

A 6-Month Open-Label Study of Vortioxetine among Cancer Patients with Major Depressive Disorder (MDD)

Chong Guan Ng^{1*}, Aya Ahmed Abousheishaa¹, Sue Yin Low², Nor Zuraida Zainal¹, Kai Shin Thong³, Azizul Bin Awaluddin⁴, Tsui Huei Loo⁵, Sapini Binti Yacob⁶, Nik Ruzyanei Nik Jaafar⁷, Nur Iwana Binti Abdul Taib⁷, Nurul Ain Binti Mohamad Kamal⁷, Fuad Ismail⁸, Wan Zamaniah Wi⁹

Abstract

Objective: Vortioxetine is a monoaminergic drug with a novel multimodal mechanism of action. We investigated its efficacy on depressive symptoms, cognitive function, and quality of life among cancer patients. **Methods:** In this multicenter, open-label, single-arm, observational study, patients received flexible doses of Vortioxetine for a period of six months. All participants were assessed at baseline and scheduled for monitoring at weeks 2, 4, 8, 12, 16, 20, and 24. Depression severity was assessed using Montgomery-Asberg Depression Rating Scale (MADRS) and the Clinical Global Impression (CGI) scale. The Perceived Deficiency Questionnaire (PDQ-5) assessed the perceived cognitive difficulties in concentration, executive functioning, and memory. The European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire (EORTC) was used to assess the patients' quality of life. Side effects of vortioxetine were monitored using the Antidepressant Side-Effect Checklist (ASEC). **Results:** Patients experienced a reduction in MADRS scores from 29.89 ± 5.997 at baseline to 11.59 ± 4.629 by Week 24. The PDQ-5 scores showed significant change from Week-4, whereas the EORTC role, emotional, and cognitive functioning scores showed a significant change from Week 2 onwards. CGI-Severity scores decreased from a baseline of 4.39 ± 0.746 to 2.41 ± 1.085 by Week 24. During the 24-Weeks of therapy, around three-quarters of the patients (73.3%) had one or more adverse events reported on the ASEC. The most frequently reported TEAEs were dry mouth, insomnia, somnolence, and headache, with more than a 30% incidence rate. **Conclusion:** Vortioxetine seems promising in the management of depression and enhancement of cognitive function and quality of life of cancer patients with Major Depressive Disorder.

Keywords: Antidepressants- oncology- depression- quality of life- cognitive dysfunction

Asian Pac J Cancer Prev, 24 (8), 2583-2591

Introduction

Depression is a leading cause of global disease burden and is one of the largest contributors to non-fatal health loss and worldwide disability (Friedrich, 2017). It is especially prevalent in individuals with chronic diseases such as cancer and is often associated with aggravated existing pain, lower quality of life, reduced treatment success (Doan et al., 2015; Friedrich, 2017), and poorer prognosis and higher mortality (Fann et al., 2008; Niedzwiedz et al., 2019; Sotelo et al., 2014). Major

depressive disorder (MDD) has also been associated with cognitive dysfunction (Lin et al., 2014) and functional impairment (Hybels et al., 2016), which significantly compounds the effect of cancer and further compromises the quality of life.

Despite the high susceptibility and prevalence of depressive disorders among cancer patients, depression is often underdiagnosed and understudied within this population. This is due in part to the overlap of depressive symptoms and common somatic symptoms in cancer, such as weight loss, sleep disturbances and fatigue, low

¹Department of Psychological Medicine, Faculty of Medicine, University of Malaya, Kuala Lumpur, Malaysia. ²Department of Psychology, Faculty of Behavioural Sciences, HELP University, Kuala Lumpur, Malaysia. ³Faculty of Medicine and Health Sciences, Universiti Tunku Abdul Rahman, Selangor, Malaysia. ⁴Department of Psychiatry and Mental Health, Hospital Putrajaya, Kuala Lumpur, Malaysia. ⁵Department of Psychiatry, Hospital Raja Permaisuri Bainun, Perak, Malaysia. ⁶Department of Psychiatry and Mental Health, Hospital Kuala Lumpur, Kuala Lumpur, Malaysia. ⁷Department of Psychiatry, Universiti Kebangsaan Malaysia Medical Centre, Kuala Lumpur, Malaysia. ⁸Department of Radiotherapy and Oncology, Universiti Kebangsaan Malaysia Medical Centre, Kuala Lumpur, Malaysia. ⁹Department of Clinical Oncology, Faculty of Medicine, University of Malaya, Kuala Lumpur, Malaysia. *For Correspondence: chong_guan@um.edu.my. Aya Ahmed Abousheishaa and Low Sue Yin have equal contribution in this study.