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Percutaneous cervical nucleoplasty using coblation technology. Clinical results in fifty consecutive cases

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Summary

Conventional open cervical discectomy, with or without bony fusion, in common neurosurgical knowledge is considered the standard treatment for cervical disc herniation. Percutaneous procedures are minimally invasive and offer decreased morbidity, require no bone graft and promise shorter recuperation time. Nevertheless, candidates for a percutaneous procedure as inclusion criteria must complain of symptoms related to contained herniated disc or focal protrusion. It does not substitute conventional open procedures required for extruded discs. We used the coblation technology for nucleoplasty of the cervical intervertebral discs. Early and long-term effects and/or complications observed with this procedure have not been reported yet. Fifty consecutive patients presenting with contained herniated cervical disc or focal protrusion causing compression of the cervical roots or cervical pain underwent a nucleoplasty procedure on the pathological disc. A randomized control group of twenty patients was treated conservatively with medical and physical therapy in the same period and completed the identical *follow-up form*. In the nucleoplasty group results were complete resolution of symptoms in 80% of cases, only 10% referred some residual cervical or radicular pain and are still under *follow-up* with a *wait-and-see* prospective. Patients who did not have a clinical resolution were treated with alternative traditional methods (10%).

Despite the relative low cases number and the limited *follow-up* the encouraging results induce us to utilize this technique in well-selected cases.

Keywords: Nucleoplasty; coblation; percutaneous; cervical; disc.

Introduction

For more than five decades despite various disadvantages, open nucleotomy has been a beneficial treatment for prolapse of the intervertebral disc. Hence minimally invasive treatment for vertebral disc diseases has increasingly been applied in the last three decades, starting with chemonucleolysis, followed by endoscopic nucleotomy, automated draw-off nucleotomy and percutaneous mechanical nucleotomy. However these methods are limited. Choy and Ascher experimentally produced the non-endoscopic percutaneous laser disc decompression and nucleotomy with good results, beneath its potential complications regarding the high level of temperatures reached.

Conventional open cervical discectomy in common neurosurgical knowledge, with or without bony fusion, is considered the standard treatment for cervical disc herniation. However, open discectomy with fusion is associated with significant local inflammation, graft donor site pain (when autologous bone graft is used), and lenghty period of convalescence. Percutaneous procedures are minimally invasive and offer decreased morbidity, require no bone graft and promise a shorter recuperation time.

Nevertheless patient candidates for a percutaneous procedure as inclusion criteria must complain of symptoms with regard to contained herniated disc or focal protrusion. It does not substitute conventional open procedures required for extruded discs.

Percutaneous decompression for treating lumbar disc herniation is a well-established technique which has demonstrated good clinical success in properly selected patients.

Plasma-mediated electrosurgery, used in other medical fields [4, 5], has proven useful for this application. Two independent outcome studies by Sharps and Isaac [2] and Singh and colleagues [3] have shown statistically significant reduction in pain up to one-year after percutaneous disc decompression using plasma-mediated electrosurgery (nucleoplasty) in the lumbar spine. Chen *et al.* [1] experimentally demonstrated in cadaveric specimens that intradiscal pressure is reduced following a decompression procedure using the coblation technology.

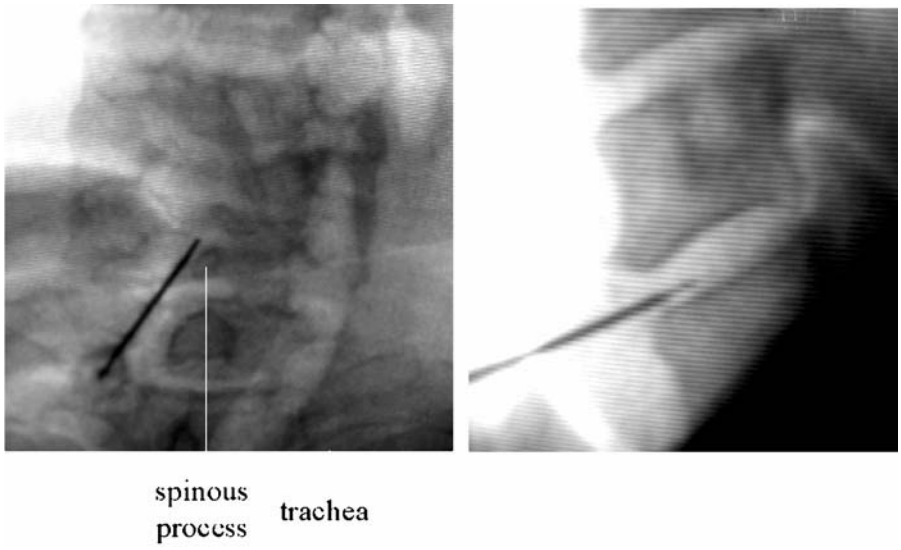


Fig. 1. Intraoperative fluoroscopic imaging in antero-posterior and lateral views during needle introduction. Appropriate positioning of the needle within the nucleus in the C5–C6 level

Nevertheless, early and long-term effects and/or complications observed with this procedure on the cervical spine have yet remained unreported. Objective of this study was to prospectively evaluate the effects and complications observed with nucleoplasty in the cervical spine as compared to conservative medical and physical treatment.

Materials and methods

From January to September 2003 fifty consecutive patients who reported having contained herniated cervical disc or focal protrusion causing compression of the cervical roots or cervical pain underwent a nucleoplasty procedure on the pathological disc. A randomized control group of twenty patients was treated conservatively with medical and physical therapy in the same period and completed the identical *follow-up*.

Inclusion criteria for the nucleoplasty procedure were disc protrusion or contained herniated disc not larger than 3 mm and not compromising more than 1/5 of the central spinal canal demonstrated on a magnetic resonance imaging (MRI). All patients reported to have persistent cervical or unilateral arm pain for a minimum of three months and had failed previous conservative treatment. Patients affected by spinal fractures, acquired stenosis, tumor, advanced spondylosis resulting in osseous foraminal stenosis or disc space collapse or with previous spinal surgery on the same level were excluded from this procedure. Presence of a radicular deficit, such as hypoesthesia or objective motor deficits or hyporeflexia were candidates for open procedure excluding nucleoplasty. Paresthesias were frequently associated with pain.

The Perc-DC SpineWand 126 mm connected to a System 2000 generator (ArthroCare Corp., Sunnyvale, CA, USA) was used to perform the nucleoplasty procedure. The device functions via plasma-mediated (coblation) electrosurgery, which fundamentally differs from traditional electrocautery and other thermal methods utilized for tissue treatments. Plasma-mediated electrosurgery uses high voltage, between 100 and 300 Volts depending on the controller setting selected, across the active and return electrodes of the device. When combined with an electrically conductive fluid (e.g. isotonic saline), the interaction creates an ionized vapor layer, or plasma, approximately 75 μm thick. Charged particles in the plasma are accelerated by the intense electric field within the plasma and carry enough energy to induce molecular dissociation, as opposed to the thermal denaturation attributed to standard electrosurgical tools. With plasma-mediated electrosurgery, a precise pathway can be produced with minimal thermal penetration into surrounding tissue. The diameter of the active tip of the Spine Wand is 0.8 mm.

The nucleoplasty procedure was always performed under intravenous sedation (Fentanyl and Propofol) with facial mask (oxygen 40%, air 60%, sevorane MAC 0,81%) via a medial approach to the sternocleidomastoideus muscle in an oblique right anterior direction to the target disc. Fluoroscopic imaging was used during the insertion of the introducer needle (19 gauge, 7,6 cm length) and wand placement with antero-posterior and lateral views. The needle was introduced until the annulus/nucleus junction was reached, the stylet was then withdrawn and replaced by the SpineWand. The wand was advanced until its tip was extended approximately 5 mm beyond the tip of the needle, which ensured that the active portion of the wand was deployed into the annulus when activated (Fig. 1). A short initial coagulation was performed when the wand was inserted, the ablation used three cycles of 8 seconds rotating the tip of the wand for 180 degrees each when withdrawal was started, the controller setting of 125 Volts caused a thermal reaction of 52 °C.

Patients were discharged 24 hours later with instructions for *follow-up* visits and placed on a standard rehabilitation program as routine following interventional spinal procedures.

Clinical status was recorded immediately postoperatively, 24 hours, 7 days and 60 days later. All patients were also asked to perform a visual analogue scale (VAS) from pre operative until their last *follow-up*. Changes in outcome measures were evaluated with Students T-test for coupled data.

Results

Nucleoplasty group

Fifty patients underwent a cervical nucleoplasty procedure for radicular unilateral or cervical pain derived from pathologic disorders of the cervical spine such as protrusions or contained herniated discs. A total number of 54 procedures were performed (4 on two adjacent levels). The C4–C5 disc level was treated in 12 cases (22%), C5–C6 in 33 (61%) and C6–C7 in 9 (17%) with the procedure described above. All patients were immediately mobilized and dismissed within 24 hours, antibiotic prophylaxis with a common cephalosporin was given in all cases.

In the immediate post-operative period and after 24 hours clinical status was almost similar to preoperative with a low percentage of patients referring amelioration of symptoms (20%).

In the precocious *follow-up* visit (one week later) 38 patients (76%) reported complete resolution of symptoms (mean VAS under 3,5), 7 patients observed a satisfactory amelioration of symptoms (14%, mean VAS varying from 3.5 to 4.8) and in 5 patients the intervention did not change clinical status (10%). In particular, patients treated on two adjacent levels had a resolution of symptoms in 3 cases (75%), one did not present amelioration of symptoms.

In the last *follow-up* (60 days) we observed a stabilization of the clinical results confirming the quota of patients with complete resolution of symptoms (40/50, 80%), only 5/7 patients (10% of all) referred some residual cervical or radicular pain and are still under *follow-up* with a *wait-and-see* prospective. Patients who did not have a clinical resolution remained stable and a month later were treated with microdiscectomy (4 cases, 1 on two adjacent levels) and with a selective analgesic treatment with Naropine and Cortisonics of the involved root (1 case).

Two patients (4%), one initially classified as complete resolution and the other one as partial, returned to our observation 3 months later declaring worsening of symptoms, MRI of the cervical spine documented persistence of the herniated disc. For these cases a microdiscectomy was proposed.

Mean *follow-up* was 3,8 months (varying from 2 to 9) and an MRI examination of the cervical spine was performed in all cases at the 4-month *follow-up*. Regression of the herniated disc shown on the MRI was confirmed in those cases with prolapsed disc and clinical resolution (Figs. 2, 3). On the other hand, when disc protrusion was the cause of persistence of symptoms, the MRI did not show a significant resolution. Nevertheless clinical improvement induced us to continue in a *wait-and-see stand-by* (see Table 1).

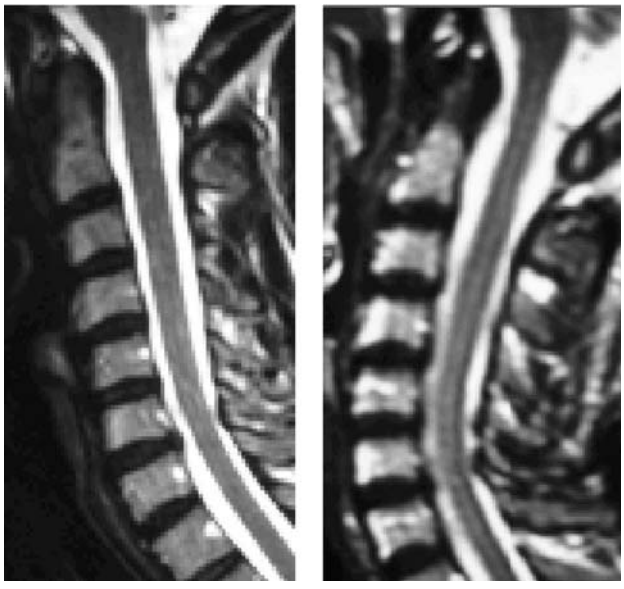


Fig. 2. Magnetic Resonance Imaging, T2 sagittal reconstruction, of the cervical spine in a young woman affected by a cervicobrachialgic pain. Preoperative imaging is shown on the left of the figure and post operative on the right. Cervical disc protrusion is evident at C6–C7 level. Nucleoplasty was performed with resolution of symptoms. On the post-operative MRI regression of the protruded disc is shown

Patients treated with nucleoplasty and having a complete resolution of symptoms returned to work after a period varying from 15 to 36 days (mean 21).

Control group

Twenty patients affected by cervical or unilateral arm pain secondary to a contained herniated cervical disc were treated conservatively for a minimum *follow-up* of three months (min. 3, max. 6, mean 4). No patients were affected by double space pathology. Medical therapy consisted of anti-inflammatory drugs and cortisonics for a period between 20 to 45 days, physical therapy included wearing of a Schanz collar for at least 30 days. All these patients were referred to a neurologist for *follow-up* as a random and "double blind" study.

At the first *follow-up* visit (one week later) 12 patients (60%) reported no change in their clinical status, 5 (25%) observed a sharp amelioration in pain and 3 (15%) had good results with the therapy. At the last

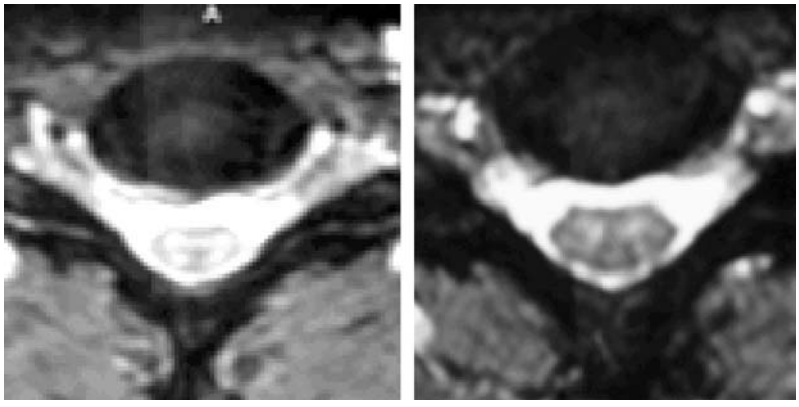
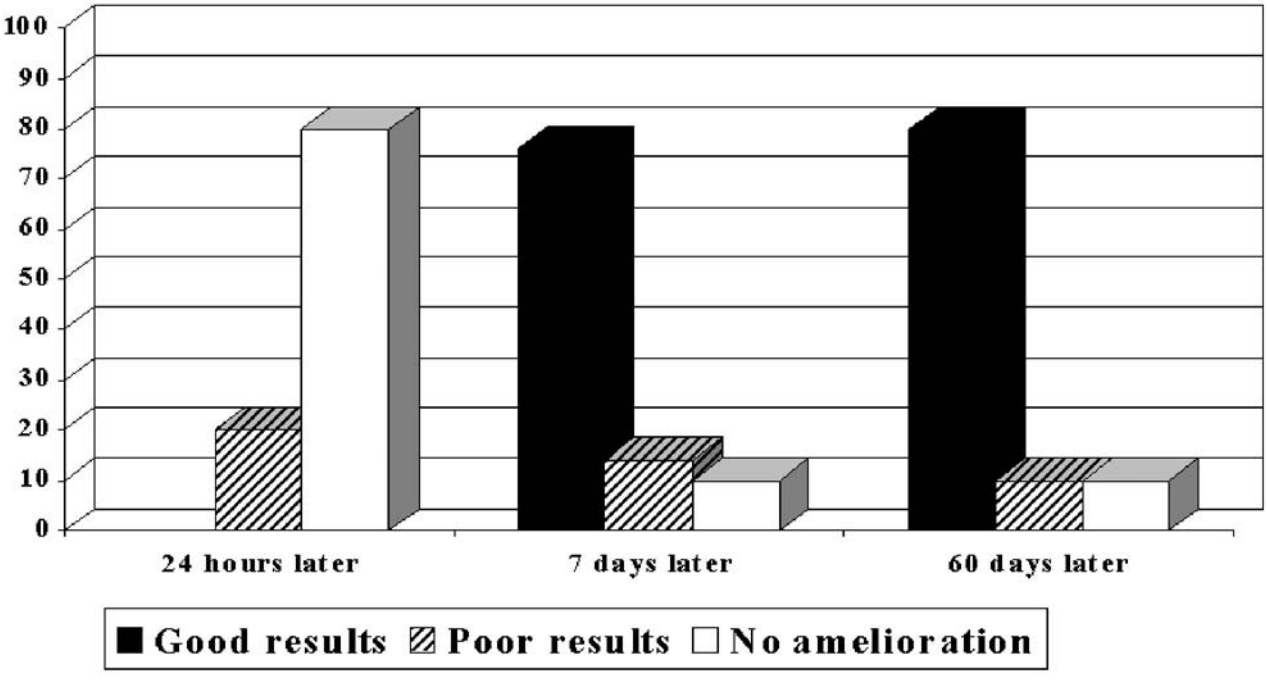


Fig. 3. Magnetic Resonance Imaging, T2 axial reconstruction of the same case as in Fig. 2. Resolution of the disc protrusion is shown

Table 1. *Clinical results. Nucleoplasty group*



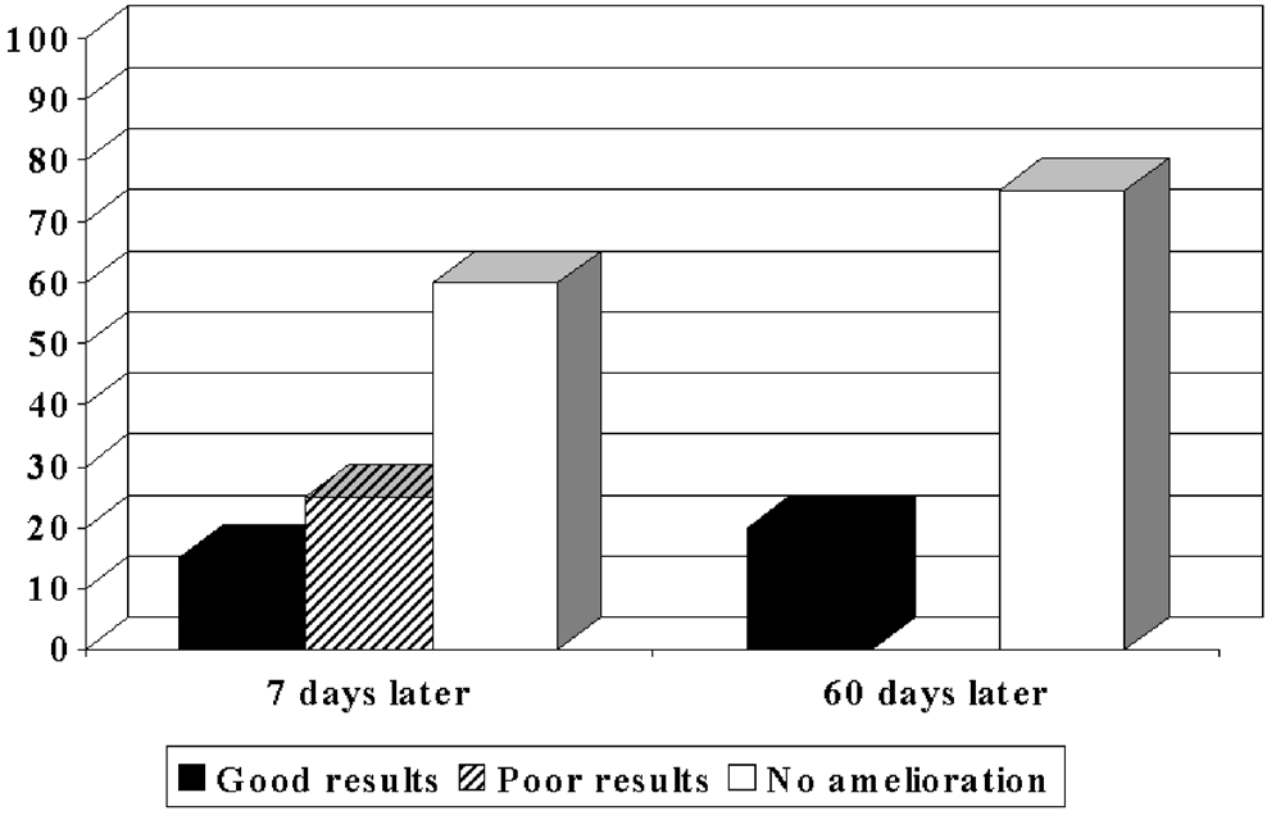
follow-up (60 days) 15 patients (75%) returned to our observation because of persisting symptoms of cervical or radicular pain, 4 patients (20%) reported complete wellness and healthy status and were submitted to a physical rehabilitation program, one patient (5%) refused prosecution of medical therapies and preferred to be followed by another center, a traditional microdiscectomy was then performed and the patient was considered as *lost at last follow up* (see Table 2). All patients repeated MRI at 3-month *follow-up*. No spontaneous regression of disc prolapse was observed, confirming it as rare incidence in cervical spine.

Patients treated conservatively returned to work after a period varying from 25 to 50 days (mean 46), nevertheless persistence of symptoms revealed their wellness to be very limited and healing could not be defined as complete.

Technical notes

Technical difficulties were encountered at the time of needle introduction into the C6–C7 space in brachytypical patients secondary to the scarce fluoroscopic visualization of the intervertebral disc, also in

Table 2. *Clinical results. Control group*



some cases where an anterior osteophyte or calcification of the anterior longitudinal ligament was present.

Discography with iodate contrast was not performed and no intraoperative prognostic indicators, such as the provocative discography, were described regarding clinical results.

No patients had the same operation again. No complications such as hemorrhages or infections were observed.

Discussion

The low temperatures used during the coblation technique is one of the most important factors for the low percentage of possible complications during surgery when compared to other methods. The three channels created with the ablative energy of the wand allow an internal decompression of the target disc with secondary reduction of intradiscal pressure.

Spontaneous regression of herniated disc is a common natural history in lumbar spine; in cervical spine this incident is rare and respective reports are few. The control group of this study confirms the importance of nucleoplasty and the non-relevant role of conservative medical or physical treatments.

The rate of patients who returned to normal quality of life and work is almost double for patients operated on with nucleoplasty than for those treated conservatively.

Clinical improvement is not always followed by complete regression of the herniated disc on MRI, nevertheless the *follow-up* confirms stabilization of recovery and clinical healing.

Statistical analysis of these data confirmed the clinical results revealing a significant improvement in percentage of patients treated with nucleoplasty ($p \leq 0{,}001$) as if compared to the control group where clinical resolution was not always reached ($p = 0{,}172$).

The possibility for the surgeon to observe neural tissue or vascular damage is almost zero.

In spite of the relatively low case numbers and the limited *follow-up* the encouraging results induce us to utilize this technique in well-selected cases.

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