safety and upper gastrointestinal (UGI) tolerability, defined as ≥ 1 moderate to severe event of nausea, abdominal pain, or dyspepsia.

Results: 362 patients were randomized and received treatment; 81 discontinued prematurely (27 celecoxib, 32 naproxen, 17 placebo), and 286 remained in the efficacy population (121 celecoxib, 107 naproxen, 58 placebo). Patient ages ranged from 42 to 90 years, with means of 65.9, 64.1, and 63.9 years for celecoxib, naproxen, and placebo, respectively. Most patients were female (67%-68%). Mean duration of OA was 4.5, 4.8, and 4.6 years for celecoxib, naproxen, and placebo, respectively. No statistically significant differences were observed between celecoxib and naproxen in the Patient’s and Physician’s Global Assessment of Arthritis, the WOMAC OA Index scores, UGI tolerability, the Pain Satisfaction Scale, and the PHQ-9. UGI events, specifically, moderate or severe nausea, abdominal pain, and/or dyspepsia, were experienced by 16 patients (5/145 [3%] in the celecoxib group, 9/141 [6%] in the naproxen group, and 2/76 [3%] in the placebo group). No statistically significant differences in UGI tolerability were observed among the treatment groups.

Conclusions: Celecoxib 200 mg qd was as effective as naproxen 500 mg bid in the treatment of the signs and symptoms of OA of the knee in Asian American patients in a trial designed to evaluate this population.

483 EFFICACY AND TOLERABILITY OF CELECOXIB IN PATIENTS WITH OSTEOARTHRITIS WHO PREVIOUSLY DID NOT RESPOND TO OR DID NOT TOLERATE NAPROXEN AND IBUPROFEN: RESULTS FROM 2 IDENTICALLY DESIGNED RANDOMIZED TRIALS

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Purpose: The purpose of these 2 identically designed studies (Study 1, Study 2) was to compare the efficacy and safety of celecoxib 200 mg once daily (qd) with placebo in patients with osteoarthritis (OA) of the knee who previously were nonresponsive to or did not tolerate treatments with both naproxen and ibuprofen (prescription strength).

Methods: Both trials were 6-week randomized, double-blind, parallel group, placebo-controlled, multicenter concurrent trials. Patients aged ≥ 40 years with active symptomatic OA of the knee in a flare state and with an American College of Rheumatology functional capacity classification I to III at baseline visit were eligible for randomization to either celecoxib 200 mg qd or placebo in a 1:1 ratio. The previous treatment durations of naproxen (at least 750 mg/d) and ibuprofen (at least 1200 mg/d) were at least 4 weeks or failure due to lack of efficacy and for any duration if failure was due to lack of tolerability. The primary efficacy variable in both trials was the change in the Patient’s Assessment of Arthritis Pain using a 100-mm visual analog scale (VAS) at 6 weeks compared with baseline. The primary analysis compared each trial separately for an intent-to-treat population. Safety assessments included adverse events (AEs).

Results: In Study 1, 380 patients (mean age 60 years) were randomized. The majority of patients in the celecoxib and placebo groups were female (62.1% and 58.9%, respectively) and white (71.6% and 73.7%, respectively). At Week 6, the least squares mean (LSM) decrease from baseline in the Patient’s Assessment of Arthritis Pain (VAS) in the celecoxib group was significantly better than placebo (27.3 vs 14.9; P < 0.001). The proportion of patients reporting AEs was similar in the celecoxib and placebo groups (all causality: 25.0% and 25.1%, respectively; treatment-related: 6.4% and 5.3%, respectively). In Study 2, 388 patients (mean age 58 years) were randomized. The majority of patients in the celecoxib and placebo groups were female (71.3% and 64.7%, respectively) and white (51.8% and 56.5%, respectively). At Week 6, there was no significant difference (P = 0.183) between the celecoxib (28.0 mm) and placebo (24.6 mm) groups in the LSM change from baseline for the Patient’s Assessment of Arthritis Pain (VAS). The proportion of patients reporting AEs in the celecoxib and placebo groups, respectively, was 22.2% and 26.2% for all-causality AEs; 6.2% and 11.5% for treatment-related AEs.

Conclusions: These 2 identically designed, concurrent, controlled trials of celecoxib 200 mg qd vs placebo in patients with OA who previously did not respond to, or did not tolerate, treatment with naproxen and ibuprofen, showed mixed results. For the primary end point of the patient’s assessment of pain, celecoxib was better than placebo in one study but not in the other study. Celecoxib was well tolerated in both trials. These discordant results highlight the challenges inherent in treating OA of the knee in patients who failed previous nonsteroidal anti-inflammatory drugs.

484 UTILITY OF MECHANICAL ASSESSMENT IN KNEE OA MANAGEMENT

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Purpose: Biomechanical factors are known to be important in the pathogenesis of OA however their assessment in clinical practice has been limited due to need for sophisticated gait laboratory assessments. Clinical decision making can be enhanced by access and interpretation of useful information during the clinical encounter. Theoretically osteoarthritis management (both the selection of intervention and its intensity) can differ according to presenting clinical features and clinician guidance. The knowledge relating to the determination of what biomechanical features are helpful in guiding therapeutic decision making in osteoarthritis (OA) is limited. The purpose of this investigation was to determine if knee kinematic measurements were associated with other clinical factors associated with knee OA such as quality of life, functional performance and depression and therefore could be used in guiding clinical decision making in OA management.

Methods: We selected a consecutive series of participants with knee OA from the Osteoarthritis Chronic Care Program (OACCP). The OACCP is a chronic disease rehabilitation program which aims to increase functional capacity and manage co-morbidities, emphasising physical activity and healthy weight management. In the OACCP, each participant is assessed by a multidisciplinary team. The team provides an individualised intervention program in addition to education about OA and any identified co-morbidity. This approach enables realistic goal setting and optimal self-management. Data (including KOOS, DASS (Depression anxiety stress scale), EQSD quality of life measure, and functional performance) is collected from assessments at 0, 12, 26 and 52 weeks into the OACCP and recorded on an electronic platform provided. Key health outcomes for participants include the level of pain experienced in the affected joint(s) and the ability to function in activities of daily life. Three-dimensional (3D) knee kinematics data: flexion/extension, abduction/adduction and tibial internal / external rotation were recorded while walking on a treadmill. Data were recorded from each participant while walking on a treadmill at a typical walking speed. These data were then used to calculate mechanical parameters such as flexion/extension motion (mean amplitude 19.5°), and external rotation at the knee. A portable 3D knee kinematic model was used to evaluate the mechanical parameters (Table 1). The amplitude of the adduction/abduction (mean 9.2° ± 3.5°) was distributed among the patients with 15% being below, 16 (27%) within and 29 (48%) above the normal walking pattern (Figure 1). Limited flexion/extension was associated with presence of depression and anxiety (p<.01), reduced functional performance on the TUG (p=.02) and impaired quality of life (activities p<.01). Higher varus angle at initial contact was associated with impaired quality of life (activities p<.01).

Conclusions: A portable kinematic assessment identified a high frequency of mechanical abnormalities in a cohort of persons with knee OA. The validity of these kinematic measures is supported by association with impaired quality of life, reduced functional performance and depression. This information was useful in guiding tailored and individualised clinical care.