Effectiveness Comparison of Nucleoplasty and Automatic Percutaneous Lumbal Discectomy Procedures in Pain and Disability Scores for Herniated Lumbar Discs

Lumbal Disk Hernileri İçin Nukleoplasti ve Otomatik Perkütan Lumbal Diskektominin Ağrı ve İşgöremezlik Skorları Üzerine Etkisinin Karşılaştırılması

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Geliş Tarihi/*Received:* 28.10.2008
Kabul Tarihi/*Accepted:* 03.04.2009

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ABSTRACT Objective: Percutaneous decompression approach is associated with potential complications, limitations and poor outcome. Nucleotomy is used for suction of disc material. Nucleoplasty (NP) procedure utilizes coblation technology which allows for decompression of the disc using radiofrequency energy. The aim of study is to evaluate the effectiveness of NP versus automatic percutaneous lumbar discectomy (APLD) in pain and disability scores for decompression of contained herniated discs. **Material and Methods:** A prospective, randomized study was conducted on 189 consecutive patients with complaints of low back pain with or without leg pain secondary to a contained lumbar herniated disc. Patients were ASA I-II physical status, and aged between 19-55 years. There were 96 patients in Group NP (67 females, 29 males), and 93 patients in Group APLD (66 females, 29 males). Control examinations were performed at 1st, 6th, 12th and 18th months and pain scores and Oswestry Disability Questionnaires (ODQ) were evaluated during controls. **Results:** The pre-procedure and post-procedure visual analog scale (VAS) scores in group APLD and NP were 6.95, 2.44 and 7.14, 2.51 respectively. The VAS scores decreased in two groups and the difference between pre-procedure and post-procedure VAS scores were statistically significant ($p<0.05$). The reduction in VAS score continued in control examinations. The pre-procedure and post-procedure ODQ scores in group APLD and NP were 41.79, 22.81 and 41.48, 22.82 respectively. These differences between pre-procedure and post-procedure scores were also statistically significant ($p<0.05$). The reduction in ODQ scores continued in control examinations. In the APLD group, there was a statistically significant prolongation in time of procedure. No complications were observed in both groups. **Conclusion:** The results of this study demonstrated a statistically significant improvement in VAS and Oswestry index scores at 1st, 6th, 12th and 18th months in both techniques. Because NP is a short and effective technique, NP should be the first choice for the treatment of symptoms associated with contained lumbar herniated discs.

Key Words: Low back pain; intervertebral disk displacement; diskectomy, percutaneous

ÖZET Amaç: Perkutan dekompresyon sınırlamaları ve komplikasyon potensiyeli olan ve hala sonuçları hakkında az çalışma bulunan bir yaklaşımdır. Nükleotomi disk materyalinin aspire edilmesi için kullanılır. Nükleoplasti (NP) işlemi disk dekompresyonu için radyofrekans enerjisi kullanan koblasyon teknolojisini kullanır. Çalışmanın amacı herniye disklerin dekompresyonunda NP ile otomatik perkütan lumbal diskektominin (APLD) ağrı ve işgöremezlik skorları üzerine etkinliğini karşılaştırmaktır. **Gereç ve Yöntemler:** Çalışma prospektif ve randomize olarak disk hernisine bağlı bel ağrısı olan ilaveten bacak ağrısı olan veya olmayan 189 hastada değerlendirildi. Hastaların ASA statüleri I-II ve yaşları 19 ile 55 arasındaydı. Grup NP'de 96 (67 kadın, 29 erkek) ve Grup APLD'de 93 (66 kadın, 29 erkek) hasta vardı. Hastalar 1., 6., 12. ve 18. aylarda ağrı skorları ve Oswestry Disability Sorgulaması (ODQ) ile değerlendirilmek için kontrol muayenelerine çağrıldı. **Bulgular:** İşlem öncesi ve sonrası VAS değerleri Grup APLD ve NP'de 6.95, 2.44 ve 7.14, 2.51 idi. Her iki grupta da işlem sonrası VAS değerleri azalma gösterdi ve işlem öncesi ve sonrası arasındaki VAS değerleri farkı istatistiksel olarak anlamlıydı ($p<0.05$). VAS değerlerindeki azalma kontrol muayenelerinde de devamlılık gösterdi. İşlem öncesi ve sonrası ODQ değerleri Grup APLD ve NP'de 41.79, 22.81 ve 41.48, 22.82 idi. Her iki grupta da işlem sonrası ODQ değerleri azalma gösterdi ve işlem öncesi ve sonrası arasındaki ODQ değerleri farkı istatistiksel olarak anlamlıydı ($p<0.05$). ODQ değerlerindeki azalma kontrol muayenelerinde de devam etti. Grup APLD'de işlem süresinde istatistiksel olarak anlamlı bir uzama saptandı. Her iki grupta da herhangi bir komplikasyon gözlenmedi. **Sonuç:** Çalışmamızda her iki teknikte de 1., 6., 12. ve 18. aylarda VAS ve Oswestry disability sorgulamasında istatistiksel olarak anlamlı bir gelişme tespit ettik. Fakat NP daha kısa ve etkili bir teknik olduğundan dolayı herniye diske bağlı semptomların tedavisinde ilk seçenek olarak tercih edilebileceği kanısındayız.

Anahtar Kelimeler: Bel ağrısı; disk hernisi; perkütan diskektomi

Turkiye Klinikleri J Med Sci 2010;30(1):201-6

Historically, percutaneous disc decompression began in 1963 with the development of chemonucleolysis.[1] Thereafter, several other minimally invasive procedures followed, including percutaneous decompression of the nucleus pulposis was developed by Hijikata[2] in 1975, automated percutaneous lumbar discectomy was reported by Onik in 1985, and laser discectomy in 1987.[3,4] Collectively, all these percutaneous decompression approaches are associated with potential complications, limitations, or poor outcomes.

Recently, percutaneous disc decompression using nucleoplasty (NP) has emerged as an effective, minimally invasive, percutaneous technique for the treatment of low back pain due to contained herniated discs.[5-9] The NP procedure utilizes coblation technology which allows the decompression of the disc using radiofrequency energy in a less damaging, low-temperature environment for the surrounding tissues.[10] Temperature is kept less than 70°C to minimize thermal penetration and adjacent tissue damage. Disc NP is a relatively new technology and there is minimal published literature and no controlled trials. The advantage is that the probe can be introduced through a relatively small 17-gauge introducer needle. However, the amount of tissue that can be vaporized is probably less than other techniques.

Automatic percutaneous lumbar discectomy (APLD) (Nucleotome, Clarus Medical, Minneapolis, MN) was introduced for the intended use for suction of disc material during percutaneous discectomies in the lumbar, thoracic, and cervical regions of the spine. A 1.5 mm (17Gauge) or 1.0 mm (19Gauge) outer diameter cannula provides access to the disc space and serves as a channel for tissue removal. When activated, the probe rotates to create suction and removes nucleus pulposus through the cannula.

NP has the theoretical advantages of prior percutaneous techniques for disc decompression such as chemonucleolysis (chymopapain), automated percutaneous lumbar discectomy and laser discectomy. The randomized controlled trials comparing the effectiveness of NP versus APLD for low back pain have not yet been performed in the literature. This technique may not have the associated complications and side effects of these previously performed techniques.[11] So, the aim of study is to compare the effectiveness of NP versus APLD in pain and disability scores for lumbar herniated discs.

MATERIAL AND METHODS

DESIGN AND PARTICIPANTS

A prospective, randomized study was conducted on 189 consecutive patients who underwent percutaneous disc decompression using either NP or APLD technique between 2005 and 2007 in Kartal Kosuyolu Heart Education and Research Hospital. The study was approved by the Scientific-Ethical Committee and was in accordance with the Declaration of Helsinki. The nature of this study and the associated risks were explained to all subjects along with an opportunity to ask questions and decide whether or not they wanted to participate, and informed consents were obtained with full disclosure.

We studied the patients with ASA I-II physical status, between the ages of 19-55 years. Each patient was randomized to one of these two groups by take a ballot from the bag. There were 96 patients in Group NP (67 females, 29 males), and 93 patients in Group APLD (66 females, 29 males). Before the procedure, all patients' (Visual Analogue Scores (VAS) (with 0= no pain to 10= worst possible pain imagined) were recorded) VAS values recorded and back pain insufficiency was assessed with Oswestry Disability Questionnaires (ODQ). This questionnaire has been designed to give an information as to how patients' back or leg pain is affecting their ability to manage in everyday life. This questionnaire consists of 10 items which reflect their disability at different activities and situations of daily life. For each section the total possible score is 5: if the first statement is marked the section score = 0, if the last statement is marked it = 5. Total point divides by 50 and then multiply by 100 and the result defines as percent disability (0% to 20%: minimal disability, 21%-40%: moderate disability, 41%-60%: severe disability, 61%-80%: crippled, 81%-100% either

bed-bound or exaggerating their symptoms.). Procedures were performed under local anesthesia with prilocaine for entry points. To provide sedation, intravenous 1 mcg/kg fentanyl and 1 mg midazolam were given during local anesthesia.

Criteria for inclusion were contained disc herniation with presence of discogenic axial back pain with or without leg pain for greater than three months, absence of neurologic deficits, and lack of response to conservative management and fluoroscopically directed injection therapies.

Exclusion criteria for this outcome analysis were uncontrolled psychological disorders. Patients presenting with disc herniation with sequestration, large contained herniation occupying one-third or more of the spinal canal, and marked spinal stenosis due to extensive osteophytosis were not considered candidates for this procedure.

PROCEDURE

Cannulation was technically specific for the herniation location. Monitored anesthesia care was used with the patient remaining awake and interactive throughout the procedure. Monitorization included electrocardiography, non-invazive arterial blood pressure and peripheral oxygen saturation.

In group NP, percutaneous disc decompression was performed on an outpatient basis in the operating room of an ambulatory surgical center. All procedures were performed using a strict sterile technique by the same doctor. Under fluoroscopic guidance with the patient in the prone position, a 17-gauge six-inch long Crawford type spinal access cannula was placed at the junction of the annulus and nucleus under local anesthesia. 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.

In group APLD, disc access was gained with a posterolateral, extrapedicular approach on the symptomatic side using the 1.5 mm (17-gauge) cannula with stylette (Nucleotome, Clarus Medical, Minneapolis, MN). This approach is similar to that used for standard lumbar discography. Once the cannula was placed, the probe (titanium auger) was then introduced through the cannula. This probe was connected to a disposable rotational motor, which mechanically aspirated nucleus along this element toward the proximal chamber. A 0.09% NaCl solution containing 160 mg gentamicin was used for irrigating the disc. Each herniation was decompressed for an average of 15 minutes (0.75 ml-2 ml of disc material removed). Objective confirmation of disc material was achieved visually.

POSTOPERATIVE CARE

Patients were discharged the same day. Muscle relaxants and NSAIDs were given to all patients after discharge. Lumbosacral steel corsets were given to patients for one week period after the procedure. Postoperatively, 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 to less than 4 kg for two weeks. Patients with sedentary or light work environments were allowed to return to work after two weeks. Control examinations were performed during 1st, 6th, 12^{th} and 18^{th} months. For assessment of pain; VAS values and for functional life quality ODQ were used during controls by an independent observer.

STATISTICAL ANALYSIS

The data acquired from the study groups were evaluated via "Statistical Package for Social Sciences for Windows 13.0" (SPSS). The Kolmogorov-Smirnov test was used to verify the hypothesis of normal distribution. Student t test was used parametric data, and Mann Whitney U test was used to evaluate nonparametric data. Data were expressed as means ± standard deviation (SD). The results were assessed in 95% safety interval and a "p" value less than 0.05 were considered significant.

RESULTS

Demographic data belonging to the groups are shown in Table 1. The groups were similar regarding age and gender. Durations of procedure were 17.2 min and 7.8 min in APLD and NP groups respectively, there was a statistically significant prolongation in time of procedure ($p<0.05$).

Only one disc procedure was performed in every individual patient. The procedures were performed at the L4-5 level in 129 patients (67.2%), at the L3-4 level in 36 patients (18.8%), and at the L5-S1 level in 24 patients (12.5%).

Mean VAS and ODQ scores of the groups are shown in Table 2. The VAS scores in group APLD and NP at pre-procedure and post-procedure were 6.95, 2.44 and 7.14, 2.51 respectively. These differences in the groups were statistically significant ($p<0.05$). The ODQ scores in group APLD and NP at pre-procedure and post-procedure were 41.79, 22.81 and 41.48, 22.82 respectively. These differences were statistically significant ($p<0.05$). Mean VAS and ODQ values in group APLD and NP at 6th, 12th and 18 months were decreased compared to pre-procedure values.

No complications, including discitis or neurological deficit related to the procedure, were observed in any of the groups.

TABLE 1: Demographic data belong to groups.

	Group NP	Group APLD	p
Sex (M/F)	28 / 68	27 / 66	0.984
Age (year)	35.53±8.53	35.32±8.33	0.865
Time of procedure (min)	7.81±0.86	17.23±0.83	0.001*

* = p < 0.05 (statistically significant)

TABLE 2: The comparison of mean VAS and ODQ scores in two groups. Mean±SD.

		Group NP	Group APDL	p
Before operation	VAS	7.14±0.88	6.95±0.87	0.085
	ODQ	41.48±3.98	41.79±4.70	0.627
1. Month	VAS	2.51±0.75	2.44±0.89	0.854
	ODQ	22.82±1.01	22.81±2.49	0.354
6. Month	VAS	2.01±0.70	1.78±0.89	0.141
	ODQ	22.80±0.94	23.02±0.90	0.276
12. Month	VAS	1.93±0.79	2.10±0.68	0.000*
	ODQ	22.82±1.16	23.08±0.78	0.147
18. Month	VAS	2.89±0.70	2.59±0.79	0.006*
	ODQ	24.32±1.97	24.50±2.62	0.351

* = p < 0.05 (statistically significant)
ODQ: Oswestry Disability Questionnaires

DISCUSSION

NP is a new minimally invasive treatment for herniated discs that uses radiofrequency (RF) energy for partial removal of the nucleus pulposus. The RF energy is used to create a plasma field of highly ionized particles that have adequate energy to disintegrate nucleus proteins.[12] The technique, offers a minimally invasive option of disc decompression while causing very little disruption of the surrounding tissue. 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.

In the study of Singh et al, the authors observed that, at 12 months 80% of the patients indicated improvement in pain relief, 59% reported a numeric pain score reduction of two or more points, and 56% reported improvement of 50% or more pain relief.[13] Functional improvement was observed in 62%, 59%, and 60% of the patients for sitting, standing, and walking abilities, respectively. Another study of Singh et al. with 47 patients undergoing NP for predominantly low back pain demonstrated significant pain relief, defined as 50% or more relief, in 63% of the patients at 6 months and 53% of the patients at one year.[14] In another study of Singh et al. performed percutaneous disc decompression using coblation in chronic back pain with or without leg pain, they observed that at 12 months, 75% of the patients indicated a decrease in their numeric pain scores, and 54% reported improvement of 50% or more pain relief.[7] Functional improvement was observed in 54%, 44%, and 49% of the patients for sitting, standing, and walking abilities, respectively.[7] Yakovlev et al. performed NP for the treatment of chronic discogenic pain, and a total of 36.4% of patients indicated pain relief of 50% or more at one

month, 54.5% at three months, 54.5% at six months, and 68.2% at 12 months.[15] Mirzai et al. performed NP in patients with lumbar herniated disc, and mean VAS scores reduced from preprocedure 7.5 to 3.1 at postprocedure six months, to 2.1 at 12 months.[16] The ODQ scores decreased from 42.2 to 24.8 at six months and 20.5 at 12 months. Sharps and Isaac performed percutaneous disc decompression using NP in 49 patients with back pain with or without leg pain, and VAS scores changed 4.28, 4.66, and 4.75 to 3.3 at the one month, 3 month, 6 month, and 12 month intervals respectively.[5] All of these studies have also shown an overall reduction in pain scores following percutaneous disc decompression using NP. On the other hand, in the review, Urrutia et al. suggest that the available evidence does not support the efficacy or effectiveness of percutaneous thermocoagulation intradiscal techniques (like NP) for the treatment of discogenic low back pain.[17] In another study, Barendse et al suggest that percutaneous intradiscal radiofrequency thermocoagulation is not effective in reducing chronic discogenic low back pain.[18] Both of the studies were related with discogenic pain, but here we performed the NP and APLD procedures for low back pain caused from herniated discs. In our study, the pain and ODQ scores continued to decrease and functional status continued to improve in our patients over the 18-month follow-up period parallel to literature. The VAS scores reduced from preprocedure 7.1 to 2 at postprocedure 6 months, 1.9 at 12 months and 2.8 at 18 months. The ODQ scores decreased from 41.4 to 22.8 at 6 months, 20.5 at 12 months and 24.3 at 18 months in our study.

In NP group, no complications were observed during or after the procedure using coblation technology. While other minimally invasive procedures, such as laser assisted disc decompression, demonstrate complication rates of 1-2%, including discitis, transient temporary parasthesia, and lesion of the endplate.[19-21]

Although the cumulative number of patients who have undergone APLD continues to grow, its long-term effect on the structure of the disc and any harmful effects have not been evaluated.[22-24] In the study of Mochida et al performed overall success rate was 71% at six months, 71% at one year, and 55% at two years.[25] In another study Onik et al APLD in 327 patients and reported in significant improvements in functionality, and pain scores (VAS) in carefully selected patients with radicular pain.[26] Patients were followed for longer than one year, 75.2% were successfully treated. They indicates that APLD can be used successfully. Dullerud et al also reported equally good results with percutaneous nucleotomy in patients with predominantly low back pain (paracentral contained herniation), as compared to those with predominantly sciatica (posterolateral contained herniation).[27] All of these studies also have shown a general decline in pain relief over time. Nezer and Hermoni[28] suggest that unless or until better scientific evidence is available, APLD and laser discectomy should be regarded as research techniques. In their review, Freeman and Mehdian arrived a conclusion that clinical outcomes after APLD treatment was at best fair and often worse compared with microdiscectomy.[29] On the other hand, the authors has not determine about NP because of the absence of randomized controlled trials in literature. In our study, the pain and ODQ scores continued to decrease and functional status continued to improve in our patients over the 18-month follow-up period parallel to literature.

The VAS scores reduced from preprocedure 6.9 to 1.7 at postprocedure six months, 2.1 at 12 months and 2.6 at 18 months. The ODQ scores decreased from 41.7 to 23 at 6 months, 23 at 12 months and 24.5 at 18 months in our study.

Despite these limitations, all techniques share the same disc access approach as applied for discography, and report low complication rates. For example, in 1989 Maroon and Allen reported no serious complications such as death, great vessel damage, or nerve injury in 1054 APLD patients treated in 35 centers. The primary complication of the procedure was reported to be discitis occurring at a rate of 0.2%. Several centers noted better results in subsets of patients having less disc material removed and less annular invasion. In APLD Group, no complications were observed during or after the nucleotomy procedure in our study.

On the other hand, NP is cheaper than APLD. Taking this into consideration and according to our results, NP is more effective and less time consuming technique for patients with contained herniated discs.

The results of this study demonstrated a statistically significant improvement in VAS and ODQ scores at 1, 6, 12 and 18 months in both techniques. Because the NP is a less time consuming and effective technique, NP should be the first choice for the treatment of symptoms associated with contained lumbar herniated discs.

Acknowledgements

We would like to thank to Assistant of Professor Emel Luleci for helping us in the statistical analysis and to M.D. Vugar Aldulkerimov for the English language review.

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