

Value of IDET Still Up in the Air After Two Randomized Controlled Trials Arrive at Conflicting Results

Two randomized controlled trials (RCTs) have come to diametrically opposed conclusions about the value of intradiscal electrothermal annuloplasty (IDET)—the thermal treatment for chronic discogenic pain.

According to the two studies, IDET either has a modestly beneficial effect in a carefully selected subgroup of patients—or has no clinical value.

It is not clear which of the studies arrived at an accurate result. Both trials were independent examinations of IDET by respected groups of researchers that followed careful protocols.

“These findings give support to both proponents and critics of IDET and ensure that debate will continue,” commented Gunnar B. J. Andersson, MD, during discussion of the two studies at the annual meeting of the International Society for the Study of the Lumbar Spine (ISSLS) in Vancouver, British Columbia.

Statistically Significant Benefit?

A study of 64 patients conducted in Texas found IDET had a positive effect on pain, function, and mood. Patients treated with IDET had a mean improvement in visual analog pain scores of 2.4 points (on a 10-point scale, 10 representing maximal pain) at six-month follow-up, compared to a 1.1-point-improvement in the sham-IDET control group. The IDET group also had an advantage in terms of scores on the Oswestry Disability Index.

“The treatment group demonstrated a statistically significant improvement in pain,” said lead author Kevin Pauza, MD. “Some members of the control group also demonstrated improvement. Both groups made functional gains.” (See Pauza et al., 2003.)

This study was designed to determine if IDET resulted in *statistically significant* benefits in terms of pain and disability. It was not designed to evaluate whether those gains were *clinically significant*.

“It is up to individual clinicians to determine if a 2.4 difference in pain scores is clinically significant or not,” said Pauza. “I think the procedure is appropriate for a selected group of patients with discogenic low back pain.”

No Clinical Value?

The RCT from Australia, by contrast, was specifically designed to see if either IDET or sham IDET resulted in a *clinically significant* improvement in pain and function. This was predefined as at least a seven-point advantage in the Low Back Pain Outcome

Continued on page 79



Award-Winning Studies

The year 2002 brought an end to the Volvo Awards, the preeminent spinal research awards presented at the annual meeting of the International Society for the Study of the Lumbar Spine (ISSLS) for a quarter century.

The year 2003 saw the inauguration of the ISSLS Awards—modeled after the Volvo Awards and designed to encourage the same tradition of research excellence.

The first trio of awards was recently presented at the annual meeting of ISSLS in Vancouver.

The first award honored a study from Japan and the United States for showing that a common hormone treatment might protect spinal nerves against injury. (See Sekiguchi et al., 2003.) Another prize went to Australian researchers who mapped the nerve supply of the intervertebral disc—in a sheep model that has clear parallels to the human situation. (See Fagan et al., 2003.) The third award went to a groundbreaking laboratory model that appears to accurately estimate the muscular forces

Continued on page 81

IN THIS ISSUE

- Back Pain and Spinal Blood Supply . . .74
- Impending Deluge of Joint Complaints?74
- The Cost-Effectiveness of Cox-2 Inhibitors—or Lack Thereof75
- Risk Factors for New-Onset Low Back Pain76
- Genetics, Physical Work Load, and Low Back Pain77
- Roundup on Lyme Disease78
- Meeting Calendar83
- The Back Page84
 - Safe Passage for Spinal Nerves,*
 - Mistaken Beliefs About Imaging,*
 - Is a Tense Disc a Healthy Disc?*

IDET

Continued from page 73

Score (LBOS), an improvement in three subscales of the SF-36 questionnaire, and the absence of any neurologic deficit caused by the IDET procedure.

"No subject in either treatment arm met the criteria for a successful clinical outcome," according to Brian J.C. Freeman, MD, et al. (See Freeman et al., 2003.)

"Our view at this stage—based on our methods—is that IDET is not an appropriate treatment," commented senior author Robert Fraser, MD.

Definitive Characterization?

Readers should wait for the published, peer-reviewed versions of both studies before making judgments about their conclusions.

They can also wait for further investigations. These studies are clearly not the last word on this thermal procedure. Several researchers at the ISSLS meeting suggested that these studies were not definitive tests of IDET—given their small size.

"It is very easy for small randomized trials to arrive at chance findings," said British researcher Jeremy Fairbank, MD.

Diagnostic Uncertainty?

Andersson noted that diagnostic uncertainty could have undermined these trials. Studies of treatments for painful discs, he suggested, may prove frustrating until researchers develop more accurate diagnostic methods.

"We are spending enormous resources developing treatments for painful discs, yet we still don't know how to diagnose them," said Andersson. "Perhaps we should spend more time researching better diagnostic methods."

Texas RCT

Pauza et al. screened 4253 potential subjects by telephone. Of these,

1360 agreed to randomization (most of the rest were geographically unsuited for the study protocol), 260 were eligible for discography, and 64 met the criteria for entry into the study after discography.

To enter the study patients had to have internal disc disruption at one or two levels. All had low back pain of at least six months' duration—pain that was exacerbated by sitting or standing and relieved by lying down. Subjects could not have more than a 30% loss of disc height at the affected levels.

The trial excluded patients with depression, spinal stenosis, spondylolisthesis, scoliosis, disc herniations greater than 4 mm, radicular pain, neurologic abnormalities, and anyone who had had previous spinal surgery. The study also excluded individuals with workers' compensation claims or anyone involved in litigation—to avoid secondary gain issues. The patients had all failed a course of conservative therapy.

All subjects had positive results on volume- and pressure-controlled manometric provocative CT/discography, and no response to sham discography pressurizations. Each disc was pressurized on three different occasions.

The subjects were randomized in a three-to-two ratio, with 37 subjects assigned to IDET. The surgeon was informed of treatment allocation in the surgery suite but did not communicate with the patients after this point.

Both groups underwent conscious sedation. In the IDET group, the catheter was introduced through a 17-gauge needle and maneuvered such that the entire posterior and bilateral posterior quadrants of the treated discs were covered by the treatment. In the control group, a needle was introduced but did not penetrate the outer annulus. Both groups were exposed to the typical sights and sounds of IDET. Neither group appeared to be aware of treatment assignment.

Both groups had identical post-operative protocols, including bracing for six weeks and supervised exercise. The subjects, physical therapists, and outcome evaluators remained blinded to treatment assignment until the six-month outcome assessment.

At baseline, the IDET group had a mean score of 6.6 out of 10 on the 10-point visual analog pain scale. The mean pain score improved to 4.2 at six-month follow-up. The mean pain score in the control group improved from 6.5 out of 10 at baseline to 5.4 at follow-up.

The IDET group had an advantage in disability scores. Mean Oswestry Disability scores improved from a mean 31.1 at baseline to 20.2 at six-month follow-up. The control group experienced a more modest improvement, from a mean 33.1 at baseline to 28.5 at six months.

RCT From Australia

The RCT from Adelaide, Australia, looked at a more diverse group of patients—including individuals on workers' compensation. The Australian patients had worse symptoms and greater disability than the subjects in the U.S. study. Their mean baseline Oswestry disability scores were about 10 points higher than those of the subjects in Texas.

Freeman et al. randomly allocated 57 patients in a two-to-one ratio, 38 to the active-IDET arm and 19 to a sham-IDET control group. Patients included in the study had to have symptomatic disc degeneration at one or two levels, posterior or posterolateral annular tears, and positive results on provocative CT/discography. All had a failed a rigorous conservative treatment protocol involving Pilates training.

All subjects underwent conscious sedation. A catheter was inserted into the disc in both the IDET and control groups. An independent technician turned on a generator to supply electrothermal energy to the IDET group—and

Continued on page 80

It is very easy for small randomized trials to arrive at chance findings.