Nucleoplasty: one-year follow-up

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\abstract

Nucleoplasty, the most advanced form of percutaneous discectomy developed to date, has important advantages as compared to other surgical methods: minimal tissue trauma, faster recovery time, local anesthetic, short duration and a painful rehabilitation period. Since the method is newly adopted in Romania, the aim of our study is to centralize the benefits and the side effects of the method in order to spread it on the national level.

\textbf{Material and methods}: A 12-month prospective, nonrandomized, human clinical study was started in the Neurology Department of the Emergency University Hospital, Bucharest, covering one year time interval (December 2006 – December 2007). The study included 60 patients presenting lumbar pathology at more than one level.

The used method was the Dekompressor, a highly efficient method for removal of intervertebral disc nucleus pulposus under fluoroscopic control. Periprocedural the patients received antibiotics treatment.

\textbf{Results}: Up to date there were no procedure related complications. 89% of patients reported improvement of the symptomatology with almost 60% the first 6 months postprocedural while 92% of patients were satisfied with results for 12 months, reporting the reduction of the analgesic intake. In 4% of cases no benefit was reported. The follow-up of the patients is still on-going.

\textbf{Conclusion}: The results of our study confirm that nucleoplasty provides the therapeutic benefits of earlier percutaneous disc decompression techniques without many side effects. Clinical results are very promising when the inclusion criteria are strictly respected and therefore we encourage the patients to expect rapid and sustained pain reduction after the procedure.

\textbf{Key words}: percutaneous discectomy, nucleoplasty, lumbar pathology, decompression

\introduction

Historically, open surgery has been used to treat \textit{sciatica}, by removing part of the intervertebral disc to provide “decompression” and relieve the pressure of the disc on adjacent nerve roots (1). The use of percutaneous procedures to decompress intervertebral discs dates back to the 1960’s. Early procedures showed conclusively that percutaneous disc decompression relieves pain for appropriate patients. Early procedures had limitations and therefore over the years a...
variety of more advanced techniques have been developed. Minimally-invasive methods have been made available, whereby the entire decompression is performed percutaneously through a needle (2,3).

The most advanced form of percutaneous discectomy developed to date is DISC Nucleoplasty. Introduced in 2000, DISC Nucleoplasty represents a minimally invasive method of disc decompression using a unique plasma technology called Coblation® to remove tissue from the center of the disc.

**AIM**

A number of multi-center randomized controlled trials are currently underway comparing Nucleoplasty to a variety of other treatment options. Since the method is newly adopted in Romania the aim of our study was to centralize the benefits as well as the side effects of the method in order to disseminate it on the national level.

**MATERIAL AND METHODS**

A 12-month prospective, nonrandomized, human clinical study was started in the Neurology Department of the Emergency University Hospital, Bucharest, covering one year time interval (December 2006 – December 2007). The study included 60 patients with age ranged of 35 to 62 years, 40% men and 60% women, presenting lumbar spine degenerative pathology at more than one level, according to the inclusion criteria mentioned bellow. Prior to percutaneous decompression, informed consent was obtained with full disclosure. Inclusion criteria (4)

Patients who can benefit from percutaneous disc decompression are those with pain arising from a contained herniated disc – that is a bulging disc where there is no rupture in the outer wall.

1. Radicular pain associated with contained disc herniation less than or equal to 6 mm
2. Clinical history and physical exam findings consistent with radiographic findings of disc herniation < 6 mm (5)
3. Duration of radicular pain greater than 6 months
4. Failure of conservative therapy including: physical therapy, therapeutic epidural injections (Dexamethasone), oral analgesics and oral or intravenous anti-inflammatory medications
5. Good to excellent short-term (<2 weeks) response to fluoroscopically guided transforaminal injection of local anesthetic and corticosteroid at symptomatic level(s)
6. Confirmatory selective segmental spinal nerve block with 0.5-1.5 cc of anesthetic providing > 80% relief of radicular pain lasting at least the duration of local anesthetic
7. Preservation of disc height (less than 50% loss)

Exclusion criteria (4)

1. Patients with no previous conservative therapy for at least 6 weeks
2. Significant and progressive neurological deficits, reflex change, patients with bladder/bowel functional loss (6,7)
3. Patients with disc extrusion, presence of a disc fragment or with disc height less than 50% of normal
4. More than two symptomatic disc levels
5. Previous open surgery at proposed treatment level
6. Spinal fracture or tumor
7. Extruded disc
8. Complete annular disruption (8)
9. Moderate to severe spinal stenosis
10. Severe degenerative disc disease
11. Bone deformities
12. Significant coexisting medical or psychological condition.

The current and newer techniques promise to further clarify multidermatomal unilateral and bilateral cross-innervation presentations. The used method was the Dekompressor, a highly efficient method for removal of intervertebral disc nucleus pulposus through the smallest available channel under fluoroscopic control. Thus, once the root(s)/level(s) were symptomatically confirmed, the Dekompressor® PLD probe was applied to extract the specific contained herniated nucleus pulposus in question.

**Benefits of Nucleoplasty** (9)

The method presents few advantages such as:

1. Minimal tissue trauma
2. It is performed using x-ray guidance
3. Short duration (less than 15 minutes) (10)
4. Use of local anesthetic drugs
5. painless and rapid rehabilitation period
6. elimination of complications that may result from open surgery
7. quick symptom relief within two weeks for most patients

During the procedure, the DISC Nucleoplasty SpineWand is introduced through a needle and placed into the center of the disc where a series of channels are created to remove tissue from the nucleus. Tissue removal from the nucleus acts to decompress the disc and relieve the pressure exerted by the disc on the nearby nerve root. As pressure is relieved, pain is reduced, consistent with the clinical results of earlier percutaneous discectomy procedures (11,12). Cannulation was technically specific for the herniation location (posterolateral vs. posterolateralcentral) (13).

The procedure is performed by specialists including pain management, neurologist, physiatrist, interventional radiologist and surgeons using x-ray guidance to accurately place the needle in the disc.

RESULTS AND DISCUSSION

Patients were evaluated at 1, 3, 6, and 12 months postoperatively, and were asked to quantify their pain using a visual analog scale ranging from 0 to 10. Patients were also surveyed in regards to their pain medication use, and functional status was quantified by a physical therapist who also used patient reports of ability to perform activities of daily living to assess status. Data were compared between baseline and at 1, 3, 6, and 12 months post-treatment.

In the literature there are mentioned few complications of the procedure (14):

1. Stolke (15) reported a complication rate of 13% with:
   - one death
   - three nerve root injuries
   - 1% discitis rate

2. Ramirez and Thisted (16,17) reviewed 28,000 discectomy procedures with:
   - 1 in 64 patients having a major complication
   - 1 in 335 having a neurological complication
   - 1 in 500 having a cardiovascular complication
   - 1 in 1700 dying from the procedure

3. Bhagia et all showed in 2006, for the 53 patients enrolled, as the most common side effects at 24 hrs postprocedure soreness at the needle insertion site (76%), new numbness and tingling (26%), increased intensity of preprocedure back pain (15%), and new areas of back pain (15%). (18)

In the current case series, percutaneous discectomy with Dekompressor® resulted in significant improvement in functionality, pain scores (VAS) and patient satisfaction in carefully selected patients with radicular pain at 1 year as confirmed by Carey et all in 2000 (19). Furthermore, these results were achieved with small volumes of disc removal (mean 1.25 cc) objectively in all patients within an average of 3 minutes. Follow-up MRI at 1 year has demonstrated as well sustained postoperative reductions in treated contained herniations without accelerated disc degeneration, auger fragmentation or tissue injury (20,21).
Despite the mentioned complications, during the present study, up to date there were no procedure related complications reported. 89% of patients reported improvement of the symptomatology with almost 60% the first 6 months post procedure and 92% of patients were satisfied with results of 12 months post procedure reporting the reduction of the analgesic intake. In 4% of cases there was no benefit of the method.

This report is a follow-up to the initial 12-month study. Discogenic leg pain was purposefully correlated between clinical exam, imaging study and response to the local anesthetic phase dermatomyaly of low-volume selective nerve root blockade. No previously operated disc level was included. Finally, all patients were given ample time to fail more conservative medical management (at least 6 months of rest, physical therapy, medication use and lack of sustained response to epidural and/or selective root block corticosteroid).

**CONCLUSION**

Nucleoplasty provides the therapeutic benefits of earlier percutaneous disc decompression techniques without many side effects. The study obtained safe and effective disc removal and pain relief with the Dekompressor® PLD probe at 1 year.

The preliminary cohort obtained safe and efficacious disc removal when inclusion criteria were strictly respected and therefore the percutaneous disc decompression/discectomy can be successfully integrated into a long-term conservative treatment program for chronic discogenic leg pain but longer follow-up is necessary.

Randomized, controlled studies are required to further evaluate its long-term efficacy.
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