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

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INTRODUCTION: Published data remain limited regarding comparative effectiveness of multiple OAK treatments on patient-generated outcomes. This analysis reports early results from the Innovations in Genicular Outcomes Registry (iGOR), an ongoing, prospective, longitudinal registry investigating numerous health outcomes of multiple OAK treatments jointly determined by physicians and patients.

METHODS: Patients with at least 1 month of follow-up who developed unilateral OAK and moderate-to-severe pain (≥4 on scale of 1 [least]-10 [worst]) on the Brief Pain Inventory (BPI-sf) before treatment (baseline) were enrolled from 6 clinical sites between September 24, 2021, and December 30, 2022. Patients received 1 of 5 nonsurgical treatments at enrollment: genicular-nerve cryoneurolysis (Cryo) or intraarticular (IA) injections of hyaluronic acid (IA-HA), ketorolac (IA-NSAID), conventional steroids (IA-CS), or triamcinolone acetonide extended-release (IA-TA-ER). 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. Each site participating in the registry obtained approval from an institutional review board before screening patients.

RESULTS: In total, 178 patients received IA-HA (n=21), IA-NSAID (n=19), IA-CS (n=75), IA-TA-ER (n=15), and Cryo treatments (n=48). The mean age was 61 years, 75% were female, and 68% were at a KL grade of ≥3. Pain severity was reduced after treatment for 3 months from 5.65 (mean baseline) to 4.58 (adjusted mean over 3 months after treatment) 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 ($P \leq 0.012$; Figure 1), and Cryo produced more pain reduction than IA-NSAID ($P=0.048$). Similarly, follow-up function was improved for 3 months after treatment from baseline (mean) to 3 months (adjusted mean over follow-up: 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 ($P \leq 0.01$; Figure 2). Cryo was associated with greater functional improvement than IA-CS ($P=0.027$). Finally, 38 patients (21%) reported using opioids during follow-up, with 22 patients being opioid naive before treatment.

DISCUSSION: 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. The prevalence of opioid use, albeit low, suggests the need for more effective OAK pain management alternatives. Future work of meaningful effect size of outcome improvement and area-under-curve analysis are needed.

SIGNIFICANCE/CLINICAL RELEVANCE: The iGOR is a first-of-its-kind, inclusive, and comprehensive registry that enables assessments of outcomes across dynamic treatment paradigms to help inform real-world OAK treatment decisions.

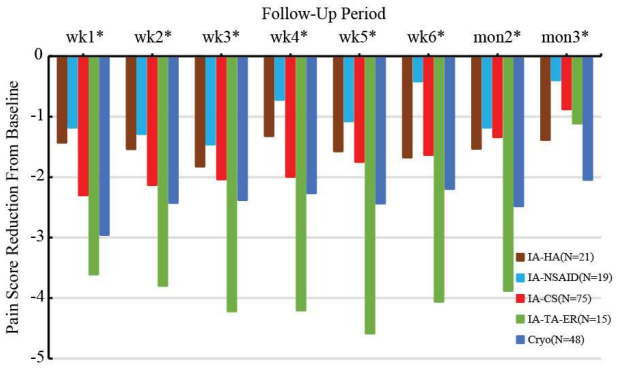

Figure 1. Reduction of Post-Treatment BPI Pain Severity Scores (From Baseline) During 3 Months of Follow-Up (*, adjusted reduction in pain scores from baseline).

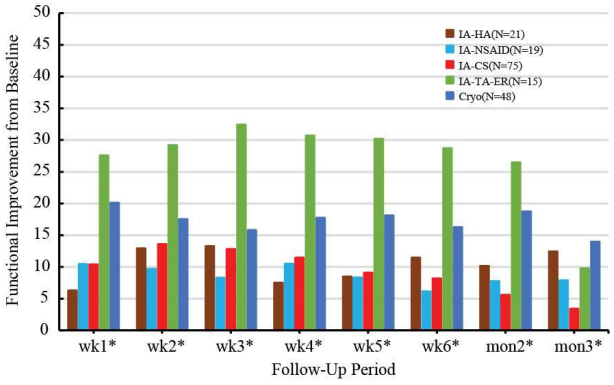

Figure 2. Improvement of Post-Treatment KOOS-JR Functional Scores (From Baseline) During 3 Months of Follow-Up (*, adjusted improvement in functional scores from baseline).