

Characterization of a patient sub-type in a depression trial using the HAM-D anxiety-somatization factor: What is the frequency of this subtype and could there be a differential response rate?

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The Methodological Question Being Addressed: Is there a sub-type in depression that can be identified using the anxiety-somatization factor for the HAM-D and, if so, does there appear to be any differential in treatment response compared to those without the sub-type characteristic.

Introduction (Aims): There is considerable literature (e.g., Farabaugh et al, 2010; Bitran et al, 2011) around the idea of an anxiety-somatization factor derived from the HAMD (though dispute continues about this particular factor's presence in the instrument, e.g. Goldberger et al, 2011). We analyzed data from a completed randomized, double-blind, placebo-controlled depression trial to determine the presence of this factor and if patients with this characteristic appeared to respond differently to treatment. The HAMD items included in this factor are: appetite, somatic symptoms general, psychic anxiety, anxiety somatic, hypochondriasis and insight.

Methods: Baseline HAM-D (HDRS-17) item anxiety-somatization factor (scores were summed according to guidance in Farabaugh et al, 2010 article and the threshold for inclusion in the was a total score ≥ 7 on these factor items). The frequency of this presentation was determined and the absolute change and by country effect sizes were computed (Kazis et al, 1989) for the overall HAM-D score from baseline to endpoint.

Results: The anxiety-somatization factor subtype was present at baseline in nearly 74% of patients in this study (145 of 196 patients) with those patients not containing these scores (lower than a sum of 7 across the six items) representing 26% (51 of 196 patients). Improvement (>0) is seen in just over 60% of cases and 24.2% of the sample improving ≥ 4 points. Effect sizes by country ranged from 1.44 (Canada) to 2.96 (Poland).

Conclusions: It appeared that the majority of patients included in this trial contained the anxiety-somatization subtype and had significant response to antidepressant treatment. This was a unique sample in that all patients received an active antidepressant in addition to adjunctive treatment or placebo. Davidson et al, 2002 noted that the presence of baseline psychic anxiety correlated significantly to treatment outcome when analyzing remission rates and Bitran et al, 2011 suggested that the presence of the anxiety-somatization factor could be an early predictor of positive treatment response. In this case it appeared that those with the anxiety-somatization subtype did appear to respond well, though with such a high percentage of the baseline cohort falling into this category we wonder if the subtype parameters may be overly broad.

Disclosures: all authors are employees of Cronos CCS

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