IDgenetix-Guided Medication Management for Major Depressive Disorder: Confirmation of Randomized Controlled Trial Outcomes by Real-World Evidence

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Background

- With the current standard of care medication prescribing strategy, more than 53% of patients with major depressive disorder (MDD) have an inadequate response to first-line treatment and over 72% of patients fail to achieve remission.[1,2]
- Pharmacogenomic (PGx) testing aims to detect variants in the human genome that affect individual response to medications.
- IDgenetix is an advanced 3-in-1 PGx test that incorporates the results of a multi-gene variant panel with drug-drug interactions and lifestyle factors to improve drug efficacy and tolerability in patients treated for MDD, anxiety, or other neuropsychiatric illnesses.
- In a previously published randomized controlled trial (RCT), IDgenetix-guided medication management significantly improved patient outcomes after 12 weeks of treatment.[3,4]

Objective

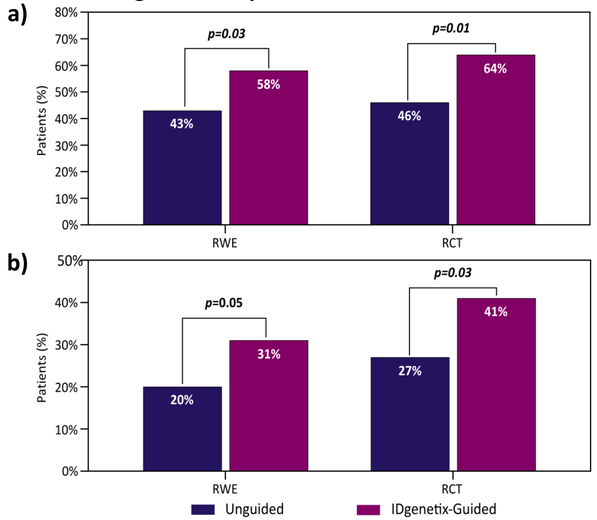
- In this study, we compared the clinical outcome results from a previously published, multi-center, RCT[3] with real-world evidence (RWE) from a single-center, non-randomized, open-label study.[5]

Methods

- Participants with moderate to severe depression at baseline were included in the analysis for the RCT (HAM-D17 ≥20, n=261) and real-world evidence (PHQ-9 ≥10, n=242).
- In both studies, response and remission rates were analyzed using Fisher's exact test for patients provided IDgenetix-guided medication management (IDgenetix-Guided) compared to patients receiving the standard of care (Unguided).

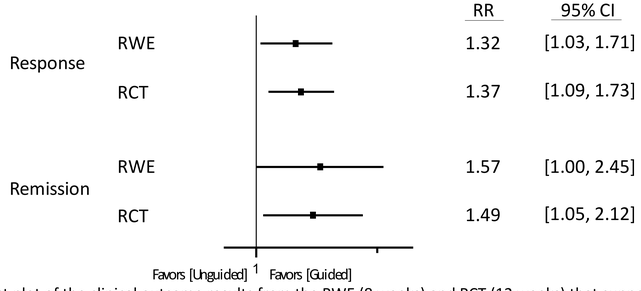
Results

Figure 1. Response and remission rates



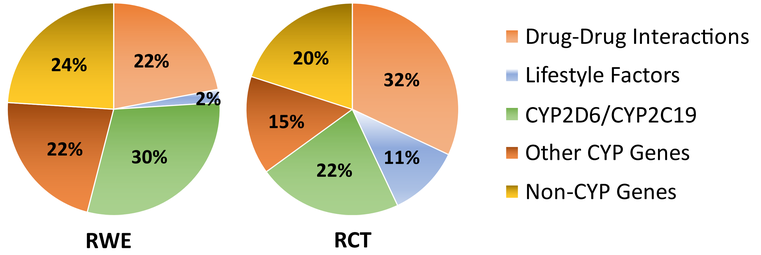
IDgenetix-guided medication management (RWE, n=120; RCT, n=140) improved response rates (a) and remission rates (b) compared to the standard of care (RWE, n=122; RCT, n=121) in participants with moderate to severe depression in the RWE at 8 weeks and the RCT at 12 weeks.

Figure 2. Risk ratios for response and remission rates



Forest plot of the clinical outcome results from the RWE (8 weeks) and RCT (12 weeks) that support the clinical utility of IDgenetix-guided medication management in patients with moderate to severe depression.

Figure 3. Sources for drug recommendations



Non-genetic drug-drug interactions and lifestyle factors accounted for 22% and 2%, respectively, of all drug recommendations in the RWE (n=110), while single-gene testing for CYP2D6 and CYP2C19 contributed 30%. In the RCT (n=261), drug-drug interactions and lifestyle factors accounted for 32% and 11%, respectively, while single-gene testing influenced only 22% of all drug recommendations.

Conclusion

- The response and remission rates from the RWE strongly correlate with those from the RCT.
- No single source accounts for the majority of drug recommendations, which is why a multi-gene PGx test that incorporates drug-drug interactions and lifestyle factors is important.
- This study provides robust evidence-based research that supports the clinical utility of IDgenetix to guide medication management in patients with MDD.

References

1. Rush et al. *Am J Psychiatry*. 2006.
2. Trivedi et al. *Am J Psychiatry*. 2006.
3. Bradley et al. *J Psychiatr Res*. 2018.
4. Cao et al. Psych Congress. 2023.
5. Cao et al. APA. 2023.

Disclosures

FC, AH, and RC are employees and stock/option holders at Castle Biosciences, Inc.