Real-World Effectiveness, Safety Profile, and Persistence of Upadacitinib. A Prototype for Collaboration Among Rheumatology Registries in Canada. The RHUMADATA-OBRI Partnership.

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Objectives: Health Canada approved Upadacitinib (UPA) in January 2020 to treat moderate-to severe rheumatoid arthritis (RA). It was launched just before the COVID-19 pandemic, making its early monitoring challenging. Virtual visits resulted in a shortage of rheumatologist-reported measures and clinical and safety outcomes. We first outline the steps to establish a collaboration between RHUMADATA and the Ontario Biologics Research Initiative (OBRI) required to monitor early UPA use. Next, we describe the characteristics and treatment retention of RA patients treated with a TNF inhibitor (TNFi) or UPA during COVID-19.

Methods: 1. Collaboration: We reviewed past collaborations and written communications (emails, phone calls, virtual meetings) between OBRI and RHUMADATA to describe the steps leading to abstract submission. 2. Treatments: Study participants were adults when diagnosed. Participants provided informed consent (IC) and were enrolled in RHUMADATA or OBRI. Data sharing was consented to by all patients. Retention curves for UPA and TNFi were analyzed but not compared.

Results: 1. Collaboration: A research question emerged from the lack of data reported for UPA. We identified the study population to determine feasibility. Comparison of data collection methods. Uniform definitions of data variables and discrepancy-handling solutions. Data collection time window and sample size were established. Data sharing was not included in the original OBRI IC. As a result, OBRI patients were asked to re-consent. Formal protocol jointly developed. Data-sharing agreement and a contract were drafted and submitted to the UHN for review and approval of ethics (REB). Data was pooled securely. The registry's baseline characteristics were analyzed, and discrepancies addressed.

Analysis. Abstract. 2. Treatments: This analysis included 260 patients (118 UPA and 142 TNFi), with average age of 61.1 (11.8), 81.5% female and 9.0% smokers. Disease duration was 13.8 (10.5) years at treatment initiation, and 64.6% and 64.3% were RF and ACPA positive. Retention was high as 96.9% of patients remained on their medications at EOS. HAQ-DI and CDAI scores are shown in Table 1.

Conclusion: 1. Collaboration: RA registries collect standard variables but pooling them requires many steps. The harmonization process must be clearly described to evaluate the analysis's quality. 2. Treatments: TNFi and UPA patients had similar treatment retention. In addition, few patients discontinued treatment over a mean (SD) follow-up of 445.7 (236.1) days. In the future, larger sample sizes will allow us to address our objectives better and account for the impact of non-randomized treatment assignments in observational studies.