Efficacy, safety, and tolerability of Vortioxetine in the treatment of Mood disorders

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Background

According to the WHO, depression affects over 350 million people worldwide. People affected by depressive symptoms has a 20-fold higher suicide risk rate [1] when compared to the general population. In the past 25 years, there have been major developments in the treatment of depression but many newly drugs introduced for the treatment of major depressive disorder (MDD) share similar putative mechanisms of action. Vortioxetine is a multi-modal antidepressant that functions at the same time as serotonin transporter (SERT) inhibitor, as well as 5-HT_3, 5-HT_7 and 5-HT_{1D} receptors antagonist, 5-HT_{1A} receptor agonist and 5-HT_{1B} receptor partial agonist [2].

Aim of the study

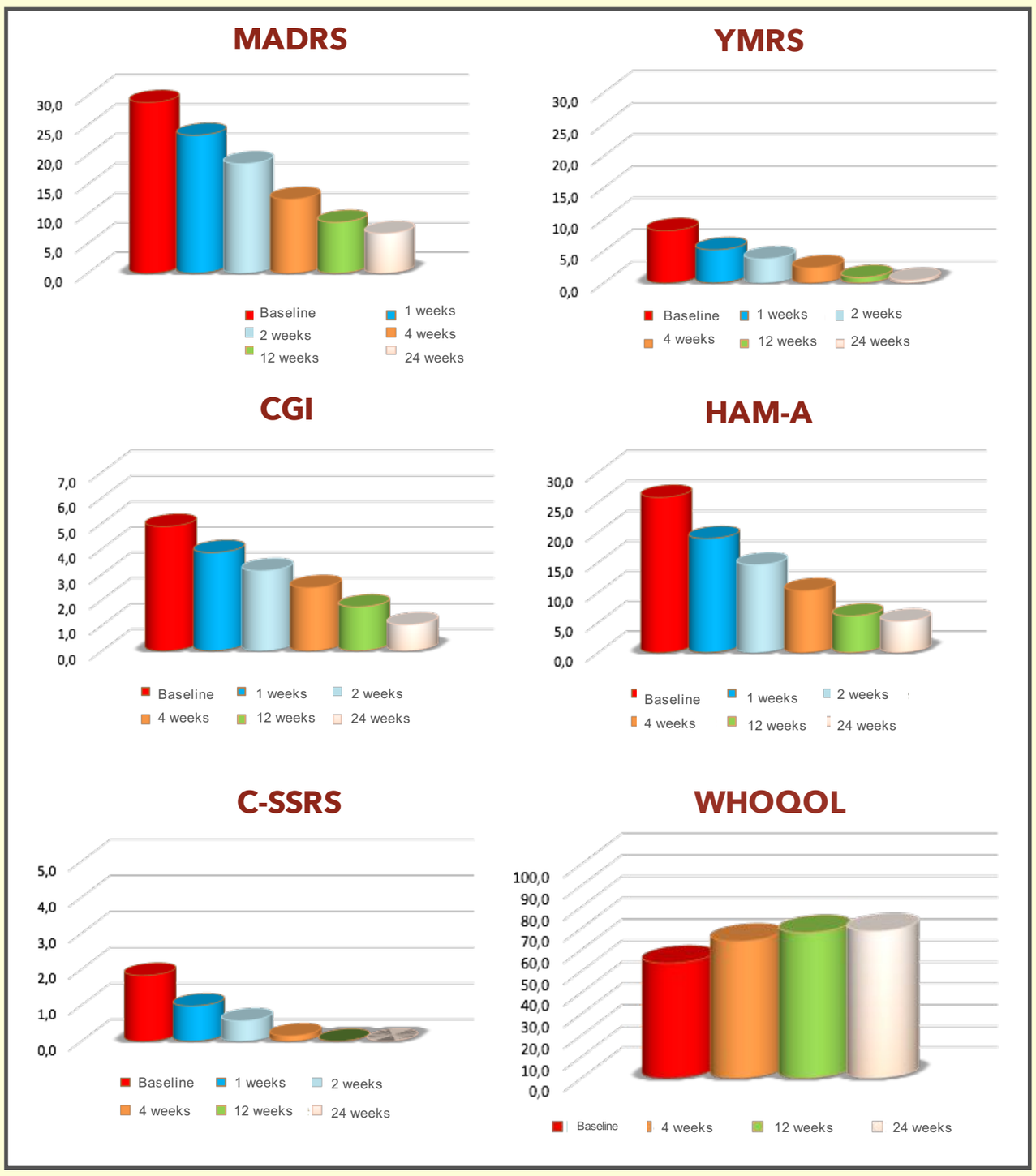
The aim of this study is to evaluate the efficacy of vortioxetine in terms of response rate to treatment (relative decrease of 50% from baseline in MADRS after 4 weeks of treatment) and tolerability (withdrawal rate for any reason or due to adverse events), in inpatients with a poor response to two previous adequate treatments (optimal dosage and duration) with two different classes of antidepressants.

Methods

The study population is composed of 75 inpatients (mean age 51±14) who met the criteria for DSM-5 Major Depressive Disorder, Schizoaffective Disorder-depressive type, Bipolar II Disorder-depressive episode, who started treatment with vortioxetine. Efficacy measures included the Montgomery-Åsberg Depression Rating Scale (MADRS), the Hamilton Anxiety Scale (HAMA), the Clinical Global Impression Scale-Severity of Illness (CGI-S), the Brief Psychiatric Rating Scale (BPRS), and the Young Mania Rating Scale (YMRS). These assessments were conducted at baseline, and then every week up to 4 weeks, and at 3 months and 6 months. Safety and tolerability were assessed through clinical interview, vital signs, laboratory values and the Columbia-Suicide Severity Rating Scale (CSSRS). The World Health Organization Quality of Life Assessment (WHOQOL) was used to evaluate global health perception at baseline and at 1, 3 and 6 months. We analyzed data with ANOVAs and *post hoc* analyses using the SPSS 20.0.

Results

Results showed a progressive, significant decrease compared to baseline ($p < 0.01$) in total MADRS scores (56.68% at week 4), CGI-S (49.18% at week 4), BPRS (36.42% at week 4), YMRS (54.14% at week 2), and HAM-A (60.13% at week 4). Vortioxetine yielded also significant progressive WHOQOL score increase (16.51% at week 4, $p < 0.01$). Moreover, CSSRS scores showed a progressive significant decrease at 1 week (80.42%, $p < 0.05$), with a complete remission of suicidal ideation after 3 months. The rate of adherence to treatment was 98.6%.



Conclusions

Results support the effectiveness of vortioxetine in patients with major depression, depression associated with anxiety, depressive episode of bipolar disorder, and schizoaffective disorder. Interestingly, clinical response was statistically significant since the first week of treatment. Furthermore, treatment with vortioxetine was not associated with increased manic symptoms, which, on the contrary, showed a significant decrease after one week. Finally, there was a significant reduction, up to a complete remission of suicidal ideation. Summarizing, data point to vortioxetine as being a valid and efficient option for treatment-resistant depression.

References

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The authors declare no potential conflict of interest