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Comparative clinical trial of S-adenosylmethionine versus nabumetone for the treatment of knee osteoarthritis: an 8-week, multicenter, randomized, double-blind, double-dummy, Phase IV study in Korean patients.

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Abstract

BACKGROUND: S-adenosylmethionine (SAMe) has antiinflammatory and analgesic effects and has been reported to ameliorate the pain and dysfunction of osteoarthritis (OA). The metabolism of SAMe can be affected by geographic or ethnic factors. However, its efficacy and tolerability versus NSAIDs have not been reported in an Asian population.

OBJECTIVE: This study compared the efficacy and tolerability of SAMe 1200 mg/d and nabumetone 1000 mg/d in Korean patients with knee OA.

METHODS: This study was an 8-week, multicenter, randomized, double-blind, double-dummy, Phase IV clinical trial. Eligible patients were aged >18 years and had knee OA according to the clinical and radiologic criteria of the American College of Rheumatology, with a symptom duration of > or =3 months and with a baseline pain rating of >40 mm on a visual analog scale (VAS) or a pain rating on the VAS that was increased by >10 mm or 20% during the washout period compared with the screening visit. After a washout period of 2 weeks, patients with OA were randomly assigned to receive SAMe 1200 mg/d (400 mg TID) or nabumetone 1000 mg once a day in the evening for 8 weeks. The primary end point was the patient's assessment of pain intensity using a VAS at week 8, and the secondary end points were functional class, patient's global assessment of disease status, physician's global assessment of response to therapy, and the Western Ontario and McMaster Universities (WOMAC) index. Adverse events were assessed based on spontaneous reports by patients during interviews and by laboratory tests.

RESULTS: One hundred thirty-four patients, all Asians, were randomly allocated to 1 of 2 treatment groups: 67 patients (56 women, 11 men; mean [SD] age, 63.9 [8.2] years) received SAMe 400 mg TID, and 67 patients (60 women, 7 men; mean age, 62.1 [8.4] years) received nabumetone 1000 mg once daily for 8 weeks. An analysis of changes in pain intensity between weeks 0 and 8 found that both SAMe and nabumetone effectively reduced pain intensity from baseline in each group (mean [SD] change: SAMe, -13.0 [20.8] mm, $P < 0.001$; nabumetone, -15.7 [20.9] mm, $P < 0.001$), and the degree of decrease in pain intensity was not significantly different between groups. Secondary end points showed significant improvements from baseline to 8 weeks in both groups. The patient's global assessment of disease status, physician's global assessment of response to therapy, and WOMAC index scores were not significantly different between the groups. Use of acetaminophen as rescue medication did not differ significantly between the groups during weeks 0 to 4 (SAMe, 88.5% [54/61]; nabumetone, 81.3% [52/64]) or weeks 4 to 8 (SAMe, 79.5% [35/44]; nabumetone, 68.5% [37/54]). No significant differences were observed between the treatments in the proportions of patients with all adverse events (SAMe, 35.8% [24/67]; nabumetone, 31.3% [21/67]), drugrelated clinical or laboratory-determined adverse events (SAMe, 22.4% [15/67]; nabumetone, 25.4% [17/67]), or discontinuations due to any

adverse events (SAMe, 13.4% [9/67]; nabumetone, 10.4% [7/67]).

CONCLUSION: This study found no significant differences in pain relief or tolerability between treatment with SAMe or nabumetone over 8 weeks in Korean patients with knee OA.

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