Characterization of a patient sub-population 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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Introduction

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. Although some (e.g., Goldberger et al, 2011) did not obtain the same factor loadings as the original (Cleary & Guy, 1975); they did show a distinct anxiety-somatization factor. 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. Understanding that there may be subtypes in depression symptomatology could help guide treatment and help better target treatments. While other subtypes have been proposed including melancholic and atypical, we focus here on the anxiety-somatization subtype as it was a clear focus of interest in this clinical trial.

Objectives

Our aim was to retrospectively analyze data from a double-blind, placebo-controlled, multicenter study of an adjunctive treatment to a monoaminergic antidepressant in adults meeting DSM-5 diagnostic criteria for Major Depressive Disorder to determine the presence and frequency of an anxiety-somatization factor identified in the literature and, thereupon, if this presence appeared to impact treatment response in any manner.

Methods

Baseline HAMD (17 item) anxiety-somatization factor scores were summed according to guidance in the Farabaugh et al, 2010 article, with the threshold for inclusion being 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 HAMD score from baseline to endpoint.

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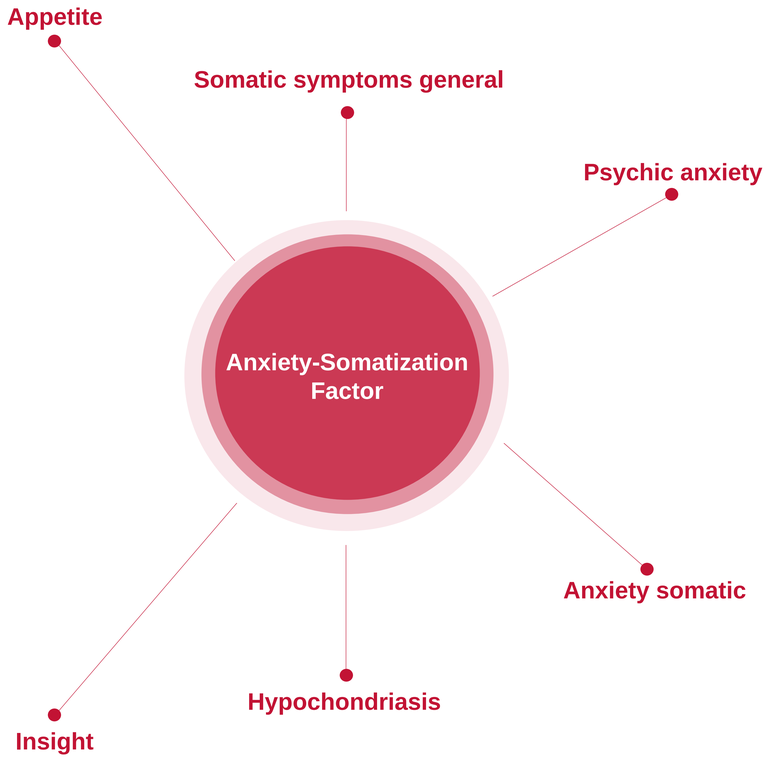
Results

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) was seen in just over 60% of cases, with 24.2% of the sample improving ≥4 points. Effect sizes by country ranged from 1.44 (Canada) to 2.96 (Poland).

Anxiety-Somatization factor items



Conclusion

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 their opinion, this could provide an important marker for clinicians to determine whether or not to continue monotherapy with a given antidepressant. 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. For this reason, future research in this area may test whether varying the severity of the summed items has an impact on response. Additionally, a factor analysis to confirm the presence of this factor in this dataset would ideally be conducted to address the concerns about factor stability indicated in Goldberger et al, 2011.

References

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