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Rectal Diclofenac Versus Oral Diclofenac in the Management of Pain after Episiotomy Repair: A Randomised Controlled Trial at LAUTECH (now UNIOSUN) Teaching Hospital, Osogbo, Osun State, Nigeria

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ABSTRACT

Background: Safe and effective analgesia following episiotomy repair reduces postpartum morbidity. Oral diclofenac has proven to be of benefit in pain control, however, there is a need for an alternative route with the same analgesic efficacy because of the common significant side effects on the gastrointestinal tract. Hence, this study compared the effectiveness of rectal diclofenac to oral diclofenac in the management of pain after episiotomy repair at LAUTECH Teaching Hospital, Osogbo.

Methods: A randomised trial was carried out among parturients that had vaginal delivery and episiotomy repair from May to October 2020. 82 parturients (41 in each arm) were randomised to either 50mg oral or 50mg rectal diclofenac 12hourly for 24 hours after episiotomy repair. Pain score and level of maternal satisfaction were assessed, degree of side effects was also measured. Chi-square and Student t-test were used to identify association.

Results: There was no significant difference between the randomised groups in any socio-demographic characteristics. Rectal diclofenac group had a lower pain score (Rectal, Mean + SD 3.15+1.35 versus Oral, 6.46 + 2.85 p-value <0.0001), less need for additional analgesia (36.6% oral versus 7.3% of rectal, p-value =0.001) and improved level of maternal satisfaction compared to oral route (68.3% in rectal versus 2.4% in oral).

Conclusions: Irrespective of any socio-demographic characteristics, rectal diclofenac is more effective, has a high degree of acceptability and maternal satisfaction than oral diclofenac following episiotomy repair.

Key words: Episiotomy Repair, Pain Management, Diclofenac, Nigeria, Maternal Satisfaction

1. INTRODUCTION

Episiotomy is a surgical procedure where an incision is made in the perineum to enlarge the vaginal opening to improve foetal and maternal outcomes.[1]

Perineal trauma affects at least 65% of women in resource-rich countries and scarce data from under-resourced countries suggests 35–45% of women who give birth in a hospital setting experience an episiotomy.[2]

Though routine episiotomies are no longer standard or recommended practice, there are clinical indications for the procedure. Those indications include aiding the delivery of the presenting part when the perineum is threatening to tear, allowing space for operative or manipulative deliveries such as in forceps delivery, shoulder dystocia or breech delivery, preventing injury of the foetus during a face presentation, to shorten the second stage of labour for foetal distress or maternal medical condition.[3]

There are various types of episiotomies; commonly used are mediolateral and the midline episiotomy. The preferred type of episiotomy by WHO and ACOG is mediolateral as it reduces the risk of complex obstetric anal sphincter injury (OASI), however, one of the disadvantages of this technique is that it causes more pain compared to midline. Therefore, the need for analgesia increases. This makes the need for adequate perineal pain management a necessity as it reduces morbidity associated with the procedure.[4]

Perineal pain following episiotomy is an acute pain that if not well managed could lead to manifestation of symptoms such as difficulty in passing faeces, abnormal sleep pattern and appetite, reduce libido, irritability, decreased concentration capacity, restriction in family, professional and social activities. This has overall negative effect on the mother and gives a negative impression about delivery.[5]

Therefore, the need for analgesia after episiotomy repair cannot be overemphasized and one of the analgesics commonly used in our clinical setting is diclofenac. It is cheap, available, stable at room temperature, easy to store and acceptable by women.[7]

Diclofenac is a non-steroidal anti-inflammatory drug (NSAID) that inhibits prostaglandin synthesis. It is used to treat mild to moderate pain and can be administered as oral, intramuscular, rectal or topically.[8] Oral formulation of the diclofenac is commonly used and has been favoured over the years, however this has a major side effect of gastrointestinal symptoms.[8] An alternative to oral formulation following episiotomy repair is the rectal route and this has been associated with less side effects on the gastrointestinal tract, a major complaint by most of the parturient. This route is also of advantage as the drug is inserted just after the repair of episiotomy which reduces the need for oral intake of the drug at interval. Diclofenac suppositories have also been found to be available, cheap and acceptable.[9]

The current practice in this centre is the use of oral diclofenac as analgesic after episiotomy repair with the associated side effects. However, rectal administration will serve as a potent alternative to oral route.

Studies on the effectiveness of the rectal route are limited while local studies are also few. Therefore, this study is focused on exploring the analgesic efficacy, side effects and maternal satisfaction with rectal diclofenac and comparing it as an alternative to oral diclofenac following episiotomy repair. This study will add to the body of knowledge in our environment.

2. METHODOLOGY

2.1 Study Area and Period:

The study was conducted at LAUTECH Teaching Hospital, now UNIOSUN Teaching Hospital, Osogbo, Osun State between May 1 and October 31, 2020. Osogbo has two local governments - Olorunda and Osogbo Local Government Areas. The town lies on Latitude 70and 460north, and Longitude 40 and 340 east. The total land area is 47km2. Osogbo is accessible from any part of the state from which patients are referred to these hospitals. The city has a population of 156,694 people.

LAUTECH Teaching Hospital is a tertiary health facility, and it offers specialized and general healthcare to the people of Osun State and neighbouring states.

2.2 Study design and population:

The study was a randomized controlled trial. Study information was provided to potentially eligible women (all women with term gestation admitted to labour ward for vaginal delivery), thereafter informed consent was taken. Inclusion criteria were eligible and consenting patients with perineum threatening to tear, patient with rigid perineum, previous trauma presenting in second stage of labour. Also, those who had instrumental vaginal delivery, assisted breech delivery and shoulder dystocia were included. Exclusion criteria included women with history of PUD, allergy to diclofenac, inflammatory bowel diseases, asthma, and aspirin allergy. Also, pregnant women in labour on epidural analgesia, those for whom vaginal delivery was not anticipated and those in whom episiotomy was contraindicated were also excluded. Eligible women were randomly allocated (using block randomisation) following delivery to study (rectal diclofenac group) group A and (oral diclofenac group) Group B using computer generated table of random numbers giving equal chance to all participants. All eligible women that were randomised allocated were followed up and involved in analysis (Figure 1) Episiotomy suturing was performed by the lead researcher or the senior registrar on call after infiltration with local anaesthetic (10mls 1% lidocaine), using Vicryl 2/0 mounted on an atraumatic needle. The repair was done in 3 layers: vaginal mucosa by continuous suturing starting from 1cm above the apex to the level of vaginal opening, the perineal muscle repaired with interrupted haemostatic sutures and skin by subcuticular sutures. After repair, the women were counselled on adequate wound care by regular antiseptic cleaning. Adequate antibiotics and analgesics were given

For the eligible women in group A which was the study group; the first rectal diclofenac sodium suppository (VoltarenR) 50mg was inserted per rectum by the researcher or the senior registrar when suturing of episiotomy was completed (zero hour). The patient was taught how to insert the second and third doses at 12 and 24 hours respectively after delivery. The women in group B were given oral diclofenac (VoltarenR) 50 mg at 0, 12 and 24 hours after delivery. All eligible women were asked about the outcome of pain experienced using numerical analogue score (This has been validated in Nigeria)[13]. Women involved in the study were adequately educated about the numerical analogue score which is a straight line with scale ranging from 0 – 10, where 0 represents no pain and 10 the worst pain patient has ever experienced. The patient marked on the line according to the pain experienced. Pain was considered mild with analogue score of 1 to 3, moderate with 4 – 6 and severe with 7 to 10. The primary outcome was pain at 12 and 24 hours after birth with rest and on movements. Secondary outcomes were the need for additional analgesia, time of repair to additional analgesic, side effects of the routes of administration and maternal satisfaction with relief of pain. The level of maternal satisfaction was measured using Likert scale. The patient who complained more pain was given additional analgesics (paracetamol tablet 1000mg 8 hourly for 24 hours. Those who were not willing to be included in the study were given due medical care without discrimination.

2.3 Sample Size Determination:

Using the formula for calculating the population standard deviation.[14]

$$S_p = \sqrt{\frac{(n_1-1)s_1^2+(n_2-1)s_2^2}{(n_1+n_2-2)}}$$

$$N = 2\times\left(\frac{z_{1-\alpha}+z_{1-\beta}}{\delta_0}\right)^2\times s^2$$

Using the work of Dasanayake DNW on a randomized controlled trial of rectal analgesia diclofenac sodium for relief of perineal pain following childbirth[14], population standard deviation is 0.1316

Using the formula for comparing the mean of two independent population, for continuous (Non inferiority design at 95% confidence level and 5% level of precision, the calculated sample size was 37 per group. Then, adding 10% non-response rate, the final sample size was 41 per group (each arm) while the total sample size, therefore was 82 patients.

2.4 Data Analysis

Data was entered and analyzed using the Statistical Product and Service Solutions (SPSS) Statistics (Version 25.0). The data was summarized and presented as tables and charts. Pearson Chi-square test and level of significance were used to test association of categorical variables. Student t-test was used to test continuous variables. The level of significance was set at 5%.

2.5 Ethical Consideration

Ethical approval was obtained from the Ethical and Research Committee of LAUTECH Teaching Hospital with approval number LTH/EC/2019/09/430. The aim of the study was explained to the study participant. Each study participant was informed about the right to withdraw their consent and stop participating at any time without any form of prejudice. Privacy and confidentiality were maintained and written informed consent was obtained from the study participants to participate in the study.

3. RESULTS

A total of 82 participants were enrolled in the study, with 41 participants randomized to the rectal diclofenac group and 41 to the oral

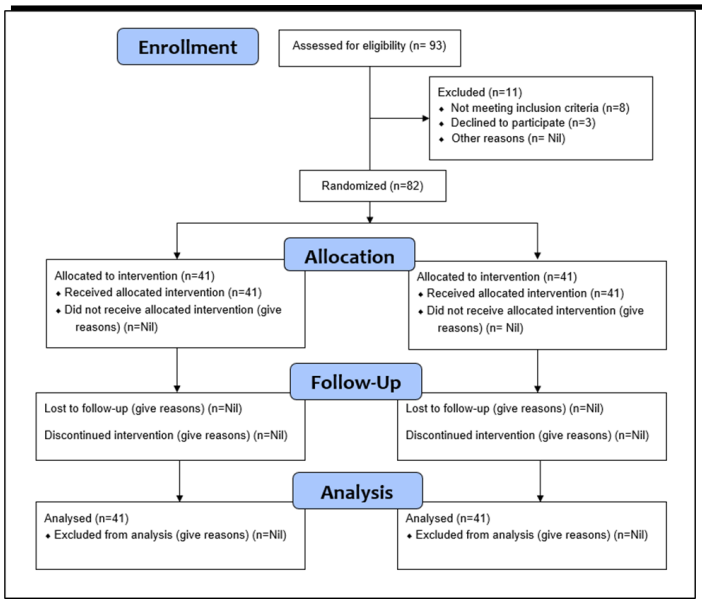

Figure 1: CONSORT Flow Diagram of Rectal Diclofenac Versus Oral Diclofenac in the Management of Pain after Episiotomy Repair

diclofenac group (Figure 1). Following randomization, there were no exclusions, and all participants completed the study as allocated.

The mean gestational age is 39.19 (±1.74) for oral and 39.12 (±1.74) for rectal group with t-test of 0.182 and p-value of 0.856. The mean duration of labour is 8.82 (±2.39) for oral and 7.97 (±2.01) for rectal group with t-test of 1.722 and p-value of 0.089

Table 1 shows baseline socio-demographic characteristics of the study population. There was no significant difference between the randomised groups in any socio-demographic characteristics (age, ethnicity, educational status, occupation, marital status, parity, mode of delivery, gestational age and duration of labour). As shown in Table 2, the primary outcome—pain score—was significantly lower in the rectal diclofenac group (Mean = 3.15, SD = 1.35) compared to the oral diclofenac group (Mean = 6.46, SD = 2.85), with a statistically significant difference ($p < 0.0001$). Table 3 shows that the need for the use of additional analgesia was significantly higher in the oral diclofenac group compared to the rectal diclofenac group (36.6% of participants in the oral group versus 7.3% of participants in the rectal group) ($p = 0.001$). Maternal satisfaction levels were also markedly higher in the rectal diclofenac group, with 68.3% of participants expressing satisfaction, compared to just 2.4% in the oral diclofenac group ($\chi^2 = 38.893$, $p < 0.0001$).

Figure 2 shows the variation in mean pain score within the 24-hour post-repair period. The rectal diclofenac group consistently had lower mean pain scores within the period both at rest and during movement, compared to the oral diclofenac group. As seen in figure 3, there was a high level of satisfaction in both oral and rectal diclofenac groups. However, a significantly higher percentage of the participants in the rectal diclofenac group were very satisfied compared to the oral diclofenac group (p-value=<0.0001).

4. DISCUSSION

The findings from this study demonstrated that rectal diclofenac is an effective alternative analgesic to oral diclofenac in pain management after episiotomy repair. It also, has better analgesic effects, decreased need for additional analgesia and increased maternal satisfaction.

Most of the participants in this study were between 21years and 30years (62.2%). This represents the most productive age of women within the reproductive cycle. This is similar to findings in studies by Naz et al and Dasanayake DLW in which 50.3% and 59.6% were within the age range respectively.[15] The majority of the respondents were Yoruba, had tertiary level of education and were

Table 1:Sociodemographic Characteristics of the Respondents

Variable	Oral (%)	Rectal (%)	Df	X^2	p-value
Age (Years)					
≤20yrs	3(75)	1 (25)	3	3.060	.383
21-30yrs	26(50.9)	25 (49.1)			
31-40yrs	12(48)	13 (52)			
>40yrs	0(0)	2(100)			
Ethnicity					
Yoruba	35(47.9)	38(52.1)	2	1.409	.494
Hausa	1(50)	1(50)			
Igbo	5(71.4)	2(28.6)			
Educational Status					
None	0(0)	1(100)	3	1.686	.640
Primary	1(33.3)	2(66.7)			
Secondary	15(55.5)	12(44.5)			
Tertiary	25(49)	26(51)			
Occupation					
Housewife	4(28.6)	10(71.4)	4	5.091	.278
Civil Servant	16(55.2)	13(44.8)			
Business	10(50)	10(50)			
Professional	7(53.8)	6(46.2)			
Others	4(66,7)	2(33.3)			
Marital Status					
Single	2(100)	0(0)	1	2.050	.152
Married	39(48.7)	41(51.3)			
Parity					
Nulliparous	21(46.7)	24(53.3)	1	0.443	.506
Multiparous	20(54)	17(46)			
Delivery Mode					
Spontaneous	37(52.1)	34(47.9)		3.575	.087
Instrumental	2(50)	2(50)	2		
Assisted	2(28.6)	5(71.4)			
Breech					

civil servants, which is a reflection of the study location occupied predominantly by the Yoruba speaking people of the south-western Nigeria and the people of Osun State are mainly civil servants.[15, 17]

Obstetric characteristics of the respondents showed that majority were nulliparous, delivered via spontaneous vaginal delivery, at average gestational age of 39 weeks and within 6-10hours duration of labour. This is similar to the findings in studies done by Naz, Dodd, Dasanayake, Searles and Prings in which most participants (58-63%) delivered at gestational age of 39-40weeks, via spontaneous vaginal delivery (79-93%) and within 5-10hours duration of labour.[15, 18] Findings from this study is further corroborated by Ojule and colleagues in South-South, Nigeria in which primiparity was reported as a major risk factor for episiotomy and perineal trauma with subsequent perineal pain.[20] Mac arthur and colleagues in the United States also concluded that between postpartum day 1 and 7, primiparous women experienced 10-30% more perineal discomfort than multiparous women.[21]

A comparative analysis of the socio-demographic and obstetric characteristics between the two groups, in terms of maternal age, ethnicity, educational status, occupation, marital status, parity, gestational age or duration of labour showed no statistical significant difference. It implies that a good randomisation was done in this study. This is in keeping with findings from studies that did similar work in which the two group were well balanced for demographic characteristics at the trial entry, labour and birth outcomes including perineal repair techniques.[12,15] Study done by Seiqa, Shakura, Abida and Arfat corroborated this finding in which demographic comparison was insignificant between the two groups.[11] This shows that findings in this study can be applied to parturient irrespective of maternal age, ethnicity, educational status, occupation, marital status, parity, gestational age or duration of labour.

The summary of the pain scores in the first 24 hours post-

Table 2: Primary Outcome Pain Score between the Study Groups

Groups	Number	Mean	Std Dev	t-Test	P-Value
Oral	41	6.46	2.85	8.027	<0.001
Rectal	41	3.15	2.85		

episiotomy repair showed that both group had lower pain scores, however, rectal diclofenac produced a lesser pain score than oral diclofenac throughout the first 24 hours (Mean: rectal, 3.15 versus oral, 6.46). This is statistically significant (p<0.0001). This is because absorption following the rectal route is less than 40 minutes with longer half-life compared to oral diclofenac.[15] This also shows that rectal diclofenac can serve as a potent alternative to oral diclofenac in the management of perineal pain following episiotomy. This finding is corroborated by Shafi, Shazia, Naheed and Rizwana in their study on the safety and efficacy of rectal diclofenac that revealed it to be a simple, effective and acceptable method of reducing pain experienced by women following episiotomy within the first 24-48 hours after child birth.[9]

Studies by Jodie, Gosh, Norland and others showed that rectal diclofenac is simple and effective anagelsic for postpartum pain after perineal repair with less side effects within the first 24hours. This will also improve maternal satisfaction with pain relief [8, 22, 23]

Furthermore, this study shows that rectal diclofenac consistently had lower mean pain scores within the 24hour period (Figure 1) which is statistically significant (p<0.001). This suggests that rectal diclofenac has a greater analgesic effect compared to oral diclofenac. This is similar to findings from study done by Naz et al in which rectal diclofenac was preferable over oral route because it results in quick relief of pain and prolonged action. Its use has also been found to be simple and highly effective in reducing perineal pain.[10]

The need for additional analgesia in this study was significantly higher in oral diclofenac than rectal route (Oral, 36.6% versus rectal, 7.3%, p=0.001). Also, hours of birth to the need of additional analgesia is longer in rectal route than oral route. This is not statistically significant (p= 0.0856).The insignificance might be due to the number of paturients recruited. Probably, if more women had been recruited, a statistical significant difference might have been observed. These findings further imply that rectal diclofenac has a greater analgesic effect than oral diclofenac within the first 24hours after episiotomy repair. Separate, similar studies done by Dodd, Shafi, and Shah corroborate these findings that the use of diclofenac suppositories has significant analgesic role especially at 24hours after administration.[9, 12, 19]

The level of maternal satisfaction was high in both groups implying both are acceptable route in pain management after episiotomy repair in the patients studied. Comparing level of maternal satisfaction between the two routes, participants were more satisfied with rectal route than oral route (Table 3, Figure 2). This was similar to the study done by Jodie et al in which there was an improved satisfaction with pain relief with rectal diclofenac and a higher degree of acceptability by women.[16] Naz et al also corroborated these findings that women who received diclofenac suppository had a higher degree of drug acceptance for rectal use and they were more satisfied with their pain relief after child birth.[10]

Comparing the side effects between the two routes of analgesia, this study reported diarrhoea as the only side effect in the two groups. It was more in oral group than rectal group, though not statistically significant (p=0.077). The insignificance may be attributed to short duration of its use and few numbers of women enrolled in this study. If more parturients had been enrolled, it might be possible to have more power to detect the statistical significant difference

4.1 Conclusion

Findings from this study showed that rectal diclofenac is a potent alternative to oral diclofenac in the management of perineal pain following episiotomy repair irrespective of the maternal age, ethnicity, educational status, marital status, occupation, gestational age, parity and duration of labour. Rectal diclofenac also had a better analgesic effect compared to oral diclofenac. There was also high degree of acceptability and maternal satisfaction with pain relief using rectal diclofenac

Table 3: Secondary Outcome Measure between Study Groups

Variable	Oral	Rectal	χ	p-value
Need additional analgesia				
Yes	15(36.6)	3(7.3)	10.250	0.001
No	26(63.4)	38(92.7)		
Prefers route of analgesia for next delivery				
Yes	36(87.8)	36(87.8)	0.000	1.000
No	5(12.2)	5(12.2)		
Satisfaction with treatment				
Not Satisfied	40(97.6)	13(31.7)	38.893	<0.001
Satisfied	1(2.4)	28(68.3)		

4.2 Recommendation

We recommend that pain management with rectal diclofenac after episiotomy repair should be a regular use as it will reduce the prevalence of maternal morbidity and advance management of postpartum perineal pain in obstetric practice

4.3 Limitation of the Study

These include inability to conduct the study for up to 48 hours after episiotomy repair. This is for ethical reason as multipara will not be delayed for 48 hours just for the purpose of the study. This is the reason why the study was limited to the first 24 hours after delivery.

In addition, pain threshold varied among the study participants which may have affected their perception of pain during the scoring using numerical rating scale

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Author's Contribution

Afolabi Adegboyega S: Conceptualization, Validation, Formal analysis, Investigation, Resources, Methodology, Data curation, Visualisation, Writing - Original draft, Writing - review & editing, Supervision

Adekanle Daniel A: Data curation, Formal analysis, Investigation, Methodology, Writing - review & editing

Awodele Kehinde: Data curation, Formal analysis, Methodology, Writing - review & editing, Supervision

Afolabi Opeyemi O: Data curation, Formal analysis, Methodology, Writing - review & editing, Supervision

Folami Emmanuel O: Data curation, Formal analysis, Methodology, Writing - review & editing, Supervision

Conflicts of Interest

The authors declare no conflicts of interest.

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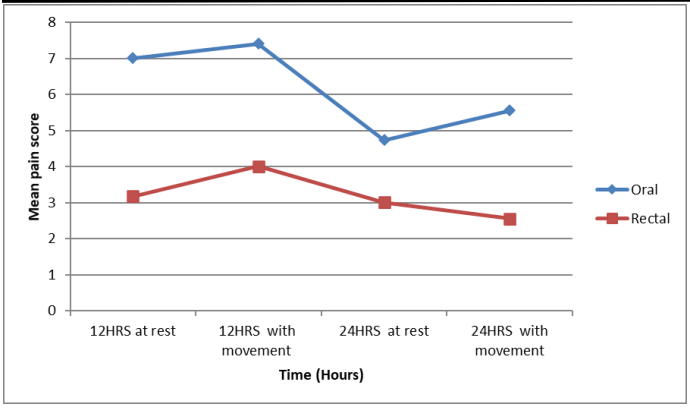

Figure 2: The Mean Score of Pain Within 24-Hour Post-Episiotomy Repair Period.

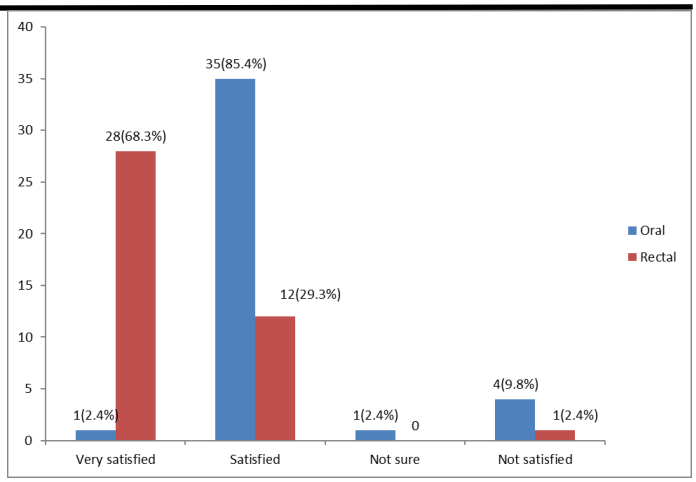

Figure 3: Level of Maternal Satisfaction with Analgesic Effects in the Two Groups.

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