Rectal versus Oral Diclofenac Sodium in Relieving Post-Episiotomy Pain: Randomized Controlled Study

Original Article

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ABSTRACT

Background & Aim: Perineal pain can be caused by surgical (episiotomy) and spontaneous trauma and lacerations after vaginal birth. Episiotomies represent one form of trauma and are equivalent to a second-degree laceration that affects the mucosa and perineal muscles. Generally, there are many methods for treatment of such pain either with pharmacological agents or non-pharmacological agents. This study aimed to compare between rectal versus oral diclofenac sodium in relieving post episiotomy pain.

Materials and Methods: A total of 184 women underwent episiotomy were enrolled in the study. Those women were randomly subdivided intro rectal group where women received 100 mg rectal diclofenac sodium and oral group where women received 100 mg oral diclofenac sodium. Need to rescue analgesia, visual analogue scale and patient's satisfaction were recorded**.**

Results: Both groups had insignificant difference as regard baseline data. But it was found that rectal group had low frequency of rescue analgesia (1.1% vs. 8.7%; *p= 0.01*), lower visual analogue scale at different time of assessment up to 24-hour after repair (*p< 0.001*), no side effects and better satisfaction in comparison to the oral group. In this study, a total of 25 (27.2%) women in the oral different side effects in form of epigastric pain and vomiting.

Conclusion: Rectal diclofenac had better analgesic effects and minor upper gastrointestinal adverse effects were less frequently reported for post-perineal repair pain after episiotomy. Similar studies are needed among larger population and in different geopolitical zones to confirm any link to regional or ethnic variation.

Key Words: Diclofenac sodium, episiotomy, rectal, satisfaction.

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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[1,2].

Post-partum pain relief is one of the ignored aspects following childbirth due to under estimation. As almost all mothers experience perineal pain in different 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[3-6].

The provision of pain relief for perineal trauma has several therapies in clinical practice, which include rectal analgesics, oral analgesics, local anesthetics, parenteral analgesics, therapeutic ultrasound and non-pharmacological applications such as baths and ice packs[7].

In general, the rectal route of analgesics administration has been favored with good compliance when oral preparations cause gastric irritation, nausea and vomiting. 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[6].

Rectal diclofenac sodium is an effective, cheep, 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, and reduced requirement of additional analgesia[8, 9].

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Although evidence of efficacy and safety of rectal analgesics in perineal pain relief is lacking especially in our locality. The aim of this work was conducted to evaluate adequacy and safety of rectal and oral diclofenac sodium in providing analgesia for episiotomy pain following childbirth.

PATIENTS AND METHODS

Study deigns and setting

A randomized controlled trial, cost effectiveness analysis was conducted at Assiut Woman Health Hospital in the period between 2020 and 2022.

Ethical consideration

The current study was approved by the Ethical Committee of Faculty of Medicine, Assiut University. All the regulations of the Ethical Committee of the Faculty of Medicine were followed. The study was registered at Clinicaltrails.gov with ID: NCT02716142.

Inclusion criteria

The enrolled any woman was scheduled for episiotomy with the following criteria;

- Age between 20 and 35 years old.

- Primigravida as elective procedure.

Exclusion criteria

- Any patient with age above 35 years old was excluded from the study.

- 3rd and 4th degree perineal tear.

Sample size calculation

The minimum sample size is determined using this G power 3.1.3. in order to detect a significant difference in pain score between two groups based on the following parameters; effect size:0.5, one tailed alpha error: 0.05, power: 0.95 and allocation ratio: 1:1; a total sample size of 88 women in each study arm. A total of 184 patients; 92 patients in the study were enrolled (Figure 1).

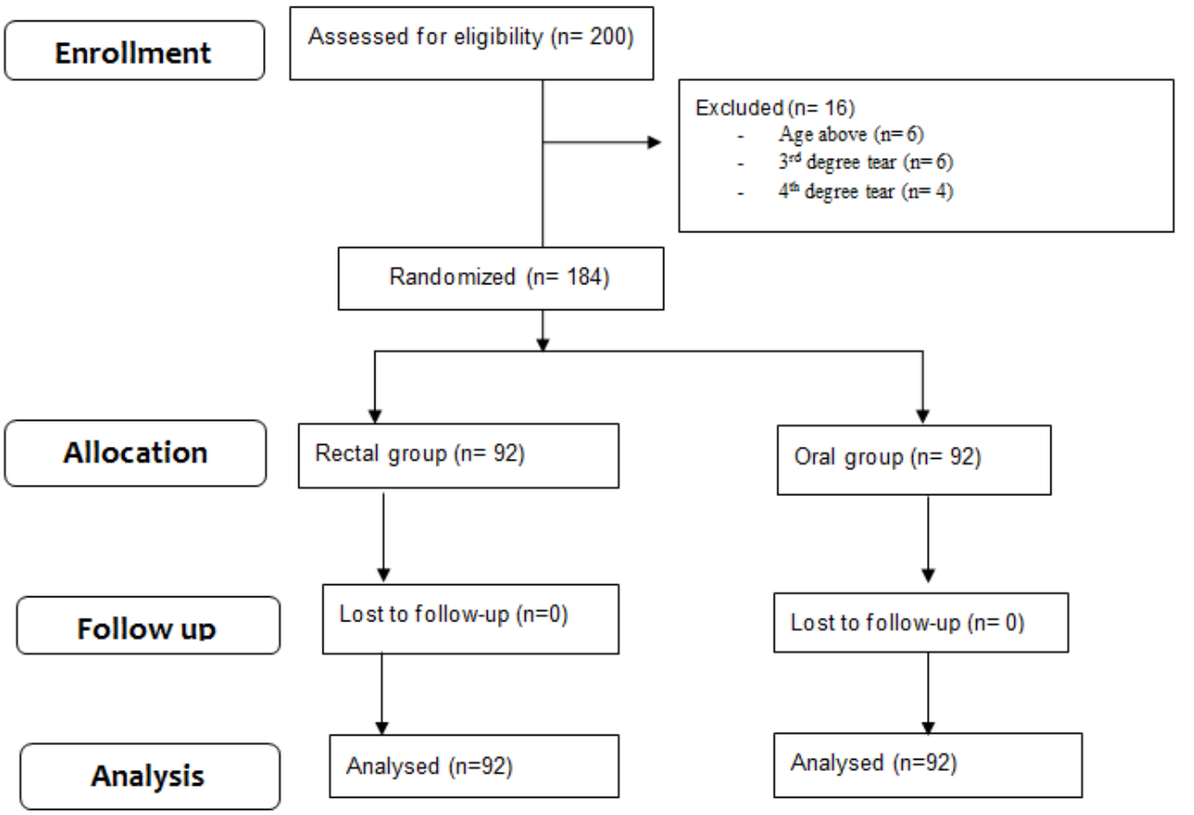

Fig. 1: CONSORT Flow Diagram of the current study

Randomization

The patients were subdivided into two groups: rectal group where women received 100 mg rectal diclofenac sodium and oral group where women received 100 mg oral diclofenac sodium. Simple randomization was performed through sequentially numbered opaque envelopes using a random numbers table (1:1 ratio) where those patients were subdivided into either underwent one of both groups.

When patient was deemed eligible for study, she took a consent and assigned a study number. Each treatment pack contained either 100 mg diclofenac sodium suppository (rectal group) or one tablet of diclofenac sodium 100 mg (oral group).

Methodology

Detailed history and physical examination were taken from selected cases. Eligible women were randomly allocated following delivery to either rectal or oral groups by using the random number table. Perineal repair or episiotomy suturing were done by house officer using polyglycolic acid (vicryl) by subcuticular suturing technique. Treatment packs was given to the women as following; 1st dose was given immediately after perineal repair; 2nd dose was given after 12 hours and 3rd dose was given after 24 hours.

Data collection sheets were completed prior to discharge from the hospital at 24 hours after birth by recall, pain score (using ten centimeters visual analogue scale) associated with resting, walking, sitting, and squatting. The patients who complain more pain were prescribed other analgesics (Paracetamol). IV 1000 mg acetaminophen was used as a rescue analgesic for any patient suffered from unbearable pain. Time and dose of rescue analgesia were recorded.

Statistical analysis

Data was collected and analyzed by using SPSS (Statistical Package for the Social Science, version 20, IBM, and Armonk, New York). The Shapiro test was used to determine compliance of the data to normal distribution. Quantitative data with normal distribution are expressed as mean ± standard deviation (SD) and compared with Student t test.

Quantitative data with abnormal distribution expressed as median (minimum-maximum) and compared by Mann-Whitney U test was used. Nominal data are given as number (n) and percentage (%). Chi2 test was implemented on such data. Level of confidence was kept at 95% and hence, *P value* was considered significant if < 0.05.

Ethics approval and consent to participate:

The current study was approved by the Ethical Committee of Faculty of Medicine, Assiut University. All the regulations of the Ethical Committee of the Faculty of Medicine were followed. The patients had clear verbal and written description about the study. Only those who consent to participate after descriptions (informed consent) were enrolled in the study according to the declaration of Helsinki. The study was registered at Clinicaltrails.gov with ID: NCT02716142.

RESULTS

Baseline data of the studied groups (Table 1):

Both groups had insignificant differences as regard baseline data ($p> 0.05$).

Duration of active phase and need to additional analgesia in the studied groups (Table 2):

Frequency of additional analgesia was significantly higher among oral group (8 (8.7%) vs. 1 (1.1%); $p= 0.01$) in comparison to rectal group.

Visual analogue scale in the studied groups (Table 3, Figure 2):

Visual analogue scale at different time of assessment either after one hour, 4-, 8-, 16- and 24-hours was significantly lower among the rectal group in comparison to the oral group ($p< 0.001$).

Side effects and patient's satisfaction among the studied groups (Table 4):

None of women enrolled in the rectal group developed any side effects of diclofenac sodium while 24 (26.1%) and 1 (1.1%) woman in the oral group developed (epigastric pain) and (epigastric pain& vomiting), respectively. There was significant difference between both groups as regard patient's satisfaction ($p< 0.001$).

Table 1: Baseline data of the studied groups

	Rectal group (n= 92)	Oral group (n= 92)	*P value*
Age (years)	24.29 ± 3.78	25.17 ± 3.64	*0.11*
Occupation			*0.21*
Housewife	86 (93.5%)	82 (89.1%)	
Employee	6 (6.5%)	10 (10.9%)	
Gravidity	0 (0-4)	0 (0-4)	*0.72*
Parity	0 (0-1)	0 (0-1)	*0.64*
Number of vaginal deliveries	0 (0-2)	0 (0-1)	*0.88*
Previous abortion	32 (34.8%)	29 (33.7%)	*0.72*
Living sibling	0 (0-2)	0 (0-1)	*0.76*
History of ectopic pregnancy	0	1 (1.1%)	*0.50*
History of vesicular mole	0	1 (1.1%)	*0.50*
Gestational age (week)	37.50 ± 1.37	37.63 ± 0.49	*0.39*

Data expressed as mean (SD), median (range), frequency (percentage). *P value* was significant if < *0.05*. CS: cesarean section

Table 2: Duration of active phase and need to additional analgesia in studied groups

	Rectal group (n= 92)	Oral group (n= 92)	*P value*
Active phase (hour)	11.15 ± 4.15	10.61 ± 2.68	*0.29*
Need to additional analgesia	1 (1.1%)	8 (8.7%)	*0.01*

Data expressed as mean (SD), frequency (percentage). *P value* was significant if < *0.05*.

Table 3: Visual analogue scale in the studied groups

	Rectal group (n= 92)	Oral group (n= 92)	*P value*
Visual analogue scale			
After one hour	3.71 ± 0.97	6.03 ± 0.58	< *0.001*
After 4 hours	2.93 ± 0.77	5.07 ± 0.52	< *0.001*
After 8 hours	2.29 ± 0.83	4.39 ± 0.61	< *0.001*
After 16 hours	1.51 ± 0.83	3.63 ± 0.59	< *0.001*
After 24 hours	0.63 ± 0.34	2.86 ± 0.43	< *0.001*

Data expressed as mean (SD). *P value* was significant if < *0.05*.

Table 4: Side effects and patient's satisfaction in the studied groups

	Rectal group (n= 92)	Oral group (n= 92)	*P value*
Side effects			< *0.001*
Nothing	92%	67 (72.8%)	
Epigastric pain	0	24 (26.1%)	
Epigastric pain and vomiting	0	1 (1.1%)	
Satisfaction			< *0.001*
Satisfied	91 (98.9%)	79 (85.9%)	
Dissatisfied	1 (1.1%)	13 (14.1%)	

Data expressed as frequency (percentage). *P value* was significant if < *0.05*

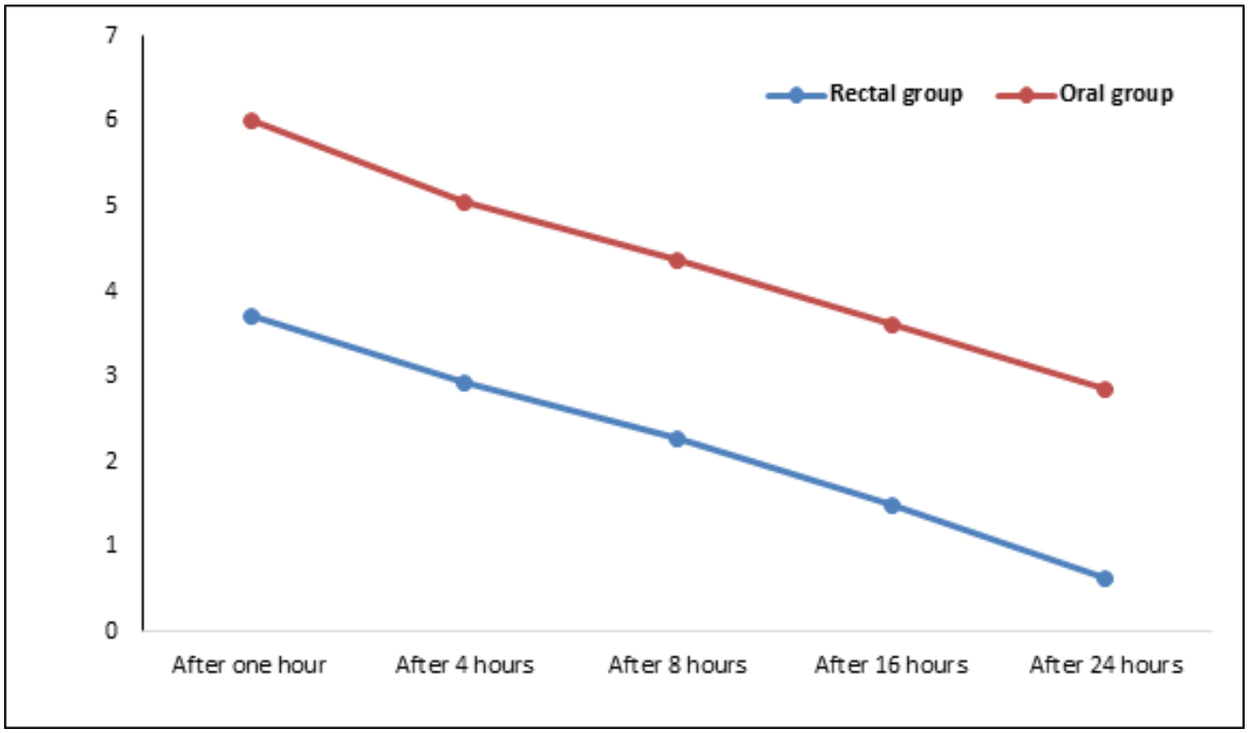

Fig. 2: Assessment of visual analogue scale at different times in the studied groups

DISCUSSION

Episiotomy is defined as perineal incisions in the second stage of labor which is performed for facilitation and shortening of the duration of the second stage of delivery, preventing possible damages to perineum, and pelvic organs, sexual dysfunctions, and severe perineal tears[10, 11].

Oral and rectal diclofenac are easy to administer however the oral route might be associated with common gastrointestinal side effects. Intramuscular route has to be given by the trained health practitioner and requires specific skills. It is also associated with adverse effects like needle accidents and injuries, local reaction, and being painful for nearly all patients[12].

Secondary to paucity in literature that compare between oral versus rectal diclofenac sodium in dealing with post-episiotomy pain, we performed this work. A total of 184 women underwent episiotomy were enrolled in the study. Those women were randomly subdivided intro rectal group where women received 100 mg rectal diclofenac sodium and oral group where women received 100 mg oral diclofenac sodium.

Baseline data in both groups in the current study was comparable. This was consistent with the study of Shafi *et al*. that enrolled 324 women were randomly allocated in two groups of 162 each. Groups A patients received diclofenac rectal suppositories. The authors found that both groups had insignificant difference as regard baseline data[9].

More recently, Nafees *et al*. studied a total of 182 female patients were divided into group A and group B. Group A was administered rectal analgesia in the form of rectal suppositories (100 mg) immediately after perineal tear repair and repeated after 6 hours. While group B received one injection of intramuscular diclofenac, immediately after perineal tear repair. The authors concluded no significant was found between both groups as regard baseline data[13].

The main findings included rectal group had low frequency of rescue analgesia (1.1% vs. 8.7%; $p= 0.01$), lower visual analogue scale at different time of assessment up to 24-hour after repair ($p< 0.001$), no side effects and better satisfaction in comparison to the oral group. In this study, a total of 25 (27.2%) women in the oral different side effects in form of epigastric pain and vomiting.

In line with this study, previous study stated that there was statistically significant difference between the two groups for sensory, affective and total pain scores at rest or with movement at 24 hours after childbirth. Pain scores were significantly lower in diclofenac group (rectal group) when compared to mefenamic acid group (oral group)[9].

Also, another study reported that diclofenac sodium suppositories group were significantly less likely to

experience pain within 24 hours of delivery (percentage of mean pain score reduction, 45%, $P < .001$) compared with those who received placebo[8]. Nafees *et al*. found that overall pain score was significantly lower immediately and 6 hours after repair in women received diclofenac sodium as rectal suppositories compared to intramuscular injection[13].

The summary of the pain scores in the first 24 hours-post-repair shows that the overall pain perception in both group of analgesia was in the mild and moderate severity range. This confirmed similar studies which revealed that diclofenac is an effective analgesia for the control of post perineorrhaphy perineal pain[8, 13, 14].

The current study acknowledges some limitations. Pain threshold varied among the study participants which affected their perception of pain during the scoring of the visual analogue scale. Another limitation was the subjective nature of the visual analogue scale in pain assessment among the parturient. This however applied to all the subjects in the study and so reduced the level of bias.

The fact that the performance and repair of episiotomy was carried out by different doctors could have affected the uniformity of the procedure. This bias was however reduced through training of the resident doctors and ensuring that all study participants were attended to by only the trained personnel. Finally, majority of the studies quoted above and this present study involved small study group. Large multicenter study would give a broader insight into the role of the study drug.

And yet the study had strength points as that the study population was homogenous in socio-demographic characteristics thereby controlling for confounders. The ability to blind the respondents to the specific route of analgesic administered has reduced bias in the study population. The assessors blinding also reduced bias in their assessment of the visual analogue scoring. The use of effective analgesia in the two study groups also removed the ethical dilemma of exposing the respondents to pain which may occur in placebo-controlled study coupled with the use of rescue analgesia.

CONCOLUSION

The findings reported in this study corroborate some earlier studies that rectal diclofenac is an effective post-perineorrhaphy analgesic. Based on the results of this study, rectal diclofenac had better analgesic effects and minor upper gastrointestinal adverse effects were less frequently reported for post-perineal repair pain after episiotomy. Similar studies are needed among larger population and in different geopolitical zones to confirm any link to regional or ethnic variation.

CONFLICT OF INTEREST

There are no conflicts of interests.

REFERENCES

1. Kalis V, Rusavy Z, Prka M: Episiotomy. In: Childbirth Trauma: Springer, 2017; 69-99.
2. Grabie Y, Jamil NZ, Schwob J, Uryash A. A Novel Therapeutic in the Management of Post-Episiotomy Pain [02M]. Obstetrics & Gynecology 2020;135:135S.
3. Mogren IM. Physical activity and persistent low back pain and pelvic pain post partum. BMC Public Health 2008;8:1-5.
4. Aziato L, Acheampong AK, Umoar KL. Labour pain experiences and perceptions: a qualitative study among post-partum women in Ghana. BMC Pregnancy and Childbirth 2017;17:1-9.
5. Åhlund S, Rådestad I, Zwedberg S, Lindgren H. Perineal pain the first year after childbirth and uptake of post-partum check-up-A Swedish cohort study. Midwifery 2019;78:85-90.
6. Francis F, Rosemol M. Is Rectal Analgesia a Better Choice for Post Episiotomy Pain?-An Interventional Study. International Journal of Nursing & Midwifery Research (E-ISSN: 2455-9318) 2019;6:62-68.
7. Şolt Kırca A, Korkut Öksüz S, Murat N. The effect of cold application on episiotomy pain: A systematic review and meta-analysis. Journal of Clinical Nursing 2022;31:559-568.
8. Dasanayake D. A randomized controlled trial of rectal analgesia diclofenac sodium for relief of perineal pain following child birth. Sri Lanka Journal of Obstetrics and Gynaecology 2014;36.
9. Shafi F. Rectal versus oral analgesia for perineal pain relief after childbirth. Journal of Rawalpindi Medical College 2011;15:56-58.
10. Malik J, Das S, Das A, Rai P. Judicial use of episiotomy in singleton normal vaginal deliveries at term: The changing trend. International Journal of Reproduction, Contraception, Obstetrics and Gynecology 2016;5:882-886.
11. Navi Nezhad M, Abedian Z, Asili J, Esmaeili H, Vatanchi A. Effect of alpha ointment (fundermol) on episiotomy wound healing in primiparous

women. The Iranian Journal of Obstetrics, Gynecology and Infertility 2017;20:58-65.

12. Sriram S. Study of needle stick injuries among healthcare providers: Evidence from a teaching hospital in India. Journal of family medicine and primary care 2019;8:599.

13. Nafees R, Safdar Z, Baig FS, Zaib S, Iftikhar A. Rectal diclofenac; an effective modality for pain relief after vaginal birth. Biomedica 2022; 38:39-43.

14. Olaniyi Fo. Rectal Versus Oral Diclofenac For Relief Of Perineal Pain After Episiotomy Repair: A Randomized Study. Faculty of Obstetrics and Gynaecology 2015.