

## Effect of diclofenac rectal suppository on pain relief after medio lateral episiotomy- a placebo controlled trial

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### Abstract

**Objective:** To assess the effectiveness of Diclofenac rectal suppository for perineal pain relief after medio-lateral episiotomy.

**Methods:** 100 pregnant women aged 20-35 years with gestational age 39-41 weeks were enrolled for this study and randomly allocated into 2 groups of 50 each to receive 100mg of diclofenac suppository or placebo suppository following medio-lateral episiotomy. Postoperative perineal pain was monitored using pain intensity scale and questionnaire which is scored as 0 = no pain, 1 = mild pain, 2 = discomforting pain, 3 = distressing pain, 4 = horrible pain and 5 = excruciating pain at 24hrs and 48hrs after child birth.

**Results:** Demographic comparison was insignificant between the diclofenac and placebo groups. Patients in the diclofenac group showed significant (p-value 0.022) relief from perineal pain at rest and at movement at 24 hours post-partum when compared with placebo group; the difference being less at 48 hours. Additional analgesia at discharge was required by 21(42%) and 34(68%) patients in diclofenac and placebo groups respectively.

**Conclusion:** The present study suggested that diclofenac has significant analgesic role in reducing perineal pain especially at 24hours after administration.

**Key Words:** Diclofenac, Pain relief, Episiotomy, Placebo controlled trial.

### INTRODUCTION

Perineal pain after episiotomy is a common complaint following vaginal birth. Pain originates from incision site, inflammation, swelling of the adjacent tissues and spasm of perineal muscles and is reported to be most severe in the immediate post-partum period.<sup>[1-6]</sup> However, the degree of perineal pain and discomfort associated with perineal trauma is often under-estimated interfering with daily activities and impacting on motherhood experiences,<sup>[7,8]</sup> with 20–25% of women continuing to experience distress and discomfort for upto two weeks after birth.<sup>[4-6]</sup> An estimated 10% of women suffer perineal pain in the three months after childbirth.<sup>[6-8]</sup>

Methods to reduce perineal trauma and the appropriate repair of any perineal damage sustained are important for avoiding and alleviating perineal pain. Factors that may influence the severity of pain

experienced include mode of birth<sup>[9]</sup>, degree of perineal

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Trauma,<sup>[10]</sup> type of suture material and perineal repair technique<sup>[11-13]</sup>.

In general medical care, the rectal route of analgesic administration has been favoured over oral preparations as they may cause gastric irritation, nausea or vomiting.<sup>[14]</sup> Evidence of the efficacy and safety of rectal analgesia is limited.<sup>[15]</sup> Studies assessing the efficacy of rectal analgesia in post-operative pain relief have indicated significant reduction in the level of pain experienced and reduced requirements for additional analgesia.<sup>[14,16-17]</sup>

This randomised, double-blind, placebo-controlled trial was designed to evaluate the efficacy of rectal diclofenac.

### MATERIALS AND METHODS

The present study was performed at the department of Obstetrics and Gynaecology, Sher-i-Kashmir Institute of Medical Sciences, Srinagar, India, during the period May 2010 to November 2010 and was approved by the Institutional Ethics Committee. All pregnant women with gestational age of 39 weeks who visited the antenatal care clinic were enrolled and informed consents were obtained.

Women who met the inclusion criteria that included singleton pregnancy, gestational age more than 37 weeks, medio-lateral episiotomy, were randomly allocated to receive either diclofenac or placebo rectal suppositories.

Exclusion criteria were vaginal tear other than second or third degree tear, operative vaginal deliveries, major postpartum hemorrhage, manual removal of placenta, and a history of NSAID allergy, gastric or duodenal ulcer, hepatic disease, renal disease and asthma. Vaginal repair was performed by resident physicians. The vaginal mucosa and adjacent tissues were sutured by either continuous or interrupted technique using chromic catgut No.1/0. The perineum was sutured by mattress sutures using chromic catgut No.2/0. All repairs were injected with 2% xylocaine (10ml) before suture.

After the completion of perineorrhaphy, the pregnant women were randomized to receive the diclofenac or placebo rectal suppositories. The randomization was allocated by random number table use, by the even and odd numbers in equal proportions. The even numbers in random number table represented the control group while the odd numbers represented the study group. Each treatment pack contained two tablets of 50 mg diclofenac or two tablets of placebo. The medications were packed in the opaque sealed containers to mask treatment allocation. The drugs were inserted into the rectum after immediate completion of perineorrhaphy, and the second tablet was offered 12-24 hours after birth. The rectal suppositories were inserted just above the external sphincter assisted by lubricant.

The pregnant women and the operators were blinded from the treatment allocation.

The questionnaires used the validated Short-Form McGill Pain Questionnaire (SF-MPQ).<sup>[18]</sup> The SF-MPQ includes a present pain intensity scale which is scored as 0 = no pain, 1 = mild pain, 2 = discomforting pain, 3 = distressing pain, 4 = horrible pain and 5 = excruciating pain. Using the SF-MPQ, women were asked to rate the pain they experienced at rest and with movement at 24 hours, 48 hours after birth. Women were asked to indicate the presence of pain on walking, sitting, voiding and on opening their bowels, as described by Kettle et al.<sup>[19]</sup>

In the puerperal period, if the women still experienced perineal pain, additional oral analgesic medications, using two tablets of 500 mg acetaminophen were prescribed on demand every 4 to 6 hours. Chi-square test was used to compare qualitative variables between the two groups. The p-value less than 0.05 was considered statistically significant.

## RESULTS

We studied 100 pregnant women with age 20-35 years who delivered by normal vaginal delivery with medio-lateral episiotomy under local anaesthesia (2% xylocaine).

Out of these 100 women 50 received diclofenac rectal suppository immediately after perineorrhaphy (study group), and remaining 50 women received placebo rectal suppository (placebo group).

**TABLE-1: Maternal demographics and labour outcomes at trial entry. Values are presented as mean [SD], median (interquartile range) or n (%) of women.**

Variable	Diclofenac N=50	Control N=50
Maternal age (years)	30 [5]	29 [6]
Maternal weight (kg)	70 [14]	68 [13]
Maternal height (cm)	166 [7]	165 [7]
Primiparous	42 (84)	40 (80)
Spontaneous vaginal birth	39 (80)	42 (84)
Episiotomy	50 (100)	50 (100)
Gestational age at birth (weeks)	39 (38-41)	39 (38-41)
Length of labour (hrs)	20 (16-24)	22 (18-26)
Local anaesthesia (2% xylocaine)	50 (100)	50 (100)
Birth weight (kg)	3 [0.5]	3 [0.5]
Apgar score <7 at 5 minutes	0 (0)	1 (2)
Chromic Catgut for perineal repair	50 (100)	50 (100)
Continuous suture to vaginal mucosa (chromic catgut No.1/0)	50 (100)	50 (100)
Interrupted suture to muscle layer (chromic catgut No.1/0)	50 (100)	50 (100)
Mattress suture to skin (chromic catgut No.2/0)	50 (100)	50 (100)

The demographic data of these two groups of patients is given in [Table 1]. The incidence of perineal pain in the two groups after 24 hours and after 48 hours of child birth is given in [Table 2]

Number of women in both the groups who required additional analgesia before discharge from hospital is given in [Table 3]. Incidence of women in both groups who complained of perineal pain after 1 week of child birth is given in [Table 3].

## DISCUSSION

An episiotomy is a procedure performed to prevent vaginal tears from occurring.<sup>[20]</sup> The subsequent perineal pain impacts either physical or mental function negatively, including successful breastfeeding,<sup>[21]</sup> physical impacts associated with reduced motility,

sitting, urinary and fecal incontinence, and sexual dysfunction. One-fourth of postpartum women may continue to experience perineal pain for up to 2 weeks postpartum, while in 10% of these women pain may persist until 3 months after childbirth.<sup>[21]</sup>

There are many methods in perineal pain relief including non - pharmacological methods and medications. Numerous non-pharmacological methods such as therapeutic ultrasound, local ice packs and a bath were found to have a positive effect<sup>21</sup>. For mild pain, acetaminophen and for moderate pain NSAIDs are widely used. However, the side effects of NSAIDs, such as gastric discomfort, peptic ulcer, nausea, and vomiting warranted us to be cautious in using these medications. Furthermore, some drugs such as aspirin have a potent ability to pass into breast milk, causing metabolic acidosis in the infants<sup>[21]</sup>.

**TABLE-2: Primary outcome measures. Values are presented as mean [SD] number of women (%) or median (interquartile range) or n (%) of women.**

Variable	Diclofenac n=50	Placebo n=50	P-value
24 hours after birth at rest present pain intensity score	19 (38)	32 (64)	0.021(S)
24 hours after birth with movement present pain intensity score	22 (44)	35 (70)	0.022 (S)
48 hours after birth at rest Present pain intensity score	17 (34)	22 (44)	0.71 (N.S)
48 hours after birth with movement Present pain intensity score	17 (34)	24 (48)	0.77 (N.S)

**TABLE 3:Secondary outcome measures. Values are presented as number of women (%) or median (interquartile range).**

Variable	Diclofenac n=50	Placebo n=50	P- value
Additional analgesia prior to discharge	21 (42)	34 (68)	0.02(S)
1 week after birth perineal pain present n=43\ 41	12 (27)	14 (34)	0.77(N.S)

The present study suggested the effectiveness of diclofenac administration for perineal pain relief at 24 hours after episiotomy to be statistically significant. It seems the effectiveness of diclofenac rectal suppository is maintained upto 48 hours after episiotomy.

In our study pain was reported by 19(38%) and by 32(64%) patients at rest and at 24 hours post episiotomy in the diclofenac and placebo groups respectively showing statistical significance (p-value 0.021).Similarly pain with movement at 24 hours was reported in 22(44%) and 35(70%), (p-value 0.022) in the diclofenac and placebo groups respectively and was

statistically significant. Non-significant difference was observed between the two groups at rest and with movement at 48 hours period on comparison between the diclofenac and placebo groups. No complications were seen in both groups.

Previous studies by Dodd et al and Searles et al,<sup>[18,22]</sup> have showed that diclofenac rectal suppositories were effective in reducing perineal pain and found statistically significant reduction in perineal pain.

The acceptability of the patient for rectal suppositories is one of the important issues. Various studies showed differing acceptance to this route of

administration as shown by the studies of Dodd et al.<sup>[18]</sup> and Carrol et al.<sup>[23]</sup> At one week after birth, women in the diclofenac group were significantly more likely to report moderate or extreme satisfaction with their perineal pain relief. At one week, 43 patients in the diclofenac group and 41 patients in the placebo group out of 50 each reported for pain relief assessment.

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.

Clinical guidelines for the use of non-steroidal anti-inflammatory drug suppositories in the management of postpartum pain indicate cautious 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.<sup>[24]</sup>

All analgesics appear superior to placebo and women should not be denied effective and lasting analgesia following perineal injury. Rectal diclofenac administered at the time of repair affords acceptable, available and inexpensive analgesia besides having lesser gastric irritation as an added advantage.

## CONCLUSION

Large randomized controlled studies are needed to compare diclofenac to other analgesics, but this study shows diclofenac to be an effective and safe method of reducing the pain following perineal trauma especially at 12 and 24 hours after administration and has a high degree of acceptability by women. Therefore the use of rectal diclofenac should be further promoted and implemented as a routine in women following episiotomy

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