



DO RECRUITMENT SOURCES IMPACT STUDY OUTCOME: ASSESSMENT BY COMPUTER AND SITE-BASED RATERS

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Introduction

Concerns about slow sample accession in clinical trials have prompted a variety of strategies that attempt to bolster recruitment. Recent large studies often extend local recruitment efforts by adding resources from experienced national recruitment vendors. Little data is available however, that compares outcomes for patients recruited from different sources, e.g. usual care providers versus mass media. Speculation about the high failure rates in CNS studies include concern that subjects are not always representative of patients seeking treatment for the disorder under study.

Computer-administered assessments offer opportunities to collect data directly from subjects across global sites and provide a useful standard for exploring hypotheses regarding the performance of recruitment strategies. Analysis of data comparing ziprasidone to placebo with the site-based rater's (SBR) and computer's ratings found no significant differences between the treatment groups. This presentation provides the outcomes for subjects based on the referral source.

Methods

Computer-administered assessments (i.e., Diagnostic Validation, Ham-D_{Comp}, MADRS_{Comp}) were included in a double-blind protocol that randomized 303 Bipolar I subjects to adjunctive treatment with ziprasidone vs. placebo for acute depression. The primary outcome variable in the parent study was change from baseline to endpoint MADRS_{SBR} score. Computer diagnostic assessment interviews were scored (0-100) using the Bipolarity Index, a measure of diagnostic confidence. Quality ratings were defined based on the absolute value of the difference between the MADRS_{Comp} and MADRS_{SBR} at baseline and categorized on a 0-4 ordinal scale. (Figure 1) Outcome on the computer assessment were defined based on change from baseline to endpoint MADRS_{Comp} score.

The analysis plan precluded inferential statistics in the absence of an overall finding of drug placebo difference.

Recruitment source was captured on the CRS Laptop for 143 subjects, who were placed into one of five categories based on referral source: psychiatry office (n=85), other medical office/posting (n=28), mass media (n=10), support group (n=5), or other (n=15). Due to the small sample size, groups were collapsed into medical vs. non-medical referral sources for these comparisons.

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One or more authors report potential conflicts which are described in the program*
*Bryce Kasuba, Suzanne Edman, Dan DeBonis, Jenn Sturgis, Eben Goodman, and GS Sachs are employees or contractors of CRS. Douglas Vanderburg, Kathleen Ice, and Michael Zelasky are employees of Pfizer.

Results

Figure 1: Rater Performance at Baseline: Distribution of Difference Scores

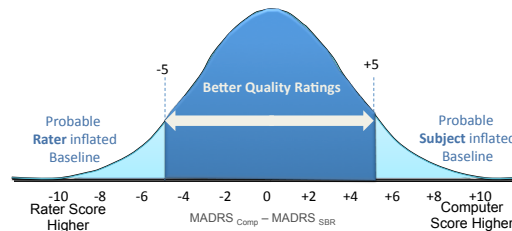


Figure 2: Quality Rating by Referral Source

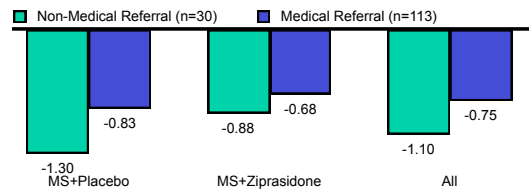


Figure 3: Placebo: MADRS Change from BL-LOCF by Referral Source

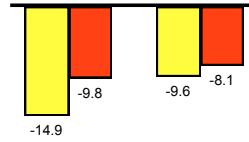


Figure 4: Overall: MADRS Change from BL-LOCF by Referral Source

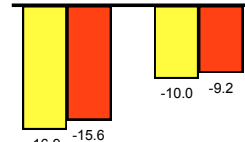


Figure 5: Better Quality: MADRS Change from BL-LOCF

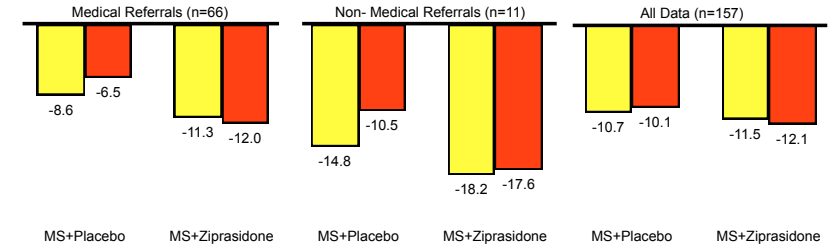
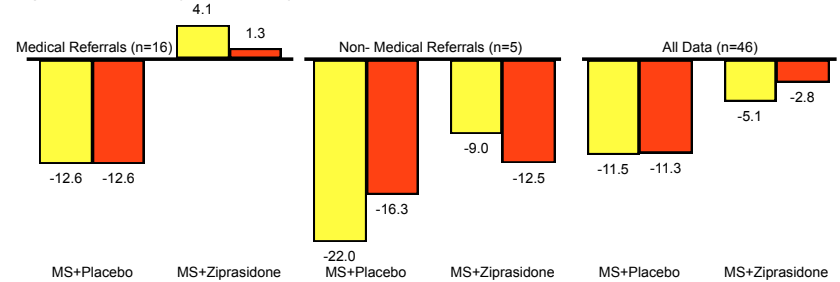


Figure 6: Lowest Quality: MADRS Change from BL-LOCF



Conclusions

Subjects that entered the trial based on referral from a psychiatrist's office or another medical office had higher quality ratings based on the difference between SBR and Comp MADRS scores at baseline than subjects responding to mass media and other non-medical sources. (Figure 2) This group also had higher Bipolarity Index scores indicating higher confidence in the diagnosis of Bipolar I disorder. Subjects who were referred to the study from non-medical sources such as mass media showed disproportionate improvement in the placebo treatment group. (Figure 3)

The use of quality scores based on tandem ratings at baseline across all referral groups may help stronger signal detection.

Targeting recruitment efforts to accession patients seeking treatment from medical professionals may help mitigate the risk of study failure.