DOI: 10.7860/JCDR/2021/48814.15350

Original Article

Obstetrics and Gynaecology Section

Management of Postcaesarean Delivery Analgesia-Diclofenac Suppository, Paracetamol Infusion and a Combination

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ABSTRACT

Introduction: One of the most important aspect of postoperative care is pain management which plays an important role in early recovery and improves patient's general condition. Paracetamol and diclofenac have an excellent safety profile when compared to opioids.

Aim: To assess and compare the analgesic efficacy and safety of individual use of Intravenous (IV) paracetamol, diclofenac suppository and in combination.

Materials and Methods: This hospital-based cross-sectional study was conducted from October 2018 to June 2020 at Department of Obstetrics and Gynaecology. A total of 90 women who underwent caesarean section were recruited for the study and were randomly allocated (lottery method) into three groups with 30 participants in each group. The patients underwent Lower Segment Caesarean Section (LSCS) under spinal anaesthesia with the same technique and medicine, (Bupivacaine 0.5%) without receiving any sedation. Group A patients received diclofenac suppository 50 mg every eight hourly, Group B received paracetamol infusion 1000 mg every eight hourly and Group C received 50 mg diclofenac suppository and 500 mg IV paracetamol every eight hourly. Pain severity (Visual Analogue Scale (VAS) score), Heart Rate (HR), Blood Pressure (BP) and side-effects were evaluated at 2,4,6,8,12 and 24 hours postoperatively. Patient satisfaction score was evaluated 24 hours after caesarean section.

Results: Age range of participants was 19 to 28 years. Mean duration of surgery (minutes) in each group were- Group A-56.5±7.49, Group B-58.27±8.06 and Group C-56.97±6.78, respectively. There was a significant reduction of pain in patients receiving paracetamol and diclofenac suppository combination group. The satisfaction score was categorised as excellent by 80% patients in Group C. In Group A 30% and in Group B 16.6% categorised as excellent patient satisfaction score. The adverse effects such as nausea and epigastric discomfort was higher (7.7%) with diclofenac suppository group followed by Paracetamol (2.2% side-effects) and minimal with combination (1%).

Conclusion: Paracetamol infusion is as effective as diclofenac suppository in reducing postoperative pain following caesarean section. Diclofenac suppository and IV paracetamol combination provides more effective postoperative analgesia compared with individual usage of IV paracetamol or diclofenac suppository in patients following caesarean section. The combined use of paracetamol and diclofenac suppository has fewer side-effects compared with individual use of either IV paracetamol or diclofenac suppository.

Keywords: Intravenous, Postoperative analgesia, Spinal anaesthesia, Visual analogue scale

INTRODUCTION

One of the most important aspect of postoperative care is pain management. Adverse side-effects and addiction of the opioids have made physicians to focus on Non-Steroidal Anti-Inflammatory Drugs (NSAID) for pain control [1,2]. Diclofenac is one of the NSAID drug, effective in postoperative pain management and also it reduces the postoperative narcotic demand [3,4]. Paracetamol is a central analgesic drug which acts primarily through inhibition of cyclooxygenase pathway and probably by indirect effects on serotonergic system [5]. Though postoperative pain is better achieved with higher modalities like epidural analgesia but lack of availability of high skilled personnel in peripheral areas of resource limited countries made NSAIDs more popular in postoperative pain management. Adverse effects of NSAIDs are nausea and epigastric discomfort. Moreover, on adding acetaminophen to NSAIDs the dosage of NSAIDS can be reduced [5].

The results of the studies comparing analgesic efficacy of diclofenac and acetaminophen are variable. A prospective cross-sectional study involved 108 patients undergoing caesarean section. Impact of 900 mg/100 mL of IV paracetamol was studied against 50 mg pethidine. Diclofenac sodium 75 mg was given intramuscularly to both groups and used as a rescue drug. There were no significant differences in the consumption of additive analgesics. The study concluded that in the postoperative pain management after caesarean section IV paracetamol is recommended as it maintained a sustained and safe analgesic as it does not have side-effects [6]. Another randomised trial involved 300 parturients scheduled for caesarean section. It compared diclofenac rectal suppository (100 mg), tramadol rectal suppository (100 mg) and glycerin rectal suppository. All the subjects received IV acetaminophen 1000 mg. The results showed highest VAS in glycerin group and least in tramadol [7].

In the above-described studies, they used diclofenac and paracetamol but they did not compare the efficacy of both the drugs against each other. Moreover, they used opioids for comparison. There are only few studies [8,9] comparing diclofenac and paracetamol for post-caesarean analgesia and there is a need for more studies comparing these two drugs for accurate results and to probe the benefits of multimodal analgesia. Siddik SM et al., compared diclofenac and paracetamol on postoperative pain after caesarean section. They reported that diclofenac effectively improves postoperative pain and reduces morphine consumption [8]. On the other hand, Shah UD et al., compared the analgesic efficacy of parenteral paracetamol and diclofenac for postoperative pain relief and found that the duration and quality of analgesia in paracetamol and diclofenac groups were similar in postoperative period [9].

Pain relief is very important in caesarean section patients, increasing the ability of self-care, leads to early discharge and also reduces the nosocomial infections and hospitalisation costs.

On alleviating postoperative pain in caesarean delivery mothers, early bonding can be established with baby resulting in early

commencement of breast feeding and good perinatal outcomes [10]. Early ambulation would also be possible. In view of the disparities in the reported studies, the present study aimed to assess and compare the analgesic efficacy and safety of individual use of IV paracetamol, diclofenac suppository and in combination.

MATERIALS AND METHODS

This hospital-based cross-sectional study was conducted from October 2018 to June 2020 at Department of Obstetrics and Gynaecology, on the patients admitted in RL Jalappa Hospital attached to Sri Devaraj Urs Academy of Higher Education and Research, Tamaka, Kolar, Karnataka, India. A proforma containing detailed information of each patient was designed according to the study protocol. Ethical clearance was obtained from the Institutional Ethics Committee (No. SDUMC/KLR/IEC/155/2018-2019). Written and informed consents were obtained from every patient.

Inclusion criteria: Age between 19 to 28 years. Pregnancy with gestational age of 37 completed weeks to 42 weeks. Women undergoing LSCS (elective and emergency) under spinal anaesthesia were included.

Exclusion criteria: Women with allergic history to acetaminophen, diclofenac or local anaesthetics. History of any cardiovascular, liver, renal disease or diabetes. Usage of analgesic drugs (opioid, NSAID, corticosteroid) within 8-12 hours were excluded.

A total of 90 women that underwent caesarean section were recruited for the study. They were randomly allocated, using lottery method, into three groups of 30 each. The patients underwent LSCS under spinal anaesthesia with the same technique and medicine, (Bupivacaine 0.5%) without receiving any sedation. Anaesthesiologist used no. 27 spinal needle and the patients were in sitting position, with the anaesthesia injected at L3-L4 and L3-L2 space.

Postoperatively, patients in group A received diclofenac suppository 50 mg every eight hourly, group B received paracetamol infusion 1000 mg every eight hourly and group C received 50 mg diclofenac suppository and 500 mg intravenous paracetamol every eight hourly. Pain severity (VAS score), HR, BP and side-effects were evaluated at 2,4,6,8,12 and 24 hours postoperatively. Patient satisfaction score was evaluated at 24 hours after caesarean section as either poor, fair, good or excellent by patient subjective assessment.

STATISTICAL ANALYSIS

Data was represented as mean and standard deviation for quantitative variables and frequency and proportion for categorical variables. Non-normally distributed quantitative variables were summarised by median and Interquartile Range (IQR). Normality check was done for all the quantitative parameters in the study population and based on that further tests were applied. For non-normally distributed quantitative parameters, median and IQR are compared between study groups using Kruskal Wallis test (>2 groups). Categorical outcomes were compared between study groups using Chi-square test/Fisher's-Exact test. The p-value < 0.05 was considered statistically significant. International Business Machines (IBM) Statistical Package for the Social Sciences (SPSS) version 22.0 was used for statistical analysis.

RESULTS

This study was conducted on 90 female subjects for caesarean section with an age group of 19 to 28 years. There was no statistically significant difference in mean age [Table/Fig-1].

There was no statistically significant difference in mean duration of surgery between all pair of study groups [Table/Fig-2].

There was no statistically significant difference in median HR, median Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP) and median Respiratory Rate (RR) at any study interval between study groups [Table/Fig-3-6]. However, the VAS scores differed significantly between the groups [Table/Fig-7]. There was statistically significant difference in median VAS score for a pair group A and group B at 2 hours, 8 hours and 24 hours and for both pairs group A/C and B/C at all time periods [Table/Fig-8].

Study group	Age (years) mean±SD	Mean difference	Fisher's LSD) (p-value)
Group A	24.93±3.88		
Group B	25±4.42		
Group C	26.1±5.46		
Group A vs B		0.07	0.956
Group A vs C		1.17	0.332
Group B vs C		1.10	0.360

[Table/Fig-1]: Comparison of mean age between different study groups.
SD: Standard deviation; LSD: Least significant difference

Study group	Duration of surgery (minutes) Mean±SD	Mean difference	Fisher's LSD) (p-value)
Group A	56.5±7.49		
Group B	58.27±8.06		
Group C	56.97±6.78		
Group A vs B		1.77	0.362
Group A vs C		0.47	0.809
Group B vs Group C		0.47	0.809

[Table/Fig-2]: Comparison of mean duration of surgery (min) between different study groups.
SD: Standard deviation; LSD: Least significant difference

Time interval (hours)	Study group median (IQR)			Kruskal-Wallis test p-value
	Group A (N=30) Heart rate	Group B (N=30) Heart rate	Group C (N=30) Heart rate	
2	80 (73,82)	82 (76,84)	82 (76,84)	0.112
4	80 (73.50,84)	82 (79,84)	82 (76,84)	0.261
6	80 (72,82)	82 (77,84)	82 (77.50,84)	0.067
8	80 (74,84)	82 (77.50,84)	82 (77.5,84.50)	0.120
12	80 (74,82.50)	82 (79.50,84)	82 (77.75,84)	0.256
24	80 (72,82)	82 (77,84)	82 (77.50,84)	0.67

[Table/Fig-3]: Comparison of median Heart Rate (HR) follow-ups after surgery between study groups.

Time interval (hours)	Study group median (IQR)			Kruskal-Wallis test p-value
	Group A (N=30) SBP (mmHg)	Group B (N=30) SBP (mmHg)	Group C (N=30) SBP (mmHg)	
2	110 (110,120)	120 (112,120)	112 (110,120.5)	0.159
4	112 (110,120)	118 (110,120)	116 (110,120)	0.690
6	112 (110,120)	116 (110,120)	113 (110,120)	0.747
8	112 (110,122)	118 (112,120)	119 (110,120)	0.870
12	113 (110,120)	117 (112,120)	113 (110,120)	0.553
24	113 (110,120)	119 (112,120)	112 (110,120)	0.66

[Table/Fig-4]: Comparison of median Systolic Blood Pressure (SBP) follow-ups after surgery between study groups.

Time interval (hours)	Study group median (IQR)			Kruskal-Wallis test p-value
	Group A (N=30) DBP	Group B (N=30) DBP	Group C (N=30) DBP	
2	80 (70,80)	80 (72,80)	80 (71.5,80)	0.747
4	80 (70,80)	80 (76,80)	80 (70,80)	0.519
6	80 (70,80)	80 (78.5,80)	80 (70,80)	0.697
8	80 (70,80)	80 (73.5,80)	80 (70,80)	0.997
12	80 (70,80)	80 (73.5,80)	80 (70,80)	0.681
24	80 (70,80)	80 (72,80)	80 (70,80)	0.590

[Table/Fig-5]: Comparison of median Diastolic Blood Pressure (DBP) follow-ups after surgery between study groups.

Time interval (hours)	Study group median (IQR)			Kruskal-Wallis test p-value
	Group A (N=30) Respiratory rate	Group B (N=30) Respiratory rate	Group C (N=30) Respiratory rate	
2	16 (16,18)	16.5 (16,18)	17 (16,18)	0.544
6	16.5 (16,18)	17.5 (16,18)	17 (16,18)	0.370
12	16 (16.75,18)	17 (16,18)	17 (16,18)	0.212
24	17 (16,18)	17.5 (16,18)	16 (16,18)	0.535

[Table/Fig-6]: Comparison of median Respiratory Rate (RR) follow-ups after surgery between study groups.

Time interval (hours)	Study group median (IQR)			Kruskal-Wallis test p-value
	Group A (N=30) VAS score	Group B (N=30) VAS score	Group C (N=30) VAS score	
2	2 (2,2)	2.5 (2,3)	1 (1,2)	<0.001
4	3 (2.75,4)	3 (2,4)	2 (1,2)	<0.001
6	3 (3,4)	3 (3,4)	2 (1,2)	<0.001
8	2 (2,3)	3 (2.75,4)	2 (1,2)	<0.001
12	3 (3,3)	3 (2.75,3)	2 (1,2)	<0.001
24	2 (2,2)	3 (2,2)	2 (1.5,2)	<0.001

[Table/Fig-7]: Comparison of median VAS Score at different follow-ups across study group.

Parameter	Study group (Median IQR)		
	A vs B	B vs C	A vs C
VAS score at 2 h **Man-Whitney (p-value)**	0.001	<0.001	<0.001
VAS score at 4 h **Man-Whitney (p-value)**	0.906	<0.001	<0.001
VAS score at 6 h **Man-Whitney (p-value)**	0.214	<0.001	<0.001
VAS score at 8 h **Man-Whitney (p-value)**	0.002	<0.001	<0.001
VAS score at 12 h **Man-Whitney (p-value)**	0.950	<0.001	<0.001
VAS score at 24 h **Man-Whitney (p-value)**	<0.001	<0.001	<0.001

[Table/Fig-8]: Multiple comparison of VAS score at different follow-ups across study group.

Side-effects were 7.7% (14/180) in group A, 2.2% (4/180) in group B and 1% (2/180) in group C. No adverse effects were noted at 24 hours [Table/Fig-9]. Patient satisfaction score was excellent in 30% in group A, 16.6% in group B and 80 % in group C [Table/Fig-10].

Adverse effects	Study group		
	Group A (N=30)	Group B (N=30)	Group C (N=30)
at 2 h			
Nausea	3 (10%)	0	0
Vomiting	0	0	0
Epigastric discomfort	0	0	0
at 4 h			
Nausea	1 (3.33%)	1 (3.33%)	0
Vomiting	1 (3.33%)	0	0
Epigastric discomfort	1 (3.33%)	0	0
at 6 h			
Nausea	2 (6.67%)	1 (3.33%)	1 (3.33%)
Vomiting	1 (3.33%)	2 (6.67%)	0
Epigastric Discomfort	1 (3.33%)	0	0
at 8 h			
Nausea	3 (10%)	0	1 (3.33%)
Vomiting	0	0	0
Epigastric discomfort	0	0	0
at 12 h			
Nausea	0	0	0
Vomiting	0	0	0
Epigastric discomfort	1 (3.33%)	0	0

[Table/Fig-9]: Comparison of adverse effects between study group.
For each hour 30 inputs (adverse effects) were taken

Patient satisfaction score	Study group		
	Group A (N=30)	Group B (N=30)	Group C (N=30)
Poor	1 (3.33%)	0 (0%)	0 (0%)
Fair	11 (36.67%)	2 (6.67%)	0 (0%)
Good	9 (30%)	23 (76.67%)	6 (20%)
Excellent	9 (30%)	5 (16.67%)	24 (80%)

[Table/Fig-10]: Comparison of patient satisfaction score across study group.

DISCUSSION

The current study findings showed that the subjects who received the combination of paracetamol and diclofenac experienced less pain and prolonged analgesia. In addition to this, there was no statistically significant difference in median HR, BP and RR at all the time periods. Patient satisfaction score was excellent among majority (80%) of the patients in the combination drug group.

Opioids and NSAIDs are the mainstay for the treatment of moderate to severe postoperative pain [11]. Since NSAIDs are devoid of opioid related adverse effects the present study compared acetaminophen and diclofenac suppository in postoperative pain management following caesarean section [12].

It was observed that pain relief by individual use of paracetamol infusion and diclofenac suppository was similar but the combination group was superior to both individual paracetamol infusion group and diclofenac suppository group in post-caesarean analgesia. The finding was consistent with the study by Munishankar B et al., where pain relief was better in patients that received combination of diclofenac (100 mg) and paracetamol (1 gm) after caesarean section when compared with either of the individual drug [13].

The study findings showed that among all the three studied groups, those who received the combination of acetaminophen and diclofenac resulted in longer analgesia and better pain control compared with the other two study groups. Similarly, Romsing J et al., study showed that the combination of acetaminophen (10-15 mg/kg) and diclofenac suppository (1 mg/kg) had better analgesia than individual use of each drugs [14]. Ong CK et al., concluded that combination of acetaminophen and NSAID's is more effective than single drug [15]. The effectiveness of acetaminophen-diclofenac in postoperative pain was found to be superior by other authors too, compared to single therapy with acetaminophen [16-18].

Supporting the results of present study, Bakhsha F et al., compared rectal diclofenac, IV paracetamol and paracetamol-diclofenac combination. The least mean pain score was found in the combination group and the highest was observed in the diclofenac group [19].

In the present study, the adverse effects such as nausea and epigastric discomfort was higher with diclofenac suppository group and minimal in the combination group. Similarly, Uzoma O et al., observed that in patients undergoing major abdominal surgeries,10% of patients receiving diclofenac suppository for postoperative pain management experienced adverse effects such as nausea, vomiting and epigastric discomfort [20]. Acetaminophen, when administered by IV route, activates the endogenous opioids pathway. Hence the side-effects on the gastrointestinal tract are less, inhibition of platelet function and reaches an effective concentration faster [21]. Due to its minimal side-effects paracetamol is well-tolerated compared to NSAIDs [13].

Diclofenac is one of the most potent cyclooxygenase enzyme inhibitors and by inhibiting the synthesis of prostaglandins it reduces inflammation and promotes peripheral analgesic effect [21,22]. In

individuals with history or risk of gastritis or peptic ulcer, paracetamol can be an alternative to diclofenac. The combination of paracetamol and diclofenac thus provides excellent analgesic effect.

Limitation(s)

Limitation of the present study was its sample size.

CONCLUSION(S)

Paracetamol infusion is as effective as diclofenac suppository in reducing postoperative pain following caesarean section. Diclofenac suppository and IV paracetamol combination provides more effective postoperative analgesia compared with individual usage of IV paracetamol or diclofenac suppository in patients following caesarean section. The combined use of paracetamol and diclofenac suppository has fewer side-effects compared with individual use of either IV paracetamol or diclofenac suppository.

Acknowledgement

Authors would like to thank the authorities of Sri Devaraj Urs Academy of Higher Education and Research for supporting this study.

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PLAGIARISM CHECKING METHODS: [Jain H et al.]
- Plagiarism X-checker: Feb 17, 2021
- Manual Googling: May 14, 2021
- iThenticate Software: May 20, 2021 (21%)

ETYMOLOGY: Author Origin

AUTHOR DECLARATION:
- Financial or Other Competing Interests: None
- Was Ethics Committee Approval obtained for this study? Yes
- Was informed consent obtained from the subjects involved in the study? Yes
- For any images presented appropriate consent has been obtained from the subjects. NA

Date of Submission: **Feb 16, 2021**
Date of Peer Review: **Apr 15, 2021**
Date of Acceptance: **May 17, 2021**
Date of Publishing: **Sep 01, 2021**