

Diclofenac Sodium Gel Effective and Safe in Elderly Patients With Osteoarthritis: Presented at AGS

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WASHINGTON, DC -- May 2, 2008 -- Diclofenac sodium gel offers elderly osteoarthritis patients an effective and well-tolerated treatment option, according to research presented here at the 2008 Annual Scientific Meeting of the American Geriatrics Society (AGS).

This randomised, double-blind, vehicle-controlled, parallel-group, phase 3 study was conducted in patients with knee osteoarthritis diagnosed clinically using American College of Rheumatology (ACR) criteria and x-ray evidence (Kellgren-Lawrence grades 1 to 3).

All patients on trial had pain only in the target knee, requiring treatment with nonsteroidal anti-inflammatory drugs or acetaminophen, explained lead author F. Michael Gloth, MD, President, Victory Springs Senior Health Associates, and Associate Professor of Medicine, Division of Geriatric Medicine and Gerontology, Johns Hopkins University School of Medicine, Baltimore, Maryland.

The study compared the efficacy of topical diclofenac sodium gel 1% (DSG) versus vehicle in this patient population. The 12-week trial was conducted in 64 centres across the United States.

Dr. Gloth and his collaborator reported their findings in a poster presentation on May 1.

A total of 492 patients were randomised to DSG or vehicle, with 4 g applied to the target knee 4 times daily.

A total of 338 patients were younger than 65 years of age; 173 of these patients were randomised to DSG and 165 to the vehicle. Among the 154 patients who were aged 65 years or older, 81 were randomised to DSG and 73 to vehicle. However, the study was not powered to show differences in efficacy between age groups, noted Dr. Gloth.

Primary endpoints, which were measured at week 12, were the Western Ontario McMaster Osteoarthritis Index (WOMAC) pain score (range, 0-20), WOMAC physical function score (range, 0-68), and Global Rating of Disease.

A modified subpopulation was used for the efficacy analysis. Patients with pain on movement in the target knee that declined in the time interval between the screening and baseline visits were excluded from the efficacy analysis, in addition

to patients presenting with at least mild pain in the contralateral knee at baseline.

The study consisted of a screening period (days -14 to -7), followed by a 7-day washout period and a 12-week treatment period with evaluations at baseline and at weeks 1, 4, and 8, explained Dr. Gloth.

In patients aged younger than 65 years, the endpoints were measured in 86 patients receiving DSG and 85 patients receiving vehicle. Differences in decline between treatment groups in WOMAC pain scores and Global Rating of Disease scores from baseline to week 12 were not statistically significant in this age group. However, the difference in decline in WOMAC physical function scores was statistically significant (6.3, with $P < .05$).

In contrast, changes from baseline to week 12 in all 3 endpoints were not statistically significant within patients aged 65 years or older.

Interestingly, in the overall study population, differences between DSG and vehicle in mean change from baseline were significant for all 3 primary efficacy endpoints, noted Dr. Gloth. The WOMAC pain score at week 12 for DSG was 5.9 and 4.7 for vehicle ($P = .023$); the WOMAC physical function scores at week 12 were 17.5 for DSG and 11.8 for vehicle ($P = .003$); the Global Rating of Disease score at week 12 was 30.0 for DSG and 22.4 for vehicle ($P = .018$).

The investigators concluded that the overall study population of patients treated with DSG showed significant improvement for all 3 endpoints.

Regarding safety, the most frequent adverse events were headache, arthralgia, back pain, application site dermatitis, and pain. Adverse events rates were similar between age and treatment groups and were generally mild to moderate in severity, said the investigators.

Musculoskeletal and connective tissue disorders were more common among DSG-treated patients (<65 years, 24.3% DSG vs 19.4% vehicle; ≥65 years, 29.6% DSG vs 19.2% vehicle).

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