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The Effectiveness and Safety of Self - manufactured and Amlodipine in Indian Patients with Knee Osteoarthritis: A Prospective Randomised Open Label Study

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Objectives

To compare diacerein and diclofenac's efficacy and long-term effects in Indians with knee osteoarthritis (OA).

Design of the Study: After a washout period of one week from NSAIDs, patients were given diacerein, diclofenac, or a combination for 12 weeks with a 4 week follow-up to see how the drugs affected them over time. The change in the 100mm visual analog scale (VAS) score from baseline after a 20-meter walk was the primary efficacy end point. The percentage change in pain, stiffness, function, and total WOMAC scores from baseline served as the secondary efficacy end point. Consumption of acetaminophen, the Knee Society Score (KSS), and the Lequesne Impairment Index (LII).

Results: Of the 189 patients who were screened, 77 completed the study and 81 had painful knee OA. As measured by the 100mm VAS score (p0.05), WOMAC scores (p0.001), and LII, KSS, and acetaminophen consumption (p0.001) at 16 weeks, diacerein outperformed both diclofenac and the combination therapy, demonstrating the drug's carryover effect. All WOMAC scores in each group differed significantly from the baseline score in an intra-group comparison. The most common side effect of diacerein was diarrhea, but it was safe and well tolerated.

Conclusions: Diacerein is effective, safe, and long-lasting.

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Introduction

Osteoarthritis (OA) is the most prevalent joint disease among humans in India and the Western world. It affects synovial joints and is characterized by progressive articular cartilage loss, subchondral bone remodeling, synovial membrane inflammation, osteophyte formation, and subchondral bone scleroris [1, 2]. OA symptoms include varying degrees of joint pain, swelling, stiffness, and loss of mobility, all of which get worse as the disease progresses. Reduced joint load, regular aerobic, muscle-strengthening, and range-of-motion exercises, keeping weight at lower levels, a knee brace, medial patella taping, wedged soles, thermal modalities, patient education, and other non-pharmacological treatments for OA are some examples [3, 4]. Nonsteroidal anti-inflammatory drugs (NSAIDs), such as selective cyclooxygenase 2 (COX-2) inhibitors, opioids, and intra-articular steroids, are used topically and systemically as part of pharmacological treatment. There is a lot of research going on in the field of disease-modifying agents that can help cartilage repair because the majority of these are only meant to improve symptomatology. Some of these medications include diacerein, glucosamine, bisphosphonates, and cytokine inhibitors. It is now widely accepted that inflammation, cartilage breakdown, chondrocyte apoptosis, and bone remodeling in OA are all mediated by interleukin-1 (IL-1) [5]. Diacerein, a slow-acting anthraquinone derivative, is used to treat OA. Diacerein has been shown to stimulate the production of cartilage growth factors like transforming growth factor in vitro in addition to inhibiting IL-1

[10]. Diacerein has been shown to significantly reduce cartilage degradation when compared to untreated animals in OA animal models [6]. Diacerein does not harm the mucosa of the upper gastrointestinal tract because it does not inhibit prostaglandins. It has been shown to significantly reduce OA symptoms in clinical trials and to have structure-modifying effects in a three-year study. In 2006, Diacerein was introduced to the Indian market and aggressively promoted as the new miracle cure for OA. At the time of the drug's introduction, there was insufficient data on the Indian population. Additionally, there are no comparable changes in diacerein users' quality of life data. Diacerein and diclofenac's effects on quality of life, efficacy, adverse effect profile, and carryover effects in the Indian osteoarthritic population were therefore the focus of this study.

Discussion

Diacerein's safety and efficacy in comparison to standard treatment protocols has been the subject of research in the Western population. It has been demonstrated to be as effective as standard NSAIDs like diclofenac and to have carry-over effects. When diacerein is stopped, this means that fewer analgesics are needed. Because of its analgesic action and carry-over effect, diacerein has a small but significant advantage over NSAIDs, according to meta-analyses and systematic reviews. The purpose of this randomized open label study was to verify these outcomes in the Indian population [7].

with diacerein alone and those treated with diclofenac in combination, despite the fact that the dose in the combination group was half of what Zheng et al. used, indicating a significant additive effect of the two medications. Diacerein alone, on the other hand, had a greater carryover effect at 16 weeks. Similar to another study by Tang these findings are similar [8].

The WOMAC score, LII, KSS, and the consumption of acetaminophen as a rescue medication were among the secondary end-points that were evaluated.

Pain, stiffness, and function are the three sub-scores that make up the WOMAC score. Tested three diacerein doses (50, 100, and 150 mg per day) against a placebo and found that the 50 mg and 100 mg per day doses significantly improved the WOMAC score when compared to the placebo treatment. In these patients, however, they were unable to demonstrate any significant improvement in the VAS score. At week 16, there was a statistically significant change in the WOMAC score in this study. Diacerein had a higher WOMAC score than the group given both diacerein and diclofenac, but only at a 50% dose, which was better than diclofenac, indicating once more the carryover effect of diacerein. Both the total WOMAC score and the pain and function sub-score saw significant improvements. Diacerein scored significantly higher on both the total score and the stiffness and function sub-scores in the research conducted by Pelletier [9].

The KSS was utilized for the third assessment. This provides an impartial evaluation of the affected joint. The groups treated with diacerein alone or in combination with diclofenac had a statistically higher score than the group treated with diclofenac alone, as was the case with the previous assessment tools.

The compilation of the extent of use of rescue medication is yet another approach to evaluating a study's efficacy. In a number of studies, acetaminophen was used as a rescue medication. In their study with diacerein, Nyugen [10]. Found that when diacerein and tenoxicam were given to patients, the need for acetaminophen as a rescue medication was significantly lower than when either drug was used alone. At week 12, the current study found that patients taking diacerein needed significantly fewer acetaminophen tablets as rescue medication than those taking diclofenac. When the group taking diclofenac alone consumed more rescue medication than the group taking diacerein and diclofenac combined, this difference grew at week 16; yet again indicating a continuation of this drug's effect. WJ Zheng. made a similar observation.

Reactivation of tuberculosis (TB) in a participant in the diacerein arm of the study was the only major adverse event in the entire study. In previous studies, this adverse event was not mentioned in connection with diacerein therapy. TNF- and IL-1 have been shown to play a crucial role in the formation of granulomas and immune protection during the early stages of granulomatous infections like TB in a number of in vitro studies. IL-12 has also been shown to have significantly increased lytic activity against cells that have M. tuberculosis infection. After being stimulated with IL-2 or IL-12, purified NK cells from healthy volunteers or HIV-1-infected subjects were found to have increased lytic activity against M. tuberculosis-infected monocytes. We hypothesize that diacerein reduces the body's resistance to tubercle bacilli, particularly during the first two months of infection, by inhibiting other interleukins like IL-12 and IL-2 in addition to IL-1. Patient created TB following 2 months of founding diacerein treatment which additionally focuses to the way that diacerein could have diminished host's interleukin levels sufficiently low to reactivate TB. However, the measurement of IL levels is needed to confirm these findings.

Conclusion

By counting the empty blister packs and the remaining capsules or tablets, the patients' compliance was evaluated. They were only given a small number of extra tablets or capsules (the investigator kept track of this number). This made it easier to determine compliance. Diacerein compliance was 93%, diclofenac compliance was 95%, and combination compliance was 96% in all three groups. Even though our study did not use double blinding, the investigators blinded the assessor and the endpoint. This kind of study is called Test review (Imminent, randomized, open-name, dazed endpoint) and has been demonstrated to be all around as successful as twofold dazed examinations.

Long-term use of NSAIDs and analgesics is well-documented in the literature but there are few clinical studies on the use of NSAIDs in patients with OA for more than six weeks. It is known that nonsteroidal anti-inflammatory drugs (NSAIDs), particularly selective COX 2 inhibitors, increase the risk of thromboembolic conditions like stroke or myocardial infarction. In this context, it is essential to keep in mind that the majority of people with OA also have cardiovascular system disorders or at least risk factors, and that the European Agency for the Evaluation of Medicinal Products

(EAEM) and the Food and Drug Administration (FDA) recommend using NSAIDs at the lowest possible dose for the shortest amount of time. Contrarily, cardiovascular adverse events in diacerein-treated patients can be considered extremely uncommon. The diacerein group was not found to have a single cardiovascular adverse event in this study. In addition, larger studies that have been ongoing for three years have shown that diacerein, in comparison to placebo, slow down the progression of hip OA joint space narrowing. The carry-over effect of its analgesic activity and its potential role in delaying the progression of the disease make it an ideal choice for the majority of OA patients, despite the fact that its short-term analgesic potential may be equal to or slightly less than that of NSAIDs. When needed, this medication can be supplemented with standard NSAIDs. The use of NSAIDs and the associated side effects will be reduced as a result of this. In any case, patient training about the sickness and the helpful job of other non-pharmacological treatments should be underlined. In conclusion, this study's findings suggest that symptomatic knee OA can be effectively treated with diacerein. Additionally, it has an acceptable safety profile and a prolonged carryover effect.

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