A prospective cohort study to assess the efficacy of a novel minimally invasive treatment option for discogenic sciatica consisting of automated percutaneous discectomy, intradiscal ozone injection and caudal epidural injection

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Authors: M. T. Crockett, P. Dicker, K. Synnott, A. Poynton, S. J. Eustace; Dublin/IE
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Purpose

Discogenic sciatica is a common and debilitating symptom. Both surgical and minimally invasive treatment options are available but none has been shown to be definitively superior. The aim of this prospective observational cohort study was to assess the efficacy and safety of a novel minimally invasive technique for the treatment of discogenic sciatica using a combination of percutaneous discectomy, intra-discal ozone injection and caudal epidural injection (APLD/Ozone/Epidural). The efficacy of this novel technique was compared to caudal epidural injection alone, the current first line minimally invasive treatment option.
Methods and Materials

This prospective observational cohort study was conducted after approval by the local ethics committee and was performed based on the Consolidated Standards of Reporting Trials (CONSORT) guidelines. Inclusion and exclusion criteria were as follows:

1. Inclusion criteria
   - Mild to moderate lumbar disc herniation (occupying <30% of spinal canal confirmed on MRI scan), contained or uncontained.
   - Sciatica +/- lower back pain correlating to the lumbar disc herniation visualised on MRI.
   - Symptoms of sciatica ongoing for at least 6 weeks.
   - Non-response to conservative management (physiotherapy/analgesia)
   - >18 years of age.

1. Exclusion criteria
   - Large disc prolapse (>5mm or occupying >30% of spinal canal)
   - Evidence of cauda equina or cord compression.
   - Significant structural deformity of spine (e.g. spondylolisthesis/scoliosis/spinal fracture)
   - Acute illness
   - Pregnancy
   - Injury litigation

No randomisation took place. Patients agreeing to take part in the study were offered one of two treatment options; caudal epidural injection alone (which would act as the comparative control group) or the novel combination treatment involving APLD, intradiscal ozone and caudal epidural in combination (which would act as the comparative experimental group). Possible risks and benefits of each treatment option were discussed and the patient was given time to make their decision. Informed consent was obtained.

Patient's demographic data and data characterising the patient's discogenic sciatica was either provided by patients or was obtained by a review of MRI reports and scans. The techniques of the two treatment options are described below:

1. Caudal epidural injection

Procedure performed under local anaesthetic with fluoroscopic guidance and with patient in prone position. Using sterile technique, access to the epidural space was obtained and confirmed using contrast. Mixture of 9ml of lidocaine and 6mg of betamethasone injected.
1. APLD, intradiscal ozone and caudal epidural injection in combination (APLD/Ozone/Epidural)

Procedure performed under local anaesthetic with fluoroscopic guidance and with patient in prone position. First, APLD was performed of the affected disc using the Stryker Dekompressor probe. Disc access was gained using a cannula; placement confirmed using fluoroscopy and probe introduced. The probe was connected to the mechanical aspirator which aspirates part of the NP. Each herniation was decompressed for 3 minutes. After completion of APLD, a spinal needle is inserted into the disc space and position confirmed. The oxygen-ozone mixture (ozone) is produced in real time by a medical ozone generator with a concentration of 30µg. 10-15ml are injected into the disc. Finally patients received a caudal epidural injection as previously.

The primary outcome measure was the McNab clinical outcome score (McNab score) and secondary outcome measures were the improvement in VAS scores for back pain and sciatica and occurrence of complications. Each patient completed a VAS score for their back pain and sciatica prior to their procedure as a baseline measurement. Patient follow up occurred, via telephone interview, 1 month after their procedure and also when the study ended. VAS scores and the McNab clinical outcome score were recorded along with any complications which had occurred.

The software used for statistical analysis was Stata 12.0 (Stata-corp, College Station, Texas). Patient characteristics were summarized and significant differences in characteristics between treatment groups were calculated using the two sample T-test or the Pearson Chi squared test.

An analysis of the efficacy of both treatment groups was performed using the following outcome measures:

1. Improvement in VAS of LBP 1 month after treatment
2. Improvement in VAS of LBP at final follow up
3. Improvement in VAS of sciatica at 1 month after treatment
4. Improvement of VAS of sciatica at final follow up
5. McNab clinical outcome score at 1 month after treatment
6. McNab clinical outcome score at final follow up

Comparisons of outcome results were made between APLD/Ozone/Epidural group and the caudal epidural group using a two sample T-test. A P-value < 0.01 indicated a statistically significant difference between the groups. The McNab score was also analysed as a categorical variable to give the percentage of patients within each treatment group with successful outcomes and the percentage with good-excellent outcomes.
The following subgroups were then analysed:

1. Patients aged less than 50 years (<50yrs)
2. Patients aged over 50 years (>50yrs)
3. Male patients
4. Female patients
5. Patients with sciatica that was worse than LBP (Sciatica>LBP)
6. Patients with LBP which was greater than sciatica (LBP>Sciatica)
7. Single level disc disease
8. Multi level disc disease
9. Patients with symptoms ongoing for less than 1 year (<1yr)
10. Patients with symptoms ongoing for over 1 (>1yr)
11. Patients with contained disc herniation
12. Patients with a non-contained disc herniation
13. Patients with signs of nerve root compression on MRI
14. Patients with no signs of nerve root compression on MRI

Within each subgroup comparisons of outcome results were made between APLD/Ozone/Epidural group and the caudal epidural group using a two sample T-test. The McNab score was also analysed as a categorical variable to give the percentage of patients within each treatment group with successful outcomes.

A power calculation demonstrated that 37 patients receiving the APLD/Ozone/Epidural treatment and 74 patients receiving caudal epidural treatment will give 84% power to detect a 30% difference in the outcome measures.
Results

Patient characteristics

132 patients were enrolled in this study, 28 (21%) received APLD/Ozone/Epidural and 104 (79%) received caudal epidural alone. Patient characteristics are recorded in Table 1.

Certain data was unavailable. 10 patients were lost to follow up and were excluded from the study. This included 3 (11%) in the APLD/Ozone/Epidural group and 7 (6.7%) in the caudal epidural group. 39 patients (32%) had documented lumbar disc herniation but not an MRI report or scan available for review. Of these 39 patients, 34 (28%) also had no record of presence of single or multi-level disc herniation. These patients with partially missing data were included in the overall analysis but excluded from analysis of the relevant subgroups.

Average patient age was 49.8 years (SD 16.55). The APLD/Ozone/Epidural group was significantly younger (40.3, SD 10.8) than the caudal epidural group (51.5, SD17.3) when analysed using the two sample T-test. The oldest patient was 84 and the youngest was 18.

73 males (59%) and 49 females (40 %) were included in this study. Using the Pearson's Chi squared test, no significant difference in gender distribution was found between the APLD/Ozone/Epidural and caudal epidural treatment groups.

Symptoms of sciatica were a prerequisite for inclusion in this study. 91 patients (75%) reported symptoms of sciatica>LBP. 31 patients (25%) reported symptoms of LBP>sciatica. Within the APLD/Ozone/Epidural treatment group, 20 patients (80%) reported symptoms of sciatica>LBP with 5 patients (20%) reporting symptoms of LBP>sciatica. Within the caudal epidural treatment group 72 patients (73%) reported symptoms of Sciatica>LBP with 26 (27%) reporting symptoms of LBP>Sciatica. There was no significant difference in type of symptoms between treatment groups.

94 patients (71%) reported symptoms ongoing for >1yr and 28 patients (21%) reported symptoms ongoing for <1yr. Within the APLD/Ozone/Epidural treatment group 15 patients (60%) reported symptoms ongoing for >1yr with 5 patients (40%) reporting symptoms of <1yr. Within the caudal epidural treatment group 80 patients (81%) reported symptoms ongoing for >1yr and 18 patients (19%) reported symptoms of <1yr. There was no significant difference in the duration of symptoms between treatment groups.

Of the patients with available MRI scans or reports:
• 68 (88%) had contained disc herniation and 11 (12%) had non-contained disc herniation. Within the APLD/Ozone/Epidural treatment group, 20 (83%) had contained disc herniations compared to 4 (17%) who had non-contained disc herniations. Within the caudal epidural treatment group, 53 patients (88%) had contained herniations compared to 7 (12%) with uncontained herniations. There was no significant difference in type of disc herniation between treatment groups.

• 36 (47%) had signs of nerve root compression on their MRI and 45 (53%) had no signs of nerve root compression. In the APLD/Ozone/Epidural group 19 (79%) had signs of nerve root compression with 5 (21%) having no signs of nerve root compression. In the caudal epidural group 20 (33%) had signs of nerve root compression whilst 40 (66%) had no signs of nerve root compression. There were a significantly greater percentage of patients with signs of nerve root compression in the APLD/Ozone/Epidural treatment group than in the caudal epidural group (Pearson’s Chi squared test).

• 35 (43%) patients had single level disc disease whilst 47 (57%) had multi-level disease. In the APLD/ozone/epidural group, 20 (71%) had single level disease whilst 8 (29%) had multi-level disease. In the caudal epidural group, 20 (33%) had single level disease and 41 (67%) had multi-level disease. There were a significantly greater percentage of patients with single level disc disease in the APLD/Ozone/Epidural than in the caudal epidural group (Pearson's Chi squared test).

Average follow up across all patients was 3.02 months (SD 1.3). There was no significant difference in follow up between APLD/Ozone/Epidural and caudal epidural treatment groups.

Table 1. Characteristics of patients included in study

<table>
<thead>
<tr>
<th></th>
<th>All patients (n=122)</th>
<th>APLD/Ozone/Epidural treatment group (n=25)</th>
<th>Caudal epidural treatment group (n=97)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average age (years)</td>
<td>49.7 (SD 16.557)</td>
<td>40.3* (SD 11.108)</td>
<td>52.2* (16.898)</td>
</tr>
<tr>
<td>Age Patients &lt;50yrs</td>
<td>65 (53.3)</td>
<td>21 (84)</td>
<td>44</td>
</tr>
</tbody>
</table>

Average follow up across all patients was 3.02 months (SD 1.3). There was no significant difference in follow up between APLD/Ozone/Epidural and caudal epidural treatment groups.
<table>
<thead>
<tr>
<th></th>
<th>Patients &gt;50yrs</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>(46.7)</td>
<td>(54.6)</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td>Male</td>
<td>73</td>
<td>18</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>49</td>
<td>7</td>
</tr>
<tr>
<td><strong>Pre-procedure symptoms</strong></td>
<td>Sciatica&gt;LBP</td>
<td>9</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>LBP&gt;Sciatica</td>
<td>31</td>
<td>20</td>
</tr>
<tr>
<td><strong>Duration of symptoms</strong></td>
<td>&lt;1year</td>
<td>28</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>&gt;1year</td>
<td>94</td>
<td>15</td>
</tr>
<tr>
<td><strong>Type of disc herniation</strong></td>
<td>Contained</td>
<td>68</td>
<td>18</td>
</tr>
<tr>
<td></td>
<td>Non-contained</td>
<td>9</td>
<td>3</td>
</tr>
<tr>
<td><strong>Degree of nerve root</strong></td>
<td>Nerve root</td>
<td>36</td>
<td>17</td>
</tr>
<tr>
<td>compression**</td>
<td>Compression</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Single or multi level disc</strong></td>
<td>No nerve root</td>
<td>41</td>
<td>4</td>
</tr>
<tr>
<td>disease**</td>
<td>compression</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Single level</td>
<td>35</td>
<td>17</td>
</tr>
<tr>
<td></td>
<td>Multi level</td>
<td>47</td>
<td>8</td>
</tr>
<tr>
<td><strong>Average duration of final follow up</strong></td>
<td>3.02</td>
<td>2.64#</td>
<td>3.12#</td>
</tr>
</tbody>
</table>
Legend:

- Numbers outside brackets = actual figures
- Numbers inside brackets = percentages unless stated otherwise
- * = Statistically significant difference in age between treatment groups
- # = No statistically significant difference between duration of final follow up
- **=this data not available on all patients in study

Overall Results

Table 2. Summary of results for all patients

<table>
<thead>
<tr>
<th>Outcome Score</th>
<th>Treatment Group</th>
<th>Caudal Epidural</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean improvement VAS back pain at 1 month</td>
<td>1.98 (1.9336)</td>
<td>1.79 (1.6962)</td>
<td>0.6320</td>
</tr>
<tr>
<td>Mean improvement VAS back pain at final follow up</td>
<td>2.1 (2.2126)</td>
<td>1.35 (1.5575)</td>
<td>0.0544</td>
</tr>
<tr>
<td>Mean improvement VAS sciatica at 1 month</td>
<td>3.48 (2.6750)</td>
<td>2.38 (2.3124)</td>
<td>0.0417</td>
</tr>
<tr>
<td>Mean improvement VAS sciatica at final follow up</td>
<td>3.36 (2.8814)</td>
<td>1.66 (2.1468)</td>
<td>0.0015</td>
</tr>
<tr>
<td>Mean McNab score at 1 month</td>
<td>3.4 (1.1547)</td>
<td>2.97 (0.8833)</td>
<td>0.0440</td>
</tr>
<tr>
<td>Mean McNab score at final follow up</td>
<td>3.28 (1.1733)</td>
<td>2.62 (0.8077)</td>
<td>0.0015</td>
</tr>
</tbody>
</table>

Numbers in brackets = standard deviation (SD)

Numbers in red indicate p-value of statistical significance

1. McNab clinical outcome score
This was the primary outcome measure which was recorded one month after treatment and at final follow up.

1. a. One month McNab score

The overall mean one month McNab score (Table 1) was higher in the APLD/Ozone/Epidural treatment group than the caudal epidural treatment group although this did not reach statistical significance. Patients treated with APLD/Ozone/Epidural had higher final McNab scores than those treated with caudal epidural except in patients with non-contained disc herniations and those with multi-level disc disease. However this difference did not reach statistical significance in any of the subgroups (Appendix: Supplementary Tables 1-7)

Graph 1 demonstrates the McNab score received by patients at one month after treatment. A McNab score of 4-5 is considered a good-excellent outcome. A McNab score of 3 and above is considered a successful outcome.

Table 2 demonstrates the percentage of patients whose treatment outcome was successful according to their one month McNab score. Overall 72% of patients had a successful outcome one month after APLD/Ozone/Epidural treatment compared to 62.8% of patients who had a successful outcome with caudal epidural treatment. The APLD/Ozone/Epidural treatment produces higher rates of success in all subgroups except patients with multi-level disc disease and patients with no signs of nerve root compression on MRI. However, no statistically significant differences were noted.

Table 3 demonstrates the percentage of patients whose treatment outcome was good-excellent according to their one month McNab score. Overall 56% of patients had good-excellent outcomes with APLD/Ozone/Epidural treatment compared to only 30.9% of patients with the caudal epidural treatment. This difference was close to significance. The APLD/Ozone/Epidural treatment produced higher rates of success in all subgroups except patients with multi-level disc disease and patients with non-contained disc herniation. None of the subgroups produced significant differences.

![Fig 1. All patients: McNab score at one month follow up](image)

**Table 3. McNab score at 1 month follow up, % of patients with successful outcome**

<table>
<thead>
<tr>
<th>Patient group</th>
<th>% of successful treatments based on 1 month McNab score</th>
<th>Caudal epidural treatment group</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>APLD/Ozone/Epidural treatment group</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient group</td>
<td>% of good-excellent outcomes at final follow up based on 1 month McNab score</td>
<td></td>
<td></td>
</tr>
<tr>
<td>-------------------------------</td>
<td>--------------------------------------------------------------------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>APLD/Ozone/Epidural treatment group</td>
<td>Caudal epidural treatment group</td>
<td>P-Value</td>
</tr>
<tr>
<td>All Patients</td>
<td>56%</td>
<td>30.9%</td>
<td>0.02</td>
</tr>
<tr>
<td>Female</td>
<td>57.1%</td>
<td>31%</td>
<td>0.17</td>
</tr>
<tr>
<td>Male</td>
<td>55.6%</td>
<td>30.9%</td>
<td>0.66</td>
</tr>
</tbody>
</table>

Table 4. McNab score at 1 month follow up, % with good-excellent outcome
The overall mean final McNab score was significantly higher in the APLD/Ozone/Epidural treatment group compared to the caudal epidural treatment group (Table 1). Patients treated with APLD/Ozone/Epidural had higher final McNab scores than those treated caudal epidural in all subgroups (appendix Table ??). McNab scores were significantly higher in the APLD/Ozone/Epidural treatment group in patients older than 50, those with symptoms ongoing for >1yr and those with single level disc herniation.

Graph 2 demonstrates the McNab score of patients at final follow up.

Table 4 demonstrates the percentage of patients with a successful outcome according to the final McNab score. Overall 68% of patients had a successful outcome at final follow up after receiving the APLD/Ozone/Epidural treatment compared to 51% of patients who had a successful outcome with caudal epidural treatment although this difference was not significant. The APLD/Ozone/Epidural treatment produced higher rates of success in all subgroups at final follow up with significant almost being reached in patients with single level disc disease.
Table 5 demonstrates the percentage of patients with good-excellent outcomes based on final McNab score. Overall 48% of patients who received APLD/Ozone/Epidural treatment had good-excellent outcome. This compares to only 13% of patients in the caudal epidural treatment group with good-excellent outcome. This difference was statistically significant. Patients treated with APLD/Ozone/Epidural had significantly higher rates of good-excellent outcome in; both female and male patients, all age groups, both symptom subgroups, patients with symptoms ongoing for >1 year, patients with contained disc herniation and patients with single level disc disease.

**Fig 2. All patients: McNab score at final follow up**

**Table 5. McNab score at final follow up, % of successful outcome**

<table>
<thead>
<tr>
<th>Patient group</th>
<th>% of successful treatments based on final McNab score</th>
<th>Caudal epidural treatment group</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Patients</td>
<td>68%</td>
<td>51%</td>
<td>0.12</td>
</tr>
<tr>
<td>Female</td>
<td>57.2%</td>
<td>45.2%</td>
<td>0.56</td>
</tr>
<tr>
<td>Male</td>
<td>72.2%</td>
<td>54.5%</td>
<td>0.18</td>
</tr>
<tr>
<td>&lt;50years</td>
<td>66.6%</td>
<td>45.4%</td>
<td>0.11</td>
</tr>
<tr>
<td>&gt;50years</td>
<td>75%</td>
<td>54.7%</td>
<td>0.43</td>
</tr>
<tr>
<td>LBP&gt;Sciatica</td>
<td>60%</td>
<td>42.3%</td>
<td>0.47</td>
</tr>
<tr>
<td>Sciatica&gt;LBP</td>
<td>70%</td>
<td>53.5%</td>
<td>0.19</td>
</tr>
<tr>
<td>Symptoms ongoing &lt;1yr</td>
<td>80%</td>
<td>66.7%</td>
<td>0.45</td>
</tr>
<tr>
<td>Symptoms ongoing &gt;1yr</td>
<td>60%</td>
<td>46.8%</td>
<td>0.35</td>
</tr>
<tr>
<td>Contained disc herniation</td>
<td>61.1%</td>
<td>50%</td>
<td>0.42</td>
</tr>
<tr>
<td>Non-contained disc herniation</td>
<td>66%</td>
<td>66%</td>
<td>1</td>
</tr>
<tr>
<td>Nerve root compression</td>
<td>64.7%</td>
<td>63.2%</td>
<td>0.92</td>
</tr>
<tr>
<td>Patient group</td>
<td>APLD/Ozone/Epidural treatment group</td>
<td>Caudal epidural treatment group</td>
<td>P-value</td>
</tr>
<tr>
<td>-------------------------------------</td>
<td>-------------------------------------</td>
<td>---------------------------------</td>
<td>---------</td>
</tr>
<tr>
<td>All Patients</td>
<td>48%</td>
<td>13%</td>
<td>0</td>
</tr>
<tr>
<td>Female</td>
<td>42.3%</td>
<td>11.9%</td>
<td>0.04</td>
</tr>
<tr>
<td>Male</td>
<td>50%</td>
<td>14.5</td>
<td>0.002</td>
</tr>
<tr>
<td>&lt;50 years</td>
<td>42.8%</td>
<td>13.6%</td>
<td>0.009</td>
</tr>
<tr>
<td>&gt;50 years</td>
<td>75%</td>
<td>13.2%</td>
<td>0.002</td>
</tr>
<tr>
<td>LBP&gt;Sciatica</td>
<td>0%</td>
<td>7.69%</td>
<td>0.004</td>
</tr>
<tr>
<td>Sciatica&gt;LBP</td>
<td>45%</td>
<td>15.5%</td>
<td>0.005</td>
</tr>
<tr>
<td>Symptoms ongoing &lt;1yr</td>
<td>50%</td>
<td>33%</td>
<td>0.38</td>
</tr>
<tr>
<td>Symptoms ongoing &gt;1yr</td>
<td>46.7%</td>
<td>8.9%</td>
<td>0</td>
</tr>
<tr>
<td>Contained disc herniation</td>
<td>50%</td>
<td>14%</td>
<td>0.002</td>
</tr>
<tr>
<td>Non-contained disc herniation</td>
<td>33%</td>
<td>16%</td>
<td>0.57</td>
</tr>
<tr>
<td>Nerve root compression</td>
<td>47%</td>
<td>15.8%</td>
<td>0.042</td>
</tr>
<tr>
<td>No nerve root compression</td>
<td>50%</td>
<td>13.5%</td>
<td>0.065</td>
</tr>
<tr>
<td>Single level disc disease</td>
<td>58.9%</td>
<td>5.5%</td>
<td>0.001</td>
</tr>
</tbody>
</table>
1. **2. Improvement in VAS LBP and sciatica scores**

This was the study's secondary outcome measure. No significant differences existed between baseline LBP and sciatica scores between the two treatment groups, overall and within patient subgroups (Appendix: Supplementary Tables 1-7).

There were improvements in LBP and sciatica scores one month after treatment and at final follow up in both treatment groups with the largest improvements found after treatment with APLD/Ozone/Epidural. However there was only a significant difference between treatment groups regarding the improvement in sciatica at final follow up (Table 1).

Graph 3 shows the overall final follow up results for each treatment group. Sciatica tends to improve more than LBP independent of treatment received and there was a greater improvement within the APLD/Ozone/Epidural treatment group than the caudal epidural treatment group.

**Fig 3. Overall results: improvement in VAS LBP/Sciatica and McNab score at final follow up**
Fig. 1: All patients: McNab score at one month follow up

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Fig. 2: All patients: McNab score at final follow up

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**Fig. 3:** Overall results: improvement in VAS LBP/Sciatica and McNab score at final follow up

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Conclusion

This prospective observational cohort study is the first to combine APLD, intradiscal ozone injection and caudal epidural injection (APLD/Ozone/Epidural) as a single minimally invasive treatment for discogenic sciatica. The aim of the study was to assess the efficacy and safety of this combination treatment and compare it to caudal epidural injection, the current first line minimally invasive treatment for discogenic sciatica. As well providing useful data in its own right, this project was designed as a pilot study with the data collected contributing to the planning of a RCT.

Results summary and analysis

Across the study population as a whole, the combination treatment of APLD/Ozone/Epidural produced superior results than caudal epidural alone in all outcome measures and at all follow up periods. It produced significantly better mean McNab scores and significantly larger mean improvements in sciatica at final follow up when compared to the caudal epidural treatment (Table 2). 72% of patients treated with APLD/Ozone/Epidural had a successful outcome at one month's follow up compared to 62.8% of patients treated with caudal epidural alone (Table 3). There was a greater difference at final follow up where 68% of patients treated with APLD/Ozone/Epidural had a successful outcome compared with 51% of patients treated with caudal epidural (Table 5). Despite these large differences in success rates, neither was statistically significant. The apparent superiority of the APLD/Ozone/Epidural treatment was more pronounced when the percentage of patients with good-excellent outcomes was calculated. At one month follow up 56% of patients treated with APLD/Ozone/Epidural had a good-excellent outcome compared to 30.9% treated with caudal epidural (Table 4) and this difference approached significance (p=0.02). Once again there was a greater difference between the treatments at final follow up where 48% of patients treated with APLD/Ozone/Epidural had a good-excellent outcome compared to just 13% treated with caudal epidural (Table 6). This difference was highly significant.

Overall the data demonstrates that the APLD/Ozone/Epidural treatment has a greater efficacy in the treatment of discogenic sciatica than caudal epidural injection alone. As well as this, the APLD/Ozone/Epidural treatment has a longer duration of action as demonstrated by the larger differences between treatment groups at final follow up when compared to one month follow up.

Within the subgroups, the APLD/Ozone/Epidural treatment had a tendency to produce better results than caudal epidural alone, although this difference did not always reach significance, possibly due to the relatively small numbers. Certain patient subgroups demonstrated excellent responses to APLD/Ozone/
Epidural treatment with higher McNab scores and significant differences in other outcome measures compared to the caudal epidural treatment. Subgroups which responded most favourably to the APLD/Ozone/Epidural treatment were:

- Age >50 (final follow up success = 75%, good-excellent 75%)
- Male patients (final follow up success = 72.2%, good-excellent 50%)
- Sciatica>LBP (final follow up success = 70%, good-excellent 45%)
- Symptoms ongoing < 1year (final follow up success = 80%, good-excellent 50%)
- Single level disc disease (final follow up success = 76.6%, good-excellent 58.9%)

All but six of the subgroups had significantly higher percentages of good-excellent outcomes in the APLD/Ozone/Epidural treatment group than the caudal epidural group at final follow up. This includes all the above subgroups as well as patients with contained disc herniation (Table 6).

Conversely certain patient subgroups responded less well to the APLD/Ozone/Epidural treatment, with relatively poor outcome scores and levels of success. The subgroups which responded least well to the combination treatment were:

- Multi level disc disease (final follow up success = 50%, good-excellent = 25%)
- LBP>sciatica (final follow up success = 60%, good-excellent = 0%)
- Non contained disc herniation (final follow up success 66%, good-excellent = 33%)

In these subgroups there was also no difference in final success or good-excellent outcome rates between APLD/Ozone/Epidural and caudal epidural treatments at final follow up (Tables 5 & 6).

This data will aid appropriate patient selection for APLD/Ozone/Epidural treatment in clinical practice and also in the subsequent RCT. Male patients, those with symptoms dominated by sciatica rather than LBP and those with single level contained disc herniation are likely to show the greatest improvement. Patients with symptoms dominated by LBP rather than sciatic and those with multi-level non-contained disc herniation are least likely to respond positively to APLD/Ozone/Epidural treatment.

Complications and side effects for each treatment were mild, rare and transient. No major complications occurring and both treatments appear to be safe. This is in agreement with the literature (REFF)

Strengths and limitations
This study has provided useful data in its own right as well as contributing to the planning of an RCT. Statistically significant differences have been found between treatment groups for a number of outcome measures. Subgroup analysis has also provided useful data which will allow more appropriate patient selection for the APLD/Ozone/Epidural treatment. When planning the RCT tighter and more appropriate inclusion and exclusion criteria can now be applied to patient selection.
References


Personal Information

Dr M.T. Crockett MB, BCh, BAO, BA, MCh, MRCS (Ire)
Department of Radiology,
Mater Misericordiae University Hospital, Eccles St, Dublin
Cappagh National Orthopaedic Hospital, Finglas, Dublin
Email: Matthewtcrockett@rcsi.ie