Measuring the severity of depression and remission in primary care: validation of the HAMD-7 scale

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Abstract

Background: Symptomatic remission is the optimal outcome in depression. A brief, validated tool for symptom measurement that can indicate when remission has occurred in mental health and primary care settings is unavailable. We evaluated a 7-item abbreviated version (HAMD-7) of the 17-item Hamilton Depression Rating Scale (HAMD-17) in a randomized controlled clinical trial of patients with major depressive disorder being cared for in primary care settings.

Methods: We enrolled 454 patients across 47 primary care settings who met DSM-IV-TR criteria for a major depressive disorder. Of these, 410 patients requiring antidepressant medication were randomized to have their symptoms rated with either HAMD-7 (n = 205) or HAMD-17 (n = 205) as the primary measurement tool. The primary outcome was the proportion of patients who achieved a-priori defined responses to 8 weeks of therapy using each instrument.

Results: Of the 205 participants per group, 67% of those evaluated with HAMD-7 were classified as having responded to therapy (defined as a ≥ 50% reduction from the pretreatment score), compared with 74% of those evaluated with HAMD-17 (p = 0.43). The difference between the groups' changes in scores from baseline (pretreatment) to endpoint was significant (p < 0.001), without a main effect of group (p = 0.84) or group-by-time (p = 0.83) interaction. The HAMD-7 test was brief to administer (e.g., 3–4 min for 85% of the primary care physicians evaluated), which facilitated the efficient and structured evaluation of salient depressive symptoms.

Interpretation: The abbreviated HAMD-7 depression scale is equivalent to the HAMD-17 in assessing remission in patients with a major depressive disorder undergoing drug therapy.

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Optimal management of major depressive disorders is enhanced by applying a chronic-illness management model with precise and measurable therapeutic endpoints.[1] In contradistinction to several other chronic medical disorders, biological markers of illness activity in depression do not currently exist. In the interim, therapeutic progress is monitored by evaluating changes both in the severity of depressive symptoms and in functional domains. This concatenation of findings is particularly disconcerting in view of the fact that most depressed patients in either primary care or psychiatric settings are not systematically evaluated with objective quantifiable measures — a modifiable deficiency in patient management.[2–6]

The most frequently reported symptomatic outcome measure in clinical trials of antidepressants has been response to treatment, arbitrarily defined as a reduction of 50% or more in total symptom severity from a pretreatment assessment of the patient's depression.[7] A categorical response to therapy that fails to achieve a fully asympomatic remitted state furnishes an unsatisfactory outcome, in that it includes patients with ongoing disease activity that is clinically significant. Patients who show improvement in symptom severity but are not asymptomatic are at risk for developing chronic depression, and continue to be vulnerable to poor outcomes and comorbid medical disorders.[8–10]

Remission is an objective outcome indicated by a quantifiable score with a depressive symptom measurement tool. In antidepressant clinical trials, the 17-item Hamilton Depression Rating Scale (HAMD-17) has been the "gold standard" for use. HAMD-17, however, has not been accepted by clinicians for many reasons,[11,12] notably psychometric deficiencies and the length of time needed to administer it.

Although several brief rating scales for depression that attempt to improve upon the limitations of HAMD-17 have recently been validated and reviewed,[11–18] none that are brief, currently available and use a remission cut-off score that correlates with the most frequently cited definition of remission (a HAMD-17 score ≤ 7)[7] have been validated in both tertiary mental health and primary care settings.

Our broad objective in using HAMD-7 was to improve upon the conceptual and pragmatic deficiencies ascribed to HAMD-17. HAMD-7 was originally derived from analyses of a natural practice database at a tertiary care centre composed of patients diagnosed with a major depressive disorder (n = 248).[14] The HAMD-17 items that were endorsed in a previous study[17] by ≥ 70% of depressed patients and were most sensi-

tive to change after 8 weeks of antidepressant efficacy formed the constituent items of HAMD-7 (Appendix 1). A remission cut-off score for HAMD-7 that correlated with HAMD-17 ≤ 7 was also determined (Appendix 2).[1,14] HAMD-7 required mere minutes to administer and served as an efficient and reliable measure of therapeutic progress and symptomatic remission.

Our main objective in this study was to validate the HAMD-7 scale in a primary care setting by comparing its psychometric properties with those of 2 accepted measurement tools, HAMD-17 and the Montgomery–Asberg Depression Rating Scale (MADRS).

Methods

A full description of the methods is available at www.cmaj.ca/cgi/content/full/173/11/1327 along with an additional flowchart, tables and appendixes.

We identified English- or French-speaking patients 18 years of age or older who met the criteria for a major depressive disorder.[19] Patients were recruited from those of 48 primary care investigators in British Columbia, Alberta, Ontario and Quebec). The final selection of primary care investigators was made after consultation with regional psychiatric consultants.

All primary care investigators were trained in good clinical practice guidelines.[20] (Details of the training and standards are available online at www.cmaj.ca/cgi/content/full/173/11/1327 in Appendix 2.) Each of the 47 sites of practice was approved by the Central Institutional Review Board (Aurora, Ont.) and the University of Alberta Research Board (Edmonton, Alta.).

Table 1: Patient characteristics and study outcomes

Characteristic or variable	HAMD-17 *(n = 205)*	HAMD-7 *(n = 205)*
Baseline characteristics		
Age, mean (SD), yr	43.1 (13.0)	42.9 (13.4)
Female, no. (%)	131 (64)	135 (66)
Single episode,* no. (%)	100 (49)	94 (46)
Concomitant medications, no. (%)	116 (57)	112 (55)
CGI-S, mean score (SD)	4.12 (0.77)	4.23 (0.76)
MADRS, mean score (SD)	28.0 (7.6)	29.8 (7.0)
HAMD scores		
Baseline, mean (SD)	23.10 (5.09)	14.00 (2.93)
End point, mean (SD)	8.06 (6.29)	5.31 (4.36)
Study outcomes: patients showing improvement, no. (%)		
Response†: score reduced ≥ 50%	152 (74)	137 (67)
Remission‡: HAMD-17 score ≤ 7 or HAMD-7 score ≤ 3	100 (49)	82 (40)

Note: HAMD = the 17-item or 7-item Hamilton Depression Rating Scale, SD = standard deviation, CGI-S = Clinical Global Impression, Severity of Illness subscale, MADRS = Montgomery-Asberg Depression Rating Scale.
*As opposed to recurrent depressive episodes.
†$p = 0.43$
‡$p = 0.17$

Eligible patients were assigned by means of computer-generated randomization numbers to HAMD-7 or HAMD-17 as the primary symptom-measurement tool before initiating 8 weeks of open-label, flexible-dose antidepressant monotherapy. Medications were chosen by the primary care investigators, in consultation with their patients, from the antidepressants available in Canada during the study (2003–2004). Although concomitant medications were permitted, patients could not be simultaneously enrolled in manual-based psychotherapy (e.g., cognitive behavioural or interpersonal therapy) or receiving electroconvulsive therapy. Symptom severity was evaluated at each visit with either the HAMD-7 or HAMD-17 tool and with the Clinical Global Impression, Improvement or Severity of Illness scales (CGI-I/S). The MADRS test was administered at baseline (visit 2) and endpoint (visit 6).

Response to therapy was defined as a reduction of ≥ 50% from pretreatment in depression symptom severity; remission was defined as a final score on HAMD-17 ≤ 7, HAMD-7 ≤ 3 and MADRS ≤ 10.

Results

Of 454 patients [164 males (36.1%) and 290 females (63.9%)] enrolled in the study, a total of 410 were randomized to HAMD-7 ($n = 205$) or HAMD-17 ($n = 205$) as the primary symptom measurement scale (Table 1).

The mean total scores were 14.00 pretreatment to 5.31 at end point, for patients evaluated with HAMD-7; and 23.10 pretreatment to 8.06 at end point, for those evaluated with HAMD-17. The overall score reduction was highly significant ($p < 0.001$), measured with either rating scale (Table 1). Between-group differences in the percentage of patients responding or remitting with therapy in the HAMD-7 group (67% responding and 40% remitting) and the HAMD-17 group (74% and 49%, respectively) were nonsignificant ($p = 0.43$ and 0.17, respectively). There was also a significant pretreatment-to-endpoint change in the standardized HAMD-17 and HAMD-7 ($p < 0.001$), without a main effect of group ($p = 0.84$) or group-by-time interaction ($p = 0.83$), suggesting that sensitivity to change was similar for both scales.

Within the group assigned to HAMD-17 as the primary symptom measurement tool, the items encompassed in the HAMD-7 scale were abstracted (HAMD-7A) and noted to highly correlate with HAMD-17 total scores ($p < 0.001$). The pretreatment-to-endpoint change in depressive symptom severity, response rate and remission rate for HAMD-7A and HAMD-17 were all significantly correlated (all $p < 0.001$).

The internal consistency of the HAMD-7, HAMD-7A and HAMD-17 ratings at each postbaseline visit was satisfactory and comparable. Comparison with the MADRS depression rating scale demonstrated that HAMD-7, HAMD-7A and HAMD-17 also showed satisfactory convergent validity in depressive symptom severity, overall change, response (≥ 50% reduction in pretreatment total MADRS score) and remission of depressive symptoms (MADRS ≤ 10). The estimation of depressive-symptom severity and change with treatment was also highly correlated between HAMD-7 and the CGI-I/S.

(Tables showing supporting data in more detail are included in the longer form of this article, available at www.cmaj.ca/cgi/content/full/173/11/1327).

Of 48 physicians, 39 (82%) completed the HAMD-7 Rating Scale Investigator Evaluation Form. Physicians reported a high overall level of satisfaction with HAMD-7, noting that it was brief to administer (3–4 minutes for 85% of respondents), which facilitated the efficient and structured evaluation of salient depressive symptoms.

Interpretation

HAMD-7 was as sensitive as HAMD-17 in estimating the severity of depressive symptoms and evaluating the effectiveness of antidepressant treatment in a naturalistic primary care setting. The proportion of patients estimated to have achieved remission with HAMD-7 was statistically similar to the "gold standard" tool, the HAMD-17 rating scale. That the brevity of HAMD-7 did not appear to compromise vital information on patient progress and outcome was indicated by a high correlation with the multidimensional MADRS and CGI-I/S scales, and by acceptable levels of sensitivity and specificity. (Sensitivity, specificity and other psychometric properties are further described in a subsequent companion paper.)

Over the past decade, a fully asymptomatic state of remission has been emphasized as a critical end point in the management of depressed patients. A universally agreed-upon criterion for remission, however, does not currently exist, which belies the clinical utility of the remission concept. Notwithstanding, the proposed definition and operational criteria for remission (HAMD-17 ≤ 7) put forth by the McArthur Foundation group,[21] which is the definition of remission most cited, has served as a useful heuristic.

Several multinational expert guidelines on the management of depressive disorders emphasize remission, an outcome that transcends response, as an achievable and more clinically relevant symptomatic endpoint.[1,22-24] Residual depressive symptoms and incomplete remission are associated with early relapse, shorter duration between depressive episodes, chronicity, poor prognosis of comorbid medical disorders, increased use of medical services, sustained elevation of suicide risk, and psychosocial and functional deficits.[25]

In the absence of a clinically useful and validated biological marker for remission in depression, clinicians are limited to empirically evaluating depressive symptoms and functional domains.[2] Paradoxically, most practitioners do not systematically evaluate patient progress with quantifiable measures. Although it is likely that clinical willingness to carefully track depressive symptoms is affected by multiple variables, it is likely that time-efficient tools would have greater acceptance in the field.

Limitations of this validation study include the heterogeneity of patients enrolled and treatment assignment. For example, diagnostic criteria for a current major depressive episode was based on clinical judgment, and there was no rigorous control for comorbidity other than the exclusion criteria described above. Although the pretreatment MADRS scores were statistically significantly higher in the group randomized to HAMD-7, the differences between the groups are clinically insignificant. A further limitation is the presumption that the threshold scores of HAMD-17 ≤ 7 or MADRS ≤ 10 are prima facie evidence of depressive episode remission. It has been reported, for example, that depressed patients with HAMD-17 scores ≤ 7 may still manifest clinically significant disease activity.[26] On a further note, we chose HAMD-17 as the primary standard because it has been the most commonly employed and familiar metric both in clinical research on depression and among clinicians. An alternative methodology could have been to compare HAMD-7 to MADRS or to the global psychopathology measure, CGI. Lastly, for various reasons 44 patients withdrew from the study after randomization but before treatment began, and were not included in the analysis. Inclusion of these patients and ascribing them an outcome did not materially change the statistical results.

In a busy primary care setting, self-administered scales[17,27] are an appealing alternative to MADRS, HAMD-17 and other lengthier depression metrics. Several studies, including a meta-analysis, have determined, however, that scales administered by clinicians may be more sensitive to change than self-rated measures, particularly in short-term studies.[28,29] A practical and meaningful marker of remission should simultaneously evaluate both symptomatic and functional outcomes. HAMD-7 is primarily a symptom-measurement tool, inviting the need for additional monitoring of functional outcomes. Moreover, the mean doses of antidepressants in the study were at the lower end of the recommended ranges. However, it should be emphasized that the naturalistic setting, nonstandardization of treatment selection and patient heterogeneity in this study reflect real-world practice.

Conclusion

The HAMD-7 rating scale is the first brief-to-administer depression scale with a remission cut-off score validated in both specialty mental-health and primary care settings. The remission cut-off score (correlating with HAMD-17 ≤ 7) differentiates HAMD-7 from any other brief measure of depression that currently exists. A therapeutic target in the management of depression should be a HAMD-7 score ≤ 3; a vista for future research will be to establish if this objective measure corresponds with an absence of disease activity (e.g., as evinced by neuroimaging and neuroendocrine biomarkers). The routine clinical use of the HAMD-7 scale provides objective quantifiable evidence of depressive symptom severity, antidepressant effectiveness and remission of disease.

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Editor's take

- It is important to determine when patients being treated with major depressive disorder recover or enter remission.
- In this RCT, patients being treated with pharmacologic agents for depression were randomized to receive ongoing assessments with a standard 17-item research questionnaire, the HAMD-17, or a shorter clinical version of the Hamilton Depression Rating Scale, the HAMD-7. The shorter version was as effective as the longer version in detecting remissions.

Implications for practice: The 7-item HAMD-7 measure of depression can be used to determine when patients with major depressive disorders are in remission.

Appendix 1: The 7-Item Hamilton Rating Scale for Depression (HAMD-7)

1. Depressed mood (sadness, having "the blues," weepiness)

- Have you been feeling down or depressed this past week?
- How often have you felt this way, and for how long?

[ ] 0 Absent
[ ] 1 Indicated only on questioning
[ ] 2 Spontaneously reported verbally
[ ] 3 Communicates nonverbally (facial expression, posture, voice, tendency to weep)
[ ] 4 Patient reports *virtually only* these feeling states in spontaneous verbal and nonverbal communication

2. Feelings of guilt (self-criticism, self-reproach)

- In the past week, have you felt guilty about something you've done, or that you've let others down?
- Do you feel you're being punished by being sick?

[ ] 0 Absent
[ ] 1 Self-reproach (letting people down)
[ ] 2 Ideas of guilt, rumination over past errors or sinful deeds
[ ] 3 Present illness seen as punishment; delusions of guilt
[ ] 4 Hears accusatory or denunciatory voices or experiences threatening visual hallucinations

3. Interest, pleasure, level of activities (work and activities of daily living)

- Are you as productive at work and at home as usual?
- Have you felt interested in doing things that usually interest you?

[ ] 0 No difficulty
[ ] 1 Fatigue, weakness or thoughts of incapacity (related to activities, work or hobbies)
[ ] 2 Loss of interest in activities (directly reported or indirectly through listlessness, indecision and vacillation)
[ ] 3 Decrease in productivity or actual time spent in activities
[ ] 4 Stopped working because of current illness

4. Tension, nervousness (psychological anxiety)

- Have you been feeling more tense or nervous than usual this week?
- Have you been worrying a lot?

[ ] 0 No difficulty
[ ] 1 Subjective tension and irritability
[ ] 2 Worrying about minor matters
[ ] 3 Apprehensive attitude apparent in face or speech
[ ] 4 Fears expressed without questioning

5. Physical symptoms of anxiety (somatic anxiety)

- How much have these things been bothering you in this past week?

DON'T RATE IF SYMPTOMS ARE CLEARLY DUE TO MEDICATION:

- In the past week, have you had any of these?
  - —Gastrointestinal symptoms: dry mouth, gas, indigestion, diarrhea, cramps, belching
  - —Vascular: heart palpitations, headaches
  - —Respiratory: hyperventilation, sighing
  - —Having to urinate frequently
  - —Sweating

[ ] 0 Absent
[ ] 1 Mild
[ ] 2 Moderate
[ ] 3 Severe
[ ] 4 Incapacitating

6. Energy level (somatic symptoms)

- How has your energy been this past week?
- Have you felt tired?
- Have you had any aches or pains or felt any heaviness in your limbs, back or head?

[ ] 0 None
[ ] 1 Heaviness in limbs, back or head (backache, headache, muscle aches; loss of energy and fatiguability)
[ ] 2 Any clear-cut symptom rates 2 points

7. Suicide (ideation, thoughts, plans, attempts)

- Have you any thoughts life is not worth living or you'd be better off dead?
- Have you thoughts of hurting or killing yourself?
- Have you done anything to hurt yourself?

[ ] 0 Absent
[ ] 1 Feels life is not worth living
[ ] 2 Wishes to be dead (or any thoughts of possible death to self)
[ ] 3 Suicidal ideas or gestures
[ ] 4 Attempts at suicide (any serious attempt rates 4)

HAMD-7 score ≤ 3 indicates full remission.
HAMD-7 score ≥ 4 indicates non/partial response.

Total score