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Effects of continuation electroconvulsive therapy on quality of life in elderly depressed patients: A randomized clinical trial

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ABSTRACT

We examined whether electroconvulsive therapy (ECT) plus medications ("STABLE + PHARM" group) had superior HRQOL compared with medications alone ("PHARM" group) as continuation strategy after successful acute right unilateral ECT for major depressive disorder (MDD). We hypothesized that scores from the Medical Outcomes Study Short Form-36 (SF-36) would be higher during continuation treatment in the "STABLE + PHARM" group versus the "PHARM" group. The overall study design was called "Prolonging Remission in Depressed Elderly" (PRIDE). Remitters to the acute course of ECT were re-consented to enter a 6 month RCT of "STABLE + PHARM" versus "PHARM". Measures of depressive symptoms and cognitive function were completed by blind raters; SF-36 measurements were patient self-report every 4 weeks.

Participants were 120 patients > 60 years old. Patients with dementia, schizophrenia, bipolar disorder, or substance abuse were excluded. The "PHARM" group received venlafaxine and lithium. The "STABLE + PHARM" received the same medications, plus 4 weekly outpatient ECT sessions, with additional ECT session as needed. Participants were mostly female (61.7%) with a mean age of 70.5 ± 7.2 years. "STABLE + PHARM" patients received 4.5 ± 2.5 ECT sessions during Phase 2. "STABLE + PHARM" group had 7 point advantage (3.5–10.4, 95% CI) for Physical Component Score of SF-36 ($P < 0.0001$), and 8.2 point advantage (4.2–12.2, 95% CI) for Mental Component Score ($P < 0.0001$). Additional ECT resulted in overall net health benefit. Consideration should be given to administration of additional ECT to prevent relapse during the continuation phase of treatment of MDD. *Clinical Trials.gov:* NCT01028508

1. Introduction

Major Depressive Disorder (MDD) is a leading cause of poor health-related quality of life (HRQOL) (WHO Guidelines Approved by the Guidelines Review Committee, 2011). The HRQOL deficits increase with depression symptom severity (McCall et al., 1999a). Age influences the HRQOL deficit patterns, with younger depressed patients reporting more problems with relationships and older depressed

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patients reporting more problems with daily living and role functioning (McCall et al., 1999a). A third of depressed patients do not respond to two or more sequential antidepressant medications, and are deemed to have treatment resistant depression (TRD) (Kubitz et al., 2013; McCall, 2007). TRD patients are candidates for electroconvulsive therapy (ECT), acknowledged as the most effective TRD treatment (Lisanby, 2007).

HRQOL is exceptionally poor in MDD patients referred for ECT, and worse than that of unselected MDD patients in general outpatient settings, (McCall et al., 2013) and HRQOL is a factor in referral patterns for ECT (McCall et al., 1999b). Naturalistic studies of MDD have shown that ECT results in improved HRQOL, with the degree of improvement greater for patients who received ECT as opposed to antidepressant medications (McCall et al., 2001). Similarly, modern ECT randomized clinical trials (RCT) not including a non-ECT comparator arm also showed improvement in QOL (McCall et al., 2011; McCall et al., 2004). Both in the naturalistic studies and the prior RCTs, improvement in HRQOL was best explained by improvement in depression symptoms, with little or no relationship to any cognitive side effects. In naturalistic studies, improvement in HRQOL was sustained over 6-months after ECT in patients with sustained remission, with HRQOL values indistinguishable from healthy population norms (McCall et al., 2013). In contrast, depressive relapse after ECT was associated with worsening in HRQOL (McCall et al., 2006).

HRQOL is central to understanding the overall net risks and benefits of treatments, including those of ECT. While ECT results in remission of depressive symptoms, it also is associated with cognitive side effects. The issue of cognitive side effects is of particular concern for the elderly population who are more vulnerable for age-related cognitive problems.(Rizzi et al., 2014) Medical decision making regarding the risk/benefit ratio of ECT could be usefully informed by the study of health related quality of life measures (Devanand et al., 1994; Scalia et al., 2007; Weiner, 1984). However, prior HRQOL studies in ECT have lacked randomized comparisons of ECT versus a non-ECT alternative group.

We present here the HRQOL outcomes as a secondary analysis from a randomized comparison of ECT combined with venlafaxine (VEN) and lithium (Li), versus VEN and Li without ECT, as continuation therapy after a successful ECT course for elderly adults with MDD.

2. Material and methods

2.1. Design overview

The *Prolonging Remission in Depressed Elderly (PRIDE)* study was a NIH-funded randomized, multi-center study that compared two post-acute-ECT continuation treatment strategies: (1) pharmacotherapy that combined venlafaxine (VEN) and lithium (Li) (*PHARM*); and (2) PHARM enhanced by the addition of an individualized, flexible, algorithm-based ECT schedule (**S**ymptom-**T**itrated, **A**lgorithm-**B**ased, **L**ongitudinal **E**CT, STABLE) (*STABLE + PHARM*) (Lisanby et al., 2008).

PRIDE consisted of two phases: in Phase 1, 240 patients, ≥ 60 years old with unipolar MDD received acute ECT 3 times per week in combination with oral VEN; in Phase 2, 120 remitters who were randomized to either PHARM or STABLE + PHARM comprised the intent-to-treat (ITT) sample. The primary efficacy outcome variable was the 24-item Hamilton Rating Scale for Depression ($HRSD_{24}$) total score measured longitudinally over 6-months. A priori secondary outcome variables included HRQOL. The results of Phase 1 have been previously reported for both antidepressant efficacy and HRQOL, (Kellner et al., 2016b; McCall et al., 2017) and the Phase 2 efficacy results have been reported (Kellner et al., 2016a). The study was approved by the institutional review board at each study site, and the investigation was carried out in accordance with the latest version of the Declaration of Helsinki.

2.2. Patient sample

Patients enrolled in Phase 1 were aged 60 years and older referred for ECT for the treatment of unipolar MDD, without dementia, with or without psychosis, with a pretreatment $HRSD_{24}$ total score ≥21. Exclusion criteria included: bipolar disorder, schizoaffective disorder, schizophrenia, dementia, delirium, intellectual disability, history of substance abuse in the past 6 months, or neurological conditions or active general conditions assumed to affect cognition or treatment response. Also, patients failing to respond to an adequate trial of Li + VEN or ECT in the current episode were excluded. Inclusion criteria for the randomized phase (Phase 2) were achievement of remission in Phase 1 defined as: (a) $HRSD_{24}$ total score ≤10 on two consecutive ratings, and (b) $HRSD_{24}$ total score did not increase > 3 points on the second consecutive $HRSD_{24}$ or remained ≤ 6. Written informed consent was obtained before entrance to Phase 1 and before randomization in Phase 2.

2.3. Treatments

2.3.1. Symptom-Titrated, Algorithm-Based Longitudinal ECT (STABLE)

STABLE featured an initial fixed, tapered, ECT treatment schedule followed by a symptom driven, flexible component, in addition to the same VEN + Li as in PHARM, and the combination is termed STABLE + PHARM. The initial fixed portion consisted of 4 ECT in one month, within specified treatment windows. Treatment frequency in the subsequent flexible component (weeks 5–24) was determined by application of the STABLE algorithm, which prescribed 0–2 ECT in a given week based upon a patient's $HRSD_{24}$ total scores, details of which have been previously reported (Lisanby et al., 2008).

2.3.2. ECT procedures

ECT was delivered with right unilateral electrode placement with a high-dose, ultrabrief pulse stimulus, (RUL-UBP) described in our earlier report (Kellner et al., 2016a). Continuation ECT in Phase 2 was administered at the same stimulus dose as the last treatment in Phase 1.

2.3.3. Medication procedures

Open label VEN was started in Phase 1 at an initial dosage of 37.5 mg *po*, with a target dose of 225 mg qD by the end of Phase 1. This dosage was continued following randomization in Phase 2. Open label Li was started at 300 mg/day on the day of randomization in Phase 2, with a target level for most patients in the 0.4–0.6 mEq/L range. For VEN and Li dosing/procedures were identical for the PHARM arm and the STABLE + PHARM arm, except that Li was withheld the night before ECT in the STABLE + PHARM arm. The schedule of clinic and telephone ratings was identical for both the PHARM and STABLE + PHARM arms.

2.4. Assessments

2.4.1. HRQOL

HRQOL was measured with the Medical Outcomes Study Short Form 36 (SF-36) (Ware and Sherbourne, 1992; Ware et al., 2003). The SF-36 was measured at baseline prior to acute ECT and again at the end of Phase 1/beginning of Phase 2. Thereafter, the SF36 was measured every 4 weeks during Phase 2. SF36 data were scored in terms of the 8 standard subscales: Physical Functioning (PF), Role Physical (RP), Bodily Pain (BP), General Health (GH), Vitality (VT), Social Functioning (SF), Role Emotional (RE), and Mental Health (MH). The score for each subscale is the weighted sum of the questions for that subscale, transformed into a 0–100 scale. Lower scores define more disability. Individual scores were then transformed into T-scores, with means of 50 and standard deviations of 10. The 8 subscales were then aggregated into the two total scores: Physical Health Factor T-score (comprised of PF, RP, BP, and GH subscales) and Mental Health Factor T-score

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