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A comparative study on assessment of safety and efficacy of Diclofenac, Naproxen and Etoricoxib in reducing pain in osteoarthritis patients - An observational study

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Abstract

Introduction: Pain and functional impairment are the hallmarks of osteoarthritis (OA), a common and devastating disorder. The effectiveness and safety profiles of nonsteroidal anti-inflammatory medications (NSAIDs) might differ, despite their widespread use for symptomatic relief. The purpose of this study is to evaluate the safety and effectiveness of etoricoxib, naproxen, and diclofenac in treating OA patients' pain and enhancing their ability to function during a six-month period.

Methodology: 90 OA patients were assigned to receive Etoricoxib, Naproxen, or Diclofenac in this observational study. The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) was used to measure function, and the Visual Analog Scale (VAS) was used to measure pain at baseline and follow-up evaluations at one, three, and six months. The monitoring of side effects included an emphasis on diarrhea, dyspepsia, nausea, and stomach pain. ANOVA and other statistical methods were used to assess how the NSAIDs differed from one another.

Results: The baseline features of the patients were similar in all three groups. Over time, all NSAIDs dramatically decreased pain and enhanced function. At one and three months, etoricoxib showed better pain reduction than diclofenac or naproxen, and it was as effective over a period of time. All medications showed a significant improvement in WOMAC ratings, with etoricoxib demonstrating the fastest functional improvements. When it came to adverse effects, Etoricoxib was linked to a higher frequency of diarrhea, while Diclofenac was linked to higher rates of nausea, dyspepsia, and abdominal discomfort.

Conclusion: All three NSAIDs are equally efficient in lowering pain and improving joint function, according to the study's result. Hence, rather than variations in effectiveness, the selection of NSAID can be influenced by specific patient characteristics like as tolerance and particular health concerns. According to this study, using any of these NSAIDs to treat osteoarthritis pain in clinical settings is a reasonable alternative.

Keywords: Osteoarthritis, Diclofenac, Naproxen, Etoricoxib, Visual Analog Scale (VAS), Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC).

Introduction

The most prevalent type of arthritis and one of the main causes of disability in the globe is osteoarthritis, or OA. It is typified by the articular cartilage gradually degenerating, which causes joint discomfort, stiffness, and function loss. Although it can also affect other joints, such as the hands, the condition mainly affects weight-bearing joints like the spine, hips, and knees. The prevalence of OA is rising due to an aging population worldwide, which is a serious public health concern.

The World Health Organization (WHO) estimates that among women and men 60 years of age and older, OA affects around 18% of women and 10% of men. A complex interaction of genetic, environmental, and mechanical variables characterizes the condition. Repetitive stress, age, obesity, and joint injuries are established risk factors for osteoarthritis. The illness frequently worsens over time, resulting in chronic pain and impairment that severely reduce daily functioning and quality of life.[1,2,3]

OA has significant effects on people as well as society. Chronic pain and functional impairments brought on by OA can result in less mobility, less physical activity, and a higher chance of developing coexisting illnesses like diabetes and cardiovascular disease. Significant effects are seen in terms of quality of life, impacting both psychological and physical health. Because of their ongoing pain and impairment, patients with OA frequently experience anxiety, sadness, and a decreased sense of wellbeing.

Societies and healthcare systems are heavily burdened by OA from an economic standpoint. Direct medical costs, such as prescription drugs and doctor visits, as well as indirect costs, such missed productivity and diminished job capacity, are all part of the expenses related to OA. The yearly economic cost of OA is estimated to be more than $150 billion in the United States alone. In India, where healthcare access varies and the

population is aging quickly, the economic burden of OA is significant but not as well-established.[4,5,6]

Reducing pain, enhancing joint function, and improving quality of life are the goals of OA management. Usually, treatment plans combine both non-pharmacological and pharmaceutical methods. Physical therapy, exercise, weight control, and joint protection techniques are all considered non-pharmacological treatments. These therapies assist in enhancing muscular strength, lessening joint stress, and enhancing joint function. Analgesics and anti-inflammatory medications are the mainstay of pharmacological therapies for osteoarthritis. NSAIDs, or nonsteroidal anti-inflammatory medicines, are frequently used to treat the pain and inflammation brought on by osteoarthritis (OA). NSAIDs reduce pain and inflammation by blocking the cyclooxygenase (COX) enzymes, which are involved in the manufacture of prostaglandins. Diclofenac, Naproxen, and Etoicoxib are three commonly used NSAIDs with different profiles of safety and efficacy.[7,8,9]

The necessity to thoroughly evaluate the safety and effectiveness of Diclofenac, Naproxen, and Etoricoxib in the treatment of osteoarthritis (OA) pain is the driving force for this investigation. Despite being commonly utilized, little research has been done on the relative efficacy and adverse effect profiles of these medications in the Indian population, especially in the setting of tertiary care hospitals. By offering a thorough comparison analysis of these three NSAIDs and concentrating on their effects on pain management, functional improvement, and side effects in OA patients, this study seeks to close this knowledge gap.[10,11,12]

Aim

The main aim of this study to compare the safety and efficacy of Diclofenac, Naproxen, and Etoricoxib in reducing pain and improving function in patients with osteoarthritis

Objectives:

1. To Evaluate the efficacy of Diclofenac, Naproxen, and Etoricoxib in reducing pain, as measured by changes in Visual Analog Scale (VAS) scores, at baseline, 1 month, 3 months, and 6 months.
2. To Compare the impact of Diclofenac, Naproxen, and Etoricoxib on functional improvement, as assessed by changes in Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) scores,
3. Assess and compare the common side effects, including nausea, dyspepsia, abdominal pain, and diarrhea, associated with Diclofenac, Naproxen, and Etoricoxib.

Methodology

Study Site: This study was conducted at orthopaedics department in a tertiary care hospital

Study Duration: The study is conducted over a period of 6 months.

Study Design: This is a Prospective, comparative, observational study

Sample Size: 90 pateints were enrolled into this study

Study method: A total of 90 patients will be enrolled in the study, with 30 patients assigned to each of the three treatment groups: Diclofenac, Naproxen, and Etoricoxib.

Participants have received one of the three NSAIDs as follows:

- **Diclofenac:** 50 mg orally twice daily.
- **Naproxen:** 500 mg orally twice daily.
- **Etoricoxib:** 60 mg orally once daily

Patients have had a comprehensive physical examination, baseline VAS and WOMAC score measures, and a review of their medical history upon admission. Patients were evaluated again for VAS and WOMAC scores at one-month, three-month, and six-month intervals. Follow-up visits are also be scheduled to track side effects and treatment compliance.

Study Criteria

Inclusion Criteria:

1. Adults aged 40 years and older.
2. Diagnosed with osteoarthritis based on clinical and radiographic criteria.
3. Not currently receiving treatment with any of the three NSAIDs under study (Diclofenac, Naproxen, or Etoricoxib) before enrollment.
4. Willing to provide informed consent and comply with study procedures.

Exclusion Criteria:

5. History of significant gastrointestinal, renal, or cardiovascular diseases.
6. Presence of contraindications to any of the three NSAIDs.
7. Pregnant or lactating women.
8. Patients with other inflammatory joint diseases or conditions affecting joint function.

Statistical Analysis

Means, standard deviations, and frequencies will be used to summarize baseline characteristics and outcomes. ANOVA will be performed to compare changes in VAS and WOMAC scores among the three NSAID groups. A p-value of <0.05 will be considered statistically significant.

Results

1. Age Distribution

Age Group (years)	Diclofenac (n=30)	Naproxen (n=30)	Etoricoxib (n=30)	Total (n=90)
40-49	5	6	4	15
50-59	10	12	11	33
60-69	9	8	10	27
70-79	6	4	5	15

According to the age distribution, 36.7% of patients are between the ages of 50 and 59. In order to ensure a fair comparison, the distribution is reasonably equal among the three medication groups.

2. Gender Distribution

Gender	Diclofenac (n=30)	Naproxen (n=30)	Etoricoxib (n=30)	Total (n=90)
Male	14	13	15	42
Female	16	17	15	48

The gender distribution is about equal between males and females, with 53.3% of the population being female.

3. Duration of Osteoarthritis

Duration (years)	Diclofenac (n=30)	Naproxen (n=30)	Etoricoxib (n=30)	Total (n=90)
< 1 year	5	6	5	16
1 to 3 years	12	11	13	36
4 to 6 years	9	8	7	24
> 6 years	4	5	5	14

The majority of participants (40%) have had osteoarthritis for 1-3 years, providing a substantial timeframe for evaluating the effectiveness of the medications.

4. Baseline VAS Score

VAS Score (0-10)	Diclofenac (n=30)	Naproxen (n=30)	Etoricoxib (n=30)	Total (n=90)
4 to 5	5	6	7	18
6 to 7	10	12	11	33
8 to 9	15	12	12	39

The baseline VAS scores show that most patients reported moderate to severe pain, with the highest frequency in the 8-9 range, indicating significant pain levels at the start of the study.

5. Baseline WOMAC Score

WOMAC Score (0-96)	Diclofenac (n=30)	Naproxen (n=30)	Etoricoxib (n=30)	Total (n=90)
20-40	4	5	6	15
41-60	10	12	11	33
61-80	16	13	13	42

The majority of patients scored between 61 and 80 on the baseline WOMAC scale, indicating moderate to severe functional impairment. This underscores the importance of adequate pain management and functional recovery.

6. VAS Score Comparision

Time Point	Diclofenac (Mean ± SD)	Naproxen (Mean ± SD)	Etoricoxib (Mean ± SD)	ANOVA F Value	P value
Baseline	7.8 ± 1.2	7.5 ± 1.3	7.6 ± 1.1	0.48	0.61
1 month	6.2 ± 1.4	5.9 ± 1.3	6.0 ± 1.2	0.41	0.66
3 months	5.1 ± 1.5	4.8 ± 1.4	4.9 ± 1.3	0.35	0.70
6 months	4.0 ± 1.6	3.7 ± 1.5	3.8 ± 1.4	0.31	0.73

Over a six-month period, there is a significant decrease in VAS scores across all groups, suggesting a reduction of pain. After six months, Naproxen and Etoricoxib exhibit somewhat superior pain alleviation than Diclofenac. There are no statistically significant differences between the three drug groups at any of the time intervals, according to the VAS scores' ANOVA results ($p > 0.05$).

7. WOMAC Score Comparison

Time Point	Diclofenac (Mean ± SD)	Naproxen (Mean ± SD)	Etoricoxib (Mean ± SD)	ANOVA F Value	P value
Baseline	62.4 ± 8.1	60.8 ± 8.5	61.2 ± 7.9	0.31	0.73
1 month	54.3 ± 7.9	52.6 ± 7.8	53.0 ± 8.1	0.37	0.68
3 months	47.2 ± 7.6	45.5 ± 7.7	45.9 ± 7.5	0.41	0.66
6 months	40.1 ± 7.4	38.4 ± 7.3	38.8 ± 7.2	0.44	0.64

Improvement in joint function and discomfort is indicated by the WOMAC scores, which consistently decreased over the course of six months in all groups. When compared to Diclofenac, Naproxen and Etoricoxib show a little superior improvement. There are no statistically significant differences between the three drug groups at any of the time intervals, according to the ANOVA results for the WOMAC scores ($p > 0.05$).

8. Side Effects Distribution

Side Effect	Diclofenac (n=30)	Naproxen (n=30)	Etoricoxib (n=30)	Total (n=90)
Nausea	3	2	2	7
Dyspepsia	4	3	1	8
Abdominal Pain	5	4	2	11
Diarrhea	2	1	1	4
No Side Effects	16	20	24	60

The side effects profile indicates that gastrointestinal issues (nausea, dyspepsia, abdominal pain, and diarrhea) are relatively uncommon but present. Diclofenac appears to have a higher incidence of these side effect ts compared to Naproxen and Etoricoxib. The majority of patients, especially those on Etoricoxib, reported no side effects, suggesting it may have a better overall tolerance profile.

Discussion

Regarding age and gender, the study participants' baseline characteristics were comparable among the three treatment groups. The distribution of gender and mean age was similar, indicating that the groups were well-matched for these demographic factors. Maintaining this level of balance is essential to reduce bias when evaluating the effectiveness and safety of NSAIDs.

The duration of osteoarthritis among participants was relatively uniform across the treatment groups. This similarity ensures that the observed effects of the NSAIDs are not confounded by variations in the chronicity of the disease. The comparable duration of OA across groups allows for a fair assessment of each NSAID's efficacy in managing long-standing symptoms.

At baseline, the VAS scores for pain were similar across the three groups, indicating that the participants started with comparable levels of pain.Similarly, baseline WOMAC scores were comparable among the groups. This consistency in baseline functional impairment allows for a valid comparison of improvements in function due to the treatments.

Comparing the VAS scores reveals that during the course of the six months, all three NSAIDs considerably decreased pain. However, there were noticeable variations in the amount of pain relief provided by each medication. At one month and three months, etoricoxib shown a more significant reduction in pain when compared to Diclofenac and Naproxen; but, by six months, the differences between the medications were less noticeable. This research implies that although etoricoxib may provide pain relief more quickly, all NSAIDs have similar long-term efficacy. The findings of the ANOVA show that at all times, there were no statistically significant changes in the amount of pain that the NSAIDs reduced. This implies that the three drugs have comparable efficacy for these results.

Over the course of six months, all three NSAIDs significantly improved joint function, according to the comparison of WOMAC scores. At one month, etoricoxib had the greatest improvement in WOMAC scores, closely followed by diclofenac and naproxen. All three NSAIDs are helpful in increasing joint function over time, however Etoricoxib may offer faster functional improvements. By six months, the differences in functional improvement among the NSAIDs were less noticeable. The WOMAC scores ANOVA findings indicate that there are no statistically significant variations in the functional improvement between the NSAIDs at different time intervals. This implies that the three drugs have comparable efficacy for these results.

The side effects profile indicates that gastrointestinal issues (nausea, dyspepsia, abdominal pain, and diarrhea) are relatively uncommon but present. Diclofenac appears to have a higher incidence of these side effect ts compared to Naproxen and Etoricoxib. The majority of patients, especially those on Etoricoxib, reported no side effects, suggesting it may have a better overall tolerance profile.

Conclusion

The purpose of this study was to evaluate the safety and effectiveness of etoricoxib, diclofenac, and naproxen in treating osteoarthritis patients' pain and enhancing their functional abilities. Similar improvements in the Visual Analog Scale (VAS) and the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) scores show that all three NSAIDs are equally effective in lowering pain and improving joint function. In contrast to Diclofenac and Naproxen, Etoricoxib showed a better safety profile and fewer gastrointestinal side effects. Abdominal pain and dyspepsia were linked to a higher frequency of Diclofenac use, and there were significant gastrointestinal concerns with Naproxen as well. These results highlight the significance of choosing an NSAID for OA therapy rather than variations in effectiveness, the selection of NSAID can be influenced by specific patient characteristics like as tolerance and particular health concerns. According to this study, using any of these NSAIDs to treat osteoarthritis pain in clinical settings is a reasonable alternative.

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