**—An evaluation of the success rate was performed on the basis of the VAS scale. The results of the VAS questionnaire were entered in a database. The success rates at 6-month follow-up was compared by means of the #2 test. $P < 0.01$ was considered to indicate a statistically significant difference. The software used for statistical analysis was Stata (version 8.2; Stata Corp, College Station, Tex).
Fig. 2: Axial CT image in 45 years old man suffering from left lumbosciatica. The image shows paravertebral approach with point of the needle in L4-L5 level. The O2-O3 mixture is distributed inside the disk.

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Fig. 1: Sagittal T2(1), T2 Fat(2), and T1(3) at the presentation of 38 years old man who suffering from lateral leg pain due to left intraforaminal disk herniation.

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Results

The success rate at sixth month after treatments was statistically significant ($\chi^2=31.31$, $P<.001$) in 106 patients (Responders 41.24% with extrusions) compared with 9 patients (Non responders 3.5% with the same discovertebral pathology) (95% CI: 64.1%, 84.4%) (Table 1). Also in 89 (Responders 34.6%) patients with protrusions the success rate at sixth month was statistically significant ($\chi^2=25.43$, $P<.001$) compared with 5 patients (Non responders 1.9% with the same discovertebral pathology) (95% CI: 73.1%, 88.4%) (Table 1). Only in the presence of bulging disk, the success rate was not statistically significant ($P>.001$) with 3 patients (Responders 1.16%) compared with 45 patients (Non responders 17.5%) (95% CI: 71.3%, 83.6%) (Table 1). Statistically significant difference ($P<.001$) was also detected in the presence of High and Low dehydration and discal degeneration as shown in table 1 with the absence of degenerative discal aspects in 185 patients (Responders 71.9%) compared with 8 patients (Non responders 3.1%) (95% CI: 76.3%, 89.4%) and high disk degeneration and dehydration in 2 patients (Responders 0.7%) compared with 45 patients (Non responders 17.5%) (95% CI: 72.3%, 81.3%). During or after the procedures, no major or minor complications were observed.
### Table 1. Comparison between Responders and Non-Responders.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Responders (n=58)</th>
<th>Non responders (n=10)</th>
<th>Total</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Type of the lumbar disk herniation</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Protrusion</td>
<td>89(34.6%)</td>
<td>5(1.9%)</td>
<td>94</td>
<td>*p&lt;0.01</td>
</tr>
<tr>
<td>Extrusion</td>
<td>106(41.24%)</td>
<td>9(3.5%)</td>
<td>115</td>
<td>*p&lt;0.01</td>
</tr>
<tr>
<td>Bulging</td>
<td>3(1.6%)</td>
<td>45(17.5%)</td>
<td>48</td>
<td>*p&gt;0.01</td>
</tr>
<tr>
<td><strong>Disk degeneration and dehydration</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>High</td>
<td>2(0.7%)</td>
<td>45(17.5%)</td>
<td>24</td>
<td>*p&lt;0.01</td>
</tr>
<tr>
<td>Moderate</td>
<td>11(4.2%)</td>
<td>6(2.3%)</td>
<td>27</td>
<td>*p&gt;0.01</td>
</tr>
<tr>
<td>Low</td>
<td>185(71.9%)</td>
<td>8(3.1%)</td>
<td>17</td>
<td>*p&lt;0.01</td>
</tr>
</tbody>
</table>

Note. Values represent the number of patients. Data in parentheses are percentage; *χ² test.

**Table 1**

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Conclusion

Because ozone is an unstable form of oxygen that, in water, reacts with organic molecules containing double or triple bonds causing an oxide reduction called ozonolysis\textsuperscript{14}, intradiscal O2-O3 mixture injection produces a chemodiscolysis of nucleus pulposus proteoglycans and dehydration followed, finally, by disk shrinkage and direct reduction of root compression\textsuperscript{15-16}. Another reason for using medical ozone to treat disk herniation is its analgesic and antiinflammatory effects\textsuperscript{17-18-19}. The effect of ozone on chemical radiculitis can also explain the clinical effectiveness of intraforaminal O2-O3 injection without intradiscal therapy\textsuperscript{20}. The reported effectiveness of the procedure is promising, with clinical success in 70%-80% of patients\textsuperscript{21}. In our study the results were 106 of 257 patients (approximately 42% ) and 89 of 257 (approximately 35%) had successful outcomes (the responders respectively with discal extrusions and protrusions) while 14 patients in a total of this groups showed unsatisfactory results (the non-responders) both with an follow-up period of 6 months. In our experience there was no significant difference between the responders and non-responders to oxygen-ozone(O2-O3) discolysis in the presence of bulging disk (p > 0.01). In addition there was no significant difference in terms of moderate degeneration and dehydratation disk but in the case of low degenerated disc the success of rate was statistically significant (p < 0.01) in 185 patients of 257. Therefore we can assume that in our experience oxygen-ozone chemodiscolysis obtains the best results in the case of extrusions and protrusions. In selected patients, even disc pathologies associated with discal degenerative can be treated, with some success. In patients with more severe degenerative changes got worse results, even if with a transient efficacy.
References


