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Research Article

COMPARATIVE EFFICACY OF COMBINED USE OF DICLOFENAC WITH THIOCOLCHICOSIDE AND DICLOFENAC ALONE IN ORTHOPEDIC PATIENTS

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ABSTRACT

The present study was undertaken with the aim of comparing the efficacy of Diclofenac along with Thiocolchicoside and Diclofenac alone administered in orthopedic patients. A prospective observational study was carried out on inpatients for the duration of six months. Patients who meet the inclusion criteria and prescribed with Diclofenac are considered in the study. Pain is assessed during three stages of the Diclofenac therapy to determine the efficacy. Total NSAIDs prescribed was found to be in 73.06% patients. Among them non-selective NSAID Diclofenac (80 %) is the most commonly prescribed non-selective NSAID followed by aceclofenac (12%) and others (8%).The muscle relaxants Thiocolchicoside is prescribed in about 50% of patients. The efficacy in reducing pain was assessed in 2 groups of patients receiving diclofenac alone and the diclofenac +Thiocolchicoside combination .Severity of pain was recorded using pain assessment scale VAS, at three stages during the hospital stay. The mean pain scores are decreased in the two groups when compared at admission and discharge. The decrease in pain score was more pronounced with Thiocolchicoside +diclofenac group than the diclofenac group alone. Results of t-test between the two groups are found to be more significant ($p<0.05$). The combination use of muscle relaxants +NSAIDs show a better improvement in pain, stiffness and physical function of the orthopedic patients than the NSAIDs alone in reducing pain.

Keywords: Thiocolchicoside, observational study, aceclofenac

INTRODUCTION

Non-steroidal anti-inflammatory drugs (NSAIDs) are among the most frequently prescribed categories of drugs worldwide in the treatment of pain and inflammation in many conditions. NSAIDs show anti-inflammatory, analgesic, antipyretic effects and also inhibit thrombocyte aggregation.[1] NSAIDs are used primarily to treat inflammation, mild-to-moderate pain, and fever.

Traditionally NSAIDs, accounts for 70% of the total prescriptions for pain. Among individual drugs Diclofenac which is a non-selective NSAID accounts for most of the prescriptions when compared to the other selective NSAIDs.

Diclofenac sodium is a potent and widely used non steroidal anti-inflammatory and analgesic compound. It is classified among the most powerful drugs of this kind, while being one of the best tolerated which acts by inhibiting cyclooxygenase activity with a reduction in tissue production of prostaglandins such as PgF_{2alpha} and PgE_2.[2] Diclofenac and its metabolites are excreted in both urine and bile. The lack of entero-hepatic recycling in man probably accounts for the reduced gastrointestinal toxicity of this drug hepatic side effects are very rare.[3]

Muscle relaxants are the other commonly used class of drugs in orthopedic patients, generally these are central nervous system depressants[4]. Although these groups of drugs usually help to reduce spasticity, but decrease in muscle tone elsewhere, may lead to a decrease in the mobility of the patient. Also the development of sedation, is found to be a major limiting factor in the use of muscle relaxants, as they can affect daily activities and decrease working capabilities [4,5]. Hence, these limiting factors in the use of muscle relaxants raised a need for an ideal muscle relaxant devoid of effects on psychomotor performance, free of sedation and higher tolerability.

Thiocolchicoside is a semi-synthetic derivative of colchicine, a natural glycoside of Superba gloriosa.[6] It's in - vitro profile shows affinity for the inhibitory glycine and GABAA receptors [7] and therefore the compound is endowed with glycinomimetic activity and is being used in rheumatology and orthopedic field for its myorelaxant property[8].It has been reported that thiocolchicoside produces muscle relaxation without any subjective or objective sedative side effects[7] as well as anti-inflammatory and analgesic effects [9].

METHODOLOGY

It is a prospective observational study conducted from October 2011 to March 2012 on patients under inclusion criteria after getting approval from Institutional Ethics Committee.

A total of 80 patients were included in this study. Only those patients who were indicated for muscle relaxants were selected. Every alternate patient on Diclofenac was prescribed with Thiocolchicoside. Thus the two groups of 40 patients each, one with diclofenac alone and diclofenac plus thiocolchicoside were assessed for efficacy and outcome of pain management. Written consent of patients was taken on informed consent form in the local language.

Inclusion

- All the patients admitted in the orthopedic ward with musculoskeletal disorder and indication for Diclofenac (NSAID) therapy.
- All the patients co administered with Muscle relaxants along with Diclofenac (NSAID) therapy.
- All the patients above 18 years age of either sex.

Exclusion

- Patients admitted other than orthopedic ward.
- Patients not indicated for NSAID therapy.
- Patients co prescribed with other analgesic drugs.
- Patients below 18 years of age.
- Patients with history of liver and kidney damage, cardiovascular disease, acid peptic diseases.
- Pregnant and lactating mothers.
- Patients with co-morbidity
- Patients requiring emergency treatment or in ICU.

PROCEDURE:

- Demographic data and relevant medical history was obtained from all patients prior to initiation of therapy.
- Forty patients were randomly selected and were prescribed with diclofenac75 mg along with Thiocolchicoside 4mg twice a day.
- Forty patients were randomly selected and were prescribed with diclofenac alone in a dose of 75 mg twice a day.
- Patients were interviewed on daily basis for the symptoms of pain and documented in symptom report form.
- Severity of pain at rest ranging from 'no pain' to 'incapacitating pain' was assessed by Visual Analogue Scale and interviewing them at three levels –
    - Before initiation of Diclofenac.
    - During the course of Diclofenac.
    - At discharge or cessation of Diclofenac.

STATISTICS

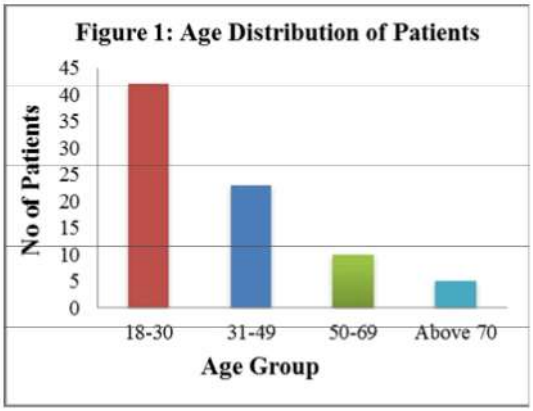
Results were expressed as mean ± standard deviation. Documented data is entered into SPSS.PC version 12.0

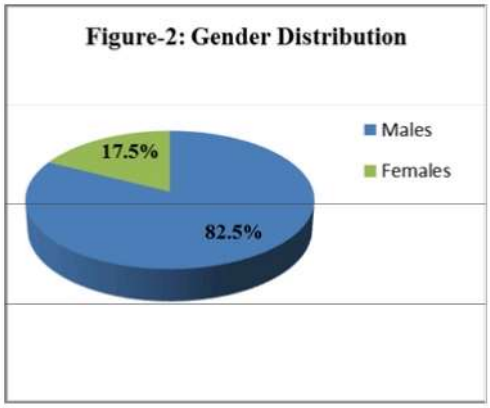
- Within the group, variables were compared with paired *t*-test.
- Between the groups, variables were compared with independent *t*-test.

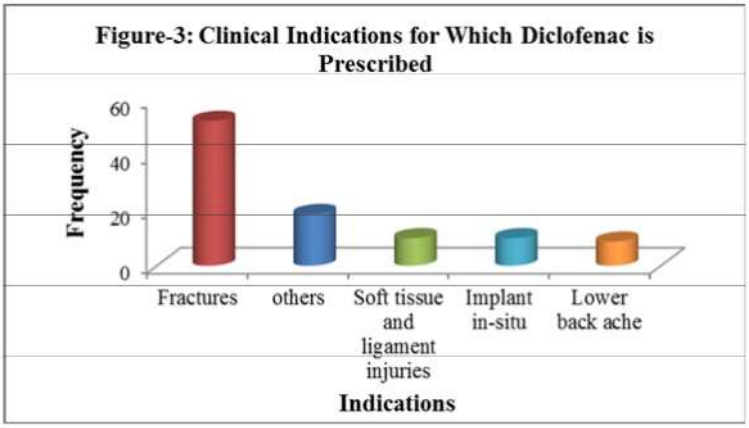
Statistical significance was taken at the 95% level ($P < 0.05$).

Table 1:Efficacy assessment of Diclofenac & Diclofenac+ Thiocolchicoside using VAS

Severity of pain based on VAS							
Diclofenac (D) group				Diclofenac+ Thiocolchicoside (D+T) group			
Mean scores of pain for 40 patients		Difference in mean scores at admission and at discharge	P value	Mean scores of pain for 40 patients		Difference in mean scores at admission and at discharge	P value
During admission	At discharge			During admission	At discharge		
5.35	1.15	4.2	<0.05	5.27	0.67	4.6	<0.05







RESULTS

Demographic details like age of the patients and the gender distribution are depicted in figure -1 & 2.

The different types of clinical conditions for which the NSAID (Diclofenac) prescribed is shown in figure -3.

Comparison of severity of pain assessed by VAS- Score of pain at admission assessed by VAS decreased significantly ($P<0.05$) as compared to baseline score within both groups i.e., group of patients receiving Diclofenac+ Thiocolchicoside (D+T) and patients receiving Diclofenac (D) alone. However, the decrease in severity of pain at discharge assessed by VAS was more pronounced within patients receiving D+T as compared to patients receiving D (Table 1)

DISCUSSION

The study reveals that the patients with age groups between 18-30 years (52.5%) are admitted in large number in the orthopedic wards, with male patients (82.5%) predominant to female patients (17.5%).

The commonest indications for prescribing Diclofenac in our study consists of fractures(52.5%)-of radius/ulna, of tibia/fibula , metacarpal etc followed by soft tissue injuries (10%) like- meniscal tear, carpal tunnel syndrome ,then comes the implant in-situs (10%) then the least number of patients with low back ache(8.75%) and 18.75% patients with miscellaneous conditions. In a study in eastern Nepal, the commonest indication for prescribing Diclofenac was fractures.[10]

NSAIDs are prescribed in 73.06% of the patients admitted in inpatient ward among which the nonselective account for 97.08% and selective for 2.92%.Among the non-selective NSAIDs, Diclofenac(80 %) is the most commonly prescribed non-selective NSAID. Elsy.M.I et al conducted a study on prescribing pattern of analgesics which shows that diclofenac is the most commonly prescribed drug (71%) followed by Paracetamol (13.5%) and Aceclofenac (11%).[11]

Efficacy of Diclofenac can be assessed by using three pain assessment scales VAS, VRS, Faces scale. Pain is assessed at three stages of hospital stay-before therapy, during therapy and at the time of discharge.

The mean+ SD scores of VAS at the three stages of pain assessment (Before therapy-5.35+2.15, During therapy-3.85+1.06, At discharge-1.15+0.85) reveals that pain is found to be decreased when three scores are compared. In a similar study conducted by Das SN et al on comparing efficacy and safety of diclofenac and pentazocin- promethazine the mean VAS score of diclofenac is decreased when they assessed the pain for 48 hrs. [12]

Skeletal muscle relaxants are a heterogeneous group of medications commonly used to treat two different types of underlying conditions: spasticity from upper motor neuron syndromes and muscular pain or spasms from peripheral musculoskeletal conditions.[13] The American Pain Society and the American College of Physicians recommend using NSAIDs as first-line treatment of acute pain and the use of skeletal muscle relaxants along with them show better effectiveness in management of pain than NSAIDs alone.

In the present study we assessed the efficacy of diclofenac and diclofenac+ Thiocolchicoside in two groups (40 patients each) by using VAS .It shows that the decrease in severity of pain was more pronounced within group of patients receiving Diclofenac+ Thiocolchicoside as compared to patients receiving Diclofenac alone and the difference between the two groups was found to be statistically significant. These results are similar to the study conducted on aceclofenac by sachdeva et al in low back pain patients which shows that the decrease in severity of pain at rest was more in group of patients receiving Thiocolchicoside+ Aceclofenac as as compared to patients receiving Aceclofenac, though the difference between the two groups was not found to be statistically significant.[14] Similar results are also found in a study conducted by Pareek A et al using aceclofenac-tizanidine in acute low back pain.[15]

CONCLUSION

Diclofenac is widely accepted and frequently used NSAID for pain management. The practice of using supplementation of muscle relaxants is also a common practice for enhanced therapeutic outcome. Our study results are very much relevant to state that Diclofenac when used along with Thiocolchicoside, a muscle relaxant produces pronounced improvement in pain, stiffness, physical function of patients as compared to the use of Diclofenac alone.

REFERENCES

1. McCormack K. Non-steroidal Anti-inflammatory drugs and spinal nociceptive processing. Pain 1994; 59:9–43.
2. Colin Dollery: Therapeutic drugs.2nd ed. Churchill Livingstone; 1999. D88-89.
3. D. Schapira, L. Bassan, A.M. Nahir and Y. Scharf, Diclofenac-induced hepatotoxicity, Postgraduate Medical Journal 1986; 62: 63-65.
4. Ketenzi A, Ozcan E, Karamursel. S. Assessment of efficacy and psychomotor performances of thiocolchicoside and tizanidine in patients with acute low back pain. International Journal of Clinical Practice. 2005; 59:764-770.
5. Woolfrey S, Kapur D. Pain, Neurological and Psychological Disorders. In: Walker R, Whittlesed C. Clinical Pharmacy and Therapeutics. Churchill Livingstone, Elsevier.London:, Edition 4, 2007: 480.
6. A.R Umarkar, S.R Bavaskar, P.N.Yewale. Thiocolchicoside as muscle relaxant: A Review. International Journal of Pharmacy and Biological Sciences 2011;1(3): 364-371
7. Patat A, Klein MJ, Surjus A, et al. Effects of acute and repeated doses of two muscle relaxants chlormezanone and thiocolchicoside, on vigilance and psychomotor performance of healthy volunteers. Human Psychopharmacology.1991; 6: 285–292.
8. WIPO; (WO/2007/009772) Thiocolchicoside Analogues with Myorelaxant and Anti-inflammatory activity.
9. Thiocolchicoside http://en.wikipedia.org/wiki/Thiocolchicoside
10. Das BP, Adhikari N, Garg M, Rauniar GP, Naga Rani MA. Utilization pattern of nonsteroidal anti-inflammatory drugs (NSAIDs) in orthopaedic practice at a tertiary care hospital in eastern Nepal. J Nep Med Assoc 2000; 39: 315-318.
11. Dr. Elsy.M.I, Dr.K.N.Ajitha. Prescribing Pattern of Analgesics in Orthopaedic Department of an Indian Tertiary Care Teaching Hospital in Kerala.Kerala Medical Journal 2008; 3: 149-152.
12. Das S N, Mohanty .M,Mohapatra .S, Verma N, Patel S.S, Patnaik. A comparative study of analgesic efficacy and safety of diclofenac sodium and pentazocin- promethazine in post operative analgesia in orthopaedic indoor patients in a tertiary care hospital. IJPI's Journal of Pharmacology and Toxicology 2010; 1:1-7
13. Alanko K, Stubb S and Kauppinen K. Cutaneous drug reactions: clinical types and causative agents. Acta Derm Venereol. 1989; 69: 223-226.
14. Boelsterli, U.A., Zimmerman, H.J., Kretz-Rommel, A. Idiosyncratic liver toxicity of Non-steroidal anti-inflammatory drugs: molecular mechanisms and pathology. Crit. Rev. Toxicol 1995; 25: 207–235.
15. Pareek A, Chandurkar N, et al. Aceclofenac – Tizanidine in the treatment of acute low back pain: a double blind, double–dummy, randomized, multicentric, comparative study against aceclofenac alone. European Spine Journal 2009; 10:1019-40

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