

Diclofenac rectal suppository: an effective modality for perineal pain

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Abstract

Objective: To determine the frequency of perineal pain after childbirth after a single dose of diclofenac rectal suppository.

Methods: This cross-sectional study was conducted at Shaikh Zayed Women Hospital, Larkana, Pakistan, from April to September 2014, and comprised patients who were admitted to the labour room for normal vaginal delivery. A single dose of rectal diclofenac suppository of 100mg was given to the patients delivered vaginally or by second-stage emergency Caesarean section. Post-partum pain was noted after 12 and 24 hours of the administration of analgesia. SPSS 16 was used for data analysis.

Results: Of the 169 subjects, 63(37.28%) were aged 20 years or less, 85(50.3%) between 21 and 30 years, and 21(12.43%) between 31 and 40 years. Frequency of perineal pain was predominantly mild in 95(56%) patients, moderate in 60(35.5%) and severe in 14(8.28%).

Conclusion: The use of non-steroidal anti-inflammatory rectal suppositories was found to be a simple and highly effective modality of reducing the perineal pain.

Keywords: Perineal pain, Rectal analgesic, Diclofenac rectal suppository, Vaginal birth. (JPMA 66: 1005; 2016)

Introduction

Perineal pain arises from perineal tears, inflammatory reaction, swelling of the adjacent tissues and the contractions of levator ani and other perineal muscles.¹ It is a common problem following episiotomy,² and vaginal delivery, and is very severe in early postnatal period.³ The severity of pain also depends on mode of delivery,⁴ degree of trauma,⁵ type of suture material used for repair and technique of perineal repair.⁶ There is a negative impact of pain on physical and psychological functions, including successful breast feeding.⁷ Physical effects associated with perineal pain include reduced motility, sitting, urinary and faecal incontinence and sexual dysfunction. A study showed that 19.6% of women reported perineal pain.⁸ Another study showed that perineal pain in one-fourth of post-partum women may continue for up to 2 weeks after delivery and among them 10% of women have persistence of symptoms for 3 months.⁹

Various treatment options are available for the relief of perineal pain after delivery. Local anaesthetics, oral analgesics, therapeutic ultrasound and non-pharmacological applications such as baths and ice pack are widely used in clinical practice.¹⁰ Analgesics can be used via oral, intramuscular (IM), intravenous (IV) and rectal route. Rectal analgesics are indicated in those

women who have gastric discomfort, nausea, vomiting and when the patient is drowsy or oral route is prohibited. Rectal route is preferable over oral route administration because half of the drug absorbed by the rectum bypasses the liver and therefore is not metabolised compared with a higher proportion of hepatic first-pass metabolism with oral administration. It results in quick pain relief and prolongs action of treatment.⁷ One of the studies has shown that use of diclofenac rectal suppository significantly reduces the perineal pain after 12 and 24 hours of administration compared to control group (4.5 vs. 0.0; $p < 0.001$; and 2.0 vs. 0.0; $p = 0.02$ for 12 hours and 24 hours respectively).⁹ The current study was planned to determine the magnitude of pain relief by diclofenac rectal suppository.

Subjects and Methods

This cross-sectional study was conducted at the Shaikh Zayed Women Hospital (SZWH), Larkana, Pakistan, from April to September 2014, and comprised patients who were admitted to the labour room for normal vaginal delivery. The sample size was calculated by using World Health Organisation (WHO) sample size determination software with 19.6% reporting perineal pain, 95% confidence interval (CI) and 6% level of precision.¹¹

Patients having singleton pregnancy with gestational age of more than 36 weeks assessed by ultrasound were included. They had normal vaginal delivery with episiotomy/ second- to third-degree perineal tear, or those who had second-stage emergency Caesarean

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section (CS). Patients who had a history of allergy to non-steroidal anti-inflammatory drugs (NSAIDs), acid peptic ulcer disease, liver problems, renal problems, assisted vaginal deliveries and per rectal bleeding were excluded. All the Patients, admitted in labour room for normal vaginal delivery who fulfilled the inclusion criteria were registered. Informed consent was obtained from the participants and approval was obtained from the ethical review committee (ERC) of the Shaheed Mohtarma Benazir Bhutto Medical University, Larkana. A single dose of rectal diclofenac suppository of 100mg was given to all the patients who delivered vaginally or by second-stage emergency CS. Post-delivery pain was noted after 12 and 24 hours of the administration of analgesia. The final outcome was measured at 24 hours by using numerical analogue score, which helps to quantify the intensity of pain (Figure-1). The numerical analogue scale is a straight line with scale ranging from 0-10, where 0 represents no pain while 10 shows worst pain ever experienced. Patients marked on the line according to the pain they experienced. Pain was considered mild with analogue score 1 to 3, moderate with 4 to 6 and severe with 7 to 10.⁸

SPSS 16 was used for data analysis. Categorical variables like mode of delivery, parity, pain score were presented in the form of frequencies and percentages, whereas continuous variables like age, gestational age and weight were expressed as mean and standard deviation (SD). Effect modifier was controlled through stratification of age, gestational age, parity, mode of delivery and applying chi square test to see their effect on outcome variables. $P \leq 0.05$ was considered significant.

Results

Of the 169 participants, 63(37.28%) were aged 20 years or less, 85(50.3%) between 21 and 30 years and 21(12.43%) between 31 and 40 years (Table-1). The overall mean age was 24.38 ± 6.23 years. Regarding parity of the women, 40(23.67%) were primipara, 43(25.44%) had 1 to 3 children, 45(26.63%) had 4 to 6 children and 41(24.26%) had more than 6 children. Spontaneous vaginal delivery (SVD) was observed in 134(79.29%) cases and 35(20.71%)

Table-1: Descriptive statics of study patients.

Variables	No of Patient	%
Age in Years		
<20	63	37.28%
21-30 years	85	50.30%
31-40 years	21	12.43%
Parity		
◆ Primipara	40	23.67%
◆ 1-3	43	25.44%
◆ 4-6	45	26.63%
◆ 7-6	41	24.26%
Mode of Delivery		
◆ Vaginal	134	79.29%
◆ C-section	35	20.71%
Type of Perineal Trauma		
With Episiotomy	51	38.06%
Only SVD	55	41
First degree tear	17	12.69%
2nd degree tear	11	8.21%

SVD: spontaneous vaginal delivery

C-section: Caesarean.

Table-2: Frequency of perineal pain after use of single dose of 100 mg of diclofenic rectal suppository.

Variables	Mild n=95	Perineal pain Moderate n=60	Severe n=14	Total
Age in Years				
◆ <20	43 (45.3%)	13 (21.7%)	7(50%)	
◆ 21-30	41(43.2%)	37 (61.7%)	7(50%)	
◆ 31-40	11 (11.6%)	10 (16.7%)	0 (%)	
Gestational Age				
◆ 37-38 weeks	58 (61.1%)	42 (70%)	11(78.6%)	111
◆ 39-40 weeks	31 (32.6%)	13 (21.7%)	2(14.3%)	46
◆ 7-40 weeks	6(6.3%)	5(8.3%)	1(7.1%)	12
Parity				
◆ Primri Para	25 (26.3%)	12(20%)	3(21.4%)	40
◆ 1-3	19(20%)	17(28.3%)	7 (50%)	43
◆ 4-6	29 (30.5%)	12(20%)	4(28.6%)	45
◆ 76	22 (23.2%)	19 (31.7%)	0%	41
Mode of Delivery				
◆ SVD	74 (77.9%)	46 (76.7%)	14(100%)	134
◆ C-section	21(22.1%)	14(23.3%)	0(0%)	35

SVD: spontaneous vaginal delivery

C-section: Caesarean.

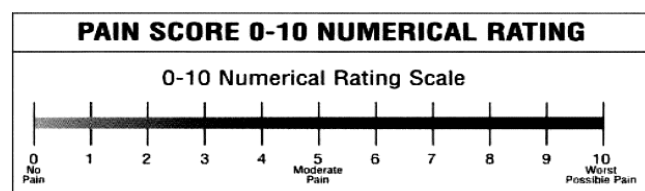


Figure-1: Pain Assessment.

were CS. Besides, 51(38%) cases of perineal trauma were related to episiotomy, 55(41%) to SVD, 17(12.69%) to first-degree tear and 11(8.21%) to second-degree tear. Perineal pain was mild in 95(56.21%) patients, moderate in 60(35.5%) and severe in 14(8.28%) patients (Figure-2). Of the participants who felt mild pain, 84(88.4%) were aged

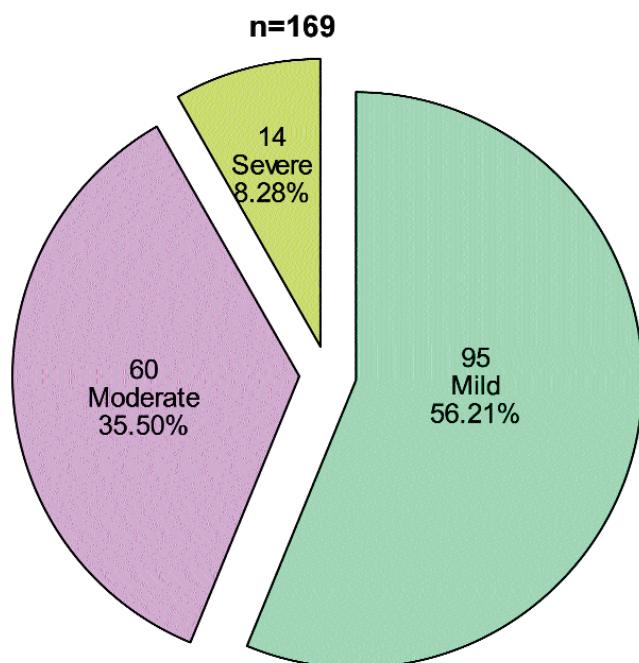


Figure-2: Frequency of perineal pain after child birth after the use of single dose of 100 mg of diclofenac rectal suppository.

below 30 years. Frequency of perineal pain was significantly associated with age, while perineal pain intensity was not significant for gestational age, parity, weight and mode of delivery of the women (Table-2).

Discussion

In developed countries at least 65% of women suffered from perineal trauma, whereas in underdeveloped countries about 35-45% of women who give birth in a hospital have an episiotomy.¹² About 20-25% of women have continuous pain and discomfort for up to two weeks after delivery,¹³ and 10% of mothers experienced pain for up to three months after delivery.^{13,14} A study showed that 94% of women suffer from one or more health issues up to six months after child birth, including perineal pain.¹⁵ Perineal pain in immediate post-partum period (within 24 hours after delivery) is greatly reduced by the use of diclofenac rectal suppositories (100mg) whose effect lasts for 24 hours. It also helps women in walking, sitting, opening their bowels, and reduces the intensity of pain experienced during movements.

In the current study the average age of the patients was 24.38 ± 6.23 years (95%CI: 23.43 to 25.3). In a study by Corkilla et al.,¹⁴ the mean age was 28 years. SVD was observed in 134(79.29%) cases and 35(20.71%) were Caesarean. In the study by Dodd et al.,¹⁰ SVD was observed in 66% patients. However, another study put the figure at

85.3%.¹⁴ In this study the most frequent perineal trauma was episiotomy, i.e. in 38.06% of the patients. Perineal pain intensity was predominantly mild (56.5%) and moderate (35.5%). It was also reported in the study by East et al.¹⁶ where 53% participants had mild, 33% had moderate pain and 3.7% had severe pain, while in 23.7% perineal trauma was due to episiotomy. Similar results were also observed in Dodd et al's study.¹⁰ Another study found that the median pain score was significantly reduced by the use of diclofenac suppositories at 12 and 24 hours after administration compared to control group.⁹ After oral administration the terminal half-life of diclofenac in plasma is 1 to 2 hours. After rectal route the half-life is longer and absorption is complete in less than 40 minutes. It is less secreted in breast milk as it is completely protein bound so it can be used safely in lactating mothers.¹⁷ In determining the acceptability of rectal analgesic suppositories, Carroll et al.¹⁸ found that only 18% of patients chose rectal suppositories as an acceptable method of pain relief. In our study the women who received diclofenac rectal suppository had a higher degree of drug acceptance for rectal use and they were more satisfied with their pain relief after child birth. Moreover, none of the women experienced any side effect after rectal use of diclofenac suppository. However, one should keep in mind the adverse drug effects while prescribing this medication.¹⁹ Since the completion of the current study, the SZWH has developed a clinical guideline for the use of non-steroidal anti-inflammatory drug suppositories in the management of post-partum pain, indicating careful use of these drugs in women with hypovolaemia, pre-eclampsia, gastrointestinal bleeding or ulceration, asthma, allergies to aspirin or other non-steroidal anti-inflammatory drugs or haematological conditions associated with prolonged bleeding time.²⁰ There appears to be a clear advantage in using non-steroidal anti-inflammatory drug suppositories to provide short-term pain relief for perineal pain after childbirth. There does not appear to be any long-term benefits of reduced perineal pain or reduced need for analgesia. Given the short half-life of non-steroidal anti-inflammatory drug suppositories, these findings are not unexpected.

Conclusion

The rectal use of diclofenac suppositories was found to be a simple and effective modality of reducing the post-natal pain experienced by women after perineal trauma in immediate post-partum period.

Disclosure: No.

Conflict of Interest: No.

Funding Sources: No.

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