

“Comparative study of analgesic efficacy of rectal suppository of tramadol versus diclofenac in suppressing postoperative pain after Cesarean section.”

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Abstract:

Background: The aim of our study was to compare the analgesic efficacy of tramadol and diclofenac sodium used as a rectal suppository and also to compare the side effects of both drugs.

Materials and Methods: The study design was prospective, randomized, single blind and hospital based. Sixty patients of ASA grade 2 posted for cesarean section were randomized to receive either rectal suppository of tramadol 100mg(n=30) Group T or rectal diclofenac 100 mg (n=30), Group D. Pain measurement was performed using visual analogue scale (VAS). Rescue analgesia was given when the VAS was noted >3 in the postoperative period up to 12 hr. Side effects like nausea, vomiting, GI bleeding were recorded during the same period.

Conclusion: Rectal suppository of tramadol as well as diclofenac are effective for postoperative analgesia in caesarian section. Diclofenac is better alternative than tramadol as it is devoid of nausea and vomiting and have longer duration.

Key words: postoperative analgesia, caesarian section, suppository, tramadol, diclofenac sodium.
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INTRODUCTION:

The cesarean birth rate in the United States is now approximately 30% of all live births. ⁽¹⁾ Increased use of the procedure has been attributed to the liberalization of indications for fetal “distress” as well as elective repeat sections. ⁽²⁾ The most common indications for cesarean delivery include failure to “progress”, non-reassuring fetal status, cephalopelvic disproportion, malpresentation, prematurity, and previous uterine surgery. Cesarean delivery is a major surgical procedure, after which substantial postoperative discomfort and pain can be anticipated. It is well documented that pain inadequately relieved is deleterious and can lead to number of complications in the postoperative period. ⁽³⁾ Untreated surgical pain may result in a decrease in alveolar ventilation and vital capacity and even pneumonic consolidation. It may be associated with deep venous thrombosis, pulmonary embolism and delayed wound healing. Attenuation of postoperative pain, especially with certain types of analgesic regimens, may decrease perioperative morbidity and mortality. ⁽⁴⁾

Many options are available for the treatment of postoperative pain including systemic analgesics like opioids and non-opioids like tramadol and ketamine as well as regional analgesia techniques like neuraxial and peripheral blocks. Tramadol is a synthetic 4-phenyl-piperidine analogue of codeine. It is a central analgesic with a low affinity for mu opioid receptor. It inhibits serotonin and norepinephrine neuronal reuptake. Tramadol is less likely to cause neonatal respiratory depression and

hence it has been recommended for analgesia in parturient undergoing vaginal delivery. Tramadol is an analgesic with mixed Opioid and non Opioid activities.^(5,6) It is increasingly used for the treatment of acute post operative and chronic pain of intermediate or severe intensity.⁽⁷⁾ One of the NSAIDS used for acute pain management is diclofenac in suppository form and other steroids have been studied for the same purpose.⁽⁸⁾ Many studies have been conducted to compare NSAIDS with opioids, but there have been no studies to determine the efficacy of suppository diclofenac and Tramadol after cesarean section. This study was designed to evaluate this idea in post cesarean pain relief in women.

MATERIALS AND METHODS :

This was prospective , randomized, double blind and hospital based study. All the women of age group 19 -30 years who were posted either for elective or emergency LSCS with ASA grade II were included in this study. The exclusion criteria was – history of bleeding, drug sensitivity to Tramadol or diclofenac , any contraindication to spinal anesthesia and ASA grade more than II.

Written informed consent was obtained from all the patient. They were given sub arachnoid block with injection bupivacaine (hyperbaric) at L4-L5 level using 25 G needle to achieve appropriate level of anesthesia. Using block randomization method, the patients were randomly divided into either of two groups –

Group T : patients receiving Tramadol 100 mg rectal suppository

Group D : patients receiving Diclofenac 100 mg rectal suppository

Assessment of pain was done using Visual Analogue Scale (VAS), that is graded ruller ranging from 0 -10 showing the minimal and maximum pain score respectively. The monitoring anesthesiologist and all the patients were explained about pain assessment process by using VAS score. The score was assessed post operatively at 1,2,3,4,5,6,7,8,9,10 hrs in recovery room.If the patient had pain during this period (i.e. VAS score > 3) inj. Pentazocine 0.4 mg /kg i.v. was given as rescue analgesia. During this period vital parameters like pulse, blood pressure, respiration and side effects like nausea,vomiting , heart burn were monitored. The data was analyzed using “unpaired t test.” P value < 0.05 was considered significant.

RESULTS:

Table1. Comparison of Mean Age, weight and duration of surgery in both groups

Sr.No.	Parameters	Diclofenac Group		Tramadol Group		‘t ₅₈ ’ value	‘p’ value	Significance
		Mean	SD	Mean	SD			
1.	Age (yrs)	23.60	3	22.57	2.64	1.42	0.16	Not Significant
2.	Weight (Kgs)	50.33	3.09	50.37	2.74	0.04	0.96	Not Significant
3.	Duration of Surgery (min)	61	6.07	60.33	5.45	0.45	0.66	Not Significant

Table 2. Comparison of Mean VAS Score in both groups

Sr.No.	Duration	Tramadol Group		DiclofenacGroup		't ₅₈ ' value	'p' value	Significance
		Mean	SD	Mean	SD			
1.	2 hour	2.20	0.61	0.6	0.5	11.12	< 0.0001	Highly Significant
2.	4 hour	2.53	0.51	2.10	0.55	3.18	0.002	Highly Significant
3.	6 hour	2.93	0.87	2.63	1.02	3.68	0.005	Highly Significant
4.	8 hour	3.77	0.57	2.07	0.98	8.22	< 0.0001	Highly Significant
5.	10 hour	3.40	0.56	2.57	0.73	4.96	< 0.0001	Highly significant

Table 3 Distribution of patients with nausea and vomiting.

Sr. No.	Nausea and Vomiting	Diclofenac Group	Tramadol Group	Total
1.	Yes	0 (0.00)	1(3.33)	01
2.	No	30 (100)	29 (96.66)	59
Total		30 (100)	30 (100)	60

Figures in parentheses show percentages.

By Fisher's exact test, $p = 0.06 (> 0.05)$, not significant.

DISCUSSION:

The analgesic regimen needs to meet the goals of providing safe, effective analgesia, with minimal side effects for the mother and her child.^(10,11) However, these new technologies are not available in many hospitals since they are expensive and require trained personnel and special equipment^(12,13).

It thus seems that tramadol may be suitable to treat post operative pain in LSCS; however after intravenous and oral administration, peak concentrations are reached rapidly and this has been associated with post operative nausea and vomiting. Rectal administration of Tramadol may be an alternative in this situation. It is convenient to use and is the established treatment for post-operative pain in adults⁽¹⁴⁾. As some patients may not feel comfortable for rectal suppository in our study we introduced suppositories under the effect of spinal anesthesia. A rectal dose of 1.5 – 2.0 mg / kg Tramadol is therapeutic.⁽¹⁵⁾ Therefore a dose of 100 mg was used in our study as suppository. After suppository absorption of active ingredient was rapid but its metabolism quickly transformed the parent drug to high levels of N-desmethyl-tramadol (M2) and N.O-didesmethyl Tramadol (M5).

Studies are not available showing the duration of analgesia after tramadol suppository. In our study, it was shown that, at 6 hours 60% patients needed first rescue analgesia in tramadol group. At 4 hours mean VAS score 2.53 and at 6 hours it was 2.93, after that rescue analgesia was given. In our study only one patient had nausea and vomiting. This low incidence of vomiting after tramadol could be because of the suppository used rectally. NSAID inhibit prostaglandin biosynthesis by blocking the cyclooxygenase enzyme, which catalyses the conversion of arachidonic acid to prostaglandin. By reducing the production of these agents, the feeling of pain may decrease in the peripheral nervous system. On the other hand NSAIDs have no effect on CNS or cause no drowsiness. Then the patients wake up early from the deep sleep which promotes surgical recovery and prevents post operative side effect. Rashid and colleagues evaluated the efficacy of 100 mg rectal diclofenac immediately after cesarean section, followed by 50 mg at 12 hrs and 100 mg at 39 hrs after the surgery. Their results showed that VAS of pain in the study group was significantly less at 12, 14 & 24 hrs after surgery compared to the control group who did not receive any drugs. Moreover, the amount of pethidine consumed and the incidence of sedation and constipation were significantly lower in the study group⁽¹⁶⁾.

Sia AT et al have compared 100mg diclofenac suppository plus 1.5mg/kg i.v. morphine, with intravenous morphine after cesarean section. They found that the wound pain and uterine contraction pain in group receiving diclofenac plus morphine was lower than in the other group.⁽¹⁷⁾ Zibzahiri, Sorrori and colleagues compared diclofenac suppository and pethidine in post cesarean section pain relief. They have concluded that diclofenac suppository is a suitable replacement for pethidine.⁽¹⁸⁾

In our study, we compared diclofenac suppository with tramadol suppository. In diclofenac group at 4 hours mean VAS score 2.1, at 6 hours it was 2.63 and at 8 hours mean VAS was 2.07, after that rescue analgesia was given. After 8 hours 60% patients needed first rescue analgesia in diclofenac group. When we compared diclofenac suppository with tramadol suppository, it was found mean VAS was less in diclofenac group and this difference was statistically significant. Also no side effect was found in diclofenac group. Thus, rectal suppository of diclofenac is better alternative for postoperative analgesia in cesarean section as compared to tramadol. There are few limitations of our study. First of all, we had 2 groups and study lacked a 3rd group of control patients to compare the effects of placebo with each of the two groups. Also the number of patients included in our study was small, so further study with large number of patients is needed.

CONCLUSION:

Rectal suppository of diclofenac and tramadol can be used for pain relief after cesarean section. Tramadol has side effects like nausea and vomiting. It seems that, diclofenac suppository is better alternative to tramadol because it has shown better analgesic effect on postoperative pain.

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