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RESEARCH ARTICLE
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A COMPARATIVE STUDY TO EVALUATE THE SAFETY & EFFICACY OF ETORICOXIB AND PIROXICAM IN PHARMACOTHERAPY OF OSTEOARTHRITIS IN TERTIARY CARE HOSPITAL KANPUR

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Abstract

Background: Osteoarthritis (OA) is a common degenerative joint disorder characterized by chronic pain and functional limitation. This study aimed to compare the efficacy, safety, and tolerability of Etoricoxib and Piroxicam in patients with symptomatic OA.

Methods:

A prospective, open-label, longitudinal study was conducted at Rama Medical College, Kanpur, involving 284 patients randomized equally into two groups: Group A (Etoricoxib) and Group B (Piroxicam). Clinical outcomes were assessed using the Visual Analogue Scale (VAS) and Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) at baseline, Day 7, and Day 15. Safety evaluation included CRP levels, liver and renal function tests, complete blood count, and monitoring of adverse effects.

Results: Both groups showed significant improvement in VAS and WOMAC scores over 15 days. However, Group A demonstrated significantly greater reductions at Day 7 and Day 15 ($p < 0.01$), indicating superior symptom control. CRP levels and organ function tests remained comparable between the groups ($p > 0.05$), suggesting similar safety profiles. Adverse effects were significantly lower in Group A, particularly for gastric discomfort ($p = 0.005$) and vomiting ($p = 0.044$), with a lower overall incidence of side effects (mean 5.42 ± 2.71 vs. 7.58 ± 5.73).

Conclusion: Etoricoxib provided more effective and better-tolerated short-term symptom relief in osteoarthritis patients compared to Piroxicam, with a comparable safety profile. These findings support its use as a preferable option for short-term management of OA symptoms.

Keywords: Osteoarthritis, Etoricoxib, Piroxicam, VAS, WOMAC, Safety, Adverse effects, NSAIDs.

Introduction: Osteoarthritis (OA) is the most prevalent form of arthritis globally and is often described as a degenerative joint disorder resulting from progressive cartilage deterioration. Although structural deformities in interphalangeal joints have been recognized since the 18th century, OA

remains primarily a mechanical and degenerative disease, distinguishing it from inflammatory arthritis.[1] It is a leading cause of disability worldwide, ranking among the top contributors to years lived with disability, particularly in older adults. Recent estimates indicate that more than 600 million individuals are affected globally, with prevalence expected to rise due to aging populations and increasing obesity rates [2].

OA ranks among the top ten most disabling diseases in developed nations, impacting approximately 4-6% of the adult population and is recognized as one of the top five chronic diseases in India. The primary aim of OA treatment is to alleviate pain and enhance functionality, as there is currently no cure for the condition; however, some treatments may help slow its progression. Treatment often involves a combination of physical therapy, medication, surgery.[3]

World Health Organization (WHO), OA affects approximately 18% of women and 10% of men aged 60 and older. The condition is characterized by a complex interplay of genetic, environmental, and mechanical factors. Established risk factors for osteoarthritis include repetitive stress, aging, obesity, and joint injuries.[4]

Osteoarthritis (OA) significantly affects quality of life, impacting both psychological and physical health.[5] Pharmacological treatments for OA mainly focus on pain relief and inflammation control. Nonsteroidal anti-inflammatory drugs (NSAIDs) are commonly prescribed to manage OA symptoms. They work by inhibiting cyclooxygenase (COX) enzymes, which are key in the production of prostaglandins that cause pain and inflammation.[6]

The impetus for this investigation lies in the need to comprehensively assess the safety and efficacy of Diclofenac, Naproxen, and Etoricoxib in managing osteoarthritis (OA)-related pain. Although these NSAIDs are widely used, there is limited comparative research evaluating their effectiveness and adverse effect profiles within the Indian population, particularly in the context of tertiary care hospitals.[7]

Symptoms of Osteoarthritis.[8]

Typical clinical features of osteoarthritis include pain during or after joint movement, particularly as physical stress is applied. Patients often experience joint stiffness-especially first thing in the morning or after prolonged rest periods. The affected joint may feel tender when touched lightly, and surrounding soft tissues can become swollen due to inflammation. Reduced flexibility is common, manifesting as difficulty achieving full range of motion in the joint. Additionally, sufferers may report a grating or crackling sensation (crepitus) when the joint moves or bears load.

Material and methods:

The study was conducted in the Department of Pharmacology in collaboration with the Department of Orthopedics, Rama Medical College, hospital & Research Centre Mandhana Kanpur Uttar Pradesh.

Study design: The study was open labeled, longitudinal study.

Sample size: total samples of 284 patients of osteoarthritis.

Inclusion criteria;

- Patients with symptomatic osteoarthritis of both genders, between age 30 to 70 years who fulfill the Western Ontario and McMaster universities osteoarthritis index (WOMAC).
- Patients having symptomatic Osteoarthritis either as a new case or as an old case following discontinuation of treatment with NSAIDS or other analgesic medications with a washout period of one week
- All these patients were examined as per the baseline criteria were be included in the study if they fit this criterion.
- Patients with a confirmed diagnosis of Osteoarthritis based on digital X-ray imaging.

Exclusion criteria;

- Smokers/ alcoholics

- Pregnant & lactating women or willing to get pregnant soon.
- Patients on steroid therapy, history of chronic infections like TB, leprosy, recent trauma, surgery and mental retardation.
- Patients with liver diseases, kidney diseases, cardiac problems, hypertension, severe anemia and neurological disorders.
- Current drug intake like anti-inflammatory and any DMARDs like Methotrexate, Azathioprine, Sulfasalazine and Hydroxychloroquine.

Result:

Table No 1: Comparison of gender among group A & B

		Groups				Total		p- value
		Group A		Group B				
		No.	%	No.	%	No.	%	
S Gender	Female	63	44.37	61	42.96	124	43.66	0.812 Not statistically significant
	Male	79	55.63	81	57.04	160	56.34	
Total		142	100.00	142	100.00	284	100.00	

The table presents the gender distribution across two groups, each comprising 142 individuals, for a total of 284 participants. Among Group A, there are 63 females and 79 males, while Group B consists of 61 females and 81 males. Overall, females account for 124 participants, and males represent 160 participants. The p-value of 0.812 indicates that there is no statistically significant difference in gender distribution between the two groups. This suggests that gender is evenly distributed and does not vary significantly across the groups.

Table No 2: Comparison of age group among group A & group B.

		Groups				Total		OR (95% CI)	P Value
		Group A		Group B					
		No.	%	No.	%	No.	%		
Age in Years	30 - 39	22	15.49	25	17.61	47	16.55	ref	1
	40 - 49	29	20.42	30	21.13	59	20.77	0.96 ((0.52, 1.77))	0.9
	50 - 59	53	37.32	55	38.73	108	38.03	0.95(0.58, 1.57)	0.83
	60 - 69	38	26.76	32	22.54	70	24.65	1.27(0.72, 2.24)	0.4
Total		142	100.00	142	100.00	284	100.00		

A total of 284 participants were equally distributed between Group A (n = 142) and Group B (n = 142). The age-wise comparison between the two groups showed no statistically significant differences. Participants in the 30–39-year age group were considered as the reference category (OR = 1). Compared to this group, those aged 40–49 years had an odds ratio of 0.96 (95% CI: 0.52–1.77; p = 0.90), those aged 50–59 years had an odds ratio of 0.95 (95% CI: 0.58–1.57; p = 0.83), and those aged 60–69 years had an odds ratio of 1.27 (95% CI: 0.72–2.24; p = 0.40). As all the confidence intervals included the null value of 1 and the p-values were greater than 0.05, the findings indicate that there was no significant association between age distribution and group membership.

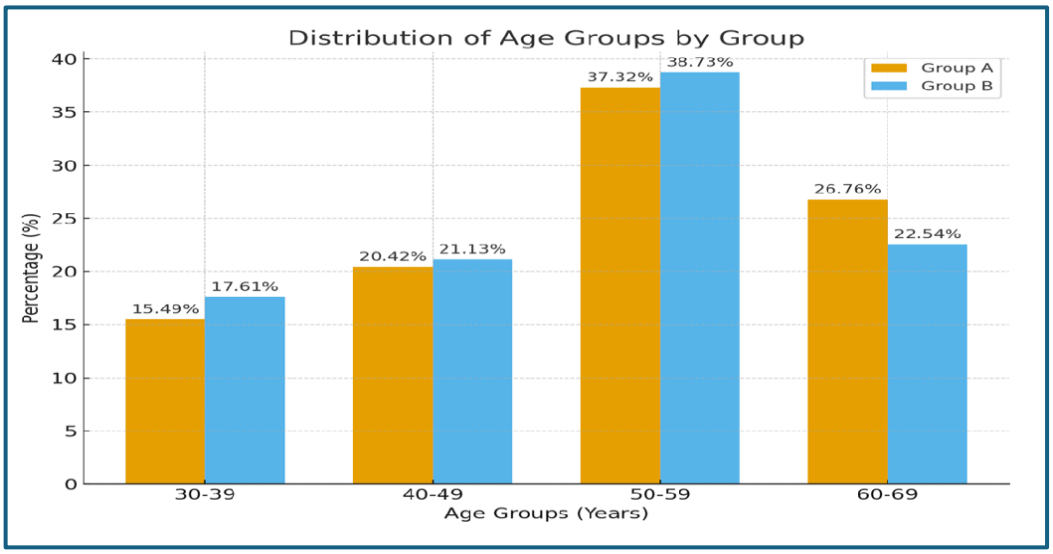

Figure 1: graphical represent Comparison of age group among group A & group B.

Table 3: Comparison of BMI among group A and B.

		Groups				Total		OR(95% CI)	P Value
		Group A		Group B					
		No.	%	No.	%	No.	%		
BMI	Normal	26	18.31	28	19.72	54	19.01	ref	1
	Obese	16	11.27	16	11.27	32	11.27	1(0.47, 2.13)	1
	Over Weight	100	70.42	98	69.01	198	69.72	1.07(0.65, 1.75)	0.78
Total		142	100.00	142	100.00	284	100.00		

A total of 284 participants were equally distributed between Group A (n = 142) and Group B (n = 142). The BMI distribution across both groups showed no statistically significant differences. Participants with normal BMI were considered as the reference category (OR = 1). Compared to them, obese individuals had an odds ratio of 1.00 (95% CI: 0.47–2.13; p = 1.00), while overweight individuals had an odds ratio of 1.07 (95% CI: 0.65–1.75; p = 0.78). As the confidence intervals included the null value of 1 and all p-values were greater than 0.05, these findings suggest that there was no significant association between BMI categories and group membership.

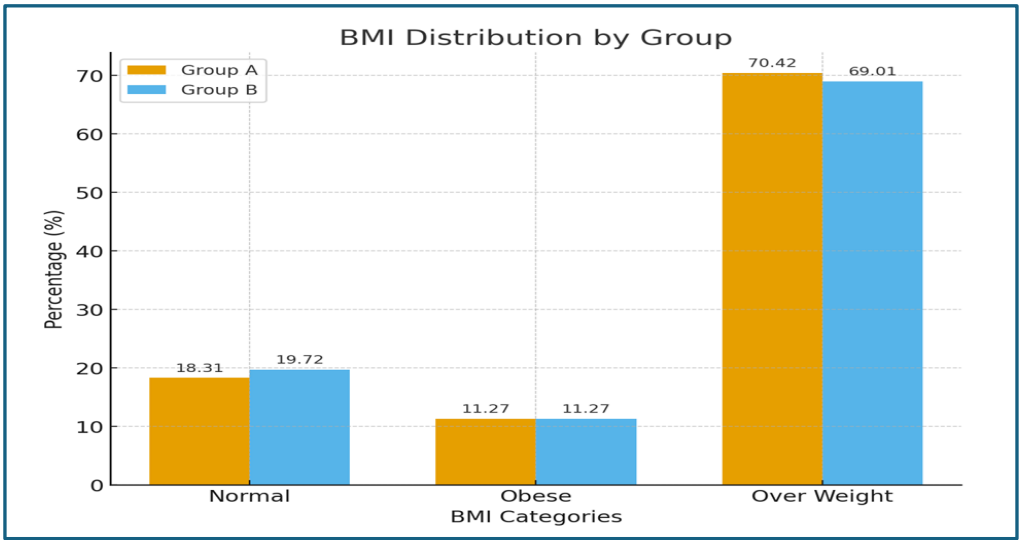

Figure 2: Graphical represents Comparison of BMI among group A and B.

Table 4: Comparison of VAS, WOMAC, scores between Group A and Group B in patients with osteoarthritis.

Parameter (Unit)	GROUP A			GROUP B			Base line p Value	7 Days p Value	15 Days p value
	Baseline	7 Days	15 Days	Baseline	7 Days	15 Days			
VAS Score	7.80±1.19	6.15±0.86	3.15±0.86	8.02± 1.48	7.17±1.50	5.02±1.48	0.186	**0.001****	**0.001****
WOMAC Score	72.60±13.90	59.53±20.50	45.11±20.3	74.76±10.90	65.82±10.73	50.78±16.72	0.160	**0.001****	**0.011***
	Highly significant								

Table. No.5 CRP scores between Group A and Group B in patients with osteoarthritis.

Parameters	Group A			Group B			Baseline p value	7 days p value	15 days p value
	Baseline	7days	15days	Baseline	7 days	15days			
CRP	4.86±1.37	4.13±1.35	3.12± 1.34	4.87±1.35	4.28±1.32	3.31± 1.26	0.924	0.343	0.220
	Not Statistically significant								

Tables indicate that while both treatment groups improved over time, the treatment used in Group A was more effective in reducing pain (VAS) and functional limitations (WOMAC) by day 7 and day 15 compared to Group B. However, there was no significant difference in CRP levels, suggesting that both treatments had a similar effect on systemic inflammation.

Additionally, Group A reported fewer adverse effects, particularly gastrointestinal issues, highlighting a better safety and tolerability profile. This suggests that the treatment in Group A not only offers better symptom relief but is also better tolerated, making it a potentially more favorable option for short-term osteoarthritis management.

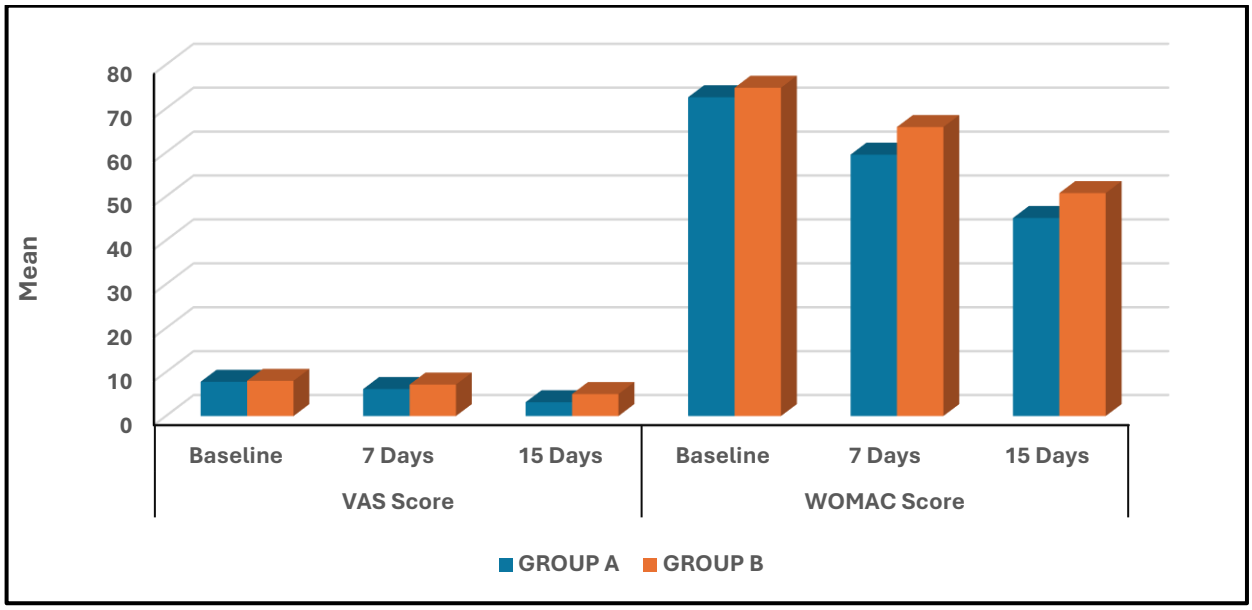

Figure 3: Graphical represents comparison of VAS, WOMAC, scores between Group A and Group B in patients with osteoarthritis.

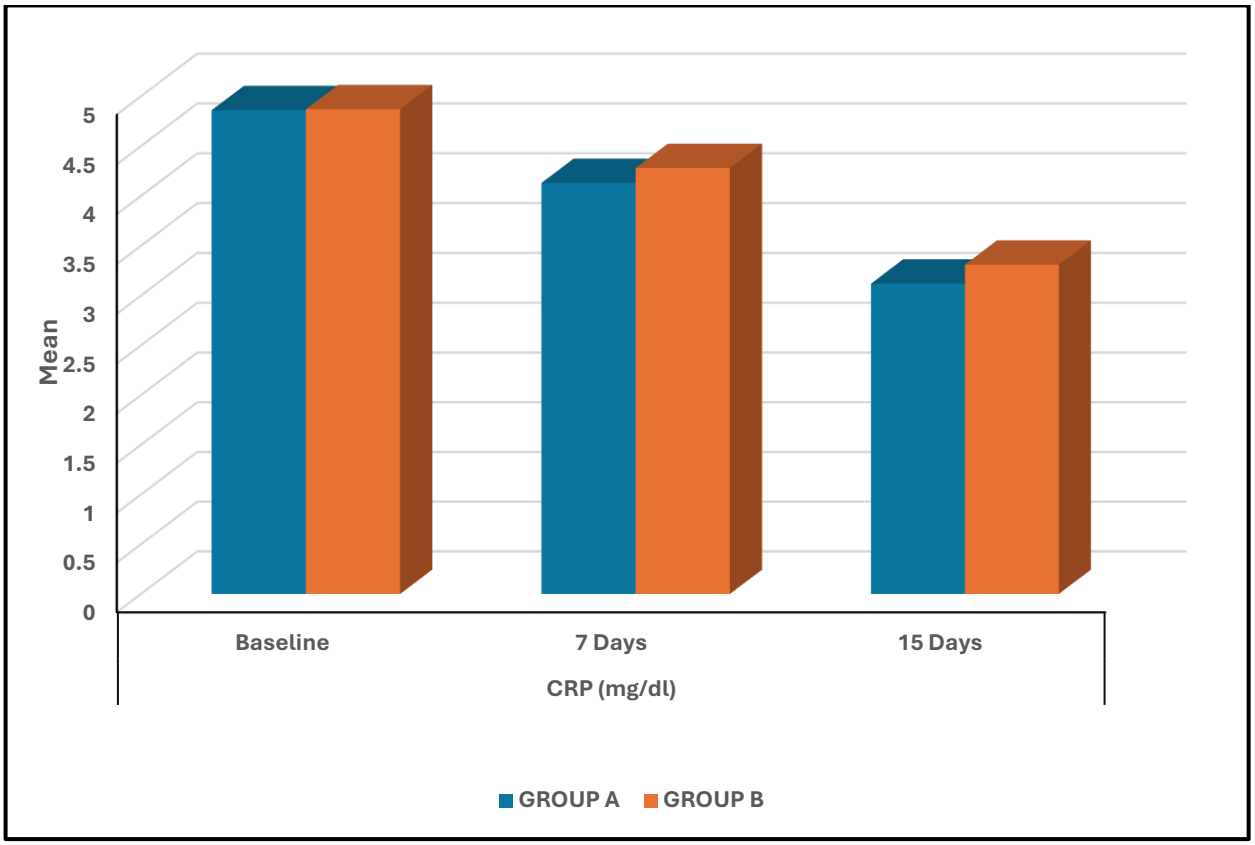

Figure 4: Graphical represents CRP in between group A & group B after 7 & 15 days of treatment.

Table 6: Comparison of Liver profile between Group A and Group B in patients with osteoarthritis.

Parameter (Unit)	GROUP A			GROUP B			Baseline p Value	7 Days p Value	15 Days p value
	Baseline	7 Days	15 Days	Baseline	7 Days	15 Days			
ALT (IU/L)	25.43±4.57	24.47±4.58	23.97± 97.18	25.64±4.61	24.96±4.41	24.54±4.33	0.706	0.306	0.279
AST (IU/L)	32.30±4.95	31.85±4.95	31.65 ± 4.95	32.51±5.03	32.06±5.03	31.86±5.03	0.721	0.711	0.684
ALP (IU/L)	82.16±8.02	81.66±8.02	81.36 ± 3.66	82.24±8.13	81.74±8.02	81.44±8.13	0.932	0.815	0.786
Bilirubin (mg/dl)	0.82 ± 0.07	0.74± 0.07	0.72 ± 0.01	0.82 ± 0.07	0.47 ± 0.07	0.70 ± 0.07	0.563	0.561	0.521
	Not Statistically significant								

The comparison of liver function parameters - ALT, AST, ALP, and Bilirubin - between Group A and Group B at baseline, 7 days, and 15 days shows no statistically significant differences at any time point (all p-values > 0.05). This indicates that neither treatment had a harmful or differing effect on liver function during the study period.

The consistency of these values across groups and time suggests that both treatments were herpetologically safe, with no signs of liver toxicity attributable to either intervention over the 15-day course. Therefore, from a hepatic safety perspective, both treatment regimens can be considered equally safe.

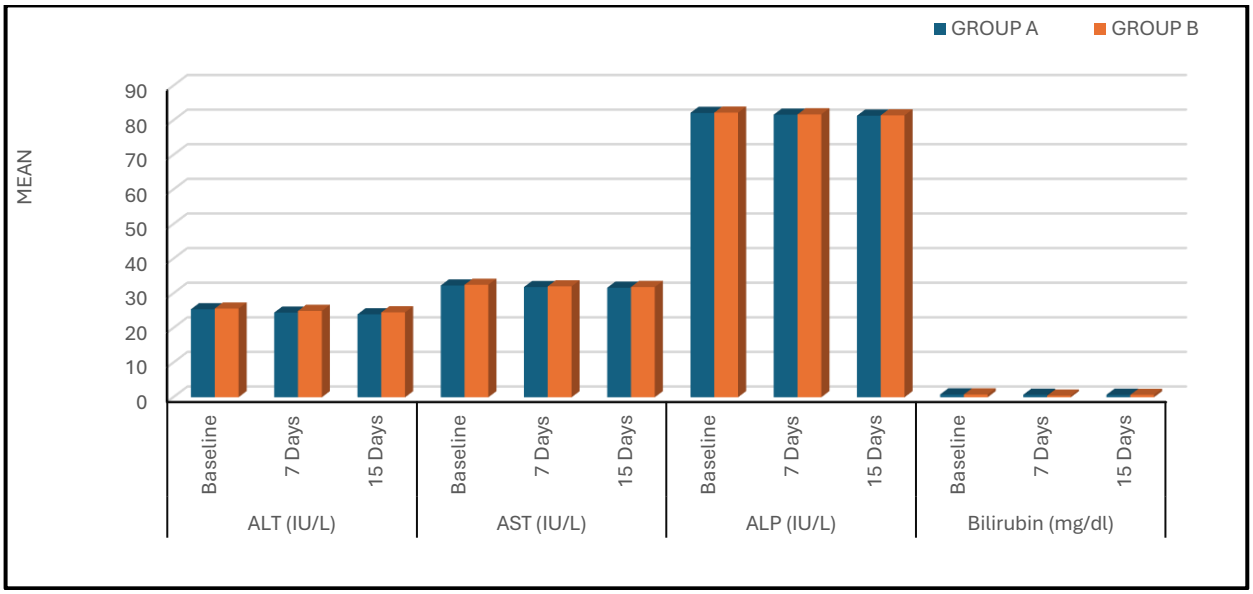

Figure 5: Comparison of mean average in Liver profile in between group A & group B after 7 & 15 days of treatment.

Table 7: Comparison of Renal profile between Group A and Group B in patients with osteoarthritis.

Parameter (Unit)	GROUP A			GROUP B			Baseline p Value	7 Days p Value	15 Days p value
	Baseline	7 Days	15 Days	Baseline	7 Days	15 Days			
Blood Urea (mg/dl)	31.87±4.80	31.37±4.80	31.12±4.80	32.01±4.83	31.57±4.76	31.37±4.69	0.807	0.716	0.658
Creatinine (mg/dl)	1.06±0.12	1.05±0.12	1.01±0.12	1.06±0.12	1.05±0.12	0.01±0.12	0.827	0.827	0.829
	Not Statistically significant								

There were no significant differences in blood urea or serum creatinine levels between Group A and Group B at baseline, 7 days, or 15 days (all $p > 0.05$). Both groups maintained stable renal function throughout the study, indicating comparable renal safety.

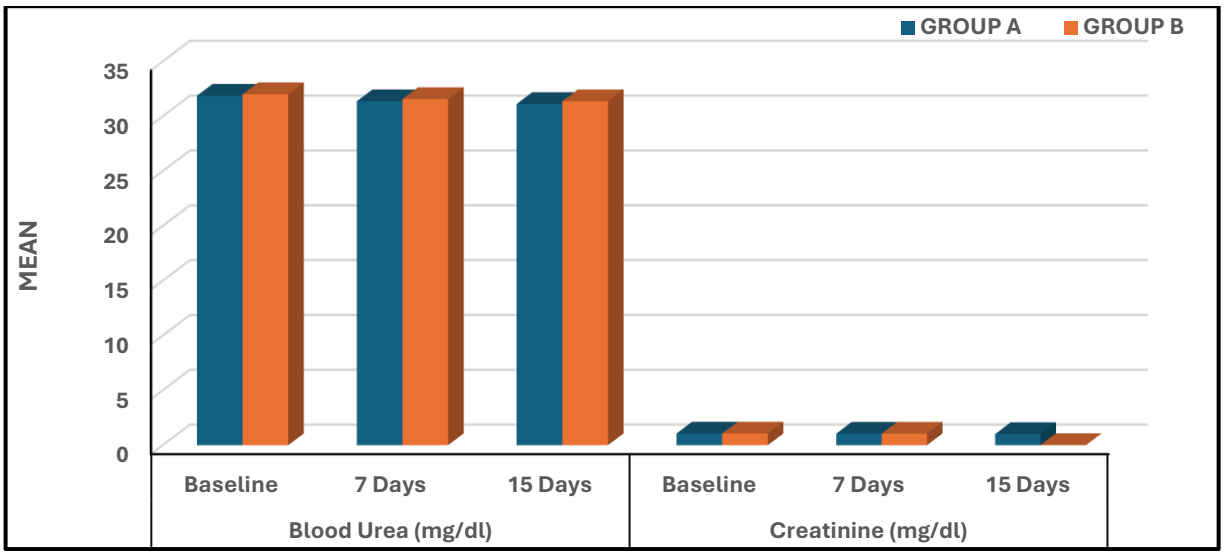

Figure 6: Comparison of mean average in Renal profile in between group A & group B after 7 & 15 days of treatment.

Table 8: Comparison of CBC between Group A and Group B in patients with osteoarthritis.

Parameter (Unit)	GROUP A			GROUP B			Baseline p Value	7 Days p Value	15 Days p value
	Baseline	7 Days	15 Days	Baseline	7 Days	15 Days			
WBC (/µL)	8495.77 ± 633.44	6995.77 ±633.44	6195.77 ±633.44	8499.29± 632.17	6999.29 ±632.17	6199.29 ±632.17	0.963	0.963	0.864
RBC (million/µL)	5.70 ± 0.22	5.00 ± 0.22	4.70± 0.22	5.702±0.23	5.02± 0.23	4.72 ± 0.22	0.490	0.452	0.442
Haemoglobin (%)	13.54±1.01	13.29±1.01	13.42±0.22	13.50±1.01	13.24±0.94	13.38±0.94	0.989	0.681	0.724
	Not Statistically significant								

WBC, RBC, and hemoglobin levels changed slightly over time in both groups, but no statistically significant differences were observed between Group A and Group B at any point ($p > 0.05$). This suggests that the interventions had no differential impact on hematological parameters.

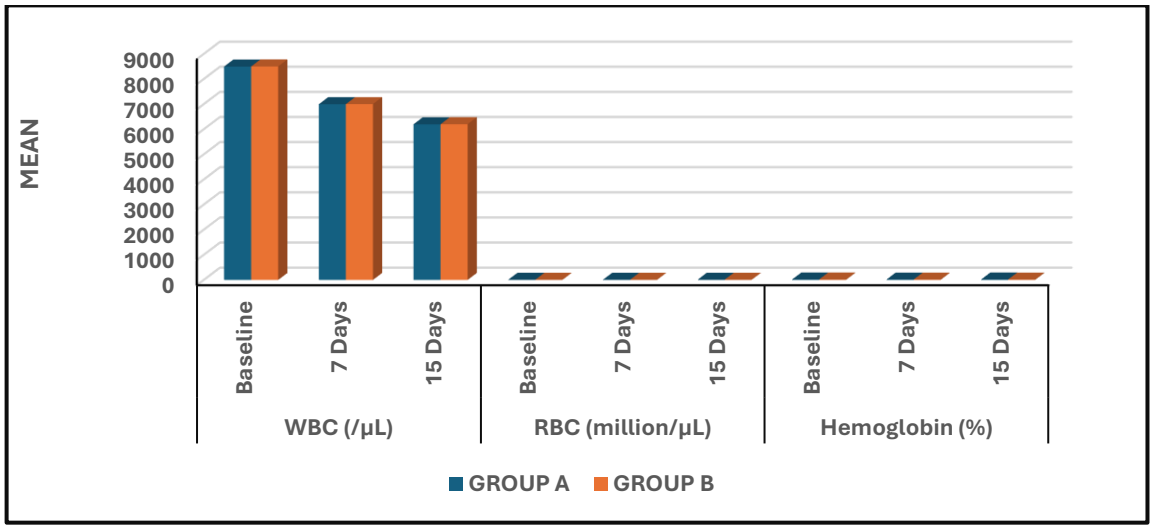

Figure 7: Comparison of mean average in CBC in between group A & group B after 7 & 15 days of treatment.

Table 9: Number of Patients with Adverse Effects - Etoricoxib versus Piroxicam (n = 142 per group)

Adverse effects	Etoricoxib (n=142)	Piroxicam (n=142)	p value
Gastric discomfort	8	22	0.005*
Nausea	6	14	0.077
Vomiting	3	10	0.044
Diarrhea	5	7	0.554
Headache	9	6	0.428
Dizziness	4	9	0.154
Hypertension	10	4	0.094
Edema	7	5	0.559
Rash	2	3	0.654
Elevated liver enzymes	6	4	0.513
Renal dysfunction	3	6	0.303
Cardiovascular problems	2	1	0.561
Mean ± SD	5.42 ± 2.71	7.58 ± 5.73	

In this study involving 142 patients per group, adverse events were assessed at baseline, Day 7**,** and Day 15 post-treatment. Etoricoxib consistently demonstrated fewer adverse effects compared to Piroxicam across all time points. Statistically significant differences were observed in gastric discomfort ($p = 0.005$), vomiting ($p = 0.044$), and total adverse events ($p = 0.005$) with these differences becoming particularly evident by Day 15. Other adverse events were comparable between groups. The mean number of adverse events was also lower with Etoricoxib (5.42 ± 2.71) compared to Piroxicam (7.58 ± 5.73), indicating better overall tolerability over the course of treatment.

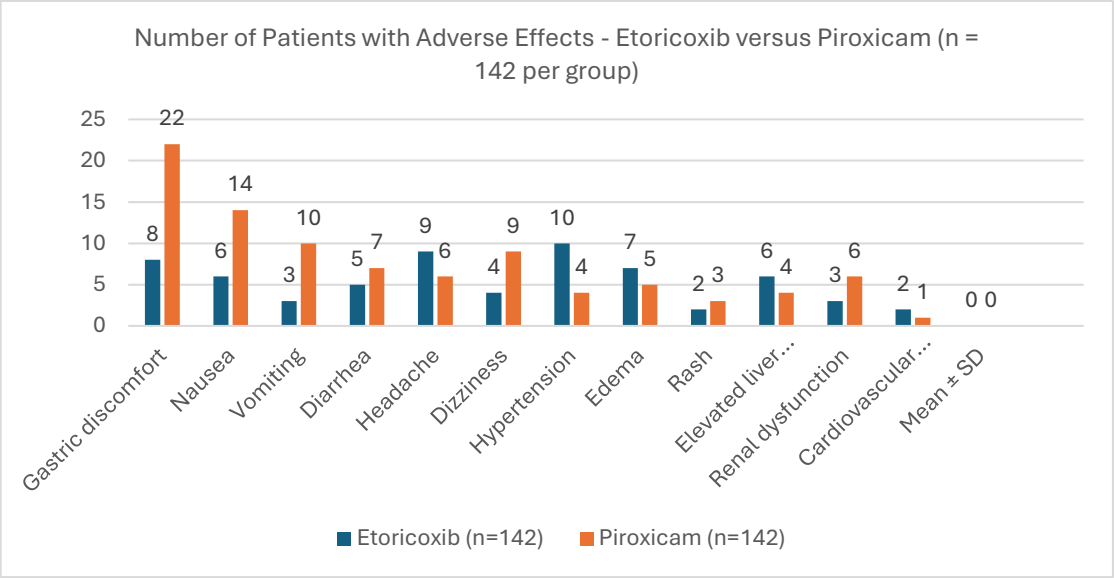

Figure 8: graph showing Adverse drug Effects in both groups.

Discussion: This study compared two osteoarthritis treatment groups with similar baseline demographics, ensuring balanced cohorts. Both groups showed significant improvements in pain and function over 15 days, with Group A demonstrating greater reductions in VAS and WOMAC scores ($p < 0.01$).[9] There were no significant differences in CRP levels or liver and renal function tests, indicating similar safety profiles. Importantly, Group A experienced significantly fewer adverse effects, particularly less gastric discomfort and vomiting ($p = 0.005$ and 0.044), highlighting better overall tolerability.

Conclusion: Both treatment groups demonstrated significant improvement in osteoarthritis symptoms over 15 days, with Group A showing greater reduction in pain and functional scores. Safety profiles were comparable in terms of CRP levels, Liver function tests, kidney function tests and blood profile. However, Group A had a lower incidence of adverse effects, particularly gastrointestinal discomfort and vomiting, indicating better tolerability. These findings suggest that the treatment used in Group A may offer more favorable short-term outcomes for osteoarthritis management.

References:

1. Sreerag J. Raj & Ms. Sheethal Kuriakose. Comparative Study to Assess the Effectiveness and Safety of Etoricoxib & Aceclofenac in Osteoarthritis Patients. Sch Acad J Pharm, 2024 Jan 13(1): 12-22.
2. Safiri S, Kolahi AA, Cross M, Carson-Chahhoud K, Moradi-Lakeh M, Almasi-Hashiani A, et al. Prevalence, incidence, and years lived with disability due to osteoarthritis: findings from the Global Burden of Disease 2019 Study. Arthritis Rheumatol. 2020;72(9):1482–93.
3. Harsimrat S. et al. A comparative study to assess the safety and efficacy of etoricoxib versus Aceclofenac in osteoarthritis Int J Basic Clin Pharmacol.2018 Oct;7(10):2010-2015.

4. Onishi K, Utturkar A, Chang E, Panush R, Hata J, Perret-Karimi D. Osteoarthritis: A Critical Review. Crit Rev Phys Rehabil Med. 2012;24(3-4):251-264. doi: 10.1615/CritRevPhysRehabilMed.2013007630. PMID: 25750483; PMCID: PMC4349405.
5. Coyte PC, Asche CV, Croxford R, Chan B. The economic cost of musculoskeletal disorders in Canada. Arthritis & Rheumatism: Official Journal of the American College of Rheumatology. 1998 Oct;11(5):315-25.
6. Magni A, Agostoni P, Bonezzi C, Massazza G, Menè P, Savarino V, Fornasari D. Management of osteoarthritis: expert opinion on NSAIDs. Pain and therapy. 2021 Dec;10(2):783-808.
7. Jagannathan H, Thota A, B. Kumarappa AK, Kishore G. A comparative study of aceclofenac versus etoricoxib in the management of acute low back pain in a tertiary care hospital. Journal of drug assessment. 2020 Jan 1;9(1):60-5.
8. Shtroblia V, Petakh P, Kamyshna I, Halabitska I, Kamyshnyi O. Recent advances in the management of knee osteoarthritis: a narrative review. Front Med. 2025; 12:1523027.
9. Wang Y, Cheng H, Zhang X, Li C, Yin P, Zhang W. Effectiveness and safety of non-steroidal anti-inflammatory drugs and opioid treatment for knee and hip osteoarthritis: network meta-analysis. Arthritis Res Ther. 2022;24(1):292.
10. Kumar, Amit, Patel, Rajesh, Singh, Manoj. et al. Comparative Efficacy of Etoricoxib 90 mg and 60 mg in Osteoarthritis Patients: A Randomized Clinical Trial. J Clin Pharm Ther. 2022;47(5):234-245.