Studies: Minimally-Invasive Cooled Radiofrequency Treatment For Low Back Pain Is Effective

Kimberly-Clark today announced the publication of two separate studies that achieved positive outcomes following use of cooled radiofrequency (RF) to treat discogenic and sacroiliac joint (SIJ) pain in the low back. The studies evaluated Kimberly-Clark's TransDiscal Cooled Radiofrequency System and SInergy Cooled Radiofrequency System and demonstrated that both treatment options provided patients who suffer from chronic low back pain with much-needed pain relief and improved quality of life benefits. Results were published in Pain Medicine, the official journal of the American Academy of Pain Medicine, the Faculty of Pain Medicine of the Australian and New Zealand College of Anesthetists, and the International Spine Intervention Society.

Dr. Leonardo Kapural of Carolinas Pain Institute and Wake Forest Brookstown Pain Center in Winston-Salem, N.C., led the first-of-its-kind double-blinded randomized controlled trial studyof 59 patients with 29 randomized to intradiscal biacuplasty (IDB) and 30 to the control group. Participating patients had a history of chronic low back pain persisting six months or longer. This type of pain is extremely debilitating, and it dramatically limits an individual's everyday activities such as sitting and driving. At the six-month follow-up, patients treated with Kimberly-Clark's TransDiscal Cooled RF System reported significantly greater improvements in restoration of physical function, and a decrease in pain, disability and opioid usage compared to patients in the control group. The study was conducted at the Department of Pain Management at the Cleveland Clinic in Cleveland, Ohio, and the Center for Clinical Research at Carolina's Pain Institute in Winston-Salem.

"Discogenic low back pain accounts for the majority of chronic low back pain. Traditional treatment options include pharmacologic, physiotherapy and surgical options such as spinal fusion or artificial disc replacement. These data are particularly encouraging because there is now additional, compelling evidence to suggest a minimally-invasive approach, such as cooled radiofrequency, can provide sustained relief to a carefully selected group of patients," said lead clinical investigator Leonardo Kapural, M.D., Ph.D. "In this study, patients treated with the TransDiscal Cooled RF System experienced clinically significant improvements in physical function compared to those in the control group."

In the same edition of Pain Medicine, a retrospective chart review found the use of cooled RF to be significantly effective for the treatment of SIJ low back pain. The European study, led by Dr. Wolfgang Stelzer of the Medical University of Vienna, Austria, examined the electronic records of 126 patients treated with Kimberly-Clark's SInergy Cooled RF System for SIJ pain. The retrospective chart review showed promising, durable improvements in pain, quality of life and reduction in medication usage.

At the one-year follow-up, 67 percent of patients stopped or decreased use of opioids, 48 percent of patients reported significant reduction in pain scores and 85 percent stated quality of life was improved or much improved. In some patients, relief was maintained up to 20 months.

These results echo published study findings from Dr. Nilesh Patel of Advanced Pain Management in Green Bay, Wis., in which patients treated with the SInergy Cooled RF System showed significant improvements in pain, disability and quality-of-life outcomes at the three-month mark. Durability of relief was maintained at the nine-month follow-up and 59 percent achieved treatment success.

Low back pain is the second most common cause of disability in U.S. adults and a common reason for lost work days, Cooled RF is a minimally-invasive non-pharmacological treatment option for those suffering from low back pain. RF energy heats the nerve tissue while circulating water moderates the temperature in close proximity to the electrode. This combination creates large volume lesions without excessive heating at the electrode. Patients are typically placed under little-to-no sedation and are released the same day.

“The promising results from these two studies further validate the effectiveness and role of cooled radiofrequency as a minimally-invasive treatment option for low back pain,” said Lisa Kudlacz, General Manager, Global Interventional Pain Management, Kimberly-Clark Health Care. “Patients with difficult-to-treat, chronic low back pain have an option that has demonstrable benefits — reduction in medication usage, significant improvement in quality of life and improved functionality — to get back to their active lifestyles.”

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