Real world effectiveness and acceptability of vortioxetine in patients with MDD in Greece

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Backround

Major Depressive Disorder (MDD) is a highly heterogenous psychiatric disorder, with a constellation of different domains of symptoms. One of its core and persistent symptoms is anhedonia, defined as the impaired capacity to experience or to anticipate pleasure, which involves non-serotoninergic pathways, such as central dopaminergic, mesolimbic and mesocortical reward circuits[1].

Vortioxetine is an antidepressant with a differentiated, multimodal mechanism of action, affecting multiple neurotransmitter systems, including the serotonin, norepinephrine, dopamine, histamine and acetylcholine systems[2]. Several studies support the broad efficacy of vortioxetine in MDD[3,4], as well as in certain aspects of MDD, such as anhedonia[5], in combination with low rates of treatment discontinuation[6].

This study is aiming to investigate the effectiveness (including depressive symptoms and anhedonia) and the acceptability of vortioxetine in real world clinical practice in patients with MDD in Greece, as a part of the first post-marketing study of vortioxetine in Greece (RELIEVE-GR).

Objectives & Methods

Objectives: The objectives of the current study were to:
1. assess real-life effectiveness of vortioxetine in i) depressive symptoms, ii) clinical global impression and iii) anhedonia.
2. assess treatment acceptability in an outpatient population in Greece, at 1 and at 3 months of treatment.

Methods: This is a non-interventional, prospective, national, multicenter open-label study of vortioxetine in outpatients with MDD in Greece. Vortioxetine was administered as monotherapy for Major Depressive Episode (MDE) at flexible dosage (5-20 mg/d). The study included 3 visits: baseline, 1 month ± 1 week, 3 months ± 2 weeks. Montgomery Asberg Depression Rating Scale (MADRS), Clinical Global Impression of Severity (CGI-S) and MADRS anhedonia factor (1,2,6,7,8 MADRS items) were used for the assessment[5].

		Mean	Median	SD	Minimum	Maximum	N (Total)
Age (years)		47.9	48.5	14.3	18.0	83.0	336
MDD duration (years)		3.5	1.0	6.1	0.0	34.0	336
						N	%
Gender	Female					216	64.3
	Male					120	35.7
Newly diagnosed patient	Yes					182	54.2
Family history of MDD	Yes					108	32.1
Number of depressive episodes	1st					163	48.5
	2nd					100	29.8
	>2nd					73	21.7

Table 1: Basic demographics.

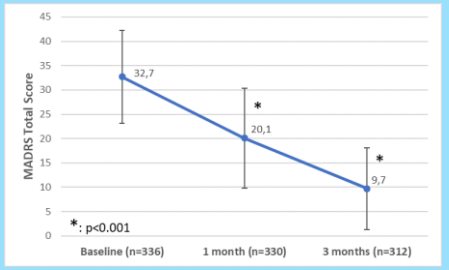

Fig 1: Mean total MADRS score. (Observed cases)

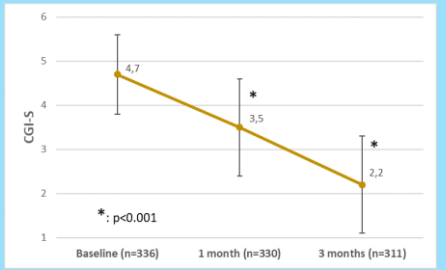

Fig 2: Mean CGI-S score. (Observed cases)

	N	%
"Investigator's decision due to AE"	1	0.3
"Patient's wish due to AE"	4	1.2
"Patient's wish for another reason"	9	2.7
"The patient did not come to the scheduled Visits"	10	3.0
"Other reason"	3	0.9
Did not discontinue	309	92.0
Total	336	100.0

Table 2: Reason of treatment discontinuation. Base: Total sample (N=336).

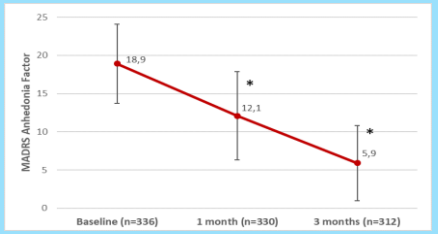

Fig 3: Mean MADRS Anhedonia Factor (Observed cases)

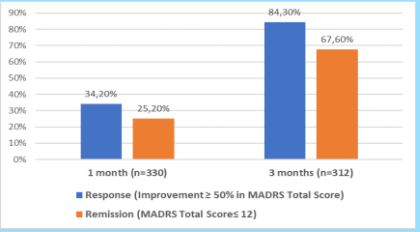

Fig 4: Rates of responded and remitted patients

The rates of MADRS responders (i.e. ≥50% improvement from baseline) and remitters (i.e. MADRS Score ≤ 12) were also calculated. Repeated measures analysis of variance was used for the evaluation of scores change along visits compared to baseline. McNemar's test was applied for the comparison of the corresponding percentages (MADRS remission and response) between visits 2 and 3. Treatment discontinuation and respective reasons were also recorded for the evaluation of treatment acceptability.

Results

- 336 patients entered the study. Basic demographics are shown at Table 1.
- Mean total MADRS Score ± SD decreased from 32.7 ± 9.5 at baseline to 20.1 ± 10.3 (p<0.001) at 1 month and to 9.7 ± 8.4 (p<0.001) at 3 months of treatment (Figure 1).
- Mean CGI-S Score ± SD improved from 4.7 ± 0.9 (markedly ill) at baseline to 3.5 ± 1.1 (moderately-mildly ill, p<0.001) at 1 month and to 2.2 ± 1.1 (borderline ill, p<0.001) at 3 months (Figure 2).
- MADRS anhedonia factor decreased from 18.9 ± 5.2 at baseline to 12.1 ± 5.8 (p<0.001) at 1 month and at 5.9 ± 4.9 (p<0.001) at 3 months of treatment (Figure 3).
- 34.2% of patients responded to vortioxetine and 25.2% were remitted at 1st month, while the corresponding rates at 3 months were 84.3% and 67.6% (p<0.001 for between visits comparisons, Figure 4).
- Vortioxetine was well tolerated with no new safety signals. 8% of patients discontinued vortioxetine treatment during the 3 months study period due to any reason (Table 2).

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Conclusions

In this outpatient population with MDD in Greece, vortioxetine, a multi-modal antidepressant with a unique mechanism of action, showed significant effectiveness in improving MDD severity, according to MADRS and CGI-S scores, both at 1 and 3 months. Moreover, vortioxetine was proved highly effective in anhedonia, which is a core characteristic of MDD, both at 1 and 3 months.

These results were combined with low rates of treatment discontinuation, implying a favorable effectiveness/acceptability profile for vortioxetine.

References

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