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## Maintenance ECT is associated with sustained improvement in depression symptoms without adverse cognitive effects in a retrospective cohort of 100 patients each receiving 50 or more ECT treatments

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### Abstract

**Background:** Electroconvulsive therapy (ECT) is the most effective acute treatment for depression, but relapse is common following discontinuation. One strategy for prolonging remission is the use of maintenance ECT, but the clinical evidence supporting its efficacy and safety are limited. We examined the effects of maintenance ECT on depression and cognition.

**Methods:** Participants were from a retrospective cohort of 100 patients receiving ECT at a freestanding psychiatric hospital and who received at least 50 treatments during a single treatment series. QIDS, BASIS-24, and MoCA were assessed at baseline and every 10 treatments thereafter during the clinical course.

**Results:** ECT was associated with a rapid decrease in depression symptoms and overall self-reported mental health status within the first 10 treatments, which was sustained throughout a median of 22.1 months of follow-up. There was no change in cognitive functioning as measured by the MoCA. Bilateral and brief pulse treatment parameters were more common by treatment 50 than at the first treatment. Most participants either continued in ECT at the end of the study period or discontinued due to sustained remission.

**Limitations:** retrospective observational study without control group who did not receive ECT.

**Conclusions:** In this ECT cohort with at least 50 treatments, improvement in depression was sustained on QIDS and BASIS-24 and adverse cognitive effects were not detected by serial MoCAs, supporting the utility of maintenance ECT in this cohort.

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**Contributions:**

JL, TM, SS, and MH designed the study. SS collected the data and treated patients. JL and TM performed the statistical analysis, and JL wrote the first draft of the manuscript. All authors contributed to and have approved the final manuscript.

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## Introduction

Depression is the leading cause of disability worldwide, affecting more than 300 million individuals.<sup>1</sup> Despite numerous approved medications for depression, remission rates with first treatment in real-world samples are low (37% with first treatment), with each subsequent medication trial showing a lower chance of remission than the previous.<sup>2</sup> In contrast, electroconvulsive therapy (ECT) remains the single most efficacious treatment for depression, with remission rates greater than 50% for both bipolar and unipolar depression.<sup>3,4</sup> Despite the cost of the procedure it may be cost-effective after as few as two failed medication trials because of its high efficacy.<sup>5</sup> One key unanswered question is how to best maintain remission once a patient has improved with ECT, since without additional treatment as many as 84% of patients relapse within 6 months of discontinuing ECT.<sup>6</sup> One strategy is the use of continuation ECT (further treatments in the 6 months following initial remission) and maintenance ECT (treatments more than 6 months following remission). A trial of continuation ECT in geriatric depression found relative superiority of ECT plus pharmacotherapy vs. pharmacotherapy alone for preventing relapse,<sup>7</sup> while a study in all adults of ECT alone vs. pharmacotherapy alone found equivalence between the two strategies at 6 months.<sup>8</sup> Despite this, the FDA's reclassification of ECT devices in 2018 specifically requires a warning that "the long-term safety and effectiveness of ECT treatment has not been demonstrated."<sup>9</sup> In order to better characterize outcomes and side effects of extended ECT treatments, this study presents of cohort of patients who each received at least 50 ECT treatments as part of a single treatment series.

## Methods

### Population and Setting

This was a single center retrospective cohort study of patients age 18 years and older who received at least 50 ECT during the study period of May 2011 through June 2019. The study population consisted of patients who received 50 or more ECT treatments as part of a single series and for whom initial and follow-up measurements were available. Patients were excluded if baseline data were not available or if data was not available for treatment  $50 \pm 3$ . All patients began with an acute course of treatment, followed by continuation and then maintenance treatment. If a patient required an additional acute course (defined as a return to thrice weekly treatments) this was treated as the beginning of a new series and was not added to data from the previous series. In contrast, if a patient's maintenance treatments were intensified (e.g. from once every 4 weeks to weekly as a result of a partial relapse) but not to the frequency of a new acute course those treatments were counted as part of maintenance and included. Patients in the cohort were followed until discontinuation of ECT, until 100 treatments were received, or until the end of the study period. This study was approved by the Partners Healthcare Institutional Review Board.

### Scales and measurements

As part of routine clinical care, the ECT service participates in the hospital's Clinical Measurement Initiative (CMI), in which patients complete computerized self-assessments. Measurement scales, treatment date, and treatment number were obtained from the CMI

database, and information about diagnosis at time of treatment initiation was obtained from the hospital's main electronic medical record. CMI scales included the Quick Inventory of Depressive Symptomatology (QIDS),<sup>10</sup> the Behavior and Symptom Identification Scale-24 (BASIS-24),<sup>11</sup> and the Montreal Cognitive Assessment (MoCA).<sup>12</sup> Measurements were obtained prior to the first treatment, and repeated every 5 (BASIS-24, QIDS) or 10 (MoCA) treatments. In order to reduce practice effects from repeated MoCA evaluations, the three alternate versions of the MoCA were used serially on different administrations. All measures were patient self-reported, with assistance by nursing staff. Demographics data were taken from the demographics section of the initial BASIS-24 survey and age is calculated at the time of the first ECT treatment.

### Treatment procedure

All patients received ECT using a Mecta Spectrum 5000Q (Tualatin, OR). As part of the hospital's routine clinical practice, seizure threshold was determined by dose titration for the first treatment, and subsequent treatments were given at six times seizure threshold for unilateral treatments or twice seizure threshold for bilateral treatments. Dosage and electrode placement were then modified by the treating psychiatrist as needed to assure adequate seizure quality and clinical response. Patients were generally referred to more intensive treatments (increased total charge, widened pulse width, or bilateral electrode placement) if symptoms had not remitted or if a patient was unable to tolerate spacing of maintenance treatments. Acute-course ECT was routinely given three times per week until clinical remission is obtained, after which time patients were offered continuation followed by maintenance treatments if clinically indicated. These were generally given weekly for at least 4 weeks and then tapered by a week at a time as tolerated. When possible the ECT was tapered off completely after the taper reached 6 weeks, however, for patients with a history of relapse or with difficulty remaining in remission during the taper, longer-term maintenance ECT was offered. If a patient had recurrence of symptoms during maintenance, this was generally addressed by increasing the frequency of treatments, intensifying treatment parameters, or considering a new acute course if symptoms were severe. Generally methohexital was used as the anesthetic agent, but etomidate, propofol, or ketamine were used at the discretion of the treating psychiatrist or anesthesiologist. Succinylcholine was used as the muscle relaxant, and low dose propofol was generally given posttreatment to help prevent posttreatment agitation.

### Statistical Analysis

Analysis were completed using R (v 3.6.1, Vienna, Austria) and Prism (v 8.2.1, San Diego CA). Primary analysis used linear regression regressing the outcome measure on the treatment number with robust standard errors to account for multiple observations of each patient over time. For analysis of QIDS and BASIS-24 a knot was placed at treatment 10, selected a priori, as the transition point from acute to maintenance treatment. As a sensitivity analysis a parallel mixed effect analysis was completed with treatments nested in patients, as was an analysis limited only to the first fifty treatments (present for all subjects by definition). The results of these sensitivity checks were equivalent and are not shown. The data on which these primary regression models are based were visualized as LOESS curves. To characterize the duration of follow-up, treatments were binned to the closest 10 and total

elapsed time in days summarized through box plots and descriptive statistics. Missing datapoints were imputed from the median of the prior and successive measurements. Differences in categorical variables were assessed using a chi-square test.

## Results

A total of 100 patients met study criteria of 50 or more treatments within a single treatment course (Table 1). The average age at initiation of ECT was 47, and 68% were female. The cohort is predominantly (95%) white and educated, with 97% high school graduates, 82% with at least some college, and 58% with at least a four-year college diploma. The primary clinical diagnoses were mood disorders, chiefly major depressive disorder (61%) and bipolar I (21%), with bipolar II (8%), schizoaffective disorder (8%) and schizophrenia (2%) accounting for the rest. The majority (65%) of treatment series were begun as an inpatient. Full demographics and cohort characteristics are shown in Table 1.

QIDS scores declined significantly during the first 10 ECT treatments, decreasing from a mean of 16.3 to a mean of 10.3 during that period (slope of QIDS vs treatment number  $-0.62$ ; 95% CI  $-0.75$  to  $-0.50$ ;  $P < 0.001$ ). QIDS continued to decline slightly over the remaining 90 treatments (slope of QIDS vs treatment number  $-0.03$ ; 95% CI  $-0.04$  to  $-0.01$ ;  $P = 0.003$ ). Consistent with the QIDS response there was a corresponding decrease in BASIS-24 total score from 1.80 to 1.18 over the first 10 treatments (slope of BASIS-24 vs treatment number  $-0.06$ ; 95% CI  $-0.08$  to  $-0.05$ ;  $P < 0.001$ ), with stability of BASIS-24 score over the remainder of the study period (slope of BASIS-24 vs treatment number 0.00; 95% CI 0.00 to 0.00;  $P = 0.031$ ). MoCA remained unchanged throughout treatment (slope of MoCA vs treatment number  $-0.01$ ; 95% CI  $-0.01$  to 0.00;  $P = 0.222$ ). Results as a function of treatment number and time since initiation of treatment are given in Figure 1. We further performed sensitivity analyses looking only at the 90 patients in the sample diagnosed with mood disorders and separately the 86 patients regardless of diagnosis with an initial QIDS 11, indicating at least moderate depression (Supplemental Table 1). The results of these subset analyses do not differ significantly from the primary analysis.

In total, patients in the cohort received 6,858 treatments. The median patient received 60 treatments, over a median of 22.1 months. In total, 210.0 patient years of follow-up are included in the cohort. There was variability in the elapsed time required to reach each treatment (Figure 2). The median patient received the 10<sup>th</sup> treatment 26 days after the first, the 20<sup>th</sup> treatment on day 86, and then each successive 10<sup>th</sup> treatment approximately 100 days later (median for treatment 30: 183d; treatment 40: 282d; treatment 50: 395d).

Right unilateral electrode placement and ultra-brief pulse width were the most common initial treatment parameters (Table 2). At treatment 10 some patients had crossed over to bilateral treatments and brief pulse treatments, a trend that continued during maintenance ECT. By treatment 50, right unilateral treatments remained most common (60%) but were used significantly less often than for initial treatments ( $\chi^2$  (1, N=100) = 25.98,  $p < 0.0001$ ). By treatment 50 there was a significant change towards brief pulse treatment, with 66% of treatments utilizing these pulse widths ( $\chi^2$  (1, N=100) = 47.29,  $p < 0.0001$ ).

Among patients who had at least 50 ECT treatments, 70% went on to receive at least 10 additional treatments, and 19% continued for 100 or more total ECT treatments. An additional 17% were continuing to receive ECT at the end of the study period. Among the 64 of patients who discontinued ECT before treatment 100 during the study period, 35 (55%) stopped treatment due to remission, 18 (28%) discontinued due to plateauing of symptoms without full remission, 6 (9%) had a relapse requiring change in treatment plan, 3 (5%) developed a medical comorbidity precluding further ECT, and 1 (<2%) each stopped due to side effects and insurance barriers (Table 3).

## Discussion

Our study of 100 patients receiving 6,858 treatments of is the largest reported description of maintenance ECT both in terms of number of patients and number of treatments. Results demonstrate sustained improvement in depression and self-reported mental health status without adverse cognitive outcomes, as measured by the QIDS, BASIS-24, and MoCA, respectively. Most patients remained in the mild depression range at the end of treatment. Patients began with acute course ECT (median time to 10 treatments 26 days) then progressively tapered treatments to an average of once every 10 days, with widening ranges of time in between treatments as patients progressed in maintenance ECT. Notably, the variability among patients in time to reach each subsequent treatment widens as the number of treatments increases. This likely reflects some patients with partial relapses requiring re-intensification of treatment to avoid full relapse (e.g. moving from monthly to weekly maintenance for a time), while others are able to continue spacing treatments without change thus taking longer to reach treatment 50. While nearly all patients began treatments with unilateral ultrabrief pulse ECT, the pulse parameters which have the least cognitive effects,<sup>13</sup> by the 50<sup>th</sup> treatment 40% were receiving bilateral treatments, and more than two thirds had transitioned to brief pulse widths. This likely reflects a true difference between initial acute course ECT and maintenance treatments, for which the increased interval between treatments may require more intense treatment parameters.<sup>14</sup> In our clinical experience patients who have not achieved full remission at the end of the acute course (and the average QIDS of the cohort at treatment 10 was 10.3, indicating continued mild depression) may be better able to tolerate the spacing of treatments during maintenance phase if more intense treatment parameters are used, and this decision is made on the basis of patient preference and intensity of residual symptoms. Fortunately, the increased interval may result in relative cognitive sparing despite the increased intensity of individual treatments. Evidence of this has been found in trials of acute course ECT comparing 2x weekly vs. 3x weekly treatments of equal treatment parameters, where less frequent treatments cause relatively fewer cognitive side effects.<sup>15,16</sup>

The choice of the MoCA as the cognitive rating scale was made on clinical grounds. The available evidence indicates that the MoCA is more sensitive than the Mini Mental State Examination for detecting cognitive impairments during ECT,<sup>17</sup> and our results indicate no significant cognitive changes using this instrument at any 10 treatment interval. This is consistent with the overall evidence of objective cognitive performance of mostly acute ECT which found most adverse effects disappearing within 3 days.<sup>18</sup> Our results are consistent with prior retrospective studies of maintenance ECT. These include Russell *et al.*, who

studied 43 patients receiving maintenance ECT for at least a year (mean 50.4 treatments). Of these 20 had baseline and follow-up MMSE and 11 had baseline and follow-up depression screening;<sup>19</sup> they likewise found improvements in depression and stable to improved cognition in patients studied. A more recent study of 199 patients (96 with > 12 lifetime treatments; 11 with > 50 treatments) over 10 years showed no increasing cognitive deterioration with increasing number of ECT sessions, although disease remission was not tracked.<sup>20</sup> A further study of 8 patients who had each received at least 100 bilateral sine wave treatments in their lifetime found no difference in cognition between them and matched controls, although no baseline cognitive testing had been performed on the cohort.<sup>21</sup>

Notably 70% of this cohort received additional treatments beyond the 50<sup>th</sup>, with a minority (19%) continuing to 100 or more ECT sessions. Of the 64% of the cohort who ultimately discontinued ECT, remission was the most common reason, followed by plateau of symptoms without full remission. Relapse (6) or the development of a medical comorbidity precluding further ECT (3) were each more common than discontinuation primarily due to side effects (1), suggesting that for this population maintenance ECT treatments were effective at achieving remission and keeping patients well.

## Limitations

Notable limitations of this study include its retrospective observational nature and lack of a non-intervention control group. Prospective trials of maintenance ECT are sparse, with a 2017 systematic review finding only two randomized prospective trials with outcomes greater than 6 months.<sup>22</sup> The first, a study of 33 geriatric patients with unipolar psychotic depression treated with maintenance ECT (28 treatments) plus nortriptyline or nortriptyline alone for 2 years, found a mean time to relapse of 23 months for ECT vs 16 months without, with comparable cognitive outcomes as measured by MMSE.<sup>23</sup> A study of 56 patients assigned to maintenance ECT (29 treatments over 1 year) plus pharmacotherapy vs. pharmacotherapy alone found relapse rates of 32% with ECT vs. 61% without at one year, and also found no difference in cognitive outcomes between the groups.<sup>24</sup> A further limitation is that our study assessed symptom severity using self-reported measures (QIDS and BASIS-24), and determined diagnosis based on clinical impression rather than a structured clinical interview. While this hinders comparison to trials using structured interviews, the data may be more applicable to ordinary clinical practice, albeit with the caveat that our sample are treated at an academic psychiatric specialty hospital. Studies in outpatients with psychotic and non-psychotic depression have found good correlation between the self-reported and clinician-rated versions of the QIDS.<sup>25,26</sup> This suggests that this self-reported metric may match clinician impression even for severely ill patients, although we are not able to assess for the magnitude of potential difference in our study population.

Another potential limitation of this study was that we were not able to reliably assess the number of previous medication trials or hospitalizations among the cohort, and so no conclusion can be drawn about how responsive this cohort may have been to other therapies. Moreover, as patients receiving ECT continued to be treated by their inpatient or outpatient

psychopharmacologists for medication management, we are unable to assess the potential effects of concomitant medication changes or maintenance medications. Furthermore, patients were excluded from the cohort if baseline and follow-up survey responses were not complete. This may exclude patients who were unable to complete these metric due to increased symptom burden or physical or cognitive limitations. Finally, membership in this cohort was restricted to patients receiving at least 50 treatments serially, and thus may represent the most ECT responsive patients or those least susceptible to ECT-related side effects. Development of predictors for ECT responsiveness is an active area of research,<sup>27–30</sup> and is beyond the scope of this paper. Our analysis of cohort members who stop receiving ECT during the study period indicate that the most common reason for dropout is remission, suggesting that those who have successfully completed 50 treatments are unlikely to experience treatment-limiting side effects with additional ECT.

An additional limitation is possible practice effects with repeated survey administration, which for our study may be particularly problematic for the MoCA as such learning effects may bias results towards improvement in cognition.<sup>31</sup> Prior studies have shown the greatest practice effect to occur between the first and second administration of the MoCA, with longer time points showing less of an effect.<sup>32</sup> In an attempt to minimize learning effects from repeated administration of the MoCA, three alternate forms of the instrument were used, with 71% of patients having a different form used for their initial and first follow-up assessment. These three versions track closely in psychometric parameters,<sup>33</sup> and are not expected to themselves bias results. Despite this, with at least 6 MoCAs administered to each member of the cohort each patient will necessarily have repeated measurements using the same version.

## Conclusions

In conclusion, this study reports a large cohort of patients receiving extended maintenance ECT treatment (a median of 60 treatments over 22 months) in a hospital-based usual-care sample. These patients experience a large and sustained improvement in depression symptoms without suffering measurable cognitive side effects on the MoCA. Further research is needed to prospectively characterize patients who may benefit from maintenance ECT, and to compare optimal dosing and timing of these treatments to best sustain remission.

## Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

## Disclosures:

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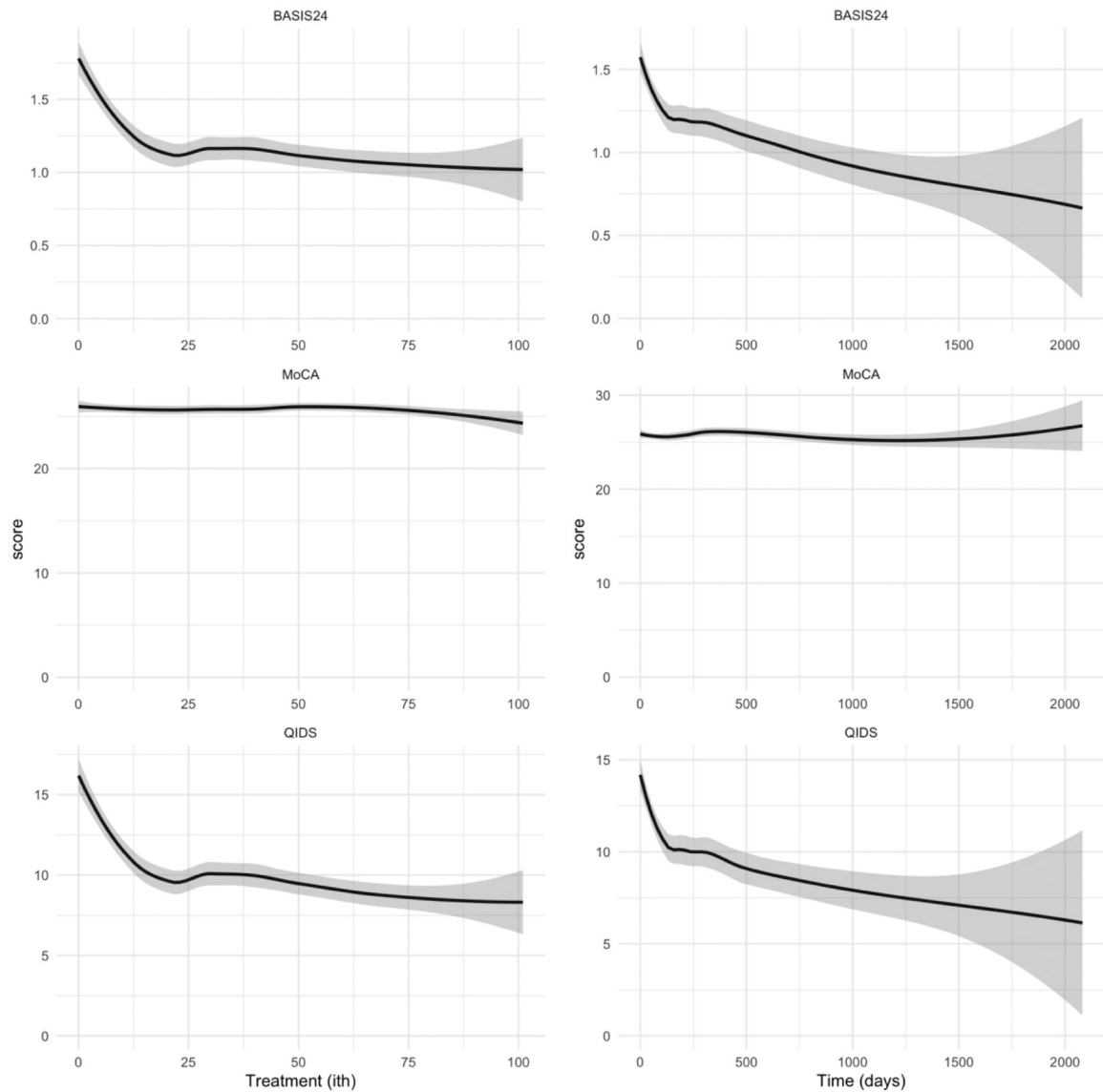
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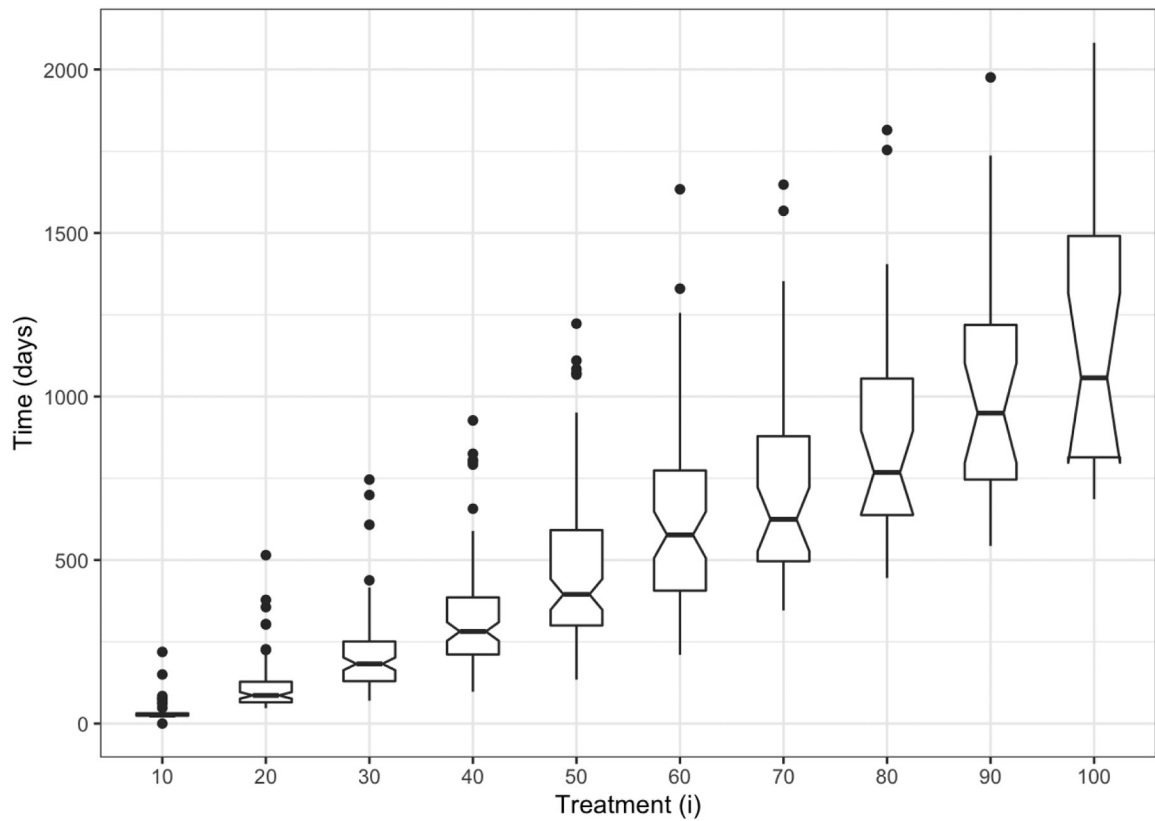
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### Highlights

- This study describes a cohort of 100 patients who each received at least 50 electroconvulsive therapy treatments, over a median period of 22 months
- During treatment there was an improvement in depressive symptoms and overall self-reported mental health outcomes which is sustained throughout the study period
- There was no detectable cognitive deficits on the Montreal Cognitive assessment at any point during treatment



**Figure 1:** Change in QIDS, BASIS-24, and MoCA with treatment number (left) and time since first treatment in days (right). QIDS and BASIS-24 sharply decline over then first 10 treatments with continued slight decline in QIDS over the remainder of the study period. MoCA scores are unchanged at any point in treatment.



**Figure 2:**

Time required to reach the indicated treatment number. The median patient took 26 days to reach the 10<sup>th</sup> treatment, consistent with a thrice-weekly treatment schedule during the acute course. It took an additional 60 days to reach treatment 20, and approximately 100 additional days for each successive 10 treatments. Treatment 50 occurred a median of 395 days (13 months) after initial treatment. Median time to dropout from the cohort was 22.1 months, and in total the cohort represents 210 patient-years of followup.

**Table 1:**

baseline characteristics of patients who received at least 50 ECT treatments in a single series and for whom initial and follow-up data are available.

	<b>Number</b>
Age mean $\pm$ SD, y	47.2 $\pm$ 16.1
18–25	10
26–40	26
41–64	48
65+	16
Female	68
Male	32
Race/ethnicity	
White	95
Black	2
Asian	0
Latino/Latina	2
Other	1
Employment in past 30 days	
Full-time	11
Part-time	6
None	68
Student	6
On disability	33
Number Missing	15
Education	
Some high school	3
High school graduate/GED	13
Some college	24
4 year college graduate	21
Postcollege education	37
Number missing	2
Subjective Physical Health	
Very poor	1
Poor	8
Good	56
Very Good	25
Excellent	8
Number Missing	2
Location where initially receiving ECT	
Inpatient	65
Outpatient	35
Clinical Diagnosis	

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	<b>Number</b>
Major depressive disorder	61
Bipolar I disorder	21
Bipolar II disorder	8
Schizoaffective disorder	8
Schizophrenia	2

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**Table 2:**

ECT treatment parameters for the first treatment (left), 10<sup>th</sup> treatment (middle), and 50<sup>th</sup> treatment (right). Over the course of maintenance ECT there is significantly increased use of bilateral electrode placement and brief pulse treatments relative to unilateral and ultrabrief treatments.

	<b>Initial Treatment</b>	<b>Treatment 10</b>	<b>Treatment 50</b>
Electrode Placement:			
Unilateral	91	84	60
Bilateral	9	16	40
Pulse Width:			
Ultrabrief (0.3–0.37 ms)	82	61	34
Brief (0.5–1 ms)	18	39	66

**Table 3:**

Reasons for dropout from the study cohort. More than a third of patients either reached 100+ ECT treatments or remained in ECT at the end of the study period. Of the rest, discontinuing treatment due to disease remission was the most common reason for study exit.

<b>Cohort status</b>	<b>Number</b>
<b>Continuing ECT</b>	<b>36</b>
Continued ECT to 100+ treatments	19
Still receiving ECT at end of study period	17
<b>Dropped out from ECT</b>	<b>64</b>
Disease in remission	35
Felt no further benefit from treatment, but not in remission	18
Relapse requiring change in treatment plan	6
Developed a medical comorbidity precluding further ECT	3
Side effects	1
Insurance issues	1