Journal of Affective Disorders 242 (2019) 87–95

Contents lists available at ScienceDirect

Journal of Affective Disorders

journal homepage: www.elsevier.com/locate/jad

Research paper

Toward a very brief quality of life enjoyment and Satisfaction Questionnaire

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ARTICLE INFO

Keywords:
Quality of life
Function
Satisfaction
Depression
Recovery
Psychosocial outcomes
Self-report

ABSTRACT

Objective: To develop and evaluate a new brief self-report measure of satisfaction/quality of life in depressed outpatients.

Methods: Using the Quality of Life Enjoyment and Satisfaction Questionnaire Short-Form (Q-LES-Q-SF) self-report from Step-1 (n = 2181) of the STAR*D trial, items were selected based on their magnitude of change with treatment and correlation with 16-item Quick Inventory of Depressive Symptomatology Self-Report (QIDS-SR_{16}). Psychometric analyses were conducted. Replication of scale performance was assessed with STAR*D Step-2 data (n = 250).

Results: The 7 items selected ("Mini-Q-LES-Q") rated satisfaction with work, household activities, social and family relations, leisure time activities, daily function and sense of well-being in the past week. This uni-dimensional scale captured 83–94% variance in Q-LES-Q-SF and had acceptable Item Response and Classical Test Theory characteristics. Baseline to exit percent changes in the Mini-Q-LES-Q and the QIDS-SR_{16} were significantly, modestly related (r = -0.552) (Step-1) and replicated (r = -0.562) (Step-2). The Mini-Q-LES-Q detected the expected improvement in satisfaction/quality of life in acute treatment, yet also identified residual deficits expected in many at acute-phase exit.

Limitations: Population norms are yet undefined. Concurrent validity with detailed, well-validated scales that assess the seven Quality of Life domains incorporated in the Mini-Q-LES-Q remains unestablished. Sensitivity to symptom changes induced by psychotherapy or somatic therapies or sensitive to the effects of therapies aimed at enhancing quality of life enjoyment and function is unknown.

Conclusion: The 7-item Mini-Q-LES-Q self-report measure satisfaction/quality of life has acceptable psychometric properties, reflects change with depressive symptom reduction, and detects residual deficits in this key clinical outcome.

1. Introduction

Changes in the nine criterion symptoms of major depressive disorder (MDD) are the primary metric to gauge the efficacy of antidepressant medications and other treatments. Symptomatic remission remains the preferred outcome of acute-phase treatment (Bauer et al., 2013; Cleare et al., 2015; Gelenberg et al., 2010; Kennedy et al., 2016; Rush et al., 2006b) (because remission is associated with a better long-term prognosis (lower risk of relapse) (Rush et al., 2006c) and better day-to-day function (Bauer et al., 2013; Miller et al., 1998; Trivedi et al., 2009) than either response (> 50% reduction from baseline) without remission or non-response.

In addition to remission or at least optimal symptom control, full restoration of function and normalization of quality of life are clinically important (Gelenberg, 2010) because they are valued highly by patients (Zimmerman et al., 2006), predict better longer-term outcomes (Jha et al., 2016a) and reduce the risk of depressive symptom relapse and risk of developing complications such as substance abuse or general medical complications (Burg et al., 2003; Williams et al., 2006).

For some depressed patients, symptom remission achieved with medication alone results in a high quality, satisfying, and fully functional life. For others, however, especially for those with more chronic courses of illness, more challenging current living situations, or more traumatic earlier life experiences, symptom reduction or even remission

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https://doi.org/10.1016/j.jad.2018.08.052
Received 4 June 2018; Received in revised form 23 July 2018; Accepted 12 August 2018
Available online 15 August 2018
0165-0327/

does not result in a full restoration of quality of life without additional treatments (Ishak et al., 2013; Lehman, 1983; Lin et al., 2014; Rush, 2015; Siqveland et al., 2015). These two important outcomes (symptom control and restoration of quality of life/function) may often occur at different times (Rush, 2015).

Depressive symptom control typically precedes normalization of quality of life by weeks to months or more. Since symptoms and quality of life reflect two different, albeit somewhat related parameters, the use of two different brief measures at somewhat different times would be the most parsimonious approach to assessing and managing each element.

We have several unifactorial, easily acquired self- or clinician-rated measures of depressive symptoms such as the 16-item Quick Inventory of Depressive Symptoms - Clinician Rating (QIDS-C_{16}) or Self-Report (QIDS-SR_{16}) (www.ids-qids.org; https://eprovide.mapi-trust.org/instruments/quick-inventory-of-depressive-symptomatology), the Patient Health Questionnaire, and the 6-item Hamilton Rating Scale or HRSD-6 (Bernstein et al., 2010; Carmody et al., 2006; Hooper and Bakish, 2000; Kroenke et al., 2001; Rush et al., 2003; Timmerby et al., 2017). On the other hand, despite the plethora of tools (Rush et al., 2008) to gauge day-to-day function, satisfaction or quality of life, the mental health field has not yet settled upon a single or even optimal combination of such measures. Ideally, these measures should be unifactorial as they are more sensitive to change than multifactorial scales (Bech, 2006). In addition, self-reports are preferred as they save clinician time and can help patients become effective partners in their own care.

This report therefore represents a preliminary attempt to develop a brief, unifactorial self-report that reflects satisfaction/quality of life using select items from the Quality of Life Enjoyment and Satisfaction Questionnaire-Short Form (Q-LES-Q-SF) - a widely accepted 14-item self-report that has been used to measure enjoyment, satisfaction and quality of life in various patient groups (Hope et al., 2009) including unipolar (Wisniewski et al., 2007) and bipolar depressed patients (Michalak et al., 2013). Psychometric properties have been established (Stevanovic, 2011) and the scale is sensitive to changes that occur with treatment (Ishak et al., 2015; Jha et al., 2014). The extraction of a subset of items from an existing scale such as the Q-LES-Q SF has two advantages: the items that are identified have already been shown to measure the construct and be sensitive to change. Secondly, investigators who have databases that include the full scale, in this case the Q-LES-Q SF, can easily conduct secondary analyses with a shorter derived scale.

Despite its advantages, the Q-LES-Q-SF has two disadvantages: its length and the likely insensitivity of selected items to change within a clinically practical time frame. That is, some of the items are likely to change only over a very long time frame (e.g. economic circumstances, living-housing situation) or they are not central to the management of mental symptoms (e.g. vison problems). In addition, item #2 measures satisfaction with mood, which is a symptom of depression and which logically argues for its exclusion when assessing Quality of Life (QoL) in depressed patients.

The following secondary data analyses were conducted to identify a limited number of Q-LES-Q-SF items that would (1) reflect the patient's current quality of life, satisfaction, enjoyment, (2) reflect the expected effect on QoL of successful depressive symptom reduction and (3) still identify a meaningful proportion of depressed patients who improved in acute-phase treatment but who would still display deficits in quality of life thereby potentially informing the need for further interventions aimed at this important outcome domain. In brief, we wanted to develop a simple clinical tool that could gauge whether additional therapies are needed despite successful symptom control by identifying persistent suboptimal quality of life/satisfaction in representative depressed outpatients initially.

This report addressed the following questions using data from the Sequenced Treatment Alternatives to Relieve Depression (STAR*D) trial (Fava et al., 2003; Rush et al., 2006; Rush et al., 2004; Trivedi et al., 2006a; Trivedi et al., 2006b).

1. Can we identify a briefer set of Q-LES-Q-SF items that change the most with acute-phase treatment of depressed outpatients and correlate with symptom reduction?
2. Does this subset of items (which we titled the Mini-Q-LES-Q) when taken together form a potentially useful, brief, unifactorial self-report measure that is sensitive to change and that has acceptable psychometric properties?
3. Does the Mini-Q-LES-Q reveal meaningful differences amongst patients who had minimal, modest and substantial levels of depressive symptoms at the end of acute-phase treatment?

2. Materials and methods

This report was based on data from STAR*D participants who entered step-1 to initially develop the subset of Q-LES-Q SF items to form the Mini-Q-LES-Q SF. We then used data from those who entered STAR*D step-2 and were randomly switched to one of three monotherapies (sertraline, bupropion–SR, or venlafaxine-XR) (Rush et al., 2006c) to test the validity of Mini-Q-LES-Q. The rationale, methods, and design of STAR*D are detailed elsewhere (Fava et al., 2003; Rush et al., 2004).

The STAR*D involved 14 regional centers across the United States that oversaw protocol implementation at public or private sector clinical sites providing primary (N = 18) or psychiatric (N = 23) outpatient care. At each site, clinical research coordinators assisted in protocol implementation and research data collection. Off-site research outcome assessors conducted telephone interviews to obtain the primary outcome (the 17-item Hamilton Rating Scale for Depression ($HRSD_{17}$) (Hamilton, 1960, 1967).

2.1. Participants

Representative outpatients 18–75 years of age with single or recurrent nonpsychotic major depressive disorder seeking care (as opposed to enrolling symptomatic volunteers) were eligible if their baseline $HRSD_{17}$ total score was at least 14 and their clinicians decided that outpatient antidepressant medication both safe and indicated.

2.2. Diagnostic and outcome measures

The diagnoses were established clinically but nonpsychotic major depressive disorder was confirmed with a DSM-IV criterion symptom checklist. Participants self-reported clinical and demographic as well as personal and family history information. A baseline Psychiatric Diagnostic Screening Questionnaire (Zimmerman and Mattia, 2001) estimated the presence of 11 potential concurrent Axis I (psychiatric) disorders.

Clinical research coordinators administered an initial $HRSD_{17}$, the QIDS-C_{16} and Self-QIDS-SR_{16} (Rush et al., 2006a; Rush et al., 2003; Trivedi et al., 2004) to assess depressive symptom severity. The clinical research coordinator at the site also completed the 14-item Cumulative Illness Rating Scale (CIRS) (Linn et al., 1968; Miller et al., 1992) to gauge the severity/morbidity of general medical conditions relevant to different organ systems. Each of the 14 illness categories was scored 0 (no problem) to 4 (extremely severe/immediate treatment required/end organ failure/severe impairment in function). The CIRS was scored based on the number of general medical condition categories endorsed (0–13, excluding the psychiatric illness category), severity index (0 to 4) (the average severity of the categories endorsed), and total severity (number of categories times severity).

The primary research outcome of STAR*D. the $HRSD_{17}$ total score. was collected by remote research outcome assessors with telephone-based structured interviews in English or Spanish. A missing exit