Original Article

Is rectal diclofenac sodium analgesia better than oral tramadol analgesia for perineal pain relief following vaginal delivery?

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Abstract

Background: To compare the efficacy of rectal Diclofenac sodium suppository with orally administered Tramadol for relief of perineal pain following vaginal delivery. **Objective:** To determine the efficacy of Diclofenac rectal suppository and oral Tramadol tablets for perineal pain relief following vaginal delivery. **Materials and Methods:** In this randomized control cross sectional study, 300 subjects were divided in two groups. Group A (150 subjects) received rectal Diclofenac sodium suppositories and Group B (150 subjects) received oral Tramadol tablets. First suppository was inserted immediately after episiotomy suturing, and second offered 12-24 hours after first dose if the lady complained of pain still. Women in group B were given oral Tramadol tablets 0 and 8 hourly. Women were evaluated for pain relief using validated short form of McGill pain questionnaire, Wong-Baker facial pain rating scale and numeric pain rating scale. **Results:** There was statistically significant difference between the two groups for sensory, affective and total pain scores at rest or with movement after 24 hours of childbirth indicating rectal suppository was superior to oral tramadol tablets. Pain scores were significantly lower in Diclofenac sodium suppository group (p value ≤ .0001) when compared to Tramadol group. The difference was not sustained 48 hours after birth. **Conclusion:** The use of rectal Diclofenac sodium suppositories is simple, faster acting, effective and safe method of reducing the perineal pain experienced by women following normal vaginal delivery within 24 hours of normal vaginal delivery.

Keywords: Diclofenac sodium suppository, Tramadol, perineal pain, vaginal delivery, Pain scoring.

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INTRODUCTION

Perineal pain by tear or episiotomy is a common problem after vaginal delivery. Perineal trauma affects at least 65% of women during childbirth in resource-rich countries and scarce data from under resourced countries suggests 35-45% of women who give birth in hospital setting experience an episiotomy. Factors that may influence the severity of pain include mode of delivery, degree of perineal trauma, type of suture material and perineal repair technique.[1,2] The provision of safe and effective pain relief for perineal trauma using rectal analgesia is one of several therapies used in clinical practice. Other options are oral analgesics, local anaesthetics, parenteral analgesics and ice packs. Evidence of the efficacy and safety of rectal analgesia is limited. The rectal route of analgesic administration has been favoured when oral preparations cause gastric irritation, nausea or vomiting.[3,4]

MATERIAL AND METHODS

Total of 300 women with episiotomy or second degree perineal tears were recruited from delivery suite. Women who had history of sensitivity to non steroidal anti-inflammatory drugs, severe asthma, severe pre-eclampsia, gastric or duodenal ulcers or major post-partum

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haemorrhage were not included in the study. Eligible women were randomly allocated to either group A or B by double blind technique to receive either diclofenac suppositories (100 mg) or oral tramadol (500mg x 8 hourly).In women included in group A, the first suppository was inserted per rectally as suturing was completed and the second was offered 12-24 hrs after childbirth. The women in group B were given oral tramadol 500mg 8 hourly for 24-48 hrs after childbirth. All women were asked to complete questionnaires prior to their discharge from hospital after 24-48 hrs of childbirth. The questionnaire used the validated short form McGill pain questionnaire made up of 15 descriptions of pain qualities; description 1-11 being sensory dimensions and 12-15 being affective dimensions. Each descriptor was then graded according to severity as "0 = No; 1 = Mild; 2 = Moderate; 3 = Severe pain, along with the help of Wong Baker's facial and Numeric pain rating scale.[5] The primary outcome was pain score at 24 and 48 hours after birth with rest and on movements. Secondary outcome measures were the need of additional analgesia and maternal satisfaction with relief of pain.

RESULTS

One hundreden fifty women were randomized to receive diclofenac suppositories in group A, and equal number of women were included in group B who received tablet tramadol orally (Table 1).

Table 1: Maternal demographics and labour outcomes at trial entry

Variables	Diclofenac (Group A) n=150	Tramadol (Group B) n=150
Maternal age(years)	23	25
Maternal weight(kgs)	64	60
Maternal height(cm)	164	165
Primigravida	80%	83%
Spontaneous vaginal delivery	93%	91%
Instrumental delivery	03%	04%
Episiotomy	88%	85%
2nd degree perineal tear	12%	15%
Gestational age at birth(wks)	39(38-41)	38(37-40)
Length of labour(hrs)	6(4-8)	7(5-9)
Local anesthetic for perineal repair	98%	99%
Continuous suture to muscles	74%	80%
Vicryl rapide for perineal repair	55%	49%
Subcuticular suture	89%	92%
Perineal repair	56%	59%
Birth weight (kgs)	2.8(2.5-3.0)	3.0(2.5-3.5)

There was statistically significant difference (p value ≤ .0001) between the two groups for sensory, affective and total pain scores at rest or with movement, at 24 hours after delivery of the baby (Table 2). Some fewer women in diclofenac group A described that their pain was intolerable. Eventually women in Group A experienced less pain at 24 hrs while walking, sitting, passing urine and opening their bowels when compared to those women who received Oral Tramadol in Group B. This difference was not seen at 48hours of delivery. There were, statistically, insignificant differences between the two groups in the need for additional analgesia prior to discharge from the hospital , time from birth to first use of analgesia and the need for and frequency of analgesia use after discharge from hospital. Women in the diclofenac group significantly reported moderate or extreme satisfaction with their level of perineal pain relief (Table 3).

Table 2: Primary outcome measures (Represented as mean)

Variables	Diclofenac Group A	Tramadol Group B	P Value
Pain scores,24hrs after birth at rest	12	24	.0001
Pain scores,24hrs after birth With movements	14	36	.0001
Pain scores,48hrs after birth at rest	9	12	1
Pain scores,48hrs after birth With movements	14	20	1

Table 3: Secondary outcome measures (Represented as percentages ;%)

Variables	Diclofenac (Group A) n=150	Tramadol (Group B) n=150	RR* (95% CI)**
Use of additional analgesia	72%	79%	0.9
Time from birth to first analgesia	06hrs	4.2hrs	0.6
Additional analgesia after discharge	86%	90%	0.9
Patient satisfaction with treatment	89%	75%	0.9

DISCUSSION

Episiotomy is the most commonly performed obstetric procedure. Episiotomy or perineal tears during childbirth are associated with significant pain in the postpartum period.[5,6] The reduction in pain experienced by women with rectal diclofenac suppositories was reflected in the need for less additional analgesia requirement prior to discharge from hospital but it was not reflected in request for additional analgesia after discharge from hospital and greater time from birth to first use of analgesia[7] The use of suppositories for the long term relief of pain and women acceptance of a rectal route of analgesia are less well addressed and reported. Our study addressed both these questions. There were no differences between the two groups in pain scores when enquired 10days after the delivery. While rectal suppositories may be effective in reducing pain experienced after childbirth, drug effectiveness becomes a secondary consideration if women are not prepared to use rectal route of administration. To find out acceptance of rectal analgesic suppositories, interviewed surgical patients (both male and female) who were asked to chose between an intramuscular route of pain relief and rectal suppositories, only 18% of patients surveyed choose rectal suppositories as an acceptable method of pain relief.[4] In contrast women receiving diclofenac suppositories in our study were more satisfied with their pain relief, and overall there was high degree of acceptance for the rectal route of administering analgesia. There appears to be a clear advantage in using rectal non-steroidal anti-inflammatory drug suppositories to provide short term pain relief at rest with movements, and minor side effects when compared to oral tramadol. There does not appear to be significant long term benefits of reduced perineal pain or reduced need for additional analgesia. According to Jayne A Searle, the mean pain scores assessed at[12, 24, 48] and 72hrs after delivery using six point numerical scoring system were significantly reduced in diclofenac suppositories group as compared to control group. In addition there was less supplementary analgesia required in diclofenac group and this was limited to paracetamol or topical treatment to the perineum.The terminal half life of oral diclofenac in plasma is 1 to 2hrs. After rectal administration, absorption is complete in less than 40 minutes. While the half life is longer after rectal administration; the total area under the curve is similar for both preparations. Diclofenac is almost completely protein bound, and as a result, minimal amount of drug is excreted in breast milk, an important consideration for women who are breast feeding.[7] In our study women, who were taking oral tramadol as analgesic for relief of perineal pain reported with high rates of minor gastrointestinal side effects predominantly nausea, vomiting and epigastric pain, while diclofenac was associated with significantly less composite minor adverse effects.

CONCLUSIONS

Rectal diclofenac suppositories should be further promoted, for pain relief, in women following episiotomy.

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