

Comparison of Rectal Diclofenac Verses Oral Mefenamic Acid in Terms of Mean Pain Score after Episiotomy

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ABSTRACT

Aim: To compare rectal diclofenac against oral mefenamic acid in terms of mean pain score after episiotomy

Methodology; A comparative data analysis from March 2020 to September 2020 was accompanied at Obstetrics and Gynecology Unit at shalamar hospital lahore, Pakistan. The duration of the study was 6 months in which a total 200 patients were taken with 100 patients allocated in each group After randomization, patient in group A will receive diclofenac suppository 100mg and patient in group B will receive oral mefenamic acid 500mg. In all episiotomies or laceration suturing will be performed after infiltration of 10ml of 2% lidocaine Data was collected sampling technique was nonprobability consecutive sampling technique and analyzed in terms of pain score.

Results: 100 patients were randomized to group A, who receive rectal diclofenac and same patients were included in group B who were given mefenamic acid orally. The pain score was observed at 06 and 12 hours respectively in both groups. The mean age of the patient in mefenamic group was 28 years and in diclofenac was 26 years. The mean pain score in mefenamic group at 06 hours was 3.68 (+ 0.875) which reduced to 1.68 (+ 0.909) at 12 hours. The mean pain score in diclofenac group was 2.99 (+ 1.00) at 06 hours which reduced to 1.07 (+ 0.856) at 12 hours. The difference between mean pain scores of both groups at 06 and 12 hours, were found statistically significant ($P < 0.001$) to suggest that rectal diclofenac was more effective in controlling perineal pain after episiotomy during child birth.

Conclusion: Rectal diclofenac is more effective than oral mefenamic acid in perineal pain control after episiotomy at 06hrs as well as at 12hrs.

Keywords: Mean pain score, visual analogue scale.

INTRODUCTION

Perinial pain arises from the spontaneous laceration or episiotomy given during child birth, originating from the tear inflammation and swelling of the perinial muscles. In the post-partum period the presence of pain causes hindrance to practice motherhood and do daily chores e.g., self and new born care, breast feeding. It also disturb the woman sleeps hampers urination and bowl emptying and decreases appetite. Physical psychological and emotional problems are born due to these difficulties that creates negative delivery experience¹.

There are two methods of perineal pain management one is non-pharmacological, other is pharmacological. Non-pharmacological management includes therapeutic ultrasound, local ice packs and bath. Medical management include non-steroidal anti-inflammatory drugs (NSAIDS) and opioids used through oral, intramuscular, intravenous and rectal routes. Advance methods for controlling pain are devised such as continuous epidural analgesia or patient controlled analgesia (PCA), but the demerits are that they are expensive and require trained personal special equipments².

NSAIDs are widely used as analgesics, but they have side effects like gastric discomfort, peptic ulcer, nausea and vomiting warranting careful administration. Aspirin can pass into breast milk, leading to metabolic acidosis.³ rectal analgesia can be used as an alternative to oral route. More

than half of the drug absorbs by rectum liver is bypassed escaping metabolism as compared to the increased portion of hepatic first pass effect when the drug is given orally is the merit of rectal route of administration. It therefore helps in relieving pain faster and increased time of action⁴.

Pain can be measured by a variety of pain scales like McGill pain questionnaire, SF-36, visual analog scale (VAS) or numeric rating scale (NRS) for pain. Numeric rating scale for pain, which is numeric version of Visual Analog Scale, measures the pain on a scale ranging from "0" to "10" where "0" represents "no Pain" and "10" represents "worst pain imaginable".⁵

The effectiveness of oral analgesia post episiotomy is well documented and a recognized fact. In contrast, the effectiveness of rectal route in our local population needs to be elucidated and implemented, if successful. Literature review has shown effectiveness of rectal diclofenac suppositories in reducing perineal pain after episiotomy with a mean visual analogue score of 2.8 (± 0.3) for diclofenac group verses 3.9 (± 0.3) for control group at 24 hours after administration⁶

Another study showed that the diclofenac given per rectal is the simplest method rapidly acting effective for a long duration is safe and is very promising in decreasing pain women felt after trauma of the premium with in first 24 hours after delivery⁽⁷⁾. Rectal diclofenac analgesia also has been found superior (mean 12 ± 6) in pain control, when compared with oral mefenamic acid (24 ± 12) in first 24 hour after childbirth⁽⁴⁾. The rationale of this study is that effectiveness of rectal diclofenac against oral mefenamic acid has been established at 24 hour, but i want to see the

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effectiveness at 06 and 12 hrs because this is the time when patient needs maximum pain relief, secondly most of the patients with vaginal deliveries either opt to go home due to social and financial constraints or are sent home early by the hospital due to burden on health care facility. So most of the time by 24 hour there is no patient available to see the effectiveness of either drug

MATERIAL AND METHODS

This comparative research was conducted at Obstetrics and Gynecology Department, Shalamar hospital Lahore.

Duration of Study: 6 months (from March 2020 to September 2020). Sample size was calculated with WHO calculator by taking level of significance = Sample Size: Sample size of 200 patients (100 in each group) is calculated with 95% confidence interval, 80 % power of test, taking expected mean \pm SD of mean pain score after 24 hours in both groups i.e 12 ± 6 in diclofenac group versus 24 ± 12 in mefenamic group in patients comparing rectal diclofenac versus oral mefenamic acid after episiotomy.

Sample Technique: Non probability consecutive sampling All women Age 18-35 years. Parity : ≤ 2 , Women who underwent episiotomy during vaginal delivery. Participants who are willing to participate in study. Term gestation (37 weeks to 42 weeks) as defined by ultrasound. Single alive intrauterine fetus in cephalic presentation. Were included in study Patient with known hypersensitivity to NSAIDs or gastric or duodenal ulcer. Rectal or anal pathology, like fissure, hemorrhoids and rectal tumor assessed clinically. Post partum hemorrhage: Blood loss of more than ml after vaginal delivery. Extensive perineal tear (3rd and 4th degree laceration): Partial or complete disruption of anal sphincter muscles is 3rd degree tear and involvement of rectal mucosa along with anal sphincter is fourth degree tear. Patients with severe cardiac, renal, respiratory or hepatic impairment assessed on history and clinical examination supported by relative investigations. Were excluded from study.

Data Collection Procedure: After taking informed consent patient who satisfy inclusion and exclusion criteria will be incorporated in study. The demographic profiles such as name, age, address will be obtained. By computer generated random number table patients will be grouped into A & B. After randomization patient in group A will receive diclofenac suppository 100mg and patient in group B will receive oral mefenamic acid 500mg. In all episiotomies or laceration suturing will be performed after infiltration of 10ml of 2% lidocaine. To reduce the biased standard suturing material and technique will be as these independent variables also effect the pain after treatment. All the observations will be noted by the one person or obstetric nurse to decrease inter-observer variation. The patient would be asked to point on the line to show the severity of pain felt by her from 0 (no Pain) to 10 (worst pain imaginable). After suturing is completed group A will receive 100mg diclofenac suppository and group B will receive 500 mg mefenamic acid orally. Repeat dose will be given after 8 hours respectively. Perennial pain will be assessed at 6 and 12 hours after episiotomy on numeric rating scale for pain and will be recorded in the Performa (ANNEX II). Patients requiring analgesia before 06 hours

will be given oral paracetamol 500mg irrespective of group. The approval of study taken from the ethical committee. All the data will be kept confidential.

Data Analysis: The collected data will be transferred and analyzed accordingly using SPSS version 22.0. Data will be stratified for age, gender, current cigarette smokers, pan/gutka and BMI to address the effect modifiers. These variables will be analyzed by using simple descriptive statistics using mean and standard deviation for quantitative data e.g., age and pain score at 06 and 12 hours. Repeated measure ANOVA will be used to compare the both groups at 06 and 12 hours and P-value ≤ 0.05 will be considered as significant

RESULTS

One hundred patients were randomized to receive rectal diclofenac and were included in group A and same number of patient received oral mefenamic acid and were included in group B. The pain score were observed at 06 and 12 hours respectively in both groups. The mean age of the patient in mefenamic group was 28 years and in diclofenac was 26 years. The mean pain score in mefenamic group at 06 hours was 3.68 (± 0.875) which reduced to 1.68 (± 0.909) at 12 hours. The mean pain score in diclofenac group was 2.99 (± 1.00) at 06 hours which reduced to 1.07 (± 0.856) at 12 hours. There was a statistically significant difference (P value < 0.001) between the mean pain scores of both groups at 06 and 12 hours, to suggest that rectal diclofenac was more effective in controlling perineal pain after episiotomy during child birth.

Table 1: Mean age of patients of both groups (n = 200)

	Diclofenac (A)	Mefenamic (B)
Mean Age	26.14 + 4.78	28.04 + 3.42

Table 2: Mean Pain Score of Rectal Diclofenac (n = 100)

	Diclofenac (A)
06 hour	2.99 + 1.00
12 hour	1.07 + 0.856

Table 3: Mean Pain Score of Oral Mefenamic : (n = 100)

	Mefenamic (B)
06 hour	3.68 + 0.875
12 hour	1.68 + 0.909

DISCUSSION

Child birth is considered as important occasion in the family. The happiness surrounding the occasion is sometimes disturbed because episiotomy is associated with severe pain in postpartum period⁸.

The objective of this study was to assess the efficacy of the rectal diclofenac against mefenamic at 06 and 12hrs and this study proved that rectal diclofenac is associated with better pain control than oral mefenamic acid. This study not only supported the previous results of Shafi.etal and Dodd JM et al at 12hrs but in addition it also proved rectal diclofenac efficacy at 06hrs after episiotomy, which is not assessed by any study previously^{9,5}.

In our society it has been observed that the acceptance of rectal suppository as a pain killer is less as compared to the oral analgesia. This study also support

this fact that being effective pain killer, rectal diclofenac should be encouraged after episiotomy, and better way to decrease its acceptance problem is that it should better be placed at the time of closure of episiotomy wound^{10,11}.

The other fact that support the use of rectal diclofenac is that half of rectal diclofenac bypasses the liver and so it has a greater drug concentration along with longer duration of action. The bypass effect also render it a fast pain relief than oral mefenamic acid.^{12,13} In comparison to that oral mefenamic acid is mostly metabolized by hepatic first pass metabolism and the required effect needs a larger dose. Rectal diclofenac is also devoid of the side effects accompanying the oral NSAID i.e gastric discomfort, nausea, vomiting and peptic ulcer.^{14,15} In contrast to epidural analgesia the treatment with rectal diclofenac is quite cheap and can be easily administered by any doctor^{16,17}.

In lieu of the results favoring rectal diclofenac as an effective post episiotomy analgesic, this study should lay the guideline to implement this type of analgesia in the best interest of patient.

CONCLUSION

Rectal diclofenac is a safe, simple and effective method of reducing pain, experienced by women following perineal trauma within 12 hours after child birth.

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