The added value of the CGI-I scale in assessing global severity: a cost/benefit analysis using data from four Phase III MDD trials


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Methodological Question

Do the CGI-I and CGI-S scales have comparable psychometric properties? Does elimination of the CGI-I scale affect study design or efficiency? How can the CGI-I and CGI-S scales be used to define response, and what cost savings might be conveyed if CGI-I were to be eliminated?

Introduction

Objectives

1. To compare the current and original scales in terms of their psychometric properties,
2. To determine whether CGI-I could be used to define response, and if so, what cost savings might be conveyed if CGI-I were to be eliminated.

Methods

The current and original scales were compared in terms of their psychometric properties, efficiency, and cost-effectiveness using data from four Phase III MDD trials: POLARIS-NCT01360645, PYXIS-NCT01727726, DELPHINUS-NCT02196506, and SIRIUS-NCT02196506. All four studies were conducted as prospective treatment phases in patients with MDD who had demonstrated moderate to severe depression prior to study entry. The CGI-I was administered at study entry, and the CGI-S was administered at every visit.

Results

Sample Characteristics

A total of 2374 subjects across the POLARIS/PYXIS/DELPHINUS/SIRIUS trials completed at least 14 weeks of monotherapy antidepressant treatment. The combined sample was predominantly female, white, and was predominantly enrolled in Phase A of the trials.

Convergent Validity

Figure 2: MADRS/CGI-S Correlation

Receiver Operating Characteristics (ROC)

Figure 3: MADRS/CGI-S Correlation

Discriminant Validity

Figure 4: Explored definitions of clinical response

Reliability

Table 1: MADRS/CGI-S Correlation

ROC curves representing the discriminability of CGI-I ≤ 2 and CGI-I ≤ 3 against clinical response.

Cost Analysis

Table 2: Program Costs Associated with the CGI-I

Conclusions

The CGI-I scale offers an added value in assessing global severity and response to antidepressant treatment. Its elimination could result in cost savings, with the potential for broader applicability in other therapeutic areas. Further research is needed to establish its validity and reliability in clinical trials.