Abstract # 0812

Real-World Utilization of Infliximab (IFX) and Its Biosimilars in Patients (Pts) with Rheumatoid Arthritis (RA) Since the First Biosimilar Approval in the US

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1. Background

Biologics have revolutionized the treatment of autoimmune diseases, though costs and payer restrictions have limited who is treated and when these agents are used. Potentially lower cost biosimilars have been developed and FDA-approved, although only 2 TNF inhibitors have been made available to patients.

Here, we describe utilization and characteristics of patients receiving infliximab (IFX) and its biosimilars in US community rheumatology practices.

2. Methods

Electronic medical records data from the American Rheumatology Network (ARN) - Trio Health Rheumatology registry was used for the study. The ARN is a physician-led and owned organization with over 200 practicing rheumatologists that supports some of the largest independent practices in the US.

Patients with RA diagnosis who initiated or switched to IFX or biosimilars since December 2016 were selected for analysis. Differences between treatment groups were assessed using t-test for continuous variables and chi-square test for categorical variables. Logistic regression model was used to evaluate binary outcome remission or low disease activity at 6 months accounting for demographic and treatment characteristics. Time to treatment discontinuation was assessed using Kaplan-Meier method.

3. Results

3156 patients met study criteria; 1972 (62%) were on IFX (775 [39%] as monotherapy) and 1184 (38%) received biosimilars (306 [26%] as monotherapy). Of patients on biosimilars, 350 (30%) switched between different biosimilars or IFX and were removed from the analysis. The remaining 834 patients were treated with infliximab-dyyb (574 [69%]) or infliximab-abda (260 [31%]).

There were no differences by age and gender between IFX and each biosimilar group [Table 1]. Compared to patients on biosimilars, those receiving IFX had longer follow-up, fewer prior DMARD or biologic regimens, and longer duration of treatment with IFX. Patients on biosimilars were less likely to be commercially insured and more likely to be on Medicaid compared to IFX. IFX patients were more likely to be in remission or with low disease activity at treatment initiation and at 6 mo since treatment initiation compared to patients on biosimilars; there were no differences between biosimilar groups.

IFX patients had smaller improvement from baseline to 6-mo CDAI compared to those on biosimilars [Table 2]. Median time to treatment discontinuation was not statistically different among groups [Figure 1]. Accounting for age, payer, regimen, corticosteroid use, duration of therapy, number of prior regimens, and baseline disease activity status, variables significantly impacting the outcome were baseline disease activity, regimen duration, and use of corticosteroids but not choice of a biologic [Figure 2].

4. Summary

Among RA patients treated with IFX and its biosimilars there were differences in demographic and baseline clinical characteristics. IFX was used earlier in the treatment journey than biosimilars with higher proportion of patients in remission at baseline and last observation. Time to treatment discontinuation was similar among groups.

After accounting for other patient and treatment characteristics, regimen choice (use of a particular biosimilar vs IFX) was not significantly associated with treatment success at 6 mo since regimen initiation.

TABLE 1: Demographic and Clinical Characteristics

no (%) unless indicated	A: IFX N=1972	B: Infliximab-dyyb n=574	C: Infliximab-abda n=260	p-values <0.05 are shown		
				A vs B	A vs C	B vs C
Age- mean (SD)	62.4 (14.1)	63.4 (13.2)	63.7 (13.5)			
Follow-up - months, mean (SD)	19.5 (9.3)	13.1 (8.7)	6.3 (3.8)	<0.001	<0.001	<0.001
Female	1525 (77)	454 (79)	211 (81)			
Race						
White	1064 (54)	289 (50)	128 (49)			
Black	60 (3)	31 (5)	10 (4)	0.007		
Other	27 (1)	7 (1)	7 (3)			
Unknown	821 (42)	247 (43)	115 (44)			
Payer						
Commercial	943 (48)	189 (33)	59 (23)		<0.001	0.003
Medicare	857 (43)	284 (49)	123 (47)			
Medicare Advantage	62 (3)	15 (3)	11 (4)			
Medicaid	82 (4)	47 (8)	63 (24)		<0.001	<0.001
other	23 (1)	39 (7)	4 (2)			
unknown	5 (0)	189 (33)	59 (23)			0.001
Region						
South	671 (34)	341 (59)	46 (18)	<0.001	<0.001	<0.001
Central	280 (14)	5 (1)	7 (3)	<0.001	<0.001	0.041
West	1021 (52)	228 (40)	207 (80)	<0.001	<0.001	<0.001
Prior regimens, mean (SD)	1.4 (1.8)	2.2 (1.9)	2 (1.6)	<0.001	<0.001	0.006
On steroids	845 (43)	238 (41)	93 (36)		0.030	
On methotrexate	843 (43)	265 (46)	116 (45)			
Baseline Rapid3, mean (SD)	4.1 (2.3) n=562	3.9 (2.4) n=294	3.2 (2.6) n=72		0.005	0.040
Baseline CDAI	12.2 (12.2) n=494	17.4 (12.5) n=324	16.1 (12.4) n=184	<0.001	<0.001	
Baseline DAS28	2.8 (1.4) n=77	4.2 (1.4) n=12	4.5 (1.7) n=20	0.003	<0.001	
Baseline remission or low disease activity (by Rapid3, CDAI or DAS28)	591 (66) n=889	180 (43) n=417	87 (43) n=204	<0.001	<0.001	

TABLE 2: Outcomes at 6 Months

Outcomes	A: IFX N=1972	B: Infliximab-dyyb n=574	C: Infliximab-abda n=260	p-values <0.05 are shown		
				A vs B	A vs C	B vs C
CDAI improvement at 6 months	-1.6 (7.9) n=330	-4.9 (11.2) n=185	-4.9 (12.7) n=60	<0.001	0.007	
Rapid 3 improvement at 6 months	-0.4 (2) n=294	-0.4 (2) n=151	-0.6 (1.4) n=15			
DAS28 improvement at 6 months	0.3 (1.1) n=56	-0.7 (1.6) n=6	-0.6 (0.8) n=5	0.048		
6-Month measurement remission or low disease activity	761 (75) n=1021	169 (60) n=284	46 (56) n=82	<0.001	<0.001	

FIGURE 1: Time to Treatment Discontinuation (months)

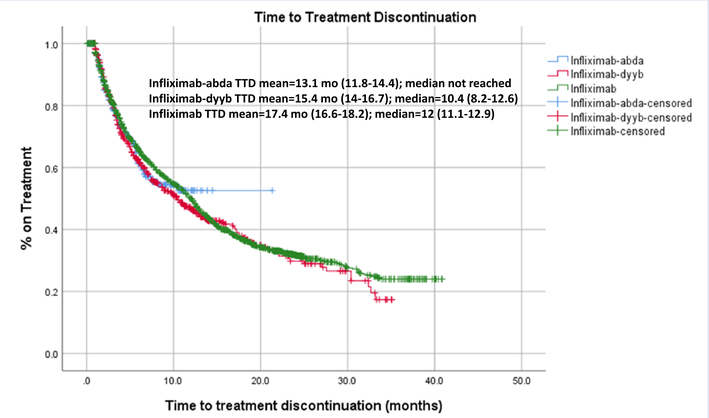
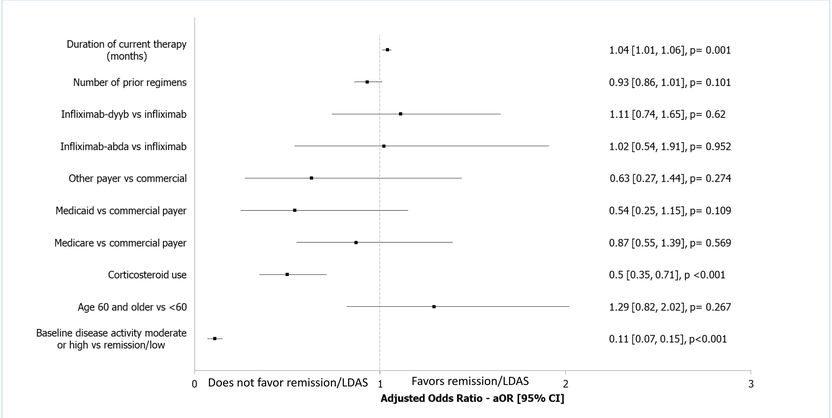


FIGURE 2: Characteristics Associated with Remission/Low Disease Activity at 6 Months Since Regimen Initiation



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