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A Comparative Study of Tramadol and Diclofenac for Post – operative Pain relief

¹Priyanka Gulia, Assistant Professor, Department of Anaesthesiology & critical care.

²Sumit Pant, Assistant professor, Department of Operation Theatre Technology SGT University.

³KC Khanduri, Professor, Department of Anaesthesiology & critical care.

⁴Sunil K Chamola, Assistant Professor Cum statistician, SGT Medical College, Gurugram, india.

Corresponding Author: Sumit Pant, Assistant professor, Department of Operation Theatre Technology SGT University.

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Abstract

Introduction: Post-operative pain is one of the reasons for increased duration of hospital stay and increased morbidity also leading to higher hospital charges.

Various factors are responsible of post-operative pain which includes patient's previous s experience, psycho logical counselling by the operating surgeon and the anesthetist, type, duration, site and type of surgery and also most importantly the type of post - operative pain management. Thought he medical field had advanced, post -operative pain is an important area of concern for both surgeons and patient.

Methodology: 60 patients undergoing surgery were enrolled in the study. Prospective randomized study design was adopted and 30 patient search were assigned in to two groups receiving injectable tramadol and injectable Diclo fenac each for 48 hours post-surgery. The pain was assessed at different time intervals according to visual analogue scale and also parameters like adverse effects and requirement frescue analgesia were noted.

Results: There was no much difference between the two groups with respect to age and gender with female predominance. There was no statistically significant difference between the two drugs in pain management though adverse effects en countered was slightly higher among patients receiving tramadol. Requirement of rescue analgesia was similar in both groups.

Conclusion: Tramadol and diclofenac are the most commonly used drugs in pain management and there was no difference in pain relief post - operatively.

Keywords: Tramadol, Diclofenac, post -operative pain, Visual Analog Scale.

Introduction

One of the leading cause of pro longed duration of hospital stay is post operative pain, increased morbidity and decreased patient satisfaction. 1 The factors which contribute to the post -operative pain include the previous sex perienced of the patient and also by the psychological support given by the treating surgeon and anesthetist, post -operative surgical site pain management, type and duration of surgery and also severity of surgical trauma. ² assessment of the pain severity and monitoring for complications are a part of post – operative pain management and due to poor mobility by the patient suffering from pain, they are a trick of developing Deep

Vein throm bosis, muscular atrophy, urinary ret entionetc..³

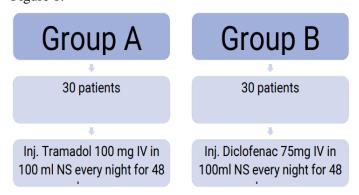
All the surgical procedures require proper management of the post – operative pain and inadequate pain manage ment can lead to morbidity and stress, prolonged recovery, high hospitalcost.^{4,5}

Even with various advancements in the medical filed, management of post operative pain is still one of the issues and of concern to patients. Hence our study was conducted tounderst and the better choice of drug in management of post operative pain and the aim of our study was to compare the analgesic efficacy for pain relief post-surgery between injectable tramadol and diclofenac and also to evaluate level of analgesia, incidence of side – effects and to find out number of patients require ing rescue analgesia.

Methodology

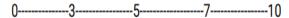
We adopted a prospective, randomized controlled study design conducted at SGT Medical College and Research Institute, Budhera, Gurugram. The duration of our study was for 6 months. 60 post -operative patients registered with the department of surgery were selected to differentiate the efficacy of analgesics for pain relief. Written informed consent was obtained from the study participants. The patients were randomly allocated in to two groups.

Figure 1:



A complete detailed history of patients, routine physical examination was conducted prior to the surgery. Basic

laboratory investigations like Haemoglobin, RBS, PTINR, Blood urea, serum creatinine, chest x-ray, ECG, HIV and HBs Ag were done. The surgical procedure to be done was explained and the post – operative pain was assessed using Visual analog scale. A10cm line on white paper indicates the patient's level of understanding of pain. The patient assesses the severity of their pain by placing a mark on a specific scale. A distance between 0 and a designated patient point will be used to calculate points.



No Pain

Maximum Pain

Score of 0-3 was considered as mild pain, 3-7 as moderate and > 7 as severe pain.

The following clinical parameters were studies

- 1. The onset of analgesia
- 2. Period of analgesia
- 3. Quality of analgesia
- 4. Cardio respiratory parameter
- 5. Side effects
- 6.Rescue analgesia if any (number of times.

Statistical analysis

Descriptive statistics will be analysed with SPSS version 25.0 software; continuous variables will be presented with as mean +/ -S D.

Categorical variables will be expressed as frequencies and percentages. Student's t- test (Independent t-test) will be used to determine the comparison between tramadol group and diclofenac group. P <0. 05 will be considered statistically significant.

Results

In our study we had enrolled 60 participants and they were divided into two groups of 30 participant seach receiving tramadol and diclofenac respectively. The data was analyzed for each group. There was no much

difference in the age wise distribution of participants between the two groups with almost qual distribution of participants (figure 1).

The mean age of the participant's receiving tramadol was 40. 53 years with a SD of 15. 18 years and the mean age of the participant's receiving diclofenac was 39. 33 years with a SD of 10. 58 years.

Female predominance was observed in our study in both the groups (figure 2).

The mean weight of the participant's receiving tramadol was 56. 23 kg with a SD of 10. 15 kg and among patients receiving Diclo fenac it was 60. 80 kg with a SD of 7.97kg.

The visual analog scale analysis indicated that there was no much difference in the pain score between the two groups and was not proven statistically significant at any duration post-surgery till 48 hours (table 1).

The incidence of adverse effects was noted slightly higher among the patients who received tramadol compared to the group receiving diclofenac. Headache (3%) and vomiting (13%) was seen among patients on tramadol while patients on diclofenac did not develop any such side effects (table 2).

Rescue analgesia wase qual in both the groups with 7 % of patients receiving rescue analgesia in both the groups (figure3).

Figure 1: Age wise distribution of the study participants

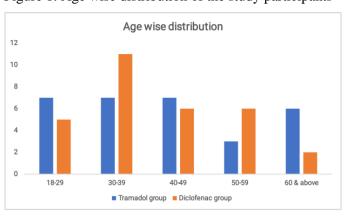


Figure 2: Gender wise distribution of study participants.

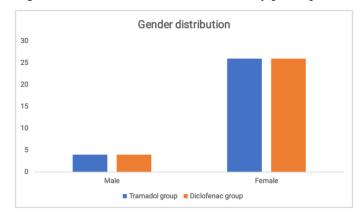


Table 1: Distribution of study participants according to VAS score.

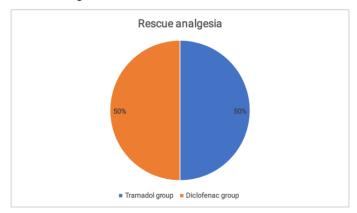
Visual analogue scale	Tramadol group	Diclofenac group	t value	p value
	(Mean ± SD)	(Mean ± SD)		
At 2 hours	8.30 ± 0.47	8.33 ± 0.48	0.273	0.786 ^{NS}
At 8 hours	7.30 ± 0.47	7.34 ± 0.48	0.273	0.786 ^{NS}
At 16 hours	6.27 ± 0.52	6.17 ± 0.46	0.787	0.434 ^{NS}
At 24 hours	4.30 ± 0.53	4.10 ± 0.31	1.78	0.081 ^{NS}
At 36 hours	3.33 ± 0.48	3.27 ± 0.45	0.55	0.581 ^{NS}
At 48 hours	2.03 ± 0.49	2.10 ± 0.31	0.632	0.530 ^{NS}

NS: Not significant at 5 % level of significance.

Table 2: Distribution of study participants based on adverse drug effect.

Adverse drug effect	Tramadol group	Diclofenac group	Total
Nausea	5 (17%)	3 (10%)	8 (13%)
Headache	1 (3%)	0 (0%)	1 (2%)
Vomiting	4 (13%)	0 (0%)	4 (7%)

Figure 3: Distribution of study participants based on rescue analgesia.



Discussion

Both medicate on groups had similar pain scores and at 48 – hour period pain scores in both study groups were significantly lower. However, there was no difference ineffectiveness between Tramadol and Diclo fenac in management of post-operative pain. The need for rescue analgesia and also the number of adverse drug events reported by patients in both groups were statistically insignificant.

Courtney etal [2001] reported that the analgesic efficacy of oral Diclofenac and Tramadol for post – tonsillectomy pain management had Similar analgesic efficacy. 6 Pagliara, etal. [1997] in their randomized trial on Diclofenac vs.

tramadol among patients with mode rate to severe musculoskeletal pain due to trauma found that tramadol had a higher analgesic activity than Diclo fenac, which differs from the findings of our study. 7 Hirkas etal., conducted a study wherein they gave 75 mg of diclofenac sodium or saline (place bo) intravenously in a single dose before surgery. Post-operative intravenous administration of diclofenac for the first 3 hours (three-way ANOVA) after surgery showed significant reduction in pain bey on d placebo. 8 Ong and Tan in their study compared post operative intravenous ketorolac to tramadol for pain control post third molar surgery and during the twelvehour study period, participants in the ketorolac group reported significant reduction in pain intensity while tramadol group had better analgesia, decreased postoperative acetaminophen use and also better general evaluation. The average tramadol analgesic duration was 8 hours, which was comparable to our study. 9

Despite initiating diclofenac infusion before surgery, M. A. Caley's etal. found that post-operative pain was present and similar to that experienced with place bo during the first post operative hours, which could be due

to a delay in Theon's et of diclofenac's effect or the drugs' limited analgesic capacity that was in sufficient to all eviate the severity of immediate post operative pain. ¹⁰ Goel etal., conducted a study comparing pre-operative analgesia with IV paracetamol and IV diclofenac sodium in patients undergoing various surgical procedures and they observed that the mean VAS score was greater in the diclofenac group during the first 4 hours, after wards there was no significant difference in pain level between the groups. ¹¹

Limitations

The limitations encountered in our study was time constraint in conduction of study, our study participants were limited to surgery patients only and the sample size was not large enough to generalize our findings.

Conclusion Both the drugs (Tramadol and Diclofenac) were comparative and both were equally effective in post – operative pain relief. They can begiven in post operative period if there are no any contraindications for the same.

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