

Oral versus Rectal Diclofenac Sodium: Comparison of efficacy for Perineal pain relief after Episiotomy

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ABSTRACT

Objective: To compare the efficacy of oral diclofenac sodium and diclofenac suppository for perineal pain relief after episiotomy.

Study Design: Prospective randomized clinical trial.

Place and Duration: Obstetrics and Gynecology Department of Pakistan Ordnance Factories Hospital, Wah Cantt from 1st Jan 2021 to 30th June 2021.

Methodology: The study included 260 patients, who were randomly divided into group A and B through a computer-generated list. Patients in group A were given diclofenac sodium tablet 50mg orally just after the completion of episiotomy repair and it was repeated after 12 hours. Diclofenac suppository 50mg was placed rectally after episiotomy repair in patients of group B and was repeated after 12 hours. Perineal pain was measured at 24 hours after episiotomy repair on Visual Analogue Scale.

Results: The mean pain score was 2.93 in diclofenac suppository group and 3.98 in oral diclofenac group. The women in suppository group had less pain than oral group and the difference was statistically significant ($p=0.001$).

Conclusion: Diclofenac suppository was more effective than oral Diclofenac Sodium for perineal pain relief at 24 hours after episiotomy.

Keywords: Diclofenac Suppository, Diclofenac Tablet, Episiotomy, Mean Pain Score, Perineal Pain Relief, Visual Analogue Scale

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INTRODUCTION

Inflammation of perineal tissues is very painful after vaginal delivery with episiotomy which is a midline or mediolateral surgical incision in perineum when foetal head is visible at

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introitus in second stage of labour.^{1,2} It was first commenced in 1950 and the main purpose is to decrease the risk of extensive lacerations of vaginal muscle and anal sphincter by providing more space during childbirth.^{3,4} Post episiotomy pain makes it difficult for new mother to move about, pass urine and stool and delays bonding with her baby.^{5,6} This highlights the importance of good analgesia after delivery so that women can restart routine chores and take care of their newborn.

Both pharmacological and non-pharmacological methods can be used to decrease pain after childbirth. Non-pharmacological methods which include ice packs, Lavender oil in sitz baths, herbal ointments massage, acupuncture and Transcutaneous electrical nerve stimulation (TENS) are not commonly used in our hospitals.⁷⁻¹¹ Drugs like acetaminophen, non-steroidal anti-inflammatory drugs (NSAIDs), and narcotic analgesics are in use for decades to reduce post episiotomy perineal pain because they are readily available and feasible.^{12,13} Among oral NSAIDs diclofenac sodium, mefenamic acid, Ibuprofen and flurbiprofen are frequently prescribed drugs for relief of episiotomy pain.¹⁴ Diclofenac sodium is available in the form of rectal suppositories, injections, topical gels and creams.¹⁵ Oral diclofenac sodium is a commonly prescribed drug and has proven efficacy to reduce pain, inflammation and fever since its introduction in 1965. NSAIDs when given by mouth can cause

nausea, vomiting and gastritis. Their prolonged use can form ulcers in stomach and duodenum, leading to perforation of gut.¹⁶ Diclofenac rectal suppository is a good substitute to avoid side effects of oral drugs. The absorption of drug from rectum is reliable, occurs in less than 40 minutes to give rapid, prolonged and effective pain relief.¹⁷ In Pakistan rectal route of NSAIDs administration is practiced infrequently due to lack of knowledge and familiarity. Only few published studies of small sample sizes to compare the efficacy of two routes are available. The objective of this study was to compare the efficacy of oral diclofenac sodium with rectal suppository for pain relief 24 hours after episiotomy. We compared the pain intensity in first 24 hours, as the pain is worse at this time and majority of our patients are discharged 24 hours after normal delivery. The rationale of this study was to provide better post episiotomy pain relief to new mothers by finding more effective route of diclofenac administration. This will not only reduce their suffering but will also help them to establish an early bond with their newborn. So, this study was conducted with an objective to compare the efficacy of oral diclofenac sodium and diclofenac suppository for perineal pain relief after episiotomy.

METHODOLOGY

This prospective randomized clinical trial was conducted in the Obstetrics and gynecology department of Pakistan Ordnance Factories Hospital Wah Cantt, from 1st Jan 2021 to 30th June 2021. The study was approved by the ethical review committee of hospital. The women who had singleton pregnancy and delivered at ≥ 37 weeks of gestation with episiotomy were included in the study. The women who received epidural analgesia in labour, required instrumental delivery, had perineal tear, uterine or vaginal packing for postpartum haemorrhage were excluded from the study. The women who had known allergy to NSAIDs, peptic ulcer, asthma, renal impairment, anal fissure and hemorrhoids were also excluded from the study.

Only patients who gave written informed consent were included in the study. They were randomized into either group A or B by using computer generated numbers. Patients in group A were given diclofenac sodium 50mg in the form of oral tablet just after the completion of episiotomy repair, and it was repeated after 12 hours. Diclofenac rectal suppository was placed at the time of episiotomy repair and was repeated after 12 hours in patients of group B.

Episiotomy repairs were performed by post graduate trainees with minimum one-year experience. All repairs were injected with 1% xylocaine without adrenaline about 15-20cc before suturing. The vaginal mucosa was sutured by continuous and muscle by interrupted technique using chromic catgut no. 2/0. The skin was sutured by subcuticular technique. This was done to avoid bias as suture material and technique both effect the post episiotomy pain.

The data about sociodemographic details and pain score was entered on a pre-designed proforma. The main outcome measure was post episiotomy perineal pain at 24 hours after birth. It was assessed on visual analogue scale (VAS) by 3 post

graduate trainees who were given training on the use of this scale to reduce interobserver bias. Visual analogue scale is a validated subjective measure for pain scoring. The pain was recorded by marking on a 10cm line that represents a continuum between "no pain" and "worst pain."

Data Analysis: All data was entered and analyzed by using SPSS version 22. For comparison of age and gestational age at delivery mean, standard deviation and p value was calculated by using Student's t-test. For comparison of parity between the two groups, chi-square test was used. To compare the mean pain score in both groups, Independent Samples t-test was used, keeping p-Value < 0.05 statistically significant.

RESULTS

Total 260 women were included in the study. No woman was excluded or dropped from the analysis. The age range of study population was 18-35 years. The mean age of women was 25.7 years. The gestational age at delivery was between 37- 41 weeks with mean gestational age of 38 weeks 5 days. Majority of women (n=197, 75.8%) were primiparous. Only 63 (24.2%) were multiparous. This is because primiparous women have rigid perineum which increases the frequency of episiotomy to prevent perineal lacerations. Both groups were comparable in terms of maternal age (p=0.113), parity (p=0.07) and gestational age at delivery (p=0.664) as shown in table -I.

Table – I: Comparison of sociodemographic characteristics of group A & B (N=260)

Variable	Group A (n=130)	Group B (n=130)	p-Value
Age in years (mean \pm SD)	25.48 \pm 2.92	26.01 \pm 2.42	0.113
Gestational age at delivery (mean \pm SD)	38 weeks 4 days \pm 6.2 days	38 weeks 6days \pm 7.1 days	0.07
Parity n (%)			0.664
	Primiparous 100 (76.9%)	97 (74,6%)	
	Multiparous 30 (23%)	33 (25.4%)	

Table – II: Comparison of Mean Pain Score at 24hrs in Group A & B (N=260)

Patient group	Mean pain Score	Standard deviation	p-Value
A	3.98	0.81	0.001
B	2.93	0.74	

The comparison of mean pain scores measured 24 hours after episiotomy repair is shown in table-II. The difference in mean pain scores between two groups was statistically significant (P=0.001). The result of our study declared rectal diclofenac sodium a better analgesic than oral tablet.

DISCUSSION

We planned this study to find more efficacious route of diclofenac administration for perineal pain relief after

episiotomy. The results of our study showed that diclofenac sodium 50mg is more effective analgesic for pain relief after episiotomy when given via rectal route than oral tablet (mean pain score 2.93 versus 3.98, $P=0.001$). Both the groups were comparable in terms of mean maternal age, parity and gestational age at the time of delivery. The acceptance of route of drug administration has a prime importance. We placed the first suppository at the time of episiotomy repair and patients willingly accepted the second dose after first experience, so there was no issue of acceptance.

Studies have compared analgesic efficacy of diclofenac suppository with placebo, NSAIDs e.g. mefenamic acid and with other suppositories e.g. indomethacin and diclofenac injection but we could find only one study of small sample size which compared diclofenac oral and rectal route for perineal pain relief after episiotomy.

The mean age of women in diclofenac oral and suppository group was 25.48 years and 26.01 years respectively. In a study by Ijaz S the mean age of women in diclofenac suppository group was 26.14 years which is very close to mean age of suppository group in our study.¹⁸ The mean age of oral mefenamic acid group was 28.04 years which is higher than oral diclofenac group in our study. Majority (67 %) women were between 21-25 years in the study by Varghese SS.¹⁹ The reason for age younger than in our study can be that he included only primiparous women in her study. Mean age of women in our study is comparable with study by Akhtar F where majority (63%) women were between 18-30 years.²⁰

In our study 76% women were primiparous and only 24% were multiparous. Varghese SS and Francis F only included primiparous women in their study.^{19,21} Only 24% were primiparous in study by Naz S, because she included cases of vaginal delivery with and without episiotomy and caesarean section.²² Mean gestational age at the time of delivery was 38 weeks 5 days in our study, which is closer to study by Varghese SS as 67 % women were between 39-40 weeks.¹⁹

Varghese et al in their study compared analgesic efficacy of oral and rectal route of diclofenac 50mg in 60 women after episiotomy.¹⁹ Pain measured on numeric pain intensity scale 12 hours after delivery showed a significant difference with mean pain score of 7.16 ± 0.83 and 3.90 ± 1.12 in oral and suppository group respectively. We calculated pain score at 24 hours instead of 12 hours and used 2 doses of both drugs but found rectal route more efficacious like the above study.

In a placebo-controlled trial Akhtar used single dose of 100mg diclofenac suppository and compared its efficacy with placebo after 24 hours, with 45 women in each group.²⁰ She observed a significant pain reduction with a mean pain score of 2.29 with diclofenac suppository which supports the result of our study (mean pain score of 2.93 in suppository group) although we used two doses of 50 mg at 12 hours interval.

Analgesic efficacy of oral paracetamol 500mg BD was compared with diclofenac suppository 75mg BD by Francis and colleagues in 30 women after episiotomy. The pain score on third postnatal was less in diclofenac suppository than paracetamol tablet group (mean pain score 1.01 versus 4.03) both during rest and physical activity.²¹ The mean pain score with diclofenac suppository was less than in our study (1.01 versus 2.93) that

might be due to small sample size (15 versus 130), higher dose (75mg versus 50mg) and longer duration of use (3 days versus 1 day). The conclusion drawn favors the results of this study that diclofenac suppository is more potent than oral pain killers for post episiotomy pain.

Ijaz et al has calculated the pain score after oral mefenamic acid 500mg 8 hourly and diclofenac suppository 100mg single dose in her study to find better route of analgesic administration after episiotomy. They included 100 patients of episiotomy and perineal tears in each group. She concluded that suppository was a better option as mean pain score at 12 hours was less in suppository than oral group (1.07 versus 1.68).¹⁸ We excluded patients with perineal lacerations to avoid bias as they experience pain depending upon extent of trauma. The mean pain score in diclofenac suppository group is less than noted in our study (1.07 versus 2.93). The reason for this difference might be a higher dose (100mg versus 50mg) and collection of data at 12 hours as compared to 24 hours in our study.

A single dose of diclofenac suppository 100mg was used by Naz et al after delivery and caesarean section to relieve pain. It was noted that 56% patients had mild, 35% moderate and 8% severe pain 24 hours after drug administration. Majority patients (78%) had only mild pain (≤ 3.5 on VAS) after episiotomy.²² This backed our results of mild mean pain score (2.93) in suppository group. Oral NSAIDs are metabolized in liver and doses required are larger as compared to rectal suppository.²³ Oral diclofenac is associated with gastric side effects in some patients which are avoidable when given by rectal route. These facts and the results of our study recommend the use of diclofenac suppository for pain relief after episiotomy. The limitation of our study is that we did not compare the pain score at start of treatment and the effects of rest and mobility on pain. The data was collected by three postgraduate trainees instead of one person so there can be interobserver bias despite training. Pain is a subjective feeling so there can be patient bias in pain scoring.²⁴ We should plan further studies to assess analgesic efficacy of diclofenac sodium in patients who had perineal tears.

CONCLUSION

Diclofenac suppository was more effective than oral diclofenac sodium for perineal pain relief at 24 hours after episiotomy.

AUTHOR'S CONTRIBUTION

Mushtaq I: Conceived Idea, Designed research methodology, Data collection, Data analysis

Kaloom S: Data analysis, Literature search, Manuscript writing, Proof reading and final approval

Nisa KU: Data Collection, Data analysis, Literature search

Jamil M: Data analysis, Manuscript writing

Safdar F: Literature Search, Data Collection

Majeed N: Literature Search, Data Collection

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