Modafinil Is Safe and Effective Treatment for MS-Related Fatigue

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Introduction

NEW YORK (Reuters Health) Feb 18 - Modafinil is an effective, well-tolerated treatment for the fatigue often experienced by multiple sclerosis (MS) patients, according to a report published in the February issue of the Journal of Neurology, Neurosurgery, and Psychiatry.

Modafinil, produced by West Chester, Pennsylvania-based Cephalon, Inc. under the name Provigil, is a novel wake-promoting agent used for excessive daytime sleepiness in patients with narcolepsy.

Dr. K. W. Rammohan, from Ohio State University in Columbus, and colleagues performed a phase II dose-escalation study of modafinil in 72 patients with MS-related fatigue.

Compared with symptom scores during a 2-week placebo run-in period, 2-week treatment with 200 mg/day of modafinil was associated with a significant improvement in multiple measures of fatigue. In contrast, 2-week treatment with 400 mg/day of modafinil was linked to an improvement in only one of these measures.

Neither dosing regimen was associated with serious adverse events, the authors note. Headache, nausea, nervousness, and asthenia were the most common adverse events.

"We really haven't had any good drugs for MS-related fatigue," Dr. Rammohan told Reuters Health. "Most of the drugs have been stimulants which have only worked in a minority of patients," he noted. Furthermore, "even when the stimulants have worked, they've only been partially effective."

Dr. Rammohan noted that "modafinil has caffeine-like properties, but it is not a stimulant." The drug "seems to be much more specific than stimulants in terms of the brain regions it activates," he said. "Because of this, modafinil doesn't seem to cause the anxiety that stimulants can produce," he added.

"For most patients, the 200 mg dose appeared to be optimal, but that doesn't mean the 400 mg dose is useless," Dr. Rammohan emphasized. "About 80% of patients said they felt best during the 200 mg/day phase, but the remainder rated the 400 mg/day phase as best," he explained.

"I don't think Cephalon is planning a phase III trial, because clinicians are already prescribing modafinil for their MS patients," Dr. Rammohan noted. "I wish they would though, because if it became an approved treatment, third party payers would be motivated to provide reimbursement."

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