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

Abstract # 0365

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1. BACKGROUND

Apremilast is a targeted immune modulating (TIM) treatment for psoriatic arthritis (PsA) that may be combined with csDMARDs, biologic therapies, or used as a monotherapy. Here we describe the utilization of and experience with apremilast in a large network of community rheumatologists.

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.

3. RESULTS

Of the 581 apremilast-treated patients in the study, 325 (56%) had no prior observed PsA treatment, 129 (22%) previously were treated with csDMARDs but not TIM drugs, and 127 (22%) had previously received TIM therapies. Two or more of the apremilast treatment groups were significantly different for gender, race, age, payer, and prior therapies; groups were not different by baseline disease severity. [Table 1] Across these groups, 227 (48%) received apremilast as a monotherapy without prior TIM therapies. A comparator group of 1662 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 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 = 0.037) and patients with severe baseline DAS (p=0.009), but not among females or non-severe baseline DAS. [Figure 2]

4. SUMMARY

The use of apremilast in US community practice is predominantly as a monotherapy. 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 or other confounding variables not present in the collected data.

TABLE 1: APREMILAST STUDY POPULATION CHARACTERISTICS

No. (%)	(1) Apremilast No Prior Therapies (N = 325)	(2) Apremilast Prior csDMARDs (N = 129)	(3) Apremilast Prior TIM (N = 127)	(4) Apremilast Monotherapy No prior TIM (N = 277)	(5) TNFi Monotherapy No prior TIM (N = 1662)	p 1v2	1v3	2v3	4v5
Female	207 (63.7)	93 (72.1)	85 (66.9)	185 (66.8)	909 (54.7)	0.099	0.585	0.416	**<0.001**
Race						0.188	**0.019**	0.747	0.135
White	199/209 (95.2)	91/94 (96.8)	92/93 (98.9)	173/183 (94.5)	828/859 (96.4)				
Black	10/209 (4.8)	2/94 (2.1)	-	9/183 (4.9)	20/859 (2.3)				
Other	-	1/94 (1.1)	1/93 (1.1)	1/183 (0.5)	11/859 (1.3)				
Unknown	116/325 (35.7)	35/129 (27.1)	34/127 (26.8)	94/277 (33.9)	803/1662 (48.3)				
Ethnicity						0.625	0.397	1	0.178
Hispanic or Latino	3/166 (1.8)	2/66 (3.0)	3/81 (3.7)	3/143 (2.1)	32/666 (4.8)				
Not Hispanic or Latino	163/166 (98.2)	64/66 (97.0)	78/81 (96.3)	140/143 (97.9)	634/666 (95.2)				
Unknown	159 (48.9)	63 (48.8)	46 (36.2)	134 (48.4)	996 (59.9)				
Age Group						0.058	0.417	0.270	**0.004**
18-44	63 (19.4)	21 (16.3)	22 (17.3)	49 (17.7)	431 (25.9)				
45-54	75 (23.1)	36 (27.9)	41 (32.3)	62 (22.4)	419 (25.2)				
55-64	113 (34.8)	30 (23.3)	38 (29.9)	93 (33.6)	409 (24.6)				
65-74	32 (9.8)	20 (15.5)	11 (8.7)	56 (20.2)	303 (18.2)				
75-100	42 (12.9)	22 (17.1)	15 (11.8)	17 (6.1)	100 (6.0)				
Payer						0.067	0.946	0.150	0.606
Commercial	237 (72.9)	82 (63.6)	94 (74.0)	196 (70.8)	1200 (72.2)				
Medicare/ Medicare Advantage	69 (21.2)	41 (31.8)	27 (21.3)	66 (23.8)	356 (21.4)				
Other	19 (5.8)	6 (4.7)	6 (4.7)	15 (5.4)	106 (6.4)				
Baseline Disease Assessment						0.781	0.256	0.261	0.975
Near Remission	21/124 (16.9)	7/38 (18.4)	2/33 (6.1)	18/102 (17.6)	107/544 (19.7)				
Low	25/124 (20.2)	5/38 (13.2)	6/33 (18.2)	18/102 (17.6)	96/544 (17.6)				
Moderate	40/124 (32.3)	12/38 (31.6)	16/33 (48.5)	31/102 (30.4)	160/544 (29.4)				
Severe	38/124 (30.6)	14/38 (36.8)	9/33 (27.3)	35/102 (34.3)	181/544 (33.3)				
No Baseline DAM	201/325 (61.8)	91/129 (70.5)	94/127 (74.0)	175/277 (63.2)	1118/1662 (67.3)				
Apremilast						**<0.001**	**<0.001**	**<0.001**	-
Monotherapy	255 (78.5)	22 (17.1)	16 (12.6)	277 (100)	NA				
+csDMARD	40 (12.3)	101 (78.3)	22 (17.3)	-	NA				
+TIM	25 (7.7)	1 (0.8)	70 (55.1)	-	NA				
csDMARD + TIM	5 (1.5)	5 (3.9)	19 (15.0)	-	NA				

FIGURE 1: TREATMENT PATHWAYS FOR FIRST APREMILAST LINE OF THERAPY

Legend: Apremilast Discontinuation; Apremilast Modification; Apremilast Persistent

First Line Apremilast: 185 (57%), 107 (33%), 33 (10%)
2nd Line Apremilast w/ Prior DMARD: 49 (46%), 34 (32%), 23 (22%)
2nd Line Apremilast w/ Prior TIM: 32 (54%), 11 (19%), 16 (27%)
3rd Line Apremilast w/ Prior DMARD: 10 (44%), 10 (44%), 3 (13%)
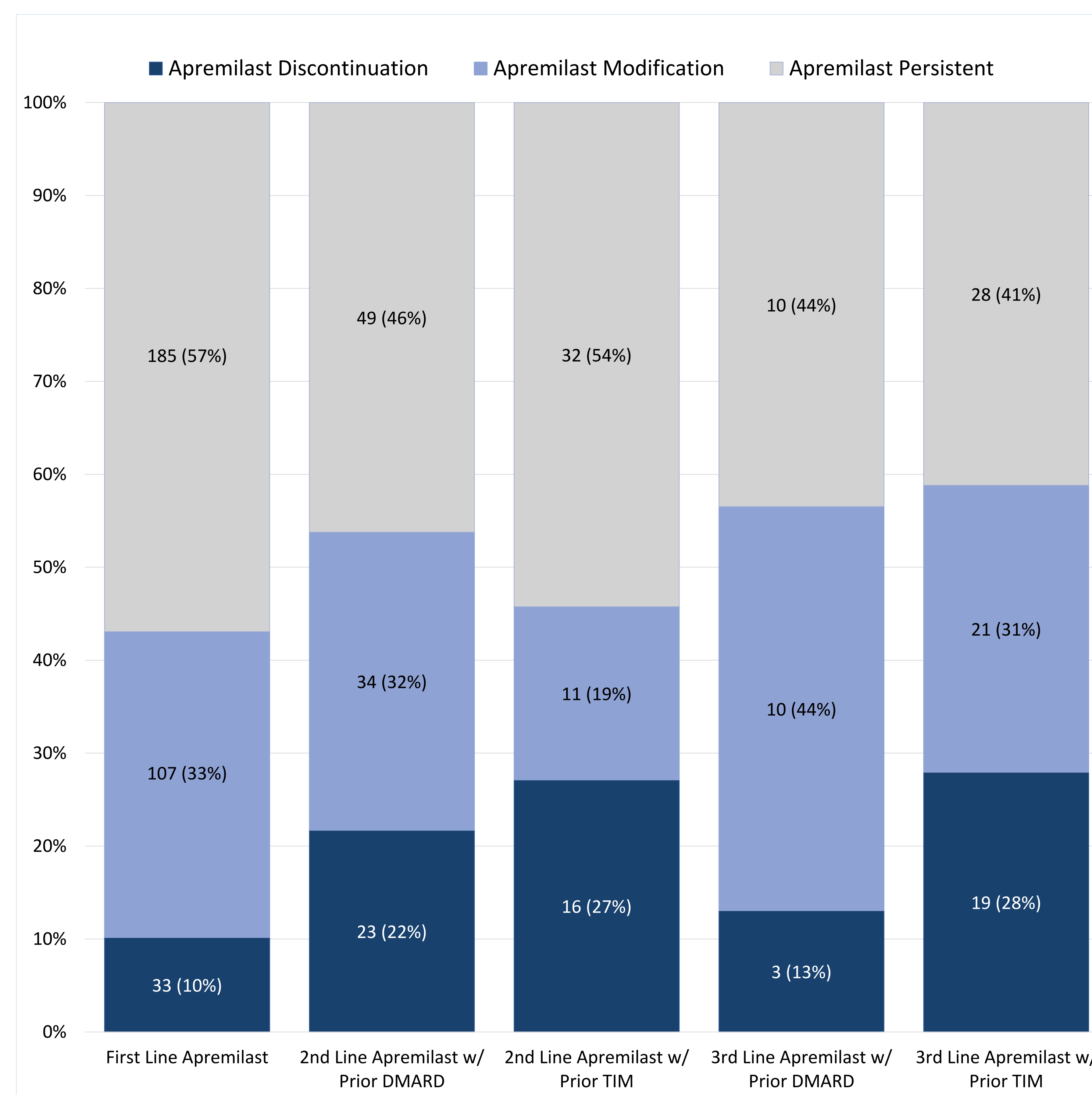3rd Line Apremilast w/ Prior TIM: 28 (41%), 21 (31%), 19 (28%)

FIGURE 2: TIME TO MODIFICATION OR DISCONTINUATION OF MONOTHERAPY APREMILAST OR TNFi

All Patients (p = 0.002); Female Patients (p = 0.1); Male Patients (p = 0.037); Remission/Low (p = 0.75); Moderate (p = 0.51); Severe (p = 0.009)