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Original Research Article

Comparative study of diclofenac, paracetamol infusion, or a combination in post-caesarean patients for pain management

Abhilasha Choudhary, Swati, Pahula Verma*

Department of Obstetrics and Gynecology, N.C. Medical College, Israna, Panipat, Haryana, India

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***Correspondence:**
Dr. Pahula Verma,
E-mail: dr.pahulaverma@gmail.com

ABSTRACT

Background: The World Health Organization (WHO) has released fresh information showingthat the number of caesarean sections performed worldwide has increased and now accounts for more than one in five (21%) deliveries. 89.8% of women experienced significant post-operative discomfort following a caesarean section and 84.2% reported to have moderate to severe pain. This study aimed to compare diclofenac, paracetamol infusion, and a combination of bothin patients of post-caesarean for pain management.
Methods: The study was a cross-sectional study carried out in the department of obstetrics and gynaecology at a tertiary care hospital in a rural area of Panipat, Haryana. A total number of 102 women who underwent caesarean section were taken for the study. They were divided into 3 groups each having 34 women. The first group was given diclofenac, the second was given paracetamol infusion and the third was given a combination of both for pain management.
Results: In our study we have done visual analog score (VAS) scoring at 0, 1, 6, 12, 18 and 24 hours and we found that the mean VAS score in group 3 was highest when compared to other two groups. We alsofound that on comparing data of VAS score between the three groups the p value came out tosignificant that is $p \leq 0.001$.
Conclusions: We found that combination therapy had good results in comparison to individual therapy and had fewer side effects.

Keywords: Diclofenac, Paracetamol, Post-operative pain, Caesarean patient, VAS score

INTRODUCTION

In cases where vaginal deliveries would be dangerous, caesarean sections are necessary to preserve lives. The World Health Organization (WHO) has released fresh information showing that the number of caesarean sections performed worldwide has increased and now accounts for more than one in five (21%) deliveries.[1]

Non-reassuring fetal conditions, inability to progress, cephalopelvic disproportion, and malpresentation, as well as past uterine surgery, are major causes of caesarean sections.[2]

Currently, one of the medical procedures that are most frequently carried out throughout the world is a caesarean section.

Discomfort brought on by pain is by far the most common problem after caesarean sections.[3] Even though pain is a natural part of recovering from surgery, it is frequently not treated effectively, which can have unfavorable consequences. Postoperative pain that is not addressed can lead to clinical and psychological changes that lower quality of life while increasing morbidity and mortality.[4]

Postoperative pain that is not well managed can dramatically increase the risk of surgical patients becoming ill, delaying their ability to recuperate in a hospital setting and resume theirnormal daily activities.[5] It has been found that 89.8% of women experienced

significant post- operative discomfort following a caesarean section and 84.2% reported to have moderate to severe pain.[6]

Pain has been classified as a serious health problem in the past few years in developed as well as developing countries.[7-10] The management of pain is very important in post caesarean women for the early mobilization of the mother and also for the newborn baby to take care of baby.[11]

Because the maximum permitted dose of the drug is typically not utilized because of concern about side effects, the unimodal approach to pain management typically results in inadequate pain control. There is now a multimodal strategy for managing postoperative pain.[12] Instead of raising the dose of a single agent to obtain better efficacy because it causes more side effects, balanced multimodal analgesia combines two or more agents that work by various pathways to generate a superior analgesic effect without having side effects.[13] These modes can enable obstetricians to do pain management in post-caesarean women as their main aim isto reduce pain with minimal side effects.

There are many drugs that can be used for pain management. These include opioids like tramadol, non-steroidal anti-inflammatory drugs (NSAIDs) like diclofenac, and analgesics like acetaminophen. However, due to the increasing addiction and side effects of opioids, theiruse has been decreasing with time. With time there has been a shift from opioids to NSAIDs.

Diclofenac a drug belonging to the class of NSAIDs effectively manages postoperativecaesarean pain while also lowering the need for narcotics.[16,17] On the other hand, the primary mechanism of action of the central analgesic medication paracetamol is suppression of the cyclooxygenase pathway, with possible indirect effects on the serotonergic system.[18]

NSAIDs are more widely used these days in postoperative pain management, even though thehigher modalities, such as epidural analgesia, are superior at managing postoperative pain but due to a shortage of highly skilled professionals in remote parts of resource-constrained countries, these modalities are not used very much.[19,20]

As every drug has side effects the NSAID side effects include nausea and epigastric pain so they should be given in combination with antacids.[21] Additionally, the dosage of NSAIDs might be decreased by mixing acetaminophen with NSAIDs. This study aims to compare diclofenac with paracetamol and a combination of both these drugs. To reduce the duration of post caesarean pain which will aid in improving self-care skills resulting in early discharge, lower chances of nosocomial infections, and lower hospital expenditures. It will even help in early bonding with the newborn and can result in an early start to breastfeeding and positive postnatal outcomes.[22]

METHODS

The study was a cross-sectional study carried out in the department of obstetrics and gynecology at a tertiary care hospital in a rural area of Panipat, Haryana. A total number of 102 women who underwent caesarean section were taken for the study. The study was done for a period of 18 months May 2022 to October 2023. They were divided into 3 groups each having 34 women. The first group was given diclofenac, the second was given paracetamol infusion and the third was given a combination of both for pain management.

Inclusion criteria

Pregnancy with a gestational age of 37 to 41 weeks, and women undergoing caesarean section (elective and emergency).

Exclusion criteria

Women with complicated pregnancy, women with systemic illness, women with a history of drug allergy to paracetamol or diclofenac, and women not giving consent were excluded.

The women were randomly divided into these 3 groups and a detailed history was taken. After taking history a complete examination was done and they underwent a caesarean section under spinal anaesthesia with the same technique. Post-caesarean women in group 1 were given an injection of diclofenac 75 mg, 8 hourlies, and in group 2 they received paracetamol 1 gram intravenous 8 hourly, and in group 3 a combination of both was given at an interval of 12 hours. Both the drugs were started 1 hour after the end of surgery till 48 hours after surgery.

After this data was recorded in Microsoft excel and was analyzed using statistical package for the social sciences (SPSS) software.

RESULTS

Table 1 shows that the mean age in group 1 is 24.62 years, in group 2 it was 25.5 years and in group 3 it was 25.88 years. The mean BMI in group 1 was 23.64 kg/m^2, in group 2 was 23.91 kg/m^{2,} and that in group 3 was 23.79 kg/m^2. It was seen that in group 1, 13 women were primigravida and 21 females were multigravida. In group 2, 9 females were primigravida and 25 females were multigravida. On the other hand, in group 3, 10 women were primigravida and 24 females were multigravida. The mean gestational age in group 1 was 38.26 weeks andthat in group 2 was 38.9 weeks and in the third group was 39.29 weeks.

It was also seen that the maximum number of women in all

groups were from rural areas (group 1- 29, group 2-29, and group 3-30). It was seen that only 5 females in groups 1 and 2 were from urban areas and 4 in group 3 were from urban areas. The modified BG Prashad grading was done for all women in group 1 women with grade 2 being 2, grade 3 being 7, grade 4 being 19, and grade 5 being 6. In group 2 women with grade 2 were 0, grade 3 were 13, grade 4 were 18, and grade 5 were 3. In group 3 women with grade 2 were 3, grade 3 were 9, grade 4 were 14, and grade 5 were 8.

The neonatal outcome of being mother-side was good in all three groups (98%, 98%, and 99% respectively). The number of women undergoing emergency caesarean section was more in all the 3 groups. In group 1, 25 underwent emergency, and 9 underwent elective caesarean section. In group 2, 27 underwent emergency and 7 underwent elective caesarean section. In group 3, 22 underwent emergency and 12 underwent elective caesarean section.

Table 2 shows the mean values of the VAS score for pain assessment in each group. It shows that at 0 hours' group 3 had a maximum mean score that is 8.9, followed by group 2 that is 8.3,and then group 1=7.9. We also found that at 1 hour again group 3 had a maximum mean score that is 6.9, followed by group 2 that is 5.7, and then group 1=5.4.

It also shows that at 12 hours' group 3 had a maximum mean score that is 3.9, followed by group 2 that is 3.5, and then group 1=3.34. At 12 hours mean VAS score was 3.56 in group 3, 2.89 in group 2, and 2.02 in group 1. Similarly, at 18 hours mean VAS was 1.54 in group 3, 0.62 in group 2, and 0.4 in group 3. At 24 hours it was 0.01 in group 3 and 0.02 in group 1. According to the table, we found that the mean VAS was maximum in group 3.

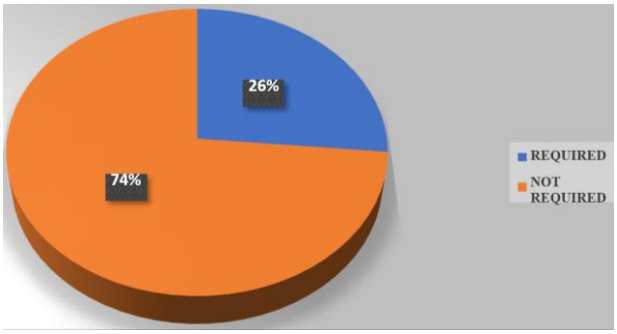

Figure 1: Distribution of women in group 1 based on rescue dose requirement.

On comparing all three groups with each other for VAS scores at 0, 1, 6, 12, 18 and 24 hours all values came out to be significant with a p value of <0.001.

Table 1: Baseline maternal characteristics and demographics.

Parameters	Group 1	Group 2	Group 3
Age (years)	24.62	25.5	25.88
BMI (kg/m^2)	23.64	23.91	23.79
Gravida			
Primi	13	9	10
Multi	21	25	24
Gestational age (weeks)	38.26	38.9	39.29
Population distribution			
Rural	29	29	30
Urban	5	5	4
Modified BG Prashad			
Grade 2	2	0	3
Grade 3	7	13	9
Grade 4	19	18	14
Grade 5	6	3	8
Neonatal outcome	98	98	99
Mother side NICU admission	2	2	1
Type of LSCS			
Emergency	25	27	22
Elective	9	7	12

Table 2: Pain assessment by VAS score.

VAS score	Group 1	Group 2	Group 3
0 hour	7.9	8.3	8.9
1 hour	5.4	5.7	6.9
6 hours	3.34	3.50	3.9

Continued.

VAS score	Group 1	Group 2	Group 3
12 hours	2.02	2.89	3.56
18 hours	0.4	0.62	1.54
24 hours	0.02	0.00	0.01

Table 3: P value for VAS score.

VAS score	Group 1 versus 2	Group 1 versus 3	Group 2 versus 3
0 hour	<0.001	<0.001	<0.001
1 hour	<0.001	<0.001	<0.001
6 hours	<0.001	<0.001	<0.001
12 hours	<0.001	<0.001	<0.001
18 hours	<0.001	<0.001	<0.001
24 hours	<0.001	<0.001	<0.001

Table 4: Need for rescue analgesia.

Rescue	Group 1		Group 2		Group 3	
	N	%	N	%	N	%
Required	9	26.4	7	20.6	0	0
Not required	25	73.6	27	79.4	34	100

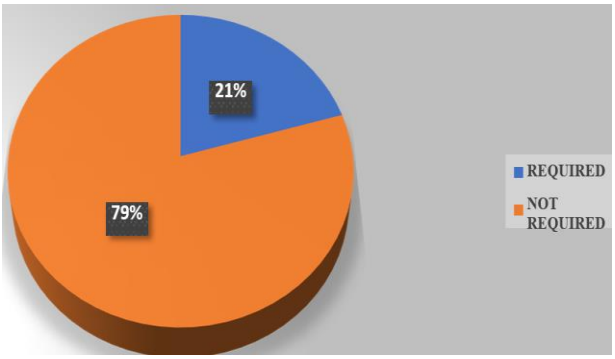

Figure 2: Distribution of women in group 2 based on rescue dose requirement.

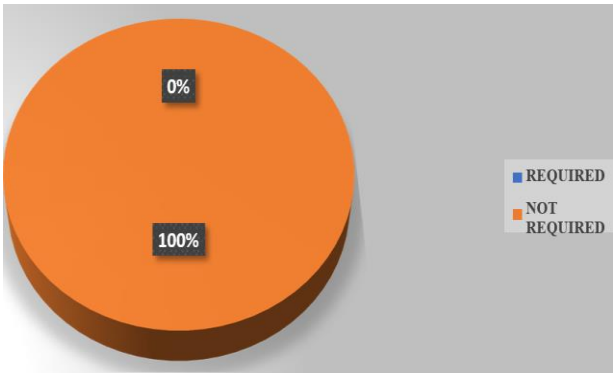

Figure 3: Distribution of women in group 3 based on rescue dose requirement.

It was found that in group 1, 9 women needed a rescue dose of tramadol and 25 women did not require any rescue therapy whereas in group 2 7 women required a rescue dose of tramadol and 27 did not require it. On the other hand, in group 3 no women required rescue therapy.

DISCUSSION

Post-operative pain management is a very important point to be taken care of after any surgery as it ensures the mental health of the patient. The mainstay of post-operative pain management is opioids and NSAIDs. Since opioids have a large number of side effects and can lead to abuse in our study, we compared diclofenac injection with paracetamol infusion and the combination of these two drugs with each other.

In our study, we found that the combination therapy with diclofenac injection and IV paracetamol provides more effective postoperative analgesia compared with that of using these drugs individually in patients following a caesarean section. Similar results were also found in other studies.

In a study by Reddy et al 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 the individual paracetamol infusion group and diclofenac suppository group in post-caesarean analgesia.[23]

The similar findings were also found in a study by Munishankar et al where pain relief was better in patients that received a combination of diclofenac (100 mg) and paracetamol (1 g) after caesarean section when compared with either of the individual drugs.[24]

In our study, we also found that the side effects seen in patients receiving only injection diclofenac were more in comparison to the effects seen when it was given in combination therapy. The combination therapy reduces the

post-operative pain as well as irritating side effects of analgesia like nausea, vomiting, and epigastric pain.

Limitation

The sample size was small.

CONCLUSION

Injection diclofenac and paracetamol infusion are equally effective in managing pain following a caesarean section. On the other hand, the combination therapy with diclofenac injection and IV paracetamol provides more effective postoperative analgesia compared with that of using these drugs individually in patients following a caesarean section. The combined use of paracetamol and diclofenac also reduces the side effects compared with individuals.

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Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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