Persistency on csDMARDs without Evidence of Rheumatoid Arthritis Control; Identifying Populations that may Benefit from Availability of Lower-Cost TNFi Biosimilars

Frick A[1], Broestl J[1], Cox K[2], Milligan K[2], Persons D[1], Milligan S[1]
[1]Trio Health Analytics, Louisville, CO, USA, [2]Trio Health Advisory, Louisville, CO, USA

1. BACKGROUND

Seven FDA-approved adalimumab biosimilars are anticipated to launch in the US in 2023, potentially yielding reductions in treatment cost –a known factor driving disparities in healthcare. Here we identify and characterize patients with RA who persist on low-cost csDMARDs without evidence of improved disease control, as a surrogate for the population who may benefit from availability of lower-cost biosimilars.

2. METHODS

Data: PIONEER-Rheumatology, an open text-enhanced EMR database specific to care given by the American Rheumatology Network. Study populations: Adult (18+y) patients with RA, first csDMARD in 2018-2021 (index), >18m follow up from index, disease assessments (CDAI, RAPID3, and/or DAS28) within -180d to +30d (baseline) and within +120d to +365d of index, remaining on csDMARDs ≥365d. [FIGURES 1&2] Minimally important difference (MID) between baseline and during csDMARD treatment defined as: CDAI >12 when starting >22, >6 when starting 10–22, and >1 when starting <10; DAS28 >1.2; RAPID3 >1.27 (10 point scale). Analyses: T-test, Pearson's chi-square, proportions comparisons by z-test, Bonferroni correction.

3. RESULTS

2342 study patients: white (56.8%), female (72.6%), commercial coverage (56.0%), and median age of 61 (IQR 51-70) with 42.3% ≥65y. [TABLE 1] Most patients had moderate/severe disease at index (70.7%) by at least 1 measure. 1360/2342 (58%) patients persisted on csDMARDs ≥365d without achieving MID. [FIGURE 2] In the subset with moderate/severe activity at baseline, MID was not achieved by 761/1656 (46%) patients. Median (IQR) disease measures at and post index are provided in TABLE 2. In contrast to those achieving MID, the population not benefiting from csDMARD had higher proportions of female gender (78.4% v 68.7% achieved MID, p<0.01), black race (11.4% v 6.6% achieved MID; p<0.01), and Medicaid coverage (7.1% v 3.6% achieved MID; p<0.01). [TABLE 1]

4. CONCLUSION

More than half of study patients (58%) – disproportionately of female gender, black race and/or Medicaid coverage – had no observed improvement in disease despite persisting on csDMARDs for ≥365d. These patients may benefit from availability of lower-cost biosimilars.

FIGURE 1: Study Diagram

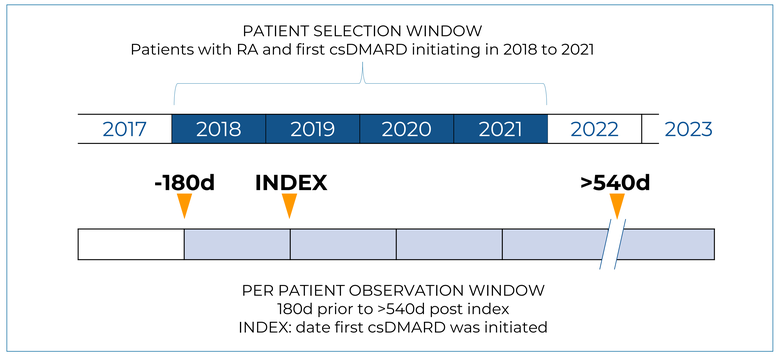

FIGURE 2: Patient Selection and Primary Result

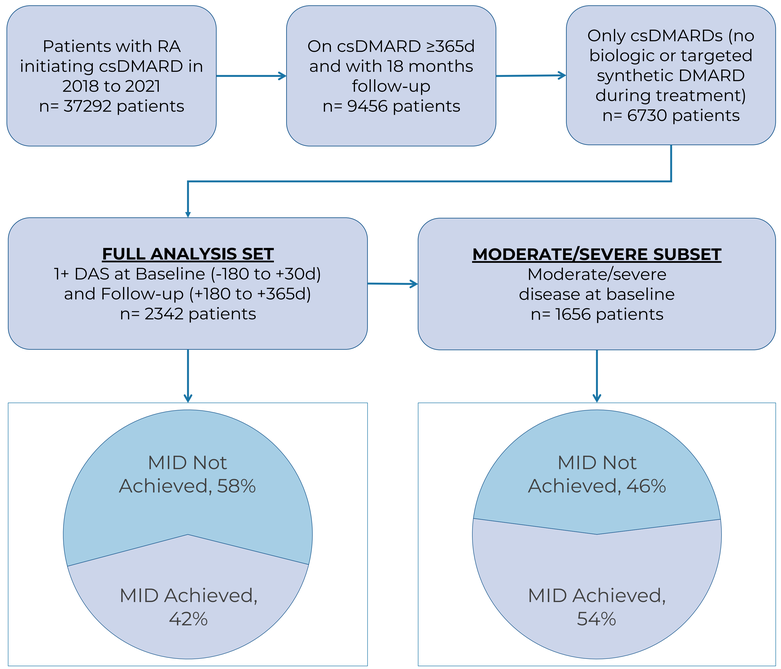

TABLE 1: Baseline Characteristics: Full Cohort

Category	Characteristic	Full Analysis Set				Moderate /Severe Subset			
		All n=2342	no MID n=1360	MID n=982	p	All n=1656	no MID n=761	MID n=895	p
Age	Med (IQR)	61 (51,70)	61 (50.75,69)	63 (52,71)	0.176	61 (51,70)	60 (51,68)	63 (52,71)	0.102
	18-39	217/2342 (9.3%)	141/1360 (10.4%)	76/982 (7.7%)		141/1656 (8.5%)	72/761 (9.5%)	69/895 (7.7%)	
	40-64	1134/2342 (48.4%)	670/1360 (49.3%)	464/982 (47.3%)		834/1656 (50.4%)	405/761 (53.2%)	429/895 (47.9%)	
	65+	991/2342 (42.3%)	549/1360 (40.4%)	442/982 (45.0%)		681/1656 (41.1%)	284/761 (37.3%)	397/895 (44.4%)	
Gender	Female	1696/2341 (72.4%)	1026/1360 (75.4%)	670/981 (68.3%)	0.001	1211/1655 (73.2%)	597/761 (78.4%)	614/894 (68.7%)	<0.001
	Male	645/2341 (27.6%)	334/1360 (24.6%)	311/981 (31.7%)		444/1655 (26.8%)	164/761 (21.6%)	280/894 (31.3%)	
	Unknown	1/2342 (0.0%)		1/982 (0.1%)		1/1656 (0.1%)		1/895 (0.1%)	
Race					0.295				0.007
	Black	184/2342 (7.9%)	124/1360 (9.1%)	60/982 (6.1%)	*	146/1656 (8.8%)	87/761 (11.4%)	59/895 (6.6%)	**
	Other	137/2342 (5.8%)	85/1360 (6.2%)	52/982 (5.3%)		94/1656 (5.7%)	48/761 (6.3%)	46/895 (5.1%)	
	White	1330/2342 (56.8%)	758/1360 (55.7%)	572/982 (58.2%)		977/1656 (59.0%)	447/761 (58.7%)	530/895 (59.2%)	
	Unknown	691/2342 (29.5%)	393/1360 (28.9%)	298/982 (30.3%)		439/1656 (26.5%)	179/761 (23.5%)	260/895 (29.1%)	
Payer Type					0.242				0.03
	Commercial	1312/2342 (56.0%)	765/1360 (56.2%)	547/982 (55.7%)		930/1656 (56.2%)	424/761 (55.7%)	506/895 (56.5%)	
	Medicaid	126/2342 (5.4%)	88/1360 (6.5%)	38/982 (3.9%)	*	86/1656 (5.2%)	54/761 (7.1%)	32/895 (3.6%)	**
	Medicare	815/2342 (34.8%)	458/1360 (33.7%)	357/982 (36.4%)		568/1656 (34.3%)	248/761 (32.6%)	320/895 (35.8%)	
	Other	62/2342 (2.6%)	39/1360 (2.9%)	23/982 (2.3%)		51/1656 (3.1%)	29/761 (3.8%)	22/895 (2.5%)	
	Unknown	27/2342 (1.2%)	10/1360 (0.7%)	17/982 (1.7%)		21/1656 (1.3%)	6/761 (0.8%)	15/895 (1.7%)	
csDMARD Duration (m)	First csDMARD	23 (19,30)	24 (19,30)	23 (19,29)	>0.9	23 (19,29)	23 (19,29)	23 (19,29)	>0.9
	All csDMARDs	25 (21,31)	26 (21,31)	25 (21,31)	0.239	25 (21,31)	26 (21,31)	25 (21,31)	0.868

*p<0.05; **p<0.01

TABLE 2: Assessments at Index & Follow-up for Moderate/Severe Cohort

Score: Med (IQR)	Result	n*	pre	post	delta
Rapid3	No MID	566	4.10 (3.10,5.57)	4.70 (3.40,5.97)	0 (-0.67,0.90)
	MID	636	4.30 (3.08,5.90)	1.60 (0.70,2.90)	-2.40 (-3.20,-1.60)
	Total	1202	4.30 (3.10,5.80)	3.10 (1.40,4.80)	-1.10 (-2.50,0)
CDAI	No MID	175	15 (12,20.75)	14.50 (10.75,18.50)	-1.50 (-4,0.50)
	MID	316	17 (11,24.12)	5.50 (2,9)	-11 (-17.50,-6.50)
	Total	491	16 (12,23)	8 (4,13.50)	-7 (-13,-2)
DAS28	No MID	240	3.99 (3.51,4.71)	3.76 (3.10,4.68)	-0.40 (-0.80,0.13)
	MID	333	4.16 (3.12,5.34)	2.30 (1.73,2.90)	-1.85 (-2.62,-1.26)
	Total	573	4.07 (3.44,5)	2.85 (2.18,3.85)	-1.07 (-2.07,-0.25)

*n do not sum to 100% as patients may have had multiple types of disease assessments (i.e. RAPID3 and CDAI)

This study was supported by Scipher Medicine. Trio Health has received research support from AbbVie, Actelion Pharmaceuticals, AstraZeneca, Gilead Sciences, GSK, Horizon Pharma, JNJ, Merck, Pharming Healthcare, Sanofi, Takeda, UCB Biosciences, and ViiV Healthcare.