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Intradiscal Biacuplasty Sustains Long-term Superiority Over Conservative Treatment for Discogenic Low-Back Pain

Feb. 18, 2016, PALM SPRINGS, Calif. – Patients treated with intradiscal biacuplasty (IDB) for discogenic back pain maintained benefits a year later, and those who crossed over to IDB treatment mid-study reported similar gains, study investigators reported. The results were presented today in a scientific poster at the 32nd Annual Meeting of the American Academy of Pain Medicine.

Contrary to the majority of chronic pain interventions, the minimally-invasive IDB demonstrated long-term benefit with no procedure-related complications, said Michael Gofeld, MD, the principal investigator and senior author.

“The results were not only statistically significant, but -- more importantly -- clinically meaningful,” said Dr. Gofeld, a practicing chronic pain management specialist and anesthesiologist at St. Michael's Hospital and Women's College Hospital in Toronto, Canada, and an associate professor of Medicine at the University of Toronto. “Without addressing disc pathology, pain and function do not get better.”

Every year, up to one in five Americans suffers from low-back pain (LBP), and discogenic pain due to degeneration of the intervertebral discs is a chief cause (*Zhang et al Int J Biol Sci* 2009;5:647–58). Sufferers are often forced to choose between conservative treatment, which includes medications such as nonsteroidal anti-inflammatory drugs and physical therapy, or more invasive fusion surgery, often with limited success or the risk of complications.

This study followed 22 patients from the original IDB and comprehensive medical management (IDB+CMM) group of a prospective, randomized, multi-center, open-label trial for an additional six months. In the original trial, the combination of IDB+CMM overwhelmingly exceeded CMM alone at six months on measures of pain, function, quality of life and global impression of change. The investigators found that statistically and clinically significant improvements over baseline were sustained at 12 months on all measures, with pain reduction of more than 2 points on the visual analog scale and a decrease of 14 points on the Oswestry Disability Index. The quality of life index also improved.

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In addition, the 25 patients who elected to cross over from CMM to the active treatment group responded similarly in terms of pain reduction and improved functional status. Importantly, without IDB, patients in the CMM group did not show improvement, Dr. Gofeld said.

The equipment to perform IDB, a technique that uses cooled radiofrequency to destroy culprit nociceptive nerves in degenerative spinal discs, was first developed by Baylis Medical Company in Canada and was approved by the U.S. Food and Drug Administration in 2007. Dr. Gofeld, who performed the first procedures in Canada, explained that patients who benefit have the following features:

- LBP without sciatica
- Disc degeneration that is limited to 1-2 levels
- Preservation of at least 50 percent of disc height
- No significant herniation

Now that clinical benefits have been established through this and previous research (Kapural et al *Pain Med* 2013;14:362-73, Kapural et al *Pain Med* 2015;16:425-31, Desai et al *Spine* 2015 [Epub ahead of print]), barriers to insurance coverage must be addressed, Dr. Gofeld said. “Once both efficacy and effectiveness are established in such a rigorous research setting, the procedure should be approved by payers. It has no CPT (Current Procedure Terminology) code, and the access for patients remains difficult.”

Poster 123 – Long-Term Results (12-Months) of a Prospective, Multicenter, Open-Label Clinical Trial Comparing Intradiscal Biacuplasty to Conventional Medical Management for Discogenic Lumbar Back Pain
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The American Academy of Pain Medicine is the premier medical association for pain physicians and their treatment teams with some 2,400 members. Now in its 33rd year of service, the Academy’s mission is to optimize the health of patients in pain and eliminate pain as a major public health problem by advancing the practice and specialty of pain medicine through education, training, advocacy and research. Information is available on the Academy’s website at www.painmed.org.

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