



## Research paper

## Quality of life across domains among individuals with treatment-resistant depression



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## ABSTRACT

**Background:** Treatment-resistant depression affects millions of people worldwide and is a leading cause of disability and suicide. Studies of treatment-resistant depression outcomes have traditionally focused on depressive symptoms and functional impairment. Quality of life (QoL) has not been well described. We aimed to measure QoL in individuals with treatment-resistant depression and to determine how QoL was related to traditional measures of symptoms and social functioning.

**Methods:** We used a reliable, cross-culturally validated questionnaire, the abbreviated World Health Organization Quality of Life scale (WHOQOL-BREF), to prospectively measure QoL in 79 patients with treatment-resistant depression who were referred for electroconvulsive therapy at a United States tertiary-care medical center. QoL was characterized in four domains: physical, psychological, social, and environmental. QoL domains were examined for association with demographic variables, patient-reported depressive symptoms, functional impairment, and childhood adversity, as well as clinician-rated scales.

**Results:** Relative to published international norms, mean QoL scores were low in physical (standardized score,  $z = -2.0$ ), psychological ( $z = -2.6$ ), and social ( $z = -1.0$ ) domains, but not in the environmental domain ( $z = 0.2$ ). After controlling for age and income, patient-rated depressive symptoms correlated with physical (Pearson correlation,  $r = -0.26$ ) and psychological ( $r = -0.43$ ) QoL, whereas adverse childhood experiences correlated with environmental QoL ( $r = -0.33$ ). Patient-rated functional impairment correlated modestly with all domains ( $r = -0.25$  to  $-0.39$ ). Surprisingly, QoL correlated very weakly with clinician-rated measures. These modest associations of QoL with other clinical scales were confirmed in multiple regression analyses.

**Limitations:** We used a single QoL instrument, which did not allow us to directly compare the WHOQOL-BREF scale with other commonly used instruments. Our sample was recruited from a single academic medical center in the Midwest region of the United States and was largely Caucasian. These factors may limit generalizability to other settings and ethnicities.

**Conclusion:** Among individuals with treatment-resistant depression, QoL is lowest in the psychological and physical domains. QoL is only modestly correlated with patient-rated symptoms and functioning, and even more weakly correlated with clinician-rated scales, indicating that measures of symptoms and functioning cannot serve as QoL proxies. QoL should be assessed when caring for patients with treatment-resistant depression. When developing novel biological, psychological, and social interventions for treatment-resistant depression, QoL should be targeted as a distinct clinical outcome.

**Abbreviations:** ACE, adverse childhood experience scale; CGI-S, clinical global impression severity scale; ECT, electroconvulsive therapy; GAF, Global assessment of functioning; HDRS, Hamilton Depression Rating Scale; MGH, Massachusetts General Hospital; PHQ-9, Patient Health Questionnaire; Q-LES-Q, Quality Of Life Enjoyment And Satisfaction Questionnaire; QoL, quality of life; SF-36, 36-Item Short Form Health Survey; TRD, treatment-resistant depression; WHOQOL-BREF, World Health Organization Quality of Life Scale, Brief Version; WSAS, Work and Social Adjustment Scale

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## 1. Introduction

Depression is a common, debilitating illness that often fails to respond to first- and second-line treatments. For example, about one-third of patients did not reach remission after multiple optimized pharmacologic trials during the STAR-D study (Rush et al., 2006). Recent estimates for treatment resistant depression (TRD), often defined by two or more treatment failures, indicate a 12-month prevalence rate of approximately 2% in the US (Nemeroff, 2007). Furthermore, long-term outcomes of TRD are typically very poor. For example, chronic TRD has been associated with poor social function, persistent symptoms, increased mortality, and a recovery rate of less than 40% over 10 years (Fekadu et al., 2009a, 2009b). TRD is increasingly recognized as a disease worthy of study in its own right, but the optimal methods of assessment of TRD have yet to be defined (Conway et al., 2017; McIntyre et al., 2014).

Quality of life (QoL) is a broad construct encompassing multiple aspects of well-being, including physical, psychological, social, and environmental components. QoL differs from other commonly-used outcome measures such as depressive symptoms and social and occupational functioning. Assessment of QoL includes questions about symptom severity and daily functioning, but beyond that it also covers subjective well-being across multiple dimensions. Because a patient's overall condition results from a complex interplay between these different dimensions, focusing only on function and symptoms may fail to improve subjective QoL. Consequently, measuring QoL has been proposed as an essential component for clinical trials in mental illness as the assessment takes into account patients' rights, autonomy, and opinions (Mas-Expósito et al., 2011; Oliveira et al., 2016; Barneveld et al., 2014; Rubio et al., 2014). There is a need for simultaneous use of multiple assessment tools – including objective evaluations via quantitative questionnaires of functioning, symptoms and measures of subjective QoL – in order to obtain a more complete clinical picture across physical, psychological, social, and environmental domains and to understand the determinants of QoL in clinical populations (Caldirola et al., 2014; Karow et al., 2014).

Previous studies have measured QoL among patients with depression, including the narrower phenotype of TRD. In a systematic review, Ishak and colleagues summarized QoL impairments in depressive disorders and QoL improvements associated with successful treatment (Ishak et al., 2011). The Quality of Life Enjoyment and Satisfaction Questionnaire (Q-LES-Q) developed by Endicott and colleagues, a sensitive measure of satisfaction and well-being across various areas of daily functioning (Endicott et al., 1993), has proven useful for measuring QoL among patients with major psychiatric disorders (Ritsner et al., 2005). Notably, across a spectrum of anxiety and depressive disorders, symptom measures were shown to explain only a small proportion of the variance in the Q-LES-Q, suggesting that QoL cannot be assessed by measuring symptoms alone (Rapaport et al., 2005). Consistent with this finding, individuals with sub-syndromal depressive symptoms reported impairment in well-being that was similar to that of fully symptomatic major depression (Judd et al., 1996). Within the specific condition of TRD, Rosenquist et al. reviewed studies of health-related QoL and highlighted the profound effects that TRD has on physical, psychological, and social functioning, as well as life satisfaction and well-being (Rosenquist et al., 2006). Most previous studies of QoL among patients with TRD have used the 36-Item Short Form Health Survey (SF-36) (McCall et al., 2011; Qiao et al., 2017; Solvason et al., 2014). The SF-36 has the favorable qualities of multi-domain assessment and availability of normative data. However, it has not been widely validated or normed across languages and cultures. The SF-36 also measures a somewhat narrower construct, health-related QoL, that is limited to the effects of diseases and treatments on QoL.

The abbreviated World Health Organization Quality of Life Questionnaire (WHOQOL-BREF) is a 26-item, 4-domain scale developed by the World Health Organization to measure QoL in the physical,

psychological, social, and environmental domains. The WHOQOL-BREF scale has become the most widely used multidimensional QoL measure in international health research (Land et al., 2011, p. 414) because it is cross-culturally validated and available in most of the world's major languages (Skevington et al., 2004). Furthermore, it is internationally normed for 23 countries all over the world. In addition, it measures the broader construct of global QoL, which is not specific to disease states (Huang et al., 2006). In contrast to health-related QoL instruments, measures of global QoL may be more useful when developing rational policies for distribution of resources for health-related versus non-health-related problems. To our knowledge, just one brief report has used the WHOQOL-BREF to measure QoL among individuals with TRD (Antunes and Fleck, 2009). They investigated the effects of electroconvulsive therapy (ECT) on QoL of a heterogeneous sample of 58 psychiatric inpatients in Brazil, some of whom had TRD, and found improvements across QoL domains.

The current study had two objectives. The first objective was to measure physical, psychological, social, and environmental QoL among a well-characterized cohort of individuals with severe TRD using a multi-domain, validated, reliable, cross-cultural instrument (i.e., the WHOQOL-BREF). The second objective was to compare QoL domains to outcome measures of symptom severity and functional impairment commonly used in studies of TRD to determine whether the WHOQOL-BREF scale provides information beyond that measured by traditional scales. The rationale was that, because the construct of QoL includes subjective symptoms of depression and perceived functional abilities, it was possible that the WHOQOL-BREF scale would strongly correlate with scales that measure severity of symptoms and functional impairment. In that case, the WHOQOL-BREF scale would be redundant and traditional measures could be used as proxies for QoL. On the other hand, the WHOQOL-BREF scale may correlate only weakly with traditional outcomes, as shown with the Q-LES-Q scale across anxiety and affective disorders (Rapaport et al., 2005). If that is the case for TRD, then QoL could not be measured by proxy and would therefore need to be assessed independently.

## 2. Material and methods

### 2.1. Study design

The Michigan Biomarkers for Refractory Depression (Bluebird) study was conducted at the University of Michigan, Ann Arbor, between 2011 and 2016. This prospective, longitudinal, observational study of TRD recruited inpatients and outpatients who were referred to the ECT Program at the University of Michigan. We focused on this patient population because it represents a relatively severe, inadequately studied subgroup of depressed patients who are high utilizers of health care resources. Here we focus on baseline clinical measures; biomarker findings and longitudinal follow-up data will be described elsewhere. The study was approved by the University of Michigan Institutional Review Board. All subjects provided written informed consent.

### 2.2. Recruitment and assessment

Eligible patients met the following criteria:  $\geq 18$  years old at the time of consent; clinical diagnosis of a moderate-to-severe depressive episode (DSM-IV/DSM-V major depressive disorder or bipolar disorder) for at least 2 months; medication resistance, defined as non-response to at least one adequate medication trial within the current episode; considering treatment with ECT; and capacity to provide informed consent. An adequate medication trial was defined by a score of at least 3 according to the Antidepressant Treatment History Form (ATHF) (Sackeim, 2001), reflecting a minimum of 4 weeks of treatment with at least one well-established antidepressant medication at a moderate-to-high dose (e.g., nortriptyline  $> 75$  mg per day for  $\geq 4$  weeks). It is important to note that we distinguished medication resistance from

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