Nigerian Medical Journal
NIGERIA MEDICAL ASSOCIATION
Print ISSN 0300-1652, E-ISSN 2229-774X

Original Research

Effectiveness of Rectal Versus Oral Diclofenac for Perineal Pain Relief following Episiotomy Repair at a Tertiary Hospital in Port Harcourt, Nigeria: A randomized controlled study.

Princeba Tamunobelema Amachree[1], *Peter Abiye Awoyesuku[1], James Enimi Omietimi[2], Roseline Beauty Iheagwam[1], Awopola Ibiebelem Jumbo[1], Monima Dumoteyim George[1].

[1]Department of Obstetrics & Gynaecology, Rivers State University Teaching Hospital, Port Harcourt, Nigeria.
[2]Department of Obstetrics & Gynaecology, Federal Medical Centre, Yenagoa, Nigeria.

Abstract

Background: Perineal pain following episiotomy repair is a common complaint after vaginal delivery and may be severe, requiring the use of strong analgesics. Diclofenac is a non-steroidal anti-inflammatory drug commonly used for pain relief. This study aimed to compare the effectiveness of rectal versus oral Diclofenac in the management of pain post-episiotomy repair.

Methodology: A prospective double-blind randomized controlled study was carried out involving 132 booked mothers who had episiotomy repair after vaginal delivery at a tertiary hospital in Port Harcourt, Nigeria. They were randomized into two groups and received either rectal diclofenac 100mg and oral placebo 12 hourly (Group A), or oral diclofenac 100mg and rectal placebo 12 hourly (Group B), for 48 hours following the repair. Perineal pain was measured using Visual Analogue Scale (VAS). Both groups were monitored for 48 hours (pain relief assessed at 6, 12, 18, 24, 36 and 48) and the analgesic effectiveness compared. The data obtained was analysed using IBM SPSS version 24. The recruitment spanned from 1st September 2023 to 30th January 2024.

Results: Both groups were similar in their baseline socio-demographic characteristics. The overall mean pain score was significantly lower in the rectal diclofenac group than the oral diclofenac group (4.14±0.42 vs. 4.30±0.44, t=2.01, p=0.048). Majority of the participants in the rectal route expressed more satisfaction (66.7% vs. 37.1%, $\chi 2$=23.08, p<0.01). The mean time interval (hours) between drug administration and the first urine void was similar in both groups (3.19±3.13 vs. 3.29±3.11, t=0.29, p=0.74), and there was no difference in the requirement for additional analgesia (12.1% vs. 9.1%, $\chi 2$=0.32, p=0.57).

Conclusion: Diclofenac suppository was more effective in management of perineal pain following episiotomy repair and the participants in the rectal route group expressed more satisfaction than their counterparts who received the oral drug.

Keywords: Episiotomy Repair; Perineal Pain; Diclofenac; Rectal Route; Oral Intake; Maternal Satisfaction; Mean Pain Score; Visual Analogue Scale.

***Correspondence:** Dr. Peter Abiye Awoyesuku, Department of Obstetrics and Gynaecology, Rivers State University Teaching Hospital, 6-8 Harley Street, Old G.R.A, Port Harcourt, Nigeria. **E-mail:** pawoyesuku@yahoo.co.uk

How to cite: Amachree PT, Awoyesuku PA, Omietimi JE, Iheagwam RB, Jumbo AI, George MD. Effectiveness of rectal versus oral diclofenac for perineal pain relief following episiotomy repair at a tertiary hospital in Port Harcourt, Nigeria: a randomized controlled study. Niger Med J 2025; 66 (3):1159- 1170.https://doi.org/10.71480/nmj.v66i3.907.

Quick Response Code:

Introduction:

Episiotomy is an intentional surgical incision made on the vagina and perineum, by skilled birth attendants, to enlarge the outlet of the birth canal and decreasing the risk of inadvertent extensive perineal lacerations. [1,2] It is one of the most performed surgical procedures in the world. Despite its benefits, episiotomy has been found to be associated with significant postpartum pain, which negatively impacts a woman's physical, emotional and psychological wellbeing. [3,4] Therefore, effective pain management is a critical aspect of postnatal care to enhance recovery and improve maternal quality of life.

Globally, episiotomy rates vary widely depending on the clinical practice which ranges from routine to selective use. The International Federation of Gynecology and Obstetrics (FIGO) and World Health Organization (WHO) recommends a restrictive approach, suggesting an optimal episiotomy rate of 10% for normal vaginal deliveries.[5,6]However studies done in various regions have reported higher rates, including 60% in India[7] and 80% in China.[8] In Nigeria, the episiotomy rate ranges from 9.3% to 40.1%, with a reported rate of 20.5% at the Rivers State University Teaching Hospital (RSUTH) Port Harcourt.[9]The variations in episiotomy rates are influenced by factors such as parity, clinical protocols and healthcare provider preferences.[10]

Post-episiotomy pain management typically involves the use of analgesics to alleviate discomfort and facilitate recovery. On-steroidal anti-inflammatory drugs (NSAIDs) including Diclofenac, are widely used due to their anti-inflammatory, analgesic, and antipyretic properties.[11] It is cheap, potent, easily accessible, effective and given as once or twice daily dosing. It is available in various formulations, including oral tablets, rectal suppositories, and intramuscular injections, each with distinct pharmacokinetic profiles and patient acceptability. [11,12]

Oral diclofenac is commonly prescribed due to its ease of administration and convenience; however, it undergoes first-pass metabolism in the liver, reducing systemic bioavailability. Also, the oral drug can induce nausea, vomiting and gastritis, and prolonged use can cause intestinal ulcers and lead to gut perforation.[13]Rectal diclofenac, on the other hand, avoids these side effects of the oral drug; it offers a reliable absorption and rapid onset of action by bypassing hepatic metabolism; providing prolonged pain relief.[13,14]Therefore, it has been suggested that the rectal route may offer superior pain control and extended duration of action compared to the oral route.

In clinical practice at the RSUTH, routine management of perineal pain following episiotomy repair involves the use of oral analgesics, including diclofenac. The rectal route for administration is seldom used due to lack of knowledge and familiarity and is used often at the discretion of the attending obstetrician leading to inconsistencies in practice and potential variations in pain relief outcomes. This study sought to bridge the knowledge gap in effectiveness and patient satisfaction between the rectal versus oral route of diclofenac for perineal pain relief following episiotomy repair at the RSUTH. Furthermore, limited local studies exist comparing the effectiveness and patient satisfaction of rectal versus oral diclofenac for pain relief post-episiotomy repair.

This study, therefore, aimed to compare the analgesic effect of, and patient satisfaction with, rectal diclofenac versus oral diclofenac in controlling pain following episiotomy repair at the RSUTH, Port Harcourt, Nigeria. The findings will provide evidence-based recommendations to optimize pain management protocols nationwide and improve the postpartum experience for women.

Patients and Methods:

Study area/setting: The study was conducted at the Department of Obstetrics & Gynaecology of the Rivers State University Teaching Hospital, Port Harcourt, Nigeria. It is the largest state-owned hospital,

located in Port Harcourt city local Government Area of Rivers State, one of the 36 states in Nigeria. Port Harcourt is a multiethnic and multicultural metropolitan city and is the State's capital. The tertiary hospital serves as a referral centre for most peripheral private and public hospitals, as well as an accredited training centre for undergraduate and postgraduate doctors. There is an average annual delivery rate of about 1800, with vaginal delivery rate of 65%, caesarean section rate of 35.0% and an episiotomy rate of about 20% of vaginal deliveries.

Ethical clearance was obtained from the Research and Ethics Committee of the RSUTH with approval number RSUTH/REC/2023329. All the participants gave written informed consent, and the study was conducted in accordance with the Declaration of Helsinki and International Conference on Harmonization of Good Clinical Practice.

Trial Registration: The trial was registered in the Database of the Pan African Clinical Trial Registry (pactr.samrc.ac.za) on 10th August 2023, with identification number of PACTR202308864630455.

Study design: This was a prospective double-blind, two-tail parallel equality randomized, placebo-controlled study. The recruitment spanned from 1st September 2023 to 30th January 2024.

Study population: The study population comprised of all women who had episiotomy repair following vaginal delivery at the RSUTH labour ward, who met the inclusion criteria.

Inclusion criteria: All booked and consenting mothers, ≥18 years of age, with singleton term pregnancies ≥37 weeks, who had either spontaneous, assisted or instrumental vaginal delivery, and had an episiotomy repaired.

Exclusion criteria: Women with contraindications to NSAIDs(e.g. peptic ulcer, liver disease, renal disease, bronchial asthma),those who had 3rd or 4thdegree perineal tear, severe primary postpartum haemorrhage ≥1000 ml, those who required specialized post-delivery pain control such as sickle cell disease patients, patients with pre-eclampsia/eclampsia, haemorrhoids assessed clinically, those on epidural analgesia and those who did not consent.

Intervention and Outcomes: One hundred and thirty-two mothers were allocated to two equal groups (A and B) of 66 each. Group A received rectal diclofenac 100mg and oral placebo 12 hourly, while Group B received oral diclofenac 100mg and rectal placebo 12 hourly. Both groups were assessed over 48 hours. The primary outcome measure was pain score at 6, 12, 18, 24, 36 and 48 hours. The secondary outcome variables were the need for additional(rescue) analgesia, interval to first micturition, and maternal satisfaction.

Sample size determination: The sample size for the study was determined using the formula for estimating the difference of continuous variables in a two-tail parallel equality randomized control trial (RCT) stated below.[15]

$$n = \frac{2\,X\,(Z_\alpha + Z_\beta)^2\sigma^2}{(\mu_o - \mu_r)^2}$$

Where, N is the required minimum sample size for each group; Z_α is the standard normal deviate at a 95% confidence interval which is 1.96;Z_β is the point of the normal distribution corresponding to the statistical power of 80% adopted for this study, which is 0.84;$\mu_o$is the mean pain score following episiotomy repair in the group that had oral diclofenac in a study by Olaniyi in 2015.[16]A mean score of 1.7±1.7 was reported at 4 hours following episiotomy repair in the oral diclofenac group in the study;$\mu_r$is the mean pain score following episiotomy repair in the group that had rectal diclofenac in the study

above. A mean score of 0.8±0.7 was reported for the rectal diclofenac group 4 hours after episiotomy repair; $\sigma^2$is the pooled variance which was calculated to be 2.88.
Substituting in the formula:

$$n = \frac{2\ X\ (1.96 + \ 0.84)^2 \text{X}\ 2.88}{(1.7 - \ 0.8)^2}$$

N ≈56. Adjusting for attrition using a rate of 15%; the adjusted sample size was approximately 66 participants needed in each group of the study hence a total of 132 mothers were recruited.

Recruitment: Term pregnant women potentially eligible for the study were identified in the antenatal clinic, given detailed information about the study, and consent obtained. When they presented in labour, they were routinely managed as for all women in labour. Those that met the inclusion criteria were identified and given further details about the study, and the written informed consent was revalidated from those who indicated interest in participating.

An interviewer-administered proforma was used to obtain information from each participant, including their sociodemographic and obstetric characteristics; the events of labour and delivery outcomes, episiotomy repair and details of intervention, the pain scores using VAS at intervals over 48 hours, and maternal satisfaction assessed at the point of discharge, were also recorded. The participants were recruited consecutively until the desired sample size was achieved.

Randomisation, Allocation and Blinding: The allocation sequence was based on computer generated random numbers. The intervention drugs were prepared and concealed by a pharmacist who was not part of the study, in opaque envelopes marked with the generated sequence numbers. All drugs were provided by the hospital pharmacist and kept in the Pharmacy Unit. Each sealed envelope contained four doses of either oral diclofenac and rectal placebo or rectal diclofenac and oral placebo. After episiotomy repair, each study participant randomly picked a number between 1 to 132 from a box and received a treatment pack from the hospital pharmacy corresponding to the research number. Each dose was administered 12 hourly over 48 hours, beginning within 30 minutes of the repair. The drugs were administered by trained Nurses.

Oral diclofenac 100mg manufactured by Novartis Pharma AG, Switzerland with manufacture date 07/2023 and expiry date 06/2026, National Agency for Food and Drug Administration and Control (NAFDAC) Registration Number 04-0033 and batch number TCUN2 and rectal diclofenac 100mg manufactured by Novartis Pharma AG, Switzerland with manufacture date 11/2022 and expiry date 10/2025, NAFDAC Registration Number 04-9012 and batch number ADPR37451 were used for the study. For lack of ideal placebos due to cost, coloured tablet Vitamin C 100mg served as the oral placebo while Anusol suppository produced by MA Holder: Church & Dwight UK Limited with expiry date 10/2026 and batch number 2181 served as the rectal placebo.

At the end of the study, unblinding was done and the allotted intervention to each sequence number was received from the Pharmacist for purposes of analysis. The patients were blinded to the treatment received and strictly received the intervention allocated to their picked number without any change.

Study procedure: Episiotomy when indicated was given as mediolateral and repaired as per standard protocol, after infiltration with 5-10ml of 2% plain Xylocaine diluted with equal volume of water for injection. The urinary bladder was emptied with a metal catheter before episiotomy was repaired. The repairs were done in 3 layers using polyglactin 910 (Vicryl) 2/0 suture mounted on an atraumatic needle. The apex of the wound was identified and Vicryl 2/0 was placed 1cm above the apex and knotted. Continuous non-locking suturing was used to repair the vaginal skin up to the level of the fourchette and then knotted. The perineal muscles were repaired with Vicryl 2/0 in three to four interrupted stitches

occluding all dead spaces. The perineal skin was repaired with Vicryl 2/0 in a subcuticular fashion. The episiotomies were all repaired with the same technique and mostly by trained senior residents to avoid bias, as suture material and technique both affect the post-episiotomy repair pain.

After the repair, the number picked and assigned to the woman from the ballot box was taken by the hospital aid to the hospital pharmacy and the appropriate drug envelope was retrieved. The drugs were administered by trained hospital nurses within 30 minutes of the episiotomy repair 12hourly for 48 hours. The women were counselled on perineal hygiene and wound care. Prophylactic antibiotics were also given. A post-delivery packed cell volume estimation was done in 48 hours and if no complaints warranting further management, the woman was discharged home.

The VAS, a validated [17] numerical analogue scale, was used to assess the severity of pain felt. It consists of a 10cm line with two points representing 0and10, where 0 represents no pain and 10 represents the worst possible pain. The pain was categorized as mild when the score was 0-3, moderate when 4-6 and severe when 7-10. The participants were asked to mark the point on the scale that best suited their pain severity at 6, 12, 18, 24, 36 and 48 hours after administration of the drugs (over periods of rest and on movement), with the average pain score at the end of 48 hours documented.

The women were told to inform the nurse when they began to feel unbearable pain from the repair site. The nurse gave intramuscular Paracetamol 600mg (rescue analgesia) and documented the time, interval and frequency of administration. The women also informed the nurse before they voided urine, and the time of first void was recorded. At the point of discharge, the women were asked to comment on their satisfaction with the pain relieve they experienced, and the proportions were analysed based on the route of administration assigned.

Data analysis: The data was crosschecked daily for correctness and completeness and was entered into an Excel spread sheet. The data was analyzed using IBM SPSS version 24 software (IBM Corporation, Chicago, IL USA). Categorical variables were summarized using frequencies and percentages, while numerical variables were summarized with mean and standard deviation. Test for significance was done to assess the differences in the primary and secondary outcomes between the two groups. The student t-test was used to assess the differences in mean pain score and mean time of first void. The Chi-square test was used to assess the difference in maternal satisfaction and the need for additional analgesia between the two groups. A p-value <0.05 was considered statistically significant. The study employed the intention to treat method of analysis for randomized controlled trial.

Results:

Six hundred and seventeen (617) women were assessed for eligibility, of these 132 women (21.4%) were eligible and recruited into the study, as shown in Figure 1. Sixty-six women were allotted and received oral placebo and rectal diclofenac suppository (Group A), while the other sixty-six women received oral diclofenac and rectal placebo (Group B). All the participants completed their VAS scoring and were available for final analysis.

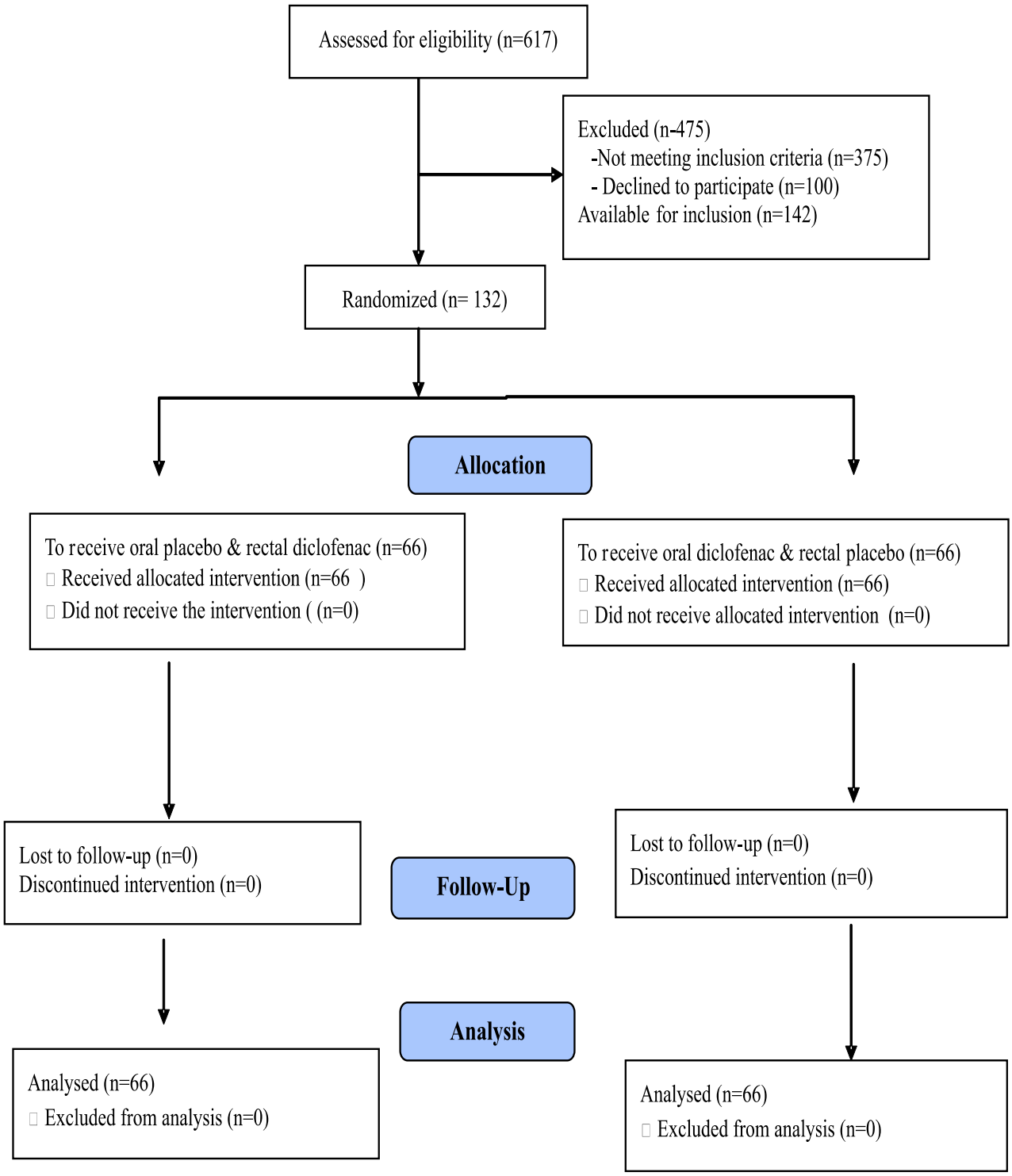

Figure 1: Consort Flow diagram for the study.

The characteristics of the study participants were as shown in Table 1. The mean maternal age of Group A participants was 30.4±4.3years while that of Group B was 29.9±4.8years; (t=0.59, *p*=0.56). The mean gestational age (GA) of Group A was 39±1.23 weeks while that of Group B was 39±1.24 weeks (t= 0.35, *p*=0.73). The mean body mass index (BMI) of Group A was 29.1±3.4kg/m^2 while that of Group B was 28.6±3.4kg/m^2 (t=0.82, *p*=0.41). There was no significant difference in duration of active labour (DOL) in the two groups (5.1±1.5 vs. 4.8±1.4 respectively; t=1.07, *p*=0.29). The parity of the women and the mean birth weight of the babies at delivery were also similar in both groups.

Table 1: Baseline characteristics of the participants in both Groups.

Variable		**Group A Rectal (n=66)**	**Group B Oral (n=66)**	**Statistical Test**	**P value**
Age (years)	Mean ± SD	30.4±4.3	29.9±4.8	t= 0.59	0.56
GA (weeks)	Mean ± SD	39±1.2	39±1.2	t=0.35	0.73
Weight (kg)	Mean ± SD	77.5±7.3	76.0±8.6	t=0.89	0.38
Height (m)	Mean ± SD	1.6±0.1	1.6±0.1	t=0.08	0.94
BMI (kg/m^2)	Mean ± SD	29.1±3.4	28.6±3.4	t=0.82	0.41
DOL (hours)	Mean ± SD	5.1±1.5	4.8±1.4	t=1.07	0.29
Parity	0	32(48.5%)	34(51.5%)	$\chi 2$=0.34	0.84
	1	14(48.3%)	15(51.7%)		
	2-4	20(54.1%)	17(45.9%)		
Occupation	Employed	21(46.7%)	24(53.3%)	$\chi 2$=0.33	0.85
	Self employed	19(52.8%)	17(47.2%)		
	Unemployed	26(51.0%)	25(49.0%)		
Religion	Christian	65(50.8%)	63(49.2%)	1.03 (fisher exact)	0.62
	Islam	1(25.0%)	3(75.0%)		
Education	Primary	3(60.0%)	2(40.0%)	$\chi 2$=0.22	0.90
	Secondary	30(49.2%)	31(50.8%)		
	Tertiary	33(50.0%)	33(50.0%)		

Marital Status	Married	59(49.2%)	61(50.8%)	$\chi 2$=0.37	0.55
	Single	7(58.3%)	5(41.7%)		
Birth weight	Mean±SD	3.6±0.4	3.6±0.32	t=0.42	0.68

Table 2 shows the comparison of the mean VAS score between the rectal and oral diclofenac groups at 6-, 12-, 18-, 24-, 36- and 48-hours post episiotomy repair. The reduction in the pain score was statistically significant at 12-, 18-, 36- and 48- hours. The mean pain score at 12 hours in the oral diclofenac group was lower than the rectal diclofenac group (4.7±0.6 vs. 4.9±0.5), however at 18-, 36- and 48- hours the rectal diclofenac group had lower pain scores. Overall, the mean pain score was significantly lower in the rectal diclofenac group than the oral diclofenac group (4.1±0.4 vs. 4.3±0.5, t=2.01, *p*=0.048).

Table 2: Comparison of mean VAS scores at 6-, 12-, 18-, 24-, 36- and 48-hours in both groups.

Pains Scores	Group A Rectal	Group B Oral	T test	P value
6 hours	5.7±0.7	5.7±0.7	0.40	0.69
12hours	4.9±0.5	4.7±0.6	2.01	0.05*
18hours	4.3±0.7	4.6±0.6	2.82	0.01*
24hours	3.8±0.7	3.9±0.6	0.94	0.35
36hours	3.3±0.6	3.6±0.6	2.39	0.02*
48hours	2.8±0.6	3.2±0.7	3.45	0.001*
Overall	4.1±0.4	4.3±0.4	2.01	0.048*

* Statistically significant.

Table 3 shows the need for additional (rescue) analgesia after the study intervention. Eight participants in the rectal diclofenac group received additional analgesia once compared with 6 in the oral diclofenac group (12.1% vs. 9.1%; $\chi 2$=0.32, *p*=0.57). Five women received the second rescue analgesia in the rectal diclofenac group compared to two in the oral diclofenac group (7.6% vs. 3.0%; $\chi 2$=1.36, *p*=0.24). There was no significant difference in the need for additional analgesia in both groups.

Table 3: Outcome on the need for additional (rescue) analgesia after the study intervention.

First rescue	Group A Rectal	Group B Oral	$\chi 2$	P value
Yes	8(12.1%)	6(9.1%)	0.32	0.57
No	58(87.9%)	60(90.9%)		
Second rescue				

Yes	5(7.6%)	2(3.0%)	1.36	0.24
No	61(92.4%)	64(97.0%)		

Regarding the mean interval (hours) between drug administration and the first urine void, there was no significant difference between women in Group A and B (3.3±3.1 vs. 3.2±3.1 respectively; t=0.29, p=0.74). Considering the maternal satisfaction expressed among women in the two routes of drug administration, 88(66.7%) women compared to 44(33.3%) in the rectal group expressed satisfaction, while only 48(37.1%) women compared to 83(62.9%) in the oral group expressed satisfaction; this difference was significant ($\chi 2$=23.08, p<0.01).

Discussion:

Studies have compared and proved the analgesic effectiveness of diclofenac suppository versus placebo, [18-20] Mefenamic acid, [21,22] Paracetamol,[23] and Indomethacin;[24]and the efficacy is not in doubt. However, not many studies, especially in our study area, have compared the rectal and oral route of diclofenac for perineal pain relief after episiotomy repair. This study aimed to compare the effectiveness of rectal diclofenac versus oral diclofenac in relieving perineal pain following episiotomy repair. The key findings were a lower pain score (better analgesia) and better maternal satisfaction with the rectal drug compared to oral diclofenac, while there was no significant difference in the need for additional (rescue) analgesia and interval to first micturition following drug administration between the two routes.

Both groups in this study were similar in all their baseline characteristics, with no significant differences between them, and therefore, the differences observed in pain management could be attributed to the effect of the intervention and not confounders. This is in keeping with findings from similar studies by Afolabi et al,[25] Mushtaq et al,[26] Ahmed et al,[27] and Seiqaet al. [28] Therefore, the findings can be applied in all women irrespective of their sociodemographic and obstetric characteristics.

As was found in similar studies, most participants were young (21-30 years) and primiparous. [25-27,29] This age represents the most productive age within the reproductive cycle, and nulliparous women commonly have rigid perineum which increases the frequency of episiotomy in a bid to prevent perineal lacerations. However, two studies done in Abakaliki, Nigeria [30] and Sri Lanka [31] contradict this finding as they observed more multiparous women had episiotomy in their study population. This difference may be due to methodological differences of the various studies, although it can also be argued that it may be related to increased fetal weight associated with increasing parity necessitating the increased need for episiotomy.

This study reported that the analgesic effect of diclofenac suppository was better than oral diclofenac for post-perineorrhaphy pain relief; the overall mean pain score was significantly lower in the rectal diclofenac group compared to their oral diclofenac counterparts. This is consistent with the findings of similar RCTs comparing rectal and oral diclofenac by Afolabi et al,[25] Mushtaq et al,[26] and Ahmed et al;[27]and is also corroborated by other studies.[23,29,32] The better and prolonged effective relief of diclofenac suppository may be related to the fast achievement of peak plasma concentration which is maintained for several hours.

In comparing the level of maternal satisfaction between both groups, there were more participants in the rectal group expressing satisfaction compared to their oral diclofenac counterparts. This was similar to the findings in the study by Afolabi et al [25] and Jodie et al,[33] who also reported their study participants receiving rectal diclofenac to be more satisfied with their pain relief after childbirth. It is worthy to note, that in a blinded controlled study where participants receive both oral and rectal drugs (albeit one is placebo), it is difficult to determine patient preference for route of administration, but rather the

satisfaction with the analgesic effect received, which may not be unconnected to the efficacy of the route of drug administration.

The need for additional (rescue) analgesia was not significantly different between both groups of this study. This is corroborated by the findings in the study by Olaniyi [16] and Onyema et al. [30] To the contrary, the study by Afolabi et al [25] and Ahmed et al [27] reported the need for additional analgesia to be significantly higher in their oral than rectal route study participants. The difference between the studies may reflect methodological differences in the dosages applied or the individual characteristics and pain perception threshold of the different study participants.

Effective postpartum pain relief is a right of all parturient women, but it is often underestimated and ignored, as most mothers experience perineal pain at different severity after childbirth. The provision of effective pain relief in modern obstetric practice is an essential component of healthcare. Studies assessing the effectiveness of rectal analgesics in post perineorrhaphy pain relief have shown significant reduction in the pain, reduced requirement for additional analgesia and better maternal satisfaction for the rectal route. Rectal diclofenac is a safe and effective, cheap and widely available, analgesic agent; and healthcare providers may consider offering this option in their individualized care plans and inclusion in protocols of management.

Limitations and strengths: Because of the subjective nature of the VAS in pain assessment and because pain is a subjective feeling, there could have been bias in pain scoring. However, because this was applicable to all the participants, the level of bias should be reduced. Also, the fact that the episiotomy was repaired by different doctors could have affected the uniformity of the procedure. Using pre-trained, experienced senior resident doctors to perform all the repairs, however, reduced this bias. Furthermore, the inability to use proper placebo due to the cost and lack of manufacturing equipment could have affected the blinding in some knowledgeable participants and investigators. The use of Anusol suppository may have introduced some analgesic effects to influence the pain score, but since this was used as a placebo for the oral diclofenac group, it did not affect the overall effectiveness of the rectal drug as supported by the findings. The use of computer generated random sequence numbers to eliminate recruitment bias, attempt at double-blinding to reduce observational bias, use of adequate sample size estimation to ensure good power of study, use of effective analgesia in both groups instead of inactive placebo in one group (removing the ethical dilemma of exposing participants to pain)and the study participants being homogenous in their baseline characteristics, were strengths of the study.

Conclusions:

The study showed that diclofenac suppository was more effective in the management of perineal pain following episiotomy repair and gave more maternal satisfaction with its use, than oral diclofenac of similar dosage regimen. Therefore, rectal diclofenac should be considered as one of the first line drugs for pain relief following perineorrhaphy and is recommended for inclusion in hospital patient management protocols. Further large multi-centre studies are advocated to investigate regional variations and improve the generalizability of the findings.

Acknowledgements: We would like to thank the study participants, the research assistants and all those who contributed in any way to the successful conduct of the study. We also appreciate all members of the Department of Obstetrics and Gynaecology of RSUTH for their cooperation.

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