

Research Article

The Primary Outcome of a Prospective Study: Nucleoplasty with Endoscopic Microdiscectomy

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Abstract

Purpose: Evaluation of combined endoscopic microdiscectomy with Radiofrequent ablation Nucleoplasty where it is predicted to show more satisfying short-term outcome.

Study Design: A consecutive cohort of 23 patients with lumbar discogenic back pain who underwent Nucleoplasty with endoscopic microdiscectomy. Outcome measurements evaluating pain intensity and functional disability were completed preoperatively, at 1 months, at 6 months, and at the 1-year follow-up visit.

Methods: All cases (N=23) following up with confirm-

ed diagnosis of contained lumbar discogenic back pain, who failed conservative treatment and fulfilled the criteria for surgical intervention, then underwent endoscopic microdiscectomy with nucleoplasty, and followed up by regular clinic visits for a period of one year maximum. Primary outcome variables that are going to be used in the research is Visual analogue scale (out of 10) and the Oswestry disability index (out of 100).

Results: Of the 23-patient cohort, the 1 year follow up rate was at 100%. The mean VAS for low back pain preoperatively, postoperatively, 1 month, 6 months, and

1 year were 9.17, 6.04, 4.57, 2.02 respectively. The functional assessment was evaluated using ODI and showed a mean of 52.75 preoperatively, and 34.96 at 1 month post operatively, 29.30 at 6 months post operatively, and 16.96 at year post operatively.

Conclusion: In this minimal invasive approach, Nucleoplasty with Endoscopic Microdiscectomy, it showed promising short-term outcomes with less post-operative pain, hospital stay, minimal blood loss and no reported post-operative complication which can be an alternative option to the standard open Microdiscectomy.

Keywords: Nucleoplasty; Minimal invasive; Lumbar disc herniation; Microdiscectomy

1. Introduction

Lumbar disc herniation can cause central canal stenosis or spinal nerve root compression. The local inflammatory response and the anatomical features of the herniated disc and spinal canal determine the resultant clinical syndrome which may include low back pain, and sciatica with or without neurological deficit [1]. In nations like the United States, its prevalence is between 8% and 57%. According to the estimate provided by the experts, nearly 29% of individuals encounter a low back pain that could disable the individual at a certain stage of his or her life [2] Mainstay of treatment for patients with radicular pain due to lumbar disc herniation involves open lumbar discectomy, and has provided excellent outcome in over six decades [3, 4].

1.1 Aim (hypothesis)

Evaluation of combined endoscopic microdiscectomy with Radiofrequent ablation Nucleoplasty where it is

predicted to show more satisfying short-term outcome, this includes shorter hospital stay, minimal blood loss, less operation time, less post-operative pain, less soft tissue injury, no reported post-operational complications (infections, post laminectomy syndrome, dural tear, and nerve root injury), and this are to be considered as our outcome variables. With comparison to the gold standard open microscopic discectomy, it is predicted to show similar long term outcome in both, pain relieve and restoration of functional activity.

1.2 Background and significance (Literature review)

Nucleoplasty (percutaneous lumbar disc decompression) is a minimally invasive procedure that utilizes radiofrequency energy as a treatment for symptomatic lumbar disc herniation, against open microdiscectomy, which would be the mainstay treatment modality. The literature reports a favorable outcome in up to 77% of patients at 6 months [5]. Minimal invasive approach for surgical treatment of discogenic back pain has increased in popularity in the recent years and was regarded as a feasible alternative option to the standard open microdiscectomy. According to one study, Patients were randomized in two groups receiving Either MAMD (minimal access microdiscectomy) or SOMD (standard open microdiscectomy). Physical and mental health and pain relief were assessed (ODI, SF-36 questionnaire, VAS leg and back pain). Results Of the 60 initial patients (SOMD: 30 pts, MAMD: 30 pts), 38 were available for long-term follow-up. Mean follow-up time was 33 months. Long-term follow-up revealed significant postoperative pain relief in both groups. Good to excellent results concerning physical and mental health and pain relief were achieved in both groups. Significantly less peridural scar tissue formation was observed in the MAMD patients, but without clinical impact. In conclusion, MAMD is a feasible

alternative to the standard open approach. Both groups show significant and long-lasting pain relief and good to excellent results regarding health-related quality of life [6]. In a prospective outcome predictor study, 87 patients who underwent percutaneous endoscopic lumbar discectomy and thermal annuloplasty (PELDTA) for discogenic low back pain (DLBP). Clinical outcomes were assessed using the visual analog scale (VAS), the Oswestry disability index (ODI), and the modified MacNab criteria. The univariate and multivariate analyses were performed to evaluate the outcome predictors. The VAS and ODI scores at postoperative 6 months and 2 years were significantly improved ($p < 0.001$). Based on the modified MacNab criteria, the global outcomes were excellent in 39 out of 79 patients (49.4%), good in 17 patients (21.5%), fair in 10 patients (12.7%), and poor in 13 patients (16.5%). Therefore, the percentage of symptomatic improvement was 83.5% and the success rate (excellent or good) was 70.9%. In the univariate and multivariate analyses, the presence of concurrent disc herniation with DLBP was the most significant predictor (OR=3.207, 95% CI 1.02–10.06, $p=0.046$). As a Conclusions, PELDTA may be effective for patients with chronic DLBP in selected cases. Central disc herniation causing DLBP was the most important predictor for clinical success [7].

2. Method

A consecutive cohort of 23 patients with lumbar discogenic back pain who underwent Nucleoplasty with endoscopic microdiscectomy between December/13/2014 to July/6/2016 were included in this prospective study. Patients were operated by the one surgeon, who used the same surgical technique at the same institution for the study period. All cases (N=23) following up at the orthopedic department with confirmed diagnosis of contained lumbar discogenic back pain, who failed

conservative treatment and fulfilled the criteria for surgical intervention, then underwent endoscopic microdiscectomy with Nucleoplasty, and followed up by regular clinic visits for a period of one year maximum. Questionnaires with outcome measurements evaluating pain intensity and functional disability were completed preoperatively, at 1 months, at 6 months, and at the 1-year follow-up visit or during telephone interviews by the independent observer. At each follow-up, the pain intensity of the low back pain was measured using a visual analog scale (VAS, 0–10 points), and the functional status was assessed using the Oswestry disability index (ODI). All patients are instructed to fill VAS and ODI survey through every visit (Preoperational, 1 month post operation, 6 months post-operation, and 1 year post-operation), where they were instructed and assisted by healthcare professionals throughout the process. Data was collected through OAISIS electronic healthcare system where all of the information were documented and acquired by co-investigators and not the main surgeon himself. No exclusion based on BMI or preoperative history of trauma was done. All patients were contacted individually via telephone and e-mail for conformation and accurate input of data and outcome subjective satisfaction of the operation. Inclusive criteria include Intractable chronic low back pain without improvement after conservative treatment for 6 months, Central or posterolateral (paracentral) contained disc herniation (Grade I and II) on magnetic resonance imaging, No history of previous back surgery, Age range from 20 to 75 years old, Level of surgery range between L3 to S1. Exclusive criteria include Age below 20 and above 75, Lateral recess stenosis, sequestered disc, Fractures, tumors, or infections, Extruded or sequestered herniations on magnetic resonance imaging, Non lumbar disc herniation, Concurrent back pain due to

other pathologies, Congenital spinal anomalies, Cases with Oswestery more than 70 , or less than 40. Primary outcome variables that are going to be used in the research is Visual analogue scale (out of 10), the Oswestry disability index (out of 100), and outcome subjective satisfaction. Secondary outcome variables that are going to be used in the research are length of operation, length of hospital stay, blood loss, postoperative infections, dural tear, reoperation, and nerve root injury. Other variables are age, gender, level of surgery, patient occupation, smoking, comorbidities, alcohol intake, history of trauma, use of steroids, sitting intolerance, and body mass index.

2.1 Surgical technique

all patient underwent general anesthesia , and positioned

on Jackson's table prone position , after confirmation of the level with C-arm, standard prep and drape was done, using one C-Arm the fluoroscope was taken lateral and the arm were moved to oblique position until the scotch view appear (Figure 1), then a guide needle passed vertically toward the middle third of the disc (Kambin Triangle, Figure 2 and 5) and a dilator passed though 8 mm incision with the portal, the positioned was checked in two planned AP and Lateral , then the endoscope thorough the portal passed until it reach the lateral border of the pedicle, using the Camera to protect the nerve root and the dura, a sharp knife penetrate the disc then using scissors and Pituitary the disc were taken until 1/3 of the disc were out (Figure 3 and 6), a radiofrequent ablation then take place (Figure 4), local xylocain 2% with depomedrole, the skin closed by 0.3 suture.

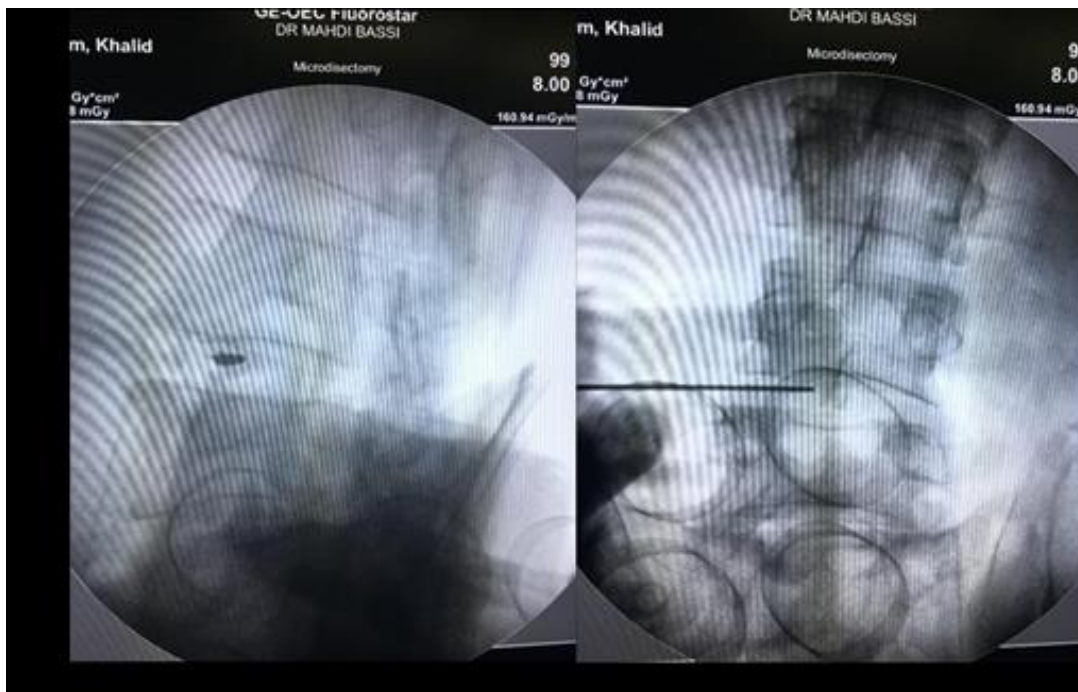


Figure 1: The needle guide. (A) AP; (B) Posterolateral.



Figure 2: The working channel positioned at kambin tringle. (A) AP; (B) Posteo-lateral.



Figure 3: Using the non toothed pituitary.



Figure 4: The tip of nucleoplasty probe in the middle of the disc.

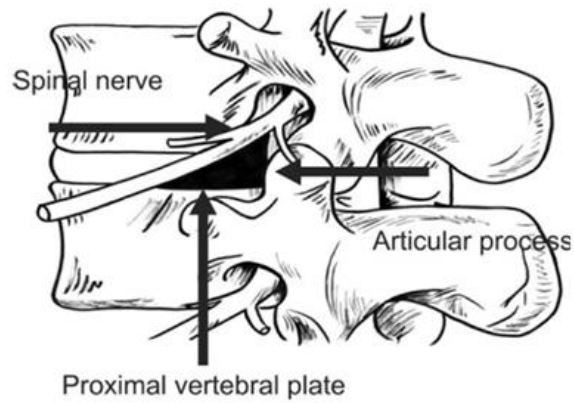


Figure 5: Schematic description of Kambin triangle.



Figure 6: Sample of removed disc material.

2.2 Statistical analysis

Statistical results were conducted using SPSS to assess statistical significance in the primary outcomes of VAS and ODI preoperatively and postoperatively at 1 month, 6 months and 1 year and to establish any correlation between different variables which are used in this study. $P < 0.05$ was considered significant.

3. Result

3.1 Patient characteristics

Of the 23-patient cohort, the 1 year follow up rate was at 100%. The mean age was 41.6 ± 12.3 years (Range 22 – 74). The study had 15 men and 8 women. 22 patients had a single level and 1 had a two-level procedure, therefore 24 discs were treated with PELDRN (Percutaneous Endoscopic Microdiscectomy and Radiofrequency Nucleoplasty). The most common segment was L4-L5 (82.6%) and L5-S1 (8.7%). The procedure was primary for 91% of the patients and a revision for 8.7%. Site of radiculopathy was assigned left, right, or bilateral with distribution of 43.5%, 34.8%, and 21.7% respectively. 21.7% of patients were

smokers, 78.3% were nonsmokers. 30.4% had history of trauma before the onset of their symptoms, while 69.6% didn't. Eleven patients (47.8%) had potentially contributing comorbidities. Usage of steroids among the patients was at 8.7%. sitting intolerance was positive in 21.7%. The mean body mass index was 30 ± 9 (Range 17.5 – 63). Among the patients 65.2% had Herniation only while 34.8% had a concurrent degenerative disc disease, 69.6% had a single herniation, while 30.4% had a grouped herniation. The duration of symptoms in months was recorded with a mean of 47.57 ± 75 . (Table 1 and 2).

3.2 Visual analogue scale scores and the Oswestry disability index assessment

The mean VAS for low back pain preoperatively, postoperatively, 1 month, 6 months, and 1 year were 9.17 ± 0.887 , 6.04 ± 2.246 , 4.57 ± 2.019 , 2.02 ± 1.379 respectively. The functional assessment was evaluated using ODI and showed a mean of 52.75 ± 14.303 preoperatively, and 34.96 ± 20.171 1 month post operatively, 29.30 ± 17.504 6 months post

operatively, and 16.96 ± 9.833 1 year post operatively. (Table 3).

3.3 Operation parameters and complications

Of the 23-patient cohort, length of operation showed an average of 1 hour and 13 mins \pm 25 mins (Range 30 mins – 2 hours). Length of hospitalization showed an average of 2 days \pm 1 day (Range 1 day – 5 days). Of this group of patients, there were no complications or sign and symptoms of post-operative infections, nerve root injury, deep venous thrombosis, dural tear (noticed during the procedure or any of its signs or symptoms during the follow up) (Table 2). A one way repeated measured analysis of variance (ANOVA) was conducted to evaluate the null hypothesis that there is no change in VAS when measured preoperatively, 1 month post-operatively, 6 months post-operatively, and 1 year post-operatively in the designated group (n=23). The result of the ANOVA indicated a significant time effect, Wilks’ Lambda = 0.035, $F(3, 20) = 186.2$, $p < 0.01$, $\eta^2 = 0.96$. Thus there is significance evidence to reject the null hypothesis (Table 4). Three paired samples t-tests were used to make post hoc comparisons between conditions. A first paired samples t-test indicated that there was a significant difference in the VAS score preoperatively (M=9.17, SD=0.887) and 1 month post operatively (M=6.04, SD=2.246) conditions; $t(22) = 5.663$, $p < 0.01$. A second paired samples t-test indicated that there was a significant difference in the VAS score preoperatively (M=9.17, SD=0.887) and 6 months post-operatively (M=4.57, SD=2.019) conditions; $t(22) = 9.406$, $p < 0.01$. A third

paired samples t-test indicated that there was a significant difference in the VAS score preoperatively (M=9.17, SD=0.887) and 1 year post-operatively (M=2.02, SD=1.379) conditions; $t(22) = 22.144$, $p < 0.01$ (Table 5). These results suggest that our procedure have a significant effect on the visual analogue scale pain score (Figure 8). Specifically, our results show that individuals undergoing the procedure display a significant decrease in the reported VAS score over time. The same analysis was conducted to evaluate the null hypothesis that there is no change in ODI when measured preoperatively, 1 month post-operatively, 6 months postoperatively, and 1 year post-operatively in the designated group (n=23). The result of the ANOVA indicated a significant time effect, Wilks’ Lambda = 0.091 $F(3, 20) = 66.876$, $p < 0.01$, $\eta^2 = 0.90$. Thus there is significance evidence to reject the null hypothesis (Table 4). Follow up three paired samples t-tests were used to make post hoc comparisons between conditions. A first paired samples t-test indicated that there was a significant difference in the ODI score preoperatively (M=52.75, SD=14.303) and 1 month post operatively (M=34.96, SD=20.171) conditions; $t(22) = 3.398$, $p < 0.01$. A second paired samples t-test indicated that there was a significant difference in the ODI score preoperatively (M=52.75, SD=14.303) and 6 months post-operatively (M=29.30, SD=17.504) conditions; $t(22) = 5.135$, $p < 0.01$. A third paired samples t-test indicated that there was a significant difference in the ODI score preoperatively (M=52.75, SD=14.303) and 1 year post-operatively (M=16.96, SD=9.833) conditions; $t(22) = 11.457$, $p = 0.015$ (Table 6).

Data	No. of patients	Percentage %
Gender		
Female	8	34.8
Male	15	65.2

Spine level operated		
L5-S1	2	8.7
L4-L5	19	82.6
L3-L4	1	4.3
L4-S1	1	4.3
Primary vs revision		
Primary	21	91.3
Revision	2	8.7
Site of radiculopathy		
Left	10	43.5
Right	8	34.8
Bilateral	5	21.7
Smoking		
No	18	78.3
Yes	5	21.7
History of trauma		
Negative	16	69.6
Positive	7	30.4
Use of steroid		
No	21	91.3
Yes	2	8.7
Sitting intolerance		
Present	5	21.7
Absent	18	78.3
Concurrent disc herniation and degeneration vs Herniation only		
Herniation only	15	65.2
Herniation plus DDD	8	34.8
Grouped herniation vs non grouped herniation		
Single	16	69.6
Grouped	7	30.4

Table 1: Descriptive statistics of frequencies among patients.

Data	Minimum	Maximum	Mean	Std. Deviation
Age	22	74	41.61	± 12.320
Body mass index	17.5	63	30.013	± 9.0810
Chronicity	1	300	47.57	± 75.212
Length of operation	0.50 (30 mins)	2	1.23 (1hr13mins)	± .42062
Length of hospitalization	1	5	1.78	± .951

Table 2: Descriptive Statistics of variables.

Data	Preoperation	1 months post-operation	6 months post-operation	1 year post-operation
VAS score (Mean ± SD)	9.17 ± 0.887	6.04 ± 2.246	4.57 ± 2.019	2.02 ± 1.379
ODI score (Mean ± SD)	52.75 ± 14.303	34.96 ± 20.171	29.30 ± 17.504	16.96 ± 9.833

Table 3: Descriptive Statistics of VAS and ODI.

		Value	F	Hypothesis df	Error df	Sig.	Partial Eta Squared
VAS	Wilks' lambda	0.035	186.229	3	20	0	0.965
ODI	Wilks' lambda	0.091	66.876 ^b	3	20	0	0.909

Table 4: Multivariate test of VAS and ODI.

(I) VAS	(J) VAS	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval for Difference		T score
					Lower Bound	Upper Bound	
1	2	3.13	0.553	0	1.528	4.733	5.663
	3	4.609	0.49	0	3.188	6.029	9.406
	4	7.087	0.32	0	6.159	8.015	22.144

1 = VAS preoperation, 2 = VAS 1 month postoperation, 3 = VAS 6 months postoperation, 4 = VAS 1 year postoperation

Table 5: Pairwise Comparisons for VAS.

(I) ODI	(J) ODI	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval for Difference		T score
					Lower Bound	Upper Bound	
1	2	17.783*	5.233	0.015	2.615	32.95	3.398
	3	23.435*	4.563	0	10.207	36.662	5.135
	4	35.783*	3.123	0	26.73	44.836	11.457

1 = ODIpreoperation, 2 = ODI 1 month postoperation, 3 = ODI 6 months postoperation, 4 = ODI 1 year postoperation

Table 6: Pairwise Comparisons of ODI.

4. Discussion

These results suggested that our procedure have a significant effect on the Oswestry disability index. Specifically, our results show that individuals undergoing the procedure display a significant decrease in the reported ODI score over time (Figure 7). Further analysis of the other variables showed no significant relationship with age, gender, history of trauma,

comorbidities, usage of steroids, herniation only vs herniation and degenerative disc disease, single herniation vs grouped herniation (Table 7). On the other hand, results show significantly better results when the operation is done as a primary procedure, rather than a revision (Table7). Results also displayed significantly better results with non-smokers and non-obese patients with regards to the disability index (Figure 9 and 10).

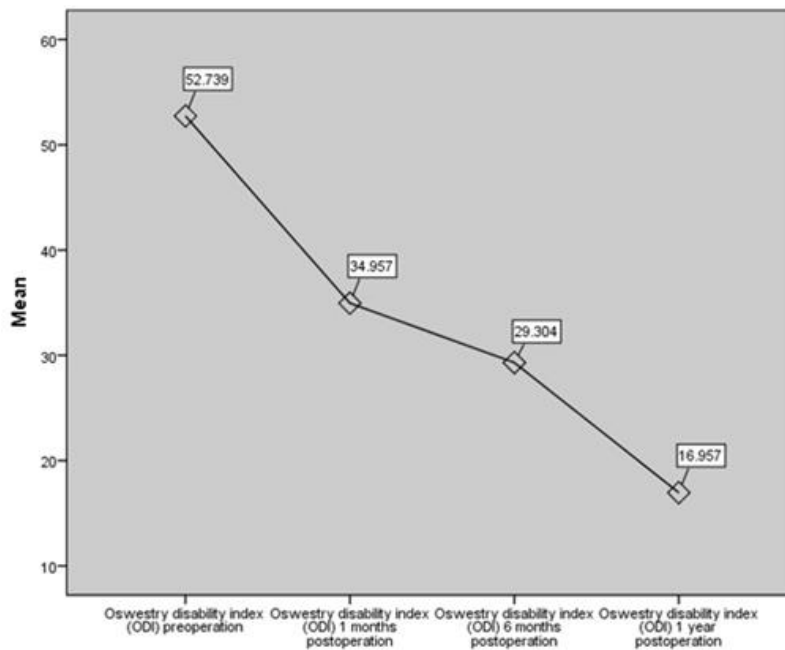


Figure 7: Chart of Oswestry Disability index (ODI) preoperative, 1 month, 6 months and 1 year post operative.

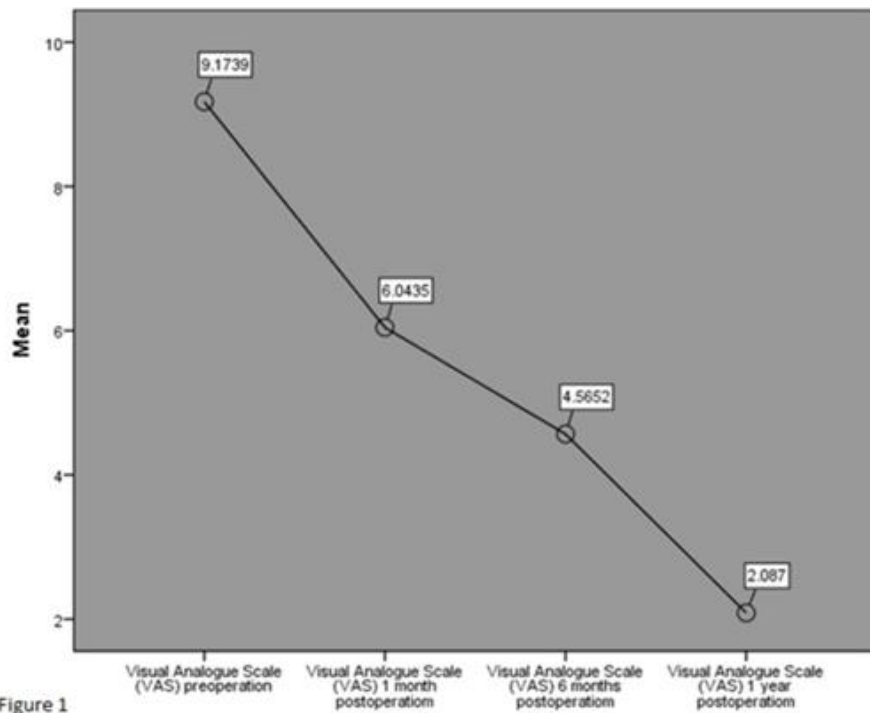


Figure 8: Chart of visual analogur scale (VAS) preoperative, 1 month, 6 months and 1 year post operative.

Parameters	<i>p</i> value with VAS	<i>p</i> value with ODI
Age	0.74	0.59
Gender	0.91	0.95
Primary vs revision	0.003*	0.019*
Smoking	0.062	0.024*
History of trauma	0.298	0.216
Comorbidities	0.357	0.698
Usage of steroid	0.7	0.7
Sitting intolerance	0.359	0.301
BMI	0.321	0.021*
Herniation only vs herniation and DDD	0.429	0.544
Single herniation vs grouped	0.676	0.852

*statistically significant value.

Table 7: Analysis for geometric and demographic parameters.

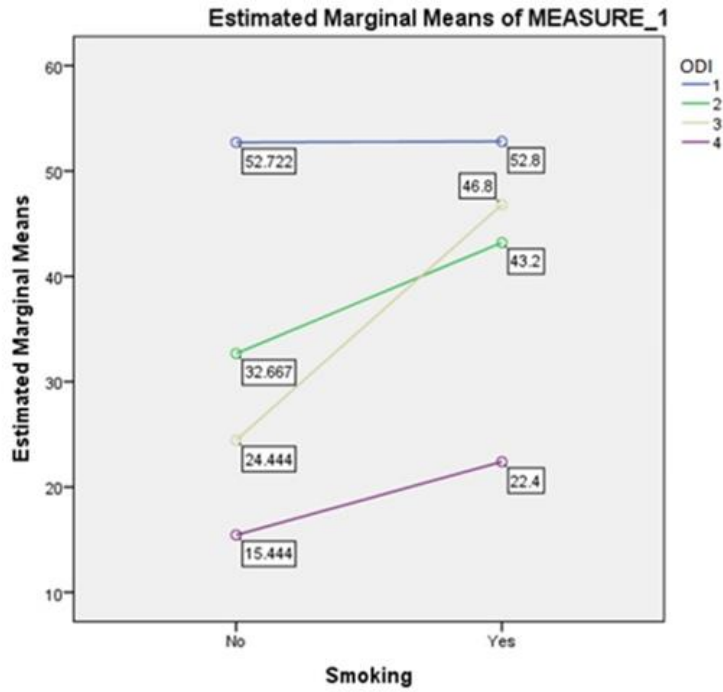


Figure 9: The effect of smoking on ODI score.

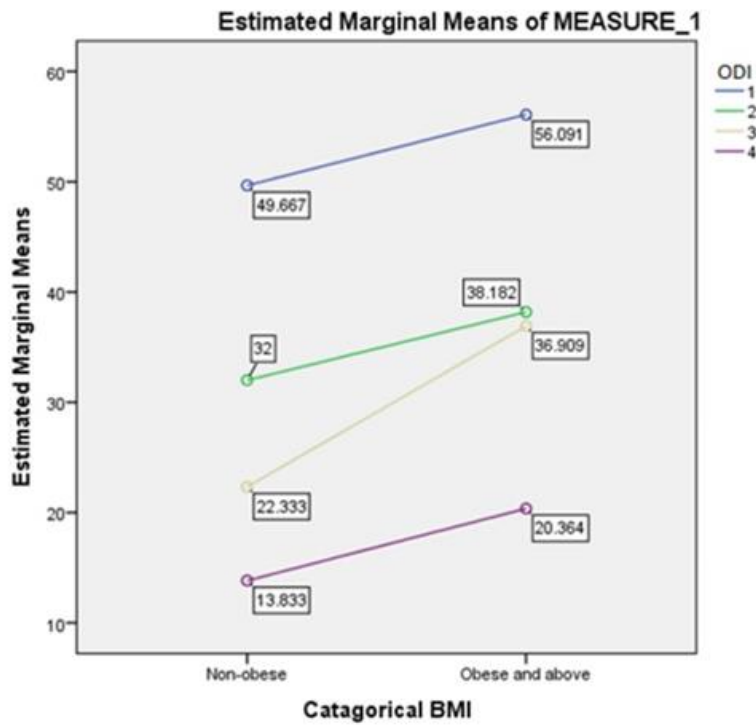


Figure 10: The effect of body mass index (BMI) on ODI score.

5. Conclusion

In this minimal invasive approach, Nucleoplasty with Endoscopic Microdiscectomy, it showed promising short-term outcomes with less post-operative pain, hospital stay, minimal blood loss and no reported post-operative complication which can be an alternative option to the standard open Microdiscectomy.

Limitation

Limitation of this study include small sample size and non-randomized selection of the samples.

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