Impact of adalimumab's patient support program on clinical outcomes in inflammatory bowel diseases: 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 inflammatory bowel diseases (IBD) such as Crohn's disease (CD)[1,2]
- Patients treated with HUMIRA® in Canada are eligible to enroll in the AbbVie Care™ patient support programs (PSP) providing a proprietary suite of services with the goal of improving patients' experiences and outcomes
- PSP were first conceived in order to provide assistance with reimbursement and medication prescription costs but are now increasingly providing additional services
- Clinical outcomes such as the Harvey-Bradshaw Index (HBI scores) are captured for patients within the AbbVie Care™ PSP for reimbursement purposes. HBI classifies patient's IBD severity into remission (≤4), mild (5-7), moderate (8-16) and severe (≥17) categories based on general clinical parameters such as well-being; abdominal pain and mass; number of liquid stools per day; complications
- A previous study demonstrated increased adherence and persistence to HUMIRA® in patients enrolled in PSP and receiving coach care calls (CCCs) compared to patients who don't receive CCCs[3]; however there is limited evidence of the impact of CCCs on clinical outcomes such as IBD severity

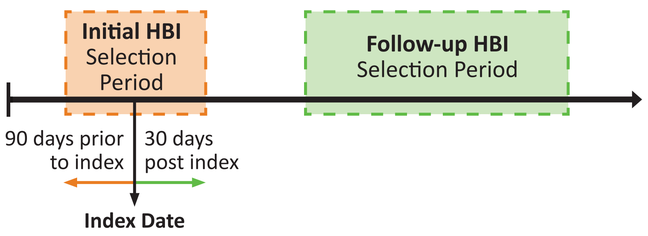
AIMS

- To compare the likelihood of achieving clinical remission (according to the HBI score) in CD patients treated with HUMIRA® enrolled in the AbbVie Care™ PSP between those receiving CCCs versus those not receiving CCCs.

METHODS

STUDY DESIGN AND PATIENT ELIGIBILITY

- A longitudinal retrospective study was conducted using de-identified aggregated patient level data collected through the AbbVie Care™ PSP
- Patients who started HUMIRA® therapy between July 2010 and October 2015 were selected and indexed on the date of their HUMIRA® injection during this period



PATIENT SELECTION CRITERIA

- Enrolled in HUMIRA® PSP after July 2010
- Patients ≥18 years of age with CD diagnosis
- Patients with ≥2 HBI assessment record
- Patient had a baseline HBI measurement between 90 days prior and 30 days after their index date
- Patients with HBI assessment between 180 to 545 days (i.e. follow-up HBI selection period) from the selected initial HBI assessments

Secondary Analysis

- In order to eliminate bias for improved HBI outcomes that were driven by persistence on therapy, a secondary analysis was performed comparing HBI outcomes in patients who were shown to be persistent on HUMIRA® throughout the assessment period[3] (CCC and no CCC)
- For this analysis, persistence on therapy was determined by linking patient data from the HUMIRA PSP and patient-level medication transaction data (LRx database) using a probabilistic matching algorithm that has been described previously.[5]

Statistical Analysis

- Robust Poisson regression analysis was used to determine the adjusted relative risk (RR) of achieving remission at the follow-up HBI assessment for patients receiving CCCs relative to patients not receiving CCCs
- All regression analysis adjusted for multiple potential confounders including, age, sex, region, biologic-naïve status, days lapsed between HBI assessments and baseline IBD severity category.

RESULTS

PRIMARY ANALYSIS – ALL CD PATIENTS

Figure 1. All CD patient selection results

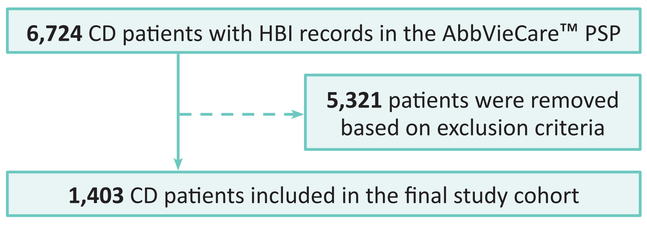


Table 1. Study Patient Characteristics

All CD Patients			
Gender	**Received CCC (N=880)**	**Didn't Receive CCC (N=523)**	**Total (N=1,403)**
Male	45%	42%	44%
Age			
18-29	25%	27%	26%
30-39	22%	25%	23%
40-49	18%	20%	19%
50-59	19%	16%	18%
60-69	11%	9%	10%
≥ 70	5%	3%	5%
Region			
West	56%	46%	52%
ON	34%	41%	36%
QC	0%	0%	0%
East	7%	4%	6%
N/A	3%	9%	5%
Biologic-Naïve Status			
Yes	32%	40%	35%
No	66%	51%	60%
Unknown	2%	10%	5%

CD: Crohn's Disease; ON: Ontario; QC: Quebec; NA: Not available

Figure 2. Care coach call (CCC) status among all CD selected patients

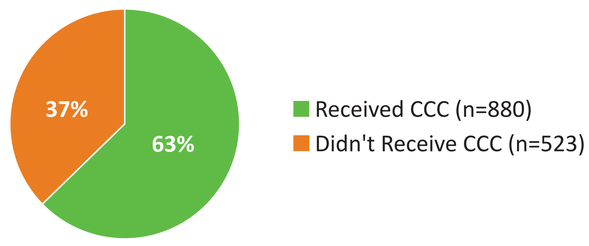
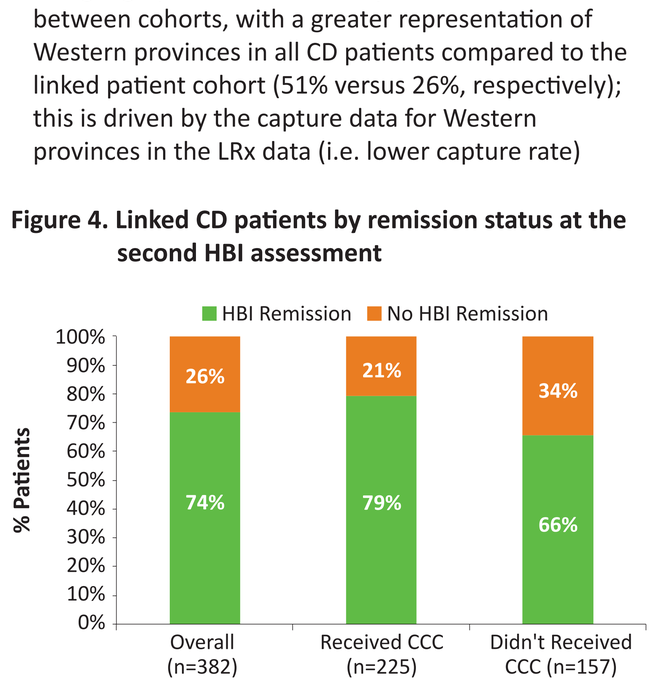


Figure 3. All CD patients by remission status at the second HBI assessment



- There was a 12% increased likelihood of achieving HBI remission among CD patients in AbbVie Care™ PSP who received CCC relative to patients who didn't receive CCC (RR=1.12; 95%CI 1.04-1.21, p=0.0025)

SECONDARY ANALYSIS – LINKED CD PATIENTS

- 382 CD patients were linked to patient level pharmacy data and were persistent between HBI assessments
- Age, gender distributions as well as biologic history and CCC status were similar between the linked and all CD patients
- The geographic distribution of patients differed between cohorts, with a greater representation of Western provinces in all CD patients compared to the linked patient cohort (51% versus 26%, respectively); this is driven by the capture data for Western provinces in the LRx data (i.e. lower capture rate)

Figure 4. Linked CD patients by remission status at the second HBI assessment

- There was a 17% increased likelihood of achieving HBI remission among linked CD patients who were persistent on HUMIRA® who received CCC relative to the group who didn't receive CCC (RR=1.17; 95%CI 1.03-1.34, p=0.0192)

CONCLUSIONS

- CD patients receiving tailored services through the AbbVie Care™ PSP in the form of CCCs have a significantly increased likelihood of achieving HBI remission within 6 to 18 months from their initial HBI assessment
- The improved clinical remission among CD patients could be justified in part by the increased persistence and adherence observed among patients in AbbVie Care™ PSP in a previous published study3.
- A secondary analysis was performed limiting the analysis to patients that were persistent on therapy and the results remained consistent, suggesting the impact of the CCC services is not limited to improved persistence on HUMIRA® alone.
- These results may help refine interventions aimed at improving clinical outcomes in CD patients.

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DISCLOSURES

Dr. John Marshall 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; Dr Neeraj Narula has served as a speaker for AbbVie, Allergan, Ferring, and Janssen. He has also served as a consultant for AbbVie, Ferring, Pfizer, Lupin, and Takeda.; Brad Millson, Katia Charland and Michael Sung are employees of QuintilesIMS and have collaborated to this study as consultants paid by AbbVie; Tania Gaetano, Kevin McHugh, Martin Latour and Marie-Claude Laliberté 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 thepublication and maintained control over the final content.

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