Cryoneurolysis for Knee Osteoarthritis in a Real-world Registry: Pain and Functional Outcomes Over 12 Months

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INTRODUCTION:

Cryoneurolysis is a denervation-based therapy that uses low temperatures (– 20 °C to – 100 °C) to induce Wallerian degeneration and reversible disruption of nerve function to block pain for extended periods. Because cryoneurolysis is a novel treatment for pain in knee osteoarthritis (OA), additional evidence is needed to further characterize its efficacy in real-world settings. The Innovations in Genicular Outcomes Registry (IGOR) is a prospective, observational registry in which clinical decision-making is performed by treating physicians and their patients who have a standardized collection of real-world data, including clinical, patient-reported, reimbursement, and healthcare resource utilization outcomes. The objective of this analysis was to evaluate real-world pain and functional outcomes following cryoneurolysis therapy for knee OA in IGOR.

METHODS:

Data on patient-reported pain and functional outcomes were collected from IGOR for up to 12 months of follow-up after cryoneurolysis treatment. There were two cryoneurolysis approaches that were evaluated: deep genicular nerve block only or combined with superficial genicular nerve (Cryo-Deep/both) and superficial nerve block only (Cryo-Superficial). Outcomes of pain and function were, respectively, assessed by the Brief Pain Inventory pain scale (BPI-Pain) and the Knee injury and Osteoarthritis Outcome Score for Joint Replacement (KOOS, JR). Time (in days) to next knee OA treatment was assessed by Kaplan-Meier survival estimates. The generalized linear mixed-effect regression models were performed to assess (1) trends of pain and functional outcomes over 12-month follow-up and (2) follow-up improvements from baseline (before treatment), with adjustment for age, sex, respective baseline outcome score, Kellgren-Lawrence (KL) grade, baseline pain catastrophic scale score, and follow-up opioid use.
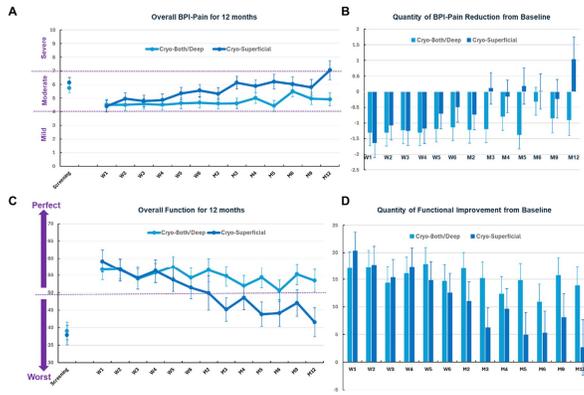
Overall, 129 patients were evaluated following cryoneurolysis (Cryo-Deep/both: n=75 (6/69); Cryo-Superficial: n=54). The mean age was 65 years, 79% of women, the mean BMI was 34.8, and 80% had a KL grade of 3 or greater.

RESULTS:

The survival estimate revealed that about 50% of patients had not switched to a new treatment at 318 days (Figure E). Moreover, patients treated with cryoneurolysis experienced moderate pain for up to 12 months (Figures A to B), with average BPI-Pain scores of 4.7 and 5.6 for Cryo-Deep/both and Cryo-Superficial, respectively. The magnitude of pain reduction from baseline over time was significant in the Cryo-Deep/both group ($P < 0.01$). Patients receiving Cryo-Deep/both demonstrated better function than the average population (mean: 50 years) for as long as 12 months after cryoneurolysis (Figures C and D). The magnitude of functional improvement from baseline over time was significant for both cryoneurolysis groups ($P < 0.01$).

DISCUSSION AND CONCLUSION:

Over 12 months of follow-up, patients receiving one of two different cryoneurolysis approaches had reduced pain and improved function. The long-lasting benefit of Cryo-Deep/both cryoneurolysis was further supported by half of the patients not switching to another therapy close to one year after cryoneurolysis, whereas over half of the patients who received conventional intra-articular injections in the IGOR cohort required a new treatment at six months (data not shown). These data support the use of cryoneurolysis for pain management in patients who have knee OA.

A Overall BPI-Pain for 12 months

Cryo-Both/Deep — Cryo-Superficial

B Quantity of BPI-Pain Reduction from Baseline

Cryo-Both/Deep — Cryo-Superficial

C Overall Function for 12 months

Cryo-Both/Deep — Cryo-Superficial

D Quantity of Functional Improvement from Baseline

Cryo-Both/Deep — Cryo-Superficial

E. Time to the next knee OA treatment

Product-Limit Survival Estimate

+ Censored

Survival Rate

Follow Up (Day)