A randomized controlled trial of rectal analgesia with diclofenac sodium for relief of perineal pain following child birth

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ABSTRACT

To evaluate rectal diclofenac sodium in the relief of perineal pain after trauma during childbirth a randomized, double blind trial was conducted. Women with an episiotomy or lesser or equal perineal tears to second degree including vestibular tears, which required suturing at the Obstetric Department (Ward 21), Professorial Unit, Colombo South Teaching Hospital, Kalubowila were enrolled.
Women were randomly allocated to either diclofenac sodium or placebo suppositories (Anusol), using a random – number table. Treatment packs contained two, diclofenac sodium 100 mg and diclofenac sodium 50 mg suppositories or two placebo suppositories, The first (diclofenac sodium 100mg or placebo) was inserted when suturing was completed, and the second (50mg diclofenac sod--ium or placebo) 12 hours after birth. Women were asked to indicate their degree of perineal pain with different activities (resting/ walking/ sitting and squatting) 24 hours after birth, using visual analogue scale. Main outcome measure was overall pain score at 24 hours after birth.

A total of 169 women were recruited, with 84 randomized to diclofenac sodium suppositories and 85 to placebo. Women in the diclofenac sodium group were significantly less likely to experience pain within 24 hours of delivery (percentage of mean pain score reduction, 45%, $P < .001$) with different activities compared placebo.
The use of rectal diclofenac sodium is a simple and effective method of reducing the pain experienced by women following perineal trauma within the first 24 hours after childbirth.

This study was done in Colombo South Teaching Hospital as a partial requirement for MD in Obstetrics & Gynaecology in March 2008. Results were included in a thesis with one published paper in Sri Lanka Journal of Obstetricians and Gynaecologists. Abstract presentation was done in annual scientific session of Sri Lanka College of Obstetricians & Gynaecologists.

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Introduction

Perineal damage can cause significant maternal morbidity both immediate and long term. Morbidity associated with child birth may affect a woman's physical, psychological and social wellbeing. A vast majority of morbidity associated with perineal trauma is under reported [1]. Perineal discomfort may disrupt breast feeding, family life and sexual relationship [2]. Majority of mothers experience perineal pain and discomfort for 10 to 12 days following childbirth, which is more severe in the immediate postnatal period and some of them will continue to have long term pain for 3 to 8 months following delivery [1,3]. Other long term morbidities associated with perineal trauma is superficial dispareunia, fecal incontinence and some degree of urinary incontinence [3, 4,5]. Trauma to perineum is very painful and distressing to mothers and it has been associated with restricted mobilization, acute urinary retention, constipation, disturbance in breastfeeding etc.

Vast majority of perineal trauma is due to intentionally made episiotomy to facilitate vaginal delivery. Episiotomy rates vary considerably in various countries according to individual practices and policies of staff and institutions. Overall rates of episiotomy in different countries range from 8% to 99% [6, 7]. In Sri Lanka almost all primipara and most of the multipara experience episiotomy in hospital practice.

Postpartum pain relief is one of the ignored aspects following childbirth due to under estimation. As almost all mothers experience perineal pain in differing severity following child birth, the provision of safe and effective pain relief in modern healthcare practice is an essential component in obstetrics as mothers do not accept perineal pain following childbirth. Currently in Sri Lanka, there is no routine practice of perineal pain relief protocol, following child birth.

The provision of pain relief for perineal trauma has several therapies in clinical practice, which include rectal analgesics, oral analgesics, local anaesthetics, parenteral analgesics, therapeutic ultrasound and non pharmacological applications such as baths and ice packs [8]. Simple oral analgesics such as paracetamol and paracetamol + Codeine can be used as pain relief

for mild pain [9]. But efficacy is poor for moderate to severe pain following more extensive trauma such as 3rd and 4th degree perineal tears. Simple analgesics have a place when combined with other pharmacological agents for additive effect [10]. Non-Steroidal-Anti-Inflammatory-Drugs (NSAID's) are important analgesics for mild to moderate pain especially associated with physical trauma to tissue with acute inflammation [11]. A wide range of drugs are available with various efficacies administered in different routes; local/oral/rectal/parenteral. Local infiltration of anesthetic agents such as lignocaine has a limited place for perineal pain relief due to its short lasting activity. Parenteral agents such as morphine and pethidine are associated with unwanted side effects e.g. drowsiness, respiratory depression, difficulty in breastfeeding etc. Therefore, these agents are not used for routine perineal pain relief.

In general, medical care, the rectal route of analgesics administration has been favoured with good compliance when oral preparations cause gastric irritation, nausea and vomiting [12]. As the rectal mucosa have a rich vascular, and lymph supply, absorption of drugs is fast and analgesic effect occurs in a shorter period than oral route. Compared to oral administration of drugs, first pass metabolism is avoided in rectal administration [11].

Rectal diclofenac sodium is an effective, cheap, widely available and safe analgesic agent for pain relief. Studies assessing the efficacy of rectal analgesics in post-operative pain relief have indicated significant reduction of pain experienced [12], and reduced requirement of additional analgesia [13,14], although evidence of efficacy and safety of rectal analgesics in perineal pain relief is lacking [15]. Aim of this study was to evaluate rectal diclofenac sodium in relief of perineal pain after trauma during childbirth.

Objective

To evaluate rectal diclofenac sodium in the relief of perineal pain following trauma within first 24 hours after childbirth.

Material and Methods

A randomized, double blind controlled trial was carried out in the Obstetrics department, Professorial Unit, Colombo South Teaching Hospital (CSTH), Kalubowila, from 1st of October 2005 to 1st of February 2006. Ethical approval was obtained from Ethics and Research Committee of CSTH.

The minimum sample size calculation was based on previous research carried out by Corkhill et al. (2001) [16], which showed a mean pain score of 43.5 (SD 21.8) using 101-point numerical rating scale for perineal pain, with rectal analgesia, to detect a clinically significant reduction in pain score from 43.5 to 32.6 in visual analogue scale). It was necessary to recruit 168 subjects to trial (5% level of significance with 90% power).

Study information was provided to potentially eligible women with the period of gestation greater than 37 weeks admitted to the unit for vaginal delivery after obtaining their informed consent. Eligible women were randomly allocated following delivery to either diclofenac sodium group or placebo suppository group using random number table. The randomisation schedules were prepared by a researcher not involved in patient care using random number tables. Perineal repair or episiotomy suturing were done by senior registrar or registrar or house officer using polyglycolic acid (vicryl) by subcuticular suturing technique. Treatment pack contained 100mg and 50mg diclofenac sodium, and placebo (Anusol suppositories, which was having least analgesic action in the perineum), 1st diclofenac sodium 100 mg suppository or placebo was inserted by midwife when suturing was completed and the second (50 mg diclofenac sodium or placebo) 12 hours after birth. The women involved in the study were blinded to the allocated treatment groups. Data collection sheets were completed prior to discharge from the hospital at 24 hours after birth by recall, pain score (using ten-centimetre visual analogue scale) associated with resting, walking, sitting, and squatting. The patients who complained more pain were prescribed other analgesics (Paracetamol). Ethical approval was obtained from the research and ethical committee of the Colombo South Teaching Hospital. Informed consent was taken from all the participants. Those who did not given giconsent were given due medical care without any discrimination.
Data were entered into a data collection sheet in the ward and confidentially stored in an ongoing electronic database. Statistical test of significance was done to analyze the result with the help of a standard statistical package, SPSS 2006. Outcome analysis was done by intention to treat with the use of parametric test (t test) and chi-square test.

Results

During this study period, a total of 532 women gave vaginal birth at the professorial obstetric unit, Colombo South Teaching Hospital (CSTH) and sustained perineal trauma requiring suturing during child birth. A total of 235 potentially eligible women were approached in the antenatal period for participation in the trial, and 201 (85%) women provided provisional informed consent, of those women 169 became eligible after birth. All 169

Trial flowchart

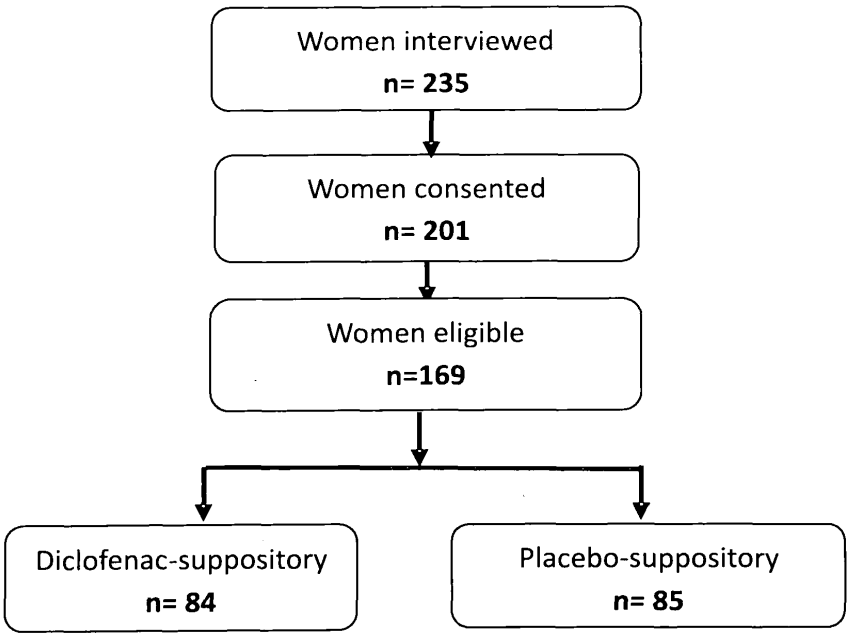

Table 1: Basic characteristics of subjects

Variables	Diclofenac Group (n=84)	Placebo Group (n=85)
Age	28.2 (yrs)	27.9 (yrs)
Gestational age	39w+ 0d	38wks+2d
Parity 1	35	33
Parity > 1	49	52
Birth Weight	2.81(kg)	2.94(kg)
Induction	31	43
Augmentation	53	42
Duration of labour	4 hrs & 50 min	4 hrs&53 mi n
MOD ;		
Spontaneous vaginal delivery	72	74
Instrumental Delivery	12	11

women were included in the analysis; with 84 randomized to receive diclofenac sodium suppositories and 85 women received the placebo. The two groups were well balanced for demographic characteristics at the trial entry and labour and birth outcomes as well as perineal repair technique. Study outcome data were available from 98% of women at 24 hours.

Table 2: Mean rating of pain intensity with different activities

Variables (Pain Rating)	Treatment Group : Mean (SD)		
	Diclofenac	Placebo	P Value
Sitting	2.5 (1.3)	5.0 (2.1)	<0.001
Walking	2.5 (1.1)	4.5 (1.5)	<0.001
Resting	1.7 (0.9)	3.6 (1.3)	<0.001
Squatting	2.6 (1.2)	4.6 (1.4)	<0.001
Overall	2.1(1.0)	4.0 (1.2)	<0.001

Table 3: Occurrence of significant side effects (Nausea, vomiting, gastric irritation, sensitivity)

Side Effects	**Placebo**	**Diclofenac**	**Total**
Present	11 (12.9 %)	14 (16.7 %)	25 (14.8%)
Not Present	74 (87.1 %)	70 (83.3 %)	144 (85.2 %)
Total	85	84	169

Table 4: Mothers' satisfaction of treatment

	More satisfied	**Satisfied**	**Not Satisfies**	**Total**
Placebo	10 (11.5 %)	21 (22.1 %)	54 (66.4%)	85 (100 %)
Drug	51 (63.2 %)	24 (26.1 %)	9 (11.7%)	84 (100 %)
Total	61	45	63	169

Table 2, shows mean rating of pain intensity with different activities and there is a statistically significant difference in less pain experienced by diclofenac suppository group compared to placebo group.

According to table 3, there is no statistically significant difference in occurrence of side effects in treatment group comparing to placebo group. Table 4 demonstrates maternal satisfaction was more with diclofenac suppository comparing to placebo.

Discussion

It clearly showed from this study, use of diclofenac sodium suppository was effective safe and well accepted by mothers for perineal pain relief following childbirth.

The women who were prescribed diclofenac suppositories were more comfortable and experienced less pain. They required less additional analgesia than placebo group. While current study did not detect the occurrence of any serious side effects associated with diclofenac administration, but still care should be maintained in prescribing this medication.

In determining the acceptability of rectal analgesic suppositories, Caroll et al., interviewed 400 surgical patients, who were asked to choose between and intramuscular route of pain relief and rectal suppositories [17]. Given a choice, 18% of patients chose rectal suppositories as an acceptable method of pain relief.

This current study assessed women's satisfaction of rectal route for the postnatal analgesics administra--tion. Women who received diclofenac suppositories in our studies were more satisfied with pain relief, and overall women who took part in the study had a high degree of acceptance for the rectal route of administration of analgesia.

The half life of diclofenac sodium in plasma is one to two hours after oral administration. 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 sodium is almost completely protein bound, and as a result minimum amount of the drug is excreted in the breast milk – an important consideration for women who are breastfeeding. While rectal suppositories may be effective in reducing pain experienced after childbirth, drug effectiveness becomes a secondary consideration, if women express reluctance to the rectal route of administration. There appears to be clear advantages in using diclofenac sodium suppositories to provide short team pain relief for perineal pain after childbirth.

The strengths of our study include use of randomised blind design, several measurements of pain insensitivity of different activities and assessment of safety of NSAIDS in breast feeding mothers. The study was limited by its small sample size due to restricted duration of research.

Conclusion

The use of rectal diclofenac sodium is effective, safe and satisfactory method of analgesic for the relieving pain experienced by women following perineal trauma within the first 24 hours after childbirth.

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