

Economic evaluation of nucleoplasty compared with conventional opened diskectomy in treatment of contained herniated lumbar disk

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Introduction : *Nucleoplasty is a minimally invasive percutaneous lumbar intervertebral disk decompression using coblation energy. The technique is indicated for patients with contained herniated lumbar disk who are unresponsive to conservative management as an alternative treatment. Many recent literatures proved that nucleoplasty is an effective procedure comparable to the standard treatment, but its long-term result is still controversial.*

Objective : *To compare effectiveness between nucleoplasty and conventional opened diskectomy and to evaluate the economical aspects of nucleoplasty*

Setting : *Department of Orthopaedics, King Chulalongkorn Memorial Hospital.*

Research Design : *A non-randomized prospective clinical trial with full economic evaluation*

Patients : *Contained lumbar intervertebral disk herniation patients with radicular pain who had undergone diskectomy and nucleoplasty at King Chulalongkorn Memorial Hospital from 2004 to 2006*

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- Methods** : *Thirty-four patients were recruited; twenty into nucleoplasty group and fourteen diskectomy group. Surgical techniques used were based on the patient's decisions. Pain intensity using 10 cm visual analogue scale and direct medical cost from King Chulalongkorn Memorial Hospital computer data base was collected. The data were analyzed using paired and unpaired student t-test for effectiveness. Cost-effective analysis and sensitivity analysis were done to evaluate the economic aspects.*
- Results** : *The success rate is 70% in the nucleoplasty group and 86% in the diskectomy group. Both techniques significantly decrease pain compared with the preoperative status. Diskectomy decreases pain more than nucleoplasty in the first month. There is no difference in the overall pain reduction. Cost of nucleoplasty is higher than diskectomy 8,225 bath net and 2,600 per 1 visual analogue scale pain reduction. Regarding sensitivity analysis, however, patients whose income is more than 1,750 baht/day are suitable to choose nuceloplasty.*
- Conclusions** : *From the current data we found that for carefully selected contained intervertebral disk patients caused by radicular encroachment who failed conservative treatment, nucleoplasty provided substantial benefit from minimally invasive technique and it is comparable between the conventional opened diskectomy and nucleoplasty in term of effectiveness and economy.*
- Keywords** : *Nucleoplasty, economic evaluation, cost effectiveness analysis.*

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- บทนำ** : นิวคลีโอพลาสต์ คือ การแทงเข็มผ่านผิวหนังเพื่อลดความดันที่หมอนรองกระดูกสันหลังโดยใช้พลังงานคลื่นวิทยุ ใช้เป็นการผ่าตัดทางเลือกสำหรับผู้ป่วยโรคหมอนรองกระดูกสันหลังโป่งพองที่ไม่ตอบสนองต่อการรักษาแบบอนุรักษ์ ซึ่งผลการศึกษาล่าสุดได้พิสูจน์ถึงประสิทธิผลเทียบเท่ากับการผ่าตัดหมอนรองกระดูกสันหลังแบบมาตรฐาน แต่ผลการรักษาระยะยาวยังเป็นที่ยกเถียง
- วัตถุประสงค์** : เพื่อเปรียบเทียบประสิทธิผลระหว่างนิวคลีโอพลาสต์กับการผ่าตัดหมอนรองกระดูกสันหลังแบบมาตรฐาน และประเมินแง่มุมทางเศรษฐศาสตร์ของนิวคลีโอพลาสต์
- สถานที่** : ภาควิชาออร์โธปิดิกส์ โรงพยาบาลจุฬาลงกรณ์
- รูปแบบการวิจัย** : การศึกษาเชิงวิเคราะห์ทางคลินิกแบบไม่สุ่ม และการประเมินทางเศรษฐศาสตร์แบบสมบูรณ
- ผู้ป่วย** : ผู้ป่วยหมอนรองกระดูกสันหลังโป่งพองที่เยื่อหุ้มแอนนูล่ายังไม่ฉีกขาด และมีอาการปวดชา ร้าวลงขา ที่ทำการผ่าตัดหมอนรองกระดูกสันหลังแบบมาตรฐาน และนิวคลีโอพลาสต์ในโรงพยาบาลจุฬาลงกรณ์ ระหว่าง ปีพ.ศ. 2547 - 2549
- วิธีการ** : ผู้ป่วย 34 คนที่เข้าร่วมการศึกษา 20 คนทำนิวคลีโอพลาสต์ และ 14 คนผ่าตัดหมอนรองกระดูกสันหลังแบบมาตรฐาน โดยผู้ป่วยเป็นคนเลือกวิธีผ่าตัด ทำการวัดระดับความปวดโดยใช้วีซวลอนาล็อกสเกลขนาด 10 เซนติเมตร และบันทึกค่าใช้จ่ายทางการแพทย์โดยตรงจากฐานข้อมูลคอมพิวเตอร์ของโรงพยาบาลจุฬาลงกรณ์ ข้อมูลด้านประสิทธิผลวิเคราะห์โดยใช้ วิธี paired และ unpaired student t-test และวิเคราะห์ข้อมูลทางเศรษฐศาสตร์โดยใช้วิธี ประสิทธิภาพ-ความคุ้มทุน และวิเคราะห์ความไว

- ผลการศึกษา** : การผ่าตัดประสบความสำเร็จ 70% ในกลุ่มที่ทำนิวคลีโอพลาสตี และ 86% ในกลุ่มผ่าตัดหมอนรองกระดูกสันหลังแบบมาตรฐาน การผ่าตัดทั้งสองวิธีสามารถลดระดับความปวดเทียบก่อนและหลังผ่าตัดได้อย่างมีนัยสำคัญ โดยผ่าตัดหมอนรองกระดูกสันหลังแบบมาตรฐานสามารถลดความปวดได้ดีกว่านิวคลีโอพลาสตีในเดือนแรก ทั้งสองวิธีไม่มีความแตกต่างกันในด้านระดับความปวดโดยรวม ค่าใช้จ่ายสำหรับนิวคลีโอพลาสตีสูงกว่าผ่าตัดหมอนรองกระดูกสันหลังแบบมาตรฐาน 8,225 เทียบกับ 2,600 บาทต่อ 1 ระดับความปวด จากวิชวลอะนาล็อกสเกล จากการวิเคราะห์ความไวพบว่านิวคลีโอพลาสตีเหมาะกับคนไข้ที่มีรายได้มากกว่า 1,750 บาท ต่อวัน
- สรุป** : จากข้อมูลที่ได้จากการศึกษาพบว่าคนไข้หมอนรองกระดูกสันหลังไป่งพองที่เยื่อหุ้มแวนนูล่ายังไม่ขาด และมีอาการปวดชา ร้าวลงขา ซึ่งรักษาไม่หายโดยวิธีการอนุรักษ์นิวคลีโอพลาสตีสามารถเป็นทางเลือกในการทำการรักษา โดยมีประสิทธิภาพใกล้เคียงกับการผ่าตัดมาตรฐาน แต่มีการลุกล้ำต่อเนื้อเยื่อน้อยกว่า และประสิทธิผลเทียบเท่ากับการผ่าตัดกระดูกสันหลังแบบเปิดในแง่ประสิทธิภาพ และ เศรษฐศาสตร์
- คำสำคัญ** : นิวคลีโอพลาสตี, เปรียบเทียบประสิทธิผล, การประเมินทางเศรษฐศาสตร์.

For patients with contained herniated lumbar disk who are unresponsive to conservative management, conventional discectomy are considered a standard treatment.^(1,2) Nucleoplasty is a minimally invasive percutaneous lumbar intervertebral disk decompression using coblation techniques. Many descriptive studies have proved that nucleoplasty is effective and safe^(9-13,18-19), but they lack comparative clinical trials and economic data.^(10,14) We conducted non-randomized prospective clinical trial and full economic evaluation to compare the effectiveness between nucleoplasty and the conventional opened discectomy and evaluate economical aspects of nucleoplasty.

Material and Method

Study populations were contained lumbar intervertebral disk herniation patients with radicular pain who had undergone discectomy and nucleoplasty in King Chulalongkorn Memorial Hospital from 2004 to 2006. Symptoms of radicular pain must be persisted more than 6 weeks. We exclude patients who had non-contained lumbar intervertebral disk herniation, neurological deficit, mental problem, spinal

infection, spinal instabilities, spinal stenosis and extensive osteophytosis. Thirty-four patients were recruited, twenty into nucleoplasty group and fourteen discectomy group.

Surgical techniques used were based on patient's decisions. All procedures in the study were performed by the same orthopaedic surgeon. Nucleoplasty was done under local anesthesia. The patient was placed in prone position. A trochar needle was penetrated into the target intervertebral disk using an oblique approach assisted by fluoroscope. Then a curved bipolar radiofrequency probe (Artrocare Perc-DLR Spine Wand, Sunnyvale, CA) was inserted through the trochar until its active tip exited the needle.(Figure 1) Six channels were created in the nucleus pulposus by advancing the radiofrequency probe and then withdraw using "coblation energy" (Arthrocare System 2000 controller). The conventional opened discectomy were performed under general anesthesia with prone position. laminotomy was done to visualize intervertebral disk lesion. The ligaments were preserved. Protruded intervertebral disk was removed using the surgical blade. All skin incisions were not longer than 5 cm.

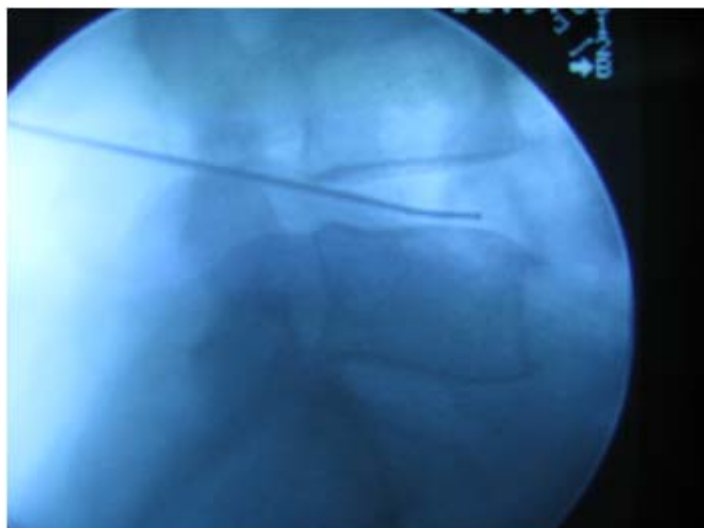


Figure 1. Shows radiofrequency probe inserted through trochar into intervertebral disk.

All patients from both groups would received same standard analgesic protocol while admission and follow-up visit. Postoperative complications such as infection, hemorrhage, or any others were recorded for further evaluation.

Data were recorded preoperatively and 1,3, 6 and 12 months postoperatively for each case. Effective results were weighted by pain intensity visual analogues scales. The data were analyzed using SPSS version 12 and Microsoft Excel 2007. Demographic data were analyzed by unpaired student *t*-test and chi-square test; effectiveness of the procedures by paired and unpaired student *t*-test, Chi-Square test and Kolmogorov-Smirnov test. The *p*-value that was less than 0.05 was considered statistically significant.

Success of the procedure evaluated from patient satisfaction, pain reduction and patient reoperation requirement. Reduction of pain score more than 4 points and patient satisfied with operative result was considered a success. If the patient not satisfied with the operation result or needed reoperation, it was considered failure. All reoperation cases used standard conventional opened diskectomy as the surgical procedure.

Total cost of treatments included reoperation cost were recorded for analysis at 1 year postoperative. Direct medical costs from both procedures were obtained from King Chulalongkorn Memorial Hospital data base; however, indirect costs such as cost from longer operative time or patient transportation were not included. For the economic analysis, overall expenditure and cost-effectiveness ratio(C/E ratio), which calculated from total cost of procedure and visual analogue scale (VAS) reduction,

were analyzed to compare cost-effectiveness between both surgical techniques.

$$\text{C/E ratio (Baht/VAS)} = \frac{\text{Total cost of procedure (Baht)}}{\text{VAS pain scale reduction}}$$

Nucleoplasty technique was required special instruments so operative cost usually higher than standard conventional technique. According to some benefits from minimally invasive technique, nucleoplasty patients can return to their work earlier⁽⁹⁻¹²⁾ that mean they can gain money faster than diskectomy patient, thus the sensitivity analysis was conducted to determine patient's income that appropriate for nucleoplasty as operative choice.

Results

Both groups were similar in characteristic except their hospital stay, return to work and operative time. Diskectomy take longer time of hospital stay, return to work and operative time than nucleoplasty almost double. Their demographic data are shown in Table 1.

Effectiveness analyses

All of operative procedures had no serious post-operative complications. Both techniques decrease pain significantly compared with the preoperative status diskectomy 5.4 (95%CI 2.9 - 8.0) vs nucleoplasty 5.0 (95%CI 3.8 - 6.2). Diskectomy decrease pain intensity more than nucleoplasty, it is found statistically significant in the first month (*p* = 0.016). There was no difference between diskectomy and nucleoplasty in the overall pain reduction. (Figure 2.)

Success rate

Considered patient satisfaction, success rate was 70% in the nucleoplasty group compare to 86% in the diskectomy group. There were 20% of nucleoplasty patients who needed reoperation and 7% for diskectomy patients.

Economic evaluation

The cost of nucleoplasty was 8,225 baht more than diskectomy and 2,600 per one visual analogue scale on pain reduction. (Table 2); whereas from the sensitivity analysis, patients with their income more than 1,750 baht/day are suitable to be operate by nucleoplasty. (Figure 3.)

Table 1. Clinical characteristics of the patients.

	Nucleoplasty (20 patients)	Diskectomy (14 patients)	
Age (Years)	35.2	38	
Gender (M:F)	8:12	9:5	
Onset (Months)	13.6	12	
BMI (Kg/m ²)	22.6	22.5	
Hospital stay (Days)	5	8	*
Return to work (Days)	12	21	*
Operative time (Minutes)	57	119	*

* Statistically significant difference (p < 0.05)

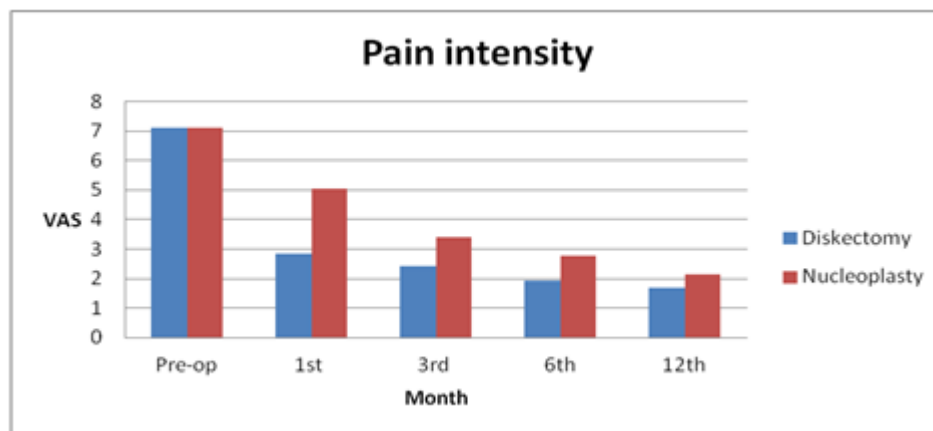


Figure 2. Demonstrated pre-operative and 1st, 3rd, 6th, 12th month post-operative pain intensity.

Table 2. Shows cost comparison between nucleoplasty and diskectomy.

	Mean of cost (Baht) (95% CI)	C/E ratio (Baht/VAS)
Diskectomy	55,606 (42,734 – 68,478)	10,243
Nucleoplasty	63,831 (48,091 – 79,571)	12,843
Cost difference	8,225 (-12,857 – 29,308)	2,600



Figure 3. Sensitivity analysis : patient’s income per day and total medical cost.

Discussion

Intervertebral disk herniation was a major problem in working age group. Pain and disability can cause absence from work and loss of job. (2) Contained herniation was defined as intacted outer layer of annulus fibrosus, but the outcome for operative treatment in this type of hernation was considered unfavorable. (1)

There were many minimally invasive technique for intervertebral disk surgery such as chemonucleolysis and electrothermal therapy. Nucleoplasty is one of minimally invasive technique using radiofrequency probe to decompress intradiscal

pressure. (3-8) Clinical results from many studies have proved that nucleoplasty is effective and safe. (9-12,18-19) Effectiveness of nucleoplasty at King Chulalongkorn Memorial Hospital is comparable to previous studies. (18,19) From our present data, nucleoplasty takes less operative time, the patients can be discharged from hospital on the same day of their surgery and they could return to work faster than the diskectomy group. However, there are several disadvantages of nucleoplasty. Nucleoplasty has higher rate of reoperation which risk the patient’s safety and also waste their time and money too.

The results from this study are demonstrated comparable effectiveness between discectomy and nucleoplasty. At 1 year, the success rate was higher in the discectomy group. Pain intensity in discectomy was decreased significantly more than nucleoplasty in first month, but overall pain reduction was indifference. Nevertheless, there are significantly different amount of patients between groups and patient occupation was not analyzed, all of these factors can affect reliability of study data and results.

In the economical aspect, nucleoplasty may be suitable for patient who have monthly income more than 50,000 baht. The patients in the nucleoplasty group could return to work 9 days faster than discectomy group. Further study with more samples and longer follow-up period may be needed to apply the results into clinical practice.

Conclusion

From current data we found that for carefully selected contained intervertebral disk patients caused by radicular encroachment who failed conservative treatment, nucleoplasty provided substantial benefit from minimally invasive technique and it is comparable to the conventional opened discectomy and nucleoplasty in term of effectiveness and economic. The effectiveness of discectomy and nucleoplasty are comparable in treatment of contained lumbar disk herniation with radicular pain. Nucleoplasty provides more benefits as it is minimally invasive technique and faster return to work. Nucleoplasty costs more than discectomy, but from sensitivity analysis, patients with income more than 1,750 baht/day are more comfortable to choose nucleoplasty

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