EXPERIENCE WITH APREMILAST IN TREATMENT OF PSORIATIC ARTHRITIS IN US CLINICAL PRACTICE; ASSESSMENTS FROM TRIO HEALTH AND THE AMERICAN RHEUMATOLOGY NETWORK (ARN)

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1. Background

As a PDE4 inhibitor, apremilast is a unique agent in the treatment armamentarium for psoriatic arthritis. It is the one targeted immune modulating (TIM) treatment that may be combined with csDMARDs, biologic therapies, or used as a monotherapy. Here we examined care for psoriatic arthritis in a large network of community rheumatologists focusing on use of apremilast relative to TNF inhibitors.

2. Methods

The American Rheumatology Network (ARN)-TRIO Rheumatology registry consists of EMR (fielded and open text), lab, procedure, infusion, medical claims, and specialty pharmacy data generated in care of >75,000 patients by ARN, a network of independent practices with >200 rheumatologists across the US. For this study, registry data were limited to patients diagnosed with PsA who initiated apremilast or TNF inhibitors between Jan 2014 to Nov 2019 with ≥6 months follow-up. Disease Assessment Scores (DAS) were calculated using CDAI or RAPID3 and analyzed categorically using a 4-grade scale. Comparisons between groups used Fisher's Exact Test for categorical variables. As a surrogate for clinical effectiveness, we examined time from apremilast monotherapy initiation to modification or discontinuation, defined as either drug discontinuation or addition of a csDMARD or TIM drug. Time to event analyses were conducted via KM curves and associated Log-Rank Test for difference in Hazard among apremilast and propensity score matched TNFi.

3. Results

Of 817 apremilast-treated patients, 378 (46%) had no prior observed PsA treatment, 205 (25%) had previous csDMARDs treatment alone, and 234 (29%) previously received other TIM therapies. Two or more of the apremilast treatment groups were significantly different for age, payer type, and regimen type; groups were not different by gender, race, baseline disease severity. [Table 1] Across these groups, 329 (40%) received apremilast as a monotherapy without prior TIM therapies. A comparator group of 2438 patients who received a TNF inhibitor (TNFi) as a monotherapy and without prior TIM was identified. Characteristics for the apremilast monotherapy and TNFi monotherapy groups differed significantly for gender and race but not for baseline disease severity. [Table 1] Patients starting apremilast with no prior TIM therapy had a higher proportion of modification of apremilast compared to discontinuation, while patients with prior TIM had higher proportion of discontinuation compared to those without prior TIM. [Figure 1] Patient median time from monotherapy start to modification or discontinuation was significantly different between apremilast (19.3 months) and matched TNFi (30.4 months, p=0.002). In subset analyses, differences in time to modification persisted between apremilast and TNFi monotherapy groups among males (p = 0.003), females (p = 0.008), and patients with severe baseline DAS (p=0.009), but not among those with non-severe baseline DAS. [Figure 2]

4. Summary

The use of apremilast in US community practice is predominantly as a monotherapy or booster with prior DMARD or other TIM. When examined as a first TIM monotherapy, time to modification or discontinuation was significantly less than comparator TNFi monotherapy-treated group. However, when stratified by gender and baseline DAS, female patients and those with low DAS had no difference in time to modification between apremilast and TNFi. These results should be viewed in light of the limitations of the study, which include potential prior treatments, other confounding variables not present in the collected data, or limited baseline DAS data.

Table 1: Apremilast Study Population Characteristics

		Apremilast Therapies						Monotherapy Apremilast vs Monotherapy TNFi				
		(1)	(2)	(3)	p			(4)	(5)	(6)	p	
Category	Characteristic	No Prior Therapies	Prior csDMARDs	Prior TIM Therapies	1v2	1v3	2v3	TNFi Monotherapy	Matched TNFi Monotherapy	Apremilast Monotherapy	4v6	5v6
N		378	205	234				2438	658	329		
Gender	Female	243 (64.3)	144 (70.2)	153 (65.4)	0.168	0.795	0.307	1291 (53.0)	434 (66.0)	217 (66.0)	<0.001	1
Race	White	221/233 (94.8)	150/152 (98.7)	158/163 (96.9)	0.142	0.624	0.686	1332/1368 (97.4)	380/390 (97.4)	196/207 (94.7)	0.058	0.069
	Black	10/233 (4.3)	2/152 (1.3)	4/163 (2.5)				25/1368 (1.8)	10/390 (2.6)	9/207 (4.3)		
	Other	2/233 (0.9)		1/163 (0.6)				11/1368 (0.8)		2/207 (1.0)		
	Unknown	145 (38.4)	53 (25.9)	71 (30.3)				1070 (43.9)	268 (40.7)	122 (37.1)		
Ethnicity	Hispanic or Latino	10/209 (4.8)	4/132 (3.0)	11/174 (6.3)	0.578	0.653	0.285	57/1240 (4.6)	11/350 (3.1)	10/187 (5.3)	0.582	0.244
	Not Hispanic or Latino	199/209 (95.2)	128/132 (97.0)	163/174 (93.7)				1183/1240 (95.4)	339/350 (96.9)	177/187 (94.7)		
	Unknown	169 (44.7)	73 (35.6)	60 (25.6)				1198 (49.1)	308 (46.8)	142 (43.2)		
Age Group	18-44	86 (22.8)	35 (17.1)	51 (21.8)	0.03	0.374	0.176	716/2435 (29.4)	181 (27.5)	63 (19.1)	<0.001	0.014
	45-54	88 (23.3)	56 (27.3)	71 (30.3)				586/2435 (24.1)	162 (24.6)	79 (24.0)		
	55-64	124 (32.8)	51 (24.9)	64 (27.4)				577/2435 (23.7)	156 (23.7)	108 (32.8)		
	65-74	34 (9.0)	27 (13.2)	21 (9.0)				434/2435 (17.8)	127 (19.3)	61 (18.5)		
	75-100	46 (12.2)	36 (17.6)	27 (11.5)				122/2435 (5.0)	32 (4.9)	18 (5.5)		
Payer Type	Commercial	219/363 (60.3)	109/200 (54.5)	136/233 (58.4)	0.056	0.691	0.035	1271/2153 (59.0)	327/576 (56.8)	183/310 (59.0)	0.598	0.717
	Medicare/ Medicare Adv.	63/363 (17.4)	52/200 (26.0)	38/233 (16.3)				388/2153 (18.0)	115/576 (20.0)	62/310 (20.0)		
	Other	81/363 (22.3)	39/200 (19.5)	59/233 (25.3)				494/2153 (22.9)	134/576 (23.3)	65/310 (21.0)		
Baseline Disease Assessment	Near Remission	11/79 (13.9)	1/20 (5.0)	4/18 (22.2)	0.004	0.743	0.048	71/373 (19.0)	21/105 (20.0)	10/69 (14.5)	0.769	0.691
	Low	21/79 (26.6)		3/18 (16.7)				73/373 (19.6)	18/105 (17.1)	16/69 (23.2)		
	Moderate	21/79 (26.6)	5/20 (25.0)	5/18 (27.8)				107/373 (28.7)	30/105 (28.6)	19/69 (27.5)		
	Severe	26/79 (32.9)	14/20 (70.0)	6/18 (33.3)				122/373 (32.7)	36/105 (34.3)	24/69 (34.8)		
	No Baseline DAS	299 (79.1)	185 (90.2)	216 (92.3)				2065 (84.7)	553 (84.0)	260 (79.0)		
Apremilast therapy	Monotherapy	300 (79.4)	29 (14.1)	45 (19.2)	<0.001	<0.001	<0.001	NA	NA	329 (100)		
	+csDMARD	50 (13.2)	165 (80.5)	60 (25.6)								
	+TIM	26 (6.9)	2 (1.0)	91 (38.9)								
	csDMARD + TIM	2 (0.5)	9 (4.4)	38 (16.2)								
Prior Treatment	Prior Dmard							230 (9.4)	63 (9.6)	29 (8.8)	0.84	0.729

FIGURE 1: Treatment Pathways for First Apremilast Line of Therapy

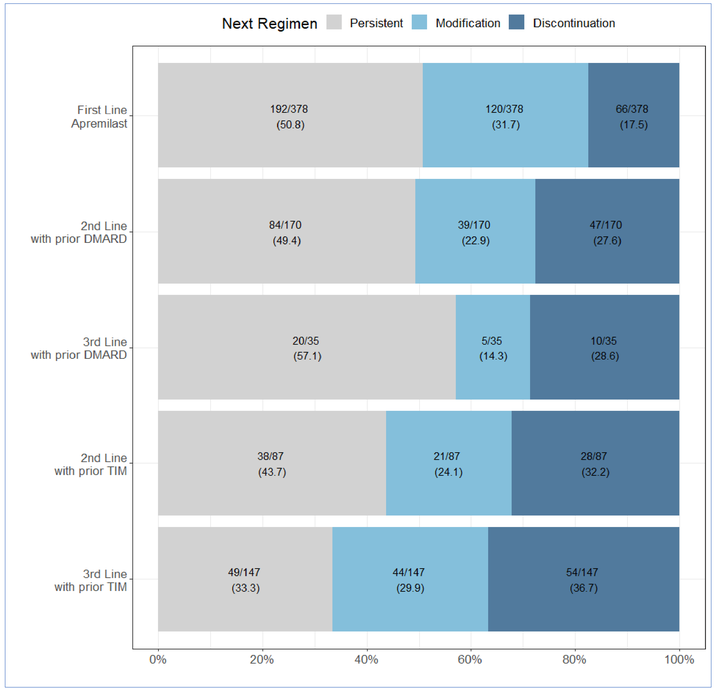
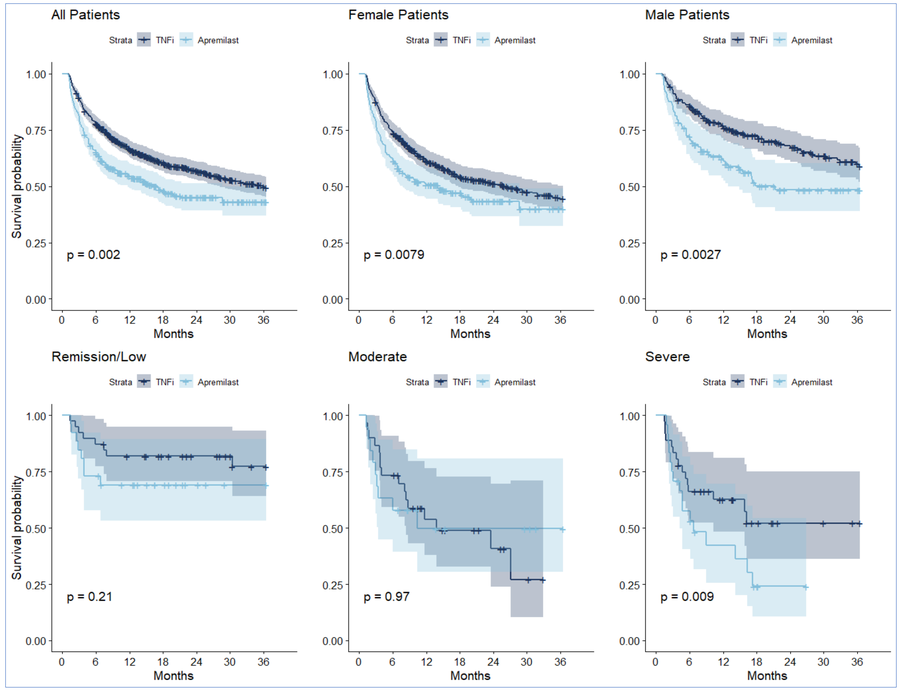


FIGURE 2: Time to Modification or Discontinuation of Monotherapy Apremilast or TNFi



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