

COMPARISON BETWEEN PER RECTAL AND INTRAMUSCULAR DICLOFENAC AS POST-CAESAREAN ANALGESIA

Dr Maham Zafar^{*1}, Dr Syeda Ali², Dr Muhammad Safdar Nazir³, Dr Nadia Naoreen⁴

^{*1}Post graduate resident Obstetrics and Gynaecology, Nishtar Medical University and Hospital, Multan

²Professor of Obstetrics and Gynaecology, Nishtar Medical University and Hospital, Multan

³Post Graduate Resident FCPS General Surgery, Nishtar Medical University and Hospital, Multan

⁴Post Graduate Resident FCPS Obstetrics and Gynaecology, Nishtar Medical University and Hospital, Multan

^{*1}mahitwenty@gmail.com, ²syedasadiq74@gmail.com, ³safdarnazir48@gmail.com, ⁴lqraa3953@gmail.com

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Corresponding Author: *

Dr Maham Zafar

Abstract

Background: Pain after cesarean section may have a negative impact on maternal healing and infant care. Diclofenac sodium commonly used for post caesarean analgesia and can be given by various routes. Administering per rectum can be provide extended pain relief and increased patient comfort compared to intramuscular injection. The present study investigated the effect of per rectal diclofenac and intramuscular diclofenac for providing analgesia following caesarean section.

Objective: To determine the effectiveness of per rectal diclofenac compared with intramuscular diclofenac in reducing post caesarean pain.

Methods: This was a randomized controlled trial was carried out in Department of Obstetrics and Gynaecology Nishtar Hospital Multan from April 2025 to July 2025. One hundred thirty-six patients undergoing elective caesarean section under spinal anaesthetic were randomly divided into two groups: 68 patients in group A were given 75 mg IM diclofenac and 68 patients in group B were given 100 mg PR diclofenac suppository. Visual Analogue Scale (VAS) was used to assess the pain severity at 12 and 24 hours after surgery. The requirement for rescue analgesia and complications was monitored.

Results: Group B (PR group) demonstrated significantly lower mean VAS scores compared to Group A at 12 hours (4.02 ± 1.41 vs. 4.55 ± 1.32 , $p = 0.024$) and at 24 hours (2.74 ± 1.62 vs. 3.82 ± 1.68 , $p < 0.001$). Additionally, the number of patients requiring rescue analgesia was significantly less in Group B than in Group A (41.2% vs 58.8%, $p = 0.039$). Furthermore, the mean TTFRA was significantly longer in the PR (rectal) group compared to the control group.

Conclusion: Per rectal diclofenac administration is more effective at providing post-caesarean analgesia than intramuscular administration, and results in less rescue analgesia being required and lower pain scores.

1. INTRODUCTION

A cesarean section is one of the biggest surgical procedures in obstetrics. It has been contributing to the survival of countless new-borns and mothers

since it was developed and is being used widely. The rate of caesarean delivery has increased over the years [1]. This increase has been primarily due to improvements in anaesthetic, surgical and

blood transfusion skills, antibiotics and the increased demand of maternal request [2].

If not provided properly after recovery from anaesthesia, the immediate postoperative period may get turbulent [3]. If the pain is not managed properly, recovery may be delayed, and there may be a lack of mother/child bonding and increased hospital stay, all having significant socio-economic implications [4]. Furthermore, poor pain management following caesarean section can be related to uterine subinvolution, risk of postpartum haemorrhage and thromboembolic complications [5,6].

Many women have moderate to severe pain after a cesarean section. So it is crucial to set up an effective, safe, cost-effective and acceptable analgesic plan. Traditionally, the primary focus of postoperative pain has been opioids, but their side effects of nausea, vomiting, sedation, constipation, and dependency are limiting their use. Non-steroidal anti-inflammatory drugs (NSAIDs), on the other hand, work by inhibiting the activity of cyclooxygenase (COX) enzymes which slow down prostaglandin production and hence the transmission of pain [7].

This requirement is further enhanced in low resource countries like Pakistan where the management of obstetric pain is not optimized [8]. This poor practice of analgesics has led to a need for better and evidence-based post-caesarean pain relief options.

There have been some studies that have compared various methods of administering analgesics after a caesarean section [9,10]. The study was a randomized controlled trial of 66 patients who underwent elective lower segment caesarean section under spinal anaesthesia at a tertiary hospital in Nigeria, who were split into two groups. The first group was given 100 mg of rectal diclofenac sodium and the second group was given 75 mg of intramuscular diclofenac sodium for 24 hours after surgery. Baseline characteristics including age (26.38 ± 3.98 years vs 28.32 ± 5.69 years) and BMI (27.23 ± 2.68 kg/m² vs 27.13 ± 2.82 kg/m²) were comparable between groups. The study reported lower pain scores in the rectal group at 12 hours (VAS 4.12 ± 1.56 vs 4.52 ± 1.39) and 24 hours (VAS 2.88 ± 1.90 vs 3.76 ± 1.75),

although differences were not statistically significant [11].

A similar randomized controlled study at Lahore General Hospital was carried out on 100 women who were undergoing caesarean section. Of the patients, 43.86% in the rectal diclofenac group and 58.14% in the intramuscular group needed to take "rescue" analgesia, the study reported. The mean time to rescue analgesia was longer for the rectal group (4.39 ± 2.78 hours) than the intramuscular group (3.92 ± 2.52 hours), indicating that the rectal route provides longer-lasting analgesia. Also, the mean 24-hour pain score in the rectal group (3.88 ± 1.90) was lower than that in the intramuscular group (4.76 ± 1.75) which corroborates the results of earlier studies [12].

We know from our best information that there was little published literature on this subject in South Punjab. Hence, this study has been planned to be carried out in the local population to validate the findings and provide evidence to minimize the morbidity of one of the most commonly performed surgical procedures while enhancing comfort of mother after surgery.

1.1 OBJECTIVES

To determine the effectiveness of per rectal diclofenac compared with intramuscular diclofenac in reducing post caesarean pain.

2. METHODOLOGY

This was a randomized controlled trial was carried out in Department of Obstetrics and Gynaecology Nishtar Hospital Multan from April 2025 to July 2025. The calculated sample size was 136 patients, and the non-probability consecutive sampling method was used to divide the patients into 2 groups consisting of 68 patients. Women aged 18 to 40 years and with a gestational age of 34 to 40 weeks at which they were scheduled to undergo elective caesarean delivery under spinal anaesthesia were chosen for participation. The drug was judged effective when compared to the severity of pain after surgery in patients who received 75 mg intrinsic diclofenac sodium (Group A) versus a 100 mg per rectum diclofenac suppository (Group B). Complications such as

surgical site infection, hematoma and wound dehiscence were monitored.

2.1 INCLUSION CRITERIA

Patients aged between 18 and 40 years, gestational age of 34 to 40 weeks, ASA grade < III (low risk patients), and who were scheduled to have caesarean section under spinal anaesthesia were included.

2.2 EXCLUSION CRITERIA

Patients with history of diclofenac allergy, peptic ulcer disease, bleeding disorders (INR > 1.5), severe PID and postoperative wound complications (hematoma, surgical site infection or wound dehiscence affecting pain assessment) were excluded.

2.3 DATA COLLECTION PROCEDURE

After obtaining ethical clearance from the Institutional Review Board at Nishtar hospital, all the eligible participants who accepted to participate were asked to provide baseline demographic data such as maternal age, BMI, ASA grade etc. Patients were well informed about the Visual Analogue Scale (VAS) before the surgery. Every surgery was carried out under spinal anaesthesia by consultant gynecologist with more than 5 years of post fellowship experience. After delivery, participants were randomly given either 75 mg intramuscular diclofenac (group A) or 100 mg rectal suppository (group B) by a coin toss. The standard post-operative care was maintained. VAS

was used to assess pain levels at 12 and 24 hours and the need for rescue analgesia was documented.

2.4 DATA ANALYSIS PROCEDURE

Data was analyzed statistically with SPSS version 25.0. The continuous variables such as maternal age, body mass index (BMI) and visual analogue scale (VAS) scores at 12 hours and 24 hours after the operation were presented as mean $\pm$ SD. Categorical variables (ASA grade, parity and need for rescue analgesia after surgery) were reported as frequencies and percentages.

To compare the mean values of each continuous variable between intramuscular (Group A) and per rectal (Group B), an independent samples t-test was used, and to compare the categorical variables between intramuscular and per rectal groups, the Chi-square test of independence was used. Potential effect modifiers (ASA grade and parity) were subjected to stratification and the independent samples t-test was performed. A p value of <0.05 was considered statistically significant.

3. RESULTS

A total of 136 patients completed the study, and were equally divided into Group A (intramuscular diclofenac, n = 68) and Group B (per rectal diclofenac, n = 68). At baseline, there were no statistically significant differences between the groups in terms of demographic variables.

Table 1: Baseline Demographic Characteristics

Parameter	Group A (IM Diclofenac, n = 68)	Group B (PR Diclofenac, n = 68)	p-value
Mean Age (years)	25.84 $\pm$ 5.12	26.11 $\pm$ 4.95	>0.05
Mean BMI (kg/m ²)	27.41 $\pm$ 2.55	27.18 $\pm$ 2.64	>0.05

The two groups were found to be comparable both in terms of age and BMI, and thus adequately randomized.

Table 2: Analgesic requirement and post-operative pain score are presented.

Outcome Parameter	Group A	Group B	p-value
VAS at 12 hours	4.55 $\pm$ 1.32	4.02 $\pm$ 1.41	0.024*
VAS at 24 hours	3.82 $\pm$ 1.68	2.74 $\pm$ 1.62	<0.001*
Rescue analgesia required	58.8% (n = 40)	41.2% (n = 28)	0.039*
Time to first rescue analgesia (hours)	3.85 $\pm$ 2.14	4.62 $\pm$ 2.31	0.045*

Table 3: Distribution of patients according to requirement for rescue analgesia.

Requirement of Rescue Analgesia	Group A (n = 68)	Group B (n = 68)	Total
Required	40 (58.8%)	28 (41.2%)	68
Not Required	28 (41.2%)	40 (58.8%)	68

This could illustrate the effectiveness of the Group B regarding the reduction of the requirement for rescue analgesics indicating a prolonged analgesic effect.

Table 4: Frequency of severity of pain in each VAS category.

Angina Score Category	Group A (n = 68)	Group B (n = 68)	p-value
Mild pain (1-3)	18 (26.5%)	35 (51.5%)	<0.01*
Moderate pain (4-6)	40 (58.8%)	29 (42.6%)	
Severe pain (7-10)	10 (14.7%)	4 (5.9%)	

*Statistically significant difference between groups

Mean VAS score was significantly reduced in the per rectal diclofenac group at 12 hours after surgery than in the intramuscular group (4.02 ± 1.41 vs. 4.55 ± 1.32 ; respectively, $p = 0.024$). This difference was greater at 24 hours, when Group B had significantly reduced pain control (2.74 ± 1.62 vs. 3.82 ± 1.68 ; $p < 0.001$).

Group B had significantly fewer animals requiring rescue analgesia (41.2%) than Group A (58.8%), showing the rectal route to be more effective at reducing the need for rescue analgesia. Also, the mean time to first rescue analgesia was significantly longer in the rectal group (4.62 ± 2.31 hours compared to 3.85 ± 2.14 hours; $p = 0.045$). There was no difference in treatment effect by stratified analysis by ASA grade and parity, and no effect modification was found in either group.

4. DISCUSSION

The high rate of caesarean delivery worldwide has raised the importance of optimizing maternal recovery and wellbeing after caesarean delivery, hence effective management of post-caesarean pain is a key objective in modern obstetric care [1,2]. The management of pain after cesarean section is a vital part of the modern practice of obstetrics, and the focus is growing on better recovery and combination strategies for pain management [3,4]. Poor pain management following surgery delays walking around, affects breastfeeding and makes it difficult for the mother to take care of the baby, which increases the risk

of developing postoperative complications due to reduced mobility [5,6].

Since the non-steroidal anti-inflammatory drugs (NSAIDs) have an inhibitory effect on the enzyme cyclooxygenase, which decreases the synthesis of prostaglandin, and thereby inhibit the inflammation and pain, diclofenac sodium is important for postoperative pain management without causing any respiratory depression or any excess sedation [7]. In Pakistan, due to the rising trend of caesarean section delivery, it becomes even more important to have safe, effective and economical postoperative analgesic options [8]. Local studies have shown that rectal diclofenac is effective in the treatment of postpartum pain and can help to increase maternal comfort [9].

Kwosah et al. reported that there was effective postoperative pain relief following caesarean section using rectal diclofenac and it was reported that there was a reduction in additional analgesics required [10]. Likewise, after caesarean section, women who received rectal Diclofenac had significantly lower pain scores than those who received intramuscular Diclofenac [11]. Zulfiqar et al. also found that the patient receiving rectal diclofenac required less rescue analgesics, which is similar to the results obtained in the present study [12].

Assessment of pain in the present study was conducted by Visual Analogue Scale (VAS) which had been found to be reliable and validated for measuring pain intensity in clinical practice [13]. Surgery itself, and the tissue damage caused by the

surgery, are important factors to postoperative pain and a good analgesia is important for healing [14]. Moreover, the results of the visual analogue scale are clinically meaningful and interpretable when they are analysed correctly [15].

There is a recent shift in recovery after caesarean delivery to opioid sparing measures and better recovery post caesarean [16]. The Society for Obstetric Anesthesia and Perinatology has suggested that multimodal analgesics should be adopted for better maternal outcomes and postoperative morbidity after caesarean delivery [17]. With the development and implementation of enhanced recovery after surgery protocols, the importance of proper postoperative analgesia in maternal recovery has been further proven to shorten hospital length of stay [18].

Furthermore, systematic reviews have shown that improved recovery protocols after caesarean section have a positive effect on clinical outcomes and mobilisation and recovery [19]. Such protocols have also started to be implemented in developing countries to improve maternal outcomes, due to effective postoperative pain management, and to decrease the burden of health services [20].

The present study showed that per rectal diclofenac sodium was more effective in postoperative analgesia than intramuscular route as evidenced by significantly lower VAS value at 12 hours and 24 hours after surgery. This is also shown by the decrease in the number of animals needing rescue analgesia in the rectal group. The pharmacokinetic benefits of rectal administration (no injection site pain and more acceptable to patients) may play a role in these observations. Based on the results of the present study, per rectal diclofenac can be included in the postoperative pain management plan after cesarean section. This can help in reducing the analgesics needed, provide comfort for the mother, ensure early mobilization and help faster postoperative recovery, even in a resource poor healthcare system.

5. CONCLUSION

Post operation Analgesia after Caesarean section is crucial for a quick recovery of the mother, for

the mother-infant bonding, and also to decrease the hospital expenditures. This randomized controlled trial has demonstrated that 100 mg diclofenac sodium is more effective for post-caesarean pain control than intramuscular diclofenac sodium 75 mg. Patients taking suppository treatment had significantly lower Visual Analogue Scale (VAS) pain severity scores at 12 and 24 hours after surgery. In addition, this group needed considerably less rescue analgesic, and had a significantly longer mean time interval before additional pain relief was needed. The results show that rectal diclofenac is a safe, effective and reliable non-opioid alternative to manage post-caesarean pain. We suggest the addition of per rectal diclofenac to the routine post-operative treatment for women in the region's health care system to improve maternal care and reduce post operative morbidity.

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