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Pentazocine with rectal diclofenac versus pentazocine alone for pain relief following caesarean delivery in Enugu, Nigeria: A randomized controlled trial

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Abstract

Objective: To measure postoperative pain relief following the use of rectal diclofenac combined with intramuscular pentazocine compared with intramuscular pentazocine alone in patients undergoing a caesarean delivery.

Methods: This single-blind randomized controlled trial enrolled pregnant women that had a caesarean section at the Enugu State University of Science and Technology Teaching Hospital,

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Enugu, Nigeria. Study participants were randomized to receive either 100 mg of rectal diclofenac given every 12 h plus 30 mg of intramuscular pentazocine given every 6 h (group A) or 60 mg of intramuscular pentazocine given every 6 h (group B). The primary outcome was the level of pain as measured using a visual analogue scale. The secondary outcomes were the level of satisfaction with pain relief and need for rescue analgesia.

Results: A total of 200 participants were randomized equally into the two groups. Participants in group A had significantly better pain control and satisfaction over the 48 h after surgery compared with group B. Significantly more of group B required rescue analgesia for breakthrough pain compared with group A.

Conclusion: Rectal diclofenac combined with intramuscular pentazocine was significantly better at controlling pain compared with pentazocine alone in the first 48 h following caesarean section.

Trial registration number: PACTR202107706925314 at www.pactr.org on 28 July 2021.

Keywords

Analgesia, pentazocine, rectal diclofenac, caesarean delivery, Enugu

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Introduction

A caesarean delivery represents the most significant operative intervention in all of obstetrics. Its development and application have saved the lives of countless mothers and infants. Over the years, the rate of caesarean delivery has been on the rise.[1,2] This is mainly due to improvements in anaesthesia, surgical techniques, antibiotics, blood transfusion services and maternal requests.[3–6]

Recent research shows a global caesarean delivery rate of 18.6%, ranging from 6–27% in the least and most developed countries.[2] The caesarean delivery rate in Nigeria varies from 18.5% to 34.5%.[3,4] Some of these rates, especially those from the Enugu State University of Science and Technology – Teaching Hospital (ESUTH), Enugu, Nigeria are double that of the World Health Organization recommended rate of 10–15%.[7]

Following recovery from anaesthesia, the immediate postoperative period can be tumultuous if adequate analgesia is not provided. This can impede recovery, decrease mother–child bonding and increase hospital stay with its consequent socioeconomic impact.[8] Poor pain control after a caesarean delivery can also lead to uterine sub-involution, increased risk of post-partum haemorrhage and thromboembolic events.[5,6] Studies have shown that a significant proportion of women experience severe pains after caesarean delivery.[9,10] It is therefore important to provide adequate analgesia and initiate a regimen that will provide effective, safe, cheap and acceptable pain relief to mothers.

Opioids have long been the main stay of analgesia since antiquity.[11] They act by inhibiting nociceptors at various sites in the body especially along the central nervous system (CNS; cerebral cortex, mid brain and spinal cord).[12] However, due to their numerous side-effects such as nausea, vomiting, sedation, constipation and tendency for addiction, their use or dose is being decreased.[11] In contrast, nonsteroidal anti-inflammatory drug (NSAIDs) act by

inhibiting the cyclooxygenase (COX) enzymes thereby decreasing the synthesis of prostaglandins and thromboxanes throughout the body.[13] This decreases pain transmission.

Effective analgesia is required in Nigerian women after caesarean delivery even more so because of the poor pattern of obstetric analgesia offered to patients.[14,15] This poor utilization of obstetric analgesia further strengthens the need for effective post-delivery analgesia especially after caesarean delivery. The use of two or more classes of analgesics could lead to better pain management and probably reduces the dose of each drug to the minimum effective dose thereby reducing the side-effects associated with higher single dose regimens.[16,17] The use of rectal diclofenac (an NSAID) and parenteral pentazocine (opioid analgesic) may provide both acute and prolonged analgesia cover through their synergistic actions and different mechanisms of action.[12,13] Studies have shown better patient satisfaction and improved recovery following combined opioid-NSAID analgesia.[16–19] The use of rectal diclofenac is more comfortable for patients, as it is rapidly absorbed with partial avoidance of the first-pass effect; unlike intramuscular diclofenac, which is painful and may rarely cause necrotizing fasciitis, limb gangrene and anaphylactic shock.[20–22]

Recently, there has been newer techniques of trying to achieve optimum analgesia after caesarean deliveries.[23–25] All of these techniques aim to provide a pain-free caesarean delivery. These modalities include transversus abdominis plane (TAP) block, ilioinguinal-iliohypogastric (IL-IH) nerve block, wound infiltration/infusion, ketamine and the use of gabapentin.[23,24] All of these newer techniques have been developed to reduce the dose of opioids required after caesarean delivery. However, most of these newer non-opioid techniques are not readily available in public hospitals in our environment.

This current study compared the effectiveness of rectal diclofenac combined with intramuscular pentazocine and intramuscular pentazocine alone for pain relief in the first 48 h following an elective caesarean delivery among pregnant women in ESUT-TH, Enugu, Nigeria. The objectives were to determine and compare the patient's level of pain perception, the level of patient satisfaction following pain relief and the requirement for breakthrough analgesia following the administration of pentazocine and rectal diclofenac and pentazocine alone among participants.

Patients and methods

Study design and setting

This single-blind randomized clinical trial recruited pregnant women that underwent uncomplicated caesarean sections under spinal anaesthesia at the Department of Obstetrics and Gynaecology, ESUT-TH, Enugu, Nigeria between 1 May 2021 and 30 November 2021. ESUT-TH is one of two teaching hospitals in the state and it offers both primary and specialized health services to the people of Enugu and its environs. The hospital is the only maternity teaching hospital located in the Government Residential Area in the heart of Enugu metropolis and it is easily accessible by several road networks. The hospital runs 24-h comprehensive maternity services and serves as a referral centre for maternity homes and health centres in Enugu state and other adjourning states in the south-east geopolitical zone of Nigeria. Enugu is the capital city of Enugu state, which is in the South-eastern geopolitical zone of Nigeria. The inclusion criteria were as follows: (i) women $\geq$18 years of age; (ii) consenting women with a singleton pregnancy at term gestations (37–42 weeks);

(iii) patients that underwent lower segment caesarean delivery under spinal anaesthesia. The exclusion criteria were as follows: (i) women with a known history of peptic ulcer disease; (ii) women with known allergies to NSAIDs and pentazocine; (iii) women with known sickle cell disease; (iv) women with asthma; (v) women with a history of stillbirth; (vi) women with opioid dependency; (vii) eclamptic and preeclamptic women on $MgSO_4$; (viii) obese women; (ix) women with a history of a caesarean section with epidural analgesia/general anaesthesia or those that used other forms of post-caesarean section analgesia such as TAP block, wound infiltration or IL-IH block; (x) caesarean deliveries that lasted >90 min. The reporting of this study conforms to the CONSORT statements.[26]

The study was approved primarily by the Ethical Review Committee of ESUT-TH before this study was commenced. Ethical approval was granted on 8 August 2018 (no. ESUTHP/C-MAC/RA/034/Vol.11/57.2). An approval was also obtained from the West African College of Surgeons before the research work was started. Written informed consent was obtained from all of the participants at the point of recruitment to the study.

Study interventions

The study involved two study, groups A and B. Group A had participants that received 100 mg of rectal diclofenac (Lofnac®; Gopalds Visram, Mumbai, India; marketed by Green Life Pharmaceutical, Lagos, Nigeria) that was given every 12 h plus 30 mg of intramuscular pentazocine (Fortwin®; Ranbaxy Labs, Gurgaon, Haryana, India) given every 6 h. Group B participants received 60 mg of intramuscular pentazocine alone given every 6 h. These medications were given immediately after surgery for 48 h. Intramuscular tramadol was used as rescue pain relief for breakthrough pain during the study and the amount administered was recorded.

Outcome measures

The primary outcome measure was the level of pain perception measured using a visual analogue scale (VAS) for pain. Prior to caesarean delivery, the participant (blinded to the treatment allocations) was taught on how to use the VAS for pain perception and the Likert scale for level of satisfaction at enrolment prior to surgery. The VAS was calibrated in mm from 0–100 mm, with a demarcated midpoint, anchored by 2 verbal descriptors, one for each symptom extreme. The pain symptom intensity was graded from 'no pain' (score of 0) to 'worst imaginable pain' (score of 100). The severity of the pain was scored as follows: no pain (0–4 mm), mild pain (5–44 mm), moderate pain (45–74 mm) and severe pain (75–100 mm). A 4-point Likert scale (very dissatisfied, dissatisfied, satisfied and very satisfied) was used.

The secondary outcomes were level of satisfaction from pain relief, need for rescue analgesia when there was moderate-to-severe pain, maternal side-effects, time of onset of bowel movement, time of onset of ambulation, time of onset of breastfeeding and discharge from hospital.

Randomization, allocation concealment and blinding

Randomization was undertaken via block randomization on blocks of 4 in a ratio of 1:1. Following determination of all possible combinations of assignments [six combinations: AABB, BBAA, ABAB, BABA, ABBA, BAAB]. The blocks were randomly chosen from random numbers generated via an uninvolved party using random number generator on Microsoft® Excel® (Microsoft Corporation, Redmond, WA, US).

Recruited patients were assigned to either group A or B. Concealment of allocation was done by means of consecutively opaque wrapped numbered envelopes. The envelopes were stowed and untied in the labour room by a member staff of the hospital that was not involved in the study. The allocations of participants were unchanged following the opening of the envelopes. Each envelope enclosed a folded slip of paper revealing either 'combined diclofenac and pentazocine (group A)' or 'pentazocine only (group B)'. The treatment allocation of each participant in the study was made known to the post-natal ward nurses (in writing) by the unit randomizing the patients. The patients in either group were blinded to the surgeons and outcome assessors (research assistants). The nurses administered both the rectal diclofenac and intramuscular pentazocine while the patient was screened from other patients in the ward.

Sampling procedure

The participants were recruited mainly from the antenatal ward and occasionally from the labour ward. Detailed histories were collected from the patients and they were told about the study and informed consent was provided. Their biodata was recorded in the proforma. The participants were subsequently randomized into either group by the randomization unit, which were not part of the study and were mostly offsite. They were usually contacted via telephone call. Visible stickers were placed on the folders of recruited patients prior to the surgery. Patients undergoing both emergency and elective caesarean sections were included in the study, with the vast majority being elective cases. The surgeries were undertaken by specialist registrars and consultants. The surgeries included both primary and repeat caesarean deliveries.

Spinal anaesthesia was administered by an anaesthetist with the patient sitting up and flexing her back as much as possible. Heavy bupivacaine (2–2.5 ml) was injected into subarachnoid space via the L3–L4 spinal space using a G-25 or G-24 Whitacre needle. A Bromage score of at least 3 was required before surgery was commenced. After surgery, the patients were taken to the post-natal ward where the VAS cards and Likert scale with pencils were given to them. They were encouraged to mark off the VAS card at the appropriate times. Visible stickers were also placed on the bed head charts to alert the nurses that the clients were participating in a study. At 1 h after caesarean delivery, the drugs were administered as described above. The pain perception was assessed by the patient using the VAS score for pain at 1 h, 12 h, 24 h, 36 h and 48 h after surgery. The Likert scale for level of satisfaction with pain relief was assessed at 48 h after surgery by the patient. The need for breakthrough analgesia, onset of initiation of breastfeeding, mobilization and maternal side-effects were checked 48 h after surgery by the research assistants. The duration of hospital stay was also recorded at discharge. The data were retrieved by research assistants that were blinded to the treatment allocations and the proforma adequately filled. The collated data were inputted in Microsoft® Excel® (Microsoft Corporation) worksheet and handed over to the statistician for analysis.

Statistical analyses

The minimum sample size (n) for the study was determined using the statistical formula stated below:[27]

$$\boldsymbol{n} = \frac{2[(\boldsymbol{a} + \boldsymbol{b})^2 \ \boldsymbol{\sigma}^2]}{(\mu_1 - \mu_2)^2}$$

where, n = sample size for each group, $a = 1.96$ i.e. Z score for α error of 5% (95% confidence level), $b = 0.80$ i.e. Z score for estimated study power of 80%, σ^2 = population variance (SD) of the outcome in the control group, $\mu_1 - \mu_2$ = minimum difference between the means of study and control groups. A related study undertaken in Abakaliki, Nigeria found the SD of the mean at 12 h pain perception on the VAS to be 3.97.[18] Assuming a standardized effect of 0.4 and an attrition rate of 5% sample size per group, total sample size for the study was 200 participants.

All statistical analyses were performed using IBM SPSS Statistics for Windows, Version 25.0 (IBM Corp., Armonk, NY, USA). Normal distribution of data was tested for. Categorical data that were normally distributed were compared using Pearson's χ^2-test. Continuous data are presented as mean ± SD and compared using Student's *t*-test for normally distributed data or Man–Whitney *U*-test for data that were not normally distributed. A *P*-value <0.05 was considered statistically significant.

Results

A total of 215 women were assessed for eligibility, of which 15 were excluded. The remaining 200 participants were enrolled into the study with 100 randomly allocated to each group. All 100 participants in both groups completed the study and had their data analysed for the primary outcome of the study. There were no significant between-group differences in the demographic and clinical characteristics shown in Table 1. The mean ± SD age of the participants in group A and B were 29.64 ± 5.90 and 30.87 ± 5.15 years, respectively (Table 1). The mean ± SD gestational age was 38.24 ± 1.41 in group A and 38.77 ± 1.51 in group B. A total of 83 of 200 participants (41.5%) in the study were between the ages of 26–32 years. Only 13 of 200 participants (6.5%) were >40 years. The majority of participants were married (195 of 200 participants; 97.5%) and had received tertiary education (179 of 200 participants; 89.5%).

Table 2 shows the level of pain perception amongst participants in the two study groups. The mean VAS score at 1 h after surgery in group A was 40.47 compared with 39.94 in group B. The difference between the two groups was not significant. The VAS pain scores were significantly lower in group A compared with group B from 12 h to 48 h after surgery ($P < 0.001$).

Table 3 shows the level of satisfaction with the pain relief. In group A, 92 of 100 participants (92%) were satisfied compared with 76 of 100 participants (76%) in group B ($P = 0.004$). There were no significant differences in the levels of satisfaction with the pain relief based on the booking status, type of caesarean delivery and prior caesarean delivery.

Table 4 shows the need for rescue analgesia in the two groups. A total of 15 of 100 participants (15%) received at least one rescue analgesia in group A compared with 26 of 100 participants (26%) in group B ($P = 0.001$).

In terms of maternal side-effects, 15 of 100 participants (15%) had drowsiness in group A, which was significantly lower than the rate seen in group B (50 of 100 participants; 50%) ($P = 0.001$) (Table 5). Nausea occurred in two participants in each group. Overall, the majority of the participants (131 of 200 participants; 65.5%) had no drowsiness or nausea. Significantly more patients in group A were ambulatory in <12 h compared with group B ($P = 0.02$). The onset of breastfeeding in <12 h was significantly more common in participants in group A compared with group B ($P = 0.003$). There were no significant differences between the

Table 1. Demographic and clinical characteristics of participants ($n = 200$) that underwent caesarean sections and were included in a study to measure the effectiveness of rectal diclofenac combined with intramuscular pentazocine (group A) and intramuscular pentazocine alone (group B) for pain relief in the first 48 h.

Characteristic	Group A $n = 100$	Group B $n = 100$	Total cohort $n = 200$	p value
Age group				
19–25 years	17 (17.0)	19 (19.0)	36 (18.0)	2.11 (0.55)
26–32 years	41 (41.0)	42 (42.0)	83 (41.5)	
33–39 years	33 (33.0)	35 (35.0)	68 (34.0)	
>40 years	9 (9.0)	4 (4.0)	13 (6.5)	
Age, years	29.64 ± 5.90	30.87 ± 5.15	31.25 ± 5.54	
Marital Status				
Single	2 (2.0)	3 (3.0)	5 (2.5)	0.009 (0.99)
Married	98 (98.0)	97 (97.0)	195 (97.5)	
Level of education				
Primary	2 (2.0)	0 (0.0)	2 (1.0)	2.06 (0.36)
Secondary	9 (9.0)	10 (10.0)	19 (9.5)	
Tertiary	89 (89.0)	90 (90.0)	179 (89.5)	
Occupation				
Professional	15 (15.0)	18 (18.0)	33 (16.5)	0.44 (0.93)
Civil servant	28 (28.0)	25 (25.0)	53(26.5)	
Business	34 (34.0)	34 (34.0)	68 (34.0)	
Unemployed	23 (23.0)	23 (23.0)	46 (23.0)	
Partner occupation				
Professional	15 (15.0)	10 (10.0)	25 (12.5)	1.15 (0.56)
Civil servant	11 (11.0)	12 (120.)	23 (11.5)	
Business	74 (74.0)	78 (78.0)	152 (76.0)	
Booking status[a]				
Booked	100 (100.0)	97 (97.0)	197 (98.5)	1.35 (0.25)
Unbooked	0 (0.0)	3 (3.0)	3 (1.5)	
Parity				
Primiparous	27 (27.0)	37 (3.07)	64 (32.0)	2.77 (0.25)
Multiparous	66 (66.0)	59 (59.0)	125 (62.5)	
Grand multiparous	7 (7.0)	4 (4.0)	11 (5.5)	
Gestational age, weeks	38.24 ± 1.41	38.77 ± 1.51	38.50 ± 1.48	

Data presented as mean ± SD or n of participants (%).

[a]Booking status defined women based on whether they had registered and attended antenatal clinics (booked) or had not registered and attended antenatal clinics (unbooked).

No significant between-group differences, $P \geq 0.05$; categorical data were compared using Pearson's χ^2-test; continuous data were compared using Student's t-test.

two groups in terms of the onset of bowel movements and duration of hospital stay.

Discussion

The objectives of this current study were to determine and compare the patient level of pain perception, their satisfaction with the level of pain relief and the need for breakthrough analgesia following administration of pentazocine and rectal diclofenac (group A) or pentazocine alone (group B) among participants undergoing caesarean deliveries in Enugu, Nigeria. The current findings

Table 2. Visual analogue scale pain scores of participants ($n = 200$) that underwent caesarean sections and were included in a study to measure the effectiveness of rectal diclofenac combined with intramuscular pentazocine (group A) and intramuscular pentazocine alone (group B) for pain relief in the first 48 h.

Postoperative time point	Group A $n = 100$	Group B $n = 100$	Statistical analyses[a]	95% CI
1 h	40.47 ± 34.27	39.94 ± 34.31	NS	0.73, 0.84
12 h	37.84 ± 24.36	55.81 ± 24.92	$P < 0.001$	0.02, 0.015
24 h	32.65 ± 20.87	52.81 ± 22.97	$P < 0.001$	0.009, 0.015
36 h	25.37 ± 16.81	44.49 ± 22.20	$P < 0.001$	0.013, 0.016
48 h	19.26 ± 15.80	36.76 ± 18.70	$P < 0.001$	0.013, 0.016

Data presented as mean ± SD.
[a]Groups were compared using Mann–Whitney *U*-test; NS, no significance between-group difference ($P \geq 0.05$).
CI, confidence interval.

Table 3. The levels of satisfaction with pain relief in participants ($n = 200$) that underwent caesarean sections and were included in a study to measure the effectiveness of rectal diclofenac combined with intramuscular pentazocine (group A) and intramuscular pentazocine alone (group B) for pain relief in the first 48 h.

	Satisfied $n = 168$	Not satisfied $n = 32$	Total cohort $n = 200$	Statistical analyses[a]
Study groups				
Group A	92 (54.8)	8 (25.0)	100 (50.0)	$P = 0.004$
Group B	76 (45.2)	24 (75.0)	100 (50.0)	
Booking status				
Booked	165 (98.2)	32 (100.0)	197 (98.5)	NS
Unbooked	3 (1.8)	0 (0.0)	3(1.5)	
Type of caesarean				
Elective	153 (91.1)	28 (87.5)	181 (90.5)	NS
Emergency	15 (8.9)	4 (12.5)	19 (9.5)	
Prior caesarean				
Previous	88 (52.4)	18 (56.3)	106 (53.0)	NS
Primary	80 (47.6)	14 (43.8)	94 (47.0)	

Data presented as *n* of participants (%).
[a]Groups were compared using Pearson's χ^2-test; NS, no significance between-group difference ($P \geq 0.05$).

showed that participants in the combined diclofenac-pentazocine group (group A) had significantly better pain control and satisfaction over the first 48 h after a caesarean section compared with pentazocine alone (group B). Significantly more participants that received pentazocine alone (group B) required rescue analgesia for breakthrough pain management compared with participants in the combined diclofenac-pentazocine group (group A).

Provision of adequate postoperative analgesia is one of the most important priorities among women undergoing a caesarean delivery.[28] The current study demonstrated that participants in the combined diclofenac-pentazocine group (group A) had significantly better pain control over

Table 4. Need for rescue analgesia among study participants ($n = 200$) that underwent caesarean sections and were included in a study to measure the effectiveness of rectal diclofenac combined with intramuscular pentazocine (group A) and intramuscular pentazocine alone (group B) for pain relief in the first 48 h.

Number of rescue analgesia	Group A $n = 100$	Group B $n = 100$	Total cohort $n = 200$	Statistical analyses[a]
0	85 (85.0)	74 (74.0)	159 (79.5)	P = 0.001
1	11 (11.0)	4 (4.0)	15 (7.5)	
2	4 (4.0)	19 (19.0)	23 (11.5)	
3	0 (0.0)	3 (3.0)	3 (1.5)	

Data presented as *n* of participants (%).
[a]Groups were compared using Pearson's χ^2-test.

Table 5. Comparison of maternal outcomes among study participants ($n = 200$) that underwent caesarean sections and were included in a study to measure the effectiveness of rectal diclofenac combined with intramuscular pentazocine (group A) and intramuscular pentazocine alone (group B) for pain relief in the first 48 h.

	Group A $n = 100$	Group B $n = 100$	Total cohort $n = 200$	Statistical analyses[a]
Maternal side-effect				
Drowsiness	15 (15.0)	50 (50.0)	65 (32.5)	$P < 0.001$
Nausea	2 (2.0)	2 (2.0)	4 (2.0)	
None	83 (83.0)	48 (48.0)	131 (65.5)	
Onset of bowel movement				
<12 h	8 (8.0)	4 (4.0)	12 (6.0)	NS
≥12 h	92 (92.0)	96 (96.0)	188 (94.0)	
Onset of Ambulation				
<12 h	23 (23.0)	10 (10.0)	33 (16.5)	$P = 0.02$
≥12 h	77 (77.0)	90 (90.0)	167 (83.5)	
Onset of Breastfeeding				
<12 h	33 (33.0)	14 (14.0)	47 (23.5)	$P = 0.003$
≥12 h	67 (67.0)	86 (86.0)	153 (76.5)	
Day of discharge				
Day 4	37 (37.0)	33 (33.0)	70 (35.0)	NS
Day 5	44 (44.0)	40 (40.0)	84 (42.0)	
Day 6	11 (11.0)	19 (19.0)	30 (15.0)	
Day 7	7 (7.0)	8 (8.0)	15 (7.5)	
Day 8	1 (1.0)	0 (0.0)	1 (0.5)	

Data presented as *n* of participants (%).
[a]Groups were compared using Pearson's χ^2-test; NS, no significance between-group difference ($P \geq 0.05$).

the first 48 h after a caesarean section compared with pentazocine alone (group B). These findings were similar to those of previously published studies undertaken in Kano, Elele, Abakaliki and Ife.[16–19] The efficacy observed with the combined drugs could be explained by the different mechanisms of action of diclofenac and pentazocine. Diclofenac is an NSAID that inhibits the COX enzymes needed for the synthesis of prostaglandins.[13] While pentazocine acts on the opioid receptors in the CNS like

other morphine-like opioids causing analgesia and sedation.[11] Secondly, the half-life of diclofenac is much longer than that of pentazocine, so it can provide analgesic cover when the effect of pentazocine wears off.[12,13] These current findings were similar to those of previous reports that suggested that the use of multimodal analgesia gives better pain relief than unimodal analgesia.[29,30]It should be noted that the level of pain perception in the first hour after surgery was not significantly different between the two groups. This could be due to the variable duration of spinal anaesthesia that was used in the patients, the varying length of time used to complete the surgery and the fixed time in which the drugs were commenced on both groups (1 h after surgery), However, after commencement of the drugs in both groups, the difference in pain perception became significantly between the two groups. It should also be noted that the mean pain score in both groups progressively decreased over the postoperative time, but this was more pronounced in group A. This could also be attributed to the synergistic effect of pentazocine and diclofenac.[18] This finding corroborates similar results obtained in Kano.[16]

The rate of satisfaction from pain relief assessed with the Likert scale was significantly higher in group A compared with group B in the current study. This was similar to previous findings.[16,17,19] These current findings could be attributed to the better pain control achieved by the multimodal drug administration in group A. However, in a similar study undertaken in Abakaliki, there was no significant difference between the two groups studied with respect to satisfaction from pain relief.[18] This difference might be due to the use of the intramuscular route of administration for diclofenac, which might be uncomfortable for the patient in addition to the intramuscular route of administration of pentazocine. The potential hazardous complications of intramuscular diclofenac, such as necrotizing fasciitis and anaphylactic shock, necessitated the choice of the rectal route.[21,22]

The need for rescue analgesia given when there was moderate-to-severe breakthrough pain was assessed in both groups. Significantly more participants that received pentazocine alone (group B) required rescue analgesia for breakthrough pain management compared with participants in the combined diclofenac-pentazocine group (group A). These findings were similar to those of a previous study.[17] This could be explained by the short half-life of pentazocine (2–3 h).[12] Even though group B participants received 60 mg of pentazocine every 6 h, the half-life and the possibility that they were not given the drug at exactly 6-hourly intervals could have contributed to the need for rescue analgesia. This current study also demonstrated a significantly higher rate of drowsiness in group B compared with group A. This could be ascribed to the CNS sedatory effects of pentazocine and the dose that was used. These findings were similar to those of previous studies.[18,30] A previous study reported significant maternal side-effects (drowsiness).[18]

There was also significantly earlier ambulation in group A, with 23% of the participants ambulating at <12 h after surgery compared with 10% in group B in the current study. This was similar to studies undertaken in Kano, Elele and Abakaliki.[16–18] Adequate analgesia encourages earlier ambulation, since the main impediment to walking, pain, had been effectively controlled. Participants receiving the combination of pentazocine and diclofenac (group A) also initiated breastfeeding significantly earlier than those in group B. This result was similar to previous studies.[16,18] However, another study found no difference in terms of commencement of breastfeeding in similar study groups.[17]

This may be accounted for by the lower dose of pentazocine (30 mg) used in their unimodal group.[17] Adequate analgesia encourages mother and child bonding since the patient can commence breastfeeding early either by lying down or sitting up. In the current study, there was no significant difference in the duration of hospital stay between the two groups, which was similar to that obtained by a study in Abakaliki.[18] This is because other factors such as type of skin incision, degree of wound healing and other maternal factors also impact on the duration of hospital stay.

Recently, there has been increased used of other analgesic modalities following caesarean delivery.[23–25] TAP block has been advocated recently.[23,24] A previous study compared multimodal analgesia similar to this current study with TAP and found less need for opioids and better VAS scores.[31] Other studies have shown more beneficial effects of TAP compared with opioids and NSAIDs when used alone or in combination.[32–34] However, TAP is not routinely performed in our centre.

This current study had several limitations. First, the inability to get a suitable placebo for rectal diclofenac made blinding of the participants difficult. Secondly, the fact that individuals have different pain thresholds might have affected the pain assessment, making it difficult to get an accurate level of pain among the participants despite the use of a VAS pain score. Minor differences in the skills of the different specialist surgeons (the minimum qualification being a specialist registrar) that operated on the participants and the extent of postoperative pain may not have been accounted for by the current assessment of the levels of pain among the participants. Thirdly, wound size was not measured during surgery and the duration of motor and sensory regeneration were not checked.

In conclusion, patients that received a combination of rectal diclofenac and intramuscular pentazocine had significantly better pain control and level of satisfaction with their pain relief compared with patients that received pentazocine alone following caesarean section in pregnant women in Enugu, Nigeria. A significantly smaller proportion of them required rescue analgesia compared with patients that received pentazocine alone. In our opinion, the combined use of rectal diclofenac and intramuscular pentazocine should be routinely recommended for eligible women after caesarean delivery.

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Author contributions

I.J.O., J.T.E. and C.N.O. were involved in the design of the study, data collection, data analysis, interpretation of the results, supervision of the research, drafting the original article and review the final draft. N.E.O., C.A.O., C.O.N., P.C.E. and F.I.A. participated in the design of the study, data collection and review of the article. G.U.E. and F.O.E. participated actively in the design of the study, analysis and interpretation of data as well as the review of the final manuscript. All authors read and approved the final draft of the article.

Declaration of conflicting interest

The authors declare that there are no conflicts of interest.

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