

NUCLEOPLASTY TREATMENT OF CONTAINED HERNIATED DISCS. STARTING A NEW EXPERIENCE

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Low back pain and sciatalgia affect an enormous amount of people, and are considered the most common cause of absence from work, for adult males.

This is largely due to degenerative processes in the intervertebral disk.

The critical review of pathogenetic mechanisms for this pathology has recently recognized the importance of chemical irritative processes.

This entails a reduction in indications for the classical surgical treatment, since mechanical compression has been understood to be a not determinant component of the matter.

Minimally invasive techniques come to be preferred since destructive effect on bony structures is eliminated, and scar formation is dramatically reduced.

The point is avoiding passage through the spinal canal, so that dural sheet is out of the risk of adhesion to ligaments and bone walls.

Coblation nucleoplasty (as proposed by Arthro Care) is a procedure which provokes ablation of the nucleus of the disk by a controlled thermal effect produced by nonconventional radiofrequency.

The apparatus consists of a radiofrequency controller, a patient cable, and an handpiece (Wand).

The system is bipolar and uses coblation technology to ablate and coagulate soft tissue.

The temperature which is obtained is 70°C on the probe and 40°C 1 mm apart from it.

Ablation process consists in ionic dissociation of molecular structure around the tip of the Spine Wand, giving origin to tissue colliquation.

A ionized vapor layer, called plasma is formed, and is the area where energy breaks molecular bonds, resulting in cellular disintegration.

One to two cc of tissue can be colliquated in the global procedure.

The majority of the degradation products will spontaneously come out through the operative canal.

PATIENTS

As proposed by the Protocol for Nucleoplasty for Lumbar Discs, conducted by C. O'Neill, patient's inclusion criteria are:

- 1) age between 18 and 55.
- 2) chronic back pain with or without radicular pain for more than three months with failed conservative treatments (activity modifications, manual therapy and non-steroidal anti-inflammatory drugs)
- 3) provocative discography positive at one level only, with a norma control level

In the period from February to June 2001, we have treated a series of 65 patients, because of lumbosciatalgic pain caused by disc pathology.

The alteration consisted in disk bulging, or contained disk herniation.

CT or MRI investigations had documented L4-L5 level involvement in 53 cases, and L5-S1 level involvement in 12.

The exclusion criteria given by the protocol have been respected.

- 1) Patient has a spinal fracture or tumor;
- 2) Patient had had previous spinal surgery at the same level;
- 3) History of abnormal blood coagulation (unregulated) or use of anticoagulant or anti-platelet therapy (i.e. aspirin);
- 4) Patient is receiving anti-psychotic therapy;
- 5) Patient is an insulin dependent diabetic;
- 6) Patient is pregnant or pregnancy suspected;
- 7) Patient has a cardiac pacemaker;
- 8) Patient has uncontrolled hypertension (systolic pressure > 160 mmHg.).

OUTCOME MEASURES

- 1) Pain (VAS)

The subject will assess their pain in the lumbar region using a VAS at baseline/pre-treatment and again at all post-treatment visits, up to two years.

- 2) Disc morphology (CT/MRI scan)

Disc morphology will be assessed pre-procedure and again at one year and two years post-procedure

- 3) Employment Status – NASS Low Back Pain Outcome Instrument

Employment history and work status (or restored function) will be assessed in part by the patient's ability to return to work as well as their capacity to engage in their pre-operative and full work responsibilities. Employment status will be assessed pre-procedure at again at each visit up to two years

- 4) Medication and Narcotic usage – Included in Follow-up Questionnaire

The subject will be asked about all medication use, frequency and dosage at each visit, up to two years

- 5) Quality of Life – Follow-up Questionnaire and SF-36

Quality of Life measures will be assessed by the follow-up questionnaire pre-procedure, and again at 1 month, 3 month, 6 month, 1 year and 2 years. Additional Quality of life measures will be assessed by the SF-36 questionnaire pre-procedure and again and 6 months and 1 year

The patient is positioned in lateral decubitus, under slight sedation, and under anesthesiological control. The approach to the disc is the posterolateral one, as for all classical percutaneous disc punctions. Fluoroscopic control has allowed a correct location of the probe in the center of the disc during the Nucleoplasty procedure and immediately after Coblation. After discography, the electrode is introduced and the guide retracted to the border of the annulus. The excursion of the electrode from the tip of the guide to the opposite margin of the nucleus pulposus will create a channel of coblated tissue. Since the electrode is slightly curved, when turned around repeating the manoeuvre multiple channels are obtained.

NUCLEOPLASTY PROCEDURE

- 1) Prepare the patient according to standard procedures for discography. Administer intravenously 2 grams Cephalosporin or 1 Gram Vancomycin. Access the disc to be treated using the sterile 17 gauge spinal needle with obturator stylet, in the same manner as for discogram.
- 2) Assure proper placement of the 17 gauge needle (with tip at the annulus-nucleus junction), confirming AP and lateral views with fluoroscopic imaging.
- 3) Using fluoroscopic imaging (as required for discography) and referencing AP and lateral views of the lumbar disc:
 - a. Introduce the Perc-D into the access needle.
 - b. Advance the tip of the wand approximately five (5) mm beyond the tip of the needle and STOP – this ensures the active section of the Perc-D is deployed into the nucleus.
 - c. With the tip of the wand remaining in the nucleus, retract the needle by approx. 5mm (the needle is now within the posterior margin of the annulus).
 - d. Make a circumferential reference mark with a Patient Marking Pen on the shaft of the Perc-D (where it exits from hub at the proximal end of the 17 gauge access needle).
 - e. Advance the tip of the Perc-D into the nucleus the desired distance for the Coblation channel, and make another circumferential reference mark on the shaft of the wand.
 - f. Withdraw the Perc-D to the first reference mark.
- 4) After confirming desired placement in the nucleus, create Coblation channels in the following sequence:
 - a. Orient the tip of the wand in the “12 o'clock” position. Confirm the orientation by ensuring the white dot on the handle of the wand is also at the “12 o'clock” position.
 - b. Use the Coblation mode while advancing the wand into the nucleus to the pre-determined depth.
 - c. Stop advancing the wand, and cease Coblation, when the second reference mark on the shaft is at the entrance into the hub of the 17 gauge needle.
 - d. Use the coagulation mode while withdrawing the Perc-D wand at approximately 0,5 cm/second.
 - e. Stop withdrawing the wand, and cease coagulation, when the first reference mark is at the wand's exit from the hub of the needle.
 - f. Orient tip of the Perc-D wand in the “2 o'clock” position, and repeat steps 3a. through 3e.
 - g. Create additional channels at the 4, 6, 8, and 10 o'clock positions.
- 5) After the channels have been created, withdraw the Perc-D from the 17 gauge needle, and then withdraw needle from the patient.
- 6) Follow standard procedure for post-procedure cleaning of the skin, and place a sterile dressing over the exit site.

NOTES

- 1) The procedure should be performed under local anesthesia to allow for patient monitoring for signs of nerve root irritation.
- 2) When performing Coblation or coagulation with the Perc-D wand, if the patient complains of sudden onset of severe pain or pain in the extremities, you must STOP the procedure, then:
 - a. Closely examine the AP and lateral views under fluoroscopy
 - b. Confirm proper placement of needle tip within the posterior margin of the annulus.
 - c. Confirm proper placement of Perc-D tip within the nucleus.
- 3) If the nerve root or spinal cord come into direct contact with the tip of the Perc-D wand during Coblation or coagulation, then serious nerve injury may result.

POST PROCEDURE

The subject will be discharged from the clinic the same day as the procedure. Prior to discharge the subject will be given instructions for follow up visits. Follow-up visits will be at one month, three months, six months, one year, and two years. Patients will be asked to fill out questionnaires on pain, medication and quality of life as scheduled in Table 4.4. If any adverse events occur, they will be recorded throughout the study.

The risks of the procedure are the possible puncture of the nerve root, or the diffusion of electrical stimuli to the root if the probe is not correctly located.

RISK BENEFITS ANALYSIS

Potential Risks

The device is FDA cleared for spinal surgical procedures and the indications for use are: resection, ablation, and coagulation of soft tissues and hemostasis of blood vessels in spinal procedures.

The risks of this procedures are similar to those associated with discography. There are, however additional risks due to radiofrequency use that are similar to the intradiscal electroThermal (IDET) procedure for discogenic pain.

Radiofrequency devices have the potential to induce neuromuscular stimulation. If in fact the Coblation device comes in direct contact with nerves or nerve roots while being activated, there is the potential of neurological damage.

Potential Benefits

Potential benefits for the subject are: pain relief and functional improvement using a minimally invasive technique as an alternative to open spinal surgery.

RESULTS

The technique is being utilized only since six months and definite result evaluation will come from the multicentric study.

At present evaluation of the results at six months shows that we have obtained positive outcomes in 83% of cases.

The quality of the results increases in the arch of the first three months postoperatively.

No side effects have been observed in the cases we have treated.

In our opinion the technique that C. O'Neill is proposing is quite effective in cases of contained disc pathology, which are the most difficult to treat in terms of conservative treatment by physical therapy, or drugs, but which are not an indication to surgery.