

## BACKGROUND

Subanesthetic doses of intravenous ketamine exert rapid benefits in patients with depressive disorders, anxiety disorders, posttraumatic stress disorder, obsessive compulsive disorder and chronic pain. Nearly all studies reflect treatment resistant patients receiving limited infusions to ketamine monotherapy in government and academic research settings. A deficit of research knowledge exists in real-world patients receiving multiple infusions of adjunctive ketamine to treatment as usual – especially maintenance treatment. The Centers of Psychiatric Excellence (COPE) created a research infrastructure to obtain registry data that tethers patient characteristics to treatment outcomes in efforts to personalize ketamine treatment based on real-world data.

## METHODS

An online database registry was created by COPE to obtain real-world data in patients receiving adjunctive ketamine. Board-certified psychiatrists at five community treatment centers provided patients with ketamine infusions (Charlotte, Houston, New York, Philadelphia, St Louis). Prospective patients completed screening scales and a telemedicine or in-person psychiatric assessment conducted by a psychiatrist determined eligibility for ketamine treatment. Once a patient was deemed medically and psychiatrically appropriate, pretreatment and posttreatment scales to each infusion were completed during acute, sustained, and maintenance phase treatments.

## RESULTS

Data from 119 patients were queried in our database registry. Validated patient and provider rating scales on symptoms severity, treatment efficacy, and side-effects were obtained. As an example, mean scores on the Montgomery-Asberg Depression Rating Scale (MADRS) in patients at baseline was 36.6 (n=119; SD=8.1) and reduced to 13 at infusion 6 (n=80; SD=9.8). This represents a 65% reduction in depressive symptoms by infusion 6 (a 30% reduction by infusion 2). Approximately 70% of patients received all six acute phase treatments within a 2 to 3 week timeframe. Sustained phase treatments then occurred weekly for the next month.

MADRS scores stayed in the range of remission of symptoms by infusion 10 (infusion 7; n=62; MADRS=13.1; SD=11.2 and infusion 10; n=40; MADRS=10.7; SD=9.2). Maintenance treatments were then provided monthly for the next 6 months. Only 10 patients continued till the end of the maintenance phase (infusion 16) and MADRS scores were 12.1 (SD=8.5).

### Patient Screening Scale (Baseline)

Screening Scales	PHQ-9	DAST-10	AUDIT-C	DOCS	PROMIS Pain Interference
Mean	21.45	2.18	2.94	22.83	22.64
Sample Size	47	44	47	47	47
Standard Deviation	7.28	8.45	8.61	17.29	12.41

### PHQ-9 (Depression)

PHQ-9	Treatment 11	Treatment 12	Treatment 13	Treatment 14	Treatment 15	Treatment 16
Mean	8.52	8.33	7.41	9.31	7.71	7.45
Sample Size	26	20	16	15	13	10
Standard Deviation	5.83	6.15	5.49	5.65	5.85	4.50

### GAD-7 (Anxiety)

GAD-7	Treatment 11	Treatment 12	Treatment 13	Treatment 14	Treatment 15	Treatment 16
Mean	5.85	6.10	6.12	6.56	5.57	6.91
Sample Size	27	21	17	16	14	11
Standard Deviation	5.33	5.33	5.33	4.72	5.46	3.67

### MADRS (Depression)

MADRS	Treatment 11	Treatment 12	Treatment 13	Treatment 14	Treatment 15	Treatment 16
Mean	10.72	13.19	11.43	14.21	14.40	12.10
Sample Size	32	26	23	19	15	10
Standard Deviation	6.86	10.56	10.34	11.04	10.11	8.48

Figure 1. PHQ-9, GAD-7, and MADRS Scores of Patients Between Ketamine Treatment 11 and Ketamine Treatment 16

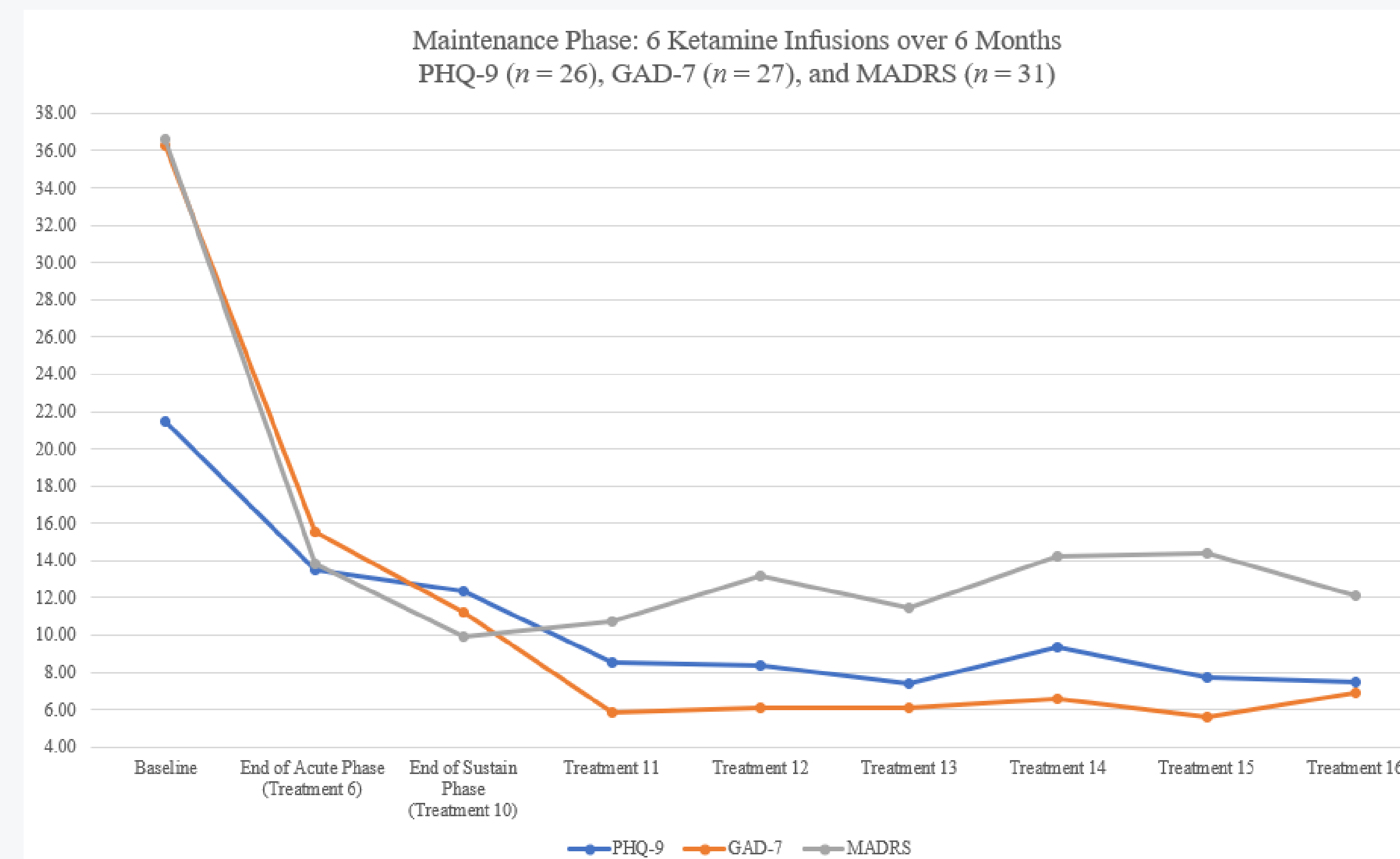
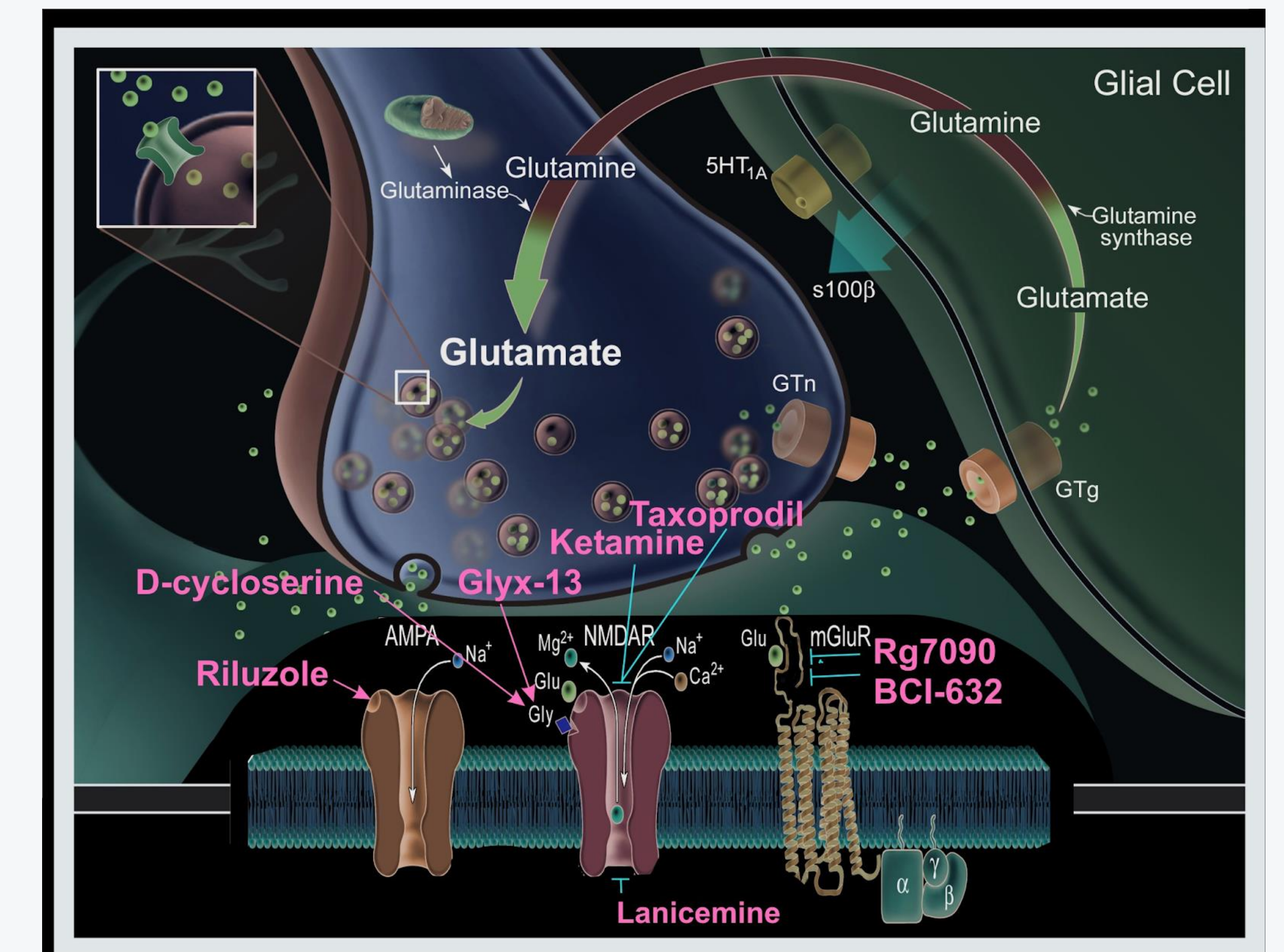


Figure 2. Ketamine and Beyond: NMDA Agents to Modulate to Mood and Anxiety



## CONCLUSIONS

This real-world data set of 119 patients undergoing ketamine treatment for depression during acute (6 infusions over 2 weeks), sustained (4 infusions over 1month) and maintenance (6 infusions over 6months) treatments demonstrated robust decreases in depression scores during the acute phase treatment (30% at infusion 2 and 65% at infusion 6). Remission of depressive symptoms (i.e., MADRS <11) occurred during the sustained and maintained phase treatments. However, only approximately half of the patients entered into the sustained treatment and 10 patients completed the maintenance phase. Development of treatment algorithms based on patient characteristics while monitoring for comorbid symptoms and abuse liability will help direct appropriateness of ketamine in the real-world setting.

## ACKNOWLEDGEMENTS

None

## FUNDING

None