Radiofrequency Nucleoplasty for Contained Lumbar Disc Herniation. A Prospective Cohort Clinical Case Study.

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Abstract

Background Data: A number of percutaneous techniques have been used in the management of lumbar disk herniation. Radiofrequency coablation is gaining popularity.

Purpose: To define the safety and efficacy of radiofrequency Nucleoplasty in the management of contained lumbar disk herniation, to better define the indications and predictors of a good outcome and to report the clinical results.

Study Design: A prospective cohort of patients with contained lumbar disk herniation that have failed conservative treatment will undergo radiofrequency Nucleoplasty.

Material and Methods: Thirty four patients with contained lumbar disc herniation underwent radiofrequency Nucleoplasty. These were 23 males and 11 females. Mean age was 36.38 years. The L4/5 level was affected in 59% of patients and 15% had a double level disk herniation.

Results: The follow up period was 12 months. This prospective evaluation demonstrated pain relief defined as 2 points or more relief in VAS, in 63% of the patients at 6 months and 50% of the patients at 1 year regarding back pain. Regarding leg pain, relief was in 92.6% of the patients at 6 months and 92.3% of the patients at 1 year.

Conclusion: Percutaneous disc decompression using radiofrequency Coblation (Nucleoplasty) is a safe and effective procedure in alleviating discogenic leg pain mainly, with or without back pain. Inclusion criteria for Nucleoplasty have to include patients with contained disc prolapse who are only younger than 40 years old, whose pain has been present no longer than 9 months and are complaining of leg pain mainly. (2012ESJ026)

Keywords: Nucleoplasty, Coblation, radiofrequency, contained disc herniation, minimally invasive.

Introduction

Over the last thirty years or so, minimally invasive percutaneous intradiscal techniques have evolved as a viable option for treatment of contained lumbar disk herniation. These techniques have ranged from intradiscal injection of chymopapain for nucleolysis, percutaneous manual nucleotomy with the nucleotome, and thermal vaporization with laser. These percutaneous disc decompression methods decrease intradiscal pressure by virtue of volumetric reduction of the nucleus pulposus using a minimally invasive approach.[6]

Among these techniques, the most recent is percutaneous disc decompression (PDD) using Coblation plasma technology (Nucleoplasty), with a percutaneous entry into the disc via a 17-gauge cannula and removal of approximately 1g of disc tissue from the nucleus pulposus. Partial removal of the nucleus pulposus in a contained disc has been shown to decompress herniated discs, relieving pressure on nerve roots.[8]

The safety and efficacy of the PDD procedure using Coblation technology has been carefully analyzed in three separate studies by Chen et al[3,4,5] They concluded that a safe volumetric removal of the nucleus is achieved and that no disruption or necrosis of the surrounding vital structures, nucleus, annulus, endplate, spinal cord, or nerve root occurs, that no change in temperature is detected at 5 mm away from the tip of the wand, and that after two channels are created within the disc, intradiscal pressure decreases dramatically.

Patients and Methods

The objective of this prospective, nonrandomized cohort study is to monitor PDD using radiofrequency Nucleoplasty in the management of contained lumbar disc herniation, evaluation of the functional outcome after the procedure and determining the factors on which the results depend upon.

The study evaluated 34 consecutive patients with complains of leg with or without back pain secondary to a contained lumbar disc herniation. These patients were enrolled in the period from October 2005 to September 2009. The procedures were performed in Cairo University hospital, Electricity hospital, Cairo and AOA Neuro-spinal Centre, Tripoli, Libya. All procedures were performed by the author.

Inclusion criteria were complains of radicular pain with or without back pain after failure of six weeks of conservative care including; "posture and activity modifications, physical therapy focusing on lumbar stabilization exercises, and oral NSAIDs". The diagnosis was confirmed with imaging studies "MRI". Exclusion criteria were; patients presenting with disc herniation with sequestration, evidence of previous back surgery, infection or spinal instability, marked spinal stenosis, or the presence of a progressive neurological deficits.

The nature of this study and the associated risks were explained to all patients. Informed consent was obtained. Data were collected for 26 of 34 patients (76.4%) at 12 months. Three patients had suffered re-injury or a new injury within 7 months of the procedure and 5 patients were lost to follow-up. The demographic data of our patients are summarized in table 1.

Table 1. Patients Demographics

Gender	Female	32.4% (11)
	Male	67.6% (23)
Age (years)	Mean±SD	36.38±8.06
	Range	21–47
Back pain duration /mos	Mean ± SD	17±13.6
	Range	1–60
Leg pain Duration /mos	Mean ± SD	9.8±5.2
	Range	3–24
Side of leg pain	Right side	53% (18)
	Left side	47% (16)
Level	L4-5	59% (20)
	L5-S1	26% (9)
	L4-5 & L5-S1	15% (5)
Activity level	Low	21% (7)
	Moderate	41% (14)
	High	38% (13)
Smoking habits	Non smoking	61.2% (21)
	Smoking	38.2% (13)

Procedure:

Nucleoplasty was performed by the author on an outpatient basis under local infiltration anaesthesia using a sterile technique. All patients received prophylactic intravenous antibiotics. It was done in a prone or semi-oblique position using a uniportal approach from the side of predominant leg pain under fluoroscopic guidance. A 17-gauge six-inch long Crawford type spinal access cannula was introduced into the disc using a posterolateral extrapedicular approach. The Perc-DLE tissue

ablation and coagulation spinal wand was placed into the access cannula and advanced until the tip of the wand was approximately 5 mm beyond the tip of the cannula, assuring that the active portion of the wand was beyond the inner layer of the annulus and was placed in the nucleus.

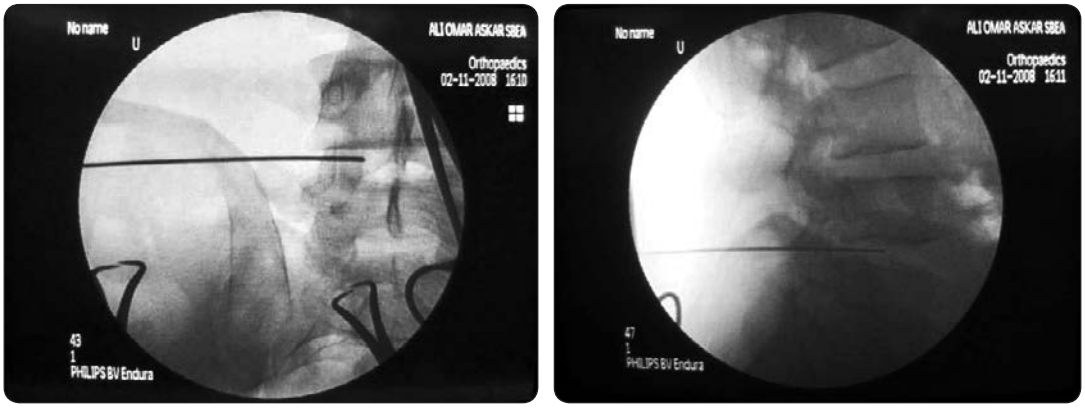

Figure 1.
AP and Lateral views showing penetration of the needle into the centre of the disc space in both views.

The process of decompression involved advancing the wand, in ablation mode, at a speed of 0.5 cm/sec and, similarly, retraction of the wand in coagulation mode. A total of six channels were created at the twelve, two, four, six, eight, and ten o'clock positions.

Patients were discharged the same day (Figure 2), and instructed to perform limited daily living activities as needed with restriction of bending and stooping and no lifting of over 5Kgs for 2 weeks. Patients with sedentary or light work environments were allowed to return to work after two weeks. We prescribed oral antibiotics a muscle relaxant and an analgesic for five days following the procedure.

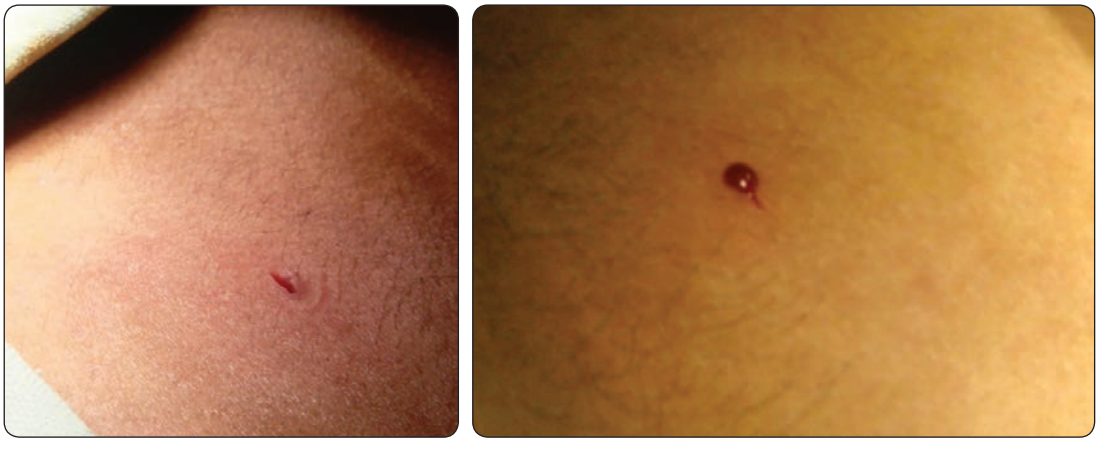

Figure 2.
Minimal access procedure with tiny wound.

Follow-up Characteristics:

Of the 34 patients; 34, 31, 27, and 26 were available for follow-up at 1, 3, 6, and 12 months respectively. Two patients were excluded from the follow-ups at 6 months and another one at 12 months because they had suffered re-injury, and underwent open surgery, while three patients were lost after the 1 month follow-up and another two after their 3-month follow-up due to relocation. All patients were included in the analysis of outcomes.

Outcome Measures:

The outcome measures used were the patient's report of the Visual Analog Scale (VAS) "a numeric pain scale of 0 to 10 (with 0 being no pain and 10 being the most severe pain)", improvement in functional capacity was calculated based on Oswestry disability score (ODS), range of movement of the lumbar spine (ROM) (as measured by Schober's test), analgesic intake, and Subjective Work Capacity (the degree of how much the patient can cope with his work demands without suffering pain, or needs help) were administered, and filled out by the patient pre-procedure, and 1 month post-procedure, three months, six months and one year post-procedure.

Statistical Analysis:

Data were statistically described in terms of range, mean±standard deviation (±SD), frequencies (number of cases) and percentages when appropriate. Comparison of quantitative variables between the study groups was done using Mann Whitney *U* test for independent samples when comparing 2 groups and Kruskal Wallis analysis of variance (ANOVA) test with Mann Whitney *U* test for independent samples as posthoc multiple 2-group comparisons when comparing more than 2 groups. Comparison of quantitative variables between pre-treatment and post treatment values was done using paired *t* test for normally distributed data and Wilcoxon singed rank test for non-normal data. For comparing categorical data, Chi square (X^2) test was performed. Exact test was used instead when the expected frequency is less than 5. A probability value (*P* value) less than 0.05 was considered statistically significant. All statistical calculations were done using computer programs Microsoft Excel 2003 (Microsoft Corporation, NY, USA) and SPSS (Statistical Package for the Social Science; SPSS Inc., Chicago, IL, USA) version 15 for Microsoft Windows.

Results

By comparing the Mean and standard deviation "SD" of the VAS for the back and leg, ROM, subjective work capacity, and the ODS, along with the minimum and maximum of each item we found a good improvement post procedure till the third month post-operative then the improvement decrease slightly towards the twelfth month but still with a statistically significant good improvement comparing to the pre-operative values (Table 2).

Pre-operatively all the patients were taking analgesics, 52.9% of patients were taking NSAID, 29.4% were on Steroids in addition to the NSAID, and 17.6% of patients were taking Tramadol as well. Post operatively all the patients stopped taking Steroids, and Tramadol, on 6 weeks post-operative 61.7% of patients were medication free, 8.8% were taking NSAID occasionally when needed, while 29.4% of patients were on regular NSAID as pain killer continuously. On 12 months post-operatively 34.6% of patients were regular NSAID users, and another 34.6% used NSAID occasionally when needed.

Table 2. Follow up Clinical Data

		MEAN	SD	MIN	MAX
VAS/BACK	PRE	7.26	1.286	5	10
	3M	4.77	1.839	0	8
	12M	5.50	1.924	2	8
VAS/LEG	PRE	7.74	1.082	6	10
	3M	3.71	2.163	0	10
	12M	4.19	1.767	1	8
ROM	PRE	13.03	1.426	11	16
	3M	14.32	1.376	12	17
	12M	14.27	1.687	12	17
SWC	PRE	50%	0.210	0%	80%
	1M	81%	0.130	60%	100%
ODS	PRE	30.96	4.653	23	40
	6M	9.81	4.386	2	20
	12M	14.58	4.884	5	25

Note; SWC: subjective work capacity, ODS: Oswestry disability score, ROM: range of movement, VAS:visual analogue scale, MIN: minimum, MAX: maimum, PRE: preprocedure, SD: standard deviation.

Comparing the results according to age, we found obvious difference with better improvement in the first group whose age 40 or less comparing to the second group whose age more than 40. The best improvement was in VAS leg pain.

Comparing the results according to Back Pain duration, we also found obvious difference with better improvement in the first group whose Back Pain duration less than 9 months, comparing to the second group whose Bach Pain duration 9 months or more. The best improvement was in VAS back.

Comparing the results according to Activity level groups, we didn't find an obvious difference between the three groups, with little improvement in VAS back, ROM, and Subjective Work Capacity in the Low activity group comparing to the Moderate activity group, and little improvement in both groups comparing to the High activity group but not statistically significant. In the VAS leg, and total Oswestry we found the improvement in the Moderate activity group better than Low activity group, Both are better than the High activity group, also statistically not a significant difference (Table 3).

Table 3. Comparison 0f VAS Back and Leg, ROM, Subjective Work Capacity and ODS In Different Groups According to Age, Back Pain Duration, Activity Level

MEAN		VAS BACK		VAS LEG		ROM		SUBJECTIVE WORK CAPACITY		ODS	
		SD	MEAN	SD	MEAN	SD	MEAN	SD	MEAN	SD	
AGE	≤ 40	5.28	2.109	3.44	1.247	14.72	1.742	82%	0.14	13.50	4.817
	> 40	6.00	1.414	5.88	1.642	13.25	1.035	77%	0.13	17.00	4.375
BACK PAIN DURATION	< 9M	4.38	2.07	3.5	2.27	14.75	1.98	83%	0.11	13	4.88
	≥ 9M	6	1.68	4.5	1.47	14.06	1.55	81%	0.13	15	4.83
ACTIVITY LEVEL	LOW	5.00	1.633	4.71	1.704	14.86	1.574	91%	0.12	14.29	6.473
	MODERATE	5.38	1.996	3.63	1.188	14.38	1.685	81%	0.12	13.13	4.518
	HIGH	5.91	2.119	4.27	2.149	13.82	1.779	76%	0.11	15.82	4.094

We measured how much improvement in our patients in VAS back and leg pain taking 2 points or more improvement as definition of improvement, and re-measured the results by taking 50% or more improvement in VAS comparing to the pre as effective pain improvement (Figure 3).

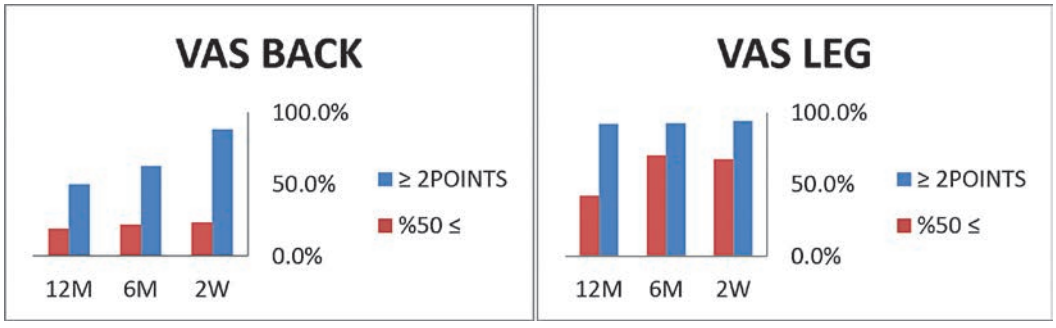

Figure 3.
Pain improvement and effective pain improvement in VAS Back and Leg as defined.

Patient satisfaction on 12 months post-operative was assessed by asking the patient the following question: having known the outcome he had from the procedure would he have undergone it and whether he would recommend the procedure to a friend 76.9% of our patients answered positively and were therefore satisfied with the procedure. There were no complications associated with the Nucleoplasty procedure using Coblation technology during the procedure or post-operatively. Specifically, there were no instances of discitis, dural tear, or neurological deficit reported related to the procedure.

Discussion

Patients involved in this analysis were unable to improve with conservative therapies including physical therapy, activity modification, and drug therapy for at least 6 weeks. All patients were nonsurgical candidates. Thus, the only treatment alternatives for these patients were limited to chronic drug therapy.

The proportion of patients with 2 points or more pain relief declined at 12 months, from a high of 88.2% at 2 weeks to 50% at 12 months for back pain, and from a high of 94.1% at 2 weeks to 92.3% at 12 months for leg pain. But the proportion of patients with 50% or more pain relieved declined at 12 months, from only 23.5% at 2 weeks to 19.2% at 12 months for back pain, and from a high of 67.6% at 2 weeks to 42.3% at 12 months for leg pain. However, this is also observed following many types of interventions in managing low back pain, both surgical and non-surgical.[2]

This evaluation is a prospective case series. It may be argued that this was not a blinded, randomized controlled analysis; however it has been noted in several studies,[1,7,9] that the results of non-randomized or observational studies are not necessarily inferior to those of randomized, double blinded, controlled trials. The typical double blinded pharmacological trials involve a drug versus placebo.

Designing a similar blinded trial for an invasive procedure versus a control or placebo arm presents logistic difficulties, since not doing the procedure in the control arm in itself would un-blind the study. While a sham procedure arm could be incorporated as a control arm, it would pose further ethical and medico-legal dilemmas.

Thus, we acknowledge that the results of this evaluation do not provide a definitive answer to the effectiveness of Nucleoplasty, but have value and provide direction for future evaluations. If we have the opportunity to repeat this study again we will change the strategy so the data recording and analysis portions will be blinded to the researchers. By changing the design to such a study, we could eliminate one of the biggest weaknesses of our study recall bias.

We also may be criticized for not performing an intent-to-treat analysis, because data were not available for 8 of the original 34 patients. However, because this study was neither randomized nor double blind, we felt that intent-to-treat analysis would not be appropriate. We do recognize that intent-to-treat analysis is important in randomized, double-blind, placebo-controlled trials, so as not to overestimate the response to treatment or underestimate the response to placebo.

Finally, this study may be criticized for providing the results after 1 year follow up in this evaluation rather than waiting for a 2 year follow up. PDD with Nucleoplasty is a minimally invasive procedure akin to interventional procedures such as IDET, etc. Thus, we believe that 1 year follow up was appropriate.

Nucleoplasty has certain advantages over other minimally invasive techniques. Because the temperature is kept low during ablation, charring or burning of surrounding tissues is minimized. The procedure is under the physician's complete control, unlike chemonucleolysis, which is dosage dependent. In addition, pressure changes are immediate, whereas chemonucleolysis may require as long as 7 days for completion.[10]

Nucleoplasty also can be performed from either side of the affected disc, not just from the ipsilateral symptomatic side. Thus, treatment approaches are not limited to one side only. Because of these advantages, Nucleoplasty has the potential to be a safe and effective treatment for contained herniated discs.

Other minimally invasive intradiscal techniques such as chemonucleolysis, percutaneous nucleotomy, percutaneous discectomy, and laser treatments have been shown to reduce intradiscal pressure[11], but have their limitations. Chemonucleolysis involves a higher risk of severe complications, especially with inexperienced physicians.[13] Chemonucleolysis with chymopapain can lead to fatal anaphylaxis[12], cartilaginous endplate damage, and hemorrhage.[11]

Conclusion

PDD using Coblation techniques represents an effective method to add to our existing armamentarium for the treatment of leg pain associated with discogenic low back pain with better improvement in leg pain compared to back pain with slight deterioration of the improvement over time. Our recommendation is to modify the inclusion criteria for Nucleoplasty to include only patients with contained disc prolapse complaining of leg pain mainly, who are younger than 40 years old whose back pain no longer than 9 months. Operating upon patients complaining of discogenic back pain only is not recommended.

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الملخص العربي

استخدام الموجات اللاسلكية لرأب النواة لعلاج الانفتاق المحتوى للغضروف القطني

البيانات الأساسية: لقد تم استخدام عدد من التقنيات عن طريق الجلد في علاج الانفتاق الغضروفي القطني. يزداد استخدام الموجات اللاسلكية في الوقت الحالي و تكتسب شعبية.

الغرض: لتحديد سلامة وفعالية رأب النواة بواسطة الموجات اللاسلكية في علاج الانفتاق الغضروفي القطني المحتوى، ولتحديد أفضل المؤشرات التي تنبئ بنتيجة جيدة وتقديم تقرير عن النتائج السريرية.

تصميم الدراسة: لفيف من المرضى المرتقبين و الذين يعانون من الانفتاق المحتوى للغضروف القطني و الذين فشل معهم العلاج التحفظي, سيخضعون للعلاج بالموجات اللاسلكية لرأب النواة.

المواد والأساليب: ٣٤ مريض: ٢٣ من الذكور و ١١ إناث الذين يعانون من فتق الغضروف القطني المحتوى خضعوا لرأب النواة بواسطة الموجات اللاسلكية. كانت هذه والإناث ٢٣ ذكر ١١. وكان متوسط العمر ٣٦.٣٨ عاما. ٥٩٪ من المرضى كانوا يعانون من غضروف الفقرة الرابعة و الخامسة و ١٥٪ كانوا يعانون من انفتاق بغضروفين.

النتائج: أظهرت النتائج تحسن في ألام الطهر في ٦٣٪ من المرضى بعد ستة أشهر من المتابعة و ٥٠٪ بعد سنة من المتابعة. بالنسبة لآلام الساق أقر ٩٢.٣٪ من المرضى بتحسن بعد المتابعة لمدة سنة واحدة.

مناقشة: توصيتنا لتعديل معايير إدراج لرأب النواة بواسطة الموجات اللاسلكية لتشمل المرضى الذين يعانون من الانفتاق المحتوى للغضروف القطني في سن أقل من ٤٠ سنة فقط من العمر، وأن تكون مدة الألم أقل من ٩ أشهر، و الذين يشكون من ألم في الساق في المقام الأول.

ختاما: إن استخدام الموجات اللاسلكية لرأب النواة لعلاج الانفتاق المحتوى للغضروف القطني هو إجراء فعال و آمن لعلاج المرضى الذين يعانون من آلام في الساق في المقام الأول.