The Impact of Treatment Switch Among Prevalent Patients with Crohn's Disease Treated with a First-Line Biologic: A US Retrospective Claims Database Study

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CONCLUSIONS

- In this real-world study, patients with CD who had a treatment switch incurred significantly higher HRU and healthcare costs
- Study limitations include the retrospective and descriptive analytical design; the fixed time window to evaluate treatment switching, which may have excluded later switchers (potential misclassification bias); the inability to distinguish newly diagnosed patients from others, as switch rates may differ between those groups; and the absence of clinical variables indicating disease severity
- The study findings suggest a potential unmet need with current treatment options and highlight the impact of switching biologics on the economic burden of patients with CD

BACKGROUND/OBJECTIVE



Crohn's disease (CD) is a chronic inflammatory bowel condition that requires lifelong



Treatment switching often occurs with biologic use among patients with CD and has been associated with worsened clinical symptoms and functional impairment²⁻⁵



Little is known, however, about the impact of treatment switching on healthcare resource utilization (HRU) and costs in CD¹

Objective: We conducted a database analysis to assess the economic burden associated with treatment switching among adults with CD in the United States

Data Source

Statistical Analyses



Data were analyzed from the IBM® MarketScan® Commercial Subset, a database consisting of employer- and health plan-sourced data containing medical and drug data for beneficiaries covered by employer-sponsored private health-insurance

Data were obtained from the period October 1, 2015, to March 31, 2020

The index date was

defined as the first

prescription fill for

a biologic

Study Population



For inclusion in the analysis, patients were adults (aged ≥18 years) who:

Had ≥6 months of continuous health plan enrollmen before their first observed diagnosis of CD

Patients were classified into switchers or non-switchers based on whether

they (1) switched to another biologic treatment for CD, or (2) switched to

5-aminosalicylic acid or immunomodulator after a discontinuation of 60

days at any time during the 12-month study period after the index date

Non-switchers (n=3,366 [84%])

1583 (47)

680 (20)

760 (23)

585 (17)

Diagnosed with CD (≥2 observed CD diagnoses ≥30 days apart)

Were treated with a first-line biologic for their CD (≥1 observed biologic prescription fill or injection on or after their first observed

(549/640)

Had ≥6 months of after their first

METHODS

continuous health plan enrollment before and ≥14 months of continuous enrollment observed biologic prescription fill or injection (Figure 1)

HRU and cost outcomes

(in 2020 US dollars) were

evaluated for a 12-month

Among switchers

period after the index date

(153/640)

switched to an immunomodulator

Figure 1. Study Design **Washout Period** Baseline Period • ≥6 months of health 6 months of health

plan enrollment

Mean time to treatment

Kaplan-Meier analyses

switch was estimated using

Study Period • ≥12 months* of health plan enrollment Baseline characteristics

Mar 31, 20

≥2 CD diagnoses on two dates ≥30 days apart

Outcomes were compared between switchers and non-switchers

unadjusted logistic regressions for categorical variables

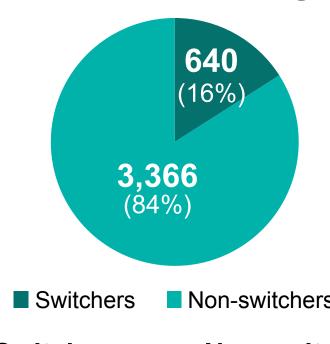
using unadjusted linear regressions for continuous variables and

*An extra 2-month follow-up period at the end of the study period (total of 14 months) was required in the sample selection for the assessment of treatment discontinuation. CD, Crohn's disease.

RESULTS

- Among 4,006 patients included in the study, 640 were switchers and 3,366 were non-switchers (**Table 1**)
- Overall, mean age was 39.5 years and 51% were female
- Patient demographics, disease characteristics, and comorbidities were similar between the groups
- The standardized difference between treatment groups exceeded 0.2 only for co-use of corticosteroids (**Table 1**)
- Time to treatment switch is shown in Figure 2

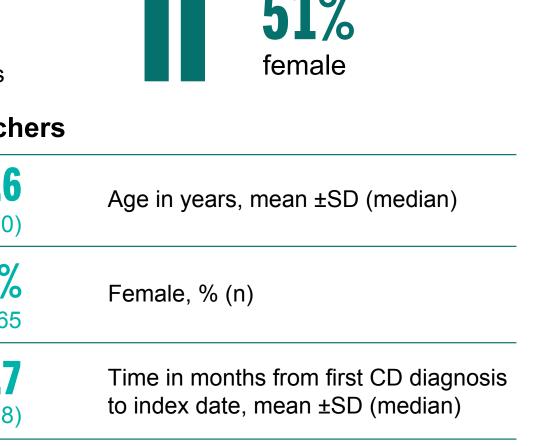
Table 1. Patient Demographics and Clinical Characteristics



±13.9 (38.5)

±8.3 (2.3)





51% female	
years, mean ±SD (median)	
e, % (n)	

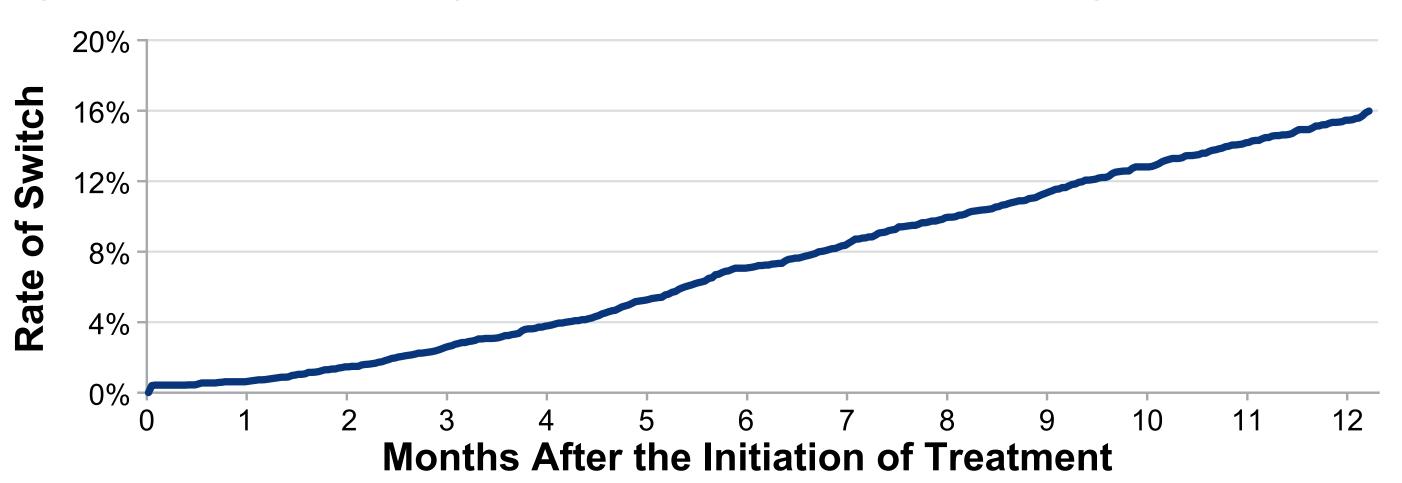
e in years, mean ±SD (median)
male, % (n)
ne in months from first CD diagnosis index date, mean ±SD (median)

% le	Cardiovascular disease	137 (21)
	Anemia	146 (23)
	Weight loss	74 (12)
	Fatigue	77 (12)
	Depression	72 (11)
:SD (median)	Perianal fistula	43 (7)
	Intestinal stricture	42 (7)
	IV corticosteroid	22 (3)
	Fistula of the intestine	11 (2)
	Renal comorbidity	4 (1)
first CD diagnosis £SD (median)	Co-medications, n (%)	
	Corticosteroids ^a	400 (63)

CD-related comorbidities, n (%)

are at the time of the index date. CD and treatment characteristics are from the 6-month baseline period before the index date. ^aStandardized difference between groups of 0.31. 5-ASA, 5-aminosalicylic acid; CD, Crohn's disease; IV, intravenous; SD, standard deviation

Figure 2. Kaplan-Meier Analysis of Time to Switch From Initial Biologic Treatment



Rates of treatment switch were 70/ at 6 months 16% at 12 months

323 (51)

230 (36)

166 (26)

172 (27)

101 (16)

	1 Month	3 Months	6 Months	9 Months	12 Months
Patients at risk, n	3,980	3,901	3,722	3,550	3,366
Cumulative number of treatment switch events, n	26	105	284	456	640
Cumulative rate (95% CI)	0.6 (0.4; 1.0)	2.6 (2.2; 3.2)	7.1 (6.3; 7.9)	11.4 (10.4; 12.4)	16.0 (14.9; 17.1)

Time to treatment switch was measured from the index date (i.e., first observed biologic prescription fill or injection) to the date of the first treatment switch. CI, confidence interval.

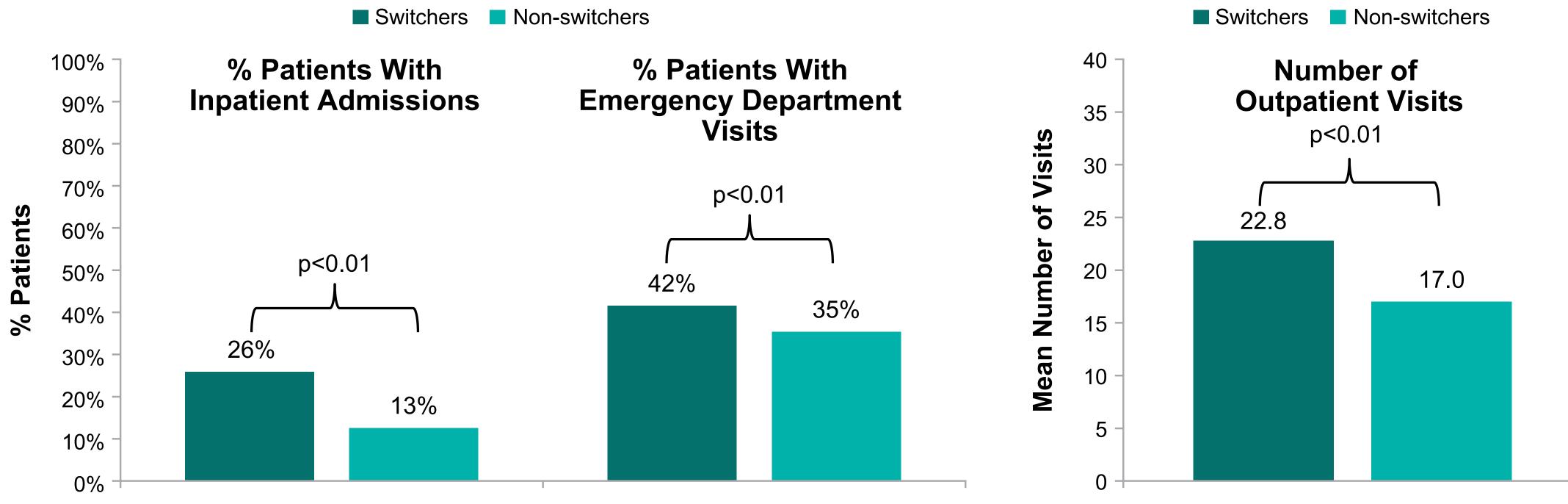
1. Privitera G. et al. *Therap Adv Gastroenterol.* 2021:14:17562848211006669: 2. Khan S. et al. *J Clin Pharm Ther.* 2019:44:495-507: 3. Patel H. et al. PLoS One. 2017;12:e0175099; 4. Van Assche G, et al. Gut. 2012;61:229-34; 5. Hoentjen F, et al. Inflamm Bowel Dis. 2013;19:761-6.

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Regarding HRU, switchers had significantly higher rates of inpatient admissions, emergency department visits, and number of outpatient visits compared to non-switchers (Figure 3)

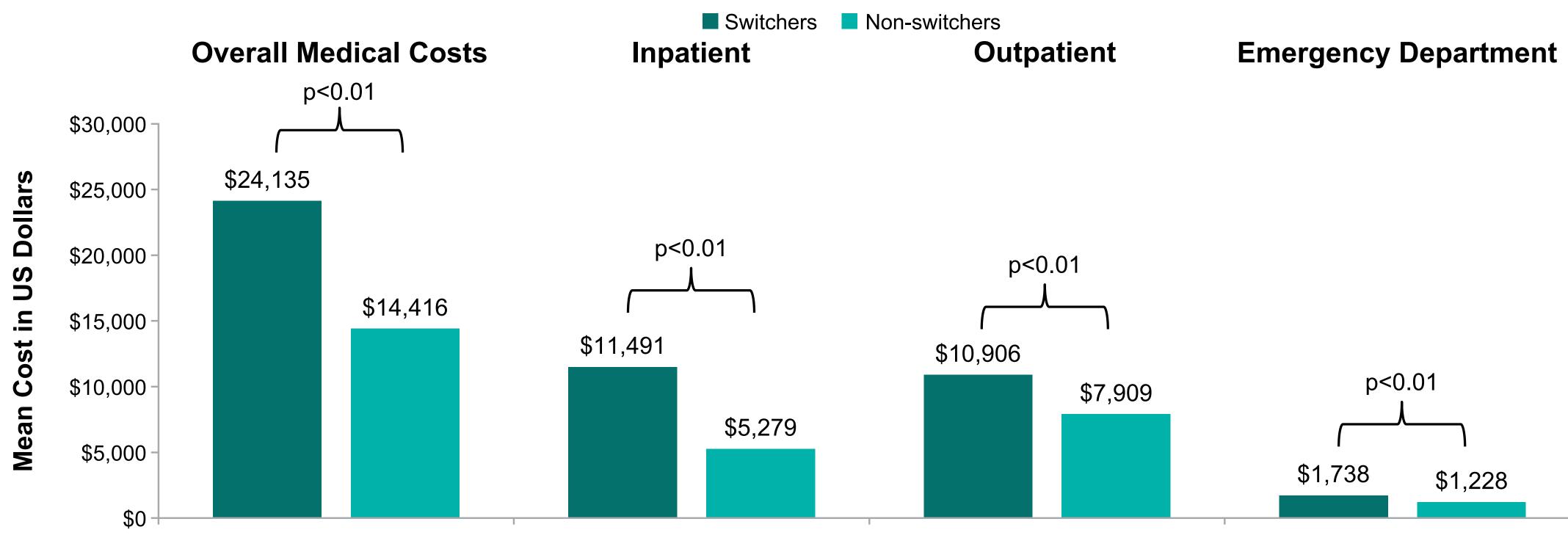
 Additionally, the rate of prolonged corticosteroid use (≥90 days) was higher in switchers compared to non-switchers (32% vs 8%, p<0.01)

Figure 3. Healthcare Resource Utilization in Switchers vs Non-switchers (12-Month Follow-up Period)



- Total all-cause healthcare costs were significantly higher among switchers than non-switchers (\$95,689 versus \$81,027, respectively, p<0.01), which was mainly driven by higher medical costs (Figure 4)
- Among age groups, switchers 30—39 years incurred the highest total healthcare costs (\$100,676 vs \$78,265, p<0.01)

Figure 4. Medical Costs Overall and by Individual Components in Switchers vs Non-switchers (12-Month Follow-up Period)



^aMedical costs include inpatient, outpatient, and emergency department costs

Myrlene Sanon, Sumesh Kachroo, Timothy Hoops, and Dominik Naessens are employees of the Janssen Pharmaceutical Companies of Johnson & Johnson. Patrick Gagnon-Sanschagrin Mikhail Davidson, Annie Guerin, and Martin Cloutier are employees of Analysis Group, Inc, which was hired by Janssen to perform study analyses. Cynthia Willey is a consultant for Goldfinch Biotech Inc. and Otsuka Pharmaceutical, and a scientific advisor or member of the Journal of Clinical Therapeutics, Editorial Board