Assessing the Severity of Anxiety Symptoms at Study Entry into Acute Schizophrenia Clinical Trials

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INTRODUCTION

- Comorbid anxiety disorder is diagnosed in over 40% of schizophrenic inpatients (Achim, 2011). Moreover, the severity of a psychotic symptoms in acutely decompensated schizophrenic patients is significantly correlated with the severity of concurrent anxiety symptoms. (Naidu, 2014).

- In the current analysis we attempted to further elucidate the relationship between anxiety symptoms and other psychopathology in acutely decompensated schizophrenia clinical trial subjects.

METHODS

- Screening and baseline data were pooled from 15 acute schizophrenia clinical trials.

- We assessed the screening and baseline severity of PANSS anxiety and tension items (G2 and G4), the proportion of subjects at study entry suffering from no anxiety (G2 score < 3), the magnitude of change in anxiety and tension between screening and baseline, and statistically compared the screening and baseline item severity (paired t-test), magnitude of change between screening and baseline (t-test) and presence of no anxiety symptoms in subjects with PANSS total below 100 with those scoring at least 100 at baseline (chi2 test).

- Additionally, in the blinded data we separately assessed the impact of change in anxiety and tension between screening and baseline on last visit change in the PANSS total using regression analysis, correcting for baseline severity and study.

RESULTS

- The dataset consisted of 4,667 screening and baseline paired PANSS assessments.

- There was no difference between screening and baseline anxiety severity (3.54(1.15) vs 3.55(1.15), p = ns) but there was a significantly higher tension severity at baseline compared to screening(3.04(0.98) vs 3.11(0.98), p < 0.001)[Figure 1].

- Unlike anxiety, tension significantly worsened by 0.07 points between screening and baseline (p < 0.05).

- No anxiety was present in 16.16% of subjects at screening and in 16.03% of subjects at baseline(NS)

- A statistically significant difference in the absence of anxiety was observed between subjects below 100 and in those scoring 100 or above at baseline (chi2 = 13.9, P < 0.001). [Figure 2]

- Screening to baseline change in anxiety or tension resulted in a significant reduction of improvement at last visit in the blinded data (p <0.05). [Figure 3]

FIGURE 1. SCREENING AND BASELINE SEVERITY
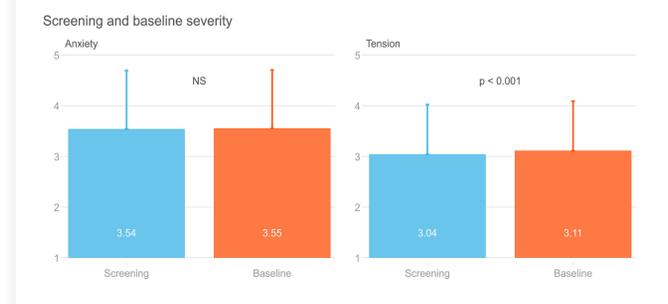
FIGURE 2. PRESENCE OF NO ANXIETY AT BASELINE BY BASELINE SEVERITY
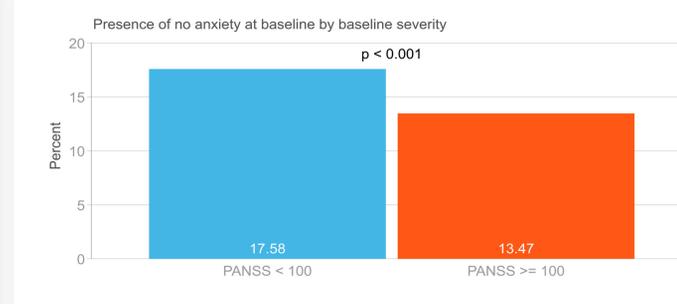
FIGURE 3. EFFECT OF SCREENING TO BASELINE SYMPTOM CHANGE ON END OF TREATMENT IMPROVEMENT
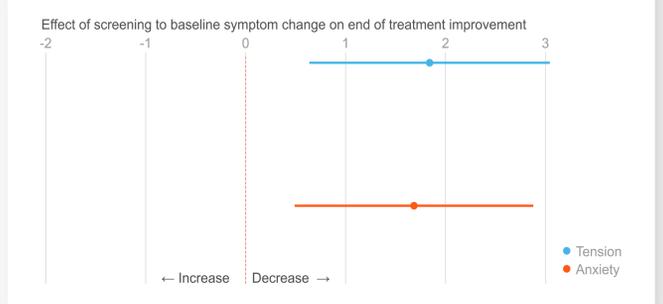
DISCUSSION

- Our sample of acute schizophrenia clinical trial subjects entered predominantly with mild to moderate symptoms of anxiety and with mild tension.

- Over 16% of the subjects had no symptoms of anxiety, and even in the group of highly symptomatic subjects, no anxiety was seen in over 13% of subjects.

- Last visit PANSS improvement from baseline was significantly affected by screening to baseline change in either anxiety or tension PANSS items.

- We plan to further assess the impact of screening to baseline changes in anxiety symptoms in unblinded data as these become available.

REFERENCES

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