

## Comparison the Postoperation Results of Discectomy with Nucleoplasty in Single Cervical Disc Herniation

### Abstract

**Background:** The standard treatment for cervical disc herniation is open discectomy surgery but some of techniques, such as nucleoplasty were applied by neurosurgeons in recent decade. The aim of this study was to compare the postoperation results of open discectomy and nucleoplasty methods in people suffering from single cervical disc herniation. **Materials and Methods:** In a clinical trial study that performed during 2012–2013, 70 patients who candidate for neck surgery were selected and randomly divided into two groups. The first group was operated with standard discectomy and the second group was operated with nucleoplasty method. All patients were followed neck pain, upper limb pain and common complications included discitis, infection and hematoma in 2 weak, 1, 2, 3, and 6 months after operation. All data were analyzed using SPSS software. **Results:** Cervical pain mean from before the operation to 6 months after operation had no significant difference between two groups, but radicular pain had significant difference in 2 and 3 months after operation ( $P < 0.05$ ). It is notable that after operation it is not observed any discitis, infection and hematoma of operated place. **Conclusion:** Doing nucleoplasty surgery in patients suffering from single cervical disc herniation causes decrease in cervical and radicular pain, at least as the same as discectomy method. Since now it is possible in our country to apply this method and on the other hand, in this method, time of surgery, postoperation complications, hospital costs, and period of convalescence is low, it is preferred in patients suffering from cervical disc and its application is advised.

**Keywords:** Cervical disc herniation, discectomy, nucleoplasty

### Introduction

Neck pain is one of the common pains among people, which makes them to seek specialized medical care to get rid of it and as a result causes their absence from work.<sup>[1]</sup> It has been reported that about 50% of western countries people suffered at least once from neck pain during their life.<sup>[1,2]</sup> In addition, about 55% of these pains were along with radicular pain.<sup>[1]</sup> Less than 5% of neck pain is as the result of disc herniation.<sup>[2-5]</sup> However, the most common reason is disc herniation radicular pain. Outbreak of disc herniation has been evaluated from 5.1% to 3.7%.<sup>[6-8]</sup>

In neurosurgery science, the standard treatment for cervical disc herniation, along with pain in hands and radicular pain, is open discectomy surgery.<sup>[9]</sup> This technic takes very little time, the amount of pain during surgery is low and the period of recovery is very fast.<sup>[10-13]</sup>

The open nucleoplasty, discharge disk was done by total prone side laminectomy. This

procedure was done under general or spinal anesthesia.

Percutaneous cervical nucleoplasty (PCN) uses Coblation Technology 6 whereby a portion of the nucleus tissue is ablated using a 1 mm diameter iPolar instrument that creates radiofrequency energy 6. This results in ablation of a portion of nucleus tissue with a low temperature (typically 40–70°C) plasma field of ionized particles 2, 6. These particles have sufficient energy to break down organic molecular bonds within the tissue, dissolving the soft tissue material of the disc nucleus 2, 6. The procedure provides a simple and efficient disk decompression method, using a controlled and highly localized ablation, with minimal damage to surrounding healthy tissue 2.

Several studies were done to evaluation of the benefit of nucleoplasty for treatment of disc herniation.<sup>[11,12,14-16]</sup> Therefore, according to the received results of previous research it seems that nucleoplasty methods is a methods with lower complications and cost and also makes better results in

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patients. However, as pain depends on demographic factors, life style and medical cares, the results may not be the same in different areas. Since there is no any useful study in Iran in this science area, this research was done with the purpose of comparing the postoperation results of open discectomy and nucleoplasty methods in people suffering from single cervical disc herniation.

## Materials and Methods

This research is a clinical trial study, which is done in Al Zahra treatment and training center during 2012–2013. Studied population were the patient suffering cervical disc herniation.

The criteria of entering to study were suffering from single cervical disc herniation, need to surgery to release the pressure on spinal root, existence of a cervical disc herniation needy to surgery, no previous surgery on cervical spine, age <60, and not having spinal canal stenosis. In addition, it is prescribed that patients who suffer from surgery complication or those are not able to receive enough dosage required for nucleoplasty method, can be omitted from the study. The required sample size is considered with the use of formula for estimating sample size to compare two means and with respect to confidence level of 95%, test of 80%. Standard deviation of pain in patients suffering from cervical disc herniation, which is estimated as 1.2 in other research and least significant difference between two groups was 0.8, estimated as 35 patients in each group.

At first to qualified patients were justified about open surgery and nucleoplasty method and after their acceptance of the study condition and writing down consent, they entered into study. Then, demographic and general information of patients were asked and were recorded in their special file along with initial examination results. Then, they were distributed into two groups of nucleoplasty and surgery with the use of allocated random block method. After their admission in surgery room, first group treated by classic method of cervical disc and second group was treated by nucleoplasty method and both were released from hospital during 24 h after operation.

In nucleoplasty, which is done in percutaneous form, controlled Radiofrequency energy is used to cut nucleus pulposus. This energy is used to decompress disc, without any damaging to surrounding tissues, but there are no enough studies yet for long time efficiency of nucleoplasty method. Studies have demonstrated PCN to be both safe and effective.<sup>[14,15,17,18]</sup> In our study of 980 nm diode laser device was used spherical kneading called plasma. In probe device through the skin and under the Centre for Adverse Reactions Monitoring

(CARM) guide was placed in the disc space. Then three fired 250 joules done (total 750J).

In open discectomy, patients were done in knee chest position and then operation was done under fenestration. In this study, all patients were operated by spinal anesthesia and by one surgeon.

Patients were asked to recourse to hospital in day 14 and month 1, 2, 3 and 6 after operation. During these days, patients were analyzed with respect to their back pain, upper limb pain and common complication resulted from operation such as discitis, infection, and hematoma of operated place. The pain of patients, before and after the operation was determined by visual analog scale (VAS)<sup>[2]</sup> criteria. In this method, patients were asked to characterize their pain in a graded line from 0 to 10. During follow-up, if one patient did not refer to the hospital, he would be called to refer to hospital for analyzing improvement situation. If he did not refer again, he would have been omitted from the study.

Our study had some limitations such as lock of patients' candidate for nucleoplasty, patients not coming on time. Furthermore, pain is a subjective symptom affects the patient's psychological condition.

Study data were located into computer after collecting and analyzed by SPSS software, (SPSS version 22, Chicago, IL, USA). Statistical tests used in this study were *t*-test, Chi-square, and ANOVA with repeated observations.

## Results

In this research, 70 persons who suffered from cervical disc were analyzed of which 13 patients were omitted from study because of not referring to the hospital (6 patients from Nucleoplasty method and 7 patients from classic surgery) [Figure 1]. Table 1 shows the demographic information distribution of patients of two groups. According to *t*-test, there were no significant difference between the

**Table 1: Distribution of demographic variables in two groups**

Variable	Group		P
	Nucleoplasty	Surgery	
Age (year)			
Mean±SD	44.9±9.4	41.3±7.7	0.12
Sex <i>n</i> (%)			
Male	23 (79.3)	24 (75.7)	0.73
Female	6 (20.7)	4 (14.3)	
Disease duration (month)			
Mean±SD	11.4±7	12.4±9.6	0.66
BMI (kg/cm <sup>2</sup> )			
Mean±SD	22.53±3.99	23.71±4.02	0.27
Occupation, <i>n</i> (%)			
Labour	0 (34.5)	5 (17.9)	0.55
Clerk	4 (13.8)	5 (17.9)	
General	11 (37.9)	14 (50)	
Housekeeper	4 (13.8)	4 (14.3)	

BMI: Body mass index, SD: Standard deviation

age, duration of sickness, and body mass index of two groups ( $P > 0.05$ ). In addition, according to Chi-square, gender and occupation of these two groups had no significant difference. The mean ( $\pm$  standard deviation) of operation time in surgery and nucleoplasty was  $2.72 \pm 0.72$  and  $3.64 \pm 1.59$  h, respectively and the difference between the two groups was statistically significant ( $P = 0.007$ ).

Table 2 and Figures 2, 3 shows the mean and standard deviation of cervical and radicular pain of these two groups from before operation to 3 months after operation. According to *t*-test, cervical pain mean from before the operation to 3 months after operation had no significant difference between two groups, but radicular pain had significant difference in 2 and 3 months after operation ( $P < 0.05$ ). On the other hand, doing repeated measures ANOVA on the noted data show that the pain

has decreases in a same level in both groups and there are no significant difference between cervical pain changes in two groups ( $P = 0.66$ ). In addition, according to noted test, radicular pain also does not show any significant difference between 2 groups. It is notable that after operation it is not observed any discitis, infection and hematoma of operated place. In the first group (nucleoplasty method), one patient was operated again. One patient in nucleoplasty group still suffered from cervical pain after 6 months. In addition, one patient in classic surgery group suffered from radicular pain 6 months after operation.

Table 3 shows the distribution of patient satisfaction in two groups. According to this table, about 6.8% from nucleoplasty group and 10.7% from classic surgery group were not satisfied by the surgery and according to Fisher's exact test, there is no any significant difference between two groups ( $P = 0.8$ ).

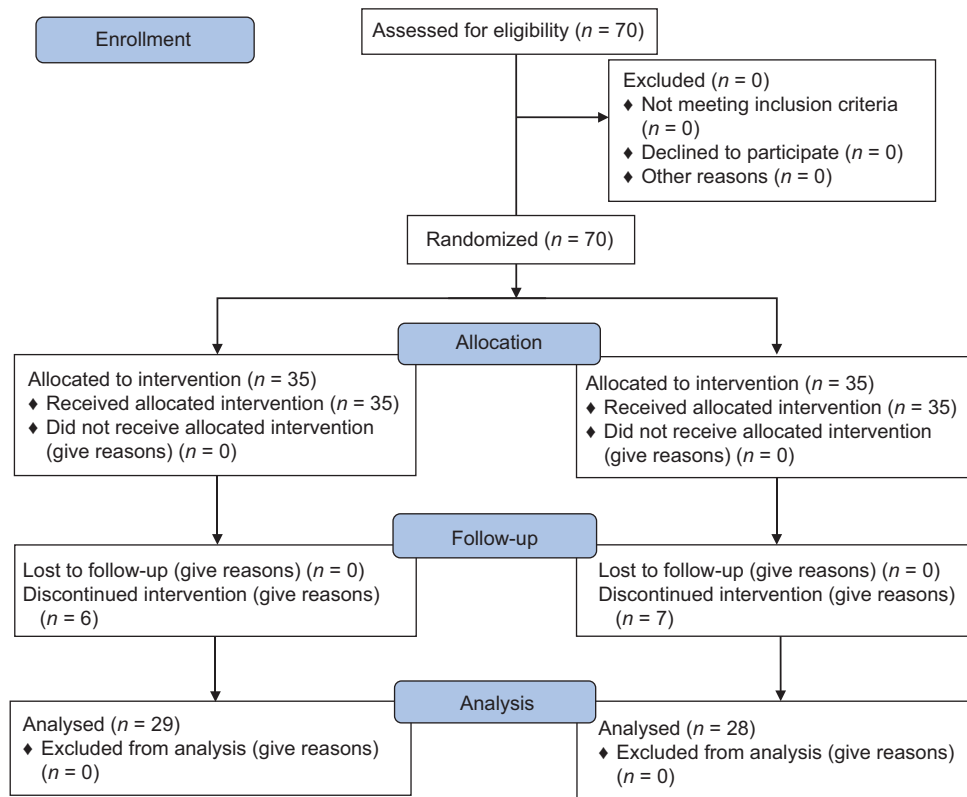


Figure 1: Study flowchart

Table 2: Mean±SD of cervical and radicular pain from before operation to 3 months after operation

Time	Cervical pain			Radicular pain		
	Nucleoplasty	Surgery	P	Nucleoplasty	Surgery	P
Preoperation	6.9±1.3	7±1.1	0.75	5.8±1.2	5.7±1.2	0.89
14 days after operation	5.3±1.5	5±1.5	0.44	4.6±1	4.7±1.4	0.69
1 month after operation	4.5±1.6	4.1±1.7	0.35	3.4±1.3	3.5±1.3	0.89
2 months after operation	3.2±1.5	3.3±1.6	0.98	2.2±1.1	2.9±1.3	0.047
3 months after operation	2.7±1.4	2.6±1.6	0.76	1.5±0.7	2.4±1.2	0.002
6 months after operation	2.3±0.99	1.9±1.03	0.16	2.3±0.47	1.6±0.8	0.17
P (difference between two groups)	0.54			0.15		

SD: Standard deviation

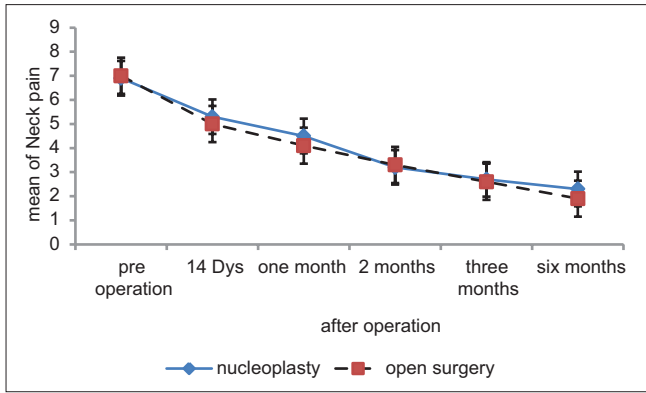


Figure 2: Mean of cervical pain from before operation to 3 months after operation in two groups ( $P = 0.66$ )

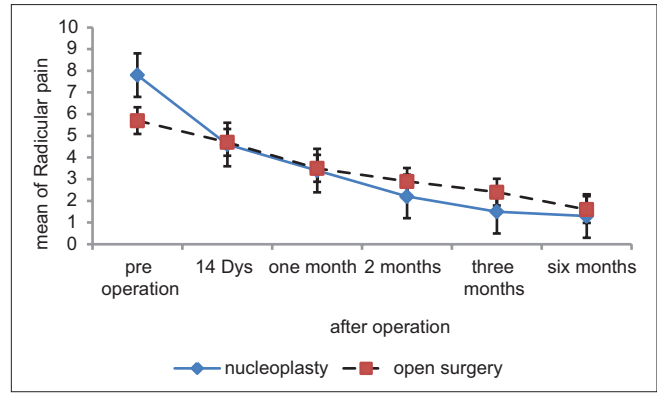


Figure 3: Mean of radicular pain from before operation to 3 months after operation in two groups ( $P = 0.18$ )

**Table 3: Distribution of satisfaction frequency of two groups' patients**

Level of satisfaction	Group				Total	
	Nucleoplasty		Surgery		n	Percentage
	n	Percentage	n	Percentage		
Completely satisfied	12	41.4	14	50	26	45.6
Satisfied	15	51.7	11	39.3	26	45.6
Nonsatisfied	1	3.4	1	3.6	2	3.5
Completely nonsatisfied	1	3.4	2	7.1	3	5.3
Total	29	100	28	100	57	100

It should be noted that unsatisfied patient were those suffered from cervical or radicular pain 3 months after operation.

### Discussion

General purpose of this study is comparing the postoperation results of discectomy to nucleoplasty in people suffering from single cervical disc herniation. In this study, 70 patients who suffered from cervical disc were analyzed 13 of which were omitted from study because of not referring to hospital.

Understudied patients had no significant difference in respect to age and gender distribution, duration of sickness and occupation and according to ANOVA with repeating observations, there is no any significant confounding effects of noted factors in the study. Therefore, it is possible to attribute the results of the study about the decrease of radicular and cervical pain to the kind of surgery.

The results of this study showed that the amount of pain 3 months after operation decreases in a same level in patients and significant difference were not seen in the follow-up times. However, patients who treated by discectomy surgery enjoyed more radicular pain 2 and 3 months after operation, but at the same time, there was not any significant difference in the procedure of radicular pain changes Therefore, with respect to received results, it can be concluded that nucleoplasty surgery at least as the

same as discectomy surgery causes decrease in radicular and cervical pain in patients suffering from cervical disc herniation and since nucleoplasty surgery is done in a small period of time and with low cost, in the case of single disk, it is preferred over discectomy surgery, especially because of its less tissue invasive, patients returns to their normal life sooner. Other done researches also report the proper efficiency of nucleoplasty method in patients who suffer from cervical disc herniation.

In one study that done by Bak *et al.* confirm that PCN for the treatment of cervical disc herniation results in a good outcome without any tampering of the stability of the cervical spine. Hence, PCN as a procedure is safe, minimally invasive, less traumatic, requiring less time with an excellent clinical outcome.<sup>[14]</sup>

In a study done by Peter *et al.*, showed that nucleoplasty-based percutaneous disc decompression in patients with symptomatic contained disc herniations is safe and improves quality of life (QOL) as measured by the short form 36, EuroQol-5D, and VAS for pain, three generic QOL outcome instruments. Nucleoplasty is an effective minimally invasive surgical treatment alternative in patients with symptomatic contained disc herniations. Further follow-up evaluation is underway to determine the durability of QOL improvement after nucleoplasty.<sup>[19]</sup>

In a study done by Bak *et al.*, 46 patients who suffer from cervical disc in a same level, were selected and treated by nucleoplasty method. Then, their clinical symptoms were analyzed by using VAS and Mac nab's criteria in 21 months. VAS score decreased from  $7.4 \pm 1.4$  to  $1.4 \pm 0.7$  ( $P < 0/001$ ) during the study. 41 patients also got a good improvement Mac nab's criteria.<sup>[14]</sup> In another research done by Salvatore *et al.*, 72 patients suffering from disc herniation were treated by nucleoplasty method and their clinical symptoms were analyzed for about 1 year. In this analyze, the average level of pain reached to 4.1 from 8.2. In addition, 17% (12 persons) of patients got complete improvement and 62% (43 persons) got good results.<sup>[15]</sup>

In a prospective evaluation done by Singh *et al.*, 57 patients who suffered from discogenic pain, were treated by nucleoplasty method and then were analyzed after 1, 3, 6, and 12 months, which their pains decrease, were more than 50%. In addition, in these periods the amount of pain decreased 80%, 74%, 63%, and 53%, respectively. Their functional activities also were improved significantly. In another research done by Zhu *et al.*, 42 patients' suffering from disc herniation, were treated by nucleoplasty method and were analyzed for about 2 years. Analyzing of these 42 patients during 2 years showed a significant improvement in VAS criteria and ODI index. In this study, the clinical results evaluated good during 2 years.<sup>[16]</sup> Finally in a systematic review that done by Jorgen 85 articles about the effect of nucleoplasty these studies represented a total of 1021 patients: 823 patients ( $\geq 892$  disks) were treated by PCN. All studies showed low methodological quality, except for two. The level of evidence of the RCTs was graded as moderate, with low to moderate applicability and clinical relevance. All included studies showed PCN to be an effective and safe procedure in the treatment of (contained) herniated discs at short-, mid-, and long-term follow-up. However, the level of evidence is moderate and shows only low to moderate applicability and clinical relevance.<sup>[20]</sup>

## Conclusion

According to the results of this study and their comparing to other studies, the general conclusion is that doing nucleoplasty surgery in patients suffering from single cervical disc herniation causes decrease in cervical and radicular pain, at least as the same as discectomy method. Also operation time in the nucleoplasty approach in lower than the open surgery. Since now it is possible in our country to apply this method and on the other hand, in this method, time of surgery, postoperation complications, hospital costs and period of convalescence is low, it is preferred in patients suffering from cervical disc and its application is advised.

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Nil.

## Conflicts of interest

There are no conflicts of interest.

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