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STUDY ON COMPARITIVE ANALYSIS OF POST OPERATIVE ANALGESIC EFFICACY OF DICLOFENAC SODIUM VERSUS TRAMADOL IN ORTHOPEDIC SURGERIES

Dr. Anil Gurlingayya Nanjannavar

Associate Professor, Dept. Of Pharmacology, Raipur Institute Of Medical Sciences, Raipur, Chhattisgarh.

ABSTRACT **INTRODUCTION:** Post-operative pain management is an important challenge in the orthopaedic department. **OBJECTIVES OF THE STUDY:** The objective of this study is to compare the analgesic efficacy of Diclofenac Sodium with tramadol in patients with postoperative orthopaedic pain. **MATERIALS AND METHODS:** An hospital based prospective observational study was undertaken in Department of Orthopedics for the duration of one year. We included 80 patients having postoperative pain, the intensity of pain was assessed using VAS (visual analogue scale). Out of 80 patients, 40 patients received tramadol thrice a day and 40 patients received diclofenac sodium thrice a day. Both the drugs were given parenterally for 24 hours followed by oral medication for next 96 hours. Primary efficacy outcome measures were pain intensity differences assessed at 0, 8hr, 16hr, 24hr, 32hr, 48hr, 72hr, 96hr and 120hr using a VAS and secondary efficacy measures included maximum fall in pain intensity, number of patients who required rescue medication and their quality of sleep in the night. **RESULTS:** mean pain intensity differences assessed on 10cm VAS were significantly better for tramadol group at all points as compared to diclofenac group. **CONCLUSION:** Tramadol has more pronounced analgesic effect than diclofenac. Thus, tramadol can be considered as an effective alternative to traditional NSAIDs in the management of post-operative pain.

KEYWORDS : Pain, Tramadol, Diclofenac Sodium, Pain Intensity, Primary And Secondary Efficacy.

INTRODUCTION

Postoperative pain is both distressing and detrimental for the patient. Postoperative pain may be a significant reason for delayed discharge from hospital, increased morbidity and reduced patient satisfaction.[1] The management of postoperative pain involves assessment of the pain in terms of intensity at rest and activity associated pain, treatment by pharmacological and non-pharmacological means as well as monitoring induced side-effects. Besides being physically and emotionally disabling, pain is associated with various physiological effects involving increased perioperative stress response.

The pain causes the patient to remain immobile, thus becoming vulnerable to deep vein thrombosis (DVT), pulmonary atelectasis, muscle wasting and urinary retention. The aims of postoperative analgesia are to achieve pain relief without nausea and drowsiness and to avoid breakthrough pain during convalescence.[2-3]

Diclofenac is a non-steroidal anti-inflammatory drug (NSAID) used for postoperative pain relief. Diclofenac has analgesic, antipyretic, and anti-inflammatory activities. Its potency against cyclo-oxygenase-2 (COX-2) is substantially greater than that of indomethacin, naproxen, or several other NSAIDs. Diclofenac is useful for short-term treatment of postoperative pain, acute musculoskeletal pain, and dysmenorrhea. There are many reasons for preference of intramuscular diclofenac for postoperative pain relief. It has got rapid absorption and rapid onset of action. It is more potent analgesic than aspirin. The selectivity of diclofenac for COX-2 resembles that of celecoxib so that the incidence of serious gastrointestinal adverse effects did not differ between celecoxib and diclofenac in the CLASS trial.[4-5]

Tramadol is a synthetic codeine analogue that is a weak μ-opioid receptor agonist. Additionally, it also works by inhibiting reuptake of uptake of norepinephrine and serotonin. In the treatment of mild-to-moderate pain, tramadol is as effective as morphine or meperidine. Tramadol has got 100% bioavailability by intramuscular route. Tramadol has rapid onset of action. There is no ceiling dose for tramadol; therefore, pain management can be individually tailored to patient/pain response. Thus, it provides additional advantage to prefer it for postoperative analgesia.[6]

OBJECTIVES OF THE STUDY

The objective of this study is to compare the analgesic efficacy of Diclofenac Sodium with tramadol in patients with postoperative orthopaedic pain.

MATERIALS AND METHODS

A prospective, randomised observational study was conducted at RIMS, Raipur from December 2019-November 2020. We included the patients above 18 years, who were willing to participate in the study weighing 50-80 kg and patients with pain intensity at rest of at least 6cm on a horizontal 10cm VAS.

Patients allergic to NSAIDs, pregnant women, patients with known h/o substance abuse, patients on CNS depressants or warfarin, raised ICP, GI bleeding were excluded from the study. Two analgesic protocols were compared for postoperative pain relief following orhtopedic surgery. Group 1 received Diclofenac Sodium 75mg/IM TID for 24hours followed by 50mg oral TID for next 4 days. Group 2 received Tramadol 100mg/IM TID for 24hours followed by 50mg oral TID for next 4 days.

Pain assessment: Pain was assessed at different time points (0, 8hr, 16hr, 24hr, 32hr, 48hr) using a VAS, a 10cm line with the maximum pain indicated at the right-hand side, and no pain at the left-hand side (0-no pain, 2-mild pain, 4- tolerable pain, 6-distressfull pain, 8-severe pain, 10-totally disabling pain). The pain level was also assessed from the quality of sleep every night using 5-point scale (0-no sleep, 1-frequent waking, 2-shallow sleep every night, 3-good sleep, 4-deep sleep) as was done by Pagliara et al.[7-9]

Efficacy Criteria: The primary efficacy outcome measures were pain intensity difference (PID) assessed at different time intervals (0, 8hr, 16hr, 24hr, 32hr, 48hr, 72hr, 96hr & 120hr) and sum of pain intensity differences (SPID) for the first 8hr, 24hr, 48hr, 72hr, 96hr and 120hr) whereas secondary efficacy measures included maximum fall in pain intensity in each group, number of patients who required rescue medication and their quality of sleep in the night.

Rescue Analgesia: If the patient complained of severe pain (>8cm on VAS), acetamenophen upto 650mg thrice a day was considered to administer to the patients needing rescue analgesia as was used by Beaulieu et al.[10]

STATISTICAL ANALYSIS

Data were recorded on predesigned proforma, entered in a Microsoft Office Excel Worksheet. Statistical analysis was done using Statistical Package for Social Sciences (SPSS). Data were expressed in mean, standard deviation (SD) and percentage. Student's t test and chi-square test were performed to determine the significance. P value <0.05 was considered to be statistically significant. All the patients were informed before surgery about the study and written informed consent was taken from them prior to the study commencement.

RESULTS

We included a total of 80 patients in our study, who were admitted to our hospital for surgical treatment as per inclusion and exclusion criteria. In the present study 46 were males and 34 were females. The patients in this study ranged from 20-60 years. Weight of the patients ranged from 55-78kgs. Clinical diagnosis of the patients included, femur fracture, tibia, humerus, malleolus, & metatarsal fractures.

Table 1: Shows the comparison of mean VAS score between tramadol and diclofenac-sodium

Time	VAS score in Tramadol group	VAS score in Diclofenac Sodium group	P value
0	6.80±0.32	6.70±0.42	NS
8	4.06±0.41	4.32±0.51	S
16	4.11±0.65	4.42±0.65	S
24	3.95±0.47	4.15±0.39	S
32	3.87±0.44	3.99±0.39	S
48	3.40±0.52	3.62±0.43	S
72	2.95±0.64	3.23±0.54	S
96	2.98±0.57	3.22±0.48	S
120	2.58±0.59	2.98±0.51	S

Note: S: Significant (p = <0.05) & NS: Not Significant (p = >0.05)

It is evident from the table 1 that the mean pain intensity difference assessed on 10cm VAS was significantly greater (P<0.05) for tramadol group compared to the diclofenac group at all the time points.

Table 2: Shows the Comparison of mean sleep score (MSS) in tramadol and diclofenac sodium group

Day	MSS score in Tramadol group	MSS score in Diclofenac Sodium group	P value
1	0.90±0.74	0.89±0.42	NS
2	1.62±0.46	1.31±0.45	S
3	2.18±0.41	1.73±0.45	S
4	2.53±0.61	2.15±0.58	S
5	3.05±0.54	2.56±0.49	S

It is evident form the table 2 that, both the groups showed improvement in the quality of sleep. However, it was more significant in tramadol group compared to diclofenac group.

DISCUSSION AND CONCLUSION

In our study, we included all the trauma patients who had suffered from fracture of their bones. The most common presentation was limb fracture, similar to the observation of Pagliara et al, who noticed that fracture of upper and lower limbs was the most common finding while studying the safety and efficacy of tramadol compared with diclofenac in traumatic musculoskeletal pain.[11]

Many patients cannot tolerate oral medication or may experience compromised gastrointestinal absorptive function after surgery; hence there is a need for the parenteral formulations of study medication. Therefore, injectable forms of the tramadol and diclofenac were used in this study for the initial 24hours followed by oral form of the drugs. Numerous studies have compared tramadol with diclofenac in post-operative pain treatment in various types of surgical procedures. However, regarding their analgesic efficacy, there is no uniform agreement and their efficacy varies from study to study.[12-15]

Alwan et al, compared the effectiveness of paracetamol, diclofenac-sodium, and tramadol in controlling post tonsillectomy pain in 60 patients in their immediate post- operative period. Tramadol and diclofenac sodium were found quite effective in controlling post tonsillectomy pain but there was no significant difference in analgesic efficacy between tramadol and diclofenac groups. [12]

Joshi et al, compared analgesic efficacy of tramadol and diclofenac-sodium used as a rectal suppository in a prospective, randomized, single blind and hospital based study in 60 patients of ASA grade 2 posted for caesarean section. Rectal suppository of diclofenac was found better alternative for postoperative analgesia in caesarean section as compared to tramadol.[14] In the present study, mean pain intensity difference assessed on 10 cm VAS was significantly greater in the tramadol group compared to diclofenac group at all the time points. Moreover, in this study, tramadol also demonstrated superiority over diclofenac in terms of secondary efficacy variables like maximum fall in pain intensity score. Tramadol group reported a maximum fall of in pain intensity score as compared to diclofenac group. Thus, though both of the drugs produced good analgesic effect in the patients, the analgesic efficacy of tramadol was found significantly superior to that of diclofenac.

CONCLUSION

The results of this study indicate that tramadol thrice a day provides an effective and well tolerated relief from postoperative pain with better quality of sleep than diclofenac-sodium thrice a day. Hence tramadol can be considered as an effective alternative to traditional NSAIDs in the treatment of postoperative pain in orthopaedic patients.

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