A Comparative Prospective Observational study of safety and efficacy of Combination of Etoricoxib and Thiocolchicoside versus Naproxen in treating lower back pain and Muscle pain

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Abstract

Safety and efficacy of Naproxen and etoricoxib, thiocolchicoside combination in treatment of lower back pain and muscle pain. After receiving permission grant from hospital administration of Medicover Hospitals Begumpet a prospective comparative study was conducted. The patient's data was collected based on inclusion and exclusion criteria in the form of data collection forms. The comparative data was analyzed on the basis of safety and efficacy of the drugs base on ADR's. This study includes 72 patients out of which 56.94% were males and 43.05% were females and were assessed for a period of 6 months. All the patient population received Naproxen and combination of Etoricoxib and Thiocolchicoside. Mainly two adverse drug reactions were observed which seizures for central nervous system were after the administration of Thiocolchicoside and bradycardia, tachycardia for cardiovascular system after the administration of Etoricoxib in the respective study. As there was no ADR observed after the administration of Naproxen, thereby we conclude that Naproxen is safer and effective than Etoricoxib and Thiocolchicoside combination. Naproxen is a safer drug for treating lower back pain and muscular pain with least or minimal side effects. As a result of this medication people showed positive and improvised response on VAS scale when compared with a combination drug. Hence naproxen is the 1st drug of choice for treating lower back pain but Thiocolchicoside alone shows better response for treating muscular spams. A combination drug of Etoricoxib and Thiocolchicoside shows better results in treating patients with osteoarthritis or rheumatoid arthritis when compared to lower back pain.

Keywords: Musculoskeletal, osteoporosis, thoracolumbar, inflammation, ankylosing Spondylitis

Introduction

Back pain is one of the most common causes for patients to seek medical care in both primary and emergency care. There is a broad range of potential etiologies for both adult and pediatric populations. It is a physical discomfort occurring anywhere on the spine / back ranging from mild to disabling. Lower back pain describes the pain between the lower edge of the ribs and the buttock. It can last for a short time or may be also for a longer time. It can affect anyone. Lower makes it hard to move and can affect quality of life and mental well-being. Lower back pain can be specific or non- specific. Specific lower back pain is pain that is caused by a certain disease or structural problem in the spine, or when the pain radiates

from another part of the body. [1], most common causes include Over use drugs, Fibromyalgia, Lack of regular exercise and being overweight increases the risk of back strains and sprains [2].and the various risk factors includes, back pain is more common with increase in age. Starting around age 30- 40,Lack of exercise, Excess weight, Physiological conditions, Depression, Anxiety, Stress can cause muscle tension, which contributes to back pain Smoking, Because smoking causes coughing which can lead disc herniation, Smoking decreases blood flow to spine, Increase risk of osteoporosis. [3] .Prevention of Backache: Exercise. Regular low impact aerobics activities those that do not strain, Walking, cycling and swimming are good choice, Talk with your health care provider about which activities to try, Build muscle strength and flexibility, Abdominal and back muscle exercise which strengthen the sore, help condition this muscle together to support back,aintain a healthy weight, Being overweight strains back muscle, Quit smoking, Smoking increases the risk of low back pain, The rink increases with the number of cigarettes smoke per day, so quitting should help reduce the pain. [4].

Naproxen:

Naproxen is a widely prescribed analgesic for a variety of ailments, including menstrual cramping, headache, muscle discomfort, tendonitis, and dental pain. In addition, it alleviates joint rigidity, inflammation, and discomfort associated with bursitis, gout, and arthritis. The term for this pharmaceutical substance is a nonsteroidal anti- inflammatory drug (NSAID). It inhibits the synthesis of specific endogenous metabolites that induce inflammation within the body. If you are managing pain for a chronic condition such as arthritis, consult your physician about non- pharmaceutical alternatives and the use of additional medications. Verify the product's ingredients before using it again, even if you have previously done so. It is possible that the manufacturer altered the ingredients. Products bearing comparable names might also comprise distinct components deigned to serve alternative functions. Importing the incorrect product could be harmful. [5,6]

Etorcoxib:

Etoricoxib is classified as a selective COX- 2 inhibitor, which is a subtype of nonsteroidal anti- inflammatory drugs (NSAIDs). This enzyme is involved in the synthesis of prostaglandin, which is physiological mediators of inflammation, pain, and fever. Etoricoxib inhibits the synthesis of prostaglandin that is implicated in the inflammatory response by inhibiting COX 2. It alleviates inflammation and discomfort associated with a variety of musculoskeletal disorders by decreasing prostaglandin production. Subsequently, it aids in the reduction of fever, discomfort, and inflammation, which are symptoms of musculoskeletal disorders and conditions such as acute gouty arthritis, rheumatoid arthritis, and osteoarthritis.

Selective inhibitor of cyclo-oxygenase 2, an enzyme involved in pain and inflammation, it is a member of the COX- 2 selective class of non- steroidal anti-inflammatory drugs, and it has analgesic and anti- inflammatory property. [7,8].

Thiocolchicoside:

It is a muscle relaxant with anti- inflammatory and analgesic effect, it acts as competitive antagonist at GABAA and glycine receptors with similar potencies, and it has strong proconvulsant activity and should not be used in seizure prone patients. It is used as muscle spam and stiffness. It works by

acting on nervous system by releasing the tension in muscles without directly affecting the muscle function. It is mostly prescribed for conditions like back pain, muscle injuries or conditions causing muscle spasms. It helps by calming the muscles. Thiocolchicoside affects the nervous system, particularly the spinal cord, to relieve muscle tension and spasms. It is often used as a short- term treatment for acute muscle conditions such as sprains, strains, or lower back pain. It helps relax the muscles, reducing pain and improving mobility. [9, 10].

Materials and Methods:

Study site: Medicover Hospitals Begumpet Hyderabad.

Design:

A hospital based prospective comparative study on safety and efficacy of naproxen, Versus combination of Etoricoxib and Thiocolchicoside in treating lower back pain and muscle pain.

Study period:

The study was conducted for 6 months (September 2023 to February 2024).

Study population:

Patient who are on medication of naproxen, Etoshine, Thiocolchicoside and Etoricoxib

Sample size:

The total numbers of patients included in the study are 72 who are on medication.

Study criteria:

Inclusion criteria:

Patients who have signed informed consent form for study participation, commitment and ability to follow criteria requirements, Patients of both genders from 18- 85 years of age with specific or non- specific lower back pain or muscular pain, the type of pain patients suffering usually has an aching character of varying intensity with the movement of bending down or in the lumbar spine certain posture like walking, the severity of pain in the lower back after most painful movement is assessed by patients using VAS (0- 100mm) is ≥ 40mm, Pain in the lower back is causing disability (Roland Morris disability questionnaires core > 5 at screening),the disease recurrent episode pain lasting at least 24 hours but not more than 3 weeks prior to enrolment in this study, the duration of completely asymptomatic period between relapses is < 6 months, Negative pregnancy test for female patients of child bearing potential.

Exclusion criteria:

Hypersensitivity to NSAIDS, muscle relaxants and use of any other NSAIDS within 24 hours prior to enrolling for the study, History of bronchial asthma, allergic rhinitis or allergic type reactions or respiratory diseases induced by NSAID's, Use of steroids in the form of intramuscular and epidural injections within 30 days of study, Use of spinal or epidural anesthesia within 3 months prior of study, History of recent back injury, trauma malignant neoplasm, HIV, alcohol or drug addiction, systemic inflammatory diseases, no specific etiology as identified by CT or MRI scans, Severe liver dysfunction, renal failure, History of ulcerative changes in gastric mucus, History of chronic heart failure, cerebrovascular disease, uncontrolled hypertension, Clinically abnormal laboratory test, Participation in another study within 3 months to prior study, History of peripheral or central neural system which can impact patient's sensitivity in the study.

Withdrawal Criteria:

The patient can withdraw from the study trial for any of the following reasons:

Informed consent withdrawal by the patient, Need for additional therapy prohibited in the protocol, Patient talking drug which are prohibited the study, Patient developing adverse reactions, Need for any surgical intervention, Pregnancy of a patient, Impossibility of contacting the patient.

Source of data collection:

The relevant and necessary data was collected from hospital records, laboratory data and patient Interview

Designing the data collection form:

A suitable data collection form was designed to collect, document and analyze the data. Data collection includes the provisions for collection information related to Patient demographic details, Chief complaints, past medical history, Family history, Physical examination, other co morbidities, Laboratory investigations, and other relevant information.

Results:

In six- month prospective research, we compared the safety and effectiveness of naproxen versus the combination of etoricoxib and thiocolchicoside in a tertiary care hospital. We monitored 72 subjects who had lower back and muscular pain during the trial to assess the efficacy and safety of naproxen as well as the combination of Etoricoxib and Thiocolchicoside.

Base line	Characteristic
Age (years)	57.75 (Mean)
Gender (Male)	56.94%
Female	43.05%
Comorbidities	
Hypertension	33.3%
Hypertension + Hyperthyroid	8.3%
Hypertension + Chronic artery disease	2.77%
Hypertension + Diabetes mellitus	16.66%
Hypertension + Diabetes mellitus + Chronic artery disease	1.38%
Hypertension + Urinary track infections+ Chronic obstructive pulmonary disease	1.38%
Hypertension + Osteoarthritis	1.38%
Diabetes mellitus + Osteoarthritis	1,38%
Hypertension + Cardiovascular arrest	2.77%
Hypertension + Diabetes mellitus + Chronic kidney disease + Chronic artery disease	1.33%
Diabetes mellitus	30.55%

Drug wise distribution:

We have observed about 72 cases of lower back pain and muscle pain, and the drugs that were monitored are Naprosyn, Etoshine and Myoril.

Drugs	Number of cases	Percentage
Naproxen (Naprosyn)	37	50.68%
Etoricocib+ Thiocolchicoside (Etoshine)	27	36.98%
Thiocolchicoside (Myoril)	9	12.32 %
Total	73	100%

Total number of subjects observed:

A total of around 72 individuals have been discovered to be experiencing lower back discomforts and muscular pain. There were a total of 41 men, which accounted for 57% of the total, and there were 31 females, which accounted for 43% of the total.

Age wise distribution:

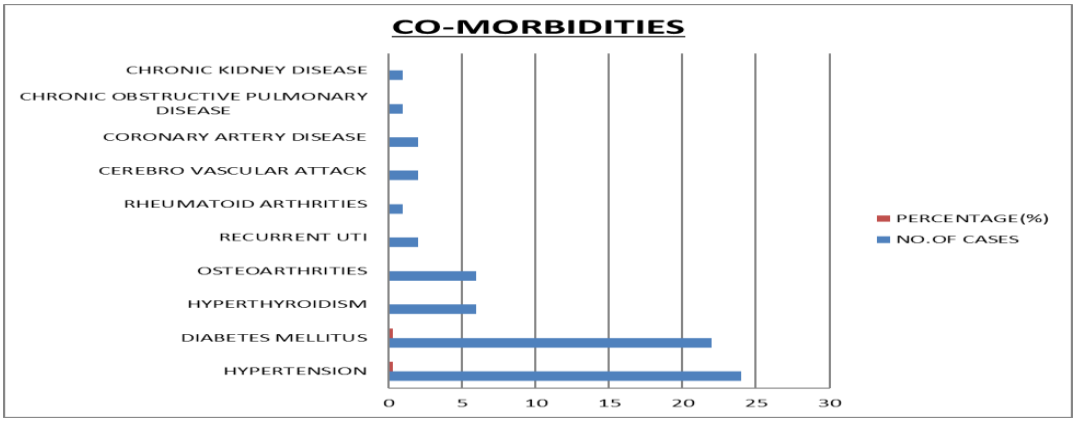
The drugs are predominantly administered across all age groups above the age of 18.

Age in years	Frequency	Percentage
18-33	10	13.8%
34-49	17	23.61%
50-65	26	36.11%
66 - 81	19	26.38%

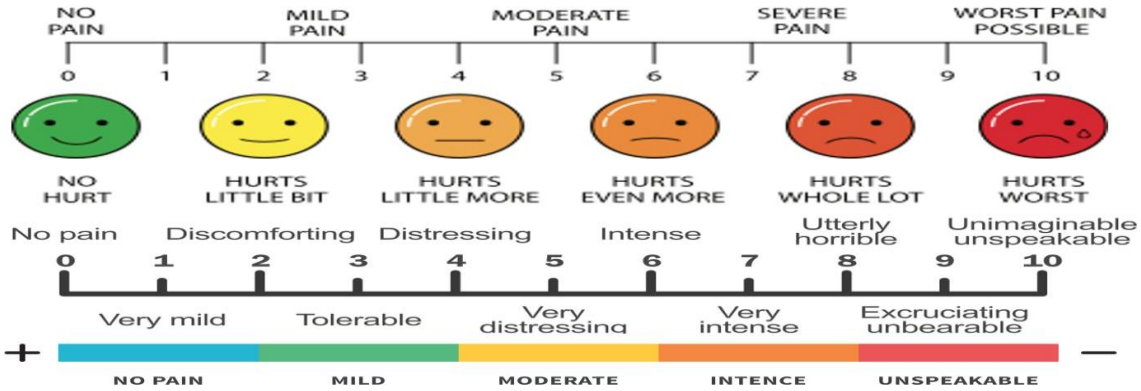
Based on comorbidities:

Comorbidities	No of cases	Percentage
Hypertension	24	33.30%
Diabetes mellitus	22	30.50%
Hyperthyroidism	6	8.30%
Osteoarthritis	6	8.30%

Recurrent Urinary track infections	2	2.70%
Rheumatoid arthritis	1	1.30%
Cardiovascular arrest	2	2.70%
Chronic artery disease	2	2.70%
Chronic obstructive pulmonary disease	1	1.30%
Chronic kidney disease	1	1.30%



PAIN SCALE MANAGEMENT BEFORE TREATMENT [VAS]



Values	Verbal Descriptive scale	Activity tolerance scale	Frequency	%
0	No pain	No pain	0	0
1 – 2	Mild pain	Can be ignored	6	8.3
3 – 4	Moderate pain	Interferer with task	25	34.7
5 – 6	Severe pain	Interferer with concentration	36	50

7 – 8	Very severe pain	Interferers with basic needs	3	4.16
9 – 10	Worst pain possible	Bed rest requires	2	2.77

Pain Scale Management after Treatment [VAS]

Values	Frequency	Percentage
0	0	0
1 – 2	52	72.22%
3 – 4	17	23.16%
5 – 6	3	4.16%
7 – 8	0	0%
9 – 10	0	0%

Adverse reactions:

Adverse effects	No of cases	Percentage
Regurgitation + Flatulence (GI)	4	5.5%
Tachycardia and Bradycardia (CVS)	3	4.16%
Seizures (CNS)	2	2.77%

Distribution of data based medication prescribed:

Treatment	No of cases	Percentage
Surgical treatment	42	58.33%
Clinical treatment	30	41.66%

Adverse Drug reactions of Thiocolchicoside

Thiocolchicoside	No of patients effected	Percentage
CNS adverse effects	2	22.22%

CVS adverse effect	0	0
Total no of patients	9	100%

Adverse Drug Reactions of combination of Etoricoxib and Thiocolchicoside:

Combination of Etoricoxib and Thiocolchicoside:	No of patients effected	Percentage
CNS adverse effect	0	0
CVS adverse effect	3	11.11%
Total no of patients	9	100%

Limitations:

We took into account a rather limited population, which is why our findings are as they are. If we conducted this on a large population, the findings could be different. The result also alters when we take into account various co-morbidities.

Comparison of ADRs among the given drugs:

Drugs	No of patients affected	Percentage
Combination of Etoricoxib and Thiocolchicoside:	3	4.15%
Thiocolchicoside	2	2.77%
Naproxen	0	0
Total no of patients	72	100%

Conclusion:

According to our findings, naproxen does not cause any adverse drug responses. However, after the administration of Thiocolchicoside to the patients, two of the patients exhibited central nervous system adverse events, including seizures. Furthermore, when Etoricoxib was delivered to the patients, three of the patients had adverse drug reactions that were connected to the cardiovascular system. It is consequently established that naproxen is safe and does not cause any adverse drug reactions.

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