Canadian Study of Adherence Outcomes in HUMIRA® (Adalimumab) Patients – Three-Year Results from the COMPANION Study in Rheumatology Patients

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BACKGROUND

- HUMIRA® (adalimumab) was the first fully humanized biologic developed in the TNF-inhibitor class and is indicated for use in autoimmune diseases including rheumatoid arthritis (RA) and spondyloarthritis (SpA)[1,2]
- Patient Support Programs (PSP) were first conceived in order to provide assistance with medication prescription costs, but are now increasingly providing additional services
- Patients receiving HUMIRA® in Canada are eligible to enroll in the AbbVie Care™ PSP providing a proprietary suite of services with the goal of improving patients' experiences and outcomes
- In addition to other services such as reimbursement support, financial assistance, and nursing services, among others, the HUMIRA® PSP services also include care coach calls (CCCs) prior to starting HUMIRA® (initial CCC) as well as during therapy (ongoing CCC)
- A previous study demonstrated increased adherence and persistence to HUMIRA® over a short period of time (i.e. 1 year) in patients enrolled in PSP and receiving CCCs compared to patients who don't receive CCCs[3]; however, there is limited evidence in Canada that demonstrates the long term impact of PSPs on patients' adherence and persistence to HUMIRA®

AIMS

- To assess the impact of patient characteristics (e.g. sex, age, diagnosis) and HUMIRA® PSP services (e.g. ongoing CCCs) on persistence and adherence to HUMIRA® over a 3-year period in the all-indication cohort and patients with RA and SpA.

METHODS

DATABASE LINKAGE AND STUDY DESIGN

- A probabilistic matching algorithm[4] was developed to link patients in the HUMIRA® PSP database to patient-level medication transaction (Rx) data
- A 3-month look-forward period was used in order to ensure patient activity
- A 26-month selection period (July 2010 to August 2012) was used in order to select and index patients on the date of their first HUMIRA® script
- A 37-month study period was used in order to assess patient persistence and adherence

| Look-Back Period (6 months) | Selection Period (26 months) | Analysis Period (37 months) | Look-Forward Period (3 months) |

- Persistence to HUMIRA® was calculated by evaluating patients' prescriptions for 36 months following the index date to the end of therapy based on >90 days without transaction data, censored for patients who remained on therapy through month 36. Because the CCC service was only available in the PSP after June 2013, only patients that had demonstrated persistence for 1 year were compared.
- Adherence to HUMIRA® was measured by evaluating patients' medication possession ratio (MPR) during their persistent period on therapy

PATIENT ELIGIBILITY

Inclusion Criteria:
- Enrolled in HUMIRA® PSP after July 2010
- Linked across PSP and longitudinal pharmacy data
- First HUMIRA® Rx between July 2010-August 2012
- For persistence measurement: patients had to be persistent on therapy for the first 12 months of HUMIRA®

Exclusion Criteria:
- Received HUMIRA® for less than 30 days
- Index date > 90 days prior to enrollment in PSP

Statistical Analysis
- Cox regression analysis to determine hazard ratios (HR) for the association between persistence and covariates including patient characteristics and PSP services
- Multivariate logistic regression analysis to determine odds ratios (OR) for the relationship between high adherence (i.e. MPR ≥ 80%) and covariates including patient characteristics and PSP services
- Adjustment for multiple potential confounders in all regression analysis were performed
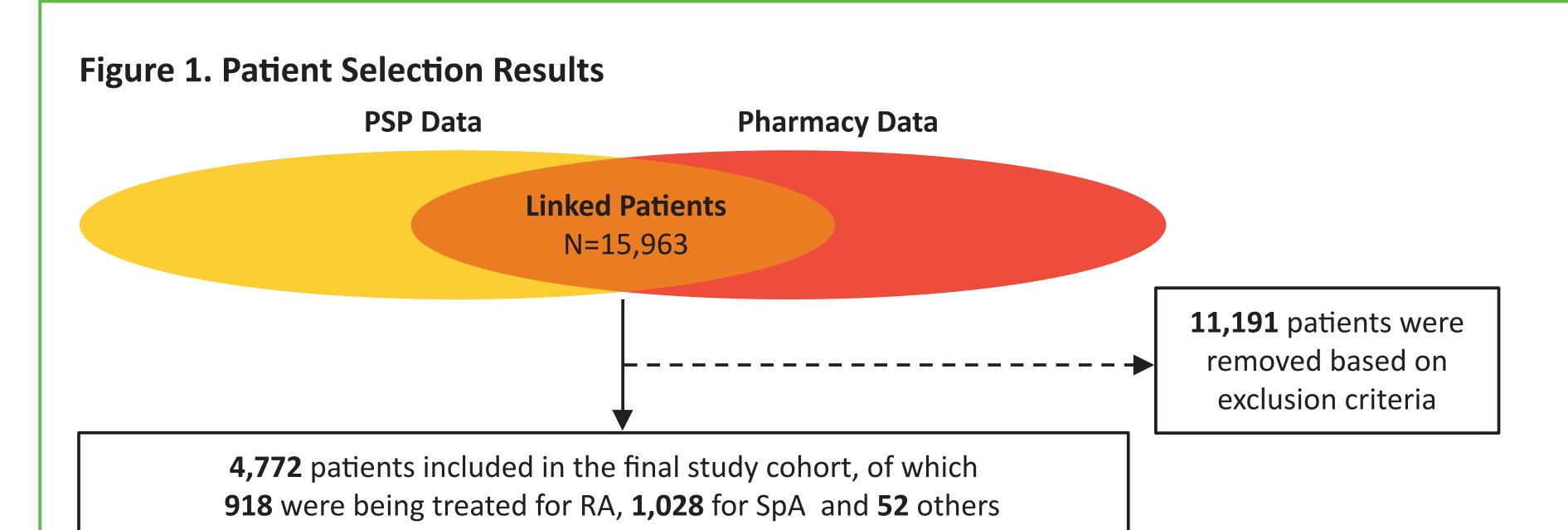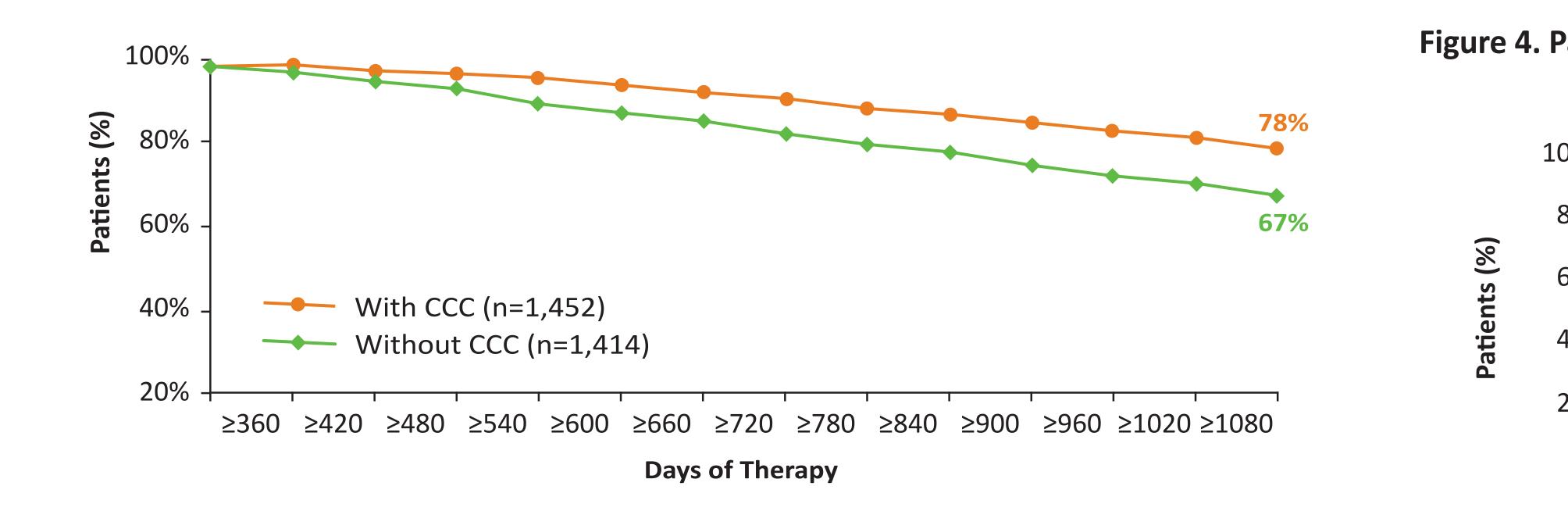
RESULTS

Figure 1. Patient Selection Results

Linked Patients N=15,963

11,191 patients were removed based on exclusion criteria

4,772 patients included in the final study cohort, of which 918 were being treated for RA, 1,028 for SpA and 52 others

Table 1. Study Patient Characteristics

	Total PSP Patients % (n=38,840)	Final Study Cohort % (n=4,772)
Gender		
Male	45%	45%
Age		
≤ 17	3%	1%
18-29	15%	9%
30-39	19%	17%
40-49	21%	21%
50-59	23%	24%
60-69	14%	17%
≥ 70	6%	11%
Diagnosis		
Crohn's	39%	40%
Ulcerative colitis	4%	2%
Rheumatoid Arthritis	19%	19%
Psoriasis	13%	15%
SpA*	23%	22%
Other or Undetermined	2%	2%

* SpA consists of patients with Ankylosing Spondylitis (AS) and Psoriatic Arthritis (PsA)

- The final study cohort provided a good representation of all patients enrolled in the PSP based on demographics and diagnosis (**table 1**)

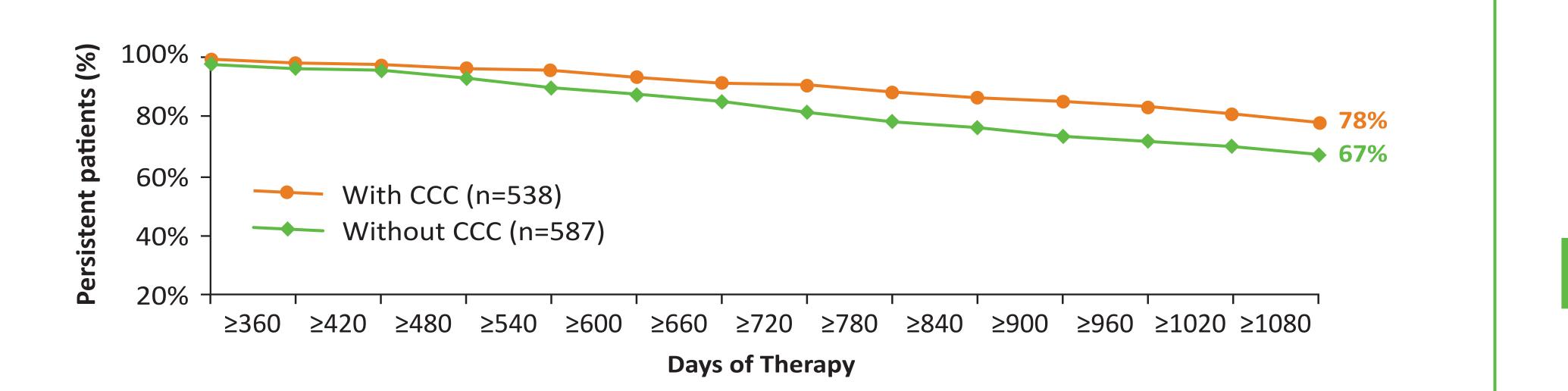### FACTORS CORRELATED TO PERSISTENCE AND ADHERENCE

- In the all-indication cohort, male patients were significantly more persistent (HR=0.866, p=0.0004) than female patients
- Older age groups (40-49, 50-59, 60-69, 70+) were more likely to be persistent relative to the 30-39 year category (HR= 0.782, p =0.0001; HR= 0.751, p <0.0001; HR=0.731, p<0.0001; HR= 0.640, p<0.0001)
- Relative to the 30-39 year category, older age groups (40-49, 50-59, 60-69, 70+) had significantly greater odds of adherence (OR =1.301, p=0.0214; OR= 1.395, p=0.0032; OR=1.440, p0.0033; OR=2.076, p<0.0001)

Figure 2. 36-month persistence by receipt of ongoing care coach calls (CCCs) among patients in the all-indication cohort
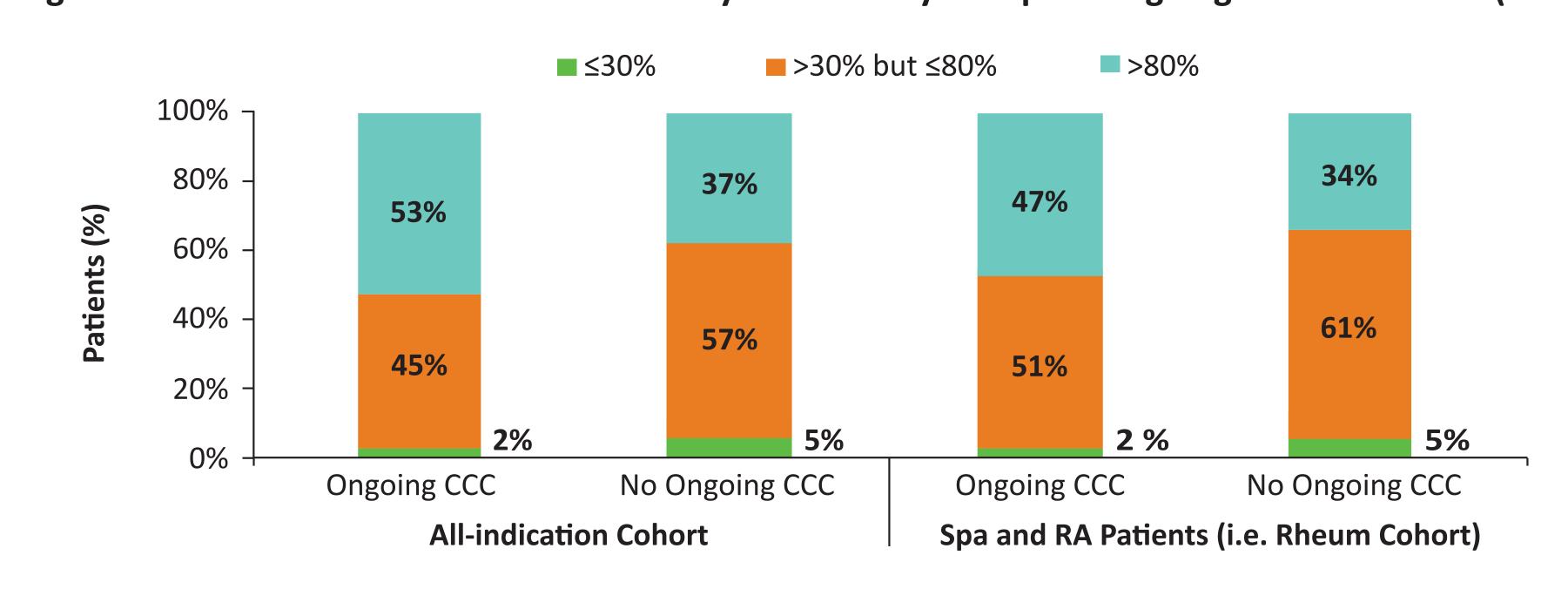

- In the all-indication cohort, patients receiving ongoing CCCs were 65% less likely to cease treatment compared to the patients who were not receiving ongoing CCCs (HR = 0.35, p<0.0001) **(figure 2)**

Figure 3. 36-month persistence by receipt of ongoing care coach calls (CCCs) for RA and SpA patients

- In RA and SpA patients receiving ongoing CCCs were 70% less likely to cease treatment compared to RA and SpA patients not receiving ongoing CCCs (HR = 0.30, p<0.0001) **(figure 3)**

Figure 4. Patient distribution of adherence by MPR and by receipt of ongoing care coach calls (CCCs)

- In the all-indication cohort, patients receiving ongoing CCCs had 124.8% greater likelihood of being highly adherent (>80% MPR) compared to those who did not receive the ongoing CCCs (OR= 2.248, p<0.0001 **(figure 4)**
- RA and SpA patients receiving ongoing CCCs have 131.5% greater likelihood of being highly adherent (>80% MPR) compared to those who did not receive ongoing CCCs (OR= 2.315, p<0.0001) **(figure 4)**

CONCLUSIONS

- After controlling for confounders, ongoing care coach calls had a statistically significant association with greater persistence and adherence to HUMIRA® over the first 36 months of treatment among patients in all-indication cohort as well as patients with RA and SpA diseases
- Male patients and older age groups (40-49, 50-59, 60-69, 70+) were significantly more persistent to HUMIRA®
- Older age groups (40-49, 50-59, 60-69, 70+) were also significantly more adherent to HUMIRA®
- These insights may help refine interventions aiming at improving treatment persistence and adherence

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ACKNOWLEDGMENTS

DISCLOSURES

Dr. Louis Bessette has served as a speaker for AbbVie, Amgen, BMS, Janssen, Roche, UCB, Pfizer, Merck, Celgene, Lilly, and Novartis and as a consultant for AbbVie, Amgen, BMS, Janssen, Roche, UCB, Pfizer, Celgene, Lilly, and Novartis. He also collaborated to research with Abbvie, Amgen, BMS, Janssen, Roche, UCB, Pfizer, Merck, Celgene, Sanofi, Lilly, Novartis. Brad Millson and Michael Sung are employees of IMS Brogan and have contributed to this study as consultants paid by AbbVie. Tania Gaetano, Martin Latour and Marie-Claude Laliberté are employees of AbbVie and own AbbVie shares.

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