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Baseline Difference between Patients' and Clinicians' Rated Illness Severity Scores and Subsequent Outcomes in Major Depressive Disorder: Analysis of the STAR*D Data

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Keywords

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INTRODUCTION

Major Depressive Disorder (MDD) is a major public health concern in that it is associated with increased functional disability and mortality[1, 2] as well as a great deal of economic loss.[3, 4] MDD is characterized by a variety of symptoms, including depressive mood, diminished interest or pleasure, feelings of worthlessness, and psychomotor agitation; therefore, it is sometimes difficult to thoroughly evaluate their symptoms. Since the appropriate evaluation of symptoms is prerequisite for effective treatment of this illness, recent guidelines recommend the use of systematic rating scales for measurement-based treatment even in daily clinical practice.[5-7]

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There are mainly two types of assessment scales of symptomatology in MDD: clinician-rated and self-rated.[8] Although concordance between clinician-rated and self-rated illness severity has been reported to be generally moderate, it is not always perfect.[9-12] For example, the presence of personality traits such as low self-esteem and co-morbid borderline personality disorder has been reported to be associated with more severe subjective psychopathology than objectively evaluated by a clinician.[13, 14] Moreover, younger age, higher educational background, and female sex are reportedly predictive of higher scores in the self-rated scales relative to the clinician-rated ones.[10, 15]

Such a gap between clinician-rated and self-rated severity of MDD is not only attributable to flaws in those assessment scales, but to this illness itself, to some extent. For example, this difference could have an impact on the treatment outcomes; patients who regard the illness as more severe than objectively assessed may be more pessimistic about antidepressant treatment, which in turn could result in unfavorable treatment outcomes. To our knowledge, only two studies have tried to address this important issue.[16, 17] Rane et al. found that a greater difference between scores in the Beck Depression Inventory (BDI) and the 21-item version of the Hamilton Depression Rating Scale ($HDRS_{21}$) predicted a slower response to regular routine treatment with pharmacotherapy, psychotherapy, and/or electroconvulsive therapy, independent of objective illness severity, in 103 patients with treatment-resistant depression. On the other hand, they failed to find any significant difference in the difference scores between the subjects who responded and those who did not.[16] Dunlop et al. conducted an analysis of data from the Prevention of Recurrent Episodes of Depression With Venlafaxine Extended Release for Two Years (PREVENT) trial, in which participants were divided into the following three groups according to discrepancies between the Inventory of Depressive Symptoms-Self Report score and the 17-item version of the Hamilton Depression Rating Scale ($HDRS_{17}$) score: concordant patients (n=714), underrating patients (n=164), and overrating patients (n=148). While overrating patients at baseline fulfilled the clinician-rated response criteria more slowly than the others, no significant differences were observed in remission or response rates between the groups.[17] However, it is somewhat difficult to extrapolate these findings to a general population with MDD since they solely focused on treatment-resistant or recurrent depression. More critically, the previous studies did not use the same scales for subjective and objective assessments.

To address the gap in the literature, in the present study, we examined the association of the difference between subjective and objective severity of the illness with the subsequent response to antidepressant treatment in a greater number of patients with MDD, using the data from the Sequenced Treatment Alternatives to Relieve Depression (STAR*D) study. In this trial, patients were assessed with both clinician-rated and self-rated scales that include exactly the same items: the 16-item Quick Inventory of Depressive Symptomatology, Clinician Rating ($QIDS\text{-}C_{16}$)[18] and the 16-item Quick Inventory of Depressive Symptomatology, Self-Report ($QIDS\text{-}SR_{16}$).[18]

MATERIAL AND METHODS

Study Design

The STAR*D trial was funded by the National Institute of Mental Health to compare the effectiveness of several medications or cognitive therapy for individuals with nonpsychotic MDD; the study was detailed elsewhere.[19, 20] Briefly, the STAR*D trial enrolled 4041 outpatients aged 18 to 75 years from primary (n=18) and psychiatric (n=23) practice settings across the United States. Participants received citalopram as their first treatment step for 12 weeks (or 14 weeks if needed) unless treatment was discontinued for any reason (Level 1); the data used in this study were derived from Level 1. Following a complete description of the study, participants provided written informed consent at study enrollment in the original studies, and this post-hoc analysis used data that were made completely anonymous.

Study Population

Inclusion criteria were: a primary diagnosis of nonpsychotic MDD based on the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) and a baseline $HRSD_{17}$ score of 14 or higher. Patients were excluded if they were diagnosed with schizophrenia, schizoaffective disorder, bipolar disorder, anorexia nervosa, a current primary diagnosis of bulimia nervosa or obsessive-compulsive disorder.

Treatment

All participants received treatment with citalopram as the first step. Citalopram was administered at 20 mg/day and could be increased to 40 mg/day by weeks 2 to 4 and to 60 mg/day by weeks 4 to 6, using a measurement-based care approach. Treatment was guided by the treatment manual (www.star-d.org) in which individualized starting doses and dose adjustments were used to minimize adverse effects, maximize safety, and optimize therapeutic benefit for each participant. The protocol recommended treatment clinic visits at weeks 0, 2, 4, 6, 9, and 12, but extra visits were allowed if needed. For participants who showed response or remission only at week 12, treatment could be extended for up to two additional weeks (i.e. 14 weeks in total) to determine whether the status was sustained.

Assessment Measures

The QIDS total score ranges between 0 and 27; a greater value indicates a more severe symptomatology in MDD. The QIDS-SR_{16} was completed by participants at baseline and at every visit to assess depressive symptoms, using a telephone-based interactive voice response system. The QIDS-C_{16} was completed by raters at baseline and at every visit. In the present study, "QIDS-SR_{16} remission" was defined as a QIDS-SR_{16} score of ≤5 and "QIDS-C_{16} remission" was defined as a QIDS-C_{16} score of ≤5 at the treatment exit. Moreover, "QIDS-both remission" was defined as both QIDS-SR_{16} and QIDS-C_{16} scores of ≤5 at the treatment exit. Remission was adopted as a primary outcome in consistency with the original STAR*D study. Response status or score changes were not used for the present analysis since they sometimes reflect different clinical conditions despite the same values.

Statistical Analysis

A baseline QIDS difference score was defined as a value of a baseline QIDS-SR_{16} score minus a baseline QIDS-C_{16} score. Associations between the baseline QIDS difference score and the three types of remission as defined above was examined by means of a multivariate logistic regression model with a step-wise variable selection method. This model contained sex, employment, income, race, physical and mental subscale scores in the 12-item Short-Form Health Survey (SF-12),[21] education, and baseline illness severity represented as a baseline $HRSD_{17}$ score as covariates that were identified as pretreatment correlates of remission at the STAR*D.[19] Estimated odds ratio (OR) for a covariate expresses the change in odds for an increase of one unit in the covariate, adjusted for all other covariates. A p-value of <0.05 was considered statistically significant (two-tailed). Statistical analyses were carried out with the SPSS Version 20 (SPSS Inc., Chicago).

Result

Subject Characteristics

Of the evaluable participants (n = 2872) who received assessments at the baseline and treatment exit and completed Level 1 of the STAR*D trial, 28.0% (n = 803), 32.8% (n = 942), 34.1% (n = 978) were QIDS-both, QIDS-SR_{16} and QIDS-C_{16} remitters, respectively. Sociodemographic and clinical characteristics of the study sample are summarized in Table 1. The baseline QIDS difference score ranged from −16 to 10 (mean ± S.D., −0.7 ± 3.1). Remission rates in relation to baseline difference scores are shown in Table 2. Interestingly, the patients whose QIDS difference scores of −10 or lower led to only 1 out of 7 (14.3%) QIDS-both remission.

Baseline difference and prediction of remission

Demographic and clinical characteristics that were independently associated with three types of remission are shown in Tables 3, 4, and 5. The binary logistic regression analyses demonstrated significant associations between greater baseline QIDS difference scores and less chances of remission in the QIDS-both and the QIDS-SR_{16}, respectively. This association was also found in terms of the QIDS-C_{16} remission at a trend level. The Hosmer and Lemeshow test suggested that logistic regression models in terms of the three endpoints (i.e. QIDS-SR remission, QIDS-C remission and QIDS-both remission) were adequate for the data (p=0.394, p=0.864, p=0.469, respectively).

DISCUSSION

There have been some reports to indicate a cross-sectional concordance or discordance of objective versus subjective rating scales in MDD.[22-24] To our knowledge, however, this is the first study to examine the association of the possible difference between subjective and objective severity with the response to antidepressant treatment in outpatients with MDD. The results indicated that patients who evaluated their symptomatology as more severe than objectively rated were less likely to achieve remission, which suggests that such a difference could serve to predict antidepressant treatment response. Alternatively, patients with MDD

who perceive the illness as more severe may need additional care in order to achieve favorable outcomes.

Characteristics of patients with MDD who over- or under-rate their symptomatology bear pertinence on treatment outcomes that we observed in the present study. For example, MDD patients who overrate their symptoms may have a lower degree of self-esteem and a higher degree of pessimism. In fact, remission was harder to achieve for patients with such features, and this was compatible with a previous report by Van Noorden et al. in that they showed baseline pessimism could predict poor treatment outcome in adult patients with MDD or dysthymic disorder in a naturalistic treatment setting.[25] On the other hand, patients who underrate their symptomatology, compared to a clinician's rating, may be more optimistic about treatment outcomes. The results are in line with Tindle et al., who conducted a post-hoc analysis of 284 depressed patients, to find that depressed optimists were more likely than depressed pessimists to achieve response to treatment.[26]

To enhance treatment outcomes of patients with MDD who perceive their symptomatology to be more severe compared to a clinician's rating, other treatment interventions such as cognitive behavioral therapy in combination with ongoing antidepressant treatment may be necessary.[27] Overrating of depressive symptoms in patients with MDD is likely attributable to their cognitive bias towards negative ideations to some extent, which could be modifiable. The lesser degree of improvements with antidepressant treatment in such patients who overrate their symptomatology in the present study may suggest the importance of the potential difference between subjective versus objective perspectives, whereby the combined use of a non-pharmacological approach may be appropriate for some patients in an effort to improve treatment outcomes.[28] On the other hand, most under-rating patients (i.e. those with baseline QIDS difference scores of −10 or lower) rarely archive remission. This fact may be, in part, attributable to possible lack of insight into the illness in this unique population. Given the very small sample size of this group, further investigations are clearly warranted to confirm this preliminary finding.

This study should be interpreted with several limitations in mind. First, the STAR*D trial was not originally designed to assess whether baseline difference between subjective and objective severity of MDD was associated with treatment outcomes; this was a post-hoc explorative examination. In addition, generalizability of our findings may be limited to some extent in light of the characteristics of the participants in the STAR*D trials; they were limited to U.S. outpatients with nonpsychotic MDD. Furthermore, all participants received citalopram at Level 1 of this trial, which hampers extrapolation of our results to other antidepressant drugs. Second, a number of variables, including the baseline QIDS difference score, emerged as the factors that were associated with remission (Tables 3-5). For instance, baseline scores in the SF-12 were also related with remission. Still, it should be noted that the baseline QIDS difference score was associated with remission independently of those other factors known as predictors of treatment outcomes. Third, while disagreement in subjective versus objective perspectives was the focus of this work, we believe that both versions do have a role and should be used complementary.[24, 29] Fourth, different methods of assessment between the QIDS-SR and QIDS-C and the order of administration of those two scales may have yielded systematic scoring differences. Moreover, the degree of

patients' comprehension of questions in the assessment may have changed with time. Finally, the usefulness of adjunctive psychological interventions for those who subjectively evaluate themselves to be worse than they actually are remains unknown from this study and should be a matter of future investigations.

In conclusion, the patients, in the STAR*D trial, who perceived their symptomatology to be more severe than objectively assessed were more unlikely to achieve remission. Such difference between ratings by clinicians and patients may derive from negatively-biased cognitive process and variations in patients' characteristics including self-esteem, confidence and pessimism or optimism. These findings may suggest that those scoring differences should be actively targeted in order to enhance treatment outcome for this frequently chronic and debilitating psychiatric condition. Moreover, further investigations are clearly warranted to elucidate which score differences among a number of items could enhance a chance of remission in patients with MDD.

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Table 1

Baseline Sociodemographic and Clinical Characteristics of 2872 Subjects

Characteristics	Subjects (N=2872)
Age, years, mean ± SD (range)	41.3 ± 13.0 (18.1 - 75.6)
Women, n (%)	1834 (63.8%)
Race	
White, n (%)	2179 (75.8%)
Black or African American, n (%)	505 (17.6%)
Others, n (%)	190 (6.6%)
Years of Education, mean ± SD (range)	13.4 ± 3.2 (0 - 26)
Employment status	
Unemployed, n (%)	1097 (38.2%)
Employed, n (%)	1613 (56.1%)
Retired, n (%)	160 (5.6%)
Family History of Depression, n (%)	1584 (55.1%)
$HRSD_{17}$ total score, mean ± SD (range)	21.8 ± 5.2 (14 - 38)
$QIDS\text{-}SR_{16}$ total score, mean ± SD (range)	16.2 ± 4.0 (3 - 27)
$QIDS\text{-}C_{16}$ total score, mean ± SD (range)	16.9 ± 3.2 (7 - 26)
Duration of current episode, month, mean ± SD (range)	24.9 ± 51.1 (0.03 - 680)

SD, standard deviation; $HRSD_{17}$, 17-item Hamilton Rating Scale for Depression; $QIDS\text{-}SR_{16}$, 16-item Quick Inventory of Depressive Symptomatology, Self-Report; $QIDS\text{-}C_{16}$, 16-item Quick Inventory of Depressive Symptomatology, Clinician Rating.

Table 2

Baseline QIDS difference score and three types of remission

Baseline QIDS difference score[a]	QIDS-both	QIDS-SR_{16}	QIDS-C_{16}
	Remission rate, % (N)	Remission rate, % (N)	Remission rate, % (N)
Total	28.0 (803/2872)	32.8 (942/2872)	34.1 (978/2872)
10	50.0 (1/2)	50.0 (1/2)	50.0 (1/2)
9	0.0 (0/4)	0.0 (0/4)	25.0 (1/4)
8	36.4 (4/11)	54.5 (6/11)	45.5 (5/11)
7	16.7 (2/12)	33.3 (4/12)	33.3 (4/12)
6	25.7 (9/35)	28.6 (10/35)	37.1 (13/35)
5	17.0 (9/53)	15.1 (8/53)	18.9 (10/53)
4	25.2 (27/107)	26.2 (28/107)	28.0 (30/107)
3	24.5 (39/159)	32.1 (51/159)	28.3 (45/159)
2	22.8 (55/241)	28.6 (69/241)	32.4 (78/241)
1	26.8 (87/325)	29.2 (95/325)	31.4 (102/325)
0	27.8 (126/454)	30.0 (136/454)	34.8 (158/454)
−1	29.1 (117/402)	34.6 (139/402)	35.6 (143/402)
−2	30.5 (96/315)	34.9 (110/315)	36.2 (114/315)
−3	24.7 (68/275)	31.3 (86/275)	34.2 (94/275)
−4	33.5 (56/167)	40.7 (68/167)	38.3 (64/167)
−5	35.3 (42/119)	43.7 (52/119)	40.3 (48/119)
−6	26.9 (25/93)	38.7 (36/93)	31.2 (29/93)
−7	42.6 (20/47)	40.4 (19/47)	42.6 (20/47)
−8	40.9 (9/22)	40.9 (9/22)	36.4 (8/22)
−9	50.0 (6/12)	58.3 (7/12)	50.0 (6/12)
−10	40.0 (4/10)	50.0 (5/10)	40.0 (4/10)
−11	0.0 (0/2)	50.0 (1/2)	0.0 (0/2)
−12	0.0 (0/3)	0.0 (0/3)	0.0 (0/3)
−14	100.0 (1/1)	100.0 (1/1)	100.0 (1/1)
−16	0.0 (0/1)	100.0 (1/1)	0.0 (0/1)

QIDS-SR_{16}, 16-item Quick Inventory of Depressive Symptomatology, Self-Report; QIDS-C_{16}, 16-item Quick Inventory of Depressive Symptomatology, Clinician Rating.

[a] A baseline QIDS difference score was defined as a value of a baseline QIDS-SR_{16} score minus a baseline QIDS-C_{16} score.

Table 3

Factors Independently Associated With Remission Defined According to the 16-Item Quick Inventory of Depressive Symptomatology, both Self-Rated and Clinician Rating (QIDS-both)[a]

	QIDS-both Remission (N=803)		
Factors	**Odds Ratio**	**95% CI**	**p-value**
Baseline QIDS difference score (unit=1)	0.953	0.925-0.982	0.002
Baseline $HRSD_{17}$ total score (unit=1)	0.969	0.950-0.989	0.003
Female gender (reference group=male)	1.289	1.077-1.542	0.006
Race (reference group=White)			<0.001
Black or African American	0.562	0.424-0.774	<0.001
Others	0.787	0.495-1.253	0.313
Education status (reference group=high school but < college)			0.046
< High school	0.944	0.601-1.090	0.725
≥ College	1.289	1.046-1.590	0.017
Employment status (reference group=employed)			0.236
Annual Income ($) (unit=10,000)	1.048	1.022-1.075	<0.001
SF-12 scores			
Physical subscale (unit=5)	1.218	1.160-1.279	<0.001
Mental subscale (unit=5)	1.139	1.066-1.216	<0.001

CI, confidence interval; $HRSD_{17}$, 17-item Hamilton Rating Scale for Depression; SF-12, 12-item Short-Form Health Survey; QIDS-SR_{16}, 16-item Quick Inventory of Depressive Symptomatology, Self-Report; QIDS-C_{16}, 16-item Quick Inventory of Depressive Symptomatology, Clinician Rating.

[a] "QIDS-both remission" was defined as both QIDS-SR_{16} and QIDS-C_{16} scores of ≤5 at the treatment exit.

Table 4

Factors Independently Associated With Remission Defined According to the 16-Item Quick Inventory of Depressive Symptomatology, Self-Report ($QIDS\text{-}SR_{16}$)[a]

	$QIDS\text{-}SR_{16}$ Remission (N=942)		
Factors	**Odds Ratio**	**95% CI**	**p-value**
Baseline QIDS difference score (unit=1)	0.944	0.917-0.972	<0.001
Baseline $HRSD_{17}$ total score (unit=1)	0.950	0.932-0.969	<0.001
Female gender (reference group=male)	1.320	1.099-1.585	0.003
Race (reference group=White)			0.002
Black or African American	0.669	0.518-0.863	0.002
Others	1.315	0.861-2.007	0.205
Employment status (reference group=employed)			0.048
Unemployed	0.816	0.672-0.990	0.039
Retired	1.192	0.807-1.761	0.378
Annual Income ($) (unit=10,000)	1.032	1.007-1.057	0.012
SF-12 scores			
Physical subscale (unit=5)	1.177	1.124-1.233	<0.001
Mental subscale (unit=5)	1.137	1.068-1.210	<0.001

CI, confidence interval; $HRSD_{17}$, 17-item Hamilton Rating Scale for Depression; SF-12, 12-item Short-Form Health Survey.

[a] Remission was defined as an exit score of ≤5 on the $QIDS\text{-}SR_{16}$.

Table 5

Factors Independently Associated With Remission Defined According to the 16-Item Quick Inventory of Depressive Symptomatology, Clinician Rating (QIDS-C_{16})[a]

	QIDS-C_{16} Remission (N=978)		
Factors	**Odds Ratio**	**95% CI**	**p-value**
Baseline QIDS difference score (unit=1)	0.973	0.945-1.001	0.055
Baseline $HRSD_{17}$ total score (unit=1)	0.964	0.946-0.982	<0.001
Female gender (reference group=male)	1.289	1.077-1.542	0.006
Race (reference group=White)			0.427
Education status (reference group=high school but < college)			0.041
< High school	0.809	0.601-1.090	0.164
≥ College	1.213	0.993-1.483	0.059
Employment status (reference group=employed)			0.001
Unemployed	0.819	0.676-0.992	0.041
Retired	1.631	1.121-2.372	0.011
Annual Income ($) (unit=10,000)	1.027	1.002-1.052	0.033
SF-12 scores			
Physical subscale (unit=5)	1.174	1.122-1.229	<0.001
Mental subscale (unit=5)	1.133	1.066-1.205	<0.001

CI, confidence interval; $HRSD_{17}$, 17-item Hamilton Rating Scale for Depression; SF-12, 12-item Short-Form Health Survey.

[a]Remission was defined as an exit score of ≤5 on the QIDS-C_{16}.