VANDERBILT HEALTH | Specialty Pharmacy

Real-World Outcomes of Adalimumab Biosimilar Transitions in Patients from Inflammatory Bowel Disease and Rheumatology Clinics

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Background

There is an unmet need for real-world patient outcomes regarding biosimilar switching in inflammatory bowel disease (IBD) and rheumatology patients.

Purpose

Evaluate clinical outcomes of patients on an adalimumab originator compared to patients switched from an adalimumab originator to adalimumab biosimilars in inflammatory bowel disease and rheumatology clinics.

Methods

Design

Single-center retrospective cohort study

Setting

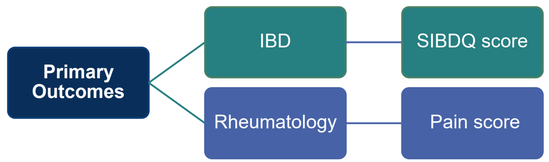
Vanderbilt Rheumatology and Inflammatory Bowel Disease clinics

Study Population

Patients who were stable on Humira®, with at least one fill for Humira® between January 1, 2024 – March 31, 2024

Compared patients who switched to a biosimilar between January 2024 and June 2024 to patients who remained on Humira®

Outcomes



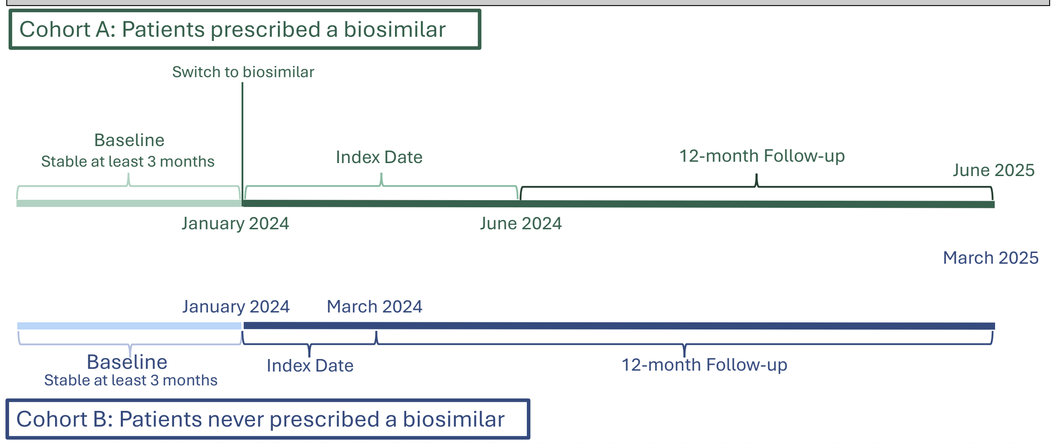
Secondary Outcomes

- Adverse events
- Switches after initial biosimilar initiation
- Reasons for switch
- One-year adherence (PDC) and persistence

Statistical Analysis

- Descriptive Statistics
- Ordinal mixed effects model to examine longitudinal pain or SIBDQ scores
- Wilcoxon rank sum test (PDC)
- Log-rank test (Persistence)

Figure 1. Study Timeline



CONCLUSION

- Biosimilar switching was not associated with differences in pain scores, while SIBDQ scores increased among those who switched.
- Formulary changes and biosimilar supply issues prompted patients to switch to biosimilar products, not patient preference.

Results

Table 1. Patient Characteristics

Characteristic	Overall n=879 n (%)	Switch Group n=259 n (%)	Non-Switch Group n=620 n (%)
Sex, Female	513 (58)	155 (60)	358 (58)
Age, Median (IQR)	47 (35-59)	46 (35-56)	48 (35-61)
Race, White	772 (88)	230 (89)	542 (87)
Pharmacy Insurance			
Commercial	710 (81)	256 (99)	454 (73)
Clinic Prescribing Humira®			
IBD	384 (44)	104 (40)	280 (45)
Rheumatology	495 (56)	155 (60)	340 (55)
Diagnosis			
Crohn's disease	318 (36)	82 (32)	236 (38)
Rheumatoid arthritis	256 (29)	81 (31)	175 (28)
Other*	305 (35)	96 (37)	209 (34)

*Other: Ankylosing spondylitis, Juvenile idiopathic arthritis, Other off-label use, Plaque psoriasis, Psoriatic arthritis, Ulcerative colitis, Uveitis

Figure 2. Post-Biosimilar Initiation Switches

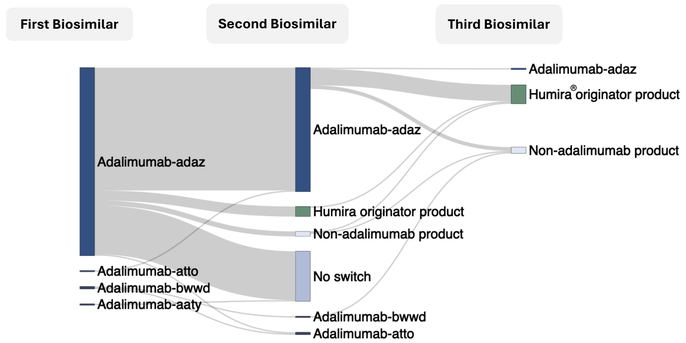


Figure 3. Adherence and Persistence

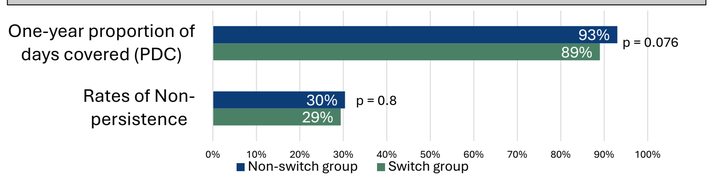


Figure 5. Longitudinal Pain and SIBDQ Scores

Inflammatory Bowel Disease (n=226)

Median baseline SIBDQ score **62 (IQR 56-64)**

Median follow-up SIBDQ score **61 (54- 65)**

Patients who **switched** to a biosimilar were more likely to have **higher SIBDQ** scores (p=0.001)

Change in SIBDQ scores over time between the two groups was significant (p = 0.002)

Rheumatology (n=215)

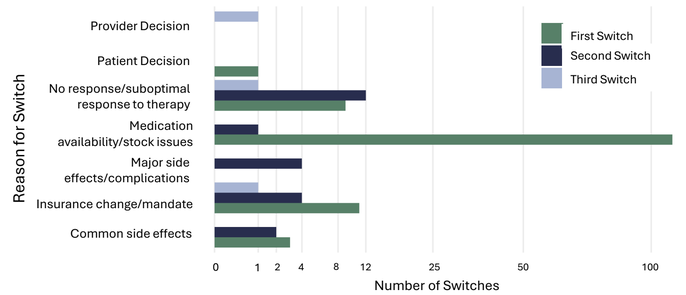
Median baseline pain score **3 (IQR 0-5)**

Median follow-up pain score **3 (IQR 0-6)**

Pain scores were **not significantly different** between switch and non-switch patients (p=0.852)

Older age was associated with **increased pain scores** over time (per 1 year, OR: 1.03, 95% CI 1.01 - 1.06, p = 0.013)

Table 4. Reasons for Switching



After biosimilar initiation, **67%** of patients required additional switches

Table 2. Adverse Events for Switch Group

8% reported experiencing adverse events within 12 months

30% had a flare or worsening symptoms within 12 months

Adverse Event	Overall N=20*
Fatigue	7 (35%)
Nausea	2 (10%)
Infection	2 (10%)
Injection Site Reaction	2 (10%)
Headache	1 (5%)
Vomiting	1 (5%)
Other	12 (60%)

*20 patients in the switch group reported an AE

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