Result of Percutaneous Disc Decompression Using Nucleoplasty in Thailand: A Randomized Controlled Trial

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Background: *Chronic low back pain is a major social, economic and healthcare issue in the Thailand. Percutaneous techniques are rapidly replacing traditional open surgery in operations requiring discectomy, decompression and fusion. The percutaneous access to the disc was first used in the 1950s to biopsy the disc with needles. Percutaneous access to the disc using endoscopic techniques was developed in the 1970s. 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 which utilizes coblation technology for ablating and coagulating the nucleus for a partial disc removal.*

Objective: *Evaluate the effectiveness of Nucleoplasty on pain in activity and improvement in MRI in patients with radicular or axial low back pain secondary to contained herniated discs.*

Design: *Prospective, Randomized, Control Trial.*

Material and Method: *Sixty-four patients were randomized in two groups equally. Thirty-two patients had undergone Nucleoplasty and another thirty-two patients had undergone conservative treatment. 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. Data were compared between baselines and at 1, 3, 6 and 12 months post-treatment. Pre-nucleoplasty MRI and Post-nucleoplasty 3 months were compared to evaluate the decrease of bulging disc.*

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 $\leq$ 0.001 for all outcome measures at all time periods) and also the bulging disc was significantly decreased 3 months following nucleoplasty.*

Conclusion: *Nucleoplasty appears to be safe and effective in Thailand. Is an effective procedure for patients presenting with discogenic back and/or radicular pain that have failed conservative therapies and are not considered candidates for open surgical interventions. A result of this analysis indicated that PDD using Coblation technology, also referred to as nucleoplasty, is an effective procedure for patients presenting with discogenic back and/or leg pain who have failed conservative therapies and are not considered candidates for open surgical interventions.*

Keywords: *Disc herniation, Low back pain, Minimally invasive, Nucleoplasty, Percutaneous disc decompression*

J Med Assoc Thai 2012; 95 (Suppl. 10): S198-S205
Full text. e-Journal: *http://jmat.mat.or.th*

The intervertebral disc is an important component of the spine. Degeneration or herniation of the disc may not only produce discogenic or compression-related 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 where cell degeneration is inevitable.

As disc degeneration progresses, a volume loss occurs within the nucleus pulposus due to a

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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 struc-tures 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) 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 re-moved 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 3.8 g including the central area of the nucleus, in contrast to removal of the hernial mass or migrated nucleus, averaging 1 g. 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 degen-eration[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 biome-chanical 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 grow-ing 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 per-cutaneous disc decompression (PDD) using Coblations™ plasma technology (Nucleoplasty™), with a minimally invasive percutaneous entry into the disc via a 17 gauge cannula and removal of approximately 1 g 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 sizes 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.

Material and Method

Design and participants

A prospective, randomized analysis was conducted on 64 consecutive patients who underwent Percutaneous Disc Decompression using Co-blation (Nucleoplasty) between July 2007 and March 2009.

Criteria for inclusion were the presence of discogenic low back pain and/or leg pain for six weeks or more months, absence of neurologic deficit, lack of response to conservative management and fluoros-copically guided injection thera-pies. The diagnosis was confirmed with positive MRI.

Exclusion criteria for this outcome analysis included presence of secondary gain issues, heavy opioid usage and un-controlled psychological disorders. Contra-indications for the procedure were evidence of infection, disc herniation with seques-tration, 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. 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 six-inch 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 stoping and lifting less than 5 kilograms 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

1. Query by estimating the VAS before treatment, after treatment 15 days, after treatment for 30 days, after treatment for 3 months, after treatment 6 months, after treatment 12 months being used. Make an appointment to follow-up with the team. The results of treatment were records at outpatient's clinic of division of spine surgery. Outcome measures included self-reported pain score on a numeric pain scale (with 0 being no pain and 10 being the most severe pain) 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.

2. Pre operative and Post operative (3 months) MRI was inspect the reduction of bulging disc.

Statistical analysis

1. The randomizations was done by computer based program.

2. Descriptive analysis was compared between pre-treatment and each post-treatment period. Means, ranges and standard deviations (SD) were calculated using a SPSS version 10.

3. T-test

3.1 Paired T-test; Pre and Post VAS in the same group.

3.2 Independent T-test; Pre and Post VAS in the difference group.

Results

From patients in the study and 64 were divided into 2 groups: Group 1. Nucleoplasty group and Group 2 Conservative group. All 64 patients who participated in the research study from start to completion.

From the study among 64 participants who had been diagnosed. Lumbar disc herniation with conditions that contain disc and a MRI to confirm the diagnosis and all the participants will be randomly divided into 2 groups one group was treated by method Nucleoplasty™. And the other one, with the number of participants is equal. Be treated by non-surgical methods.

$$n/group = \frac{2(Z_{\alpha/2}+Z_{\beta})^2\sigma^2}{\delta^2}$$

$$= \frac{2(1.96+1.28)^2(3.33)}{(3.00)^2}$$

$$= 25.87$$

Fig. 1 Sample size calculation

		Nucleoplasty		Conservative	
		N	%	N	%
Sex					
	Male	13	40.63	15	46.88
	Female	19	59.38	17	53.13

Fig. 2 Demographic characteristics

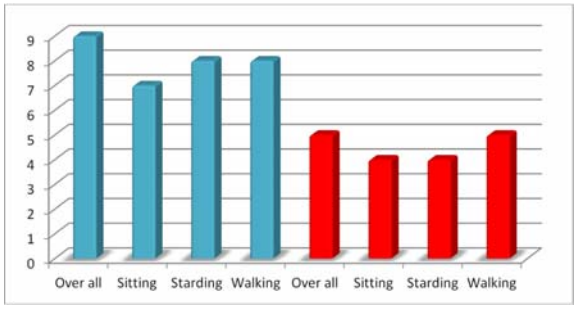

Fig. 3 VAS before Nucleoplasty (Blue) and Post Nucleoplasty (Red) 15 days

The group was treated by Nucleoplasty. It is found that can reduce pain (VAS) was significantly statistical significance. Since after Nucleoplasty is only 15 days and still reduce the pain of patients in this group to apply throughout the period of study (12 months). The result is pain can reduce both the overall pain, while sitting, standing, and walking. There was a statistical significance.

The group treated by non-surgical methods, it could not reduce pain (VAS) was significantly. However, unlike with the group was treated Nucleoplasty, especially after 1-15 days to receive treatment.

The results were compared in the study group and two groups can be concluded that Nucleoplasty™. Can help reduce pain statistical significantly quickly and better than group treated by non-surgical methods, during the first 15 days of starting treatment in overall pain score (by Mann-Whitney U test).

When compare the shrinking of the bulging

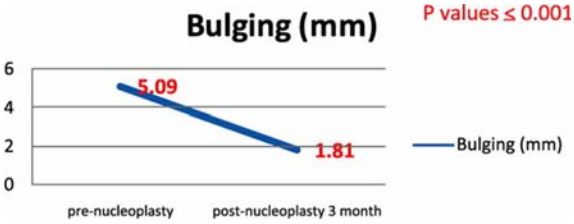

Fig. 4 The reduction of the bulging disc after a 3 month

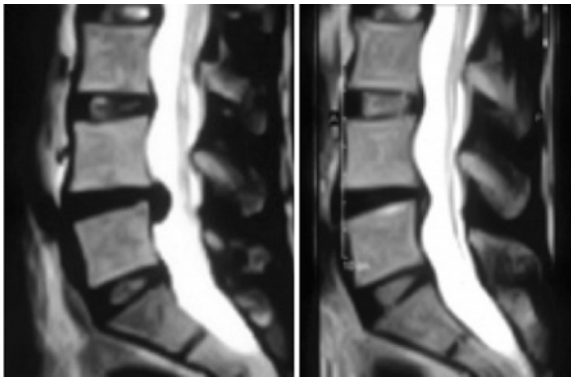

Fig. 5 MRI Pre-Nucleoplasty and Post-Nucleoplasty 3 months

disc before treatment and after receiving treatment 3 months who had been randomly assigned to the group treated by nucleoplasty seem to be shrinking important statistically significantly ($p < 0.001$) by the pre treatment mean bulging = 5.09 mm. And after the participant three months mean bulging = 1.81 mm. Which it confirms that the treatment method, Nucleoplasty™. That can reduce the amount of actual bulging disc herniation and provable.

Discussion

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. Management of discogenic pain is difficult and complex and riddled with high failure rates.

Percutaneous disc decompression using Coblation technique is yet another therapeutic option. Co-blation has been in use for orthopaedics arthroscopic procedures since the mid 1990s and was approved for use in the spine in 2000. Nucleoplasty™ using Coblation technology involves the use of Radiofrequency energy to dissolve the nuclear material through molecular dissociation. The RF energy is used to create a plasma field of highly ionized particles that have adequate energy to disintegrate nucleus proteins. The temperature is kept below 70°C to minimize tissue damage. As several studies by Mochida et al[24] and Sortland et al[25] have indicated, there appears to be an inverse correlation between the amount of disc material removed and the longterm 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. Singh et al recommended utilizing strict inclusion criteria especially for patients suffering with only low back pain. Prior to Nucleoplasty, these patients were required to have a positive provocative discography test and fail conservative management, including fluoroscopically directed epidural steroid injections. Radiographic findings alone were not the sole determination of pain origin and for patient inclusion. From our study. A prospective, randomized controlled trial, participants in all, 64 studies have demonstrated that the treatment of Contained Lumbar disc herniation. Found that treatment method, Nucleoplasty has the ability to reduce overall pain in the early stages of treatment in the last 15 days of starting treatment. Compared to treatment has not been operative fact ($p < 0.001$), but when follow-up and sustainability of these two groups compared, a head-to-head, it was found that the two groups do not differ statistically significant. But have changed in a good way, is to reduce the pain clearly on track until the end 12 months of the calculated statistics of study compares two groups that result from that there is no difference of significance may be caused by many factors involved. For example are the Number of drugs patients take or to buy the pain-killer drugs themselves or to take without informed physician who collected the data (Dr. Roongrath Chitragran MD), which may cause the error of the data. And there may be other factors to affect the result of pain from a query. Such as waiting for long time to see a doctor, hot air at the examination room, want to hurry back home.

Conclusion

Nucleoplasty appears to be safe and effective procedure for patients presenting with discogenic back and/or radicular pain who have failed conservative therapies and are not considered candidates for open surgical interventions in Thailand. Results of this analysis indicated that PDD using Coblation technology, also referred to as Nucleoplasty is Effective minimally invasive surgical treatment for contained herniated discs and appears significant improvement in quality of life at 3 months and continued at 6 months, No infections or nerve root injuries. Similar to other interventional spine procedures, careful patient selection for Nucleoplasty is necessary to achieve successful outcomes. The results of this study in Thailand demonstrated a statistically significant improvement in pain and functional status at 12 months.

Potential conflicts of interest

None.

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ผลการรักษาภาวะหมอนรองกระดูกปลิ้นด้วยวิธี Nucleoplasty ในประเทศไทยโดยวิธีสุ่มกลุ่มตัวอย่างมีกลุ่มควบคุม

รุ่งรัฐ จิตตการ, สมภพ ภู่พิทยา, วรัท ทรรศนะวิภาส

วัตถุประสงค์: *เปรียบเทียบผลการรักษาการเปรียบเทียบ ผลการรักษา (คะแนน VAS) ระหว่างการรักษาแบบไม่ผ่าตัดและการรักษาด้วย Nucleoplasty และทำการเปรียบเทียบ MRI ก่อนและหลังผ่าตัดโดยวัดการลดลงของหมอนรองกระดูกที่ปลิ้น*

วัสดุและวิธีการ: *ทำการคัดเลือกผู้ป่วยที่ได้รับการวินิจฉัยว่ามีภาวะหมอนรองกระดูกทับเส้นประสาทที่ยังไม่มีภาวการณ์แตกของหมอนรองกระดูก และมีความสมัครใจที่จะเข้าร่วมการวิจัยฯ แบ่งกลุ่มประชากร (ผู้ป่วย) ออกเป็นสองกลุ่ม กลุ่มละเท่าๆ กันโดยการสุ่มแบ่ง ให้ผู้ป่วยในแต่ละกลุ่มประเมินอาการของตนเองตลอดการวิจัยโดยใช้แบบฟอร์มประเมิน VAS ก่อนและหลังได้รับการรักษา 15 วัน, หลังรับการรักษา 30 วัน, หลังรับการรักษา 3 เดือน, หลังรับการรักษา 6 เดือน, หลังรับการรักษา 12 เดือน ผู้ป่วยในกลุ่มที่ได้รับการรักษาโดยวิธี Nucleoplasty จะได้รับการตรวจเพิ่มเติมด้วยตรวจด้วยฃลื่นแม่เหล็กไฟฟ้า (Magnetic resonance imaging; MRI) ภายหลังได้รับการรักษา 3 เดือน*

ผลการศึกษา: *กลุ่มที่ได้รับการรักษาโดยวิธี Nucleoplasty นั้นพบว่าสามารถลดความปวด (VAS) ได้อย่างมีนัยสำคัญทางสถิติ ตั้งแต่หลังได้รับการทา Nucleoplasty เพียง 15 วัน และยังคงลดความปวดของผู้ป่วยในกลุ่มนี้ไปตลอดระยะเวลาที่ทาการศึกษาวิจัย (12 เดือน) โดยผลการลดปวดนั้น สามารถที่จะลดได้ทั้งความปวดโดยรวม (Overall), ขณะนั่ง, ยืน, เดิน อย่างมีนัยสำคัญทางสถิต ในกลุ่มที่ได้รับการรักษาโดยวิธีไม่ผ่าตัดนั้นพบว่าสามารถลดความปวด (VAS) ได้อย่างมีนัยสำคัญทางสถิติได้เช่นกันแต่แตกต่างกับ กลุ่มที่ได้รับการรักษาโดยวิธี Nucleoplasty นั้นคือกลุ่มที่ไม่ได้ผ่าตัดจะมีอัตราการลดของความปวดช้ากว่าในกลุ่มที่ได้รับการรักษาโดย Nucleoplasty โดยเฉพาะช่วย 1-15 วันหลังการได้รับการรักษา*

สรุป: *Nucleoplasty ที่ทำในประเทศไทยนั้นมีความสามารถในการลดความปวดโดยภาพรวมในช่วงแรกของการรักษาในช่วง 15 วันหลังการเริ่มรักษา เมื่อเปรียบเทียบกับการรักษาแบบไม่ได้รับการผ่าตัดจริง ($p < 0.001$) แต่เมื่อติดตามผลการักษาของทั้ง 2 กลุ่มโดยเปรียบเทียบกันแบบ head-to-head นั้นพบว่า ระหว่าง 2 กลุ่ม ไม่มีความแตกต่างกันอย่างมีนัยสำคัญทางสถิติ แต่มีการเปลี่ยนแปลงไปในทางที่ดี คือลดความปวดได้อย่างชัดเจนเมื่อติดตามไปจนครบ 12 เดือน*