Acta Neurochir (Wien) (2007) 149: 495–500
DOI 10.1007/s00701-007-1146-9
Printed in The Netherlands

Acta Neurochirurgica

Clinical Article

Six months post-operative clinical and 24 hour post-operative MRI examinations after nucleoplasty with radiofrequency energy

T. Calisaneller[1], **O. Ozdemir**[1], **E. Karadeli**[2], and **N. Altinors**[1]

[1] Neurosurgery Department, Baskent University Faculty of Medicine, Turkey, Konya
[2] Radiology Department, Baskent University Faculty of Medicine, Turkey, Konya

Received October 11, 2006; accepted February 21, 2007; published online April 13, 2007

Summary

Background. Minimally invasive techniques are gaining popularity for the treatment of discogenic low-back pain. Nucleoplasty is a relatively new procedure that uses radiofrequency energy to disintegrate and evacuate the disc material. The purpose of this study is to examine the early post-operative radiological changes after lumbar nucleoplasty and to assess the short-term effects of this procedure on discogenic lower back pain and leg pain.

Methods. Twenty nine patients between the ages of 32 and 59 years (mean 44.14, SD 7.11 years) were included in the study. Visual Analogue Scale (VAS) scores of the patients were recorded in the pre-operative period and 24 hours, 3 months and 6 months after the procedure. Additionally, pre-operative and post-operative lumbar magnetic resonance imaging (MRI) examinations of these patients were compared.

Findings. The mean pre-operative VAS score was 6.95 (range 3.0–10.0, SD 1.87) and the mean post-operative VAS scores at 24 hours, 3 months and 6 months were 2.46 (range 0–8.0, SD 2.07), 4.0 (range 0–10.0, SD 3.09) and 4.53 (range 0–10.0, SD 3.6), respectively. There were statistically significant reductions ($p < 0.001$) in VAS scores for all post-operative time points when compared to pre-operative values. Nucleoplasty did not produce obvious changes at least on the early post-operative MRI examination.

Conclusions. Although, nucleoplasty appeared to be a safe minimally invasive procedure, the value of this new technique for the treatment of discogenic low-back pain remains as yet unproven. Further randomised placebo-controlled studies with longer follow-up are needed to elucidate the effects of nucleoplasty on discogenic low back and leg pain.

Keywords: Co-blation; discogenic pain; minimally invasive surgery; nucleoplasty.

Introduction

Minimally invasive techniques are gaining popularity as an alternative treatment for degenerative lumbar disc disease in order to reduce the morbidity caused by open surgery. One of the aims of these techniques may be to decrease the intra-discal pressure by shrinking or removing the pain generating disc material. Several percutaneous procedures have been utilised for that reason including chemonucleolysis with chymopapain, intra-discal laser discectomy, automated percutaneous lumbar discectomy and intra-discal electrothermal therapy (IDET). Although these techniques have several advantages over open surgery, they also have some serious drawbacks. Utilizing chemical agents can cause damage to or haemorrhage into the cartilaginous end-plate and excessive thermal energy may result in osteonecrosis of the vertebral bodies [9, 14].

Nucleoplasty (NP) with radiofrequency energy is a relatively new minimally invasive technique that uses radiofrequency (RF) energy to disintegrate and evacuate the disc material. The tip of the catheter creates a low-temperature plasma field that breaks down the molecular

bonds of the disc material into elementary molecules and low molecular gases. By creating channels in the degenerative disc, approximately two millilitres of disc material can be removed and intra-discal pressure is reduced. Since NP is a non-chemical non-heat driven procedure, it provides an immediate decrease in the intradiscal pressure without any harmful chemical or thermal effects on the surrounding structures. The term ''Nucleoplasty'' should not be confused with the term ''Disc Arthroplasty'' in which a device is implanted surgically for replacing the nucleus pulposus. In spite of substantial literature on the other percutaneous techniques, there are only a limited number of studies concerning the clinical and radiological results of NP. The purpose of this study is to examine the early post-operative radiological changes after lumbar NP and to assess the short-term effects of this procedure on discogenic low back pain and leg pain.

Methods and material

Twenty-nine patients between the ages of 32 and 59 years (mean 44.14, SD 7.11 years) were included in the study. The gender distribution indicated that 24% ($n=7$) were male and 76% ($n=22$) were female. Of these patients, 90% ($n=26$) underwent one-level and 10% ($n=3$) underwent two level NP. All patients received at least six weeks of various conservative treatments prior to the procedure. The inclusion criteria were low back pain and/or leg pain lasting more than six months, MRI evidence of diffuse bulging and/or protrusion $\leq$5 mm at one or two levels. The exclusion criteria were disc bulges greater than 5 mm, loss of normal disc height greater than 30%, patients who had a history of previous low-back surgery, those with neurological deficits and patients who had serious medical conditions such as malignancy, infection or coagulopathy. In addition to demographic and clinical data of the patients, pre-operative and post-operative (24-hour, 3-months and 6-months) Visual Analogue Scale (VAS) pain scores and pre-operative and 24 hour post-operative MRI findings were recorded.

The detailed surgical method for NP is described elsewhere [13]. Briefly, the patient was placed in the prone position on the surgical table and after appropriate sterile preparations the treatment level and entry point were determined by using fluoroscopy views with lateral, posterior-anterior and 45 degree oblique projections. A local anaesthetic was applied 8–10 cm lateral to the midline on the most symptomatic side of the patient and the annulus fibrosus was punctured using a 17-gauge needle was inserted obliquely via Kambin's working triangle (Fig. 1). The needle was advanced until it reached the medial border of the pedicle at the posterior–anterior fluoroscopic view to reach the border between the annulus and the nucleus pulposus. The radiofrequency wand (Arthrocare Corporation, Sunnyvale, CA) was introduced through the needle and channels into the nucleus pulposus by inward–outward and rotational movements. After the co-blation procedure, the wand was removed and the needle was left in place for 20 more seconds for the release of the gases. No pre-operative or post-operative analgesics and/or sedation were administered to the patients. They received bed rest for 24 hours and lumbar MRI examinations were performed before discharge.

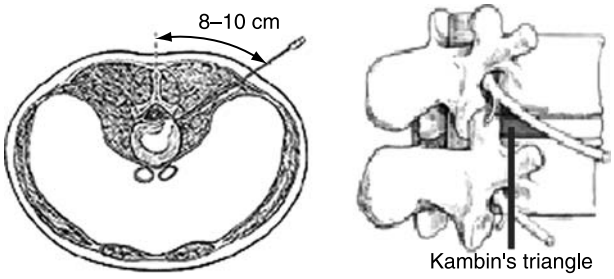

Fig. 1. Drawings illustrating the entry point of the catheter for nucleoplasty. The intervertebral disc is punctured with a 17-gauge needle inserted through Kambin's triangle, from 8 to 10 cm lateral to the midline at an oblique angle of 45-degrees

The statistical analysis of the pre-operative and post-operative VAS scores was performed by using the paired-samples *T*-test on a SPSS computer programme. Additionally, pre-operative and post-operative 24-hour MRI examinations (T1 and T2 weighted sagittal and axial images) were compared for any changes in the amount of the herniation, changes in the intensity of the disc, changes in the intervertebral foraminal size and for the existence of vertebral end-plate oedema.

Results

A total of 32 NP procedures were performed on 29 patients in this series. Of these, 87.5% ($n=28$) were at the L4/5 level and 12.5% ($n=4$) at the L3/4 level. All procedures were considered technically successful and no neuro-vascular or infection related complications were detected during the post-operative course.

Demographic data with the results of MRI examinations and VAS scores are as summarised in Table 1. The mean pre-operative VAS score was 6.95 (range 3.0–10.0, SD 1.87). The mean post-operative VAS score (Fig. 2) at

Table 1. *Demographic data, radiological findings and VAS scores of the patients*

Patient no.	Age	Sex	Level of discopathy	Degree of herniation	Change in the degree of herniation on 24-hours Postoperative MRI-scan	Change in the intensity of disk on 24-hours Postoperative MRI-scan	Change in the foraminal size on 24-hours Postoperative MRI-scan	Preoperative vertebral endplate edema on Preoperative MRI-scan	Postoperative vertebral endplate edema on 24-hours Postoperative MRI-scan	Preoperative VAS	VAS at 24 hours post-surgery	VAS at 3 months post-surgery	VAS at 6 months post-surgery
1	48	F	L4-5	DB	no	no	no	no	no	5.5	4.5	6	9
2	38	F	L4-5	DB	no	no	no	no	no	9	1	8	6
3	50	F	L4-5	DB	no	no	no	no	no	9.5	1.5	6	8
4	38	F	L4-5	DB + CP	no	no	no	no	no	8	2	7.5	7
5	37	M	L4-5	DB + CP	no	no	no	no	no	3	1	0	0
6	45	M	L4-5	DB	no	no	no	no	no	7.5	2.5	7.5	10
7	41	M	L4-5	DB	no	no	no	no	no	9	1	3	3
8	56	F	L4-5	DB	no	increased	no	no	no	9	1	5	9
9	41	F	L4-5	DB + CP	no	no	no	no	no	5.5	6	4	5
10	40	F	L3-4	DB + LPP	no	increased	no	no	no	5	0	0	0
11	39	F	L4-5	DB	no	increased	no	no	no	3	0	0	0
12	35	F	L4-5	DB	no	no	no	no	no	6	4.5	10	10
13	38	F	L4-5	DB	no	no	no	no	no	7.5	1	1	1
14	38	F	L4-5	DB	no	no	no	no	no	8	4	8	8
15	51	F	L4-5	DB	no	no	no	no	no	6	2	5	2
16	41	M	L4-5	DB	no	no	no	no	no	9	3	7	10
17	50	F	L3-4, L4-5	DB + CP	no	no	no	no	no	9	8	9	10
18	59	F	L3-4, L4-5	DB	no	no	no	no	no	9	0	0	0
19	43	F	L4-5	DB	no	no	no	no	no	5	2	1	1
20	41	F	L4-5	DB	no	no	no	no	no	6	5	3	3
21	49	M	L4-5	DB	no	no	no	no	no	7	4	4	5.5
22	48	F	L4-5	DB	no	no	no	no	*yes*	7.5	1.5	1	1
23	57	F	L3-4, L4-5	DB	no	no	no	no	no	7	2.5	3	2
24	41	F	L4-5	DB	no	no	no	no	no	10	5	5	5
25	53	F	L4-5	DB	no	no	no	no	no	6.5	1.5	5	5
26	51	F	L4-5	DB + CP	no	no	no	no	no	5	0	1	5
27	44	M	L4-5	DB + CP	no	no	no	no	no	6	0	0	0
28	36	F	L4-5	DB	no	no	no	no	no	8	2	1	1
29	32	M	L4-5	DB	no	no	no	no	no	5.2	5	5	5

DB Diffuse bulging, *CP* central protrusion, *LPP* left paracentral protrusion.

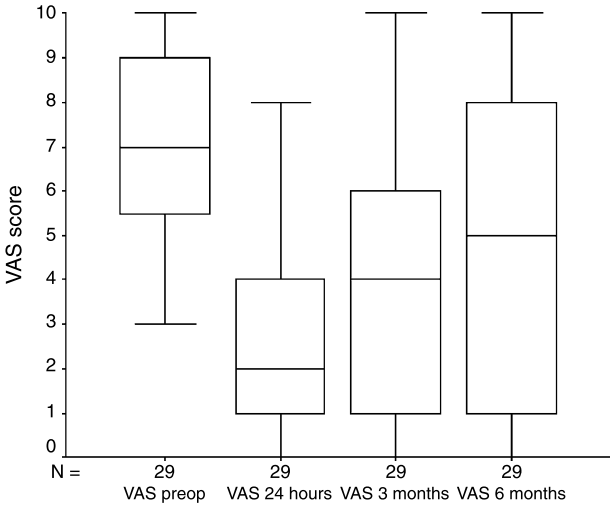

Fig. 2. Mean VAS scores at pre-operative and post-operative (24-hours, 3 month and 6 month) time points ($n = 29$)

24 hours was 2.46 (range 0–8.0, SD 2.07), at 3-months 4.0 (range 0–10.0, SD 3.09) and at 6-months 4.53 (range 0–10.0, SD 3.6). There were statistically significant reductions ($p < 0.001$) in VAS scores for all post-operative time points when compared to pre-operative values.

Among 29 patients, 75.9% ($n = 22$) reported a $\geq$50% reduction in pain scores while 20.69% ($n = 6$) reported less than 50% reduction. One patient reported an increase in the pain score as compared to pre-operative values at the post-operative 24-hour time point. At the 3 month post-operative follow-up, 48.28% ($n = 14$) of patients reported a $\geq$50% reduction, 44.82% ($n = 13$) less than 50% reduction and two patients (6.9%) an increase in VAS scores as compared to pre-operative values. At 6 months after the procedure, more than half of the patients (51.72%, $n = 15$) reported a $\geq$50% reduction in pain and 31.03% ($n = 9$) of the patients reported less than 50% reduction in VAS scores. Five patients (17.25%) reported increased VAS scores as compared to pre-operative values. In addition, 48.27% ($n = 14$) reported worse VAS scores at 6 months post-operatively than at 24 hours after NP, and 31% ($n = 9$) reported worse pain scores at 6 months than at 3 months after the treatment.

All patients had some degree of diffuse bulging ($\leq$5 mm) on the pre-operative MRI examinations. Additionally, six patients had central and one patient a left paracentral protrusion on the preoperative MRI. Post-operative 24-hour MRI examinations revealed no changes in the type or amount of the herniation. Similarly, there were no changes in the size of the intervertebral foraminae at the treated levels. Among 32 treated levels, we found increased intensity in three intervertebral discs and vertebral end-plate oedema in one other patient post-operatively. All of the patients with MRI changes had single-level disease and there was no clear relationship between the MRI changes and VAS scores. Radiological findings in this study revealed that the NP procedure had no obvious effect, at least, on the early post-operative MRI examinations.

Discussion

NP is a relatively new (approved by FDA in 1999) minimally invasive technique for the treatment of discogenic low back pain and leg pain. The procedure involves the percutaneous insertion of a co-blation (controlled ablation) probe into the targeted disc and creation of a series of six channels at 60 degrees angular spacing within a period of 3 minutes. The probe has a special radio frequency tip that generates a plasma field at low temperatures (50–70 °C). The application of RF energy on the disc material results in breakdown of molecular bonds of the tissue into elementary molecules and low molecular gases. Finally, these gases are removed through the introducer needle. The whole procedure results in removal of up to 20% of the disc material and reduction of intra-discal pressure. Pig cadaveric studies on NP revealed that it had no overt thermal damage on the surrounding annulus fibrosus, vertebral end-plates or the spinal cord and the nerve roots [5]. However, by using human cadaveric disc specimens, Nau *et al*. showed that incorrect positioning of the probe might cause high temperatures and lethal thermal doses in small regions outside the nucleus pulposus [8].

Candidates for NP are patients with discogenic low back and/or leg pain with MRI findings of disc bulges or protrusions $\leq$5 mm and failed conservative measures after six weeks of treatment. The contraindications include severe disc degeneration with loss of normal disc height more than 30%, spinal stenosis, disc sequestration, previous surgery of the targeted level and systemic causes such as malignancy or infection. Potential serious complications of NP are neurovascular injury to adjacent structures or post-operative spondylodiscitis. However, no such complications are reported in the literature. Recently, Bhagia *et al*. reported short term complications of NP and concluded that most of these were related to the needle insertion site even though a few patients reported increased back pain and new tingling numbness post-operatively [2]. We did not encounter any serious complications in our study.

Only a limited number of clinical studies on NP are available in the English scientific literature. Sharps and Isaac reported a success rate of 67% in the patients with a previous history of low-back surgery versus 82% in the group without a history of previous surgery at 12-month follow-up [12]. In the study by Singh *et al*. 79% of the patients reported greater than 50% pain relief at 3-month follow-up and this percentage had dropped to 59 and 56% at 6-month and 12-month follow-ups, respectively [13]. Finch *et al*. reported that 34% of their patients had a decrease of greater than 50% in their VAS scores after NP at one-year follow-up [6]. Reddy *et al*. announced functional improvement and reduction in pain medication use similar to other studies, VAS scores in their study displayed a steady increase after the first three months [10]. A few more studies have been published recently. Marin reported an 80% improvement in pain scores with no worsening at six to 12-month follow-up and concluded that NP might be an efficacious method for the treatment of contained disc herniation [7]. Reverberi *et al*. compared epidural steroid injections to NP and revealed better results with nucleoplasty [11]. In our study, 28 out of 29 (96.59%) patients reported some degree of improvement in VAS scores, while only 22 (75.9%) patients reported a $\geq$50% reduction in pain at postoperative 24-hour. At 3-month follow-up, 27 out of 29 (93.1%) patients reported an improvement in their pain scores, however the number of the patients reporting a $\geq$50% reduction in pain reduced to 14 patients (48.28%). At 6-month follow-up, the number of the patients reporting some degree of improvement in their VAS scores was 24 (82.75%) and the number of the patients reporting a $\geq$50% reduction was 15 (51.72%). Our findings are consistent with the results of other studies in the literature. Interestingly, the number of patients reporting worse VAS scores after NP increased gradually over six months in our study; one patient at the 24-hour stage (3.4%), two patients at 3 months (6.9%) and five patients at 6 months (17.25%). Moreover, the number of patients reporting worse VAS scores at 6 months follow-up than at 24 hours postoperatively was 14 (48.2%). This gradually increasing pattern of the VAS scores in our study and the data in the current literature introduce the conclusion that the possible effect of NP with RF energy for the treatment of discogenic low-back pain has not been proven yet and further clinical studies with much longer follow-up than 6 months are needed.

In the histopathological studies with pig cadaveric discs, NP has been shown to remove disc material without structural damage to the adjacent structures [5]. However, the long-term effects of NP on the treated and the adjacent discs remain uncertain. It is possible that co-blation may cause some degenerative effects on the treated and/or the adjacent levels on long-tem follow-up which may result in increased discogenic pain. Additionally, NP may cause some degree of spinal instability over time which could contribute to the pain sometime after treatment.

In order to detect the early radiological results of NP, we performed postoperative MRI examinations of the patients at 24 hours. The results revealed that co-blation of the intervertebral disc did not resulted in any obvious changes in the early MRI examinations. Three patients showed increased disc intensity and one patient showed vertebral end-plate oedema in the post-operative MRIs. Since we did not encounter any infection related complications, these changes can be attributed to heat effect of the procedure. Nevertheless, our findings on post-operative MRIs did not correlate with the follow-up VAS scores and due to small numbers we were not able to draw a conclusion from these findings. On the other hand, co-blation did not cause changes in the type or amount of the disc herniation nor in the size of the intervertebral foramina. Although our results only represent early MRI findings after NP, significant radiological improvements of the CT or MRI findings at six months were reported by Alexandre *et al*. [1]. Chen *et al*. investigated pressure changes after NP in human cadavers and reported that the procedure effectively reduced intra-discal pressure in a younger healthy disc (age 54), but in the older degenerative discs (ages 77 and 81) the effect on intra-discal pressure was minimal [4]. The authors concluded that pressure reduction through NP is highly dependent on the degree of spine degeneration. The ages of the patients in our study (mean 44.14, SD 7.11 years) were similar to the younger cadaver in the Chen study and NP yielded favourable results. Additionally, in the IDET studies, it has been shown that a temperature of 40 °C has a neural nociceptor ablative effect [3, 15]. The radiological findings after NP in our study suggested that the pain relieving effect can be due to immediate reduction in the intra-discal pressure and/or nociceptive ablative effect of co-blation on the nerve fibre network innervating the inner and outer annulus fibrosus rather than changing the amount of disc herniation. On the other hand, the gradual increase of the postoperative VAS scores in the long term follow-up patients suggests that the placebo effect might also be a good explanation for the early (24 hours) postoperative clinical improvement.

In conclusion, although NP appeared to be a safe minimally invasive procedure, the value of this new technique for the treatment of discogenic low-back pain has not been proven yet. Small numbers, relatively short-term follow-up and the absence of a control group are the weaknesses of our study and further randomised placebo-controlled studies with longer follow-up are needed to elucidate the effects of NP on discogenic low back and leg pain.

References

1. Alexandre A, Coro L, Azuelos A, Pellone M (2005) Percutaneous nucleoplasty for discoradicular conflict. Acta Neurochir Suppl 92: 83–86
2. Bhagia SM, Slipman CW, Nirschl M, Isaac Z, El-Abd O, Sharps LS, Garvin C (2006) Side effects and complications after percutaneous disc decompression using coblation technology. Am J Phys Med Rehabil 85(1): 6–13
3. Bono CM, Iki K, Jalota A, Dawson K, Garfin SR (2004) Temperatures within the lumbar disc and end-plates during intradiscal electrothermal therapy: formulation of a predictive temperature map in relation to distance from the catheter. Spine 15; 29(10): 1124–1129; discussion 1130–1131
4. Chen YC, Lee SH, Chen D (2003) Intradiscal pressure study of percutaneous disc decompression with nucleoplasty in human cadavers. Spine 1; 28(7): 661–665
5. Chen YC, Lee SH, Saenz Y, Lehman NL (2003) Histologic findings of disc, end plate and neural elements after coblation of nucleus pulposus: an experimental nucleoplasty study. Spine J 3(6): 466–470
6. Finch PM, Price LM, Drummond PD (2005) Radiofrequency heating of painful annular disruptions: one-year outcomes. J Spinal Disord Tech 18(1): 6–13
7. Marin FZ (2005) CAM versus nucleoplasty. Acta Neurochir Suppl 92: 111–114
8. Nau WH, Diederich CJ (2004) Evaluation of temperature distributions in cadaveric lumbar spine during nucleoplasty. Phys Med Biol 21; 49(8): 1583–1594
9. Nordby EJ, Wright PH, Schofield SR (1993) Safety of chemonucleolysis. Adverse effects reported in the United States, 1982–1991. Clin Orthop Relat Res 293: 122–134
10. Reddy SA, Loh S, Cutts J, Rachlin J, Hirsch J (2005) New approach to the management of acute disc herniation. Pain Physician 8: 385–390
11. Reverberi C, Bottoli MG, Pennini M, Gabba E (2005) Disc coablation and epidural injection of steroids: a comparison of strategies in the treatment of mechanical spinal discogenic pain. Acta Neurochir Suppl 92: 127–128
12. Sharps LS, Isaac Z (2002) Percutaneous disc decompression using nucleoplasty. Pain Physician 5: 121–126
13. Singh V, Piryani C, Liao K, Nieschulz S (2002) Percutaneous disc decompression using coblation (Nucleoplasty™) in the treatment of chronic discogenic pain. Pain Physician 5: 250–259
14. Tonami H, Kuginuki M, Kuginuki Y, Matoba M, Yokota H, Higashi K, Yamamoto I, Nishijima Y (1999) MR imaging of subchondral osteonecrosis of the vertebral body after percutaneous laser diskectomy. AJR Am J Roentgenol 173(5): 1383–1386
15. Wang JC, Kabo JM, Tsou PM, Halevi L, Shamie AN (2005) The effect of uniform heating on the biomechanical properties of the intervertebral disc in a porcine model. Spine J 5(1): 64–70

Comment

Calisaneller *et al.* conducted a well-designed study about nucleoplasty with radiofrequency energy for back and/or leg pain (probably) due to a contained disc bulging from the lower lumbar spine.

The follow-up, however, is limited to only 6 months. Taking into account the fact that 14 patients already had poor VAS scores at that short time interval of 6 months, than at 24 hours postoperative assessment, and that 9 patients were worse at 6 months than at 3 months, the main message of this paper should be that nothing has been proven yet as to the value of this relatively new technique. This is similar to the situatiion with IDET (Intradiscal Electro-Thermal Therapy).

J. Goffin
Leuven

Correspondence: Tarkan Calisaneller, Baskent Universitesi Hastanesi, Beyin Cerrahisi B-blok zemin kat, Hoca Cihan Mahallesi, Saray caddesi, No. 1 Selcuklu/Konya, ZIP code: 42080, Turkey. e-mail: tarkan_ca@yahoo.com