



ORIGINAL RESEARCH PAPER

Orthopaedics

ANALGESIC EFFICACY POST MAJOR ORTHOPAEDIC SURGERY – A COMPARATIVE STUDY: DICLOFENAC VS TRAMADOL

KEY WORDS: Tramadol hydrochloride ; Diclofenac sodium ; post operative pain; visual analogue scale .

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ABSTRACT

Post-operative pain management is a major concern in orthopaedic surgery. Every surgeon has a post-op pain management protocol, though the ideal regimen or combo was always a debate. NSAIDs and Opioids occupy the majority in pain management regimen. In this study, the analgesic efficacy of Tramadol hydrochloride (Opioid) and Diclofenac sodium (NSAID) in patients undergoing a major orthopedic surgery was investigated and compared. A total of 50 randomly selected preoperatively and were grouped into receiving either one of the drug. Postoperative pain was evaluated by using a visual analogue scale (VAS) assessing at 6, 12, 18, 24, 32, 40, 48, 56, 64, 72, 80, 88, 96, 104, 112, 120 hours post-surgery. Tramadol hydrochloride showed significance in the early postoperative period (<40 hours) but later anti-inflammatory action of Diclofenac sodium indicates to be an enhanced analgesic (64 to 104 hours). However, no significance was noted in VAS score after 104 hours post-surgery.

INTRODUCTION

Post-operative pain is the reason for anguish, delay in discharge from the hospital, affects the rehabilitation and recovery to work (ShuklaAK et SrivastavAK .,2015). The treating physician does everything to decrease the postoperative pain without leading to more adverse problems, such as respiratory or vascular depression, gastrointestinal and visceral motility disorders, and drug tolerance and dependence (Lanzetta A et all.,1998). Diclofenac sodium, one of the most commonly used analgesic is a Non steroidal anti-inflammatory drug has an added anti-inflammatory effect crucial for post-operative analgesia. The primary mode of action responsible for its anti-inflammatory, antipyretic and analgesic action is inhibition of prostaglandin synthesis by inhibition of the rapidly expressed prostaglandin-endoperoxide synthase-2 (PGES-2) / as cyclooxygenase (COX-2). It also shows bacteriostatic activity by inhibiting bacterial DNA synthesis. (Dastidar SG et all.,2000)

Tramadol hydrochloride is an opioid analgesic used to treat mild to moderate pain; Tramadol has analgesic effects through a variety of different mode of action on the noradrenergic system, serotonergic system. Tramadol acts as a racemic mixture, the positive enantiomer inhibits serotonin reuptake while the negative enantiomer inhibits noradrenaline re-uptake, by binding to and blocking the release (Dayer P et all.,1994)

Post-operative pain tolerance differs for every individual and has to be plotted and managed separately for different individuals. For that reason, pain management can be independently adapted to each patient and pain reaction. Thus, it provides additional advantage to prefer it for orthopedic post-operative analgesia .Up to date only fewer articles have brought the attention to the comparative study of Diclofenac sodium and Tramadol hydrochloride and most of them are outdated and non-conclusive.

AIM:

To evaluated and compare the analgesic efficacy between Diclofenac sodium and Tramadol hydrochloride following a major orthopedic surgery.

METHODOLOGY:

Study design: This is a prospective hospital based randomized control study of patients following a major orthopedic surgery done in department of the orthopedics, Apollo hospitals, Chennai between June 2021 and December 2021 (6 months).

Sample size: A total of 50 patients, who had recently sustained a fracture and planned for surgical fixation, were taken for the study. The patients were explained and consent for the study

was obtained. The patients were divided into two groups of 25 members each based on selecting lots – Tramadol group or Diclofenac group.

Data collection procedure:

Each patient was well-informed in detailed about the pain assessment, the contents of the study and the pain assessment using visual analogue scale prior to the surgery. A well informed consent was taken from the patients regarding the study. Patients who were not able to express their pain in form of the visual analogue scale and patients who are not co-operating to participate in the study were excluded. Patients who were allergic to either drugs, had head injury, bleeding disorders, gastric ulcers or renal disorders were also excluded. Post-surgery, the patients were administered Diclofenac sodium (75mg Intra-muscular) or Tramadol hydrochloride (100 mg in 100ml normal saline infusion) thrice daily on 0-1 day. From 2nd to 5th day, tab. Diclofenac Sodium 50mg or tab. Tramadol 50mg were administered thrice a day. Information was collected by the investigator through a visual analogue scale at 6, 12, 18, 24, 32, 40, 48, 56, 64, 72, 80, 88, 96, 104, 112, 120 hours following the surgery. Patients with raised intracranial pressure or patients below the age of 18 years or patients with allergies to opioids or NSAIDs were excluded from the study taking into consideration their potential to cause a negative response on the patients (Paudel et all.,2017). The Visual analogue scale is used as measurement instrument for assessing the pain with no pain (score 0) on the left hand side and most severe pain on the right hand side (score 10). The data was collected from the patients at the said time interval. Any adverse effects following the administration were noted. Once the data was collected it was entered into excel sheet for data analysis

DATA ANALYSIS:

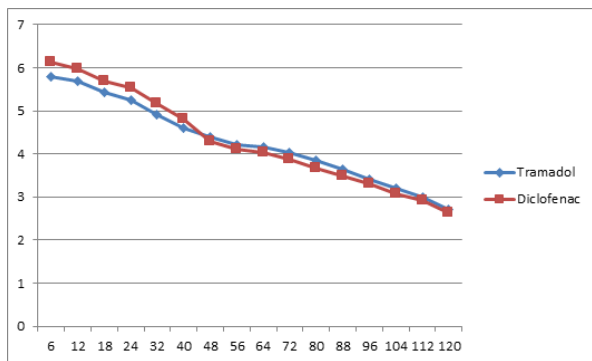
The data which was collected is tabulated and statistically analyzed using Statistical Package for Social Sciences (SPSS) and MS excel. P-value of <0.05 were considered for significance.

RESULT:

Time (Hours)	Tramadol		Diclofenac		Mean diff	P Value	Significance
	Mean VAS	SD	Mean VAS	SD			
6	5.8	0.66	6.12	0.71	-0.64	<0.05	Significant
12	5.68	0.7	5.96	0.68	-0.28	<0.05	Significant
18	5.44	0.68	5.68	0.67	-0.24	<0.05	Significant
24	5.24	0.64	5.52	0.69	-0.28	<0.05	Significant
32	4.92	0.61	5.16	0.64	-0.24	<0.05	Significant
40	4.6	0.56	4.8	0.59	-0.2	>0.05	Not significant
48	4.4	0.55	4.3	0.57	0.1	>0.05	Not significant

56	4.2	0.52	4.12	0.51	0.08	>0.05	Not significant
64	4.16	0.48	4.04	0.5	0.12	<0.05	Significant
72	4.04	0.5	3.88	0.47	0.16	<0.05	Significant
80	3.84	0.48	3.68	0.45	0.16	<0.05	Significant
88	3.64	0.47	3.48	0.43	0.16	<0.05	Significant
96	3.44	0.38	3.3	0.4	0.14	<0.05	Significant
104	3.2	0.41	3.08	0.38	0.12	<0.05	Significant
112	3	0.39	2.92	0.36	0.08	>0.05	Not significant
120	2.72	0.36	2.64	0.33	0.08	>0.05	Not significant

1. The mean VAS score was found lesser in Tramadol hydrochloride group at 6, 12, 18, 24 and 32 hours following the surgery compared to Diclofenac sodium group with mean difference of 0.64 to 0.2. The correlation was found significant in this time frame (p-value <0.05).
2. The mean VAS score was found lesser Diclofenac sodium group at 64, 72, 80, 88 and 104 hours following the surgery compared to Tramadol hydrochloride group with mean difference of 0.16 to 0.12. The correlation was found significant in this time frame (p-value <0.05).
3. The mean VAS score difference at 40, 48 and 56 hours following the surgery was not significant (p-value >0.05) with both Tramadol hydrochloride and Diclofenac sodium having similar analgesic efficacy around this time frame.
4. The mean VAS score difference after 104 hours (112 hours and 120 hours) following the surgery was not significant (p-value >0.05) with both Tramadol hydrochloride and Diclofenac sodium having similar analgesic efficacy around this time frame.
5. The mean VAS score in the initial hours following the surgery (up to 40 hours) indicated the better analgesic effect of Tramadol hydrochloride probably due to its initial sedative effects. However, after 56 hours post-surgery (64 to 104 hours), Diclofenac sodium gives a better analgesic activity and relieve of the pain symptoms incurring its anti-inflammatory effect. However, both drugs were found to be equally effective after 104 hours post-surgery.



DISCUSSION :

Diclofenac sodium can be considered as a first choice anti-inflammatory agent. In numerous clinical trials the efficacy of Diclofenac is established and has been compared to other NSAIDs and analgesics. It has an early onset and longer duration of action. When given intramuscularly its action potential is much higher than other analgesics. With various clinical trials and usage it has been proven as better tolerable and a safe NSAID. (Todd .PA et Sorkin .EM., 1988)

Tramadol is another commonly used and safe analgesic for post-operative pain. It produces relief of mild, moderate and severe pain (varying acute and chronic pain states) by using opioid and monoaminergically-mediated antinociceptive mechanisms. Tramadol is not as effective as morphine in severe pain on the other hand it is devoid of the adverse effects caused by the drugs of same class such as respiratory depression. Tramadol also has the minimal dependence and tolerance levels and an exceptionally little abuse potential compared to other analgesics. (Bamigbade .TA et Langford .RM., 1998)

There are a lot of studies conducted on the comparative effect between the Diclofenac sodium and Tramadol hydrochloride but not all have acquired similar results nor followed a similar pattern of study.

(Chandanwale et al, 2014) conducted a five day randomized control study with 204 patients with severe pain due to osteoarthritis , rheumatoid arthritis .They were divided into two groups. one group received a combination of paracetamol –tramadol and the other diclofenac-tramadol .A significant reduction in vas score was seen in group receiving diclofenac.

(Tuzuner AM et al, 2007) Conducted a study on pain assessment after bimaxillary osteotomy and other musculoskeletal procedures . 36 patients were divided into three groups based on randomized control envelope techniques .They received diclofenac , tramadol and saline(placebo) respectively. Following the operation they were given postoperative analgesia .And the assessment of pain were conducted The group which received tramadol had better pain relief followed by diclofenac than saline

(Pandit et all., 2011) conducted randomized control , comparative study between diclofenac and tramadol among 50 patients undergoing third molar surgery. They were divided into two groups and were given analgesics Intravenously before the operation . Following the operation, pain and acetaminophen consumption was accessed. diclofenac showed better pain scores and greater time for analgesic rescue compared to tramadol .

(wilder-smith et all., 2003) The postoperative pain was studied following the cesarean section and combined efficacy of Tramadol and Diclofenac was estimated .Three groups were divided based on double blinded randomised control trail. The combination of Tramadol and diclofenac with each other and with placebo was studied. The combination of Tramadol and Diclofenac was found to be more effective having greater analgesic rescue time .

In the study conducted by (pauzel et all., 2017) 60 patients were taken in randomized control trail they were divided into two groups receiving tramadol hydrochloride and diclofenac sodium .The study was conducted at (2,4,8,16,24,32,48,72,96, 120) hours following the surgery. A better response was recorded with Tramadol hydrochloride among these patients on the visual analogue scale.

The present study deals with post operative pain assessment taken at every 6 hours after the surgery till day 1 and every 8 hours following that till day five .

The patients were picked based on the lot technique . They were divided into two groups receiving tramadol hydrochloride and diclofenac sodium respectively. All patients in the study groups received either of the analgesic , no saline or placebo group was taken into the study considering the severity of post operative pain in the orthopedic surgery.

The result showed minor p value and mean significance for Diclofenac sodium for a longer duration postoperatively even though Tramadol hydrochloride had stronger potential instantaneously subsequently after the surgery

CONCLUSION:

The participants demonstrated better response to Tramadol hydrochloride in initial hours following the surgery till up to 40 hours post the surgery and better response to Diclofenac sodium few hours later to it from 56 hours to 104 hours following which it was not significant

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