Efficacy and safety of Kami-guibi-tang for mild cognitive impairment: a pilot, randomized, double-blind, placebo-controlled trial

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Abstract

Background: Mild cognitive impairment (MCI) is considered an intermediate phase between normal aging and dementia. As the majority of cases of amnestic MCI (aMCI) progress to Alzheimer’s disease (AD), it is considered the prodromal stage of AD, and a treatment target for prevention of further cognitive decline. However, no medications have been shown to have symptomatic or preventive benefits in MCI. Kami-guibi-tang (KGT) is a traditional herbal formula used in Korean medicine to treat amnesia, which is reported to increase acetylcholine levels via activation of choline acetyltransferase. The objective of this study was to evaluate the efficacy and safety of KGT in patients with aMCI.

Method: This study was designed as a single-center, randomized, double-blind, placebo-controlled pilot study. Participants diagnosed with aMCI were randomized to receive either KGT or placebo granules for 24 weeks. The efficacy measure was a change in the Seoul Neuropsychological Screening Battery (SNSB) score. The safety measures included the occurrence of adverse events and abnormalities in vital signs and blood chemistry, electrocardiogram (ECG), and brain magnetic resonance imaging (MRI) findings.

Result: A total of 16 patients in the KGT group and 14 patients in the placebo group were investigated in the study. The mean score of Clinical Dementia Rating-Sum of Boxes (CDR-SB) significantly improved from 1.53 (0.64) points to 1.13 (0.62) points in the KGT group ($p = 0.010$), whereas it worsened from 1.61 (0.88) points to 1.75 (0.94) points in the placebo group. There was a significant difference in the CDR-SB scores between the two groups after the intervention ($p = 0.045$). The total SNSB-D scores and the scores in the memory domain after the treatment were significantly higher than the baseline values in the KGT group, but not in the placebo group. The frequency of adverse events was not significantly different between the two groups, and there were no abnormalities in vital signs or blood test, ECG, and brain MRI findings after the intervention.

Conclusion: KGT may provide a safe and effective treatment option for patients with aMCI. Further studies with a larger sample size are needed to validate the findings.