Pain Physician. 2005;8:385-389, ISSN 1533-3159

A Retrospective Evaluation

New Approach to the Management of Acute Disc Herniation

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Background: Over 500,000 percutaneous disc decompression procedures have been performed in the past 20 years. Various percutaneous techniques include chemonucleolysis, percutaneous lumbar discectomy, and laser discectomy which have reported success rates in the 70% to 75% range. This retrospective evaluation of 49 patients who underwent nucleoplasty procedures for treatment of herniated discs, evaluates the effectiveness of nucleoplasty in the reduction of pain, improvement of functional activity, and reduction of pain medication.

Objective: To illustrate the effectiveness of nucleoplasty in reducing low back pain in symptomatic patients with contained herniated discs.

Study design: A retrospective, non-randomized study.

Methods: Forty-nine patients with either axial or radicular low back pain who had undergone the nucleoplasty procedure were included in this analysis. Patients were categorized in one of three different groups depending on time elapsed since the procedure was performed: less than 6 months, between 6 months and 1 year, and greater than 1 year.

Pain reduction, work impairment, leisure impairment, medication use and patient satisfaction were all recorded during this study. Pain was quantified using a numeric pain scale from 0 to 10. Work and leisure impairment were measured on a scale of 1 to 5, with 1 signifying no impairment and 5 signifying extreme impairment. Medication use and patient satisfaction were also measured on a scale of 1 to 5.

Results: Significant pain relief, functional improvement, and a decrease in medication use were achieved following nucleoplasty. There were no complications associated with the procedure.

Conclusion: Nucleoplasty should be used in those patients who fail conservative medical management including medication, physical therapy, behavioral management, psychotherapy, and who are unwilling to undergo a more invasive technique such as spinal surgery.

Keywords: Nucleoplasty, disc herniation, Coblation, low back pain

The percutaneous decompression of herniated discs is a well-established clinical approach with over 500,000 procedures performed during the past 20 years. Several percutaneous techniques are in practice including chemonucleolysis, percutaneous lumbar discectomy, and laser discectomy. These procedures have reported success rates of 70% to 75% but each has its limitations. The use of chymopapain showed that disc decompression could be used as a treatment modality for back and leg pain due to herniated discs (1); however, it resulted in an unacceptable level of complications and is no longer available in the United States (1, 2). Automated percutaneous lumbar discectomy (APLD) and laser discectomy are in limited use today due to a combination of clinical, design, patient comfort, and cost factors (3-7).

The nucleoplasty procedure is minimally invasive and utilizes Coblation™ technology to create a plasma field at the tip of the device. The plasma field contains sufficient energy to cleave molecular bonds, thereby ablating tissue. The ablation process creates small channels within the disc, removing that portion of tissue. Coagulation mode is then applied to thermally treat the channels to further decompress the intervertebral disc.

The objective of this study is to illustrate the effectiveness of the nucleoplasty procedure in reducing pain, improving functional activity, and reducing pain medication use in symptomatic patients with contained herniated discs. Several studies have been performed which show that nucleoplasty is effective in reducing pain. One study has shown that nucleoplasty has success rates of up to 80% with a visual analog scale (VAS) pain score reduction of up to 57% (8). Other studies showed that 79% - 85% of patients reported VAS pain score reductions at 1-, 3-, 6-, 9- and 12-month follow-ups (9, 10). None of the studies we have reviewed have monitored pain reduction, functional activity, and medication use in nucleoplasty patients more than one year following the procedure.

Methods

Sixty-seven consecutive patients who had undergone nucleoplasty procedures between January 1, 2002, and May 31, 2003, were selected for this retrospective study. Of the 67 patients contacted, 49 patients completed the survey (73%). Of the 18 patients who did not participate, 13 patients could not be reached while the remaining five simply did not want to participate in the study. While there was no inclusion criteria for the study itself, patients were selected to undergo nu-

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Disclaimer: There was no external funding in the preparation of this manuscript.
Conflict of interest: None
Manuscript received on 7/10/2005
Revision submitted 8/26/2005
Accepted for publication 9/1/2005
The information in this retrospective review was presented at the Radiological Society of North America 89th Scientific Assembly and Annual Meeting, November 30, 2003 – December 5, 2003, McCormick Place, Chicago, IL (Educational exhibit 0844VI-e)

cleoplasty based on the presence of either radicular/axial symptoms or axial symptoms. Radicular criteria for inclusion include the following: leg pain > back pain, evidence of contained posterior disc protrusion on MRI, positive discography with concordant pain, or failed selective nerve root block. Axial criteria for inclusion include the following: failed conservative therapy for 3 months, evidence of contained central focal disc protrusion on MRI, or positive discography with concordant pain. Patients were excluded from the study if there was a loss of more than 50% of disc height, evidence of severe disc degeneration, a fracture or tumor of the spine, or moderate to severe spinal stenosis.

The risks, benefits, and alternatives of the procedure were explained in detail to each patient and consent forms were signed. Each patient was given premedication including 25 mgs of Vistaril, 0.5mg of Ativan, and 0.5mg of Xanax approximately 30 minutes before being brought to the neurointerventional suite. In the neurointerventional operating theater, each patient was given a gram of intravenous Ancef®. The patient was placed in a prone position on the table, prepped, and draped in the usual sterile fashion.

Using standard techniques, the back was evaluated fluoroscopically and the involved disc space was opened up in the frontal view by rotating in a craniocaudal direction. Under fluoroscopic guidance, a 25-gauge tuberculin needle followed by a 6-inch, 22-gauge spinal needle, followed ultimately by a 17-gauge, 6-inch Crawford needle were used to access the disc. Intravenous contrast was administered when the Crawford needle was placed inside the nucleus pulposus at the junction of the nucleus and the annulus. This discogram was used to confirm discogenic pain or the presence of herniation or degeneration. Through this approach, contrast fills the disc from side-to-side, eventually permeating throughout the entire disc.

Percutaneous discectomy was performed with the aid of an ArthroCare® wand. As suggested by the manufacturer, a total of six passes were performed. Following percutaneous discectomy, the trocar was pulled back into the Crawford needle, and a selective nerve root block was performed using 2 cc of 0.25% preservative free bupivacaine and 60 mg of methylprednisolone. The needle was removed and a Syvek Patch® placed over the wound site. Fentanyl and Versed were administered during the procedure as part of conscious sedation and were monitored continuously by the radiology nurses.

Several months after the procedure, all of the patients were contacted via phone and were asked questions from a standardized script by a trained volunteer who was not blinded to the study. Patients were asked to quantify pain, how much pain interfered with work and hobbies, pain medication use, and if previous spinal surgeries were performed before the nucleoplasty procedure was performed. Patients were then asked to quantify their pain, work impairment, leisure impairment, and medication use after the nucleoplasty procedure. Finally, patients were asked to quantify their satisfaction level on a scale from 1 to 5, and asked if they would recommend the procedure to a friend with back pain.

Pain was quantified using a numeric pain scale from 0 to 10. Work and leisure impairment were measured on a scale of 1 to 5, with 1 signifying no impairment and 5 signifying extreme impairment. Medication use and patient satisfaction were also measured on a scale of 1 to 5 as shown in Tables 1 and 2.

The 49 patients were then divided into three separate groups based on the time elapsed since the nucleoplasty was performed: Group 1 – less than six months (n = 16); Group 2 – six months to one year (n = 22); Group 3 – greater than one year (n = 11). All procedures were performed under local anesthesia and written informed consent was received from all patients.

Table 1. *Medication Use Scoring Scale*

1	No medications
2	Occasional non-narcotic
3	Daily non-narcotic
4	Occasional narcotic
5	Daily narcotic

Table 2. *Patient Satisfaction Scoring Scale*

1	Unsatisfactory
2	Satisfactory
3	Good
4	Very Good
5	Excellent

Pre-procedure and post-procedure means, ranges, and standard deviations were calculated. VAS pain score data, work impairment, leisure impairment, and medication use were analyzed using a two tailed paired student t-test with statistical significance set at a p-value <0.05.

Results

Patient Demographics

Patient demographics are illustrated in Table 3.

Pain Reduction

On average, there was a 3.67 reduction in VAS score with a mean baseline VAS score of 8.08.

Figure 1 illustrates the pain score both before the nucleoplasty procedure and after the procedure. A significant reduction in pain in all groups was shown following the nucleoplasty procedure with p-values of 0.000036, 0.000009, and 0.017, for groups 1, 2, and 3 respectively.

Functional Improvement

Figure 2 illustrates the level of work impairment both before and after the nucleoplasty procedure. A significant reduction in work impairment in all groups was shown following the nucleoplasty procedure with p-values of 0.015, 0.00024, and 0.041, for groups 1, 2, and 3 respectively.

Figure 3 illustrates the level of leisure impairment both before the nucleoplasty procedure and after the procedure. A significant reduction in leisure impairment in all groups was shown following the nucleoplasty procedure with p-values of 0.019, 0.0018, and 0.029, for groups 1, 2, and 3 respectively.

Pain Medication Use

Figure 4 illustrates the level of pain medication use both before and after the nucleoplasty procedure. A significant reduction in pain medication use in all groups was shown following the nucleoplasty procedure with p-values of 0.038, 0.00056, and 0.035, for groups 1, 2, and 3 respectively.

Satisfaction

Most patients surveyed would recommend nucleoplasty to a friend. Group 3 had a 91% (10/11) recommendation rate, followed by Group 1 at 75% (12/16), and Group 2 at 73% (16/22). All three groups surveyed showed similar satisfac-

Table 3. *Patient demographics*

		Group 1	Group 2	Group 3	Total
Gender	Male	10	16	7	33
	Female	6	6	4	16
Age (years)	Mean	43	45	48	45
	SD	12	10	9	11
	Range	22-67	29-64	34-64	22-67
Origin of pain	Trauma	10	5	3	18
	Work related	2	5	2	9
	Other	4	12	6	22
Duration of pain	Mean	5	5	5	5
	SD	4	6	6	5
	Range	1-15	1-25	1-20	1-25
Previous discectomy		6% (1)	5% (1)	2% (1)	6% (3)
Occupation entails strenuous activity		31% (5)	19% (4)	9% (1)	20% (10)
Decompression sites	L2-L3	0% (0)	5% (1)	9% (1)	4% (2)
	L3-L4	19% (3)	9% (2)	18% (2)	14% (7)
	L4-L5	63% (10)	59% (13)	18% (2)	51% (25)
	L5-L6	0% (0)	0% (0)	9% (1)	2% (1)
	L5-S1	19% (3)	23% (5)	45% (5)	27% (13)
	T7-T8	0% (0)	5% (1)	0% (0)	2% (1)
	Multiple levels	6% (1)	5% (1)	18% (2)	8% (4)
Classification of pain	Axillary	31% (5)	32% (7)	64% (7)	39% (19)
	Radicular	31% (5)	45% (10)	36% (4)	39% (19)
	Both	38% (6)	23% (5)	0% (0)	22% (11)

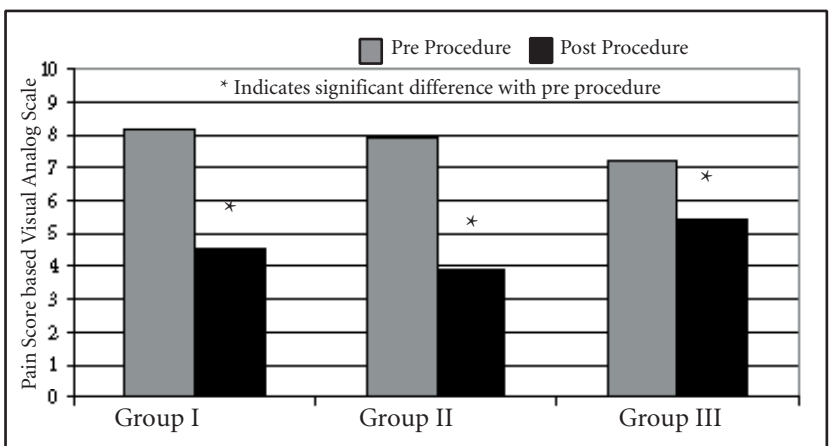

Fig. 1. *Pain reduction*

tion rates averaging slightly above "good" on the scoring scale (3.06, 3.09, and 3.27 for groups 1, 2, and 3 respectively).

Complications

There were no neurological or other complications resulting from the procedure.

Discussion

This retrospective evaluation of 49 patients shows that nucleoplasty leads to a statistically significant reduction in low back pain. Other studies have defined significant pain relief as the reduction of pain by at least 50%; by that standard we found that pain relief was achieved in 56.4% (9/16), 64.6% (14/22), and 45.0% (5/11) for groups 1, 2, and 3 respectively.

Of the seven patients in Group 1 who did not have significant pain relief, four patients went on to have spinal surgery to help with the pain. Only one out of those four patients expressed that they were "unsatisfied" with the nucleoplasty procedure.

In Group 2, eight patients did not report significant pain relief and four patients underwent surgery to alleviate their back pain. All four of the patients who had surgery responded that they were "unsatisfied" with the nucleoplasty procedure.

Of the six patients in Group 3 that did not report significant pain relief, only two went on to receive spinal surgery and both expressed that they were "satisfied" with the nucleoplasty procedure.

The proportion of patients who had achieved at least a 50% reduction in pain varied among the three groups. It increased from roughly 56% in Group 1, to 65% in Group 2, and decreased greatly to 45% in Group 3. The general decline in 50% pain relief over time has been observed in many different interventions for low back pain (11, 12). Our VAS pain results are consistent with one other study which showed downward trends in pain scores initially over the first three months, with a steady increase thereafter (8). One thought is that continued trauma, either due to aging or injury, may be continuing in these patients. While the nucleoplasty procedure reduces volume and intradiscal pressure, the underlying cause of the disease may still be present and if not corrected, may continue the progression of the disease.

Our results illustrate that pain reduction is still present more than 1 year after the procedure; however, the decrease in pain relief over time is concerning and further research will have to be performed to isolate the nature of the recurring back pain.

Our study may be criticized because of our study design which included non-randomization of patients, gathering baseline data after the procedure had been performed, and non-blinding of the data during the recording and analysis phase of the study. We will attempt to address each issue.

While we recognize that the gold standard of studies is the randomized,

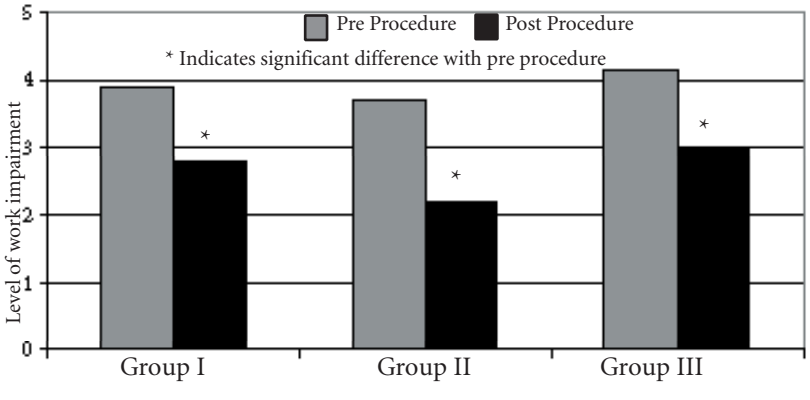

Fig. 2. *Work impairment*

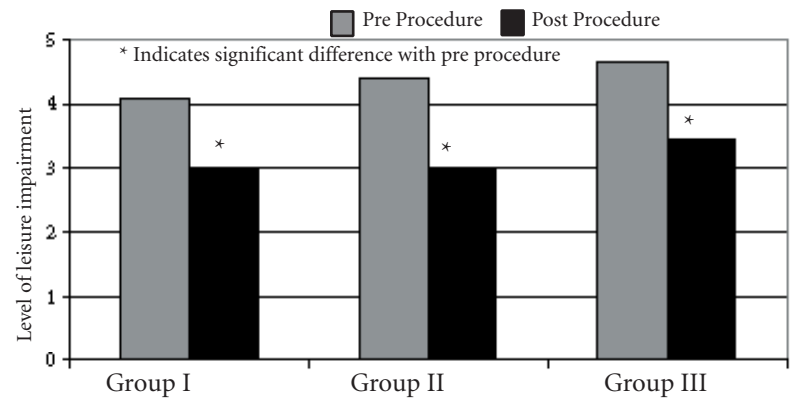

Fig. 3. *Leisure impairment*

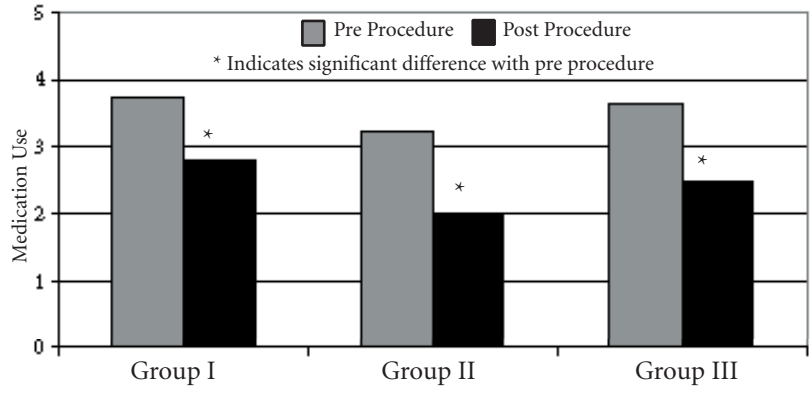

Fig. 4. *Pain medication use*

double-blind study, due to ethical concerns and other logistical problems, randomized interventional studies are not widely performed. If we could repeat the study again, we would change the design to a prospective study where the data recording and analysis portions would be blinded to the researchers. By changing the design to such a study, we could eliminate one of the biggest weaknesses of our study – recall bias. We did not have the foresight to record patient baseline data during the pre-procedural office evaluation. While we agree that the study design would have been much stronger had we reduced potential recall bias, our mean baseline VAS pain score of 8.08 is consistent with other pain scores in at least one other study (8).

Our results may not show as great a reduction on the VAS pain scale because our inclusion criteria were less stringent. Several of the studies excluded patients with herniations greater than one-third the diameter of the spinal canal, while we excluded patients if they had herniations greater than one-half of the spinal canal diameter (8-10). While we still demonstrated a significant reduction in pain on the VAS scale, we may have shown an even greater reduction in pain and an even higher percentage of patients with at least a 50% reduction of pain had our criteria been less inclusive. By accepting patients with larger herniations, we included patients with more severe back problems who might not have found as much relief through nucleoplasty. The fact that we were able to demonstrate pain relief in this more complicated patient group illustrates that the nucleoplasty procedure shows promise as a therapeutic interventional technique.

Conclusion

Our study shows statistically significant reductions in pain and the use of pain medications, and improvements in function as a result of using nucleoplasty to percutaneously decompress the disc. Nucleoplasty should be used in those patients who fail conservative medical management including medication, physical therapy, behavioral management, psychotherapy, and/or chiropractic treatment, and who are unwilling to undergo a more invasive technique such as spinal surgery.

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