

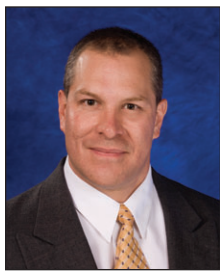
Minimally-Invasive, Interventional Spine Treatment — PART II

Diagnostic and therapeutic intradiscal interventions for pain generated from internal disc disruption.



In the last issue, we examined the common procedures and spinal injections not exclusively involving the discs and presented the most common spinal procedures utilized to diagnose and treat spinal (axial/radicular) pain. We continue our examination of the importance of minimally invasive interventional spinal treatment with a focus on pain generated from the spinal intervertebral discs.

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Diagnostic Provocation Discographic Injections

Lumbar provocation discography remains a controversial diagnostic technique; and even more so with cervical/thoracic discography. To appreciate the historical controversy surrounding discography is to understand that its inception was a tenuous one, tainted by admonitions, suppositions, and contradictions. Proponents believe discography uniquely shows internal disc anatomy and identifies clinically symptomatic (painful), or asymptomatic (non-painful) discs. In 1934, Mixer and Barr first called attention to the pathoanatomy of the herniated lumbar disc and its relationship to radicular dysfunction from neural compression. In 1952, Pierre Erlacher established the correlation of the nucleogram to nuclear anatomy by investigating cadaveric discs using contrast material and histological stains. The precise technique for lumbar discography was described in 1952 by Cloward and Bussard. Since those initial procedures were performed, improved techniques and technological advances — and a better understanding of pain — have provided much needed refinement of discography as a potentially valuable diagnostic test.

The presence of degenerative disc changes does not necessarily correlate with clinical symptoms or a painful internal disc. Provocative diagnostic testing for concordant discogenic pain is the most important aspect of discography and provides information regarding the clinical significance of concordant disc abnormalities. There is literature that suggests that the presence of outer annular fissures/ruptures (i.e., HIZ, high intensity zones) are significant predictors of a painful degenerative disc rather than the degree of disc deterioration. CT-discography has been shown to have higher sensitivity and specificity than individual CT scans, myelography, and CT-myelography for internal disc disruption (IDD, a chemically-mediated abnormality of the nucleus pulposus and annulus fibrosus with/without disc contour defects), herniated nucleus pulposus (HNP), recurrent disc herniation, and foraminal disc herniation. CT-discography interpretation is highly reproducible for grading annular de-

generation and disruption (e.g., Dallas Discography Criteria). The presence of a “high intensity zone” (HIZ) on magnetic resonance imaging (MRI) has been shown to correlate 100% with an outer annular rupture by CT-discography imaging, although 54% of discs with annular ruptures did not show a HIZ on MRI. The sensitivity and specificity of an HIZ in identifying those discs that exactly reproduce discographic pain was 82% and 89%, respectively. Although MRI with gadolinium may be more accurate than CT-discography in distinguishing recurrent disc herniations from postoperative scar tissue, CT-discography is more sensitive than myelography, CT scans, or CT-myelography for determining intradiscal morphology. At the present time, MRI does not appear to be as sensitive or specific as CT-discography in determining whether or not a disc is symptomatic. Discography and CT-discography have found abnormalities despite normal MRI scans and, conversely, found asymptomatic discs in the presence of significantly abnormal MRI studies. Although MRI can reliably detect disc degeneration and, in certain cases, predict painful annular ruptures, many believe that only provocative discography can consistently determine the presence or absence of symptomatic annular ruptures/fissures.

Lumbar discography uniquely tests for concordant pain reproduction in addition to investigating the internal disc structural integrity. In cases of IDD and indeterminate nuclear changes on MRI, discography can be beneficial. The major indications for lumbar discography include:

- Surgical planning for a lumbar fusion/artificial disc replacement/percutaneous disc decompression.
- Identifying the presence or absence of a painful disc among multiple degenerative discs;
- Testing the structural integrity of an adjacent disc to a known abnormality such as spondylolisthesis or fusion;
- Evaluating a suspected lateral/foraminal or recurrent disc herniation.

In addition, discography is an integral part of intradiscal therapeutic procedures (e.g., intradiscal electrothermal annuloplasty/decompression, annular denervation, percutaneous radiofrequency/laser microdiscectomy). According to the 1988 Position

Statement on Discography by the Executive Committee of the North American Spine Society: "Discography is indicated in the evaluation of patients with unremitting spinal pain, with or without extremity pain, of greater than 4 month's duration, when the pain has been unresponsive to all appropriate methods of conservative therapy..." Although controversial, the concept of discogenic pain is described as a centralized/axial, nonradicular pain produced during certain provocative maneuvers. Patients can also have diffuse, nondermatomal lower limb pain that is associated with the lower back pain but not typically in isolation. Lumbar discography is believed to identify the presence or absence of symptomatic discs in patients with chronic axial low back pain. Therefore, proponents argue that the value of discography lies in its ability to provocatively test the discs for reproduction of discogenic back and, occasionally, leg pain.

In appropriately trained hands, the risk of complications from lumbar discography is very minimal. Potential complications from discography include discitis, nerve root injury, subarachnoid puncture, chemical meningitis, bleeding, and allergic reactions. These adverse events can be minimized by pre-treating individuals for contrast dye allergies, using non-ionic contrast dye, and using meticulous sterile techniques. Prophylactic antibiotics (intravenous, intradiscal, and oral) may substantially further decrease the risk of infections.¹⁻³³

Therapeutic Intradiscal Procedures

The application of lumbar discography in diagnosing internal disc disruption (IDD) has provided the interventional spinal specialist with information in order to consider various non-surgical and surgical treatment options. The following sections briefly discuss some of the methods of minimally-invasive therapeutic intradiscal procedures which are being used for internal disc disruption and contained disc herniations:

- IntraDiscal ElectroThermal (IDET/EDD) Annuloplasty/Decompression,
- Percutaneous Mechanical Disc Decompression (DeKompressor)
- Percutaneous Laser Disc Decompression (PLDD-LASE), and
- Percutaneous Radiofrequency (RF) Intradiscal (Nucleoplasty)/Annular (DiscTrode) Neurolysis.

IntraDiscal ElectroThermal (IDET/EDD) Annuloplasty

IDET/EDD annuloplasty (using the SpineCATH Intradiscal Catheter; Smith-Nephew, Inc.) is a novel addition to the interventional physician's armamentarium of treatments for patients with painful degenerative disc disease and IDD. IDET/EDD provides a new outpatient treatment option for patients who would not be recommended for—or who do not elect—other more invasive treatments such as lumbar disc surgery (i.e., open discectomy or surgical fusion). The SpineCATH intradiscal catheter has been approved by the Federal Drug Administration (FDA) for use in treating symptomatic patients with annular disruption of contained lumbar herniated discs. This new technology has been developed to safely treat intervertebral discs in a minimally-invasive manner and still provide physicians with a definitive approach to addressing internal disc disruption. The intradiscal catheter delivers controlled thermal energy directly to the annular wall and disc nucleus via a resistive heating coil; which then aims to create temperature-controlled coagulation and shrinkage of intradiscal collagenous tissue. The SpineCATH system was developed to thermo-coagulate annular tissue/nociceptors, thermally modulate intradiscal collagen tissue, cauterize granulation tissue, as well as reduce nuclear volume in small, contained disc herniations. The steerable catheter design allows for precise intradiscal navigation for percutaneous spinal intervention. Usually performed under light conscious sedation, the catheter is inserted through a 17-gauge introducer trocar needle and is easily positioned with fluoroscopic guidance. Since this procedure is significantly less invasive than other disc surgeries; the result is a percutaneous, outpatient procedure that is no more invasive than a lumbar discogram. The initial success rate for the procedure, variably depending on patient selection, has been noted to be around 60-75%.

The disc itself is a virtually avascular structure which allows heat to be held in the tissue with relatively little fluctuation during treatment. Adjacent structures are protected from thermal injury by the vascular circulation outside the disc which quickly dissipates any heat conducted beyond the disc. Temperature and power control give the IDET/EDD catheter the optimal ability to deliver focused energy

at the point of contact. Heat is transferred by conduction from the catheter to the adjacent disc tissue. Temperature sensors deliver feedback to the generator which adjusts power levels as necessary to reach and maintain set target catheter temperatures. Optimum treatment temperatures are followed as previously documented in temperature mapping experiments done in the cadaveric and in-vivo validation studies. These mapping studies indicated that optimal temperature levels (80–90 deg C) are reached for achieving collagen modulation and for nociceptor destruction in the outer annular wall (47-49 deg C)—while maintaining low epidural temperature levels (maximum 40.6 deg C) to avoid damaging myelinated nerves. The generator controls the SpineCATH catheter temperature accurately and precisely to maintain the optimum treatment temperature. These validation studies also documented an average total disc volume reduction of 12.7% (range: 10-16.7%) due to morphologic changes in the outer disc surface. It was estimated that in the area of treated tissue alone (tissue reaching at least 60 degrees C) there was an approximate 40% decrease in disc tissue volume.

The indications noted for the IDET/EDD annuloplasty procedure include axial back pain and mild referred leg pain due to symptomatic (painful) internally disrupted disc with annular fissures (documented through discography) and symptomatic (painful) contained-disc herniation without significant radicular symptoms. Other potential IDET/EDD candidates include:

- Patients with discogenic pain after a previous discectomy;
- Disc space volume >50%;
- Some multi-level degenerative disc disease involvement;
- Discogenic pain above or below a previous fusion.

The procedure is contraindicated in patients with the following:

- Severe radicular symptoms due to frankly herniated discs or sequestered/extruded discs on MRI;
- Compressive pathology due to significant spinal stenosis;
- Segmental instability/lithesis;
- Severely collapsed discs (<50% disc volume).

The complications are similar to those noted in the discography section previously stated.

Percutaneous Mechanical Disc Decompression (DeKompressor)

Percutaneous lumbar discectomy (PLD) procedures have been around for over three decades, in one form or another, using different technologies for relief of axial lower back and radicular pain; and with success rates of over 90%, for open surgical discectomy over the last 50 years. Benefits resulting from the use of PLD techniques have been reported to include: good-excellent success rates, reduced procedural trauma, lower outpatient treatment costs, rapid post-surgical rehabilitation progress, and lower morbidity rates. Less invasive methods for percutaneous discectomy and intradiscal disc decompression will play an important role in the future treatment of patients suffering from the effects of disc herniations/compressions. The “DeKompressor” (from Stryker, Inc.) involves a 1.5mm diameter percutaneous lumbar discectomy probe to perform mechanical disc decompressions using a highly efficient, minimally-invasive mechanical method for aspiration and removal of intervertebral disc nucleus pulposus — via creating a channel and intradiscal evacuation entirely under fluoroscopic guidance. The patented probe tip utilizes an Archimede’s extraction pump principle to mechanically remove nucleus pulposus from the affected disc herniation or contained disc bulge. This results in intradiscal pressure reduction and subsequent decompression of the surrounding affected nerve root with resulting radicular/axial pain relief. Further controlled, randomized clinical research studies are needed to validate this technique although, under good selection criteria guidelines, the initial results seem promising.

Percutaneous Laser Disc Decompression (PLDD)

The PLDD procedure has been around for over two decades in one form or another using different laser types, technology, and methodology. The LASE method (Clarus Medical Systems, Inc., Minneapolis, MN) of PLDD is relatively new (within 15 years) with an endoscopically, visualized fiberoptic scope and utilizing the Holmium YAG laser. The technique is designed to reduce the bulging nucleus enough to eliminate the pressure it is placing on the surrounding nerve. A miniature endoscope with a laser fiber is inserted into the disc, leaving an incision

through the skin which is less than 0.25 inch. The LASE endoscope allows the physician to view the bulging nucleus tissue and remove it with the laser fiber using high temperature thermocoagulation/extraction. By removing/thermocoagulating the affected nuclear disc tissue with concurrent suction/lavage of extracted tissue, the pressure on the injured nerve root is reduced or eliminated along with the resultant pain. Over 50,000 LASE procedures have been performed since inception. Multiple studies have shown that around 80% of properly selected patients with contained herniated discs having lower back and leg pain, may benefit from this procedure. The essence of the procedure is that it performs an outpatient discectomy without the risks of routine open invasive surgery. The procedural recovery time is approximately 2-4 weeks. Although not a panacea, the procedure is less indicated in primarily axial back pain of discogenic etiology, lumbar stenosis due to degenerative conditions, or failed back surgery syndrome with perineural scar tissue. The complications and risks are similar to those noted for the IDET and lumbar discography procedures.

Percutaneous Radiofrequency (RF) Intradiscal/Annular Neurolysis

Percutaneous Radiofrequency (RF) Annular Neurolysis or Denervation was developed primarily by M.E. Sluijter in the 1980’s. Dr. Sluijter proposed a method to denervate the intervertebral disc through thermocoagulation and reported a series of patients who had obtained relief of their chronic low back pain with annular denervation. It was proposed as a treatment for internal disc disruption (IDD) and painful disc degeneration (PDD). Annular denervation uses the same technology used in percutaneous radiofrequency (RF) neurolysis utilized to treat spasticity, malignant pain, trigeminal neuralgia, and zygapophyseal joint medial branch nerve pain. Dr. Sluijter theorized that intradiscal placement of a RF probe would globally increase disc temperature and produce neurolysis of the nociceptive fibers found in the outer annulus. Critics argued that the lesion generated by the RF probe (which technically only covers a 6mm radius from the probe tip) would not reach the annular fibers but previous studies have noted elliptical or spheroid denervation areas secondary to induced

tissue temperature elevation and not from any direct heating effects of the probe itself. Therefore the area of coagulation is dependent on temperature, probe size, and probe orientation. Similar to the IDET and PLDD procedures, the RF annular denervation procedure needs further clinical studies and consistent clinical results but seems safe for the treatment of IDD and PDD refractory to conservative care (e.g., Radionics DiscTrode Annuloplasty). The indications, risks, and complications are similar to the IDET, PLDD, and lumbar discography procedures. The risk of infection, hemorrhage, and neurologic insult is considered to be significantly reduced when compared with any open surgical disc procedure.³⁴⁻⁵⁵

Percutaneous intranuclear radiofrequency discectomy (e.g., Arthrocare Disc Nucleoplasty), a minimally-invasive intradiscal procedure utilizing a patented “Coablation” technology for the ablation and coagulation of intradiscal soft tissue, combines elements of previous approaches for partial decompression of nucleus pulposus. The procedure builds upon the benefits of these previous approaches by providing a more controlled, efficient, and practical method of nuclear tissue extraction, while retaining the underlying minimally-invasive rationale. Originally devised by ArthroCare Corp. in Sunnyvale, California, disc nucleoplasty utilizes a multifunctional bipolar radiofrequency device which generates a “cold-energy” plasma-enhanced process, in which radiofrequency energy is applied to a conductive medium (saline) to generate a precisely-focused, low-temperature ionic plasma field around the electrode at the tip of Perc-DLE/DLR SpineWand (“Coablation”). The plasma of highly-ionized particles have enough energy to break the molecular bonds within tissue at low temperatures (~40-70 deg C). A series of 6-9 channels are created in the disc nucleus by radiofrequency ablation and coagulating tissue. Approximately 1-2 cc of nuclear tissue, or roughly 10-15% of nucleus pulposus is thus thermally removed. This highly-focused, controlled thermal coablation technique allows an effective percutaneous disc decompression with minimal risk of thermal injury to surrounding tissue. The procedure is performed in an outpatient setting with fluoroscopic guidance and conscious sedation. Initial clinical study results up to one to two years following the procedure have

shown that VAS pain scores, as well as narcotic use are substantially reduced; with patient satisfaction as high as 89%. However, further prospective, controlled, randomized studies should be undertaken to demonstrate the benefits, limitations, and clinical outcomes of this novel procedure.

Conclusions

Part II of this two part series has examined the diagnostic and therapeutic intradiscal, minimally-invasive interventions available for treatment of pain originating from spinal vertebral discs. The objective of these minimally-invasive interventional techniques is to diagnose and stabilize spinal-based pathologies that generate pain so that the patient can engage in comprehensive rehabilitation and subsequent improvements in quality of life with reduction in overall pain conditions. The combination of these therapeutic intradiscal procedures—together with neuromuscular rehabilitation—continues to demonstrate exceptional results. ■

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