https://doi.org/10.29309/TPMJ/2026.33.07.10246 www.theprofesional.com

ORIGINAL ARTICLE

Analgesic efficacy of diclofenac and paracetamol versus pethidine for post operative pain after cesarean section.

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ABSTRACT… Objective: To compare the analgesic efficacy of diclofenac sodium and paracetamol versus pethidine after cesarean section. **Study Design:** Quasi-experimental study. **Study Design:** Department of Anesthesia, CMH Skardu. **Period:** 1st Feb 2022 to 31 July 2022. **Methods:** Female patients with age from 18-40 years, ASA I or ASA II, singleton pregnancy on ultrasonography at term pregnancy planned for Lower segment cesarean section (LSCS) were included in the study. Sampling was done using a non-probability consecutive allocation of 152 patients with 76 participants in each group. Patients from Group A received intravenous pethidine while patients from Group B received per rectal diclofenac sodium and paracetamol intravenously. Recorded variables were Age, BMI, ASA grade and post operative pain on a VAS at 0 hours, 06 hours and 12 hours. **Results:** Mean age of 28.21 ± 5.79 years in Group A and 29.40 ± 5.84 years in Group B. Body mass index among the groups revealed mean values of 22.72 ± 1.64 kg/m^2 and 22.65 ± 1.65 kg/m^2 in Group A and Group B respectively. Post LSCS pain at 06 hours among the groups was reported by 27(35.5%) patients in Group A as compared to 10 (13.2%) patients in Group B (P=0.01). At 12 hours 30(39.5%) patients experienced pain in Group A as compared to 11(14.5%) patients in Group B with a p-value of 0.01. **Conclusion:** Analgesic efficacy of diclofenac and paracetamol was superior to pethidine for post operative pain after cesarean section.

Key words: Analgesia, Diclofenac, Paracetamol, Pethidine.

Article Citation: Orakzai A, Khalid M, Feroze F, Faheem MSB, Orakzai UA, Attique F. Analgesic efficacy of diclofenac and paracetamol versus pethidine for post operative pain after cesarean section. Professional Med J 2026; 33(07):1217-1221. https://doi.org/10.29309/TPMJ/2026.33.07.10246

INTRODUCTION

Lower segment cesarean section (LSCS) is a common surgical procedure and a balanced approach with the aim to provide adequate anesthesia and analgesia plays a pivotal role in achieving desirable results post operatively.[1] The multisystemic effects of pain due to sympathetic stimulation can lead to a range of complications including hypertension, tachycardia, tachypnea, decreased cerebral, renal and hepatic blood flow. These widespread undesirable effects of the uncontrolled sympathetic activation can eventually result in grave complications with higher rates of morbidity and mortality.[2]

Several techniques have been employed over the years to achieve adequate analgesia post operatively in patients undergoing LSCS. These techniques employ the use of two major group of analgesics including opioids and non-opioid analgesics.[3] Over a period of time the use of opioid analgesics have shown surprising results in achieving adequate analgesia after LSCS, but such patients are prone to the adverse reactions of opioids including nausea, vomiting, pruritis and respiratory depression. On the other hand, non-opioid analgesics offer analgesia and fewer adverse effects as compared to opioid analgesics.[4]

With the advances in the medical science a number of opioid and non-opioid drugs have been administered to offer analgesia but none to date are considered gold standard. Recent trials advocate the use of multimodal approach which can decrease the amount of opioids consumed and hence result in better outcomes with lesser complications in the post operative period.[5]

Non-steroidal anti-inflammatory drugs are widely used analgesics which work by the inhibition of cyclooxygenase enzyme pathway leading to analgesic and antipyretic effects.

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Article received on:
15/12/2025
Accepted for publication:
07/03/2026

Paracetamol works by inhibition of COX-2 pathway leading to prostaglandin inhibition and exhibiting antipyretic and anti-inflammatory effects.[6] Diclofenac belongs to the same class and works by inhibition of COX-1 and COX-2 enzymes leading to anti-inflammatory, antipyretic and analgesic effects.[7] Pethidine is an opioid widely used as an analgesic which acts as an agonist of meu receptors. It is thought to be 8-10 times less potent than morphine with a shorter duration of action. It is available in oral and injectable form and is widely used for analgesia or post anesthesia shivering in patients.[8]

Novel therapies are constantly introduced in the field of anesthesiology with the aim to reduce the post operative complications. The numerous side effects of the opioid analgesic drugs has opened a pathway to innovations which can replace or decrease the quantity of opioids used for analgesia.[9] A multimodal approach conducted stepwise to reduce the consumption of opioids can lead to achieving adequate analgesia without increasing the length of hospital stay and hence reduce the side effects of opioids.[10]

Our study was aimed to compare the analgesic efficacy of a combination of diclofenac and paracetamol versus pethidine in patients after lower segment cesarean section.

METHODS

The quasi-experimental study was conducted at Secondary care hospital for a period of 6 months from 1st Feb 2022 to 31 July 2022 in the department of Anesthesia, Combined Military Hospital Skardu after obtaining approval from the Ethical review committee of the hospital (ERC number E-2/22).

A sample size of 152 participants(76 patients in each group) was calculated by using 5% level of significance, 90% power of test with expected percentage of pain in both groups i.e., opioids as 38%[11] and NSAID's as 15%[11]. Technique of sampling employed for distribution of patients was a non-probability consecutive sampling with 76 patients in Group O and 76 patients in Group N. Patients from Group A received intravenous pethidine while patients from Group B received per rectal diclofenac sodium and paracetamol intravenously.

Inclusion Criteria

Female patients with age from 18-40 years, ASA I or ASA II, singleton pregnancy on ultrasonography at term pregnancy planned for Lower segment cesarean section (LSCS) were included in the trial.

Exclusion Criteria

Patients were excluded with history of allergies to any medications, ASA III or ASA IV, intraoperative bleed of more than 1500ml or if hysterectomy was done.

All the participants who were at term singleton pregnancy were included in the trial on the basis of inclusion criteria. These participants underwent pre-anesthesia evaluation as per the institutional protocol and a written informed consent about the procedure and the research was obtained. On the basis of history, examination and laboratory investigations when anesthesia fitness was documented by classified anesthesiologists, patients were prepared for the surgical procedure and kept Nil per oral 08 hours before the procedure. On the day of surgery patients were transferred to operation theatre and noninvasive monitoring was attached before commencement of the procedure. Noninvasive blood pressure, electrocardiography, temperature, pulse oximetry and pulse contour analysis was performed as per routine. Patients underwent preloading with Ringer lactate fluid via an intravenous cannula already placed on the upper limb. After adequate hydration patients were placed in sitting position and space between Lumbar vertebrae 3 and Lumbar vertebrae 4 was identified. Under aseptic measures a local anesthetic infiltration was done using injection lignocaine (20mg/ml) 3 ml at the injection site. After adequate time of the local anesthetic application spinal anesthesia was administered with a 27g spinal needle when free flow of cerebrospinal fluid was confirmed. A dose of 10 to 12.5 mg using injection bupivacaine(0.5%-5mg/ml) was used for spinal anesthesia. Patients were placed in supine position with a wedge placed under the right hip for the effect of spinal anesthesia to take place. Baseline vital parameters were recorded for each patient. The effect of spinal anesthesia was confirmed using a Bromage Scale and surgical procedure was confirmed when adequate anesthesia was achieved. Under spinal

anesthesia lower segment cesarean section was done and vital signs were recorded after every 5 minutes. At the commencement of the procedure patients from Group A received injection pethidine 20 mg stat dose and received the same after every 04 hours for the next 12 hours. Patients from Group B received diclofenac sodium 2 tablets per rectally and inj paracetamol 1g intravenously as stat dose and then after every 4 hours for the next 12 hours. Post operative pain was assessed at 0 hours, 06 hours and 12 hours using a visual analog scale. Pain scale of ≥4 on a visual analogue scale as reported by participants was recorded as inadequate analgesia and rescue pethidine was administered for the treatment of pain in a dose of 20mg intravenous stat.

SPSS version 23 was used for analysis of the data. For nominal data frequency and percentage was used however mean and standard deviation was used for continuous variables. Chi square test was applied for nominal and independent t-test was used for continuous data with a p-value of ≤0.05 considered as significant.

RESULTS

Total participants recruited in the study were 152 with a mean age of 28.21 ± 5.79 years in Group A and 29.40 ± 5.84 years in Group B. Body mass index among the groups revealed mean values of 22.72 ± 1.64 kg/m^2 and 22.65 ± 1.65 kg/m^2 in Group A and Group B respectively. ASA grades, age and BMI distribution among the participants are shown in Table-I. Post LSCS pain at 06 hours among the groups was reported by 27(35.5%) patients in Group A as compared to 10 (13.2%) patients in Group B (P=0.01). At 12 hours 30(39.5%) patients experienced pain in Group A as compared to 11(14.5%) patients in Group B with a p-value of 0.01. The number of patients with adverse reactions recorded in Group A were 09(11.8%) as compared to 06(7.9%) in Group B.

DISCUSSION

This prospective quasi experimental trial was conducted to compare the efficacy of diclofenac and paracetamol versus pethidine for post operative cesarean section analgesia. In our study we concluded that analgesia was better achieved with lesser pain scores as indicated on a visual analogue scale by combination of dicloran and paracetamol as compared to pethidine. Analgesia was recorded as adequate for all the participants when pain score of less than 3 on a visual analogue scale was recorded at different intervals. Post LSCS pain at 06 hours among the groups was reported by 27(35.5%) patients in Group A as compared to 10 (13.2%) patients in Group B (P=0.01).

TABLE-I

Characteristics of participants (n=152)

Variables		Group A (n = 76)	Group B (n = 76)	P-Value
Age in years Mean ± S.D		28.21 ± 5.79	29.40 ± 5.84	0.207
Body Mass Index in kg/m^2 Mean ± S.D		22.72 ± 1.64	22.65 ± 1.65	0.806
ASA grade n(%)	ASA I	49(64.5%)	56(73.7%)	0.219
	ASA II	27(35.5%)	20(26.3%)	

TABLE-II

Incidence of pain and adverse reactions among groups (n=152)

Variables	Group A (n = 76)	Group B (n = 76)	P-Value
Patients with post operative pain in recovery n(%)	22 (28.9%)	13(17.1%)	0.083
Patients with post operative pain at 06hours n(%)	27(35.5%)	10 (13.2%)	0.001
Patients with post operative pain at 12hours n(%)	30(39.5%)	11(14.5%)	<0.001
Adverse reactions n(%)	09(11.8%)	06(7.9%)	0.415

At 12 hours 30(39.5%) patients experienced pain in Group A as compared to 11(14.5%) patients in Group B with a p-value of 0.01. Similar to our study Darvish H et al found that combination of diclofenac and paracetamol achieved superior analgesia with only 16.7% patients experiencing pain(using VAS) as compared to 38% patients when intravenous pethidine was used. Similarly, the additive meperidine was used in 36.7% patients in participants who received opioids as compared to 6.7% of patients who received NSAIDS.[11]

Evaluation of analgesic effects of NSAIDS in another trial compared the use of diclofenac sodium suppository, intravenous paracetamol and the combination of both drugs for post operative cesarean section analgesia. Better analgesia was achieved in patients who received a combination therapy as compared to a single analgesic and this was indicated by a greater satisfaction rate of 80% in patients receiving diclofenac suppository and intravenous paracetamol as compared to 30% and 16% in patients receiving diclofenac and intravenous paracetamol respectively.[12]

Meperidine has been in use for acute pain in several surgeries including LSCS, orthopedic, cardiothoracic and general surgeries. The synthetic opioid has a shorter duration of action which can cause side effects like respiratory depression and sedation. Another narrative after evaluation of the analgesic efficacy of meperidine states that meperidine was associated with more side effects exhibiting a similar or inferior analgesic properties as NSAIDS.[13]

Another randomized control trial compared the analgesic efficacy of pethidine and paracetamol in patients who underwent nailing for tibial fractures under spinal anesthesia. Participants of pethidine group received the drug in the dose of 1mg/kg body weight at 6,12 and 24 hours while patients from the comparison group received paracetamol at a dose of 15 mg/kg intravenously at the same intervals. Mean pain intensity on a VAS (at 06 hours postoperatively) reported was 65.47 ± 9.88 in paracetamol group as compared to 69.97 ± 11.65 in pethidine group. This revealed that analgesia was better provided by paracetamol as compared to pethidine postoperatively in patients with tibial fractures.[14]

The use of intravenous paracetamol is a common technique for acute pain in the perioperative period. Patients undergoing cesarean section who received intravenous paracetamol had lesser pain scores on a VAS as compared to placebo. The paracetamol receiving group received fewer opioids in comparison to the placebo group.[15] In a similar trial a combination of paracetamol and meperidine was used in comparison with patients who received either meperidine or paracetamol. The mean pain scores after cesarean section were lesser when combination therapy was used as compared to a single therapy. Similarly in patients receiving monotherapy analgesia paracetamol achieved better analgesia as compared to meperidine.[16]

Recent research in the field of anesthesia and analgesia for cesarean section have revealed that 63% of the patients who underwent cesarean section experience pain of variable intensity in the post operative period. Meperidine, paracetamol and diclofenac are the common analgesics used and can achieve analgesia.[17]

Several newer techniques for providing analgesia include intrathecal and ultrasound guided regional blocks for offering analgesia, but no single technique has been considered as gold standard.[18] Our study proves that the use of NSAIDS in combination can offer better analgesia with lesser pain scores as compared to pethidine in patients who have undergone LSCS under spinal anesthesia.

CONCLUSION

Analgesic efficacy of diclofenac and paracetamol was superior to pethidine for post operative pain after cesarean section.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

SOURCE OF FUNDING

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

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AUTHORSHIP AND CONTRIBUTION DECLARATION	
1	**Attique ur Rehman Orakzai:** Conception of study, data collection.
2	**Maliha Khalid:** Data analysis.
3	**Faheem Feroze:** Critical review.
4	**Muhammad Shaheer Bin Faheem:** Discussion writing.
5	**Umer Attique Orakzai:** Proof reading.
6	**Fatima Attique:** Manuscript.