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Comparative Study of Rectal Tramadol versus Diclofenac in Post Cesarean Section Pain Management

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Abstract

Context: Post Cesarean section substantial postoperative discomfort and pain can be anticipated. Pain inadequately relieved is deleterious and lead to number of complications in the postoperative period. The analgesic regime needs to meet the goals of providing safe and effective analgesia with minimal side effects for the mother and child. We conducted this study to formulate post-operative pain management strategies regarding the use of non-opioid analgesics.

Aim: This study was conducted with aim to compare the analgesic efficacy of Tramadol and Diclofenacsodium as rectal suppository in post-operative cesarean section.

Settings and Design: This study was a randomized, controlled trial, carried out at tertiary care centre in India. The sample size for this study was calculated to be 50 in each group.

Methods and Material: Adult (19-30 years) American Society of Anesthesiologist grade-I and II posted for cesarean section were included in the study. Patients were randomized by simple randomization method to receive either rectal suppository of Tramadol (Supradol) 100 mg or Diclofenac (Justin) 100 mg. Suppository was introduced immediately after the surgery before shifting the patients to postoperative ward. Pain measurement in the postoperative period was performed using Visual Analog Scale at 0, 2, 4, 6, 8, 10 hours.

Statistical Analysis Used: All data on categorical variables were presented as frequencies and percentages. Chi square test was used to compare the frequencies and percentages. All the statistical analysis were carried out at 5% level of significance and p value <0.05 was considered significant. Chi square test was used to compare the frequencies and percentages.

Results: Statistically significant differences between two groups in VAS score was seen at 4, 6, 8 and 10 hours after surgery. 80.4% of cases among Tramadol group needed rescue analgesia at 8 hours and 98.2% at 10 hrs. among Diclofenacgroup Only 4.2 % cases needed rescue analgesia at 8 hrs and 6.3 % at 10 hours.

Conclusion: Diclofenac-suppository has better analgesic effect as compared with Tramadol suppository on postoperative pain.

Keywords: Diclofenac; Tramadol; Rescue Analgesia; Cesarean Section; Postoperative Pain.

Introduction

Cesarean delivery is a major surgical procedure after which substantial postoperative discomfort and pain can be anticipated [1]. Pain inadequately relieved is deleterious and lead to number of complications in the postoperative period [2]. The analgesic regime needs to meet the goals of providing safe and effective analgesia with minimal side effects for the mother and child.

Tramadol is a synthetic analogue of codeine. It has central analgesic action and is a m-opioid receptor agonist. The non-opioid component is mediated through α_2-agonist and serotonergic activity. It inhibits the re-uptake of norepinephrine and serotonin [3]. Tramadol is used primarily to treat mild-severe pain, both acute and chronic [4]. Infants breastfed by mothers taking Tramadol were

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exposed to about 2.88% of the dose the mother were taking. There was no evidence of this dose having a harmful effect on the newborn [5].

Diclofenacsodium is a Non Steroidal Anti-Inflammatory Drug (NSAID). Diclofenacis used to treat pain, inflammatory disorders and dysmenorrhea. NSAIDs inhibit the biosynthesis of prostaglandins by preventing the substrate arachidonic acid from binding to the cyclooxygenase (COX) enzyme active site [4].

Some studies have shown that single dose administration of 100mg Diclofenacsuppository is effective in reducing post-cesarean epidural local anesthetic / opioid requirements by 33% for the first 24 hrs post-operatively [7].

We conducted this study to formulate post-operative pain management strategies regarding the use of non-opioid analgesics.

Materials and Methods

This study was conducted with aim to compare the analgesic efficacy of Tramadol and Diclofenacsodium as rectal suppository in post-operative cesarean section.

This study was a double blinded, randomized, controlled trial, carried out at tertiary care center in India. This trial was approved by institute ethical committee.The sample size for this study was calculated to be 50 in each group.

Adult (19-30 years) American Society of Anesthesiologist (ASA) grade-I and II posted for cesarean section were included in the study. Patients with history of allergy to any drug, altered bleeding and clotting time, obesity, anorectal complications, any systemic diseases (cardiovascular, neurological, respiratory, hepatic and renal), contraindication for spinal anesthesia and dire emergency cases were excluded from the study.

All the patients were explained about the procedure, route of administration of the drug and use of visual analogue scale scoring system before surgery. Written informed consent was obtained. Per-rectal examination of all the patients was done by the duty surgeon to exclude ano-rectal complication.

Patients were randomized by simple randomization method to receive either rectal suppository of Tramadol (Supradol) 100 mg or Diclofenac(Justin) 100 mg. Hypersensitivity (intradermal) test was performed with the respective drugs before anaesthesia. Opioid or NSAID were avoided as premedication.Suppository was introduced immediately after the surgery before shifting the patients to postoperative ward.

Pain measurement in the postoperative period was performed using Visual Analog Scale (VAS) at 0, 2, 4, 6, 8, 10 hours. VAS will be taken as 0 for patients in sleep. Rescue analgesia Injection Tramadol (1.5-2mg / kg) in 100ml of Normal salinewas given as infusion over 15 mins if VAS was noted >4 in the postoperative period up to 10 hours. During this period vital parameters like pulse, blood pressure, and respirationwere monitored.

The data was analysed using Microsoft Excel 2010 and SPSS (Version 19) software. All data on categorical variables were presented as frequencies and percentages. Chi square test was used to compare the frequencies and percentages. All the statistical analysis were carried out at 5% level of significance and p value <0.05 was considered significant. Chi square test was used to compare the frequencies and percentages. All the statistical analysis were carried out at 5% level of significance and p value <0.05 was considered significant.

Results

Total hundred cases were included in study, fifty in each group. The Baseline characteristics like age, parity and weight were similar among both groups (Table 1). Comparison of VAS score is given in Table 2. Initially at 2 hrs, there was no significant difference among both the groups.

Table 1: Baseline characteristics

Parameter	Diclofenac group	Tramadol group	p value
Age (Yrs) (Mean ±SD)	22.35 ± 3.54	23.12± 3.24	· 0.05
Weight (Kg) (Mean ±SD)	48.86±4.14	49.02 ± 3.87	· 0.05
Parity			
Primi	7	5	· 0.05
Multi	43	45	· 0.05
Duration of surgery (Min) (Mean ±SD)	55.87 ± 9.37	54.96 ±9.85	· 0.05

Table 2: Comparison of VAS Score

Time	Tramadol group (Mean ±SD)	Diclofenac group (Mean ±SD)	p value
2 hour	0.81 ± 0.32	0.72 ± 0.34	> 0.05
4 hour	1.75 ± 0.52	0.93 ± 0.33	· 0.01
6 hour	2.99 ± 1.34	1.01 ± 0.46	· 0.01
8 hour	3.82 ± 1.66	1.20 ± 0.89	· 0.01
10 hour	4.13 ± 1.89	2.88 ± 1.37	· 0.01

Statistically significant differences between two groups in VAS score was seen at 4, 6, 8 and 10 hours after surgery. 80.4% of cases among Tramadol group needed rescue analgesia at 8 hours and 98.2% at 10 hrs. among Diclofenac group Only 4.2% cases needed rescue analgesia at 8 hrs and 6.3% at 10 hours. There were no significant adverse effects seen among both the groups.

Discussion

Cesarean delivery is a major surgical procedure. The adequate postoperative analgesia is important to provide early ambulation of mother for newborn care with minimal side effects for mother and her child. Opioid analgesics are usually avoided due to its undesirable side effects like nausea, vomiting, drowsiness, itching, dry mouth, dizziness, constipation and respiratory depression [8,9].

Tramadol is an opioid analgesic, which can be effectively used for postoperative analgesia [10,11,12]. Compared to other opioids, respiratory depression and constipation are considered less of a problem with Tramadol [13]. A study shows that rectal route of Tramadol is a better alternative to the intravenous route in comparison with duration of analgesia, nausea and vomiting [14]. After rectal administration of the Tramadol suppositories, the absorption of the active ingredient is rapid enough for therapeutic purposes and that the extent of the absolute bioavailability is higher than after oral administration of Tramadol , probably due to a reduced first-pass metabolism after rectal administration [15].

NSAIDs like Diclofenachave been routinely used for postoperative analgesia. They are beneficial in mild to moderate pain in post-operative period [16]. Similar study with Tramadol suppository 100 mg 6th hourly was compared with acetaminophen / codeine suppository 1000 / 20 mg qds showed no difference in pain score but nausea, vomiting was higher in Tramadol group [17].

Dr. Joshi Vyankatesh compared rectal Tramadol (100 mg) with rectal Diclofenac (100 mg) after cesarean section for postoperative analgesia. 60% of patients of Tramadol group needed rescue analgesia at 6 hours, 60% of patients of Diclofenacgroup needed rescue analgesia at 8 hours. Only one patient complained of nausea, vomiting with Tramadol group [18].

In our study 80.4% of patients receiving Tramadol suppository needed rescue analgesia at 6 hours and 98.2% at 8 hours, whereas, patients who received Diclofenacsuppository did not need the rescue analgesia up to 10 hours. Both groups tolerated the drug similarly and no significant side effects were seen. Limitation of our study is that we studied only for 10 hours postoperatively with the single dose of Diclofenacand Tramadol suppository.

Conclusion

Diclofenacsuppository has better analgesic effect as compared with Tramadol suppository on postoperative pain.

Conflict of Interest: NIL

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