EVALUATION OF PERCUTANEOUS DISC DECOMPRESSION USING COBLATION IN CHRONIC BACK PAIN WITH OR WITHOUT LEG PAIN

Vijay Singh, MD, Chandur Piryani, MD, and Katherine Liao, MD

The intervertebral disc is the focal point of pathology for most low back pain. Contained disc herniation is a common cause of low back pain and, when unresponsive to conservative measures, is often treatable by disc decompression.

To evaluate the safety and efficacy of percutaneous disc decompression using Coblation (Nucleoplasty) in the treatment of back and/or leg pain associated with contained disc herniation, a prospective, non-randomized cohort analysis was conducted in an interventional pain management practice. Patients were followed for twelve months post procedure.

Eighty patients who presented with discogenic low back pain with or without radicular pain associated with contained disc herniation underwent percutaneous disc decompression using Coblation™ technology (Nucleoplasty™) after failing at least 3 months of conservative and injection therapies.

Overall, 75% of patients indicated a decrease in their numeric pain scores at 12 months with a statistically significant reduction in numeric pain scores of 2.43 ± 2.47 (p<0.0001) compared to baseline. A total of 54% of patients indicated pain relief of 50% or more at twelve months. Additionally, significant improvement was reported by 54%, 44%, and 49% of patients in sitting, standing and walking abilities, respectively, at 12 months. There were no instances of complications.

These results indicate that disc decompression using Coblation (Nucleoplasty) is a safe and efficacious procedure for reducing discogenic low back pain with or without leg pain.

Keywords: Percutaneous disc decompression, nucleotomy, contained disc herniation, discogram, coblation, nucleoplasty, radiofrequency, discitis

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Funding: There was no external funding in preparation of this manuscript.

Outside of the disc, the anterior and posterior longitudinal ligaments, which may be stretched by herniation or chemically irritated by the release of inflammatory chemicals from within the disc, are also richly innervated, providing another potential pain source (15).

Despite the multiple pain reception regions within the disc and spine, disc degeneration often occurs without any related discomfort. Herniations are present in up to 28% of asymptomatic individuals (19). Symptomatic disc herniation may be treated using a variety of modalities.

In 1934, Mixter and Barr (21) identified disc herniation as a source of radicular symptoms, and since then discectomy has been the most prevalent treatment for this condition. In the case of low back pain arising from contained disc herniations, Carragee et al (22) have reported that open surgical discectomies have a high failure rate (76%) when size of the herniation is less than 6 mm. In a separate prospective observational study (23) of 187 patients looking at the effects of fragment type and annular competence on clinical outcomes after lumbar discectomy, they reported that patients with no-fragment, contained group did poorly (38% recurrent or persistent sciatica).
compared to those with fragments.

Size and type of herniation is, however, only one of the factors in the success of disc decompression for symptomatic herniation. Amount of disc material removed has a significant impact on the success of discectomy (24). In one of the reports, data collected on 42 patients treated with automated percutaneous discectomy, indicated that patients who had undergone treatment with a 2 mm Nucleotome with removal of 1.95 g of disc material reported more satisfaction than those treated with a 2.5 mm Nucleotome with removal of, on average, 3.88 g of disc material (25). A two-fold decrease in success rates for discectomy, from 71% to 36%, was seen in patients with a large amount of disc material removed, averaging 3.8g including the central area of the nucleus, in contrast to removal of the hernial mass or migrated nucleus, averaging 1g. In addition, there was a more pronounced and rapid decrease in disc height coupled with a more drastic and pronounced increase in disc dehydration in the patients where a larger amount of material was excised (26). Mochida et al (26), during their analysis of disc material removal, have concluded that nucleotomy to reduce disc herniation should mimic asymptomatic disc degeneration and should therefore produce a gradual degenerative course, which cannot be achieved with removal of a large amount of disc material.

Annular integrity may be another important variable in achieving a more beneficial outcome for patients undergoing disc decompression. Annular repair occurs very gradually and a large incision into a degenerated-herniated disc will result in a decrease in anular strength during the healing process (27). Analysis of proteoglycan synthesis and degradation indicate that replacement of proteoglycan molecules within the disc may take up to 3 years (28). Three separate analyses have concluded that the box incision method leads to significantly poorer healing (29). Patients with post-operative scar tissue have been reported to have more severe complications (30). In comparison, epidural and foraminal adhesions and scarring is greatly reduced following minimally invasive, percutaneous procedures.

Percutaneous intradiscal entry is required for minimally invasive disc decompressive techniques. In view of the growing knowledge regarding the factors affecting annular healing and disc integrity, it has become imperative to search for techniques, which are minimally disruptive to the annular structure.

In the last two decades, there has been a gradual evolution in minimally invasive procedures. Among the several minimally invasive disc decompression techniques, the most recent is percutaneous disc decompression (PDD) using Coblation’s® plasma technology (Nucleoplasty™), with a minimally invasive percutaneous entry into the disc via a 17gauge cannula and removal of approximately 1g of disc tissue from the nucleus pulposus.

Since it was approved for use in spine in 2000, PDD with Coblation has been widely used. Within the last year, several analyses have been published on the efficacy of this technique. However the patient sample size of 1-year follow-up were relatively small. Follow-up data at 1 year was reported for 13 patients by Sharps and Isaacs (34) and 41 patients by Singh et al (35) while 6 months data included 14, 30, and 45 patients respectively (36-38). Based on the encouraging results from these initial studies the current analysis was undertaken to include a larger patient sample prospectively followed for 1 year.

**METHODS**

**Design and Participants**

A prospective, nonrandomized cohort analysis was conducted on 80 consecutive patients who underwent Percutaneous Disc Decompression using Coblation (Nucleoplasty) between October 2000 and March 2002.

Criteria for inclusion were the presence of discogenic low back pain and/or leg pain for three or more months, absence of neurologic deficit, lack of response to conservative management and fluoroscopically guided injection therapies. The diagnosis of discogenic pain was confirmed with positive provocative discography with elicitation of concordant pain and identification of at least one control disc negative for provoked pain.

Exclusion criteria for this outcome analysis included presence of secondary gain issues, heavy opioid usage, and uncontrolled psychological disorders. Contra-indications for the procedure, were evidence of infection, disc herniation with sequestration, large contained herniation occupying one-third or more of the spinal canal, marked spinal stenosis due to extensive osteophytosis, and equivocal discography results.

**Procedure**

Percutaneous disc decompression using Coblation (Nucleoplasty) was performed on an outpatient basis under monitored anesthesia care in the operating room of an ambulatory surgical center. All procedures were performed using a strict sterile technique by the corresponding author. Under fluoroscopic guidance with the patient in a prone or semi-oblique position, a 17-gauge six-inch long Crawford type spinal access cannula was placed at the junction of the anulus and nucleus. A Perc-DLE wand (ArthroCare, Inc. - Sunnyvale, CA) was advanced into the disc via the spinal access cannula. After confirming proximal and distal channel limits within the disc, disc decompression was initiated. The decompression process involved advancing the wand, in ablation mode, to the distal channel limit at a speed of 0.5 cm/sec and, retraction of the wand in coagulation mode, to the proximal channel limit at the same speed. Six channels were created at the twelve, two, four, six, eight, and ten o’clock positions.

Post-operatively, patients were allowed to perform limited walking, standing, and sitting as needed during activities of daily living, however, they were instructed to limit bending and stooping and lifting less than 10 pounds for 2 weeks. Patients with sedentary or light work environments were allowed to return to work after two weeks. Home exercise instructions were provided to patients by a qualified instructor.

**Outcome Measures**

Patients were asked to complete a questionnaire via phone or during post-
procedure physician visit at 1, 3, 6, and 12 months. Outcome measures included self-reported pain score on a numeric pain scale (with 0 being no pain and 10 being the most severe pain) and percent of pain relief as compared to the intensity of pain prior to the procedure. Functional improvement was measured based on patients reported ability to sit, stand, and walk without significant or intolerable pain in the following categories: less than 15 min., 15 to 30 min., 30 to 45 min., 45 min. to 1 hour, 1 to 2 hours, and greater than 2 hours.

Statistical Analysis

Outcome measure data was compared between pre-treatment and each post-treatment period. Means, ranges, and standard deviations (SD) were calculated using a Microsoft® Excel work sheet. For percentage outcomes and non-parametric values, 95% confidence intervals and Wilcoxon signed rank test were used to determine statistical significance, respectively. Variations in outcome data between subgroups based on demographic characteristics (age, weight, etc.) were determined using the Student’s t-test with a two-tailed comparison. Results were considered statistically significant if the p-value was equal to or less than 0.05 for continuous variables.

RESULTS

Patient Characteristics
A total of 80 patients, 56 females and 24 males, aged 15-62 (44.8 ± 10.1 years) underwent Percutaneous Disc Decompression. Data was collected for sixty-nine of 80 patients (86%) at 12 months. Of the eleven patients not included, five patients had suffered re-injury or a new injury due to a fall within 4 months of the procedure and 6 patients were lost to follow-up due to relocation. Participant

Table 1. Demographic characteristics

<table>
<thead>
<tr>
<th>Variable</th>
<th>Male (N=30)</th>
<th>Female (N=70)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td>Male (N=18)</td>
<td>Female (N=51)</td>
<td>0.49</td>
</tr>
<tr>
<td>Age (Years)</td>
<td>4.08</td>
<td>4.60</td>
<td></td>
</tr>
<tr>
<td>Onset of Pain</td>
<td>15-44 yrs (31)</td>
<td>&gt; 44 yrs (38)</td>
<td>0.18</td>
</tr>
<tr>
<td>Duration of Pain</td>
<td>3.98</td>
<td>4.86</td>
<td></td>
</tr>
<tr>
<td>Distribution of Primary Pain</td>
<td>Mostly Back (71% (57)</td>
<td>Mostly Leg (9% (7)</td>
<td>0.95</td>
</tr>
<tr>
<td>Body Mass Index</td>
<td>4.44</td>
<td>4.59</td>
<td></td>
</tr>
<tr>
<td>Smoking Habits</td>
<td>4.24</td>
<td>4.86</td>
<td></td>
</tr>
<tr>
<td>Level(s) of Decompression</td>
<td>Single level (79% (54)</td>
<td>Multi-level (13% (9)</td>
<td>0.48</td>
</tr>
<tr>
<td>Previous Surgical Intervention</td>
<td>Yes (60)</td>
<td>No (9)</td>
<td>0.14</td>
</tr>
</tbody>
</table>

Table 2. Influence of demographic characters on post-Nucleoplasty numeric pain score at 12 months

<table>
<thead>
<tr>
<th>Variable</th>
<th>12 Month Numeric Pain Score Values</th>
<th>p - value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td>Male (N=18)</td>
<td>Female (N=51)</td>
</tr>
<tr>
<td>Age (Years)</td>
<td>4.08</td>
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<td>4.59</td>
</tr>
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<td>4.24</td>
<td>4.86</td>
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<tr>
<td>Level(s) of Decompression</td>
<td>Single level (54)</td>
<td>Multi-level (15)</td>
</tr>
<tr>
<td>Previous Surgical Intervention</td>
<td>Yes (60)</td>
<td>No (9)</td>
</tr>
</tbody>
</table>

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Table 3. Numeric pain score results reported by patients post-percutaneous disc decompression (PDD)

<table>
<thead>
<tr>
<th>Follow-up</th>
<th>Percentage</th>
<th>95% Confidence Interval (Low, High)</th>
<th>Average Improvement in Pain Scores from Baseline</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 month (N=79)</td>
<td>82%</td>
<td>(72%, 90%)</td>
<td>3.04 ± 2.29</td>
</tr>
<tr>
<td>3 month (N=75)</td>
<td>79%</td>
<td>(68%, 87%)</td>
<td>2.79 ± 2.50</td>
</tr>
<tr>
<td>6 month (N=72)</td>
<td>76%</td>
<td>(65%, 86%)</td>
<td>2.67 ± 2.62</td>
</tr>
<tr>
<td>12 month (N=69)</td>
<td>77%</td>
<td>(65%, 86%)</td>
<td>2.43 ± 2.47</td>
</tr>
</tbody>
</table>

Table 4. Proportion of patients reporting sitting ability prior to and after PDD

<table>
<thead>
<tr>
<th>Time</th>
<th>Number of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-PDD (N=80)</td>
<td>3 month (N=75)</td>
</tr>
<tr>
<td>15 min</td>
<td>54% (43)</td>
</tr>
<tr>
<td>15-30 min</td>
<td>20% (16)</td>
</tr>
<tr>
<td>30-45 min</td>
<td>9% (7)</td>
</tr>
<tr>
<td>45 min -1 hr</td>
<td>5% (4)</td>
</tr>
<tr>
<td>1-2hr</td>
<td>3% (2)</td>
</tr>
<tr>
<td>&gt;2 hr</td>
<td>10% (8)</td>
</tr>
</tbody>
</table>

Fig 1. Proportion of patients reporting improvement in numeric pain scores post-percutaneous disc decompression (PDD)

Fig 2. Self-reported numeric pain score pre and post-Nucleoplasty

Outcomes

Overall, 75% (52/69) of patients indicated a decrease in their numeric pain scores at 12 months (Fig. 1 and Table 3) with a statistically significant reduction in numeric pain scores of 2.43 ± 2.47 (p<0.0001) compared to baseline (Fig. 2). A total of 54% of patients indicated pain relief of 50% or more at twelve months (Fig. 3). Additionally, 54%, 44%, and 49% of patients indicated statistically significant improvement in sitting, standing and walking ability, respectively, at 12 months as compared to baseline (Tables 4-6).

Employment

Ten patients (15%) who had previously been unemployed secondary to back pain improved enough to rejoin the work force.

Safety

There were no complications associated with the PDD procedure using Coblation technology during the procedure or post-operatively. Specifically, there were no instances of discitis, dural tear, or neurological deficit related to the procedure.

Discussion

Chronic back pain is a ubiquitous and functionally disabling condition. Back pain is frequently of multifactorial etiology with several different pain gen-
erators in the back and the spine contributing to a patient’s symptoms (39, 40). Discogenic pain is one of the major components of the low back pain syndrome. Imaging modalities including CT and MRI are frequently used to screen for disc disease. There is however, less than optimum correlation between visualized structural abnormalities and a pain-generating disc (41). Discography remains the mainstay for isolating the pain-generating disc from one which appears abnormal on imaging studies (42-45). Discography has also been shown to improve outcome following surgical interventions involving both open procedures as well as minimally invasive techniques (46-48). Patients included in our analysis had undergone discography to localize the pain generating disc level.

Management of discogenic pain is difficult and complex, and riddled with high failure rates (48). Traditional treatment methods have included physical therapy, activity modification, NSAIDS and fluoroscopically guided injection therapies, all with varying degrees of success. There is a wide body of literature on the potential adverse effects of long term NSAID and acetaminophen use. Several of these studies from this country (49, 50), as well as Europe (51-53) have made an epidemiological correlation between the use of these medications and the development of renal failure. In a case-control study, Kaye et al (54) reported a slight

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**Table 5. Proportion of patients reporting standing ability prior to and after PDD**

<table>
<thead>
<tr>
<th>Time</th>
<th>Pre-PDD (N=80)</th>
<th>3 month (N=75)</th>
<th>6 month (N=72)</th>
<th>12 month (N=69)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;15 min</td>
<td>61% (49)</td>
<td>33% (25)</td>
<td>38% (27)</td>
<td>42% (29)</td>
</tr>
<tr>
<td>15-30 min</td>
<td>21% (17)</td>
<td>12% (9)</td>
<td>14% (10)</td>
<td>9% (6)</td>
</tr>
<tr>
<td>30-45 min</td>
<td>3% (2)</td>
<td>17% (13)</td>
<td>7% (5)</td>
<td>12% (8)</td>
</tr>
<tr>
<td>45 min-1 hr</td>
<td>3% (2)</td>
<td>3% (2)</td>
<td>3% (2)</td>
<td>4% (3)</td>
</tr>
<tr>
<td>1-2 hr</td>
<td>10% (8)</td>
<td>27% (20)</td>
<td>26% (19)</td>
<td>29% (20)</td>
</tr>
<tr>
<td>Significance of Improvement from Pre-Op</td>
<td>N/A</td>
<td>&lt;0.0001</td>
<td>&lt;0.0001</td>
<td>0.0005</td>
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</tbody>
</table>

**Table 6. Proportion of patients reporting walking ability prior to and after PDD**

<table>
<thead>
<tr>
<th>Time</th>
<th>Pre-PDD (N=80)</th>
<th>3 month (N=75)</th>
<th>6 month (N=72)</th>
<th>12 month (N=69)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;15 min</td>
<td>55% (44)</td>
<td>29% (22)</td>
<td>33% (24)</td>
<td>42% (29)</td>
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<tr>
<td>15-30 min</td>
<td>20% (16)</td>
<td>12% (9)</td>
<td>11% (8)</td>
<td>7% (6)</td>
</tr>
<tr>
<td>30-45 min</td>
<td>5% (4)</td>
<td>15% (11)</td>
<td>7% (5)</td>
<td>7% (6)</td>
</tr>
<tr>
<td>45 min-1 hr</td>
<td>5% (4)</td>
<td>4% (3)</td>
<td>4% (3)</td>
<td>3% (2)</td>
</tr>
<tr>
<td>1-2 hr</td>
<td>3% (2)</td>
<td>9% (7)</td>
<td>11% (8)</td>
<td>7% (6)</td>
</tr>
<tr>
<td>&gt;2 hr</td>
<td>13% (10)</td>
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<td>33% (23)</td>
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<tr>
<td>Significance of Improvement from Pre-Op</td>
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<td>&lt;0.0001</td>
<td>&lt;0.0001</td>
<td>0.0008</td>
</tr>
</tbody>
</table>

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Fig 3. Proportion of patients reporting 50% more pain relief post-percutaneous disc decompression (PDD)

Fig 4. Proportion of patients reporting an increase in duration of sitting, standing and walking ability post-percutaneous disc decompression (PDD)
increase in renal cancer with heavy acetaminophen use. In a comment in the Hypertension journal, Dedier et al (55) reported a significantly increased trend towards incidental hypertension with increased use of aspirin, acetaminophen and other NSAIDs.

Long-term opiate therapy for benign pain is controversial. Although it may be effective in controlling the pain symptoms nonetheless there are concerns regarding abuse, dependence and diversion for illicit use (56-61).

Concerns over the long term usage of NSAIDs, acetaminophen and opiates have prompted a need for a treatment method/methods, which would reduce the long term usage of these medications for control of benign discogenic spinal pain. Minimally invasive intradiscal techniques have emerged as viable options for this indication. In a recent analysis from the U.K., Knight and Goswami (62) have reported sustained clinical benefit in 52% and functional improvement in an additional 21% of 348 patients treated with a KTP 532 laser. Others including Bosacco et al (63) and Pettine and Donner (64) have reported success rates ranging from 54 to 60%. Similar results have been reported for IDET by Saal and Saal (65), Singh (66) and Wetzel and McNally (67).

Percutaneous disc decompression using Coblation technique (Nucleoplasty) is yet another therapeutic option. Coblation has been in use for orthopedic arthroscopic procedures since the mid 1990s (68-70) and was approved for use in the spine in 2000. Nucleoplasty using Coblation technology involves the use of Radio-frequency energy to dissolve the nuclear material through molecular dissociation (68). The technique, offers a minimally invasive option of disc decompression while causing very little disruption of the surrounding tissue (71). Preserving the integrity of these tissues may maintain the flow of nutrients to the cells of the nucleus pulposus, resulting in an increased degree of cellular rejuvenation following the procedure. As several studies by Mochida et al (24, 72) and Sortland et al (25) have indicated, there appears to be an inverse correlation between the amount of disc material removed and the long term results. Excessive tissue removal leads to accelerated disc degeneration and instability. The Coblation procedure is also attractive in this regard as it involves removal of only a small amount of disc material, typically in the range of 1 ml (68).

This prospective, non-randomized study shows significant improvement in the pain relief and functional improvement for a patient group who were unable to find relief through conservative therapies.

As borne out by the results of this analysis, Percutaneous disc decompression using Coblation techniques, represents an effective method to add to our existing armamentarium for the treatment of discogenic low back pain. It may be argued that this was not a blinded, randomized controlled analysis, however it has been noted in several studies (73-75), that the results of non-randomized or observational studies are not necessarily inferior to those from randomized, double blinded, controlled trials. The typical double-blinded pharmacological trials involve a drug versus placebo. Designing a similar blinded trial for an invasive procedure versus a control or placebo arm presents logistic difficulties, since not doing the procedure in the control arm in itself would un-blind the study. While a sham procedure arm could be incorporated as a control arm, it would pose further ethical and medico-legal dilemmas. The large sample size in our analysis is very significant from a statistical standpoint.

Future research could also be directed towards increasing oxygenation during the procedure to enhance cellular metabolism and promote healing (76), implantation of healthy disc cells to replenish disc height and stability (77), or application of growth factors to repair the annular tissue (78, 79).

CONCLUSION

In conclusion, the preliminary results of a prospective, non-randomized series showed that disc decompression using Coblation (Nucleoplasty) is a safe and effective procedure in alleviating discogenic back pain, with or without leg pain. The results of this study demonstrated a statistically significant improvement in pain and functional status at 12 months.

REFERENCES

Singh et al • Evaluation of Percutaneous Disc Decompression


