Original Article

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Post-Operative Analgesia with Preventive and Post-Operative Rectal Diclofenac in Patients undergoing Caesarean Section Under Spinal Anesthesia: A Comparative Study

Augustine Benny[1], Shwetha Susan Thomas[2], Manjit George[3]

Author's Affiliation:

[1,2]Junior Resident, Department of Anesthesiology, MOSC Medical College, Kolenchery, Kerala 682311, India. [3]Consultant Anesthetist, North Cumbria Integrated Care NHS Trust, UK.

Abstract

Background and aims: To study the analgesic efficacy of preventive rectal Diclofenac in comparison to post-operative rectal Diclofenac in elective caesarean section surgeries.

Methodology: After obtaining approval from institution ethics committee, patients undergoing elective caesarean section under spinal anesthesia were included in the study and divided into two groups ED(Early Diclofenac) & LD(Late Diclofenac), differing in the time of administration of first dose of 100mg rectal Diclofenac. Pain scores were noted at 12 & 24 hours post administration of first dose of rectal Diclofenac, using the numerical rating score. Rescue analgesia was given in form of Tramadol infusion. Time to first rescue analgesia, post-operative pain scores at 12& 24 hours, cumulative opioid requirements and side effects if any were noted.

Results: We observed a statistically significant difference in the time to first rescue analgesia between the two groups. There was no statistically significant difference in the average pain scores, cumulative opioid requirements and side effects between the two groups.

Conclusion: Rectal Diclofenac is an effective modality for treatment of postoperative pain after caesarean section. Preventive rectal Diclofenac, in comparison to postoperative Diclofenac significantly prolongs the duration to first rescue analgesia. The two groups did not differ significantly in the cumulative opioid consumption at 24 hours. There was no statistically significant difference in pain scores at 12 and 24 hours between the two groups. The average pain scores in both groups were around 3/10.

Keywords: Diclofenac; Preventive; Multimodal analgesia; Postoperative; Caesarean.

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Corresponding Author: Augustine Benny, Junior Resident, Department of Anesthesiology, MOSC Medical College, Kolenchery, Kerala 682311, India.
Email: augustinebenny06@gmail.com

Introduction

Post-operative pain, both acute and chronic, has significant bearing on the overall recovery and satisfaction of the patient. Traditionally, opioids are used for post-operative pain relief, but have side effects such as nausea, vomiting, sedation and respiratory depression. Use of multimodal analgesia helps in reducing opioid requirements and thereby associated side effects. The role of preventive analgesia in reducing acute and chronic pain is well documented. Severe post-op pain after caesarean section can be distressing for a mother who's sitting up and nursing her baby. When planning for postoperative analgesia for caesarean section, these concepts of multimodal and pre emptive analgesia could be made use of, to ensure better results.

Rationale

Preventive analgesia is based on the principle that administration of analgesics even before the first incision gives better post-operative pain relief.[1] Use of rectal Diclofenac in immediate postoperative period after caesarean is widely practiced. Common practice in our institution is to give Diclofenac suppository post operatively once patient reaches the Obstetric ICU. Rescue analgesia is given in the form of parenteral Tramadol. Through this study we aim to find out whether early administration of rectal Diclofenac has a better postoperative analgesic effect in comparison to late administration of rectal Diclofenac in patients undergoing caesarean section.

Review of Literature

Pain is defined as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage".[2] Traditionally opioids like Morphine, Pethidine, Tramadol and Fentanyl are used to provide postoperative analgesia.

Altered processing of afferent pain input can result in amplification of postoperative pain. Preventive analgesia is an antinociceptive treatment, which prevents the altered processing of this afferent input.[3] An editorial on preventive analgesia in the British Journal of Anaesthesia has commented on the significance of preventive analgesia in reducing chronic pain.[4]

The concept of multimodal analgesia is very popular and refers to the administration of two or more drugs that act by different mechanisms for providing analgesia which may be administered via the same route or by different routes.[5] Addition of analgesic adjuvants like NSAIDs (Diclofenac, Paracetamol, Ketorolac), alpha-2 agonists (Dexmedetomidine) and local anesthetic infusion (Lignocaine) has shown excellent analgesic and opioid sparing effects.[6–8]

In patients undergoing caesarean section, poor pain control results in reduced maternal satisfaction and longer hospital stay. Pain scores of 4/10 or above are unacceptable and need to be treated.[9] The incidence of chronic post-surgical pain at 3 months after caesarean section is as high as about 18% according to studies by Nikolajsen et al.[10] and Jin et al.[11] In patients undergoing caesarean section, for postoperative analgesia, National Institute for Health and Care Excellence, (NICE) UK recommends the administration of intrathecal Diamorphine, I.V. Patient Controlled Analgesia (PCA) using Morphine and non-steroidal anti-inflammatory drugs, provided there are no contraindications to it.[12] In Indian scenario, Diamorphine is not available and PCA Morphine may be available only at few centres.

Hence, postoperative analgesia for caesarean section mostly comprises of a combination of parenteral opioids (Morphine, Pethidine, Tramadol) and NSAIDs (Diclofenac, Paracetamol). Intramuscular administration of Diclofenac is painful. Diclofenac administered rectally, is a safe and convenient approach resulting in complete absorption and sustained release of drug providing early onset and long duration of post-operative analgesia. Study by Olofsson et al has shown that addition of rectal Diclofenac significantly reduces the postoperative opioid requirements in caesarean section patients.[13]

The other techniques of analgesia described in patients undergoing caesarean section are wound infiltration analgesia, Bilateral Tranversus Abdominis Plane(TAP) block, Continuous Epidural Analgesia and Intrathecal Morphine.[14] Wound infiltration technique is useful but limited by the duration of action of local anaesthetics.[15] This can be overcome by use of wound soaker catheters.[16] Bilateral TAP blocks have demonstrated opioid sparing effects.[17] Continuous epidural technique offers excellent analgesia, both for labour pain and post-operative pain. Intrathecal Morphine gives longer duration of pain relief, but at the expense of side effects such as nausea, vomiting and pruritus.[18]

Aims and Objectives

Aim:To study the analgesic effectiveness of

preventive rectal Diclofenac in comparison to postoperative rectal Diclofenac in elective caesarean section surgeries.

Objectives

- To compare time to first rescue analgesia in patients given rectal Diclofenac preventively and post operatively.
- To compare the pain scores in patients in the two groups at 12 & 24 hours post-surgery.
- To compare total opioid requirements of patients in the two groups in the first 24 hours.
- To evaluate side effects like nausea, vomiting and increased bleeding.

Materials and Methodology

This study was done as part of an ICMR STS (Indian Council of Medical Research- Short Term Studentship) program, which is time limited and to be completed over two months. After getting Institutional Ethics Committee approval(Ref-MOSC/IEC/287/2018), we did this prospective observational study in post-operative ICU and wards of Obstetrics and Gynaecology in our Medical College Hospital, over a period of two months, June to July 2018.

Sample size was calculated for true probability that mean Numerical Rating Score(X) of LD group (post-operative analgesia) would be greater than the mean score(Y) ED group (preventive analgesia) of i.e. P[A>B]>1/2. Sample size calculated using the Mann-Whitney U test.

$$n = \frac{\left(Z_{\alpha/2} + Z_{\beta}\right)^2}{12c(1-c)(p^n - 0.5)^2} \qquad \text{where,}$$

P^n = Probability of a score from X being larger than a score from Y is greater than ½, c=1/(1=k), where k is the allocation ratio.

$Z_{\alpha/2}$ =1.96, Z_{β} =0.84

For a power of 80% and alpha error of 5%, sample size is 54; hence two groups of 27 subjects each were included.

Patients selected were parturients with no comorbidities (ASA Class II) undergoing elective caesarean section under spinal anaesthesia and given Diclofenac suppository perioperatively .Patients coming under ASA Class III or more, receiving general anaesthesia or epidural anaesthesia, receiving adjuvants like Clonidine along with spinal anaesthetic, patients with contraindication to Diclofenac (Asthma, Peptic ulcer, allergies to NSAIDs, renal and hepatic diseases) and pregnancy induced hypertension(PIH) were excluded from the study.

Methodology

54 parturients undergoing elective caesarean sections done under spinal anaesthesia were included in the study. All patients received oral premedication, Tab Metoclopramide 10 mg and Tab Ranitidine 150 mg, two hours prior to surgery. Patients were met preoperatively and informed consent was taken. They were educated about pain assessment using the Numerical Rating Scale. Intravenous access using 18 G cannula was routine for all subjects and Ringer Lactate was started. Routine patient monitoring including ECG, Non Invasive BP and Pulse Oximetry was initiated.

Under strict aseptic precautions, spinal anaesthetic was administered in the left lateral decubitus position using 25 Gauge Whitacre spinal needle. All patients received the standard dose of 2ml 0.5% heavy Bupivacaine and Fentanyl 10 micrograms intrathecally. We had two groups of 27 patients each, Early Diclofenac (ED) group receiving rectal Diclofenac immediately after the spinal anaesthetic, before the surgery starts (preventively) and Late Diclofenac (LD) group of patients receiving rectal Diclofenac after the spinal anaesthetic only after reaching the ICU (post-operatively).

Both groups receive rescue analgesia in the form of parenteral Tramadol as intravenous infusion (100 mg in 100 ml NS over 15 minutes as the first dose and 50mg in 100 ml NS over 15 minutes for subsequent doses, if required upto a maximum of 4 doses) in the first 24 hours. Another dose of rectal Diclofenac, 50 mg was given to all patients, 8 hours after the initial dose, thus limiting it to the maximum daily dose of Diclofenac-150mg/day. Inj. Ondansetron 4 mg I.V was prescribed as antiemetic for all patients receiving Tramadol.

Time of first administration of 100mg Diclofenac is taken as Time Zero (To) in the two groups. Time to first rescue analgesia is compared between the two groups. The pain score of patients in the two groups are compared at 12 & 24 hours using numerical rating scale (0-10). Cumulative opioid requirements in first 24 hours is compared between the two groups. Side effects like nausea, vomiting and increased bleeding were assessed.

The results were tabulated and subjected to statistical analysis. The time to first rescue analgesia was analyzed statistically using the Mann Whitney

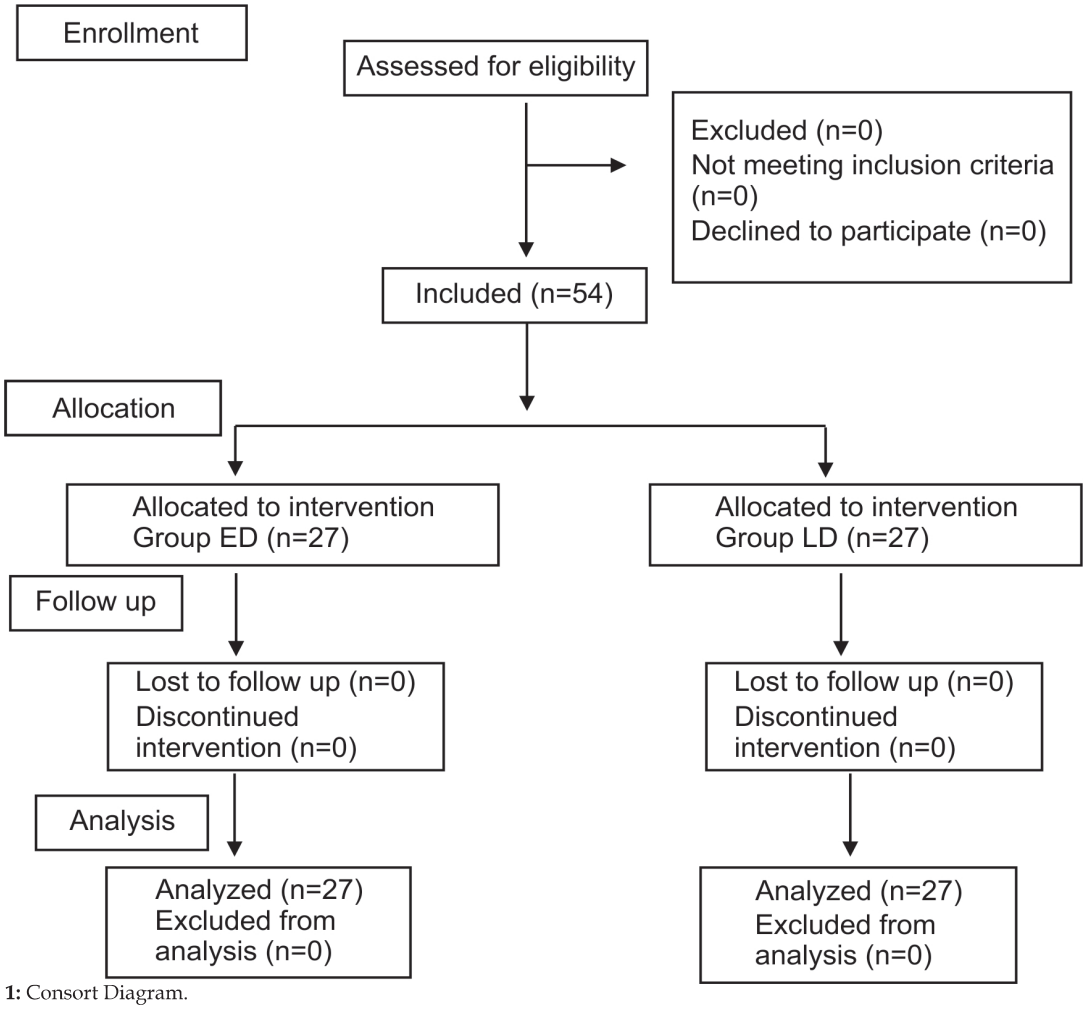

Fig. 1: Consort Diagram.

U test. The pain scores were analyzed statistically using the Repeated Measures Anova test and the total opioid requirement was analyzed using the Mann Whitney U test.

Results

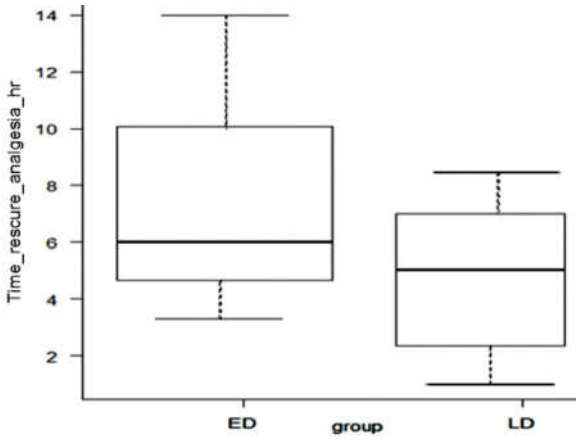

Fig. 2: Median time to rescue analgesia in Groups ED and LD.

The patient demographics such as age and weight were comparable in both the groups as evident from table 1. All patients included in the study had high school education or above.

Table 1: Patient Demographics.

Parameter	Group ED	Group LD
Age	29.29 +/- 4.03	27.96 +/- 4.36
Weight	64.11 +/- 2.06	64.59 +/- 1.60
Duration of surgery	63.14 +/- 5.05	63.03 +/- 4.33

Table 2: Median time to rescue analgesia in Groups ED and LD.

Group	Median	Q1, Q3	U Statistic	P value
ED	6	4.3, 10.15	190	0.011
LD	5.05	2.32, 7	-	-

The median time to rescue analgesia in Groups ED and LD was 6 hours and 5.05 hours respectively. Refer table 2 and Figure 2. We have performed Mann-Whitney U test to check if there is any difference in average time to rescue analgesia between ED and LD groups. There was a statistically significant difference between the two groups in the average time to first rescue analgesia. (p= .01)

Table 3: Average pain scores at 12 and 24 hours in Groups ED and LD.

	Mean (SD)	
Groups	**12 hr.**	**24 hr.**
ED	2.96 (1.22)	2.89(1.34)
LD	2.93 (1.07)	3.15 (1.46)

Table 4: Average Tramadol consumption in 1st 24 hours in Groups ED and LD.

Group	Median	Q1,Q3	U Statistics	P value
ED	100	100,125	294	0.43
LD	100	100,100	-	-

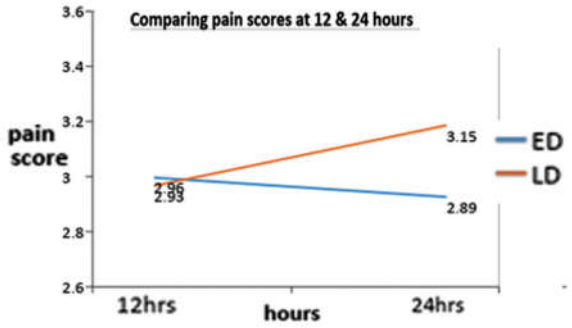

Fig. 3: Average pain scores at 12 and 24 hours in Groups ED and LD.

The average pain scores in groups ED and LD at 12 hours were 2.96 and 2.93 and 2.89 and 3.15 at 24 hours respectively. We performed Repeated Measures Anova to check if there is any significant difference in pain scores between ED and LD groups at 12 & 24 hours. It was observed that there was no significant difference in the average pain scores between ED and LD groups at 12 and 24 hours (p=.73). It was also observed that there was no significant difference in the average pain scores between the two different time points i.e. 12 and 24 hours (p= .63). Refer figure 3 and table 3.

The median dose of Tramadol used in 24 hours was same in both groups- 100 mg. We have performed Mann Whitney U test to check if there is any statistically significant difference in the cumulative opioid requirement between ED and LD groups. It was observed that there was no statistically significant difference between the groups (p= .43). Refer table 4. None of the patients had nausea, vomiting or excessive bleeding.

Discussion

This study was undertaken to evaluate the effect of preventive rectal Diclofenac in the management of post-operative pain in patients undergoing caesarean section under spinal anesthesia. The analgesic efficacy was assessed in terms of time to first rescue analgesia, mean pain scores at 12 and 24 hours and cumulative opioid requirements at 24 hours. Side effects such as excessive bleeding, nausea and vomiting if any, were noted.

Preventive analgesia has a clear role in the management of acute pain and to some extent in prevention of chronic pain.[19] It reduces the postoperative opioid requirements and also prevents establishment of central sensitization thereby, reducing the incidence of chronic pain[3] Preventive administration of rectal Diclofenac has shown to be effective in management of post-operative pain in a variety of surgical settings.[6,13,20,21] Addition of rectal Diclofenac significantly reduces the postoperative opioid requirements in caesarean section patients as demonstrated in the study by Oloffson et al. and Rashid et al.[13,21]

Multimodal analgesia offers superior analgesia and reduced opioid consumption. The options for components of multimodal therapy for caesarean section pain include opioids, NSAIDs, Paracetamol, Local Anaesthetic infiltration, TAP block, Epidural local anaesthetic with or without opioid and intrathecal opioid.[13] We have used a combination of Tramadol (Opioid) and Diclofenac (NSAID) as analgesic regime for caesarean section.

Our study showed that preventive rectal Diclofenac in comparison to postoperative rectal Diclofenac, prolonged the time to first rescue analgesia. This result was consistent with the meta analysis study findings by Ong et al.[19]

In our study we could not observe any statistically significant difference in pain scores at 12 and 24 hours between the two groups. The mean pain scores at 12 hours was 2.96 in ED group and 2.93 in LD group, while at 24 hours, the pain scores were 2.89 in ED group and 3.15 in the LD group. Although the mean pain score was lower in the ED group compared to LD group at 24 hours, it was not statistically significant. The mean pain scores at 12 and 24 hours postoperatively was around 3/10 in our study population, which was fairly good.

There was no statistically significant difference in the cumulative opioid consumption between the patient groups in the first 24 hours. The average 24 hour opioid consumption in our study population was fairly low (Tramadol 100 mg). This reflects excellent postoperative analgesia when using this combination of parenteral Tramadol and rectal Diclofenac. Side effects such as nausea and vomiting were absent. This could be consistent

with reduced opioid requirements and use of Ondansetron as antiemetic in both the groups. There was no incidence of significant bleeding in either of the groups.

Limitations

Pain is a subjective entity which necessitates a large sample size for proper interpretation of the results. Due to the limited time period allotted for the study, we had to limit ourselves to a smaller sample size. As there was no formal follow-up of these patients after discharge from the hospital, the incidence of chronic postsurgical pain could not be evaluated.

Conclusion

Rectal Diclofenac, as part of multimodal analgesia, is effective for treatment of post-operative pain after caesarean section. Preventive rectal Diclofenac in comparison to postoperative rectal Diclofenac, significantly prolongs the time to first rescue analgesia. Cumulative opioid consumption at 24 hours did not vary between the two groups. There was no statistically significant difference between the groups in terms of average pain scores at 12 and 24 hours postoperatively. No side effects such as nausea, vomiting or increased blood loss were noted in either of the groups.

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