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

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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, nonrandomized cohort analysis was conducted in an interventional pain management practice. Patients were followed for twelve

The intervertebral disc is an important component of the spine. Degeneration or herniation of the disc may not only produce discogenic or compressionrelated pain but may also significantly influence the integrity of other load bearing structures within the spine (1, 2).

Maintenance of disc integrity is directly correlated with supply of nutrients and removal of waste from the cells of the nucleus pulposus, however the central disc is an avascular structure. The majority of nutrients passing to the central disc are diffused through the endplates while a lesser amount travels through the anulus fibrosus (3). The central disc cells may be 6-8 mm away from either of these structures, forcing them to function in an anaerobic environment (4-7). With aging, disease, or injury, the structures through which nutrients diffuse may become less permeable to the essential blood supply, forcing more of the disc to function anaerobically. This nutritional suffocation provides an intradiscal environment

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

where cell degeneration is inevitable.

As disc degeneration progresses, a volume loss occurs within the nucleus pulposus due to a decrease in proteoglycan and water concentration, which may or may not be accompanied by structural changes in the endplate (8). Due to the lack of nutrients and oxygen, the cells are forced to metabolize anaerobically, generating large amounts of lactic acid, increasing acidity and further degrading the intradiscal matrix (3, 9). The strength of the lumbar disc depends on the fluid exchange and balance of proteoglycan synthesis and breakdown within the matrix. As these components decrease, the applied load is transferred to the anulus and posterior elements of the spine (10). This transfer greatly increases the probability of anular tear and/or herniation (11, 12).

The outer rim of the annulus is innervated by the meningeal branch of the recurrent sinuvertebral nerve, as well as the rami communicantes from multiple superior and inferior dorsal root ganglia (13-15). With degeneration, anular tearing, and herniation, these nerves may further invade the deeper intradiscal structures as far as the outer rim of the nucleus pulposus and create additional pain reception sites within the disc itself (16-20). 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)

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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), a decrease in strength of 40-50% (30), and an increase in severe and early disc degeneration (27). Another analysis (31) indicated that square, circular, cross, and slit incisions each produce a larger range in motion during axial moment loadings. Annular entry with a 2.5 mm OD trocar, maintained disc integrity during biomechanical loading (30).

Another important factor affecting the outcome after surgical procedures is

formation of adhesions and scar tissue. Adhesions between the posterior anulus and the nerve root are common following discectomies (32). Patients with post-operative scar tissue have been reported to have more severe complications (33). 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 CoblationsTM plasma technology (NucleoplastyTM), 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 Isaac (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 1year.

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 sixinch long Crawford type spinal access cannula was placed at the junction of the annulus 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

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 pvalue was equal to or less than 0.05 for continuous variables.

Cander	Male	30% (24)	
Gender	Female	70% (56)	
Ann ((100x0)	Mean ± SD	44.8 ± 10.1	
Age (Years)	Range	15 – 62	
Onset of Pain	Traumatic	15% (12)	
	Non-traumatic	85% (68)	
Duration of Pain (Years)	Mean ± SD	5.5 ± 6.0	
	Range	0.25 - 30	
BMI (Body Mass Index)	Mean ± SD	29 ± 5.6	
Cmaking Habita	Nonsmoking	65% (63)	
Smoking Habits	Smoking	35% (28)	
level(c) of Decomprosed	Single level	79% (54)	
Level(s) of Decompression	Multi-level	21% (13)	
Distribution of Primary Pain	Mostly Back	71% (57)	
	Mostly Leg	9% (7)	
	Equal Back and Leg	9% (7)	
	Other	11% (6)	

Table 1. Demographic characteristics

Results

Patient Characteristics

A total of 80 patients, 56 females and 24 males, aged 15-62 (44.8 \pm 10.1 years) underwent Percutaneous Disc Decom-

pression. Data was collected for sixtynine 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 2. Influence of demographic characters on post-Nucleoplasty numeric pain score at 12 months

Variable	12 Month Numeric Pain Score Values		p - value	
Gender	Male (N=18)	Female (N=51)	0.49	
	4.08	4.60		
	15-44 yrs (31)	> 44 yrs (38)	0.18	
Age (Years)	3.98	4.86		
Onset of Dein	Traumatic (58)	Non-traumatic (11)		
Onset of Pain	4.44	4.59	0.95	
Duration of Pain	Pain < 3 yrs (20)	Pain ≥ 3 yrs (49)	o (8	
	4.83	4.32	0.48	
	< 30 (43)	≥ 30 (26)	0.34	
buy mass muex	4.22	4.87		
Smoking Habits	Nonsmoking (44)	Smoking (25)		
Smoking Habits	4.24	4.86	0.00	
Level(s) of Decompression	Single level (54)	Multi-level (15)	0.20	
	4.69	3.67		
Distribution of Primary Pain	Primary Back (46)	Other (23)		
	4.65	4.09	0.42	
Previous Surgical Intervention	Yes (60)	No (9)		
	4.28	5.72	0.14	





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



characteristics are shown in Table 1. Influence of demographic characters on post-Nucleoplasty numeric pain score at 12 months showed no statistically significant differences (Table 2).

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 \pm 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-

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

	Patients reporting improvement in numeric pain scores (%)		Average Improvement in Pain Scores from Baseline	
Follow-up	Percentage	95% Confidence Interval (Low, High)	Average ± SD	p values
1 month (N=79)	82%	(72%, 90%)	3.04 ± 2.29	<0.0001
3 month (N=75)	79%	(68% , 87%)	2.79 ± 2.50	<0.0001
6 month (N=72)	76%	(65% , 86%)	2.67 ± 2.62	<0.0001
12 month (N=69)	77%	(65%, 86%)	2.43 ± 2.47	<0.0001

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

Time	(Number of Patients)			
	Pre-PDD (N=8o)	3 month (N=75)	6 month (N=72)	12 month (N=69)
<15 min	54% (43)	24% (18)	35% (25)	38% (26)
15-30 min	20% (16)	8% (6)	8% (6)	12% (8)
30-45 min	9% (7)	20% (15)	7% (5)	6% (4)
45 min -1 hr	5% (4)	4% (3)	7% (5)	6% (4)
1-2hr	3% (2)	16% (12)	4% (3)	4% (3)
>2 hr	10% (8)	28% (21)	39% (28)	35% (24)
Significance of Improvement from Pre-Op	N/A	(0.0001	<0.0001	0.0001



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 postpercutaneous disc decompression (PDD)

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

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

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

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

Time	(Number of Patients)			
	Pre-PDD (N=8o)	3 month (N=75)	6 month (N=72)	12 month (N=69)
<15 min	55% (44)	29% (22)	33% (24)	42% (29)
15-30 min	20% (16)	12% (9)	11% (8)	7% (5)
30-45 min	5% (4)	15% (11)	7% (5)	7% (5)
45 min -1 hr	5% (4)	4% (3)	4% (3)	3% (2)
1-2hr	3% (2)	9% (7)	11% (8)	7% (5)
>2 hr	13% (10)	31% (23)	33% (24)	33% (23)
Significance of Improvement from Pre-Op	N/A	(0.0001	<0.0001	0.0008

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.

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