Effectiveness and safety of citicoline in mild vascular cognitive impairment: the IDEALE study;

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BACKGROUND The studio di intervento nel decadimento vascolare lieve (IDEALE study) was an open multicenter Italian study, the aim of which was to assess the effectiveness and safety of oral citicoline in elderly people with mild vascular cognitive impairment.

METHODS The study was performed in 349 patients. The active or citicoline group was composed of 265 patients and included 122 men and 143 women of mean age 79.9 ± 7.8 years selected from six Italian regions. Inclusion criteria were age ≥ 65 years, Mini-Mental State Examination (MMSE) score ≥ 21, subjective memory complaints but no evidence of deficits on MMSE, and evidence of vascular lesions on neuroradiology. Those with probable Alzheimer's disease were excluded. The control group consisted of 84 patients, including 36 men and 48 women of mean age 78.9 ± 7.01 (range 67-90) years. Patients included in the study underwent brain computed tomography or magnetic resonance imaging, and plasma dosage of vitamin B12, folate, and thyroid hormones. Functional dependence was investigated by scores on the Activities of Daily Living (ADL) and Instrumental Activities of Daily Living (IADL) scales, mood was assessed by the Geriatric Depression Scale (GDS), and behavioral disorders using the Neuropsychiatric Inventory scale. Comorbidity was assessed using the Cumulative Illness Rating Scale. An assessment was made at baseline (T0), after 3 months (T1), and after 9 months (T2, ie, 6 months after T1). The main outcomes were an improvement in MMSE, ADL, and IADL scores in the study group compared with the control group. Side effects were also investigated. The study group was administered oral citicoline 500 mg twice a day throughout the study.

RESULTS MMSE scores remained unchanged over time (22.4 ± 4 at T0; 22.7 ± 4 at T1; 22.9 ± 4 at T2), whereas a significant difference was found between the study and control groups, both in T1 and in T2. No differences were found in ADL and IADL scores between the two groups. A slight but not statistically significant difference was found in GDS score between the study and control groups (P = 0.06). No adverse events were recorded.

CONCLUSION In this study, citicoline was effective and well tolerated in patients with mild vascular cognitive impairment. Citicoline activates biosynthesis of phospholipids in neuronal membranes, increases brain metabolism as well as norepinephrine and dopamine levels in the central nervous system, and has neuroprotective effects during hypoxia and ischemia. Therefore, citicoline may be recommended for patients with mild vascular cognitive impairment.