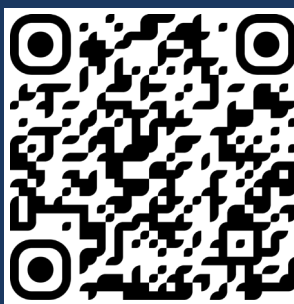


Real-World, Long-Term Impact of Transitioning From Oral Antipsychotics or Aripiprazole Once-Monthly to Aripiprazole 2-Month Ready-To-Use in Adults Diagnosed with Bipolar I Disorder: The REAL-BD Study

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Background



Bipolar I disorder (BP-I) is a chronic psychiatric disorder characterized by ≥1 episode of mania.¹ Antipsychotics as maintenance pharmacological treatment are a first-line therapy option for the management of BP-I.¹

Aripiprazole monohydrate is an atypical antipsychotic that is approved in the United States (US) for the maintenance treatment of adults diagnosed with BP-I.^{2,3}

- Aripiprazole once-monthly (AOM) is a long-acting injectable (LAI) formulation that was approved in 2017 for the maintenance monotherapy of BP-I.²
- Aripiprazole 2-month ready-to-use (Ari 2MRTU) is an LAI formulation that was approved in 2023 for the maintenance monotherapy treatment of BP-I, and is administered once every 2 months.³

Pharmacometric and clinical trial data indicate comparable pharmacokinetic, safety, tolerability, and clinical stability outcomes with Ari 2MRTU and AOM in adults diagnosed with BP-I.⁴⁻⁶

Per the US label, patients diagnosed with BP-I can transition to Ari 2MRTU from an oral antipsychotic or AOM.³ However, there are limited data in a real-world setting demonstrating clinical outcomes following this transition to Ari 2MRTU.

The observational REAL-BD study aimed to evaluate real-world, long-term clinical outcomes in patients diagnosed with BP-I who transitioned to Ari 2MRTU following treatment with an oral antipsychotic or AOM.

Methods

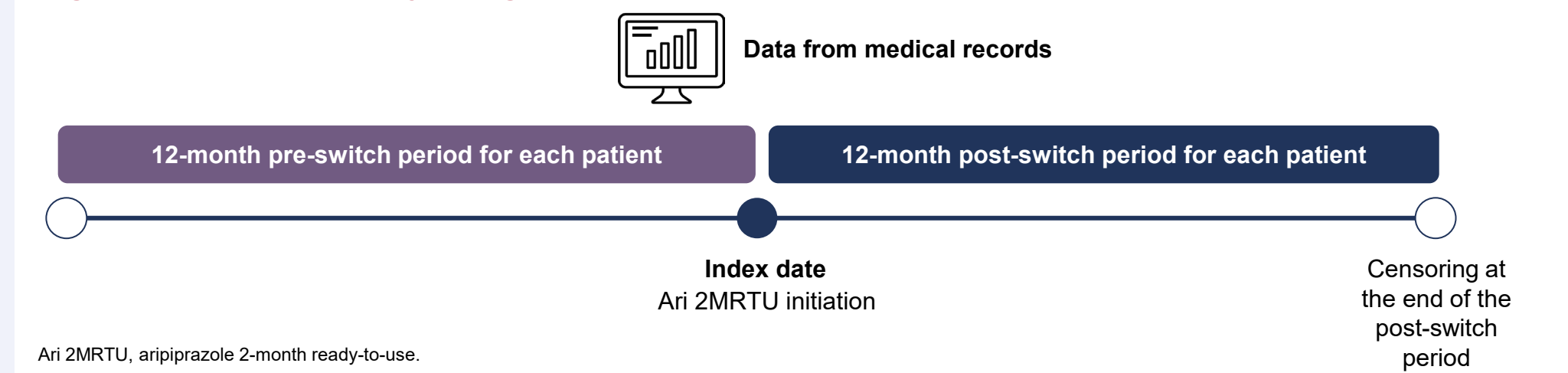
Study design and patients

- The REAL-BD study was a retrospective, non-interventional, pre–post chart review study performed in multiple community outpatient psychiatric centers and private practices in the US.
- The study comprised a 12-month pre-index period and a 12-month post-index period, with Ari 2MRTU initiation as the index date (**Figure 1**).
- Eligible patients were adults aged 18–64 years, diagnosed with BP-I (for ≥1 year), who initiated Ari 2MRTU after ≥1 year of receiving an oral antipsychotic (non-clozapine) or AOM. Selection criteria were based on a real-world population of patients eligible to initiate Ari 2MRTU per the US label.³

Outcomes and analysis

- Primary outcome:** The proportion of patients with an inpatient psychiatric hospitalization due to any mood episode (manic or depressive, with or without mixed features).
- Key secondary outcomes:**
 - Proportion of patients with post-index clinical worsening (the need for the addition of a mood stabilizer, antidepressant or antipsychotic medication, and/or an increase in benzodiazepine dose above the highest permitted dose)
 - Proportion of patients who discontinued post-index due to lack of efficacy
 - Proportion of patients with a post-index unscheduled psychiatric visit (including physician/emergency room visits, partial hospitalization program visits, and/or intensive outpatient program visits for any mood episode)
 - Proportion of patients reporting suicidal ideation, reported by the physician via structured fields in the electronic case report form.
- Other secondary outcomes included the proportion of patients with all-cause hospitalization.
- Hospitalization and suicidal ideation outcomes were assessed in the 12 months before versus the 12 months after the index date using a nonparametric exact McNemar’s test, with statistical significance at a 2-sided alpha level of 0.05.

Figure 1. REAL-BD study design



Results

- Data were available for 72 patients diagnosed with BP-I: n=67 (93.1%) transitioned from a prior oral antipsychotic (non-clozapine) and n=5 (6.9%) transitioned from AOM.
- Among the overall study population, the mean age at index was 32.4 years (median 30.6 years), 45 (62.5%) patients were female, and 40 (55.6%) patients were White (**Table 1**).
- Overall, 61 (84.7%) patients completed 12 months of follow-up and 56 (77.8%) patients completed 12 months of continuous treatment with Ari 2MRTU.

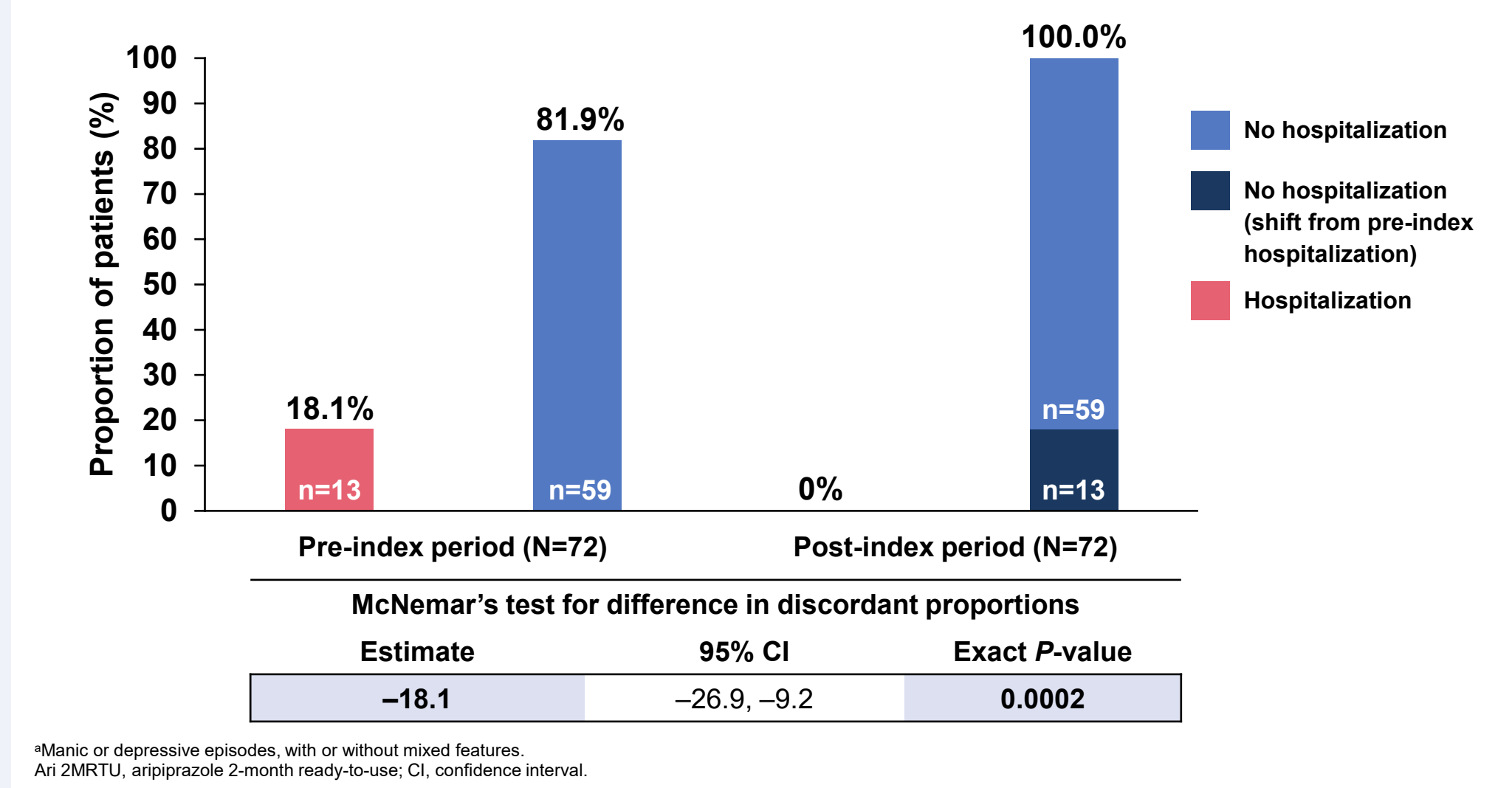
Table 1. Baseline demographic and clinical characteristics

Characteristic	Prior oral antipsychotics (n=67)	Prior AOM (n=5)	Total (N=72)
Age at Ari 2MRTU initiation (years), mean (min, max)	32.7 (18.4, 63.3)	28.0 (18.6, 35.1)	32.4 (18.4, 63.3)
Female sex at birth, n (%)	40 (59.7)	5 (100)	45 (62.5)
Race, n (%)			
Asian	4 (6.0)	0	4 (5.6)
Black/African American	14 (20.9)	1 (20.0)	15 (20.8)
White	37 (55.2)	3 (60.0)	40 (55.6)
More than 1 race	3 (4.5)	0	3 (4.2)
Other/not reported	9 (13.4)	1 (20.0)	10 (13.9)
Hispanic/Latino ethnicity, n (%)	21 (31.3)	1 (20.0)	22 (30.6)
Age at diagnosis of BP-I, (years), mean (min, max)	28.1 (12.7, 56.5)	21.7 (15.9, 28.1)	27.7 (12.7, 56.5)

AOM, aripiprazole once-monthly; Ari 2MRTU, aripiprazole 2-month ready-to-use; BP-I, bipolar I disorder; max, maximum; min, minimum.

- In the primary outcome analysis, the proportion of patients with an inpatient psychiatric hospitalization due to any mood episode was 18.1% pre-index and 0% post-index, representing an 18.1% reduction ($P=0.0002$) (**Figure 2**).

Figure 2. Proportion of patients with a psychiatric hospitalization due to any mood episode^a



- In the 12-month post-index period, 4 (5.6%) patients experienced clinical worsening, no patients discontinued Ari 2MRTU because of a lack of efficacy, and 1 (1.4%) patient had an unscheduled psychiatric visit (**Table 2**).
- The proportion of patients reporting suicidal ideation is shown in **Table 3**.
- The proportion of patients with an all-cause hospitalization was 23.6% pre-index and 2.8% post-index, representing a 20.8% reduction ($P=0.0003$) (**Figure 3**).
- A total of 11 patients (15.3%) discontinued Ari 2MRTU, and discontinuation was most often due to loss to follow-up (n=5 [6.9%]) (**Figure 4**).

Table 2. Proportion of patients with clinical worsening, discontinuation due to lack of efficacy, or an unscheduled psychiatric visit in the post-index period (N=72)

Outcome	Post-index, n (%)
Proportion of patients with clinical worsening	4 (5.6%)
Proportion of patients with discontinuation due to lack of efficacy	0 (0.0%)
Proportion of patients with an unscheduled psychiatric visit ^a	1 (1.4%)

^aIncludes physician/emergency room visits, partial hospitalization program visits, and/or intensive outpatient program visits for any mood episode

Table 3. Proportion of patients reporting suicidal ideation (N=72)

Outcome	Pre-index, n (%)	Post-index, n (%)	McNemar's test for difference in discordant proportions
Proportion of patients reporting any suicidal ideation	34 (47.2%)	19 (26.4%)	-20.8 (95% CI: -32.3, -9.3) $P=0.0015$
Proportion of patients reporting active suicidal ideation ^a	20 (27.8%)	3 (4.2%)	-23.6 (95% CI: -34.8, -12.4) $P=0.0002$
Proportion of patients reporting passive suicidal ideation ^b	25 (34.7%)	17 (23.6%)	-11.1 (95% CI: -23.6, 1.4) $P=0.1338$

^aRefers to current thoughts of killing oneself, accompanied by an explicit intent, method, or formulated plan to take action; ^brefers to a wish to be dead or a desire to cease existing, without specific plans or immediate intent to act
CI, confidence interval

Figure 3. Proportion of patients with an all-cause hospitalization

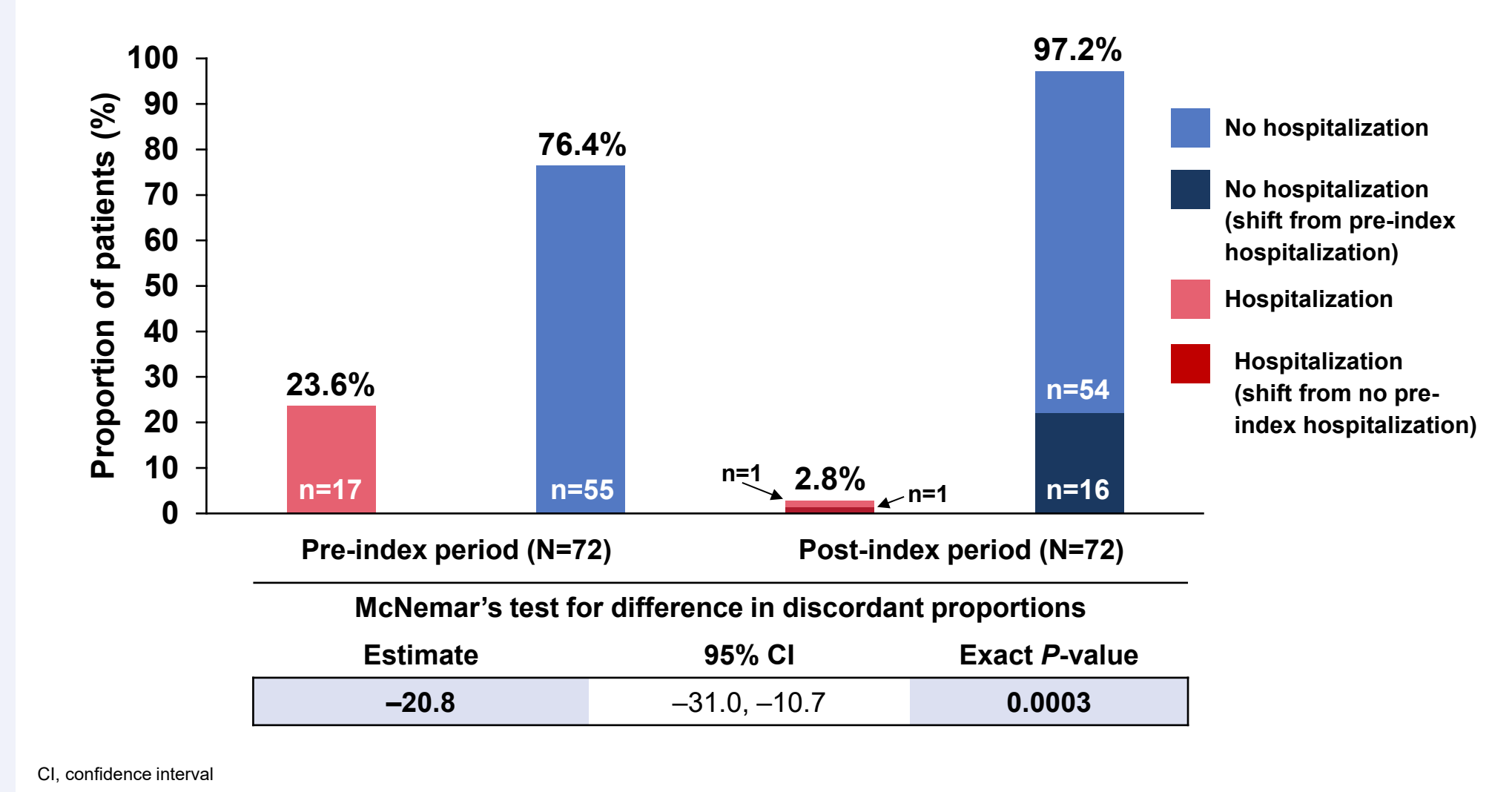
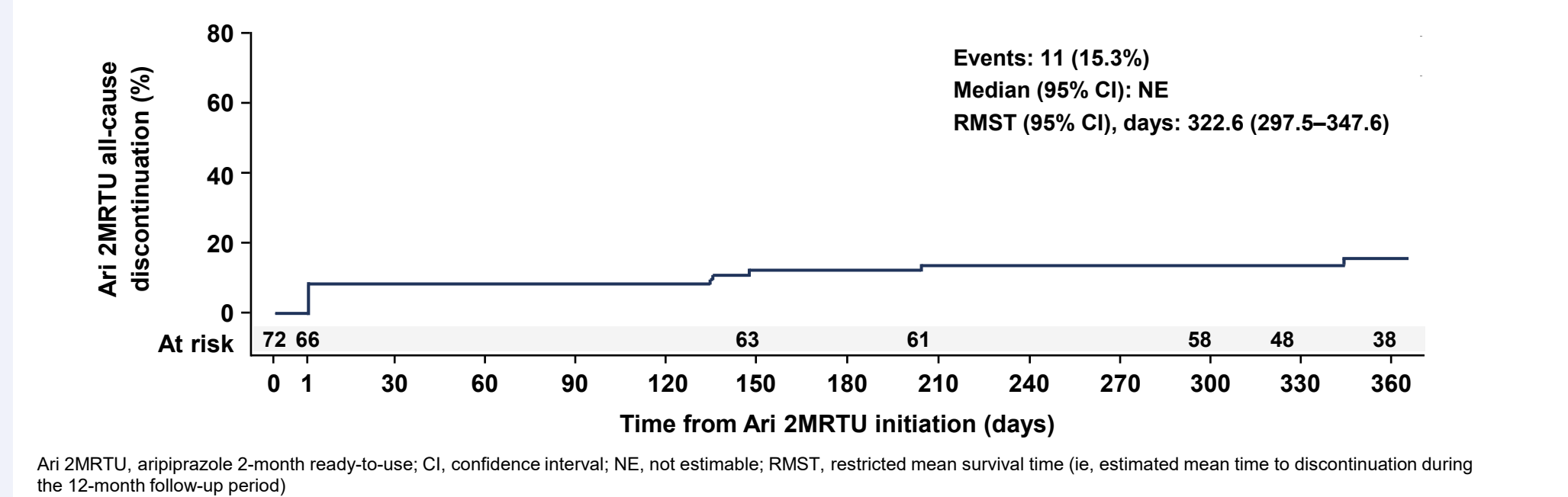


Figure 4. Time to all-cause discontinuation in the post-index period (N=72)



Limitations

- Interpretation of the data is limited by the retrospective pre-post study design and small sample size; causal associations cannot be made.
- Suicidal ideation may not be assessed in a consistent manner across clinical sites.
- While race/ethnicity balance aimed to be representative of the US patient population, enrollment was limited to 6 sites, with a disproportionate contribution from 1 site, potentially reducing generalizability or revealing site-specific treatment patterns

Conclusions

- In this real-world study, transition to Ari 2MRTU was associated with:
 - An 18.1% reduction in inpatient psychiatric hospitalization due to any mood episode, compared with prior treatment;
 - A 20.8% reduction in all-cause hospitalization;
 - Low rates of clinical worsening and unscheduled psychiatric care, and no discontinuations due to lack of efficacy.
- These findings support the feasibility of transitioning from an oral antipsychotic or AOM to Ari 2MRTU in clinical practice, and provide real-world descriptive evidence that outcomes remained favorable during the 12 months after transition to Ari 2MRTU for the long-term maintenance pharmacological treatment for adults with BP-I, reflected by clinical stability and low rates of treatment discontinuation in the post-transition period.

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Disclosures

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