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Comparison of the effect of oral Diclofenac potassium (Cataflam) with Diclofenac sodium suppository on postoperative cesarean section pain; a randomized clinical trial

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ABSTRACT

Background and aims: Postoperative pain after cesarean section is one of the important issues in gynecology. Opioids and non-steroidal anti-inflammatory drugs (NSAIDs) are two of the drugs that are used for cesarean pain management. Considering the adverse effects of opioids in the mother and the baby, NSAIDs are preferred in the post-cesarean pain management. This study was designed to compare the effect of oral diclofenac potassium (Cataflam) with diclofenac sodium suppository on postoperative cesarean pain.

Materials and methods: This randomized clinical trial was conducted on patients who underwent cesarean section in Taleghani Hospital during 2019. Patients were randomly divided into two groups based on flipping coin. The first group received 100 mg of oral diclofenac potassium every 6 hours and the second group received 100 mg of diclofenac sodium suppository every 6 hours. The pain was assessed 30 minutes, 2 hours, 6 hours, 12 hours, 18 hours and 24 hours after the intervention using visual analogue scale (VAS) before and after analgesics.

Results: Eighty-four patients were included in the final analysis. The mean of VAS during the intervention in the diclofenac sodium suppository group and in the Cataflam group was 3.42 ± 2.1 and 1.93 ± 2.4 respectively (P value = 0.011). Twenty-eight among 46 patients who received opioids due to severe pain (66.7%) were in the diclofenac suppository group and 18 of them (42.9%) were in the Cataflam group (P value = 0.021).

Conclusion: Diclofenac potassium tablets and diclofenac sodium suppository can reduce the post cesarean pain. The efficacy of diclofenac potassium tablets (Cataflam) is significantly higher than the diclofenac suppository; however, the complication rate was not significantly different.

INTRODUCTION

Acute postoperative pain is one of the common complications after surgical operations which can cause different morbidities for patients [1]. Postoperative pain has a nociceptive character and results from tissue and organ lesions in the acute phase and results from neuropathy and inflammation in the chronic phase [2]. Inappropriate management of postoperative pain is associated with high rate of morbidity, impaired quality of life; prolong hospital stay, slow recovery and increasing the costs of care [3].

Cesarean section is the most common inpatient surgical operation in the world [4]. Acute postoperative pain is common after caesarian section [5]. Post cesarean section pain management is necessary for the efficient activity of mother and the best care of the newborn [6]. Thus, uncontrolled pain may be associated with the delay in the bonding with the infant and increase the risk for thromboembolism due to limited mobilization [7].

Opioids were usually used for the management of postoperative caesarian pain; although, the rate of complications is high in the context of opioids consumption [8]. Recently, new analgesics and new techniques are used for the pain

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reduction after caesarian section surgery instead of opioids usage [9]. Non-steroidal anti-inflammatory drugs (NSAIDs) are a common group of nonopioids analgesics that are used for pain management after obstetric surgeries [10].

Diclofenac is one of the NSAIDs that is used for post caesarian pain control in recent studies [11]. However, the efficacy of different forms of diclofenac is still controversial. The aim of this study was to determine the effects of oral diclofenac potassium (Cataflam) and diclofenac sodium suppository on postoperative caesarian pain control

MATERIALS and METHODS

Study Design

This study was a randomized double-blind clinical trial that was conducted on patients who underwent elective caesarian section in Taleghani Hospital during 2019. The inclusion criteria were age between 18 to 45 years. Patients who had the history of liver, kidney, cardiovascular and cerebrovascular diseases in addition to hypertension, gastrointestinal bleeding, coagulation disorders, eclampsia, asthma and sensitivity to NSAIDs in addition to post-operative bleeding were excluded from the study. Convenience sampling was used for sample selection; furthermore, flipping coin was used for randomization of the patients.

Surgical Technique

All patients underwent caesarian section by through of spinal anesthesia. Bupivacaine 0.5% with the dose of 12.5 milligrams was injected spinally for patients; moreover, caesarian section was done for patients through Pfannenstiel incision. After the surgery, 5 milligrams of morphine sulfate were infused intravenously for primary sedation; in addition, morphine infusion was repeated in the context of severe pain every two hours in the NPO time. Moreover, patients who had VAS score more than 3 in the context 3 doses of morphine sulfate were excluded from the study.

Intervention

After the surgical operation and primary sedation in the NPO time, patients were classified randomly to two groups with the allocation of 1:1 in the PO time. One group was received 100 milligrams of diclofenac suppository every six hours and another group was received 100 milligrams of diclofenac pill with the same dosage. The intervention was done by nurses who were blind from the study process. In addition, patients who had drug complications such as hypertension, dermatological complications, nausea and vomiting, were excluded from the study. Furthermore, in the study timelines (6th, 12th, 18th and 24th hours after the intervention), if the patients had VAS more than 3 in the concept of Cataflam or diclofenac suppository consumption, 5 milligrams of morphine sulfate was used for the sedation of patients.

Patients Assessment

Mean arterial pressure (MAP) in addition to the pulse rate, the severity of pain related to visual analogue score (VAS) and the need for opioids were evaluated before the intervention, 30 minutes after the intervention and at the second, 6th, 12th, 18th and 24th hours after the intervention. In addition, the need for morphine sulfate in the PO time for each group of the intervention were evaluated at the end of the intervention.

Statistical Analysis

All of the information was entered into the SPSS software version 15. Student t-test was used for comparing the severity of pain between the two groups. Furthermore, Chi-Square test was used for analyzing other variables in this study.

Ethical Consideration

This study was conducted after getting permission from the ethical committee of Shahid Beheshti University of Medical Sciences with the registration number of: IR.SBMU.MSP.REC.1395.405

RESULTS

One-hundred patients had the inclusion criteria and entered in the study at the baseline. Sixteen patients were excluded from the study due to personal reason. Eighty-four patients included in the final analysis.

The mean age of patients was 32 ± 4.23. In addition, 40.4%

TABLE 1. Demographic Factors of the patients

variable		Diclofenac Sodium group (n=42)	Cataflam group (n=42)
Age	18-24	10 (23.8%)	9 (21.4%)
	25-31	16 (38.1%)	16 (38.1%)
	32-38	14 (33.3%)	16 (38.1%)
	39-45	2 (4.8%)	1 (2.4%)
Number of Pregnancies	1	16 (38.1%)	18 (42.9%)
	2	18 (42.9%)	14 (33.3%)
	3	4 (9.5%)	5 (11.9%)
	More than 3	4 (9.5%)	5 (11.9%)
Number of C/S	1	27 (64.3%)	25 (59.5%)
	2	14 (33.3%)	16 (38.1%)
	3	0 (0%)	1 (2.4%)
	More than 3	1 (2.4%)	0 (0%)

TABLE 2. Mean arterial pressure in the patients

	Variable	Diclofenac Suppository group	Cataflam group	
MAP	Before the intervention	98.2 ± 12.3 (95% CI 93.3-103)	97.4 ± 14.6(95% CI 91.6-103)	0.7
	30 minutes after the intervention	97.5 ± 18.7 (95% CI 90-105)	98.6 ± 8.6 (95% CI 95.2-102)	0.8
	2 hours after the intervention	93.9 ± 11.4 (95% CI 89.3-98.5)	97.1 ± 10.5 (95% CI 92.9-101)	0.4
	6 hours after the intervention	95.7 ± 19.8 (95% CI 87.8-104)	97.8 ± 21.3 (95% CI 89.3-106)	0.5
	12 hours after the intervention	94.3 ± 20.4 (95% CI 86.1-102)	95.2 ± 33.1 (95% CI 82-108)	0.4
	24 hours after the intervention	94.1 ± 15.5 (95% CI 87.9-100)	96.5 ± 16.9 (95% CI 89.7-103)	0.5

TABLE 3. Mean pulse rate per minute in the patients

	Variable	Diclofenac Suppository group	Cataflam group	
Pulse Rate	Before the intervention	95.1 ± 10.2(95% CI 91-99.2)	93.3 ± 11.3(95% CI 89.9-96.7)	0.6
	30 minutes after the intervention	93 ± 12.1(95% CI 88.2-97.8)	92.4 ± 13.6(95% CI 88.3-96.5)	0.6
	2 hours after the intervention	89.5 ± 16.3(95% CI 83-96)	89.1 ± 18.6(95% CI 83.5-94.7)	0.8
	6 hours after the intervention	85.6 ± 9.8(95% CI 81.7-89.5)	84.2 ± 14.7(95% CI 79.8-88.7)	0.7
	12 hours after the intervention	83.7 ± 8.4(95% CI 80.3-87.1)	83.4 ± 7.5(95% CI 81.1-85.7)	0.9
	24 hours after the intervention	80.6 ± 5.4(95% CI 78.4-82.8)	78.2 ± 6.5(95% CI 76.2-80.2)	0.7

TABLE 4. Mean VAS in the patients

	Variable	Diclofenac Suppository group	Cataflam group	
MAP	Before the intervention	5.25 ± 2.3(95% CI 4.55-5.95)	5.43 ± 1.8(95% CI 4.89-5.97)	0.2
	30 minutes after the intervention	4.99 ± 1.9(95% CI 4.42-5.57)	5.01 ± 2.2(95% CI 4.34-5.67)	0.15
	2 hours after the intervention	3.85 ± 1.4(95% CI 3.43-4.27)	3.05 ± 0.9(95% CI 2.78-3.32)	0.02
	6 hours after the intervention	2.98 ± 1.1(95% CI 2.65-3.31)	2.03 ± 1.4(95% CI 1.61-2.45)	0.018
	12 hours after the intervention	2.09 ± 0.9(95% CI 1.82-2.36)	1.18 ± 0.8(95% CI 0.938-1.42)	0.012
	24 hours after the intervention	1.25 ± 0.7(95% CI 1.04-1.46)	0.84 ± 0.5(95% CI 0.689-0.991)	0.01

of patients did not have the history of previous pregnancies. Moreover, 61.9% of samples did not have the history of caesarian sections.

The results of other demographic factors are presented in Table 1.

The mean MAPs, the mean of pulse rate per minute and the mean Visual Analogue Score (VAS) of the patients in the study intervals are presented in Table 2, 3 and 4 respectively.

Need for Opioids

Forty-six patients (54.7%) were received opioids in addition to the interventions due to severe pain. Twenty-eight among 46 (66.7%) were in the diclofenac suppository group and 18 of them (42.9%) were in the Cataflam group (P value = 0.021).

Drug Side Effects

Sixteen patients (19.04%) had drug related side effects which seven of them were in the diclofenac suppository group (43.75%) and 9 of them were in the Cataflam group (56.25%). There are not any significant differences between the two groups in the drug side effects (P value = 0.235).

DISCUSSION

In the current study, the amount of pain in the patients that measure with Visual Analogue Scale (VAS), decreased significantly in both groups of intervention which can be related to the effect of analgesics, wound healing process and patients stress. Moreover, the mean Visual Analogue Score (VAS) of the patients at the second, 6th, 12th, 18th and 24th hours after C/S in the Cataflam group is lower than the Diclofenac sodium group ((Table 4). It is concluded that Cataflam is more effective for the post caesarian pain in patients in compare to Diclofenac suppository. The analgesic effects of Cataflam tablets have been confirmed in other studies [12, 13]. In addition, the high efficacy of Diclofenac sodium suppository in reducing postoperative pain, especially perineal pain, has been demonstrated in other studies [14, 15]. Consuming NSAIDs after the caesarian section for pain relief can reduce the need for opioids [16]. In this study, the need for opioids in the Cataflam group was lower than Diclofenac suppository group.

Considering the results of this study, the mean MAP was not significantly different between the two groups after the intervention. This result was in line with the findings of Dilger et al. who stated that short-term use of diclofenac did not affect the blood pressure [17]. However, many studies have suggested that Diclofenac inhibition effect on COX-2 increases

blood pressure, which is not associated with our findings [18, 19]. It seems that the period of Diclofenac consuming is related to its effect on blood pressure; in the other hand, the negative effects of Diclofenac on blood pressure may be manifest in long term use of this drug instead of a 24 hours period.

In this study, the mean heart rate per minute before the intervention was significantly higher in compare to the after the intervention. This finding is consistent with the results of the study of Hinz et al. and Ibrahim et al. [18, 20]. In fact, the study found that Cataflam and Diclofenac suppository both can significantly reduce the heart rate in patients; although, there are not any differences between two of them.

CONCLUSION

Diclofenac potassium pill (Cataflam) is more efficient than Diclofenac sodium suppository in the pain reduction after caesarian section. Moreover, Cataflam consumption can be related to lower dose of opioid use after caesarian section,

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