# Early Outcomes of the Innovations in Genicular Outcomes Registry (iGOR): A Prospective Cohort Study Assessing Real-World Outcomes of Treatments for Osteoarthritis of the Knee Pain

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INTRODUCTION: The Innovations in Genicular Outcomes Registry (iGOR) is a prospective, observational, longitudinal, multicenter cohort study designed to assess the impact on several health outcomes of patient-physician–chosen interventions for the management of symptomatic osteoarthritis of the knee (OAK). In contrast to clinical trials with rigid eligibility criteria, which may not be generalizable, the inclusive and comprehensive design of iGOR enables an assessment of outcomes of multiple OAK treatments across dynamic treatment paradigms, reflecting real-world practice. The present analysis reports early comparative pain and function outcomes for multiple nonsurgical treatments in a feasibility cohort.

METHODS: Patients were enrolled across the United States and received OAK treatments. They completed electronic instruments before (baseline) and after treatment to assess pain, function, sleep disturbance, quality of life, and satisfaction over 18 months. Adverse events and healthcare resource utilization were extracted from medical records. Subsequent treatments after initial enrollment treatment were followed similarly. The present analysis assessed patients with at least 1 month of follow up who had unilateral OAK and moderate-to-severe pain ≥4 on scale of 1 (least)-10 (worst)] on the Brief Pain Inventory (BPI-sf) at baseline and were enrolled from 6 clinical sites between September 24, 2021, and December 30, 2022. Patients received 1 of 5 nonsurgical treatments at study enrollment: intra-articular (IA)-hyaluronic acid (IA-HA), IA-ketorolac (IA-NSAID), IA-conventional steroids (IA-CS), IA-triamcinolone acetonide extended-release (IA-TA-ER), or genicular-nerve cryoneurolysis (Cryo). Post-treatment outcomes included pain severity from BPI-sf and function [scale of 0 (worst)-100 (perfect)] from the Knee Injury and Osteoarthritis Outcome Score for Joint Replacement (KOOS-JR) at weeks 1 through 6, then at 2 and 3 months. The multivariable mixed-effects modeling was conducted for outcome comparison among treatments with adjustment for age, sex, study site, Kellgren-Lawrence (KL) grade, baseline score of pain severity or function, pain catastrophizing, and analgesic use at each assessment.

RESULTS: There was a total of 178 patients, including 130 IA-injections (21 IA-HA, 19 IA-NSAID, 75 IA-CS, 15 IA-TA-ER), and 48 Cryo treatments. The mean age was 61 years (range 32-82), 75% were female, and 15% were Medicaid beneficiaries. Most patients were obese (mean body mass index [BMI] 35 kg/m$^2$), with 68% at a KL grade of at least 3. During the 3 months of follow up after treatment, pain severity was reduced in all 5 treatments (Figure 1). Specifically, numerical reductions for pain severity were observed from 5.65 (mean baseline) to 4.58 (adjusted mean over 3 months) for IA-HA, 6.93 to 5.75 for IA-NSAID, 6.16 to 4.59 for IA-CS, 6.35 to 3.01 for IA-TA-ER, and 6.51 to 3.81 for Cryo. IA-TA-ER was associated with the greatest reduction in pain severity compared with all other IA-injections ($P$≤0.012), and Cryo produced more pain reduction than IA-NSAID ($P$=0.048; Figure 2). Similarly, follow-up function was improved for 3 months after treatment (Figure 3). Numerical improvements in functional scores from baseline (mean) to 3 months (adjusted mean over follow up) were 47.39 to 55.81 for IA-HA, 38.90 to 51.08 for IA-NSAID, 44.34 to 50.65 for IA-CS, 39.76 to 66.91 for IA-TA-ER, and 38.36 to 59.19 for Cryo. The IA-TA-ER injection was associated with the greatest functional improvement compared with all other IA-injections ($P$≤0.01). Cryo was associated with greater functional improvement than IA-CS ($P$=0.027; Figure 4). Finally, 38 patients (21%) reported using opioids during follow up, 22 (14%) of which were opioid naïve before treatment.

DISCUSSION AND CONCLUSION: The iGOR is a unique, first-of-its-kind, inclusive, and comprehensive registry capturing outcomes for a variety of KOA treatments in the real world. Early results demonstrated numerical improvements in pain and function for 5 nonsurgical treatments, with IA-TA-ER showing the greatest improvement over other treatments. Cryo was associated with somewhat more improvement than IA-NSAID and IA-CS in pain and function, respectively. Nevertheless, a future study of minimal clinically important difference analysis is required to determine whether the observed improvements are clinically meaningful. The prevalence of opioid use, albeit low, also suggests the need for more effective OAK pain management alternatives.