

PREVIDA IN PAKISTAN: IMPACT OF VORTIOXETINE ON SEVERITY, COGNITIVE DYSFUNCTIONS, AND FUNCTIONALITY IN PATIENTS WITH MAJOR DEPRESSION

FAREED ASLAM MINHAS¹, RUSHAM ZAHRA RANA², SYED USMAN HAMDANI³, MOWADAT HUSSAIN RANA⁴

1. Karakoram International University Gilgit 2. Combined Military Hospital, Kharian Cantt



Introduction

Depression is a disease that affects approximately 264 million people each year globally¹. Severe depression when left untreated is associated with an increased risk for recurrence, comorbidity, suicide attempts and substance abuse². Despite a vast armamentarium for depression such as antidepressants, psychotherapies and other nonpharmacological treatments, and homeopathic strategies, a considerable percentage of patients remain unresponsive or respond poorly to available treatments.

In the PREVIDA study we have studied the performance of vortioxetine as a medication intervention in depression across Pakistan on almost 500 patients³.

The **primary objective** of the present study was to assess the impact of vortioxetine treatment on MDD over three months in real-world psychiatric practices across Pakistan.

The **secondary objective** were (a) to assess the impact of a three-month treatment of vortioxetine on severity of major depression symptoms from both patient's and psychiatrist's point of view, cognitive dysfunctions, work and productivity, and adherence to treatment (b) description of tolerability and safety of vortioxetine in daily practice.

Methods

Participants

The study was conducted in 16 psychiatry outpatient clinics in seven cities across Pakistan namely Rawalpindi, Faisalabad, Peshawar, Quetta, Wah, Multan, Lahore, Karachi and the state of Azad Jammu and Kashmir. An opportunity sample of 498 patients aged 18 and over, attending out-patient psychiatric clinics in the study sites with a diagnosis of MDD were asked to participate in the study.

Inclusion Criteria

- Patients clinically diagnosed with an active episode of major depression in the current visit to the clinic/hospital/treating psychiatrist
- Between 18-65 years of age
- Patients who have been prescribed vortioxetine

Exclusion Criteria

- The patient with concurrent diagnosis or past history of any of the following: schizophrenia or other psychotic disorders, bipolar disorder, dementia or any other neurodegenerative disease, alcohol or substance dependence, any psychiatric disorder due to a general medical condition or psychoactive substances
- Patients with any physical condition that can cause cognitive dysfunction such as head trauma, chronic illnesses (e.g. diabetes mellitus, hypertension, anaemia, epilepsy, cerebrovascular accident etc.)
- The patient is a member of the study personnel or of their immediate families, or is a subordinate (or immediate family member of a subordinate) to any of the study personnel.
- Patients resisting treatment or those who might resist treatment based on clinical evaluation by the psychiatrist

Procedure

- Data was collected when patients initiated treatment (baseline) and at approximately **1 week (+/- 3 days), 1 month (+/- 7 days) and 3 months(+/- 14 days)** after treatment initiation. Treatment was prescribed in line with clinical practice guidelines in vogue.

Results

- Summary statistics of patient demographic variables (**Table 1 and Table 2**)

Table 1: Summary of patient demographics

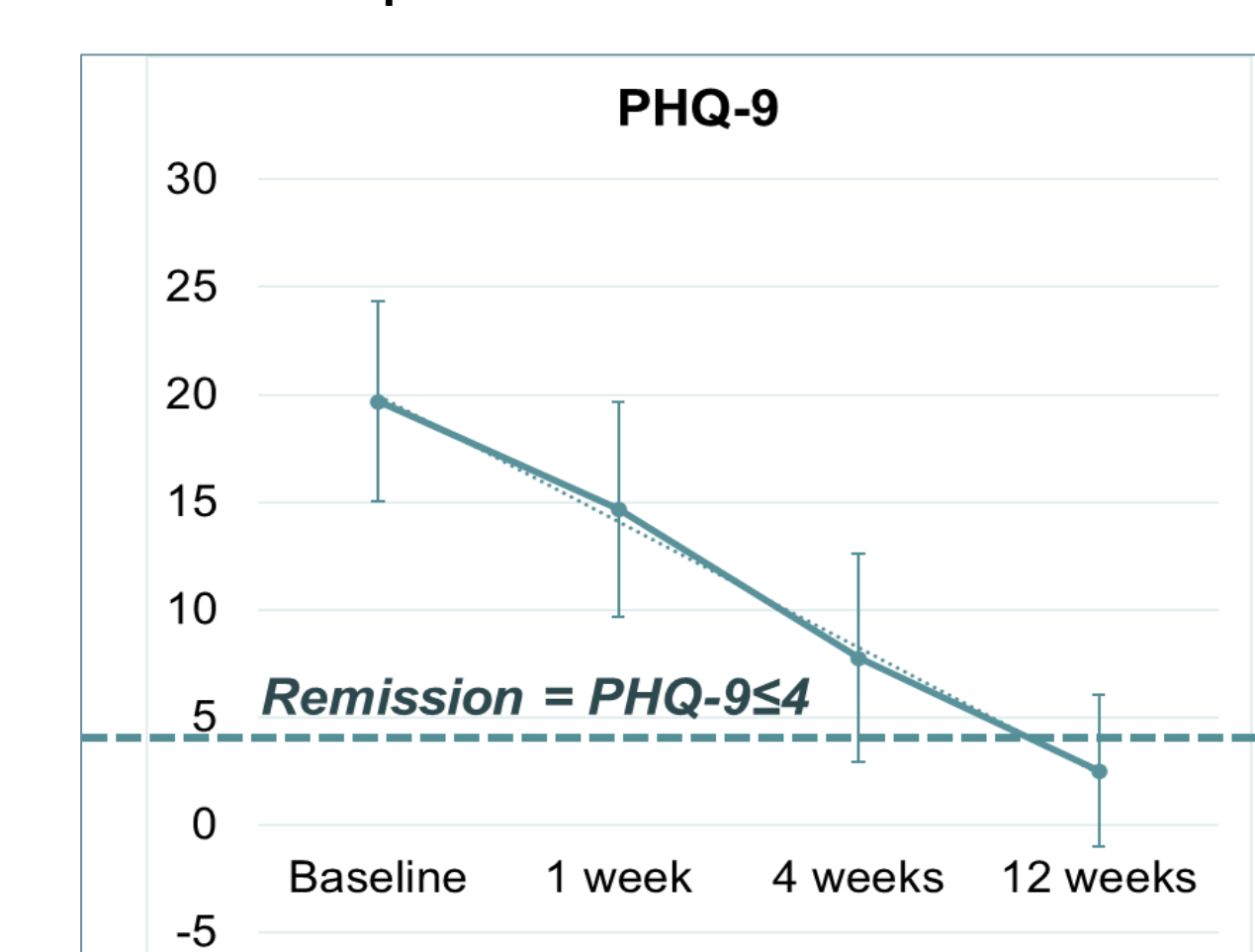
Variables		(%)
Age (M[SD])		34.64 [11.284]
Gender	Males	255 (51.2%)
	Female	243 (48.8%)
Education (M[SD])		10.35 [5.159]
Marital status	Single	134 (26.9%)
	Married or living as a couple	351 (70.5%)
	Divorced/Separated	13 (2.6%)
Living status	City	351 (70.5%)
	Small Town	77 (15.5%)
	Rural	70 (14.1%)

Table 2: Summary of patient demographics

Variables		(%)
Main Work Status	Paid work	115 (23.1%)
	Self-employed such as own your business	71 (14.3%)
	Student	76 (15.3%)
	Keeping house/house maker	168 (33.7%)
	Retired	9 (1.8%)
	Unemployed (health reasons)	37 (7.4%)
	Unemployed (other reasons)	16 (3.2%)
	others	6 (1.2%)
Employment Type	Manager work	22 (4.4%)
	Professional (Health, teaching, legal)	41 (8.2%)
	Associate professional (e.g. technical, nursing)	3 (0.6%)
	Clerical work/secretary	9 (1.8%)
	Skilled labourer (e.g. building, electrical etc)/ factory worker)	27 (5.4%)
	Services/sales (retail)	7 (1.4%)
	Other	7 (1.4%)
	Missing	382 (76.7%)

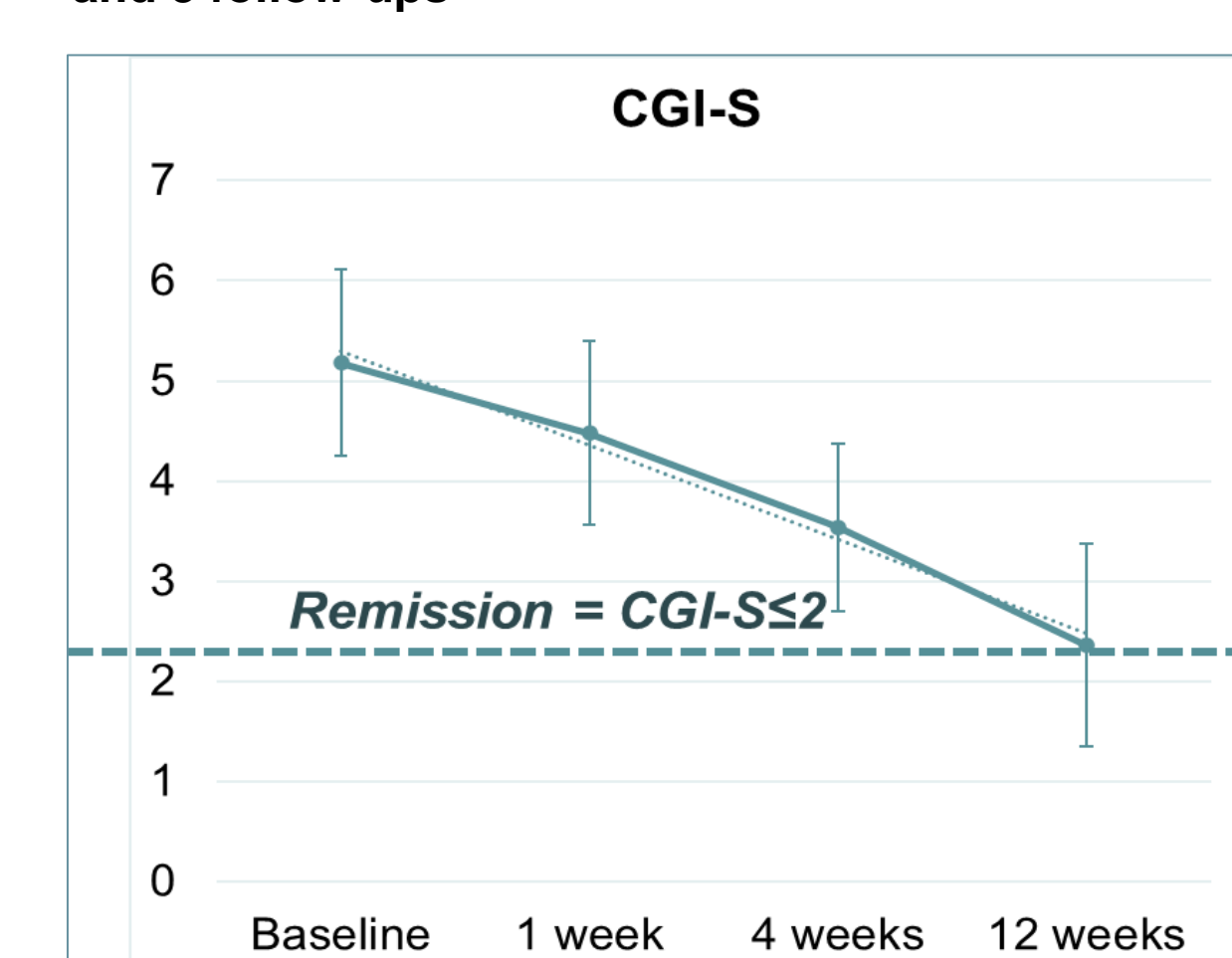
- **Depression severity** was greatly reduced with vortioxetine treatment (PHQ-9/CGI-S) (**Figure 1 and Figure 2**)

Figure 1: Mean (SD) scores of PHQ-9 baseline, 1, 2 and 3 follow-ups



PHQ-9, Patient Health Questionnaire-9; $p < 0.001$

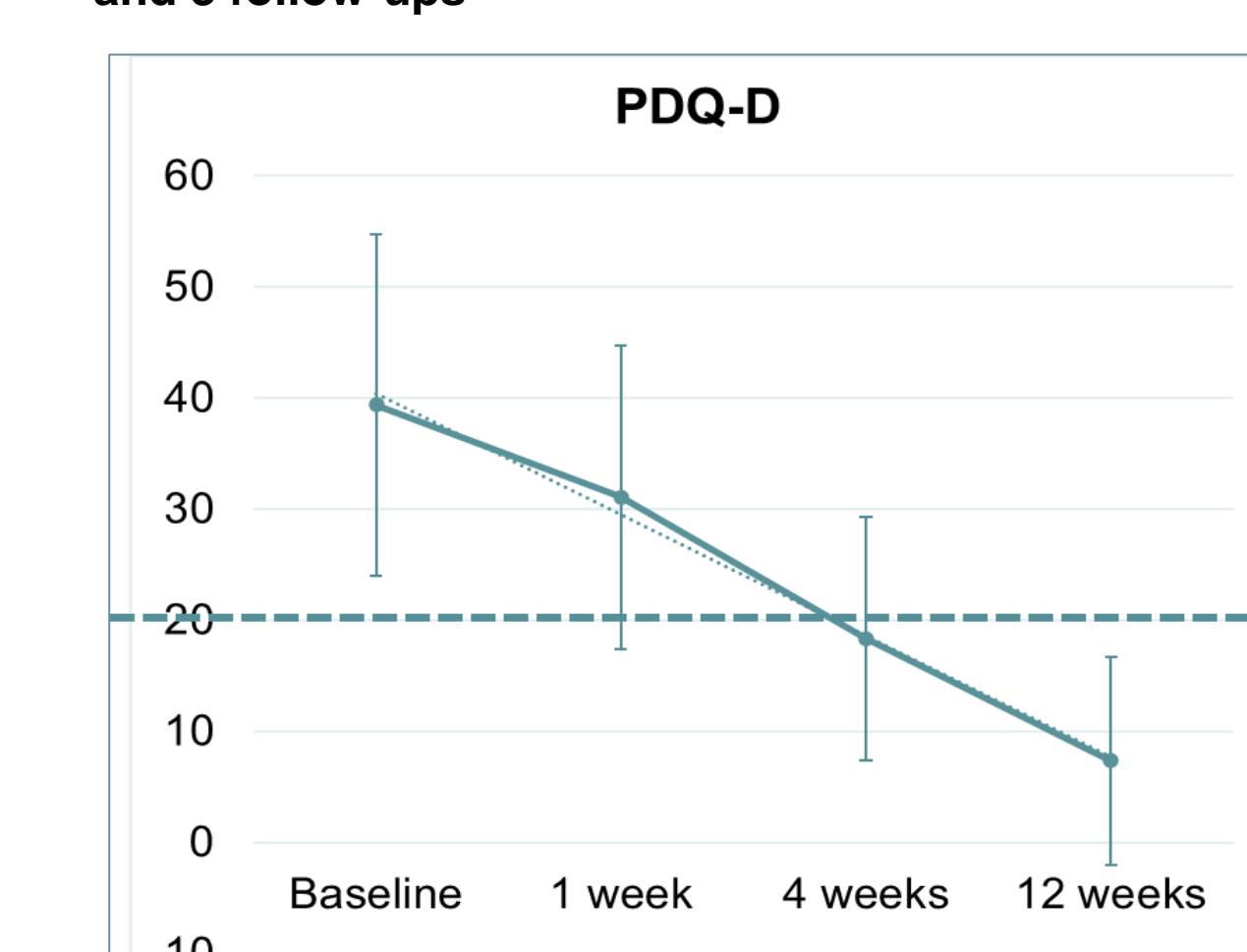
Figure 2: Mean (SD) scores of CGI-S baseline, 1, 2 and 3 follow-ups



CGI-S, Clinical Global Impression - Severity; $p < 0.001$

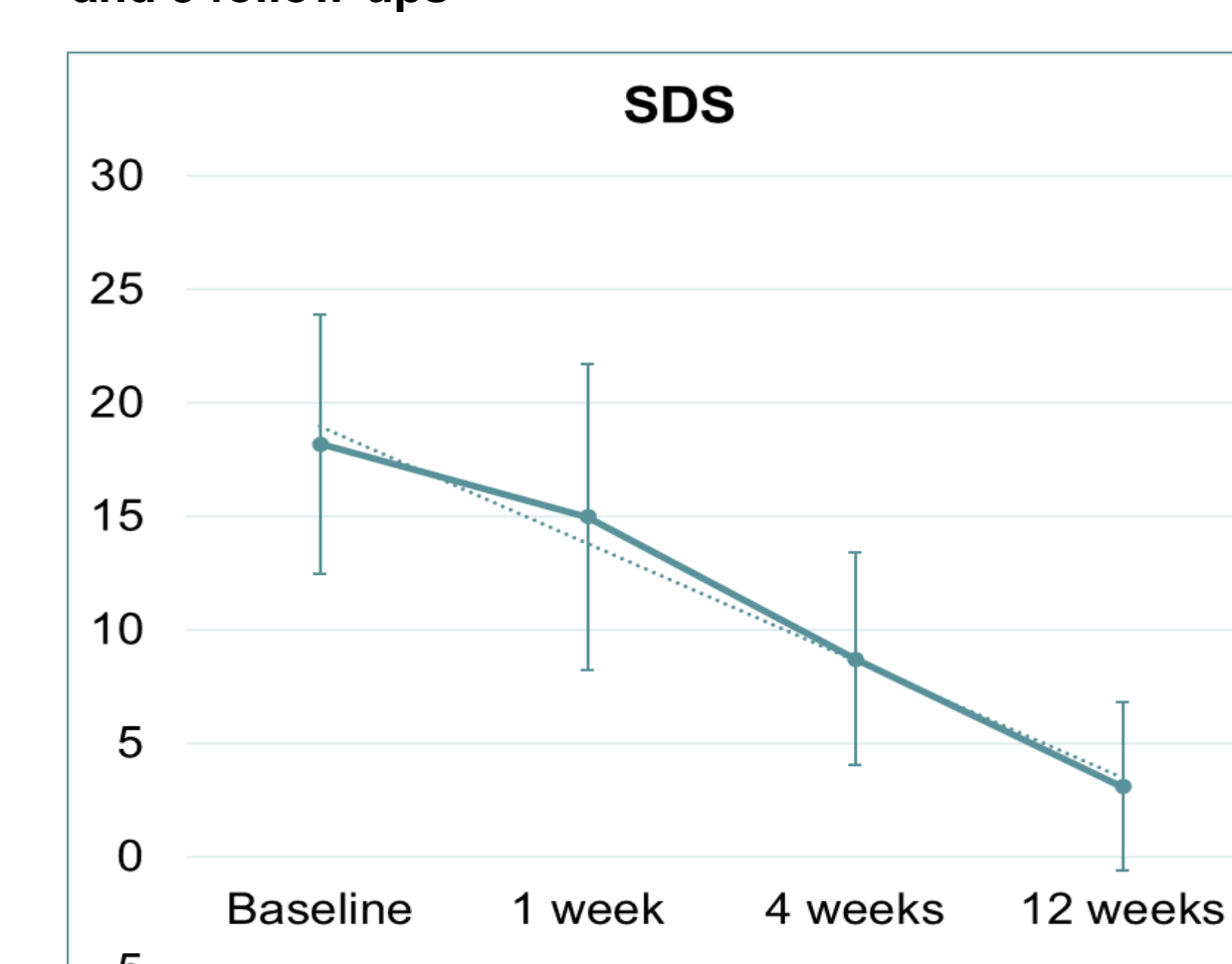
- **Cognition (PDQ-D) and functioning (SDS)** was significantly improved with vortioxetine (**Figure 3 and Figure 4**)

Figure 3: Mean (SD) scores of PDQ-D baseline, 1, 2 and 3 follow-ups



PDQ-D, Perceived Deficits Questionnaire- Depression scale; $p < 0.001$

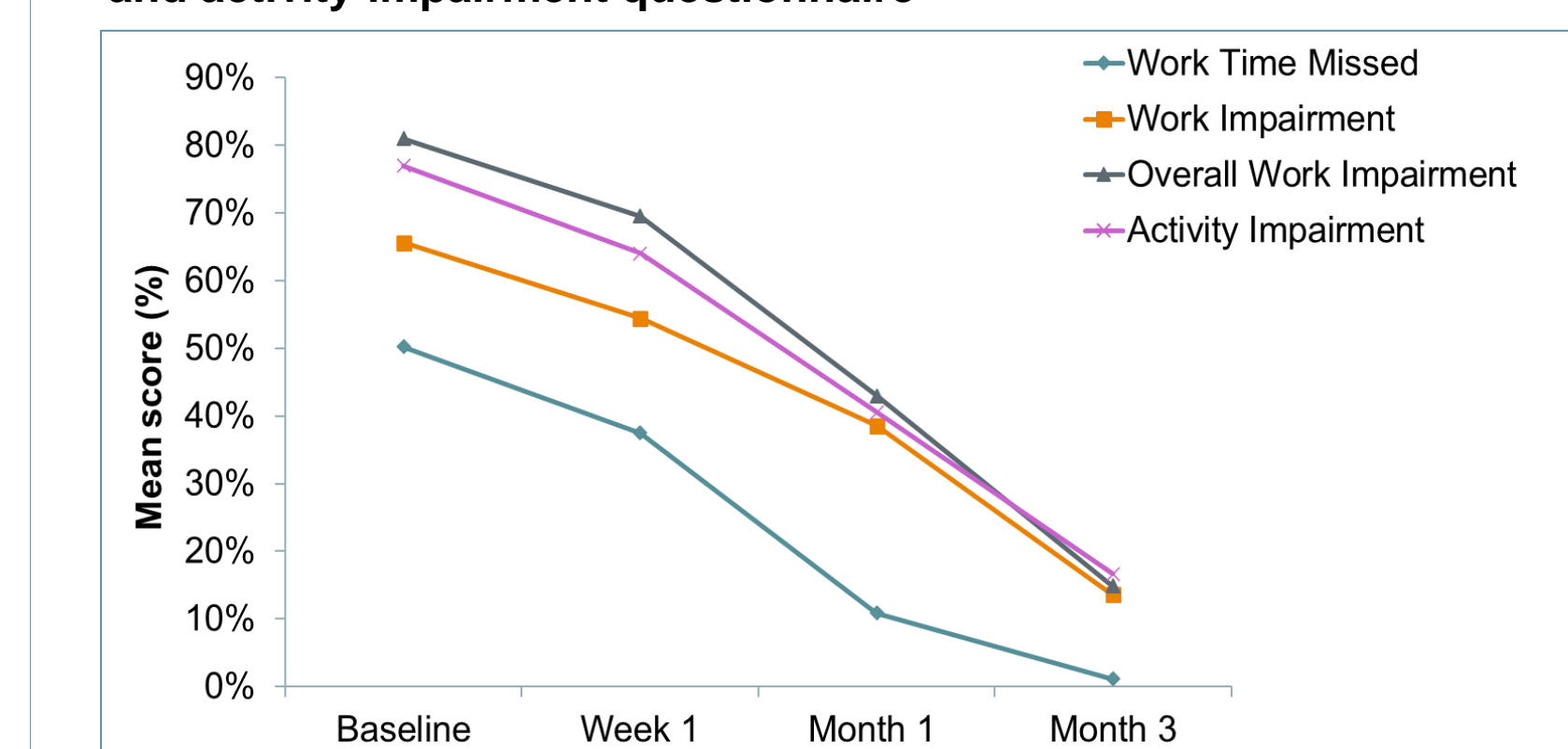
Figure 4: Mean (SD) scores of SDS baseline, 1, 2 and 3 follow-ups



SDS, Sheehan Disability Scale; $p < 0.001$

- **Work productivity and activity impairment** was significantly improved with vortioxetine treatment (**Figure 5**)
- **Response and remission rates** were high after vortioxetine treatment (**Figure 6**)
- The incidence of **adverse drug reactions** were low throughout study (**Table 3**)

Figure 5: Overall work impairment measured through work productivity and activity impairment questionnaire

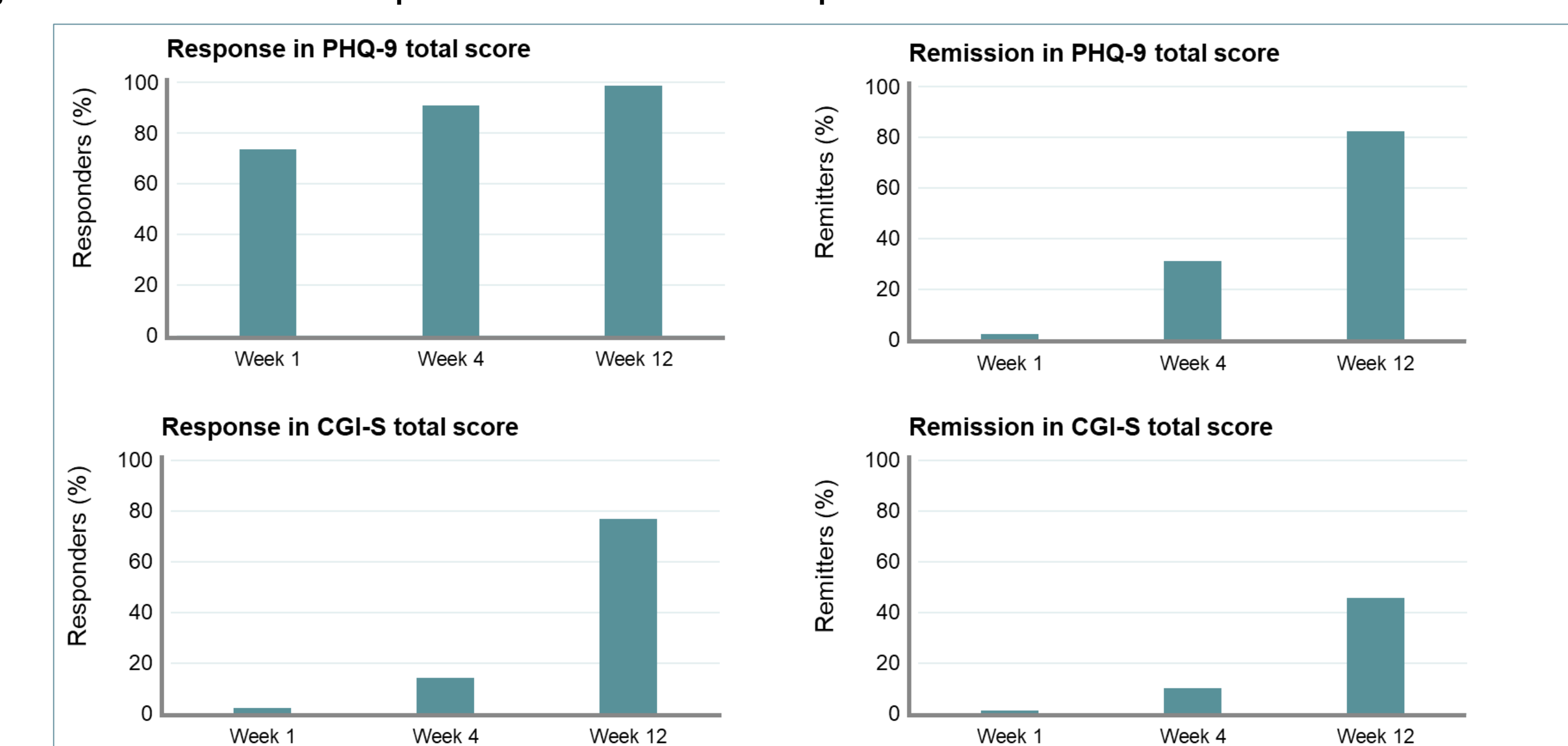


WPAI: Work Productivity and Activity Impairment, $p < 0.01$

Table 3: Number of adverse events recorded throughout study period

Adverse drug reaction	%
Headache	3
Severe irritability	3
Nausea & vomiting	3
Orthostatic hypotension (black out on change of posture)	1
Skin rashes	1
Vertigo	1

Figure 6: Patients defined as responders and remitters for each post-baseline visit



Response is defined as 'a patient with a reduction of score by 50% from baseline score'. Remission is defined as 'a patient with a total score of PHQ-9 ≤ 4 or CGI-S ≤ 2; PHQ-9, Patient Health Questionnaire-9; CGI-S, Clinical Global Impression - Severity

Conclusion

- This is a large real-life study evaluating the effect of vortioxetine in MDD in Pakistan
- In this 12-week study, vortioxetine has shown to **improve depression severity, cognition and functioning**
- The **response and remission rates** with vortioxetine treatment were **particularly high** in this study
- All in all, the study has successfully shown that **vortioxetine is a useful addition in the list of antidepressants in use in Pakistan**

Acknowledgements

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