EE484

Evaluation of Health Care Resource Utilization and Costs Among Bio-Experienced Crohn's Disease Patients Treated With Biologics With Two Years of Follow-Up

A. Cyhaniuk[1], R. Zhao[2], Z. Ding[2], P.Gupta[1], S. Kachroo[2]

[1]STATinMED Research, Ann Arbor, MI; [2]Janssen Scientific Affairs, LLC, Horsham, PA

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BACKGROUND

- Crohn's disease (CD) is a chronic inflammatory disease of the gastrointestinal tract, which is associated with high healthcare utilization, especially rates of hospitalization, emergency room (ER) use, and high healthcare costs resulting in estimated direct medical costs of $3.48 billion in the United States in 2016.[1,2]
- Many new biologic therapies have been recently approved for CD. However, there is limited real-world evidence on the health care resource utilization (HCRU) and costs of biologics among bio-experienced CD patients over a 2-year follow-up period.

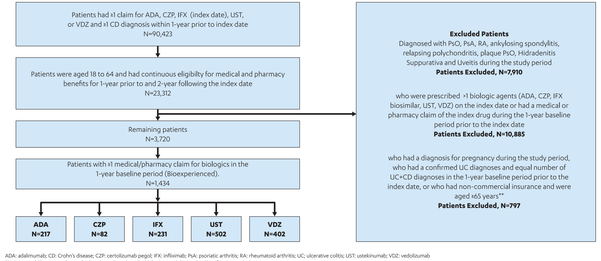
OBJECTIVE

This study examined Crohn's Disease (CD)-related health care resource utilization (HCRU) and costs among bio-experienced CD patients treated with biologics over a 2-year follow-up period. We examined the CD patients treated with adalimumab (ADA), certolizumab pegol (CZP), infliximab (IFX), ustekinumab (UST), and vedolizumab (VDZ). To be defined as bio-experienced patients, the included CD patients were required to have prior biologic usage in the baseline period.

METHODS

- Databases: The study used claims data pooled from three US commercial databases: IQVIA PharMetrics™, IBM® MarketScan®, and Optum Clinformatics
- Study Period:
  - September 26, 2015 – February 29, 2020 (For Optum Clinformatics and for IQVIA PharMetrics)
  - September 26, 2015 – September 30, 2019 (For IBM MarketScan)
- Identification Period:
  - September 26, 2016 – February 29, 2018 (For Optum Clinformatics and for IQVIA PharMetrics)
  - September 26, 2016 – September 30, 2017 (For IBM MarketScan)
- Index Date: Index date was defined as the first claim date for ADA, CZP, IFX, UST, or VDZ among adult patients with ≥1 CD medical claim and ≥1 medical/pharmacy claim for the study biologic agents. Patients could be assigned to multiple cohorts if they used more than one biologic during the identification period, i.e., study cohorts were not mutually exclusive. CZP was excluded from further analysis due to small sample size.
- Baseline Period: 1-year prior to the index date
- Follow-up Period: 2-year post the index date
- Only confirmed CD patients identified by a claims-based algorithm were included in the study cohort.

Figure 1. Patient Selection Criteria



ADA: adalimumab; CD: Crohn's disease; CZP: certolizumab pegol; IFX: infliximab; PsA: psoriatic arthritis; RA: rheumatoid arthritis; UC: ulcerative colitis; UST: ustekinumab; VDZ: vedolizumab
*Patients could be assigned to multiple cohorts based on the biologics used during the identification period
**A modified algorithm based on the Manitoba study was used to exclude patients with an ulcerative colitis (UC) diagnosis or those with equal number of UC and CD diagnosis.[1,3]

Baseline and Outcome Variables

- Baseline variables: age, sex, US geographic region, Charlson comorbidity index (CCI) score, baseline comorbidities, and baseline biologic use.
- Outcome variables: health care resource utilization (HCRU) and associated costs in the second year of follow-up period were evaluated, including emergency room (ER) visits, surgery claims, and inpatient stays. CD-related (defined as claims associated with a CD diagnosis, treatment for CD and its comorbid conditions) and all-cause HCRU and associated costs were reported.

Statistical Analysis

- Descriptive analyses were conducted in the pooled population. Means and standard deviations were computed for continuous variables, and frequency and percentages were calculated for categorical variables.
- The percentage change in CD-related hospitalization, ER visits, surgeries and associated costs were calculated.

Relative change from baseline= (Utilization or cost during follow up - Utilization or cost during baseline)/Utilization or cost during baseline period

- Pre- vs Post-Index Analysis: For each study biologic, CD-related and all-cause HCRU and costs were compared between the baseline and the second year of follow-up period using a paired two-sample t-test (for continuous variables) or McNemar's test (for categorical variables). A p-value of <0.05 was considered statistically significant.
- Costs were adjusted to 2019 US dollars.

RESULTS

A total of 1,434 bio-experienced CD patients were identified of which 217 [15.1%] were treated using ADA, 82 [5.7%] using CZP, 231 [16.1%] using IFX, 502 [35.0%] using UST, and 402 [28.0%] using VDZ.

CZP patients were not included in the analyses because of small sample size.

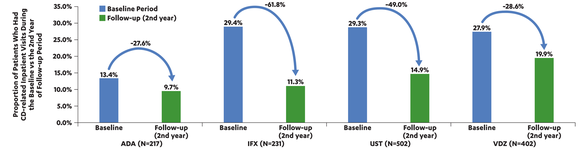
- Patients on UST and VDZ were slightly older and had slightly higher CCI score (**Table 1**).
- Selected comorbidities among bio-experienced CD patients included anemia, anxiety, fatigue, and depression (**Table 1**).
- A higher proportion of bio-experienced UST patients used more than 1 biologic during baseline period.

Table 1. Descriptive Baseline Characteristics

Characteristics	Adalimumab N=217	Infliximab N=231	Ustekinumab N=502	Vedolizumab N=402
Age, mean	38.0	37.6	40.8	41.3
Age group, in years (%)				
18-34	40.6%	45.5%	33.7%	30.3%
35-54	44.2%	43.7%	49.2%	52.5%
55-64	15.2%	10.8%	17.1%	17.2%
Sex, %				
Male	57.1%	51.5%	56.6%	51.7%
Female	42.9%	48.5%	43.4%	48.3%
US geographic regions, %				
Northeast	17.1%	22.5%	18.9%	17.9%
North Central	31.3%	34.6%	31.7%	32.8%
South	41.5%	33.3%	36.3%	41.5%
West	9.7%	9.1%	12.%	7.7%
Unknown	0.5%	0.4%	0.2%	0.0%
Charlson comorbidity index score, mean	1.0	1.0	1.3	1.3
Comorbidities, %				
Anemia	28.1%	31.2%	40.6%	31.1%
Anxiety	18.4%	20.8%	22.7%	20.6%
Antherosclerosis	0.0%	0.4%	1.0%	0.5%
Celiac disease	1.8%	2.6%	4.0%	3.7%
Cholelithiasis	3.7%	3.9%	3.2%	3.0%
Chronic pain	4.1%	4.3%	6.8%	7.0%
Depression	12.9%	17.7%	20.3%	17.9%
Diabetes	6.0%	2.2%	5.0%	3.7%
Fatigue	15.7%	16.0%	14.7%	16.2%
Fistula	6.0%	9.5%	11.6%	7.0%
Obesity	6.9%	12.1%	9.8%	10.2%
Venous Thromboembolism	2.3%	0.9%	3.6%	3.0%
Baseline Biologic Use (UST, VDZ, ADA, IFX, CZP), %	100%	100%	100%	100%
ADA	0.0%	81.0%	45.0%	53.7%
CZP	11.5%	7.8%	12.5%	12.9%
IFX	80.6%	0.0%	26.5%	40.0%
UST	1.8%	3.0%	0.0%	2.0%
VDZ	10.6%	13.9%	31.7%	0.0%
# of biologics during baseline period, %				
Only 1 biologic	95.9%	93.5%	83.7%	91.0%
2 biologics	3.7%	6.5%	15.1%	8.5%
3 biologics	0.5%	0.0%	0.6%	0.2%
4 or more biologics	0.0%	0.0%	0.6%	0.2%

*Due to rounding of the percentages, some of the categorical variables might not add up to a 100%.

Figure 2. Pre-post CD-related and All-cause Hospitalization and Associated Costs Among Bio-experienced Crohn's Disease Patients Treated With Biologics

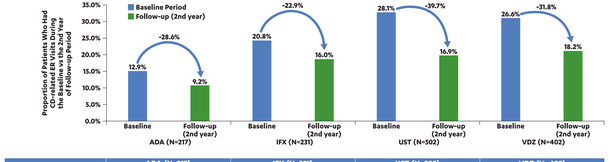


	ADA (N=217)		IFX (N=231)		UST (N=502)		VDZ (N=402)	
	Baseline vs Follow-up (2nd year)	Relative change from baseline	Baseline vs Follow-up (2nd year)	Relative change from baseline	Baseline vs Follow-up (2nd year)	Relative change from baseline	Baseline vs Follow-up (2nd year)	Relative change from baseline
CD-related inpatient utilization	13.4% vs 9.7% (p=0.3222)	-27.6%	29.4% vs 11.3% (p<0.0001)	-61.8%	29.3% vs 14.9% (p<0.0001)	-49.0%	27.9% vs 19.9% (p=0.0253)	-28.6%
Mean annual CD-related inpatient costs	$9,380 vs $3,806 (p=0.0263)	-59.4%	$14,263 vs $6,537 (p=0.0185)	-54.2%	$13,888 vs $6,134 (p<0.0001)	-55.8%	$9,868 vs $9,769 (p=0.9622)	-1.0%
All-cause inpatient utilization	13.4% vs 9.7% (p=0.3222)	-27.6%	29.4% vs 12.6% (p<0.0001)	-58.0%	29.3% vs 15.3% (p<0.0001)	-47.6%	28.1% vs 20.9% (p=0.0461)	-25.7%
Mean annual all-cause inpatient costs	$11,097 vs $4,916 (p=0.0449)	-55.7%	$15,376 vs $7,347 (p=0.0185)	-52.2%	$15,343 vs $7,795 (p<0.0004)	-49.2%	$10,751 vs $11,692 (p=0.6806)	8.8%

ADA: adalimumab; CD: Crohn's disease; IFX: infliximab; UST: Ustekinumab; VDZ: vedolizumab
Relative change from baseline=(Utilization or cost during follow up-Utilization or cost during baseline)/Utilization or cost during baseline period
Note: Statistical significance represented by p-value <0.05 and by colored cells.

- Compared to baseline, proportion of patients with CD-related inpatient stays decreased significantly for IFX (29.4% vs 11.3%; p-value <0.0001), UST (29.3% vs 14.9%; p-value <0.0001), and VDZ (27.9% vs 19.9%, p-value =0.0253) in the second year of follow-up. ADA cohort had a numeric decrease in CD-related inpatient stays. A similar decreasing pattern was also observed for all-cause inpatient stays.
- The mean annual CD-related inpatient costs decreased significantly by $5,573 (p-value =0.0263) for ADA, $7,726 (p-value =0.0185) for IFX, and $7,755 (p-value < 0.0001) for UST in the second year of follow-up relative to baseline. This cost slightly decreased numerically for VDZ by $98 (p-value =0.9622) in the second year of follow-up relative to baseline.
- The mean annual all-cause inpatient costs decreased significantly by $6,182 (p-value =0.0449) for ADA, $8,030 (p-value =0.0185) for IFX, and $7,548 (p-value =0.0004) for UST in the second year of follow-up relative to baseline. This cost slightly increased for VDZ by $941 (p-value =0.6806) in the second year of follow-up relative to baseline.

Figure 3. Pre-post CD-related and All-cause Emergency Room Visits and Associated Costs Among Bio-experienced Crohn's Disease Patients Treated With Biologics

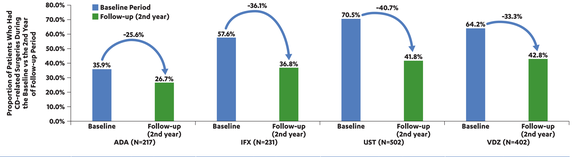


	ADA (N=217)		IFX (N=231)		UST (N=502)		VDZ (N=402)	
	Baseline vs Follow-up (2nd year)	Relative change from baseline	Baseline vs Follow-up (2nd year)	Relative change from baseline	Baseline vs Follow-up (2nd year)	Relative change from baseline	Baseline vs Follow-up (2nd year)	Relative change from baseline
CD-related ER utilization	12.9% vs 9.2% (p=.3123)	-28.6%	20.8% vs 16.0% (p=0.2781)	-22.9%	29.3% vs 16.9% (p=0.0003)	-39.7%	26.6% vs 18.2% (p=0.0139)	-31.8%
Mean annual CD-related ER costs	$336 vs $149 (p=0.1102)	-55.8%	$518 vs $546 (p=0.9137)	5.5%	$781 vs $328 (p<0.0003)	-57.9%	$733 vs $437 (p=0.1454)	-40.4%
All-cause ER utilization	23.0% vs 20.7% (p=0.6815)	-10.0%	34.2% vs 27.3% (p=0.2081)	-20.3%	39.4% vs 28.5% (p=0.0035)	-27.8%	34.9% vs 28.4% (p=0.0838)	-18.7%
Mean annual all-cause ER costs	$669 vs $401 (p=0.0858)	-40.2%	$878 vs $813 (p=0.8306)	-7.4%	$1,248 vs $655 (p=0.0009)	-47.5%	$1,713 vs $1,051 (p=0.2712)	-38.6%

ADA: adalimumab; CD: Crohn's disease; ER: Emergency room; IFX: infliximab; UST: Ustekinumab; VDZ: vedolizumab
Relative change from baseline=(Utilization or cost during follow up-Utilization or cost during baseline)/Utilization or cost during baseline period
Note: Statistical significance represented by p-value <0.05 and by colored cells.

- Proportion of patients with CD-related ER visits decreased significantly for UST (28.1% vs 16.9%; p-value =0.0003) and VDZ (26.6% vs 18.2%; p-value =0.0139), and numerically for ADA (12.9% vs 9.2%; p-value =0.3123) and IFX (20.8% vs 16.0%; p-value =0.2781) during the second year of follow-up compared to baseline. Decreasing trend was also observed for all-cause ER visits.
- The mean annual CD-related and all-cause ER costs decreased significantly for UST in the second year of follow-up relative to baseline. Numerical decreases in CD-related ER costs and all-cause ER costs were observed among patients treated with ADA and VDZ.

Figure 4. Pre-post CD-related Surgeries and Associated Costs Among Bio-experienced Crohn's Disease Patients Treated with Biologics



	ADA (N=217)		IFX (N=231)		UST (N=502)		VDZ (N=402)	
	Baseline vs Follow-up (2nd year)	Relative change from baseline	Baseline vs Follow-up (2nd year)	Relative change from baseline	Baseline vs Follow-up (2nd year)	Relative change from baseline	Baseline vs Follow-up (2nd year)	Relative change from baseline
CD-related surgeries	35.9% vs 26.7% (p=0.1033)	-25.6%	57.6% vs 36.8% (p=0.0015)	-36.1%	70.5% vs 41.8% (p<0.0000)	-40.7%	64.2% vs 42.8% (p<0.0001)	-33.3%
Mean annual CD-related surgeries	$5,277 vs $2,145 (p=0.1042)	-59.4%	$7,061 vs $3,851 (p=0.1389)	-45.5%	$5,895 vs $3,461 (p=0.0145)	-41.3%	$4,531 vs $4,072 (p=0.6685)	-10.1%

ADA: adalimumab; CD: Crohn's disease; IFX: infliximab; UST: Ustekinumab; VDZ: vedolizumab
Relative change from baseline =Utilization or cost during follow up-Utilization or cost during baseline)/Utilization or cost during baseline period

- Compared to baseline, proportion of patients with CD-related surgeries decreased significantly for IFX (57.6% vs 36.8%, p-value =0.0015), UST (70.5% vs 41.8%, p-value <0.0001), and VDZ (64.2% vs 42.8%; p-value <0.0001) and numerically for ADA (35.9% vs 26.7%; p-value =0.1033) in the second year of follow-up.
- CD-related surgical costs also decreased significantly by $2,434 (p-value =0.0145) for UST and numerically by $3,133 (p-value =0.1042) for ADA, $3,210 (p-value =0.1389) for IFX, and $459 (p-value =0.6685) for VDZ during second year of follow-up compared to baseline.

LIMITATIONS

- National drug code (NDC) and healthcare common procedure coding system (HCPCS) codes were used to identify all biologic claims. For UST, permanent HCPCS codes for intravenous UST were not available for until January 2018. It is possible that some UST induction doses were not adequately captured.
- Analysis of claims data depends on correct diagnosis, procedure, and drug codes. Coding errors can result in misclassification.
- The findings from this study are descriptive in nature, and therefore should not be used to make any comparisons between products studied.

CONCLUSIONS

- There appeared to be varying levels of baseline disease severity among treatments studied.
- Among bio-experienced CD patients treated with biologics, there were decreases in the proportion of patients with CD-related and all-cause ER visits, inpatient stays, surgeries, and associated costs from baseline to the second year of follow-up.

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DISCLOSURES

Ruizhi Zhao, Zhijie Ding, and Sumesh Kachroo are employees of Janssen Scientific Affairs, LLC and Johnson & Johnson. Anissa Cyhaniuk and Parul Gupta are employees of SIMR, LLC and supported this study as a paid consultant to Janssen Scientific Affairs.

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