ORIGINAL ARTICLE

# Efficacy of IDET for Relief of Leg Pain Associated with Discogenic Low Back Pain

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■ **Abstract:** Intradiscal electrothermal annuloplasty (IDET) is an effective treatment for chronic discogenic low back pain (LBP). However, efficacy of IDET for the treatment of referred leg pain has not been examined. This study was performed to assess the long-term efficacy of IDET for the treatment of referred leg pain in chronic discogenic LBP patients. Data were retrospectively analyzed as an IDET case series from January 1999 to December 2000. The IDET procedure was performed at 1–3 symptomatic levels confirmed by pressure-controlled discography. General pain outcome was evaluated by Visual Analog Scale (VAS). LBP and leg pain were assessed separately using five-point pain scales (subsets of the North American Spine Society [NASS] LBP outcome assessment instrument: 0 = no pain, 4 = worst pain) at the 18-month follow-up. Among 129 patients who underwent IDET, 30 patients underwent subsequent back surgery and were excluded from the study, giving a total of 99 patients. Eighty-three patients (83.8%) had leg pain without sciatica. Fifty-two (52.5%), 21 (21.2%), and 8 (8.0%) patients showed LBP > leg pain, LBP = leg pain and LBP < leg pain, respectively. Fifty-three out of 83 patients (63.9%) showed post-IDET improvement in pain, with a mean VAS score of 3.28 ± 2.31. Thirty patients (36.1%) showed no improvement. A statistically significant ($P < 0.05$) improvement in subjective back and referred leg pain was observed. Improvements in back and referred leg pain were well-correlated ($r = 0.721$, $P < 0.01$). A relatively large number of LBP patients who underwent IDET (84%) presented with referred leg pain without sciatica. The IDET procedure afforded improvements in leg pain that correlated well with improvements in back pain (0.75/4 and 0.88/4, respectively). These data suggest that IDET may relieve associated limb pain in chronic discogenic LBP patients. ■

**Key Words:** IDET, leg pain, discogenic low back pain

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## INTRODUCTION

Up to 70 % of patients with chronic axial low back pain (LBP) without nerve root involvement either present with or report previously experiencing referred limb symptoms.[1,2] While radicular pain originates from the irritation of a spinal nerve or neurons in the dorsal root ganglion, referred pain describes pain that is not localized at the site of its cause, but occurs at an adjacent or distant area. The suggested physiologic basis for referred pain is convergence of afferent neurons onto common neurons within the central nervous system, such that it is difficult to distinguish which part of the body is responsible for input.[3]

Somatic afferents from the lumbar spine (eg, muscles, ligaments, facet joints, and intervertebral discs) converge on the same neurons in the dorsal horn as afferent nerves from the lower extremity.[4,5] Experimental studies[6,7] have shown that referred leg pain may be reproduced via noxious stimulation of the interspinous ligament, facet joint, and paravertebral muscles. In vivo human study has demonstrated that noxious stimulation of the intervertebral disc causes referred pain that can radiate into the distal extremity and may extend below the knee.[6]

Because discogenic LBP patients may have accompanying referred leg pain, treatments such as IDET might prove beneficial for the treatment of associated leg symptoms without involvement of spinal nerve root. IDET is a well-accepted treatment for chronic discogenic LBP.[8–11] Although there is considerable controversy regarding the mechanism of IDET, data have suggested that the destruction of nociceptive nerve endings and/or the alteration of the mechanical properties of disc tissue are involved.[8–11]

Previous clinical studies of IDET have investigated LBP improvement only, without considering changes in leg symptoms. In this study, chronic discogenic LBP patients without signs nerve root involvement who underwent IDET were studied with the goal of assessing changes in referred leg pain.

## MATERIAL AND METHOD

All data were collected prospectively from January 6, 1999 to January 6, 2000. Data were retrospectively analyzed as an IDET case series. During this time frame a total of 129 patients underwent an IDET procedure Thirty of these patients underwent subsequent surgery and were excluded from the study. Ninety-nine patients met all inclusion criteria (vide infra) and were available for 18-month follow-up. Informed consent in which the potential risks of IDET were outlined was given prior to the procedure. Subjects were required to have discogenic LBP, a recent magnetic resonance imaging (MRI) scan, and lumbar spine discography within the last 6 months.

### Inclusion Criteria

Participation required back pain or back pain with referred leg and buttock pain of >6 months duration, lack of response to previous conservative treatment including nerve blocks, absence of tension signs during straight-leg raising, non-focal neurological abnormalities, MRI negative for nerve root compression, disc protrusion ≤2 mm, and positive discogram with annular tear.

### Exclusion Criteria

Subjects with allergy to any contrast media, iodine, or cephalosporin antibiotics and inability to undergo MRI scanning because of ferromagnetic implants, claustrophobia, or inability to tolerate positioning for MRI or discography were excluded. We also excluded patients who had unstable medical conditions, previous spinal surgery, instability and spondylolisthesis, spinal stenosis, and reduced disc height >50%. Patients unable to speak English were also excluded to ensure accuracy of outcome.

### IDET Procedure

The IDET procedure utilized a navigable intradiscal catheter with a thermal resistive coil. Using standard discographic techniques under conscious sedation, an Oratec Interventions 30 cm spineCATH catheter (Oratec Interventions, Inc., Menlo Park, CA) with a 6-cm active electrothermal tip was inserted anteriorly into the annulus or nucleus via a 17-gauge introducer. The active tip was advanced anterior-laterally inside the nuclear tissue, and directed circuitously to return posteriorly, providing an ideal position to heat the entire posterior annulus. Catheter positions and locations were assessed by fluoroscopy. After positioning, heat was generated along the active portion of the catheter. Heating commenced at 65°C and was increased 1°C every 30 seconds to achieve a final temperature of 80–90°C, giving a total treatment time of 13.5–16.5 minutes. The standard protocol was terminated at back pain >6/10. If tolerated by the patient without excessive sedation, the final temperature was maintained for an additional 4 minutes, affording a total heating time of ~10 minutes with an 80°C maximum temperature.

### After-Treatment Protocol

Patients were requested to limit physical activities (eg, standing > 1 hour, heavy lifting) for the first 6 weeks. Patients were encouraged to walk and do exercises. After 6 weeks they were advised to resume normal activities.

### Evaluation of Outcome

Patients were interviewed preoperatively and at 18 months post-procedure. All assessments were incorporated into our own evaluation sheet, which included the following: (1) Visual Analog Scale (VAS) for total body pain; and (2) Five-point pain scales (0 = not at all, 1 = slightly, 2 = moderate, 3 = very, 4 = extremely painful) from subsets of the North American Spine Society (NASS) LBP outcome assessment instrument for back and leg pain. Patients were partitioned into three groups: (1) leg pain dominant; (2) back pain dominant; and (3) leg and back pain the same. Differences between groups were then analyzed.

### Statistical Analysis

All statistical analyses were executed using SPSS/PC+ software (SPSS, Inc., Chicago, IL) utilizing the Mann–Whitney *U*-test. To compare non-numeric parameters, the $\chi^2$-test was used.

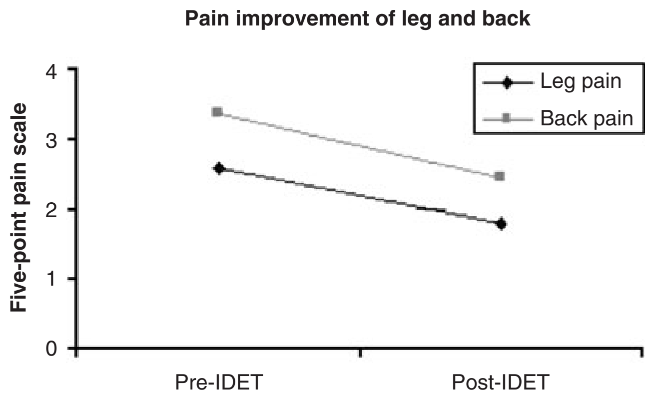


**Figure 1.** Five-point pain scale scores for pre-and post-IDET leg and back pain. Note that the improvements in back and leg pain were well correlated.

## RESULTS

### Sample Characteristics

Among the 129 patients who underwent IDET, 30 patients were excluded for further evaluation because of subsequent back surgery. The study group consisted of 99 patients (48 male, 51 female; mean age, 42.7 years; age range, 17–62 years). Eighty-three patients in the group (83.8%) had leg pain without sciatica. Of 83 patients, the numbers of the patients having LBP > leg pain, LBP = leg pain, and LBP < leg pain were 47 (56.6%), 25 (30.1%), and 11 (13.3%), respectively. The mean duration of preoperative pain was 41.20 ± 9.14 months (range: 6–182 months). The average follow-up time was 18.0 ± 4.0 months. Sixty-one patients (73.5%) experienced post-procedure pain flare with a mean duration of 28.7 days. There were no infectious, neurologic deficits, or bleeding complications.

### Changes in Leg and Back Pain

Forty-two patients (51.9%) showed an improvement in leg pain. The mean improvement in the five-point pain score was 1.90/4. Twenty-three patients (28.4%) showed no change. Sixteen patients (19.8 %) reported aggravation of pain, with a mean score of −1.19/4. Decrements in the five-point pain scale for post-IDET back and leg pain were statistically significant ($P < 0.05$). Pre- and post-IDET back pains (3.37 ± 0.82 and 2.59 ± 1.08, respectively) were more severe than pre-IDET and post-IDET leg pain (2.36 ± 1.25 and 1.79 ± 1.35, respectively; $P < 0.01$; see Figure 1).

With VAS score change for leg pain, patient groups with LBP > leg pain, LBP = leg pain, and LBP < leg pain showed VAS score improvements of 1.13 ± 3.13, 2.28 ± 2.49, and 2.64 ± 3.41, respectively.

### Correlation of Back and Leg Pain Improvement

Improvements in back and leg pain were similar (0.89 ± 1.17 and 0.75 ± 1.48, respectively; see Figure 1). The increments in back pain and referred leg pain were significantly correlated ($r = 0.721$, $P < 0.01$).

## DISCUSSION

Referred limb symptoms have been reported in LBP patients with incidences ranging from 20–30% to 70%.[1,12–14] However, our results show a much higher incidences of associated leg pain (up to 84%). This result may be explained by two factors: (1) meticulous detection of leg pain; and (2) inclusion of pain originating from other sources. Patients with even mild leg pain (eg, leg pain on the order of ~5% total body pain) were included in the leg pain group. All types of leg pain were included, with the exception of radiating leg pain originating from spinal roots. As a result, leg pain from a range of different foci could have been included. However, these data show that post-IDET improvements in leg pain were well-correlated with improvements in back pain, suggesting that the majority of pain was of discogenic origin and hence responsive to IDET. Ohnmeiss et al.[2] reported a significant relationship between patients indicating lower extremity pain and the presence of symptomatic disc disruption. In their results, among patients indicating lower extremity pain, 81.7% had symptomatic disc disruption. Among those indicating pain radiating below the knee, 84.1% had symptomatic disc disease. The results of this study indicate that lower extremity pain was as likely to be associated with symptomatic disc disruption.

Discogenic LBP patients may have accompanying referred leg pain. Because symptoms distributed along the leg often involve the sciatic nerve or nerve root, referred pain is often misdiagnosed as radiating pain caused by nerve root compression. Differential diagnosis of radicular pain and referred pain is not straightforward. The distinction is paramount for management of LBP, however, as a result of the differences in treatment: treatment of referred pain is similar to that of axial back pain, and laminectomy and discectomy are often unsuccessful. Techniques such as IDET have the potential to treat referred limb symptoms and back symptoms simultaneously. However, the efficacy of IDET for the treatment of referred pain in discogenic LBP patients has not been reported. This article provides the first evidence that discogenic pain treatments such as IDET may provide comparable improvement in both referred leg pain and back pain in discogenic LBP patients.

While referred pain symptoms may be experimentally reproduced via injection of chemical irritants into the spinal bones, facet joints, ligaments, and muscles, the exact lesion site of clinical referred pain frequently remains unknown. It has been suggested that the extensive network of interconnecting sensory nerves supplying tissues of the low back, pelvis, and thigh may be involved, such that injury to any of these structures permits pain to radiate to any of the other structures. About 12% of patients in our study were placed in the leg pain symptoms > back pain symptoms group. Leg pain in these patients was the least responsive to IDET. This result suggests that the majority of patients in this group may have leg pain of non-discogenic origin.

This study is the first attempt to evaluate the efficacy of IDET for associated leg symptoms in discogenic LBP patients. Each patient met clinical criteria for IDET treatment, including chronic discogenic LBP unresponsive to conventional conservative treatment with positive discogram. We have shown that IDET may relieve associated limb pain in chronic discogenic LBP patients. Further clinical and experimental study of the mechanism is necessary. Validation of these results via placebo-controlled randomized trails and studies comparing IDET with alternative treatments are also needed.

## CONCLUSION

In this study we confirmed previous reports that many patients with LBP also have lower extremity pain. Eighty-four percent of LBP patients who underwent IDET presented with referred leg pain without sciatica. The IDET procedure afforded improvements in leg pain that correlated well with improvements in back pain (0.75/4 and 0.88/4, respectively) with high correlation each others. These data suggest that IDET may relieve associated limb pain, which is same or less degree than back pain, in chronic discogenic LBP patients.

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