

Positive and Negative Symptom Predominance in the Screening Period in Acute Schizophrenia Trials: An Exploratory Analysis

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INTRODUCTION

- We have previously reported that on average 38% of subjects entering acute schizophrenia clinical trials have negative symptoms more severe than positive symptoms (Daniel and Kott; 2017).
- We have as well observed that the positive vs. negative symptom predominance may change between screening and baseline.
- In the current analysis we further explored this phenomenon of symptom predominance changes in screening period.

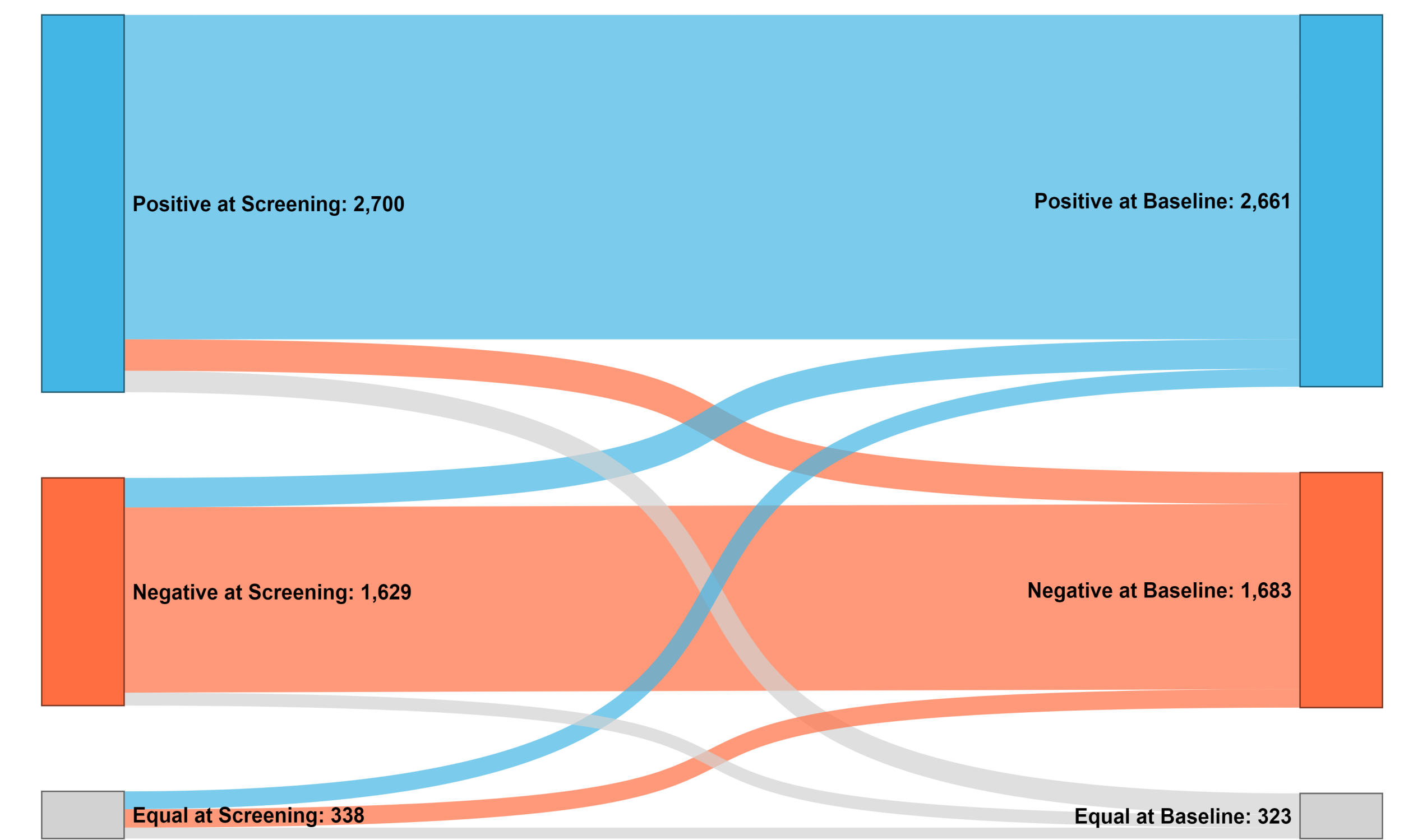
METHODS

- Screening and baseline data were pooled from 15 acute schizophrenia clinical trials.
- The severity of positive and negative symptoms was derived from the PANSS positive and negative subscales.
- Symptom predominance was determined based on the difference between positive and negative PANSS items as follows:
 - positive predominance (positive symptoms more severe than negative)
 - negative predominance (negative symptoms more severe than positive)
 - no predominance (severity of negative and positive symptoms is the same)
- Lastly we assessed whether symptom predominance changed between screening and baseline and if so, in which direction.
- The impact of change in predominance between screening and baseline was then assessed in the blinded data on the last visit PANSS change from baseline, correcting for study and baseline severity using regression analysis.

RESULTS

- The dataset consisted of 4,667 pairs of screening and baseline ratings and 4,144 last visit assessments.
- 35% of screening visits and 36% of baseline visits had negative symptoms more severe than positive.
- In 7% negative and positive symptoms were equally severe at both screening and baseline.
- Symptom predominance between screening and baseline changed in 9.3% of cases, in 4.8% from negative to positive and in 4.5% from positive to negative.
- No effect of change in predominance between screening and baseline on last visit change from baseline was observed.

FIGURE 1: SYMPTOM PREDOMINANCE AT SCREENING AND BASELINE



DISCUSSION

- In the current dataset negative symptom predominance occurred in around 35% of screening or baseline visits.
- Changes in symptom predominance in the screening period occurred in over 9% of data and were equally likely to be from negative to positive or from positive to negative symptoms.
- In the blinded data the changes seem to have no effect on end of treatment PANSS change, but more meaningful differences might be seen in unblinded datasets.
- We plan to reassess the impact on symptom predominance change on unblinded datasets as these become available.

REFERENCES

Daniel, DG; Kott, A: Effect of Predominance of Negative Symptoms at Baseline on Change in the PANSS Total in Acute Schizophrenia Trials-An Exploratory Analysis, Poster presentation at the 2017 CNS summit