Efficacy and safety of galantamine in the treatment of Alzheimer?s Disease and Alzheimer?s Disease with cerebrovascular (Mixed Dementia) (GAL-DEM-402)

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Abstrak

Penelitian ini bertujuan menilai efektivitas dan keamanan Acetylcholinesterase Inhibitor Galantamine pada penderita Alzheimer dan Alzheimer?s Disease (AD) yang disertai dengan penyakit serebrovaskular (AD+CVD atau Mixed Dementia). Galantamine diberikan selama 6 bulan pada 28 penderita AD dan AD + CVD. Evaluasi kognitif dilakukan dengan menggunakan Mini Mental State Examination (MMSE), Restricted Reminding (RR), Neuropsycholgy Assessment, evaluasi fungsi global dengan Clinical Dementia Rating (CDR), evaluasi perubahan perilaku dengan Neuropsychiatric Inventory (NPI). Hasil penelitian pada 28 penderita AD dan AD + CVD, Galantamine memberikan perbaikan fungsi kognitif yang bermakna secara klinis maupun statistik setelah terapi 6 bulan dibandingkan data dasar awal (skor MMSE p<0.05, skor RR p<0.05, NA p<0.05), perbaikan fungsi global (CDR p<0.05) dan perbaikan gejala perilaku (NPI p<0.05). Efek samping ringan (32%) mual-mual dan anokresia terjadi saat titrasi dosis obat dan dapat diatasi dengan domperidone. Disimpulkan bahwa Galantamine efektif memberikan perbaikan fungsi kognitif, fungsi global, gejala perilaku dan aman serta dapat ditoleransi dengan baik. (Med J Indones 2007; 16:94-100).

<hr>This study was aimed to evaluate the efficacy and safety of Acetylcholinesterase Inhibitor Galantamine (Reminyl®) for patients with Alzheimer?s Disease (AD) and Alzheimer?s Disease with cerebrovascular Disease (AD+CVD or mixed Dementia). A 6-month open label observational study of Galantamine has been conducted on 28 patients with AD and AD+CVD patients. Primary endpoints were cognitive performance as assessed using the Mini Mental Scale Examination (MMSE), the Restricted Reminding Test), the Neuropsychology Assessment, the Clinical Dementia Rating (CDR) to assess global function and the Neuropsychiatric Inventory (NPI) to assess behavioral symptoms. Patients were also monitored for safety evaluation. Six month Galantamine group had a significant better outcome of cognitive performance, global function and behavioral symptoms compared with the baseline data as were assessed using the MMSE (p<0.05), the Restricted Reminding (p<0.05), the Neuropsychology Assessment (p<0.05), the CDR (p<0.05) and the NPI (p<0.05). Minimal adverse events (32%) were anorexia and nausea. It is concluded that Galantamine has a significant benefit to improve cognitive, global function, behavioral symptoms and only caused minimal adverse events. (Med J Indones 2007; 16:94-100).