Development of a Real-World Ketamine Database Registry: Centers of Psychiatric Excellence (COPE)

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BACKGROUND

Subanesthetic doses of intravenous ketamine exert rapid benefits in patients with depressive disorders, anxiety disorders, posttraumatic stress disorder, obsessive compulsive disorders 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 subanesthetic infusions of adjunctive ketamine. The Centers of Psychiatric Excellence (COPE) has created a research infrastructure to obtain registry data that tethers patient characteristics to treatment response in efforts to personalize ketamine treatment based on real-world data.

METHODS

An on-line 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, Atlanta, Houston, New York, Philadelphia, and St. Louis). Screening scales were completed by patients. 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 for ketamine treatment, pretreatment and posttreatment scales were completed at each infusion. Patients received 6 infusions over 2 weeks (3 infusions a week) and then 4 infusions weekly to total 10 infusions.

RESULTS

Patient and provider data from two of six COPE clinics were primarily used in this analysis. Out of 979 inquires, 84 patients were considered appropriate, signed informed consent, and received ketamine treatments. 58 patients were captured in our database registry. Validated patient and provider rating scales on symptoms severity, treatment efficacy, and side-effects were obtained. As an example, baseline Montgomery-Asberg Depression Rating Scale (MADRS) scores in patients was 36 (n = 58; SD = 8) and reduced to a score of 12 by treatment 6 (n = 41; SD = 10). This represents a 67% reduction in depressive symptoms by treatment 6 and a 30% reduction by treatment 2. Depression scores at treatment 5 (MADRS = 13, n = 44) were no different than at treatment 6 (MADRS 12, n = 41). Only 2 of 58 patients had a MADRS score that was higher at their last treatment than at baseline. Approximately 70% of patients received all 6 treatments with more people not opting for the remaining 4 infusions, likely due to having remission of symptoms.

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 1	Treatment 2	Treatment 3	Treatment 4	Treatment 5	Treatment 6	Treatment 7	Treatment 8	Treatment 9	Treatment 10
Mean	36.05	26.72	23.52	21.40	14.65	13.53	14.63	13.42	10.47	12.32
Sample Size	57	56	50	45	44	41	27	22	20	18
Standard Deviation	10.36	11.54	13.00	12.77	11.52	11.00	8.90	7.21	7.21	6.41

GAD-7 (Anxiety)

GAD-7	Treatment 1	Treatment 2	Treatment 3	Treatment 4	Treatment 5	Treatment 6	Treatment 7	Treatment 8	Treatment 9	Treatment 10
Mean	36.29	27.42	24.36	22.88	16.17	15.50	14.39	12.72	9.85	11.18
Sample Size	54	53	48	43	42	40	29	24	22	21
Standard Deviation	12.16	12.53	13.52	12.68	12.36	11.93	9.03	6.60	6.61	5.55

MADRS (Depression)

MADRS	Baseline	Treatment 1	Treatment 2	Treatment 3	Treatment 4	Treatment 5	Treatment 6	Treatment 7	Treatment 8	Treatment 9	Treatment 10
Mean	36.57	25.29	22.10	19.89	12.93	12.07	13.81	11.81	7.78	10.40	9.88
Sample Size	58	56	50	45	44	41	27	21	18	14	8
Standard Deviation	8.00	10.75	12.76	12.91	10.94	10.06	10.15	8.84	8.26	8.42	8.00

CGI-S (Global Impression of Severity)

CGI-S	Baseline	Treatment 1	Treatment 2	Treatment 3	Treatment 4	Treatment 5	Treatment 6	Treatment 7	Treatment 8	Treatment 9	Treatment 10
Mean	36.10	27.65	24.79	23.30	16.21	15.18	14.63	13.34	10.34	12.03	10.43
Sample Size	56	55	49	44	43	40	28	23	21	20	8
Standard Deviation	11.26	12.06	13.04	12.21	11.98	11.37	9.01	7.18	7.17	6.21	4.22

CGI-I (Global Impression of Improvement)

CGI-I	Treatment 1	Treatment 2	Treatment 3	Treatment 4	Treatment 5	Treatment 6	Treatment 7	Treatment 8	Treatment 9	Treatment 10
Mean	36.29	26.50	23.62	20.64	14.38	13.10	14.74	13.46	9.67	11.68
Sample Size	58	56	50	45	44	41	27	21	18	16
Standard Deviation	9.26	10.85	12.48	12.55	11.43	10.58	9.43	8.05	7.75	7.33

COPE DRS (COPE Dissociation Scale)

COPE DRS	Treatment 1	Treatment 2	Treatment 3	Treatment 4	Treatment 5	Treatment 6	Treatment 7	Treatment 8	Treatment 9	Treatment 10
Mean	3.37	3.33	2.80	2.64	2.43	2.38	1.54	1.25	2.19	2.67
Sample Size	57	55	50	44	42	34	24	20	16	12
Standard Deviation	4.60	4.17	3.47	3.08	2.72	3.12	2.30	2.40	3.17	2.96

Figure 2. Plots of results showing concordance

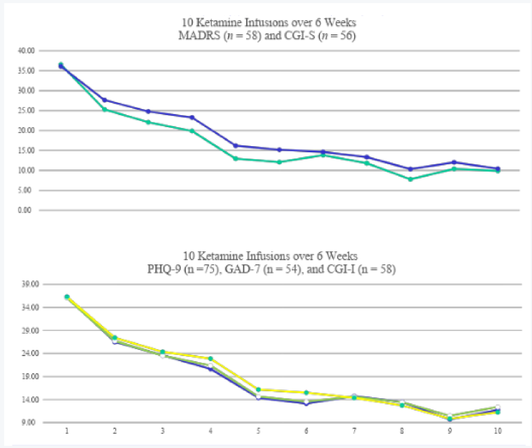
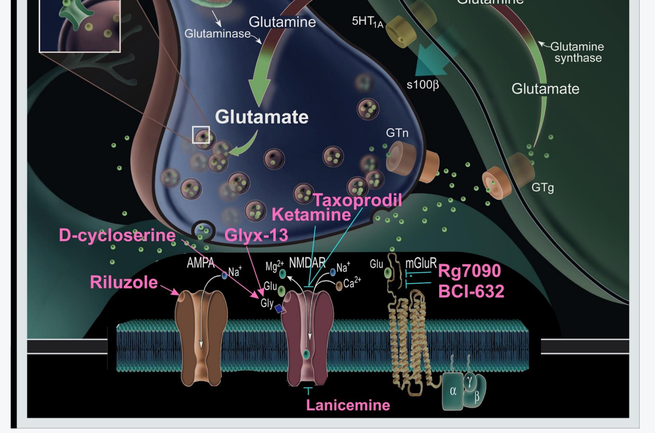


Figure 3. Ketamine and Beyond: NMDA Agents to Modulate to Mood and Anxiety



CONCLUSIONS

A database registry was created by COPE to obtain real-world data in patients receiving adjunctive ketamine. Patients reported changes in symptom ratings that were concordant with provider ratings. Ketamine is effective in reducing depression and anxiety symptoms in real world patients.

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