Biological Initiation Risk in Psoriatic Arthritis Patients Starting Treatment with Apremilast vs. Methotrexate: 1-Year Retrospective Analysis of a US Claims Database

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Background

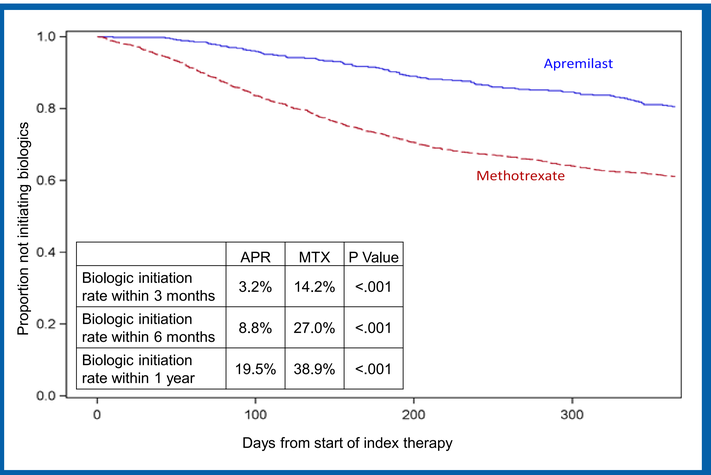
- Psoriatic arthritis (PsA) treatment guidelines suggest oral small molecules as first line therapy.[1]
- Methrotrexate (MTX) and apremilast (APR) are the most used options.[2]
- Evidence comparing APR and MTX in treatment of PSA is limited.[3]

Objective

To compare the risk of biologic initiation in biologic-naïve PsA patients receiving APR or MTX.

Methods

- Retrospective cohort study using IBM® MarketScan® Commercial and Medicare Supplemental databases.
- Systemic-naïve adult patients with PsA initiating APR or MTX during identification [ID] period (1/1/2015 to 12/31/2018)
  - ≥2 medical claims with ICD-9/10-CM with ≥1 by a rheumatologist, or
  - ≥1 diagnosis for PsA recorded by a rheumatologist AND with ≥1 diagnosis for PsO recorded by a dermatologist, or
  - ≥1 diagnosis for PsA by a rheumatologist AND ≥1 diagnosis for PsO by a dermatologist during study period (1/1/2014 to 12/31/2019).
- Index date defined as date of first APR or MTX fill during the ID period.
- Individuals analyzed as part of their index treatment group regardless of subsequent changes in therapy. Patients were followed for one year.
- Demographics, comorbidities, medication use, and healthcare utilization were analyzed during the baseline period.
- Biologic initiation rate and time to biologic initiation during the follow-up period were analyzed.
- Index therapy proportion of days covered (PDC), rate of discontinuation (a ≥60-day gap in days' supply for the index drug), rate of switch to a biologic or non-index treatment, and rate of restarts were analyzed during the follow-up period.
- Post index risk of biologic initiation was compared between APR and MTX users with logistic (odds ratio [OR]; adjusted rates) and Cox (hazard ratio [HR]) regressions.
  - Regression models adjusted for age, sex, region, index year, prescriber specialty, comorbidities, medication use, and healthcare utilization and costs in the pre-index.
  - P-values and 95% confidence intervals (CIs) were reported.



	APR	MTX	P Value
Biologic initiation rate within 3 months	3.2%	14.2%	<.001
Biologic initiation rate within 6 months	8.8%	27.0%	<.001
Biologic initiation rate within 1 year	19.5%	38.9%	<.001

Figure 1: Time to biologic initiation during the follow-up period

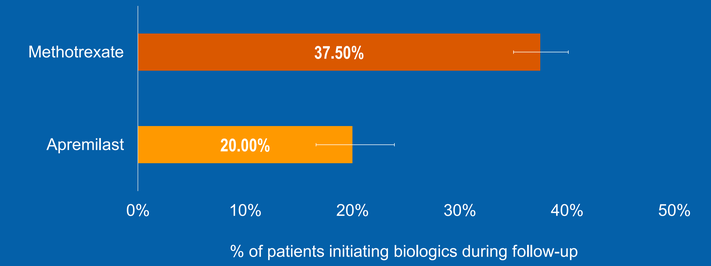


Figure 2: Adjusted rates of biologic initiation

Conclusions

- Systematic-naïve adult patients with PsA who initiated APR were more adherent to their index therapy and had a lower likelihood of biologic initiation when compared with patients initiating MTX.
- Among patients who initiated biologics, APR delayed time to biologic initiation versus MTX.
- APR use may delay initiation of the next line of treatment in patients with PsA, consistent with better symptom control and outcomes when compared to MTX use.

Table 1: Baseline patient characteristics, utilization, and costs

		Apremilast	Methotrexate	All	P Value
	N (%)	534 (25.2)	1,582 (74.8)	2,116 (100)	
Age, years	Mean (SD)	50.5 (11.6)	50.4 (11.3)	50.4 (11.3)	0.938
Female	no. (%)	317 (59.4)	854 (54.0)	1,171 (55.3)	0.031
Insurance type					0.767
Commercial	no. (%)	480 (89.9)	1,429 (90.3)	1,909 (90.2)	
Medicare supplemental	no. (%)	54 (10.1)	153 (9.7)	207 (9.8)	
Prescriber specialty[a]					<.001
Dermatologist	no. (%)	47 (8.8)	50 (3.2)	97 (4.6)	
Rheumatologist	no. (%)	165 (30.9)	1,162 (73.5)	1,327 (62.7)	
Primary care/PA/NP	no. (%)	72 (13.5)	81 (5.1)	153 (7.2)	
Other/Unknown	no. (%)	250 (46.8)	289 (18.3)	539 (25.5)	
Charlson comorbidity index	Mean (SD)	0.7 (1.3)	0.6 (1.1)	0.6 (1.2)	0.024
No. of chronic conditions	Mean (SD)	4.6 (2.1)	4.2 (2.1)	4.3 (2.1)	<.001
PsO	no. (%)	384 (71.9)	940 (59.4)	1324 (62.6)	<.001
Pain medications[b]	no. (%)	327 (61.2)	1,049 (66.3)	1,376 (65.0)	0.034
NSAIDs	no.(%)	252 (47.2)	848 (53.6)	1,100 (52.0)	0.010
Glucocorticoids	no. (%)	188 (35.2)	699 (44.2)	887 (41.9)	<.001
Diagnostic (X-ray, MRI)	no. (%)	342 (64.0)	1,147 (72.5)	1,489 (70.4)	<.001

Results

- 2,116 patients with PsA newly treated with APR (n=534) or MTX (n=1582) were identified.
- Prescriber specialty differed significantly between groups as did mean number of comorbidities (**TABLE 1**).
- Unadjusted outcomes **(TABLE 2, FIGURE 1)**
  - At the end of follow-up, fewer APR patients (19.5%) than MTX patients (38.9%) initiated biologic treatment (P<0.001) Median time to biologic initiation (among initiators) was 187 days (APR) vs 120 days (MTX) (P<0.001).
  - The median PDC for the index therapy was 0.73 for the APR cohort and 0.59 for the MTX cohort (P=0.007).
  - The rate of index therapy discontinuation was lower in APR vs MTX (52.1% vs. 57.6%; P=0.024). Among discontinuers, 24.1% restarted APR vs 14.5% of MTX (P<0.001).
- After adjusting for confounders,
  - APR patients still had lower risk of biologic initiation when compared with MTX patients (HR, 0.46 [95% CI, 0.37–0.57]; P<0.001)
  - The likelihood of biologic initiation was statistically significantly lower with APR treatment (OR, 0.42 [95% CI, 0.32–0.54]; P<0.001)
- The adjusted rate of biologic initiation was lower in patients who used APR vs MTX (20.0% [95% CI: 16.6%-23.9%] vs 37.5% [35.0%-40.1%]) **(FIGURE 2).**

Table 2: Adherence to index therapy during 1-year follow up

		Apremilast	Methotrexate	All	P Value
PDC of index therapy	Mean (SD)	0.62 (0.32)	0.57 (0.34)	0.58 (0.34)	0.007
Days on index therapy	Mean (SD)	237.8 (134.7)	218.4 (138.6)	223.3 (137.9)	0.005
Discontinuation/Switch	no. (%)	278 (52.1)	912 (57.6)	1,190 (56.2)	0.024
Restart index therapy	no. (%)	67 (24.1)	132 (14.5)	199 (16.7)	<.001

Abbreviations: PDC, proportion of days covered; SD, standard deviation.

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References

1. Gossec L, Baraliakos X, Kerschbaumer A, et al. Ann Rheum Dis. 2020;79(6):700-712. doi:10.1136/annrheumdis-2020-217159
2. Coates LC, Kavanaugh A, Mease PJ, et al. Arthritis Rheumatol. Published online March 2016:n/a-n/a. doi:10.1002/art.39573
3. Betts KA, Griffith J, Friedman A, Zhou Z-Y, Signorovitch JE, Ganguli A. Curr Med Res Opin. 2016;32(4):721-729. doi:10.1185/03007995.2016.1140026