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Pain Relief After Episiorrhaphy: A Randomized Control Trial Comparing Rectal With Oral Diclofenac At A Teaching Hospital, Southeast, Nigeria.

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ABSTRACT
Background: *Episiotomy is the commonest surgical procedure performed on parturient. It is usually associated with perineal pain which is particularly severe in the first 24 hours post repair. Perineal pain after episiorrhaphy if not adequately managed maypreven good immediate post-partum care for the newborn including breastfeeding. This study compared the efficacy of single dose rectal diclofenac with oral diclofenac for the relief of perineal pain within 24 hours after episiotomy repair.*
Methods*: A randomized controlled trial that involved 146 women that had episiorrhaphy between June and December 2021. The women were randomized into two groups of 73 women each using computer generated random numbers. One group received 100mg of diclofenac suppository statim while the other group received 2 doses of 50mg of oral diclofenac 12 hours apart, both for 24 hours after episiorrhaphy. Pain was assessed at 1, 4, 8, 16 and 24 hours post episiorraphy using a Visual Analogue Scale. Maternal satisfaction for the mode of the pain relief was assessed using the Likert scale after 24 hours, categorized into: no pain (0cm), mild (1-3cm), moderate (4-7cm) and severe (8-10cm), while satisfaction was categorized into: Very satisfied, Satisfied, Neutral, Dissatisfied, Very dissatisfied. Data obtained was analyzed using Statistical Package for Social Science software (SPSS) version 25 and analysis done.Student t-test was used for comparison between the group means for continuous variables while Chi-squared test was used to compare categorical variables. Statistical significance was obtained when p-value was ≤ 0.05.*
Results: *The mean difference in pain relief at the different time intervals was statistically significant in favor of rectal diclofenac group. Overall comparison after 24 hours showed that rectal diclofenac was approximately 4 times better in relieving perineal pain after episiorhaphy. The difference in the maternal satisfaction was statistically significant in the rectal diclofenac group (p<0.001).*
Conclusion: *Rectal diclofenac had better analgesic effects and greater satisfaction for relief of perineal pain for the clients within 24 hours after episiorrhaphy.*
Keywords:*Episiotomy, episiorraphy, diclofenac, pain relief, visual analogue scale.*

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I. Introduction

Episiotomy is the commonest minor obstetric procedure [1,2]. It is a surgical incision of the vagina and the perineum done to enlarge the introitus during childbirth [3,4]. It is usually done to prevent perineal tears and to facilitate delivery. Episiotomy was initially done as a routine procedure especially in primigravidas at the late second stage of labor [4,5]. Currently, restrictive episiotomy is advocated as against routine episiotomy to avoid unnecessary adverse effects associated with episiotomy [3,4,6].

The rate of episiotomy varies considerably from country to country and in different studies within a country [7]. Factors such as birth weight, booking status, higher gestational age etcetera, also affect the rate of episiotomy [8]. In Nigeria, some studies showed that the rate of episiotomy ranges from 21% to 62 % [8,9]. The prevalence around the globe also differs significantly ranging from 8% to 100 % [4,10]. The large gap in the

rate around the world is due to differences in policy regarding the use of episiotomy, either routine or restrictive use [4].

There are different methods of episiotomy but midline and the mediolateral types are the most commonly performed ones [4,11]. Episiotomy is performed with Episiotomy scissors. Anesthetic infiltration is required for the procedure and for its repair after delivery. Episiotomy can cause significant maternal morbidities, both immediate and long-term sequelae including perineal pain and discomfort [4,12]. Perineal pain is one of the commonest morbidities associated with episiotomy and this is more severe in the first 24 hours [12]. Perineal pain is transmitted through the pudendal nerves to the spinal segments of S2 to S4.Perineal pain from episiotomy is very distressing to mothers and it has been associated with restricted mobility, dyspareunia, acute urinary retention, constipation, disturbance in breastfeeding etc. Factors that may influence the severity of pain include type of suture materials, episiotomy repair technique, extension of the episiotomy and other associated perineal trauma [13].

Provision of safe and effective postpartum pain relief is an integral and essential component of modern obstetric practice and thus should not be ignored [12]. Several formulations and pharmacological preparations (such as acetaminophen, opiods, non-steroidal anti-inflammatory drugs (NSAIDS) etcetera) are used in clinical practice to achieve pain relief after episiorrhaphy through different routes with oral and rectal routes the most common [13]. Diclofenac is one of the commonly used NSAIDS for post episiotomy pain relief [12]. It is readily available, effective, affordable and widely acceptable. It has anti-inflammatory, antipyretic, anti-edematous and analgesic properties [14,15]. These properties are the needful in effective relief of pain and other morbidities associated with episiotomy.

The occasional adverse effects associated with the use of diclofenac in pain relief such as abdominal pain, nausea, dyspepsia, are notable when injudiciously extended and or high doses are used, thus using the lowest effective dose for the shortest duration is very essential [16]. Diclofenac can be administered through various routes which include oral, parenteral, rectal and topical. Oral diclofenac is commonly used in our center due to its ease of administration, availability and the reduced cost. However, due to the increased side effects, especially gastrointestinal adverse effects, diclofenac suppository is considered. The use of diclofenac suppositories for the relief of episiotomy pain is gaining wider acceptability by women [13]. Rectal administration ensures greater absorption as hepatic first-pass effect is avoided [13,14]. It is also the drug of choice when a patient is drowsy, unconscious or in clinical scenarios where oral route is contraindicated [14].

However, the efficacy of the suppository route in comparison with the oral route for the purpose of post episiorrhaphy pain control has been poorly investigated, hence the need for this study. Every woman looks up to that special time when the baby is born and the joy that comes with postpartum, but perineal pain especially from episiotomy occasionally interferes and sours the period.Episiotomy pain is one of the most common causes of immediate postpartum morbidities. It arises from the trauma to the nerve endings following the surgical cut, inflammation, swelling of adjacent tissues, and contraction of levator ani and other perineal muscles [17,18].

A recent study showed that 90% of all women with or without obvious perineal trauma have perineal pain in the first 24 hours after birth, and close to 100% of them following episiotomies [19]. Episiotomy rate in Nigeria is still high ranging from 21% to 62% [8,9,20,21]. Thus, these proportions experience post episiotomy pain and other acute effects of the pain such as restriction in mobility, disturbance in caring for the baby, difficulty in urination, defeacation, and other functional activities. There is differential perception of post episiotomy pain by different women as some feel little pain whilst others describe it as intense [13,14]. This is affected by many physiological and psychosocial factors including fear, anxiety, previous experience, type of suture material and style of closure; also, degree of support and companionship [22]. It is very important and as one of good maternity practices to ensure that women are pain-free postpartum.Several pharmacological and non-pharmacological methods have been employed to reduce post episiotomy pain with the most common one being the use of NSAIDS such as diclofenac via oral and rectal routes [23]. The route and choice of NSAIDS are determined by factors such as pharmacodynamics of the drugs, side effects, cost, availability, administration convenience, patient's satisfaction and secretion in the breast milk.

A mediolateral episiotomy cuts through the vaginal wall, bulbospongiosus, the superficial and deep transverse perineal muscles, skin over the ischioanal fossa and anterior pubococcygeal fibers of levator ani [25,26]. A median episiotomy involves incision through the posterior vaginal wall, perineal skin, perineal body and some fibers of the external anal sphincter [25]. Injury to the pudendal nerve or its branches can cause pain in the innervated regions, for example, as a result of compression of the nerve in the pudendal canal from prolonged labor or from cutting injury during a mediolateral episiotomy [25-27]. Due to the gap in the sequence of dermatomes between L1 at the front and S3 farther back, a pudendal nerve block will not anaesthetize the whole vulva, the anterior part must be locally infiltrated to supplement the main nerve block [28].

II. Materials and Methods

The State is located in the south eastern part of Nigeria, created on October 1, 1996 and has 13 local government areas, with Abakaliki, the state capital as the only urban settlement in the state, and Afikpo as a semi-urban settlement. The state has an estimated population of about 2.8 million people; and occupies a land mass of 6400 square kilometers [29]. The vegetation characteristic of the area is the tropical rain forest with an average annual rainfall of 1600mm and an average atmospheric temperature of 32^0C [29]. Two main seasons – wet and dry – characterize the area. The Igbos are the predominant ethnic group in the state. Majority of these people are subsistence farmers, artisans, traders and civil servants. They are predominantly Christians.

The Hospital, serves as a major referral center for the state and other surrounding states of Enugu, Benue, Abia and Cross River states. The average antenatal booking is about 4,200 clients per annum, while the total antenatal clinic attendance averages 21,000 per annum, with an average annual delivery rate of 3,100 (vaginal delivery rate: 2,148) and episiotomy rate of about 25% (unpublished data). The department has established protocols for management of specific cases which are in accordance with international best practices, and are displayed in the labor ward, antenatal ward and the accident and emergency unit of the hospital. These protocols serve as guides, as patient management is still individualized.

The study was a randomized control study that compared the efficacy of single dose rectal diclofenac with oral diclofenac for perineal pain relief in the first 24 hours after episiorrhaphy. The study lasted for a period of 6 months from JULY to December 2021. The Participants included parturients that had uncomplicated mediolateral episiotomy following delivery at the labor ward of the Hospital and met the inclusion criteria. The inclusion criteria were; Uncomplicated pregnancy, Gestational age of 37 weeks and above who had episiotomy, Singleton gestation, Vaginal delivery, Instrumental vaginal delivery, Consented women. The exclusion criteria were; those that declined consent, Postpartum hemorrhage, Women who had perineal tear, History of peptic ulcer diseases, History of bleeding coagulopathies, Adverse reaction or hypersensitivity to diclofenac, Any woman with special postpartum pain relief plan such as sickle cell disease patient, Preeclamptic/eclamptic, renal and liver diseases patients and Parturient on epidural anesthesia.

Sample Size calculation

The minimum sample size was determined using statistical formula for non-inferiority study [30]

$N = 2 \times \{\underline{Z_{1-\alpha} + Z_{1-\beta}}\}^2 \times \delta^2$
$\{\delta_o\}^2$

N = number of patients per group

$Z_{1-\alpha}$ = Standard normal deviate of type 1 error

$Z_{1-\beta}$ =Standard normal deviate of type 11 error

δ_o= Clinically acceptable margin

δ^2 = Population variance (pooled standard deviation of both comparison groups)

$Z_{1-\alpha} = 1.64$

$Z_{1-\beta} = 0.845$

$\delta_o = 0.3$ (from Olaniyi) [31]

$\delta^2 = 0.7$ (from Olaniyi) [31]

Substituting,

$N = 2 \underline{\{1.64+ 0.845\}^2} \times (0.7)^2$
$\{0.3\}$

$N = 2 \times (2.485/0.3)^2 \times 0.49$

$N = 2 \times (8.23)^2 \times 0.49$

$N = 2 \times 67.73 \times 0.49$

$N = 66.4$

Adding 10% attrition = 66/10 = 6.6, Approximately 7

N = 66 + 7 = 73. Therefore, 73 eligible women were recruited per arm.

Sampling Method

The recruitment of participants was by simple random sampling done in the Antenatal clinic and labor ward from gestational age of 36 weeks. The participants were counselled on what the research was all about and those who consented and met the inclusion criteria were randomized. The eligible participants were randomized by means of computer-generated random numbers using the software Research Randomizer$^{(R)}$. Using the software, seventy-three numbers were randomly generated from a pool of one hundred and forty-six (1-146) and the first set of numbers was assigned Study Group (rectal group), while the remaining seventy-three was automatically assigned Control Group (oral group). The randomized treatment numbers (1-146) were inscribed on sealed opaque envelopes containing a piece of paper with inscription rectal or oral respectively that

matched the corresponding randomized group number on the envelope. These envelopes were arranged sequentially and kept in a box from which each eligible participant was serially picked from as they were recruited. Each selected envelope was opened individually and allocated to the corresponding treatment group it contained. The study was an open-label study. The researcher and the assistants knew the type and route of the diclofenac being given to each participant. Each participant also was aware of the route and formulation of diclofenac that was administered.To minimize bias, the assessor of the visual analogue scale involved different research assistants aside from the one that administered the study drug for a particular patient.To minimize loss to follow-up, the phone numbers of the participants were collected.

ProcedureforMedoilateralEpisotomy

Having validated the informed consent, the patient was positioned in a dorsal position. The vulva was cleaned with savlon swab and the patient draped accordingly. The perineal site for the episiotomy was infiltrated with 10 ml of 1 % plain lignocaine. Two gloved fingers were placed in the vagina between the fetal presenting part in the vagina and the perineum. An incision was then made with episiotomy scissors when the perineum distended during contractions at crowning. The incision started from the center of the fourchette and directed diagonally at 45^{o}, either to the left or right and extended about 4 cm in a single straight cut (directed towards ischial tuberosity).

Episotomy Repair

The episiotomy repair was done immediately after the expulsion of the placenta. The patient was placed in a lithotomy position under a good source of light. Continuous knotless technique was the method used for the episiotomy repair. Using Vicryl 2/0 mounted on atraumatic needle No 9, a non-locking continuous suturing of the vaginal mucosa was done starting about 1 cm above the apex of the episiotomy. Perineal muscles were re-approximated with 3-4 interrupted sutures and lastly the skin was closed with continuous subcutaneous suturing. The episiotomy and the repair were done by the investigator and the assistants.

Drug Packaging and Dosage

Each treatment pack contained a 100 mg diclofenac suppository or two tablets of 50 mg oral diclofenac. The treatment packs were kept refrigerated inside the labor ward room. The dosage for the rectal diclofenac was stat dose suppository containing 100 mg diclofenac sodium while that of the oral diclofenac were two doses of 50 mg of diclofenac sodium that were administered 12 hours apart. Subjects in each group of the study received the analgesics for a duration of 24 hours.

The rectal and oral diclofenac that were used for the study were (Voltaren®) manufactured by Novartis Pharma AG, Basel, Switzerland and with approved NAFDAC number. The drugs were purchased from a reputable pharmaceutical shop in Abakaliki. They were of the same batch number and expiry dates. This ensured that participants received the same quality of drugs.

Administrationof Rectal Diclofenac

The rectal diclofenac, 100mg stat, was administered immediately (within 3 minutes) after the episiotomy repair. Prior to the administration of the rectal diclofenac a verbal consent was obtained from the participant. The patient was readjusted in dorsal position; the buttocks were digitally parted with the index finger and thumb of the left hand while the perianal region was lubricated with K-Y jelly which reduced friction and ensured easy passage of the drug. The rectal diclofenac was removed from the container by an assistant and gently inserted deep into the rectum above the anal sphincter.

AdministrationofOral Diclofenac

The oral diclofenac was administered by nurses that were educated about the study. The nurse, having obtained a verbal consent from the participant dispensed a 50 mg diclofenac tablet in the drug envelope immediately after the episiotomy repair which was swallowed with a cup of water by the participant. The second dose of the drug was administered 12 hours later in the postnatal ward by nurses who also were part of the study.

Oral acetaminophen was used as rescue analgesia at a dose of 1000 mg and was administered anytime any participant complained of significant pain. The time of administration of rescue analgesia was documented and the dose of rescue analgesia administered to the subjects in the different study groups within the period of 24 hours (not less than 8 hours apart) was noted.

Data Collection

Maternal demographics, obstetrics and other delivery details were entered in a proforma. Severity of pain was recorded at 1, 4, 8, 16 and 24 hours and at demand for rescue analgesic. The time for demand of rescue

analgesia and the number of times that rescue analgesia were administered was recorded. The patient was monitored for a 24-hour period for possible side effects of the analgesic agents. The patient's overall satisfaction with the analgesic method was recorded after 24 hours with a 5-point Likert scale.

Data Analysis

Data was collated, tabulated then statistically analyzed using the Statistical Package for Social Science (IBM SPSS) software (version 25, Chicago II, USA). Continuous variables were presented as mean and standard deviation (Mean ± 2SD), while categorical variables were presented as numbers and percentages/proportions.Student t-test was used for comparison between group means for continuous variables while Chi-squared test was used for categorical variables. A difference with a P-value ≤0.05 was considered statistically significant.

Ethical Issues

Ethical clearance was obtained from the Research and Ethics committee of the Teaching Hospital. Each eligible parturient was informed about the study, objectives, procedure and full implication of participation before recruiting those who signed informed consent form. Each of the patients was made to know that their involvement was voluntary and that they could withdraw from participating at any point during the study. They were made to understand that declining or withdrawing from the study will not have any effect on their care from the labor ward staff.All information including history, physical examination findings and results obtained from the participants were kept strictly confidential and was used only for the study. The participants identity was kept confidential by the investigator(s).Method of patient selection was scientifically objective and this ensured fairness. The research did not affect resources for the care of the patient as logistics and manpower were provided by the researchers and assistants. The researchers bore the cost of the investigations and drugs.

III. Results

Table 1: Socio-demographic characteristics of the paturients

Socio-demographic Characteristics	Rectal Diclofenac (n=73)	Oral Diclofenac (n=73)	Testof significance	P-value
Maternal age (yrs)				
<20	1 (1.4%)	1 (1.4%)		
20-35	41(56.2%)	48(65.8%)		
>35	31(42.5%)	24(32.9%)		
Mean (SD)	31.6 (5.2)	30.4 (4.7)	t = 1.463	0.146
Educational status				
None	2 (2.7%)	4 (5.5%)	χ^2= 3.640	0.299
Primary	6 (8.2%)	12(16.4%)		
Secondary	20(27.4%)	21(28.8%)		
Tertiary	45(61.6%)	36(49.3%)		
Occupation				
Civil servant	39(53.4%)	36(49.3%)	χ^2=0.556	0.906
Trader	16(21.9%)	15(20.5%)		
Artisan	8 (11.0%)	10(13.7%)		
Unemployed	10(13.7%)	12(16.4%)		
Marital status				
Single	8 (11.0%)	3 (4.1%)	χ^2=4.091	0.147
Married	63(86.3%)	64(87.7%)		
Divorced/Separated	2 (2.7%)	6 (8.2%)		
Religion				
Christianity	71(97.3%)	67(91.8%)	χ^2=2.402	0.323
Islam	2 (2.7%)	4 (5.5%)		
Others	0 (0.0%)	2 (2.7%)		
Ethnicity				
Igbo	67(91.8%)	63(86.3%)	χ^2=1.308	0.704
Yoruba	3 (4.1%)	5 (6.8%)		
Hausa	2 (2.7%)	3 (4.1%)		
Others	1 (1.4%)	2 (2.7%)		

The socio-demographic characteristics of the participants are shown in table 1.

There was no statistically significant difference between the groups in any of the socio-demographic parameters.

The majority of the women (56.2% and 66.7% for rectal diclofenac group and oral diclofenac group respectively) involved in the study were between 20 and 35 years of age. The mean maternal age for the rectal diclofenac group was 31.6 years (±5.2 years) and the oral diclofenac group was 30.4 years (± 4.7 years).

The table also shows that majority of the women had some form of education for both groups, 97.3% for rectal diclofenac group and 94.5% for oral diclofenac group respectively.

The occupations of the participants were similar in both groups. Majority were civil servants, 53% and 49.3% for the rectal diclofenac group and oral diclofenac group respectively.

The majority of the women involved in the study were also married. Christianity was the predominant religion for the participants as seen in the table; 97.3% of the women in the rectal diclofenac group and 91.8% in the oral diclofenac group were Christians respectively.

Majority of the women in the study were Igbo; 91.8% for the rectal diclofenac group and 86.3% for the control group respectively.

Table 2 shows clinical and obstetrics characteristics of the patients.

The difference in clinical and obstetrics characteristics in the two groups were not statistically significant. Majority of the women were booked, of which 76.7% and 69.9% were booked women in rectal diclofenac and oral diclofenac groups respectively.

The parity of the majority (58.9% rectal diclofenac vs 56.2% oral diclofenac group) of the participants was 1 to 4. The mean gestational age at delivery was 39 weeks $\pm$7.5 weeks for the rectal diclofenac group and 39.3 weeks $\pm$7.9 weeks for the control group. The mean maternal weights were 72.6 $\pm$9.3kg and 73.6 $\pm$11.4kg for rectal diclofenac and oral diclofenac groups respectively. The mean birth weights (SD) were 3.4 $\pm$ 0.5kg and 3.4 $\pm$ 0.6kg for rectal diclofenac and oral diclofenac groups respectively.

Table 2: Clinical and obstetric characteristics of the patients

Clinical and Obstetric Variables	Rectal Diclofenac (n=73)	Oral Diclofenac (n=73)	Test of significance	P-value
Booking status				
Booked	56(76.7%)	51(69.9%)	χ^2= 0.875	0.350
Unbooked	17(23.3%)	22(30.1%)		
Parity				
0	22(30.1%)	16(21.9%)	χ^2=3.662	0.160
1-4	43(58.9%)	41(56.2%)		
≥5	8 (11.0%)	16(21.9%)		
Median (Range)	3 (0 – 8)	4 (0 – 9)		
Gestational age at delivery (weeks)				
37–38	33(45.2%)	24(32.9%)		
39–41	38(52.1%)	46(63.0%)		
≥42	2 (2.7%)	3 (4.1%)		
Mean (SD)	39.0 (7.5)	39.3 (7.9)	t=0.235	0.814
Maternal weight (kg)				
<50	1 (1.4%)	2 (2.7%)		
50–89	63(86.3%)	58(79.5%)		
≥90	9 (12.3%)	13(17.8%)		
Mean (SD)	72.6 (9.3)	73.6 (11.4)	t=0.581	0.562
Birth weight (kg)				
<2.5	0 (0.0%)	2 (2.7%)		
2.5–3.5	44(60.3%)	40(54.8%)		
3.6–4.5	29(39.7%)	31(42.5%)		
Mean (SD)	3.4 (0.5)	3.4 (0.6)	t=0.000	1.000

Table 3a compares the proportion of patients that had different levels of perineal pain relief between rectal diclofenac and oral diclofenac groups using their VAS pain scores at 1, 4, 8, 16 and 24-hours intervals after episiorrhaphy. The table shows that no patient had severe pain after 1-hour post repair. It was also observed that there is no difference in relief of severe pain between the two routes of administration of diclofenac. At 4 and 24 hours, the proportions of patients having mild pains are the same in both groups. The table also shows that the time interval for maximum pain relief was 8 hours for rectal group (76.7%), while it was at 16 hours for oral group (12.3%).

The table also shows the proportion of women that needed rescue analgesia (1000mg stat); 3 women in rectal diclofenac group vs 4 women in oral diclofenac group respectively. The absolute risk of needing rescue analgesia in rectal diclofenac group was less (4.1%) in comparison to (5.5%) oral diclofenac group.

Table 3a: Comparison of VAS at 1, 4, 8, 16- and 24-hours intervals

VAS time	Rectal Diclofenac (n=73)	Oral Diclofenac (n=73)
VAS 1 hr post repair		

0	11(15.1%)	6 (8.2%)
1-3	53(72.6%)	36(49.3%)
4-7	7 (9.6%)	25(34.2%)
8-10	2 (2.7%)	6 (8.2%)
VAS 4 hrs post repair		
0	40(54.8%)	7 (9.6%)
1-3	30(41.1%)	30(41.1%)
4-7	3 (4.1%)	36(49.3%)
VAS 8 hrs post repair		
0	56(76.7%)	8 (11.0%)
1-3	16(21.9%)	19(26.0%)
4-7	1 (1.4%)	46(63.0%)
VAS 16 hrs post repair		
0	44(60.3%)	9 (12.3%)
1-3	25(34.2%)	49(67.1%)
4-7	4 (5.5%)	15(20.5%)
VAS 24 hrs post repair		
0	16(21.9%)	5 (6.8%)
1-3	39(53.4%)	39(53.4%)
4-7	18(24.7%)	29(39.7%)

Proportion that needed rescue analgesia
3(4.1%)
4(5.5%

Table 3b:
Comparing Mean VAS scores at time intervals between the two groups.

Time interval (hours)	Mean VAS scores Rectal Diclofenac (n=73)	Oral Diclofenac (n=73)	t-test	P-value
1	2.2±1.8	3.6±2.5	3.883	<0.001
4	1.0±1.3	3.5±2.0	8.955	<0.001
8	0.5±1.0	4.0±2.1	12.857	<0.001
16	1.0±1.4	2.5±1.7	5.820	<0.001
24	2.4±1.9	3.3±1.9	2.862	0.005

Table 3b compares the mean VAS pain scores at the respective time intervals between the two groups. The results show that women in the rectal diclofenac group had lower mean VAS pain scores at each time interval ($p<0.05$). The table also shows the pain trends in each group. It shows that the time interval for maximum mean pain relief was at 8 hours for rectal group (0.5±1.0), while it was at 16 hours for oral group (2.5±1.7).

Table 4: Comparing the efficacy of rectal diclofenac in perineal pain relief 24 hours after episiorrhaphy.

Group	Perineal Pain relief		Total	Odd Ratio	95% CI	P value
	Yes	No				
Rectal diclofenac	16(21.9%)	57(78.1%)	73 (100%)	3.8	1.227-14.042	0.009
Oral diclofenac	5 (6.8%)	68(93.2%)	73 (100%)			
Total	21(14.4%)	125(85.6%)	146(100%)			

Table 4 shows the odds of having pain relief with rectal route of diclofenac 24 hours after episiorrhaphy. From the table, the probability of having pain relief with rectal route of diclofenac is about 4 times that of oral route (OR =3.8, 95% CI 1.227-14.042).

Table 5: Comparing patients' satisfaction with the treatment

Maternal Satisfaction	Rectal Diclofenac (n=73)	Oral Diclofenac (n=73)	$\chi 2$	P-value
Dissatisfied	1 (1.4%)	7 (9.6%)	28.347	<0.001
Neutral	7 (9.6%)	30(41.1%)		
Satisfied	63(86.2%)	36(49.3%)		
Very satisfied	2 (2.7%)	0 (0.0%)		

Table 5 compares patients' satisfaction in both treatment groups after 24 hours. The table shows that 2 women (2.7%) were very satisfied in the rectal diclofenac group as against none in the control group. Sixty-three women (86.2%) vs 36 women (49.3%) were satisfied in rectal and oral diclofenac groups respectively. The overall difference in the satisfaction is statistically significant ($p<0.001$) in favour of rectal diclofenac group.

IV. Discussion

The findings from this study show that rectal diclofenac is an effective and safe agent for perineal pain relief 24 hours after episiotomy repair.

The mean maternal age of the respondents in the rectal diclofenac group was 31.6 $\pm$ 5.2 years which was similar to the findings in studies done in Ido-Ekiti and Srinagar India, where the mean ages were 30.8$\pm$4.6 years and 30 years respectively [31,32]. This represents the mid reproductive age among the respondents. Majority of the women in the study were Igbo, Christians and civil servants. Thisreflects of the ethnic background of the people of Ebonyi state who are Igbo and predominantly Christians. Majority of the women that seek health care in the study center are civil servants with a tertiary level of education thus the greater number of booked women in both groups. There was no statistically significant difference in gestational ages at delivery and maternal weights in both rectal and oral diclofenac groups ($t=0.235$, $p=0.814$ and $t=0.581$, $p=562$ respectively). This similarity ensured a similar bio-physiological environment for the respondents in both groups. There was no statistically significant difference in both groups for parity ($p>0.160$). The median parity for the rectal group was para 3 and range 0-8, while that of oral diclofenac was para 4 and range 0-9. The finding indicated a higher number of multiparas that went into labor during the study period and the high incidence of episiotomy among them may not be unrelated to increased fetal weight gain in multiparas with associated advanced age as seen in them. This is similar to finding in a study that was done in Sri Lanka [12]. However, this finding was not similar to other studies which had greater incidence of episiotomy among primigravidas.[14,20, 21,33, 31] This may suggest that these centers subconsciously apply a policy of routine episiotomy to primigravidas. Also, there was no statistically significant difference in the birth weights for the study groups with mean birth weights of 3.4 $\pm$0.5 kg and 3.4 $\pm$0.6 kg respectively for rectal and oral diclofenac groups, $t=0.000$, $p=1.000$.

The summary of mean VAS pain scores at the respective time intervals between the two groups shows that women in the rectal diclofenac group had lower mean VAS pain scores at each time interval of 1,4,8,16 and 24 hours post episiorrhaphy. It shows that rectal diclofenac achieved a greater perineal pain relief than oral diclofenac; $p<0.001$, <0.001, <0.001, <0.001 and 0.005 at 1, 4, 8, 16 and 24 hours respectively. This finding was similar to other studies that compared the efficacy of rectal diclofenac in post episiorrhaphy perineal pain relief. [12,13,31,34]The greater efficacy of rectal route may be related to ease of achieving peak plasma concentration which is within 1 hour and the active plasma concentration can last up to 24 hours especially slow release formulations [23,35]. In contrast, Achariyapota et al in their study found no statistically significant difference at 1-hour post repair with rectal diclofenac [14].

The highest in perineal pain relief trend with rectal diclofenac was seen 8 hours post repair where the maximum proportion of 56 (76.7%) women recorded no pain. The mean VAS pain score of 0.5±1.0 ($t=12.857$, $p<0.001$) at the 8-hour post repair was also the lowest mean pain value. This trend is comparable to the study in Ekiti state by Fatai where there was pain relief in the entire patient that had rectal diclofenac at 8 hours post administration [31]. Unlike oral diclofenac that has about 20% reduction in plasma concentration after reaching peak concentration, rectal diclofenac peak plasma concentration is maintained for several hours as described earlier.

This study shows that overall efficacy of rectal diclofenac when compared with oral in perineal pain relief 24 hours after episiorrhaphy is about 4 times more. (OR =3.8, 95% CI= 1.227-14.042). This may be attributed to enhanced local anti-inflammatory properties of rectal diclofenac and also to greater amount of available active serum concentration of the drug due to avoidance of hepatic first-pass effect [13,14]. The result is comparable to Cochrane finding by Hedayati et al which concluded that women were less likely to experience pain at or close to 24 hours after birth with rectal diclofenac compared with placebo (Relative risk 0.37, 95% CI 0.10 – 1.38) [36] and a RCT by Dodd et al who found that women that had rectal diclofenac were significantly less likely to experience pain at 24 hours after episiorrhaphy while walking, sitting, passing urine and on opening bowels compared to women who received placebo [34].

Furthermore, this study also found that fewer women in the rectal diclofenac group had need for rescue analgelsia. Three women (4.1%) in rectal diclofenac group as against 4 women (5.5%) in oral diclofenac group respectively needed rescue analgesia. This is comparable to findings in other related studies across the globe. [13,35,38,38]This may be attributed to peak plasma concentration from rectal route which lasts up to 24 hours especially slow release formulations [23,35]. Similarly, Fatai and Dodd et al found no significant differences in

the need for additional analgesia [34,31]. Though, Fatai in his study used a ceiling dose (100mg) of both oral and rectal diclofenac 12 hourly in his study and this might have affected the need for additional analgesia in both arms [31].

In terms of maternal side effects, this study reported more side effects in the oral diclofenac group when compared to those administered per rectum. Eight respondents (11%) experienced heartburn which is one of the most commonly experienced side effects of oral diclofenac.

Women that received rectal diclofenac were in overall significantly more satisfied with the mode of treatment in comparison to oral diclofenac ($p<0.001$, $\chi^2=28.347$). This is comparable to findings in other similar studies [13,34].This might be attributed to the effective pain control, absent significant side effects and single dosage for the rectal diclofenac.

V. Conclusion

The findings from this study corroborate most of the earlier studies that affirms the effectiveness of rectal diclofenac in relieving perineal pain associated with episiotomy. Comparably, from the study the rectal diclofenac was a more potent analgesia in post-episiorrhaphy pain relief than oral diclofenac, and also with higher satisfaction profile for the users. A single dose of 100mg rectal diclofenac which was used in the study was well tolerated and effective in achieving statistically significant perineal pain relief precluding the need for multiple dosing associated with low dose oral diclofenac.

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Conflict of Interest

The Authors declare no Conflict of Interest.

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