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Rheumatoid arthritis, Real-world evidence, Disease-modifying Drugs (DMARDs)

Real-world Effectiveness, Safety, and Persistence of Upadacitinib. Canadian rheumatology registry collaboration. RHUMADATA-OBRI partnership.

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Background:

In January 2020, Upadacitinib (UPA) was approved in Canada to treat moderate-to-severe RA. Early monitoring was challenging because it was launched just before the COVID-19 pandemic. Clinical and safety outcomes were lacking from virtual visits. We first outline the steps to establish a collaboration (**Co**) between RHUMADATA and the Ontario Biologics Research Initiative (OBRI) required to monitor early UPA use. Next, we describe the characteristics (**Tx**) and treatment retention of RA patients treated with a TNF inhibitor (TNFi) or UPA during COVID-19.

Objectives:

To outline the steps taken to establish a collaboration between RHUMADATA and OBRI, and present an example (TNFi and UPA treatments) resulting from this collaboration

Methods:

Co
OBRI and RHUMADATA have reviewed past collaborations and communications (emails, phone calls, virtual meetings) and identified the required next steps.
Tx
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:

Co

- We identified the study population to determine the feasibility
- Comparison of data collection methods
- Uniform definitions of data variables and discrepancy-handling solutions
- Data collection time window and sample size were established
- OBRI patients were asked to re-consent as data sharing was not included in the original IC
- Formal protocol jointly developed
- Data-sharing agreement and a contract were drafted and submitted to the UHN for ethics review and approval (REB)

- Data was pooled securely
- Baseline characteristics were analyzed, and discrepancies were resolved
- Analysis
- Abstract

Tx

The analysis included 260 patients (118 UPA and 142 TNFi) with an average age of 61.1 (11.8) years, 81.5% women, and 9.0% smokers. At treatment initiation, disease duration was 13.8 (10.5) years, and 64.6% and 64.3% were RF and ACPA positive. Retention was high, as 96.9% of patients remained on their medications. HAQ-DI and CDAI scores are shown in Table 1.

Conclusion:

Co

RA registries collect standard variables but pooling them requires many steps. The harmonization process must be clearly described to evaluate the analysis's quality.

Tx

Treatment retention was similar between TNFi and UPA. Over a mean (SD) follow-up of 445.7 (236.1) days, few patients discontinued treatment. Our objectives will be better addressed, and non-randomized treatment assignments will be more adequately accounted for in the future with larger sample sizes.

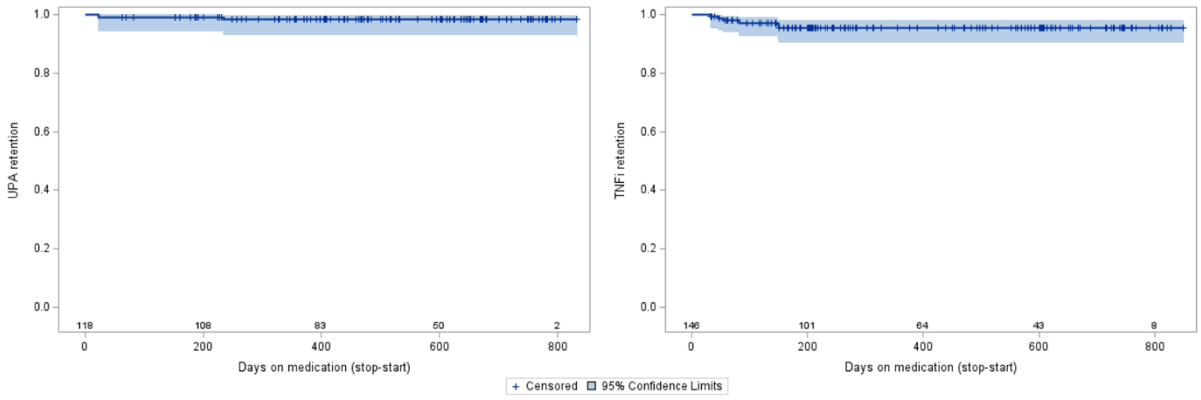
References:

Table 1. Characteristics of selected patients[1]

	Treatment	
	TNFi (142)	**UPA (118)**
Female	109/142 (76.8%)	103/118 (87.3%)
Age @ treatment initiation (TI)	61.3 (12.9)	60.9 (10.2)
Current smoker	13/125 (10.4%)	7/98 (7.1%)
Disease duration @ TI, years	14.4 (11.0)	13.1 (9.8)
Rheumatoid factor (RF) positive	94/133 (70.7%)	65/113 (57.5%)
Anti-citrullinated protein/peptide antibody (ACPA) positive	67/103 (65.0%)	59/93 (63.4%)
Days on AT (end-start)	392.1 (249.6)	510.1 (201.7)
Previous csDMARDs	129/142 (90.8%)	84/118 (71.2%)
Previous advanced treatment (AT)	96/142 (67.6%)	68/118 (57.6%)
Concomitant use of MTX	83/142 (58.5%)	48/118 (40.7%)
ESR @ TI (mm/hr)	21.3 (18.1), 79	23.9 (24.0), 73
ESR @ follow-up (FU) (mm/hr)	19.6 (17.5), 39	18.8 (18.0), 36
CRP @ TI (mg/L)	8.6 (13.3), 96	8.9 (16.4), 97
CRP @ FU (mg/L)	9.3 (15.1), 44	3.4 (4.4), 49
HAQ @ TI	1.0 (0.7), 100	1.3 (0.7), 86
HAQ @ FU	1.0 (0.8), 42	1.0 (0.7), 37
CDAI @ TI	16.2 (13.6), 65	23.7 (13.2), 65
In remission	11/65 (16.9%)	0/69 (0.0%)
In low DA	25/65 (38.5%)	10/69 (14.5%)
CDAI @ FU	14.2 (12.6)	17.0 (14.3)
In remission	4/26 (15.4%)	3/29 (10.3%)
In low DA	11/26 (42.3%)	10/29 (34.5%)

[1] For categorical variables, results are presented as n/N (%), where N is the number of non-missing data points. Continuous variables are presented as mean (standard deviation), N.

Figure 1. Retention UPA and TNFi



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