



A PROSPECTIVE COMPARATIVE STUDY ON THE EFFICACY OF ACECLOFENAC AND DICLOFENAC IN LOW BACK PAIN

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ABSTRACT

A hospital based prospective observational study entitled as Prospective comparative study on the efficacy of Diclofenac and Aceclofenac in patients with low back pain in a multispecialty tertiary care hospital was done over a period of six months. The aim of this study was to compare the analgesic effect of Diclofenac and Aceclofenac in patients with low back pain. Total 158 cases of patients were collected from the orthopaedic outpatient department, out of which Aceclofenac and Diclofenac were sorted out equally according to physician's prescription. Pain Score was measured before and after treatment by using numeric pain rating scale and marked carefully. The data was statistically analysed through statistical package for the social science (SPSS). It was concluded on the basis of collected results. The conclusions showed that low back pain was found to be more in females than in males. While comparing pain intensity before and after treatment, the most predominant pain was observed before the treatment with either Aceclofenac or Diclofenac. There was a significant reduction in the mean pain intensity in patients who were prescribed with Aceclofenac when compared with Diclofenac in the study.

KEYWORDS: Numeric pain rating scale, pain intensity, low back pain, comparative efficacy.

INTRODUCTION

Low back pain is a symptomatic and a self-limiting condition which includes pain, muscle tension or stiffness, and is localized between the shoulder blades and the folds of the buttocks, with or without spreading to the legs (sciatica). In a national survey, 40% of the adults were found to have suffered from back pain which had lasted for more than one day and they had sought medical advice. In general 60-80% of the world's population experience low back pain during some point in their life. Back pain is the second most common reason for visiting a physician.

Low back pain is usually defined as the duration of an episode, which persists for less than 6 weeks; sub-acute low back pain which persists between 6 and 12 weeks; chronic low back pain which persists for 12 weeks or more. The management of low back pain depends on cause of pain and it can be non-surgical or surgical treatment and medication therapy. Medications commonly used include NSAIDs and muscle relaxants. However, the rationale behind this study was to compare the analgesic effect of Aceclofenac and Diclofenac. So, this study will fulfil the gap and serve as a reference for the physicians, for choosing the most suitable NSAID among these for such patient.

MATERIALS AND METHODS

The study was conducted for a period of 6 months in 158 low back pain patients came to orthopaedic department after getting clearance of institutional ethics committee in Cosmopolitan hospital, Trivandrum (Kerala). The study included the patients diagnosed with low back pain who are willing to participate in the study. The study excluded patients who are allergic to NSAIDs and patients who are not willing to participate in the study. The objective of our study is to compare the analgesic efficacy of Aceclofenac and Diclofenac in low back pain patients.

A written informed consent was taken in prescribed format from the parents of patients diagnosed with low back pain. All information relevant to the study was collected from the case records. The demographic characters, clinical features and other details were documented in the proforma. The pain intensity after giving Aceclofenac and Diclofenac were assessed using numeric pain rating scale. The collected data were recorded in Microsoft excel sheet and workload is entered as numeric code. For the analysis we had used SPSS (Statistical Package for Social Science) software.

RESULTS

On the basis of the study conducted in orthopaedic department of a tertiary care hospital for a period of 6 months, the following results were obtained. There were 158 patients who met the inclusion criteria of our study.

Gender distribution of low back pain patients

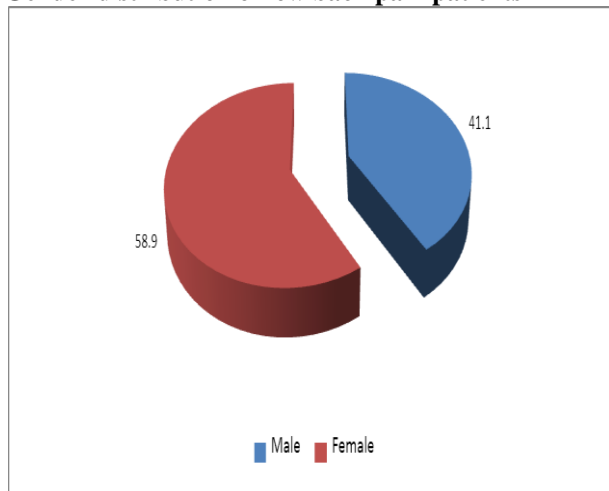


Figure 1: Distribution according to sex.

Out of 158 patients enrolled in the study 65 (41.11%) patients were males and 93(58.9%) were females. It

suggest that majority of patients were females compared to males.

Intensity of pain in patients with low back pain

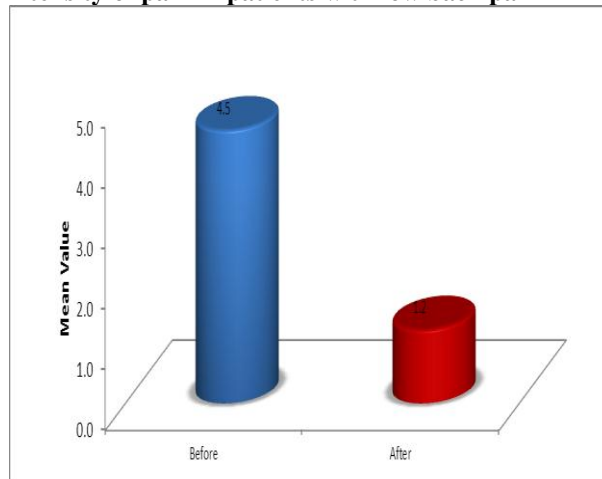


Figure 2. Graph showing mean effectiveness of aceclofenac among patients with low back pain.

The above figure shows that the mean pain intensity before treatment with aceclofenac is 4.5 and the mean pain intensity after treatment with aceclofenac is 1.2.

Table 1: Potency of efficacy of aceclofenac among patients with low back pain.

Pain	Mean	SD	N	Mean Difference	Paired t	p
Before	4.5	0.9	79	3.3	30**	0.000
After	1.2	0.5	79			

**:- Significant at 0.01 level

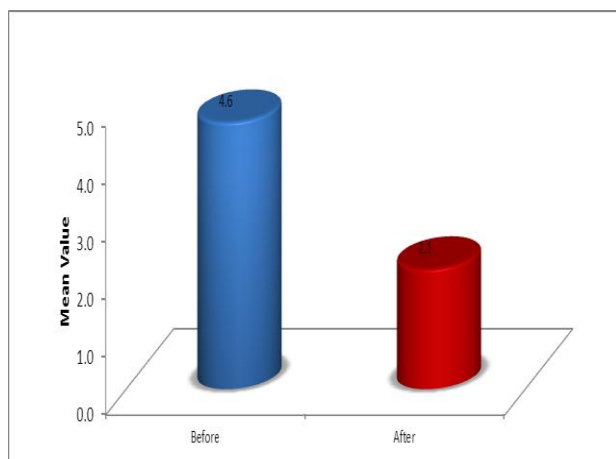


Figure 3. Graph showing mean effectiveness of diclofenac among patients with low back pain.

The above figure shows that the mean pain intensity before treatment with aceclofenac is 4.6 and the mean pain intensity after treatment with diclofenac is 2.1.

Table 2: Potency of efficacy of diclofenac among patients with low back pain.

Pain	Mean	SD	N	Mean Difference	Paired t	P
Before	4.6	0.8	79	2.6	21.71**	0.000
After	2.1	0.6	79			

**:- Significant at 0.01 level

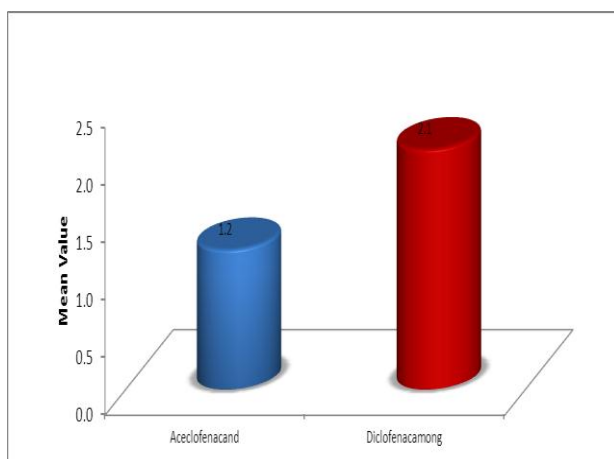


Figure 4. Graph showing Comparison of the efficacy of aceclofenac and Diclofenac among patients with low back pain.

The mean pain intensity of aceclofenac is 1.2 and the mean pain intensity of diclofenac is 2.1. This suggest that the mean pain intensity of aceclofenac is less than mean pain intensity of diclofenac. This shows that the pain intensity is reduced more after treatment with aceclofenac compared to diclofenac.

Table 3 Comparison of the efficacy of aceclofenac and Diclofenac among patients with low back pain

	Mean	SD	N	t	P
Aceclofenacand	1.2	0.5	79	9.72**	0.000
Diclofenacamong	2.1	0.6	79		

**:- Significant at 0.01 level

DISCUSSION

From the study of 158 patients during a period of 6 months in a tertiary care hospital it was found that low back pain was most commonly seen in females 93 (58.9%). Similar results were found in study done by Manek and Macgreger. In the present study, the two NSAID's were effective in reducing low back pain, which is similar to the findings of another study done by koes et al, It concluded that NSAID's were the drugs of choice for acute uncomplicated low back pain. Findings of study done by schattenkirchner and Milachowski also showed better efficacy and tolerability profiles of aceclofenac in low back pain patients, which were similar to our findings.

The result on pain severity shows that before treatment with Aceclofenac 60(75.9%) patients had very severe pain and 19(24.1%) patients had moderate pain. After treatment with Aceclofenac the pain intensity decreases, that is 64(81.0%) patients had no pain, 13(16.5%) had mild pain and 2(2.5%) had moderate pain. Before treatment with Diclofenac 65(82.3%) patients had very severe pain and 14(17.7%) had moderate pain, after treatment with Diclofenac the pain decreases that is 13(16.5%) patients had no pain 46(58.2%) had mild pain and 20 (25.3%) had moderate pain.

This result shows that both the two NSAID's are effective in reducing the pain intensity. While comparing both these drugs, the result shows that Aceclofenac is better in reducing the pain intensity than diclofenac. Similar results were observed in study conducted by Srijana Bhattarai et al.

CONCLUSION

The present study was conducted to compare the analgesic effect of Aceclofenac and Diclofenac and to assess the quality of life of low back pain patients. From the study, using a sample size of 158 patients who had low back pain. We got information about the intensity of pain before and after treatment with the two analgesics in low back. From analysis, we found the necessity to assess the intensity of pain to select an appropriate analgesic agent to reduce the pain and provide an effective treatment to the patient as part of the study. This study was monocentered, it involved limited sample size and duration of study was also limited. Therefore further studies need to be done on large population and at different centres, to extrapolate the findings of the efficacy of Diclofenac and Aceclofenac.

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