

# Adjuvant Rectal Diclofenac for Post Operative Analgesia after Caesarean Section—A Randomized Controlled Study

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## Abstract

**BACKGROUND:** Pain management following caesarean section still remains a challenge in our environment. Most potent analgesics are either not readily available or expensive. Diclofenac suppository is an NSAID that can be used for postoperative analgesia. It is available and affordable. **OBJECTIVE:** To compare the efficacy and safety of combined rectal diclofenac and intramuscular pentazocine with intramuscular pentazocine alone for post operative pain control following lower segment caesarean section. **METHODOLOGY:** A total of 120 women who met the selection criteria scheduled for caesarean section under spinal anaesthesia with bupivacaine were randomized into two equal groups to receive either 75 mg diclofenac suppository 12 hourly for 24 hours or one anusol suppository (the placebo) 12 hourly for 24 hours. Both groups received pentazocine as primary analgesia. **RESULT:** The primary outcome measure is the proportion of patients with severe pain at 24 hours using the visual analogue rating scale. Secondary outcome measures are the time from surgery to ambulation, Passage of flatus, maternal satisfaction and presence of complications. Statistical analysis was done using spss version 22 and graph pad statistical package. Student T-test was used for continuous variables whereas chi square was used for categorical variables  $P < 0.05$  was considered to be statistically significant. **CONCLUSION:** Adjuvant rectal diclofenac is superior to pentazocine alone in the management of pain after caesarean section. Less number of patients had moderate to severe pain at 24 hours post operation. Maternal satisfaction in relation to pain management is better with diclofenac suppository. The levels of complications were comparable in both groups.

## Keywords

Pain, Caesarean Section, Diclofenac, Placebo, Suppository

## 1. Introduction

Pain in the post operative period is an important impediment to recovery from surgery and anaesthesia. Hence reducing pain after caesarean section or any other surgery is very important [1] [2].

Pain is an unpleasant subjective, sensory and emotional experience associated with real or potential tissue damage or described in terms of such damage [3].

It is an unavoidable post surgical experience and even the most fortunate of patients is not exempted.

Pain management after caesarean section is more complicated because the patients are young, healthy and active who are eager to care for their new born babies. Since the first post partum hours and days are important for interaction between mother and newborn, pain should not interfere with the mothers' ability to nurse her baby [2] [3].

An individual who undergoes surgery would probably consider it his or her right to obtain adequate post operative analgesia. This however is not often the case [4].

Patients continue to suffer silently from post operative pain perhaps because of lack of resolute resolve on the part of the health care providers to relieve this pain.

If one considers adequate pain relief to be a basic right of the patient, which indeed it is, failure to provide it when available may be an ethical violation of the right of patients to benefit from scientific progress and the right to healthcare and protection [4] [5] [6].

In a survey of women's assessment of intra-and post-partum care following vaginal delivery or caesarean section at the University of Nigeria Teaching Hospital, Enugu, Nigeria, poor pain relief was noted by the majority of women as one of the dissatisfying aspects of their care [7] similarly, a study at the University of Ilorin Teaching Hospital (UIH), Ilorin, Nigeria revealed that as much as 54.6% of patients reported moderate to severe pain on the first day following caesarean section [8]. A study done at the University of Benin Teaching Hospital, found that 85% of women would request analgesia in labour if it were available. Yet only 40% of women received any analgesic intervention [9]. A study of postpartum pain in Ibadan, Nigeria showed that two-thirds of patients complained of moderate to unbearable pain twenty-four hours postoperatively [10].

Post operative pain control is an important aspect of post operative care in all surgical subspecialties and more so in obstetrics where it affects mother to child bonding and may also blunt the anticipated joy and excitement that follows the birth of a newborn [3] [11] [12] [13]. Adequate analgesia after caesarean section therefore provides opportunities for mother-child bonding, early ambulation and discharge, hence leading to greater overall patient satisfaction [13] [14].

Patients after caesarean section suffer from two kinds of acute pain: wound pain and spasmodic uterine contraction pain [3] [13] [15]. The ideal analgesic regimen following caesarean section should therefore be able to control pain arising from these two sources. Also, it should be one that is cost effective, sim-

ple to administer and with minimal impact on staff workload. It should provide consistent and high quality pain relief while catering for wide inter-patient variability but have a low incidence of side-effects and complications. It should not interfere with the maternal care of the newborn or with the establishment of breastfeeding and there should be minimal drug transfer into breast milk and no adverse effects on the newborn [13] [16].

The management of acute pain after caesarean section has evolved considerably over the last decade. The general approach to pain management after caesarean section is changing, shifting away from traditional opioids-based “unimodal” therapy toward a “multimodal or balanced” approach.

Several methods for post operative pain are available. Commonly used are opioids such as morphine, pethidine, fentanyl and pentazocine [11]-[16]. Opioids (in particular neuraxial morphine) are effective analgesics and are generally recognized as the “gold standard for post operative analgesia [12] [16] [17]. However, their major disadvantage is the associated sedation, nausea, respiratory depression and risk of addiction [3] [12] [16]. These side effects are dose dependent and also related to the frequency of administration [3] [17]. Some of the more potent opioids such as morphine, pethidine and fentanyl are quite expensive and not readily available in many centres in our environment. This is largely as a result of stringent laws regarding prescription and dispensing of these drugs and strict import restrictions because of fear of addiction and abuse [10] [11] [12] [16]. Less potent opioid derivatives such as pentazocine are therefore commonly used for pain control following caesarean section in our environment [8] [10] [11]. When used alone in the immediate post operative period (*i.e.* the first 24 hours following surgery), as is common in our environment, pentazocine may not provide sufficient analgesia as would more potent opioids such as pethidine [8]. Also, like other opioids, it is not effective in controlling pain arising from spasmodic uterine contractions [3] [18] [19] [20]. There may therefore be a need for an adjuvant analgesic agent in the immediate post operative period that would complement the analgesic properties of commonly used opioids without increasing their side effects.

The unimodal approach (*i.e.* the use of a single analgesic) is commonly used in our environment [8] [10]. Kolawole *et al.* showed that intermittent intramuscular administration of a single analgesic (pentazocine in 86.4% of cases and tramadol in 13.6% of cases) was the method used for immediate post operative pain control following caesarean section in all patients studied [8]. A multimodal approach is presently being advocated [13] [16] [21] [22]. It involves the use of a potent opioids regimen, such as patient-controlled analgesia, neuraxial opioids or parenteral opioids, in combination with other classes of analgesic drugs (usually non-opioids) [13] [16]. Theoretically, the use of analgesic drugs in combination allows for additive or even synergistic effects in reducing pain while decreasing the side effects produced by each class of drug because smaller drug doses are required [21] [22]. One of such regimen is the combination of an opioid with a non-steroidal anti-inflammatory drug (NSAID) [3] [19]. The

opioid is the primary analgesic agent while the NSAID is a secondary or adjuvant analgesic.

Diclofenac sodium is a potent prostaglandin synthesis inhibitor, a non-steroidal anti-inflammatory drug (NSAID) that is usually administered for the relief of musculoskeletal pain and the treatment of inflammations of joint because of its potent analgesic and anti-inflammatory properties [23] [24]. It is also effective in controlling pain from spasmodic uterine contractions and are good antipyretics, reducing postoperative fever-a quality that opioids do not possess [23] [24] [25]. They are available as parenteral, oral and suppository preparations [25]. Use of suppository is easy, painless and there is no need for injection devices. Suppository preparations are particularly suitable in patients who cannot tolerate orally or in whom oral intake is not desirable as is the patient in the immediate post operative period. Also, due to the stimulation of gastrointestinal tract, occurrence of ileus following surgery becomes less likely [26] [27]. Several studies have shown that use of diclofenac sodium (parenteral or rectal) as secondary analgesic following caesarean section is safe and effective in improving the analgesic efficacy of administered opioids as well as reducing the overall opioid requirement [23] [24] [26] [28].

The aim of this study is to ascertain the efficacy and safety of suppository Diclofenac sodium as an adjuvant analgesic agent in the first 24 hours after caesarean section, in low risk patients (*i.e.* without contraindications to the use of NSAIDs) in a resource constrained environment such as ours where a less potent parenteral opioid (in this case pentazocine) is used as the primary modality for the control of acute pain following caesarean section.

## **2. Aim and Objectives of the Study**

### **2.1. Aim of the Study**

To compare the efficacy and safety of combined diclofenac suppository and intramuscular pentazocine with intramuscular pentazocine alone for post operative pain control following transverse lower segment caesarean section.

### **2.2. Objectives**

To compare the proportion of patients with severe pain assessed at 6, 12, 24 and 48 hours post caesarean section among patients managed with combined rectal diclofenac suppository and intramuscular pentazocine and those managed with intramuscular pentazocine alone, at Federal Teaching Hospital, Abakaliki.

To determine if there is any difference in the occurrence of post operative complications between the two groups of patients.

To compare overall patient's satisfaction between the two modalities of treatment.

### **2.3. Null Hypothesis**

There is no difference in the proportion of patients with moderate to severe pain

assessed 24 hours' post-caesarean section in patients treated with combined rectal diclofenac suppository and intermittently administered intramuscular pentazocine compared with those treated with intermittently administered intramuscular pentazocine and placebo suppository.

## **2.4. Alternative Hypothesis**

There is a difference in the proportion of patients with moderate to severe pain assessed 24 hours' post-caesarean section in patients treated with combined rectal Diclofenac suppository and intermittently administered intramuscular pentazocine compared with those treated with intermittently administered intramuscular pentazocine and placebo suppository.

## **3. Methodology**

This is a prospective randomized, double blind, placebo controlled study was conducted at the Obstetrics and Gynaecology Department of Alex Ekwueme Federal University Teaching Hospital, Abakaliki between September 2022 and August 2023. This hospital serves as a major referral center for Ebonyi, Benue and Cross River states. Patients are usually referred from general hospitals, government owned health centers, private hospitals and from other department in the hospital. The patients are usually from different socio-economic settings.

The Obstetrics and Gynaecology Department of Federal teaching Hospital Abakaliki has an annual delivery rate of about 3500 and a caesarean section rate of about 25% presently. Most caesarean sections are done by consultants and senior registrar cadre (especially emergencies).

### **3.1. Study Population**

The study population consist of parturients scheduled for elective or emergency caesarean section who meet selection criteria. Eligible parturients were counseled regarding the study preoperatively. Also, they were educated on the method that would be used in assessing their level of pain following surgery. Those who gave written informed consent were enrolled for the study. Full ethical approval to proceed with the study was obtained from the Research Ethical committee of the Hospital. Also, a prior pilot study was carried out.

### **3.2. Inclusion Criteria**

Willingness to be part of the study.

Healthy parturients at or beyond term scheduled for caesarean section (elective or emergency) and who do not have any contraindication to the use of Non-steroidal anti inflammatory drugs, (NSAID) nor have any of the exclusion criteria.

### **3.3. Exclusion Criteria**

Women with a history of hypersensitivity to non-steroidal anti-inflammatory drugs

History of renal impairment, pre-eclampsia, severe asthma, and gastric or duodenal ulcer.

Antepartum haemorrhage or major postpartum haemorrhage (defined as blood loss greater than 1000 mL). Also, liver or kidney disease, blood disorders, ulcers, heart disease, alcohol use, high blood pressure, eye disease, rectal bleeding, nasal polyps, any allergies—especially aspirin/NSAID allergy

### 3.4. Refusal to Participate in the Study

Patients who undergo general anaesthesia or inability to rate pain due to psychiatric illness.

All eligible parturients received the same form of anaesthesia for caesarean section. Anaesthesia was by spinal anaesthesia with 2 - 2.5 mg hyperbaric Bupivacaine. Also, Intramuscular (IM) pentazocine 30 mg 4 hourly in the first 24 hours was given to all parturients as the primary analgesic, for post operative analgesia. Those who required rescue analgesia in the two groups were compared.

A researcher not involved in the care of the parturients randomly assigned eligible parturients who had given informed consent into two groups, using a computer-generated random number schedule:

Group A (**study group**): received Rectal diclofenac 75 mg 12 hourly  $\times$  2 doses. (Adjuvant analgesic).

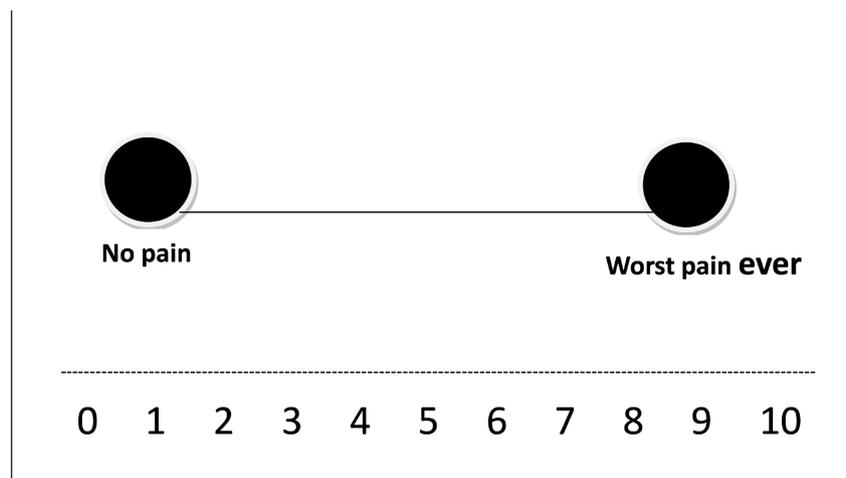
Group B (**Placebo group**): received one rectal tablet of a placebo suppository (Anusol) 12 hourly  $\times$  2 doses.

Anusol suppository (containing Bismuth oxide anhydrous, zinc oxide, Balsam Peru, Bismuth Subgallate) is chosen as the placebo because it has no analgesic property [29]. It has antiseptic, anstringent and emollient properties and is normally used to relief discomfort associated with minor anorectal conditions such as haemorrhoids. Its effect is exerted locally and absorption is minimal hence no systemic side effects is expected [29].

Group allocation was predetermined and placed on consecutively numbered and sealed opaque envelopes. The envelopes contained the study drug diclofenac suppository or the placebo-anusol suppository) for the subjects.

Once the subject was found to be eligible and had given informed consent she was assigned a sequential study number corresponding to the number on the envelope containing the medication; which was opened and treatment commenced. The drug contained in the envelope (either the study drug or placebo) was administered to the patient as a rectal suppository after surgery (at the time of administering the first dose of pentazocine), which was chosen to be two hours after surgery for uniformity. A second dose was repeated in the 12<sup>th</sup> hour by assistants that were not involved in data collection or analysis. The research assistants were Registrars in the Department of Obstetrics and Gynaecology and there had a period of pre-study training. The researcher and the subjects were blinded to which treatment each subject received, until the end of the study, when the envelope number codes were revealed.

Following administration of the rectal medications, the researcher/an assistant interviewed the patients and assessed their level of pain using the visual analogue scale (VAS). The visual analogue scale (VAS) which consist of a pictorial representation on a 10 cm straight line in which the far left end indicates “no pain” while the far right end indicates the “worst pain ever”. Also there is another line exactly the same length and parallel to the first one (*i.e.* 10 cm) calibrated from 0 to 10 with 0 corresponding to “no pain” and 10 to “the worst pain ever”, as shown below. The patients were instructed to point to the position on the line between the faces to indicate how much pain they were currently feeling. The patients were shown the numbered scale. This was used by the researcher to quantify the level of pain on a scale of 0 to 10 corresponding to the point where the patients will indicate the pictorial line. Patients’ level of pain was checked at 6 hours, 12 hours, 24 hours and 48 hours post operatively. The visual analogue scale is shown below:



\* The Visual Analogue Scale (VAS). Card is folded at the dotted line.

The values on the pain scale correspond to pain levels as follows:

0 = no pain;

1 - 3 = mild pain;

4 - 6 = moderate pain;

7 - 10 = severe pain.

This VAS for pain assessment was done at rest at each time of assessment.

The primary outcome measure is the occurrence of moderate to severe pains at 24 hours post operatively using the visual analogue rating scale. Secondary outcome measure is the need for rescue analgesia (total dose used for this purpose) in both groups, Incidence of post-operative pyrexia, time from surgery to ambulation, presence of complications such as postpartum haemorrhage, hematomas, bleeding from wound.

Other parameters such as the demographic variables, mean age, parity, gestational age at delivery, indication for caesarean section and mean duration of surgery were also obtained. At the end of the first day, the patients were asked

whether they are satisfied with the analgesic protocols. Patient responses of “perfect”, “very good” and “good” is regarded as “good results” *i.e.* satisfactory, while “intermediate” and “bad” were regarded as “bad results” *i.e.* not satisfactory. Information regarding gastrointestinal status like the presence of abdominal distension and the time from surgery to the first passage of flatus was also noted.

### 3.5. Sample Size

The calculation of the number of subjects required was based on the following assumption and data.

A type I error ( $\alpha$ ) of 10% and type II error ( $\beta$ ) of 20% together with a power of 80% and a level of significance of 0.05. on the basis of a previous indigenous report by Kolawole on the post operative pain management following caesarean section at University of Ilorin Teaching Hospital (UIH), Ilorin, Nigeria, in which 54.6% of patients managed with a unimodal pain therapy, (IM pentazocine mainly) experienced moderate to severe pains 24 hours after surgery as assessed by verbal rating scale, it is therefore assumed that a 25% decrease in this percentage (*i.e.* the effect size) is significant when adjuvant rectal diclofenac is added. The calculation is as shown below using the formula for calculating sample size for a randomized controlled study with two independent samples with a dichotomous proportion outcome [30].

$$M (\text{size per group}) = C \times \frac{\pi_1(1-\pi_1) + \pi_2(1-\pi_2)}{(\pi_1 - \pi_2)^2}$$

where:

$C = 7.9$  for 80% power;

$\pi_1$  = proportion estimate for control group;

$\pi_2$  = proportion estimate of treatment group;

$$\pi_1 = 54.6\% = \frac{54.6}{100} = 0.546;$$

$$\pi_2 = (\pi_1 - \text{the effect size}) \text{ i.e. } 54.6\% - 25\% = 29.6\% = \frac{29.6}{100} = 0.296.$$

Therefore:

$$M (\text{size per group}) = 7.9 \times \frac{0.546(1-0.546) + 0.296(1-0.296)}{(0.546 - 0.296)^2};$$

$$M (\text{size per group}) = 57.67.$$

Therefore for a two-sided test of 5% and two independent samples with a dichotomous proportion outcome (in this case proportion of parturients with moderate to severe pain 24 hours post operatively) sample size is about 60 subjects per group. (A total of 120 subjects).

Statistical analysis was performed using Student's t-test for continuous variables and chi-square test was used for categorical variables. P-value < 0.05 was considered significant. Analysis was performed using SPSS version 22 and Graph Pad Instant Statistical Package.

## 4. Results

In the study, 120 subjects were randomized into two equal groups with 60 patients each in the diclofenac (group A) and placebo (group B) respectively.

**Table 1** represents the socio-demographic data of both study and placebo groups. The overall mean age of the patients in the study population was  $28.55 \pm 3.50$  years. There was no statistically significant difference in the social-demographic data of both groups.

Also, there is no statistically significant difference in the type of caesarean section, indication for caesarean section, and cadre of surgeons that performed the surgery between both study group and placebo groups, as shown in **Table 2**.

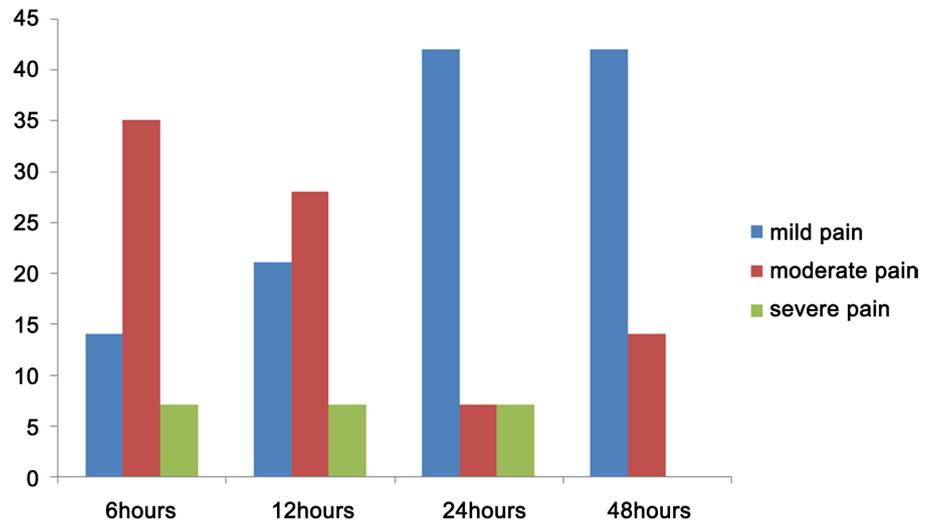
The assessment of pain at 6<sup>th</sup>, 12<sup>th</sup>, 24<sup>th</sup> and 48<sup>th</sup> hours post-operation among the study population was shown in **Table 3**. There is statistically significant difference in the perception of pains at 6<sup>th</sup>, 12, 24<sup>th</sup> and 48<sup>th</sup> hours post-operation. Also, more patients in the placebo group required more rescue analgesia compared to Diclofenac group. Diclofenac also helped in early ambulation after surgery, shortened the period of passage of first flatus from surgery, reduced duration of hospital stay and improved patients' satisfaction post-operation (**Figures 1-3**).

The side effects and complications observed were similar between the Diclofenac and placebo groups. Post-operative pyrexia occurred in 3.38% of patients in the Diclofenac group compared with 8.40% in the placebo group.

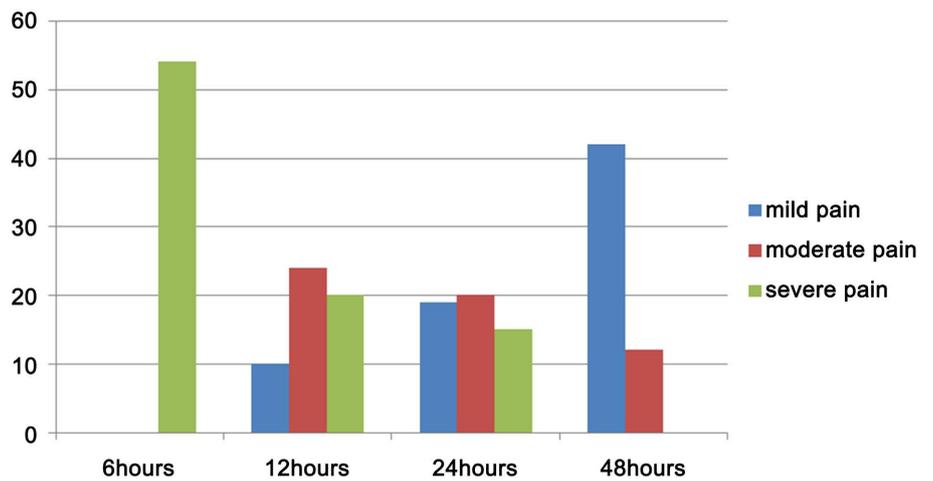
There was no case of secondary post-partum haemorrhage or wound haematoma among patients in both groups. Although a few patients expressed some discomfort with the need for repeated rectal administration of the drugs, otherwise the drugs were generally well tolerated and there was no incidence of diarrhea or anorectal irritation.

**Table 1.** Characteristics of the patients in the study.

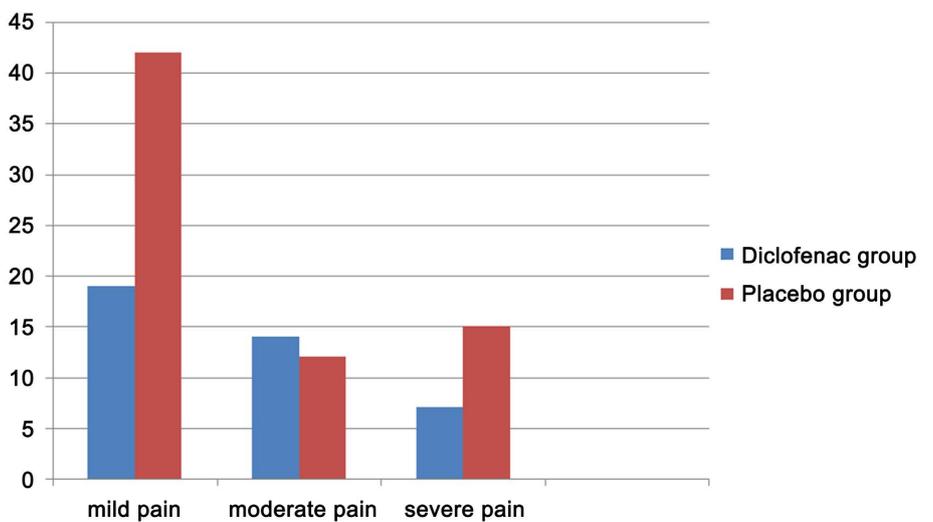
Characteristic	Group A n = 60 (%)	Group B n = 60 (%)	P-Value	X <sup>2</sup>
Mean age (years)	28.75 ± 3.60	29.83 ± 3.56	0.29	10.76
Gestational age* (Weeks)	35.50 ± 0.40	39.06 ± 0.63	0.42	36.25
Parity:	0	8 (13)	10 (16.7)	
	1 - 2	30 (50)	26 (43.3)	
	3 - 4	15 (25)	16 (26.6)	
	≥ 4	7 (12)	8 (13.4)	
BMI (kg/m <sup>2</sup> )	31.88 ± 2.31	28.92 ± 2.60	0.37	10.27
Level of Education:				
No formal education	5 (8.33)	7 (11.67)		
Primary	10 (16.67)	16 (26.7)		
Secondary	30 (50)	33 (55)		
Tertiary	15 (25)	4 (6.67)		



**Figure 1.** Pain assessment in Diclofenac Group.



**Figure 2.** Pain assessment in Placebo Group.



**Figure 3.** Pain assessment at 24 hours in both Groups A and B.

**Table 2.** Type of caesarean section, indication and mean blood loss.

Type of caesarean section	Group A (%)	Group B (%)		
Elective	38 (63.3)	34 (56.7)		
Emergency	21 (37.50)	24 (44.6)		
Indication(s) of caesarean section**				
Characteristic	Group A n = 60 (%)	Group B n = 60 (%)	P-Value	X <sup>2</sup>
≥2 previous C/S	22 (36.67)	11 (18.33)		
Obstructed labour	11 (18.33)	10 (16.67)		
One previous c/s	4 (6.67)	10 (16.67)		
CPD	3 (5)	10 (16.67)		
Foetal distress	13 (21.67)	7 (11.67)		
Transverse/oblique lie	4 (7.14)	3 (5.56)		
Cord prolapse	0 (0.00)	3 (5.56)		
Foetal macrosomia	7 (11.67)	12 (20)		
Mean duration of surgery* (min.)	57.38 ± 6.33	60.17 ± 8.66	0.33	36.05
Mean blood loss at surgery* (ml)	452.00 ± 105.49	491.28 ± 99.92	0.24	12.92

**Table 3.** Pain scores and outcome measures in the study.

Outcome measures	Group A n = 60 (%)	Group B n = 60 (%)	P-Value	X <sup>2</sup>
Pain score (VAS score) at				
6 hours:				
Mild	15 (25)	0.00		
Moderate	37 (61.7)	0.00		
Severe pain	8 (13.33)	60 (100)	<0.001	85.205
12 hours:				
Mild	22 (37)	11 (18.33)		
Moderate	30 (50)	27 (45)		
Severe pain	8 (13.33)	22 (36.67)	<0.00	35.58
24 hours:				
Mild	45 (75.00)	19 (31.67)		
Moderate	8 (13.33)	24 (40.0)		
Severe pain	7 (12.50)	15 (27.8)	<0.001	43.67
48 hours:				
Mild	46 (76.67)	45 (75)		
Moderate	14 (23.33)	15 (25)		
Severe pain	0.00 (0)	0.00 (0)	0.16	8.28
Total no. of rescue analgesia	2 (3.33)	21 (35)		
Mean time from surgery to ambulation (hours)	18.63 ± 3.26	29.22 ± 3.60	<0.001	52.05

**Continued**

Mean time from surgery to 1 <sup>st</sup> passed flatus (hours)	20.50 ± 6.0	24.0 ± 5.0	0.13	
Mean duration of hospital stay (days)	5.5 ± 1.21	7.33 ± 0.97	0.20	19.73
Maternal satisfaction:				
Satisfied	56 (93.33)	45 (75)		
Not satisfied	4 (6.67)	15 (25)	0.11	13.97
Post operative pyrexia	2 (3.38)	5 (8.40)		

**5. Discussion**

This study was conducted to evaluate the effectiveness and safety of rectal Diclofenac as an adjuvant analgesic in a resource constrained setting where more potent opioids are not readily available and hence a less potent opioid derivative-pentazocine is more commonly used as the primary analgesic following caesarean section. Adequate pain control following caesarean section should be aimed at, irrespective of one's setting practice, not only is this good practice, it is as well the right of the patients [4] [6].

In the study, intermittently administered intramuscular pentazocine was used in all patients as the primary analgesic in the first 48 hours following elective or emergency caesarean section. This is comparable to the practice in similar settings in our environment [8] [9] [10] [11] Kolawole *et al.* in their review of the common methods used for post operative pain management following caesarean section at the University of Ilorin Teaching Hospital, Ilorin, Nigeria, found that surgeon prescribed, nurse administered intermittent intramuscular post operative pain control in all the patients evaluated. Pentazocine was used in 86.4% of patients while tramadol was used in 13.6% of patients [8]. This is quite different from other previous studies (mostly from developed countries) on pain control following caesarean section where most opioids and opioid derivatives were administered with patient controlled analgesia (PCA) or patient controlled epidural analgesia (PCEA), that require the presence of anaesthetist, special equipment and well trained nurses, to supervise the care of these patients [17] [19] [24]. This practice is not routine in our environment presently. It probably will be in the nearest future, when there is more interest and funding of post operative analgesia.

In this study, majority of the patients were multiparous (87.5% and 85.3% for the Diclofenac and placebo groups respectively). This is similar to the findings from previous studies [31] [32]. In the study by Surakarn *et al.* in Thailand, aimed at evaluating the effectiveness of intramuscular Diclofenac for post operative analgesia following caesarean section, 70% and 85% of patients in the diclofenac and placebo groups respectively were multiparous [31]. Also most of the patients in this study had secondary level of education. This is the general pattern observed among the patients seeking obstetric services in our facility.

In this study, unlike in the study of Olofsson *et al.* where only patients who

had elective caesarean section were studied, patients scheduled for both elective and emergency caesarean sections were recruited, the majority of whom had elective caesarean section. Thus most of the caesarean sections were carried out by senior registrar cadre who more often perform the emergency surgeries especially during call hours.

Diclofenac sodium is a potent non-steroidal anti-inflammatory drug (NSAID) that is effective in the control of visceral pain following caesarean section [12] [13]. The findings from this study shows that the use of Diclofenac suppository as an adjuvant to intermittently administered IM pentazocine is associated with better pain control when compared with Pentazocine and placebo. The proportion of patients with moderate to severe pains assessed at 6 hours, 12 hours and 24 hours were significantly lower in the Diclofenac group compared with those in the placebo group. Only 13.3 (8/60) of the patients in the Diclofenac group still had moderate pain at 24 hours post caesarean section compared to 40.0% (24/60) of those in the placebo group. While 28.3 (17/60) of the patients in the placebo group still complained of severe pain 24 hours post caesarean section (Twenty one of whom had additional rescue analgesia with an extra dose of IM pentazocine). Only 11.67% (7/60) of the patients in the Diclofenac group still had severe pains 24 hours post operatively. In the study by Kolawole *et al.*, 54.6% of the patients (managed with a unimodal therapy with intermittently administered IM pentazocine or tramadol) still complained of moderate to severe pains 24 hours post caesarean section [8]. This is comparable to 40.0% of patients in the placebo arm of present study (Who had intermittent IM Pentazocine plus placebo) who still had moderate to severe pains 24 hours post operatively. In this study, adjuvant suppository Diclofenac apparently reduced the proportion of patients with moderate to severe pains at 24 hours by about 25%. Moderate to severe pain in group A was 25% (15/60) while moderate to severe pain in the placebo group was 68.3% (41/60). This difference is statistically significant  $P < 0.001$ .

Most of the previous studies on rectal Diclofenac for post operative pain control are from settings where more potent opioids are used as the primary analgesic agent and the main challenge in these settings, is reducing the side effects associated with the opioids without necessarily compromising efficacy [19] [32] [33]. These side effects of opioids are generally dose dependent and have grave consequences on the obstetric patients in the immediate post operative period [3] [16] [17]. Opioids are associated with the risk of respiratory depression, sedation and constipation, which could prevent early ambulation and breastfeeding [12] [16] [17]. The use of Diclofenac preparations in these studies are aimed at primarily reducing the amount of opioids required and hence their untoward effects, while maintaining or in fact, improving efficacy; a concept referred to as “balanced analgesia”. In this study however, the setting is quite different. The use of rectal Diclofenac is to compliment the analgesia provided by less potent opioid derivative (pentazocine) used as the primary analgesic agent. There is

paucity of studies in the literature with similar design as the present study in Nigeria.

In a similar study by Surakam *et al.* in Thailand, the effectiveness of intramuscular Diclofenac for post caesarean section pain control was assessed. In this randomized controlled trial, all the patients had spinal anaesthesia with 10 - 12 mg hyperbaric bupivacaine plus 0.2 mg morphine [31]. Forty patients in each group were randomized to receive either two doses of 75 mg of intramuscular Diclofenac 12 hours apart or only to receive rescue analgesia with intramuscular tramadol 50 mg.

Those in the study group who required additional analgesia for intractable pain also had 50 mg of intramuscular Diclofenac administered. The number of patients requiring rescue analgesia was the primary outcome of interest. Two patients required rescue analgesia in the Diclofenac group compared to 21 (35%) of patients who required rescue analgesia in the placebo group [P = 0.05] [31]. This study however had no placebo control group; hence a placebo effect could not be excluded. Though the design of the by Surakarn *et al.* is quite different from this study, it however is in keeping with the finding from this study that Diclofenac is effective for pain control after caesarean section (even when used alone as in their study).

The finding of better pain control after caesarean section with the use of adjuvant Diclofenac suppository in this study is quite remarkable. This is because apart from allowing early mother to child bonding and earlier commencement of breastfeeding, adequate analgesia affords early ambulation after caesarean section, thus decreasing the risk of thrombo-embolism which is a recognized complication from prolonged immobilization following pelvic surgery especially in pregnancy; which in itself is a risk factor for venous thrombo embolism [3] [13] [16]. In this study the mean duration from surgery to first ambulation was shorter in the Diclofenac group compared to the placebo group;  $18.08 \pm 3.26$  hours versus  $29.2 \pm 3.6$  (6.85) hours respectively.

Suppository preparations are generally known to have stimulatory effect on the gastrointestinal tract hence reducing the incidence of post operative lieus in patients who have had an abdominal/pelvic surgery [34] [35]. Findings from this study show that use of rectally administered Diclofenac is associated with earlier time from surgery to first passage of flatus compared to placebo. Anusol (used as the placebo in this study) itself has stimulatory effect on the gastrointestinal tract. It contains Bismuth oxide anhydrous. Zinc oxide, Balsam Peru and Bismuth subgallate [29]. It acts locally and has a protective and soothing effect on the mucous membrane of the rectum [29]. It is used primarily to provide symptomatic relief of uncomplicated haemorrhoids or post operatively after ano-rectal surgical procedures [29]. This study however showed that rectal Diclofenac may have more gastrointestinal stimulatory effect than anusol. Similar finding of a shorter time from surgery to passage of first flatus was also noted among patients who received intramuscular Diclofenac alone or a combination of Diclo-

fenac and meperidine compared to those who had Intramuscular meperidine alone in the prospective randomized controlled trial by Bozkurt *et al.* [23].

Patient's satisfaction is an essential consideration concerning many interventions in clinical practice, especially in this era of evidence based medicine and when the choices of patients are increasingly becoming important. This study shows that a majority of patients in the Diclofenac group were satisfied with analgesia compared to those in the placebo group, 93% (56/60) versus 75 (45/60) respectively [P = 0.11]. Generally, however, the level of patient's satisfaction was appreciably high in both groups. This finding is comparable to the finding in the local study by Kolawole *et al.* in Ilorin, in which as much as 85.2% of patients expressed satisfaction with the level of pain relief from the use of intermittently administered intramuscular pentazocine or tramadol.

Non-steroidal anti inflammatory drugs (NSAIDS) have been associated with increased risk of bleeding following surgery due to their adverse effect on platelet function and uterine contractibility [25] [36]. For this reason patients with increased risk of bleeding or platelet dysfunction (e.g. patients who had Pre-eclampsia, gastric or duodenal ulcer, antepartum haemorrhage or major post partum haemorrhage; defined as blood loss greater than 1000 mL) were excluded from this study. There was no case of secondary postpartum haemorrhage or wound haematoma prior to discharge home in any of patients recruited in both groups of this study. This finding of no untoward effect with the use of Diclofenac is similar to that from prior studies [19] [26] [27] [28]. Although some patients in both arms of the study expressed some reservation with regards to repeated suppositories administration, the drugs were generally well tolerated.

## 6. Conclusions

Post operative pain control is a very important aspect of post operative care.

The use of 75 mg of rectal Diclofenac administered 12 hourly for the first 24 hours following transverse lower segment caesarean section is safe and effective as an "adjuvant analgesic" to intermittently administered intramuscular pentazocine—a less potent opioid derivative, used as the primary analgesic agent. It is associated with a significant reduction in the proportion of patients with moderate to severe pains assessed 24 hours post operatively, a shorter duration from surgery to ambulation as well as a shorter duration from surgery to first passage of flatus. Also, it is associated with a better overall patient satisfaction compared to intermittently administered intramuscular pentazocine alone. This finding is of relevance especially in resource constrained settings like ours where adequate analgesia can still be achieved even when more potent such as pethidine, fentanyl and morphine are not readily available.

## 7. Recommendation

We recommended that the approach towards immediate post operative pain control (especially following caesarean section) in our environment be changed

from the present “unimodal approach” to one with a “multimodal strategy” involving the use of at least two different analgesic agents with different mechanisms of action such as the combination of an NSAID (e.g Diclofenac) and an opioid or opioid derivation (e.g Pentazocine) as was done in this study. Further studies are required to ascertain if a single higher dose of Diclofenac suppository, for instance 100 mg, administered immediately after surgery, while cleaning up the patient still in the theater, will be as effective for the post operative pain control. This may be beneficial in reducing the discomfort to the patients associated with repeated rectal doses. It is also recommended that similar studies be carried out in other study groups in our environment, especially following gynaecological procedures such as myomectomy and hysterectomy. These patients are also mostly managed by a unimodal strategy for immediate post operative analgesia in our environment.

## 8. Limitations of the Study

1) In this study though maternal satisfaction with analgesic used is what was evaluated, responses of patients may be influenced by other factors such as neonatal outcome as well as the psychological state of the patient at the time of evaluation.

2) Pain assessment in this study was done with patients at rest (lying down or sitting up). Pain assessment should ideally also be done during specifically directed movements.

3) Bowel motion could be influenced by anusol hence affecting result.

4) Maternal pain perception for elective and emergency caesarean section would not be the same. This will also affect result.

5) Study was expensive.

6) Data collection was difficult because it required staying at the hospital premises late into the night.

## Conflicts of Interest

We declare that there is no conflict of interest with respect to this research work.

The cost of the study was borne entirely by the researchers.

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