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RESEARCH ARTICLE

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A Pre-Post Study on Efficacy of Celecoxib and Ibuprofen for Acute Low Back Pain among Orthopaedic Patients at Security Forces Hospital, Makkah, Saudi Arabia

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Abstract

Background: The safety and efficacy of Celecoxib and Ibuprofen have not been adequately examined among orthopaedic Arab patients. This prospective study was carried out to compare the benefits of Celecoxib and Ibuprofen with reference to factors affecting patients with acute low back pain. **Methods:** Pre-post study was carried out at orthopaedic Out Patient Department at Security Forces Hospital, Makkah, and KSA. One hundred and nine patients were randomly selected and assigned randomly to two treatment groups: Celecoxib 400 mg, and Ibuprofen 100 mg. Pain was assessed using the World Health Organization pain scale. The decrease in pain score was calculated using a standardized system and was recorded on Day 5 and Day 10 of the patients follow up visits. Paired sample t-test, Mann-Whitney test and Chi-Square test were used at alpha level 0.05. **Results:** All the patients were Saudi nationals. Patients' age for Celecoxib group ranged from 20 – 59 years (34.2 + 10.9), while for Ibuprofen group ranged between 22 – 57 years (31.3 + 7.3). There were significant reductions in pain by both Celecoxib and Ibuprofen at the second follow-up visit, for all patients during walking, twisting, and while sitting in chair ($p < 0.05$). Celecoxib (400 mg) was superior to Ibuprofen (100 mg) in reducing acute low back pain of the study population ($p < 0.05$). The pain scores of patients receiving celecoxib and ibuprofen were significantly improved from Day 5 to Day 10. **Conclusion:** Celecoxib was more effective than Ibuprofen in reducing acute low back pain among the study population.

Key words: Acute Low Back Pain, Evaluation, Management, Non-Steroidal Anti-Inflammatory Drugs, Orthopaedic Patients, Outpatient, Pain Scale.

INTRODUCTION

Acute low back pain (ALBP) may be defined as an episode which persists for less than 6 weeks, and is associated with actual or potential tissue damage.[1] ALBP is among the most common reasons for patients to seek medical care, and is usually localized between the shoulder blades and the folds of the buttocks.[2,3] Over 40% of hospitalized patients and those presenting to the emergency department were reported to be suffering from ALBP.[4] Up to 80% of the world population were found to have complained from acute/chronic low back pain during some point in their life.[5] The management of ALBP depends on the cause of pain, and can be medical, surgical, or both. Medical treatment usually includes drug therapy, rest, and exercise. Surgical treatment is

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indicated when medical treatment fails. Non-steroidal anti-inflammatory drugs (NSAIDs) eg Celecoxib, Ibuprofen, as well as muscle relaxants are the commonly used drugs for treatment of ALBP. In a multidisciplinary expert panel study from the Middle East region,[4] on drug treatment of acute low back pain, NSAIDs were recommended for treatment of ALBP. The American Pain Society conducted an important study on the recommended drugs for low back pain, NSAIDs, including Ibuprofen, were ranked first as short term effective drugs against ALBP.[2] In a recent study at a tertiary care hospital in Nepal, NSAIDs were reported to be effective and safe for treatment of ALBP.[4] In the Kingdom of Saudi Arabia (KSA), the prevalence of low back pain was reported to be 18.8% among the general population in a study from Qassim region.[6] However, in a categorized surgical room staff of a tertiary care hospital in Makkah, the prevalence of low back pain was found to be 74.2%.[7] Most of the published research from KSA was on evaluating the effects of NSAIDs among categorized patient groups such as nurses, school workers, dental professions, and surgical room staff.[8-11] Celecoxib was the first NSAID designed to alleviate acute pain by inhibiting the activity of the enzyme COX 2 responsible for pathogenesis of pain. Ibuprofen is the NSAID which is commonly used instead of Celecoxib for emergency treatment of ALBP among orthopaedic patients. To the best of our knowledge, and literature search, the safety and efficacy of Celecoxib and Ibuprofen have not been adequately examined among orthopaedic Saudi patients.

The purpose of the present prospective study was to compare the benefits of Celecoxib and Ibuprofen with reference to factors affecting acute low back pain among patients seen at Security Forces Hospital -Makkah (SFH-M) KSA. We also aim to determine the association of patient age, gender, with the safety and efficacy of Celecoxib and Ibuprofen.

MATERIAL AND METHODS

Study Design and Setting: Prospective pre-post comparative study was carried out at orthopaedic Out Patient Department (OPD), SFH-M, KSA. The study duration was around six months (September 2015 – March 2016).

Ethics and Research Approval: The review board of Security Forces Hospital, Makkah, has approved this study (14/5/2015). Written informed consent form was read, explained and signed by all patients enrolled in the study.

Population and sampling: The study population was 109 patients, enrolled by random sampling. These patients then were assigned randomly to the treatment groups: celecoxib or ibuprofen. Patients were either considered or not in this study based on the following criteria:

Inclusion Criteria: Orthopaedic male/female out-patients who are 20 years of age or over; acute low back pain with duration of less than 6 weeks and patients who are prescribed Celecoxib 400 mg, and Ibuprofen 100 mg; only.

Exclusion Criteria: Patients with back pain due to malignancy, infection, metabolic disease; patients with back pain referred from other organs; pregnancy or lactating females; patients not complying because of mental disease or drug addiction and patients allergic to Celecoxib or Ibuprofen.

Evaluation: Two forms were employed in this study: Form 1 for demographic data of patients (Annex 1). Form 2 for numeric pain rating. The analgesic strengths used in this study was Celecoxib 400 mg, and Ibuprofen 100 mg. The decrease in pain score was calculated using a standardized system and was recorded on Day 5 and Day 10 of the patients follow up visits at orthopaedic OPD. The adverse drug reactions was recorded based on patient description. Pain was assessed using the modified World Health Organization pain scale (Annex 2).[12] The rating scale was adapted for Acute Low Back Pain ranged from 0 to 10: 0 = No pain, 1-2 = Mild pain, 3-5 = Moderate pain, 6-7 = Severe pain, 8-9 = Very severe and 10 = Untolerable pain.

Statistical Analysis: Statistical analyses and comparisons were performed by SPSS version 24 (IBM Corp. Released 2016. IBM SPSS Statistics for Windows, Version 24.0. Armonk, NY: IBM Corp.). Descriptive statistics i.e. frequency (percentage), mean (sd) and median (IQR) were used to describe the data, while paired sample t-test, Mann-Whitney test and Chi-Square test were used for the inferential statistics at alpha level 0.05.

RESULTS

One hundred and nine patients with acute low back pain who had presented to orthopaedic OPD of Security Forces Hospital-Makkah were recruited for this study. Among them 51 were prescribed Celecoxib (400 mg), while 58 were prescribed Ibuprofen (100 mg). All the study population were Saudi nationals. Age range for Celecoxib group was 20 – 59 years (34.2 $\pm$ 10.9), while for Ibuprofen group the age range was 22 – 57 years (31.3 $\pm$ 7.3). Gender for both groups showed male preponderance of 69 versus 40 for females, giving a ratio close to 2:1 (Table 1). There were no significant differences between gender in terms of age in both study groups (Celecoxib, p =0.380 and Ibuprofen,

ANNEX 1: Patient Data Collection: Questionnaire

Serial Number …… Patient File Number ……

Age …… Gender (A) Male …….. (B) Female ……

Occupation ……

Nationality (A) Saudi …….. (B) Non-Saudi ……

1. Pain Duration (A) Less than 6 weeks …… (B) More than 6 weeks …….
2. Allergy to Celecoxib or Ibuprofen (A) Yes …….. (B) No …….
3. Analgesic prescribed now (A) Celecoxib …….. (B) Ibuprofen …….
4. Dose details ……
5. Side Effects

   (A) Nausea ……

   (B) Vomiting ……

   (C) Headache ……

   (D) Abdominal Pain …….

   (E) Rash ……

   (F) Others (specify) ……...……
6. Smoker (A) Yes …….. (No) ……
7. Exercise / Physical activity (A) Yes …….. (B) No …….
8. If Yes, (A) Everyday ……. (B) Once/Week …… (C) Twice/Week ……..
9. Sick Leave given (A) Yes …….. (B) No ……

Table 1: Demographic features of orthopaedic patients who received Celecoxib or Ibuprofen for acute low back pain

	Celecoxib (n=51)	Ibuprofen (n=58)	*p* value
	n (%)	n (%)	
Gender			0.910*
Males	32 (62.7)	37 (63.8)	
Females	19 (37.3)	21 (36.2)	
Age (Median (IQR), years)	30.0 (25.0-46.0)	30.0 (25.0-37.0)	0.408**

Note: * analysis was carried out using Chi-Square test; ** analysis was carried out using Mann-Whitney test

ANNEX 2: Rating Scale for Acute Low Back Pain

Key : 0 = No pain, 1-2 = Mild pain, 3-5 = Moderate pain,

6-7 = Severe pain, 8-9 = Very severe, 10 = Untolerable pain

1. Describe your back pain NOW Score ……...……(1st Visit)
2. Describe your back pain AFTER DRUG INTAKE Score ……....(2nd Visit)
3. Do you have pain *during walking* NOW Score ……(1st Visit)
4. Do you have pain *during walking* AFTER DRUG INTAKE Score ……(2nd Visit)
5. Do you have pain *when twisting* NOW Score ……...…(1st Visit)
6. Do you have pain *when twisting* AFTER DRUG INTAKE Score ……...…(2nd Visit)
7. Do you have pain *when sitting in chair* NOW Score ……(1st Visit)
8. Do you have pain *when sitting in chair* AFTER DRUG INTAKE Score ……(2nd Visit)
9. Do you have pain *when lying in bed* NOW Score …… (1st Visit)
10. Do you have pain *when lying in bed* AFTER DRUG INTAKE Score ……...… (2nd Visit)

p=0.061).

The results of the test statistics (Figures 1 - 6) show significant reduction in pain by both Celecoxib and Ibuprofen at the second follow-up visit, for all patients during walking, twisting, and while sitting in chair. These pain reductions were analyzed by paired t-test and showed statistically significant ($p < 0.05$).

Celecoxib (400 mg) was superior to Ibuprofen (100 mg) in reducing acute low back pain of the orthopaedic study population (Figures 7 – 9). The difference in pain reduction between the two drugs using paired t-test was statistically significant ($p < 0.05$).

Table 2 shows significant differences in pain score after the second visit for both celecoxib and ibuprofen groups. The pain scores of patients receiving celecoxib and ibuprofen were significantly improved from Day 5 to Day 10.

DISCUSSION

According to Atlas *et al.* and Griffin *et al.* low back pain is usually self-limited which many patients treat themselves and at times the pain can be severe.[13,14] It could cause major pain, disability and costly medical condition.

There are several treatment options for patients with low back pain. There was statistical evidence of short-term improvement and effectiveness of NSAIDs versus placebo.[14] NSAID therapy was better than acetaminophen therapy but was not more effective than muscle relaxants or narcotics.[14] All NSAIDs are equally effective with minimal side-effects. Our study compared the benefits of Celecoxib, a COX-2 selective inhibitor and Ibuprofen, a NSAID with reference to factors affecting acute low back pain among patients. The findings showed both drugs were effective in reducing pain when compared between the first and second visits. Further analysis comparing the two study groups indicated that celecoxib was more effective when compared to ibuprofen. This finding is contrast from a study by Salo *et al*[15] No significant difference was found in their study when compared between celecoxib and ibuprofen among patients with acute pain in the emergency department. Van Tulder *et al*. noted that Ibuprofen is highly recommended than other NSAIDs because of its lower cost and GIT side-effects. In addition, according to them, the COX-2 inhibitors such as celecoxib or rofecoxib are more expensive and show no greater effectiveness than ibuprofen. One advantage of using the COX-2 is in patients who are significantly higher risk for GIT bleeding or peptic ulcer disease.

Back pain even though is usually acute is both a major

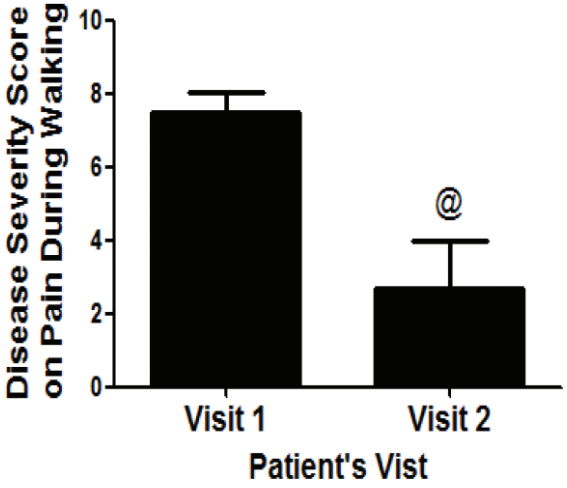

Figure 1: Celecoxib effect during walking

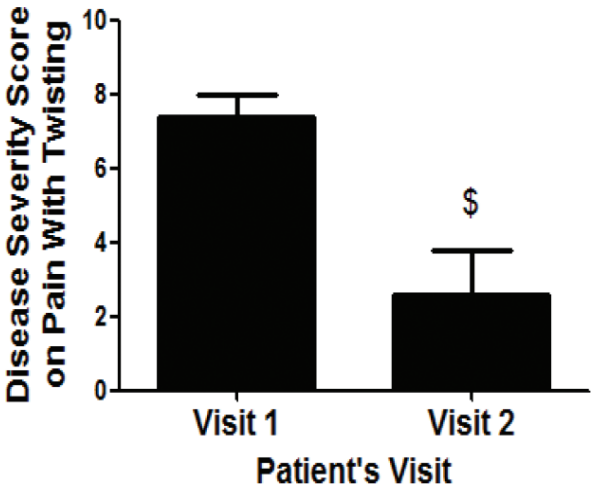

Figure 2: Celecoxib effect during twisting

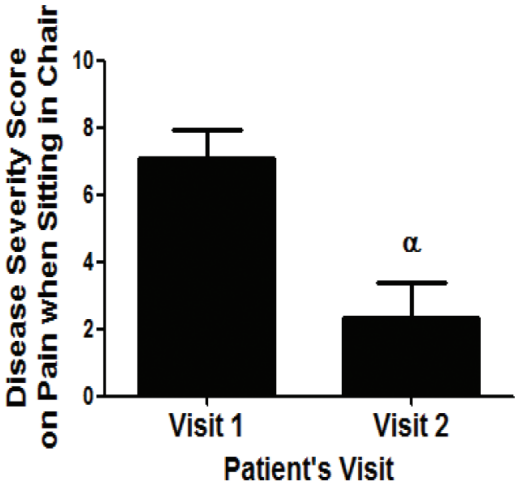

Figure 3: Celecoxib effect while sitting in chair

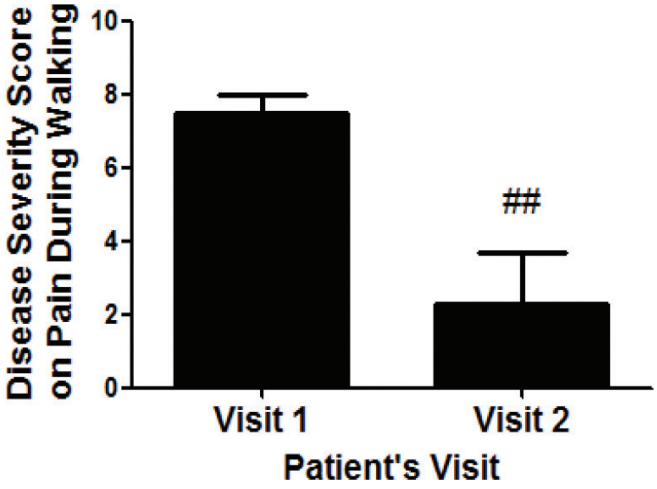

Figure 4: Ibuprofen effect during walking

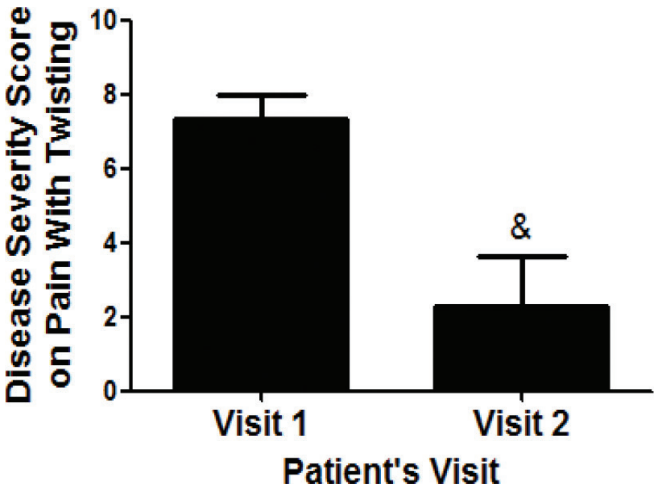

Figure 5: Ibuprofen effect during twisting

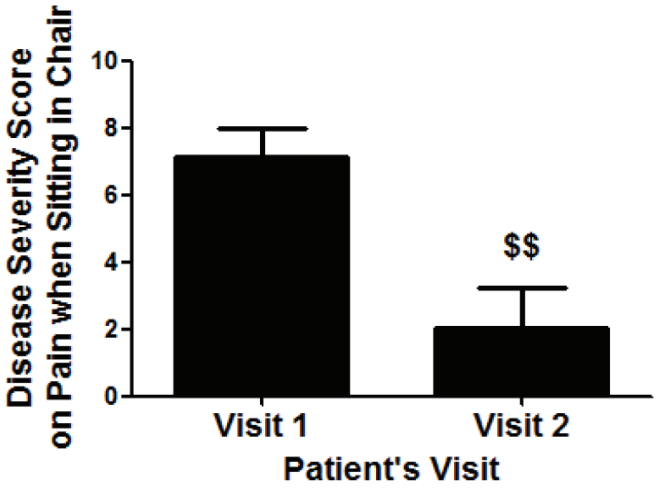

Figure 6: Ibuprofen effect while sitting in chair

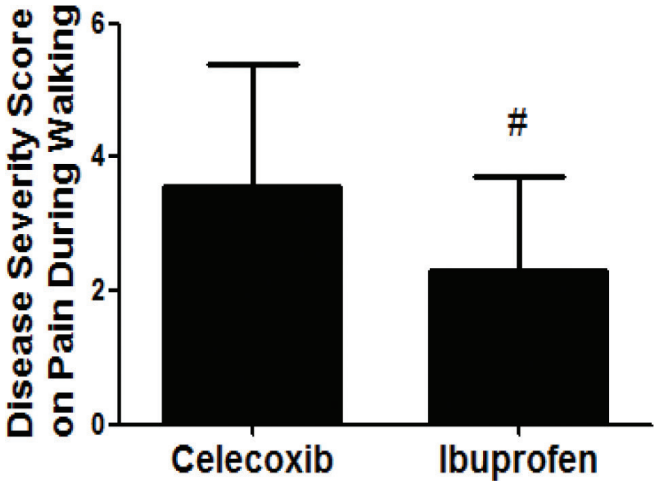

Figure 7: Celecoxib effect versus Ibuprofen effect during walking

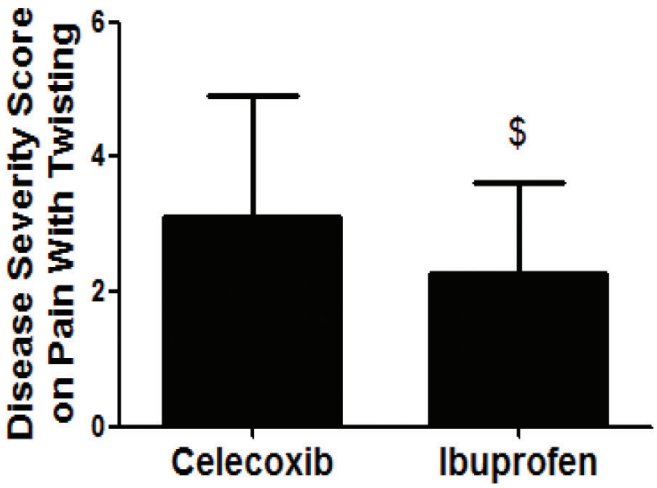

Figure 8: Celecoxib effect versus Ibuprofen effect during twisting

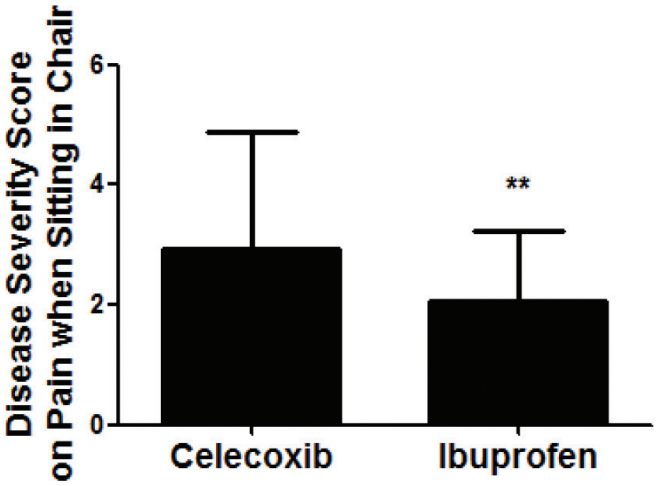

Figure 9: Celecoxib effect versus Ibuprofen effect while sitting in chair

cause of temporary disability and a challenge to medical and surgical treatment decisions. Patients must be taught on how to cope and getting the most cost-effective treatment. Our study did not take into consideration the cost of the treatment. Future study should look into drug side-effects and economic aspect of managing acute low back pain among the patients in the middle-east region. Drug therapy only provide temporarily relief for acute low back pain. Other modalities should also be explored. Non-steroidal anti-inflammatory drugs bring the pain to a tolerable level, but they should not be taken for short duration e.g. up to 12 days.[12]

Our study has provided evidence on the use of NSAIDs among Arab patients in KSA. We had modified the WHO analgesic ladder to ensure its appropriateness in evaluating

Table 2: Comparison of pain score during 1st vs 2nd visits for difference conditions after taking Celecoxib or Ibuprofen

Item	Mean difference (SD)	t value	p value*
Celecoxib			
Back pain (pre) – Back pain (post)	4.765 (1.124)	30.271	.000
Walk (pre) – Walk (post)	4.824 (1.276)	26.996	.000
Twist (pre) – Twist (post)	4.784 (1.172)	29.164	.000
Sit (pre) – Sit (post)	4.765 (1.106)	30.762	.000
Bed (pre) – Bed (post)	5.314 (1.421)	26.702	.000
Ibuprofen			
Back pain (pre) – Back pain (post)	5.155 (1.182)	33.222	.000
Walk (pre) – Walk (post)	5.172 (1.365)	28.849	.000
Twist (pre) – Twist (post)	5.069 (1.282)	30.105	.000
Sit (pre) – Sit (post)	5.103 (1.252)	31.038	.000
Bed (pre) – Bed (post)	5.552 (1.379)	30.667	.000

Note: * analysis was carried out using paired t-test

acute low back pain. These modifications are necessary for knowledge transfer in pain management.

CONCLUSION

This study showed that both ibuprofen and celecoxib were effective in reducing pain when compared between the first and second visits. In addition, celecoxib was more effective when compared to ibuprofen.

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Conflict of interest: No conflict or competing interests.

Abbreviations: None

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