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# Rectal diclofenac; an effective modality for pain relief after vaginal birth

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## ABSTRACT

**Background and Objective:** Vaginal delivery (VD) is the safest delivery option for the mother and is associated with quick recovery and minimal maternal morbidity and mortality. However, one of the commonest fears among women about VD is pain. This study aims to assess the effectiveness of diclofenac suppositories (per rectum) compared to the intramuscular diclofenac for the pain relief in females after VD.

**Methods:** This prospective comparative was study conducted at the Emergency Section (labor room) of Obstetrics & Gynecology Department in one of the tertiary care teaching hospitals of Lahore, Pakistan. A total of 182 female patients undergoing VD were selected and further divided into group A and group B. Group A was administered rectal analgesia in the form of rectal suppositories (100 mg) immediately after perineal tear (first and second degree only) repair and repeated after 6 hours. While group B received one injection of intramuscular diclofenac, immediately after perineal tear repair. The pain score was measured on a graphical score using Graphic Rating Scale, immediately at rest, during movement, and during urination. The pain score was reassessed after 6 hours with the same parameters and compared between both groups.

**Results:** The overall pain score was significantly lower immediately ( $p = 0.004$ ) and 6 hours ( $p = 0.002$ ) after VD in group A at rest, during movement, and during urination as compared to group B.

**Conclusion:** The use of rectal diclofenac suppositories is a simpler and more effective and acceptable method of reducing the pain experienced by the women following perineal trauma after vaginal childbirth.

**Keywords:** Normal vaginal delivery, episiotomy, rectal diclofenac, intramuscular diclofenac, analgesia, pain, suppository.

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## Introduction

Vaginal delivery (VD) is considered as the safest delivery option for the mother.<sup>1,2</sup> It is not only safe but also associated with quick recovery and minimal maternal morbidity and mortality.<sup>3</sup> However, one of the commonest fears among the women about VD is pain.<sup>4</sup>

The most common reason for pain after VD is perineal trauma and injury.<sup>5</sup> The exact rate of perineal trauma especially after episiotomy is difficult to estimate. A major factor particularly in developing countries is the availability of data. The rates of performing episiotomy vary according to the country and the workload of the clinical settings where gynecologists and obstetricians are practicing. World Health Organization (WHO) recommends that the rates of episiotomy should not be more than 10% among all vaginal births.<sup>6</sup> After this recommendation

by WHO, the overall rate of episiotomy during 2006-2013 in the United States dropped from 17.3% to 11.6%.<sup>7</sup>

After VD, the maximum requirement of analgesia is within 24 hours.<sup>8</sup> The perineal pain is reported to be in the most severe form in the immediate period. However, in a certain percentage of women, this pain and discomfort may be continued even weeks after childbirth. There are certain factors that might be influencing the pain relief immediately after delivery. Both surgical repair techniques and types of sutures are important in this regard.<sup>9</sup>

Analgesia after childbirth has a wide range and multiple options.<sup>10</sup> It includes pharmacological as well as non-pharmacological options. Pharmacological analgesia options include oral, parenteral, intramuscular, regional, and local

infiltration. Intramuscular diclofenac has been used for the postpartum analgesia for long time. It is an effective and time-tested analgesia.<sup>11</sup> However, it requires a parental route and requires skills and expertise.

American College of Obstetrics & Gynecology recommends safe and effective analgesia during childbirth.<sup>12</sup> The need for the analgesia is often underestimated especially in developing countries because the workload at Obstetric clinics is out of proportion with the limited staff and resources available.<sup>13</sup>

The choice of analgesia depends on certain factors. Non-steroidal anti-inflammatory drugs (NSAID) are the most widely used analgesic options after childbirth. These can be used through oral, rectal as well as intramuscular route. Oral and rectal diclofenac are easy to administer however the oral route might be associated with common gastrointestinal side effects. Intramuscular route has to be given by the trained health practitioner and requires specific skills. It is also associated with adverse effects like needle accidents and injuries, local reaction, and being painful for nearly all patients. Furthermore, especially in developing countries, the use of syringes could be a source of blood-borne infections like hepatitis & AIDS if precautions are not adapted properly.<sup>14</sup>

Pain estimation after childbirth can be done by different techniques; the graphical score using Graphic Rating Scale is a numerical pain score using the terms mild, moderate and severe.<sup>15</sup> The aim of the study was to compare the pain relief after childbirth by using NSAID through different routes. This study compared the effectiveness of NSAID by intramuscular and rectal routes in terms of pain score that was observed immediately and 6 hours after VD.

## Methods

This comparative prospective study was conducted at the emergency department (labor room) of Lahore General Hospital (LGH), a tertiary care teaching hospital of Lahore affiliated with Post Graduate Medical Institute and Ameer Ud-Deen Medical College Lahore, Pakistan. The study was conducted for 3 months; September, 2021 to November 2021. Total patients delivered in this duration were 1,089. Only 184 patients were selected based on inclusion criteria and were further divided randomly into two groups, A and B. A written informed consent was taken from all recruited patients.

Inclusion criteria for the patients included primigravida with singleton term pregnancy at 37 or above gestational age. All these patients had cephalic presentation, spontaneous labor with normal duration of labor, and delivered vaginally with episiotomy. Exclusion criteria included patients with known hypersensitivity to NSAID, rectal or anal pathology like fissure, fistula, hemorrhoids and/or rectal neoplasms. Patients

with prolonged labor, instrumental deliveries, postpartum hemorrhage, retained placenta, cesarean section, and third and fourth degree perineal tears were excluded. Furthermore, patients with gastric or duodenal ulcer, severe cardiac, renal, respiratory, or hepatic impairment were also excluded.

For all patients, the demographic details were obtained and filled in the specified proforma including hospital registration number, contact details, name, age and occupation with national identity card number and address by the doctors in the labor room. It also included the basic information like body mass index (BMI), blood group & Rh factor and hemoglobin level. Further details included final diagnosis of the patient, gestational age by her last menstrual period. Details obtained regarding any comorbid conditions in the pregnancy for the exclusion criteria were also recorded. Duration for the first, second and third stage of labor were recorded.

Group A was allocated for rectal analgesia in the form of rectal suppositories, 100 mg, given immediately after perineal tear (first and second degree only) repair and repeated after 6 hours. While group B received one injection of intramuscular diclofenac, immediately after perineal tear repair. All selected patients were randomly divided into two groups. Pain score was assessed immediately at rest, during movement, and during urination. The pain score was reassessed after 6 hours with the same parameters. The post-graduate training doctors under the supervision of a consultant, on duty, recorded all the observations in the proforma.

The ethical committee of the LGH, Lahore, Pakistan, approved the study.

## Statistical analysis

Statistical Package for the Social Sciences version 25.0 was used for data entry and analysis; mean and standard deviation were given for continuous variables and frequencies and percentages were given for categorical variables. Pearson's chi-Square test was used to check the association between categorical variables; results were considered significant if  $p$ -value was  $\leq 0.05$ .

## Results

The mean of maternal age was  $26 \pm 3.98$  years in group A and  $28 \pm 5.69$  years in group B. The mean of BMI was  $27 \pm 2.68$  in both groups. Most of the females were homemakers and residents of the Lahore city. The mean hemoglobin concentration (g/dl) was  $10.56 \pm 1.05$  in group A and  $10.77 \pm 1.15$  in group B. The mean gestational age was  $37 \pm 1.97$  (weeks) in both groups. The mean of infant weight at the time of birth was  $2.93 \pm 0.50$  kg in group A and  $3.07 \pm 2.12$  kg in group B (Table 1).

**Table 1.** Socio-demographic characteristics of patients in both groups.

Variables	Suppository (group A)	Intramuscular (group B)
Maternal age (years) mean $\pm$ SD	26.38 $\pm$ 3.98	28.32 $\pm$ 5.69
Maternal BMI (kg/m <sup>2</sup> ) mean $\pm$ SD	27.23 $\pm$ 2.68	27.13 $\pm$ 2.82
Occupation [n (%)]		
House wife	90 (97.8)	87 (94.6)
Working woman	2 (2.2)	5 (5.4)
Residence [n (%)]		
Lahore	76 (82.6)	83 (90.2)
Other cities	16 (17.4)	7 (9.8)
Blood group [n (%)]		
A+	13 (14.1)	12 (13.0)
A-	11 (12.0)	2 (2.2)
B+	17 (18.5)	21 (22.8)
B-	6 (6.5)	6 (6.5)
AB+	15 (16.3)	14 (15.2)
AB-	5 (5.4)	5 (5.4)
O+	22 (23.9)	27 (29.3)
O-	3 (3.3)	5 (5.4)
Hemoglobin (g/dl) mean $\pm$ SD	10.56 $\pm$ 1.05	10.77 $\pm$ 1.15
Obstetric history [n (%)]		
Primigravida	92 (100)	92 (100)
Gestational age at birth (weeks) mean $\pm$ SD	37.87 $\pm$ 1.97	37.52 $\pm$ 2.11
Birth weight (kgs) mean $\pm$ SD	2.93 $\pm$ 0.50	3.07 $\pm$ 2.12

All selected patients had spontaneous labor with normal duration. All the patients had VD with episiotomy. Regarding fetal outcomes, 34 (37%) patients delivered female child and 55 (59%) had male baby in group A, while in group B, 37 (40%) had female and 55 (59%) had male baby (Table 2). After VD, the overall pain score was lower in group A at rest, during movement, and during urination. The pain score was significant immediately and after 6 hours of delivery in group A ( $p$ -value = 0.004, 0.002 respectively) (Table 3).

## Discussion

The role of effective analgesia after childbirth has a wide range and multiple options. The aim of the study was to find out the simple, safe, easy to administer, and effective analgesic option after childbirth in women presenting at our tertiary care hospitals. This study compares the role of rectal versus intramuscular diclofenac for the pain relief after vaginal birth. The pain score was checked at rest, during movement, and during urination.

The requirement of analgesia after childbirth is variable and subjective. The use of a numerical score for the women's perception of pain can help us to assess the need for

analgesia requirements. Accordingly, the dose and duration of analgesia can be tailored on individual basis, especially after childbirth.

Regarding demographic details, the age range of women in our study was between 25 and 30 years and similar results were found in the study of Khorsandi et al.<sup>16</sup> Majority of the patients in both groups (around 80%) were from Lahore city and study of Zakerihamidi et al.<sup>17</sup> conducted in an urban city showed the similar results. Zakerihamidi et al.<sup>17</sup> also speculates that the residential area of the mother also positively influences the pain score after vaginal birth and thus effects the analgesia requirements from case to case. Similar to the study of Quoc Huy et al.<sup>18</sup> the average gestational age in both groups in our study was more than 37 weeks (only term pregnancy included). All three stages of labor including first, second and third were same in both groups. The patients with prolonged labor were excluded from the study as it might need higher analgesia doses and duration.<sup>19</sup>

In the present study, group A had significant pain relief ( $p = 0.004$ ) after childbirth as compared to the group B. This result is comparable to the study of Wilasrusmee et al.<sup>20</sup>

**Table 2.** Obstetric characteristics of enrolled patients in both groups.

	Suppository (group A)	Intramuscular (group B)
Labour [n (%)]		
Spontaneous	92 (100)	92 (100)
Stages of labor (mean ± SD)		
First (hours)	6.09 ± 1.62	5.82 ± 1.81
Second (hours)	2.10 ± 1.21	2.55 ± 1.37
Third (minute)	15.57 ± 9.55	17.86 ± 6.67
VD [n (%)]		
Episiotomy	92 (100)	92 (100)
Outcome [n (%)]		
Female	34 (37.0)	37 (40.0)
Male	55 (59.8)	55 (59.8)
Intrauterine Device (IUD)	3 (3.3)	-

**Table 3.** Outcome measures after delivery in both groups.

	Suppository (group A)					Intramuscular (group B)				
	No pain	Mild	Moderate	Severe	p-value	No pain	Mild	Moderate	Severe	p-value
Pain score after delivery										
At rest	39	14	3	-	0.004	36	23	6	3	0.811
During movement	31	19	4	-		20	22	19	7	
During urination	34	18	3	-		28	18	11	11	
Pain score after 6 hours										
At rest	57	31	4	-	0.002	53	35	4	-	0.000
During movement	21	53	17	1		12	41	24	15	
During urination	31	41	19	1		21	35	21	15	

on 71 patients who reported that rectal analgesia in the form of NSAID had significant analgesic effects ( $p = 0.001$ ) immediately and 6 hours after vaginal birth.

Similarly, the studies with a comparable sample size reported by of Dodd et al.<sup>21</sup> (73 patients in each group) and Searles and Pring.<sup>22</sup> (100 patients) concluded a satisfactory and significant pain relief ( $p < 0.05$ ) with rectal use of diclofenac after childbirth.

### Conclusion

The use of rectal diclofenac suppositories is a simple and effective method of reducing pain immediately following perineal trauma experienced by the women after VD.

### Limitations of the study

The data is limited from one center only and patients were not followed up for more than 6 hours to take record of any painful event thereafter. Multicentric data with follow-up of at least 24-48 hours may be carried out to determine the efficacy of post-partum analgesia of rectal route.

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### List of Abbreviations

BMI	Body mass index
LGH	Lahore General Hospital
NSAID	Non-Steroidal Anti Inflammatory drugs
VD	Vaginal delivery
WHO	World Health Organization

### Conflict of interest

None to declare.

### Grant support and financial disclosure

None to disclose.

### Ethical approval

The Institutional Ethical Review Board of the Post Graduate Medical Institute, Ameer Ud-Deen Medical College, and Lahore General Hospital approved the study vide Letter No. 00/36/21, dated 28/09/2021.

### Authors' contribution

**RN:** Study design, acquisition of data, drafting of manuscript.

**FB:** Analysis and interpretation of data and intellectual input in the manuscript.

**SZ:** Data acquisition, analysis and interpretation.

**ZS, AI:** drafting of manuscript and intellectual input in the manuscript.

**ALL AUTHORS:** Approval of the final version of the manuscript for publication.

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