Effectiveness and tolerability of Vortioxetine in Affective Disorders: a naturalistic study

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Introduction. Vortioxetine is a novel antidepressant with multimodal activity [1]. In the last decade, it has been approved worldwide [2;3].
Objectives. The present naturalistic study aimed to characterize effectiveness and tolerability of vortioxetine in affective disorders in real clinical practice.
Methods. Study total sample consisted of 48 outpatients, treated with vortioxetine and mainly with a primary diagnosis of Major Depressive Disorder/MDD, Bipolar Disorder/BD, Generalized Anxiety Disorder/GAD, Panic Disorder/PD, Obsessive Compulsive Disorder/OCD, Adjustment Disorder/AD. Collected variables included socio-demographic, clinical and three periodic psychometric evaluations (T0=week 0, T1= week 4 and T2= week 12; including Hamilton Depression Rating Scale (HAMD), Montgomery-Åsberg Depression Rating Scale (MADRS), Hamilton Anxiety Rating Scale (HAMA), Young Mania Rating Scale (YMRS), Clinical Global Impression (CGI)- Efficacy Index, Dosage Record Treatment Emergent Symptom and Treatment Emergent Symptoms Write-In scales). Statistical analyses were performed.

Table 1. *Main socio-demographic and clinical characteristics of the study sample*

	Total Sample N=48	
Gender	Male	N=17 (35.4%)
	Female	N=31 (64.6%)
Age	50.38 ± 16.69	
Age at onset	36.13 ± 16.93	
Vortioxetine dosage	12.92 ± 5.68	
Psychiatric diagnosis	MDD	N=21 (43.8%)
	BD 1	N= 5 (10.4%)
	BD 2	N=11 (22.9%)
	GAD	N=3 (6.3%)
	PD	N=2 (4.2%)
	OCD	N=3 (6.3%)
	AD	N=1 (2.1%)
	Other	N=2 (4.2%)
Comorbidities	No	N=23 (47.9%)
	Yes	N=25 (52.1%)

Side effects	Yes	N=13 (27.1%)
	No	N=35 (72.9%)
Type of side effects	Gastrointestinal	N=8 (16,6%)
	Libido reduction	N=1 (2,1%)
	Gastrointestinal + other	N=4 (8,3%)
Associated therapy	Any	N=44 (92%)
	Antidepressants	N= 13 (27.1%)
	Stabilizers	N=29 (60.4%)
	Benzodiazepines	N=16 (33.3%)
	Antipsychotics	N=27 (56.3%)
Dropout	Yes	N=16 (33.3%)
	No	N=32 (66.7%)
Reasons of dropout	Side effects	N=6 (37.5%)
	Non efficacy	N=7 (43.8%)
	Switch maniacale	N=1 (6.2%)
	Others	N=2 (12.5%)

Figure 1. *Psychometric scales across time in the total sample*

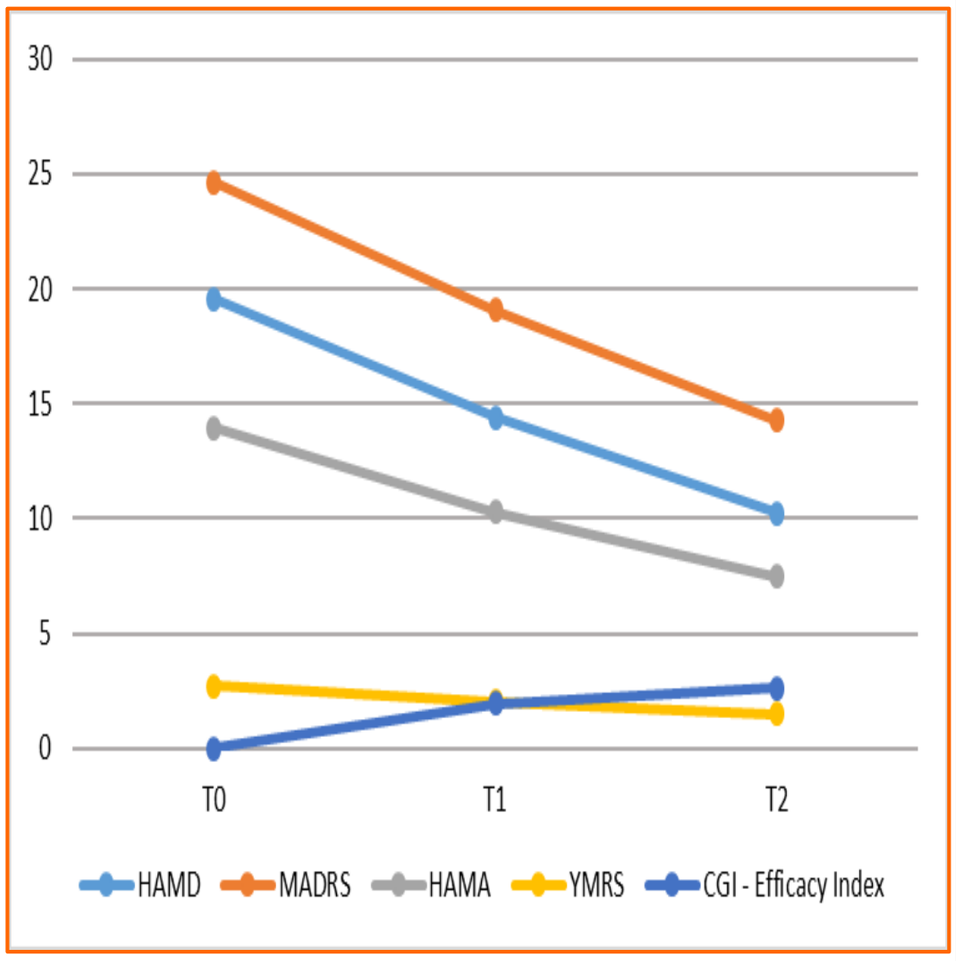

Table 2. *Psychometric evaluation across time for the total sample and for two different dosage subgroups*

		T0	T1	T2	P
HAMD	**Total sample**	**19.58 ± 5.29**	**14.40 ± 5.05**	**10.23 ± 6.48**	**0.000**
	Vortioxetine ≤ 10 mg	20.37 ± 6.26	14.56 ± 6.16	10.52 ± 7.43	0.584
	Vortioxetine > 10 mg	18.57 ± 3.59	14.19 ± 3.25	9.86 ± 5.16	
MADRS	**Total sample**	**24.67 ± 5.29**	**19.06 ± 5.50**	**14.27 ± 7.10**	**0.000**
	Vortioxetine ≤ 10 mg	24.81 ± 6.34	18.37 ± 6.32	13.81 ± 7.67	0.505
	Vortioxetine > 10 mg	24.48 ± 3.64	19.95 ± 4.21	14.86 ± 6.44	
HAMA	**Total sample**	**13.98 ± 4.91**	**10.31 ± 4.19**	**7.48 ± 4.86**	**0.000**
	Vortioxetine ≤ 10 mg	14.56 ± 5.48	10.44 ± 4.69	7.85 ± 5.61	0.651
	Vortioxetine > 10 mg	13.24 ± 4.07	10.14 ± 3.55	7.00 ± 3.77	
YMRS	**Total sample**	**2.71 ± 1.54**	**2.06 ± 1.49**	**1.52 ± 1.49**	**0.000**
	Vortioxetine ≤ 10 mg	3.00 ± 1.49	2.22 ± 1.45	1.56 ± 1.58	0.273
	Vortioxetine > 10 mg	2.33 ± 1.56	1.86 ± 1.56	1.48 ± 1.40	
CGI – Efficacy Index	**Total sample**	-	**1.96 ± 1.19**	**2.63 ± 1.54**	**0.000**
	Vortioxetine ≤ 10 mg	-	1.91 ± 1.39	2.57 ± 1.71	0.909
	Vortioxetine > 10 mg	-	2.03 ± 0.89	2.70 ± 1.33	

Results. Most common primary diagnoses were MDD (43.8%) and BD (33.3%), with an overall comorbidity rate of 52 %. Associated medications (stable across follow up) were present in 92 % of patients and the mean vortioxetine dosage was 12.92 ± 5.68 mg. Repeated measures ANOVA highlighted a significant improvement of HAM-D, MADRS, HAM-A, YMRS and CGI-efficacy index across time. The 33.3 % of the total sample dropped out, of which mainly because of non efficacy (43.8%) and side effects (37.5%). Of the total sample, 16.6% reported gastrointestinal, 2.1% sexual and 8.3% combined side effects (gastrointestinal + other).
Conclusions. Although limited study sample, the present report highlights vortioxetine good effectiveness on affective symptoms together with partial tolerability and moderate rate of discontinuation. Larger sample and further studies are warranted to better characterize vortioxetine effectiveness and tolerability in clinical practice.

References

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