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Original research article

A Comparative Study of Diclofenac and Tramadol Alone and in Combination in Obstetrics

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Abstract

Background: In obstetrics, post-cesarean discomfort is a frequent source of acute pain. Recovery from surgery and anaesthesia is significantly hampered by pain in the immediate postoperative period.

Aim: In this research, patients undergoing elective caesarean deliveries under spinal anaesthesia were examined to determine the effectiveness of postoperative analgesia and the incidence of side effects of the centrally-acting drug tramadol and the peripherally-acting drug diclofenac alone and in combination.

Methodology: The study 60 participants were randomly assigned to one of three groups of 20 patients each to undergo the following treatments: lower doses of tramadol and diclofenac (Group D), and tramadol (Group TD).

Result: Tramadol and diclofenac together generated substantially more rapid analgesia than either drug alone did, and side effects were less common.

Conclusion: We come to the conclusion that using tramadol and diclofenac together as part of a multimodal post-cesarean treatment strategy resulted in superior analgesia than either drug alone and a decrease in side effects. This combo method of pain relief is better and more advantageous.

Keywords: Post-cesarean pain, Diclofenac sodium, Tramadol hydrochloride

Introduction

A common source of excruciating pain in obstetrics is post-cesarean discomfort. There is insufficient pain alleviation, and the patient's satisfaction is frequently insufficient. These patients are always young, healthy, and active women who are ready to look for their infants. Postpartum period days and hours are crucial for the relationship between new mothers and their babies, and pain must not prevent the mother from nursing the child [1]. Effective postoperative analgesia has historically been achieved with opioids and nonsteroidal anti-inflammatory medications (NSAIDs).

Opioids make a person drowsy, which makes it difficult for a mother to interact with her child. NSAIDs administered alone are insufficient to deliver efficient analgesia. In order to increase efficacy and lessen adverse effects, a multifunctional approach was established, in which analgesic are administered in combination.

The combination of components should show additive or synergistic analgesia, and this interaction should allow lower dosages of each medication to be used in combination, leading to an enhanced safety profile, are the two key requirements that analgesic combos must meet [2]. This overview emphasises the therapeutic effects of combining analgesics with various mechanisms of action, notably an NSAID like diclofenac with an opioid like tramadol.

Method:

The current study was carried out in the Department of Pharmacology, Hitech Medical College & Hospital, Bhubaneswar, Odisha. The study included 60 patients who underwent lower segment caesarean sections in total. The institutional research and ethical research committees approved the study. Before a patient or close relative could participate in the study, written informed consent had to be obtained from them. The research consisted patients between the ages of 19 and 36 who underwent lower segment caesarean deliveries while under spinal anaesthesia with American Society of Anaesthesiologists Classes 1 and 2.

Patients with a history of peptic ulcers or gastrointestinal bleeding, opiate usage during the previous 25 days, pregnancy or eclampsia, respiratory disease, or intra-operative problems from a modified surgical procedure were excluded from the trial. Tramadol (Group T), diclofenac (Group D), tramadol, and diclofenac were given as medications to the reported 60 participants, who were randomly assigned into three groups of 20 each (Group TD)

The patient was informed about the VAS prior to surgery, and it was used to measure pain. VAS was used to rate each patient's level of pain and degree of pain alleviation after receiving the medication injection. At 1, 3, 5, 7, 10, 12, and 25 hours, the severity of the pain was assessed, and analgesia had started by then. When the VAS was greater than 4 or the patient requested it, a fourth dose was given. Up until the initial need for rescue analgesia, the time of effective analgesia was measured. The total number of dosages administered was noted. Additionally, the negative effects associated with the various regimens were contrasted.
SPSS software was used for all data analysis. The data was presented as mean SD. To assess pain scores, the Kruskall-Wallis test was used, followed by the Mann-Whitney test for intergroup comparison. ANOVA was used to evaluate the data on the onset, duration, and number of dosages, followed by the Least Significant Analysis of variance for post-hoc analysis. Chi-square test was used to compare side effects. It was deemed statistically significant at $p < 0.04$.

Results:

At the first sign of tolerable pain following surgery, 60 patients were randomly assigned into three groups of 20 patients each to receive either tramadol, diclofenac, or tramadol plus diclofenac IM. The three group patients characteristics did not significantly differ from one another **(Table 1).**

Table 1: Demographic data and Baseline characteristic

Characteristic	Group D (n=20)	Group T (n=20)	Group TD (n=20)
Gestational Age (weeks)	38.71 ± 1.35	38.61 ± 1.14	38.41 ± 1.66
Height (cm)	155.31 ± 4.81	154.91 ± 3.08	155.81 ± 5.25
Age (years)	22.42 ± 2.77	21.91 ± 2.28	38.41 ± 1.66

D: Diclofenac, T: Tramadol, TD: Combination of tramadol and diclofenac

In the first five hours after surgery, vital indicators like blood pressure, pulse, and respiration rate were monitored regularly. The findings indicate no appreciable clinical variance. In comparison to taking either tramadol or diclofenac alone, the combination of the two drugs considerably increased the time until analgesia set in **(Table 2).**

Table 2: Incidence and prevalence of analgesia in cohort.

Parameter	**Group T (n=20)**	**Group D (n=20)**	**Group TD (n=20)**
VAS at 3 hr	2.86 ± 0.81	2.76 ± 0.76	1.96 ± 1.34
VAS at 5 hr	2.41 ± 1.01	2.26 ± 0.93	1/46 ± 1.13
VAS at 7 hr	3.26 ± 0.82	3.21 ± 1.11	2.12 ± 1.16
Duration of analgesia	550.66 ± 94.43	412.01 ± 72.91	538.01 ± 89.64
Onset of analgesia	36.51 ± 9.20	24.16 ± 9.20	18.32 ± 6.73
Dosage in 25 hr	2.66 ± 0.4	3.71 ± 0.5	2.51 ± 0.3
VAS scores are expressed as Mean ± SD, T: Tramadol, D: Diclofenac, TD: Combination of tramadol and diclofenac, VAS: Visual Analog Scale. *denotes $p < 0.04$ and considered significant			

Table 3: The combination synergistic effect may be to blame for this

Symptoms	Group D (n=20)	Group T (n=20)	Group TD (n=20)
Dizziness	2	4	5
Drowsiness	6	8	7
Vomiting	4	3	6
Nausea	8	5	2
D: Diclofenac, T: Tramadol, TD: Combination of tramadol and diclofenac			

Compared to patients receiving tramadol, patients getting diclofenac alone experienced much earlier onset. Given that all of the patients were pregnant, the late onset of analgesia in the tramadol group may have been caused by altered sensitivity. Tramadol alone or in combination with diclofenac required significantly fewer dosages to be administered to patients than diclofenac alone.

Discussion:

According to research, postoperative pain is a type of acute pain brought on by surgical trauma, an inflammatory response, and the start of an afferent neural barrage [7]. In obstetrics, post-caesarean section discomfort is a frequent source of acute pain. Recovery from surgery and anaesthesia is significantly hampered by pain in the immediate postoperative period. The observations and those from the literature imply that taking tramadol and diclofenac together enhances discomfort over taking either medicine alone. Patients who got both tramadol and diclofenac simultaneously experienced less pain than those who received only tramadol or just

diclofenac. In the literature, the idea of a multimodal strategy to pain control that uses a variety of medications that reduce pain using several pathways has been frequently discussed. With a large sensitivity for receptors and a poor affinity for and receptors, tramadol is a centrally-acting analgesic.

Along with its effects as an opioid agonist, tramadol also improves the performance of the spinal descending inhibitory pathways by preventing the absorption of norepinephrine and 5-hydroxytryptamine in neurons and by presynaptic enhancement of 5-HT release. [8] Instead of providing afferent block, NSAIDs like diclofenac reduce the amount of prostaglandins produced by injured peripheral tissues. According to some data, NSAIDs may play a key role in the non-opioid supraspinal nociceptive reflex's ability to reduce sensory input [9]. Diclofenac may provide superior quality analgesia in the postoperative period than tramadol because of its effects on reducing prostaglandin synthesis, which may help it relieve pain brought on by uterine contractions. In this trial, the tramadol group's onset of analgesia occurred 36.4±9.20 min quicker than it did in the study by Norman R. Rosenthal et al.[10], where it took 51 min.

51 minutes were spent on the study by Norman R. Rosenthal et al. This might be as a result of the oral delivery method for tramadol that was used in their study. In comparison to Zuniga et alstudy[11], where the onset of analgesia was 18 min, the diclofenac group's onset of analgesia was 24.16 ±10.08 min. This could be as a result of the pain model they researched being post-operative molar extraction. Tramadol's analgesic effect lasted for a similar amount of time in this study as it did in the Dellikanvet et. Al. [12], which measured 559 ± 86.43. It was similarly comparable to the study conducted by Prabhakar et al.[13] where the duration of analgesia for the diclofenac group was 400.00 ± 75 min. the frequency of unfavourable effects of each individual medicine by lowering the dose. In our research, a similar outcome was attained with a reduction in the frequency of nausea, drowsiness, and dizziness in the group receiving diclofenac and tramadol together. In this investigation, the frequency of nausea and vomiting was comparable to that in the study by Smith et al. [14]. In this study, sleepiness occurred less frequently than in the study by Smith et al. This could be as a result of the study's use of morphine as a rescue analgesic. The prevalence of sleepiness and lightheadedness in the tramadol group is similar to the findings of the study conducted by Ahmed et al [15]. With respect to the study conducted by Prabhakar et al., the incidence of vomiting and sleepiness in the diclofenac group is comparable ($p > 0.05$) [13].

Conclusion:

It can be concluded that using tramadol and diclofenac together, along with a multidisciplinary approach to post-caesarean treatment, resulted in superior analgesia than either drug alone, as well as a decrease in adverse effects. This combination method of pain relief is better and more advantageous. Additional research is necessary to assess the effectiveness in diverse clinical circumstances and to assess the efficacy of various medication formulations for improved analgesia.

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