Canadian Study of Outcomes in HUMIRA® (Adalimumab) Patients with Support for Adherence - Results from the COMPANION Study

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BACKGROUND

- HUMIRA® (adalimumab) was the first fully human biologic developed in the TNF-inhibitor class and is indicated for use in autoimmune diseases including rheumatoid arthritis (RA), ankylosing spondylitis (AS) and psoriatic arthritis (PsA)[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)
- Lower persistence and adherence can result in treatment being less effective, which can increase the use of healthcare resources[3,4]; there is limited evidence in Canada that demonstrates the impact of PSPs on patient outcomes

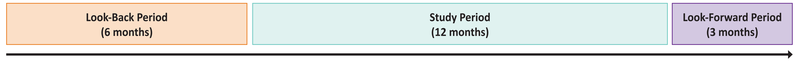
AIMS

- 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®
- To assess the impact of initial CCCs on treatment abandonment (failure to initiate therapy after enrollment in the PSP)

METHODS

DATABASE LINKAGE AND STUDY DESIGN

- A probabilistic matching algorithm[5] was developed to link patients in the HUMIRA® PSP database to patient-level medication transaction (Rx) data
- Patients who started HUMIRA® therapy between July 2010 and August 2014 were selected and indexed on the date of their first script during this period
- A 6-month look-back period was used to ensure patients were naïve to HUMIRA®
- A 3-month look-forward period was used in order to ensure patient activity
- A 12-month study period was used in order to assess patient persistence and adherence



- Persistence to HUMIRA® was calculated by evaluating patients' prescriptions for 12 months following the index date to the end of therapy based on >90 days without Rx data, censored for patients who remained on therapy through month 12
- 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 2014

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

RESULTS

Figure 1. Patient Selection Results

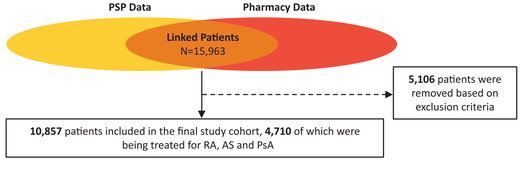
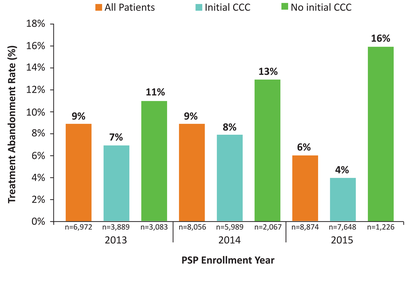


Table 1. Study Patient Characteristics

	Total PSP Patients % (n=38,840)	Final Study Cohort % (n=10,857)
Gender		
Male	45%	45%
Age		
≤ 17	3%	1%
18-29	15%	10%
30-39	19%	17%
40-49	21%	21%
50-59	23%	24%
60-69	14%	17%
≥ 70	6%	9%
Diagnosis		
Crohn's	39%	39%
Ulcerative colitis	4%	3%
Arthritis	19%	19%
Psoriatic Arthritis	10%	10%
Psoriasis	13%	14%
Ankylosing Spondylitis	13%	13%
Other or Undetermined	2%	2%

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

Figure 2. Treatment abandonment rate by PSP enrollment year



- Treatment abandonment **(failure to initiate therapy after enrollment in the PSP)** was >80% more frequent in patients that did not receive an initial care coach call (p<0.0001) **(figure 2)**

FACTORS CORRELATED TO PERSISTENCE AND ADHERENCE

- Male patients were significantly more persistent (HR=0.801, p<0.0001) and adherent (OR=1.127, p=0.0095) than female patients
- Patients aged 0-17 years were more likely to be persistent than older patients (HR=0.442; 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 =1.267 (p=0.0013), OR= 1.241 (p=0.0028), OR=1.354 (p=0.0001), OR=1.438 (p=0.0003))

Figure 3. 12-month persistence by receipt of ongoing care coach calls (CCCs)

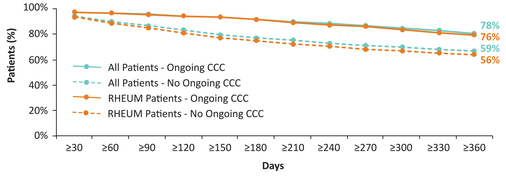
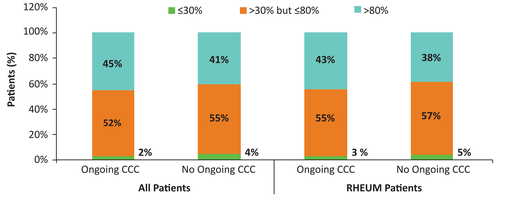


Figure 4. Patient distribution by MPR and by receipt of ongoing care coach calls (CCCs)



- In general, patients receiving ongoing CCCs were 72% less likely to cease treatment (HR = 0.282, p<0.0001) and have 49% greater odds of being highly adherent (>80% MPR) compared to those who did not receive the ongoing CCCs (OR=1.492, p<0.0001) **(figures 3 & 4)**
- RA, AS and PsA patients receiving ongoing CCCs were 74% less likely to cease treatment (HR =0.259, p<0.0001) and have 61% greater odds of being highly adherent (>80% MPR) compared to those who did not receive ongoing CCCs (OR=1.613, p<0.0001)

CONCLUSIONS

- After controlling for confounders, ongoing care coach calls had a statistically significant association with greater persistence and adherence to HUMIRA® over the first 12 months of treatment in all patients including patients with RA, AS and PsA diseases
- Treatment abandonment rate was significantly higher in patients who were enrolled in PSP but did not receive an initial care coach call
- Male patients and older age groups (40-49, 50-59, 60-69, 70+) were significantly more adherent to HUMIRA®
- Male patients, and patients aged 0-17, were significantly more persistent to HUMIRA®
- These insights may help refine interventions aiming at improving treatment persistence and adherence

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DISCLOSURES

Gerega S, Millson B, Sung M, and Oraichi D are consultants paid by AbbVie to collaborate on this study. Bessette L 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. Marshall J has served as a speaker for AbbVie, Allergan, Ferring, Janssen, Procter & Gamble, Shire, and Takeda. He has also served as a consultant for AbbVie, Allergan, Astra-Zeneca, Boehringer-Ingelheim, Celgene, Celltrion, Ferring, Hospira, Janssen, Merck, Pfizer, Procter & Gamble, Shire, and Takeda. Lebovic G has no disclosures. Gaetano T, Gazel S, Latour M and Laliberté MC are employees of AbbVie and own AbbVie shares. Financial support for the study was provided by AbbVie. AbbVie participated in the design of the study, interpretation of data, review, and approval of this publication. All authors contributed to the development of the publication and maintained control over the final content.

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