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Efficacy and safety of Aceclofenac in the treatment of osteoarthritis: a randomized double-blind comparative clinical trial versus Diclofenac – an Indian experience;

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ABSTRACT

Objective: Osteoarthritis is one of the most common forms of arthritis seen in primary care. Non-steroidal anti-inflammatory drugs (NSAIDs) play an important role in the management of osteoarthritis. However, gastrointestinal (GI) side effects limit their use. Cyclooxygenase-2 (COX-2) selective inhibitors exhibit better GI tolerability than conventional NSAIDs, but their cardiovascular safety is controversial. An NSAID with high efficacy, high GI tolerability and devoid of adverse cardiovascular effects is therefore a profile preferred by physicians. Aceclofenac is an anti-inflammatory and analgesic drug with preferential COX-2 inhibition. The objective of this study was to assess the efficacy and safety of aceclofenac in the treatment of osteoarthritis in an Indian population.

Research design and methods: The trial was controlled, comparative, randomized, and double-blind. The study included 247 patients (82 males and 165 females, 40–82 years), suffering from osteoarthritis. Patients were randomized to receive either aceclofenac (100 mg twice daily) or diclofenac (75 mg twice daily).

Main outcome measures: Clinical assessment was done at screening, randomization, and at 2 weeks, 4 weeks and 8 weeks of treatment by calculating Western Ontario MacMaster (WOMAC) scores, time taken to walk 100 feet, visual analogue scores for pain, investigator's assessment on a Likert scale and joint tenderness. Tolerability assessment was based on adverse events. Patient compliance was also assessed.

Results: Aceclofenac was found to be statistically superior to diclofenac in efficacy parameters of WOMAC scores, investigator's assessment and joint tenderness. Aceclofenac was found to be statistically superior to diclofenac in terms of epigastric discomfort, dyspepsia and abdominal pain. Compliance was also better with aceclofenac. The overall response of patients' osteoarthritis to aceclofenac was found to be statistically superior to diclofenac by both physician and patient.

Conclusions: Aceclofenac is an effective and well-tolerated drug in osteoarthritis in the Indian setting.