

Paper #43

Cryoneurolysis for Temporary Relief of Pain Associated with Knee Osteoarthritis: A Multi-Center, Prospective, Double-Blind, Randomized, Controlled Trial

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Introduction: The purpose of this study was to evaluate the effect of cryoneurolysis on knee pain associated with osteoarthritis.

Methods: In this 2:1 prospective, double-blind, randomized, sham-controlled trial 180 patients with OA received percutaneous cryoneurolysis or sham treatment of the Infrapatellar Saphenous Nerve (ISN). WOMAC Pain and Total scores were recorded at baseline and 30 and 60 days post-treatment. VAS Pain scores were collected at baseline and at 1, 7, 30, 60, 90 days post-treatment. Adverse events were also recorded.

Results: At 30 and 60 days post-treatment the WOMAC Total Score, a measure of knee pain, stiffness and function, was significantly improved (lower) for the cryo groups versus the sham (65.21 vs. 105.11, $p < 0.0001$; 69.94 vs. 94.93, $p = 0.0093$, respectively). The change from baseline for the WOMAC Total Scores was also significantly improved (lower) for the cryo groups versus the sham (-81.43 vs. -42.83, $p = 0.0001$; -76.57 vs. -53.34, $p = 0.0145$, respectively). At these same time points the WOMAC Pain Scores (13.45 vs. 22.21, $p < 0.0001$; 13.97 vs. 19.30, $p = 0.0093$, respectively) and VAS Pain Scores (26.29 vs. 42.77, $p = 0.0006$ and 27.72 vs. 37.44, $p = 0.0426$, respectively) were significantly lower for the cryo group versus the sham. The percent of VAS Pain Responders, defined as a patient who experiences at least a 30% reduction in VAS Pain Score compared to baseline, was higher for the cryo group at every time point in comparison to the sham group (1: 84.7 vs. 70.9; 7: 76.4 vs. 70.4; 30: 71.4 vs. 48.2; 60: 69.6 vs. 58.9; 90: 77.2 vs. 65.4). There were no serious device-related adverse events.

Conclusions: Results from this prospective, double-blind, randomized, sham-controlled trial demonstrate that cryoneurolysis of the ISN results in reduced pain and stiffness and improved functionality for patients with knee pain associated with osteoarthritis.

Notes
