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Retrospective Study

Outcomes of Percutaneous Disc Decompression Utilizing Nucleoplasty for the Treatment of Chronic Discogenic Pain

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Background: Percutaneous disc decompression utilizing Nucleoplasty has emerged as one of the minimally invasive techniques for treatment of low back pain and lower extremity pain due to contained herniated discs. Only 1 study to date has examined its effect on functional activity and pain medication use; however, results were not analyzed over time, and recall bias was a limitation.

Objective: Evaluation of the effect of Nucleoplasty on pain and opioid use in improving functional activity in patients with radicular or axial low back pain secondary to contained herniated discs.

Design: Retrospective, non-randomized case series.

Methods: Twenty-two patients who had undergone Nucleoplasty were included in the analysis. Patients were evaluated at 1, 3, 6, and 12 months postoperatively, and were asked to quantify their pain using a visual analog scale ranging from 0 to 10. Patients were also surveyed in regards to their pain medication use, and functional status was quantified by a physical therapist who also used patient reports of ability to perform activities of daily living to assess status. Data were compared between baseline and at 1, 3, 6, and 12 months post-treatment.

Results: Reported pain and medication use were significantly decreased and functional status was improved at 1, 3, 6, and 12 months following Nucleoplasty (P values $\leq$ 0.0010 for all outcome measures at all time periods). There were no complications associated with the procedure and we found continued improvements over time.

Conclusion: Nucleoplasty appears to be safe and effective. Randomized, controlled studies are required to further evaluate its long-term efficacy.

Key words: Discectomy, disc herniation, low back pain, minimally invasive, Nucleoplasty, percutaneous disc decompression.

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Over the past 4 decades, there has been increased interest in developing minimally invasive techniques for the treatment of disc herniations and chronic discogenic pain (1,2). This trend may be related to concerns relative to surgical trauma, potential complications of operative interventions including death (3-5), and questionable efficacy in relieving discogenic pain (6).

Historically, percutaneous disc decompression began in 1963 with the development of chemonucleolysis (7). Thereafter, several other minimally invasive procedures followed, including percutaneous decompression of the nucleus pulposis developed in 1975 by Hijikata (8), automated percutaneous lumbar discectomy reported by Onik in 1985 (9), and laser discectomy in 1987 (10). Collectively, all these percutaneous decompression approaches are associated with potential complications, limitations, or poor outcomes.

Percutaneous lumbar discectomy violates the annular integrity due to the sizable incision required to reach the nucleus. This may accelerate future disc degeneration, and the outcome may be equivocal (11). Laser discectomy is lengthy, requires bulky and expensive equipment, may inflict endplate damage, and may result in significant intraoperative and postoperative pain and spasm (12). Chemonucleolysis using chymopapain may lead to over-decompression due to difficulty in predicting the amount of nucleus that would be digested and can cause paralysis due to transverse myelitis, anaphylaxis, bleeding, or endplate injury (13,14).

Recently, percutaneous disc decompression using Nucleoplasty has emerged as an effective, minimally invasive, percutaneous technique for the treatment of low back pain due to contained herniated discs (15-18). This procedure is attractive because it does not require expensive equipment, takes minimal time to perform, does not cause significant intraoperative or postoperative pain, is safe, and allows for quick rehabilitation. The Nucleoplasty procedure utilizes Coblatiom technology which allows for decompression of the disc using radiofrequency energy in a less damaging, low-temperature environment for the surrounding tissues (19).

Currently, there are few studies supporting the efficacy of percutaneous disc decompression utilizing Nucleoplasty for the treatment of chronic discogenic pain. Several studies have shown that Nucleoplasty does effectively reduce pain in patients with contained herniated discs (15-18). Only one study to date has examined the effect Nucleoplasty has on functional activity, pain relief, and pain medication use (18). However, this study did not analyze results over time and recall bias was a major limitation of the study. In the present report, outcomes of 22 non-randomized patients treated with percutaneous disc decompression utilizing Nucleoplasty were examined relative to the following endpoints: reduction of pain, improvement in functional activity, and reduction of opioid use longitudinally over 1 year in patients with radicular or axial low back pain secondary to contained herniated discs.

Methods

Patient Selection

This retrospective study of a case series of non-randomized patients was conducted in the Department of Interventional Pain Management at Marshfield Clinic, a large, multispecialty, private outpatient clinic in central Wisconsin. Patients (n=22) who had undergone percutaneous disc decompression using Nucleoplasty between February 2004 and August 2005 in the course of clinical care were selected for inclusion (54.5% male, 45.5% female; mean age 39 years; range 22– 51 years). Patients' medical charts were reviewed, and pertinent data such as age, gender, smoking history, involvement in litigation processes, history of drug and alcohol abuse, location of pain, levels of performed procedure, duration of the procedure, pre- and post-procedural visual analog scale (VAS) pain scores, functional status, and medication intake were abstracted.

Percutaneous Disc Decompression Utilizing Nucleoplasty

Inclusion criteria to select patients for percutaneous disc decompression using Nucleoplasty included

1) Duration of radicular or axial low back pain of 6 or more months with failed conservative treatment including fluoroscopically-directed injection techniques (e.g. lumbar epidural steroid blocks, selective nerve root blocks, facet and sacroiliac joint injections) which were performed as part of each patient's diagnostic and therapeutic algorithm (20)
2) no history of neurological deficit
3) preserved disc height (e.g. <50% loss)
4) discography confirming concordant pain at each suspected level and ruling out involvement at other levels

5) contained disc protrusion on magnetic resonance imaging study.

Exclusion criteria which ruled patients out as candidates for percutaneous disc decompression using Nucleoplasty included

1) infection
2) spinal tumor or fracture
3) more than 2 symptomatic levels
4) disc sequestration or spinal stenosis on magnetic resonance imaging study
5) history of open disk surgery at suspected levels
6) prominent coexisting psychological disorders.

All patients were treated on an outpatient basis in the operating room of the ambulatory surgery center. Percutaneous disc decompression using Nucleoplasty was performed under monitored anesthesia care in the usual sterile fashion. Under fluoroscopic guidance with the patient in the prone position, a 17-gauge, 6-inch Crawford needle was advanced via a left or right posterolateral discography approach to the junction of the annulus and nucleus. The Spine wand (ArthroCare Spine, Inc., Sunnyvale, CA) was inserted into the disc through the needle. The proximal and distal limits for intradiscal movement of the wand were identified, and disc decompression was started. At each level, 6 channels were made circumferentially at the 12, 2, 4, 6, 8, and 10 o'clock positions. Every channel was created by advancement of the wand in ablation mode and by its retraction in coagulation mode. After withdrawal of the wand, 2 mL of 0.25% bupivacaine with 40 mg cefazolin was injected, and the needle was removed. There were no complications and there were no instances in which the intrathecal space was violated or increased resistance was noted.

Outcome Measures

Patients were evaluated by an independent evaluator preoperatively and at 1, 3, 6, and 12 months postoperatively. Data collected included VAS pain scores, pain medication intake, and functional abilities, including changes in performance levels of activities of daily living.

Pain. At each evaluation, patients were asked to quantify their overall pain using a VAS pain score ranging from 0 to 10. Justification for use of the VAS includes ease of use, previous validation and widespread use for measuring sensitivity to treatment effects, and its allowance for quantifiable statistical evaluations of significance (21, 22).

Opioid intake. Patients were also surveyed in regards to their use of opioids. For the purposes of this study, opioid use was considered to be reduced if a patient reported complete cessation of opioids or a daily reduction of 50% or more.

Functional status. Patients' functional status was quantified by a physical therapy assessment and by patients' self-reports of ability to perform activities of daily living such as bathing, functional mobility, dressing, etc. The physical therapy assessment consisted of objective evaluations of each patient's quality of movement, including his/her ability to transfer without compensations, ability to ambulate without compensations, and other measures of mobility such as rolling from side to side, reaching over head, bending at the waist, etc. For the purposes of this study, any noted improvement in the physical therapy assessment or patients' reports of an increased ability to perform activities of daily living was recorded as improved functional status.

Statistical Analyses

Outcome measure data at baseline was compared longitudinally to evaluations taken at 1, 3, 6, and 12 months during the post-treatment period. The sign test was used to determine the changes for physical function and medication intake, while the Wilcoxon matched-pairs signed-ranks test was used for VAS pain score analysis. Furthermore, Fisher's exact test and the Wilcoxon ranks sum test were used to identify the significant factors in association with the changes. All statistical tests were two-sided, and P values < 0.05 were considered to be statistically significant.

Results

Patient Demographics

Analysis of outcomes of percutaneous disc decompression utilizing Nucleoplasty was performed on 22 patients. Patient gender distribution was 54.5% male, 45.5% female with a mean age of 39 years, ranging from 22 to 51 years. Axial back pain was reported by 18% of the patients, while 82% reported back and leg pain. Most patients (81.8%) had pain for over a 12-month duration. Smoking was reported in 54.5% of the patients, while 9% were involved in active litigation, and 22.7% had a history of drug and alcohol abuse. Mean procedure duration was 7.9 minutes per disc. Baseline and post-procedure data for each patient are included in Table 1.

Table 1. *Baseline and post-procedure data for all 22 patients*

Subject	Baseline VAS (meds)	VAS score				Medicine				Physical				Return to work			
		M1	M3	M6	M12	M1	M3	M6	M12	M1	M3	M6	M12	M1	M3	M6	M12
1	9 (yes)	9	5	5	4	D	D	D	D	I	I	I	I	Ny	Ny	Y	Y
2	8 (yes)	4	4	4	4	S	S	S	S	I	I	I	I	Ny	Ny	Ny	Ny
3	8 (yes)	0	0	0	0	D	N	N	N	I	I	I	I	Y	Y	Y	Y
4	5 (yes)	4	3	3	2	D	D	D	D	I	I	I	I	Ny	Y	Y	Y
5	10 (yes)	10	10	10	10	S	S	S	S	S	S	S	S	Ny	Ny	Ny	Ny
6	8.5 (yes)	8.5	8.5	8.5	8	S	S	S	D	S	S	S	I	Ny	Ny	Ny	Ny
7	5 (yes)	5	4	4	3	S	S	D	D	S	S	I	I	Ny	Y	Y	Y
8	8 (yes)	4	4	4	4	S	S	D	D	I	I	I	I	Ny	Ny	Y	Y
9	7 (yes)	5	0	0	0	S	D	N	N	S	I	I	I	Y	Y	Y	Y
10	8 (yes)	8	4	4	4	D	D	D	D	S	I	I	I	Ny	Y	Y	Y
11	7 (yes)	0	0	0	0	N	N	N	N	I	I	I	I	Y	Y	Y	Y
12	8 (yes)	8	4	4	4	S	S	S	S	S	I	I	I	Ny	Ny	Ny	Y
13	8 (yes)	1	0	0	0	N	N	N	N	I	I	I	I	Y	Y	Y	Y
14	7 (yes)	4	4	4	2	D	D	D	D	I	I	I	I	Ny	Ny	Ny	Ny
15	7 (yes)	7	7	7	6	S	S	S	D	S	S	S	I	Ny	Ny	Ny	Ny
16	7 (yes)	4	3	3	3	D	D	D	D	I	I	I	I	Ny	Y	Y	Y
17	9 (yes)	9	9	9	9	S	S	S	S	S	S	S	S	Ny	Ny	Ny	Ny
18	7 (yes)	7	7	7	7	S	S	S	S	S	S	S	S	Ny	Ny	Ny	Ny
19	6 (yes)	3	0	0	0	N	N	N	N	I	I	I	I	Ny	Y	Y	Y
20	7 (yes)	0	0	0	0	D	N	N	N	I	I	I	I	Y	Y	Y	Y
21	8 (yes)	4	3	1	0	D	D	N	N	I	I	I	I	Ny	Ny	Ny	Y
22	9 (yes)	9	9	9	9	S	S	S	S	S	S	S	S	Ny	Ny	Ny	Ny

Where D=decrease, S=same, N=none, I=improvement, Y=yes, and Ny=not yet.
Meds=medicine, M1=month 1, M3=month 3, M6=month 6, and M12=month 12.

VAS=visual analog scale.

Table 2. *Change in post-procedure VAS pain scores over time*

Difference from baseline	1 month	3 months	6 months	12 months
Mean	-2.41	-3.55	-3.63	-3.98
Median	-1.5	-4.0	-4.0	-4.0
Range	(-8.0, 1)	(-8.0, 0)	(-8.0, 0)	(-8.0, 0)
Signed-ranks test P value	0.0005	< 0.0001	< 0.0001	< 0.0001

Pain Reduction

VAS pain scores significantly decreased for 54.5%, 72.7%, 72.7%, and 72.7% of patients at 1, 3, 6, and 12 months, respectively with a mean decrease of 2.41 (P = 0.0005), 3.55 (P < 0.0001), 3.63 (P < 0.0001), and 3.98 (P < 0.0001) noted, respectively (Table 2; Fig. 1).

A total of 36.4% of patients indicated pain relief of 50% or more at 1 month, 54.5% at 3 months, 54.5% at 6 months, and 68.2% at 12 months (Fig. 2).

Functional Improvement

Physical function significantly improved at 1, 3, 6, and 12 months with P values of 0.0005, < 0.0001, < 0.0001, and < 0.0001, respectively (Table 2). Overall 54.5%, 68.2%, 72.7%, and 81.8% of patients indicated improvement of functional status at 1, 3, 6, and 12 months, respectively (Fig. 3).

One month after the procedure, 22.7% of patients returned to work, 45.5% at 3 months, 54.5% at 6 months, and 63.6% at 12 months (Fig. 4).

Pain Medication Use

The percentages of patients reporting a reduction in opioid intake were 50% at 1 month (P = 0.0010), 55.5% at 3 months (P = 0.0005), 63.6% at 6 months (P = 0.0001), and 72.7% at 12 months (P < 0.0001) (Fig. 5).

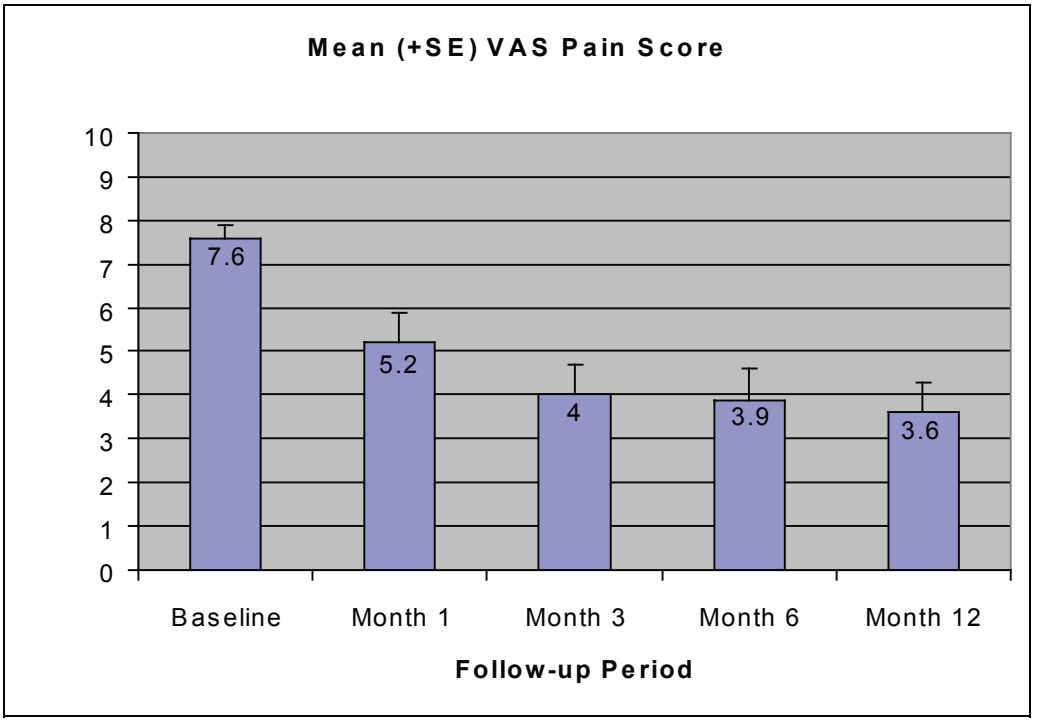

Fig. 1. *Mean pain VAS scores post-percutaneous disc decompression.*

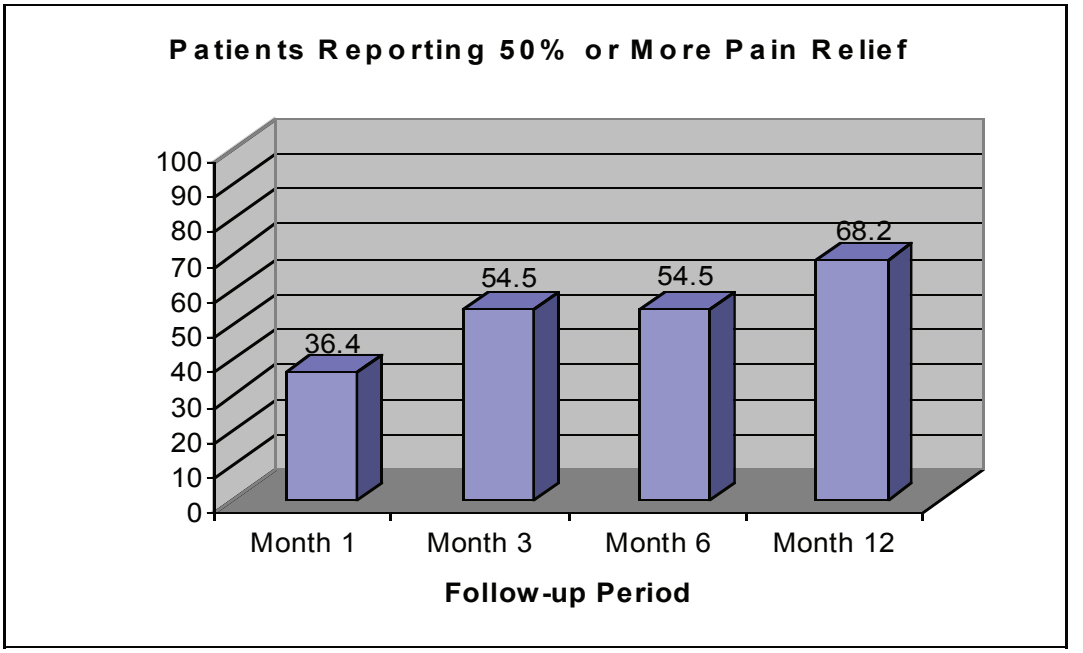

Fig. 2. *Percentages of patients reporting 50% or more pain relief post-percutaneous disc decompression.*

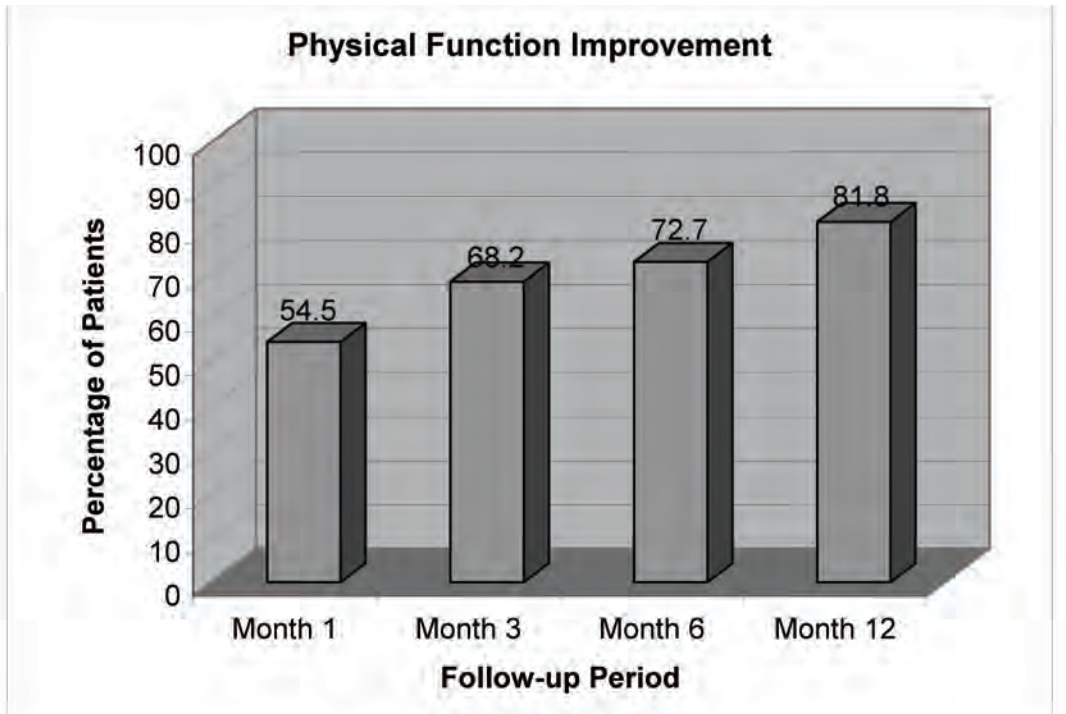

Fig. 3. *Percentages of patients reporting an increase in physical function after Nucleoplasty.*

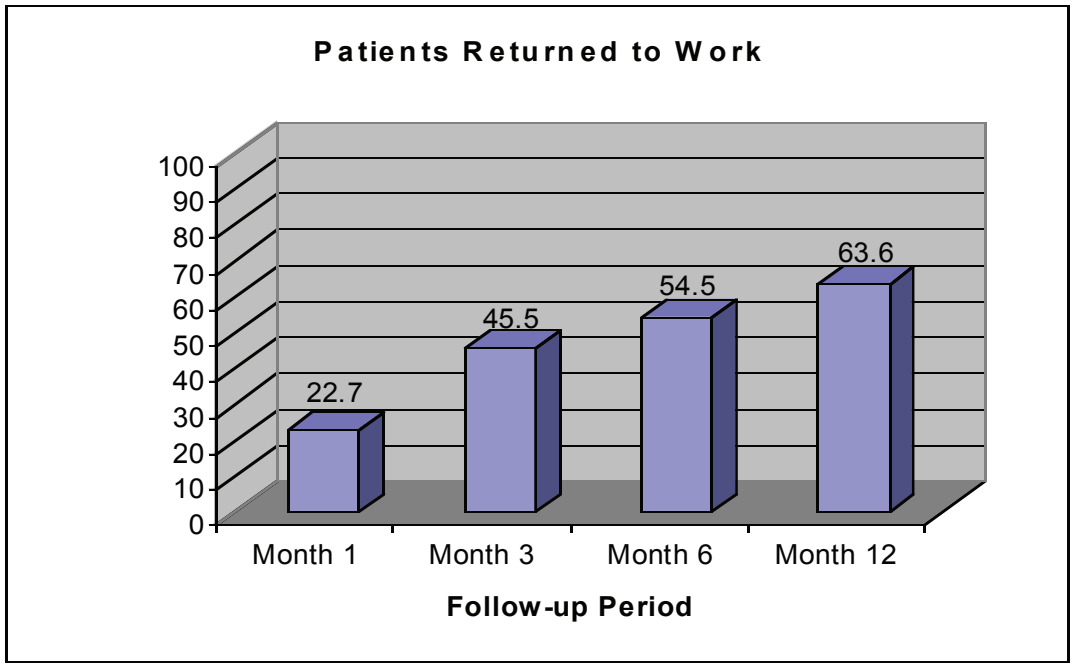

Fig. 4. *Percentages of patients returned to work.*

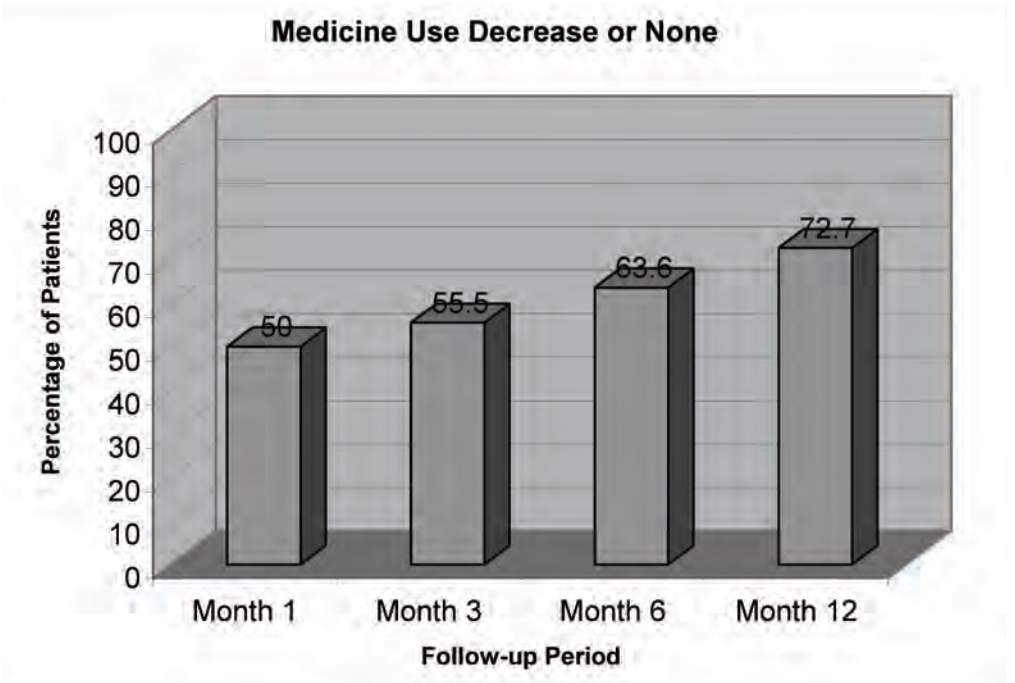

Fig. 5. *The percentages of patients reporting reduction or discontinuation of medication intake.*

Failure of Treatment and Complications

Failure of treatment was associated with a history of drug and alcohol abuse and showed no relation to duration of pain, levels of performed procedure, gender, current or past involvement in litigation processes, or history of smoking. A previous report by Boswell and Wolfe (23) suggested a potential risk with intradiscal injection of the antibiotic cefazolin; however, in our study, there were no intraoperative or postoperative complications associated with Nucleoplasty.

Discussion

This retrospective study demonstrated a statistically significant improvement in VAS pain scores and functional status and a reduction in medication intake in a group of patients with radicular or axial low back pain who failed conservative treatment, had derived no benefit from various injection techniques, and were not candidates for spine surgery. Moreover, we did not offer this procedure to patients with a history of open disk surgery at suspected levels, as these patients are considered poor surgical candidates and have historically been a challenging population to treat.

Among the patients in our study, a history of drug and alcohol abuse was significantly associated with poor outcomes. History of alcohol and drug abuse, psychological distress, and depression has previously been associated with poorer outcomes in patients following minimally invasive discectomy (24). Therefore, based on these findings, we have modified our practice in the terms of the patient selection; all patients eligible for Nucleoplasty are sent for psychological assessment.

The results of this study are similar to those reported by Alo et al in 2004 (25). In his study, Alo used a Dekompressor 1.5 mm percutaneous discectomy probe to mechanically debulk the disc material allowing for a reduction in intradiscal pressure. Although Alo et al utilized different technology, they achieved the same goal as we did in our study using Nucleoplasty. The mechanisms underlying the successes of both procedures are postulated to be related to disc remodeling, which results in volume reduction with a subsequent decrease in intradiscal pressure and concomitant reduction in release of inflammatory mediators.

Although other studies have also shown an overall reduction in pain scores following percutaneous disc decompression using Nucleoplasty (15-18), these studies have shown a general decline in pain relief over time. Interestingly, pain scores and medication use continued to decrease and functional status continued to improve in our patients over the 12-month follow-up period.

Whereas injection of 2 mL of 0.25% bupivacaine with 40 mg of cefazolin was the usual practice applied to our patients and has been uneventful, at least 1 report suggests a risk associated with the introduction of a large volume of potentially toxic intradiscal antibiotic (23). In their report, however, the antibiotics gained access to the intrathecal space, whereas in our application, this was systematically avoided. Pre-procedural discography provided additional assurance that no extravasations of contrast material were noted before proceeding with the intervention. While we believe the risk to be small, it should be taken under advisement while evaluating patient eligibility.

This study has inherent limitations. The sample size is small and results may not be generalizable to all patient populations. Moreover, the retrospective nature is an obvious weakness. Although this study is retrospective and has a small sample size, it does help to provide a preliminary framework for the planning of future prospective, randomized, controlled studies comparing Nucleoplasty with other conservative, non-surgical interventions and other minimally invasive interventional techniques such as percutaneous laser discectomy or disc decompression using the Dekompressor.

Conclusions

The findings of this retrospective study suggest that Nucleoplasty can be a safe and effective procedure for patients with radicular and axial low back pain secondary to contained herniated discs. Prospective, randomized, controlled studies are needed to further evaluate the long-term efficacy of percutaneous disc decompression using Nucleoplasty and to determine the patient characteristics for whom this procedure is most beneficial.

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