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Clinicians' Preferences and Perspectives on the use of Polmacoxib for Managing Osteoarthritis

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Abstract

Objective: To gather clinicians' preferences and perspectives on managing osteoarthritis (OA) using polmacoxib in Indian settings.

Methodology: The cross-sectional study was conducted using a 23-item, multiple-response questionnaire to collect perspectives from specialists experienced in managing OA in routine clinical practice in India. The study included questions on current prescription practices, clinical observations, preferences, and experiences related to polmacoxib use in OA treatment. Descriptive statistics were used to analyze the data, and categorical variables were presented as percentages to provide a clear understanding of their distribution.

Results: The study included responses from 281 clinicians. Among them, 45% reported prescribing polmacoxib to 26–50% of their OA patients. Additionally, 48% indicated that polmacoxib is more commonly used in OA patients with comorbid conditions. According to 54% of respondents, the key advantages of polmacoxib include its novel tissue-specific transport mechanism that ensures sustained drug delivery to inflamed tissues, lack of COX-2 inhibition in calcium-rich tissues, and a favorable tolerability profile, particularly in terms of cardiovascular, renal, and gastrointestinal safety. Nearly 86% of participants highlighted several benefits of polmacoxib over etoricoxib, such as greater potency at a lower dose (2 mg/day versus 60–120 mg/day for etoricoxib), a lower risk of gastrointestinal side effects, and tissue selectivity. Approximately 86% of experts identified the unique features of polmacoxib as including a faster onset of symptom relief, convenience of once-daily dosing, the lowest recommended NSAID dose (2 mg/day), significantly improved gastrointestinal safety, and enhanced cardiovascular safety due to its tissue-selective COX-2 inhibition.

Conclusion: The study highlights the preference among Indian clinicians for the use of polmacoxib in OA management, especially in patients with comorbidities. Clinicians cited its tissue-selective action, low effective dose, improved gastrointestinal and cardiovascular safety, and once-daily dosing as key advantages. Overall, polmacoxib is perceived as a potent, well-tolerated alternative to traditional NSAIDs in clinical practice.

Introduction

Globally, osteoarthritis (OA) affects approximately 7.6% of the population, and its burden is projected to increase by 60% to 100% by 2050. [1,2] It is the most common joint disease, with a prevalence ranging from 22% to 39%, and is the second most frequent rheumatologic condition in India.[3] OA is more prevalent in women than in men, with the incidence rising significantly with age. Knee OA is a major contributor to mobility impairment, especially among females. Additionally, OA ranks as the 10th leading cause of nonfatal disease burden worldwide. [4,5]

The management of OA typically involves a combination of non-pharmacologic approaches, such as physical therapy and lifestyle modification, and pharmacologic interventions, including acetaminophen and nonsteroidal anti-inflammatory drugs (NSAIDs).[6,7] However, long-term NSAID use is associated with adverse gastrointestinal, renal, and cardiovascular effects, especially in elderly patients, highlighting the need for safer and more tolerable therapeutic alternatives and newer NSAIDs with improved safety profiles for OA treatment.[8]

Polmacoxib, a novel NSAID, has emerged as a promising therapeutic option for the management of OA. It is a selective cyclooxygenase-2 (COX-2) inhibitor that functions through a unique dual mechanism by inhibiting COX-2 and binding strongly to carbonic anhydrase (CA), an enzyme responsible for regulating pH balance in the body. [9] This dual mechanism is intended to reduce the cardiovascular risks typically associated with selective COX-2 inhibition, while potentially enhancing its anti-inflammatory efficacy at sites of joint inflammation. In conditions where both COX-2 and CA are co-expressed, polmacoxib's strong affinity for CA may modulate the extent of COX-2 inhibition. Studies have shown that its COX-2 inhibitory effect may vary depending on the concentration of CA in the local environment. Its favorable safety and efficacy profile supports its long-term use, particularly in patients with comorbid cardiovascular or gastrointestinal risks, where traditional NSAIDs may be contraindicated. [10,11]

Polmacoxib is approved for the treatment of OA in South Korea, Turkey, and across the Middle East and North Africa region, which includes 19 countries. Most recently, in 2023, it received approval from the Drug Controller General of India for the treatment of idiopathic primary OA affecting the hip and knee joints. [11,12] Despite the availability of several clinical studies, the clinician's perspectives in actual practice remain limited. This study is intended to gather expert opinion on the role of polmacoxib in the management of OA, evaluating their perspectives on its efficacy, safety, and practical utility in clinical settings.

Methodology

We carried out a cross-sectional study among clinicians across

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India who manage OA from June 2024 to December 2024. The study was conducted after receiving approval from Bangalore Ethics, an Independent Ethics Committee, which was recognized by the Indian Regulatory Authority, the Drug Controller General of India.

An invitation was sent to leading clinicians in managing OA in the month of March 2024 for participation in this Indian survey. About 281 clinicians from major cities of all Indian states, representing the geographical distribution, shared their willingness to participate and provide necessary data. The questionnaire booklet titled PRIMER (Polmacoxib Expert Perspective in Management of Osteoarthritis) was sent to clinicians who were interested in participating in this study. The questionnaire consisted of 23 items focused on current clinical experiences, prescription practices, treatment observations, and expert feedback related to OA management. Participants were allowed to skip any questions they did not wish to answer, with unanswered questions considered unattempt. Clinicians were instructed to complete the questionnaire independently without consulting colleagues. Written informed consent was obtained from all participants prior to the study.

Statistical Analysis

Data analysis was performed using descriptive statistics. Categorical variables were summarized as frequencies and percentages to illustrate their distribution. To facilitate better visualization of the data, bar graphs were created using Microsoft Excel 2019 (version 16.0.17928.20114).

Results

The study included 281 experts, of whom 70% reported that approximately 11% to 25% of patients with OA presenting to routine practice are under 50 years of age. More than half (55.52%) of the clinicians reported that 31% to 40% of patients with OA are men. About 51% of the clinicians opined that patients screened for OA more often belong to urban areas. According to 48% of the participants, the key factor contributing to the increasing disease burden of OA in India is a sedentary lifestyle. About 50% of the respondents stated that elderly patients pose unique challenges in OA management.

As reported by nearly half the participants (47.33%), lack of awareness is the most common limitation in OA treatment. Around 45% of the clinicians stated that about 26% to 50% of patients with OA have a higher BMI (overweight or obese), while 41% reported that 11% to 25% of patients have a higher BMI. According to 43% of the clinicians, about 26% to 50% of patients have knee OA, while 41% indicated that 11% to 25% of patients have knee OA. Around 42% of respondents opined that 11% to 20% of patients have hip OA. More than half (56.94%) of the participants reported that OA of the hand or shoulder is more common among elderly patients.

Approximately 56% of clinicians opined that older age is the most common attributing factor for OA in the majority of patients. As reported by 56% of the respondents, etoricoxib is the most commonly preferred NSAID. Nearly 52% of clinicians stated that paracetamol is prescribed in about 11% to 20% of OA patients. Approximately 43% of respondents reported that 26% to 50% of patients required additional NSAIDs or other analgesics for pain management, while an equal proportion indicated that 11% to 25% of patients required such additional medications. Nearly 41% of respondents each reported that gastrointestinal side effects from traditional NSAIDs occur in 11% to 25% and 26% to 50% of OA patients, respectively.

Approximately 44% of participants reported that 11% to 25% of patients with OA on NSAIDs experience cardiovascular or renal adverse effects. Nearly 46% of clinicians opined that the risk of gastrointestinal-related side effects is the drawback of COX-2 selective NSAIDs. According to 45% of respondents, about 26% to 50% of patients with OA are prescribed polmacoxib (Figure 1). Approximately 48% stated that patients with OA and comorbid conditions are more likely to use polmacoxib (Figure 2).

Approximately 54% of respondents reported that the advantages of polmacoxib include a novel 'tissue-specific' transport mechanism designed to deliver sustained levels of the drug to inflamed tissues, minimal COX-2 inhibition in calcium-rich tissues, and a better overall tolerability profile (cardiovascular, renal, and gastrointestinal) (Table 1). According to 86% of participants, the advantages of polmacoxib over etoricoxib are its higher potency at a lower dose (2 mg/day of polmacoxib versus 60-120 mg/day of etoricoxib), lower risk of gastrointestinal-related events, and the fact that etoricoxib lacks tissue selectivity (Table 2).

Polmacoxib has high tissue selectivity, whereas naproxen, ibuprofen, and diclofenac have low tissue selectivity. Additionally, polmacoxib offers improved cardiovascular safety, while naproxen, ibuprofen, and diclofenac are associated with a higher risk of gastrointestinal events. These advantages of polmacoxib over the other NSAIDs were reported by 87% of clinicians. The majority of respondents (85.77%) reported that the unique features of polmacoxib include quicker onset of relief from OA symptoms, a convenient

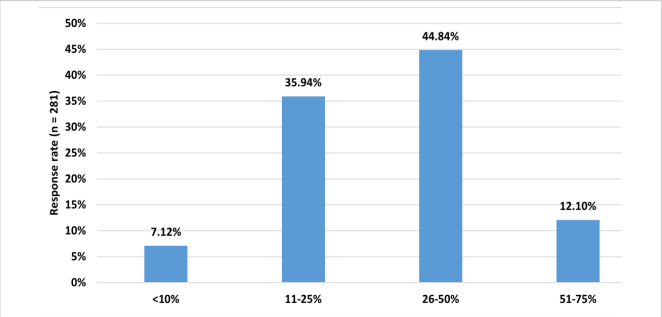

Figure 1: Distribution of responses to the proportion of patients with OA prescribed polmacoxib

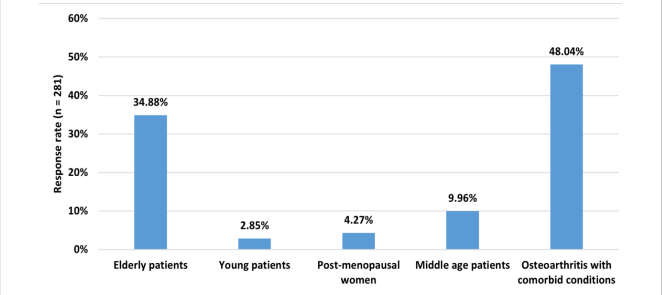

Figure 2: Human microbiota composition in different locations (oral cavity, respiratory tract, skin, gut, and vagina).

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Table 1: Distribution of responses to the advantages of polmacoxib in the management of OA

Advantages	Response rate (n = 281)
Provides a novel 'tissue-specific' transport mechanism that is designed to deliver sustained levels of drug to inflamed tissues	19.22%
Does not inhibit COX-2 in CA-rich tissues	9.61%
Better tolerability profile (CV renal and GI tolerability profile)	17.44%
All of the above	53.74%

Table 2: Distribution of responses to the advantages of polmacoxib over etoricoxib

Advantages	Response rate (n = 281)
Polmocoxib is more potent 2 mg /day of polmacoxib versus 60-120mg /day of etoricoxib	6.05%
The risk of GI-related events is less with Polmacoxib	3.91%
Etoricoxib is non-tissue-selective	4.27%
All of the above	85.77%

Table 3: Distribution of responses to the unique features of polmacoxib

Features	Response rate (n = 281)
Quicker onset of relief from the signs & symptoms of OA	2.49%
Convenient once-a-day dosing regimen, unlike most other NSAIDs	1.42%
The recommended dose is only 2 mg/day dose the lowest dose among the NSAIDs	2.49%
Significantly improved GI safety in comparison with other NSAIDs	1.07%
Polmacoxib's tissue-selective COX-2 inhibition mechanism provides enhancement of cardiovascular safety over currently available NSAIDS	6.76%
All of the above	85.77%

once-daily dosing regimen, the lowest recommended dose among NSAIDs (2 mg/day), significantly improved gastrointestinal safety, and enhanced cardiovascular safety due to its tissue-selective COX-2 inhibition mechanism (Table 3).

Discussion

The study highlights evolving clinical practices in OA management across India, with a shift towards individualized treatment, especially in younger, urban, and comorbid populations. The present study showed that a significant proportion of clinicians prescribed polmacoxib to their OA patients. Similarly, a cross-sectional study conducted in routine clinical settings across India reported that many clinicians had incorporated polmacoxib monotherapy into their treatment protocols, reflecting its growing acceptance and integration into standard OA management.[13] Hussain et al., in their review of polmacoxib, concluded that this drug presents a promising therapeutic option for the management of OA and other inflammatory conditions.[10]

In the current study, clinicians reported that patients with OA and comorbid conditions are more likely to be prescribed polmacoxib, highlighting its perceived safety profile in complex patient subsets. Supporting this observation, Sinha et al. compared polmacoxib 2 mg to celecoxib 200 mg in patients with idiopathic OA of the hip or knee and concluded that polmacoxib is non-inferior to celecoxib in terms of safety and efficacy, making it a viable alternative, particularly for patients where traditional NSAIDs may be contraindicated.[14] Similarly, Lee et al. reported that polmacoxib 2 mg is relatively well tolerated and may be preferable for pain relief in OA patients due to its reduced gastrointestinal side effects compared to traditional NSAIDs.[15]

The current study respondents highlighted several key advantages of polmacoxib, emphasizing its unique tissue-specific transport mechanism, which enables sustained delivery of the drug to inflamed tissues. Studies have also demonstrated that erythrocytes contribute to the tissue-specific delivery of polmacoxib, transporting the drug preferentially to CA-deficient inflamed tissues. While in circulation, polmacoxib remains bound to CA within erythrocytes, which helps maintain low systemic exposure and allows focused release at the sites of inflammation. This targeted delivery is believed to maximize therapeutic benefit in osteoarthritic joints while minimizing adverse effects on the cardiovascular, renal, and gastrointestinal systems. [16,17,11]

A comprehensive review has further supported its superior tolerability profile, attributing this to its targeted delivery and selective action at sites of inflammation. These properties position polmacoxib as a promising alternative to conventional NSAIDs, offering meaningful improvements in safety and efficacy.[9] Studies have shown that erythrocytes provide a tissue-specific transport mechanism delivering sustained levels of the drug to CA-deficient inflamed tissues. This, in turn, helps maintain low systemic exposure as polmacoxib is transported in a combined state with CA within the erythrocytes. Thus, polmacoxib is believed to offer maximum effectiveness in inflamed osteoarthritic joints while reducing its effects on the cardiorenal system or the gastrointestinal tract. [16]

In the present study, polmacoxib demonstrated several advantages over etoricoxib. Notably, it is more potent, with an effective dose of just 2 mg/day compared to the 60–120 mg/day typically required for etoricoxib. Additionally, polmacoxib is associated with a lower risk of gastrointestinal-related adverse events. Lee et al. reported that polmacoxib 2 mg was well tolerated and showed superior efficacy to placebo and non-inferiority to celecoxib after six weeks of treatment in patients with OA.[15] Their findings support the potential of polmacoxib as an effective analgesic with a reduced GI side effect profile. Further reinforcing its safety profile, Easwaran et al. demonstrated that polmacoxib does not significantly affect blood pressure or heart rate, and clinical trials have not reported an increase in cardiovascular events, highlighting its favorable cardiovascular safety profile.[11] Despite NSAIDs, chondroitin sulfate supplementation and intra-articular injections of hyaluronic acid have also been used in the management of OA for their effectiveness on pain symptoms and joint mobility.[18]

The present study provides valuable insights into the use of polmacoxib in the management of OA within Indian clinical practice. These findings hold significant relevance, given the limited published literature on polmacoxib use in the Indian context. One of the major strengths of the study is the use of a structured and validated questionnaire. However, several limitations must be acknowledged. The study relies solely on expert opinion, which may introduce inherent biases due to variations in individual clinical experience

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and preferences. Additionally, the study methodology may not fully capture emerging trends or newly evolving clinical evidence. The absence of direct patient data limits the ability to correlate clinician-reported findings with real-world clinical outcomes. These limitations should be considered when interpreting the results. Future research should include prospective observational studies or real-world evidence to validate clinician perceptions and provide a more comprehensive understanding of polmacoxib's role in OA management.

Conclusion

The study findings indicate that a substantial proportion of clinicians favor the use of polmacoxib, particularly in patients with comorbid conditions, citing its favorable efficacy and safety profile. The key advantages identified include its tissue-selective mechanism, lower effective dose, improved gastrointestinal and cardiovascular tolerability, and convenient once-daily dosing. These findings suggest that polmacoxib is perceived as a potent and well-tolerated therapeutic option, offering meaningful benefits over traditional NSAIDs in routine clinical practice.

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Author contributions

Both authors have contributed equally to the development of the manuscript.

Disclosure of compliance with ethical principles

The study was conducted after receiving approval from Bangalore Ethics, an Independent Ethics Committee, which was recognized by the Indian Regulatory Authority, Drug Controller General of India.

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