Perspective Evaluation

Differential Treatment of Nerve Root Compression Pain Caused by Lumbar Disc Herniation Applying Nucleoplasty

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Background: Nucleoplasty is a minimally invasive intervention use to perform disc decompression in cases of nerve root compression caused by disc herniation. It is important to find rational guidelines for choosing between nucleoplasty and microsurgery.

Objective: To analyze factors that may impact the results of nucleoplasty, and to validate the rational guidelines between minimally invasive treatment and open surgery.

Study Design: Prospective, non-randomized, cohort study with a minimal follow-up period of 18 months.

Methods: Patients were given a neurological examination, visual analogue scale and Oswestry disability questionnaire, obligatory MRI, optional RCT, and discography, only before nucleoplasty. Patients have been divided into the following groups: Group 1 – patients with a disc protrusion treated with nucleoplasty (n = 46), which has been divided into Subgroup 1A, those with a disc protrusion size ≤ 5 mm (n = 24), and Subgroup 1B, those with a disc protrusion size 6 – 9 mm (n = 22); Group 2 – patients with a disc extrusion treated with nucleoplasty (n = 27); Group 3 – patients with a disc extrusion or sequester treated with microdiscectomy (n = 65).

Outcome Measures: Clinically significant outcomes were a 50% relief of pain intensity and a 40% decrease of Oswestry Disability Index (ODI).

Results: A decrease of pain intensity and disability was found in all groups of patients, $P < 0.0001$; SP (statistical power) = 99 – 100%. Subgroups 1A and 1B showed no clinically significant differences in outcome, $P = 0.99$; SP = 5.3. Clinically significant results: Group 1 – 78%; 95% CI (confidence interval) [66; 90%], Group 2 – 44%; 95% CI [25; 65%], Group 3 – 93%; 95% CI [85; 98%]. Total annulus disruption increases the rate of unsatisfactory results of nucleoplasty, OR (odds ratio) = 4.5; 95% CI [1.57; 12.87] (logistic regression model, $P = 0.0034$). Nucleoplasty performed in cases of uncontained disc herniation (disc extrusion) have a significantly higher rate of unsatisfactory results versus microdiscectomy, OR = 19.06; 95% CI [2.29; 68.73] (logistic regression model, $P < 0.0001$).

Limitations: This study was limited by the small number of patients in each group.

Conclusion: The size of the disc protrusion does not significantly affect the outcome of nucleoplasty. The rational guideline for choosing between the 2 types of surgery is the integrity of the annulus.

Key words: disc herniation, nucleoplasty, microdiscectomy, annulus integrity

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Chronic low back pain caused by degenerative processes in the spinal column is one of the most common ailments in modern industrial societies. It ranks first among all musculoskeletal disorders and is associated with serious financial and social consequences (1). Multiple interventional technqiues have been described in management of chronic, persistent, spinal pain, non-responsive to conservative management (2-21). It has been found that nerve roots are involved in the pathological process in only 20% of patients presenting with low back pain with sciatica (22). Conservative care, and interventional techniques with epidural injections provide relief in a significant proportion of patients (7-25). However in non-responsive patients, persistent compression may lead to irreversible structural changes in nerve roots. This may be the cause of chronic neuropathic pain. It has been found that structural changes appear after one month of nerve root compression and irreversible changes appear after 3 months of persistent compression (26). This supports the opinion that when patients do not respond to conservative care after one to 3 months, a more aggressive therapy of nerve root decompression should be applied.

It has been established that open surgery has disadvantages such as intraoperative tissue damage, epidural fibrosis, and scar formation (27-30). Removal of excessive disc material may diminish the efficacy of surgical intervention and may lead to the progression of the degenerative processes in the structures of vertebral segment (31,32). It has been found that annulus integrity has an impact on the results of disc herniation removal. Fragmentation of the annulus increases the rate of the unsatisfactory results up to 27% (33). In order to minimize tissue damage, annulus destruction, and epidural scar formation, several technologies based on percutaneous disc decompression (PDD) have been introduced into clinical practice (2-5).

PDD is based on the principle that a small reduction of volume in a closed hydraulic space can promote a dramatic decrease of pressure (34-36). Once intradiscal pressure is relieved, the disc is supposed to down-regulate inflammatory mediators, reduce in size, and initiate a healing process, thereby alleviating chemical, mechanical, and neural genesis of discogenic pain (37). Nucleoplasty, which is one of these technologies, has been used clinically since 2000 as a minimally invasive intervention to perform PDD using coblation technology. The nucleoplasty procedure is conducted using a bipolar radiofrequency-based spine wand precise tissue that has sufficient energy to break molecular bonds at relatively low temperatures (typically 40°C to 70°C) (38). This achieves removal mediated by plasma field thereby preserving the integrity of surrounding healthy tissue (39-41). The nucleoplasty procedure relieves pain by decreasing intradiscal pressure through the partial ablation of the nucleus pulposus, eliminating the disc protrusion and associated compression of the nerve root.

The safety of the nucleoplasty PDD procedure has been evaluated in pre-clinical and clinical studies. Chen and colleagues (40,42) concluded that safe, volumetric removal of the nucleus is achieved with no disruption or necrosis of the nucleus, annulus, endplate, spinal cord, or nerve root, and there is no change in temperature 5 mm away from the tip of spine wand. After channels within the disc are created, intradiscal pressure decreases dramatically (43). The mechanism of clinical efficacy of the nucleoplasty procedure was explored in a pre-clinical study by O'Neill et al (44). The results of this study demonstrated that nucleoplasty alters the expression of inflammatory cytokines, which may be related to the mechanisms of pain relief and repair response within the disc (44).

The results of clinical studies of comparable design and criteria show that nucleoplasty provides clinically significant pain relief in 56% – 88% of cases of nerve root compression caused by disc protrusion contained disc herniation (2,36,46-50). No irresolvable complications or adverse events related to the procedure have been reported (51). It should be noticed that researchers use different criteria for nucleoplasty indication. In a majority of studies the absolute size of the disc herniation is limited to up to 5 mm (47,52,53). On the other hand, Singh et al (50) recommends the relative size of the disc herniation be limited to up to a third of the sagittal diameter of the vertebral channel. Unreasonable overextensions and restrictions on the indications for the use of nucleoplasty may lead to undesirable effects. It may discredit the method in the first situation and lead to a longer recovery period in the second. The goal of this study is to better understand the treatment efficacy and rate of symptom improvement in patients undergoing the disc nucleoplasty procedure and to find rational guidelines for choosing between minimally invasive treatment and open surgery.

Methods

Participants from March 2006 to October 2007, 88 patients underwent nucleoplasty using coblation technology and 74 patients were treated with microdiscectomy. All patients were given a standard neurological examination. In all cases there was a prevalence of leg pain in the autonomous zone of the compromised nerve root innervation. All patients were grouped by neurological deficit. Only patients with mild motor and sensitive deficit were enrolled. MRI tomography was administered in order to confirm nerve root compression and to classify disc herniation according the morphology. Disc herniation was classified as a disc protrusion if the greatest distance between the edges of disc material displaced from the disc space was less then a distance between the edges of the base measured at the same plane (contained disc herniation). Disc herniation was classified as extrusion (uncontained disc herniation) when displaced disc material beyond the outer annulus has the maximal size at any plane greater then the distance between the edges of the base at the same plane on MRI images (54). Discography was administered in order to confirm annulus integrity. The aim of discography was only to determine the morphology of disc herniation (containment), not pain provocation.

Outcome Measures

Pain intensity had been estimated using the visual analogue scale (55,56) (scaling 0 – 100 in order to achieve a continuous data set). Pain disability had been estimated by the results of Oswestry disability questionnaire V1 (57). Clinically significant results were a 50% decrease in pain intensity score (VAS) and a 40% decrease of pain disability (ODI) (46). If open surgery was required at the same level during the follow-up, the result was considered unsatisfactory. The minimal follow-up period was 18 months. Patients were examined at one month, 3 months, 6 months, 12 months, and 18 months (patients were examined clinically, and using the visual analogue scale and Oswestry disability questionnaire).

Inclusion Criteria

Inclusion criteria were evidence of nerve root compression, pain resistant to conservative treatment including selective nerve root blocks during at least one month with pain intensity of no less than 40 (visual analogue scale 0 – 100) and disability of no less then 40% (Oswestry questionnaire 0 – 100) (11-13).

Exclusion Criteria

Exclusion criteria were litigation, uncontrolled psychological disorders, evidence of instability of the segment, evidence of infection, severe and progressive neurological deficit, previous spinal surgery, and evidence of spinal stenosis. Potential benefits, potential risks, advantages, and disadvantages were explained and written informed consent was received from all patients.

Intervention

All microdiscectomies were performed by the same surgeon using standard techniques. Standard microdiscectomy includes transmuscular approach, translaminar approach to the structures of the epidural space, reconstruction of lateral channel, if required, disc herniation removal, and disc revision in cases of fragmented annulus fibrosus. During all interventions no diathermy was used in the epidural space and no damage of the epidural veins occurred; the absolute hemostasis was achieved.

Nucleoplasty was performed by several physicians under sterile conditions in the lateral position using fluoroscopic guidance under moderate sedation. A lateral extrapedicular approach was used to introduce a 17-gauge 6-inch long Crawford spinal cannula inside the disc via the triangle described by Kambin (58) towards the junction of the annulus fibrosus and nucleus pulposus. The spinal wand was placed into the cannula and advanced until the active tip was 5 mm beyond the cannula. This positioning of the device in the beginning of the channel corresponds to a circumferential reference mark on the shaft of the spinal wand. Using blunt dissection, the spinal wand was advanced up to the junction of the annulus and nucleus pulposus on the opposite side. This position was marked by a depth stop marker. Then 6 channels were created at the 12, 2, 4, 6, 8, and 10 o'clock positions. Ablation mode was used to advance the wand at a speed of 0.5 cm/sec. Coagulation mode was used to retract the wand at a speed of 0.25 cm/sec. Nucleoplasty was followed by the selective block of the involved nerve root using betamethasone and lidocaine.

Post Procedure Follow-Up

Daily activity after nucleoplasty was restricted in the following way: for the first 3 days sitting and walking was limited to up to 10 – 20 minutes at a time; for the next 6 weeks sitting was limited to 30 – 45 minutes at a time. No driving was allowed for the first 2 days and lifting was limited to 3 – 4 kg during the first 2

weeks. After the microdiscectomy the hospital stay was 5 – 10 days. Sitting was greatly limited during the first month, and lifting was limited to 3 – 4 kg during first 3 months and to 6 – 10 kg during the next 3 months. One month after all types of surgery, spine extensor exercises and abdominal braces were recommended.

Statistics

The statistical analysis results of microdiscectomy were analyzed in 65 patients (88%), and the results of nucleoplasty were analyzed in 73 patients (83%).

The following statistical criteria were applied for the analysis of data sets: Fishers exact test was used for dichotomized data sets; if a statistically significant difference was established, the logistic regression analysis was applied (quasi-Newton algorithm). Analyzing continuous data sets statistical criteria were applied according to the results of the normality test (Shapiro-Wilk test). If normality was rejected, the Wilcoxon test, Kruskal-Wallis test, and Friedmans test were applied. In case of normally distributed data sets the one-way ANOVA and Students t-test were applied. Statistical power was calculated using the Monte-Carlo method (2000 simulations). Ω-squared Anderson-Darling, Kolmogorov-Smirnov, and chi square goodness of fit tests were applied for the distribution fitting of the data sets (required for the statistical power calculation using the Monte-Carlo method).

Results

Patient Characteristics

According to the disc herniation morphology and applied intervention all patients were divided into the following groups:

Group 1 — patients with a disc protrusion (contained disc herniation) proven by the results of discography, and disc protrusion size limited to 9 mm inclusive. This group consisted of 46 patients and was divided into 2 subgroups:

Subgroup 1A — patients with a disc protrusion size up to 5 mm inclusive — 24 cases. In this subgroup, signs of spondyloarthrosis were presented in 15 cases (including signs of lateral channel narrowing in 3 cases).

Subgroup 1B — patients with a disc protrusion size of 6 – 9 mm inclusive — 22 cases. Signs of spondyloarthrosis were presented in 13 cases (including signs of lateral channel narrowing in 2 cases).

The reason to make such a subdivision was a belief that nucleoplasty may be effective only in cases when the disc protrusion size does not exceed 5 mm.

Group 2 — patients with disc extrusion (uncontained herniation). These patients insisted on nucleoplasty despite a total annulus disruption. This group consisted of 27 patients.

Signs of spondyloarthrosis presented in 15 cases (including signs of lateral channel narrowing in one case).

Group 3 — patients with disc extrusion or disc sequester who had undergone microdiscectomy — 65 cases. In this group signs of spondyloarthrosis were presented in 42 cases (including signs of lateral channel narrowing in 4 cases).

Initial characteristics of the groups are presented in Table 1.

Groups were tested for homogeneity (data sets are presented in Table 1). There was no difference in the proportions of patients by gender (Fisher's exact test, $P > 0.1$ in all paired comparisons). No differences concerning age were found (one-way ANOVA, $P = 0.4908$). No differences were found in the rate of spondyloarthrosis and lateral channel narrowing signs (Fisher's exact test, $P > 0.1$ in all paired comparisons).

Table 1. *Initial characteristic of groups*

	Subgroup 1A	Subgroup 1B	Group 3	Group 4
N	24	22	27	65
Female	8	7	15	33
Smoking	10	12	18	48
Age	m=46.0+2.61 SD=12.81	m=41.77+2.20 SD=10.31	m=41.22+2.0481. SD=10.64	m= 43.55+1.3001. SD=10.48
Pain intensity	M=67.5 UQ=90.0 LQ=60.0	M=70.0 LQ=70.0 UQ=80.0	M=60.0 UQ=70.0 LQ=60.0	M=75.0 UQ=90.0 LQ=65.0
Pain disability	m=63.67+3.62 SD=17.74 M=64	m=64.27+3.13 SD=14.66 M=65	m=61.41+2.76 SD=14.32 M=62	m=69.81+2.19 SD=17.64 M=68

m – mean, M – median, SD – standard deviation, LQ – low quartile, UQ – upper quartile (datasets are presented according to the normality of distribution

Pain and Function

In relation to pain intensity (VAS) and pain disability (ODI) no statistically significant differences were found between subgroups 1A, 1B, and group 2 — all groups treated with nucleoplasty (for pain intensity $P = 0.2365$, Kruskal-Wallis test; for pain disability $P = 0.7911$, one-way ANOVA). Pain disability and pain intensity differed significantly in groups 2 and 3 (for pain intensity P = 0.0059, Mann-Whitney test, SP 84.9%; for pain disability $P = 0.0309$, Students T-test, SP 66.6%).

The results before the one month of follow-up were omitted because of the influence of the epidural blockage used after nucleoplasty.

Patients were investigated one month after surgery and significant decreases in pain intensity and pain disability were found in all groups (Table 2).

The 2-sided Wilcoxon match-paired test with continuity correction was applied in all cases.

During follow-up the following results were analyzed:

Subgroup 1A

The values of pain intensity and pain disability during follow-up are presented in Tables 3 and 4.

No differences were found in patients' conditions until the 12-month of follow-up ($P = 0.5890$ for pain intensity and $P = 0.1956$ for pain disability, Freidman's test). At the 12-month follow-up significant increases of pain intensity and disability were found, comparing 6 and 12 months results ($P = 0.030$, SP 31% for pain intensity; $P = 0.006$, SP 36% for pain disability, 2-sided Wilcoxon match-paired test with continuity correction). Further became stabilization of patients condition:comparing 12 and 18 month results no differences were found ($P = 0.2107$ for pain intensity, $P = 0.0821$ for pain disability, 2-sided Wilcoxon match-paired test with continuity correction). Open surgery was performed in one case because of a sequestration. Stable clinically significant results during follow-up were found in 19 cases.

Table 2. *Pain intensity and pain disability, 1 month after the intervention*

	Subgroup 1A	Subgroup 1B	Group 3	Group 4
N	24	22	27	65
Pain intensity	M =0.0 UQ =5.0 LQ =0.0;	M =20.0 UQ =30.0 LQ =0.0	M =20.0 UQ =40.0 LQ =0.0	M =15.0 UQ =20.0 LQ =0.0
P value	*P*<0.0001	*P*<0.0001	*P*<0.0001	*P*<0.0001
Power	100%	100%	99%	100%
Pain disability	M =0.0 UQ =4.0 LQ =0.0;	M =6.0 UQ =28.0 LQ=0.0	M =14.0 UQ =38.0 LQ =0.0	M =22.5 UQ =32.0 LQ =0.0
p value	p<0.0001	p<0.0001	p<0.0001	p<0.0001
Power	100%	100%	99%	100%

Table 3. *Value of pain intensity during follow-up, patients with disc protrusion≤5 mm.*

	1st month	3rd month	6th month	12th month	18th month
Mean	6,5217	6,3043	6,0870	14,7826	11,5217
Median	0	0	0	0	0
Upper quartile	0,0	0,0	0,0	20,0	20,0
Low quartile	0,0	0,0	0,0	0,0	0,0

Table 4. *Value of pain disability during follow-up, patients with disc protrusion≤5 mm.*

	1st month	3rd month	6th month	12th month	18th month
Mean	5,7391	4,8696	4,8696	14,5217	9,1304
Median	0	0	0	0	0
Upper quartile	0,0	0,0	0,0	16,0	16,0
Low quartile	0,0	0,0	0,0	0,0	0,0

Subgroup 1B

No statistical differences were found in relation to pain intensity and pain disability during follow-up (P = 0.1811, P = 0.8627 respectively, Freidman's test). Data sets are presented in Tables 5 and 6. Open surgery was performed in 3 cases: in one case microdiscectomy was performed because of sequester formation, in 2 cases stabilization of the vertebral segment was performed because of developed instability. Stable significant results were found in 17 cases.

Comparing subgroups 1A and 1B, negligible differences in the results were found. There were no differences in the rate of clinically significant results and re-interventions during follow-up (P = 0.9999, SP = 5.3%; P = 0.3364, SP = 20.6% respectively, Fisher's exact test). Using the 2-sample Kolmogorov-Smirnov goodness-of-fit test it was found that subgroups 1A and 1B were equal concerning pain intensity and pain disability after one year of follow-up (P > 0.5 for pain intensity and disability). The results of the analysis show that subgroups

Table 5. *Value of pain intensity during follow-up, patients with disc protrusion 6-9 mm.*

	1st month	3rd month	6th month	12th month	18th month
Mean	14.2105	6.3684	10.7895	8.9474	9.7368
Median	0	0	0	0	0
Upper quartile	20.0	10.0	15.0	10.0	10.0
Low quartile	0.0	0.0	0.0	0.0	0.0

Table 6. *Value of pain disability during follow-up, patients with disc protrusion 6-9 mm.*

	1st month	3d month	6th month	12th month	18th month
Mean	11.5789	7.3684	10.0526	9.3684	8.8421
Median	4	0	0	4	0
Upper quartile	12.00	12.00	18.00	12.00	12.00
Low quartile	0.00	0.00	0.00	0.00	0.00

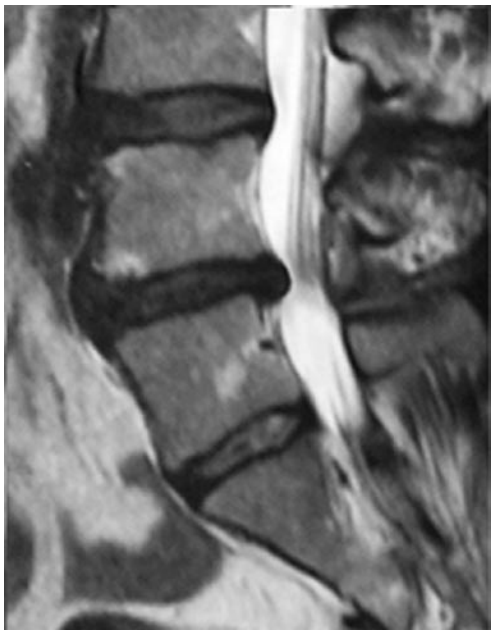

Fig.1. *Scan before nucleoplasty applied in case of disc protrusion.*

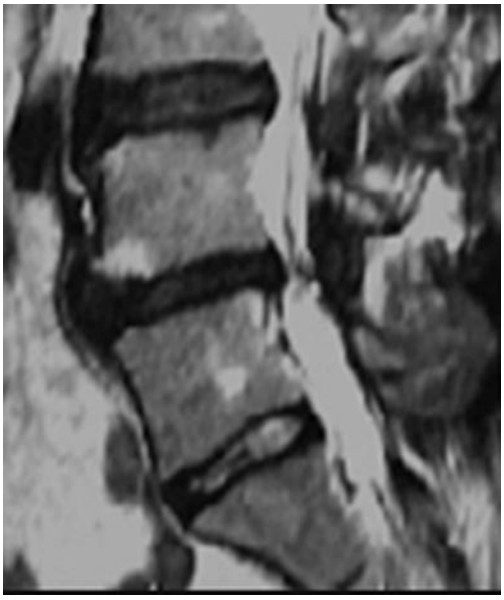

Fig.2. *Scan 2 months after nucleoplasty applied in case of disc protrusion.*

1A and 1B should be merged into one group of patients with a contained disc herniation — disc protrusion size ≤ 9 mm.

In group 1 (patients with disc protrusion size ≤ 9 mm) overall stable significant results were found in 36 cases — 78%; 95% CI [66%; 90%], total pain relief during follow-up was established in 24 cases — 52%; 95% CI [37%; 67%].

Figures 1 and 2 demonstrate the result of nucleoplasty applied in a case of disc protrusion of 5 mm (scans with the maximal size of disc herniation, Fig. 1, before; Fig. 2, 2 months after nucleoplasty).

Group 2

Exacerbation of pain caused by the size of the disc herniation and sequester formation was found in 9 cases during the first 3 months in this group. Microdiscectomy was performed in these cases. The results were considered to be unsatisfactory. The values of pain intensity and pain disability during follow-up are presented in Tables 7 and 8. Data sets illustrate the significant exacerbation of pain intensity and disability during the first 3 months (P = 0.0271, SP = 31.9% and P = 0.01423, SP = 29.7% respectively, Wilcoxon match-paired test with continuity correction) and the further stabilization of patients' conditions (P = 0.5376 for pain intensity and P = 0.1643 for pain disability).

Patients after re-interventions were excluded from this analysis because the obtained pain relief cannot be associated with nucleoplasty.

During follow-up stable significant results were found only in 12 cases — 44%; 95% CI [25%; 65%], total pain relief was found in only 4 cases — 15%; 95% CI [4%; 33%].

Figures 3 and 4 demonstrate the result of nucleoplasty performed in a case of disc extrusion (scans with the maximal size of disc herniation, Fig. 3, before; Fig. 4, 3 months after nucleoplasty). This decrease in disc herniation size was enough to obtain nerve root decompression and total stable pain relief.

Fig. 5 and 6 demonstrate the result of nucleoplasty performed in a case of disc extrusion (Fig. 5, before nucleoplasty; Fig. 6, one month after nucleoplasty). Total annulus disruption was confirmed by discography. After nucleoplasty a small extruded disc fragment remained in the lateral channel, the result was unsatisfactory.

Group 3

The data sets concerning pain intensity and pain disability after microdiscectomy are presented in Tables 9 and 10.

Summarizing the observed effect, no tendency was found concerning pain intensity. The observed effects can be explained by undulation of the disease manifestations. During the first 6 months a significant decrease of pain disability was found (P < 0.0001, SP = 98%) with further stabilization of patients' conditions (comparing 6, 12, and 18 month results P = 0.8175, Freidman's test).

Recurrence of disc herniation was observed in 2 cases and re-operations were performed.

During the follow-up period, a stable significant result was found in 61 cases — 94%; 95% CI [85%; 98%], and total pain relief was found in 36 cases — 55%; 95% CI [42%; 68%].

Fig. 7 and 8 demonstrate the result of microdiscectomy performed in a case of disc extrusion (Fig. 7, before the intervention; Fig. 8, 5 months after). Stable clinically significant pain relief was found during the follow-up period.

Table 7. *Value of pain intensity during follow-up, patients with disc extrusion treated with nucleoplasty.*

	1st month	3rd month	6th month	12th month	18th month
Mean	12,2222	20,8333	22,2222	22,50	23,3333
Median	10	15	20	20	12,5
Upper quartile	20,0	40,0	40,0	40,0	40,0
Low quartile	0,0	0,0	0,0	10,0	10,0

Table 8. *Value of pain disability during follow-up, patients with disc extrusion treated with nucleoplasty.*

	1st month	3rd month	6th month	12th month	18th month
Mean	9,1111	15,6667	17,0	19,4444	19,3333
Median	6	12	14	18	15
Upper quartile	16,0	28,0	32,0	36,0	36,0
Low quartile	0,0	0,0	0,0	4,0	6,0

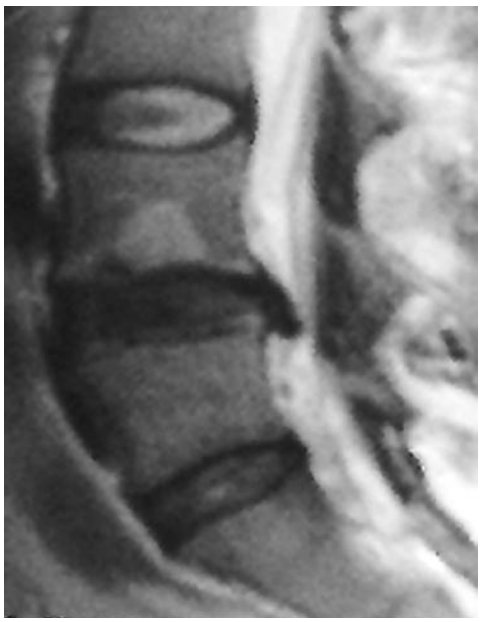

Fig. 3. *Scan before nucleoplasty applied in case of disc extrusion.*

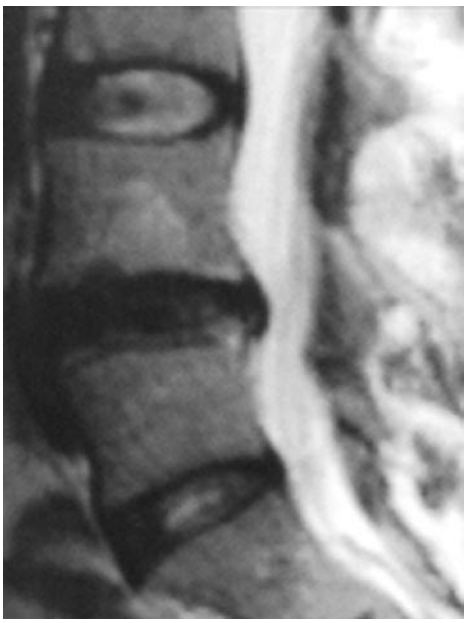

Fig. 4. *Scan 3 months after nucleoplasty applied in case of disc extrusion.*

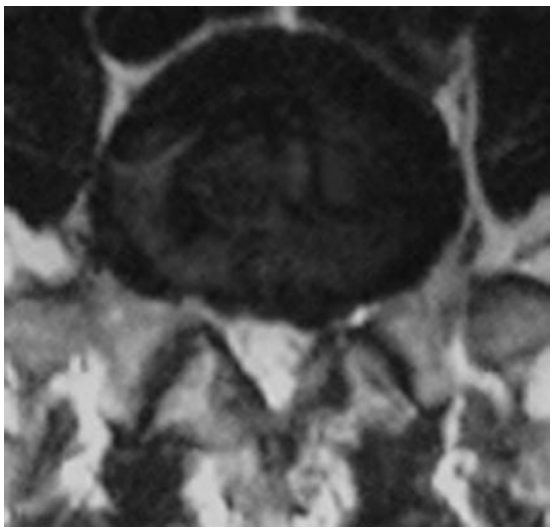

Fig. 5. *Scan before nucleoplasty applied in case of disc extrusion with total annulus disruption.*

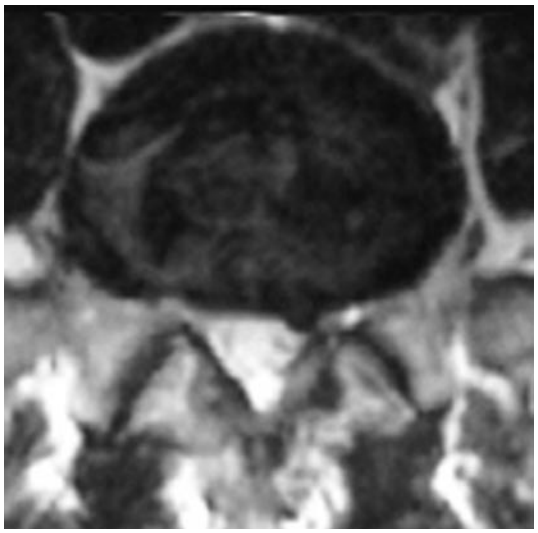

Fig. 6. *Scan 1 months after nucleoplasty applied in case of disc extrusion.*

Table 9. *Value of pain intensity during follow-up, patients with disc extrusion or sequester, microdiscectomy applied.*

	1st month	3rd month	6th month	12th month	18th month
Mean	15.6769	13.6154	8.8461	12.9538	11.2461
Median	15	10	0	0	0
Upper quartile	20.0	20.0	10.0	20.0	20.0
Low quartile	0.0	0.0	0.0	0.0	0.0

Table 10. *Value of pain disability during follow-up, patients with disc extrusion or sequester, microdiscectomy applied.*

	1st month	3rd month	6th month	12th month	18th month
Mean	19.3231	14.2769	9.2615	8.8	8.5846
Median	22	14	0	4	0
Upper quartile	32.0	24.0	14.0	14.0	14.0
Low quartile	0.0	0.0	0.0	0.0	0.0

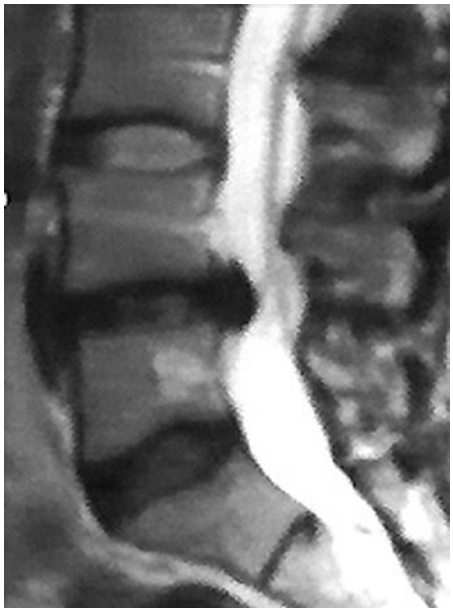

Fig. 7. *Scan before microdiscetomy applied in case of disc extrusion*

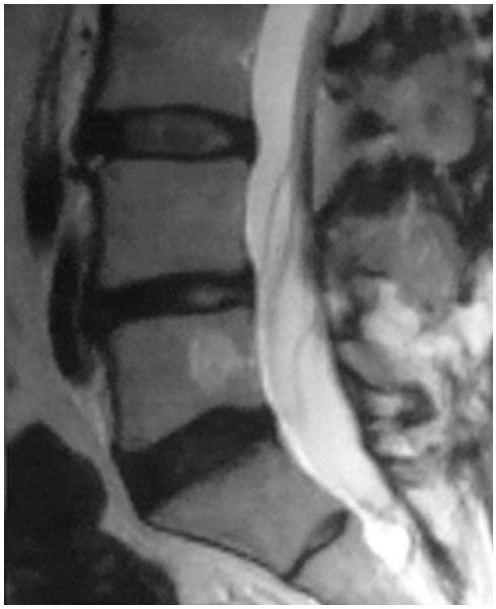

Fig. 8. *Scan 5 months after microdiscetomy performed.*

In order to find out if disc herniation morphology impacts the results of nucleoplasty, the groups of patients with disc protrusion (Group 1) and disc extrusion (Group 2) treated with nucleoplasty were compared. According to the results of the interval estimation, the following differences were found: the rate of poor outcome and open surgery re-interventions were higher in the group with total annulus disruption (disc extrusion) and the rate of total pain relief was lower. In order to evaluate these differences logistic regression analysis was applied.

Concerning the rate of open re-interventions the following non-linear model was estimated: regression coefficient B0 = -3.5151; 95% CI [-5.5724; -1.4578]; *P* = 0.0007. Odds ratio = 4.1; 95% CI [1.1782; 14.2672]. Goodness-of-fit $\chi 2$ = 5.3646; *P* = 0.0206.

Concerning the rate of poor outcome: B0 = -2.785011; 95% CI [-4.4065; -1.1635]; *P* = 0.001. Odds ratio = 4.50; *P* = 0.0043; 95% CI [1.573; 12.8728]. Goodness-of-fit $\chi 2$ = 8.562122; *P* = 0.0034.

Concerning the rate of total pain relief: B0 = -1.92322; 95% CI [-3.5211; -0.3254]; *P* = 0.0164. Odds ratio = 6.2727; 95% CI [1.8328; 21.4685]. Goodness-of-fit $\chi 2$ = 10.9683; *P* = 0.00098.

The results of the regression analysis confirm the significance of the differences between the groups and lead to the conclusion that total annulus disruption in cases of disc extrusion is associated with more poor results and less total pain relief rate after nucleoplasty.

In order to find out how surgical tactics impact the results of discogenic nerve root compression treatment, the group with disc extrusion treated with nucleoplasty (Group 2) and the group with disc extrusion or sequester treated with microdiscectomy (Group 3) were compared.

Using interval estimation the following differences between Groups 2 and 3 were found: the rate of poor

outcomes was higher in Group 2, and the rate of total pain relief was lower. The following non-linear models were estimated.

Concerning the rate of poor outcomes: B0 = -5.6723; 95% CI [-7-8636; -3.4810]; $P < 0.000001$. Odds ratio = 19.0625; 95% CI [2.2870; 68.7301]. Goodness-of-fit $\chi 2 = 26.564$; $P < 0.00001$.

Concerning the rate of total pain relief: B0 = -2.1816; 95% CI [-3.6452; -0.7181]; $P = 0.0039$. Odds ratio = 7.1379; 95% CI [2.1820; 23.3507]. Goodness-of-fit $\chi 2 = 13.963$; $P = 0.00019$.

Significant models with a significant regression coefficient were estimated in all cases. The results of the analysis support the conclusion that in cases of uncontained disc herniations microdiscectomy has a higher efficacy than nucleoplasty.

Complications

There were no major complications related to the nucleoplasty procedure.

Discussion

Nucleoplasty provides significant pain relief in patients with nerve root compression caused by contained disc herniation. This conclusion is supported by the results of scientific research (2,36,45-50,52,53). The limitation of a disc herniation to the size of 5 mm as an indication for nucleoplasty is questionable. The size of a disc herniation of more than 5 mm does not contradict the main principle of this technology — closed hydraulic space inside the disc. Likewise it is established that clinical manifestations of disc herniation are dependent not only on the herniation size but also on the size of the reserve spaces of the vertebral channel (2-5,59,60). Statistical analysis supports the conclusion that there are negligible differences in the results between subgroups of patients with disc protrusions up to 5 mm and 6 – 9 mm (maximal type I error values and minimal values of the statistical power testing H1 hypothesis concerning the homogeneity of data sets sometimes provides the conclusions that there are no differences at all). One of the highest rates of clinically significant results after nucleoplasty (88%) was reported by Mirzai (47); one of the restrictions for the nucleoplasty indication was the limitation of a disc herniation size up to 5 mm. Knowing the number of enrolled patients in this study, it is easy to estimate the 95% CI for the success rate: [77%; 95.6%]. Using interval estimation it is possible to conclude that there is no significant difference in the success rate with those estimated in our study with a disc protrusion size ≤9 mm; 95% CI [66%; 90%]; $P = 0.2732$, Fisher's exact test, and the statistical power of effect achieves only 26%. Otherwise the results of our study show that if we use a disc herniation size of 5 mm as a limitation for the indication for nucleoplasty, about 50% of patients who improved after nucleoplasty would be excluded. The relative size of the disc herniation to the sagittal size of the vertebral channel seems to be more adequate indication for nucleoplasty.

Total annulus disruption is a factor that affects the results of nucleoplasty. Patients with a total annulus disruption compared to patients with contained disc herniation showed a significant decrease in success rate and total pain relief. This conclusion is supported by the results of the regression analysis. In case of uncontained disc herniation the microdiscectomy is more effective than nucleoplasty. This only confirms the results of preclinical studies: the lateral extrapeducular approach of nucleoplasty rules out the exposure of the disc fragment inside the vertebral channel, and the decrease of pressure inside the disc is lower than in cases of contained disc herniations. If microdiscectomy is performed in cases of uncontained disc herniation, the rate of total pain relief and the clinically significant result is higher than in cases when nucleoplasty is performed. This conclusion is also supported by regression analysis. This confirms the hypothesis that this overextension of indications for nucleoplasty cannot be considered rational.

The limitation of this scientific research is the small number of patients in all groups. This leads to the instability of some mathematical models; nevertheless, all of the effects have enough statistical power to support present conclusions.

The results of this study show that the unreasonable restriction of the indication for nucleoplasty may lead to patients who may benefit from minimally invasive surgery being excluded and a longer recovery period. The overextension of indications for nucleoplasty is not rational and may discredit this technology. The only rational guideline between these 2 types of surgery seems to be the annulus integrity.

Conclusion

It is evident that nucleoplasty cannot substitute for open surgery. The main benefit of this technology seems to be a faster recovery period. Overall, the higher effectiveness of nucleoplasty over microdiscectomy is questionable. It seems that these 2 modalities have a clear boundary based on disc herniation morphology. That is why any extension of indications for nucleo-

plasty must be based on valid conclusions. On the other hand, the attempt to achieve a maximal clinical results by using too strict of a selection and missing patients who may benefit from this technology also cannot be considered rational.

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