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Percutaneous disc decompression in the management of chronic low back pain

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Low back pain (LBP) has been estimated as the leading cause of disability in the United States for patients less than 45 years of age and the second leading cause of missed workdays. It has been estimated that 60%–80% of adults experience significant back pain at some time during their lifetime [1]. The annual social and economic costs are great, with more than 10 million individuals affected and more than \$20 billion spent on treatment [2]. In the past, treatment options were limited, given the difficulty of diagnosing specific sources of LBP. New advances in technology have provided insights into different causes of LBP [3,4] and have refined our ability to treat a variety of back conditions.

Among the various etiologies of LBP, discogenic pain is believed to arise from annular fissures extending from the nucleus to the outer annulus. Nerve endings may become exposed to enzymes and degradation products. The combination of mechanical loading and neural and inflammatory factors leads to discogenic pain [5,6]. When the nucleus pulposus herniates through the annular fissures into the spinal canal and compresses neural structures, the clinical picture of sciatica/radicular pain is observed.

Most cases of LBP and sciatica improve with 4–6 weeks of conservative treatment consisting of limited bed rest (1–2 days), nonsteroidal antiinflammatory medications, exercise regimens, epidural steroids, and patient education [7]. Approximately one third of patients with chronic discogenic LBP confirmed by discography do not respond to conservative treatment alone [8]. When legitimate incapacitating

symptoms continue despite conservative treatment attempts, more invasive spinal procedures and intradiscal treatment may be appropriate [7]. Surgery, typically involving laminectomy and microdiscectomy, has been shown to have excellent clinical outcomes in patients with disc extrusion and neurologic deficits. Patients with disc herniation <6 mm, however, have fair or poor surgical outcomes [9]. In addition, conventional open disc surgery entails risks of general anesthesia, nerve damage during access to the spinal canal, epidural fibrosis, consequent chronic postoperative pain syndrome, and adjacent spinal instability [10,11].

Over the last 40 years several percutaneous intradiscal therapies have been developed for disc decompression to relieve chronic discogenic back pain or radicular leg pain without the risks of open disc surgery. These minimally invasive procedures include chemonucleolysis, percutaneous nucleotomy, percutaneous discectomy, and intradiscal laser treatments. These procedures have been shown to reduce intradiscal pressure [12,13], but they all have their limitations.

Percutaneous intradiscal procedures

Minimally invasive techniques providing percutaneous access to pain-generating discs have been developed to treat discogenic LBP or sciatica. Chemonucleolysis, percutaneous nucleotomy, automated percutaneous lumbar discectomy, intradiscal laser discectomy, intradiscal radiofrequency ablation, Intradiscal Electrothermal Annuloplasty (IDET), and nucleoplasty are techniques that incorporate this approach. These techniques have been used for treating

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discogenic LBP or radiculopathy by way of partial removal of the nucleus pulposus to reduce intradiscal pressure. Partial removal of the nucleus pulposus has been shown to decompress herniated discs, relieving pressure on nerve roots and, in some cases, offering relief from discogenic pain [13–15].

Chemonucleolysis

Chemonucleolysis using chymopapain, the first percutaneous intradiscal therapy, involves enzymatic dissolution of nucleus pulposus by way of hydrolysis of the charged proteoglycan component in the nucleus pulposus [16]. After the first isolation of chymopapain from crude papain derived from the papaya fruit in 1941 [17], animal studies pursued possible clinical applications [14,18,19]. In 1963, chymopapain first was injected in a human patient for the treatment of unremitting sciatica caused by a herniated lumbar nucleus pulposus [20]. This procedure predominantly relieves radicular pain rather than back pain. Proper patient selection is paramount for the success of chemonucleolysis. Classic indications are symptomatic lumbar disc displacement indicated by MRI, CT scan, or myelography, and absence of other major causes of symptoms.

For the next 20 years, the efficacy of chymopapain was examined in clinical trials, and Chymodiactin, a new formulation of chymopapain, was approved for clinical use in 1983 [14]; however, complications began to be reported. Intense back pain and stiffness were observed in 20%–40% of cases. Though rare, fatal complications such as anaphylaxis, transverse myelitis, cartilaginous endplate damage, and hemorrhage were reported [16,21,22]. It was suggested that an anaphylactic immunologic reaction induced by antigens of the chymopapain protein and neurotoxicity were the main causes of adverse affects [23,24].

Although less allergenic enzymes have been discovered, they are restricted to use in animal studies (eg, chondroitinase ABC) [25,26] or there are insufficient data to support clinical use [27]. The manufacture and distribution of Chymodiactin was ceased in October 1999, ending for the time being its use in the United States [14]. Despite terminated use of chymopapain in most centers in the United States, some physicians continue to state that chemonucleolysis is safe, effective, and economical given appropriate patient selection and proper surgical technique [28].

Percutaneous discectomy

Since the 1970s, percutaneous discectomy by way of manual nucleotomy through a cannula [10,13,29]

and automated percutaneous lumbar discectomy (APLD) [10,13,30] were developed.

Percutaneous manual nucleotomy

In 1950, annular puncture was used to allow the disc to extrude into the retroperitoneum and not into the spinal canal [31]. The technique involved the use of specialized forceps and curettes to remove the disc through a cannula placed percutaneously on the posterolateral aspect of the annulus first introduced by Hijikata et al in 1975 [29]. Thereafter, some development in equipment continued, and published studies demonstrated safety and efficacy. This technique has not been widely accepted or practiced because of several factors, including high complication rate, technical difficulty performing in the L5-S1 interspace and on obese patients, and large cannula size [14].

APLD (Automated percutaneous lumbar discectomy)

Onik et al redesigned and reengineered the percutaneous discectomy technique, introducing the automated technique for disc removal in 1984 [30]. An 8-inch-long probe is inserted through a 2.5-mm cannula positioned against the annulus fibrosus and used both as a cutting instrument and for aspiration of disc material. Following development of an instrument permitting safe puncture of the L5-S1 interspace [32], use of this technique was increased and expanded for treatment of far-lateral disc herniations [33]. Patient selection criteria are critical. If disc herniation is >50% of the anteroposterior diameter of the spinal canal or extruded disc fragments are observed by neuroimaging, the outcome will be poor [34].

Despite its simplicity and the desirability of less invasive approaches, many investigators have not embraced APLD for herniated disc treatment. Clinical efficacy studies have reported various success rates ranging from 29%–80% [14,35,36]. Aside from the initial result reported by Maroon and Onik [37], clinical efficacy has not been well demonstrated. In addition, Onik and Epstein reported major cauda equina syndrome in patients treated using inappropriate techniques [38,39]; however, clinical studies continue and APLD remains a significant, minimally invasive technique for herniated disc.

Intradiscal laser discectomy

This intradiscal treatment technique uses laser energy to vaporize part of the nucleus volume to debulk the disc space and decrease discal pressure for regression of disc protrusion. Use of the laser in intradiscal procedures began in the 1980s [40]. Various types of lasers have been evaluated for effec-

tiveness, safety, and ease of use [15,41]. The most common lasers for disc decompression are potassium-titanyl-phosphate (KTP), neodymium:yttrium-aluminum-garnet (Nd:YAG), and holmium:YAG (Ho:YAG). The Nd:YAG laser has not been approved yet for use in the United States. The choice of laser depends on its ability to deliver energy through a fiberoptic system, tissue absorption/ablation properties, and the amount of thermal generation and spread. Theoretically, various complications from thermal damage to adjacent structures are possible. These complications can be avoided when the procedure is performed correctly [42].

Laser discectomy yields variable success rates depending on the type of laser energy used [41, 43,44] and is significantly less effective than chemonucleolysis [45]. Percutaneous laser nucleolysis is more expensive than APLD and has been shown to have inadequate temperature control, causing damage in nerve root tissue, the vertebral body, and endplates [12,46,47]. As a result, at this time laser discectomy has a limited role in the management of patients with LBP and sciatica. New developments in lasers and endoscopy that improve the view field may facilitate use of this technique for percutaneous disc decompression and may permit treatment of more severe herniated discs.

Intradiscal radiofrequency ablation

Intradiscal radiofrequency (RF) ablation is the fifth percutaneous disc treatment developed for treating chronic LBP. A high frequency alternating current flows through the intradiscal needle electrode to produce a lesion in the nucleus pulposus, reducing nociceptive input from a painful intervertebral disc.

Innervation of the disc is complex. Intervertebral discs are surrounded by a continuous network of nerve fibers innervating the outer and inner annulus fibrosis [48]. As a result, selective denervation is not possible. It has been suggested that percutaneous intradiscal radiofrequency thermocoagulation (PIRFT) might be used to reduce nociceptive input from the intervertebral disc [49]. In this technique, an RF-lesion is made in the center of the disc using the disc material as a vehicle for heat, causing thermal damage to free nerve endings in the outer annulus fibrosis. This technique cannot transfer adequate thermal energy for discal nerve tissue ablation, however, and a straight needle system cannot access the broad expanse of the posterior annular wall where nociceptors are located [50]. Instead, adjacent tissues are subject to rapid heating, vaporization, or pyrolysis. Needle positioning and heating parameters need

to be further clarified by way of future research and efficacy of intradiscal radiofrequency treatment for discogenic LBP [49,51].

Intradiscal electrothermal annuloplasty

Intradiscal electrothermal annuloplasty (IDET) is a minimally invasive procedure for managing chronic low back pain of discogenic origin in patients failing conservative treatment regimens and who otherwise may be a candidate for spinal fusion [52,53]. The therapeutic efficacy of intradiscal heating depends on the transfer of heat through the nucleus, annulus, or both. The IDET procedure may relieve discogenic pain through numerous mechanisms, including alteration of spinal segment mechanics by way of collagen modification, thermal nociceptive fiber destruction, biochemical mediation of inflammation [54], stimulation of an outer annular healing response, cauterization of vascular ingrowth, and induced healing of annular tears [55]. This procedure is not for decreasing intradiscal pressure, therefore, but rather to relieve pain by way of thermal ablation of nerve endings. Typical IDET procedures can generate sufficient heat to produce nerve ablation [56]. Placement of the heating element in the middle or outer annulus within 5–10 mm more readily achieves desired temperatures.

Putative selection criteria include unremitting LBP of at least 6 months' duration unimproved by aggressive nonoperative care, negative SLR, MRI negative for a neural compressive lesion, <30% decrease in disc height, positive low pressure discography (generally <30 psi above opening), no prior surgery, disc protrusion less than 3 mm, and absence of instability and stenosis [57].

Initial results for IDET shown by Derby et al [58] and Saal et al [54] gave positive response rates of 73% and 80%, respectively. Early studies, however, were reported by physicians with a positive bias for the procedure. Subsequent studies [59–61] have shown average decreases in visual analog scale (VAS) scores of 62.5%–72%, with decreases in SF36 body pain of 59%–78% and reported similar outcomes: one third of the patients were significantly better, one third slightly or questionably better, and one third the same or worse. Proper catheter position is key. Derby et al reported that 73% of patients with good to excellent catheter position had a favorable outcome. Only 16.5% of those with fair catheter placement had good outcomes [60]. Spinal fusion was performed in less than 5% of patients treated with IDET, although some patients require spinal surgery 6–18 months after the procedure [62].

Nucleoplasty

Nucleoplasty, approved by the Food and Drug Administration for treatment of contained herniated discs as of June 2001, builds on the earlier percutaneous intradiscal treatment concepts of chemonucleolysis and nucleotomy and radiofrequency ablation. During conventional electrosurgery, local tissue temperatures can be in excess of 400°C, with rapid tissue heating, significant collateral tissue damage, and deep thermal penetration. In contrast, nucleoplasty is a non-heat-driven process that uses Coblation technology, using bipolar radiofrequency technology applied to a conductive medium (eg, saline) to achieve tissue removal with minimal thermal damage to collateral tissues. This process creates a plasma field of highly ionized particles surrounding the electrode that have adequate energy to disintegrate molecular bonds within the nucleus material. Temperature is kept less than 70°C to minimize thermal penetration and adjacent tissue damage. A recent study demonstrated minimal increased temperature in adjacent neurovascular structures (spinal cord, nerve root, and vasculature) when Coblation was performed at a distance greater than or equal to 5 mm away, that is, when Coblation is performed at the central portion of the disc [63]. The products of the non-heat-driven process are elementary particles and low molecular weight gases that are removed quickly from the surgical site. The Coblation technique thus causes a localized, low temperature molecular disintegration. The result is volumetric nucleus tissue removal by way of creation of multiple intradiscal channels by the wand, with minimal collateral tissue necrosis, as illustrated in a recent histologic study [64]. These channels then are sealed by way of coagulation following withdrawal of the wand.

Reductions in nuclear tissue volume on the order of 10% have been observed. Pain reduction may arise from a decrease in intradiscal pressure. Because this is a new method, few outcome studies have been completed. In one study, nucleoplasty gave an overall 79% success rate with a 67% success rate in patients with previous surgery [65]. Like other decompressive techniques, this procedure is designed to treat patients with extremity pain caused by smaller disc protrusions. There is a growing trend to perform nuclear decompression and heating treatments in the same session [66].

In a study by Derby [67], discs that were diagnostic for reproducing back pain during discography could be categorized into low-pressure sensitive discs (also known as chemically sensitive discs) and mechanically sensitive discs. Low-pressure sensitive disc

levels are sensitized to reproduce concordant pain when there is small increase (lower than that of physiologic mechanical load) in intradiscal pressure; mechanically sensitive discs are painful only if high pressure is applied into the disc, implying other structural pathology contributing to pain. It is reasonable to suspect that the small reduction in intradiscal pressure during nucleoplasty is more efficacious for chemically sensitive discs when small changes in pressure provide relief, whereas intradiscal pressure reduction may not take away most pain from mechanically sensitive discs with multiple pain sources. Previous studies have demonstrated that after intradiscal pressure reduction, water may be reabsorbed quickly, and the disc gains height, volume, and elasticity [68]. A cadaveric study by the first two authors demonstrated that nucleoplasty was highly effective at reducing intradiscal pressure in nondegenerated contained discs, but had minimal effect in reducing intradiscal pressure in severely degenerative discs [68] in which most nucleus material already has desiccated. Nucleoplasty thus is not effective in treating severely degenerated discs.

Technically, nucleoplasty is performed easily by experienced interventional spine specialists who feel comfortable with needle placement in discography procedures. In the authors' hands, nucleoplasty is easier to perform than nucleotomy. One does not have to pre-bend the introducer needle for the L5/S1 space because of its relatively small 17-gauge introducer needle. To ensure patient comfort and to prevent inadvertent nerve root injury, the authors recommend performing a radiculogram prior to disc puncture, permitting visualization of the spinal nerve roots via injected contrast media. During Coblation, patients usually do not feel discomfort, because ablation and coagulation take place within the nucleus with minimum sensory innervation. The patient should be monitored closely and should remain awake and responsive throughout the procedure to provide information to the treating physician. Despite evidence of safety [63], the authors find it imperative to be aware of any extreme pain or neurologic symptoms in the back or leg that may indicate damage to vital neural elements during nucleoplasty. In doing so, the physician can reposition the instrument rapidly or abort the procedure to avoid potential neurovascular damage. Discography is not required when the patient presents with classic clinical symptoms of radiculopathy consistent with corresponding MRI or electrodiagnostic (EDX) findings.

Making too large of a channel may afford rapid contraction of intervertebral disc volume, which, based on poor results obtained with nucleotomies

when large volumes of nucleus volume were removed, may affect outcome adversely [69]. In addition to mechanical factors, intradiscal thermal effects may play a role in nucleoplasty either by way of collagen remodeling and thickening or thermocoagulation of abundant nociceptors (eg, small, unmyelinated fibers) and sensitized mechanoreceptors [6,60,70] within the symptomatic discs.

Even though sufficient clinical safety data has not yet been reported, it seems likely that a good outcome may be obtained when the procedure is performed using strict patient selection criteria as follows: normal psychometric test, chronic discogenic LBP, adequate disc height (>50% of normal), contained disc herniation <6 mm, radicular symptoms (patient presented clinically with sciatica with mild positive sitting straight leg raise without paresis or paralysis on examination with correlation of MRI findings).

Clinical experience with this new technology in a larger patient population over a longer follow-up period is needed to validate its benefits. In the early stages of investigation, nucleoplasty seems to be a promising treatment for contained disc herniation (<6 mm) with or without radiculopathy and as a potential alternative to other minimally invasive percutaneous disc decompression procedures. Nucleoplasty does not replace microdiscectomy or fusion. Nucleoplasty may serve as an armamentarium, however, filling the gap between conservative treatments and open spinal procedures.

Summary

Although there has not yet been a percutaneous intradiscal procedure developed with the superior therapeutic efficacy of open surgery, these procedures are less invasive and avoid the complications of open surgery. All of these procedures have limitations, but their therapeutic effect increases substantially given careful patient selection and proper technique. New appliances and techniques to treat LBP or sciatica continue to evolve, and numerous controlled studies are underway. With tremendous technologic advances, use of minimally invasive techniques to treat chronic back pain continues to expand.

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