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Journal of Drug Assessment

ISSN: (Print) 2155-6660 (Online) Journal homepage: https://www.tandfonline.com/loi/ijda20

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To cite this article: Hema Jagannathan, Amulya Thota, Ashok Kumar B Kumarappa & Githa Kishore (2020): A comparative study of aceclofenac versus etoricoxib in the management of acute low back pain in a tertiary care hospital, Journal of Drug Assessment, DOI: 10.1080/21556660.2020.1734008

To link to this article: https://doi.org/10.1080/21556660.2020.1734008

Accepted author version posted online: 24 Feb 2020.

A comparative study of aceclofenac versus etoricoxib in the management of acute low back pain in a tertiary care hospital

Hema Jagannathan[1], Amulya Thota[1], Ashok Kumar B Kumarappa[2], Githa Kishore[1]

[1] Visveswarapura Institution of Pharmaceutical Sciences, Pharmacy Practice, Karnataka, India
[2] Kempegowda Institute of Medical Sciences, Pain Management, Karnataka, India

Correspondence: Hema Jagannathan, Visveswarapura Institution of Pharmaceutical Sciences, Pharmacy Practice, 22nd Cross, Sidanna Layout BSK 2nd Stage, Bangalore, Karnataka 560070, India. Email: hema_j2006@yahoo.co.in

Transparency

Declaration of funding

There is no funding to disclose.

Declaration of financial/other relationships

The authors and peer reviewers on this manuscript have no relevant financial or other relationships to disclose.

Acknowledgements

We express our gratitude to Dr. Shivananda S., Professor and Head of the Department of Orthopaedics KIMS Hospital for his support. We extend our thankfulness to Dr. G.Y. Narmada, Honorable Principal, for her support.

ABSTRACT

Background: The aim of management of acute low back pain is to alleviate the pain in quickly and improve functional ability. Nonsteroidal anti-inflammatory drugs are the first line of treatment. The challenge lies in deciding which NSAIDs will provide greater symptomatic relief, while also being cost effective.

Objective: To compare the effectiveness of aceclofenac and etoricoxib in the management of acute low back pain.

Methods: This prospective, open label, observational study was conducted at a tertiary care hospital. Patients over 18 years of age and presenting with low back pain of less than 6 weeks duration were enrolled in the study. 50 patients with nonspecific low back pain were randomized into two groups: Group A received aceclofenac (2mg/kg) twice a day and Group B received etoricoxib (1mg/kg) twice a day for one week. The Numerical Rating Scale (NRS) and Oswestry Low Back Disability Index (ODI) determined the clinically meaningful outcomes.

Results: The decrease in pain intensity in Group A was 52.27%, while in Group B it was 62.53%. However, the decrease in pain scores between the groups was not statistically significant (p=0.3795). Improvement in functional ability in Group A and Group B was 57.01% and 61.48%, respectively. However, this improvement between the groups was not statistically significant (p>0.999) at the end of one week. The average cost effectiveness ratio indicated that etoricoxib was the dominant treatment over aceclofenac. Therefore, etoricoxib was found to be the cost-effective option for short-term pain relief in acute low back pain for one week.

Conclusion: Both aceclofenac and etoricoxib were clinically effective in reducing the pain intensity and in improving functional ability. However, etoricoxib was found to be the cost-effective intervention.

Keywords: acute low back pain; aceclofenac; etoricoxib; cost effectiveness

INTRODUCTION

Low back pain (LBP) is defined as pain and discomfort localized below the costal margin and above the inferior gluteal folds, with or without radiating to the legs (sciatica) [1].LBP is a symptomatic and a self-limiting condition. It includes pain, muscle spasm or stiffness. Acute low back pain is defined as an episode which persists for less than 6 weeks [2].

Being a common musculoskeletal condition, the point prevalence among the world population ranges between 60-80% [3].The risk of LBP increases above 35 years of age and prevalence being more among female population. People involved in jobs requiring prolonged sitting and standing, handling of heavy loads are at greater risk [4]. Etiology of LBP can vary from mechanical, systemic and non-specific causes. About 90% of patients are diagnosed with Non-specific pain which is defined as "low back pain not attributed to known, recognizable and specific pathology" [5]. It is possibly from a sustained and muscle spasm [6].

The aim of treatment of acute low back pain is to obviate the pain in the shortest duration and improve the functional ability. Nonsteroidal Anti-inflammatory drugs are the first choice of treatment since they reduce pain, improve functional ability and have an acceptable tolerability profile [7].

Aceclofenac is a preferential COX-2 inhibitor with anti-inflammatory and analgesic properties. Aceclofenac also targets the synthesis of glycosaminoglycan and mediates chondroprotective effects [8]. It presents with more gastrointestinal side effects like dyspepsia, abdominal pain and nausea [9].Etoricoxib is a COX-2 selective inhibitor with anti-inflammatory, analgesic properties and potential antineoplastic properties. It presents with lesser incidence of gastrointestinal side effects but increased cardiovascular adverse events [10].

Along with efficacy, cost of the drug plays a vital role in ensuring adherence to a therapy. Cost-effectiveness analysis (CEA) is a pharmacoeconomic method for assessing the health gains relative to the costs of different health interventions. It directly relates the financial and scientific implications of different interventions [11]. This method helps to assess whether the additional cost paid is worth the additional benefit.

There is paucity of cost effectiveness analysis studies comparing NSAIDs in the management of acute low back pain. The objective of the study was to evaluate the effectiveness and determine the more cost effective intervention between Aceclofenac and Etoricoxib in the management of acute nonspecific low back pain. Data on the cost effectiveness of drugs for acute low back pain will be invaluable to healthcare professionals for better informed decision making when choosing treatments.

MATERIALS AND METHODS

Study design

A prospective, open label, comparative observational study was conducted in the Department of Pain Management and in the Department of Orthopaedics of a tertiary care hospital, Bangalore on patients with acute low back pain prescribed with Aceclofenac (2 mg/kg BD) and Etoricoxib(1mg/kg BD). The study was conducted in accordance to the permission granted by the institutional ethical committee. [IR No: VIPS/IEC/2017-04].

Sample Size Calculation

We assumed a standard deviation change in Oswestry Disability Index of 9.9 and minimum clinically important difference on the Oswestry Disability Index of 8.0 [12].

At 5% level of significance and 80% power of test, ß of 0.2, the sample size was calculated to 24 patients per group. Additional 10% was added to compensate the patients loss to follow up. Hence, the sample size was calculated to be 30 patients in each group.

Study Criteria

Outpatients between 18-80 years of age presenting with low back pain of duration less than 6 weeks and prescribed with Aceclofenac (2 mg/kg BD) or Etoricoxib (1mg/kg BD) were included in the study. Patients with back pain caused by malignancy and/or infection, fractures, Non- compliant patients, patients with renal or/and hepatic impairment, patients with rheumatological problems, patients with disc herniation, patients with cardiovascular disorders, patients on antidepressants and anticoagulants and pregnant and lactating women were excluded.

Study Procedure

A total of 60 patients participated in the study. All the patients were informed about the purpose and requirements of the study and details of the drugs. Written informed consent was obtained from the patients prior to their enrollment in the study. Details of the patient's demographic profiles, medication history, socio-economic status, and social history were recorded on a specially designed form.

Interventions

Patients prescribed with Aceclofenac (2 mg/kg BD) were assigned to Group A.

Patients prescribed with Etoricoxib (1mg/kg BD) were assigned to Group B by the physician.

The patients were followed up for a period of one week.

Outcome measures

The primary outcome in this study was improvement in pain and functional disability. The severity of acute low back pain and the efficacy of the drugs in reducing the pain were assessed using Numerical rating Scale. The Numerical rating Scale (NRS) is a segmented 11-point numeric scale with 0 representing "no pain" and 10 representing "worst pain imaginable" [13].

Patients are required to self-report the pain intensity. Hence to facilitate this, the Wong-Baker Faces Pain Rating Scale was used in our study as an aid so that the patient can report their pain intensity with ease by looking at the visual representation of various intensity of pain [14]. Oswestry Disability Index (ODI) questionnaire which is considered as the gold standard to assess degree of disability in acute low back pain was used in our study to assess the functional disability [15].

The baseline NRS scores and ODI scores were recorded at the start of the study. After a follow up period of one week, the scores were again recorded to analyze any clinically significant change in pain intensity and functional disability.

The average cost-effectiveness ratio (ACER) is the ratio of the cost to benefit of an intervention. ACER estimates average cost spent per effect [16].The analysis included the direct costs incurred by patients for drug acquisition, consultation costs, cost involved in the treatments of adverse events and cost of co-prescribed drugs. Costs incurred were estimated for a period of one week.

Statistical analysis

Shapiro-Wilk test and Jarque – Bera test were used to assess the normal distribution of the data. Normality tests were performed using XLSTAT package version 2018.2. Suitable parametric (like t test) and non-parametric tests (like Wilcoxon sign ranked test and Mann Whitney U Test) were carried out for analyzing the data at 5% level of significance ($p<0.05$) using Graphpad Prism software 7.04.

RESULTS

Socio-demographic details

During the 6 month study period, 60 patients were enrolled in the study (Figure 1). 2 patients did not give consent, 3 patients were not eligible and 5 patients were lost to follow up.

The socio demographic details of the patients are detailed in Table 1.

The complaint of acute low back pain was common in patients in the age group of 40-50 years (36%). Acute LBP was more prevalent among females (62%) when compared to males (38%).

Majority (52%) of the patients were homemakers. 88% of the study subjects were found to work for 8-12 hours a day. 6% of the subjects consumed alcohol (60-100ml per day) and 8% were smokers. The mean BMI among females was around 26.6 and among males was around 29.4

Primary Outcomes

Pain Intensity– Numerical rating Scale

In Group A, there was about 52.27% reduction in pain intensity post treatment with Aceclofenac. The average decrease in pain score was found to be 2.32 which was statistically significant at $p<0.0001$ (Wilcoxon signed ranked test). (Table 2).In Group B, there was about 62.53% decrease in the pain intensity. The average decrease in pain score was found to be 3.36 which was statistically significant at $p<0.0001$ (Wilcoxon signed ranked test) (Figure 2). However, the decrease in pain intensity between the two groups treated with Aceclofenac and Etoricoxib was not statistically significant at $p=0.3795$ (Mann Whitney U test).

Functional Disability- ODI

In patients prescribed with Aceclofenac (Group A), the functional ability was improved around 57.01%. There was an average decrease in ODI score by 15.08 which was statistically significant at $p<0.0001$ (Paired t test) (Table 3). In patients prescribed with Etoricoxib (Group B), there was about 61.48% reduction in ODI scores (Figure 3).There was an average decrease in ODI score by 18.24 which was statistically significant at $p<0.0001$ (Paired t test).Though clinically significant, the improvement in functional disability between the two groups treated with Aceclofenac and Etoricoxib was not statistically significant ($p>0.999$). (Unpaired t test)

Apart from the drugs under study, the participants were co-prescribed with other drugs like proton pump inhibitors, neuroprotectants, muscle relaxants and drugs for their co-morbid conditions which is been presented in Table 4.

Cost effectiveness analysis

Cost-effectiveness analysis identifies the intervention which have the potential to yield the greatest improvement in health for the least resources. The costs incurred for the drugs including co-prescribed drugs, diagnostic methods used and physician consultation costs were estimated. The cost of the drugs were obtained from CIMS, Jan-Apr 2018.

The average decrease in NRS and ODI scores were used as primary outcomes.

Average Cost Effectiveness Ratio (ACER)

The average cost-effectiveness ratio (ACER) is the ratio of the cost to benefit of an intervention. There was a greater decrease in the pain intensity and better functional ability in patients receiving Etoricoxib when compared with patients receiving Aceclofenac.

Upon calculation it was found that the ACER of Etoricoxib was less when compared to Aceclofenac indicating Etoricoxib is the cost effective intervention. Hence, it is evident that Etoricoxib is the dominant treatment over Aceclofenac for duration of one week, making it the cost effective option for short term pain relief in acute low back pain

DISCUSSION

Low back pain is a common self-limiting musculoskeletal condition mostly with a nonspecific etiology which presents with pain, muscle tension and stiffness. In our study population, acute low back pain was more common in the patients in the age group of 40-50 years. The mean age in all the study subjects was found to be 41.67 years.

In a study conducted by Rishabh Gupta and co-authors, it was found that low back pain was common in 3rd and 4th decade of life. The average age of patients was found to be 38.39 years [17].

In our study, 62% of the total study subjects were females. The female preponderance can be attributed to Spinal osteoarthritis, joint degeneration psychological factors, female hormone fluctuation and menstrual history.

Around 52% of the total subjects were homemakers and 24% were professionals. A similar epidemiological study conducted by Mohd.Nazeer, reported that housewives formed the majority of cases (66%) [18].

The various reasons attributed could be the unduly working hours, working posture, and physical exhaustion. Majority of the patients reported to be working for 8-12 hours a day.

Majority (70%) reported to have a sedentary lifestyle. In our study about 80% of the total study subjects were literates (attended more than primary education).

The mainstay of the management for acute low back pain is to alleviate the pain in the shortest duration with least side effects. Analgesics are the first line of drugs since they provide symptomatic relief and have an acceptable tolerability profile.

The challenge lies in selecting the most effective, safest and cost effective analgesic.

Aceclofenac, a preferential COX-2 inhibitor and Etoricoxib, a selective COX-2 inhibitor both have analgesic, anti-inflammatory effects. However they differ in their adverse effect profile.

Aceclofenac is associated with more GI harm while Etoricoxib is associated with less GI adverse effects and more Cardiovascular adverse effects [24]. The information about their adverse effect profile is based on the literature search.

Based on our study results, Etoricoxib demonstrated a greater reduction in pain (62%) when compared with Aceclofenac (52%). Also the improvement in the functional disability was more in Etoricoxib (61%) when compared with Aceclofenac (57%). None of the study participants discontinued the therapy and no adverse effects were reported.

Proton pump inhibitors were co-prescribed with NSAIDs to prevent GI discomfort.

28% in group A and 20% in group B were prescribed with Pantoprazole.

Proteolytic enzymes play a key role in reducing inflammation by causing the lysis of the peptide bonds [19]. Enzymes like serratiopeptidase, trypsin were co-prescribed in the present study. About 44% of the study population were given proteolytic enzymes.

Low back pain is generally associated with muscle spasms. Hence muscle relaxants are frequently co-prescribed with NSAIDS.

In our study, Thiocolchicoside (4mg) was the most commonly prescribed muscle relaxant. It is a GABA agonist and acts on the muscular contracture by activating the GABA-nergic inhibitory pathways thereby acting as a potent muscle relaxant [20]. 84% of the total patients enrolled in the study were co-administered with muscle relaxant (Table 4).

Neuromodulators are also given to treat neuropathic pain. Methylcobalamin and Pregabalin, Gabapentin were co-prescribed along with NSAIDs in patients with neurological deficits. Methylcobalamin has an important role in the regeneration of myelin sheath and helps to restore the function of the nerve in neuropathy [21].

Gabapentin and Pregabalin have a high affinity for the auxiliary α2δ subunits of the voltage-gated calcium channel and thus blocks Ca^{2+} influx into nerve terminals, which leads to reduced transmitter release [22]. 34% of the patients with LBP were prescribed with Gabapentin alone. 14% of the subjects were prescribed with Methylcobalamin and Pregabalin as a combination.

Cost effectiveness analysis highlights the interventions that are relatively inexpensive, yet have the potential to reduce the disease burden substantially. Costs are measured in a common monetary value and the effectiveness in terms of physical units. The Average Cost effectiveness Ratio calculated for one week indicated Etoricoxib to be dominant over Aceclofenac indicating Etoricoxib is the cost effective intervention.

Our study is in agreement with a study conducted in Norway by Jeroen P. Jansen where they evaluated the Cost-Effectiveness of Etoricoxib versus Celecoxib and Nonselective NSAIDs in the Treatment of Ankylosing Spondylitis.

Their economic evaluation suggested that Etoricoxib was the most cost-effective initial NSAID treatment for Ankylosing Spondylitis patients since there was a >98% probability that treatment with Etoricoxib resulted in greater Quality Adjusted Life Years than the other interventions [23].
There are certain limitations in our study. The above study was a single centre, open label study. Also the shorter duration of study period and the smaller size is another limitation.

Low back pain is a common complaint and patients prefer speedy recovery. Also there are a number of NSAIDs available to reduce pain. Therefore, further studies are need to be carried on large populations and at different centers to extrapolate the findings of the safety and efficacy of NSAIDs.

CONCLUSION

According to the results of the present prospective observational study, both Etoricoxib and Aceclofenac are equally effective in reducing the pain intensity and improving the functional ability in acute low back pain. However Cost effectiveness analysis indicated Etoricoxib to be a more cost effective intervention when compared with Aceclofenac. Hence both Etoricoxib and Aceclofenac are effective analgesics in acute low back pain, nonetheless Etoricoxib was estimated to be a cost effective intervention.

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Table 1: Socio-demographic details of the study participants.

Demographic Variable	Aceclofenac (n = 25)	Etoricoxib (n = 25)
Age (mean ± SD) years	45.04 ± 4.24	39.68 ± 19.09
Gender, no. (%)		
Female	17 (68)	14 (56)
Male	8 (32)	11 (44)
Profession, no. (%)		
Homemaker	14 (56)	12 (48)
Professionals	4 (16)	8 (32)
Farmer	7 (28)	3 (12)
Student	0 (0)	2 (8)
Working hours, no. (%)		
4-8 hours	1 (4)	4 (16)
8-12 hours	23 (92)	21 (84)
12-16 hours	1 (4)	0 (0)

Table 2: Pre and post treatment Numerical rating Scale scores in both groups.

Numerical Rating Scale	**Group A (Aceclofenac) N=25**		**Group B (Etoricoxib) N=25**	
Parameters	**Baseline**	**Follow up**	**Baseline**	**Follow up**
Mean± SD	4.52±0.82	2.2±0.95	5.44±1.41	2.08±1.28
Median	4	2	5	2
p value	<0.0001		<0.0001	
Average decrease in pain score	2.32 (52.27%)		3.36 (62.53%)	

Table 3: Pre and post treatment Oswestry Disability Index scores in both groups.

Oswestry Disability Index	Group A (Aceclofenac) N=25		Group B (Etoricoxib) N=25	
Parameters	**Baseline**	**Follow up**	**Baseline**	**Follow up**
Mean± SD	26.96±5.69	11.88±7.46	29.84±5.35	11.6±5.77
p value	<0.0001		<0.0001	
Average decrease in ODI score	15.08 (57.01%)		18.24 (61.48%)	

Table 4: Drugs co-prescribed with the interventional drugs.

Drugs administered	**Total no. of Patients**	**Percentage**
GROUP A (n = 25)		
Aceclofenac + Muscle Relaxant (Combination)	22	44%
Aceclofenac + Paracetamol (Combination)	1	2%
Aceclofenac + Paracetamol + serratiopeptidase	2	4%
GROUP B (n = 25)		
Etoricoxib + Muscle Relaxant (Combination)	23	46%
Etoricoxib 90mg alone	2	4%

Drugs co-prescribed in both the groups				
Name of the drugs	Group A		Group B	
	No. of Patients	Percentage	No. of Patients	Percentage
Pantoprazole	7	28%	5	20%
Gabapentine	9	36%	8	32%
Proteolytic enzymes	6	24%	15	60%
Vitamin B_{12}+Pregabalin	3	12%	4	16%
Inj.Vitamin B_{12}	1	4%	1	4%

Figure 1: Flow chart of the Study Design