Acta Biomed 2018; Vol. 89, Supplement 1: 220-229 DOI: 10.23750/abm.v89i1-S.7025 © Mattioli 1885

Original article

Clinical and instrumental assessment of herniated discs after nucleoplasty: a preliminary study

Alessandro Liguori[1], Federica Galli[1], Martina Gurgitano[1], Anna Borelli[1], Marco Pandolfi [1], Ferdinando Caranci[2], Alberto M. Magenta Biasina[1], Giovanni G.M. Pompili[1], Claudia L. Piccolo[3], Vittorio Miele[3], Carlo Masciocchi[4], Giampaolo Carrafiello[1]

[1] Unità Operativa di Radiologia Diagnostica e Interventistica, Università degli Studi di Milano, Azienda Ospedaliera San Paolo; [2] Unità Operativa di Radiologia Diagnostica e Interventistica, Università del Molise; [3] Azienda Ospedaliera Careggi, Dipartimento di Radiologia d'emergenza, Università di Firenze; [4] Department of Biotechnology and Applied Clinical Science, University of L'Aquila, Italy

Summary. *Background and Aim:* The therapy for low back pain boasts different approaches; one of these is nucleoplasty. We wanted to assess the effectiveness of nucleoplasty both by clinical response both by MR imaging evaluation, including even extrusions larger than one third of the spinal canal. *Methods:* Fifty-seven patients were treated with nucleoplasty in our hospital, 11 of these patients accepted both clinical and MRI evaluation after six months from treatment. The clinical evaluation was performed with Visual Analogue Scale (VAS) of pain, scored before and after the procedure. MRI evaluation consisted of analysing some imaging parameters of disc protrusions before and after the treatment. *Results:* In 10 out of 11 (91%) patients, VAS was reduced and only 1 out of 11 (9%) had the same pain after procedure. The mean of decrease of VAS score was 64%. In our population 8/11 (72%) patients had a herniation larger than 1/3 of the sagittal diameter of spinal canal and 100% of them had an improvement with a mean VAS reduction value of 75%. With MRI evaluation, the mean percentage of expulsion before and after treatment was respectively 40% and 34%. The expulsion decreased in 7/13 discs, remained equal in 4/13, and increased in 2/13 discs. Among the 9 larger protrusions, 3 didn't change, 6 reduced with a decrease mean value of 13%. Other MRI parameters didn't change significantly. *Conclusions:* Our preliminary experience supports the success of coblation on pain relief, aiming to show progressively that this treatment is suitable even in case of great extrusions, which are generally treated only with surgical approach. It's not clear the usefulness of MRI control yet, even if in most of cases we could have found a certain reduction of expulsion degree. (www.actabiomedica.it)

Key words: disc protrusion, nucleoplasty, Visual Analog Scale (VAS), Magnetic Resonance Imaging (MRI)

Introduction

Spinal pain is one of the most frequently reported symptoms in the industrialized world, in particular low back pain.

According to a study by Schmidt et al. (2007), conducted in the Federal Republic of German, the point-prevalence for back pain was 34.2%, one year prevalence was 75.5% and lifetime prevalence was 85.2% (1-5). Another study by Deyo et al. (2006), conducted in USA, confirmed the high prevalence of back pain with a point-prevalence of 26.4% (6-14).

The intervertebral disc, because of its highly specialized role and relatively susceptible nature, is one of the major sources of low back pain syndrome (15-21).

Aging, stress and traumas cause a disc degeneration phenomenon and the loss of volume of pulp nucleus due to a decrease proteoglycans and water concentration (22-24). Because of the lack of nutrients and oxygen, cells are forced to metabolize anaerobi-

cally, generating a large amount of lactic acid; it leads to an increase in acidity resulting in further degradation of the intradiscal matrix (25-30).

Low back pain is treated with various modalities including epidural injections, percutaneous adhesiolysis, intradiscal therapy or annular thermal therapy, and mechanical disc decompression for disc-related pain, either discogenic or secondary to disc herniation, radiculitis, spinal stenosis, or post surgery syndrome (3, 12, 16, 31-35).

Treatment of discogenic low back pain is based on the theory that a small reduction in disc volume, involving removal of part of the nucleus via surgical or minimally invasive methods, can result in a large change in intradiscal pressure (15).

The primary modality of treatment remains either open discectomy or microdiscectomy, but several alternative techniques to open discectomy including automated percutaneous lumbar discectomy (APLD), percutaneous lumbar laser disc decompression, mechanical disc decompression with Dekompressor, and nucleoplasty have been described (8, 36-40).

In recent years, the general trend in spinal surgery is shifting toward minimally invasive procedures and lower cost. Nucleoplasty is a relatively new, minimally invasive therapeutic option that has been used for spinal procedures since July 2000 (41-45).

Nucleoplasty uses radiofrequency energy to remove nuclear material and to create small channels within the disc. With Coblation technology, radiofrequency energy is applied to a conductive medium, creating the formation a highly focused plasma field to form around the energized electrodes. The plasma field is composed of highly ionized particles. The created channel is thermally treated, producing a zone of thermal coagulation. Thus, nucleoplasty combines coagulation and tissue ablation (patented Coblation technology) to form channels in the nucleus and decompress the herniated disc (36, 46-50).

Clear inclusion criteria is missing in literature. Most scientific works exclude from nucleoplasty herniations larger than one third than the sagittal diameter of the spinal canal. This criterius was not assumed in our work in order to test the efficacy of coblation treatment even in case of spinal canal reduction greater than 50%.

The aim of our study is to evaluate the outcome of patients with intervertebral disc protrusions and herniations after coblation treatment, both by visual analog scale (VAS) of pain both by magnetic resonance imaging (MRI), performed before and after the treatment.

Materials and Methods

Population

In our Hospital 57 patients were treated with nucleoplasty between September 2016 and May 2017, 10 patients for a cervical protrusion, 47 for a lumbar.

Criteria of inclusion for treatment were the presence of spinal radicular pain due to disc protrusions and herniation.

Exclusion criteria for this procedure included severe spinal stenosis due to osteophytosis, presence of secondary pain issues, gait disorders depending on different neurological or orthopaedic pathology.

We selected the first 30 patients, whose treatment was done six months before: 19 refused the post coblation clinical evaluation with VAS scale and MRI examination, 11 accepted the control. Finally, these 11 cases were selected and considered in the present study (8 male, 3 female, mean age 57 years).

Nucleoplasty tecnique

Percutaneous disc decompression (PDD) using Coblation technology was performed under local anesthesia in a prone position; different radiologists used a uniportal approach under fluoroscopic guidance, entering the disc from the left side or from the predominant pain side. A 17-gauge six-inch long Crawford type spinal access cannula was introduced into the disc using a posterolateral extrapedicular approach. The access cannula was positioned at the junction of the anulus and nucleus . The exact position of the needle tip was confirmed on anteroposterior and lateral views. Discography was performed via the spinal needle to evaluate the configuration of the disc and the integrity of the fibrosus annulus, and a pain provocation test was performed by injection of contrast medium to deter-

mine whether the pain was discogenic in origin (Fig. 1a-b). The Perc-DLE tissue ablation and coagulation spinal wand (ArthroCare, Inc. - Sunnyvale, CA) was placed into the access cannula and was 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. A circumferential reference mark on the shaft of the spine wand was placed adjacent to the needle hub at the entry site, marking the proximal channel limit. The wand was advanced until it came into contact with the annulus on the opposite side. The depth stop marker on shaft of the Perc-DLE spine wand was advanced close to the needle hub to designate the distal channeling limit. Each channel was created by advancement of the wand in the ablation mode for 6-8 s followed by retraction in the coagulation mode for 10-15 s. A total of six channels were created at the twelve, two, four, six, eight, and ten o'clock positions to ensure adequate decompression of the disc space. We observed patients at least 6 hour after procedure and patients were advised to stay in bed for the 1st day following the procedure. No lifting of weights, bending, or stooping was permitted for 2 weeks following percutaneous disc decompression. Patients were returned to sedentary or light work after two weeks and were provided with home exercise instructions by a qualified physical therapist.

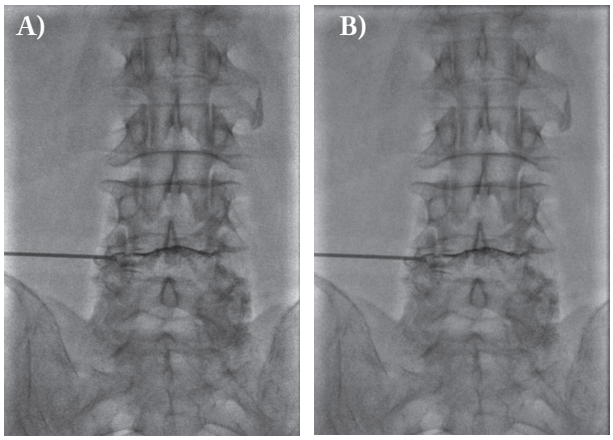

Figure 1. Discography after position of the cannula, during the procedure of coblation of a lumbar herniation at L4-L5 in a 74-year-old man. A. latero-lateral view; B. antero-posterior view

Pain evaluation

We considered VAS as analogic scale pre and post coblation: the VAS is a standardized instrument for measuring pain.

Patients rated the intensity of their subjectively experienced pain on a 10cm scale from 0 (no pain) to 10 (greatest imaginable pain) with a space of one centimetre between the individual values (51).

MR technique

The MRI examinations pre coblation were performed in different medical centres.

All MRI examinations post coblation were performed with a 1.5 T scanner (Optima MR450w GEMSGEMS, GE medical systems). The examination protocol applied consisted of sagittal and transverse sequences with a slice thickness of 4 mm, FSE T1 (TE 12, TR 680), FSE T2 (TE 100, TR 3300) and STIR (TE 54, TR 4370) weighted.

Imaging analysis

Two radiologists in consensus, with ten and five years of experience in spine imaging retrospectively, evaluated all the MRI examinations in order to determine the following parameters of disc protrusion pre and post coblation:

- Percentage of expulsion: percentage of the spinal canal antero-posterior diameter, occupied by herniated disc (fig. 2 a-b).
- Maximum thickness of disc (fig. 3a-b).
- Angle of disc herniation (following the classification of NASS) (52).
- Presence of arthrosic degeneration signs.
- Intensity change of disc.

Results

Among 30 patients selected in our study, who performed nucleoplasty in a period of six months before, 11 accepted to come to our hospital both for a clinical evaluation of pain and for an instrumental evaluation. The work is still in progress and we are going to recruit further patients with the same follow up time.

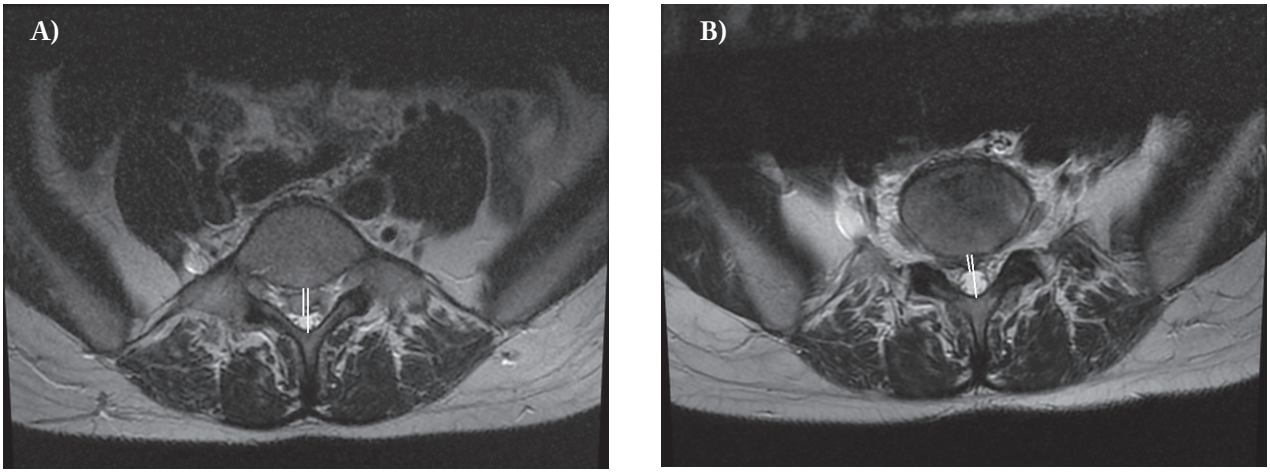

Figure 2. Axial T2 image at MRI evaluation of percentage of expulsion pre (A) and post coblation (B) in a 39-year-old woman with a large migrated herniation at L5

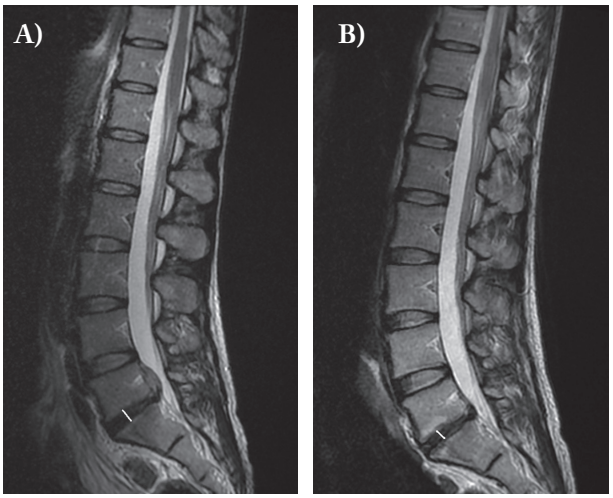

Figure 3. Sagittal T2 image at MRI evaluation of maximum thickness of disc in a 39-year-old woman with a large migrated herniation at L5-S1 (A. pre coblation; B. post coblation)

Table 1. Pain VAS in our 10 selected patients, pre and post coblation

PTS	AGE	SEX	VAS PRE	VAS POST
1	66	M	3,5	0
2	41	F	9	6
3	74	M	8	2
4	59	F	10	10
5	60	M	6	5
6	39	M	7,5	0,8
7	61	M	10	0
8	79	M	10	0
9	47	M	10	5
10	60	M	6,5	1
11	40	F	10	5

Pain evaluation

In 10 out of 11 (91%) patients, VAS was reduced and only 1 out of 11 (9%) had the same pain. (Tab. 1)

Among these 10, in 8 (80%) patients the extent of decrease of VAS score was equal or greater than 50%, and in 2 (20%) patients it was less than 50% (respectively of 37% and 16%). The mean VAS reduction value for all patients is 64%.

In 8 out of 11(72%) patients we found herniation larger than 1/3 the sagittal diameter of spinal canal and 100% of them had a clinical improvement (Tab. 2) with a main VAS reduction value of 75%; specifically 7/8 patients reported a decrease of VAS pain >50%, 1/8 patient reported a decrease of 37%.

Imaging analysis

All the 11 patients underwent to coblation for lumbar protrusion, of whom 2/11 performed a double coblation, due to the presence of 2 significant concomitant protrusions, so we finally considered 13 discs; 9/13 disc protrusions were larger than one third of spinal channel.

Of each disc, we reported the following parameters (Tab. 2):

Table 2. MRI parameters of the 13 selected discs pre and post coblation

DISC	LEVEL	MRI PRE			MRI POST				ARTHROSIS
		thickness (mm)	part of disc circonference (°)	espulsion %	thickness (mm)	part of disc circonference (°)	espulsion %	intensity change	
1	L4-L5	10	>180°	45%	10,3	>180°	39%	no change	yes
2	L5-S1	11,7	>180°	39%	11,9	>180°	27%	no change	yes
3	L5-S1	9	<90°	35%	9	<90°	35%	no change	yes
4	L4-L5	15	>180°	41%	15	>180°	41%	no change	yes
5	L4-L5	8,7	>180°	15%	8,6	>180°	17%	dehydration	yes
6	L3-L4	11	<90°	28%	11	<90°	17%	no change	yes
7	L4-L5	8	90°-180°	21%	8	<90°	37%	no change	yes
8	L5-S1	7	>180°	44%	6	>180°	44%	no change	yes
9	L5-S1	11	<90°	80%	10	>180°	60%	no change	yes
10	L4-L5	9	<90°	42%	9	<90°	38%	no change	yes
11	L4-L5	8	<90°	36%	8	90-180°	23%	no change	no
12	L4-L5	9	90°-180°	30%	9	90°-180°	30%	no change	yes
13	L5-S1	7	<90°	60%	6	<90°	40%	no change	no

- Percentage of expulsion: mean percentage of expulsion before and after treatment was respectively 40% and 34%. The expulsion decreased in 7/13, remained equal in 4/13 discs, and increased in 2/13. Among 9 larger protrusions, 3 didn't change, 6 reduced with a decrease mean value of 13%.
- Maximum thickness of disc: we reported a decrease mean value of 0,2 mm.
- Angle of disc herniation: 5/13 discs with >180° circumference protrusion didn't change after treatment; 8/13 discs with <180° circumference protrusion had variable behavior (5 didn't change, 2 increased and 1 decreased).
- Presence of arthrosic degeneration signs: 11/13 intervertebral levels were affected by arthrosis, 2/13 wasn't.
- Intensity change of disc: 1/11 disc showed sign of dehydration.

Discussion

Chronic back pain is one of the most frequently occurring types of pain in modern industrial societies. Probably it is generated by a combination of mechanical and neural mechanisms(40, 45, 53-57).

Hydrostatic pressure, between the disc and vertebral endplates, plays a very important role in the regulation of nutrient supply to the disc and in removal of waste from cells of the nucleus pulposus, which is an avascular structure. With aging, disease or injury the disc degeneration progresses causes a drop in the hydrostatic pressure mechanism of regulation (58-60).

Treatment is based on the theory that a small reduction in disc volume, involving removal of part of the nucleus via surgical or minimally invasive methods, can result in a large change in intradiscal pressure (25).

Coblation technology involves the use of radiofrequency energy to determinate a gentle removal effect on target tissue with minimum dissolution effects on surrounding vital structures.

Our first assessment was about clinical trend: 10/11 patients had a pain relief; 1/11 didn't have any change, either positive or negative. In one successful case the improvement was only one point of VAS.

This datus agrees with the meta-analysis of Institute of Medical Statisics, Informatics and Epidemiology (IMSIE), University Hospital of Cologne, which confirms the positive outcome of coblation in at least 17 studies by VAS (61).

No strict inclusion criteria are present in literature, even if it's recommended to treat little contained erniation (15, 61-65). Nevertheless we chose to include also patients with herniation that was larger than 1/3 the sagittal diameter of spinal canal and whom were asking a not invasive procedure to reduce the unbearable pain, in particular 8/11 patients (72%) had

these features. All patients with this type of herniation reported a decrease of VAS pain >50%, except one patient who reported a decrease of 37%. As result, we found that also these patients can benefit by treatment with a significant reduction of pain VAS and we are going to recruit other similar patients to have stronger evidence.

We have though to consider that the patients disappointed from the treatment were less available to the control we proposed six months later; that caused necessarily a bias in our population.

As second assessment we considered the response on MRI examinations.

An innovative perspective of our work, not present in literature, consists in the using of an instrumental evaluation of anatomic evidence by six-months post-operative MRI analysis; so we assumed this period of time suitable in order to consider accomplished every post-treatment tissue modification(66-70).

In 2007 T. Calisaneller et Al. lead an MRI evaluation after 24 hours from the procedure and only a clinical assessment after 3 and 6 months, aiming for further studies with longer follow up (62, 71).

The most remarkable result of our MRI analysis was the reduction of the percentage of disc expulsion (7/13 discs): 6 of these reducing protrusions were larger than one third of spinal canal with a decrease mean value of 13%. Therefore, there was not only a success in pain reduction but also in MRI features. Despite of small number of cases, this result is encouraging for the extrusions, which were excluded from most of approved coblation criteria.

However, both patients, whose six months post-operative MRI showed an increase of disc protrusion, detected at the same time an improvement of their clinical conditions and a reduction of pain. In the other 4 cases, the decrease of painful symptoms measured by VAS, wasn't linked with reduction of the disc protrusion, which remain equal.

Moreover we didn't found worthy changing of other anatomical MRI parameters we evaluated: the thickness of disc, the angle of circumferential protrusion or the hydration state.

As a matter of fact, it is already known that nucleoplasty induces only a little volume loss of nucleus pulposus and Masala et al. in their work reported approximately a removal of 1 cm^3 of tissue volume (15). However, this relatively small tissue reduction is connected to a significant improvement of clinical conditions. Percutaneous disc decompression, irrespective of the technique, is based on the principle that a small volume loss in a closed hydraulic space, like an intact disc, results in a disproportionately large drop of pressure (25, 72-75). For this reason, nucleoplasty can cause an improvement of clinical conditions and a pain relief even if clear disc modifications aren't evident. Coblation of the nucleus pulposus causes disc shrinkage with a vacuum effect, able to relieve pressure from the roots. This decompression leads to higher axonal, liquoral, and hematic flow rates, bringing about a resolution of the periradicular inflammatory mechanism and a better endorphin diffusion (15). Also T. Calisaneller et Al. report in their work that, the poor radiological findings after nucleoplasty suggest that the pain relieving effect can be due just to the reduction in the intra-discal pressure and/or nociceptive ablative effect of coblation on the nerve fiber network (62).

Fangan and co-workers described in details discal innervation. They identified areas where innervation is most concentrated as the perianular connective tissue and the central endplate; some of the nerves identify in this area may function as nociceptors (76-80). Thus it is likely that coblation nucleoplasty has an effect on discogenic pain since it denervates in a concentrated manner the central endplate area (72).

Another considered MRI parameter was the presence/absence of arthrosis, but it didn't represent a discriminant factor for the outcome of treatment.

About the increase/decrease of disc intensity, we have to affirm that it is not reliable, because some pre-treatment MR exams were made in other medical center, using different machine from ours and that involve a remarkable interpretative difficulty.

Moreover, in MRI examination after nucleoplasty we never observed scar or adhesions tissue between the posterior annulus and the nerve root (failed back syndrome), which are instead common complications in traditional surgical treatments (34, 81-85).

In conclusion, with our preliminary experience we can support the success of coblation on pain relief, aiming to show progressively that this treatment is

suitable even in case of extrusions, which are generally treated only with surgical approach; it's not clear the usefulness of MRI control yet, even if in most of cases we have found a certain reduction of expulsion degree.

Limits of our work were the absence of a double-blinded analysis of MRI evidence and, of course, the small numbers of our case group. However we don't consider accomplished this study yet, sure enough we are still recruiting more patients in our hospital to perform both clinical and MRI controls after six months from treatment and we are confident we can increase our records to obtain stronger results.

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Received: 15 September 2017
Accepted: 20 December 2017
Correspondence:
Dr. Alessandro Liguori
Unità Operativa di Radiologia Diagnostica e Interventistica
Università degli Studi di Milano
Azienda Ospedaliera San Paolo
via A. di Rudinì 8, 20142 Milano, Italia
Tel. +39 02 81844796
Fax +39 02 50323393
E-mail: alessandroliguori.medicina@gmail.com