Outcomes with Infliximab and Its Biosimilars in Patients with Rheumatoid Arthritis (RA): Real-World Experience 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 are currently commercially available to patients.

This retrospective observational study describes outcomes at 6 months among RA patients receiving infliximab and its biosimilars in US community rheumatology practices.

2. Methods

Electronic medical records from the American Rheumatology Network (ARN) - Trio Health Rheumatology registry were used for the study. The ARN is a physician led and owned organization with over 200 practicing rheumatologists across the US. Trio Health, an exclusive partner to ARN for data aggregation and analytics, collects and matches data from ARN providers and servicing specialty pharmacies.

Patients with RA diagnosis who initiated or switched to infliximab or biosimilars since December 2016 were selected for analysis. Logistic regression was used to evaluate binary outcome remission or low disease activity at 6 months (vs moderate or high disease activity) accounting for patient characteristics (age, payer, regimen, glucocorticoid use, number of prior regimens, and baseline disease activity). Time to treatment discontinuation was assessed using Kaplan-Meier method.

3. Results

Of 2806 patients, 1972 (70%) received infliximab and 834 (30%) biosimilars: infliximab-dyyb (69%) or infliximab-abda (31%).

Compared to those on biosimilars, infliximab patients had significantly (p<.001) fewer prior synthetic disease-modifying antirheumatic drugs (DMARDs) or biologic regimens (mean regimens 1.4 (SD 1.8) vs 2.2 (1.9) infliximab-dyyb, 2 (1.6) infliximab-abda), were less likely to be Medicaid insured (4% vs 8% infliximab-dyyb, 24% infliximab-abda), were more likely to be in remission or with low disease activity at treatment initiation (66% vs 43% infliximab-dyyb, 43% infliximab-abda) and at 6 months since treatment initiation (75% vs 60% infliximab-dyyb, 56% infliximab-abda) [Table 1].

Infliximab 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].

In multivariable analysis variables significantly associated the outcome were baseline disease activity, payer type, and use of glucocorticoids but not choice of a biologic [Figure 2]. Patients with high or moderate baseline disease activity, on Medicaid as opposed to commercial insurance, and those receiving glucocorticoids were less likely to achieve remission or low disease activity at 6 months post regimen initiation.

4. Summary

Among RA patients treated with infliximab and its biosimilars there were differences in demographic and baseline clinical characteristics. Infliximab 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 treatment groups.

After accounting for patient characteristics, regimen choice was not significantly associated with treatment success at 6 months since regimen initiation.

TABLE 1: Demographic and Clinical Characteristics

no (%) unless indicated	A: Infliximab 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 glucocorticoids	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: Improvement in Disease Activity Scores Outcomes at 6 Months

Outcomes	A: Infliximab 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)

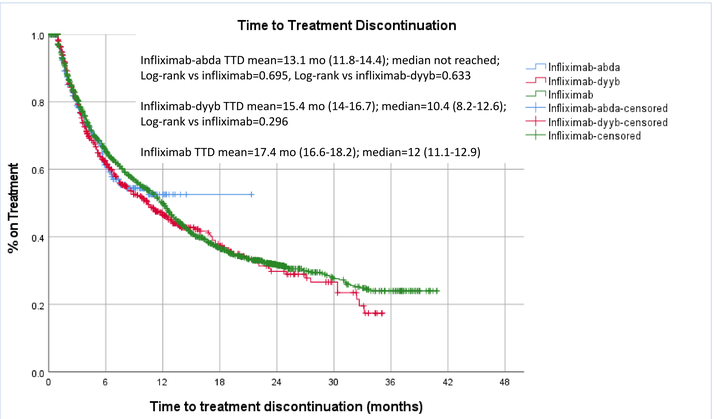
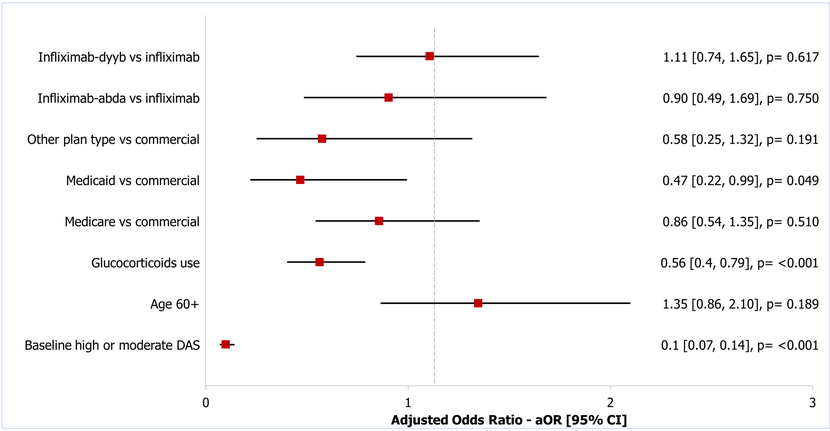


FIGURE 2: Characteristics Associated with Remission/Low Disease Activity at 6 Months Since Regimen Initiation



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