Percutaneous Nucleoplasty Using Coblation Technique for the Treatment of Chronic Nonspecific Low Back Pain: 5-year Follow-up Results

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Abstract

Background: This study evaluated the efficacy of percutaneous nucleoplasty using coblation technique for the treatment of chronic nonspecific low back pain (LBP), after 5 years of follow-up.

Methods: From September 2004 to November 2006, 172 patients underwent percutaneous nucleoplasty for chronic LBP in our department. Forty-one of these patients were followed up for a mean period of 67 months. Nucleoplasty was performed at L3/4 in 1 patient; L4/5 in 25 patients; L5/S1 in 2 patients; L3/4 and L4/5 in 2 patients; L4/5 and L5/S1 in 7 patients; and L3/4, L4/5, and L5/S1 in 4 patients. Patients were assessed preoperatively and at 1 week, 1 year, 3 years, and 5 years postoperatively. Pain was graded using a 10-cm Visual Analogue Scale (VAS) and the percentage reduction in pain score was calculated at each postoperative time point. The Oswestry Disability Index (ODI) was used to assess disability-related to lumbar spine degeneration, and patient satisfaction was assessed using the modified MacNab criteria.

Results: There were significant differences among the preoperative, 1-week postoperative, and 3-year postoperative VAS and ODI scores, but not between the 3- and 5-year postoperative scores. There were no significant differences in age, sex, or preoperative symptoms between patients with effective and ineffective treatment, but there were significant differences in the number of levels treated, Pfirrmann grade of intervertebral disc degeneration, and provocative discography findings between these two groups. Excellent or good patient satisfaction was achieved in 87.9% of patients after 1 week, 72.4% after 1 year, 67.7% after 3 years, and 63.4% at the last follow-up.

Conclusions: Although previously published short- and medium-term outcomes after percutaneous nucleoplasty appeared to be satisfactory, our long-term follow-up results show a significant decline in patient satisfaction over time. Percutaneous nucleoplasty is a safe and simple technique, with therapeutic effectiveness for the treatment of chronic LBP in selected patients. The technique is minimally invasive and can be used as part of a stepwise treatment plan for chronic LBP.

Key words: Discogenic Low Back Pain; Follow-up; Nonspecific Low Back Pain; Nucleoplasty; Surgical Treatment

Introduction

Low back pain (LBP) is defined as an ache or discomfort in the lower part of the back, with or without leg pain. LBP is very common and affects 80% of individuals at some point in their life. According to the National Center for Health Statistics, back pain is the most frequent cause of limitation of activity in people younger than 45 years. Lumbar disc degeneration is one of the most common causes of chronic LBP. Although back pain may be associated with intervertebral disc herniation, Dillane *et al*.[1] reported that the specific cause of LBP was unknown in 79% of men and 89% of women. In the majority of these cases, there is no identifiable relationship between the imaging findings and the clinical complaints, and the patient is diagnosed with nonspecific LBP. It is assumed that a large proportion of nonspecific LBP is discogenic in origin. A study of patients with chronic LBP found that 39% had internal disc disruption, with concordant pain provocation on discography indicating that the pain was discogenic in origin.[2]

The traditional approach to the management of chronic LBP has been conservative, including medication, physical therapy, behavior management, and psychotherapy. In recent years, the general trend in spinal surgery has been toward minimally invasive procedures and lower cost. Nucleoplasty is a new, minimally invasive therapeutic option that has been used for spinal procedures since July 2000. Percutaneous nucleoplasty was introduced to China in 2002, and has

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been widely used for the treatment of chronic LBP over the past 10 years. Many studies have reported on the short- and medium-term outcomes after percutaneous nucleoplasty for the treatment of LBP, but long-term outcomes after this procedure have not previously been reported. The aims of this retrospective study were to report the clinical outcomes in patients treated with percutaneous nucleoplasty for LBP in our department who were followed up for at least 5 years, and to evaluate the efficacy of this procedure for the treatment of chronic nonspecific LBP.

Methods

Patients

A total of 172 patients underwent percutaneous nucleoplasty for chronic LBP in our department from September 2004 to November 2006 and were retrospectively reviewed. Forty-one of these patients who met the inclusion criteria [Table 1] and were followed up for a mean period of 67 months (range, 58–84 months) after the procedure were included in this study. Nucleoplasty was performed at L3/4 in 1 patient; L4/5 in 25 patients; L5/S1 in 2 patients; L3/4 and L4/5 in 2 patients; L4/5 and L5/S1 in 7 patients; and L3/4, L4/5, and L5/S1 in 4 patients. Plain radiography (anteroposterior and lateral views) and magnetic resonance imaging (MRI) of the lumbar spine and discography of the suspected discs were performed in all patients for diagnosis. All patients were diagnosed with either discogenic LBP (positive discography findings) or nonspecific LBP (negative discography findings).

Percutaneous nucleoplasty procedure

Percutaneous nucleoplasty was performed in the operating room with the patient in the prone position, under mild sedation. The soft tissues were infiltrated with local anesthetic for 8–10 cm lateral to the midline of the spine. Under fluoroscopic guidance, a 17-gauge Crawford spinal needle (Coblation®, Arthrocare Spine, USA) was inserted into the nucleus pulposus of the involved disc at a 45° angle through the annulus fibrosus. The exact position of the needle tip was confirmed on anteroposterior and lateral views. Discography was performed via the spinal needle to evaluate the configuration of the disc and the integrity of the annulus fibrosus, and a pain provocation test was performed by injection of contrast medium to determine whether the pain was discogenic in origin. A SpineWand cable connected to the Arthrocare System 2000 controller set at power level 3 was inserted into the disc using the same access. The coagulation pedal on the foot controller was depressed for half a second. If stimulation movement of the lower extremity was observed, the pedal was immediately released, and the SpineWand tip was repositioned. With clockwise rotation of the needle tip, a total of six channels were created (at the 2, 4, 6, 8, 10, and 12 o'clock positions). Each channel was created by advancement of the wand in the ablation mode for 6–8 s followed by retraction in the coagulation mode for 10–15 s. At the end of the procedure, 2 mL of broad-spectrum antibiotic was injected into the disc. Patients were advised to stay in bed for the 1st day following the procedure. From the 2nd day, regular indoor and outdoor activities were permitted, including back muscle exercises. No strenuous activity was allowed for 3 months after the procedure.

Table 1: Inclusion and exclusion criteria

Inclusion criteria
Patients diagnosed with discogenic pain by discography
Age ranging from 18 to 55
Over 6 month's duration of LBP
Preservation of disc height ≥70%
Failure of conservative therapy more than 8 weeks
The patients with a negative result of discography but with specific degenerative changes
On MRI (such as black disc or Modic change [phase I or II])*
Exclusion criteria
Patient with significant neurological deficits and/or asymmetrical reflex
Previous spine trauma or spine surgery
Congenital or secondary spinal deformity
Spinal fracture or tumor
Moderate to severe central spinal canal or foraminal stenosis
Disc herniation or prolapsed intervertebral disc
More than 3 suspected levels involved
Diabetic, heavy opioid usage or drinking
Significant co-existing diseases
Uncontrolled psychological disorders

*These patients were diagnosed with nonspecific LBP rather than discogenic LBP. LBP: Low back pain; MRI: Magnetic resonance imaging.

Outcome assessment

Patients were asked to grade their pain using a 10-cm Visual Analogue Scale (VAS) with 0 indicating no pain and 10 indicating severe pain, and the percentage reduction in pain score was calculated at each postoperative time point. The Oswestry Disability Index (ODI) was used to assess disability due to lumbar spine degeneration, and postoperative patient satisfaction was assessed using the modified MacNab criteria. Patient satisfaction was categorized as follows: Excellent (no discomfort, no pain, no neurological signs), good (mild discomfort, no pain, no neurological signs), fair (partial relief of pain, partial relief of neurological signs), or poor (no relief of pain, no relief of neurological signs). Treatment was considered to be effective if patient satisfaction was excellent or good, and ineffective if patient satisfaction was fair or poor. The preoperative intervertebral disc height, Pfirrmann grade of intervertebral disc degeneration, and provocative discography findings were also recorded. Outcomes were assessed preoperatively and at 1 week, 1 year, 3 years, and 5 years postoperatively, by an independent evaluator.

Statistical analysis

Statistical analyses were performed using SPSS 10.0 software (Spss, Inc.,Chicago, IL, USA) and Microsoft Excel 2010 (Microsoft, Inc., Redmond, Washington, USA). The ODI and VAS scores were not normally distributed and were compared using the Wilcoxon rank sum test. The

relationships between preoperative factors and postoperative patient satisfaction according to the modified MacNab criteria were assessed using the Chi-square test. Results were considered statistically significant at $P \leq 0.05$.

Results

All percutaneous nucleoplasty procedures were successfully performed, and no procedure-related complications were observed. Out of a total of 172 patients who underwent lumbar percutaneous nucleoplasty, 41 patients (58 discs) with complete follow-up information for 5 years were included in the analyses. The mean VAS pain score decreased from 7.9 ± 0.7 preoperatively to 3.4 ± 0.5 at 1 week, 2.9 ± 0.6 at 1 year, 2.9 ± 0.4 at 3 years, and 2.5 ± 0.4 at 5 years postoperatively. The mean ODI score decreased from 58.9 ± 6.1 preoperatively to 42.1 ± 4.2 at 1 week, 25.8 ± 3.8 at 1 year, 25.4 ± 4.0 at 3 years, and 23.0 ± 2.9 at 5 years postoperatively. There were significant differences among the preoperative, 1-week postoperative, and 3-year postoperative VAS and ODI scores ($P < 0.05$), but not between the 3- and 5-year postoperative scores. Postoperative patient satisfaction was significantly associated with the number of levels of treated (single vs. multiple), the Pfirrmann grade of intervertebral disc degeneration (≤III vs. >III), and the provocative discography findings (positive vs. negative). Excellent or good patient satisfaction at the last follow-up was achieved in 71.5% of patients with treatment of a single level, but only 38.5% of patients with treatment of multiple levels [Table 2]. There were no significant differences in age, sex, or preoperative symptoms between patients with effective and ineffective treatment. Excellent or good patient satisfaction was achieved in 87.9% of patients after 1 week, 72.4% after 1 year, 67.7% after 3 years, and 63.4% at the last follow-up.

Table 2: Comparisons between patients with effective and ineffective treatment

Potential factors	Effective[a]	Ineffective[b]	Total	χ^2	*P*
Age (years)					
>50	8	6	14	0.36	0.55
≤50	18	9	27		
Gender (*n*)					
Male	15	8	23	0.07	0.79
Female	11	7	18		
Clinical symptom (*n*)					
No leg pain	14	7	21	0.19	0.66
With leg pain	12	8	20		
Levels involved (*n*)					
Single level	21	7	28	5.11	0.02
Multi levels[c]	5	8	13		
Classification of MRI[d] (*n*)					
≤Grade III	19	6	25	4.37	0.04
>Grade III	7	9	16		
Results of PD[e] (*n*)					
Positive	23	9	32	4.49	0.03
Negative	3	6	9		

α=0.05. [a]Effective treatment was defined as excellent or good postoperative patient satisfaction according to the MacNab criteria; [b]Ineffective treatment was defined as fair or poor postoperative patient satisfaction according to the MacNab criteria; [c]Treatment of two or more levels; [d]Pfirrmann grade of intervertebral disc degeneration; [e]Provoked discography findings. MRI: Magnetic resonance imaging.

Discussion

Nonspecific low back pain

The lower back is commonly defined as the area between the bottom of the rib cage and the top of the buttock crease. Chronic LBP is one of the most common health complaints.[3] The lifetime prevalence of LBP is reported to be as high as 84%, and the prevalence of chronic LBP is about 23%, resulting in disability in 11–12% of the population. LBP is, therefore, a major public health problem worldwide.[4] Nonspecific LBP is the most common type of chronic LBP and is characterized by complaints of tension, pain and/or stiffness in the lower back, which are not related to a specific identified cause. The pain may range from mild to severe and is typically felt in the lower back, but can also radiate into one or both buttocks and thighs.[3] Several structures in the back may contribute to back pain symptoms, including the intervertebral joints, discs, and connective tissues, but the exact causes of LBP are still unclear. Multiple factors may be related to the development of LBP, such repeated flexion, rotation, and lifting.[5] It was recently reported that mechanical factors such as lifting and load carrying probably do not have a major pathogenic role in the development of LBP, but that genetic factors are important.[6] There is currently no noninvasive clinical test that can differentiate between discogenic and nondiscogenic chronic LBP. MRI discography has been widely used to study the phenotype of patients with discogenic pain, with evaluation of features such as high-intensity zone lesions and Modic changes. The validity of using high-intensity zone lesions as indicators of discogenic pain has been questioned,[7,8] but the Modic change seems to be a useful sign of discogenic pain.[9] Nine of the patients in the present study were diagnosed with nonspecific LBP based on typical symptoms and negative provoked discography findings. These patients had some signs of degenerative disease on MRI, but no specific cause of pain was identified. MRI showed both Modic changes (type I in six patients, type II in three patients) and a black disc indicating disc degeneration (Pfirrmann grade III in six patients, grade IV in three patients). The remaining patients were all diagnosed with discogenic LBP.

Therapeutic mechanism of percutaneous nucleoplasty

Low back pain is usually benign and self-limiting, with a resolution within 6 weeks, with or without treatment. Up to 30% of patients with LBP subsequently experience recurrent or persistent symptoms. There are currently few treatment options available for patients with chronic LBP. The first line of treatment is usually conservative, including medication and/or a multidisciplinary approach. When conservative treatment fails to provide satisfactory

pain reduction, invasive treatment is considered. A variety of minimally invasive procedures have recently been introduced for the treatment of chronic LBP, such as intradiscal electrothermal therapy, laser spine surgery, and nucleoplasty. Percutaneous nucleoplasty using coblation technique is a relatively new therapeutic option that was approved for the treatment of LBP in July 2000. The therapeutic mechanism of percutaneous nucleoplasty is thought to be based on intradiscal decompression. Coblation technique involves the use of radiofrequency energy to excite the electrolytes in a conductive medium such as saline solution, creating a 1-nm thick region of precisely focused plasma at the tip of the wand. The energized particles in the plasma have sufficient energy to break molecular bonds, enabling excision or destruction of soft tissue such as the disc nucleus. The products of the low-temperature process are elementary particles and low-molecular-weight gases, which are quickly exhausted through the surgical access. Use of coblation technique enables gentle removal of a portion of the nucleus tissue, resulting in decompression of the herniated disc. Although discogenic pain is one of the best indications for use of coblation technique, we found that the theory of relieving mechanical compression could not explain the clinical outcomes in all our patients. For example, in nine patients diagnosed with nonspecific LBP, more than 2 mL of contrast medium was injected into discography and the contrast medium injected into the disc rapidly spread outside the annulus fibrosus, indicating a full-thickness tear of the annulus fibrosus. It was interesting that these patients experienced improvement of their symptoms after undergoing nucleoplasty using coblation technique. At the last follow-up, 33.3% of these nine patients were still satisfied with the outcome. These results cannot easily be explained by the classic theory of intradiscal decompression because patients with tears in the annulus fibrosus did not have high intradiscal pressure. It is postulated that the mechanism underlying the success of percutaneous nucleoplasty also involves the reduction of the release of inflammatory mediators.[10] In a previous study using an animal model, we found that use of coblation technique reduced phospholipase A2 activity in degenerated intervertebral discs, suggesting that the effects of coblation energy on inflammatory factors may be one of the mechanisms underlying the success of this treatment.[11]

Indications for percutaneous nucleoplasty and efficacy of treatment

Many factors can affect the efficacy of percutaneous nucleoplasty, with one of the most important being the severity of spinal degeneration. We suggest that the intradiscal decompression effect of nucleoplasty is not effective in patients with severely degenerated discs.[12] Integrity of the annulus fibrosus is also considered to be an important factor for achieving a beneficial outcome after nucleoplasty.[13] For these reasons, the best indications for nucleoplasty using coblation technique are discogenic LBP and contained disc herniation. Previous clinical studies have reported variable outcomes using this technique. Sharps and Isaac[14] reported a success rate of 82% in patients with no prior surgical intervention.[14] Romanitan *et al*.[15] treated 60 patients with lumbar spine pathology at more than one level, and reported that 92% were satisfied with the outcome after 12 months. Ai-Zain *et al*.[16] reported a significant decline in the patient satisfaction rate from 73% in the early postoperative period to 61% at 6 months and 58% at 1 year postoperatively. Our study found satisfactory results, with a patient satisfaction rate of 87.9% in the early postoperative period and 72.4% at 1 year postoperatively. There was a significant decline in patient satisfaction over time to 67.7% at 3 years and 63.4% at >5 years postoperatively. In addition, the best improvements in VAS and ODI scores were at 1 year postoperatively. These findings indicate that the short-term outcomes may be better than the long-term outcomes after nucleoplasty using coblation technique. All patients in our study underwent the discography to evaluate the integrity of the annulus fibrosus before undergoing nucleoplasty. We performed nucleoplasty in nine patients with a full-thickness tear in the annulus fibrosis, and at the last follow-up three of these patients (33.3%) were still satisfied with the procedure. Based on our clinical experience, negative provoked discography findings do not seem to be an absolute contraindication to nucleoplasty using coblation technique, but the patient satisfaction rate was higher among patients with positive provoked discography findings. The number of levels treated and the preoperative grade of intervertebral disc degeneration were also associated with the postoperative patient satisfaction rate. These results indicate that fewer levels of intervertebral disc degeneration, greater intervertebral disc height, and a lower grade of intervertebral disc degeneration were associated with better outcomes. Other factors such as age, sex, and preoperative symptoms (with vs. without leg pain) were not associated with postoperative patient satisfaction.

Limitations

This study has several limitations. First, this is a retrospective study. Prospective, randomized, controlled studies are needed to determine whether percutaneous nucleoplasty is superior to other treatment options for LBP such as nonsurgical interventions and other minimally invasive procedures. Second, the sample size is relatively small, and the findings may not be applicable to all patient populations. Third, some important factors associated with the progression of chronic LBP, such as smoking, body weight, and occupation, were not included in the analyses.

Conclusions

Our findings indicate that percutaneous nucleoplasty is a simple, safe, and effective therapeutic option for the treatment of chronic LBP, especially in selected patients with early intervertebral disc degeneration. Although the short- and medium-term outcomes after this procedure appear to be satisfactory, long-term follow-up shows a significant decline in patient satisfaction over time. As percutaneous nucleoplasty is a minimally invasive and safe technique, it can be used as part of a stepwise treatment plan for chronic LBP.

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