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Enclosure:

POSTER: Urganus A, Nag S, Awasthi S et al. Presented at Psych Congress, September 17-19, 2025, San Diego, CA

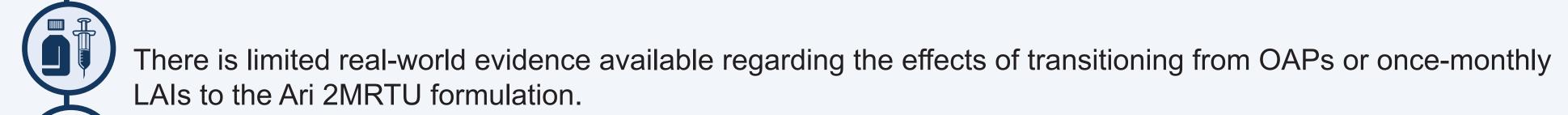


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Background

The development of long-acting injectables (LAIs) marked a significant advancement in the treatment of schizophrenia by addressing adherence challenges.¹⁻³ Aripiprazole once-monthly 400 mg (AOM 400) was approved in 2013, and in 2023, the 2-month Ready-To-Use formulation (Ari 2MRTU) was approved, offering the potential to further improve adherence/persistence and reduce



LAIs to the Ari 2MRTU formulation.

The impact of this transition on medication adherence, HCRU, and related costs remains largely unknown.



This study aims to address this important gap by examining HCRU and related costs among individuals diagnosed with schizophrenia who transitioned treatment to ARI 2MRTU in routine clinical settings.

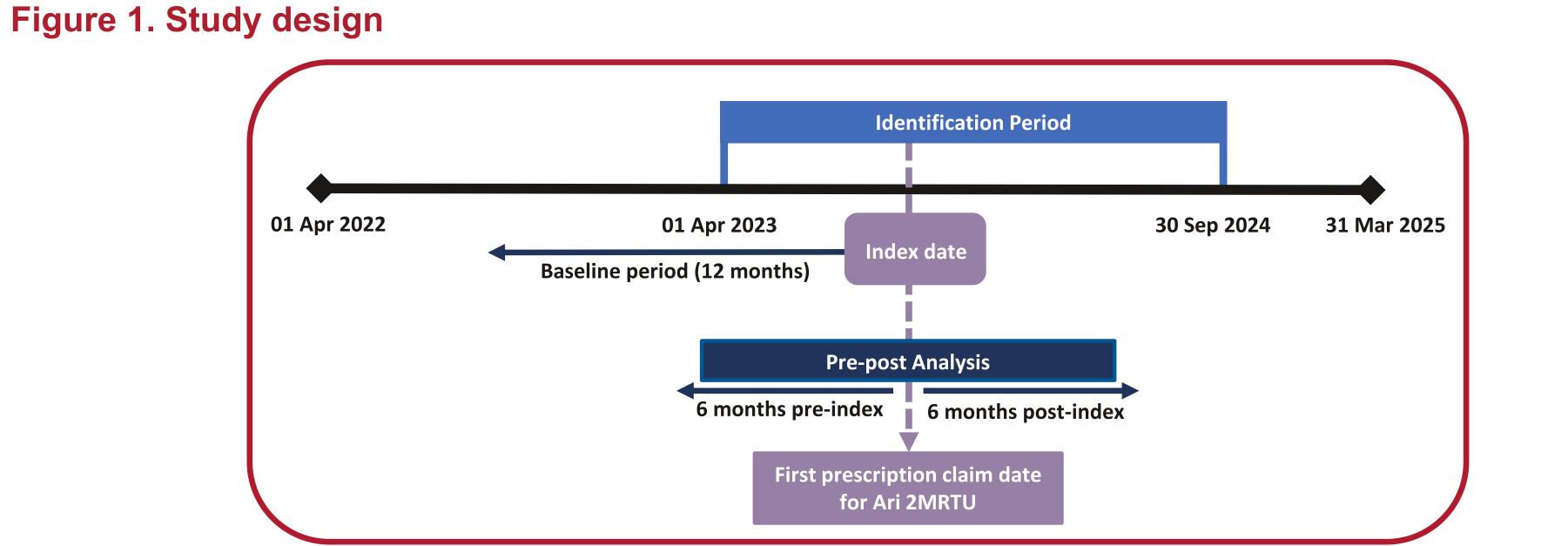


STUDY AIM: Assess patient characteristics, medication adherence, and HCRU among patients diagnosed with schizophrenia who transitioned from OAPs or aripiprazole once-monthly (AOM) to Ari 2MRTU, using a pre-post design.

Methods

Retrospective non-interventional database cohort study using Kythera Labs closed claims data (1 April 2022 - 31 March 2025)

• Commercial and Medicaid-insured US adults (≥18 years) diagnosed with schizophrenia who transitioned from OAPs or AOM to Ari 2MRTU



Ari 2MRTU, Aripiprazole 2-Month Ready-To-Use

Cohort Assignment

 OAPs → Ari 2MRTU Cohort: Patients diagnosed with schizophrenia who initiated treatment with OAPs prior to transitioning to Ari 2MRTU

- AOM → Ari 2MRTU Cohort: Patients diagnosed with schizophrenia who were treated with AOM prior to transitioning to Ari 2MRTU

Descriptive Baseline Characteristics

 Demographic and clinical variables, including mental health and systemic health comorbidities

Outcomes Measured 6-Months Pre- and Post Transition of

- Proportion of days covered (PDC): Ratio of days covered by the medication (without overlap) to total days in the pre-/post-transition
- Medication possession ratio (MPR): Ratio of the number of days' supply to the total number of days in the pre-/post-transition period Adherence: Percentage of patients with MPR ≥0.8 (medication available ≥80% of days)

Healthcare Utilization (HCRU): All-Cause and Schizophrenia-Related • # inpatient/outpatient/emergency department (ED) visits per patient

Hospital length of stay (LOS)

All-cause Inpatient/outpatient/ED/total medical costs per patient

Results

• After applying the inclusion and exclusion criteria, the cohort consists of a total of 755 patients diagnosed with schizophrenia, who transitioned to Ari 2MRTU from either OAPs or AOM (Figure 2).

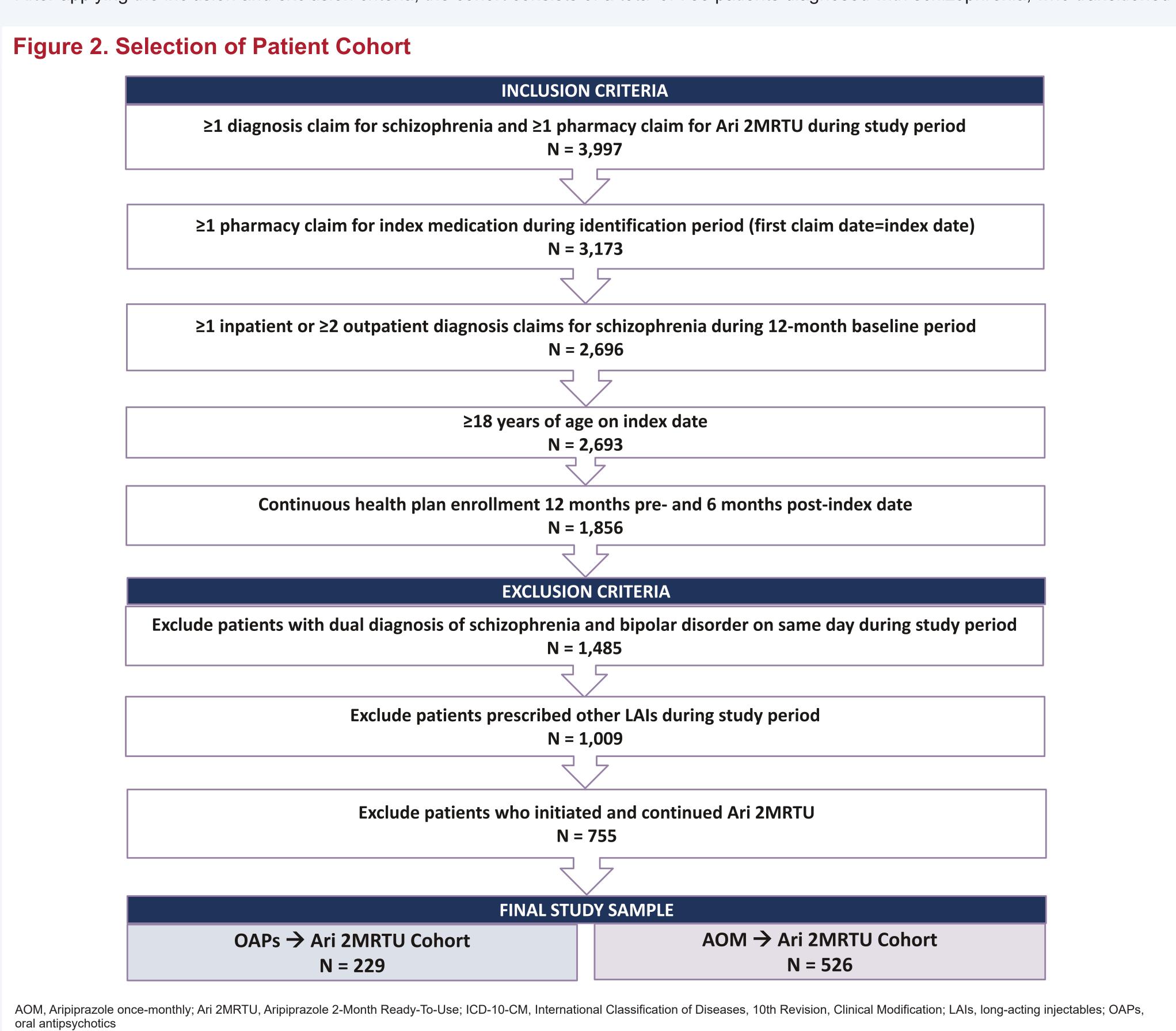


Table 1. Baseline Demographics of Patients Diagnosed with Schizophrenia who Transitioned from OAPs or AOM to Ari 2MRTU

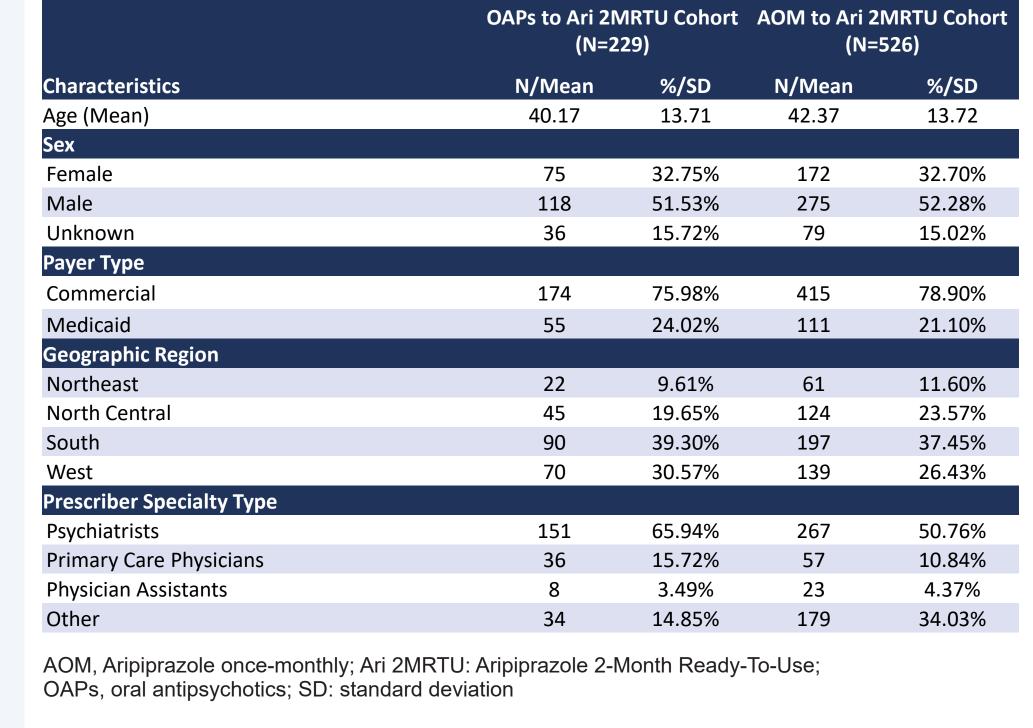


Table 2. Baseline Clinical Characteristics of Patients Diagnosed with Schizophrenia who **Transitioned from OAPs or AOM to Ari 2MRTU**

Characteristics	(N=229)		(N=526)	
	N/Mean	%/SD	N/Mean	%/SD
Charlson Comorbidity Index score categories				
0	127	55.46%	327	62.17%
1	57	24.89%	100	19.01%
≥2	45	19.65%	99	18.82%
Mental Health Comorbidities				
Major depressive disorder	67	29.26%	110	20.91%
Anxiety disorders	98	42.79%	160	30.42%
Post-traumatic stress disorder	39	17.03%	61	11.60%
Any substance use disorder	130	56.77%	229	43.54%
Any mental health comorbidity	172	75.11%	323	61.41%
Systemic Health Comorbidities				
Diabetes	72	31.44%	139	26.43%
Obesity	47	20.52%	107	20.34%
Hypertension	74	32.31%	166	31.56%
Dyslipidemia	54	23.58%	129	24.52%
Sleeping disorders	43	18.78%	96	18.25%
Any systemic health comorbidity	146	63.76%	313	59.51%

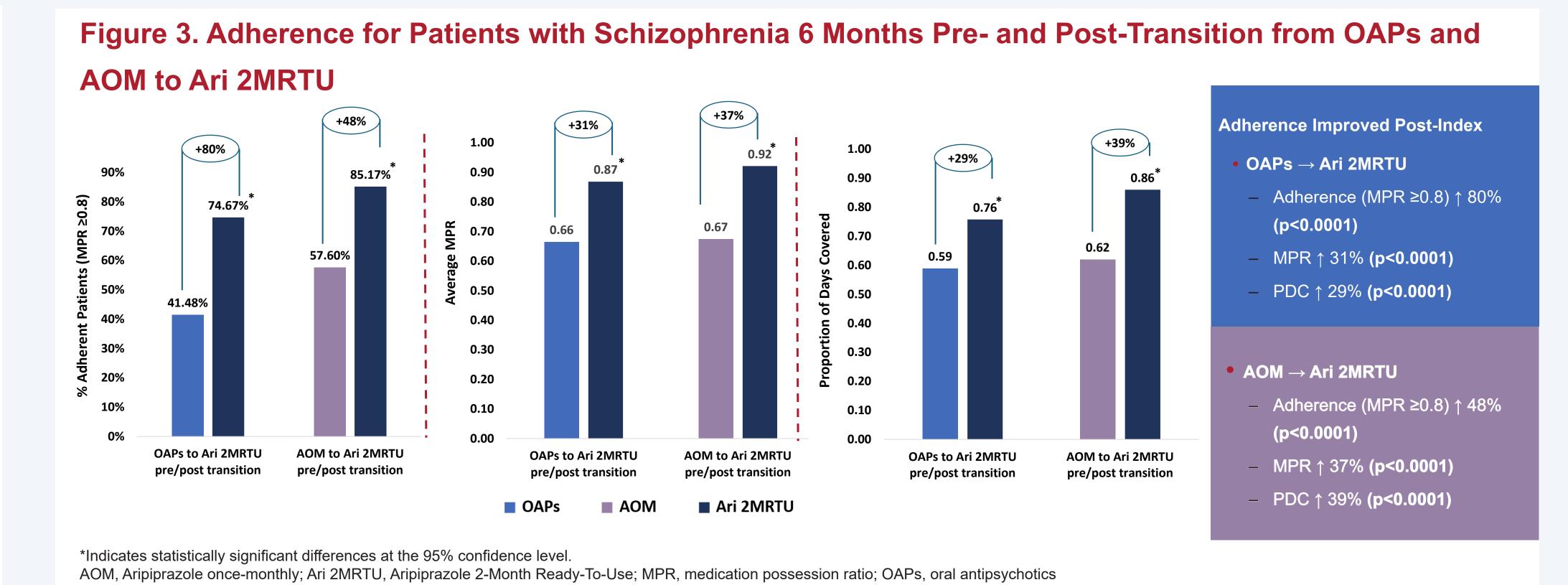


Figure 4A. All-cause and Schizophrenia-related Number of Visits and Length of Stay 6 Months Pre- and **Post-Transition from OAPs to Ari 2MRTU**

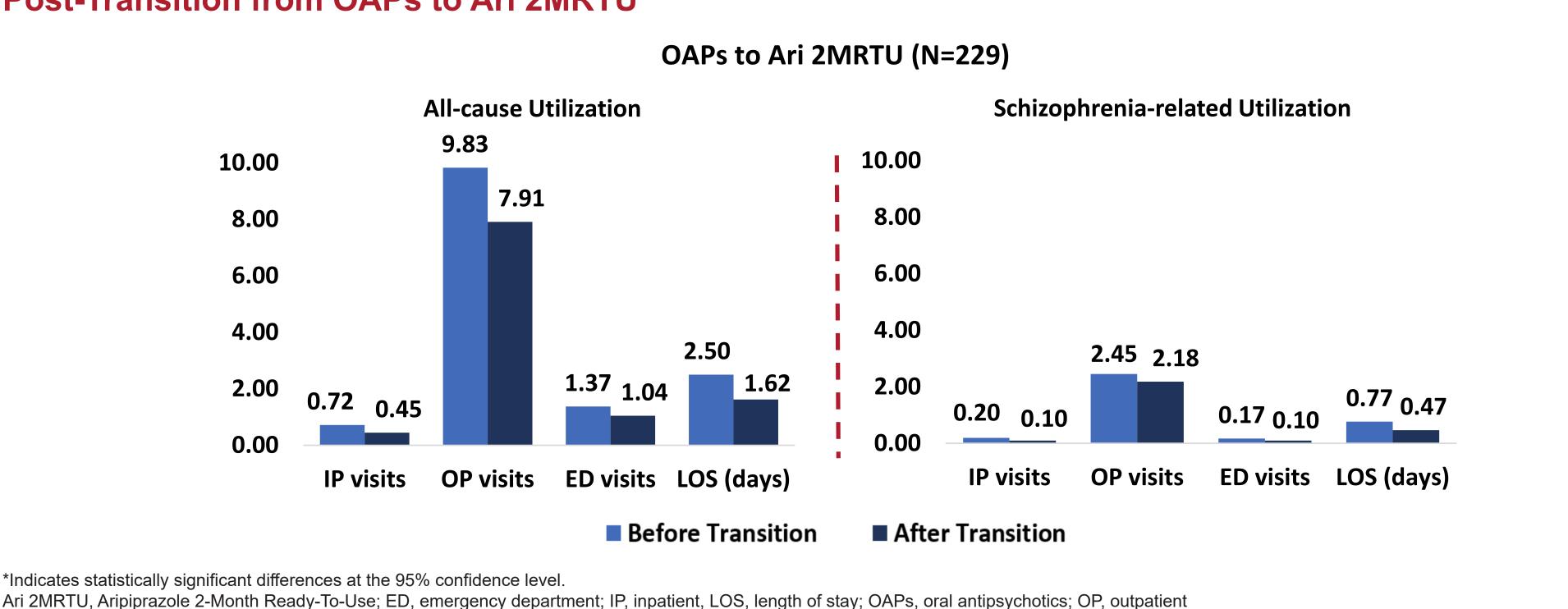


Figure 4B. All-cause and Schizophrenia-Related Average Number of Visits and Length of Stay 6 Months **Pre- and Post-Transition from AOM to Ari 2MRTU**

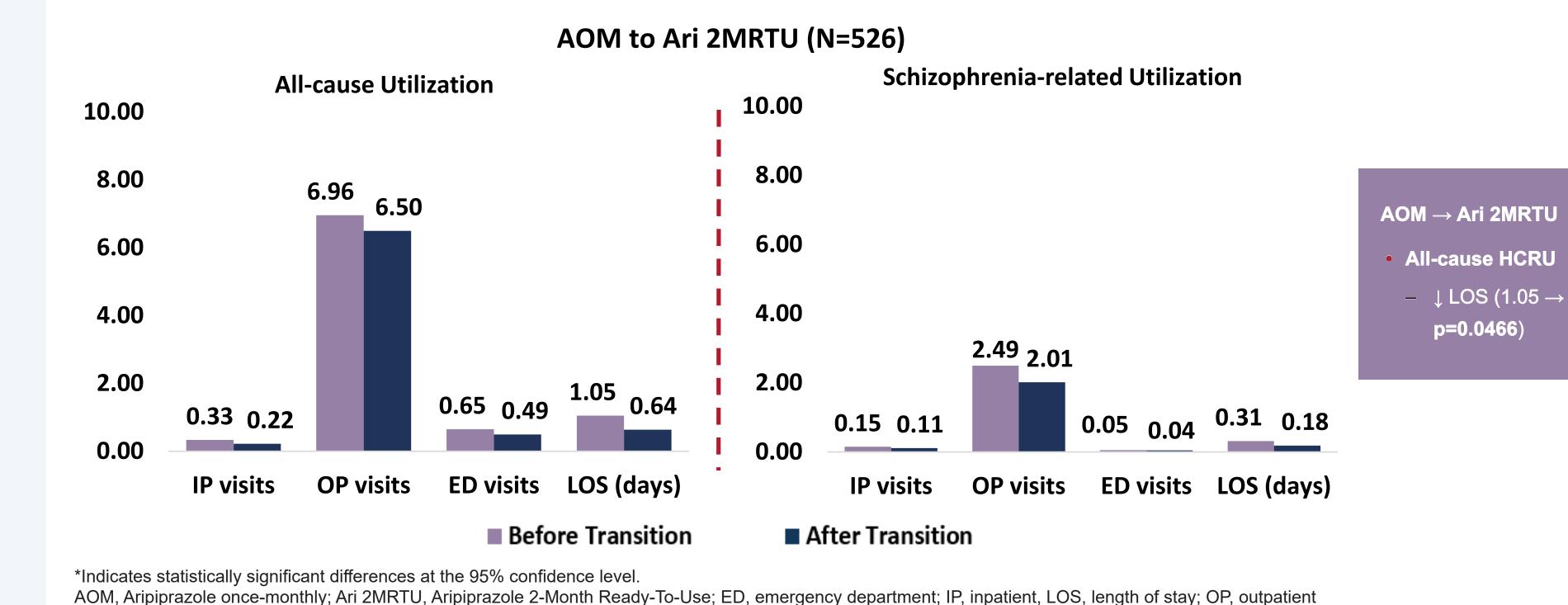
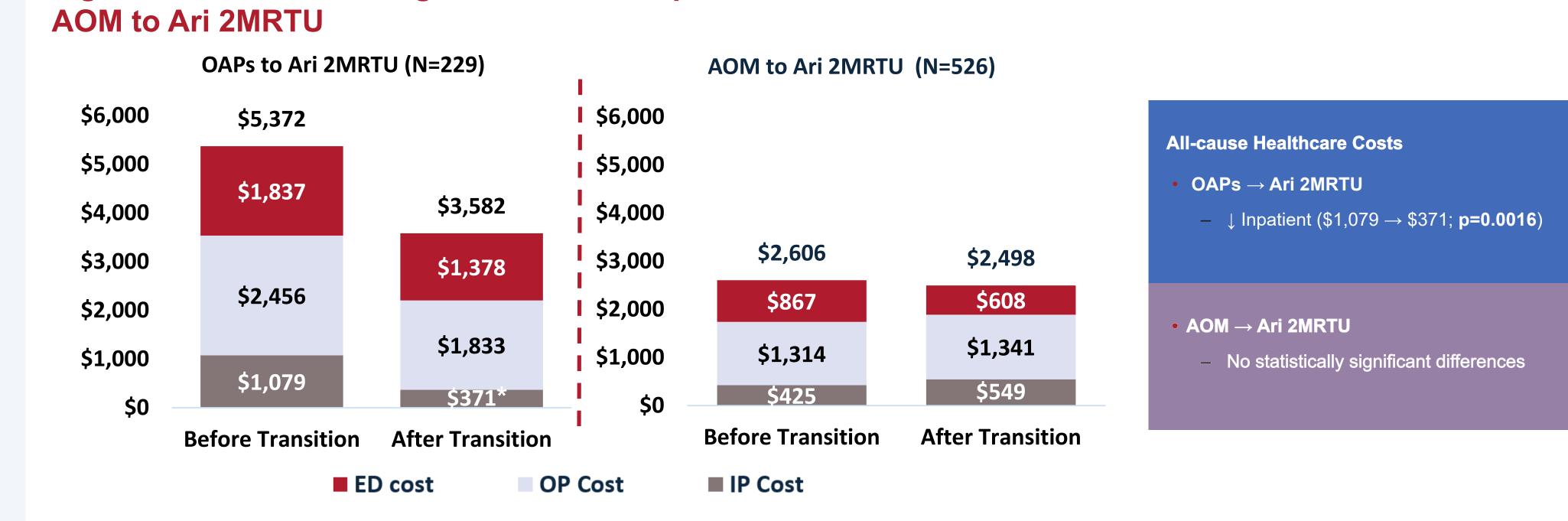


Figure 5. All-cause Average Medical Costs per Patient 6 Months Pre- and Post-Transition from OAPs and



Limitations

- Claims data may be incomplete or misclassified despite quality checks.
- Diagnosis codes do not confirm disease (possible miscoding or rule-out codes).
- Limited clinical detail (e.g., severity, lab values) may affect interpretation.
- This analysis is focused on a short 6-month pre-post framework. This is likely resulting in the small sample sizes that may be related to
- reduction in power and lack of significance, thus potentially underestimating the effect of pre-post changes in HCRU.¹⁰

AOM, aripiprazole once-monthly; Ari 2MRTU, Aripiprazole 2-Month Ready-To-Use; ED, emergency department; IP, inpatient; OAPs, oral antipsychotics; OP, outpatient

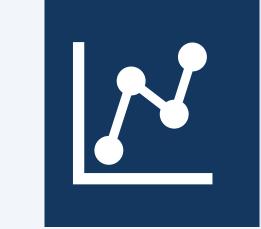
Conclusions



- In this pre-post descriptive study, among patients diagnosed with schizophrenia in a real-world setting, transitioning to Ari 2MRTU resulted in:
- Significant improvement in medication adherence, which is consistent with prior research showing that longer dosing intervals improve adherence;4,5,8,9 and
- Reductions in HCRU, and lower medical costs possibly due to the improved adherence.^{5,8,9}



The findings of this study highlight the potential role of Ari 2MRTU with a once every 2-month LAI dosing interval in lowering HCRU burden among patients diagnosed with schizophrenia in a real-world setting.



 Further research with larger and more diverse patient populations and a longer-term follow-up period is needed to provide additional evidence on the impact on HCRU burden and related costs of Ari 2MRTU among patients diagnosed with schizophrenia in a real-world setting.

6. Drugs.com. https://www.drugs.com/history/abilify-maintena.html. Accessed Jul

7. Marek S, et al. Neuropsychopharmacol 2025; 50: 52–57.

9. Lin J, et al. J Behav Health Serv Res 2013; 40 (3): 355-66.

8. Shah A, et al. Adv Ther 2018; 35 (11): 1994-2014.

LOS $(1.05 \rightarrow 0.64 \text{ days})$

- . Patel MX, et al. Br J Psychiatry Suppl 2009; 52: S1-4. 2. Kane JM. J Clin Psychiatry 2007; 68 Suppl 14: 27-30.
- 3. Kaplan G, et al. Patient Prefer Adherence 2013; 7: 1171-80.
- 4. Biagi E, et al. Adv Ther 2017; 34 (5): 1036-1048.
- 5. Lin D, et al. CNS Drugs 2021; 35 (5): 469-481.

Disclosures

SA. KSBL, NA: employees of Otsuka Pharmaceutical Development & Commercialization, Inc.

AU: employee of Lundbeck LLC

KH, MY: employee of H. Lundbeck A/S. OB, KR: employee of Columbia Data Analytics, a consultant for Otsuka Pharmaceutical Development & Commercialization, Inc. (Princeton, NJ, USA) and H. Lundbeck A/S (Valby, Denmark).

Sponsorship

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