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A Comparative Study of Diclofenac with Paracetamol versus Diclofenac with Serratiopeptidase in Pain Associated with Soft Tissue Injury

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Abstract: ***The point of the executives is to ease the pain rapidly and improve practical capacity. NSAIDs are the primary line treatment. Serratiopeptidase is the proteolytic enzyme. The challenge lies in deciding whether only NSAIDs or NSAIDs with proteolytic enzyme will give more prominent indicative help, while additionally being savvy. the primary goal is to think about the adequacy of diclofenac with paracetamol and diclofenac with serratiopeptidase in the administration of delicate tisssue injury. This prospective, open label, observational study was conducted at a tertiary care hospital. Patients over 18 years of age and presenting with soft tissue injury pain (elbow pain, knee pain, general pain, back pain) of less than 6 weeks duration were enrolled in the study. Forty patients with soft tissue injury pain were randomized into two groups: Group A got diclofenac with paracetamol (50mg/325mg) double a day and Group B got diclofenac with serratiopeptidase (50mg/10mg) double a day for 1 week. The Numerical Rating Scale (NRS) determined the clinically significant results. The decrease in pain intensity in Group B was (MEAN= 3.76), while in Group A it was (MEAN= 3.93). The average cost-effectiveness ratio indicated that diclofenac wit paracetamol was the dominant treatment over diclofenac with serratiopeptidase. Therefore, diclofenacc with paracetamol was found to be the cost-effective option for soft tissue injury pain relief in for 1 week. Both diclofenac wit paracetamol and diclofenac with serratiopeptidase. were clinically effective in reducing the pain intensity and in improving functional ability. H owever, diclofenac wit paracetamol was found to be the cost-effective intervention.***
Keywords: Paracetamol, diclofenac, Serratiopeptidase, soft tissue injury, pain.

I. INTRODUCTION

A delicate tissue injury is the harm of muscles, tendons and ligaments all through the body. Normal delicate tissue wounds generally happen from an injury, strain, an oddball blow bringing about a wound or abuse of a specific piece of the body. Delicate tissue wounds can bring about torment, enlarging, swelling and loss of capacity. THE REST, ICE, COMPRESSION AND ELEVATION (RICE) technique is the most ideal approach to treat intense delicate tissue wounds, like injuries and injuries. Progressed treatment alternatives for more genuine delicate tissue harm might incorporate infusions, bracing and exercise based recuperation

Diclofenac belongs to the Nonsteroidal Anti-inflammatory Drugs class of medicines. Diclofenac Tablet is a prescription medicine that is used to relieve pain and inflammatory conditions of joints. This medicine works by restricting the functions of natural enzymes (Cyclooxygenase -1 and Cyclooxygenase-2) in the body which prevents the release of inflammatory agents, Diclofenac Tabletcannot be used to treat pain that occurs after or before heart bypass surgery The typical dose of Diclofenac is 100-200 mg in one day. If you have taken more than the recommended dose of Diclofenac, an activated charcoal (60 to 100 g in adults, 1 to 2 g/kg in children) may be given. Passing the contents of the bowels out of the body (osmotic cathartic) within 4 hours of ingestion with large overdose (5 to 10 times the usual dose) should be recommended

Paracetamol belongs to a class of medicines called Nonsteroidal Anti-inflammatory Drugs. Paracetamol is used to relieve mild to moderate pain from a headache, toothache, cold, flu, joint pain, or periods pain. This medicine works by reducing the activity of certain chemicals in the body to provide pain-relieving effects.Paracetamolis also used to reduce fever. This medicine reduces fever by increasing the loss of heat from the body. The typical dose of Paracetamolis 1000 mg every 4-6 hours while symptoms last (not more than 4000 mg in one day). The maximum adult dose of Paracetamol is 4000 mg in a day. In the case of poisoning. N-acetylcysteine may be used as an antidote up to 24 hours after overdose of Paracetamol. It is best to use N-acetylcysteine within 8hours of overdose. Oral methionine may be also be used if the patient is in a remote area without access to a medical facility.

Serratiopeptidase Tablet is used for Bones and joints pain, Muscles pain, Swelling, Bloating, Blood clots, Sore throat, Headache, Ear infections, Muscles ache, Migraine and other conditions. Serratiopeptidase Tabletworks by helping the body in breakdown of

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protein. Serratiopeptidase reduces pain and swelling without inhibiting prostaglandins and has no gastrointestinal adverse effects. It also acts by enhancing blood circulation due to proteolytic effect, removing damaged and denatured proteins and cellular debris, and modulating inflammatory cytokines. Serratiopeptidase is a proteolytic enzyme, meaning it breaks down proteins into smaller components called amino acids. It's produced by bacteria in the digestive tract of silkworms and allows the emerging moth to digest and dissolve its cocoon

II. METHODOLOGY

A. Study Design

A prospective, open label, comparative observational study was conducted in the Department of Pain Management and in the Department of Orthopedics of a tertiary care hospital, Bangalore on patients with soft tissue injury pain prescribed diclofenac with paracetamol (50mg/325mg) and diclofenac with serratiopeptidase (50mg/10mg).

B. Sample size Calculation

At 5% level of significance and 80% power of test, ß of 0.2, the sample size was calculated as 20 patients per group. An additional 10% was added to compensate for the patients lost to follow-up. Hence, the sample size was calculated to be 20 patients in each group.

C. Study Criteria

Outpatients between 18–80 years of age presenting with soft tissue injury pain (elbow pain, knee pain, general pain, back pain) of duration less than 6 weeks and prescribed with diclofenac with paracetamol (50mg/325mg) and diclofenac with serratiopeptidase (50mg/10mg) were included in the study.

Patients with back pain caused by malignancy and/or infection, fractures, non-compliant patients, patients with renal and/or 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.

D. Study procedure

A total of 40 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. Each group consist of 5 elbow pain, 5 knee pain, 5 general pain, 5 back pain patients respectively

E. Interventions

Patients prescribed with diclofenac with paracetamol (50mg/325mg) were assigned to Group A. Patients prescribed with diclofenac with serratiopeptidase (50mg/10mg) were assigned to Group B by the physician. The patients were followed up for a period of 1 week.

F. Statistical analysis

Collected data was tabulated and analysed using SAS 9.3.14 through PROC MEANS AND PROC NPAR1WAY and also MS EXCEL was used to do graph .

III. RESULTS AND DISCUSSION

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 the 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". The baseline NRS scores is recorded at the start of the study. In group A mean score of back pain, elbow pain, general pain, knee pain are 3.64, 4.72, 3.52, 3.84 respectively. In group B mean score of back pain, elbow pain, general pain, knee pain are 3.84, 4.38, 3.52, 3.32 respectively shown in table 1

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Table 1: numerical rating scores in both groups

PAIN	N Obs	Variable	Label	N	Mean	Std Dev	Minimum	Maximum
BACK PAIN	5	Diclo+Para	Diclo+Para	5	3.6400000	0.1140175	3.5000000	3.8000000
		diclo+serap	diclo+serap	5	3.8400000	0.3646917	3.2000000	4.1000000
ELBOW PAIN	5	Diclo+Para	Diclo+Para	5	4.7200000	0.6942622	3.9000000	5.5000000
		diclo+serap	diclo+serap	5	4.3800000	0.4604346	4.1000000	5.2000000
GENERAL PAIN	5	Diclo+Para	Diclo+Para	5	3.5200000	0.4147288	3.0000000	4.0000000
		diclo+serap	diclo+serap	5	3.5200000	0.0836660	3.4000000	3.6000000
KNEE PAIN	5	Diclo+Para	Diclo+Para	5	3.8400000	0.2607681	3.6000000	4.2000000
		diclo+serap	diclo+serap	5	3.3200000	0.2280351	3.0000000	3.6000000

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

Fig 1 shows scores which is given by the elbow pain patients in both the groups, and mean score of group A was 4.72 and mean score of group B was 4.38, therefore group B drug was better than group A drug

Fig 2 shows scores which is given by the knee pain patients in both the groups, and mean score of group A was 3.84 and mean score of group B was 3.32, therefore group B drug was better than group A drug

Fig 3 shows scores which is given by the general pain patients in both the groups, and mean score of group A was 3.52 and mean score of group B was 3.52, therefore both group B drug and group A drug is better

Fig 4 shows scores which is given by the back pain patients in both the groups, and mean score of group A was 3.64 and mean score of group B was 3.84, therefore group A drug was better than group B drug

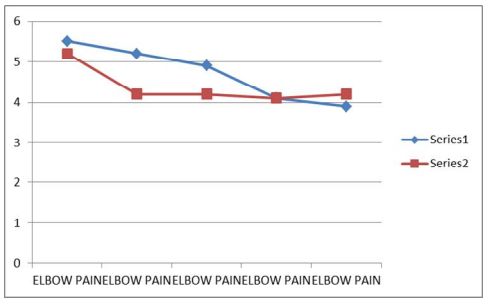


Fig 1: comparsion between elbow pain patients

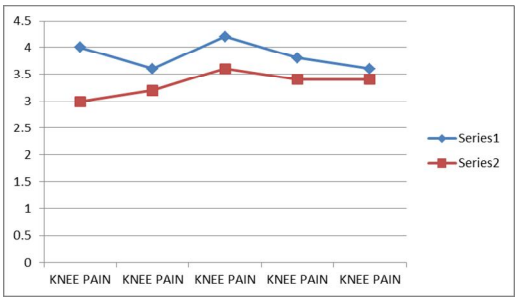


Fig 2: comparison between knee pain patients

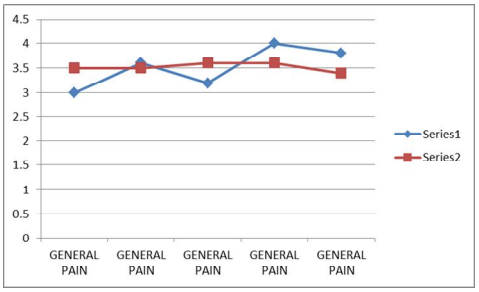


Fig 3: comparison between general pain

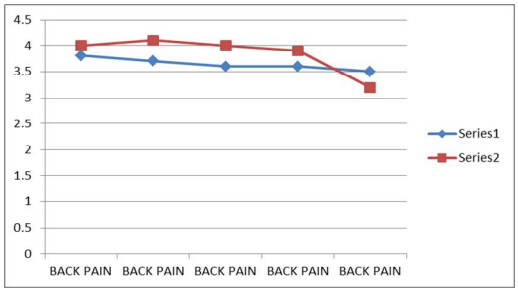


Fig 4: comparison between back pain patients

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Table 2 : overall numerical rating scores of both the groups

Variable	Label	N	Mean	Std Dev	Minimum	Maximum
Diclo+Para	Diclo+Para	20	3.9300000	0.6224738	3.0000000	5.5000000
diclo+serap	diclo+serap	20	3.7650000	0.5039580	3.0000000	5.2000000

A. Cost-effectiveness analysis

Cost-effectiveness analysis identifies the intervention which has 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, January–April 2018.

The average decrease in NRS scores is used as primary outcomes.

B. 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 diclofenac with serratiopeptidase (50mg/10mg) when compared with patients receiving diclofenac with paracetamol (50mg/325mg)

Upon calculation it was found that the ACER of diclofenac with paracetamol (50mg/325mg) was less when compared to diclofenac with serratiopeptidase (50mg/10mg) , indicating diclofenac with paracetamol is the cost-effective intervention. Hence, it is evident that diclofenac with serratiopeptidase is the dominant treatment over diclofenac with paracetamol for a duration of 1 week, since coming in the costeffective option for short-term pain relief diclofenac with paracetamol is better than diclofenac with serratiopeptidase

IV. DISCUSSION

A soft tissue injury is the damage of muscles, ligaments and tendons throughout the body. Common soft tissue injuries usually occur from a sprain, strain, a one off blow resulting in a contusion or overuse of a particular part of the body.

In our study group B [diclofenac with serratiopeptidase (50mg/10mg)] was better than group A [diclofenac with paracetamol (50mg/325mg)] but coming to the cost effectiveness, group A [diclofenac with paracetamol (50mg/325mg)] is better than group B [diclofenac with serratiopeptidase (50mg/10mg)] for short term pain relief by comparing with Srijana Bhattarai , Himal Paudel Chhetri , Kadir Alam , Pabin Thapa The decrease in average pain scores was more in the patients treated with aceclofenac (4.83 ± 0.537), followed by that in those who were treated with naproxen (4.13 ± 0.067) and diclofenac (3.84 ± 0.086). The decrease in pain scores was found to be lowest among patients who were treated with nimesulide (2.11 ± 0.148).

In our study group B [diclofenac with serratiopeptidase (50mg/10mg)] was better than group A [diclofenac with paracetamol (50mg/325mg)] but coming to the cost effectiveness, group A [diclofenac with paracetamol (50mg/325mg)] is better than group B [diclofenac with serratiopeptidase (50mg/10mg)] for short term pain relief by comparing with Sanjeev Kumar , Seema Rani , Ramchander Siwach , Prem Verma conducted a study and there was no statistically significant difference in pain relief and muscle spasm among the treatment groups but clinically showed better improvement in the Group A. The adverse drug reactions occurring during study showed a statistically significant better safety profile in the Group A than Group B.

V. CONCLUSION

According to the results of the present prospective observational study, both diclofenac with serratiopeptidase (50mg/10mg)and diclofenac with paracetamol (50mg/325mg)] are equally effective in reducing the pain intensity and improving the functional ability with soft tissue injury pain (elbow pain, knee pain, general pain, back pain). However, cost-effectiveness analysis indicated diclofenac with paracetamol to be a more cost-effective intervention when compared with diclofenac with serratiopeptidase. Hence, both diclofenac with paracetamol and diclofenac with serratiopeptidase are effective analgesics in soft tissue injury pain, nonetheless diclofenac with paracetamol was estimated to be a cost-effective intervention.

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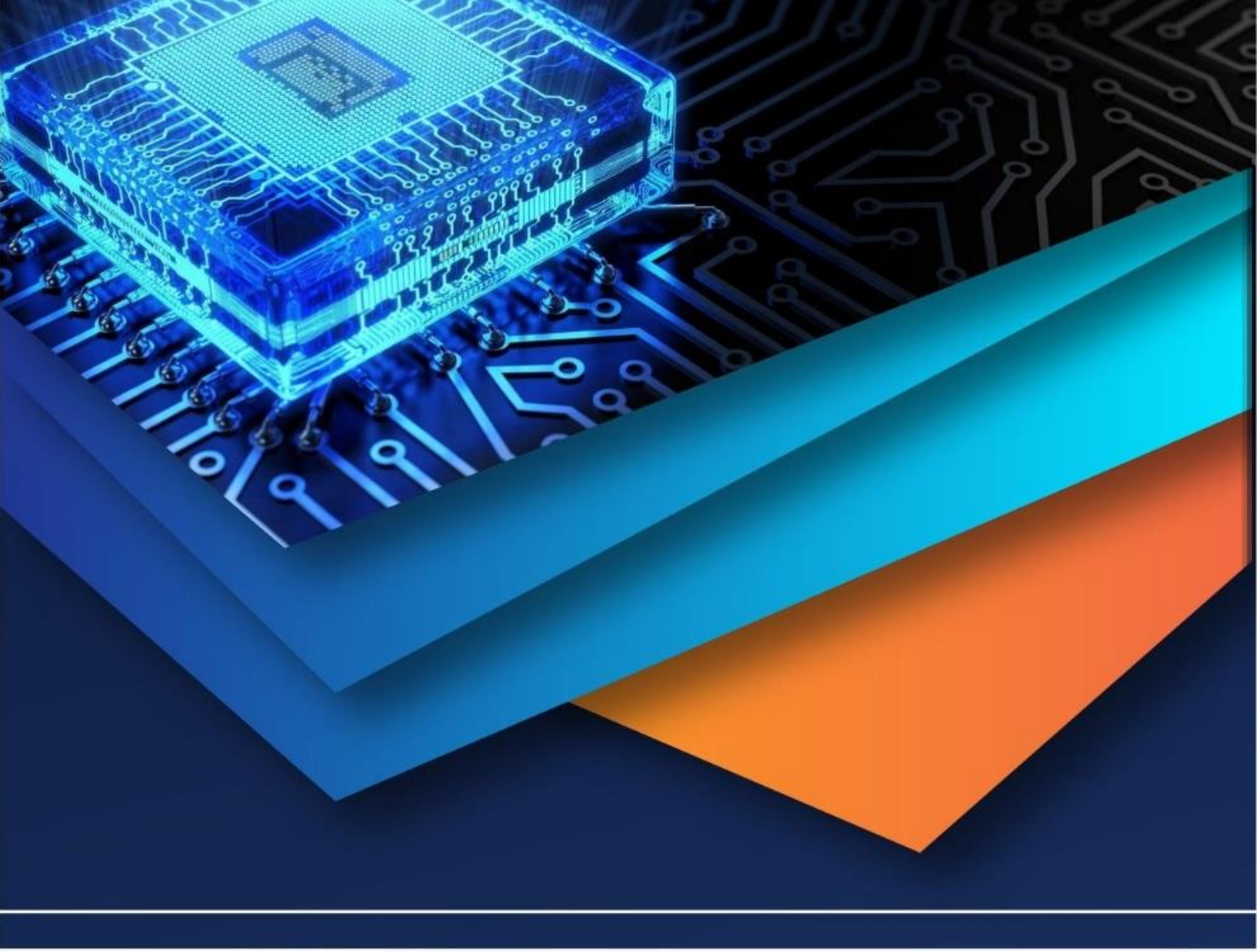
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