

PW01-08 - EVALUATING PREDICTORS FOR REMISSION WITH PLACEBO USING INTEGRATED DATA FROM PATIENTS WITH MAJOR DEPRESSIVE DISORDER

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Objectives: To identify predictors of remission with placebo treatment in double-blind randomized controlled trials (RCTs) in major depressive disorder (MDD) based on baseline characteristics.

Methods: 989 placebo-treated MDD subjects with baseline Hamilton Depression Rating Scale total score (HAMDT17) ≥ 15 who completed 7-8 weeks of treatment from 8 duloxetine RCTs with placebo lead-in were included. Remission was defined as HAMDT17 endpoint score ≤ 7 . Stepwise logistic regression and classification and regression tree (CART) methods were used to identify predictors of remission. Data were randomly split into training data (N=791, 80%) for model selection and test data (N=198, 20%) for validation. Predictive quality of models was assessed by ROC curves.

Results: In the logistic regression analysis, out of >50 potential pre-treatment predictors, the HAMDT17 score, age, Hamilton Anxiety Scale item 14 (HAMA14: behavior at interview) and length of current MDD episode (length) were found to be most predictive for remission on placebo. These variables were also identified as top predictors by the CART method that identified 2 subgroups: "HAMA14=0 OR (HAMDT17 < 22 AND length < 18 weeks)" (45% remitted), "HAMA14 > 0 AND (HAMDT17 ≥ 22 OR length ≥ 18 weeks)" (21% remitted). However, the predictive power was weak for both methods with areas under the ROC curve (test data) of 67% and 56%, respectively.

Conclusions: Baseline risk factors for non-remission after 7-8 weeks of placebo treatment were older age, more severe depressive symptoms, apparent anxiety, and a longer duration of current MDD episode. These results are consistent with previous findings and may aid in the design of RCTs.