HHS Public Access

Author manuscript

Eur Arch Psychiatry Clin Neurosci. Author manuscript; available in PMC 2022 February 01.

Published in final edited form as:

Eur Arch Psychiatry Clin Neurosci. 2021 February ; 271(1): 191–197. doi:10.1007/s00406-020-01202-2.

Rate of Continuing Acute Course Treatment using Right Unilateral Ultrabrief Pulse Electroconvulsive Therapy At a Large Academic Medical Center

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Abstract

Objectives: Right unilateral ultrabrief pulse (RUL-UBP) ECT has emerged as a promising technique for minimizing cognitive side effects of ECT while retaining clinical efficacy, but it is unknown how often patients will require alternative treatment parameters and at what point in the treatment course this occurs. To better define this problem, this study analyzes continuation in RUL-UBP ECT in a retrospective cohort of patients beginning acute course treatment.

Methods: A single-center retrospective chart review was conducted of adult patients receiving a first lifetime course of ECT from 2010–2017 starting with RUL-UBP treatment parameters.

Results: 1,793 patients met study criteria. Patients received a mean of 10.0±3.2 ECT treatments, of which a mean of 8.4±3.4 were RUL-UBP treatments; proportion using RUL-UBP through 12 treatments was 57.8%. In total, 65.6% of patients were treated with RUL-UPB ECT exclusively. Mean dose increased from 7.6x seizure threshold at the second RUL-UBP treatment to 14.3x seizure threshold at the twelfth RUL-UBP treatment. Rates of continuation in RUL-UBP ECT did not differ based on age or on primary diagnosis of major depression vs. bipolar disorder.

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Conflicts of Interest

THM receives research funding from the Stanley Center at the Broad Institute, the Brain and Behavior Research Foundation, National Institute of Mental Health, National Human Genome Research Institute Home, and Telefonica Alfa. Dr. Forester receives research support from the National Institute on Aging, Biogen, Lilly, the Rogers Family Foundation, and the Spier Family Foundation. He reports consulting for Biogen. The remaining authors have no disclosures to report.

Ethics approval

This study was approved by the Partners Healthcare Institutional Review Board

Data Availability Statement

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

Conclusions: Among patients beginning acute-course treatment using RUL-UPB ECT, two thirds were treated with these parameters exclusively. Among patients who received twelve RUL-UBP treatments, mean final dose was 14.3x seizure threshold. Further studies regarding optimal dosing of RUL-UBP ECT are indicated.

Keywords

electroconvulsive therapy; cohort studies; survival analysis; ultrabrief pulse

Introduction

Electroconvulsive therapy (ECT) is an effective treatment for depressive disorders,[1] and after 80 years of use remains a critical tool for psychiatric treatment.[2] A key focus of modern ECT research is maintaining therapeutic efficacy while minimizing cognitive side effects. This includes the use of right unilateral (RUL) electrode positioning and ultrabrief pulse (UBP) stimulation parameters, in which the duration of the electrical stimulus is reduced to < 0.5 ms.[3] This more efficiently induces a therapeutic seizure and likely reduces deleterious cognitive effects, but with the potential cost of decreased efficacy requiring more overall treatments than other stimuli.[4–6] One possible treatment algorithm involves the use of RUL-UBP stimuli at the beginning of an acute course, with a switch to alternative (brief pulse or bilateral) treatments if remission is not achieved.[7] Data from a large clinical sample would help assess the overall efficacy and tolerability of RUL-UBP ECT and help providers better understand what fraction of patients may be successfully treated using this technique. This study analyzes the probability of remaining in acute course RUL-UBP ECT among patients who begin treatment using these stimulus parameters.

Methods

Population and Setting

This was a retrospective cohort study from a single center of patients receiving an index course of RUL-UBP ECT (defined as a pulse width of <0.5 ms) at a freestanding academic psychiatric hospital from Nov 2010 to June 2017. Patients were followed for the first 12 treatments (defining the end of a typical acute course) or until discontinuation of ECT treatment. Patients were excluded from the study population if they were known to have had prior ECT, if their ECT course did not begin with a RUL-UBP dose titration, or if they were younger than 18. This retrospective cohort study based on chart review was approved by the Partners Healthcare Institutional Review Board.

Treatment procedure

All patients received ECT using a Mecta Spectrum 5000Q (Tualatin, OR). Seizure threshold was determined by dose titration at the first treatment, with subsequent suprathreshold treatments generally given thrice weekly. Dose, pulse width, and electrode placement were then modified by the treating psychiatrist based on clinical response. 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. Seizure presence and duration were determined based on two

lead bifrontal or fronto-mastoid EEG and the “cuff method” of inflating a BP cuff on one calf prior to muscle relaxant administration. Diagnosis is the primary clinical diagnosis at the time of first treatment, using ICD-9 codes through 2015 and ICD-10 codes thereafter.

Statistical Analysis

Kaplan-Meier analysis of duration of treatment, in terms of number of completed treatments, was performed using Prism (v 8.4.0, San Diego CA). For RUL-UBP survival analysis, patients who were transitioned from RUL-UBP ECT to another treatment modality (brief pulse or bilateral treatments) during the first 12 treatments were defined as events; those who discontinued ECT entirely, but had their last treatment using a RUL-UBP stimulus, were defined as censored. For survival analysis in ECT overall, all patients who stopped treatment prior to the twelfth treatment were counted as events. Comparisons between multiple survival curves are made using the logrank test. The eventual outcome of treatment as a binary outcome was analyzed using logistic regression and the final treatment dose using ordinary least-squares using R (v 3.6.1, Vienna, Austria).

Results

During the study period 1,924 patients received a first lifetime course of ECT, of whom 64 were initially treated with RUL-brief pulse parameters and 67 were treated with bilateral electrode placement, leaving a study population of 1,793 patients. Of these, 773 (43.1%) were male, and the mean age at the time of titration was 46.3±16.6 years (Table 1). The majority of patients (1420; 79.2%) were diagnosed with unipolar depression, with an additional 283 (15.8%) diagnosed with bipolar disorder and 90 (5.0%) with other diagnoses. Methohexital was the anesthetic for 1735 patients (96.8%), with three given propofol and one ketamine. Anesthetic was not recorded for 54 patients (3.0%). Participants received a mean of 10.0±3.2 ECT treatments, of which a mean of 8.4±3.4 were RUL-UBP treatments. Consistent with a thrice weekly treatment schedule, the median patient received treatment #4 one week after the initial treatment and treatment #7 a week later, with a slight spacing to treatment #10 on day 23 and treatment #12 on day 30 (Table S1). A total of 606 patients (33.8%) received 12 consecutive RUL-UBP treatments. An additional 571 patients (31.8%) discontinued ECT before treatment #12 but received RUL-UBP ECT as their last treatment (mean of 6.3±3.2 treatments). The remaining 616 patients (34.4%) were transitioned from RUL-UBP treatments to another modality after a mean of 6.9±2.4 RUL-UBP treatments; of these, 569 were receiving brief pulse treatments and 172 were receiving bilateral treatments at time of last treatment. Kaplan-Meier analysis of duration of treatment (Figure 1) yields a proportion in RUL-UBP ECT of 57.8% at treatment #12, with a proportion in any type of ECT of 61.5% over the same number of treatments.

Mean dose at treatment #1 was 22.7±24.0 mC [8], increasing to 168.3±84.8 mC for treatment #2 (7.6x initial dose). There was an increase in charge over the remainder of the acute course (Figure 2). The 606 patients who received twelve RUL-UBP treatments had a final mean dose of 316.4±135.4 mC at treatment #12, or 14.3x initial dose. The 571 patients who discontinued ECT had similar increase in charge, with a mean charge of 213.8±134.4 mC at the last RUL-UBP treatment before censoring (9.7x initial dose). The 616 patients

transitioned to other treatment stimuli had a more rapid increase in RUL-UBP dose over the first twelve treatments, up to 334.1±150.3 mC for the final RUL-UBP treatment (15.1x initial dose). A histogram of administered doses is shown in Figure S1. Of the 15,118 RUL-UBP treatments, 12,018 (79.5%) used one of four doses: 19.2 mC (generally for treatment #1), 115.2 mC, 230.4 mC, and 345.6 mC.

There was no significant difference in duration in UPB treatments or ECT overall based on the age of the patient (Figure 3; P=0.60 for RUL-UBP survival and P=0.18 for survival in any ECT, logrank tests). Likewise, patients with unipolar depression diagnoses (1420) and those with bipolar disorders (283) had equal duration in UBP and overall treatment (Figure 4; P=0.35 for RUL-UBP survival and P=0.33 for survival in any ECT, logrank tests).

In a multivariable linear model of final UBP dose male sex and older age were each associated with higher final dose whereas initial seizure threshold ≤ 19.2 mC was associated with a lower final dose and diagnostic categories were not significantly associated (Table 2; R^2=0.04). In a similar multivariable logistic model of transition from RUL-UBP to other treatment parameters, male sex was associated with greater odds of dropout (aOR 1.15–1.71), whereas age, diagnostic category, and initial seizure threshold ≤ 19.2 mC were not significantly associated (Table S2; R^2=0.01)

Discussion

In this large single-center cohort, among patients who began treatment with RUL-UBP ECT, 33.8% received 12 consecutive RUL-UBP treatments, 31.8% discontinued ECT before treatment #12 but received RUL-UBP ECT as their last treatment, and 34.4% were transitioned from RUL-UBP to other parameters. Overall this analysis supports the utility of RUL-UBP ECT, with approximately two thirds of patients treated with exclusively these parameters. Unfortunately our ECT treatment records are not linked systematically to clinical outcomes data, so we cannot directly assess response to treatment or potential side effects. Nonetheless these results place some bounds on the range of likely outcomes. In general, chief reasons for discontinuing ECT during an acute course include clinical remission requiring no further treatments, lack of efficacy, and intolerable side effects. In contrast, switching from RUL-UBP to more intensive treatment parameters (brief pulse or bilateral) will generally only occur in the case of insufficient clinical response as side effects are generally worse with other treatment types. Furthermore, continuing in ECT at an approximately thrice weekly schedule (indicating an ongoing acute course) implies that neither remission nor intolerable side effects have occurred. Given this, perhaps the most favorable interpretation of these results from the perspective of RUL-UBP ECT is that the method achieves remission in fewer than 12 treatments in approximately 1/3 of patients (reflecting the 571 who discontinue treatment), is unsuccessful in 1/3 of patients (the 616 who require alternative treatment parameters), and is tolerable and partially effective in the remaining 1/3 (the 606 receiving twelve RUL-UBP treatments). A worst-case interpretation could view patients who discontinue treatment as dropping out due to lack of efficacy or side effects, implying even lower effectiveness. The two largest prospective trials of ECT, the CORE and PRIDE trials, both indicate that the mean number of treatments required to reach remission of depression is 7.3,[9, 10]. This is comparable to the mean number of treatments

in the patients who discontinue ECT prior to treatment #12 (6.9 among the 571 patients) which suggests that many of this group may in fact have discontinued treatment due to remission.

A potential difference in required number of treatments for RUL-UBP ECT vs. other ECT treatment types remains an area of active investigation. One single-center study found an increase in number of treatments from 8.8 using RUL-brief pulse to 10.9 using RUL-UBP.[5] Likewise one prospective trial found a mean of 18 RUL-UBP treatments to achieve remission,[11] and a meta-analysis found an average of 8.7 treatments for RUL-brief pulse ECT vs 9.6 for RUL-UBP ECT.[6] Our finding of 10 overall treatments, and 8.4 RUL-UBP treatments, is consistent with this range, but without a comparison group treated with a different ECT type we are unable to comment on whether RUL-UBP ECT requires a different number of treatments.

Patients who remained in RUL-UBP ECT were similar in age to those who did not remain in RUL-UBP treatment, and duration in RUL-UBP ECT did not differ based on age. ECT is preferentially used in older patients,[12] who due to medical comorbidities may be at higher risk of complications from untreated depression and thus require expedient treatment of mood disorders.[13] The results from this study that geriatric patients remained in RUL-UBP treatments at equal rates to younger patients suggests similar tolerability of this treatment methodology across the age span. Male sex was positively associated with transition from RUL-UBP to other treatment types in our logistic model, with an odds ratio for dropout of 1.4 relative to female sex. This may be due to underlying differences in male and female patients referred to ECT, with one study indicating that female patients are referred to ECT after fewer medication trials than male patients, perhaps reflecting different degrees of treatment resistance.[14] Notably, the logistic model of transitioning from RUL-UBP ECT to other treatment types explained the minority of variance in the data, indicating a great degree of unexplained variability in which patients can successfully continue in treatment with RUL-UBP ECT.

Many more patients with unipolar depression than bipolar disorder were treated in our study, but there were equal duration in RUL-UBP ECT among both. This is consistent with meta-analyses showing equivalent overall response to ECT in major depressive disorder and bipolar depression,[15, 16] but with a slightly faster response in bipolar depression.[16] Since this study only examines individuals who started treatment with RUL-UBP ECT, the generalizability of this finding may be limited as the most severely ill patients of either diagnosis may have been treated with bilateral or brief pulse treatments, so they would not have been included in this study population. Nonetheless this result is suggestive that, consistent with meta-analysis of prior trials using a variety of ECT stimulus parameters, RUL-UBP can be used similarly in unipolar and bipolar illnesses.

With regards to stimulus dosing, all patients in this study had individual seizure threshold determination at treatment #1. They were subsequently treated at a mean of 7.6x seizure threshold at treatment #2. Following treatment #2 there was an increase in applied charge throughout the acute course in all patient groups. Those who discontinued ECT before treatment #12 but had all treatment using RUL-UBP and those who continued RUL-UBP for

at least twelve treatments had comparable rates of dose increase. In contrast, the patients who were switched from RUL-UBP had more rapid increases in applied charge, and by treatment #7 had a higher mean RUL-UBP dose than the other groups did at treatment #12. By treatment #12, patients continuing in RUL-UBP ECT were treated at 14.3x initial dose, far in excess of the often-suggested 6–8x seizure threshold dosing.[17] This may be partially mitigated by a rise in seizure threshold during the course of ECT,[18, 19] but as this effect does not occur in all patients and does not result in a doubling of initial ST it would not fully explain the increased doses seen here. While many prospective studies have not reported the final applied charge, the EFFECT-Dep trial of unilateral brief pulse ECT vs bilateral ECT reported that unilateral patients had a dose increase from 6x seizure threshold to 9.6x seizure threshold over a mean of 7.8 sessions.[20] Likewise the protocol in the PRIDE trial using RUL-UBP ECT in combination with venlafaxine in geriatric patients with unipolar major depression set an initial dose of 6x seizure threshold, increasing by 50% at treatment #6 and an additional 50% at treatment #9 in the event of non-remission, representing a final dose of 13.5x threshold. Potential superior effects of higher doses are consistent with a brief pulse study finding greater efficacy with fixed high doses.[21] Further study will be required to assess the efficacy, cognitive side effects, and optimal timing of these higher doses. In our multivariate linear model of final RUL-UBP dose, male sex and older age were associated with higher doses, a trend that has previously been established in initial seizure thresholds for RUL-brief pulse and bilateral ECT.[22, 23] Initial seizure threshold ≤ 19.2 mC was associated with lower final dose in the multivariable model adjusting for age, sex, and diagnostic category. This model explained the minority of variance in the data highlighting the as yet unexplained variability in patient dosing. A further potential source of variability in dosing is that the MECTA ECT instrument permits adjustment of parameters, including pulse width, frequency, and stimulus duration, and that as a result some net doses can be administered in different ways.[3] Among the seven most common doses in this study, only the 230.4 mC dose was administered multiple ways (800 mA, 0.3 ms pulse width, 60 Hz frequency, 8 s duration, administered 5,271 times; 800 mA, 0.3 ms pulse width, 80 Hz frequency, 6 s duration, administered 463 times). As there are likely differing effects of amplitude,[24] duration,[25] and frequency [26] in addition to pulse width, this may contribute to variation in outcomes.

Strengths of this study are its large sample size and consistent treatment procedures during the study period. Notable limitations include its retrospective observational nature and lack of control group, which prevents analysis of causality and comparison to other treatments. Additionally, our ECT treatment records are not linked systematically to the patient's general medical record, so we are unable to assess number of prior medication trials, hospitalizations, or other treatments, so no conclusion can be drawn about how responsive this cohort may have been to alternative treatments nor the effects of potential concomitant medication changes. Moreover, diagnoses used in this study were made clinically by the treating physician and not using structured interviews, hindering comparison to some prior research studies but reflecting usual clinical practice.

Conclusion

Among 1,793 patients beginning acute-course treatment using RUL-UPB ECT, two thirds were treated with these parameters exclusively. Among patients who received twelve RUL-UBP treatments, mean final dose was 14.3x seizure threshold. Further studies regarding optimal dosing of RUL-UBP ECT are indicated.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Funding

This work was supported by the National Institute of Mental Health (R25MH094612, JL; R56MH115187 and R01MH120991, THM; 5R01MH112737-03, MEH), the National Institute on Aging (5R01AG061100-02; BPF), and the Brain and Behavior Research Foundation (NARSAD 26489; THM). The sponsors had no role in study design, writing of the report, or data collection, analysis, or interpretation.

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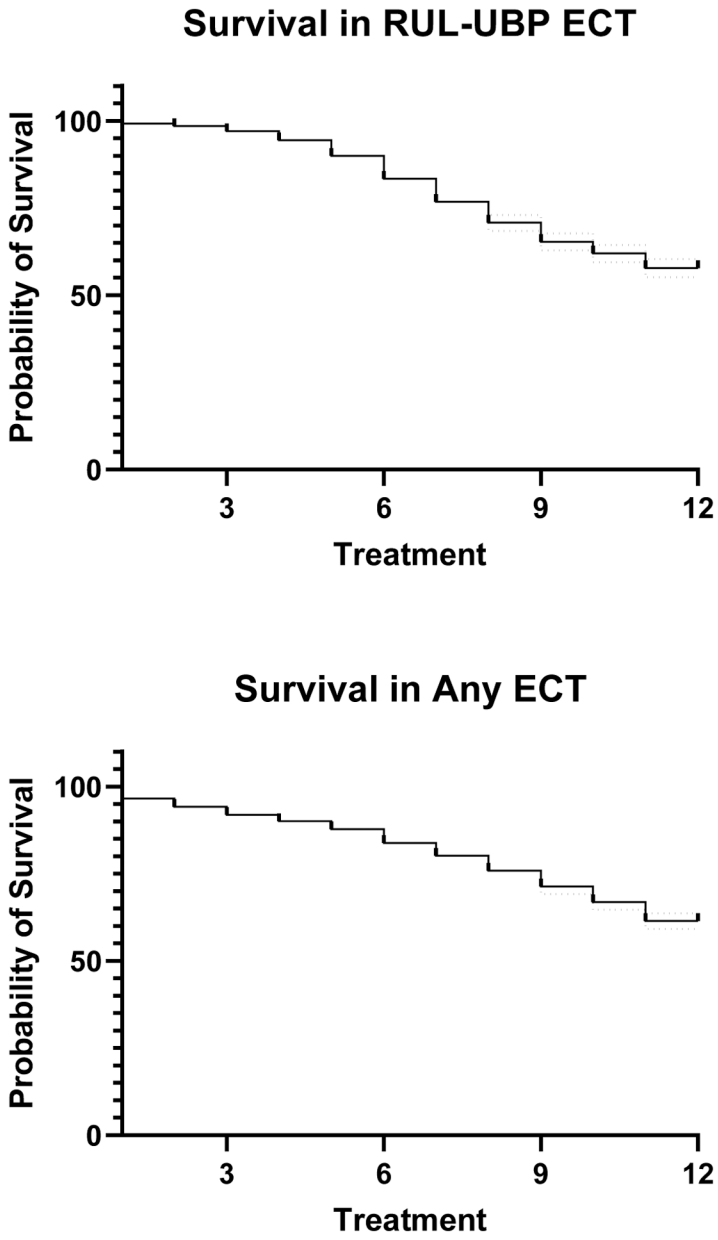

Figure 1:

Top: Kaplan-Meier analysis for remaining in RUL-UBP ECT. Patients who are transitioned to other treatment parameters before treatment #12 are counted as events, while those who discontinue ECT entirely but have their last treatment with RUL-UBP are censored. Survival probability is 57.8% at treatment 12. Bottom: Kaplan-Meier analysis for remaining in any type of ECT, with discontinuation of ECT for any reason treated as an event. Survival probability is 61.5% at treatment #12. 95% confidence intervals for survival curves are shown as dashed lines.

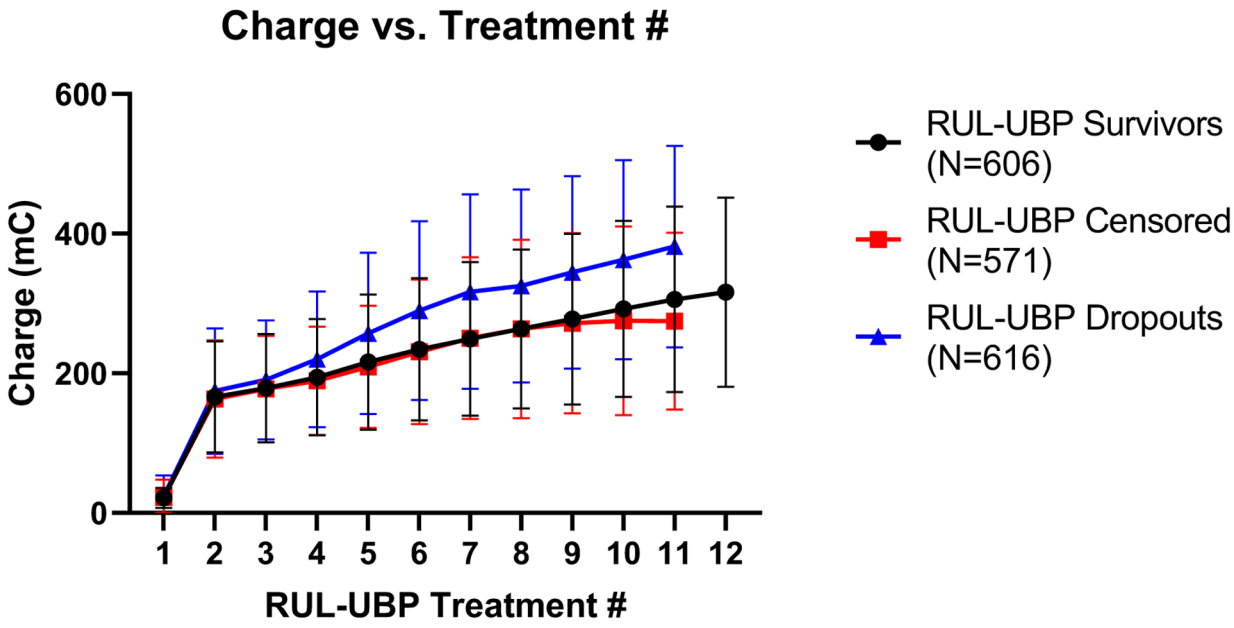

Figure 2:
change in applied charge over acute course ECT. After initial seizure threshold determination there is a jump to 7.6x threshold at treatment #2 followed by a continued rise in charge over the remainder of the acute course.

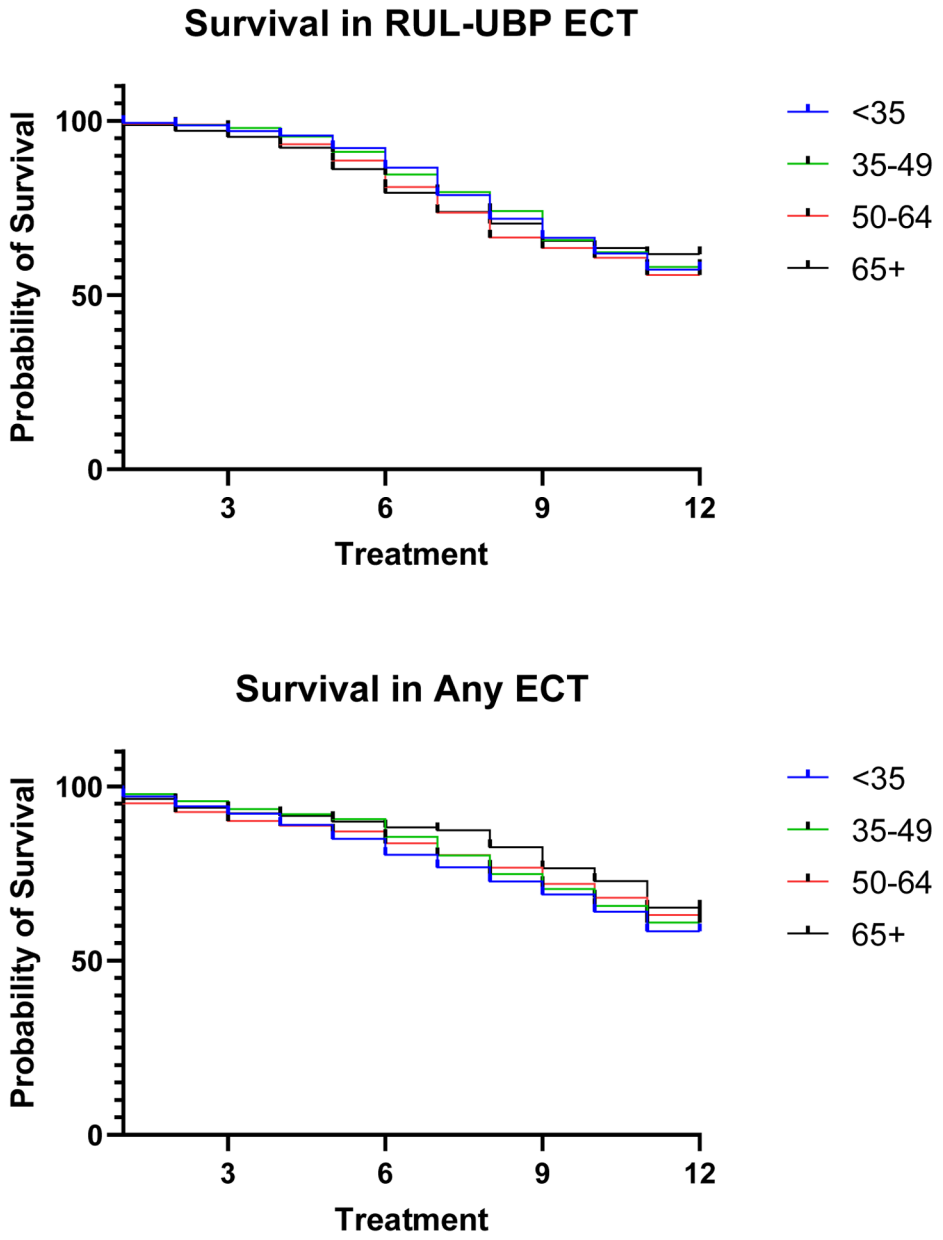

Figure 3:

Top: Kaplan-Meier analysis for remaining in RUL-UBP ECT, broken down by age. Survival proportions do not differ significantly among the 4 age buckets (P=0.60, logrank test). Bottom: Kaplan-Meier analysis for remaining in any type of ECT, broken down by age. Survival proportions likewise do not differ significantly among the 4 age buckets (P=0.18, logrank test).

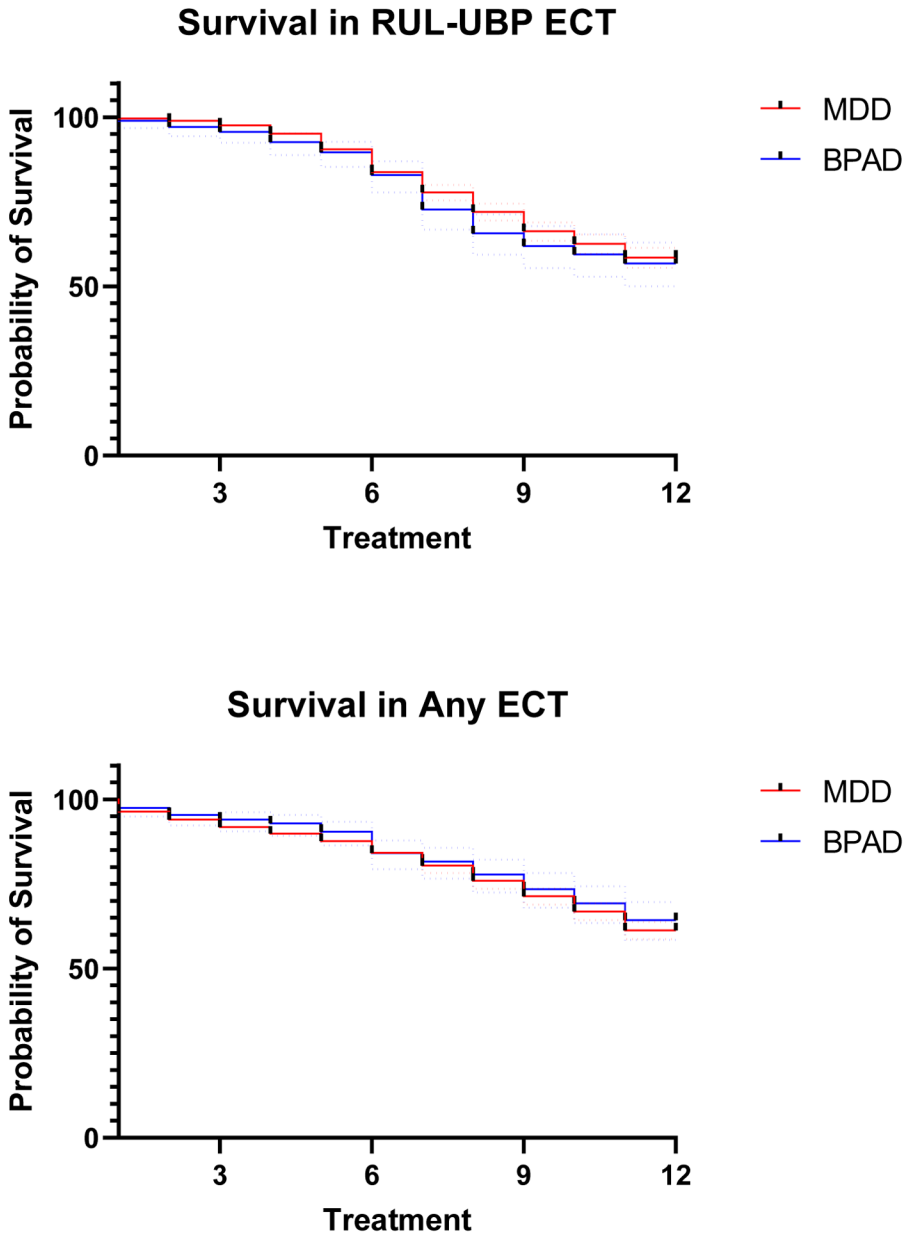

Figure 4:

Top: Kaplan-Meier analysis for remaining in RUL-UBP ECT among patients with a diagnosis of major depressive disorder (red) or bipolar disorder (blue). Survival proportions do not differ significantly among the two diagnoses (P=0.35, logrank test). Bottom: Kaplan-Meier analysis for remaining in any type of ECT among patients with a diagnosis of major depressive disorder (red) or bipolar disorder (blue). Survival proportions do not differ significantly among the two diagnoses (P=0.33, logrank test). 95% confidence intervals for survival curves are shown as dashed lines.

Table 1:

characteristics of the cohort, overall and separated based on outcome during acute course treatment. UBP survivors each received twelve RUL-UBP treatments. UBP censored patients discontinued ECT prior to the twelfth treatment, but had all treatments using RUL-UBP stimuli. UBP dropouts transitioned from RUL-UBP ECT to another stimulus type (brief pulse or bilateral electrode placement) prior to the twelfth treatment.

	All patients	UBP survivors	UBP censored	UBP dropouts
N	1793	606	571	616
Sex = male (%)	773 (43.1)	246 (40.6)	228 (39.9)	299 (48.5)
Age (yrs; mean (SD))	46.3 (16.6)	46.7 (16.8)	45.5 (16.5)	46.7 (16.4)
Diagnosis				
Major depressive disorder (%)	1420 (79.2)	482 (79.5)	459 (80.3)	479 (77.8)
Bipolar disorder (%)	283 (15.8)	99 (16.3)	81 (14.2)	103 (16.7)
Other (%)	90 (5.0)	25 (4.1)	31 (5.4)	34 (5.5)
Anesthetic at 1st Tx				
Methohexital (%)	1735 (96.8)	585 (96.5)	549 (96.1)	601 (97.6)
Propofol (%)	3 (0.2)	1 (0.2)	1 (0.2)	1 (0.2)
Ketamine (%)	1 (0.1)	0 (0)	1 (0.2)	0 (0)
Etomidate (%)	0 (0)	0 (0)	0 (0)	0 (0)
Unknown (%)	54 (3.0)	20 (3.3)	20 (3.5)	14 (2.3)
# of treatments (mean (SD))	10.0 (3.2)	12 (0)	6.3 (3.2)	11.4 (1.4)
# of UBP treatments (mean (SD))	8.4 (3.4)	12 (0)	6.3 (3.2)	6.9 (2.4)
	Treatment #1	Treatment #12	Last before censoring	Last before dropout
Dose (mC; mean (SD))	22.7 (24.0)	316.4 (135.4)	213.8 (134.4)	334.1 (150.3)
Dose (mC; median)	19.2	230.4	230.4	230.4

Table 2:

Linear regression of final UBP dose on sex, age (z-score), diagnosis (major depressive disorder, bipolar disorder, other), and initial seizure threshold ≤ 19.2 mC.

Predictors	Estimates	CI	p
Sex (male)	17.74	3.93 – 31.55	**0.012**
Age (z-score)	26.54	19.58 – 33.50	**<0.001**
Diagnosis			
MDD	14.41	−17.32 – 46.15	0.373
BPAD	20.54	−14.55 – 55.63	0.251
Initial ST ≤ 19.2 mC	−33.44	−56.67 – −10.20	**0.005**